TITOLO

EVALUATION OF ANKLE PROPRIOCEMENT AND STABILITY IN PATIENTS AFFECTED BY TRAUMATIC LATERAL ANKLE INSTABILITY BEFORE AND AFTER EXTERNAL ANKLE LIGAMENT RECONTRUCTION

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Premise

Proprioception

Proprioception represents the ability of the central nervous system to perceive the position and movement in the space of the body and its parts. It is very important both for a control mechanism on the correct execution of the movement, and for a mechanism of possible correction in the case in which, unexpected external phenomena, are to disturb the strategically programmed motor projects. The term proprioception has been used incorrectly as a synonym and interchangeable with kinesthetic, sense of common position, balance and reflexive articular stability. The term was coined by Sherrington in 1906 (70) from "receptus" (act of receiving) and "propius" (from himself) to define the sense of perception of body position understood as "conscious awareness", literally the "conscious" awareness ", the awareness of the position of the limbs in space. Proprioception is defined as the sense of position and movement of the limbs and of the body that is independent of sight. It is an important component of the mechanisms that control and stabilize posture, ie the ability to maintain a position of the body and limbs and their orientation in space.
Continuous postural "adjustments" are required to perform a movement. These adjustments appear even more important in sporting activities, but the same applies when switching from a bipedal support to a monopodalic support, or when climbing stairs. They immediately implement automatisms that "rearrange" the body in space.
It is not a matter of voluntary responses, which would take too long a time, but of unconscious automatisms: there is an already established "program" that the organism applies without effort. All this information reaches the central nervous system, where an answer is processed, which is immediately "postponed" to the muscles, where it translates into the execution of inexpensive and coordinated movements. We can distinguish two components of proprioception: a conscious called "proprioception" and an unconscious called "archaeoproprioception".
The conscious component provides the sensation of joint position (position in which a limb is located) and the sensation of joint movement. The information coming from conscious proprioception is transmitted through the backbone and partly through the spino-cervical tract, and is used to facilitate the most complex motor activities. The unconscious archaeoproprioception is the basis of the reflexes that make the body stable. It is an automatic system that does not involve consciousness. When you walk, you realize the surrounding environment without thinking of the muscles that move, balance, posture and everything works automatically. It affects the most primitive structures developed in the course of evolution: the spinal cord and the trunk of the brain, brain, cerebellum, medulla oblongata. The unconscious proprioception is important in the coordination of the simplest motor activities and in the maintenance of posture.
So proprioception is a complex anatomical structure, which consists of nerve centers and pathways and structures that respond to commands coming from the nervous system; there is a continuous exchange of messages between the external and internal environment, almost a telephone exchange that distributes information between muscles, tendons and the central nervous system.
The tibio-tarsic articulation has various functions: support of body load, movement, static and dynamic control, allows running, walking, jumping, landing from a jump absorbing the impact. And, no less important, it plays a fundamental role in providing a stable but flexible support base, through biomechanical compensation mechanisms, in the coordination of hip and knee movement.

Therefore, the tibio-tarsic is a joint of central importance for the implementation of the mechanisms of body proprioception.

Proprioception and ankle

Ankle instability

Ankle instability refers to a condition of weakness, more frequently arising after one or more distortional traumas. The patient reports it as a subjective feeling of insecurity and failure of the tibio-tarsal joint.
Ankle sprain is one of the most frequent traumas; in North America the prevalence is about 1 in 10,000 per day in the general population; in sports patients the percentage rises considerably, reaching about 40% of total sports injuries. The reason is related to the forces applied during competitive activity and body weight.
The most frequent distortion trauma is that in inversion, which occurs during a plantar flexion movement and inversion of the foot with an excess of supination of the ankle and extrarotation of the tibia.
This traumatic movement leads to a stretching or injury of the lateral ligament compartment, consisting of the anterior peroneo-astragalic ligament, peroneo-calcaneal and posterior peroneal-astragalic ligaments.
Approximately 40% of patients who have undergone an ankle sprain will experience relapsing sprains due to instability generated by the first trauma. This group of patients is most at risk of developing an early osteoarthritis due to the excessive consumption of articular cartilage.
Intrinsic predictive factors of ankle sprain include anatomical features, functional deficits in isometric strength, flexibility, joint proprioception, muscle reaction time, postural stability, dominant limb, Body Mass Index (BMI) and previous distortive trauma.
Despite the extensive research developed in recent years, to date a common vision for the assessment of ankle instability has not yet been reached. This is due to the multitude of tools and techniques used to quantify postural stability.
In general, the methods used today test the static, dynamic and functional postural stability. Clinical tests (mCTSIB, BESS) and instrumental tests (test with platform) are used to quantify the static stability; to quantify the dynamic stability a change of position of the patient is generated (change of direction or a jump) or a perturbation of the support surface is created. To quantify the functional stability we use exercises using a support base able to create continuous position changes (gait analisysis).

2. OBJECTIVES

The aim is to study the effectiveness of the ankle external ligament reconstruction according to the modified Bröstrom-Gould technique through the study of the postural control with:
- a computerized oscillating platform, Delos device (www.delos-international.com), in particular in its proprioceptive component;
- using the Modified clinical test Star Excursion Balance Test (mSEBT);
- through evaluation questionnaires (FAAM, AOFAs, SPPB).

To date, in fact, there are scientific works, also produced by our Institute (Giannini et al., 2014), which evaluated patients pre- and post-operatively, but only through clinical score.

Patients will then undergo a preoperative evaluation and a second evaluation at an average time of 4 months from the surgery.
Primary outcome: evaluation of the modified Bröstrom-Goulde technique for ankle external ligament reconstruction.
Secondary outcome: comparison between Delos and mSEBT as stability and proprioception evaluation techniques.

3. STUDY DESIGN

Will be included in the study all the patients who undergo surgery for lateral capsular-ligament instability during 18 months after EC approval (probably end on August 2019), in accordance with the criteria specified below. Each patient will sign an informed consent for participation in the study.

Inclusion and exclusion criteria for patients enrolled in the study

The study population consists in patients with chronic post-traumatic lateral ankle instability who must undergo ankle external ligament reconstruction.

Inclusion criteria:
Patients will be recruited according to the following inclusion criteria:

- patients who must undergo surgery;
- patients of both sexes aged between 18-40 years;
- patients who have given their informed written consent to participate in the study;
- patients who have given their readiness to reach the Institute to perform the 4-month check-up.

Exclusion criteria:

- patients with BMI> 30 kg / m2;
- patients with rheumatoid arthritis;
- patients with chronic inflammatory joint diseases;
- patients with pre-existing abnormalities of the ambulatory kinematics (amputations, neuro-muscular diseases, polio, hip dysplasias);
- patients with Severe arthrosis of the ankle (Kellgren-Lawrence> 3);
- patients with Severe knee arthritis (Kellgren-Lawrence> 3);
- patients with ACL injury;
- patients with severe postural instability;
- patients with cognitive impairments;
- patients with concomitant neurological diseases.

4. MATERIALS AND METHODS

The study of posture and control of movement in humans requires technological supports capable of providing accurate, reproducible and repeatable information on displacement and / or position in real time.

The Delos Postural Proprioceptive System is an oscillating platform that uses electronic tilting tables (on a single axis or three axes) at high frequency which allows very short stopping and reversal times. Furthermore it is possible to assign position tasks and maintain a specific inclination.

Moreover, the combination of tilting and translating table with an electronic sensor that provides visual feedback in real time, greatly increases the number of biomechanical situations to be managed in the unit of time. The inclination of the table, which at every moment is communicated through the track on the monitor, hooks the subject to a new situation to be managed. The nerve centers, thanks to the high flow of afferent signals, are trained to interpret them correctly and to provide adequate responses faster and faster. The visual feedback involves a flow of high frequency proprioceptive signals able to reprogram the postural control and movement system, considerably higher than a situation managed with eyes closed or with the aid of a mirror. In fact, with closed eyes there is a greater commitment on the part of the other sensory analyzers, but in the absence of visual feedback the number of biomechanical situations to be managed is drastically reduced with consequent reduction of the flow of proprioceptive signals, while the use of a mirror as Visual feedback is of no use as it is a complex piece of information that requires long time for cortical processing to be used. For this reasons this system can be uses for diagnose and quantify ankle instability.

mSEBT (modified Star Excursional Balance Tests)

In recent years within the orthopedic and physiatric discipline the interest in the development of tests that allowed to evaluate the stability of the ankle joint can be used, which can be used to quantify the ligament damage resulting from a trauma or that allow to evaluate the improvement after a surgery or rehabilitative treatment.
The Star Excursional Balance Test (SEBT) is a clinical test designed to assess the dynamic physical performance of ankle. The first literary references date back to 1998 and the test provided, remaining in balance with the ankle in the studio, reaching the maximum possible distance with the contralateral foot along the well-determined axes (see figure below) by making 12 attempts in each direction in two distinct days.
More recently, through statistical analysis studies, a large data redundancy has been demonstrated with too great a difference in the various attempts along the 8 directions. Therefore, the latest studies suggest to perform the test along only three axes (anterior, posteromedial and posterolateral). The three axes will be arranged through an angle of 135 ° (between the anterior line and the posteromedial line, between the anterior and posterolateral line) and an angle of 90 ° (between the posteromedial and the posterolateral). Moreover, the attempts to be carried out have been reduced to 3 for each direction that can be performed after a few minutes of rest making the test run easier with a timing of less than 60 minutes. This is referred to as the modified Star Excursional Balance Test (mSEBT). You will then get 3 final values, one for each direction that will be the result of the average of the three tests performed.
The results obtained will then be standardized for the length of the patient's limb, so as to obtain comparable values between the different patients. The length of the limb will be calculated at the supine patient, from the antero-superior iliac spine (SIAS) to the apex of the medial tibial malleolus; the length will be calculated on both limbs twice and an average of the obtained values will be made.

To standardize the mSEBT, the average value of each single direction will be divided by the average length of the limb and multiplied by 100%.
To evaluate an effective improvement of joint stability, the outcome of the post-operative test must have a percentage increase. The percentage proposed by Remko van Lieshout et al. in his study he is at least 6.9% for the right limb and 5% for the left (in a patient with a right-hand limb). While Fitzgerald A. et al. they considered valid percentages between 2.95% and 9.4% and Filipa et al. 1.75% and 9.5% to attest to an improvement in post rehabilitative joint stability. Therefore, in our work, in the light of the indicated values, we will adopt those proposed by Remko van Lieshout et al. being also the most recent study on the subject.

SURGICAL TECHNIQUE AND POSTOPERATORY COURSE

The surgical technique that will be used in this scientific research is the modified Bröstrom-Gould technique.
Originally described by Bröstrom in 1966, it is a technique that provides an anatomical reconstruction of the lateral ligament compartment of the ankle in the component of the PAA and the PC, imbricating them with the joint capsule. In 1980 the intervention was modified by Gould, who added, as part of the repair, the suture of the lower part of the extensor retinaculum. The anatomical access to the lateral ligamentous compartment is obtained by means of a small curved cutaneous incision at the apex of the external malleolus; the technique then provides the suture, by means of detached transosseous points, of the ligamentous compartment and of the retinaculum, as previously mentioned.
In the postoperative period the patient will have a period of immobilization (21-30 days) in a pinstriped bootie or Walker tutor. After the first period of immobilization the patient will start walking with progressive load until complete protected by a non-articulated ankle brace, which will take several times a day to mobilize the ankle. At a distance of about 35-60 days, during a second check as per "standard care", the guardian will be abandoned in favor of comfortable footwear and the patient will be able to start the active FKT of muscular and proprioceptive strengthening.

CLINICAL SCORE

The clinical scores used for the overall assessment of the patient are (see attachments):
- AOFAs
- SPPB
- FAAM
- SF12.

Respectively, the American Orthopedic Foot and Ankle Score (AOFAs), is a clinical test commonly used in scientific literature (Leigheb et al), which serves to evaluate, in terms of value from 0 to 100, autonomy, pain, stability , ankle alignment and patient's heel.

The Short Physical Performance Battery (SPPB) is a test used to evaluate the functionality of the lower limbs. It consists of 3 different sections:
1. evaluation of the balance in 3 tests:
   • maintaining the standing joint position for 10 "
   • maintaining the semi-tandem position for 10 "(toe on the side of the heel)
   • maintaining the tandem position always for 10 "(big toe behind the heel).

The score varies from a minimum of 0 if the patient fails to maintain the standing joint position for at least 10 "to a maximum of 4 if he is able to complete all three tests.

2. gait evaluation on 4 linear meters the score of the section varies based on the time required for the test from 0 if incapable, to 4 if it succeeds to accomplish the task in less than 4.1 "

3. evaluation of the ability to perform, for 5 consecutive times, the sit to stand from a chair without using the upper limbs that for the test must be crossed in front of the chest the score varies from 0 if unable to 4 if the test is carried out in less than 11.2 ".
The total score of the scale therefore has a range from 0 to 12.

Foot and Ankle Ability Measure (FAAM): translation and validation of the Italian version of the ADL module (FAAM-I / ADL) F. SARTORIO, S. VERCELLI, ELISABETTA BRAVINI *, SERENA BARGERI **, MICHELA MOROSO **,
G. PLEBANI ***, G. FERRIERO.) Is a test used to assess patient autonomy in everyday life, by means of targeted and specific questions.
The SF12 test is the short version of the SF-36 (link) questionnaire. Through 12 of the 36 questions of the original questionnaire it allows to investigate the two synthetic indexes, PCS Physical Component Summary for the Physical State and MCS Mental Component Summary for the State of Mental. The strong points of this questionnaire are the brevity and the relative ease of use. In Italy, the questionnaire was used inter alia in 2000 in a ISTAT multiscopo survey on the health status of Italians and a reference database is available with data on a sample of 61.434 representative subjects of the Italian population. Also for this short form the literature is rich in experiences and studies that prove its validity and reliability.

Study sample

All continuous variables will be expressed as mean ± standard deviation (SD). The dichotomous or pyrotechnic variables will be expressed as frequency and percentage. To test the effects of the treatment on continuous variables, the ANOVA will be used for repeated two-way measurements (2 groups × 2 times). Percent Delta scores will be calculated for each participant and each continuous outcome as follows: (T1 - T0) * 100 / T0. To evaluate the effect of categorical variables on the Delta percentage scores one-way ANOVA will be used if the variables will be normally distributed and homoschedastic, otherwise non-parametric tests will be used: Mann Whitney (2 groups, pre and post operative). To evaluate the effect of continuous or rank variables on the percentage Delta scores, the correlation by Spearman ranks will be used. To assess the distribution of values between dichotomous or categorical variables, the Chi Squared Fisher test will be used (2 pre and post operative groups). For all tests, $p < 0.05$ will be considered significant. Statistical analysis will be carried out using the statistical package for social sciences (SPSS), software version 15.0 (SPSS Inc., Chicago, USA).

Visits and examinations scheduled by the study

Pre-operatively:
- Evaluation of static and dynamic physical performance by means of the Delos apparatus with the Riva method
- Evaluation of dynamic physical performance through mSEBT tests and SPPB tests
- Physiatric / orthopedic visit with collection of:
- Clinical scores (FAAM, AOFAs)
- Objective examination
- Score to evaluate the satisfaction perceived by the patient (SF12).

Post-operatively:
- Evaluation of static and dynamic physical performance by means of the Delos apparatus with the Riva method
- Evaluation of dynamic physical performance through mSEBT tests and SPPB tests
- Physiatric / orthopedic visit with collection of:
- Clinical scores (FAAM, AOFAs)
- Objective examination
- Score to evaluate the satisfaction perceived by the patient (SF12).

Potential risks

There are no potential risks.

Duration of the study

The study will last for 18 months.

Month 1 - Team training involved in the study
Months 2-12 - Selection, enrollment and treatment of patients
Month 18 - Medium-term analysis of critical aspects
Months 5-16 - Post-treatment clinical evaluation after 4 months
Months 16-18 - Data analysis and dissemination of results.

The approval of the Ethics Committee will be considered as the starting date of the experimentation.

5. ETHICAL AND ADMINISTRATIVE ASPECTS

Informed consent

Each patient will be explained in a simple and comprehensive way the conduct of the study, will also be given the opportunity to ask questions to clarify any doubt. The informed consent form will be delivered to the patient and a signed copy will be included in the medical record.
The doctor who will carry out the pre-and post-operative visit will report in the health documentation the modality and the time of acquisition of the Informed Consent.Confidenzialita' dei dati e proprieta' dei risultati

The management of the study documentation and the confidentiality of the data will be carried out by PI (Dr Massimiliano Mosca).

The principal investigator undertakes to produce the final report, publish all the data collected as described in the protocol and to ensure that the data are reported responsibly and consistently.

In particular, the publication of data deriving from this study will take place independently of the results obtained.

Bologna, lì 01-10-2018

Dr Massimiliano mosca

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