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A new protocol from real joint motion data for wear simulation in total knee arthroplasty: Stair climbing

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ABSTRACT

In its normal lifespan, a knee prosthesis must bear highly demanding loading conditions, going beyond the sole activity of level walking required by ISO standard 14243. We have developed a protocol for in vitro wear simulation of stair climbing on a displacement controlled knee simulator. The flexion/extension angle, intra/extra rotation angle, and antero/posterior translation were obtained in patients by three-dimensional video-fluoroscopy. Axial load data were collected by gait analysis. Kinematics and load data revealed a good consistence across patients, in spite of the different prosthesis size. The protocol was then implemented and tested on a displacement controlled knee wear simulator, showing an accurate reproduction of stair climbing waveforms with a relative error lower than 5%.

1. Introduction

Total knee replacement (TKR) is nowadays a well-established orthopaedic procedure that helps patients to restore joint functionality and relieve pain caused by severe degenerative joint diseases [1]. Research studies continue to report on different aspects that are thought to be paramount to improve and enhance TKR efficacy and durability. In spite of improvements in surgical techniques and materials, the long-term fixation of an implant inside the bone continues to be an issue. Aseptic loosening is the main reason for revision surgery, which usually results from bone osteolysis in response to wear debris. For this reason, in vitro wear investigations are necessary to determine prior to implantation the probability of damage or time dependence of wear, and to assess the likely amount of wear debris. But for doing so, these tests procedures should include realistic loading patterns typical of everyday life activities for the wear simulation to be as realistic as possible.

To assess the behaviour and the problems associated to TKR component wear, in particular polyethylene inserts, multi-station in vitro wear simulation systems have been used extensively, mainly with the implementation of joint kinematics experienced by the knee during level walking [2–7]. This approach gradually led to the optimization of TKR designs, particularly surface finishing and materials, resulting eventually in a remarkable reduction of wear [7–9]. Currently, two simulation concepts are available and defined in the ISO 14243-1/3 standards: the force control (FC) and the displacement control (DC) [10,11]. In both these guidelines, level walking is the sole activity of daily living that is represented for testing. Four degrees of freedom of knee joint motion are actively controlled while the other two are left free to move passively. The difference between the two wear simulation concepts lies within the control mode of the anterior–posterior movement (AP) and the internal–external rotation (IE). In FC-based simulators, a rotational torque expressed in Newton-metres (Nm) is assigned to IE, while AP is generated by a shear force in Newtons. Because of the use of the forces generated at the interface between the tibial and femoral components only, the FC strategy is problematic in a knee simulator. In addition, there are no continuous linear relationships between the control output (displacement and/or velocity) and the controlled parameter (force). In DC-based simulators, the AP displacement and IE rotation are close-loop controlled by displacement feedback and these closely follow the displacement command profiles. Therefore, DC wear simulators need to have an independent control of the tibial baseplate motion and/or the AP and IE forces for each station, or a way of measuring the resultant force and torque.

Level walking profiles have been widely applied in wear testing of TKR implants as the most prevalent motor task [12], and

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have prompted a vast number of studies [3,5,13–15]. In the normal lifespan of a TKR, the prosthesis must bear a large spectrum of loading conditions associated with many daily living activities. These cause higher local stress concentrations (e.g. stair ascent and descent, deep squatting, chair raising and sitting) that can affect prosthesis durability, by activating different UHMWPE wear and failure mechanisms compared to the abrasive–adhesive phenomenon simulated with the level walking profiles [7,16–18]. This is one reason why TKR wear analysis is moving towards the implementation of other daily living activities [7,18], to better describe and investigate prosthesis wear resistance and to offer better versatility, thus allowing the inclusion of those patients expected to recover to full mobility.

For the implementation of realistic overall loading scenarios during in vitro wear testing for human joint prostheses, typical daily frequency and duration of these standard living activities are necessary, but only a few papers are available about this subject [12]. In all hip replacement patients, level walking was the most common locomotion activity, accounting for about 90% of all the activities during the day; stair ascent and descent represented 8%, getting up and sitting in a chair the remaining 2% [12]. Based on these observations, the impact of implementing various possible activity scenarios also on TKR wear analysis was proposed [18]. The same authors [7] later proposed a protocol for wear simulation under conditions of highly demanding activities. However, relevant joint kinematic patterns were gathered from disparate published data, including different implant designs, experimental methods and operators. As aforementioned, no studies have tested thoroughly for wear testing kinematics and loading specifications that emulate other daily activities, as based on real knee joint measures from a coherent source and to be used in DC simulators. To contribute to this, the present study is focussed on developing such a protocol by analysing stair climbing, a highly demanding motor task never dealt with before in in vitro TKR wear simulation. In particular, a consistent data set of real and pertinent human motion data was analyzed and arranged explicitly for the purpose, i.e. according to the requirements of the simulator. For this aim, state-of-the-art three-dimensional fluoroscopy and gait analyses [19–23] were utilized for in vivo knee joint measurements obtained during the execution of a number of daily living activities.

2. Materials and methods

2.1. Kinematic data collection

Knee joint kinematics data were taken from a study based on fluoroscopic analysis [24], where fifteen patients underwent TKR and were analyzed during stair climbing at 6 months' follow-up using a standard 3D video-fluoroscopy technique. All subjects were implanted with the Scorpio NRG® (Stryker Orthopaedics, Mahwah, NJ, USA) prosthesis, where tibial size ranged from 3 to 11 and femoral size was between 5 and 11. This is a fixed bearing posterior-stabilized design expected to maintain a large contact area while allowing a large IE rotation [25]. An iterative procedure was used to obtain 3D positions and orientations of the two metal components, using a CAD-model-based shape matching technique with a tested accuracy of less than 0.5 mm and 1° in the sagittal plane [26]. The fluoroscopic series of images, used for the kinematic variables assessment, were acquired at 10 frames per second [24]. Flexion/extension (FE) and IE between the tibial and femoral components were calculated according to a standard joint convention [27]. The AP translation was also calculated and normalized to the tibial base plate AP length, to give this indication independently to the prosthesis size [24].

2.2. Axial load data collection

Axial load data were taken from state-of-the-art gait analyses performed on twenty healthy volunteers [28]. Ground reaction force data were collected by two synchronized force plates (Kistler Instrument AG, Switzerland) sampling at 100 Hz. The stair ascending motor task data were collected three times for each subject. The foot contact with the stair was measured by the force plate underneath and was used to identify a single cycle of the task [28]. The axial loads were normalized by body weight in Newtons. A standard protocol [29] was utilized for bone segments tracking, relevant anatomical reference frame definition, and calculating joint kinematics.

2.3. Data manipulation and analysis

For each patient, FE and IE rotations, and AP translation from fluoroscopic analysis were smoothed by interpolating splines, and time normalized to the percentage of the motor task cycle. The differences between the patient's maximum and minimum for each kinematic parameter were calculated at 0% and 100% of the cycle. The time-histories of the fifteen patients of the different kinematics parameters were resampled to obtain the mean value and normalized waveforms constituted by 100 points, as required by the knee simulator. Another important requirement to be fulfilled was the congruency between initial and final point values in each profile to ensure continuity during wear simulation.

Since the patients underwent left or right TKR, to perform the average fluoroscopy, a sign change was required for IE and AP for the right TKR to pertain all patients to the left side. Average curves of FE and IE rotations and AP translation were computed for the fifteen patients. The axial load from gait analysis was reported in the tibial anatomical reference frame [30], since the hydraulic cylinder of the simulator dictates the axial load on the tibial tray. The curves were interpolated with a piecewise polynomial function, i.e. interpolating splines, to obtain a final average load waveform in function of the percentage of cycle constituted by 100 points. The pattern of variations of axial load over the twenty subjects was computed versus the percentage of stair ascending cycle and thus represented by a box and whiskers plot. The waveform of the axial load was calculated as the average for all subjects, where the axial load of each subject was first averaged over the three repetitions. Since the obtained axial load is adimensional, it was multiplied by the average body weight (626.86 N) [28] to obtain an axial load curve expressed in Newtons.

All the calculations were performed by the Matlab programme (Version R2012b, The Mathworks, Inc).

2.4. Protocol evaluation on knee wear simulator

The experimental protocol for the simulator, including kinematics and load data, was implemented on a DC knee wear simulator (Shore Western Mfg., Monrovia, USA), which is a "three-plus-one" station machine. The test was performed on two mobile bearings TKR (Genus mobile bearings, Ala ORTHO S.r.l., Milan, Italy) for 100,000 cycles. The lubricant used was distilled water. A sampling rate of 100 Hz was used to record the output corresponding data for FE and IE rotations, AP translation and axial load, at the same time.

3. Results

The patterns of variations and the mean values over the fifteen patients of the FE and IE rotations and AP tibial translation versus the % of stair ascending cycle are reported in Figs. 1–3, respectively. High consistency over the patients and subjects analyzed