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Wear simulation of total knee prostheses using load and kinematics waveforms from stair climbing

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ABSTRACT

Knee wear simulators are meant to perform load cycles on knee implants under physiological conditions, matching exactly, if possible, those experienced at the replaced joint during daily living activities. Unfortunately, only conditions of low demanding level walking, specified in ISO-14243, are used conventionally during such tests. A recent study has provided a consistent knee kinematic and load data-set measured during stair climbing in patients implanted with a specific modern total knee prosthesis design. In the present study, wear simulation tests were performed for the first time using this data-set on the same prosthesis design. It was hypothesised that more demanding tasks would result in wear rates that differ from those observed in retrievals.

Four prostheses for total knee arthroplasty were tested using a displacement-controlled knee wear simulator for two million cycles at 1.1 Hz, under kinematics and load conditions typical of stair climbing. After simulation, the corresponding damage scars on the bearings were qualified and compared with equivalent explanted prostheses.

An average mass loss of 20.2 ± 1.5 mg was found. Scanning digital microscopy revealed similar features, though the explant had a greater variety of damage modes, including a high prevalence of adhesive wear damage and burnishing in the overall articulating surface.

This study confirmed that the results from wear simulation machines are strongly affected by kinematics and loads applied during simulations. Based on the present results for the full understanding of the current clinical failure of knee implants, a more comprehensive series of conditions are necessary for equivalent simulations *in vitro*.

1. Introduction

Total knee arthroplasty (TKA) is a consolidated orthopaedic procedure in case of severe knee arthritis (Jevsevar, 2013; Rönn et al., 2011). Although there is a good survival rate of primary TKA (92–100% at 10 years follow-up), many failures still occur, usually associated to polyethylene wear, secondary osteolysis and, ultimately, loosening of the implants (Sharkey et al., 2014). The main concern about TKA is its ability to reproduce physiological kinematics at the replaced knee, usually expressed in terms of patterns of joint rotations in the three anatomical planes, of the location and motion of the functional axis, and of the tibio-femoral contact points on the medial and lateral condyles, whose dynamic reveal much of the so called femoral rollback (Saveh et al., 2011; Siston et al., 2006; Walker et al., 2010).

Dynamic *in vitro* testing of the human knee continues to be an area of interest to the orthopaedic biomechanics community. A number of different styles of machines with varied capabilities have been designed to simulate loads and motions at joint level during various task scenarios. In particular, in order to implement realistic loading conditions in *in vitro* TKA wear testing, typical frequency and duration of the main daily living activities would be necessary. For this reason, prosthesis wear analysis is evolving from the traditional loading and kinematics conditions of the simple level walking, as specified in the ISO-14243, towards more demanding activities of daily living (Abdel Jaber et al., 2014; Cottrell et al., 2006; Gilbert et al., 2013). This is expected to result in a more accurate description of wear resistance ability of current TKA designs, particularly when considering patients who have recovered full mobility.

A knee simulator is a machine that can dynamically reproduce loads and motions of the knee on either cadaver specimens or complete set of prostheses. These machines are frequently operated in

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load or displacement control (Affatato et al., 2008; D'Lima et al., 2008) and are not overly constraining, therefore the knee is free to move and react to the applied loads. Despite these knee simulators are usually able to replicate the physiological conditions of gait, there is very limited experience on the simulation of high loads typically associated to more demanding activities such as stair climbing and descending, chair rising and sitting, squatting, etc. Since in the normal lifespan a replaced knee must bear a large spectrum of loading conditions, likely activating various UHMWPE wear and failure modes due to correspondingly different stress concentrations, wear simulation is moving toward the analysis of activities of daily living by establishing more realistic and biomechanically sound testing inputs to the simulator machines (Franta et al., 2011; Schwiesau et al., 2014, 2013b). These original simulations are becoming more and more important also because knee prosthesis are implanted in younger and more active patients who want to maintain their lifestyles, which is more demanding than those of older adults.

Stair climbing is a common activity of daily life. Kinematic and kinetic studies have shown that, in comparison to level walking, larger rotations and moments are experienced at the knee joint (Andriacchi et al., 1980; Jevsevar et al., 1993). The biomechanical analysis of this motor task has contributed to the understanding of various load and kinematics conditions at this human joint during common locomotion activities, both in the physiological knee and after TKA. Unfortunately, this knowledge has not been exploited yet in wear simulation testing, where emulation of high demanding daily activities from real knee joints, including load and kinematics from a coherent source, is aimed at.

The objective of this study is to address this lack, by exploiting a previously validated protocol for *in vitro* wear simulation of stair climbing (Battaglia et al., 2014), based on a real kinematics collection of corresponding patients obtained by fluoroscopy, and on gait analyses from a number of healthy volunteers. A suitable adaptation to a displacement-controlled knee simulator was arranged, and a wear simulation of a relevant TKA design performed. To the authors' knowledge the present is the first wear simulation study carried out on a specific TKA design, where kinematics is coherently taken during stair climbing from patients implanted with exactly the same design. Damage scars on polyethylene bearings obtained after this simulation were qualified and also compared with corresponding explanted TKA. Comparisons with coherent wear testing literature were also used to draw general conclusions. It is hypothesised that knee joint wear simulations, based on more demanding tasks and corresponding coherent waveforms, result in (i) wear rates different from those resulting from standard ISO-14243 as observed in the literature, and also in (ii) damage scars on the polyethylene components more similar to those observed in the same implant design after explantation.

2. Materials and methods

2.1. Data input to the wear simulator

In vivo kinematic and axial load data during stair climbing exercise were derived from previously published studies (Catani et al., 2011; D'Angeli et al., 2014, 2013), suitably adapted to this study aim according to a validated protocol for *in vitro* wear simulation (Battaglia et al., 2014). In brief, knee kinematic data as resulting after TKA were taken from fifteen patients (Catani et al., 2011). These were implanted with Scorpio NRG® fixed bearings posterior stabilized (PS) prosthesis (Stryker® Orthopaedics, Mahwah, NJ-USA) and analyzed by video-fluoroscopy during stair climbing at 6 months follow-up. Three-dimensional pose reconstruction during motion for the femoral and tibial metal components was performed using an accurate iterative model-based shape-matching technique (Banks and Hodge, 2004). Relevant knee kinematics, including flexion–extension (FE) and internal–external rotation (IE), were assessed (Cappozzo et al., 1995). Anterior–posterior (AP) translation was normalised to the tibial base plate AP length (Belvedere et al., 2013). Axial load data in physiological conditions were taken from twenty healthy volunteers (D'Angeli et al., 2013, 2014). These were analyzed during stair climbing by state-of-the-art gait analysis synchronised with two force plates. Relevant bone segments tracking, anatomical reference frame definition, and joint kinematics were calculated according to a standard protocol (Leardini et al., 2007); axial load was normalised by body weight in Newtons.

As required by the subsequent simulation, motion and axial load data were reported in the tibial anatomical reference frame, suitably smoothed and resampled, and relevant time-histories were normalised as % of a stair climbing cycle (Battaglia et al., 2014). For each parameter, mean waveforms were calculated by averaging values over patients/volunteers at each % of motor cycle; in addition, to

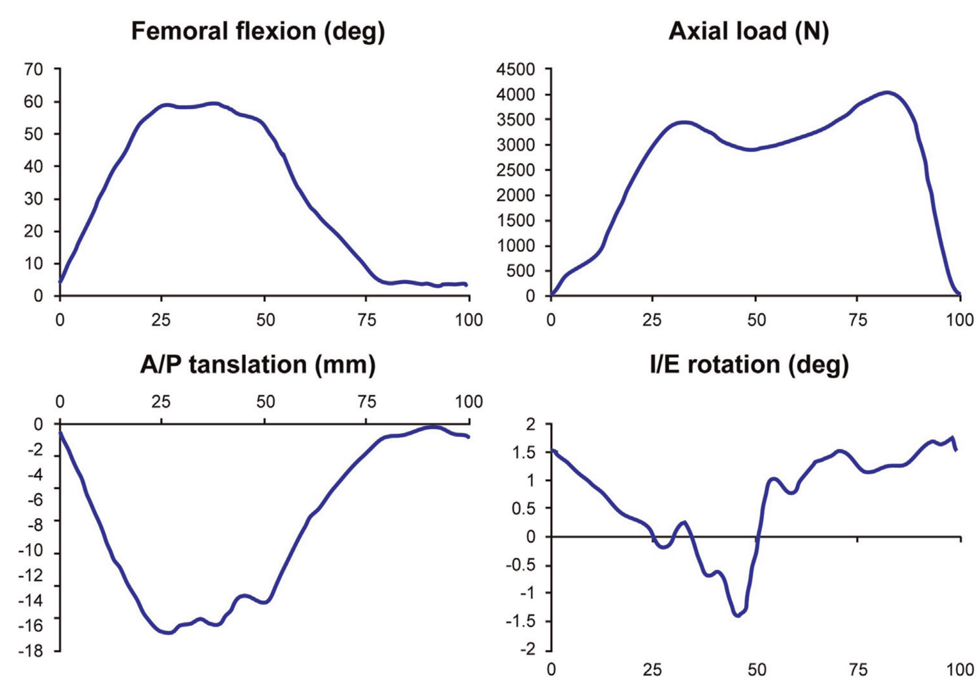

Fig. 1. Input data for axial load, femoral flexion (Flex=flexion, Ext=extention), tibial anterior/posterior (AP) displacement and internal/external (IE) rotation angle of the stair climbing curves.

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