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A new protocol for wear testing of total knee prostheses from real joint kinematic data: Towards a scenario of realistic simulations of daily living activities

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A B S T R A C T

A new tendency in the field of wear testing of total knee replacements is represented by realistic simulations of various motor tasks of daily living (chair sitting and rising, squat, stair ascent, etc.). Various studies have shown in fact the limits of the ISO 14243 standards, in particular the concern about the ability of the level walking simulations to recreate the main wear mechanisms which occur on the knee implant during its *in vivo* lifespan. The recently proposed protocols for the simulation of these motor tasks still lack accuracy and consistency between the various degrees of freedom, which are necessary for a good replication of the mechanical behavior in a replaced knee.

In the present study a realistic scenario for simulation of various motor tasks using a displacement controlled wear testing machine is presented. Stair climbing, chair sit/stand cycle, and squat cycle were analyzed through video-fluoroscopy in a population of knee replacement patients to extract flexion/extension and intra/extra rotation angles, together with anterior/posterior translation. Corresponding axial load data were arranged by gait analysis from a control population. The proposed protocol was tested on a displacement controlled wear simulator.

Kinematic and load data revealed good consistency across subjects. The knee simulator showed an accurate reproduction of the various motion and load patterns, with average error lower than 5%. The obtained dataset for wear simulator, containing all the displacement and loading parameters for stair climbing, chair sit/stand and squat activities, is fully reported.

1. Introduction

Total knee replacement (TKR) is a surgical operation used to restore the joint functionality in case of severe degenerative pathologies (Jevsevar et al., 1993; Rönn et al., 2011). Despite a high rate of survival of these implants (Carr et al., 2012; Wylde et al., 2007) a most important remaining challenge is to develop a joint replacement that will last the whole patient lifetime while the patient performs normal daily activities. Long-term implant mobilization and aseptic loosening of the femoral, tibial or patellar component (or a combination), polyethylene damage and wear phenomena (DoOLU, 2006; RIPO, 2012) remain the predominant causes of failure in TKR (Schroer et al., 2013; Sharkey et al., 2014, 2002). In this respect, artificial knee joints must be tested in wear simulators before receiving the necessary approval for clinical use. These tests represent an important phase of research and evaluation for the optimization of prosthetic materials as well as of the design of the prosthesis (Muratoglu et al., 2007, 2002; Wright and Chitnavis, 2011).

A knee wear simulator is a machine capable to reproduce loads and motion typical of the knee joint during activity, operating basically under two different concepts: force control and displacement control (DC) (Affatato et al., 2008a; D'Lima et al., 2008), Wear of the polyethylene, typically fixed to the tibial component, is influenced by several factors (Affatato et al., 2008b; Billi et al., 2010; Gabriel et al., 1998; Wasielewski et al., 1994): materials, design, patients' height and weight, joint loading during daily activities, etc. (Brown and Bartel, 2008; Fisher et al., 2004; McEwen et al., 2005; Nevelos, 2004; Utzschneider et al., 2009; Whittaker et al., 2010). Many of these factors have been investigated,

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but the contribution of patient-specific daily physical activities is still not fully understood. The current ISO 14243 defines loads, motions and methods used for these in vitro simulations. This guideline, despite revisited over time, are based on analytical studies dating back to more than 40 years ago (Morrison, 1969, 1970) and give indication only about level walking, whereas TKR components experience during the day and throughout the human life a much larger variety of more demanding physical activities, which imply complex combinations of load and motion. Highly demanding activities, such as stair climbing or sitting on a chair, are frequently performed also by TKR patients, and may produce higher wear rates due to the high stresses generated at the prosthetic articular surfaces.

Research on artificial joints is moving therefore towards the *in vitro* simulation of a larger spectrum of daily living motor tasks other than normal level walking (Abdel Jaber et al., 2014; Abdel-Jaber et al., 2015; Cottrell et al., 2006; Gilbert et al., 2013; Reinders et al., 2015; Schwiesau et al., 2013b). It is thought that the implementation in *in vitro* wear tests of additional simulation conditions typical of daily living activities would provide important information still missing in the knowledge of the tribological aspects and wear phenomena which lead to TKR failure.

There is limited experience in research literature on the implementation of these novel displacement and load configurations on a machine suitable for knee joint simulations (Abdel Jaber et al., 2014; Abdel-Jaber et al., 2015; Reinders et al., 2015; Schwiesau et al., 2013b). With this in mind, the aim of the present study was to present a complete protocol for wear tests of activities of daily living for TKR to be used on DC knee simulators. To the best of our knowledge, this is the first study to provide a set of such waveforms, derived from real and non-invasive techniques, and tested on a DC knee wear simulator.

2. Materials and methods

2.1. Kinematic data collection

Joint kinematics in replaced knees was derived from 3D video-fluoroscopy based studies previously reported (Catani et al., 2011). These were patients implanted with Scorpio NRG PS prosthesis (Stryker Orthopaedics, Mahwah, NJ, USA), of various sizes ranging from size 3 to 11 for the tibial base plate and from size 5 to 11 for the femoral component. Tree-dimensional positions and orientations of the TKR metal components were obtained by CAD model-based shape matching, with an accuracy lower than 0.5 mm and 1°, according to an established technique (Banks and Hodge, 1996). The fluoroscopic images obtained at 10 frames per second allowed to calculate relative angles of Flexion/Extension (FE) and IE rotation between femoral and tibial components; in addition relative AP translation was calculated and normalized on the tibial baseplate anterior/posterior length in order to have this information independent from the prosthesis size, as described previously (Belvedere et al., 2013).

In the present paper, the following two major high demanding activities were analyzed derived from the original dataset of 15 TKR patients at six months follow-up (Catani et al., 2011): stair climbing, and chair sitting and standing. Corresponding data from a squat cycle were obtained from 6 of this original patient's cohort. The joint motions of each patient were recorded three times for each task. All data were analyzed using the same reference frames and the same operators, in order to minimize inconsistencies.

2.2. Axial load data collection

Axial load (AX) data had been collected from gait analysis performed on twenty healthy volunteers executing the same motor tasks, as reported previously (D'Angeli et al., 2014, 2013). Two synchronized force plates were used to determine the ground reaction force, sampling at 100 Hz. Each subject underwent three measurements for each task. Axial loads had been reported to the tibial anatomical reference frame and normalized by body weight in Newtons (D'Angeli et al., 2014, 2013).

2.3. Post-processing and data manipulation

From these original kinematic and load data, a first operation of data cleaning was performed by eliminating from the analysis all abnormal recordings and unreasonable values. Linear regression models were used to identify and discriminate different patterns in the DOF waveforms, for removing from the dataset the less recurrent ones. This operation allowed revealing primary and secondary knee motions patterns for AP translations and IE rotations for all the three motor tasks inside the patients group. Data analysis revealed two distinct motion groups for both AP and IE kinematic variables. For our purposes we selected the groups that included the highest number of patients, always keeping correlation between the single patient AP and IE variables. This method has been used previously in the literature (DesJardins et al., 2007; Ngai and Wimmer, 2015; Ngai et al., 2009).

As described in a previous paper (Battaglia et al., 2014), AP reference frame origin was chosen at the center of the tibial tray, according to video-fluoroscopy data acquisitions. AP translation coordinates required a sign change in order to be reported to the femoral reference frame, with the origin located in the middle of the simulator FE rotation axis, since in the DC wear simulator AP translation and IE rotation are applied to the tibial tray and the femoral component undergoes only FE rotation. (Banks and Hodge, 1996; Joint et al., 2000; Ngai and Wimmer, 2015; Ngai et al., 2009; Uvehammer et al., 2000a, 2000b).

For the present study, displacement and load data set were obtained through a post-elaboration process performed in Matlab programme (Version R2015b, Mathworks, Inc). FE and IE rotations, and AP translation from fluoroscopic analysis and AX from gait analysis were first averaged over the repetitions for each patient, then resampled and time normalized to the percentage of the motor task cycle by interpolating splines. AX was multiplied by the average body weight of the patients group (626.86 N) (Belvedere et al., 2013) to obtain an AX curve expressed in Newton [N].

For each DOF a mean waveform was determined by using trimmed mean, excluding the outliers according to a 10% threshold, so as to obtain a waveform representative of the large majority of real *in vivo* knee joint motions during these motor tasks. The obtained mean waveforms were resampled to 100 points, as required by the knee simulator, with congruency between initial and final point values to ensure continuity during the present wear simulation of the cyclic activities.

Simulation frequency for each motor task was calculated based on the time spent by each patient to perform the specific activity, averaged over the three repetitions. For each motor task, the upper bound frequency over all patients was chosen, which resulted in 1.1 Hz for stair climbing and 0.5 Hz for sit/stand and squat cycles.

2.4. Protocol evaluation on knee wear simulator

The implementation of these tasks was made on a three-plus-one station DC knee wear testing machine (Shore Western Mfg., Monrovia, CA-USA), with left-side knee orientation. A short test was performed on two posterior stabilized fixed bearing prostheses of the same design (Stryker Scorpio NRG, size 7, left knee, 8 mm thickness insert of GUR 1020 UHMWPE) for 100'000 cycles, using distilled water as a lubricant in order to evaluate the mechanical performance of the knee simulator on the basis of the input waveforms. Since the range of motion for all DOF varies appreciably for each motor task, particular care was given to the calibration of the machine. Simulator actuators underwent mechanical revision prior to testing and a specific calibration was required for the load and displacement sensors for each motor task, in order to ensure a suitable frequency response and guarantee minimum deviation between the input values sent to the machine and the ones really executed by the machine. Particular care was taken during fixation of the TKR to the simulator, evaluating the starting position in terms of AP displacement between femoral and tibial components, as described above. The fixation was performed also according to standard mechanical alignments between the femoral and tibial components, by considering the same coordinates systems that were used for AP translation estimation from video-fluoroscopy data. Neutral knee axis was equal to 0 and no varus/valgus condition was implemented. Femoral joint rotation axes were also taken into account during femoral component fixation in order to reproduce the rotation axes highlighted during video-fluoroscopy. Outputs were recorded at a frequency of 1000 Hz every 10 min in order to analyze possible errors and deviations from the input signal for all DOF. Testing the obtained data set for the three motor tasks on the knee simulator allowed to evaluate the deviation between the input and the output signals in terms of relative errors over the percentage of the cycle. Average errors between the input and the output signals were also calculated.

3. Results

High consistency over the analyzed subjects was observed both in displacement and load data (Figs. 1–3, Tables 1 and 2). However,