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Effect of joint laxity on polyethylene wear in total knee replacement

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ABSTRACT

Experimental simulator studies are frequently performed to evaluate wear behavior in total knee replacement. It is vital that the simulation conditions match the physiological situation as closely as possible. To date, few experimental wear studies have examined the effects of joint laxity on wear and joint kinematics and the absence of the anterior cruciate ligament has not been sufficiently taken into account in simulator wear studies.

The aim of this study was to investigate different ligament and soft tissue models with respect to wear and kinematics.

A virtual soft tissue control system was used to simulate different motion restraints in a force-controlled knee wear simulator.

The application of more realistic and sophisticated ligament models that considered the absence of anterior cruciate ligament lead to a significant increase in polyethylene wear ($p=0.02$) and joint kinematics ($p<0.01$). We recommend the use of more complex ligament models to appropriately simulate the function of the human knee joint and to evaluate the wear behavior of total knee replacements. A feasible simulation model is presented.

1. Introduction

Wear of ultrahigh molecular weight polyethylene (PE) in total knee replacement (TKR) is a particularly important factor for the longevity of the implant (Argenson et al., 1992; Blunn et al., 1997; Engh et al., 1992). Wear debris has been shown to lead to cellular reactions that result in periprosthetic bone loss and loosening of implants (Amstutz et al., 1992; Revell et al., 1997). Preclinical wear testing of TKR is important for the provision of appropriate wear models and for the investigation of wear behavior. Knee simulators are used for such tests. Several factors that influence wear such as implant design, manufacturing, sterilization method, joint lubrication, patient weight, and activity level have been studied (Schmalzried et al., 1999). Wear is also highly dependent on kinematics; increased AP translation (anterior–posterior translation) and IE rotation (internal–external rotation) have been reported to raise PE wear in TKR (Kawanabe et al., 2001; McEwen et al., 2005). The motion of the natural knee is governed by active forces that originate from the muscles as well as dynamic and gravitational forces (Mikosz et al., 1988; Morrison, 1970). These forces must be restrained by the passive structure of the joint. Due to their passive elastic behavior, the soft tissues, and in particular the ligaments, provide the restraining forces needed to balance the active forces during physiological motion (Ma et al., 2003; Shelburne et al., 2004). Several studies have described the soft tissue reaction in the human knee as a non-linear elastic material, and have highlighted the importance of the cruciate ligaments (Butler et al., 1980; Fukubayashi et al., 1982; Kanamori et al., 2002; Markolf et al., 1984; Shoemaker et al., 1985; Woo et al., 2002); in the absence of the anterior cruciate ligament (ACL) joint laxity is increased. This is of particular importance because the ACL is commonly sacrificed during the implantation of a TKR. Increased laxity will directly affect the joint kinematics (Walker et al., 2003). In wear simulator studies increased AP translations and IE rotations of the TKR have been reported when laxity was raised (Haider et al., 2006; White et al., 2006). However, the effect of increased laxity on implant wear is unknown. Furthermore, most wear studies to date have not sufficiently simulated the ligaments (D'Lima et al., 2001; Laurent et al., 2003; Tsukamoto et al., 2006). At best, mechanical springs were used to replicate the ligaments (Benson et al., 2001; Schwenke et al., 2005; Walker et al., 1997). However, the linear behavior of mechanical springs does not represent the asymmetric non-linear soft tissue motion restraint in vivo. Additionally, motion restrain caused by the springs used in those studies was too high and both physiological and postoperative joint laxity

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were not sufficiently represented (Butler et al., 1980; Fukubayashi et al., 1982; Kanamori et al., 2002; Markolf et al., 1981; Shoemaker et al., 1985; Woo et al., 2002).

This study was designed to demonstrate that applying a realistic asymmetric non-linear soft tissue motion restraint and including the absence of the ACL will (1) increase joint kinematics (AP translation and IE rotation) and thus (2) increase PE wear in simulator studies. To tests these hypotheses, a wear study based on two different soft tissue models was performed using a force-controlled knee simulator.

2. Materials and methods

Two wear tests were performed to investigate the effect of different laxities on PE wear and joint kinematics. For the first test linear motion restraints of 30 N/mm for AP translation and 0.6 Nm/° for IE rotation, according to ISO standard 14243-1:2002(E), were chosen to simulate the intact cruciate ligaments. For the second test, asymmetric non-linear motion restraints were adopted from biomechanical studies that simulated the clinical situation of a sectioned ACL (Fukubayashi et al., 1982; Kanamori et al., 2002). The ligament models are shown in Fig. 1 (AP translation) and Fig. 2 (IE rotation).

Motion restraints for sectioned ACL were implemented according to the following polynomial equations:

For AP motion the restraining force (RF_{AP}) is valid in a specific value range (V_{AP}) and depends on the AP displacement (x_{AP}):

$$RF_{AP} = 5.66 \times 10^{-4}\ \frac{\mathrm{N}}{\mathrm{mm}^5} \times x_{AP}{}^5 - 2.02 \times 10^{-2}\ \frac{\mathrm{N}}{\mathrm{mm}^4} \times x_{AP}{}^4 + 0.27\ \frac{\mathrm{N}}{\mathrm{mm}^3} \times x_{AP}{}^3 - 1.09\ \frac{\mathrm{N}}{\mathrm{mm}^2} \times x_{AP}{}^2 + 2.60\ \frac{\mathrm{N}}{\mathrm{mm}} \times x_{AP} + 1.90\ \mathrm{N} \tag{1}$$

with

$$V_{AP} = \{x_{AP} \in \mathbb{R} \backslash -10 < x_{AP} < 20\} \tag{2}$$

For IE motion the restraining torque (RT_{IE}) depends on IE rotation (x_{IE}), valid for a specific value range (V_{IE})

$$RT_{IE} = 0.20 \times 10^{-5}\ \frac{\mathrm{Nm}}{\mathrm{deg}^5} \times x_{IE}{}^5 + 0.25 \times 10^{-4}\ \frac{\mathrm{Nm}}{\mathrm{deg}^4} \times x_{IE}{}^4 - 4.13 \times 10^{-4}\ \frac{\mathrm{Nm}}{\mathrm{deg}^3} \times x_{IE}{}^3 - 2.32 \times 10^{-3}\ \frac{\mathrm{Nm}}{\mathrm{deg}^2} \times x_{IE}{}^2 + 0.31\ \frac{\mathrm{Nm}}{\mathrm{deg}} \times x_{IE} - 1.68\ \mathrm{Nm} \tag{3}$$

with

$$V_{IE} = \{x_{IE} \in \mathbb{R} \backslash -20 < x_{IE} < 20\} \tag{4}$$

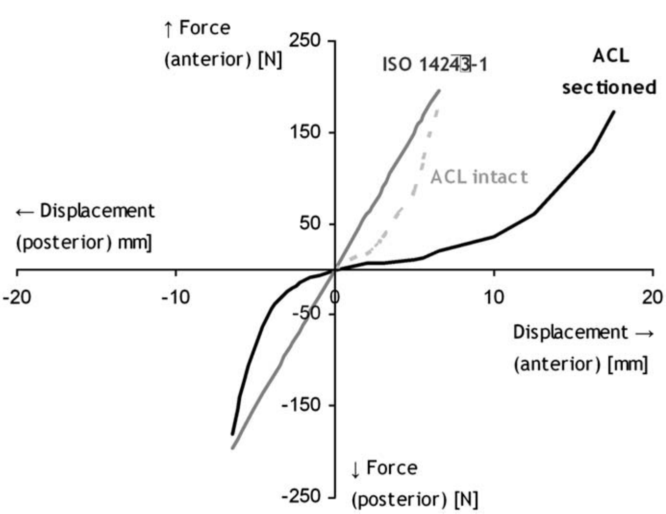

Fig. 1. Motion restraint for AP translation according to the 14243-1:2002(E) is based on a linear approximation of the tibial anterior–posterior displacement when the ACL is intact. A sectioned ACL increases tibial anterior–posterior displacement. In the neutral zone (displacement close to zero) the slope of the curve according to the 14243-1:2002(E) standard is much higher compared to the asymmetric and non-linear curves given by Fukubayashi et al. (1982) even for an intact ACL.

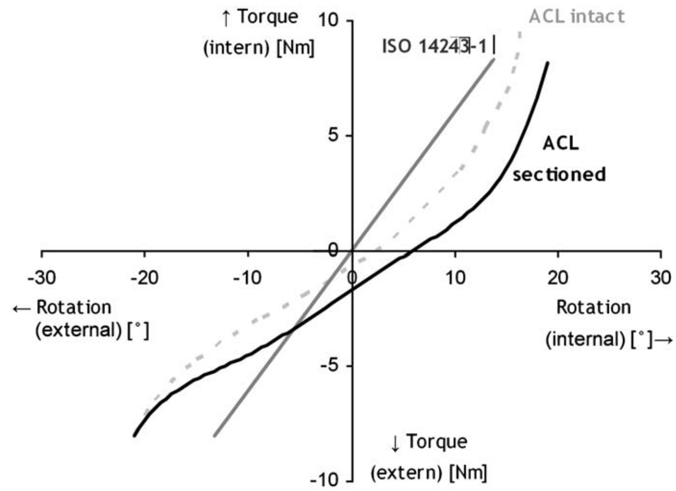

Fig. 2. Motion restraint for the IE rotation according to the 14243-1:2002(E) is based on a linear approximation of the tibial IE rotation. Close to the neutral zone the motions restraint for an intact or sectioned ACL is almost linear. Nevertheless, the slope of the curve according to the 14243-1:2002(E) standard is much higher compared to the curves of an intact or sectioned ACL as given by Kanamori et al. (2002).

Fig. 3. The ultracongruent fixed bearing TKR implant used in the study (mounted in a wear station of the simulator).

The only parameter to be altered in both tests was the motion restraint. This allowed different motion restraints to be investigated separately.

For each wear test, three wear specimens and one soak control specimen were used. An ultracongruent fixed bearing design (Columbus® UC, Aesculap AG, Tuttlingen, Germany) was evaluated in this study (Fig. 3). The medium-sized components were manufactured in a similar manner: the femoral components and

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tibial trays were made of cast CoCr29Mo6 alloy according to ISO 5832-4:1996(E) and tibial inserts were made of UHMWPE (GUR 1020) according to ISO 5834-2:2006(E). The thickness of the γ-irradiated (dose: $\sim$30 kGy) tibial inserts was 10 mm. Force-controlled simulation according to ISO 14243-1:2002(E) was carried out on a modified (Kretzer et al., 2008) AMTI knee simulator (Model KS2-6-1000, Advanced Mechanical Technology Inc., Watertown, MA, USA) (Fig. 4). A virtual soft tissue control system according to White et al. (2006) was used to simulate different motion restraints. The virtual soft tissue control system embodies the relationship between configuration and restraint force in a real-time, cubic–spline algorithm for each controlled degree-of-freedom. The cubic–spline can be modified so as to permit the settings of different input–output relationships such as linear, non-linear, and asymmetric relationships, which represent the desired characteristics of soft tissue restraint.

The following test parameters were employed according to the ISO 14243-1:2002(E) standard: a maximum load of 2600 N, a flexion angle of 0°–58°, an AP force of −265 to 110 N, and an IE torque of −1 to 6 Nm. Compressive load was offset medially 5.2 mm from the varus–valgus rotational axis to create higher forces on the medial compartment (Andriacchi et al., 1986; Harrington, 1983; Kretzer et al., 2008). Simulation lasted for a total of 5,000,000 loading cycles at a frequency of 1 Hz. Prior to simulation, the tibial inserts were presoaked in serum and gravimetrically measured at weekly intervals until the incremental mass change of the inserts was less than 10% of the cumulative mass change. Only compressive load was applied to the soak control specimens during the course of the simulation. Magnitude and frequency of the compressive load were the same for the soak control and wear specimens. After every 500,000 cycles, all components (wear specimens and soak controls) were cleaned and gravimetrically measured according to the ISO 14243-2:2000(E). The weight change in each wear specimen was corrected for fluid absorption by subtracting the weight gain of the load soak control at each measurement interval. The wear rates of the wear specimens were calculated based on linear regression (weight change as function of cycles). To minimize inter-station variability, tibial inserts were rotated between wear stations every 500,000 cycles. Simulation was carried out in recirculated diluted calf serum (PAA Laboratories GmbH, Pasching, Austria), maintained at 37 °C in sealed chambers. Sodium azide and ethylenediamine tetraacetic acid (EDTA) were added to retard bacterial growth and minimize layers of calcium phosphate on the implant surfaces. A protein concentration of 30 g/l was chosen according to Noordin et al. (1997). Serum was replaced every 500,000 cycles.

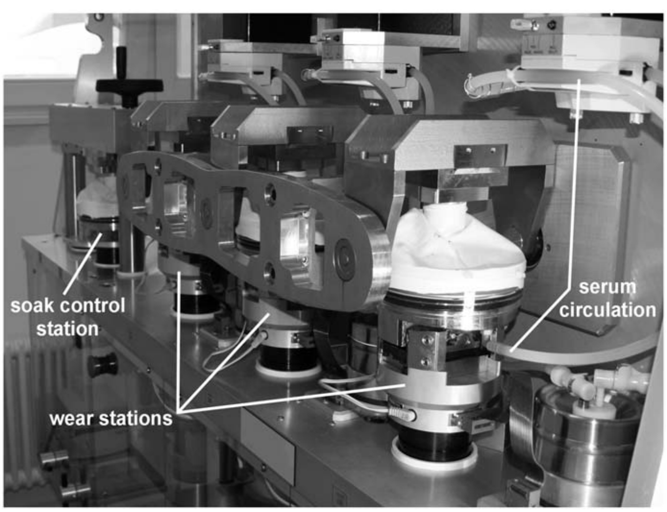

Fig. 4. Experimental setup: AMTI knee simulator with wear and soak control stations as well as serum circulation system.

Kinematic implant data (AP translation and IE rotation) were recorded during simulation to evaluate the mobility of the implants. Wear scars were documented photographically after 5,000,000 load cycles.

Student's *t*-test for two independent parametric samples was used to compare wear rates, AP translation and IE rotation of both ligament models. The level for statistical significance was set at $p \leq 0.05$. All statistical analyses were performed using the SPSS® (SPSS® for Windows 16.0.1, SPSS Inc., Chicago, USA). All data are presented as the mean ± 95% confidence interval (CI).

3. Results

In the absence of the ACL, simulating asymmetric non-linear soft tissue motion restraint increased AP translation by 38% and IE rotation by 47%. The total AP translation significantly increased from 2.98 mm (CI: ±0.12 mm) to 4.82 mm (CI: ±0.13 mm) when non-linear soft tissue motion restraint was introduced ($p < 0.01$). Similarly, total IE rotation significantly increased from 4.09° (CI: ±0.10°) to 7.69° (CI: ±0.46°) ($p < 0.01$).

In the absence of the ACL, wear rates increased by 40% compared to the ISO 14243-1:2002(E) conforming linear motion restraints. Allowing for weight increases of the soak control inserts, an average wear rate of 4.8 mg/10E6 cycles (CI: ±1.9 mg/10E6 cycles) was measured (non-linear soft tissue motion restraint). In contrast, the ISO 14243-1:2002(E) conforming linear motion restraints resulted in an averaged wear rate of 2.9 mg/10E6 cycles (CI: ±0.7 mg/10E6 cycles). This difference was statistically significant (p=0.02).

Increased IE rotation and AP translation as well as increased wear resulted in larger wear scars on the superior surface of the tibial inserts (Fig. 5). Polishing and burnishing were the dominant wear mechanisms.

4. Discussion

For the preclinical wear evaluation of TKR, proper simulation conditions that are as close as possible to the physiological situation are essential for obtaining experimental wear rates that are comparable to clinical wear rates. However, even with the same implant design, clinical wear rates are often reported to be higher than those from simulator studies (Kop et al., 2007); McEwen et al., 2001). This discrepancy may be related to different patient activities, surgical alignment or the ageing condition of the PE. DesJardins et al. (2007) investigated kinematics after TKR surgery using fluoroscopic analysis, and compared these results with kinematics from force-controlled wear simulation on the same implant design. They generally reported good agreement between clinical and simulator kinematics. However, AP translation was 41% higher in the clinical situation compared to

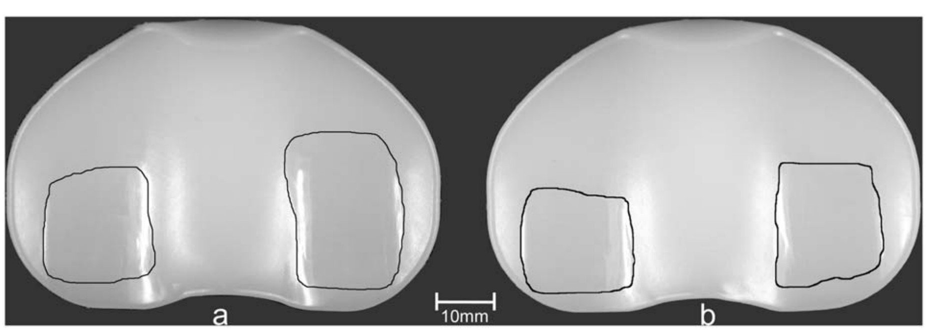

Fig. 5. Wear scars on the superior surface of the tibial inserts are larger when simulating non-linear soft tissue motion restraints (a), compared to the 14243-1:2002(E) conforming linear motion restraints (b).

simulator data. Their results points out the important difference between in vivo and in vitro kinematics in TKR.

To the authors' knowledge, this study is the first to investigate the effect of different joint laxities on PE wear by analyzing different motion restraint models in a knee wear simulator. Although the sample size was small with three wear specimens in each group, this knee simulator study showed that the PE wear rates and kinematics were significantly increased when more realistic soft tissue motion restraints were applied that considered the absence of the ACL.

When the absence of ACL was simulated in this study, the AP translation increased by 38% and IE rotation by 47%, which agrees well with clinical findings. Depending on the knee flexion angle, Markolf et al. (1984) investigated the AP translation for ACL-deficient knees compared to healthy knees. They reported an increase in AP translation between 34% and 57% depending on the flexion angle. Similarly, Samukawa et al. (2007) reported an increase in IE rotation between 29% and 39% in the ACL-deficient knees. These clinical findings support the results of the present study. Increased AP translation and IE rotation with increased laxity have also been reported from experimental simulator studies (Haider et al., 2006, White et al., 2006).

In this study, a virtual soft tissue control system was used to simulate different motion restraints. This was capable of tracking the desired forces, motion and motion restraints with an RMS error of less than 2% (White et al., 2006). The soft tissue motion restraint model was adopted on the basis of the data given by Fukubayashi et al. (1982) and Kanamori et al. (2002). Fukubayashi et al. investigated the AP translation as a function of the AP force in human knee specimens for intact and sectioned ACL (Fig. 1). In the neutral zone (displacement close to zero) the force needed to cause a relative motion between the femur and tibia is low for both intact and sectioned ACL. Isolated section of the ACL clearly increased joint laxity. Fig. 1 also presents the motion restraint according to 14243-1:2002(E). Close to the neutral zone, the slope of the ISO curve is higher in magnitudes compared to the data given by Fukubayashi et al. (1982). In Fig. 2 motion restraints for IE rotation according to Kanamori et al. (2002) and 14243-1:2002(E) are shown. Close to the neutral zone the motion restraints for an intact or sectioned ACL act in an almost linear manner. Again, the slope of the curve according to the 14243-1:2002(E) standard is higher compared to the data given by Kanamori et al. (2002). This discrepancy is also supported by other biomechanical studies on the function of the ligaments and soft tissues in the knee joint (Butler et al., 1980; Markolf et al., 1995; Shoemaker et al., 1985).

PE wear in TKR is influenced by many parameters. For example the type of PE (e.g. crosslinked vs. conventional) (Muratoglu et al., 2007), the conformity of the inlay and the loading conditions (Galvin et al., 2009), as well as the implant concept (e.g. fixed vs. mobile) (Haider et al., 2008) have an effect on PE wear. Additionally implant kinematics are important. Higher AP translation and IE rotation have been shown to increase PE wear in TKR (Kawanabe et al., 2001). In the absence of the ACL, AP translation increased by 38%, IE rotation by 47% and the PE wear rate by 40% in our study. Thus, our study underpins the effect of implant kinematics on PE wear. The mean wear rate for the inlays tested in accordance to ISO 14243-1:2002(E) (linear motion restraint) was 2.9 mg/10E6 cycles in the current study. Grupp et al. (2009) investigated the same implant design using a deep dished PE inlay. Their study was also performed in accordance with the ISO 14243-1:2002(E) and they reported a mean wear rate of 2.2 mg/10E6 cycles. Although the congruency of the inlay in the study by Grupp et al. (2009) was slightly different to the present study (ultracongruent inlay) agreement between both studies can be confirmed.

To date, increased laxity due to the absence of the ACL and asymmetric non-linear motion restraints have not been sufficiently taken into account in other simulator wear studies. Mechanical springs have mostly been used so far (Benson et al., 2001, DesJardins et al., 2007, DesJardins et al., 2000, Schwenke et al., 2005, Walker et al., 1997). However, mechanical springs are known to act linearly and therefore do not represent the asymmetric non-linear in vivo soft tissue motion restraint. Additionally, the stiffness of these springs is often too high to represent a sectioned ligament, which commonly exists when implanting a TKR (Benson et al., 2001, Schwenke et al., 2005). Haider et al. (2008, 2006, 2002) proposed a triphasic spring model to simulate the knee laxity. They recommended a gap in the AP direction to remove stiffness around the neutral position. However, the mechanical arrangement of the springs by Haider et al. (2008, 2006, 2002) leads to coupled motion restraints for AP and IE. Thus, stiffness is also completely removed around the neutral zone for the IE rotation. In fact, for AP direction ligament stiffness is reduced around the neutral position but the stiffness is not zero and for IE direction ligament stiffness is not particularly reduced around the neutral zone (Butler et al., 1980, Fukubayashi et al., 1982; Kanamori et al., 2002; Markolf et al., 1981; Markolf et al., 1984; Shoemaker et al., 1985). Since November 2008 a revised version of the ISO 14243-1:2002(E) has been available as the ISO/DIS 14243-1(2008). This draft defines a triphasic spring model for AP translation and IE rotation as described by Haider et al. (2008, 2006, 2002). However, the use of an asymmetric non-linear soft tissue motion restraint model that is independent for AP translation and IE rotation seems to be more advisable.

In Fig. 5 the wear scar areas on the superior surface of the tibial inserts are shown. These surface alterations do not solely represent surface wear because they may also be related to creep. Thus, the dimension of these areas should be interpreted carefully with respect to wear and kinematics. The simulation is limited to level walking in the current study. Patient activities such as climbing the stairs and getting up from a chair may substantially influence in vivo knee wear behavior. The authors believe that the surgical technique used, and in particular the alignment, also play a major role in kinematics, wear and long-term stability. Consequently, clinical studies are needed to verify the results of this experimental study. Furthermore, the conformity of the implant may cause changes in kinematics and PE wear. Follow-up studies are therefore needed to assess the influence of different implant concepts, in combination with realistic joint laxities, on PE wear and joint kinematics.

5. Conclusion

Care should be taken when simulating the complex mechanism of the human knee joint, as ligament motion restraints strongly influence joint kinematics and PE wear in simulator wear studies. Therefore, appropriate ligament models should be used to evaluate the wear behavior of a TKR. This study provides a mathematical ligament model that accounts for the absence of the ACL. Further experimental studies examining the influence of surgical technique, alignment and implant design may prove to be essential.

Conflict of interest statement

Our study was funded through the Ministry of Art and Science of Baden-Württemberg, Germany.

In support of our research materials and components were supplied by Aesculap AG, Tuttlingen, Germany.

Neither we nor a member of our immediate families received payments or other benefits or a commitment or agreement to provide such benefits from a commercial entity.

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