DETECTION OF THE ILEOTIBIAL BAND TENSION THROUGH DIRECT PALPATION: RELIABILITY ASSESSMENT STUDY

08-31-2022

ID: ITB01

Approved by IRB ManusSapiens on 08-31-2022

Protocol n° 2022/004

(translated version)

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Introduction

The iliotibial band (ITB) is a thick fibrous fascial tissue that lies between the iliac crest and the anterolateral region of the thigh. Proximally it represents the insertional tendon of two muscles placed in parallel: the tensor fascia latae (TFL) anteriorly; the superficial gluteus maximus posteriorly (Standring 2004).

Several researches link an incorrect ITB tension to some pathologies, such as: iliotibial band syndrome (Foch et al. 2020; Friede et al. 2020; Friede et al. 2022); patellofemoral chondropathy (Park et al. 2016); cruciate ligament injury (Cibulka and Bennett 2018; Liebensteiner et al. 2020; Xu et al. 2021; Runer et al. 2022); low back pain and sciatica (Arab et al. 2010).

The mechanical importance of ITB is highlighted by the prevalence with which the latter is involved, particularly in runners, in fact 5 to 14% of all running-related injuries involve ITB (Van Der Worp et al. 2012).

One would expect that for a structure so susceptible to injuries and with a close functional connection with various pathologies, there would be a reliable evaluation and diagnosis test, but unfortunately this is not the case.

The manual tests proposed in the literature to evaluate the tension of the ITB are the classic (Ober 1936) and the modified Ober test (Kendall 1994, page 57). In the literature there are some studies (Melchione and Sullivan 1993) that have validated the repeatability of the Ober test, both the classic and the modified one, but none has ever confirmed its validity. Both of these tests indirectly evaluate the tension of the ITB through the degree of adduction of the femur.

The work of Willett et al. (2016), carried out with cadaveric findings, reports that the structures involved during passive adduction of the femur are different and the main ones that limit the excursion are the gluteus medius, the minimus and the capsulo-ligamentous structure. The question that arises spontaneously, taking into consideration the results of this last study, is: how else can we evaluate the tension of the ITB in order to be able to correlate it to the pathology reported in the literature? From the lack of validation of the manual tests described in the literature and commonly used in clinical practice, the need emerges for a new test that makes the assessment of the ITB tension more reliable.

The direct manual evaluation of the tension of the ITB certainly turns out to be more specific (valid/accurate) but arises doubts as to how reproducible it can be.

The proposed study will try to investigate the reliability of direct palpation of the ITB, investigating the reproducibility of the intra- and inter-examiner evaluation performed on the same day (intra-day) and validate the result of the palpatory examination with an instrument that measures tissue tension . It will also be evaluated whether concordance can be improved by appropriate training.

Material and Methods

The recruitment phase involves the enrollment of asymptomatic young/adult subjects for pathologies of the lower limbs which, in the opinion of the subject himself or the examiner, make detection difficult.

The number of subjects to be recruited was chosen following the indications provided by the International Academy of Manual/ Musculoskeletal Medicine (Patijn 2019).

The enrollment will take place in three distinct phases, each for every phase of the study which involves the evaluation of subjects. In the first (baseline sampling) 40 subjects will be recruited, in the second (verification

sampling) 20 and in the third (final sampling) 40. Consent will be requested each time. Since it is possible that the same subject is recruited several times (since it is not relevant for the purposes of the assessment whether the subjects are different or the same - Patijn 2019) the total number of subjects involved may vary between a minimum of 40 and a maximum of 100.

MyotonPRO (MyotonPRO-Estonia) is a digital palpation device for the non-invasive measurement of the condition of muscle tone, myofascial stiffness and elasticity with good validity and repeatability of the results both in healthy subjects (Chen et al. 2019) and in pathological subjects (Garcia-Bernal et al. 2021). The device features a mechanical actuator, which delivers a percussive pulse to the myofascial structure and records the response. Subsequently, filtering and digital processing are used to process the data and calculate numerical parameters of muscle tone, biomechanical and viscoelastic properties.

Inclusion criterion

- subjects aged between 18 and 40 years.

Exclusion criteria

- Clinically evident pain symptoms which, in the opinion of the subject or the examiner, may prevent the execution of the test (for example hip pain while maintaining the sampling position);

- obvious excess weight (BMI greater than 28 kg/m2) which could undermine the manual and instrumental result obtained.

Project phases

The project includes 6 phases:

I phase - agreement in principle on the sampling method;

II phase - recruitment;

III phase - first sampling;

IV phase - training on perception and concordance;

V phase - second sampling to verify the progression of the agreement;

VI phase - third manual sampling and evaluation with Myoton.

Description of the phases

I phase - The two examiners together with the principal investigator perform 2 hours of training to standardize the sampling method (localization of the point to be evaluated of the ITB and intensity of pressure of the fingertips to be used) and discussion on the tension gradation detected on the ITB with some volunteers.

II phase - The recruitment will be carried out through the search for volunteers among the students of the OSCE-Bologna school of osteopathy, through announcement in the classroom and publication of the

recruitment in the FB social group of the school (OSCE planet) and WhatsApp groups of students organized by year.

III phase - First sampling of manual evaluation only, using a sample of 40 subjects (both limbs), as proposed in the literature (Patijn 2019).

The operators identify if there is an equal or different stiffness between the right and left ITB.

There will be a double evaluation for each sampling session: 1) if there is a uniformity of the tension between the two sides, or if there is a prevalence on one side; 2) quantification of the difference, if present, with a graduation in 3 levels.

In the first sampling, the examiner will indicate with + 1 a greater tension on the right side; - 1 on the left side; 0 if there are no significant differences.

The second sampling consists in identifying, when present, the graduation of the tension difference between the two sides, arITBrarily divided into 3 levels. The examiner will then report:

+ 3 to indicate more tension on the right with a large difference from the left;

+ 2 to indicate greater tension on the right with a medium difference compared to the left;

+ 1 to indicate more tension on the right with a slight difference from the left;

0 to indicate an insignificant prevalence of tension on one side with respect to the other;

- 3 to indicate greater tension on the left with a large difference compared to the right;

- 2 to indicate greater tension on the left with an average difference with respect to the right;

- 1 to indicate more tension on the left with a slight difference compared to the right.

IV phase - The manual examiners carry out a period of training on perception and agreement, lasting about 20 hours. This training is done using tools (gold standard) made specifically to change the state of density and tension of elastic structures and ropes that simulate the ITB, connected to dynamometers to quantify the state of tension. In vivo evaluation, between operators, are used to verify the exact point of where to take the tension sample and compare the tension data obtained for the construction of the agreement.

V phase - The second sampling to verify the progression of manual agreement, as proposed in the literature (Patijn 2019), is carried out by evaluating the tension of the ITBs, with the same method as the first sampling with volunteers, but in a reduced sample (about 20 subjects). If from the statistical processing of the results of this trial evaluation a good improvement in the agreement is highlighted, compared to the previous sampling (baseline) weighted Cohen's K value greater than or equal to 0.60, the program moves on to the VI phase; otherwise, there will be additional training.

VI phase - The definitive manual sampling consists in repeating, using the same modality of the first evaluation (baseline), with different or identical subjects of the first sampling. The number of subjects will always be 40 evaluated by both examiners and each examiner will evaluate the same subject twice about 20-60 minutes apart. The same subjects will be tested, after the manual evaluation, with the Myoton using the

modality previously described. The results of the Myoton are automatically stored in the preset instrument with the subject ID and downloadable to the computer in an Excel worksheet.

All the data obtained is collected and processed by the examiner who does not participate directly in the data collection using an Excel spreadsheet and/or the R program.

Operators and Settings

Operators

Five operators will participate in the study:

- 1 operator, outside the sampling room, performs: registration by anonymizing the subject with an ID which is assigned to the subject by means of a piece of paper; distributes the information and collects informed consent to participate in the study; performs the post-collection processing (tabulation and statistics) of the collected data.

- 2 operators, inside the sampling room, carry out the manual sampling of the tension of the ITB;

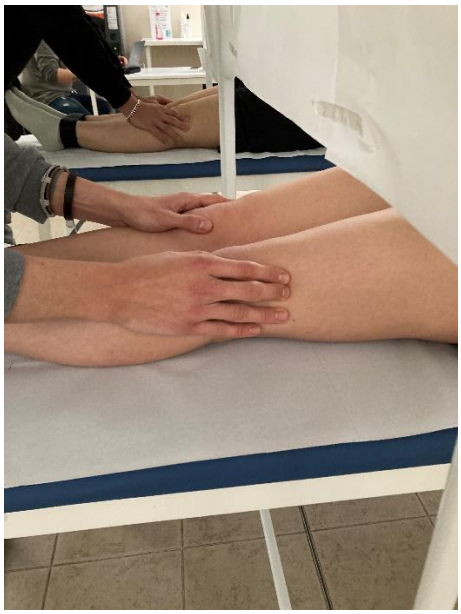
- 1 operator, inside the sampling room, carries out the instrumental sampling (Myoton) of the tension of the ITB;

- 1 operator, inside the sampling room, who organizes the entry and exit of the subjects evaluated, giving the detection times.

Settings

The samplings will be made in a room with two beds arranged about 3 meters apart and two desks. A screen, placed on both beds, will cover the examined subject from the pelvis upwards. The same subject is evaluated, on the same day, by both examiners twice, approximately 20-60 min apart.

Two subjects at a time are made to enter the room where the two manual examiners are present; a third examiner will use the Myoton.



When the 2 subjects enter the room and lie down in a supine position on the bed, with both limbs uncovered, the operator keeps their feet together, with a Velcro strap, to symmetrize the major axis of the feet and indirectly rotation of the hip.

During this preparation of the subjects to test, the manual examiners are turned away so as not to identify the test subjects. Once the positioning is complete, the examiners turn around and have 15 seconds to evaluate the assigned subject (see figures - examiner A always evaluates the subject on the right bed first while examiner B the one on the left); once the subject has been evaluated and the subject's identification code has been reported on a piece of paper with the result of the evaluation which is placed in a container, they go on to evaluate the subject lying on the opposite bed and repeat the same procedure for recording and storing the data detected.

Once the manual evaluation test has been carried out by both examiners, the subjects, before getting off the bed, are evaluated by the examiner who uses the Myoton, following the instructions recommended by the manufacturer. The examiner traces an X with a pen on the evaluation point, about 5 cm proximally from the joint line and 1 cm from the anterior edge of the ITB, and then carries out the evaluation which automatically takes place through 3 impulses. The result is automatically stored in the preset instrument with the subject ID.

The parameters measured and stored are:

F – Natural oscillation frequency [Hz], which characterizes the tone or tension S – Dynamic stiffness [N/m]

D – Logarithmic decrease of the natural oscillation, which characterizes the elasticity R – Mechanical stress relaxation time (ms)

C – Ratio of strain and relaxation time, which characterizes the “Creep” (Deborah number).

At the end of all the evaluations, the examiner who manages the Myoton downloads the detected data onto the computer which is automatically stored on an Excel sheet.

After the manual and instrumental detection, the subjects leave the sampling room and remain in the area for when they will be recalled for the second evaluation.

At a variable distance of 20-60 minutes from the first survey, the tested subjects are recalled, this time only for the manual re-evaluation, in the same way as in the previous evaluation, using a different sequence and identification code from the one used in the first examination.

Outcomes

The study foresees the following outcome:

verify the increase in the agreement after the specific training (comparison between the agreement of the first sampling and that of the final sampling).

Expected total duration

The total duration of the study including all the phases reported is approximately 2 months.

Statistical processing

Processing of descriptive data of the subjects (age, weight and height).

Evaluation of intra and inter examiner agreement by means of weighted Cohen's K with use of sampling evaluation divided into 3 intervals (+1, 0, -1) and 7 intervals (+3, +2, +1, 0, -1, -2, -3).

The Myoton data are processed by subtracting the average data of the three measurements (automatically carried out by the instrument) of the right limb from that of the left. The data obtained is categorized into 3 levels to be compared, again using weighted Cohen's K, with the data from the manual evaluation.

Bibliography

Arab AM, Nourbakhsh MR. The relationship between hip abductor muscle strength and iliotibial band tightness in individuals with low back pain. Chiropr Osteopat. 2010 Jan 13;18:1.

Chen G, Wu J, Chen G, Lu Y, Ren W, Xu W, Xu X, Wu Z, Guan Y, Zheng Y, Qiu B. Reliability of a portable device for quantifying tone and stiffness of quadriceps femoris and patellar tendon at different knee flexion angles. PLoS One. 2019 Jul 31;14(7):e0220521.

Cibulka MT, Bennett J. How weakness of the tensor fascia lata and gluteus maximus may contribute to ACL injury: A new theory, Physiotherapy Theory and Practice, 2018 DOI: 10.1080/09593985.2018.1486492.

Foch E, Aubol K, Milner CE. Relationship between iliotibial band syndrome and hip neuromechanics in women runners. Gait Posture. 2020 Mar;77:64-68.

Friede MC, Innerhofer G, Fink C, Alegre LM, Csapo R. Conservative treatment of iliotibial band syndrome in runners: Are we targeting the right goals? Phys Ther Sport. 2022 Mar;54:44-52.

Friede MC, Klauser A, Fink C, Csapo R. Stiffness of the iliotibial band and associated muscles in runner's knee: Assessing the effects of physiotherapy through ultrasound shear wave elastography. Phys Ther Sport. 2020 Sep;45:126-134.

Garcia-Bernal MI, Heredia-Rizo AM, Gonzalez-Garcia P, Cortés-Vega MD, Casuso- Holgado MJ. Validity and reliability of myotonometry for assessing muscle viscoelastic properties in patients with stroke: a systematic review and meta-analysis. Sci Rep.

2021 Mar 3;11(1):5062

Kendall FP, Kendall McCreary E, Geise Provance P: I muscoli. Funzione e test. Verduci Editori. Roma 1994

Liebensteiner M, Runer A, Kranewitter C, Nachtigal P, Giesinger J, Dammerer D, Henninger B. MRI visibility of the anterolateral ligament and the deep structures of the iliotibial tract. J Exp Orthop. 2020 May 6;7(1):25.

Melchione WE, Sullivan MS. Reliability of measurements obtained by use of an instrument designed to indirectly measure iliotibial band length. J Orthop Sports Phys Ther. 1993;18(3):511–515.

Ober FR: The role of the iliotibial band and fascia lata as a factor in the causation of low-back disabilities and sciatica. J Bone Joint Surg 1936, 18:105-110.

Park JH, Kang SY, Choung SD, Jeon HS, Kwon OY. Effects of tibial rotation on Ober's test and patellar tracking. Knee. 2016 Aug;23(4):600-3.

Patijn, J. Reproducibility protocol for diagnostic procedures in Manual/Musculoskeletal Medicine. Manuelle Medizin 2019; 57, 451–479.

Runer A, Dammerer D, Kranewitter C, Giesinger JM, Henninger B, Hirschmann MT, Liebensteiner MC. Injuries to the anterolateral ligament are observed more frequently compared to lesions to the deep iliotibial tract (Kaplan fibers) in anterior cruciate ligamant deficient knees using magnetic resonance imaging. Knee Surg Sports Traumatol Arthrosc. 2022 Jan;30(1):309-318.

Standring S.Gray's Anatomy: the Anatomical Basis of Clinical Practice, 39th edn. Edinburgh: Elsevier/Churchill Livingstone 2004, pag. 1337-8.

van der Worp MP, van der Horst N, de Wijer A, Backx FJ, Nijhuis-van der Sanden MW. Iliotibial band syndrome in runners: a systematic review. Sports Med. 2012 Nov 1;42(11):969-92. doi: 10.2165/11635400-000000000-00000

Willett GM, Keim SA, Shostrom VK, Lomneth CS. An Anatomic Investigation of the Ober Test. Am J Sports Med. 2016 Mar;44(3):696-70.

Xu J, Han K, Su W, Jiang J, Yan X, Yu J, Dong S, Zhao J. A Secondary Injury of the Anterolateral Structure Plays a Minor Role in Anterior and Anterolateral Instability of Anterior Cruciate Ligament-Deficient Knees in the Case of Functional Iliotibial Band. Arthroscopy. 2021 Apr;37(4):1182-1191.