OFFICIAL TITLE: Functional recovery after monolateral or bilateral total hip arthroplasty

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Study coordinator:

Roberto Gatti
Phone: +39 0282246929
Fax: /
e-mail: roberto.gatti@hunimed.eu

Guido Grappiolo
Phone**:** +39 0282248225
Fax: /
e-mail: guido.grappiolo@mac.com

Glossary of abbreviations

THA	Total Hip Arthroplasty
CoP	Centre of Pressure
MVC	Maximal Voluntary Contraction
TUG	Time Up and Go Test
NRS	Numeric Rating Scale

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1 Background and introduction

Total hip arthroplasty (THA) is an effective treatment for many hip joint diseases, able to improve patients' functional level and quality of life and to make the return to the activities of daily living possible [1] [2]. The improvement in surgical techniques had made the bilateral THA surgery possible, through one-stage procedure [3]. It seems not to be linked to increased in mortality rate or postoperative complications respect to the same two-stage procedure. [4] [5] [6].
The goal of the surgery is not only the pain relief, but also the functional recovery, which could take place through adaptive mechanisms of the non-afflicted limb. Simultaneous bilateral THA surgery doesn't allow these adaptive mechanisms and our clinical observation suggests that in this condition, the recovery of the operated limb could be faster. This is not a new hypothesis, in fact the use of the residual motor potential when adaptive strategies are not possible, has been largely demonstrated in the functional recovery of stroke patients [7]. In this case, the application of movement restrictions to the non-affected body segments and the intensive use of the affected side, promotes the motor and functional recovery [8]. Some authors suggest to apply similar approaches in other pathological conditions [9] [10].

2 Rationale of the study

Actually there are no studies investigating the motor and functional recovery of unilateral THA patients compared to simultaneous bilateral THA patients. Our clinical observation induce to speculate that simultaneous THA patients could achieve better functional and motor recovery of affected limbs caused by the impossibility to develop adaptive mechanisms with the contralateral side.

3 Object of the study

3.1General objectives

The aim of the study is to evaluate the lower limbs motor and functional recovery in subjects who undergone to unilateral o simultaneous bilateral THA.

3.2 End-points

3.2.1 Primary endpoints

The primary endpoint the evaluation of postural stability and the weight distribution during a stabilometric task performed in "open eyes" and "closed eyes" conditions, and during a "voluntary swing" condition. The postural stability and weight distribution will be evaluated through two force platforms (P-6000 BTS SpA). The platforms will calculate the weight distribution between the two lower limbs and the antero-posterior and mid-lateral displacement of the Centre of Pressure (CoP) applied on the ground. An optoelectronic system with passive markers composed of six infrared cameras (Smart DX, BTS SpA) and 4-channel surface electromyography (FREEEEMG 1000, BTS SpA) will also be used. The markers will be placed on anatomic bony landmark according to the Davis model in order to reconstruct the pelvis, hip, knee and ankle kinematic on the sagittal plane during the stabilometric task [11]. The surface electromyography will be placed on the anterior tibialis and gastrocnemius medialis of both limbs, according to SENIAM recommendation in order to evaluate the muscles activations normalized respect to the maximum voluntary contraction (MVC), the timing of muscle activation respect to the movements of the tibiotarsic joint during the "voluntary swing" and the frequency of activation during the three trials [12].

3.2.2 Secondary endopoints

The secondary endpoint is the spatio-temporal parameters, the kinematic and dynamic profiles and the muscular activities evaluation during the gait. The analysis will be done through the same technologies described before. The force platforms (P-6000 BTS, SpA) will allow to calculate the ground reaction force. The optoelectronic system (Smart DX, BTS SpA) with the passive markers placed on the skin according to the Davis model will be used to estimate the spatio-temporal parameters and the pelvis, hip, knee and ankle kinematic during the step cycle. The eight-channel surface electromyography (FREEEMG 1000, BTS SpA) will be adopted to calculate muscle activation timing during the gait. The probes will be placed on the anterior tibialis, gastrocnemius medialis, rectus femoris, gluteus medius, according to SENIAM recommendations [14]. The ability of the subject to maintain the limb in isometric flexion and abduction position with the knee extended for 10 seconds will also be evaluated. The evaluation of walking ability will be performed through Time Up and Go Test (TUG). At the end of each task, the perception of pain will be investigated through the Numeric Rating Scale (NRS).

4 Patient selection criteria

4.1 Inclusion criteria

- Age between 40 and 65 years old.
- THA surgery for primary or secondary arthrosis.
- THA surgery for primary osteonecrosis.
- Walking ability for at least 50 m without aids.

4.2 Exclusion criteria

- THA surgery for severe dysplasia (Crowe III e IV).
- THA surgery for anchylosis, sub-ankylosis or surgical fusion of the hip joint.
- THA surgery for a traumatic event.
- THA surgery after previous femoral and / or pelvic osteotomy
- Partial or total THA revision
- Concomitant presence of neurological or musculoskeletal disorders that could affect motor and functional recovery.

5 Study design

The study is a prospective observational study.

5.1 General Design

Unilateral THA and simultaneous bilateral THA patients will be recruited. They will be evaluated through three stabilometric tests, gait analysis, two strength tests, TUG and pain (NRS). The session trials will be done the day before surgery, seven and forty day after surgery. The stabilometric tasks, the two strength tests and the NRS will be performed also after three days. The stabilometric test will be characterized by "open eyes", "closed eyes" and "oscillations" conditions. The first two stabilometric tests (“open eyes” and “closed eyes”) will last 45 seconds and will be repeated three times. Patients will be asked to keep the erected station with the parallel feet placed at an intermalleular distance of 5 cm. Their arms should be relaxed along their sides. The patient has to maintain the balance looking at a point in front of him placed at 2 meters of distance in “open

eyes" condition. During the "oscillation" task, the subject, will be asked to perform three oscillations on the platforms, one after 10 seconds from each other. The gait analysis will consist of 4 trials in which the subject will be asked to walk on the gaitwalk. During the evaluation session all subjects will wear their underwear and the performance will be recorded through two cameras (eVixta, BTS SpA) in order to check the correct performance. Before the stabilometric tests and gait analysis, the two strength tests will be performed. In the first case patients will asked to lie in supine position, to keep the hip with the knee completely extended up to 45 ° for 10 seconds. In the second case patients will asked to lie on his side, to keep the hip abduction with extended knee for 10 seconds. Strength tests will be repeated for the two lower limbs both. The TUG before gait analysis, will consist of standing up from a chair, walking for 3 meters, to turning a cone and to sitting again, the operator will assess the time of the test. The TUG will be repeated for three time after a break of 1 minute and only the best performance will be considered. At the end of each single test the subject will be asked to quantify pain perceived through the NRS scale. This instrument consists of a visual 10 cm line, numbered from 0 to 10, where 0 corresponds to "no pain" and 10 to "maximum pain imaginable".All the tests listed will be performed by a single operator.

6 Statistical consideration

6.1 Sample size

This protocol refers to a pilot study and therefore there aren't normative data. In literature we found studies evaluating the postural stability in THA patients, which enrolled 20 subjects [13]. For the following protocol, 30 subjects for each group will be considered in order to estimate the change of these parameters between-groups.

6.2 Analysis

The statistical analysis will be performed at the end of the study through SPSS 20.0. Categorical variables will be described in terms of proportion, while the continuous variables will be described in terms of mean and standard deviation or median and interquartile ranges. Outcomes measures will be checked for normality through Kolmogorov-Smirnov test. T-Student test will be used to confirm the homogeneity of the demographic and continuous variables before surgery for stabilometric task (weight distribution between the two lower limbs, mid-lateral and anterior-posterior displacement of the CoP, pelvis, hip, knee and ankle kinematic, muscular activation normalized by MVC, timing of the muscle activation respect to the movements of the tibiotarsic joint and activation frequency) , during gait analysis (ground reaction force, spatio temporal parameters, pelvis, hip, knee, ankle kinematic and timing of muscles activation), during the segmental strength test (time of the support of the lower limbs in the position decided by the operator), related to the TUG (execution time of the trial) and to the NRS scale (value from 0 to 10). The inter-group and intra-group differences after will be evaluated by ANOVA test for repeated measurements and then an eventual post hoc analysis will be conducted. The statistical significance value will be set at Alpha=0.05.

7 Withdrawal of subjects

The patients that for any reason will decide to, they will be immediately excluded from it. The incompleted acquisitions will be excluded from the analysis.

8 Forms and procedures for collecting data and data managing

An Excel file (Attachment B) will be filled in with demographic variables and outcome measures. It will be secured by a password. Only two investigators will collect the data in order to reduce errors.

9 Etical consideration

9.1Patient protection

The responsible investigator will ensure that this study is conducted in agreement with the Declaration of Helsinki and with the laws and regulations of the country, whichever provides the greatest protection of the patient.

The protocol has been written, and the study will be conducted according to the ICH Guideline for Good Clinical Practice. The protocol and its annexes are subject to review and approval by the competent Independent Ethics Committee(s) ("IEC").

9.2 Subject identification – Personal Data protection

All records identifying the subject must be kept confidential and, to the extent permitted by the applicable laws and/or regulations, not be made publicly available.The name of the patient will not be asked for nor recorded at the Data Center. A sequential identification number will be automatically attributed to each patient registered in the study. This number will identify the patient and must be included on all case report forms. In order to avoid identification errors date of birth, sex, weight height will also be reported on the case report forms. Only people who are actively involved in the study can access to the database. Each subject will be informed by means of an appropriate data protection module and each of them will also be sign an informed consent without which he / she will not be involved in the study.

9.3 Informed consent

All patients will be informed of the aims and the development of the study. They will be informed as to the strict confidentiality of their patient data. It will be emphasized that the participation is voluntary and that the patient is allowed to refuse further participation in the protocol whenever he/she wants. Documented informed consent must be obtained for all patients included in the study before they are registered at the Data.

10 Conflict of interest

No one between members study has a conflict of interest.

11 Data ownership

According to the ICH Guidelines on Good Clinical Practice and considering the study as a single-institution one the owner of the data is Humanitas Research Hospital.

12 Publication Policy

After completion of the study, the project coordinator will prepare a draft manuscript containing final results of the study on the basis of the statistical analysis. The manuscript will be sent to a an appropriate scientific journal. All publications, abstracts, presentations, manuscripts and slides including data from the present study will be reviewed by the Study Coordinator.

13 Study time table

1. Patients enrollement : January 2018

2. Data analysis: May 2018
3. Submission of the report: July 2018

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