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Application of T-Thesys Therapy in post-operative recovery in knee-surgical interventions: A case study

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ABSTRACT

T-Thesys therapy is an innovative treatment that can be used even in the presence of recent injuries. For this reason, we studied the T-Thesys use in the post-operative phase of the anterior cruciate ligament (ACL) reconstruction of the knee. For our study, we selected 51 patients for ACL surgery, and we divided participants in two groups: the Experimental Group (EG) and the Control Group (CG). The EG consisted of 34 patients (age: 26.9 ± 7.65 years) who underwent T-Thesys therapy after surgery, while the CG included 17 patients (age: 26.7 ± 6.8 years) who was not subjected to T-Thesys therapy after surgery. T-Thesys therapy was performed on a daily basis and participants' parameters were monitored throughout the treatment. For the EG, we did not find any significant differences, however, subjective disorders seemed to disappear, almost entirely, at the seventh application. The CG showed no significant differences, even in the subjective disorders investigated. Therefore, the therapeutic treatment associated with T-Thesys therapy seems to not show any efficacy compared to the surgical treatment alone. However, from our findings emerged differences which tend to highlight a better clinical response, a faster recovery time, an improvement on the quality of life in patients, and, moreover, a better use of the National Health System resources.

Keywords: Anterior cruciate ligament; Knee; Rehabilitation; Integrated treatment; T-Thesys therapy.

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INTRODUCTION

The widespread of mass sport activities and the excessive training in elite sport have increased the phenomena of functional overload syndrome (Franklyn-Miller et al., 2014). The latter often requires immediate diagnostic activities and subsequent applications of non-invasive therapies that allow athletes to return to sport as soon as possible (Badtieva et al., 2018; Dobrindt et al., 2012). For this reason, researchers are always studying novel experimental non-invasive therapies for rapid physical conditioning (Coscia et al., 2019).

The progress of technology, electronics and computer technology applied to medicine has led to an increase in the development and production of electromedical instruments and their consequent use is fundamental in several medical fields (Byrne et al., 2018; Kasha and Banga, 2008; Pariser and Ballard, 2014; Vahed et al., 2018). The electromedical progress has made possible the use of new therapeutic strategies for the treatment of periskeletal soft tissues such as meniscus, ligaments, synovium, cartilages, joints, tendons and muscles with new therapeutic approaches (Foti et al., 2009; Francavilla et al., 2015; Gharaibeh et al., 2012; lovane et al., 2020; Slavotinek, 2010). It is widely known that these structures are easily subject to functional overload injuries and are also difficult to access for treatment (Arnason et al., 2004). The accurate efficiency of these modern electromedical equipment has completed and partly changed the therapeutic procedures, however leaving the main role to surgery.

It is widely recognized that serious and disabling injuries occur by recurrence of previous injuries not completely healed (Aicale et al., 2018). In particular, athletes that are constantly exposed to overuse, due to the sport specific gesture, experience interactive microtrauma (Bell et al., 2018). These types of injuries, because of not occur in specific events but for repetition of a specific and often erroneous sports gesture, are usually underestimated both by the athletes and the coaches with consequent chronicization and deterioration of the athletic conditions (Francavilla et al., 2016).

The concept of clinical recovery of musculoskeletal injuries in athlete should be evaluated following a complete recovery of the injured district, of the areas strictly connected to it and, in general, of the whole organism (Aicale et al., 2018; Bell et al., 2018). The "restitutio ad integrum" of the damage is half of the work. After an injury, the practice to follow should be the use of an effective, time rapid and, concurrently, safe therapy (especially non-invasive) and avoiding, when possible, surgery. Moreover, respect recovery times and modes represent 50% of the therapy in the athlete.

The surgical intervention, associated with T-Thesys therapy (BIO - EJT SRL; Milan, Italy), allows for a targeted and accurate treatment, thus facilitating faster recovery and safer return to sport avoiding the risk of recurrence.

T-Thesys therapy is an innovative treatment that can be administered even in the presence of recent injuries. Since this treatment does not need for skin contact, we investigated the T-Thesys use in the post-operative phase of the Anterior Cruciate Ligament (ACL) reconstruction in order to evaluate any positive effect. In fact, T-Thesys therapy could be able to relieve pain, reduce inflammation, and recover the joint and its function or, in general, the injured structures involved.

The purpose of this study was to investigate the therapeutic efficacy of T-Thesys treatment in the post-operative phase of knee surgery, that is the reconstruction of the ACL, on the effect in recovery time and the consequent athlete's return to sport (Ardern et al., 2016; Toonstra and Mattacola, 2013).

METHODS

Participants

A number of 34 patients (26 males and 8 females; age: 26.9 ± 7.65 years) for ACL reconstruction which constituted the experimental group (EG) (Table 1), and a number of 17 patients (10 males and 7 females; age: 26.7 ± 6.8 years) for the control group (CG) (Table 2) were recruited for the study. Participants of both groups were homogeneous in terms of characteristics of clinical history and associated pathology to ACL injury.

Table 1. Clinical history of the EG.

Pathology	Gender (n, %)		Age (mean ± SD)		TOT
Pathology	Female	Males	Females	Males	(n, %)
Subsidence	6, 18%	13, 38%	32.2 ± 5.78	27.8 ± 9.19	19, 56%
Medial meniscus injury	5, 15%	13, 38%	23.2 ± 5.72	24.9 ± 5.16	18, 53%
Lateral meniscus injury	1, 3%	5, 15%	33	25.6 ± 4.1	6, 18%
Chondropathies	-	5, 15%	-	32.4 ± 12.18	5, 15%
Synovitis	-	1, 3%	-	29	1, 3%
Previous interventions	6, 18%	14, 41%	-	-	20, 59%

Legend. EG, Experimental Group; n, number; %, percentage; SD, standard deviation; TOT, total.

Table 2. Clinical history of the CG.

Gende	Gender (n, %)		Age (mean ± SD)	
Female	Males	Females	Males	(n, %)
6, 35%	3, 18%	32.2 ± 5.8	22 ± 6.93	9, 53%
3, 18%	3, 18%	26 ± 2.83	25 ± 7.81	7, 36%
1, 6%	1, 6%	33	18	2, 12%
1, 6%	-	22	-	1, 6%
-	1, 6%	-	24	1, 6%
5, 29%	2, 12%	31 ± 7.53	23 ± 4.24	7, 41%
	Female 6, 35% 3, 18% 1, 6% 1, 6% -	Female Males 6, 35% 3, 18% 3, 18% 3, 18% 1, 6% 1, 6% - 1, 6%	Female Males Females 6, 35% 3, 18% 32.2 ± 5.8 3, 18% 3, 18% 26 ± 2.83 1, 6% 1, 6% 33 1, 6% - 22 - 1, 6% -	Female Males Females Males 6, 35% 3, 18% 32.2 ± 5.8 22 ± 6.93 3, 18% 3, 18% 26 ± 2.83 25 ± 7.81 1, 6% 1, 6% 33 18 1, 6% - 22 - - 1, 6% - 24

Legend. CG, Control Group; n, number; %, percentage; SD, standard deviation; TOT, total.

Procedure

All participants were subjected to a pre-test assessment and a post-test assessment, respectively before and after the rehabilitation protocol including: joint conditions (dry, swelling, mellow, hyperthermia); clinical conditions (arthrocentesis, residual hematoma, articularity, drainage, pain, functional limitations, pain during exercise, subjective disorders) (Monticone et al., 2011). Afterward, the EG was subjected to T-Thesys therapy after surgery, while the CG participants were not given any type of treatment after surgical intervention.

T-Thesys therapy was administered to all EG participants with a daily frequency and an intensity of 4-6 μA for 15 minutes from the day following the intervention and for the entire hospitalization period.

Participants of both groups performed the same post-operative rehabilitation protocol (both for aspects related to medical therapies and for rehabilitation procedures).

The rehabilitation procedure was composed by the following steps (Kvist, 2004):

• 1st day: bed rest and isometric exercises of the quadriceps:

- 2nd and 3rd day: isometric exercises of the quadriceps; walking (using two crutches and to partial load) with a blocked brace in extension to 0°:
- 4th day: knee mobilization up to 90° with the assistance of the therapist; walking with an articulated brace from 0° to 90° and partial load;
- from the 5th until the 7th day (discharge day): knee mobilization associated with isometric exercises.

Statistical analysis

For statistical analysis we calculated means, standard deviations (SD), percentages (%) and percentage change (Δ %) for studying variables distribution. A t-test for independents groups was computed to compare EG and CG data. For percentages comparison we carried out the formula according to which, to be significant, the difference in absolute value at the level of probability of 5%, must be ≥ that multiple of K (1.96) of the mean square deviation of a normal curve multiplied by the $\sqrt{}$ of \sum of the products of each percentage (p) by the complement q (q = 1-p), divided by N of the sample of the other percentage compared:

$$p^1 - p^2 \ge 1.96$$
. $\sqrt{p^1}$. $q^1 + p^2$. $q^2 / N^2 N^1$

The significant level was set at p < .05.

RESULTS

The EG showed the following joint conditions results (Table 3): as concern swelling, the 6% of patients showed this condition at the 1st application, while at the end of the therapy we recorded the 21% of patients; regarding dryness and mellowness no significant changes were found as described for the application in knee replacement operations (Monticone et al., 2012); while hyperthermia was present only for 18% of patients and occurred only on the first day.

		Joint Conditions (n, %)			
		Dry	Swelling	Mellow	Hyperthermia
1st application time	Group EG	29, 85%	2, 6%	3, 9%	6, 18%
1 st application time	Group CG	14, 82%	2, 12%	1, 6%	5, 29%
Ord application time	Group EG	18, 53%	11, 32%	5, 15%	-
3 rd application time	Group CG	10, 59%	6, 35%	1, 6%	-
Eth annication time	Group EG	8, 24%	14, 41%	6, 18%	-
5 th application time	Group CG	8, 47%	6, 35%	3, 18%	-
7 th application time	Group EG	22, 65%	7, 21%	5, 15%	-
	Group CG	12, 71%	3, 18%	2, 12%	-

Legend. EG, Experimental Group; CG, Control Group; n, number; %, percentage.

For the clinical conditions' evaluations (Tables 4-6), drainage was abundant in 53% of the EG and moderate in the remaining 47% of patients, though it was necessary only on the first day after the surgery. At the same time, the 15% participants of the EG showed residual hematomas that were remained constant until the 7th application with T-Thesys therapy. The results for the articularity (joint angle degree) showed an increase of 6° (from 91° at the 5th to 97° at the 7th application) with a simultaneous and progressive reduction of pain from the 1st to the 7th application. Subjective disorders disappeared almost entirely at the 7th application. Furthermore, lower pain level during exercise was found.

Table 4. Clinical conditions for EG (after T-Thesys) and CG.

		Clinical Conditions (n, %)				
		1st application	3 rd application	5 th application	7 th application	
		time	time	time	time	
Arthrocentesis	Group EG	14, 41%	7, 21%	6, 18%	6, 18%	
Arthrocentesis	Group CG	7, 41%	5, 29%	3, 18%	2, 12%	
Residual hematoma	Group EG	5, 15%	-	-	-	
Nesidual nematoma	Group CG	2, 12%	-	-	-	
Articularity (joint angle	Group EG	-	-	91.3 ± 6.3	97 ± 7	
degree)	Group CG	-	-	91.8 ± 6.2	99.1 ± 7.3	
	Group EG (abundant)	18, 53%	-	-	-	
	Group CG (abundant)	9, 53%	-	-	-	
Drainage	Group EG (moderate)	16, 47%	-	-	-	
Dialilage	Group CG (moderate)	8, 47%	-	-	-	
	Group EG (absent)	-	-	-	-	
	Group CG (absent)	-	-	-	-	

Legend. EG, Experimental Group; CG, Control Group; n, number; %, percentage.

Table 5. Clinical conditions before (pre-test) and after (post-test) treatment for EG (T-Thesys) and CG (no T-Thesys).

		Clinical Conditions (mean ± SD)				
		1st application	3rd application	5 th application	7 th application	
		time	time	time	time	
Pain	Group EG	5.26 ± 1.94	3.62 ± 1.82	2.41 ± 1.35	1.62 ± 0.64	
raiii	Group CG	5.1 ± 2.3	3.5 ± 2.1	2.4 ± 1.5	1.5 ± 0.7	
	Group EG	1.59 ± 0.55	-	-	-	
	Group CG	1.7 ± 0.5	-	-	-	
C. matianal	Group EG	-	1.15 ± 0.35	-	-	
Functional	Group CG	-	1.1 ± 0.3	-	-	
limitations	Group EG	-	-	1.06 ± 0.24	-	
(SCALE)	Group CG	-	-	1	-	
	Group EG	-	-	-	1.03 ± 0.17	
	Group CG	-	-	-	1	
	Group EG	2.24 ± 0.6		-	-	
	Group CG	1.4 ± 0.5	-	-	-	
D	Group EG	-	1.94 ± 0.59	-	-	
Pain during	Group CG	-	2.1 ± 0.4	-	-	
exercise	Group EG	-	-	1.62 ± 0.49	-	
(SCALE)	Group CG	-	-	1.6 ± 0.50	-	
	Group EG	-	-	-	1.32 ± 0.47	
	Group CG	-	-	-	1.2 ± 0.4	

Legend. EG, Experimental Group; CG, Control Group; SD, standard deviation. Note. Algometric scale subjective, absent pain = 1 point; maximal pain = 10 points.

Table 6. Subjective disorders for EG (T-Thesys) and CG (no T-Thesys).

		Clinical Conditions (mean ± DS)				
		1st application	3 rd application	5 th application	7 th application	
		time	time	time	time	
	Group EG	3.15 ± 0.43	-	-	=	
	Group CG	3.3 ± 0.5	-	-	-	
Subjective	Group EG	-	3.62 ± 0.59	-	-	
Subjective disorders	Group CG	-	3.8 ± 0.8	-	-	
(SCALE)	Group EG	-	-	4.15 ± 0.49	-	
(SCALE)	Group CG	-	-	4.4 ± 0.5	-	
	Group EG	-	-	-	4.21 ± 0.4	
	Group CG	=	-	-	4.5 ± 0.5	

Legend. EG, Experimental Group; CG, Control Group; SD, standard deviation.

Note. Algometric scale subjective, absent disorder = 1 point; maximal disorder = 5 points

Comparison results did not show any significant differences for all the responses of the participants (Table 7).

Table 7. Statistical analysis.

Clinical Conditions		1 st application time	3 rd application time	5 th application time	7 th application time
	Δ %	2.9	5.9	5.9	5.9
Dry	Val.	23.9	38.4	42.9	33.1
•	р	n.s.	n.s.	n.s.	n.s.
	$\Delta^{\circ}\!\!\%$	5.9	2.8	6	3
Swelling	Val.	55.4	46.9	46.9	53.8
•	р	n.s.	n.s.	n.s.	n.s.
	$\Delta\%$	2.9	8.8	0.1	2.9
Mellow	Val.	61.6	72.4	52.8	56.4
	р	n.s.	n.s.	n.s.	n.s.
	$\Delta^{\circ}\!\!\%$		8.8	-	5.8
Arthrocentesis	Val.	-	24.7	-	21.1
	р		n.s.	n.s.	n.s.
Articularity (idint andla	DIFF.			0.5	2.2
Articularity (joint angle	MED.	-	-	0.04	0.14
degree)	Р			n.s.	n.s.
	DIFF.	0.16	0.12	0.01	0.12
Pain	MED.	0.119	0.11	0.36	0.89
	р	n.s.	n.s.	n.s.	n.s.
	DIFF.	0.11	0.05	0.06	0.03
Functional limitation	MED.	0.24	0.19	0.94	1.76
	р	n.s.	n.s.	n.s.	n.s.
	DIFF.	0.16	0.16	0.06	0.03
Pain during exercise	MED.	0.812	2.13	-	-
	р	n.s.	n.s.	n.s.	n.s.
	DIFF.	0.15	0.18	0.25	0.29
Subjective disorders	MED.	-	-	-	-
	р	n.s.	n.s.	n.s.	n.s.

Legend. Δ %, percentage change.

DISCUSSION

The aim of the present study was to evaluate any benefits of the T-Thesys therapy use after ACL reconstruction. The findings we found suggest that the T-Thesys treatment associated to the surgical intervention did not show any significant differences compared to the surgical intervention only.

In particular, outcomes found on dryness and mellowness can be explained by the fact that the presence of liquid can occur few days after the start of T-Thesys therapy. This counteracts the potential effects of the treatment. In addition, it should be taken into account that the response in knee mobilization after surgery is different among people (Minafra et al., 2007). The percentage of swelling had a peculiar trend, resulted at the end of the treatment above the recorded pre-test value. As concern the parameters articularity in angle degree showed a moderate improvement, though not statistically significant. Moreover, a simultaneous and progressive reduction in pain was achieved at the 7th application.

Although no statistically significant, differences we found tend to a better clinical response compared to surgical treatment alone (Oliva et al., 2013).

Furthermore, we observed that the cost of the T-Thesys therapy use is economically justified and within the universally accepted limits considering the hospitalization days reduction and the savings on anti-inflammatory drugs. These considerations play a key role in the use of the National Health System resources, in the hospital management and, also, in the consequent improvement of the quality of life in patients.

CONCLUSIONS

In conclusion, our results suggest that, for this kind of knee surgery, the therapeutic treatment with T-Thesys after ACL reconstruction does not have any additional benefits compared to the surgical treatment alone. In our opinion, the insufficient efficacy of this therapeutic device could be due to several biological variables subsequent to the surgery such as: the joint condition of dry, which appear to decrease after the treatment with T-Thesys and the simultaneous increase in swelling and mellow, that occur from the 3rd to the 7h application, seems to demonstrate the ineffectiveness of the therapy.

The apparent deterioration can be interpreted as a subjective response to the knee mobilization after surgery. However, though the results were not statistically significant, it is necessary to report a better clinical response compared to the surgical intervention only. Previous studies demonstrated the efficacy of this treatment in musculotendinous and skeletal injuries (epicondylitis, muscle bruise and distraction, tenosynovitis, fibromyositis, cervicobrachialgia, post-traumatic edema, amputation stumps, bursitis and capsular-ligament distraction) (Francavilla et al., 2016; Ridola et al., 2007).

Based on our clinical experience, we found the use of T-Thesys therapy useful in the treatment of the traumatological sports diseases.

Finally, it is important to highlight the easy use of this device, the non-invasive method of application, the high tolerability threshold (in no case was it necessary to interrupt the therapeutic treatment), and the absence of side effects both locally and systemically.

Regarding the economic management of patients suffering of traumatic sports diseases or of degenerative soft tissue diseases, the treatment with T-Thesys seems to reduce cost management in terms of diminution

of anti-inflammatory and pain-relieving drugs use and hospitalization days spent. Features that increase the quality of life of patients and, moreover, let to a rapid return to sport.

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