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Comitato Etico

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*SC Laboratorio Analisi del Movimento*  
IOR-IRCCS

## VALIDATION OF A NEW TECHNIQUE FOR THE EVALUATION OF THE PATELLO-FEMORAL JOINT KINEMATICS

Institutional Protocol ID: 39521/2012 (CINE-FEMORO), 16<sup>th</sup> November, 2012

## STUDY PROTOCOL

The aim of this study is to test in vivo a new technique to evaluate the kinematics of the patello-femoral joint in patients undergoing total knee replacement. In particular, this study is divided into two steps. In the first step, the acquisition of knee kinematics is acquired intra-operatively. This will allow the surgeon to have a more complete comprehension of the knee functioning. Moreover, since the prosthetic implantation can potentially alter the functioning of both tibio-femoral joint and patello-femoral joint, it is necessary, in a second step, to perform knee kinematic evaluations at 6-months follow-up on the same patients. In this way it will be possible to evaluate the biomechanical behavior of the replaced knee joint and to observe anomalies / differences with respect to both normal and pre-implantation joint. In the second phase, the acquisitions will be performed using videofluoroscopic and roentgen-stereophotogrammetric techniques. Moreover, always in the second phase, the clinical evaluation of enrolled patients allow to identify the specific advantages and potential complications associated with the prosthesis implantation .

This study involves the recruitment of 20 patients selected for total knee replacement. The specific inclusion and exclusion criteria that can allow an adequate intra- and post-operative functional evaluation are reported in the main document.

During the surgery, the alignment of the prosthetic components will be performed with the aid of a standard surgical navigation system (Stryker® - Leibinger, Freiburg-im-Breisgau, Germany) in addition to standard navigation-based procedure for femur and tibia prosthesis component positioning. Particularly, the intra-operative acquisitions of the tibio-femoral and patello-femoral morphology and kinematics will be performed by means a navigation system equipped with an additional innovative device for patellar-based data acquisitions. In addition to standard navigation steps, originally the surgeon will now collect the patellar medial, lateral and distal prominences, along with the anterior and the posterior aspect; this will allow to assess exactly the real patellar thickness and to set via computer-assistance the more proper position of the patellar cutting jig; once the patellar cut is executed, the surgeon can select the best location for positioning the patella polyethylene component using navigation-based data, in addition to usual visual inspection and standard, i.e. not computer-assisted, procedures. Six months after the surgery, 3D vidoe-fluoroscopic analysis and gait analysis combined with electromyography will be performed on the same patients to evaluate in vivo replaced knee kinematics and kinetics during the execution of a number of motor tasks of daily living; clinical scoring will be performed at 6, 12 and 24 months follow-ups.

## STATISTICAL PLAN

The population size was estimated by considering previously reported data obtained using the same acquisition technique of the present study [1,2], and by meeting the criteria for achieving differences in measurements with 80 % statistical power and an  $\alpha$ -level of 0.05. The differences in patellar implantation parameters and kinematic variables and before and after total knee replacement treatment were tested for significance using the paired t-test and one-way analysis of variance. P values were considered significant for  $p < 0.05$ .

1. Belvedere C, Ensini A, Feliciangeli A, Cenni F, D'Angeli V, Giannini S, Leardini A (2012) Geometrical changes of knee ligaments and patellar tendon during passive flexion. *J Biomech* 49:3 45:1886-1892.
2. Belvedere C, Ensini A, Leardini A, Bianchi L, Catani F, Giannini S (2007) Alignment of resection planes in total knee replacement obtained with the conventional technique, as assessed by a modern computer-based navigation system. *Int J Med Robot* 3:117-124.

## DECLARATION OF CONSENT

I declare to have received from Dr. \_\_\_\_\_ exhaustive explanations regarding the request to participate to the experimental study (study title: \_\_\_\_\_), whose details are reported in the annexed study protocol.

I also declare that I have been able to discuss on the study aims, to ask all relevant questions that I have deemed necessary and to have received satisfactory answers, as well as to have had the opportunity to inform me about the details of the study with a person of my trust.

I therefore freely agree to participate in the experimentation, having completely understood the meaning of the participation request and having understood the risks and benefits involved.

I have also been informed of my right to have free access to the documentation related to the experimental evaluation and to the evaluation expressed by the Institutional Ethics Committee.

Date Signature of the patient

\_\_\_\_\_

Date Signature of the doctor who informed the patient

\_\_\_\_\_

[In case the patient can not read and / or sign]

I \_\_\_\_\_ testify that Dr. \_\_\_\_\_ has fully explained to Mr. \_\_\_\_\_ the features of the experimental study, as reported in the annexed documentation, and that I, by having had the opportunity to ask all the questions that I deemed necessary, freely accepted to participate to this the study.

Date Signature of the independent witness

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