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The influence of a single-radius-design on the knee stability

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Abstract. Prostheses with single radius (SR) design were supposed to be as good as the physiological kinematic and stability of the knee. This *in-vitro* biomechanical study compared SR to a multiple radius (MR) design on the one hand and seven left human knee specimens were used. The SR and MR knee prosthesis where implanted with a navigation system. We measured varus/valgus deviation of the mechanical axis and the deviation of the joint-line to the epicondyle-line in different knee flexion degrees (0°, 30°, 45°, 60° and 90°) with and without 15 Nm of varus and valgus stress.

Without varus/valgus-stress in all three groups (physiological knee, SR and MR prosthesis) the results were located on the varus-site. The variation of the SR was less than the MR, without being significant. Under varus and valgus stress varus/valgus axis deviation constantly grew. From 0–60° no significant deviation between the two prosthesis models was found. At 90° flexion varus/valgus deviation with the SR component was significantly ($p \leqslant 0.05$) smaller compared to the MR design.

This *in-vitro* study showed that the SR prosthesis is significantly more stable in the coronal plane than the MR in higher flexion degrees. This could have an improved effect on biomechanical stability with a higher clinical function after SR-TKA.

Keywords: Single radius, multiple radius, knee, arthroplasty

1. Introduction

Gold standard for the therapy of progressed knee arthritis is Total Knee Arthroplasty (TKA) [1]. The expectations of the postoperative result differ from one patient to the other regarding their age. 90% of the patients are expecting a significant reduction of pain in combination with a better life quality, longer painless walking distance, improvement of daily work activity and psychological gain [2,3]. Due to the growing activity of operated patients, such as swimming, cycling, walking, playing tennis and golf the requirements on the implants steadily grow. Prostheses with a single radius design of the femoral prosthesis condyles (SR) were developed trying to reach the physiological kinematic of the knee and fulfil the above-mentioned requirements [4]. Femorotibial biomechanics are influenced by a number of factors, mainly by the design of the prosthesis [5]. The design of the femur component should correspond with the anatomical design of the femur to avoid high ligament tension, to protect the soft tissue and to preserve the knee balance. Kessler et al. explained that a femur component with a SR would show less deviation from the flexion and extension axis than a MR component with multiple radii

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(MR) [6]. Compared with a MR design the flexion and extension axis of the SR is more similar to the transepicondylar line, which means that it is located more posterior than a varying axis of the MR. This leads to a longer lever arm of the quadriceps muscle and in consequence to a lover retro patellar surface pressure [7–10]. Hollister et al. and Churchill et al. underline that the best soft-tissue balancing of SR prosthesis is achieved by adjusting the femoral axis to the transepicondylar line. As a result an equal flexion and extension gap can be achieved in 0°–110° [11,12].

The single radius femoral component (SR) is supposed to achieve a natural movement of the knee joint and perform a flexion up to 150° with a stable collateral tension. Furthermore the prosthesis is meant to a have a high conformity during the joint movement, reduce the contact force and the abrasion and therefore perform a longer standing time.

The aim of the presented study was to prove the above-mentioned comparing ligament stability in a SR prosthesis (Triathlon®, Stryker) with a femoral multiple radius (MR) prosthesis (Duracon®, Stryker) and mark out the differences.

We hypothesized, that the SR design prostheses on the one hand show a lower varus/valgus deviation of the mechanical lower leg axis and on the other hand show a more balanced flexion and extension gap compared to the MR design. Furthermore a higher accuracy of implantation with a navigation system was suspected.

2. Methods

Seven human knee specimens with an average age of 60 years (44–77) were resected 25 cm above and below the joint line. To reconstruct a full lower extremity to use a navigation system for implantation and measurement a complete half pelvis with hip and femur made of sawbone was fixed above and a lower leg below the cadaver knee. After that the knee was fixed in a custom-made fixation frame.

For measurement of the knee kinematics with varus-valgus deviation and later the TKA implantation a navigation-system (Stryker-Leibinger) with the infrared-system Polaris Hybrid® (Northern Digital) was used with corresponding trackers placed in the femur and the tibia, which were recognized with a pointer, according to previous studies [13]. This provided a higher accuracy in implantation and allowed measurements during motion. The measurements were done in coronal neutral position without any deviation stress, followed by varus and valgus stress with 15 Nm in various degrees of knee flexion (0, 30, 45, 60, 90 degrees). Thus a varus or valgus moment was developed by a direct lateral or medial pulling force of 50 N at 0,3 m distal to the joint line using a calibrated spring scale [14].

The following variables were measured and saved by the navigation system: the internal and external rotation in degrees, as well as the varus and valgus deviation of the mechanical axis of the lower leg in the frontal plane in degrees. After that the distance between the tibial and femoral component medial and lateral (deviation), which represented the length of the collateral ligaments was recorded in mm with the navigation system. All the above-mentioned measurements were made with 3 repetitions.

After measurement of the physiologic knee, two different total knee arthroplasty (TKA) systems were implanted through medial parapatellar arthrotomy: the Duracon® system with a multiple radius femur component (MR), and the Triathlon® with a single femoral radius (SR) (Stryker) (Fig. 1). Both can be used with the same tibial component and with the same inlays between 9–25 mm. To fit on the same bone cuts of the SR prosthesis the backside of the femoral MR-prosthesis was modified by mechanic abrasion. The abrasion did not change the axis and geometry of the multiple radius and therefore did not falsify the results.

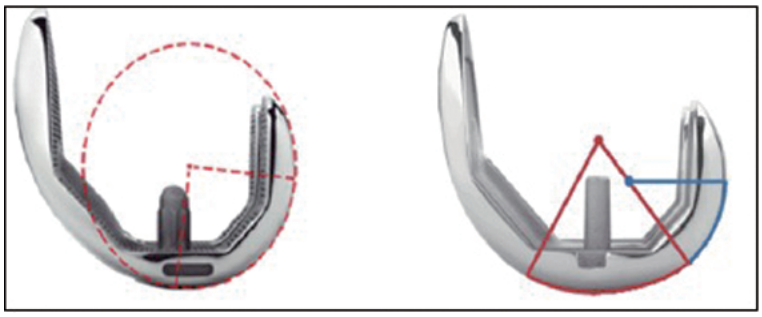

Fig. 1. Schematic description of a single radius prostheses (left) and a multi radius prosthesis (right) with their rotation axis [14]. (License number: 2734170007640).

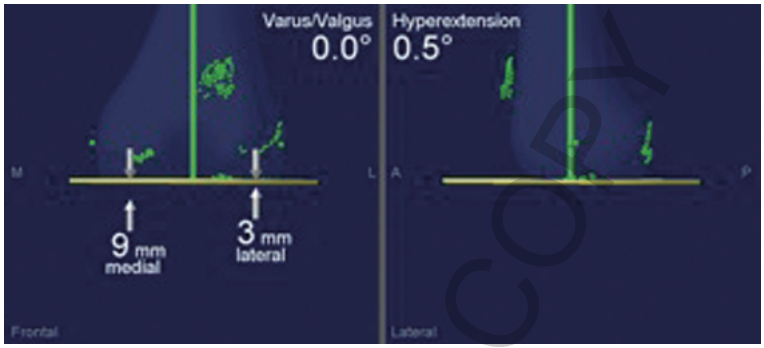

Fig. 2. On-screen display of femoral bone cut; the green cluster represent digitalized surface points on the bone. Left: In the frontal plane the horizontal yellow line indicates the distal bone cut, the vertical green line indicates mechanical axis of the femur. Right: In the lateral view the yellow line indicates the distal femoral end, the green line shows the mechanical axis of the femur in the ap-projection.

The fine-tuning of the bone cuts on femur and tibia were controlled by the computer assisted navigation system. The resection depth on the femur was 10 $\pm$ 2 mm medial and lateral, 0° $\pm$ 2° rotation and flexion/extension 0° $\pm$ 2° (Fig. 2). On the tibia medial and lateral resection was done as necessary to get an equal gap, the varus-and valgus adjustment was 0° $\pm$ 2° and the tibial "posterior slope" was 3° $\pm$ 2 (Fig. 3). The ligament balancing was performed with a balancer. Following the bone cuts done with the Thriathlon instrumentary the tibial base plate was implanted and afterwards the MR femoral component was adjusted to the femur. The flexion and extension gap was controlled with the corresponding inlays.

After measurement and explantation of the MR component, the measurements were repeated with the same tibial base plate and the same inlay with the SR component.

The different measurements cycles of the physiological knee were compared with the data of the SR and MR prosthesis. Using the Student T-Test (STT) on the supposition of a normal distribution, the average, standard deviation (SD) and statistic significance was calculated. The level of significance was set to $p \leqslant 0.05$.

3. Results

The rotation measurement without varus/valgus stress showed in the physiological knees 1.5° (SD = $\pm$ 7.5) external rotation (ER) of the tibia in reference to the femur in full extension. With increasing

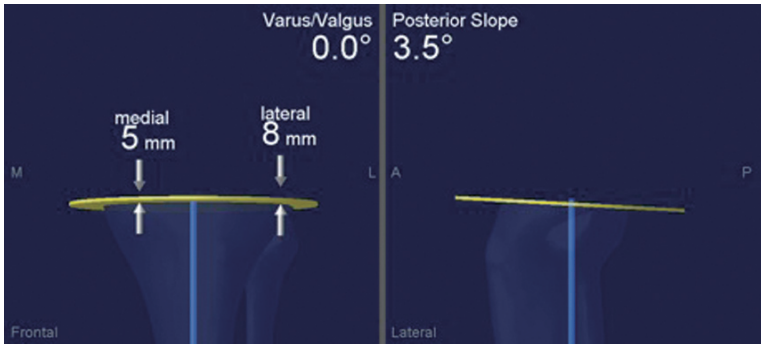

Fig. 3. On-screen display of tibial bone cut; Left: In the frontal plane the horizontal yellow line indicates the distal bone cut, the vertical blue line indicates the mechanical axis of the tibia. Right: In the lateral view the yellow line indicates the posterior slope of the tibia, the blue line shows the mechanical axis of the tibia in the ap-projection.

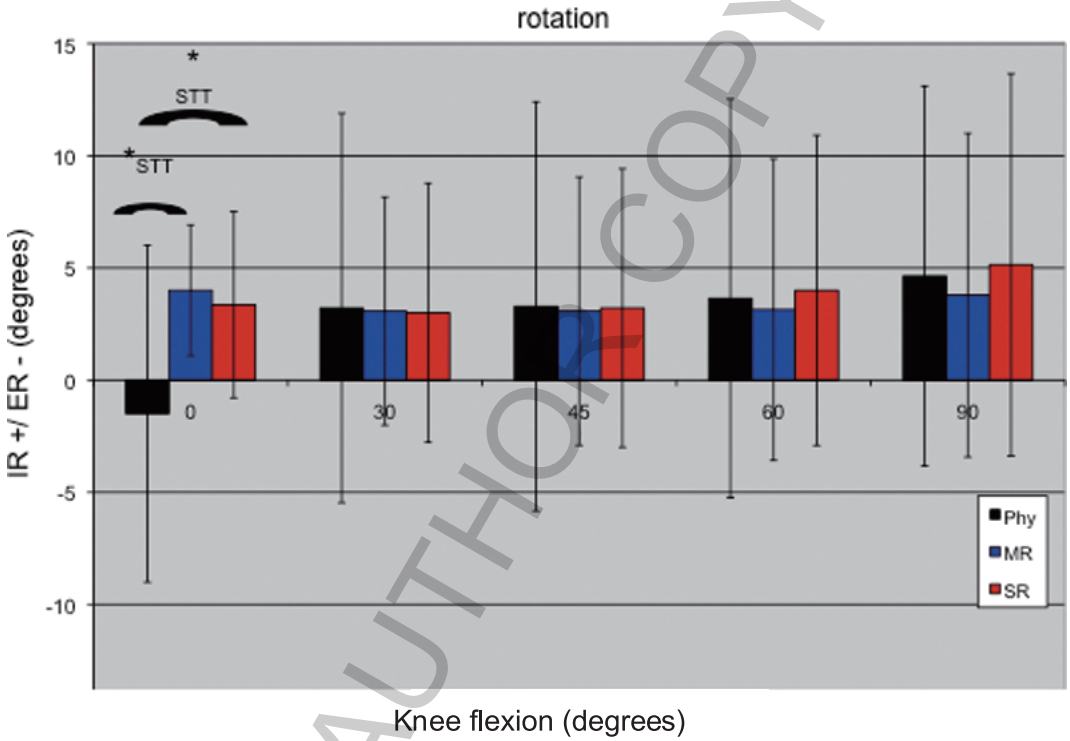

Fig. 4. Rotation of the tibia relative to the femur (internal rotation (IR+)/ external rotation (ER-) in degrees as a function of knee flexion in degrees under physiologic conditions (Phy) and after TKA with a single (SR) and a multiple (MR) condylar radius design of the femoral component.

flexion angles the internal rotation of the tibia increased up to 4.6° (SD = ± 8.5) at 90° flexion. After implantation of MR design the tibia showed only significantly higher internal rotation (IR) with 4.0° (SD = ± 2.9, $p = 0.03$) at 0° knee flexion, 3.1° (SD = ± 6.1) at 30–60° and 3.8° (SD = ± 7.2) at 90° without any significance. The results of the SR prosthesis also showed significant internal rotation compared to physiologic conditions in all flexion angles with 3.4° at 0° knee flexion (SD = ± 4.2, $p = 0.03$) (Fig. 4).

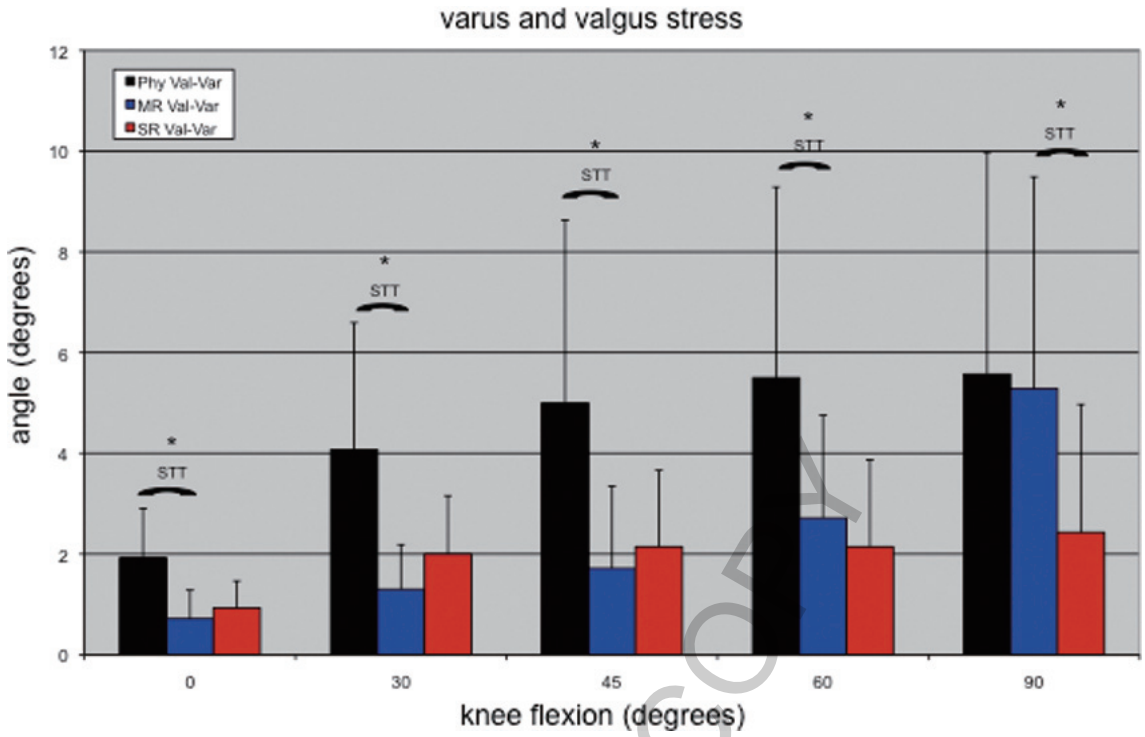

Fig. 5. Difference of varus/valgus deviation of the mechanical axis of the lower leg after application of 15 Nm varus and valgus stress in different knee flexion degrees under physiologic conditions (Phy) and after TKA with a single (SR) and a multiple (MR) condylar radius design of the femoral component.

The varus and valgus deviation without any varus/valgus stress showed constant varus deviation throughout the entire flexion range. For the physiological knees the deviation varies between 4.1° (SD = ± 3.8) in 30° flexion and 1.6° (SD = ± 3.8) in 90°. The MR result was between 1.2° (SD = ± 1.19) and 1.9° (SD = ± 1.5), the SR result between 0.4° (SD = ± 2.4) and 1.7° (SD = ± 1.5). The SR design had less deviation than the other 2 groups in the frontal plane without showing any significance between the groups.

With varus stress of 15 Nm the angle of coronal deviation increased constantly from 0° to 90° knee flexion. Maximum deviation angle was measured in the physiological knee, increasing from 1.9° (SD = ± 2.8) in 0° flexion to 5.6° (SD = ± 3.1) in 90° flexion. With the MR prosthesis the angle increased from 0.7° (SD = ± 2.1) in 0° to 5.3° (SD = ± 1.8) in 90° flexion and showed a significant difference to the physiological knee at nearly all measurement points (0° flexion: 0.7° (SD = ± 3.4, $p = 0.01$); 30° flexion: 1.3° (SD = ± 2.9, $p = 0.05$); 45° flexion: 1.7° (SD = ± 2.6, $p = 0.05$); 60° flexion: 2.7° (SD = ± 1.9, $p = 0.05$). After implanting the SR design the deviation was 0.9° (SD = ± 1.3, $p \geqslant 0.05$) at 0° and 2.14° at 60° flexion (SD = ± 1.8, $p \geqslant 0.05$). With 2.4° (SD = ± 1.1, $p = 0.04$) deviation at 90° flexion the SR design showed significant less deviation compared to the MR design (Fig. 5).

Without varus or valgus moment the femoral and tibial distance (here described as medial and lateral deviation) in all three measurement series for the lateral side was nearly similar in all conditions. Lateral deviation is described with negative values. The lateral deviation was −3.8 mm (SD = ± 2.4) at 0° in the MR prosthesis. The maximal deviation was 7.5 mm (SD = ± 5.5) at 90° in the physiological knee. The deviation increased constantly in all three measurement from 0° to 90° without showing any

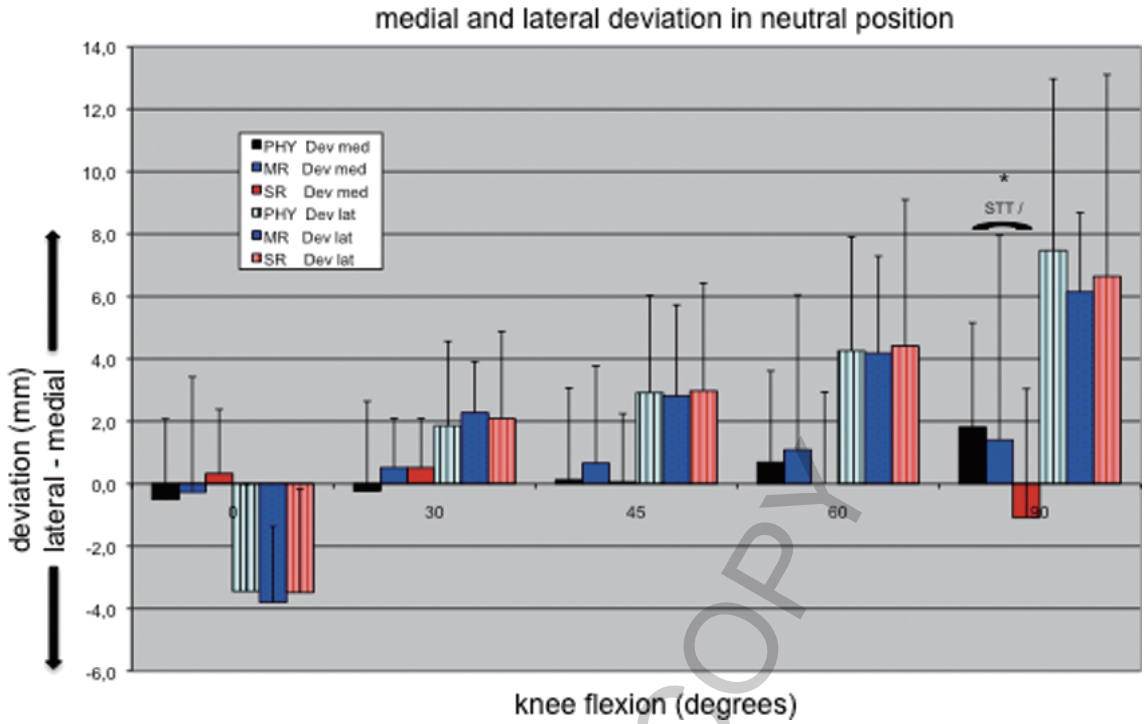

Fig. 6. Medial and lateral deviation in neutral position without application of varus/valgus stress under physiologic conditions (Phy) and after TKA with a single (SR) and a multiple (MR) condylar radius design in mm in function of the knee flexion in degrees.

significance ($p = 0.17$–0.95). Looking at the medial deviation the data was closer to the zero line than the lateral deviation. The range of medial deviation was highest in the physiological knee ranging from -0.5 mm (SD = ± 2.6) to 1.8 mm (SD = ± 3.3), followed by the MR from 0.3 mm (SD = ± 3.7) to 1.4 mm (SD = ± 6.6) and ’0,3 mm (SD = ± 2.1) to 1,1 mm (SD = ± 4.1) in the SR. At 90° flexion the medial deviation of the SR was significant to the physiological knee ($p = 0.02$) (Fig. 6).

The medial deviation with valgus stress in the physiological knee increased from -1.5 mm (SD = ± 2.4) at 0° to 2.6 mm (SD = ± 2.6) at 45° flexion and than decreased to 0.5 mm (SD = 1.4) at 90°. After the MR prosthesis was implanted the data varied from 0°–60° between 0.0 mm (SD = ± 3.1) to 0.9 mm (SD = ± 2.6). At 90° flexion the medial deviation was 2.9 mm (SD = ± 1.6). The medial deviation with the SR design during the entire flexion movement was measured between 0.0 (SD = ± 3.8) and 1.1 mm (SD = ± 2.3). Observing all three measurement series the deviation of the two prosthesis models decreased compared to physiologic conditions. Starting from 45° angle the deviation of the SR was decreased to the MR. At 90° the medial deviation of the MR was measured to be higher, but not significantly. The results of the medial deviation with valgus stress also showed no significance between the three groups ($p \geqslant 0.05$).

The lateral deviation with combined results of varus and valgus stress varied from 1.4 (SD = ± 2.6) and 2.7 mm (SD = ± 3.1). The SR model showed deviation between 0.2 mm (SD = ± 2.1) at 30° and 1.9 mm (SD = ± 1.7) at 90°. After the implantation of the MR prosthesis the deviation was measured between 0.5 mm (SD = ± 1.3) at 45° and 60° and 1.8 mm (SD = ± 2.2) at 90°. While the maximum lateral deviation of the two prosthesis was measured at 90°, the one for the physiological knee was at 60° flexion. The results after implantation of the prostheses were smaller at all flexion degrees compared to

the physiological knee. Up to 45° knee flexion the lateral deviation was smaller for the SR compared to the MR design, at 60° nearly similar and at 90° slightly higher, showing no statistical significance.

4. Discussion

The aim of this study was to compare the knee kinematics after implantation of a femoral single radius design with a femoral multiple radius design. This test set-up allows reproduction of various degrees of knee-flexion whilst using the navigation system enabled measurement of the kinematics. In terms of knee joint stability the SR model used in this study showed superior results than the MR prosthesis. These results represent a biomechanical supplement to the *in-vivo* results, which had shown that the SR is superior to the MR in patients' satisfaction and better flexion angle in deep flexion [15].

The leg stability was one of the key issues of our study, therefore the deviation of the mechanical axis of the lower leg in the coronal plane under varus und valgus moment was measured from 0–90°. Especially in 90° knee flexion the SR design showed significantly ($p \leqslant 0.05$) less medial deviation than the MR design compared to the physiologic kinematics. In conclusion the SR prosthesis has greater stability in higher flexion degrees. Various authors underline the greater stability of the SR design compared to the MR [7,11,12] explaining it with the change of the flexion and extension gap during the middle part of the knee flexion movement, which leads to the so-called "mid-flex-instability" [6]. Reaching an equal flexion and extension gap has a high clinical relevance. An inappropriate adjustment can lead to asymmetric abrasion of the inlay and in consequence to aseptic loosening [16,17]. In this study the deviation was measured in order to measure the flexion and extension gap. The results show that the SR prosthesis leads to a more balanced flexion and extension gap. The isometric ligament tension in the SR design can be explained by the single flexion/extension axis, which corresponds with the insertion of the collateral ligaments. In the MR design the collateral ligaments are more stressed due to the changing flexion/extension axis [15].

Sikorsky et al. supports the hypothesis saying that only SR design prosthesis leads to a balanced flexion and extension gap with balanced ligament tension, which was also shown by Wang et al. and Kessler et al. [6,18,19]. Ligament balancing is one of the major challenges in the TKA. While some surgeons rely on their experience, some use balancers to achieve an equal ligament tension. Briard postulates objective measurement tools, which allow measuring ligament tension during the flexion process [20].

Although Oberst et al. could show no significant difference between TKA implantation with or without navigation system [21], our test setup in addition showed that the navigation system could provide superior measurement of the flexion and extension gap as well as stability especially in motion, which is one of the important requirements for good long-term results.

Nevertheless, limitations of this *in-vitro* biomechanical test setup had to be addressed: To ensure the most precise implantation of the prosthesis the navigation system was used, which requires an entire lower extremity. One limitation was the replacement of the missing pelvis, proximal femur a distal tibia with saw bone, which could have a negative effect on accuracy and precision of the measurements. To reduce this, we ensured firm fixation with the specimens by double screw fixation. Furthermore 7 specimens for each group seem to be a small number to generate statistically significant results. Trying to use the smallest possible number of human specimens, expecting a high difference between the groups due to already known studies and due to the precise test setup, we still think reliable results with significance could be performed with the number of 7 knees used.

Another critical point was the applied varus and valgus stress. The stress was applied by a manual spring. The spring balance only allowed a manual fixation, but due to the repeated measurement cycles using the same knee specimen a high reliability could be performed.

First *in-vivo* tests [7,15] underlined the advantages of the SR design: faster rehabilitation of the patients, less postoperative knee pain and a better function in deep flexion. The results of this study can be used as a basis for further *in-vitro* tests.

Conflict of interest

The authors declare that they have no conflict of interest.

Acknowledgments

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