Muscle activation of the lower limb in response to a mid-lateral imbalance in monopodal stance: a preliminary experimental study

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Approved by Comitato Etico di Area Vasta Nord RER

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(translated version)

A. Title of the study (translated)

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B. Promoter and participants

1) Promoter: Manusapiens, a non-profit technical-scientific association with the aim of promoting research and dissemination of manual and functional therapy.

2) Principal Investigator (PI): Corrado Borghi, Biomedical engineer (PhD) and physiotherapist (Unimore adjunct professor)

3) Responsible Investigator: Corrado Borghi, Biomedical engineer (PhD) and physiotherapist (Unimore adjunct professor)

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D. Background

From a neurophysiological point of view, maintaining balance is a complex function, especially in the high instability of one-foot support (monopodalic support). It requires the integration of many systems for the collection of information (vestibular apparatus, proprioception, baroception, sight), for the processing of the information itself (carried out by the central nervous system - CNS, with particular contribution from the cerebellum), and for the activation and management of the responses to be given (through the muscles) (Horak, 1986; Winter, 1995; Adkin, 2000; Wang, 2014).

The "static" monopodalic posture (i.e. in a position that is as still as possible), with the drastic reduction of the support base that it entails, undermines the balance maintenance system and generally requires significant muscle activation with consequent energy expenditure.

For this reason, it is widely used to evaluate and train the balance itself. In the literature, it has been extensively analyzed for therapeutic exercise, functional assessment and sports training (Katayama, 2004; Chang, 2005; Granacher, 2011; Greenwood, 2011; Pfusterschmied, 2013; Brachman, 2017; Alfuth, 2017; Rahman, 2017). The goals are to test and/or increase balance, proprioception, strength and muscle endurance. A major issue concerns the prevention of falls in the elderly (Donath, 2016; Kurz, 2018; Granacher, 2011; Muehlbauer, 2015).

Another aspect of interest linked to the analysis of monopodalic support is the study of the strategies for maintaining balance and stabilization of the joints (Kristensen, 2016; Wolburg, 2016; Mirzaie, 2019; Kurz, 2018).

Numerous studies in the literature have examined static monopodalic equilibrium, taking into account different experimental conditions and outcome measures. Usually, with regard to muscle activity, the average intensity of activation and response latency were measured (Greenwood, 2011; Dingenen, 2015; Donath, 2016; Wolburg, 2016; Alfuth, 2017; Rahman, 2017; Mirzaie , 2019; Kurz, 2018). A distinction has never been made, however, between activities related to medial and lateral imbalances respectively, if not at the level of the ankle (Morey-Klapsing, 2005). There is therefore no global approach, which involves at least the entire lower limb, and evaluates in detail the motor strategies used by the body to obtain balance.

E. The Study

Hypothesis and rationale. Colonna (2012) assumes, basing on the interpretative approach of myofascial chains, that the management of balance occurs through the anterior and posterior spiral chains. According to the myofascial chain approach, muscles are no longer considered independent, but connected in series via the connective tissue (muscle fascia, tendons, ligaments, ...). The concept of myofascial chains suggests that mechanical force can be transferred not only within a limb between synergistic or antagonistic muscles, but also between muscles arranged in series (Wilke, 2018).

Colonna’s hypothesis, which has never been experimentally verified, is based on the intuitive search for the most effective system to respond to the perturbations that destabilize the equilibrium. The "cruciate" system that the spiral chains form in the lower limb appears to be the most appropriate response, as it is more stabilizing.

This preliminary study is not intended to provide direct treatment indications. It is therefore not a study aimed at clinical practice.

The aim is to carry out a preliminary study to test the reasonableness of the hypothesis that the spiral myofascial chains intervene in the monopodalic equilibrium, verifying the feasibility of the proposed method to analyze the response to a medial and lateral imbalance.

The results of this study will be used to determine the opportunity for future investigations (with statistically significant number of subjects, assessment of muscle activation variations as a function of different pathologies, etc.) and the eventual definition of an optimal experimental setting and methodology.

F. Study design.

Setting: preliminary experimental

Type: non-pharmacological

Organization: monocentric

Enrollment: consecutive

Conduction: open

G. Population

The study aims to carry out a preliminary assessment of the feasibility and reasonableness of hypotheses. The sample to be examined must therefore be composed of healthy subjects, in order to limit the variables determined by possible pathologies that alter physiological behavior. The age of the subjects must allow a full maturity of the neuro-musculoskeletal system and precede its degeneration. As this is a preliminary study, a sample size to provide statistical significance is not sought. The sample must be functional to test the method and to verify whether the hypothesized motor strategy can be detected in the subjects considered. The recruitment can be achieved through the search for volunteers among the acquaintances of the experimenters.

Number of subjects: 5

Inclusion criteria: healthy adult subjects, aged between 18 and 65 years.

Exclusion criteria: skeletal or neuromotor pathologies, past or current, which may compromise the maintenance of balance and / or modify the strategies in implementing it (in the opinion of the investigators).

H. Outcome measures

The core of the study consists in carrying out a measurement of activation of the muscles of the lower limb. In particular, it will be necessary to measure this activation as a response to an imbalance / perturbation in monopodal stance.

Muscle activity will be evaluated for 1500ms, 500ms before and 1000ms after the disturbance. The early response to the stimulus will be identified in the interval of 100-500ms after the stimulus.

The muscles considered will be, for the anterior spiral chain, the adductor longus and the peroneus longus, for the posterior spiral chain, the glutei (medium and large) and the tibialis anterior. Therefore, both muscles of the thigh (glutei and adductor longus) and of the leg (peroneus longus and tibialis anterior) will be examined.

The goal is to understand which of these muscles are activated together, in particular if the muscles belonging to the same myofascial chain are activated together. The simultaneous activation will be measured with the calculation of the correlation coefficient. The hypothesis of spiral chains use for the balance will be

considered reasonable if it is possible to observe greater correlation between the peroneus longus-adductor longus and between the glutei-tibialis anterior than the correlation between the glutei-peroneus longus and between the tibialis anterior- adductor longus.

The outcome measures will therefore be:

• Maximum intensities of early activation, normalized with respect to the electrical intensity measured in the maximal contraction, respectively in response to a stimulus that causes a medial and lateral imbalance;

• Correlation coefficients between the electrical activities of:

- adductor longus-peroneus longus
- glutei-tibialis anterior
- glutei-peroneus longus
- adductor longus-anterior tibialis

in response to a stimulus that causes medial imbalance;

• Correlation coefficients between the electrical activities of:

- adductor longus-peroneus longus
- glutei-tibialis anterior
- glutei-peroneus longus
- adductor longus-anterior tibialis

in response to a stimulus that causes lateral imbalance.

I. Measurement methods

Setting

The subjects involved in the research will be analyzed at the LAMBDA laboratory (UDGEE), AUSL-IRCCS of Reggio Emilia.

Tools

The elective methodology for this type of investigation is the electromyographic analysis, which allows to highlight the timing of muscle activation and therefore the motor coordination that underlies the balance. Surface electromyography will be used, which is neither painful nor invasive.

The detection system is able to acquire up to 16 channels with a sampling frequency of 1000Hz. Each channel corresponds to a device capable of pre-filtering and amplifying the signal, before transmitting it via wireless to the PC dedicated to the acquisition of the signal itself. Each of these devices is placed on a muscle. The connection with the skin takes place via two adhesive electrodes in Ag-AgCl, equipped with conductive gel (they are the same used for the electrocardiogram). The electrodes measure a potential difference, recording the surface current generated by muscle contraction (as does the ECG for the heart).

During the measurement, other parameters are monitored by:

• force platforms: two AMTI® platforms capable of detecting the center of pressure (COP), the direction and the intensity of the resultant of the forces applied on them with a frequency of 1000Hz;

• optoelectronic system: Vicon® system (Oxford Metrics Group, UK) with 7 infrared cameras capable of detecting the position in space of reflective markers with an accuracy of 1mm (for the identification of the 3D position of a marker it is necessary that it is visible for at least two cameras at the same time; each camera

is equipped with a crown of infrared LEDs to increase the visibility of the markers without disturbing the acquired subjects; the sampling frequency is 100Hz, sufficient to accurately detect the body kinematics;

• video cameras: two video cameras with perpendicular axes that acquire at 100Hz and allow you to immediately provide an overview.

Thanks to these systems it is possible to monitor the movement of the COP with respect to the foot in support (it allows to visualize the medial and lateral imbalance), and to evaluate the loads and movements of the various body segments (the motor strategies for maintaining balance are displayed).

Measurement protocol

The analysis will be carried out on the right lower limb of each subject.

The electromyographic devices will be applied to the tibialis anterior, peroneus longus, gluteus medius, gluteus maximus and adductor longus.

The reflective markers will then be applied (using double-sided tape) according to the Total3DGait protocol, which identifies the body segments of the forearms, arms, trunk, pelvis, thighs, legs, and feet.

The subject must position himself with his right foot on a force platform.

The toe of the left foot will be allowed to rest on the ground (on the other power platform placed at the rear), with the verbal indication to load as little weight as possible on it: this indication is aimed at reducing muscle activation in the absence of external perturbations, in order to highlight only the activity caused by the perturbations themselves. Only acquisitions in which the load on the left foot will be less than 30% of the weight will be considered valid.

The hands will be placed on the hips to limit the variables to be controlled and to standardize the posture, in order to focus the contribution to the balance of the lower limb. The left thigh has to be kept vertical. Finally, it will be required to find, within the constraints described above, the posture that is as comfortable as possible, with minimal muscle contraction. The distance between the feet is therefore freely chosen by each subject.

The operator positions himself behind the subject to be examined, and without being seen performs lateral thrusts with the medial margin of the hand at the proximal third of the thigh. At least ten pushes per side will be performed, with random timing. The thrusts will be quick but without causing pain.

The operator will then request maximal contractions from the subject, in order to normalize the electrical activity of each muscle with respect to its maximum. It will be required to perform the dorsiflexion and pronation of the foot against resistance, then the adduction, abduction and extension of the hip.

The whole procedure takes about an hour.

Data processing

Electromyographic signals are processed in the following way:

• high pass filter: to eliminate any disturbances (movement artifacts) and keep only the high frequency signal typical of muscle activity;

• rectification: the signal, which is an oscillation around zero, is taken only as an absolute value;

• envelope: application of the Root Mean Square on a span of 200ms (before and after) and moving average, to quantify the extent of muscle activation;

• normalization: muscle activation is normalized with respect to the maximum contraction value; it is therefore expressed as a percentage of this value;

• median: for each muscle of each subject the median of the different response activations is calculated; the median, once a series of values has been placed in ascending order, is constituted by the central value; compared to the average, it allows to reduce the influence on the final value of the most anomalous cases compared to the majority;

• correlation coefficient: calculation of the correlation coefficient to verify any synergies present between the different muscle groups.

J. Duration of the study

Total expected duration: 6 months

Enrollment: 1 month

Measurements: 2 months

Data processing: 3 months

K. Statistical aspects

As this is a preliminary study, a sample size such as to provide statistical significance is not sought. The sample must be functional to test the method and to verify if in the subjects considered it is possible to detect an (indicative) trend that is consistent with the hypothesized motor strategy. For this reason, the number of 5 subjects was considered suitable and no parameters to be considered statistically significant will be calculated.

L. Data management (privacy)

Acquisition data are automatically stored on the laboratory's dedicated PC.

The data of each subject are recorded with an identification number, without reference to personal data of the subject.

Access to the PC is password protected, and the PC is not connected to the internet.

Data processing is carried out directly on the PC itself, so no data transfers must take place.

The CRF forms for data collection will be in paper format.

M. Authorization aspects

It is believed that the study does not present critical issues from an ethical point of view, as measurements are carried out with methods used in ordinary clinical activity and which are non-invasive, non-dangerous, short-term and on healthy subjects.

The consent to the study will be signed before the measurements are taken, after a detailed explanation provided to each subject regarding the measurements themselves and the method of analysis.

No financial agreements are envisaged. The study is carried out as a consensual agreement between all the parties involved.

The AUSL-IRCCS di Reggio Emilia will process the personal data of the subjects participating in the trial as independent Data Controller, pursuant to and for the purposes of the European legislation referred to in GDPR 679/2016 and, as currently applicable, of Legislative Decree 196/2003 .

The AUSL-IRCCS di Reggio Emilia is the owner of the data collected in clinical practice and for the use of personal and sensitive data of patients for research purposes, the express consent of the interested party will be requested, as required by the aforementioned legislation, on the basis of documents approved by the competent Ethics Committee .

The data will be used solely for the purpose of carrying out this study.

The Scientific Responsible of the study is identified as the Delegate for the processing of personal data, pursuant to the Deliberation of the General Manager n. 284/2018, and will appoint with a specific written deed the other collaborators as persons authorized to process personal data under the authority of the owner and the data processing delegate, pursuant to GDPR 679/2016.

The study will be activated only after obtaining the favorable opinion of the Comitato Etico di Area Vasta Nord RER and will be carried out in accordance with this protocol, any amendments introduced and will be conducted in accordance with the ethical principles of the Declaration of Helsinki.

The data will be managed ensuring the protection of privacy in accordance with the provisions of the law (GDPR 679/2016).

The data necessary to respond to the objectives of the study will be recorded in coded form (in accordance with the GDPR 679/2016), therefore the processing of personal data will take place in such a way that the data can no longer be attributed to a specific data subject without the use of additional information, information that will be stored separately and will be subject to technical and organizational measures designed to ensure that it is not attributed to an identified or identifiable natural person. The data will be stored, whether in paper or electronic form, in places or media protected from access by unauthorized persons or intrusion by third parties.

The PI will file and keep in paper format in a protected place, the patient's personal data combined with the assigned ID, together with the signed and dated informed consents and the clinical documentation collected according to the methods of its center (reports, copy of the relevant parts of the medical record).

N. Responsibility and publication policy

The data collected will be the property of the promoter.

O. Insurance aspects

Since it is believed that the measurement setting is safe and that the measurements to be carried out do not present risks, as they are non-invasive and non-dangerous, the stipulation of a specific insurance is not considered necessary.

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