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On the biotribology of total knee replacement: a new roughness measurements protocol on *in vivo* condyles considering the dynamic loading from musculoskeletal multibody model

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ABSTRACT

In severe conditions of osteoarthritis, total replacement of the knee joint is essential and it is a well-established surgical procedure performed to relieve patient's discomfort and to restore function in knee osteoarthritis. Surface roughness of knee prostheses components has been suggested as contributing to the mechanism for premature prosthesis failure and is very important to improve tribological performance. The objective of this research was to characterize the roughness of tibial ultra-high-molecular-weight-polyethylene of retrieved knee implants through an optical profiler, discussing the results in the context of the acting loads obtained from a multibody musculoskeletal model. The authors looked for roughness differences between medial and lateral condyles considering the different load exposure of the two condyles. As prove of the different stress to which the two areas are subjected, the authors simulated the loads acting on a knee joint by developing a model in AnyBody Modelling System™.

11 total knee prostheses, of the same design and all posterior stabilised, were considered in this study. Roughness and topographic surface were acquired on them. These knee prostheses were explanted from 11 patients (mean age of 68 years) after a mean of 3.2 years. Statistical tests outlined a difference in surface roughness when different sizes of implants are considered, whereas the authors did not find a statistically significant difference between medial and lateral condyles in term of their surface roughness.

1. Introduction

Over the past five years a greater number of primary knee replacements were performed [1,2] and today, total knee replacement (TKR) is a successful procedure that offers pain relief to a lot of patients. However, failure of such implants is still a matter under investigation and wear is among the primary cause of this failures [3,4]. It is well known that the knee is a complex system of tissues that provide mobility and support to the body. It experiences different motion conditions and it is therefore subjected to multiple loads as a person walks, runs, or does any other type of load-bearing activity [5]. All these conditions affect the surface characteristics of the involved materials and so the joint performance [6,7]. Surface roughness is a measure of the vertical deviations on the surface. High values of surface roughness of the femoral component has been proposed as an important factor inducing premature prosthesis failure [2]. Damage on the articular surfaces of the implant components due to particles debris, can cause further damage on the softer tibial polyethylene menisci increasing wear and failure of the implants [8]. A good variety of studies focused in analyzing surface roughness in TKR [9–13] and nowadays an abundance of information exists regarding the surface roughness of femoral components and of polyethylene spacer. In other words, surface roughness of implant components could be a causative mechanism for premature prosthesis failure. Malikian and coworkers [8] recorded roughness measurements on 14 retrieved cemented femoral knee and they found that the average lateral condyle surface roughness was 0.032 μm, and the average medial condyle surface roughness was 0.028 μm. Heyse et al. [14] compared the surface roughness of 10 retrieved posterior-stabilized Genesis II TKA and they found that the retrieved components showed significantly ($p < 0.0001$) lower roughness for the OxZr elements than the CoCr elements. Scholes et al. [2] measured the surface roughness of 19 retrieved total knee replacements using a non-contacting profilometer: they found that all femoral components were rougher after their time *in vivo* and this roughness was more noticeable on the lateral condyle than the medial.

Several systems are used to obtain surface metrological information:

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from the conventional contact instrument to the latest atomic force microscope (AFM), passing through the optical techniques. The most common used instrument is the stylus profilometer, whose main components are a stylus and its diamond pin. The resolution of the stylus limits these instruments, which are also not sensitive to surface reflectance or color. The pin radius, the pressure applied and the material hardness have high influences on the measurement. The stylus can even damage and modify the examined surface during his motion. Instead, optical techniques are contactless, which excludes the risk of damaging surfaces. They can be used to obtain accurate information on the material loss by wear, through 3D images [15–18]. Optical methods have higher measurement speed and can acquire 3D profiles in a single observation, whereas stylus profilometers need multiple ones. Main drawbacks in contactless techniques are the higher costs and the higher number of error sources.

Many Authors focused on the analysis of loads acting on knee joint for different activities, as level walking, climbing stairs or running to estimates a more realistic load profile and, thereby, obtain a more realistic behavior of the artificial knee joints during wear simulations [19–21]. In these works it is highlighted a strong inter-individual variation of load patterns among the analyzed subjects mainly due to anthropometric features specific to each patients. We have used a musculoskeletal modelling software, with different gait patterns, to estimate loads acting on knee joint during level walking. This would lead to a better understanding of the loads acting on a knee implant and gain evidences of the different loads acting on medial and lateral condyle. This hypothesis is based on a previous work [22] where the authors found different wear intensity on the condyles of the same inserts material here analyzed, i.e. ultra-high-molecular-weight-polyethylene (UHMWPE).

The objective of this research is to find a correlation between the loads acting on the condyles and the surface roughness of 11-explanted UHMWPE inserts of the same design, in order to correlate the activity intensity of the patients to the alteration of the bearing couple in TKA.

2. Materials and methods

2.1. Patients

In this study, we selected 11 total knee prostheses from the REPO database (Register of Explants of Orthopedic Prosthesis) that collects and classifies medical devices explanted at Rizzoli Orthopaedic Institute (Bologna. Italy). Since the tribological and wear behavior of a TKR is strongly influenced by prosthesis type, design, stabilization and fixation [23,24], to prevent the variability in surface roughness due to these factors we selected the largest TKR group available with the same characteristics. The chosen prostheses have the same design (NexGen, Zimmer, Warsaw, Indiana) and were all cemented fixed bearing inserts and posterior stabilized (the UHMWPE meniscal component snaps or press fits into the tibial tray). They were explanted from 11 patients after a mean of 3.2 years (from 1.1 to 7.4 years); the patients were 9 women and 2 men with a mean age of 68 years (48 minimum and 77 maximum) at implantation. These prostheses patient's details are shown in Table 1.

2.2. Roughness measurements

To characterize the surface roughness of the specimens, four indicators were gained: Ra, Rt, Rq and Rsk as already considered in previous works [12,25,26]. The main defining element of a real surface is the mean roughness Ra, which is the average of the absolute values of the profile deviations from the mean line. The Peak-to-Peak height, represented by Rt, according to ISO, ASME and reference [27–31] is defined as the vertical distance between the highest peak and lowest valley in the evaluation length. Moreover, we choose to consider also the Rq parameter as it is used for the determination of surface separation between bearing surfaces also to predict the fluid-film lubrication regime [32–34]. Rq is the up-to-date term for what was called root-mean-square or RMS. Rq is more sensitive to occasional peak and valleys, making it a useful complement to Ra, it is the geometric average height of roughness-component irregularities from the mean line. However, these parameters are insufficient to properly characterize a surface. Thus, it is of fundamental to measure other values such as Rsk, Skewness index of the surface profile. The Skewness (Rsk) represents the degree of symmetry of the surface heights about the mean plane. Rsk may be:

a. equal to 0 when the distribution around the mean is normal (Gaussian function);
b. lesser than 0 when the distribution is negative and the profile is plain;
c. greater than 0 when the distribution is positive and the profile is rich in peaks.

Surface roughness analyses were performed for UHMWPE menisci of all the retrieved specimens for both medial and lateral condyles.

2.3. Surface analyses of UHMWPE menisci

The topographic surface acquisitions, by 3D optical profiler, were performed using a Sensofar PLu Neox profilometer (Sensofar, Terrassa, Spain), which gathers three-dimensional images, working either as confocal microscope or white light interferometer, depending on the selected optics [18]. In this work, the profiler was used in confocal mode, selecting a confocal objective with 20× magnifications. Six topographies were performed for each polyethylene compartment; three profiles were extracted for each topography, obtaining a total amount of 18 measurements per implant. The acquisition length on the Z-axis had a mean value of 160 μm, and it was varied according to the natural curvature of the surfaces. The extended topography of 1 × 4 stitched acquisitions, covered an area of 0.477 mm × 2.07 mm. All the specimens underwent the same procedure before acquisition: the samples were cleaned in an ultrasonic bath of distilled water for five minutes, then dried in ambient controlled temperature.

After the acquisition procedure, the elaboration of results was gained through the software Scanning Probe Image Processor (SPIP, Image Metrology A/S, Hørsholm, Denmark). The Gaussian filter (ISO 16610-21) was applied to evaluate the roughness parameters (namely, Ra, Rt, Rq and Rsk): cut-off length was equal to 0.25 mm and evaluation length to 1.25 mm.

2.4. Statistical analysis

The measured roughness values were evaluated using a nonparametric Mann-Whitney (M-W) test and therefore a least significance difference as *post hoc* test. Statistical significance was set at $P < 0.05$. The analyses were, at first, executed comparing the medial ***vs.*** the lateral compartment for each specimen to investigate whether the micro-morphological behavior differs between medial and lateral compartments. Moreover, the authors goal was to understand if prosthesis size influences the surface roughness parameters distribution. Hence, we selected the two largest groups available in our cohort – size 3 and size 4 – and compared medial ***vs.*** lateral roughness parameters using a nonparametric M-W test.

In addition, any possible correlation of the variables "follow-up", "age at surgery" and "BMI" with the analyzed surface roughness parameters was investigated, using Pearson correlation coefficient.

2.5. Multibody simulation

The AnyBody Modelling System™ (AMS) [35] is a musculoskeletal modelling and simulation program. This multibody software combines