

SOLICITUDE MEMORY FOR INVESTIGATION PROJECT

Effect of kinesiotaping in shortening rehabilitation deadlines in sportsmen operated of anterior cruciate ligament: Randomized clinical trial, double blinded and multicentre

FINAL DEGREE PROJECT

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Abstract

<u>Background</u>: There is not much scientific evidence available about this application of kinesiotaping (KNT) due to it being a new and recent technique of application in physiotherapy world. This study is pioneer in demonstrating the effectiveness of KNT in shortening deadlines of recuperation time after a cruciate ligament (ACL) surgery.

<u>Objectives</u>: To demonstrate the capacity of KNT to recover the correct muscular tone in hamstrings and this make a reduction in recovery times after an ACL surgery in athletes.

<u>Material and methods</u>: Selected for this randomised clinical trial multicentre a total of 36 patients, all of them athletes and that have had suffered and ACL surgery, divided randomly in two different groups (1) conventional treatment + KNT and (2) conventional treatment + placebo taping. Variables to analyse will be measured at the beginning of the treatment, every month, and from fifth month every week until treatment is finished.

<u>Expected results</u>: patients who are established in group two treatment (KNT) reflect better results concerning functionality range joint motion, pain, and above all recovery deadline. With these possible results we could define KNT as an adequate technique for the ACL treatment to reduce recovery time in athletes.

1. BACKGROUND AND ACTUAL STATE OF THE THEME

1.1. Anterior cruciate ligament rupture: repercussion in athletes

Anterior cruciate ligament (ACL) break is one of the most common injuries in sport world. According to a study made by Hootman *et al*¹, that realize a 16-year following in USA college sports, it is the most common injury just after an ankle sprain. Affecting in a more considerate and significative way to women. (*See ACL description in annex I*).

When an ACL break is produced, being the main knee static stabilizer instability is created. This situation in non-sportive people does not require a surgical intervention, but in athletes this surgery is vital for a recovery and being able to return to high competition.

The injury mechanism is usually a knee abrupt rotation with the foot fixed to the ground, but furthermore we can also find cases in which it is produced by a forced knee hyperextension or direct traumas in the knee.¹⁹

For a correct diagnostic it is required a good anamnesis and exploration, where it is asked for the injury mechanism and it is observed the apparition of bruising and swelling. Physical exploration allows us to detect hemarthrosis, and anterior instability through specific techniques such as anterior draw test, Lachman test or Pivot Shift test. Magnetic Resonance is the first option complementary test where, a part from the broken ACL, it is possible to see if there are other associated injuries such as meniscus or collateral ligaments.

In athletes' case, once the injury is diagnosticated and the inflammatory initial process has been reduced and there is a slight recovery of joint movement, it is preceded to the surgical reparation. Three different types of techniques can be used in this type of surgical intervention. These are autografts of hamstring tendons; a synthetic plasty or finally the Bone-tendon-Bone technique¹⁵, which uses one third of the patellar tendon. This last technique is the most used and the one we will be studying in this intervention. This consists, as said before, in the extraction of one

third of the patellar tendon, with a bit of tibial plateau and a bit of patella, and then this being grafted in place of the broken ACL (see annex II).

This process of rehabilitation often consists in about eight months to one year in normal patients. On the other hand professional athletes get a recovery in more or less six or seven months, thanks to the means they have and the strong necessity of returning to their profession.

1.2. Kinesiotaping

Kinesiotaping (KNT) or Neuromuscular taping^{21,22} is a technique of recent application in worldwide physiotherapy. This type of taping presents specific characteristics (*annex IIIa*) in its composition, which added to its application variability's (*annex IIIe*) being able to change tensions or origins and insertions this could give different effects on patients (*annex IIIb and IIIc*). It does not focus only on joint movement limitation, but it acts on peripheral nervous system, which will have, and effect on central nervous system and therefore on contractile muscle properties. In addition it is able to incise in ligament processes, tendon affectation, lymphatic and circulatory processes, etc.

With this type of treatment we pretend to achieve a recovery in functionality and muscle properties in those who incise in knee biomechanics, mainly hamstrings muscles, moreover to use the capacity of this taping to accomplish a good joint congruence and reduce swelling and sprain.

1.3. Scientific evidence of kinesiotaping

After an extensive bibliographic research has been done in five different scientific databases with related results, published since 2009 and with an adequate evidence level, there are found several articles about KNT application in quadriceps in patients that have had an ACL² surgical intervention and applications of KNT in

normal people and athletes^{4,5,6} in different injuries. However no article checks the efficiency of hamstring application to improve and reduce recovery time after the surgery.

Oliveira et ale realise a study about the application of KNT, in operated patients of ACL but just applying it in quadriceps. At the end of the study they conclude that there is no improvement in their objectives with the application of KNT. Lumbroso et al³, demonstrate that the application of KNT in adult and young patients produces an immediate increase of strength of gastrocnemius. Whereas in hamstrings strength does not increase until two days have past from the application. Lins et al4, define the utilisation of KNT in adult healthy women that realise sport regularly KNT does not improve the functionality in their lower limb muscles or in general. Also they end up proposing a continuity of studies in the use of KNT in patients under treatment. Nunes et al5, test out the effectiveness of KNT to get an increase of strength and jump in sane athletes. They cannot demonstrate any effectiveness. Fu et al⁶, also try to demonstrate the effectiveness of KNT in gaining strength in sane athletes. But as in the previous study they are not able to demonstrate any effectiveness. In two systematic revisions about the effects of KNT^{7,8} they conclude that there is no sufficient evidence to recommend KNT as a systematic way of treatment and there is more investigations needed.

There is only one point in common in mostly all articles, and we find it in their conclusions, where they sentence that more research must be done in this type of treatment due to it being such a new technique there is not enough evidence.

1.4. Why is important to study Kinesiotape?

Kinesiotaping (KNT) has had a recent rise due to the advertisement that professional athletes, majorly in football, have been giving. However, there are some aspects unsolved, such as: what validity does KNT have? Can it be beneficial in people that are athletes? How do we apply it? Could KNT help in ACL recuperation and shorten their recovery?

KNT is a more or less new technique and that is why there is not much scientific evidence. There is no evidence showing KNT increasing strength in a healthy

athlete⁶, however, in a patient who has an imbalance between his two limbs, is KNT capable of normalizing muscular tone? Our investigation centres in trying to shorten recuperation periods especially in athletes, increasing muscular tone and see the effects that is has over pain, joint stiffness and other ACL surgery complications that may appear.

In sport (more professional than amateur) it is primordial that athletes return to their activity as soon as possible and this injury has them away of sports grounds for at least 6 months. With this study we pretend to improve quality of life and shorten deadlines in ACL operated patients. Positive results would shorten recuperation periods, making professional athletes return to their job as soon as possible (avoiding a considerable loss of money for them and their team) and making amateur athletes being able to full fill their hobby.

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3. Hypothesis

Null hypothesis (H0): Neuromuscular taping (NMT), used to increase hamstring muscular tone is not effective for shortening deadlines in patients that have been operated of anterior cruciate ligament (ACL).

Alternative hypothesis (H1): The use of NMT to increase hamstrings and a prevention treatment is useful to shorten deadline in patients that have been operated of ACL.

4. Objectives

Principal:

- 1. To demonstrate the capacity of NMT to recover the normal tone of leg muscles.
- 2. To know a way of making rehabilitation shorter in operated patients of ACL.

Secondary:

- 1. To know the techniques of NMT to increase muscle tone.
- 2. To give validity to NMT and introduce physiotherapy in a much more important way in multidisciplinary teams.
- 3. To determine if NMT gives a benefit when normalising the healing of ACL.

5. Project Methodology

5.1. Design

Random clinical trial, double blinded and multicentre.

5.2. Participants

Athletes that have been intervened of an ACL rupture and sent to us by the Catalan Federation of rugby, football, basketball or 5 a side football and they fulfil the inclusion criteria presented ahead.

- <u>Inclusion criteria:</u> 1) aged between 18-35 years old; 2) federated sports; 3) diagnosed with a broken ACL; 4) intervened surgically of the ACL with the bone-tendon-bone technique; 5) lack of strength and/or decrease in joint movement.
- <u>Exclusion criteria</u>: 1) previous joint degenerative pathologies and/or muscular in lower limb 2) previous surgery in affected knee; 3) bilateral ACL injury; 4) allergy or intolerance to KNT.

5.3. Sample size

Sample size was calculated by accepting a difference between treatment of 60 days in time recuperation, with a standard deviation (SD) of 60, for an alpha risk of 0.05 and a beta risk of 20% in a bilateral contrast. In base of these estimations we precise a minimum of 16 patients per treatment group. Sample size is over estimated to cover up to a 20% of possible losses, so we select 36 patients. (Annex VII)

- Recovery time (in days): treatment ending will be evaluated by means of the Askling H Test, which measures the moment a patient can re-introduce himself to his sport after suffering a hamstring injury. Askling CM, 2010
 - 2) **Muscular strength** of hamstring will be evaluated with hydraulic dynamometry pull/push with protocol proposed by *Bandinelli S, 1999*. Also as a qualitative way the Oxford-Daniels scale will be passed. (*Annex VI*).
 - 3) Muscular volume by measuring the thigh perimeter in middle third of femur, just the middle point between anterior superior iliac spine and patella; muscular echography of hamstring muscle.
 - 4) **Joint articular range** will be analysed by goniometry, comparing always the other limb (not affected) measures. Measures will be taken actively first and passively after.
 - 5) **Pain** evaluation: it will be evaluated in a subjective way with the visual analogue scale (VAS) (*Annex VI*). Moreover an objective measure will be done with a pressure pain threshold in a specific pain point and always perpendicular to this same point.
 - 6) Complications: the most dangerous complication after an ACL intervention is a need for a second surgery, for a meniscal tear, a wound dehiscence, chondral pathology or intraa-articuar scarring. Finally, other complications can rather be wound problems, such as infection, sensory nerve damage, muscle tendon injury, tibial periostitis or suspected meniscal tears and chondral lesions. (Mohtadi N, 2015)

5.5. Intervention

Subjects will be divided randomly in two different groups. Depending in which treatment they are applied.

- Group I: Conventional physiotherapy + KNT,
- Group II: Conventional Physiotherapy + placebo taping with similar appearance to KNT.

Both groups will receive three sessions per week of one-hour duration, in which the pertinent treatment will be realised for a maximum of 7 months or passing the Askling H test. (Askling CM, 2010)

Conventional physiotherapy consists of five phases:

<u>Phase I:</u> First day after the intervention, passive knee movements with continuous passive motion machine (CPM) up to 90°-100° + ankle active exercises + isometric quadriceps exercise + walk with two sticks and kneepad blocked at 30° + cryotherapy.

<u>Phase II:</u> Third day the patient receives hospital discharge and 3 times a week physiotherapy sessions start. In these sessions we will muscle up the knee starting with isometric exercises and straight leg rise. Move the knee passively to 100 degrees (CPM). Passive patella movement. When session finishes ice for 10 to 15 minutes. This will be the protocol to follow until the second week after intervention. It is important to get out of this phase with a full knee extension.

Next weeks we will continue to work on muscle potentiation (not only quadriceps but hamstrings as well, and we introduce static bicycle without resistance) and we try to achieve 120 flexion degrees. Walking will still be done with two sticks and kneepad blocked at 45 degrees.

<u>Phase III:</u> In the next phase we go unblocking the knee during marching until we are able to walk without it and without sticks. For that we continue muscling all the leg not just the knee realising different exercises. We start doing different exercises in open kinetic chain and postural control.

In this phase we take away the kneepad and the sticks and we continue with leg muscling. We start with swimming and proprioception exercises in open kinetic chain and slow jogging. Plain ground and no direction or speed changes. We continue with no resistance bicycle.

<u>Phase IV:</u> After three months we increase charge in all the exercise mentioned before. According to patients evolution we start introducing closed kinetic chain proprioception exercises and postural correction. We start to introduce change speeds and direction changes while jogging.

<u>Phase V:</u> Last months, from the seventh to ninth are to introduce the athlete to his sport. Running in plain grounds changing speeds directions and ground level. Aerobic conditioning, we also increase resistance in bicycle. This last month targets to recuperate sports gesture and submit the knee to similar forces that would suffer while practising the sport. We continue with proprioception exercises and postural correction.

Group I: subjects established randomly in this group receive exactly the same treatment described in group I, but KNT is added. This consists in the utilisation of neuromuscular taping which is used to recover hamstrings functionality and stabilises a forward tibia translation. With this application it is pretended to gain a correct biomechanics, a good anterior knee stabilisation to reduce the tension made over the plasty and consequently reduce recovery time and shorten the final deadline. This treatment will initiate during second phase.

This taping is applied following the method designed by Kase Kenzo in hamstrings. We search a tonic action to gain a faster activation in hamstrings in order to gain a tibia stabilisation and consequently reduce the tension made over the plasty.

For the application in hamstring we will use the "I" technique that permits us treat as an equal femoral biceps and semimembranosus and semitendinosus. The elected tape is the 5cm one. A strip is used of femoral biceps and another for semimembranosus and semitendinosus.

Firstly the patient is placed standing with a neutral position of hips and knee. Its ankle rests in the floor. Continuously the tape first base is anchored with no tension at all. The anchor is put in the isquiatic tuberosity, it is done like this for both strips (proximal to distal application).

Once we are in this point patient must realize a full knee extension and a body flexion to have a slight previous stretch of his hamstrings for being able to apply KNT. For the femoral biceps strip the patient is asked to go and touch his contralateral foot, due to femoral biceps is a tibia external rotator. On he other hand for semimembranosus /semitendinosus strip the patient is asked to go and touch his homolateral foot, due to this two muscles are internal tibia rotators.

Thirdly it is preceded to paste the active part of each strip, applying a tension between 15%-50% (to accomplish the desired tonifying effect) through out all the hamstring muscle in direction to tibia and peroneus.

Finally semimembranosus and semitendinosus base collocation is in the internal side of the tibia; femoral biceps base is divided in two small heads, one goes to peroneus while the other one is anchored in external part of tibia. All bases are pasted without tension. (Annex VIII)

The bandage is change once or twice a week depending on the wear

Group II: Patients established in this group receive conventional physiotherapy treatment and a placebo treatment simulating KNT, without therapeutic application. This treatment will initiate during second phase. For this taping an elastic tape will be used substituting conventional KNT. For taping collocation we put the athlete in the same position and we follow the same guide as in group I.

5.6. Randomization procedure and blinding

Randomisation procedure in this case study will be done through randomising informatic programs, this will provide a simple random sample. Before group assignation, patients are informed that they can be randomly divided in to two groups.

This is a double-blinded study. This first blind is achieved by randomising group assignation. Both groups will receive a treatment and a treatment with tape, one with KNT and the other group with elastic tape, but they do not know which of both is placebo and which has a therapeutic application. Double blind is obtained by differentiating physiotherapists that will apply the KNT to patients and investigators that will be in charge of recollecting all data; this will have no constancy of the work done by one or other group.

5.7. Data collection

Data collecting or variables to study will be realized in different phases of the study. Firstly an initial valuation will be done before any treatment. After diverse measures will be realized through out the treatment, these will be performed after first and third months and weekly from the 5th month forward.

5.8. Statistical analysis

Categorical variables will be expressed with their frequency and their percentage; quantitative variables, with their average and their standard deviation. In the bivariate analysis the following test will be used: Chi Squared or Fisher test, 't' student or 'U' of Mann-Whitney depending the type of data to analyse and their application condition. For the study of variable through out time tracking, it will be used an analysis of variance for repeated measures. To analyse relations between quantitative variables Pearson correlation coefficient will be used. Finally alpha risk level is accepted for hypothesis contrast as 0.05.

5.9. Ethic aspects

During the whole process of the study it will follow national and international guidelines for investigation in human beings described in the Deontological code in the Helsinki declaration. Regarding confidentiality guidelines it will follow the legal normative about data confidentiality (Organic Law 15/1999, 13 December) on the protection of Personal data (LOPD).

Before the start of the study, all patients will be informed about objectives and possible complications from derived from the trial. Therefore, before their inclusion all candidates will sign a written and informed consent. (*Annex V*)

6. Work Plan

6.1. Developed stages

First year:

- Patient recruitment and posterior randomizing. Initial clinical and functional evaluation.
- Stipulated Intervention (three sessions per week during seven to nine months).
- Result collection, after first and third months and weekly from the 5th month forward.
- Confection of database and annual memory.

Second year:

- Continuing fieldwork started last year.
- Actualization of database.
- Communication and exposition of results in national and international congress.
- Elaboration of original article.
- Confection of final memory.

6.2. Tasks distributions for researchers

Physiotherapists Daniel Franco Vargas and Alberto Hernández Morales will carry out coordination and direction. Tasks that will be carried out by main investigators are: (1) Selection of candidates, (2) Clinical and functional initial evaluation (3) Final clinical evaluation, (4) Coordination and supervision of both groups (5) Results diffusion and (6) Manuscripts confection.

- Physiotherapist collaborator 1: He will realize the following tasks; help main physiotherapists. (1) Clinical and functional initial evaluation (2) Final clinical evaluation, (3) Patients randomising procedure, (4) KNT group treatment coordination
- Physiotherapists collaborators 2 y 3: these will realize the following actions (1) KNT collocation in group I, (2) Elastic tape placebo colocation in group II and (3) Control and substitution of bandages.
- **Physiotherapists collaborators 4 y 5**: there will realise the following tasks:
 - (1) Clinical and functional valuation measures through out the treatment and
 - (2) Data recollecting procedure.

*To assure a correct collocation on KNT, it is required the participation of physiotherapists formed with KT2 kinesiotape level.

It is estimated the average number of physiotherapists/investigators for the realisation of this project, but this cannot be confirmed until the confirmation of the available budget.

7. Study Limitations

One of the main limitations that this study can present is the variability of physiotherapeutic treatment that there are in a first phase in different hospitals. To try and reduce this variability we propose a standard protocol of actuation for patients treated in this study.

Another limitation that could be found is the one produced by the number of abandons or patients completing our treatment and not filling the final questionnaires at the end of the six months and at the end of the year (being this really important for the study). There is no other way of calculating or avoiding these abandons, but to fight back we try to get a sample big enough for being able to bring out acceptable methodological results.

It could also happen a bias in results produced for possible parallel treatments that those proposed in our study, or for the no fulfilment of the whole treatment. To avoid this situation the only possible measure is insisting in the accomplishment of the treatment and make sure that patients inform the team of any other treatment they do outside the study.

To end up and assure a correct data collection we require the help of technique personal that guarantees as much as possible an homogeneous data collection. Being these totally alien to the type of treatment that patients receive and being able to make a double blind.

8. Investigators Experience

This investigation is promoted by the physiotherapists Daniel Franco Vargas and Alberto Hernández Morales, both with large experience in sport physiotherapy and in KNT. Moreover they collaborate with different sports federations and this is an advantage when communicating with different candidates.

A part of a high experience in sports physiotherapy it counts with the necessary infrastructure for the realisation of the study, where also we find some necessary tools for the realisation of it. This last detail would mean a reduction in final costs.

9. Requested Budget

The project counts with main investigators that are in charge of direction and coordination of all the study. This includes the supervision through out the whole treatment, result analysis, discussion and posterior diffusion. But a part of having main investigators it is required a subvention for hiring other professionals (the number of these vary according to the quantity of the subvention) to assure a correct application of treatment and a correct data collection, these being completely alien between themselves. This is of vital importance to avoid bias.

Subvention required includes necessary material to carry out the project, such as material for evaluations and material for both treatments. It also includes material for data collection and data analysis. In addition it is required informatics license to analyse data and random procedures.

For all said before, it is considers that the budget is correctly adjusted to minimum necessities and study factability, even more forecasting the applicability and utility of expected results.

A head it is exposed a detailed sample of solicited material in this subvention.

Requested Budget			
Personal expense	Euros		
Hiring of 5 physiotherapists (15 h/week for 7 months)	25,200 (12/h)		
Hiring of echo graphic specialist and material (80 h)	2,400 (30/h)		
Subtotal personal expense	27,600		
Expense execution			
a) Goods and service acquisitions			
3 dynamometer (hydraulic dynamometer pull/pus)	1,560 (520/u)		
3 algometry of pressure (algometry analogic FPK 20)	1,444.8 (481.6/u		
Paying statistic software license IBM SPSS	5,000		
Diverse informatics material	500		
80 Kinesiotape (Leukotape K 5m)	960 (12/u)		
160 Elastic tape (tensoplast® sport 3cm x 2'5m)	536 (3.35/u)		
Latex gloves without Kinefis dust (100u)	5.45		
4 neutral massage cream Kinefis (500ml)	27.8 (6.95/u)		
Bibliography and expenses of article publication	1,000		
Subtotal	11,034.05		
b) Travel and subsistence	I		
Result presentation in national and international congresses	1,000		
Subtotal	1,000		
Subtotal execution expenses	12,034.05		
Total requested	39,634.05		

^{*}There is no need of buying more material for rehabilitation due to it being available where the study takes place.

10. Project Relevance

This Project is presented with the aim of investigating a new field of treatment that has a strong rise in physiotherapy during this last decade, kinesiotape.

The anterior cruciate ligament injury is one of the principal athlete injuries. This, though all the new techniques that are being applied and deadlines are being shorten has a long recovery time, from 6 to 9 months approx. So in this study we pretend to investigate the probability of reducing deadlines using KNT.

In addition this study will try to demonstrate clinically satisfactory results in ACL rehabilitation, in order to promote KNT investigation.

With a positive result in this group, sport entities and individual athlete will be capable of saving time of inactivity and therefore money, due to it being their profession. We are trying to make professionals return to their profession as soon as possible. If with KNT we are able of achieving a major stabilisation of the knee we can prevent injury relapses in this athletes.

Annex I. Anterior Cruciate Ligament

Cruciate ligaments are in charge of stabilizing the tibia anteroposterior in relation to the femur. Specifically anterior cruciate ligament limits the anteriorization of the tibia. A part of limiting the anteroposterior movements it is also responsible of limiting the internal rotation of the tibia, with this movement it gets tensed and with an external rotation it relaxes.

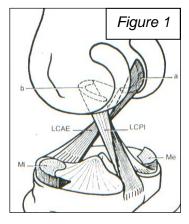
Ligaments are in the centre of the articulation and they are undercrossed between them.

- Posterior cruciate ligament or PCL is characterised by:
 - Tibial insertion from the posterior retro-spinal surface to the posterior horn of intern and extern meniscus.
 - o It is oblique, up, in front and intern crossed on itself.
 - o Femoral insertion at the end of intercondylar notch.
 - Fibres expand to the posterior horn of external meniscus.
- Anterior cruciate ligament or ACL is characterised by:
 - Tibial insertion from pre-spinal surface between anterior horn of internal and external meniscus.
 - Oblique up, back and extern, crossed on itself.
 - Femoral insertion is in axial face of extern condyle.
 - o Fibres expand to anterior horn of intern meniscus.

Both are characterised by being recovered by synovial but being extra-synovial; and for presenting connections with the articular capsule. The only plane where

these two don not cross themselves is transversally, they do in sagittal and frontal plane.

ACL has two fascicles, one that is anterior-medial and another posterior-medial. Anterior-medial fascicle gets tensed during knee flexion, while posterior-lateral fascicle gets tensed during knee extension. These are well vascularized structures, geniculate artery is the



main responsible of it, which penetrates and arrives to the ligament through the posterior articulation capsule.

Annex II. Surgery technique

ACL rupture presents several techniques for its reparation, such as auto grafts, allografts or synthetic plastys. Inside auto grafts we find those produced from hamstrings or through the bone tendon bone technique. This last reparation method is selected for this study.

Bone-tendon-bone technique (*Alejandro I, 1998*): is the election technique for reparation of an ACL rupture. This consists in the extraction of the middle third of patellar tendon, and an extraction of bone form the patella origin and the tibia insertion. Thanks to these bone extractions, it is permitted a bone-to-bone fixation inside the articulation, reducing recuperation times and adaption of the plasty to the organism.

Surgical process description:

Patient is put at a 90°-knee flexion, once put in this position; a longitudinal incision is made from the inferior patella pole to the anterior tibia tuberosity (ATT). After opening the peritendon the central part of the tendon is extracted with a wide of 9-10mm united to a bone patellar and tibia fragment pierced with Kirschner needles. Through the holes just made some steel wires are passed to facilitate the plasty collocation (occasionally also for its fixation). Parallel to this Hoffa fat is removed. Once reached this point an intrarticular exam is done to see other associated injuries. It is practised by means of this approach, an external and internal menistectomy. Condyloplasty, this is done with a chisel and a drill. Tibial and femoral tunnels are practised with a 10mm drill helped with an Acufex guide and after tunnels are shaved with a spoon of the same calibre. Continuously the graft is introduced passing it first through the femoral tunnel, being the patellar bone fragment anchored in this segment. Isometric is tested in flexion and extension, and as well possible frictions of the plasty with the fixation screws. Finally the incision is sewed.

Illa. KNT characteristics

- Soft Cotton textile, breathable, hypoallergenic, and water resistant; providing a 3-5 days resistance.
- Skin similar lightness and thickness.
- It possesses a 130-140% longitudinal elasticity, making sure muscle does not over stretch or over contracture.
- Previous 10% stretching.
- Only sticks once.
- Heat aids adherence to skin.
- No pharmacological components.

IIIb. KNT effects

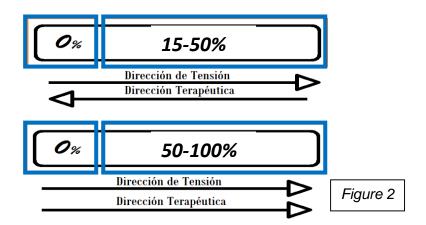
- Improves muscular function, increasing or decreasing tone depending on its collocation
- Improves articular function, through proprioceptive stimulation, biomechanical joint correction (position and movement) and enhancing stability.
- Acts as analgesic, activating endogen systems.
- Improves blood circulation.
- Helps in lymphatic circulation.
- Reduces inflammation, reducing heat excess and eliminating throw-out substances.
- Neuroreflex mechanism, capacity to treat intern organs by means of reflex relation with skin, muscles, joints and viscera.
- Reduces muscular fatigue.

IIIc. Effects on muscle

For achieving these desired effects of relaxation/tonification in muscles, we must take into consideration diverse factors, such as direction of applied tension and therapeutic direction (direction form queues to base).

Tension direction always follows the direction in which the tape is placed, form first anchored base to second anchored base. On the contrary therapeutic direction varies in function of the quantity of longitudinal tension applied to the tape, if applied with less of 50% tension these both direction will be opposite. With a higher 50% tension both direction will follow the same direction.

With this we understand that not only we depend on the origin/insertion theory to gain effects on muscle, but it depends in applied tension.



IIId. Application guide

- Inform the patient in what does the method consist.
- Treatment skin zone must be clean, dry and fat free.
- Treatment zone must be hair free.
- Bases or anchors have to be cut in circular position and put without tension.
- Folds must be avoided and wrinkles through out the tape.
- Scrub after applying to give heat and therefore improve attachment to skin,
- If allergy signs or itch appears between 20-30' after collocation remove it.

- It must be placed with a longitudinal tension.
- With a less of 50% tension we have a direction to first anchor, while with a higher tension there is a contrary tension direction.

Ille. Ways of applying KNT

We find different ways of application forms described by Kase Kenzo, in order to the response we want to find, where we want this response to refer and muscle type.

Technique type	Indications	Application	Form
I technique	Indicated for great tension quantities.	Over muscular belly.	
Y technique	Indicated for little tension quantities (normotensive)	Surrounding muscular belly.	IV
X technique	Fascia work or different muscles (origin-insertion)	Central X point is applied over muscular belly and strips surround muscle	IX
Star technique	For trigger points	Over point to treat.	**
Fan technique	Lymphatic or anti-	Over zone to	
(octopus)	inflammatory edema.	treat in direction to near ganglia.	
Web technique	More specific than fan technique.	Over zone to treat in direction to near ganglia.	
Donut technique	To increase space.	Central point over zone to treat.	

3f.Contrindications:

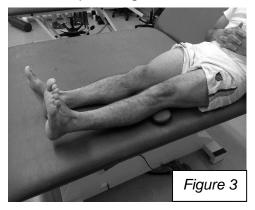
- Not justified use of KNT.
- Thrombosis: KNT improves blood circulation making thrombus to move.
- Wounds: It is not advisable to apply directly over a skin wound due to textile not being sterilised. But if it is collocated surrounding it can improve curating.
- Severe traumas: must not apply it until not having a previous diagnostic.
- Carcinomas: due to KNT improving blood circulation.
- Irritability: if produced and irritability in the zone where it is applied, treatment must be interrupted.
- Diabetes: not demonstrated but it has been seen that KNT changed insulin necessity.

Annex IV. Conventional treatment 10,11,12,13,14

Phase I

In hospital realize isometric exercises for their quadriceps (figure 3), the exercise consists in pushing the knee against the bed (as if you had a pillow under your knee and you want to squeeze it), this exercise must be done between 3 or 4 times during the day and 10 repetitions. It is 5 seconds pressing and 5 seconds

resting. Furthermore in this first phase we apply ice to the knee 3 times a day and with a continuous passive motion machine (CPM) patients realize flexo-extensions of their knee. Kneepad for walking is blocked at 30 degrees, and patient walks with two sticks. (Bian et al, 2015)



Phase IIa

Once hospital discharge is given we continue with muscle potentiation, besides isometric exercises mentioned before we realize strait leg rises and passive movements of knee and patella. In strait leg raise the patient must bend the other knee to protect lower back spine and with the affected limb we try to rise it a palm or two from the bed hold it up for 5 seconds at least and lower it in a slow way, rest for 5 seconds and start again.

If in the physiotherapy gym in where we are there is no CPM it is the physiotherapist who makes the passive movement of the limb. In this phase we must not pass 100 degrees so we do not put much tension in the plasty. If it is a machine the one doing the exercise it can be done for 30 or 40 minutes on the other hand if it is the physiotherapist who carries out the movement it is for a bit less than 30 minutes.

Moreover we will realize passive patella movements and we end up with ice for 10-15 minutes. (Figure 4)

We conclude this phase when patient reaches full extension of his knee.



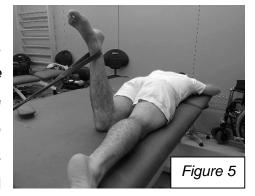
Phase IIb

In this phase we work on muscle potentiation (both legs) and we work on joint movement. Passively we try to reach 120 degrees and march with two sticks and kneepad blocked at 45 degrees. For further potentiation we realize static bicycle without resistance for 30 or 40 minutes.

Phase III

The objective of this phase is unblocking kneepad and passing from a two sticks walk to one stick march and finally no stick march. To comply this objective we continue enhancing muscle tone in both legs, so a part of static bicycle we start

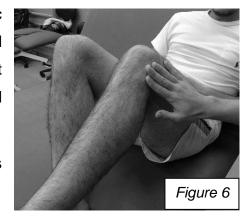
doing eccentric exercises (*Schmitt B, 2012*). We realize exercises with theraband®. In a prone position we do hamstrings curls (*Figure 5*), 3 series of 15 repetitions with both legs the return movement is against theraband® to make quadriceps eccentric exercise. In this same position we put a weigh in the ankle and



same exercise, the return to initial position must be slow so hamstrings work in an eccentric way. With same theraband® in supine decubitus we realize dorsal and plantar flexion so we start working gastrocnemius. In open kinetic chain we realize knee extensions and as before we return really slowly to work quadriceps in an eccentric way. 3 series of 15 repetitions. Important to work on both legs.

We start working proprioception in open kinetic chain. Patient will be in supine decubitus and physiotherapist moves his knee while patient makes a small opposition. These are small movements, quick and rhythmic. (*Figure 6*)

We abandon this phase once the patient is capable of walking without sticks and kneepad.



Phase IVa

In this phase we have already achieved complete movement and we explicitly work in muscle potentiation. In addition to exercises mentioned before we start to introduce eccentric exercises in closed kinetic chain, such as squads (*Figure 7*). We do 4 series of 10 repetitions each without additional weight. We continue working in proprioception in open kinetic chain as described in previous phase and bicycle with little resistance. Also start with swimming and if possible running

(smooth jog) in plain ground and without direction changes. Walk inside water (hip height) is a way of gaining strength with both legs and without putting tension in the plasty.



Phase IVb

This phase is important to increase charge in all exercises. Slowly we go increasing resistance in bicycle, longer runs and as patient progresses we introduce changes of direction. We pass from a slow jog to a faster jog. We also introduce proprioception in closed kinetic chain. Squads with some weight are introduced as well and we increase weight depending on tolerance. We continue realizing swimming and walking inside water to increase strength.

Proprioception exercises in closed kinetic chain:

Initial position is both feet separated at shoulder level and semi-flexion knee (15 degrees).

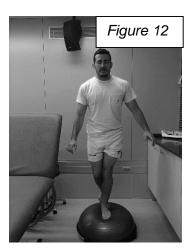
- Initial position and hold it for 15 seconds, 5 times.
- Initial position and closed eyes.
- Initial position but just in one leg standing. (Figure 8)
- Previous position and closed eyes. (Figure 9)
- Initial position in unstable ground.
- Initial position in unstable ground and closed eyes.
- One leg position in unstable ground (if patient can not achieve this position
 we can make a semi one leg position by leaning just the tip of one foot on
 the ground). (Figure 10-11)
- One leg position in unstable ground and closed eyes. (Figure 12)
- All the previous steps but with unbalancing done by the therapist.









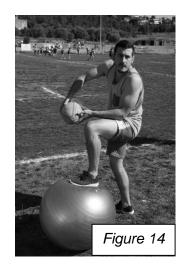


Realize all this exercises for 15 seconds 5 times and repeat them through out the day. The patient and his tolerance decide progression. These exercises are for improving proprioception not balance, this means that exercises must consist of small movements not big unbalances, that is not proprioception.

Phase V

This last phase is only for athletes, it is the phase were physiotherapists and physical trainers work along to prepare the sportsman and have him in optimal condition and for him to get used to this repetitive movement and put his knee under pressure so during the activity the knee does not suffer.









As KNT cannot be applied in a placebo way (just putting it in the skin does some effect in the skin or muscle) we apply tensoplast® in this group instead of KNT.

Finally insist on prevention of possible recurrence. (Sugimoto D. 2015)

Effect of kinesiotaping in shortening rehabilitation deadlines in sportsmen operated of anterior cruciate ligament. Randomized clinical trial, double blinded and multicentre.

Investigators Daniel Franco Vargas and Alberto Hernández Morales, graduated by the 'Universitat Autónoma de Barcelona' are interested in knowing if a conventional rehabilitation program with a kinesiotape (KNT) application is more effective in the process of recuperation in patients, like yourself, have suffered a anterior cruciate ligament (ACL) rupture, and a posterior surgical repair. It is for this reason that you have been selected to participate in this study.

Your participation will suppose a benefit for both parts, for you and for our investigation in this field, as it will permit us to know the benefit of the application of mentioned treatment in the prevention of possible sequels.

The objective of the exposed information in this document is soliciting your participation in this study, offering necessary information for you decision taking, free and voluntarily, to accept or reject the participation in the study. In this sense we say we inform and request authorization is a mandatory standard for sanitary personnel who treat you.

Rehabilitation improves patient recuperation after an ACL surgery, but in this study we want to test if thanks to the utilisation of KNT we could reduce considerably recuperation deadlines, for as soon as possible competitive comeback.

KNT is a recent application technique in physiotherapy. This type of taping possesses some specific characteristics that give an improvement in muscle functionality; pain reduction; edema and swelling; improves joint biomechanics and lymphatic and blood circulation.

Therefore with this type of taping what we pretend to improve is muscular functionality that has been affected after the surgical intervention, related with knee biomechanics (specifically hamstrings muscles, which are anterior tibia stabilizers), to accomplish good joint congruence, help in the function of the plasty and improve muscular tone.

Rehabilitation program that you will receive will consist in 1 our treatment 3 days a week for a total of seven months or clinical discharge moment. Evolution valuation of efficiency treatment will take place during the whole treatment, after first and third months and weekly from the 5th month forward.

Patients are divided in to two groups; both groups will receive their pertinent treatment. This division will be random and done by raffle in which all patients will have the same possibility.

Privacy: during the study course, national and international guidelines exposed by the Deontological Code of the Helsinki declaration in human beings will be followed. In what data confidentiality guidelines refers to we will follow legal normative (Organic Law 15/1999, 13 December) on the protection of Personal data (LOPD), for what all personal involved in any stage of the study, will respect your privacy, your confidentiality, your clinical history as well as a no exposition to no authorised personal, about your name or other personal data.

Right to interrupt study: Decision of participating in this study is completely voluntary from the patient. Investigators and/or physiotherapists in the study will make sure in all moment your health, and will also solve and doubt about the treatment. If decided to interrupt the study in any moment, you find yourself in full freedom of doing it when desired, without this decision affecting your normal treatment after your LCA surgical intervention.

- I state I have read the informative paper that I have been delivered about the study.
- I understood that in this study new physiotherapeutic knowledge are provided.
- I have done questions, and resolved doubts about this study before confirming my participation.
- I understood that my participation in this study is totally voluntary and that I can abandon in any moment, without this making a repercussion in my treatment.

I give my full consent to participate in this study, as well as giving permission for my clinical history data is used during the investigation, deleting always any information that could identify me.

Name and surname	Signature	Date
I confirm that I explained all the info	ormation to the patient involv	ing the project, as well
as resolving all presented doubts.		







Project investigation responsible

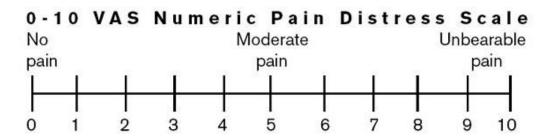


Annex VI. Valuation scales

Oxford-Daniels

Degree	Description	
0	No muscular response	
1	Muscle realises visible/palpable contraction without movement	
2	Muscle realizes all movement without resistance or gravity.	
3	Muscle realizes all movement against gravity without resistance.	
4	Whole joint movement against gravity and slight resistance.	
5	Muscle supports maximum manual resistance with whole movement and against gravity.	

• VAS (Visual Analogue Scale)



Annex VII. Sample size formula and table

$$n = \frac{2 \sigma^2}{(\mu_2 - \mu_1)^2} * f(\alpha, \beta)$$

B (error tipus II)					
		0.05	0.1	0.2	0.5
	0.1	10.8	8.6	6.2	2.7
α	0.05	13.0	10.5	7.9	3.8
error tipus I	0.02	15.8	13.0	10.0	5.4
	0.01	17.8	14.9	11.7	6.6

Annex VIII. Kinesiotaping photos



