On the Roughness Measurement of the Knee Femoral Components

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Introduction

A total knee replacements (TRK) currently implanted is formed by a metallic femoral component and a tibial component formed by a metallic support plate and a polyethylene insert [1]. Aseptic loosening of the femoral, or tibial, or patellar component (or a combination), and wear phenomena are among the most common causes of failure of TKR [2–3–4–9]. Moreover, abnormal stresses at the joint interface may increase polyethylene wear and as a consequence cause the failure of the implant [5]. The finishing surface of the metal components is a very important factor to minimize the polyethylene wear rate and then the progressive production of metal and plastic debris [5–6–10]; a high surface roughness of the metallic component, due to inaccurate machining or to the damage produced by a third-body, can dramatically increase the wear rate [7]. There is a large consensus in the literature on the role of surface roughness on the volumetric wear rates, for that concern the hip prostheses, while no report are available for the knee prostheses [6–8–11]. The purpose of this study is to develop a protocol for the roughness characterization of TKR metal components, considering a limited number of points on every surface.

Materials and Methods

Six mobile TKR divided into different sizes (three TKR of size 2 and three TKR of size 6) were tested on a knee joint simulator to compare the wear behaviour of each groups. After 2×10^6 cycles the weight lost by the polyethylene inserts was measured with gravimetric method and the surface roughness of the metallic components was assessed in terms of average surface roughness R_a and skewness R_{sk}.

The measurements of the surface profile were performed on all metal components using a dimensional contact SRM machine (Hommel Tester T8000, Hommel Werke, Germany) equipped with a diamond stylus tip of radius 0.020 mm and a M1 digital filter assigned according to DIN 4777 part 1. The machine provides various measuring ranges (absolute), from ±8 to ±8000 mm with a resolution from 1 to 1000 nm respectively. Immediately before measurement, the specimens were wiped with acetone. Sampling lengths were taken using a cut-off of 0.25 mm. The choice of the cut-off is of fundamental importance to determine a representative parameter, in order to estimate the correct roughness measurements as recommended by the aforementioned ISO normative. The system is computer-controlled and all surface parameters were recorded for each measurement. The software provided a dimensional and topographic view of the head surface and characterized it in terms of surface profile parameters. Roughness measurement involved 29 points on each femoral condyle and about 25 points on each metal tibial plate. Inspection of the articulating surfaces with the unaided eye revealed that wear occurred primarily on the distal region of the condyles where the femoral component articulated against the plateau of UHMWPE tibial component, so for surface roughness analysis was identified an area which covered the majority of the worn area on each condyle. Having analyzed implants of two different sizes (size 2 and size 6) the measures of the areas are different and proportionate to the size of the implant, so we have an area of 30.7 mm × 25 mm for the size 6 and an area of 23 mm × 20.3 mm for the size 2.

The points on which to perform the measurements within the considered area have been identified by the intersection between horizontal planes and segments of the main surface. Within the entire surface of the analyzed tibial plate the areas have been identified.

Results

The results obtained from roughness measurements were statistically analyzed in order to assess their significance and then see if the proposed protocol is designed to provide a proper surface characterization. The analysis of the results was performed by ANOVA and t test. In both cases the tests return a value, "P value", according to which the difference between groups is significant or not. The groups appear to have no significant difference if the "P value" is greater than 0.05, otherwise the test highlights the differences between the groups and, specifically, the number of measurements taken is insufficient.

The data collected has shown an increased roughness upon wear testing for both the investigated TKR sizes. As shown in the tables 1–2–3–4, almost all of the groups analyzed, no statistical differences (ANOVA and t-test) were observed between the groups for both the parameters Ra and Rsk. The analysis attest that the method used to derive the positions of measurement is valid for the femoral and tibial components obtained from in vitro tests.

The work carried out has confirmed the importance of the parameter Ra in the description of the surface of the femoral components, but at the same time showed the validity of the parameter Rsk, which in some cases result is a better descriptor roughness for the areas studied which integration of information collected from Ra, in fact, in many cases the surface of the metal components assumes negative values of asymmetry, indicating diminishing peaks. The study has tried to draw a line guide for further investigations to develop a protocol that allows users to make measurements of the roughness parameters on the metal components of knee prostheses.

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