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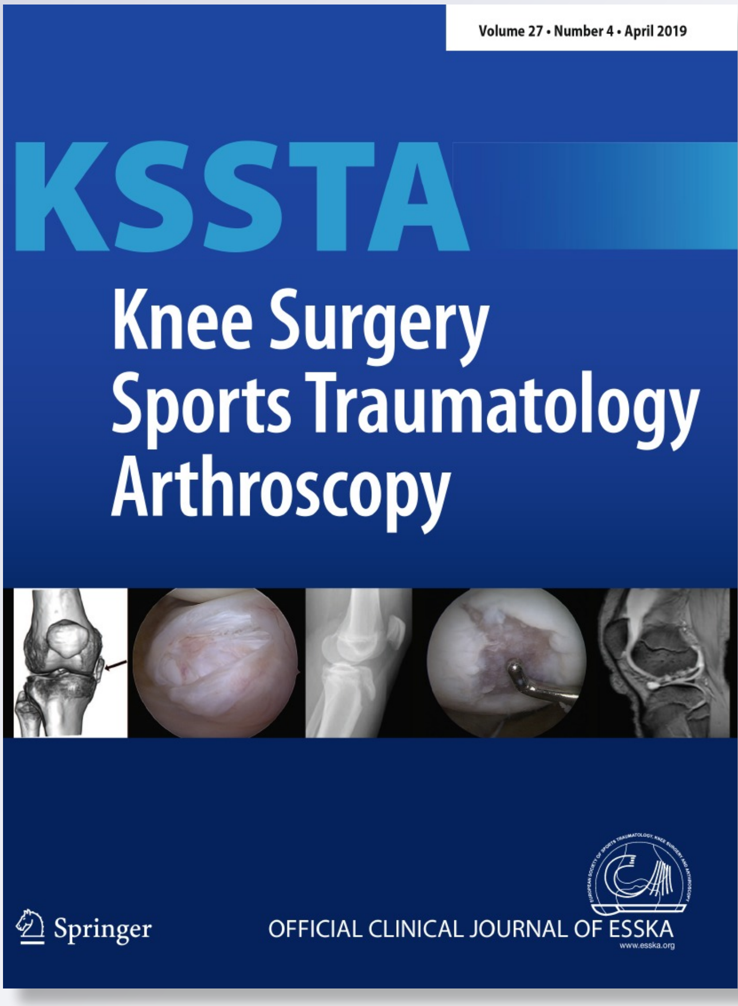

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Asymmetric polyethylene inserts promote favorable kinematics and better clinical outcome compared to symmetric inserts in a mobile bearing total knee arthroplasty

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Abstract

Purpose This study aims at comparing the effects of symmetric and asymmetric designs for the polyethylene insert currently available and also for mobile bearing total knee arthroplasty (TKA). The investigation was performed both clinically and biomechanically through finite element analysis.

Methods 303 patients, with a mobile bearing TKA, were analyzed retrospectively. All patients received the same femoral and tibial components; for the insert, 151 patients received a symmetric design (SD) and 152 an asymmetric design (AD). Additionally, a 3D finite element model of a lower leg was developed, resurfaced with the same TKAs and analysed during gait and squat activities. TKA kinematics, and bone-stresses were investigated for the two insert solutions.

Results After surgery, patients' average flexion improved from 105°, with 5° of preoperative extension deficit, to 120° (AD-group) and 115° (SD-group) at the latest follow-up. There was no postoperative extension deficit. No pain affected the AD-group, while an antero-lateral pain was reported in some patients of the SD-group. Patients of the AD-group presented a better ability to perform certain physical routines. Biomechanically, the SD induced higher tibial-bone stresses than the AD. Both designs replicated similar kinematics, comparable to literature. However, SD rotates more on the tray, reducing the motion between femoral and polyethylene components, while AD permits greater insert rotation.

Conclusion The biomechanical analysis justifies the clinical findings. TKA kinematics is similar for the two designs, although the asymmetric solution shows less bone stress, thus resulting as more suitable to be cemented, avoiding lift-off issues, inducing less pain. Clinically, and biomechanically, an asymmetric mobile bearing insert could be a valid alternative to symmetric mobile bearing insert.

Level of evidence Case–control study retrospective comparative study, III.

Keywords TKA · Mobile bearing · Asymmetric insert · Symmetric insert · Insert congruency · Biomechanics · Kinematics

Introduction

Total knee arthroplasty (TKA) is a highly successful and reproducible treatment for knee patients, with more than 600,000 surgeries performed each year in the USA [26]. The goal of knee replacement is to achieve normal function and kinematics. To best meet every patient's demand, several solutions for TKA designs are currently available. However, it is not always immediately possible to select the best matching solution, and a potential reason lies in the lack of clinical and biomechanical evidence-based justifications on the effects of the different features characterizing the different designs [29, 30, 43, 44, 46, 50].

Mobile bearing (MB) total knee arthroplasty (TKA) designs offer the theoretical advantage of increased implant conformity, and therefore contact area, minimizing polyethylene contact stress and therefore wear [6, 17, 27]. This motion, through the tibial tray-polyethylene bearing articulation, theoretically minimizes the transfer of torsional stresses to the fixation interfaces that are present with fixed bearing TKA prosthetic designs [27]. Usually, MB inserts

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are symmetric (SD), however, among the different designs available on the market, GENUS MB (Adler Ortho, Cormano, Milan, Italy) also proposes the asymmetric design (AD) for the insert (GENUS LS). In detail, only the top of the inserts differs for its congruencies while size, dimensions and features are the same in order to be coupled with mobile bearing tibial component (Fig. 1).

To check and to understand the real benefits of an asymmetric mobile bearing design, the aim of this work is to investigate such inserts both from a clinical and a biomechanical point of view. In detail, a retrospective clinical study of 303 patients was performed; additionally, a biomechanical finite element (FE) model of a knee was developed, based on a previously validated finite element model [4, 20, 21], and replaced with the same two MB TKA solutions. The kinematics and kinetics data, in terms of contact forces and areas and bone stress, during walking and squat motor tasks, were compared among the models. These outputs are also compared to the retrospective follow-up results to potentially explain the clinical findings.

The novelty of this study concerns in the investigation, for the first time, of the potential benefits of an asymmetric solution for mobile bearing TKA through clinical and biomechanical evidences. The results could be used to help the understanding of patient's dissatisfaction after a TKA, usually related to joint kinematics and kinetics that is far from the physiological one [6, 9, 17, 26, 27, 29, 32, 37, 43, 44, 51].

Materials and methods

Clinical study

Every patient gave his/her written informed consent to have his/her clinical records later used for this prospective study. In the period 2012–2015, the first author (GC) performed 303 consecutive primary MB TKA in 303 patients [109 males (36%), median 70.0 years (56–87 years), 171 right knees (56%)].

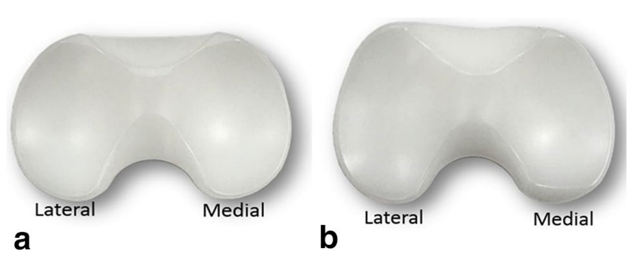


Fig. 1 Overview of the insert design analyzed in this study: **a** symmetric insert design (SD), **b** asymmetric insert design (AD)

In all the procedures, a Genus MB (Adler Ortho, Milan, Italy) was used. Genus MB got 5A* recognition. All TKAs were cemented and patella was not resurfaced. Medial para-patellar approach was adopted for all patients. For all patients, the same designs of the femoral and the tibial components were used, while two possible selections were available for the polyethylene insert: the symmetric design (SD) and the asymmetric design (AD).

The SD insert was used on 151 patients [35% males, 57% right knee, median 70.0 years (56–87 years)], while the AD solution was adopted for the remaining 152 patients [37% males, 56% right knee, median 70.0 years (56–83 years)]. For the group undergoing the SD insert the preoperative median flexion was 102.8° (93°–112°), while for the patients of the AD insert the preoperative median flexion was 105.1° (95°–110°).

The PCL was preserved in all patients, and ligaments release was avoided whenever possible by the using of a ligament adjustable spacer (EMAS, Extra-Medullary Alignment System) offered by the manufacturer [8]. In detail, the EMAS device allows for femoral component positioning and joint balancing without requiring the use of intramedullary rods, avoiding violation of the intramedullary canal, potentially enabling the incidence of fat embolism and perioperative blood loss or femoral fractures risk in the case of osteoporotic bone [5, 29, 52].

Particular care was taken to reduce the bone cut, thus preserving bone integrity. In particular, the 10 mm insert, the smallest thickness proposed by the manufacturer, was used in 88% of the cases. In detail, the 10 mm insert was used as SD insert, on 127 patients, 12 mm on 20 patients and 14 mm for the remaining 4 patients. For the other group 135 patients received the 10 mm insert and the remaining 17 patients received the 12 mm insert. This choice was decided following the study of Berend et al. [3] in which the author found that "thicker" bearings (≥ 16 mm) were associated with higher failure rates at midterm to long-term follow-up.

Clinical and radiographic evaluations were performed at 6 months and 1 year after the operation by the first authors (GC) together with an experienced surgeon belonging to his staff. Standing AP, lateral, and Merchant radiographs were evaluated according to the system of the Knee Society for bone cement interface radiolucency, polyethylene wear, any change in the position of the component, alignment, and osteolysis.

The Knee Society score and the Oxford score were calculated pre-operatively for all patients and also at 6 months and 1 year post-operatively. The active range of motion was determined with the use of a standard clinical goniometer.

Biomechanical study

The finite element model developed for this study was based on a previously validated and published knee finite element model [20].

Mechanical-equivalent synthetic femur and tibia bones (Sawbones, Sweden) were reconstructed from computed tomography (CT) images. The images were imported in an image processing software (Mimics 17.0, Materialise, Leuven, Belgium) and segmented to generate the 3D structures of interest in the leg [11, 46]. Anatomical landmarks were also analyzed and highlighted to detect the anatomical and mechanical axes of the two bones and the insertions of the collateral ligaments and posterior cruciate ligament [23, 49]. Based on the landmarks, the bones were aligned with a physiological configuration and ligament length was respected using the location of the insertion area [20, 21].

Using such references, the GENUS MB femoral and tibial components were implanted using the surgical technique provided by the manufacturer. A mechanically aligned position was considered for both the femoral and tibial component [21]. Two different models were obtained firstly by implanting the SD insert and secondly the AD insert. In agreement with the clinical study, a 10 mm insert was used for both models. Figure 2 shows the two models.

Linear elasticity was used to model all the materials considered in this study [27, 29, 40, 41]. According to the literature [24, 25, 40, 41], the cortical bone was considered transversely isotropic, while the cancellous bone and ligaments were considered isotropic. Additionally, every ligament was modeled as a beam with a specific cross-sectional area and with a validated initial pre-strain [24, 33, 39, 52]. The material properties of the knee model used in this study are reported in Table 1.

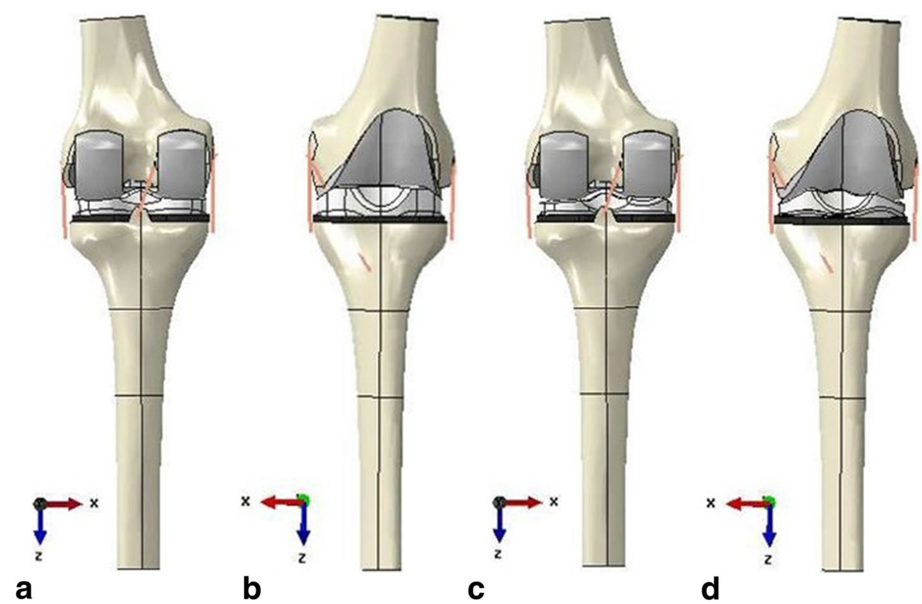


Fig. 2 Finite element models used for this study: **a** SD insert, posterior view; **b** SD insert anterior view; **c** AD insert, posterior view; **d** AD insert anterior view. The *z*-axis is aligned with the tibial mechanical axis while the *x*-axis represents the medio-lateral axis (medial side positive)

Table 1 Material properties of the knee model

Material	Model	Young's Modulus [MPa]	Poisson's ratio	ε_r
Cortical bone	Transversely isotropic	$E_1 = 11{,}500$	$\upsilon_{12} = 0.58$	NA
		$E_2 = 11{,}500$	$\upsilon_{13} = 0.31$	
		$E_3 = 17{,}000$	$\upsilon_{23} = 0.31$	
Cancellous bone	Elastic isotropic	2130	0.31	NA
PCL	Elastic isotropic	177	0.45	0
MCL	Elastic isotropic	332	0.45	0.04
LCL	Elastic isotropic	345	0.45	0.08

For the cortical bone, the direction E_3 represents the axial direction. ε_r represents the pre-strain of the ligaments

ACL anterior cruciate ligament, *PCL* posterior cruciate ligament, *LCL* lateral collateral ligament, *MCL* medial collateral ligament

The material of the femoral component, tibial insert and tibial tray were, respectively, cobalt-chromium alloy (CoCr), ultra-high-molecular weight-polyethylene (UHMWPE) and titanium alloy (Ti6Al4V). The materials were assumed to be homogeneous, isotropic, and linear elastic [11, 18, 23, 41]. The material properties, in terms of Young's Modulus and Poisson's ratio, were: CoCr: $E = 220.000$ MPa, $\nu = 0.3$ [16]; UHMWPE: $E = 685$ MPa, $\nu = 0.4$ [34]; Titanium: $E = 110.000$ MPa, $\nu = 0.3$ [18].

A coefficient of friction of 0.2 was considered for the interaction between the femoral component and the tibial insert [20, 45].

The tibia is fixed in the region corresponding to the ankle [11, 18, 24, 41]. Loads and kinematics were applied to the femur to dynamically replicate walking and squatting motor [19, 22, 34–36]. In particular, for the simulated gait task, the boundary conditions were defined by the ISO-14243-1 [22, 35] in terms of flexion extension, axial force, antero-posterior translation and internal–external rotation. For the squat motor task, up to 120°, the tibio-femoral force and the patellar forces were simulated according to previous experimental activities [1, 19, 30, 36, 50]. The time to complete this task was set up to 10 s.

Tetrahedral elements with element sizes between 1.5 and 4 mm were used for the mesh of all the components of the models. To reduce the discretization error, a convergence test was performed to check the selected element size mesh quality for every region of the model. Abaqus/Explicit version 6.13-1 (Dassault Systèmes, Vélizy-Villacoublay, France) was used to perform all the finite element simulations.

The results were analyzed in different regions of interest selected for the two developed models (Fig. 3). In particular, the tibial stress was analyzed in the medial and lateral region, with a depth of 50 mm (Fig. 3a, b) and in an additional distal

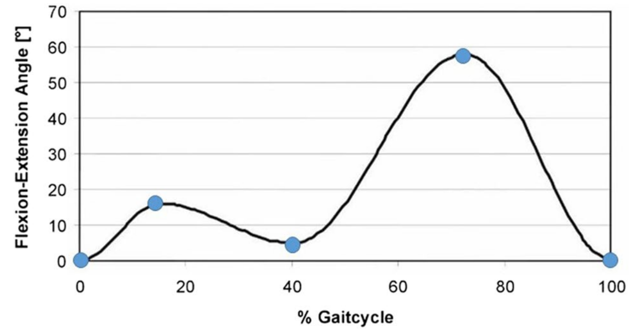


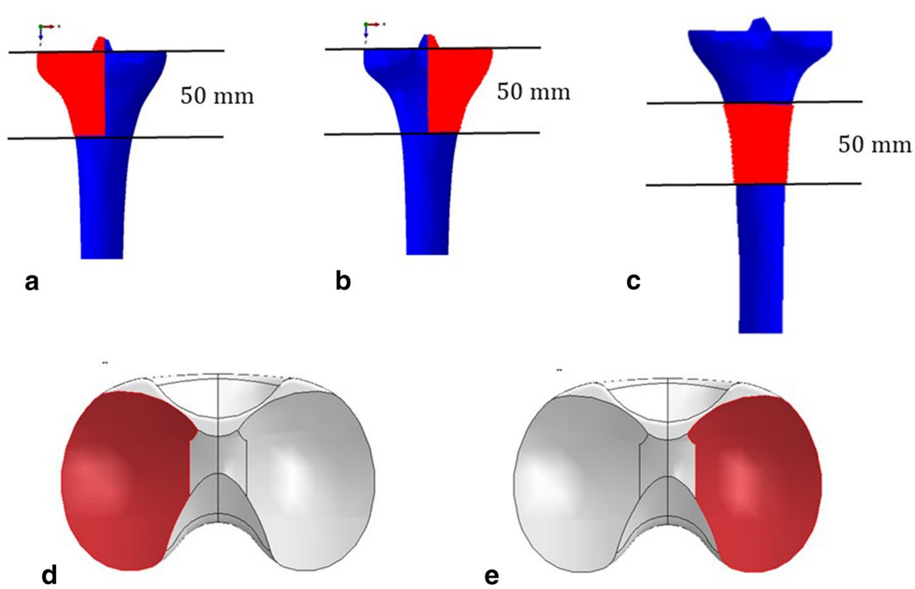
Fig. 4 The curve represents the flexion extension angle during the gait cycle %. The blue points represent the instants considered for the analysis

region, still with a depth of 50 mm (Fig. 3c). This depth under the tibial cut allows the understanding of the stress distribution in a region of interest still close to the cut, but mainly proximally located for a more global overview. In each region, the bone stresses were compared among the models, during the simulated activity, analyzing both the cortical and cancellous bones. Moreover, the polyethylene medial and lateral surfaces in contact with the femoral component were considered to evaluate the contact area and force during the movements (Fig. 3d, e).

Furthermore, to investigate the TKA kinematics, the internal–external rotations and anterior-posterior displacement of the polyethylene and femoral components, with respect to the tibia, were also included in the study.

The outputs were analyzed and compared at 0%, 15%, 40%, 70%, and 100% of the gait motor task (that correspond to a flexion angle, respectively, of 0°, 15°, 5°, 60°, and 0°, see Fig. 4) and 0°, 30°, 60°, 90°, and 120° of flexion for the squat motor task.

Fig. 3 Regions of interest analyzed in this study: **a** lateral proximal tibial, **b** medial proximal Tibia, **c** distal tibia, **d** lateral polyethylene region, **e** medial polyethylene region. The figures **d** and **e** are relative to the SD insert; similar regions were analyzed for the AD insert



Statistical analysis

A power analysis, performed with G*Power 3.1.2 [12, 13], showed that assuming an alpha error of 0.05 (universally accepted), a beta error of 0.2 (giving a power of 80%) and an effect size of 0.35 [28], the total sample size needed was 272. The selection of 150 patients for each group, bringing a total sample size of 303, was therefore considered adequate for the study. The range of motion and the scores of the clinical results are presented as means and standard deviation. The Wilcoxon–Mann test was used for ordinal variables and the *t* test for numerical variables. Shapiro–Wilk test was performed to check the normality of the data. Null hypotheses of no difference were rejected if two-sided *p* values were less than 0.05. Data were analyzed statistically using Matlab (MATLAB and Statistics Toolbox Release 2012b, The MathWorks, Inc., Natick, Massachusetts, United States).

Results

Clinical study

No significant differences were found in the demographic characteristics of the two analyzed groups.

All surgeries were successful without any relevant intra-operative or post-operative complication.

At the latest follow-up, the patients of the AD-group reported 120.2° median flexion (range 110°–135°) without any extension deficit; while SD-group showed a lower median flexion (115.0°, range = 105°–133°), even if not significantly (n.s.).

No pain affected the patients with the AD insert, while an antero-lateral pain was reported in some cases by the patients belonging to the SD-group. Additionally, greater self-confidence during the movements was observed in the patients with AD insert.

Both Knee Society Score [42] and Oxford Score [9] were compared statistically to evaluate the clinical performance and degree of satisfaction after the TKA and are reported in Fig. 5. Both the scores increase significantly at 6 months and at 12 months follow-up ($p < 0.05$). Moreover, the values of both scores are statistically higher at 6 months and at 12 months in the AD insert with respect to the SD insert ($p < 0.05$).

Biomechanical study

For the three regions of interest, Fig. 6 illustrates the average bone stress (average of the nodal stress) calculated during the stance and swing phase of gait for the cortical and for the cancellous bone. From this picture, it can be seen that the AD insert induces lower tibial stress in both cortical and cancellous bone for all medial, lateral and distal regions either in stance and swing phases of the gait.

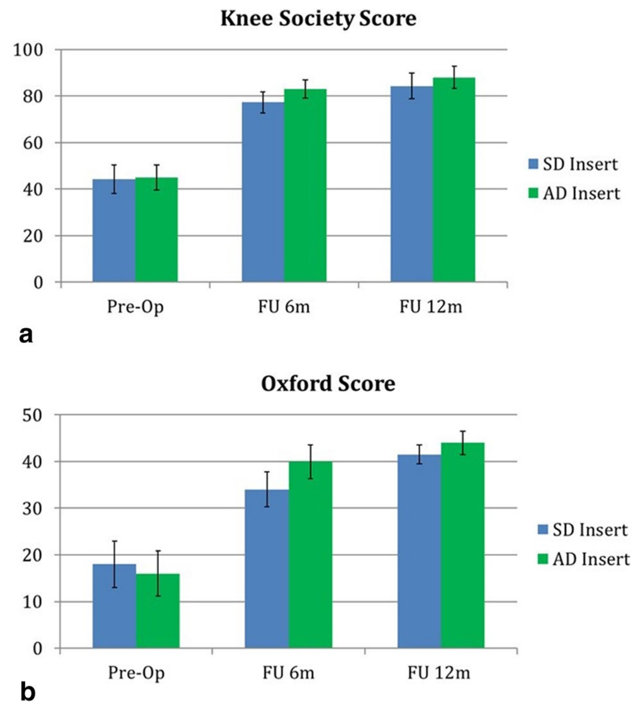


Fig. 5 **a** Knee Society Score for the SD insert (in blue) and AD insert (in green) at Pre-Op, 6 months and 12 months follow-up; **b** Oxford Score for the SD insert (in blue) and AD insert (in green) at Pre-Op, 6 months and 12 months follow-up

Figure 7 reports the information of the average Von Mises, compressive and shear stresses during gait (A) and squat (B) for the two inserts analyzed. The figures were obtained using an innovative graphical method of representing data [36].

The biomechanical analysis shows that the SD insert generally induces higher bone stresses (darker color) than the AD. Moreover, in AD design, shear stress is generally lower than the SD design.

Figure 8 reports the antero-posterior displacement of the medial and lateral contact points for the gait motor task for both insert designs at the % of gait cycle reported in Fig. 4. From the figure it is clear how the AD enables a close to natural kinematics during walking, both for stance and swing phase, while the SD inserts do not pivot during the stance phase but only during swing phase.

Figure 9 reported the internal–external rotation of the femoral component and of the insert for both designs for the squat motor task. Integrating the calculated contact area and contact pressure for every increment of the simulation, the centroid of the pressure is determined, and thus the contact point is known [3, 9]. Both the SD and AD inserts induce similar amplitudes of tibio-femoral internal–external rotation, but achieved differently. In fact, the AD insert design,

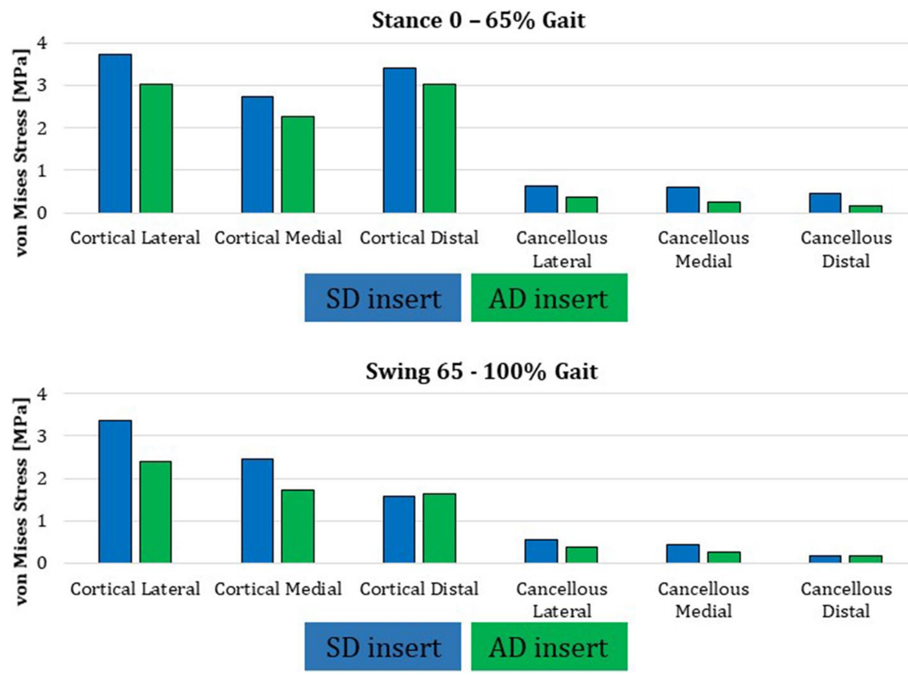


Fig. 6 average Von Mises stress for the different regions of interest during the stance (up) and swing (low) phase of gait for the cortical and for the cancellous bone in the two inserts analyzed

due to the higher congruency, permits higher intra-extra rotation of the polyethylene insert (and similarly a higher AP motion of the lateral side). This means that internal–external rotation is not only guaranteed by the congruencies between femoral component and tibial insert, but also by the coupling system between the insert and the tibial component.

Discussion

The most important finding of the present study was that an asymmetric mobile bearing insert can provide better clinical performances (KSS and Oxford scores) both at 6 months and 1 year post-op compared to a standard symmetric insert design. The biomechanical study showed that the AD insert design provided closer behavior to native joint than the SD insert during both gait and squat tasks. Accordingly, the clinical evidence showed that the patients operated with the AD had a higher satisfaction level and a better ability to perform physical activities as shown by the better Oxford score seen for that group.

Moreover, the biomechanical study showed a lower level of stress transferred by the implant to the bone for the MB TKA with the AD insert in comparison to the case with the SD solution. This finding could explain the reason why, in the clinical study, some SD-patients reported antero-lateral pain, while none of the AD-group recorded this issue.

The particular surgical technique employed including no femoral canal invasion, PCL preservation, and minimal, if any, soft-tissue releases was probably instrumental in improving patients' post-op performances.

Several assumptions were made in the FE models; firstly, the geometries of the different structures are based on only one geometry and no variation of the anatomy of the specimen was considered in this study. However, this decision was taken using a verified, previously used model in the biomechanical field [31, 46, 48]. Another assumption was that the ligaments were modelled as beams, as commonly used in literature, and in previously validated ligaments models [22].

The material models of the different structures in this study incorporated several assumptions, although the behavior of the structures approximated their natural behavior. The material properties of the bony structures as well as the soft tissues, were assumed as linear elastic and homogeneous. As it is well known, the cortical as well as the cancellous bones contain spatial inhomogeneity in their properties [41]. Some studies in the past already incorporated a Neo-Hookean material model to predict the non-linear stress–strain behavior of the ligaments that undergo large deformations [10, 14, 15]. Another limitation of this study lies in the use of a linear model for the polyethylene, which could provide an overestimation in the local value of the polyethylene stress under plasticization [21]. However, the aim of this study was to perform a comparative study, using the same approach and compare the different configurations.

In this study, a full knee model, including pre-strained ligaments, was used. As reported by Innocenti et al. [20], the inclusion of the collateral ligaments in the numerical models is fundamental in obtaining a realistic load, and therefore, bone stress distribution. Furthermore, Godest et al. [16] described the role of the surrounding tension within the soft tissues, and they reported that both the

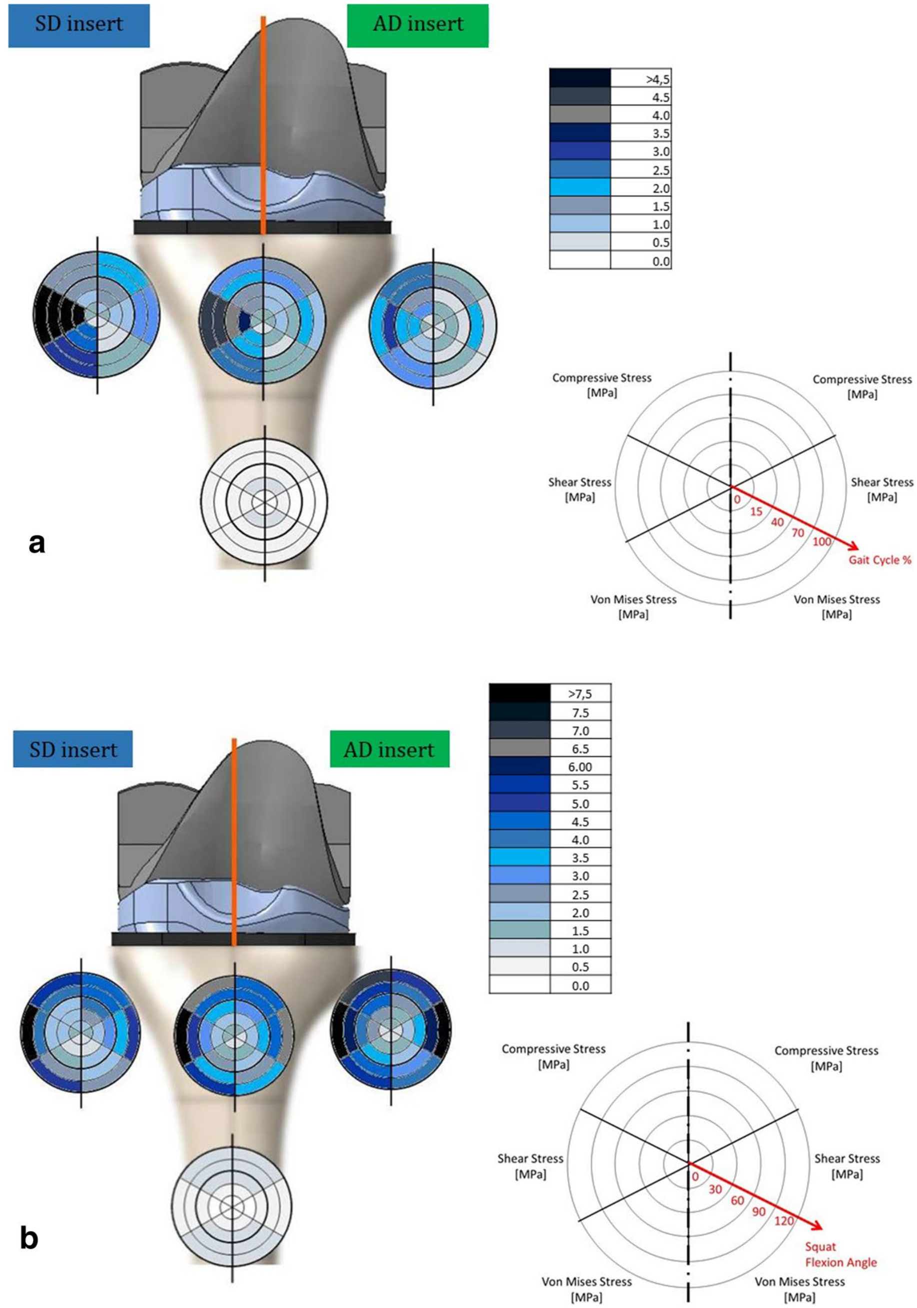


Fig. 7 comparison among the average Von Mises, compressive and shear stresses during gait (**a**) and squat (**b**) for the two inserts analyzed. This graph is obtained using an innovative graphical method of representing data [43]. In details, in the medial, lateral, proximal and distal region of the bone, a circle is reported. As explained on the empty disk on the right, each circle is divided in different sectors that represent a different output at a different % for the gait cycle and different flexion angles for the squat. Each sector is shown in a different color, from white to black, as indicated in the legend, corresponding to the different values of stress

relative position of the components and the tension of the surrounding soft tissues have an impact on the results. Moreover, Raminaraka et al. [38] agreed also that the stresses inside the soft structures, as well as joint bearing forces, are required to better understand the biomechanical behavior of the knee. This study confirmed the conclusions of the two previous studies.

Clinical and biomechanical results are in agreement. In fact, it is shown how both MB solutions are able to achieve good results for the patients. However, thanks to the lateral sliding solution, better performances are achieved and the patient is more self-confident with the implant.

The global kinematics outputs are similar for the two solutions. However, there is a difference in how the global kinematical is determined. In fact, the femoral component is almost constrained in the congruency of the SD insert, thus the polyethylene insert must perform all the movement especially in internal–external rotation. On the other hand, thanks to the lateral sliding feature, there is relative movement between the femoral and the polyethylene insert and the polyethylene insert rotates less than the SD model/design. Thanks to the two relative motions, the AD design results as being more mobile than the SD model/design, as the clinical evidence demonstrates. Additionally, the AD design is able to achieve greater

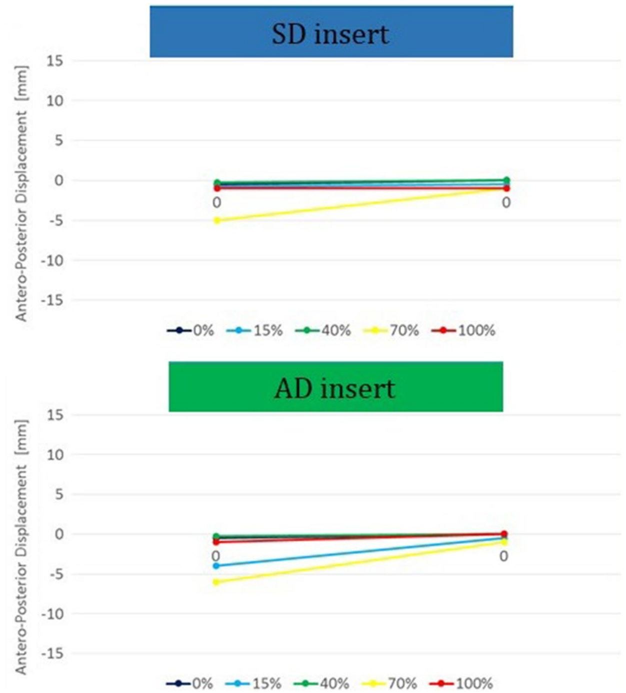


Fig. 8 The antero-posterior displacement of the medial and lateral contact points, for the gait motor task, for the two insert designs in function of the % of gait cycle reported in Fig. 4

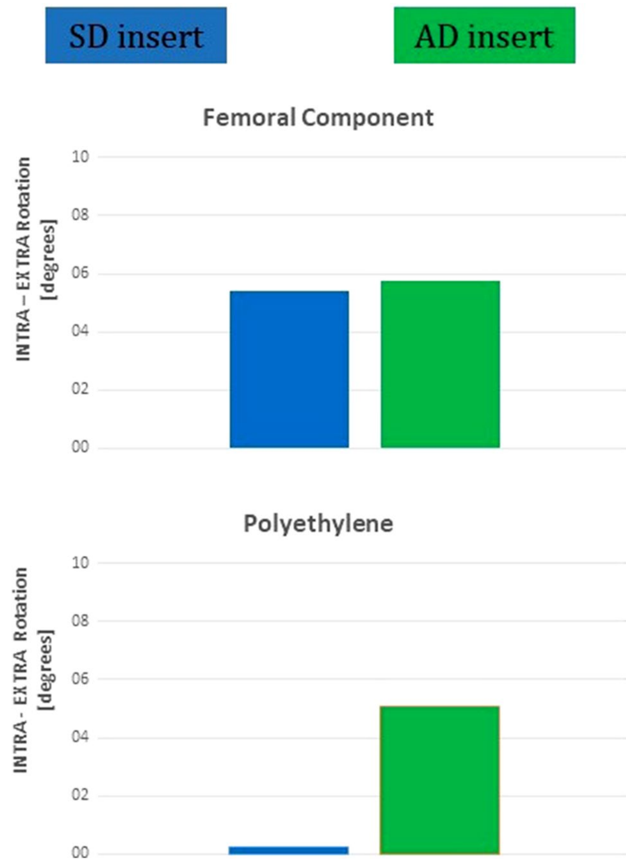


Fig. 9 Internal and external rotation of the femoral component and of the insert, for both designs for the squat motor task

antero-posterior movement that is less constrained than in the SD design. That could be an explanation for the anterior knee pain that some patients felt only with the SD design caused by more constrained forces on the patella.

Generally, the differences in shear and compression stresses of the two designs are extremely important for the consequences involved during the motor tasks. The increase in motion of the AD design will reduce the stress transmitted to the tibial-bone, especially the shear stress. That can be related to the fact that many patients feel less pain with the AD design and this can be explained with the lesser stress of the AD type rather than with the standard model/design. As a consequence, AD implant stability and lifetime are improved when the TKA is cemented.

The results of this retrospective comparative study demonstrate that, both clinically and biomechanically, an asymmetric mobile bearing insert could be a valid alternative to symmetric mobile bearing insert; surgeons could, therefore, considered this option as a possible design in the prosthesis selection for a patient.

Conclusions

The biomechanical analysis justifies the clinical findings. Kinematics is similar for the two designs, although the AD solutions show reduced bone stress, thus resulting as being more suitable to be cemented, also avoiding lift-off issues, and inducing less pain.

Asymmetric mobile bearing insert is shown to provide better clinical performances (KSS and Oxford scores) both at 6 months and 1-year post-op compared to a standard symmetric insert design.

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Compliance with ethical standards

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

Ethical approval All procedures performed in this study involving human participants were in accordance with the ethical standard of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

Informed consent Every patient gave his/her written informed consent to have his/her clinical records later used for this prospective study.

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