Toward the interpretation of the combined effect of size and body weight on the tribological performance of total knee prostheses

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Abstract

Purpose The research questions of the present study were: (1) Is total knee prosthesis wear behaviour influenced by implant size, body weight and their combined effect? (2) Are these findings significant and helpful from a clinical point of view?

Methods Two very different sizes of the same total knee prosthesis (TKP), previously tested with ISO 14243 parameters, were tested on a knee simulator for a further two million cycles using a modified ISO 14243 load waveform. Roughness examination was performed on the metallic components. Gravimetric and micro-Raman spectroscopic analyses were carried out on the polyethylene inserts.

Results The average volumetric mass loss was $69 \pm 3 \text{ mm}^3$ and $88 \pm 4 \text{ mm}^3$ for smaller and bigger size, respectively. Bigger TKPs are little influenced by an increased load, while the wear trend of the smaller TKP showed a redoubled slope, and more significant morphology changes were observed. However, the two sizes seem to behave similarly when subjected to a load increase of 15 %; the slope of the volumetric mass loss trend was comparable for the two sets of inserts, which did not appear significantly different also at the molecular level. Roughness average parameters of the lateral femoral condyle support this evidence.

Conclusions It can be asserted that the body weight and implant size are relevant to the understanding of TKP

wear behaviour. A post-implantation body weight increase in a patient with smaller knee dimensions could result in more critical effects on prosthesis long-term performance.

Keywords Knee size · Body weight · TKP wear · Mobile TKR · Knee simulator · Raman spectroscopy

Introduction

Total knee replacement (TKR) is the most important surgical procedure performed to recover the knee functionality in cases of diseases affecting the joint [1, 2]. Even if there was an improvement in procedures of TKR [3], in vitro determination of wear rate constitutes a significant aspect in the preclinical validation of a prosthesis [4, 5]. The wear of ultra-high molecular weight polyethylene (UHMWPE) prosthesis and its overall performance is influenced by many variables (including lubricant, load, sliding distance, design, patient weight, etc.), so that a pre-clinical wear test could be used to simulate in vitro the interaction between these factors [6, 7].

The tribological behaviour of a total knee prosthesis (TKP) is, however, strongly influenced by the implant design [8–10]. A proper choice of the prosthesis design and size is of paramount importance for TKR success [11]. Nowadays several TKP designs, shapes and sizes have been conceived, in order to fit most patient anatomies and with the final aim to lessen implant wear [6, 12]. A surgeon can choose between two types of tibial inserts, which differentiate fixed and mobile TKP. A fixed knee prosthesis causes high torque at bone-implant interface, which increases the risk of component loosening, even if it provides high conformity and low contact stress [13, 14]. The mobility and the conformity of tibio-femoral bearing surfaces provided by the mobile design ensure lower contact stress with respect to the fixed bearing design and improve wear resistance, thus involving a lower

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risk of loosening [15]. Moreover, mobile bearings permit the existence of both free rotation and high conforming articulating surface [13]. The resulting kinematics at the articulating surfaces of the UHMWPE bearings from different prostheses differ greatly and UHMWPE wear is dependent on the kinematics to which the material is subjected [16, 17]. Therefore, there is concern as to whether contact areas at the articulating surface could affect UHMWPE wear [18–20], with subsequent release of particulate wear debris that may induce biological responses leading to osteolysis and loosening of the implant [21, 22]. Only few studies have investigated the influence of implant size on wear performance and load distribution in the tibial bone [23, 24], whereas a pre-clinical evaluation may be helpful. In fact, due to the complex morphometric relationship of the knee and to the serious problems arising from both undersizing and oversizing of implant components, the surgeon choice of the proper TKP size is pivotal and a tribological study on this concern may be helpful for the pre-surgical decision [25]. Moreover, it has also to be pointed out that often the patient weight does not simply reflect the knee size, and it is not surprising to observe patients with the same weight but very different knee sizes. With regards to the patient weight, epidemiologic studies have revealed a strong association between obesity and hip and knee joint replacement surgeries, due to the strong link between increased body mass index (BMI) and the risk of developing osteoarthritis in both joints [26]. Nevertheless, some frequency-matched case-control studies, aimed at the evaluation of the clinical outcomes of total hip replacement (THR) or TKR in overweight and obese patients, did not show any relevant association between increased patient weight and the risk of revision surgery or other complications, also in cases of morbid obesity [27, 28]. However, we are unaware of any previous study on this issue from a tribological perspective.

The loads on the knee joint are usually expressed in percentage of body weight. Direct measurement of knee forces in vivo after TKR has revealed that the load peak, for normal walking, ranges between 1.8 and 2.5 times the body weight [29]. The well established in vitro procedures for TKP wear simulation entail the application of the load profile recommended by the ISO 14243 standard protocol, which establishes the loading and displacement parameters for wear-testing machines considering a standardised body weight. In a prior work, we analysed the behaviour of two very different TKP sizes of the same prosthesis design that underwent an in vitro testing under the simulating conditions recommended by ISO 14243 [30, 31]. Following the first research, we decided to perform the wear test for a further two million cycles using this modified ISO 14243 waveform in order to evaluate the wear effects due to a higher load. In the present study, the load profile of the ISO standard 14243, was multiplied by a factor of 1.15, which reflects a body weight increase of 15 %. This was an attempt to simulate the effect of an increased body

weight on the tribological behaviour of the considered TKPs, which are different in size, as previously discussed. This study could provide additional important information to that already described, since it clarifies the characteristics of the long-term wear resistance of the materials. Our research questions were: (1) can the implant size, the body weight, and their combined effect be considered important determinants of in vitro prosthesis performance and, thus, influential concerns on TKP general outcomes? (2) Are these findings significant and helpful from a clinical point of view?

Materials and methods

Specimens

Two very different sizes of the same commercially available TKP design (TKA Genus mobile bearings, Ala ORTHO S.r.l., Milan, Italy), i.e. size #2 (small) and #6 (large), were investigated. Three samples of each size were investigated. The tested specimens had been previously subjected to an in vitro wear simulation for two million cycles (Mc). Major details are available in literature [30]. After that first test, all the components (femoral, tibial, and menisci specimens) were tested on the same knee simulator for the other two Mc (for a total of four Mc).

Wear test protocol

The second in-vitro wear test on the eight specimens previously tested in [30] was performed for the other two Mc using a “three-plus-one” stations simulator (Shore Western Mfg., Monrovia, USA). The eight specimens include four specimens (three plus one control) for each size (#2 and #6). Three specimens were placed on three different stations, while the fourth station was taken by the soak control specimen, to estimate the total change in mass due to lubricant absorption, according to ISO 14243–2. This wear test was performed on the same aforementioned specimens, using the same simulator, same kinematics and same lubricating conditions used in [30] as recommended by ISO 14243. In the previous study, a simplified gait cycle was reproduced, according to ISO 14243–3 and on the basis of a consolidated internal protocol [32–34]. Instead, a new approach has been introduced in this study with regards to the applied load. In fact, as already explained in the Introduction section, the load profile of the ISO standard 14243, was multiplied by a factor of 1.15, which simulates an increase of 15 % of body weight in the attempt to investigate the effect of an increased body mass index on the tribological behaviour of TKP.

Gravimetric, roughness and micro-Raman assessments

Gravimetric wear was evaluated every 0.4 Mc for two Mc, in addition to the 2 Mc previously tested in [30], to reach a cumulative wear test length of four Mc. Mass loss was determined using a microbalance (SARTORIUS AG, Göttingen, Germany) with an uncertainty of ± 0.01 mg and an accuracy of 0.01 mg. Each measurement was repeated three times and mean values were used. Dividing the progressive gravimetric data (mass loss) by the polyethylene density (0.934 g/cm^3) specified by the manufacturer, the volumetric wear was assessed.

To correlate the wear behaviour of the UHMWPE specimens, a Kolmogorov-Smirnov non parametric test was applied, setting the statistical significance at $P < 0.05$. A Hommel Tester T8000 (Hommel Werke, Germany) was employed to investigate the surface roughness of both tibial and femoral surfaces of the TKP specimens, as described in a previous work [35]. Roughness was measured on both tibial and femoral surfaces, as done above [30]. Before measurements, all components were cleaned with acetone. A cut-off of 0.25 mm and a sampling length of 1.5 mm were used. Roughness measurements were done at the beginning and at the end of the tests. In the evaluation of the superficial changes of the prosthetic specimens, two roughness parameters, i.e. Ra and Rsk, were considered, in agreement with our previous study [35]. Ra is the arithmetic average value of the deviations of the roughness profile filtered from the mean line into the sampling length (DIN 4768, ISO 4287), while Rsk is the skewness of the profile and indicates the symmetry of the profile [36].

As in our previous study [30], the UHMWPE components were analysed by micro-Raman spectroscopy. Micro-Raman spectra were acquired using a Jasco NRS-2000C instrument with a microscope of $100\times$ magnification. All the spectra were recorded in back-scattering conditions following a consolidated protocol [30]. The tested components were examined in both their articulating and back surfaces, in the most worn areas. On each component 20 spectra or more were recorded and these data were compared with those obtained after the first test [30].

It is well known that UHMWPE is characterised by three phases [33, 34]: an amorphous phase, an orthorhombic crystalline one and a disordered third phase. As reported in our previous study [21], the fraction of each phase (α_a , α_o and α_b , respectively) in UHMWPE inserts was evaluated according to the equations developed by Strobl and Hagedorn [35]:

$$\alpha_o = \frac{A_{1416}}{0.46 \times A_{1295+1305}} \quad (1)$$

$$\alpha_a = \frac{A_{1080}}{0.79 \times A_{1295+1305}} \quad (2)$$

$$\alpha_b = 1 - (\alpha_o + \alpha_a) \quad (3)$$

where A_{1416} and A_{1080} are the areas of the Raman bands at 1416 and 1080 cm^{-1} , respectively; $A_{1295+1305}$ is the area of the internal standard (i.e. independent of chain conformation) band group.

The A_{1080} band area was determined after a curve fitting analysis of the $1040\text{--}1105 \text{ cm}^{-1}$ range by means of a commercial software (Opus 5.0 from Bruker Optik GmbH, Germany). Curve fitting was performed on the original spectra after baseline correction, using the Levenberg-Marquardt algorithm. The Raman components were described as linear combinations of Gaussian and Lorentzian functions.

The distribution of the Raman data was checked through a preliminary Kolmogorov-Smirnov non-parametric test. After that, a parametric t-test was applied; statistical significance was set at $P < 0.05$.

Results

As reported in our previous study [30], at the end of the first in-vitro test, the average volumetric loss was $21 \pm 1 \text{ mm}^3$ and $41 \pm 2 \text{ mm}^3$ for size #2 and size #6, respectively. Starting from this condition, at the end of the 2 Mc simulation of the present in-vitro study, for a cumulative test length of 4 Mc, the average volumetric loss was $69 \pm 3 \text{ mm}^3$ and $88 \pm 4 \text{ mm}^3$ for size #2 and size #6, respectively (Fig. 1). The trend of the average volumetric wear for the two sizes in the first (zero to two Mc) and second (two to four Mc) tests is shown in Fig. 1. The cumulative volumetric mass loss remained lower for the polyethylene inserts of size #2, during the whole test. However, some remarkable aspects can be noticed. The data corresponding to each test of each TKP size were satisfactorily fitted using linear regression models, as evident from the R^2 values reported in Fig. 1.

Until 2 Mc of testing, the size #6 showed a double volumetric mass loss with respect to the size #2, mirrored by a double slope. After the imposition of an increased load in the in-vitro simulation, in the interval from two Mc to four Mc, the wear trendline of the TKP size #2 showed a redoubled slope, which became comparable to the slope of the TKP size #6 trendline. Instead, the wear trend of the size #6 maintained the same behaviour observed in the first two million cycles. In fact, the slope of the average volumetric mass loss for the size #6 did not show any significant difference in the two intervals of the in-vitro wear simulation applying the standard ISO load profile and afterwards the modified one.

The roughness parameters for both the femoral and the tibial metallic components of the two TKP sizes are reported in Table 1.

As expected, the data revealed that the roughness parameters worsen as wear increases. The Rsk values are all negative, highlighting diminished peaks. Statistically significant differences were found (t-test) between the two sizes, with regards

Fig. 1 Trend of the volumetric mass losses for the two sets of UHMWPE inserts (i.e. size #2 and size #6) tested using a knee joint simulator for a total of 4 Mc. The equations and the R^2 values of the lines fitting the data, corresponding to each test of each TKP size, are shown

to both the Ra and the Rsk parameters; the only exception was found in the analysis of the Ra parameters of the lateral femoral condyle (p -value=0.51), which suggests a non-statistical difference between the two sizes. The reported data clearly showed an increased roughness upon further wear for both the TKP sizes.

To investigate the effects of wear on UHMWPE at a molecular level, the inserts were analysed by Raman spectroscopy. As examples, Fig. 2 reports some representative average micro-Raman spectra recorded on the inserts of size #2 and size #6. The assignments of the bands have been given according to the literature [37, 38].

The corresponding α_o , α_a and α_b mean values calculated from the spectra are reported in Fig. 3.

With regards to the insert of size #2, the average spectrum recorded on its top after the second test showed a certain weakening of the 1416 cm^{-1} band (δCH_2 mode of the crystalline orthorhombic phase [37, 39]), if compared with that recorded on the top of the same component at the end of the first test (i.e. before the second test); see Fig. 2a. The data reported in Fig. 3 confirmed this trend from a quantitative

point of view; the α_o orthorhombic content on the top of the insert decreased from 0.56 ± 0.04 to 0.52 ± 0.04 ($P > 0.05$). An analogous trend was obtained on the bottom of the same insert: the α_o value decreased to 0.46 ± 0.03 , in agreement with the lower relative intensity of the 1416 cm^{-1} band (Fig. 2a). Significant differences were observed for the α_a amorphous content, which upon the second test significantly increased on the top of the insert of size #2 (Fig. 3), as revealed by the increase in the relative intensity of the bands due to the amorphous phase at about 1080 , 1440 and 1460 cm^{-1} (Fig. 2a); the third phase (α_b) remained nearly the same (Fig. 3). With regards to the insert of size #6, the average spectrum recorded on its top after the second test was not significantly different from that obtained before (i.e. at the end of the first test, spectrum not shown); actually, as can be seen in Fig. 3, the α_o , α_a and α_b values recorded after the first and the second tests were not significantly different ($P > 0.05$). With regards to the insert of size #6, the average spectrum recorded on its top after the second test was not significantly different from that obtained before (i.e. at the end of the first test, spectrum not shown); actually, as can be seen in Fig. 3, the α_o , α_a and α_b values recorded after the first and the second tests were not significantly different. Instead, the values (in particular the amorphous content, α_a) obtained on the bottom of the insert were significantly different from those recorded on the top; the spectrum recorded on the former area, if compared with that recorded on the latter (Fig. 2b), showed with lower intensities the bands of amorphous PE at about 1460 , 1440 , 1305 and 1080 cm^{-1} (and, accordingly, a lower α_a value, i.e. 0.148 ± 0.006 versus 0.178 ± 0.012 , see Fig. 3) and a slightly stronger band at 1416 cm^{-1} (and, accordingly, a slightly, not significantly higher α_o value, i.e. 0.52 ± 0.04 versus

Table 1 Average roughness parameters measured after 4 Mc of testing on femoral and tibial components for TKP size #2 and size #6

Roughness parameters at 4 MC	Femoral components		Tibial components	
	Size #2	Size #6	Size #2	Size #6
Ra [μm]	0.22 ± 0.16	0.19 ± 0.19	0.10 ± 0.08	0.18 ± 0.09
Rsk	-0.52 ± 0.88	-1.02 ± 1.40	-0.97 ± 1.27	-0.81 ± 0.67

Fig. 2 **a** Average Raman spectra of an insert of size #2: (*black*) at the end of the first test, top (articulating surface); (*red*) at the end of the second test, top (articulating surface); (*gray*) at the end of the second test, bottom (back surface). **b** Average Raman spectra of an insert of size #6: (*blue*) unworn sample; (*red*) at the end of the second test, top (articulating surface); (*gray*) at the end of the second test, bottom (back surface)

0.48 ± 0.05 , see Fig. 3). The bottom of the insert appeared more similar to the unworn component than to its top, as can be seen from the spectra reported in Fig. 2b, as well as the quantitative data reported in Fig. 3.

Discussion

A number of studies have investigated the effect of several patient-related factors affecting wear (patient weight, activity level, joint lubrication, motion patterns, etc.) [6, 7]; however, the tribological behaviour of a prosthesis is deeply influenced by the implant design.

An intra-operative variable that is recognised to impact on the load pattern as well as the tribological performance of the prosthesis is the sizing [24]. Due to the complex

morphometric relationship of the knee, loss of conformity and abnormal loading can originate from a size mismatch [11, 12].

Serious problems arise from both undersizing and oversizing of the implant components; thus the surgeon's choice of the most suitable TKP size is critical and should be preceded by a tribological research on this issue [25]. The in vitro wear of TKP with different sizes has been approached in a previous study that up to now is the first in-vitro study in which two equal mobile TKPs with different sizes underwent a direct tribological comparison [30]. The results obtained in that test allowed to conclude that the larger UHMWPE inserts (size #6) presented an about two-fold increased volumetric wear with respect to the smaller ones (size #2); however, due to the lower contact pressure experienced, the larger UHMWPE inserts underwent less significant morphology

Fig. 3 Mean values ($\pm$ standard deviations) of α_o , α_a and α_b calculated from the Raman spectra recorded on the selected inserts of size #2 and size #6 after the first and second tests. The data obtained from an unworn UHMWPE insert of size #6 are reported for comparison

changes on a molecular scale than the smaller ones; actually, it is recognised that a low pressure is the precondition of low wear [24, 40, 41].

In the present study, the same TKPs tested in the above mentioned previous study [21] underwent an in vitro test for another two Mc, for a cumulative test length of four Mc. Differently from the first research, in this work the in vitro simulation entailed the application of a modified load. The recommended ISO 14243 load profile was increased by a factor of 1.15, which reflects a body weight increase of 15 %, in the attempt to simulate the effect of an increased BMI on the tribological behaviour of the different sized TKPs.

After the imposition of an increased load in the in vitro simulation, in the interval from two Mc to four Mc, the wear trendline of the TKP size #2 showed a redoubled slope, which became comparable to the slope of the TKP size #6 trendline. Instead, the wear trend of the polyethylene inserts of size #6 maintained the same behaviour observed in the first two Mc. In fact, the slope of the average volumetric loss for the size #6 did not show any significant change in the two intervals of the in-vitro wear simulation.

It was established that the Archard Law, which states that the wear volume is proportional to contact load [42], is not able to completely predict UHMWPE wear, since it is also a function of contact area [18]. The algorithm proposed by Strickland et al. [20] has stressed the need for a more complex UHMWPE wear prediction equation. Experimental studies on UHMWPE subjected to multi-directional sliding against a metallic counterface highlighted the so-called “cross-shear” effect, involving a principal molecular orientation acquired by the polymeric chains [43]. In the direction perpendicular to the principal molecular orientation, named cross-shear direction,

there is a strain softening phenomenon responsible for wear debris release [43]. The wear rate in total hip prostheses was found to increase with the average sliding distance, with the inverse of the average aspect ratio of the motion loci and with the product of both [44]. However, this result cannot be extended from hip to knee total prostheses because of the different sliding ratios. In our study, the higher volumetric wear rate for the larger TKP insert size is obtained, probably, as a result of an increased sliding distance, despite a lower contact pressure.

Those findings were also confirmed by Kang et al. [45] in hip bearings, which found a higher volumetric wear rate in larger prostheses.

Several aspects can be noticed from the findings of the present study, which, however, has to be considered preliminary and gives some introductory key to the interpretation of these complex wear phenomena.

As to our first research question, it is possible to assert that the weight and the size are not irrelevant to the understanding of TKP wear behaviour. In fact, it may be affirmed that the applied load influences the TKP tribological performance. The findings of the present study could also suggest that the larger TKP size is little influenced by the modified load and the effect of an incremented load on the volumetric wear of the larger prosthesis is almost negligible; an analogous result was found also at the molecular level. Actually, upon the second test, the UHMWPE inserts of size #6 did not show, in their upper surfaces, any remarkable change in the α_o , α_a and α_b values, and the back surfaces were very similar to the unworn components (Fig. 3). Instead, in agreement with the results reported in the first test [30], upon the second test, the UHMWPE inserts of size #2 showed detectable

morphological changes in terms of α_o , and α_a values in both their upper and back surfaces (Fig. 3), due to the higher contact pressure experienced. However, it must be stressed that the increase in the applied load induced a change in the wear mechanism, at the molecular level; in the first test, the inserts of size #2 underwent an increase in the ortho-rhombic content upon mechanical stress [30], while in this second test, their amorphous content increased, as observed in previous studies [31].

Another remarkable aspect, evincible from the observation of the very similar slopes in the second test, is that the two sizes seem to behave similarly when subjected to an increased load. Ra parameters of the lateral femoral condyle, which suggest a non-statistical difference between the two sizes, could support this evidence from the gravimetric assessment.

In regards to our second research question, the findings of the present study could be associated with relevant clinical implications. Some frequency-matched case–control studies [27, 28] did not show any relevant association between increased patient weight and the risk of revision surgery. Instead, this in vitro study suggests the possibility of different long-term performance of knee prosthesis according to the subjective parameters as the body weight and the anthropometrics dimensions. The apparent contrast between this evidence can be justified since said case–control studies, differently from this in vitro test, do not include the level of activity of a patient, which can potentially vary between patients with diverse BMI. The present work can suggest also the following clinical implication: a post-implantation body weight increase (of about 15 %) in a patient with small anatomical knee dimension could have a more critical effect on prosthesis long-term performance, with respect to those expected in patient with greater knee anatomy. However, only two very different TKP sizes were tested in this work. Further studies are needed to investigate other sizes and implant designs, to clarify the concept of “small” and “big” and to permit a generalisation of the findings, which are actually limited. An analysis of the mechanical aspects, as pressure distribution and contact path, will be conducted in future to have a deep understanding of the tribological phenomena. Future research will be addressed to extend the knowledge of the tribological repercussion of the TKP sizing as well as the applied load and their concurrent action, with the final aim to give clear indication to the surgeon. The evidence from this study may, however, give a first indication of this combined effect.

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Conflict of interest The authors declare that they have no conflict of interest.

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