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Original article

Posterior Stabilized Versus Cruciate Retaining Total Knee Arthroplasty Designs: Conformity Affects the Performance Reliability of the Design over the Patient Population

Marzieh M.Ardestani[1,*], Mehran Moazen[2], Yang Wenjian[1], Ehsan Maniei[3] and Zhongmin Jin[1, 4]

[1]State Key Laboratory for Manufacturing System Engineering, School of Mechanical Engineering, Xi'an Jiaotong University, Xi'an, China

[2]Medical and Biological Engineering, School of Engineering, University of Hull, Hull, UK

[3]Biomedical Engineering Department, Amirkabir University of Technology, Tehran, Iran

[4]Institute of Medical and Biological Engineering, School of Mechanical Engineering, University of Leeds, UK

□*Corresponding author (M.M. Ardestani)

Tel.: +0-86-029-83395122; E-mail: mostafavizadeh@yahoo.com

Abstract

Commercially available fixed bearing knee prostheses are mainly divided into two groups: posterior stabilized (PS) versus cruciate retaining (CR). Despite the widespread comparative studies, the debate continues regarding the superiority of one type over the other. This study used a combined finite element (FE) simulation and principal component analysis (PCA) to evaluate "reliability" and "sensitivity" of two PS designs versus two CR designs over a patient population. Four contemporary fixed bearing implants were chosen: PFC (DePuy), PFC Sigma (DePuy), NexGen (Zimmer) and Genesis II (Smith&Nephew). Using PCA, a large probabilistic knee joint motion and loading database was generated based on the available experimental data from literature. The probabilistic knee joint data was applied to each implant in a FE simulation to calculate the potential envelopes of kinematics (i.e. anterior-posterior [AP] displacement and internal-external [IE] rotation) and contact mechanics. The performance envelopes were considered as an indicator of performance reliability. For each implant, PCA was used to highlight how much the implant performance was influenced by changes in each input parameter (sensitivity).

Results showed that (1) conformity directly affected the reliability of the knee implant over a patient population such that lesser conformity designs (PS or CR), had higher kinematic variability and were more influenced by AP force and IE torque, (2) contact reliability did not differ noticeably among different designs and (3) CR or PS designs affected the relative rank of critical factors that influenced the reliability of each design. Such investigations enlighten the underlying biomechanics of various implant designs and can potentially lead towards optimized implants for specific patient groups.

Keywords: Total knee arthroplasty, Inter-patient variability, Stanmore knee simulator, Principal component analysis, Finite element simulation, Sensitivity

1. Introduction

Total knee arthroplasty (TKA) is one of the most prevalent treatments for severe knee osteoarthritis. A number of different fixed bearing knee prostheses have been designed and are currently available in the market. These are mainly divided into two groups: posterior stabilized (PS) versus cruciate retaining (CR). In CR designs, posterior cruciate ligament (PCL) is preserved [1, 2] while in PS, PCL is resected and a post-cam mechanism is accommodated in the implant structure to compensate its function [3-5].

A number of clinical studies have compared PS designs versus CR designs from the perspective of survivorship, patient satisfactory, post-surgery complications and knee functional score [6-10]. Of particular interest is to compare these two designs in terms of knee joint kinematics [11, 12] and contact mechanics [13, 14] since these factors substantially affect the aforementioned clinical outcomes. Several studies concluded the superiority of CR [15, 16] or PS designs [11, 12, 17-21] while others demonstrated no significant differences between these two designs [22-25]. This inconsistency perhaps comes from the inherent limitations of clinical investigations, e.g. small number of patients and large inter-patient variability [26, 27]. An alternative approach to compare and contrast these designs could be in terms of their "reliability" and "sensitivity". "Reliability" highlights the extent to which the performance of the implant (i.e. kinematics and contact mechanics) is robust to inter-patient variations and implies the repeatability of the outcomes over a patient population. "Sensitivity" provides insights into critical factors affecting the performance of a particular design. Such evaluations are challenging to perform via in vitro cadaveric studies due to number of patients and resources required.

Computational models based on finite element (FE) method, present an alternative approach to in vivo and in vitro investigations [28-30] while validation of such models is crucial to build confidence in their predictions. This can be achieved by comparing the FE predictions against in vitro tests and clinical data [29, 31-34] or more importantly by providing realistic input parameters (e.g. based on in vivo studies) for FE models [35, 36]. Nevertheless, in comparative studies when for example several implants are tested under similar condition, the comparative nature of the study can still remain valid while the effect of various parameters can be tested in a controlled fashion [37-40].

Recently , probabilistic methods have been combined with FE solvers to evaluate the impact of various parameters on the clinical performance of TKA, including design geometry [35, 41] , component alignment [39, 42, 43] and loading variability [38, 44]. Compared to the deterministic FE studies, probabilistic FE investigations provide a more realistic understanding of the clinical outcome. Beside this, principal component analysis (PCA) has been combined with these probabilistic studies [44-47]. The latter approach enables us to generate large probabilistic databases representing the inherent variability of a patient population or to model the complicated interactions between input variables and output metrics in terms of sensitivity indices. The aforementioned studies however have mostly attempted to investigate PS designs [35, 41] or CR designs [38-40] . To best of our knowledge, no previous computational study has compared PS versus CR in a systematic approach.

This study aimed to evaluate the reliability of four fixed-bearing knee implants, including two different PS designs and two CR designs and assess the sensitivity of each design due to inter-patient variability. Patient population was modelled via a large probabilistic database of joint loadings and flexion angle, generated through PCA. Implants were investigated in terms of kinematics (i.e. anterior-posterior displacement and internal-external rotation) and contact mechanics (i.e. contact pressure and contact area), calculated based on finite element model of an in vitro knee simulator.

2. Materials and methods

Experimental gait data was obtained from a published repository (section 2.1). This experimental database was then enlarged through PCA and a large probabilistic database of inter-patient knee joint data was created (section 2.2). Probabilistic knee joint data (i.e. 3D knee joint loading plus flexion angle, as used in the in vitro knee simulator) were applied to four different knee implants in a finite element simulation to calculate the resultant kinematics and contact mechanics of each implant (section 2.3). The performance envelopes were then computed as an indicator of the performance reliability. Furthermore, PCA was used to calculate the performance sensitivity of individual implants due to the inter-patient variations (section 2.4). It should be noted that PCA was used for a twofold purpose: (1) to enlarge the experimental repository and generate a probabilistic database which accommodated sufficient inter-patient variability and (2) to calculate the sensitivity indices of each implant due to different parameters. Figure 1 shows a schematic diagram of the proposed methodology.

2.1. Experimental measurements

An experimental repository of gait data was obtained from the literature (https://simtk.org/home/kneeloads ; accessed on March 2014). This database comprised three dimensional ground reaction forces (Force plate, AMTI Corp., Watertown, MA,USA) and marker trajectory data (10-camera motion capture system, Motion Analysis Corp., Santa Rosa, CA,USA) , measured within a number of level-walking trials for five subjects with unilateral knee implants (four males, one female; height: 170.6±5.7 cm; mass: 70.4±6.0 kg). A detailed description of this database has been given elsewhere [48]. Using marker data and ground reaction forces, 3D joint loadings and kinematics were then extracted from a multi-body dynamic analysis. Detailed description of this multi-body dynamic analysis has been presented elsewhere [49]. In brief, a musculoskeletal model was used in AnyBody software (version 5.2,193 AnyBody Technology, Aalborg, Denmark) based on the University of Twente Lower Extremity Model (TLEM) [50]. Marker trajectory data and ground reaction forces were applied to this model to calculate joint angles and joint loadings. For the rest of this study, 3D knee joint loading (axial force, anterior-posterior [AP] force and internal-external [IE] torque) and knee joint flexion angle were considered as "knee joint data", required for FE simulation.

2.2. Principal component analysis-based statistical model of knee joint motion and loading

From a technical point of view, knee joint data are "inter-dependent" variables that cannot be randomized individually. To randomize these variables and create a large probabilistic inter-patient database, PCA was used [46]. In this technique, "inter-dependent" variables were mapped into a reduced number of corresponding "independent" variables (principal component values) that can be randomized separately. Randomized independent variables were then inversely mapped into their original inter-dependent variables. A more detailed study of PCA technique can be found in [51]. Probabilistic knee joint data were as follow:

(1) A total of eighty experimental knee joint data sets, obtained from the published repository, were arranged in a matrix X:

$$X = [x_1, x_2, x_3, \dots\dots, x_{80}] \tag{1}$$

Where x_i is a single experimental set:

$$x_i = [\ KF\ \ Fx\ Fz\ Mz]\quad 1 \le i \le 80 \tag{2}$$

In the above equation, KF is knee flexion angle, F_x is AP force, F_z is axial load and M_z is IE torque. Since the above data have different units (e.g. forces in N, moment in N.m and angle in deg), X was normalized by row-wise standard deviation and then mean centered to generate $\hat{X}$ [46, 51].

(2) Using PCA, a total of four eigenvectors and the corresponding eigenvalues, associated with the above four variables, were computed for the experimental data set ($\hat{X}$). The importance of eigenvectors was ranked with respect to the associated eigenvalues. Higher eigenvalues meant the associated eigenvectors were more essential and descriptive for the data set ($\hat{X}$) and the lower eigenvalues referred to the less-important features that might be caused by noise.

(3) The first three important eigenvectors which explained 96% of the variance in $\hat{X}$, were arranged in the matrix E. The experimental data set ($\hat{X}$) was then transformed into principal component (PC) values without significant loss of information:

$$\text{PC value} = \hat{X} \times E \tag{3}$$

In other words, matrix $\hat{X}$, consisted of four inter-dependent variables, was transformed into a reduced number of three secondary independent variables (PC values) that can be randomized separately.

(4) For the computed PC values, row-wise mean (m) and standard deviation (d) were computed over all the eighty experimental data sets. Each PC value was randomly sampled from a normal distribution with a mean value of m and a standard deviation value of ±2d. Randomized PC values ($\tilde{P}$) were then mapped into their original variables (angle, force and moment variables) resulting in a probabilistic data set of knee joint variables (Y) while the correspondence between variables was preserved:

$$Y = \tilde{P} \times E^{-1} \tag{4}$$

in the above equation, E^{-1} represents the inverse of matrix E. The aforementioned methodology can be studied in more details elsewhere[46].

2.3. Knee prostheses and finite element analysis

Explicit finite element models of four fixed-bearing tibiofemoral knee implants were developed in the commercial finite element package; ABAQUS/Explicit (version 6.12 Simulia Inc., Providence, RI, USA) using computer aided design (CAD) models (Figure 2). These included two PS designs: PFC (DePuy , Johnson & Johnson, Leeds, UK) and Genesis II (Smith & Nephew, Memphis, TN, USA) and two CR designs: NexGen (Zimmer Inc , Warsaw, IN, USA) and PFC Sigma (DePuy , Johnson & Johnson, USA). Lesser constraints of NexGen [34, 40] compared to PFC Sigma [32] suggested that PFC Sigma had higher conformity than NexGen. Also , Genesis II had higher conformity than PFC [52, 53]. Hence, for the rest of this study, PFC Sigma and Genesis II were referred as high conformity designs (in comparison with PFC and NexGen) whilst PFC and NexGen were considered as low conformity implants in their respective category.

Each tibiofemoral knee implant consisted of two main parts; femoral component and tibia insert. Rigid body assumptions were applied to both femoral and tibia insert components, with a simple linear elastic foundation model defined between the two contacting bodies [37]. Penalty based contact condition was specified at the tibia insert and femoral component interface with a friction coefficient of 0.04 [37]. Modified quadratic tetrahedron 10-node elements (C3D10M) were used to mesh the tibiofemoral knee implants in ABAQUS. Here, it should be pointed out that due to rigid body assumptions, solid parts could have been transformed into shell models and meshed with shell elements. This could have reduced the computation cost of FE simulation and produce the same results with C3D10M element. However , solid elements (C3D10M) were still used in the present study, with the aim of calculating wear and deformation in future. Convergence was tested by decreasing the length of elements from 8 mm to 0.5 mm in five steps (8, 4, 2, 1,and 0.5 mm). The solution converged on the parameter of the interest (≤ 5% - contact pressure) with over 86000 elements.

The Stanmore simulator is a well-established load-controlled knee simulator [54, 55] in which in vivo environment of the knee joint is replicated through applying the appropriate forces and moments to the femoral and tibial components. Soft tissue constraints have been modelled with a mechanical spring-based assembly consisting of four linear springs (Figure 3). For the PS implants , resected anterior cruciate ligament (ACL) as well as posterior cruciate ligament (PCL) were simulated with a translational stiffness of 7.24 N/mm , positioned in both anterior and posterior sides of the tibial component [56, 57] while medial collateral ligament (MCL) and lateral collateral ligament (LCL) were simulated by adding a rotational stiffness of 0.3 N/deg to the springs [32]. For the CR implants , resected ACL and retained PCL were simulated with a translational stiffness of 7.24 N/mm on the anterior side and 33.8 N/mm on the posterior side of the tibial component [34, 56] with a 0.3 N/deg rotational stiffness mimicking the collateral ligaments (MCL and LCL). A spring gap of 2.5 mm was considered at each side to simulate anatomical laxity (Figure 3) and the axial force was applied with a 5 mm medial offset from the central axis of the femoral component to simulate the natural varus loading of the knee joint [56].

The loading and boundary conditions, adopted in the load-controlled Stanmore simulator, were consistent with ISO Standard 14243-2 [58] as follows: (1) tibia insert was free in medial-lateral degree of freedom whilst it was constrained in superior-inferior, flexion-extension and valgus-varus directions. AP force and IE torque were applied to the tibia insert; (2) femoral component was free in valgus-varus direction whilst it was constrained in anterior-posterior, medial-lateral and internal-external degrees of freedom. Flexion angle and axial load were applied to the femoral component. Probabilistic load and boundary conditions were obtained from the randomized knee joint data (angle, force and moment), generated in section 2.2. The FE model estimated the performance of TKA designs in terms of AP displacement, IE rotation, contact pressure and contact area over the entire flexion cycle.

2.4. Principal component analysis of sensitivity

Traditional sensitivity analysis often discards the potential inter-dependencies between input variables and therefore is not applicable to study knee joint with highly inter-dependent variables (angle, force and moment). Instead, a principal component-based technique was adopted following [44]. PCA is used to measure the sensitivity of an output metric due to changes in inputs that are in turn coupled to each other. A data matrix (T) was constructed from probabilistic knee joint data (section 2.2) and resultant performance measures (section 2.4):

$$T = [KF, Fx, Fz, Mz\ ,\ \text{performance measures}] \qquad (5)$$

PCA was applied to calculate the eigenvectors and eigenvalues for the probabilistic matrix T. Here, each eigenvector consisted of two separate parts: one part was related to the "knee variables" (i.e. flexion angle, AP force, axial force and IE torque) and the other part was related to the "performance measures" (i.e. AP displacement, IE rotation, contact pressure, contact area). Using eigenvectors, the data matrix T was transformed into a secondary orthogonal data space of PC values:

$$\text{PC value} = T \times E_T \tag{6}$$

In the above equation, E_T is the feature matrix which contained all eigenvectors of matrix T. PC values were in fact the secondary independent variables for primary inter-dependent variables (knee variables and performance measures). The average PC values, over all probabilistic data sets, contained two separate parts associated with the "knee variables" and "performance measures". The first part represented how the coupled knee variables varied together and the second part explained how the resultant performance measures changed accordingly. For each implant, the proportions of the PC values corresponding to the "knee variables" to the PC values associated with the "performance measures" were considered as the sensitivity indices (SI) of the performance measures due to the knee variables ($0 \leq SI \leq 1$). The aforementioned methodology has been adopted from literature and more details can be found elsewhere[44].

3. Results

The PCA-based statistical model of knee joint data was randomly sampled and a total number of two hundreds probabilistic data sets were created. The probabilistic variables had similar waveforms to the corresponding experimental measurements (Figure 4). The above probabilistic knee data were applied to each knee implant in a FE simulation and the resultant kinematics (AP displacement and IE rotation) and contact mechanics (contact pressure and contact area) were computed. The predicted envelopes of kinematics are presented in Figures 5 and 6. The AP displacement and IE rotation of PFC implant varied by up to 7.5 mm and 6.2° and the AP displacement and IE rotation of NexGen implant varied by up to 3.5 mm and 5.7° . The other two implants however showed lower variability of 2.2 mm and 2.5° for Genesis II, and 2.8 mm and 3.25° for the PFC Sigma. The envelopes of contact pressure and contact area demonstrated no considerable differences across the available implants (Figures 7 and 8) and varied by up to 12 MPa and 135 mm^2 for the PFC sigma and 14 MPa and 100 mm^2 for the PFC implant. The contact pressure and contact area of Genesis II implant varied by up to 11 MPa and 150 mm^2, whilst the NexGen implant varied by up to 12 MPa and 120 mm^2.

Sensitivity indices highlighted the critical factors that mostly affected the performance metrics of each implant (Figure 9). In general, AP displacement was mainly affected by knee flexion angle and AP force (Figure 9a). The IE rotation was highly sensitive to changes in the knee flexion angle and IE torque (Figure 9b). Contact area was sensitive to the knee flexion variations (Figure 9c) whilst contact pressure was mainly affected by changes in the knee flexion and axial knee joint loading (Figure 9d). The relative importance of critical factors however differed over different designs. More specifically, lesser conformity designs were more sensitive to inter-patient variations of AP force (PFC: SI=0.85; NexGen: SI=0.62) than high conformity designs (PFC Sigma: SI=0.42, Genesis II: SI=0.33). Similarly, lesser conformity designs were more sensitive to the variations of IE torque (PFC: SI=0.79; NexGen: SI=0.65) than high conformity designs (PFC Sigma: SI=0.45, Genesis II: SI=0.38). By comparison, kinematics of high conformity CR design (PFC Sigma) was mainly dependent on the knee flexion angle rather than AP force or IE torque. For a low conformity CR design (NexGen) and a low conformity PS designs (PFC) however, the relative ranks of the knee flexion and load were changed and AP force or IE torque variations played a more important role to alter kinematics rather than knee flexion. Moreover, the high conformity PS design (Genesis II) was equally affected by both force variations and flexion changes. It is also noteworthy that NexGen could accommodate more knee flexion angle variability ($SI \cong 0.3$) than PFC Sigma ($SI \cong 0.50$), PFC ($SI \cong 0.43$), and Genesis II ($SI \cong 0.36$).

4. Discussion

4.1. The rationale behind chosen input variables

The overall in vivo performance of a total knee replacement is dictated through a complicated interaction of three different groups of factors: (i) patient-specific variables such as patients' musculature and soft tissues , (ii) surgical techniques and (iii) implant designs [35, 41]. The latter, implant design, has been of particular interest as reported in the literature[59-63] and there has been a great effort to compare PS versus CR designs[11, 12, 16-22, 24, 25]. The conventional approach has been to compare the absolute performance of PS and CR under similar loading conditions or to compare over a very few numbers of subjects (due to the financial cost and ethical limitation of humanoid tests). Therefore results are often inconsistent from one study to another.

The main motivation of our study was to provide an alternative approach to compare and contrast these designs in a larger scale from the perspective of inter-patient variability. Inter-patient variability denotes a variety of different aspects such as significant differences in patient anatomy, muscle-tendon strength and lower limb alignment, all which result in joint loading variability. In fact inter-patient variability in joint loading is the main aspect that has been most highlighted in literature [26, 27, 38, 64]. Therefore, in the present study, patient-population was mainly outlined in terms of probabilistic joint loading and flexion angle. From this perspective, the performance should be repeatable in a large scale and over a patient population. Consequently, our findings showed that performance repeatability (reliability) is related to the conformity of the design, not to the type of the design (CR or PS).

4.2. The rationale behind chosen performance criteria

Total knee replacement performance can be investigated through a variety of different criteria including (1) clinical outcome (i.e. survival rate , revision rate and knee clinical scores), (2) functional outcome (i.e. lower limb joint moments , knee flexion and range of motion), (3) kinematics (AP and IE laxity, femoral roll back and impingement) (4) contact mechanics (contact position , pressure and area) and last but not least (5) tribological behavior (wear, wear scars and deformation).

Clearly the aforementioned criteria are linked to each other e.g. the underlying contact mechanics and kinematics have an impact on the tribological behaviors which all then lead to an overall impact on the functional outcome which in turn impacts the clinical scores. However, from a technical point of view, each group of the aforementioned performance criteria is most suitable for a special direction of investigation. For example, in order to investigate the effect of surgical or inter-patient variables, clinical scores and functional outcomes are usually adopted in literature [65-69]. In order to investigate the impact of implant design, tribological behavior, contact mechanics, and kinematic outcomes have been commonly used as key factors. Particularly, because of the competing effect of implant design on kinematics and contact mechanics[63], these two performance criteria have been widely adopted in literature when investigating the impact of the implant design on the performance of TKA [11-14, 35, 41]. Therefore, the basic contact mechanics, i.e. contact area and pressure, on one side and basic kinematic data, i.e. anterior-posterior displacement and internal-external rotation, were chosen as performance criteria in this study.

4.3. Principal component analysis

In the traditional scenario of random sampling, input parameters are perturbed independently whereas the interactions between inputs are often ignored. Therefore, the conventional randomizing techniques (e.g. Latin hyper cube sampling) cannot be used to randomize knee data since load components and flexion angle are highly coupled to each other and cannot be randomized separately. In other words, correspondence should be preserved between knee data in order to generate a valid randomized data set. Galloway et al [46] suggested using PCA to provide a valid large probabilistic database of knee joint variables (section 2.2). Moreover, in the conventional sensitivity analysis, a single input is perturbed while other inputs are kept constant. This technique cannot be employed to evaluate the sensitivity of an output measure due to the changes in inter-dependent inputs since all inputs are altered simultaneously. For example, the overall variation in the kinematics of TKA is the result of simultaneous changes in knee joint loadings and knee flexion angle. Similarly, Fitzpatrick et al [44] suggested using PCA as an alternative to calculate the sensitivity indices (section 2.4).

4.4. Validation

Overall, the general trends of finite element computations were well compared with the previously published experimental and computational literature for PFC [52], PFC Sigma [32] and NexGen [34, 40]. Experimental or computational data for Genesis II in Stanmore knee simulator were not found in literature for comparison. Beside this, lesser conformity designs are expected to have lower constraints and higher contact pressure values whilst higher conformity designs are expected to have higher constraint and lower contact pressure values. These are consistent with the present findings. Lesser conformity designs for example, had an average AP displacement of 10 mm and IE rotation of 6° with the maximum contact pressure values below 40 MPa for PFC, and AP displacement of 4.5 mm and IE rotation of 7. 5° with the maximum contact pressure values below 35 MPa for NexGen. Higher conformity designs however, had an average AP displacement of 2.3 mm and IE rotation of 2.5° with the maximum contact pressure values below 22MPa for Genesis II and an average AP displacement of 4 mm and IE rotation of 3.5° with the maximum contact pressure values below 27 MPa for PFC Sigma.

Present findings were also consistent with the available literature: lesser conformity designs had higher kinematic variability than higher conformity designs [70] and were mostly affected by AP force and IE torque [38]. However, part of the present predictions were in contrast with a previously published study that compared the variability of two low conformity and high conformity CR designs [38]. In that study, the authors found similar kinematic and contact reliability for both designs. Although in the present study contact mechanics variability did not differ noticeably, the high conformity CR design indicated higher kinematic reliability over low conformity CR design. The possible explanation is that Laz et al [38] used fairly small perturbation levels (i.e. 20.6 N for AP force, 0.37 N.m for IE torque, 18.7 N for axial force and 0.11 ° for flexion angle) compared to the present study (i.e. 44 N for AP force, 2.5 N.m for IE torque, 344 N for axial force, and 6° for flexion angle). Also, the overall performance variability of CR designs, achieved in their study, was much lower than the present study.

4.5. Contribution of this study

Contribution of the present study, to the available literature, can be outlined both in terms of methodology and insights. In terms of methodology, first, previous comparative studies have been mostly in vivo or in vitro "clinical" investigations limited to a small number of patients. Hence, results differed noticeably from one laboratory to another. This study developed a computational framework to compare the reliability and sensitivity of CR and PS designs over a large patient population. Second , available "computational" studies have mainly ignored the inter-dependency of variables and randomized loading components separately [35, 38-41, 43], used simplified linear sensitivity indices such as Pearson correlation [35, 41] and utilized relatively small variability levels [38, 39] to evaluate CR or PS TKA. The present study on the other hand, considered the inter-dependency of the knee joint variables and used a more rigorous sensitivity approach based on PCA and utilized higher variability levels to compare CR versus PS designs.

In terms of insights, the present findings provided a quantitative understanding of the performance variability and the critical factors that affect the potential outcome of each implant. Major findings can be outlined as: first, kinematic reliability of TKA was directly affected by conformity such that higher conformity designs indicated more reliable kinematics over the patient populations, second, contact reliability did not differ noticeably among different designs, and third, CR or PS designs affected the relative rank of critical factors that affect the reliability of each design.

From this perspective, a specific design may produce better kinematics but this level of kinematics may not be guaranteed to be repeatable over all patients. For example, our results indicated that a low conformity

CR design produced the least constraint and provided the highest range of kinematics but this level of kinematic performance might not be achievable over all patients since results highlighted the low reliability of this design when considering inter-patient variability. Instead, a small increase in the conformity increased the constraint but made more confidence in the expected clinical outcome.

4.6. Limitations and future research directions

There were several limitations in this study. First, only one source of variability (load and angle) was considered to compare CR and PS designs. Considerable inter-subject variability has been reported in soft tissue, patients' musculature, component alignment and surgical techniques which should be considered for further comparison. The primary aim of the present study was to present a new approach to compare different designs and establish the required methodology. Nevertheless, the presented framework is equally applicable to study a wider range of inter-patient variables over different surgical techniques. Second, the initial experimental database consisted of five subjects. Further numbers of patients are required to confirm the aforementioned findings and elicit stronger information which can subsequently provide improved comparison of PS and CR designs. Third, rigid body constraints were applied in the finite element simulation to both femoral component and tibia insert. In fact Halloran et al [37] showed that rigid body analysis of the tibiofemoral knee implant calculates contact pressure and area similar to a full deformable analysis whilst rigid body simulation would be much more time-efficient. Accordingly, rigid body constraints were applied to both femoral and tibia inserts to perform the analyses with a reasonable computational cost.

Several future directions can be considered from this study. First, patient population variability can be modelled more precisely by considering soft tissue. In the present study, inter-patient variability was modelled in terms of perturbations in the flexion angle and joint loadings and TKA designs were simulated in a computational model of Stanmore knee simulator. TKA designs may be implanted in a finite element model of human leg including relevant soft tissue. Patient variability can be then modelled more precisely by perturbing the soft tissue parameters such as tendon length or ligament stiffness. Second, other daily activities such as stair ascending/descending, jumping or running may be investigated to find whether the reliability of a design differs among activities. For example, whether the most reliable design for normal walking still can produce consistent performance over the patient population while running?

5. Conclusions

A combined finite element simulation and principal component analysis was used to evaluate the "reliability" and "sensitivity" of four different fixed-bearing knee implants with different conformities and different designs (PS vs CR). Results implied that (1) conformity directly affected the reliability of the TKA over a patient population such that lesser conformity designs (PS or CR), had higher kinematic variability and were more affected by AP force and IE torque, (2) contact reliability did not differ noticeably among different designs (3) CR or PS designs affected the relative rank of critical factors that influenced the reliability of each design.

To the best of authors' knowledge, previous probabilistic studies have mostly focused on one type of implants: PS or CR design and this is the first computational study in which both designs have been compared in a probabilistic finite element approach. Compared to the available clinical literature which compared PS versus CR for a small number of patients in terms of absolute kinematics or contact mechanics, present study compared the variability of the kinematics and contact mechanics of PS versus CR designs for a large inter-patient database (reliability) and highlighted the key factors that affected each implant (sensitivity). Such study therefore could discriminate between different designs and provide further insights for comparison purposes.

Conflict of interest statement

The authors have no conflict of interests to be declared.

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Figure

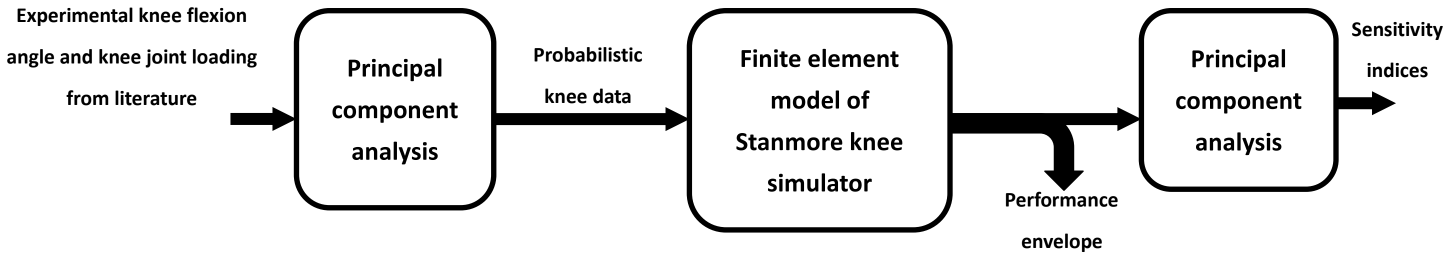

Figure 1 A schematic diagram of the proposed methodology

Figure

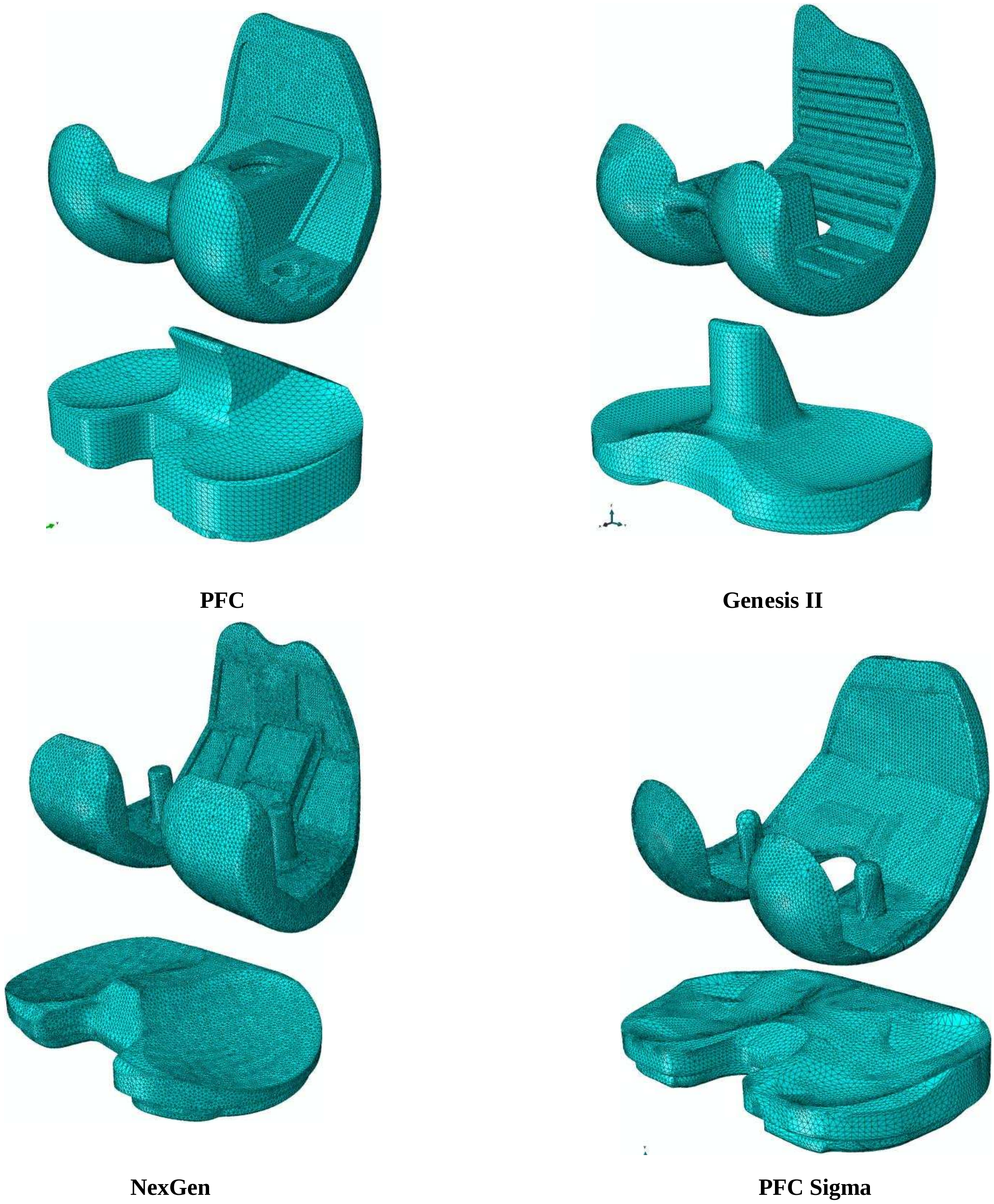

Figure 2 CAD models of implants which were considered in this study

Figure

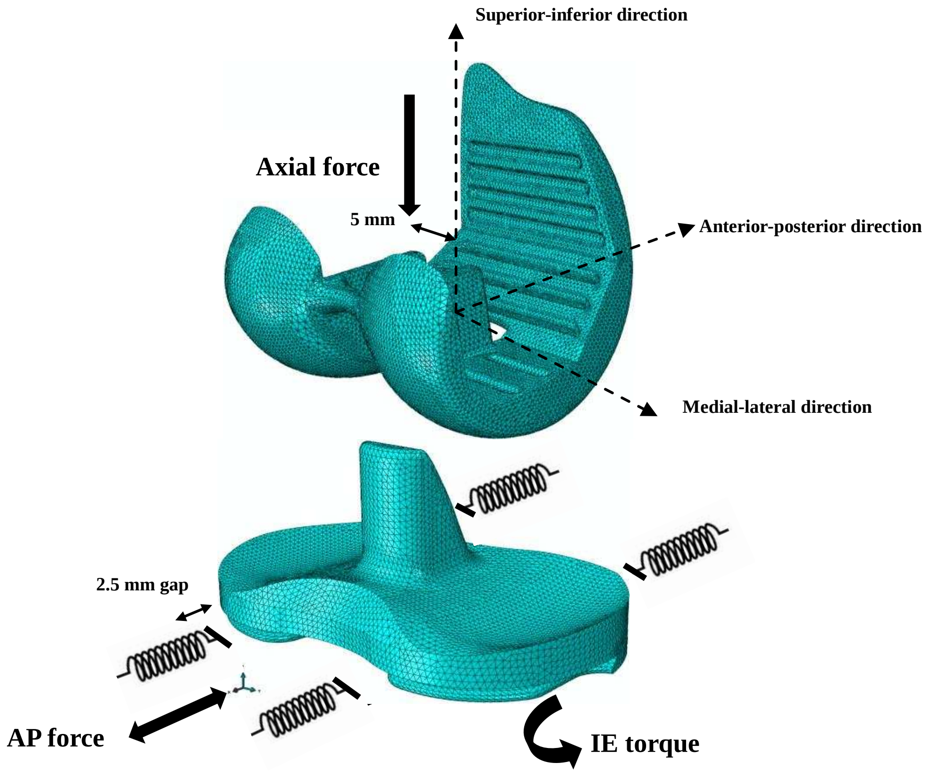

Figure 3 Finite element model of load-controlled Stanmore knee simulator

Figure

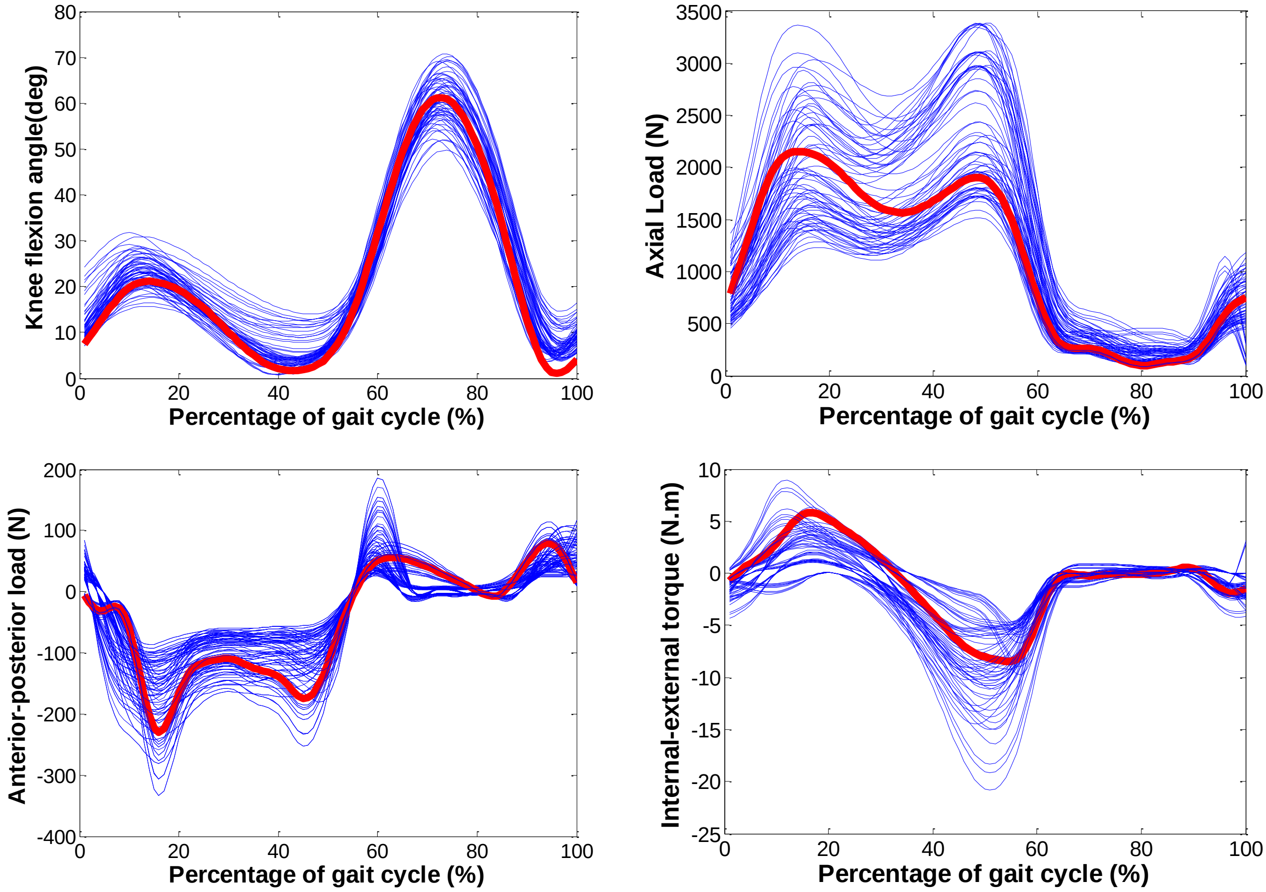

Figure 4 Probabilistic knee data (blue) were seen to be similar in pattern to the original experimental data (red).

Figure

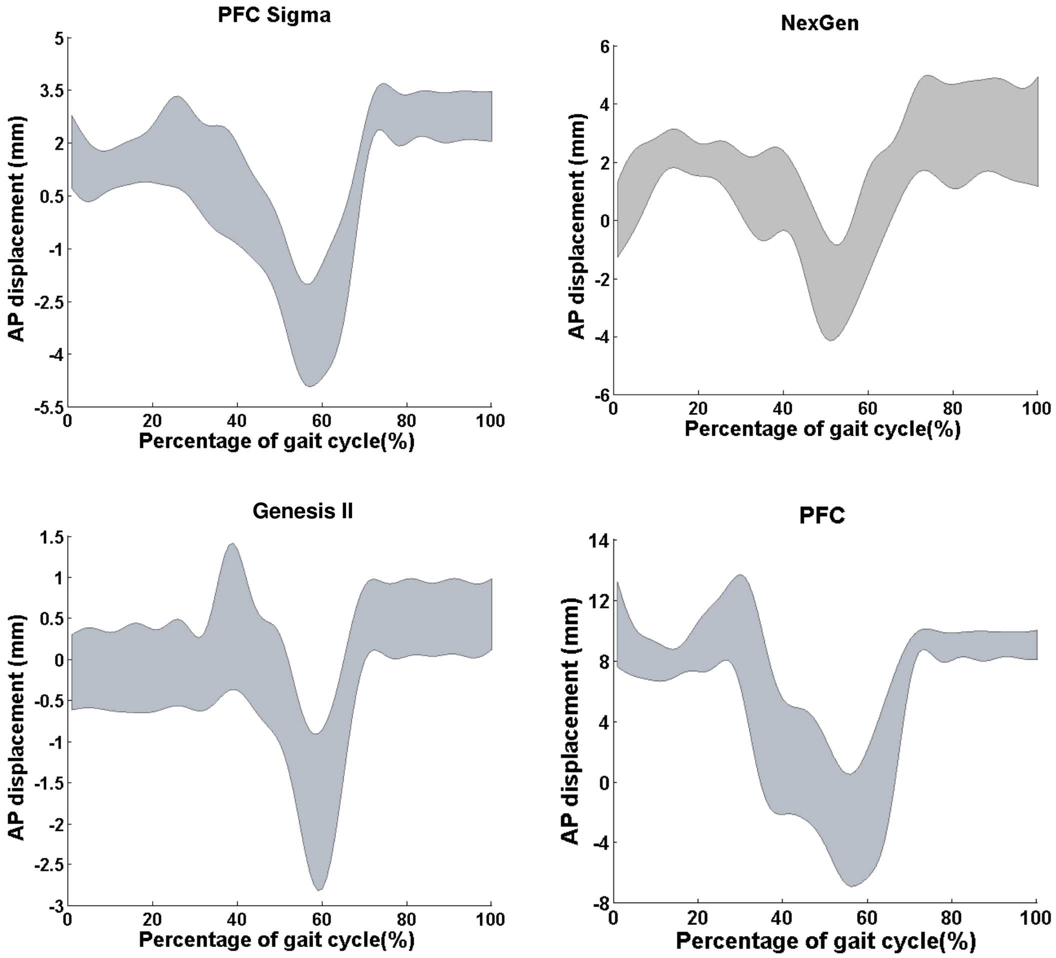

Figure 5 Probabilistic envelopes of anterior-posterior displacement.

Figure

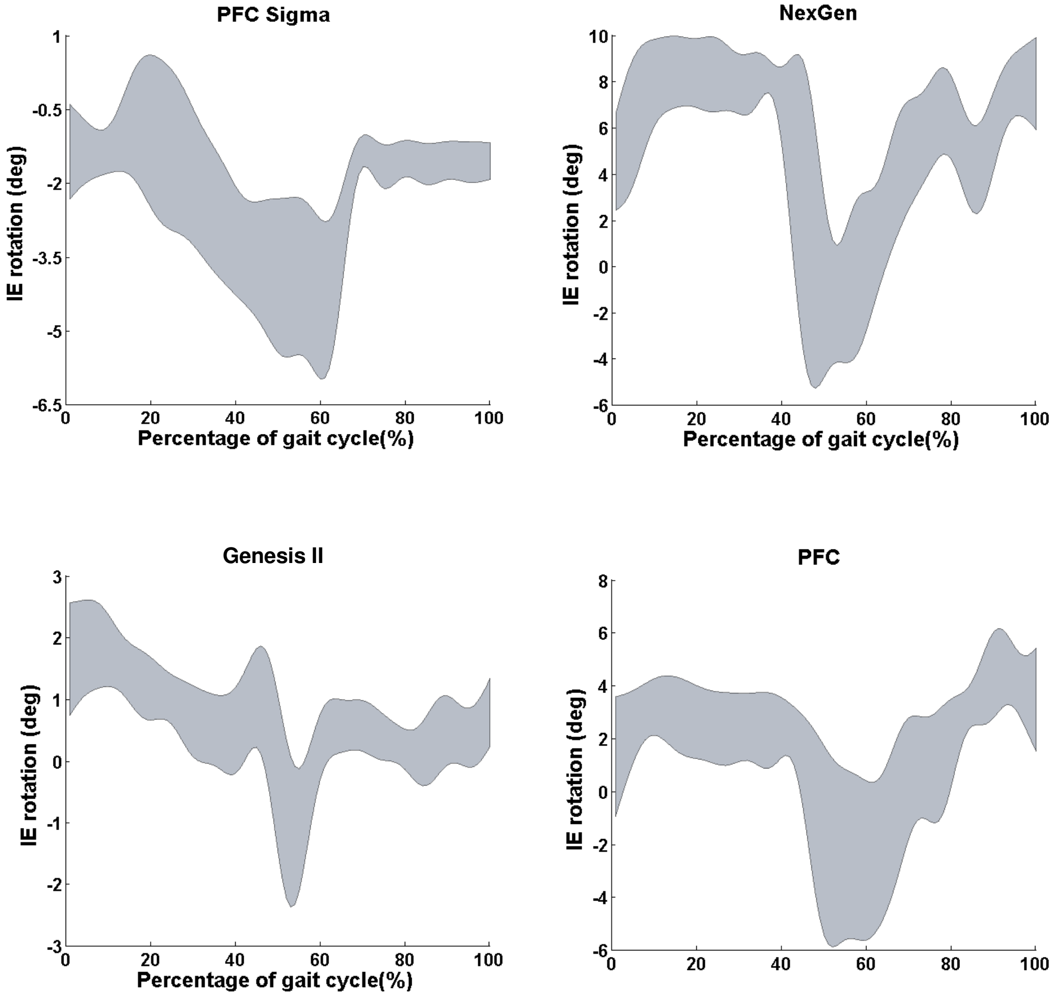

Figure 6 Probabilistic envelopes of internal-external rotation.

Figure

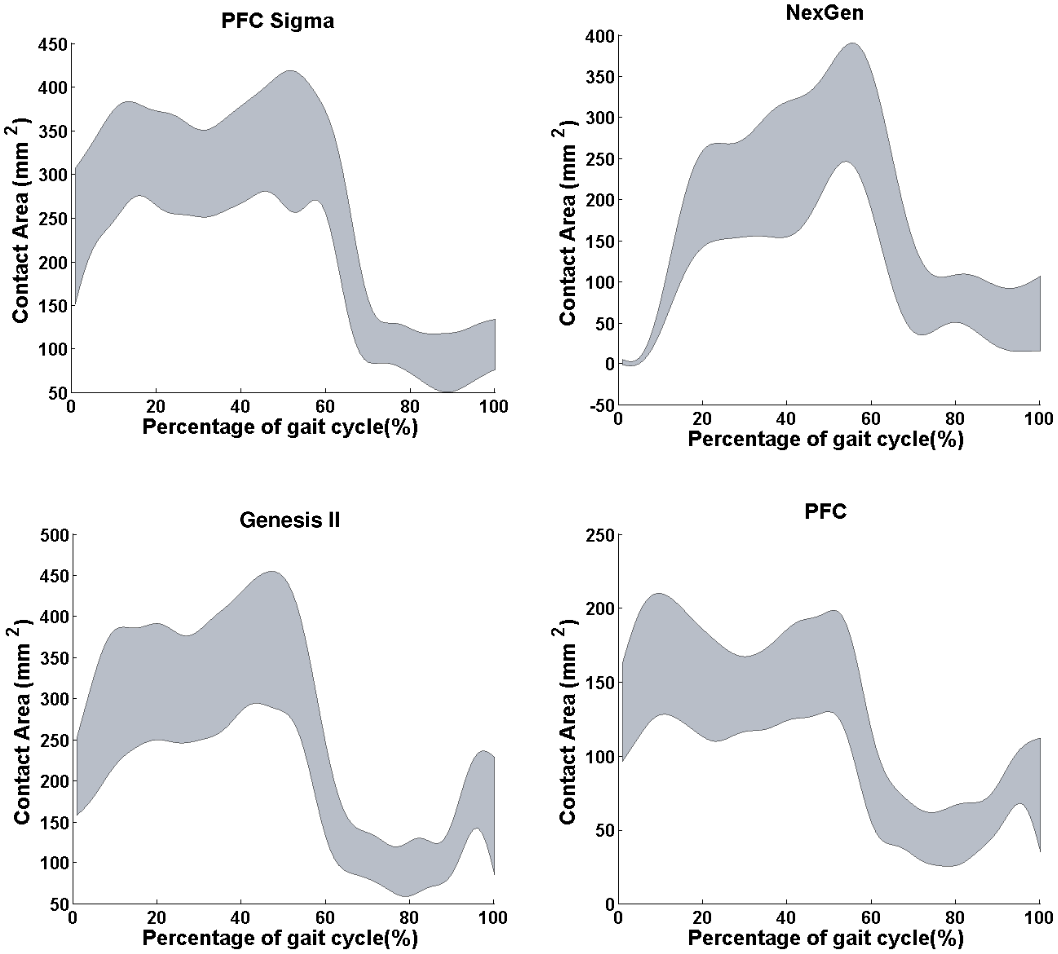

Figure 7 Probabilistic envelopes of contact area.

Figure

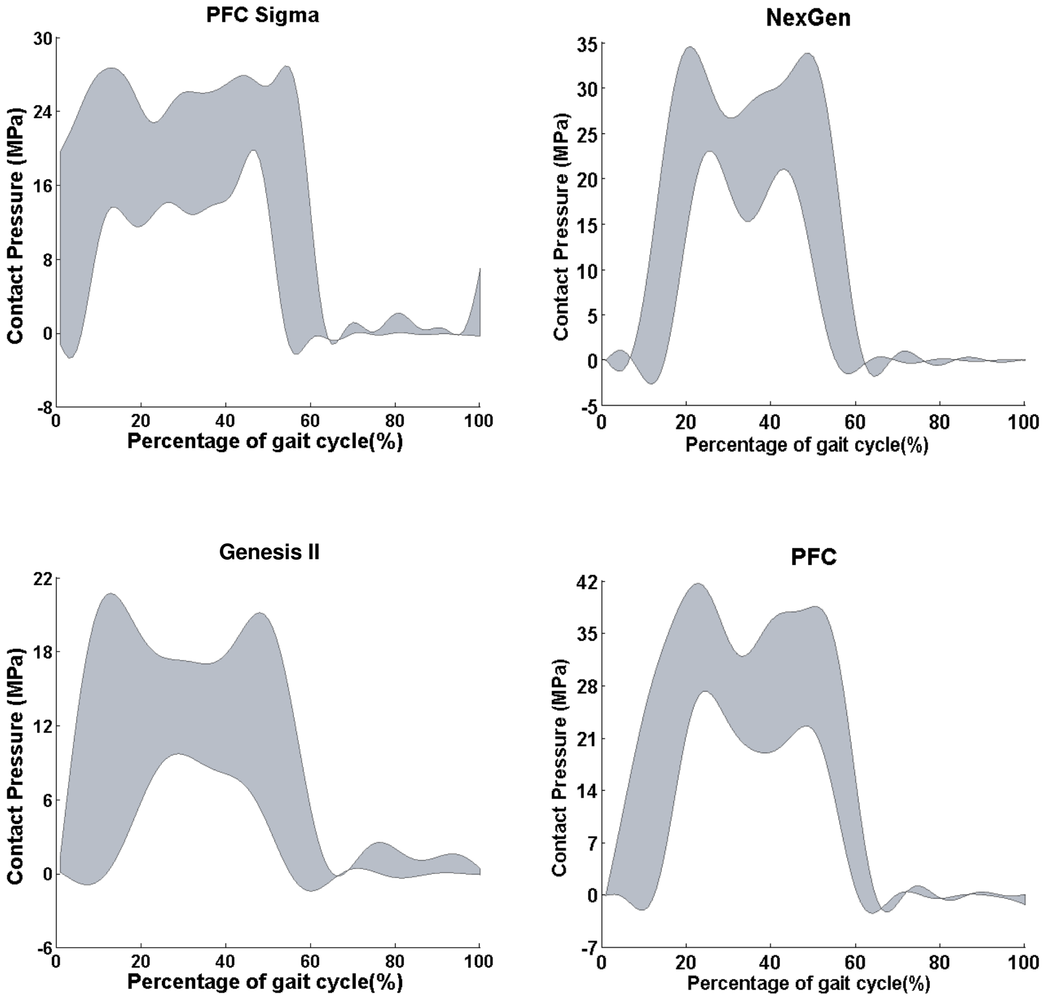

Figure 8 Probabilistic envelopes of contact pressure.

Figure

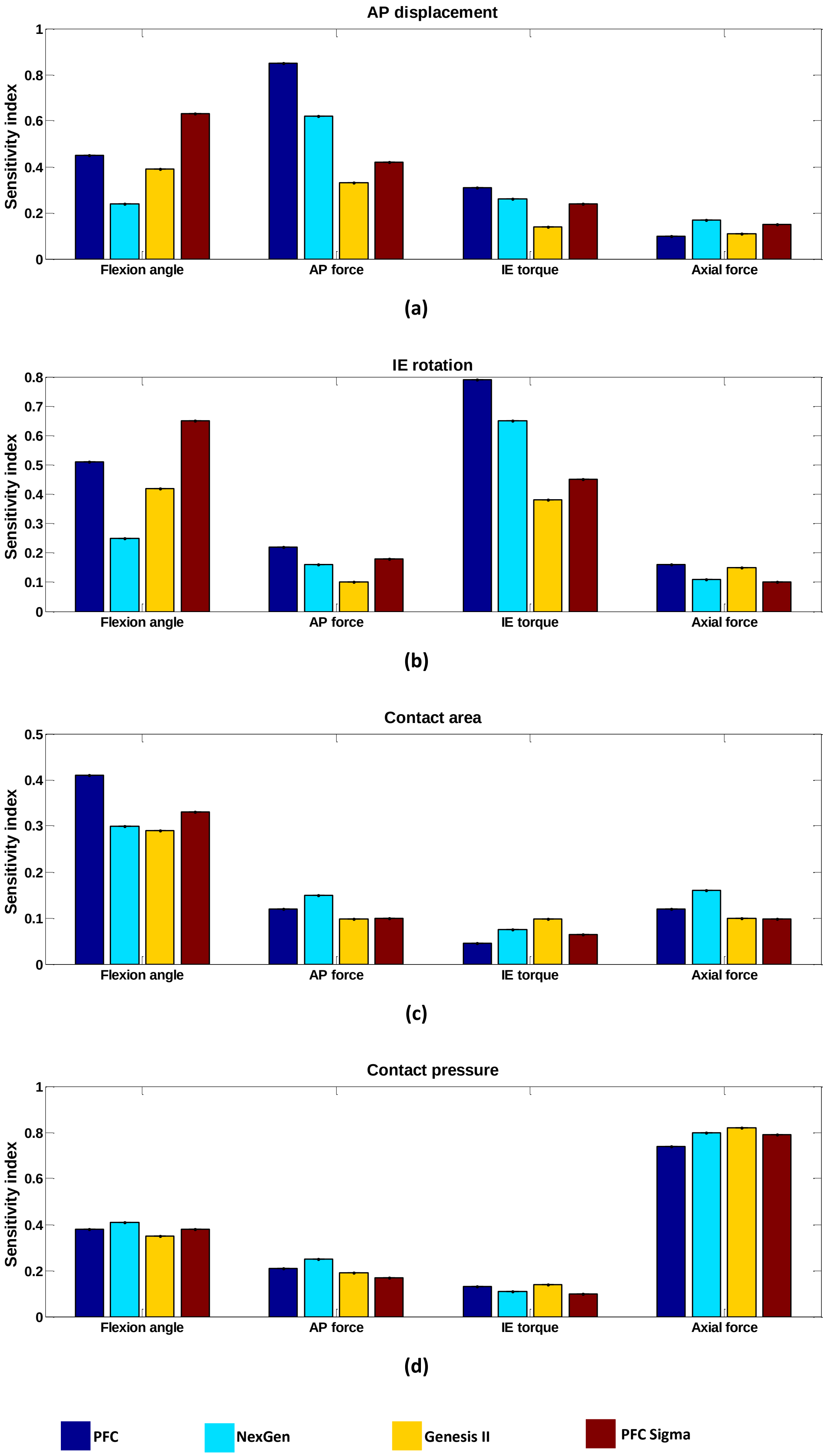

Figure 9 Quantitative sensitivity indices of performance (kinematics and contact mechanics) due to inter-patient variations of load and knee flexion.

Table

Table 1 Description of the implants used in this study

Implant	Femur	Tibia	Generic description
PFC	Multi-radius	Symmetric	Posterior stabilized low conformity
NexGen	Multi-radius	Asymmetric	Cruciate retaining low conformity
PFC Sigma	Multi-radius	Symmetric	Cruciate retaining high conformity
Genesis II	Multi-radius	Asymmetric	Posterior stabilized high conformity