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# Conventional and Highly Crosslinked Polyethylene in Total Knee Arthroplasty—A Design-Independent Wear Investigation

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**Abstract: Introduction:** Improvement of total knee arthroplasty (TKA) materials is one promising approach for extending the lifetime of endoprostheses. The target of this study was to evaluate the sufficiency of TKA-design-independent rolling–sliding screening tests. Additionally, this study attempted to assess the relevance of the design of TKA systems for wear performance by comparison with a simulator study. **Materials and Methods:** A TKA-design-independent rolling–sliding testing machine was employed at ISO (the International Organization for Standardization) 14243-near conditions and physiologic level unidirectional rolling–sliding. Contact surfaces were generalized into elementary forms at curvatures of real endoprostheses: CoCr-cylinders on flat UHMWPE (ultra-high-molecular-weight-polyethylene) cuboids. Materials varied in resin and crosslinking. One conventional UHMWPE and three highly crosslinked polyethylenes were charged with an axial load of 2.5 kN for 5 million cycles. Wear was determined gravimetrically and the ranking was compared to a simulator study. **Results:** No statistically significant differences between either material were found. This was inconsistent with the results of a simulator survey. **Conclusions:** The results of the study indicate that this type of screening test is not able to correctly rank UHMWPE for use in TKA systems. The use of a UHMWPE plate in the test setup with a rolling–sliding cylinder is capable of producing visible wear marks in the bearing area, but the setup followed by a gravimetric measurement does not show reliable results. As the tested materials did not significantly vary in wear performance, it can be concluded that for differences in TKA wear-production, the design of TKR-systems can matter.

**Keywords:** rolling–sliding; UHMWPE; crosslinking; TKA; wear; debris; simulator

## 1. Introduction

As materials used for total knee arthroplasty (TKA) are subject to wear, for a substantial number of patients the first prosthetic treatment of this joint is unfortunately not the last. In these cases, revision-TKA is very often indicated because of the insufficient long-term wear resistance of the polymeric parts of the artificial joint [1]. Due to the success of this surgery shown by a high patient satisfaction level [2] with low morbidity and low mortality [3], Kurtz et al. projected a growth of 673% of TKA between 2005 and 2030 in the USA [4]. In respect to this development, further possible improvements should be debated for primary and revision surgery [5], in particular to provide improved materials that can better resist wear. Applied UHMWPEs suffer from different material-specific insufficiencies [6], which are dependent on their respective basic bulk material and their multi-staged manufacturing process [7].

The use of radiation-induced crosslinking in knee arthroplasty is still discussed controversially [8]. Crosslinked UHMWPE without post-treatment following the initial radiation process has a tendency to oxidize in vivo which leads to worsening of chemical, physical [7], and mechanical properties, and therefore potentially contributes to early failure of the prostheses [9].

The predominant movement of the artificial knee in the sagital plane is a combination of a rollback of the femoral condyles upon the tibial plateau and a slidingmotion between these articulation partners [10]. As a consequence of these kinematics, the ISO 14243 standard describes adequate motion patterns [11]. Appropriate formulae for the description of the rolling–sliding-ratio were pointed out by Naegerl et al. and are supplemented in Figure 1 [12].

$$\rho = \frac{u_2}{u_1} \qquad \text{const.:} \quad \rho = \frac{\Delta s_2}{\Delta s_1}$$

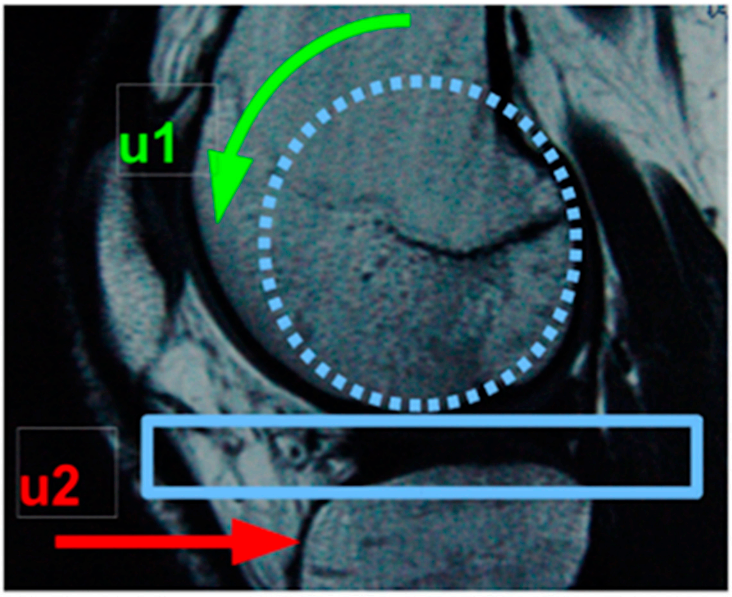


**Figure 1.** Schematic illustration of participants of a rolling–sliding movement of the knee at the end of extension. $u_1$ represents the rolling movement, $u_2$ the sliding movement. Rolling–sliding ratio ρ equals the quotient of the participating speeds; for constant movement in a certain time step, this is equivalent to the quotient of the covered distances.

It has been shown that the coefficient of friction is dependent on the particular rolling–sliding ratio [13], and that there is influence of this slip ratio on the wear of ultra-high-molecular-weight-polyethylene (UHMWPE) [13].

Numerous test procedures have been designed and published addressing TKA materials, e.g., pin-on-disk (ASTM-standards), or knee simulators, mostly according to ISO 14243 [10,11,14].

Common design-independent material test procedures do not represent rolling–sliding movement at the human knee resembling loading patterns [15], while results of simulator studies always depend on the mounted TKA designs which have relevant influence on resulting wear [10]. Less commonly known are various rolling–sliding testing rigs that have successfully been introduced and published, but are not internationally standardized, providing substantial differences e.g., in rolling–sliding motion profiles and/or load sequences [10,16]. In addition to the abovementioned testing setups, there is yet another testing rig which was used in this study. The testing machine accompanies oscillating rolling–sliding with ISO 14243-like test conditions and ISO 14243-near but constant loading pattern, as well as contacting parts of TKA-like dimensions and materials [11]. However, it was demonstrated that simulator tests that represent level walking alone are not sufficient to reproduce in vivo failure modes [17]. Furthermore, as the simulator tests are done on the full TKA, they are believed to include design-specific wear characteristics, which are known to differ from bulk material testing [18].

The aim of this study was to compare current clinically-used UHMWPE materials, independent of TKA design, in an unidirectional rolling–sliding testing station with a focus placed on the detection of possible wear production differences between highly crosslinked UHMWPEs. We hypothesized lower wear rates for crosslinked polyethylene analogous to knee simulator-based studies.

## 2. Materials and Methods

### *2.1. Materials*

Three types of UHMWPE were highly crosslinked with one conventional polyethylene (PE) type used as reference material. Two of the tested materials were produced of GUR (Granular, UHMWPE, Ruhrchemie) 1020 resin and two were made of GUR 1050 (Table 1).

**Table 1.** Tested materials and manufacturing details.

| **Material** | **A** | **B** | **C** | **D** |
|---|---|---|---|---|
| | Aesculap—Experimental | Zimmer Prolong™ | Zimmer Durasul™ | Stryker X3™ |
| **Type of Polyethylene** | Conventional | Highly Crosslinked | Highly Crosslinked | Highly Crosslinked |
| **Production Resin** | GUR 1020 | GUR 1050 | GUR 1050 | GUR 1020 |
| **Irradiation Method** | - | β- (Electron Beam-) Irradiation 65 kGy | β- (Electron Beam-) Irradiation 95 kGy | γ -Irradiation Sequential Irradiation 3 × 30 kGy |
| **Accumulated Irradiation Dose** | 25–40 kGy | 65 kGy | 95 kGy | 90 kGy |
| **Post Irradiation Aftertreatment** | No | Remelting | Remelting | Sequential Annealing (3× Annealed—one following each radiation step) |
| **Sterilization Method** | β- (Electron Beam-) Irradiation 25–40 kGy in nitrogen atmosphere | Gasplasma | Ethylenoxide (EtO) | Gasplasma |

Three samples of each of the four different UHMWPEs were tested in this study. The materials were machined into equally shaped blocks to fit inside the testing bowl (Figure 2).


**Figure 2.** Schematic drawing of the specimen—size values in mm.

### *2.2. Methods*

#### 2.2.1. Lubrication of Samples

According to the ISO 14243 standard, the contact surfaces were lubricated by newborn-calf-serum (Biochrom AG, Berlin, Germany) EDTA and Amphotericin B was added to the lubricant for pH stability and anti-fungal agency [11]. The protein concentration of the lubricant was adjusted to 30 g/L using deionized water. The sample's surrounding fluid temperature was 37 ± 2 °C during testing (applied load and movement), meeting ISO 14243 standard [11].

### 2.2.2. Simulator Station

The testing station used in this study (Figure 3) is a unique construction, developed to explore rolling–sliding-phenomena and the resulting wear behavior of biomaterials.

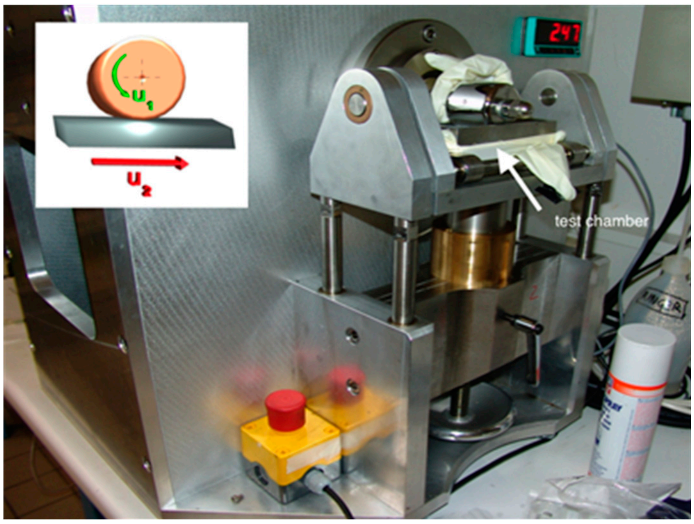


**Figure 3.** Rolling–sliding testing rig, schematic drawing of articulating parts, and analogue knee motion (extension). The specimen is embedded in the test chamber, which is rubber sealed.

The relevant parts of ISO 14243 knee simulators were simplified to enable comparative material testing. In order to best eliminate the influence of prostheses-designs, shapes of articulating surfaces were reduced to their elementary basic forms while maintaining clinically relevant parameters and dimensions. Analogue counterparts are described in Table 2.

**Table 2.** ISO 14243-corresponding parts of the rolling–sliding testing rig.

| Knee Simulator | Rolling–sliding Testing Rig |
|---|---|
| Femoral condyles | Cylinder, CoCr-Alloy, diameter: 40 mm (width: 50 mm) |
| Tibial insert | Plane polymer sample |

The movement profile of the testing unit was adjusted to meet heavy load during normal gait, similar to simulator studies following ISO 14243-1 [11]. At a frequency of 2Hz, a constant vertical load of 2.5 kN using a rolling–sliding ratio of $\rho$ = 1:2 was used. The test parameters are summarized in Table 3.

**Table 3.** Corresponding parameters of ISO 14243 knee simulators and of the rolling–sliding test station.

| Knee Simulator | Rolling–sliding Test Station |
|---|---|
| ISO 14243-1 movement profile | Rolling–sliding, cyclic sinus shaped anterior-posterior-movement at a constant rolling–sliding ratio of $\rho$ = 1:2 |
| Frequency 1 Hz | Frequency 2 Hz |
| ISO 14243-1 load profile | Constant vertical load of 2.5 kN |

### 2.2.3. Gravimetric Measurements

A control specimen of each UHMWPE was used to allow for mass gain by fluid absorption. The test specimen and the control specimen were both pre-soaked in test lubricant until saturation of the absorbed fluid—following ISO 14243-2—for 14 days. Before being installed inside the testing rig, no increase of weight was measured in each sample [19]. A special accuracy weighing machine (Sartorius® BP211D, Göttingen, Germany) was employed to enable high accuracy standard in weighing samples, featuring readability of 10 µg. A plate degasser (PD3, Edwards, Manor Royal, Crawley, West Sussex, UK) was used to monitor dryable lubricant uptake. Drying procedures met ISO 14243-2 demands [19]. To further enhance accuracy in gravimetric measurement, a correction of buoyant force was calculated to consider mass of air upon the balance displaced by the specimen, hence barometric pressure, temperature, and air humidity were incorporated in quantification of mass change.

#### 2.2.4. Duration of Testing

After each 500,000 cycles of testing, the serum was removed and the specimens were cleaned, dried, and weighed as indicated in ISO 14243-2 [19,20]. They were then reinstalled inside the rig, lubricated again and the tests were continued for another 500,000 cycles before the next measurement procedures took place. The test was completed after a total of 5.0 million cycles per specimen.

#### 2.2.5. Statistical Analysis

All values were presented as means and standard deviations. In order to distinguish significant results from tendencies, analysis of variance (ANOVA) was performed. In addition, the area under curve method (AUC) was used to detect even minute significant differences between each material. Significance was defined by a $p$-value $< 0.05$. After this, materials were ranked according to their wear performance. This ranking was finally compared to the ranking of a previous study [18].

## 3. Results

There were no statistically significant observable differences ($p = 0.17$) observable in gravimetrically detectable wear between the four materials throughout the 5.0 million cycles test. Figure 4 displays a comparison chart with all materials' corrected mass changes of the rolling–sliding test and respective standard deviations at the end of the survey.

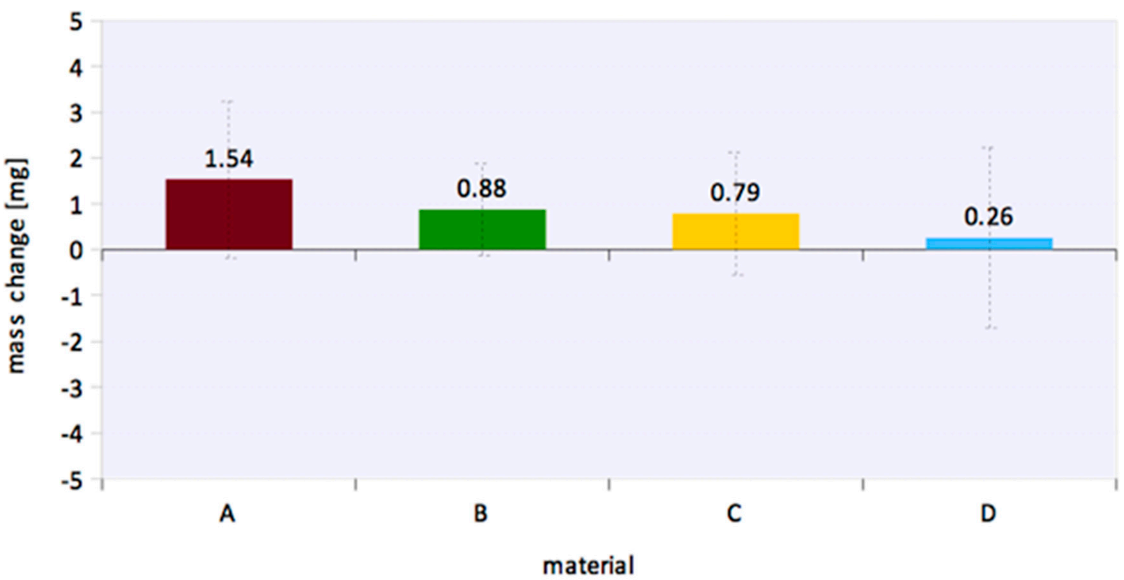


**Figure 4.** Mean-corrected mass change of materials A–D after 5.0 million cycle tests including standard deviations.

All materials ended up with corrected mean mass changes in the positive value range, not becoming statistically significant. All corrected mean values remained in the range between +0.26

and +1.54 mg. Soak-corrected mass change of five out of the 12 samples finished the test cycles inside the negative value range, pointing out the existence of wear. The developments of mean-corrected changes of mass over test cycles are shown in Figure 5.

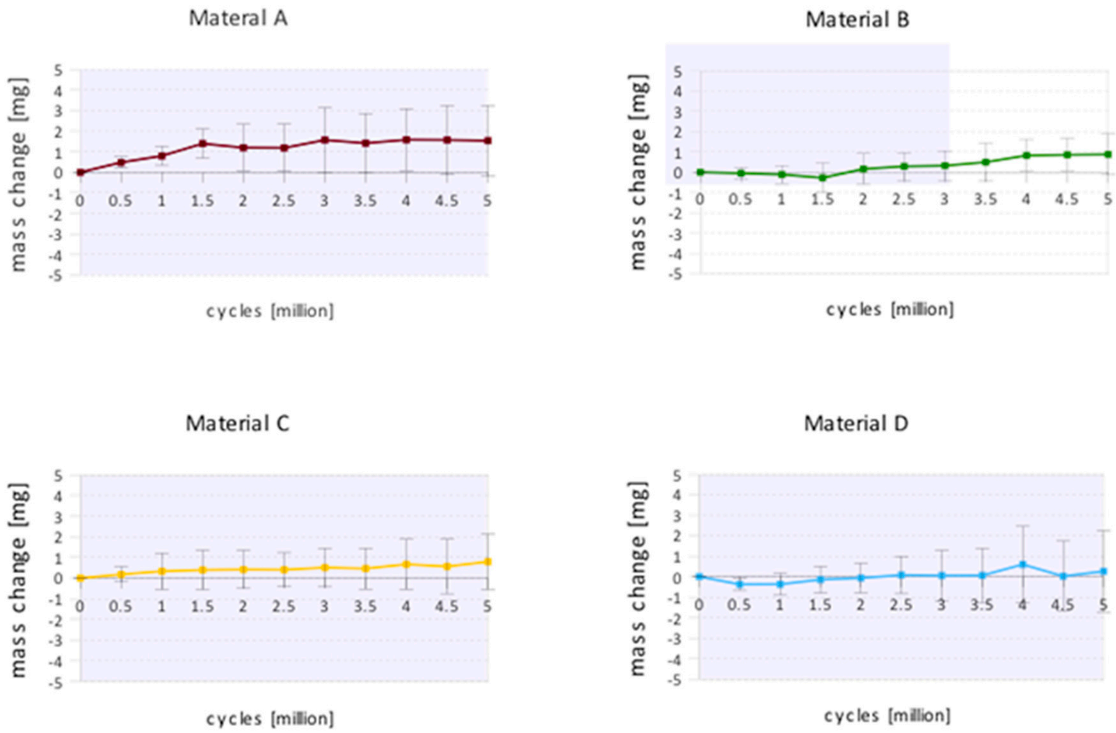


**Figure 5.** Developments of mean-corrected mass changes over a number of test cycles of materials A–D, including standard deviations.

As a consequence of the absence of significant differences, the attempt to rank the tested materials with respect to their wear performance failed in this survey.

## 4. Discussion

In order to evaluate the relevance of design-independent unidirectional rolling–sliding-testing machines with respect to TKA material testing, a testing-station was employed, which accompanied ISO 14243-close stresses and design-influence free femur- and tibia-representing parts. An advantage with respect to lower wear rates was hypothesized for the crosslinked polyethylenes compared to a conventional UHMWPE. Despite the closeness to the ISO standard, this survey did not determine significant differences in wear performance. This does not correlate with a simulator study carried out earlier by our group [18], which was consistent with findings of Hermida et al., where in a simulator test material D presented significantly less wear than material B [21].

Crosslinking through irradiation leads to higher wear resistance in UHMWPE [20]. As mentioned by Dumbleton et al., there is a trend in wear reduction accompanying increased radiation doses, while a single step irradiation dose of about 100 kGy and higher results in less effective crosslinking and in increasing difficulties to eliminate free radicals with the annealing process [22]. The radiation dose is not completely linked to the crosslink density, which is relevantly causal for the improved wear properties of UHMWPE [22].

The authors hypothesized a wear ranking according to a previous study [18], from most wear to least wear as A > B > C > D. This hypothesis had to be rejected as, in this study, a reduction of wear could not be proven by the means of crosslinking UHMWPE with respect to a unidirectional stress profile at physiologic kinematics resembling an ISO-near physiologic level stress profile.

This is in accordance with a comparable survey, a rolling–sliding tribological study carried out by Van Citters et al., who also found no statistically significant differences in wear production when testing clinically relevant crosslinked UHMWPE of varied radiation doses (50, 65, and 100 kGy) [16]. Although volumetric wear was determined, the authors could also not rank these materials on the basis of significant values [16]. Noteworthy differences between the studies were nevertheless oscillating frequency, surface diameter of articulating elements, volumetric versus gravimetric wear determination, and protein-concentration of sample lubrication [16]. The TKA-design-independent testing-machines published by Goebel et al. [23] and by Richter et al. [10] are described as producing simulator-like wear amounts with simplified kinematics consisting of a repeating series of pure rolling followed by a pure slidingmotion. These simulators did not represent a rolling–sliding movement that is defined by different velocities of constantly changing contact surfaces [12].

The fact that significantly different wear performances could not be determined in this study, despite being measured as significantly different in a former simulator study [18], may arise from the different prosthesis designs in simulator tests, as it was shown that the design is responsible for the resulting loading pattern, e.g., by decoupling multidirectional stresses using rotating platform devices, which limit crossing motions on the UHMWPE inserts [16]. In respect to the results of this study, the design of modern TKA systems plays an important role in wear generation. In conducting UHMWPE wear studies, one must therefore consider specific TKA designs if the results are to be used for clinically relevant material evaluation and selection. The fact that a large UHMWPE plate was used with a relatively small bearing surface in contrast to the larger bearing area of UHMWPE inserts of common TKA designs may be a contributing factor to the detected mass uptake. A gravimetric wear measurement should be combined with a volumetric wear measurement to verify the results.

Another result of this survey, that no statistically significant amount of wear was found with respect to the applied stresses, does reconfirm the very low wear of modern UHMWPE materials under physiologic unidirectional rolling–sliding loading patterns.

A possible "soak-corrected" loss of mass through wear is inside the range of an additional weight gain, which is believed to be caused by the fact that the soaked specimen was not tested in these rolling–sliding tests. Mean mass changes of nearly all materials, including respective standard deviations, were observed to overlap the zero value, which describes the statistically calculated possibility of the absence of measurable weight loss induced by wear.

The quantitative results of this study display positive mean values of the mass change of soak-corrected materials. Even if these mean values were significant, the result of the survey would be unclear because of the high level of mass increase of the wear charged samples compared to the soak control specimens. A positive end value points out an overlap of mass gain over a possible existing mass loss caused by wear. This effect has been reported as "negative wear" [24] and, in this study, it was monitored on most of the tested samples throughout the testing period despite the employment of soak correction.

The testing machine used in this study does not exactly represent human gait, which is to be simulated in the mentioned standard. The constant vertical load is applied stationary upon a reciprocating UHMWPE insert and thus results in a sinus-like dynamic stress on either locus of the polymer contact surface. The amplitude of the change inside the molecular structure of the UHMWPE is nonetheless of a lower extent, which could in theory lead to a decrease of wear, analogous to what was shown for femoral lift-off—which is an extrapolation of vertical force alteration—inside TKA systems [25]. Additionally, any change of stress, an increase as well as decrease, can lead to enhanced production of wear [26].

In the same context, the cylinder of the employed testing machine, which represents the femur component of a TKA system, was geometrically different from real TKA femur components, in particular with respect to their curvature in the frontal plane. This allowed testing to be as universally valid and TKA-design-independent as possible. The cylinder was therefore a simplification, mimicking the single radius design of femoral components in the sagittal plane. Hence, the applied stress inside the polyethylene can slightly differ from real femoral components, which again might lead to decreased or increased wear [24]. Despite this potential alteration in internal bulk stresses, the size of the contact surface area was found to be comparable to that of common knee endoprostheses.

It is agreed that serum protein concentration can affect the results of UHMWPE wear studies [27]. To better meet physiologic conditions, it was decided to use newborn-calf-serum, diluted to a protein concentration of 30 g/L [28]. The indications by ISO 14243, a protein concentration of down to 17 g/L, were found not to be physiologically adequate [27,29]. In these terms, the development and standard usage of a synthetic lubricant that better matches in vivo artificial joint synovial fluid would be of substantial benefit [29]. Higher protein concentrations can reduce wear [30], but nevertheless the physiologic condition is desirable to reach relevance and therefore is used in TKA studies [30].

The results of this study show positive mean values of weight changes—"negative wear"—of nearly all tested specimens, despite having been soak-corrected. Difference in serum composition has been reported to result in the alteration of serum uptake [27]. As proteins can be charged by shear forces in simulator studies [31], the soak control specimens were placed inside the same bowl as the test specimen, which is not practiced in common knee simulators. Wetting both the soak and the test specimens inside the same serum composition in the very same bowl at all times was employed to further enhance the accuracy of gravimetric measurements as near-zero wear was estimated. As the crosslink density is commonly measured by the means of a swell-ratio [15,22], increased crosslinking might also result in an increasing difficulty for the diffusion molecules of the lubricant to pass the molecular structure of UHMWPE on their way into the bulk of the polymer substance which is linked closer, if there are more crosslinks. In addition, diffusion is expected to also depend on the morphologic structure of the amorphous regions of UHMWPE [32]. It can be hypothesized that this effect could, to a very low amount, result in higher dynamically induced fluid uptake, linked to the morphology of UHMWPE and hence dependent on crosslinks. A linkage of decrease of mass gain by serum uptake to an increasing degree of crosslinking, which is believed to be linked to wear decrease [18], can on the other hand affect the gravimetric determination of alteration of wear in simulator tests. More crosslinks might, with this respect, lead to a crosslink-dependent fault in liquid absorption correction. This could lead to an overestimation of wear of crosslinked polyethylenes by relatively lower serum absorption when compared to uncrosslinked materials. In the authors' opinion, to survey highly wear-resistant UHMWPE under low cross-shear conditions, charged with physiologic loading pattern, a more accurate determination of test lubrication uptake is desirable. Future developments should include a soak control specimen with applied dynamics, without the creation of abrasive wear in terms of the loss of mass, which might be realized by the use of a rolling kinematic in combination with an equivalent vertical loading upon the soak specimen. This may not, however, cause a significant change in the relative ranking between the different materials in our study, as previous studies have shown that even the favor of a passive soak control is not predicted to alter the relative ranking between different materials in wear tests [15].

## 5. Conclusions

Screening tests of UHMWPE materials for the use as tibial inserts in TKA devices by means of unidirectional rolling–sliding machines at ISO 14243-near stresses do not necessarily rank the materials correctly. This study using TKA-design-independent testing of materials found no statistically significant differences in gravimetrically detectable wear between the surveyed crosslinked polyethylenes when physiological load was applied under unidirectional reciprocating motion. This suggests that the possible wear performance differences observed between different TKA systems, which is typically quantified using testing methods that employ unidirectional stresses, might be caused by the individual design of the prosthesis.

Wear was existent in some of the samples without becoming statistically significant for the represented materials. It was mostly overlapped by dynamically induced additional fluid uptake, which took place although the vertical load was kept constant, and was hence caused supposedly by the horizontal movement under static pressure. A casual gravimetric wear measurement seems to be inadequate and should be combined with a volumetric wear measurement to verify the results. This could also be of importance for knee wear studies. It is desirable to develop methods of standardization for design-independent rolling–sliding testing at normal physiological loading to enhance knowledge in terms of basic material science to enable qualitative comparison of UHMWPEs and further substances for use in TKA, although, with respect to clinical use, the testing of UHMWPEs for the use as tibial inserts is substantial and should be carried out in combination with the acquired design to be relevant for the evaluation and selection of the appropriate plastic.

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**Author Contributions:** Volkmar Jansson and Sandra Utzschneider conceived and designed the experiments; Matthias Woicinzski analyzed the data; Alexander C. Paulus wrote the paper.

**Conflicts of Interest:** The authors declare no conflict of interest.

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