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Varus or valgus positioning of the tibial component of a unicompartmental fixed-bearing knee arthroplasty does not increase wear

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Abstract

Purpose Higher revision rates were shown in varus- or valgus-positioned tibias in unicompartmental knee arthroplasty (UKA), but more than 15% of UKA prostheses are implanted with more than 5° of varus or valgus**.** This study aimed to analyze the wear rate in UKA when implanting the tibial component in either varus or valgus position versus a neutral placement at 90° to the tibial anatomical axis. The study hypothesized that a 5° varus or valgus positioning of the tibial plateau will generate less wear compared to a neutral alignment.

Methods Wear was experimentally analyzed on a medial anatomical fixed-bearing unicompartmental knee prosthesis (Univation, Aesculap, Germany) in vitro with a customized, four-station, servohydraulic knee wear simulator, reproducing the walking cycle. The forces, loading and range of motion were applied as specified in the ISO 14243–1:2002, 5 million cycles were analyzed. The tibial components of the medial prostheses were inserted in a neutral position, with 5° varus, and 5° valgus ($n = 3$, each group).

Results The wear rate decreased significantly with a 5° varus positioning (6.30 ± 1.38 mg/million cycles) and a 5° valgus positioning (4.96 ± 2.47 mg/million cycles) compared to the neutral position (12.16 ± 1.26 mg/million cycles) ($p < 0.01$ for the varus and the valgus position). The wear area on the inlay was slightly reduced in the varus and valgus group.

Conclusion A varus or valgus "malpositioning" up to 5° will not lead to an increased wear. Wear was even less because of the reduced articulating contact area between the inlay and the femur. A slight varus positioning of the tibial component (parallel to the anatomical joint line) positioning can be advocated from a point of wear.

Level of evidence Experimental study.

Keywords Wear · Varus valgus alignment · UKA

Introduction

Unicondylar arthroplasty of the knee (UKA) in medial knee osteoarthritis is a successful procedure; however, national registries reported higher revision rate of UKA compared to that of TKA [7, 19]. To optimize the survival rate after UKA, further research is mandatory, especially in the optimal positioning of UKA prosthesis, which is still unclear. After a medial UKA, the leg should be positioned in slight varus or neutral position, and an overcorrection should be avoided [10]. The positioning of the tibial implant in terms of slope should be positioned between 3° and 8° of tibial slope [21–23]. Concerning the positioning of the tibia in the coronal plane (varus/valgus), a varus of more than 5° could lead to early loosening [2].

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Furthermore, there is concern that a varus or valgus positioning of 5° or higher leads to a reduced contact area and higher wear especially in fixed-bearing UKA [6]. Freehand implantation analysis of the positioning showed a varus or valgus positioning of more than 5° and 3° in 14% and 35% of the cases, respectively [3, 20]. Therefore this study aimed to investigate changes of wear during varus or valgus positioning of a fixed-bearing unicondylar knee prosthesis in vitro. The study hypothesized that a 5° varus or valgus positioning of the tibial component results in less wear compared to that with a neutrally aligned tibial component due to a reduced contact area [15, 17].

Materials and methods

Prosthesis and embedment

Fixed-bearing anatomical unicompartmental knee prostheses (Univation fixed, Aesculap AG, Tuttlingen, Germany) were used for the in vitro wear analysis. Femoral components and tibial trays were made of CoCr29Mo. Tibial liners were made of ultra-high molecular weight polyethylene (UHMWPE; GUR 1020; β-sterilized 25–40 kGy, packed under N_2). The medial tibial component was aligned in a different varus or valgus angle (5° valgus, neutral, and 5° varus, Fig. 1). To compensate a mediolateral translation in the knee caused by this condition, the lateral component had to be aligned in the opposite varus or valgus angle to stabilize the system. Femoral component position was standardized according to ISO 14243–1:2002 standard by embedding both condyles with resin (Isocyanat/Polyol, Rencast® FC 53) to a steel rod for each of the three samples mounted on the wear simulator. Flexion axis was also set according to the standard with the centers of two circles that fit best to the sagittal section of the posterior femoral component (j-curve). To standardize mediolateral position of the femoral component a custom-made bridge fixation (width 42.65 mm ± 0.1 mm) was used.

Fig. 1 Alignment of the medial UKA in the knee wear simulator (left knee). In the middle, the alignment is neutral; on the left, it is aligned in 5° valgus; and on the right, it is aligned in 5° of varus

Wear simulator testing

The wear simulator testing was undertaken as published before [21]. For each position (neutral, 5° varus, and 5° valgus), three prosthesis samples were embedded in a customized servohydraulic knee wear simulator (EndoLab GmbH, Thansau, Germany) for the wear analysis. The simulator mimics walking in a plane for 5.0 million cycles as specified in the ISO standard (ISO 14243–1:2002; Fig. 2). Internal/external rotational torque, anterior posterior force, and axial force were generated with hydraulic cylinders accordingly. The axial force was applied in a mediolateral compartment loading from 60 to 40%. To simulate the knee ligaments, the wear simulator includes spring restraints of 30 N/mm in anterior–posterior direction and 600 Nmm/° in internal–external rotation direction. The following test parameters were simulated within the wear simulator as specified by the ISO: a maximum load of 2600 N, a flexion angle of 0°–58°, AP force of – 265 to – 110 N, and an IE rotational torque of – 1 to – 6 Nm.

A fourth prosthesis sample was used as a load soak control by applying only axial load without flexion, AP force, and tibial torque. The components were lubricated using a mixture of new-born calf serum and distilled water to reach a protein content of 30 g/l. Additives for stabilization of

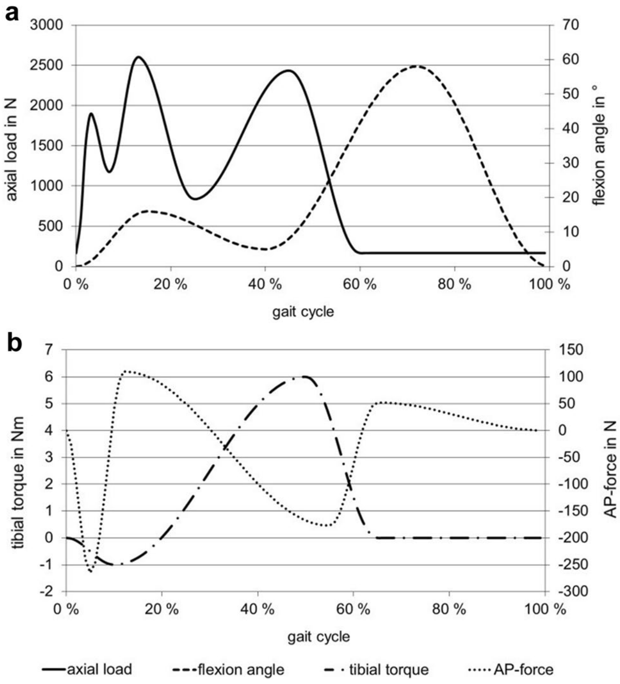

Fig. 2 Applied axial load, flexion angle (both **a**), tibial torque and AP force (both **b**) during one cycle according to ISO 14243–1:2002

pH value (EDTA, AppliChem, Darmstadt, Germany) and prevention of fungal growth (Amphotericin B Biochrom, Berlin, Germany) were added to the lubricant. Before the beginning of the tests, conditioning of the UHMWPE liners was necessary. Therefore, all inlays were stored in the lubricant until there was no increase in weight.

As specified by the ISO standard, the lubricant was replaced every 500,000 cycles. At this point, the UHMWPE liners were cleaned gently and weighted using an analytical balance (Sartorius BP211D, Germany) with an accuracy of 0.01 mg after every 1,000,000 cycles. Finally, gravimetric wear measurements were corrected with the load soak control and air buoyancy.

Visual Interpretation of the wear areas

In every million cycles, the inlays were scanned to assess the wear area (Epson Expression 1680 Pro with 300 dpi; scaling 1 mm) (Seiko Epson, Tokyo, Japan). After 5 million cycles the interpretation of the wear area and pattern was done visually and by microscope (Keyence, VHX 500) (Keyence, Germany, Neu-Isenburg) [16]. The calculation of the wear area was done with Photoshop CC 2018 (Adobe, San Jose, California, United States) by marking the wear area automated within the program and having a caliper within the picture. One pixel had a resolution of 0.04 mm/pixel. The error on accuracy and repeatability for this procedure proofed in literature to be less than 3.4% [8].

Statistical analysis

An unpaired *t* test was used for the analysis of the different wear rates per million cycles (GraphPad Prism 5, GraphPad Software Inc., San Diego, United States). *p* value was set to 0.05. Normal distribution of wear rates was checked by Shapiro–Wilk test (SPSS Statistics 25, IBM, Armonk, New York, United States). Post hoc power analysis (G*Power 3.1.9.4, University of Kiel) for neutral alignment and 5° varus showed a statistical power of 98% (α err prob = 0.05; effect size = 4.43) and for neutral alignment and 5° valgus a statistical power of 91% (α err prob = 0.05; effect size = 3.67).

Results

The wear rate decreased significantly when positioning the prosthesis in 5° varus or 5° valgus compared to that in the neutral position ($p < 0.01$). The difference of the wear rate between the 5° varus and 5° valgus positioning of the tibia was not significant ($p = 0.46$) (Table 1). The visual analysis of the surface of the inlays showed that the wear was slightly more lateral in valgus positioning, and in the varus positioning (middle), the wear area was nearly identical to that in neutral positioning. The surface area in which wear occurred was reduced in both the varus and valgus groups compared to that in the neutral group (Fig. 3). Wear pattern showed mainly polished wear areas with striated patterns and slight scratches (Appendix A in ESM). In detail, the neutral alignment showed more striated patterns, whereas the varus and valgus positioning showed more polished areas. There were no signs of delamination on any of the analyzed inlays.

Table 1 Wear rate of the medial unicondylar knee prosthesis depending on the positioning of the tibial component in the coronal plane

	Wear rate (mg/million cycles)
Neutral position (0°)	12.16 ± 1.26
5° varus	6.30 ± 1.38
5° valgus	4.96 ± 2.47

Discussion

The most important finding of this in vitro study was a decrease in the wear rate with 5° varus or 5° valgus positioning of the tibial plateau of a fixed-bearing medial UKA. In the valgus position, the wear area was more pronounced on the lateral edge of the inlay; in the varus group, it was nearly comparable to the neutral position. The surface in which the wear occurred was reduced in the valgus and slightly in the varus position compared to that in the neutral position.

Diezi et al. analyzed the prints positioned between 6 different unicondylar knee protheses and loaded the knees with 500 N. They showed that a varus positioning of the prosthesis would lead to a reduced contact area between the inlay and the femoral component. The reduction of contact area was different between the tested prostheses but was only reported in the figures in their study, the absolute values were not reported. However the difference between the neutral and the 5° varus positioning was around 20% [6]. This difference in the contact area was comparable to the difference shown in the present study. Diezi et al., concluded that the reduced contact area in varus or valgus positioning would lead to a higher wear rate. However, the present study showed a reduced wear rate in the varus and valgus positioning. It has been shown that a reduced contact area will lead to a reduced wear [15, 17]. In the present analysis a varus or valgus positioning of the UKA, led to less contact area and with this less wear occured. This is true as long as the yield stress of the polyethylene in general 22 MPa is not exceeded [1]. When this stress is exceeded, larger damage to the polyethylene can be expected.

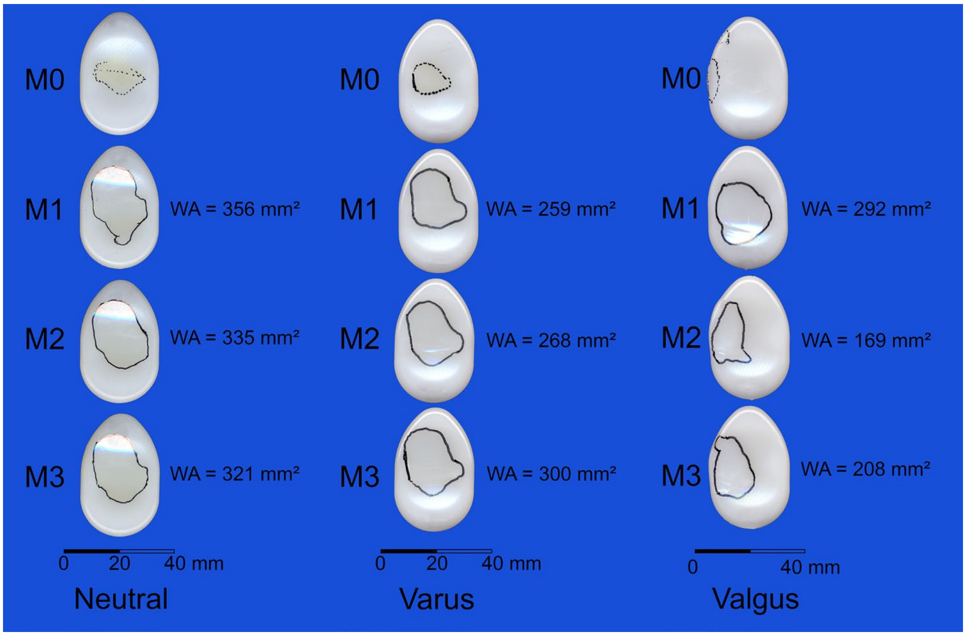

Fig. 3 Wear traces on the inlays (left knee). The scans were taken after 5 million cycles. Visible wear-tracks were found inside the encircled areas. Left figure, inlays with a neutral position; middle figure, inlays in the varus position; right figure, inlays positioned in 5° valgus. (M0, non-loaded control). The wear area (accuracy and repeatability < 3.4% [8]) was reduced in the valgus inlays and slightly in the varus compared to the neutral inlays. In the valgus inlays wear occurred more on the lateral side

The visual analysis showed that the wear area was relatively central in the varus group; however, in the valgus group, there was a lateralization of the wear area on a smaller surface. Since the valgus position of the tibia leads to a deeper position of the tibia on the lateral side, the femoral component will probably slip in this direction and lead to more wear on the lateral side of the inlay. In this case, a higher stress could probably occur in more extreme loading conditions in the valgus position. In this study, only the normal gait was examined and with this no signs of delamination were observed on the inlay. Under more severe loading conditions as they occur in daily living; higher loads on the inlay are expected to potentially exceed the yield stress of the polyethylene and leading to delamination of the inlays with the reduced contact area encountered in valgus positioning of the tibia [25]. These results are supported by a finite-element (FE) analysis showing that a valgus positioning of 3° of the tibia led to higher von Mises stresses in the inlay compared to a varus positioning of 3° [11].

Positioning the tibia in a slight varus appears to be advantageous compared to valgus positioning at least for the analyzed design in this study. There is an ongoing discussion if the tibial component should be positioned in a slight varus of 3°–4°, parallel to the native joint line, or if it should be positioned 90° to the axis of the tibia [4, 13].

The aforementioned FE study also showed that a slight varus positioning of 3° would not alter the loads under the tibial component; on the contrary, a valgus positioning would lead to more strain under the tibial component. In the FE model, strains increased when the tibia was positioned at 6° varus or valgus, and the authors concluded that a varus or valgus of 6° should be avoided [11]. These results are supported by a further FE study that showed that the contact stress on the PE insert and lateral articular cartilage increased more in a valgus position of the tibia compared to the slight varus positioning of 3° [12]. From a clinical point of view it was shown that the varus position of the tibial component should, however, not exceed 5° as this was significantly associated with mechanical failure [5]. The present study showed that varus positioning would reduce wear. Thus, with regard to a point of wear and the strains on the tibial bone, positioning of the tibial component in 3° varus (anatomical) has no disadvantages compared to neutral positioning.

The wear rate in the neutral position of 12.16 mg/million cycles was comparable to the wear rate observed in other studies analyzing the same prosthesis with 10.40 and 10.54 mg/million cycles [9, 22]. In another study with the same prosthesis, the wear was slightly low (7.51 mg/million cycles). However, this study used a different lubricant and simulator which could explain the differences, as different simulators can lead to small differences in the generated forces. The differences can also be explained by differences between the batches the polyethylene. Every batch has to fulfill minimal criteria, sometimes the polyethylene is of higher quality and this leads to a reduction in wear which can be up to 30% (personal communication, BBraun Aesculap, Tuttlingen, Germany). Finally, under different testing conditions, Laurent et al. reported a wear rate of 7.1 mm^3/million using another fixed-bearing UKA [14]. This study used a different in vitro wear simulator with an equal load being applied on the medial and lateral side of the knee which is not in accordance with the ISO standard, the native knee and the other wear studies. In all these studies as in the present a medial load of 60% is applied as this is more physiological. This probably explains the reduced wear observed in this study.

This study has limitations. First, the lateral prosthesis was positioned in the opposite inclination in the coronal plane to stabilize the knee simulator. In an attempt, the medial tibial component only was embedded with 5° valgus, and the lateral component was placed in neutral position. However, after a few cycles, this led to knee dislocation. Therefore, the lateral component had to be embedded with 5° varus and then valgus positioning to attain an "A" or "V" positioning of the components. With this, stabilization of the simulator was warranted over 5 million cycles. The stabilization in vivo is warranted by the ligaments; therefore, the positioning of the lateral component in varus and then in valgus probably not influenced the wear rate of the medial prosthesis.

Second, only three specimens/group were tested. However, wear simulation tests are time-consuming, and in most studies, only a limited number of prostheses is tested [9, 14, 21, 22]. Even if only three samples were used, a significant difference was observed.

Third, this study only analyzed wear under walking conditions and activities such as climbing stairs, squatting, and raising from a chair were not analyzed even if they influence wear [18].

Besides, the daily activity of patients has a wide range. According to the new literature patients walk up to 1.13 (SD 0.56) million cycles per year [24], which is not addressed in the current ISO standard. Therefore 5 million cycles simulated in this study may represent only 5 years in situ for active patients. This increased amount of walking cycles and different activities should be studied in the future.

Conclusion

This in vitro study showed that a varus and a valgus positioning of the tibial component reduces wear rate compared a neutral positioning of 90° to the tibia due to a reduced contact area between the inlay and the femur. The contact area was shifted more to the lateral edge in valgus positioning, which could lead to more wear in highly demanding activities. A slight varus positioning of the tibial component (parallel to the anatomical joint line) did not result in an altered contact area and has no disadvantages compared to positioning of 90° to the tibia. As a clinical consequence, the present findings suggest that from a point of wear, slight varus positioning of UKA prosthesis up to 5° can be advocated.

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Compliance with ethical standards

Conflict of interest VJ and PEM are advising surgeons of Aesculap, Tuttlingen, Germany. VJ, PEM and PW are advising surgeons for Medacta, Castel San Pietro, Switzerland. MW, CS and PW received research funds from Aesculap R&D projects. This did not, however, influence the study design or the collection, analysis, and interpretation of the data. It also did not influence the decision to submit the manuscript for publication.

Ethical approval This article does not contain any studies with human participants or animals performed by any of the authors.

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