MUSCLE ACTIVATION THRESHOLDS BEFORE AND AFTER TOTAL KNEE ARTHROPLASTY

Protocol of a Randomized Comparison of Minimally Invasive vs. Standard Approach

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Abstract: After total knee arthroplasty (TKA) patients often ask when they can resume car driving. This question was the aim of some studies in the past, however it is not clear whether minimally invasive surgery (MIS) for total knee replacement has benefits in terms of faster recovering times. With the present study protocol the effects of two surgery techniques for TKA (MIS vs. standard approach) on motor performance parameters will be tested during the performance of an emergency brake in a car simulator. The brake response time components and the muscle activation thresholds of four muscles involved in the task will be the outcomes of the study.

1 INTRODUCTION

Minimal invasive surgery (MIS) for total knee arthroplasty (TKA) has been used for several years as an alternative to standard approaches. Different MIS techniques have been described in the literature (Laskin, 2003): mini-arthrotomy, mini-midvastus (Floren et al., 2008, Haas et al., 2006), medial squad-sparing and mini-subvastus (Schroer et al., 2008). Supporters of MIS techniques go from the assumption that a smaller soft tissue injury with a reduction of the muscle quadriceps lesion leads to a faster rehabilitation with better early functional outcomes, less pain and shorter stay duration. Critics fear a reduction of the intra-operative overview with consecutive failure especially in relation to the alignment of the prosthesis.

After TKA patients frequently ask when they can resume car driving. Five studies on this topic were published in the past years (Spalding et al., 1994, Pierson et al., 2003, Marques et al., 2008b, Marques et al., 2008a, Dalury et al., 2010). All studies investigated the effects of TKA on brake response time (BRT), an important human factor used in traffic accident prevention and research. The results of the studies document a BRT increase after right TKA. The time frame needed for the BRT to return to preoperative values varied among the studies and ranged from 8 (Pierson et al., 2003) to 4 weeks (Dalury et al., 2010). In a study by Dalury and colleagues (2010), where the patients were submitted to "contemporary TKA with less tissue disruption", the BRT of all patients returned to preoperative values 4 weeks after surgery. A small group of patients reached the preoperative values already 2 weeks after surgery.

The aim of this randomized controlled trial is to study the effects of two surgical technics used for TKA (MIS vs. standard approch) on motor performance parameters such as brake response time (BRT), reaction time (RT), foot transfers time (FTT), brake pedal traveling time (BPTT) and the activation thresholds of four muscles of the right leg during the performance of a emergency brake in a car simulator.

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2 METHODS AND MATERIALS

2.1 Study Design

To study the effects of both surgical techniques on the study variables a randomized controlled trial with one between-subject factor (intervention group: MIS and Standard) and one within-subject factor (time: one day before and 8 days, 30 and 40 days after surgery) was designed. After consent to participate, the patients will be randomly assigned to a group (MIS or Standard approach).

The study protocol was approved by the Ethics-Committee of the Federal State of Hamburg, Germany (Project Nr.: PV3349). The trial registration number at the German Clinical Trial Database (DRKS) is: DRKS00000552.

2.2 Patient Selection

The patient selection will take place at the Schön Klinik Hamburg-Eilbek in Hamburg, Germany. The patients arriving at the clinic for elective right TKA will be asked if they are car drivers. If the patient drives regularly (at least once a week) he/she will be informed about the study and asked to participate.

2.2.1 Inclusion Criteria

- Indication for TKA of the right knee;
- The patient is an active driver;
- Consent to participate in the study.

2.2.2 Exclusion Criteria

- Body Mass Index > 40 Kg/m^2;
- Valgus or Varus deformity > 20°;
- Range of Motion < 75°;
- Neurological disorders such as Parkinson's disease;
- Rheumatoid arthritis.

2.2.3 Sample Size

A sample size of 2x25 Patients will be aimed.

2.3 The Car Simulator

The car simulator was made based on a European middle class car. It was used during two previous studies (Marques et al., 2008a, Marques et al., 2008b) and was now equipped with new instruments.

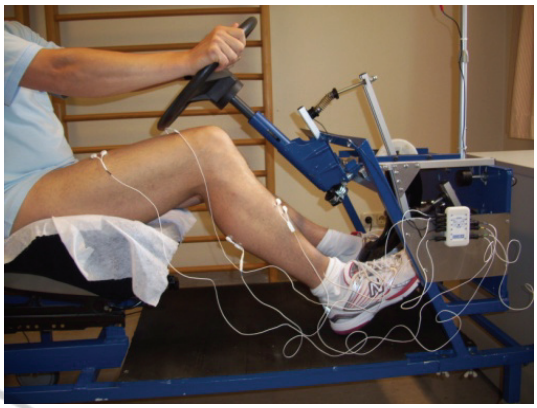

Figure 1: Car simulator with BioPlux Research system.

2.3.1 Instruments / Equipment

The data acquisition system consists of a BioPlux Research system with wireless connectivity via Bluetooth (PLUX –wireless biosignals). A trigger will be used to command the stimulus light (red LED) turn on/off. Two load cells are connected with both pedals (break and accelerator). Four surface electromyography (sEMG) signals will be acquired from 4 muscles involved in the task. The following acquisition channels will be used:

- Channel 1: Trigger
- Channel 2: Load cell of the accelerator
- Channel 3: Load cell of the brake pedal
- Channel 4: sEMG M. rectus femoris
- Channel 5: sEMG M. vastus medialis
- Channel 6: sEMG M. tibialis anterior
- Channel 7: sEMG M. gastrocnemius

The channel sample rate will be set at 1000Hz.

2.3.2 Electrode Type and Position

Surface EMG signals will be recorded using silver-silver chloride (Ag/AgCl) pre-gelled electrodes (MultiBiosensors). The electrode locations will be found via palpation of the subjects anatomy over the appropriate muscle belly, according to the recommendations of the European SENIAM-Project (Surface Electromyography for Non-Invasive Assessment of Muscles). Electrode sites will be shaved, abraded and cleaned with isopropyl alcohol to reduce impedance.

Figure 2: Electrode position.

2.4 Study Outcomes

The brake response time (BRT) is a very important human factor in accident prevention research. The BRT can be fractionated in several components. The primary outcomes of this research project are components of the BRT and are defined below.

2.4.1 Primary Outcomes

- Brake Response Time (BRT): time frame between the onset of the red LED and the achieving of a brake force on the brake pedal of 100N (ms);
- Reaction Time (RT): time frame between the onset of the red LED and the initiation of the movement of the foot on the accelerator pedal (ms);
- Foot Transfer Time (FTT): time frame between the initiation of the movement of the foot on the accelerator pedal and the first contact with the brake pedal (ms);
- Brake Pedal Travelling Time (BPTT): time frame between the first contact with the brake pedal and the achieving of a brake force of 100N on the brake pedal (ms);
- Movement Time (MT): sum of the FTT and BPTT.

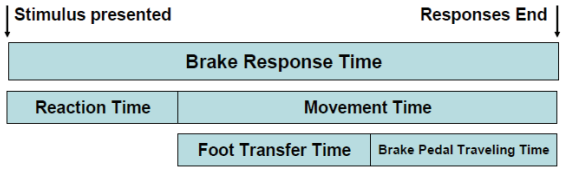

Figure 3: Brake response time components

2.4.2 Secondary Outcomes

The secondary outcomes are the time frames between the onset of the red LED and the muscle activation thresholds of the above referred muscles.

3 DATA EXTRACTION AND ANALYSIS

The patients will perform 10 emergency brake test trials in a simple task, followed by 10 emergency brake test trials in a more complex task in a car simulator. The data of the 10 test trials on each task (simple and complex) will be saved separately as text files with the use of the software program Monitor Plux.

3.1 Data Extraction

The signals collected are of three types: digital signal (from the light trigger); force signals from the accelerator and brake pedal load cells; and sEMG signals from four muscles.

The digital signal is used to slice the signals in the 10 breaks in each of the tasks. The force signals are calibrated considering that in the initial instant the foot is not pressing any of the pedals and the acquired value in the initial 100ms is considered the zero of the load cells. This signal is low pass filtered with cut frequency at 10Hz with a 4th order Butterworth IIR filter.

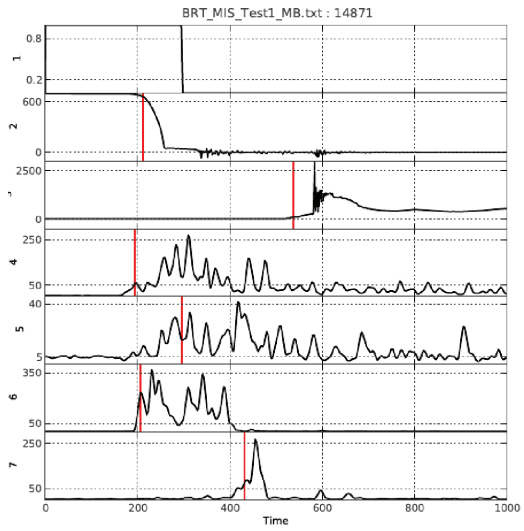

Figure 4: Graphic of one test trial in the simple task with the 7 channels (1 Trigger; 2 Accelerator; 3 Brake pedal; 4-7 sEMG signals of the 4 muscles) and the red lines marking the detected thresholds for each signal.

The sEMG signals are filtered with an envelope detector that consists of a low pass filter of 5 Hz (Butterworth IIR filter 4th order) after computing the absolute value.

An adaptation of the Hodges onset detector (Hodges and Bui, 1996) was created to be used on force and sEMG signals on positive or negative transitions.

3.2 Data Analysis

Mean values of the ten test trials for each task will be calculated for each subject. A 2x4 ANOVA for repeated measures will be performed to detect differences within a surgery group along the time and between the two groups (MIS vs. standard) at each assessment day. Multiple comparisons will be made with paired t tests using the Bonferroni adjustment of alpha. All statistical tests will be carried out using the SPSS software. For all statistical tests, the .05 level of probability will be accepted as the criterion for statistical significance.

4 DISCUSSION

The available evidence on which physicians and doctors can relay when advising patients on when they should resume car driving after TKA is few.

The components of BRT were investigated in 4 studies (Spalding et al., 1994, Marques et al., 2008b, Marques et al., 2008a, Dalury et al., 2010). Ten days after TKA central aspects related with stimulus perception, response selection and response initiation seem not to be affected, once RT was not changed (Marques et al., 2008a, Marques et al., 2008b). TKA seems to affect peripheral aspect related to the execution of the movement. The soft tissue lesion may be the cause of such performance decreases after TKA.

In the past years minimally invasive approaches for TKA have been used. The question whether a smaller tissue lesion will improve the performance of the patients will be investigated in this study.

The results of this study will increase the body of evidence on this issue and will add a comparison of two surgical techniques with a more detailed view over the brake response time components and over the effects of TKA on neuromuscular function of four muscles involved in the task.

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