The use of rapid prototyping to simulate knee joint abnormalities for experimental cadaver research: a validation study with replica implants of the native trochlea

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The use of rapid prototyped implants to simulate knee joint abnormalities for in-vitro testing: a validation study with replica implants of the native trochlea

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Abstract

To investigate the biomechanical effect of skeletal knee joint abnormalities, the authors propose to implant pathologically shaped rapid prototyped implants in cadaver knee specimens. This new method was validated by replacing the native trochlea by a replica implant on four cadaver knees with the aid of cadaver-specific guiding instruments. The accuracy of the guiding instruments was assessed by measuring the rotational errors of the cutting planes (on average 3.01° in extension and 1.18° in external/internal rotation). During a squat and open chain simulation the patella showed small differences in its articulation with the native trochlea and the replica trochlea, which could partially be explained by the rotational errors of the implants. This study concludes that this method is valid to investigate the effect of knee joint abnormalities with a replica implant as a control condition to account for the influence of material properties and rotational errors of the implant.

Keywords

trochlear dysplasia; rapid prototyping; kinematics; patellofemoral pressures; in-vitro experiment

Introduction

Skeletal abnormalities are an important cause of abnormal joint function, disability and pain. In general, these abnormalities can be visualised on medical images and can thus be linked to the medical history and the clinical examination of the patient. Consequently, the appropriate treatment can be selected.

In the knee joint, patellofemoral disorders have received a lot of attention in literature to properly diagnose its exact aetiology and focus on a proper treatment regime.[1] Still, the patellofemoral joint and its pathology is probably the least understood field in the knee joint.[2] Dysplasia of the femoral trochlea has been reported as the primary factor in patellar instability.[3] Patients with this condition are at risk to suffer from patellar dislocations at younger age and from patellofemoral osteoarthritis at higher age.[3,4] The precise relation between trochlear dysplasia and patellar instability however is difficult to investigate because the aetiology of patellar instability is multifactorial.[3] Therefore, in-vitro experiments or computer simulations, in which these associated variables can be controlled, are more appropriate to investigate the biomechanical effect of trochlear dysplasia than in-vivo analyses.

Modifying the trochlear geometry while all other factors remain unaltered sets high technological requirements. Consequently, only few methods have been described to evaluate the biomechanical effect of trochlear dysplasia as an isolated factor.[5-8] In 2005 and 2008, Amis and colleagues simulated trochlear dysplasia in cadaver specimens by removing a wedge of bone to flatten the lateral trochlea[7] and by lifting the articular cartilage to elevate the central groove.[8] To quantify the effect of trochlear dysplasia, the patellofemoral kinematics and stability were measured before and after simulating trochlear dysplasia. This method showed to be a successful technique to compare the function of the normal patellofemoral joint with the function of a surgically modified patellofemoral joint.

Trochlear dysplasia however can occur in many variations: with or without the presence of a trochlear bump and with a shallow, flat or convex trochlea[3], which cannot be simulated by conventional surgery on one single cadaver knee specimen.

To overcome this limitation, this study investigates the possibility of replacing the native cadaver trochlea by different types of rapid prototyped (RPT) implants for experimental testing. The authors hypothesize that this method facilitates the investigation of isolated geometrical abnormalities in all their variations.

The aim of this study is (i) to describe this novel methodology of replacing the native trochlea by a rapid prototyped trochlear implant and (ii) to validate this technique by comparing the geometry and the patellofemoral kinematics and kinetics of four cadaver knees before and after implantation of a RPT replica of the trochlea (hereafter referred to as replica implant).

Methods

Four unmatched fresh frozen cadaveric knees, both male and female (aged 75– 85 years) were thawed at room temperature. Before medical images were obtained, a water-soluble X-ray contrast medium (Iodixanol, Visipaque, GE Healthcare, London, UK) was injected in the knee joint to visualize the cartilage. The knees were scanned with a Toshiba/Aquilion helical multislice computed tomography (CT) scanner (Toshiba Medical Systems, Otawara, Japan). The slice interval was 0.5 mm, the image matrix was 512 × 512 pixels and the pixel size was 0.728 mm. The CT images showed trochlear cartilage damage in cadaver knee 1 and no abnormalities in the other three knees. The arthro-CT data were loaded in a 3D image processing software system (Mimics 14.12, Materialise, Haasrode, Belgium) and the images were realigned to obtain an anatomical position of the femur. After alignment, the femoral bones were reconstructed including the cartilage and the trochlear implants and guiding instruments were designed.

Manufacturing of the replica implants and guiding instruments

Design of the replica implants. After reconstruction of the 3D femur models, the trochlear parts were separated from the femur models by the cutting planes. These planes were aligned parallel to the posterior condylar line (1), and intersected with a proximal landmark at the level of the supra-trochlear shaft (2) and with a distal landmark just anterior to the notch (3) (Figure 1(a)). As a result, the separated trochlea incorporated the contact region with the patella from 0 to 60° of knee flexion.

In the design of the replica implant, the loss of bone caused by the saw blade was taken into account by adding a layer of 1.2 mm at the contact area of the 3D trochlea.

Design of the guiding instruments. Cadaver-specific guiding instruments were designed to ensure correct orientation of the surgical saw blade when resecting the cadaveric trochlea (Figure 1(b)). The guiding instruments were featured with a number of inspection holes allowing for monitoring its position on the bone. At the lateral side of the instrument a guiding block was provided to guide the surgical saw blade in a correct position through the cadaveric femur bone (Figure 1(b)). Pinholes were created at the anterior and lateral side to fix the guiding instrument on the bone with four orthopaedic screws. Once the trochlear bone was resected, a second guiding instrument was placed on the trabecular bone surface of the distal femur (Figure 1(c). This guiding instrument was featured with a cylindrical guide with a diameter of 27 mm to guide a biconvex patellar reamer (Genesis II, Smith & Nephew, Inc., Memphis, TN) with a diameter of 26 mm. This guided reamer reamed a socket in the trabecular bone in which a cylindrical fixation component could be cemented (Versa Bond, Smith & Nephew Inc., Memphis, TN) (Figure 1(d)). With this fixation component, one implant could easily be replaced by another between the test sessions.

Rapid prototyping of the implants and guiding instruments. The great advantage of 3D printing is that very complex structures can be manufactured for one-off applications. In addition, it is possible to combine different types of materials in one single model. Because the implants will be used for biomechanical testing, it is important to mimic the material properties of the in-vivo trochlea as closely as possible. In-vivo situations, the trochlear cartilage articulates with the patellar cartilage and is exposed to a wide range of loads up to 10 times the body weight. To accomplish this highly demanding function, the trochlear cartilage has excellent frictional and load bearing properties[9,10]; increased loads in the patellofemoral joint provoke an increase of the patellofemoral contact area[11,12], resulting in a better distribution of the contact forces and a reduction of the peak stresses on the cortical bone underneath. Because this mechanism is most likely attributable to the soft nature of cartilage and because one of the aims of this study was to investigate the patellofemoral contact area and pressure, the hardness of the outer layer of the implants was carefully chosen. A multi material 3D Connex350™ printer (Objet Ltd., Rehovot, Israel) printed the trochlear implants as one single model with a rubberlike photopolymer to simulate the bone (90-100 shore

A, Objet code: DM_9895/9795) and with a softer rubberlike photopolymer to simulate the cartilage layer (80-90 shore A, Objet code: DM_9885/9785). Both materials are a combination of a flexible resin TangoBlackPlus® and a hard resin VeroWhitePlus® (Objet Ltd., Rehovot, Israel). After the horizontal layers were built up with a thickness of 0.028 mm (assuring a high resolution), the material was exposed to UV radiation to obtain a glossy, smooth and more planar surface.

The guiding instruments, which will be used to assure accurate placement of the implants, were printed with the Objet Eden350V printer (Objet Ltd., Rehovot, Israel) with a layer thickness of 0.016 mm. A translucent acrylic-based photo polymer (FullCure 720®) was selected to print the guides in order to facilitate monitoring of the saw blade position and orientation.

Accuracy of the replica implants and guiding instruments

The accuracy of the implants in the cadaver is determined by geometrical and positioning errors of the implants and guiding instruments.

Geometrical errors can occur at each stage of the process, from the acquisition of CT slices to the segmentation, the manufacturing and finishing process. Though the accuracy of the models is dependent on the scanner type, scanning parameters and reconstruction settings, we accept an error of 0.15 mm for the implant design in the current study based on literature values.[13,14] The accuracy of the manufacturing and finishing process of the Connex printer is reported to be between 0.10 and 0.30 mm (Objet Ltd., Rehovot, Israel).

Positioning errors can be caused by inaccuracy or insufficiency of the guiding instruments and can be evaluated by comparing the planned cutting plane with the actual cutting plane. To measure the positioning errors, the pre-operative models of the femur, the implants and the cutting planes were imported in the post-operative scans. Consequently, the pre-operative models were positioned on the post-operative femur models by registration tools in Mimics and the angles between the planned and actual cutting planes were measured in the axial plane (internal/external rotation error) and sagittal plane (flexion/extension rotation error). The angle was defined positive in the axial plane when the actual cutting plane was rotated externally with respect to the planned cutting plane. In the sagittal plane the angle was defined positive when the actual cutting plane showed more flexion compared to the planned cutting plane. The distance between the planes was calculated and visualized in the open-source program pyFormex (http://pyformex.org).

Effect of the replica implants on the patellofemoral kinematics and kinetics.

The impact of the geometrical and positioning errors and the influence of the RPT material properties were assessed by repeating identical experimental tests before and after the replica implants were placed in four cadaver knees. The four knees were mounted in the Smith & Nephew test rig to perform a squat simulation (between 35-75° knee flexion) and an open chain extension simulation (between 5-65° knee flexion) as described by Victor and colleagues.[15] The patellofemoral kinematics and kinetics were continuously monitored by a Vicon system (Vicon, Oxford, UK) and a calibrated pressure sensor which was fixed between the patella and the femur by stitching the sensor to the soft tissues around the patella (Tekscan, South Boston, MA, USA). The critical kinematic and kinetic parameters being the patellofemoral rotation, tilt, mediolateral translation, contact area and mean contact pressure were analysed according to Belvedere et al.[16] Lateral tilt, internal rotation of the patellar apex and medial translation were defined as positive (Figure 2).

To demonstrate how well the kinematics and kinetics of the replica implants correspond to those of the native knees, Bland-Altman plots were created and paired samples correlation tests were performed.[17] To investigate if the observed differences between the native and replica condition were randomly distributed, paired samples correlation tests were performed between the differences (Native – Replica) and the mean values ([Native + Replica]/2) of the patellofemoral rotation, tilt, mediolateral translation, contact area and contact pressure.[17]

To investigate to what extent the variation in differences between the native knee and replica implant can be explained by the rotational errors in the cutting plane, linear regression analysis was performed with the differences in kinematic and kinetic parameters as dependent variables and the rotational errors of the cutting plane as independent variables.

Results

Accuracy of the replica implants and guiding instruments

Post-operative CT scans were performed to define and evaluate the actual cutting plane. The contours of the 3D replicas on the CT scans showed to be in line with the contours of the cadaver femur (Figure 3). The rotational errors between the planned and the actual cutting plane were evaluated quantitatively in Mimics in the axial and sagittal plane and are listed in Table 1.

In the axial plane, the mean absolute rotational error was 1.18 ± 0.63°, the actual cutting plane was rotated internally in three knees and externally in one knee compared to the planned cutting plane. The mean absolute rotational error in the sagittal plane was 3.01 ± 0.64° and occurred systematically in extension.

The distance between the planned and the actual cutting plane was calculated in pyFormex and is represented by a colour plot on the anterior surface of the trochlea of knee 4, positioned on the actual cutting plane (Figure 4). As a consequence of the extension error, the implant showed a positive offset in the distal area and a negative offset in the proximal area (Table 1).

Effect of the replica implants on the patellofemoral kinematics and kinetics

Squat simulation. All parameters demonstrated highly significant correlations between the native and replica condition (Table 2). The patellofemoral rotation and tilt showed a small mean difference between the native and replica condition (< 0.5°), but the patella shifted on average 3.8 mm less medially in the replica condition compared to the native condition (Figure 5). All kinematic parameters showed that the difference between the native and replica condition (Native - Replica) was related to the mean value ([Native + Replica] / 2): with increased mean internal rotation, lateral tilt and medial translation of the patella, the difference between the native and replica condition was significantly smaller (or more negative) for rotation and larger for tilt and mediolateral translation (Figure 5, Table 2). Patellofemoral contact area and contact pressure showed small mean differences between the replica and the native condition (6.3 mm^2 and 0.01 MPa) (Figure 6). The differences in contact area were randomly distributed and the differences in contact pressure were smaller (more negative) when the mean contact pressure increased (Figure 6, Table 2).

Linear regression showed that the variation in differences in patellofemoral rotation, mediolateral translation and contact pressure could be explained by the rotational errors of the cutting plane for respectively 33% ($p<0.001$), 50% ($p<0.001$) and 31% ($p<0.001$). The variation in differences in patellar tilt and contact area could not be explained by the rotational errors of the cutting plane.

Open chain simulation. All parameters demonstrated highly significant correlations between the native and replica condition (Table 2). The patellofemoral kinematic parameters showed small mean differences between the native and replica condition (< 0.5° for tilt and rotation and < 0.5 mm for translation) (Figure 5). The differences were randomly distributed for the mediolateral translation (Table 2). All other parameters showed that the difference between the native and replica condition (Native - Replica) was related to the mean value ([Native + Replica] / 2): with increased mean internal rotation, lateral tilt and medial translation of the patella, the differences between the native and replica condition were significantly smaller (or more negative) for rotation and larger for tilt and mediolateral translation (Figure 5, Table 2). Patellofemoral contact area and pressure showed small mean differences between the replica and the native condition; the mean differences were 12.5 mm^2 and 0.05 MPa (Figure 6).

Linear regression showed that the variation in differences in patellofemoral tilt, mediolateral translation and contact pressure could be explained by the rotational errors of the cutting plane for respectively 50% ($p<0.001$), 79% ($p<0.001$) and 35% ($p<0.001$). The variation in differences in patellar rotation and contact area could not be explained by the rotational errors of the cutting plane.

Discussion

This study shows that the proposed method allows physical simulation of skeletal geometries by RPT and that biomechanical experiments can be performed with these RPT implants. However, a number of issues should be taken into account when this technique is applied to investigate the effect of skeletal abnormalities.

Accurate placement of the trochlear implants in the cadaver is critical for the patellofemoral rotation, tilt, mediolateral translation, contact area and contact pressure. In orthopaedics, it is generally accepted that rotational errors in the axial and sagittal plane should be within 3°.[18] In procedures with standard guiding instruments (intramedullary or extramedullary rods that can be aligned along bone axes under visual alignment), only 70–85% of cases are placed within these boundaries.[18] In the current study, custom made guiding instruments were based on arthro-CT images. CT scans are considered to be the ultimate tool to define the bony surface.[19,20] But this technique is no longer accurate when articular cartilage irregularities are present.[21] Therefore arthro-CT scans were performed to assure accurate definition of both bone and cartilage. Nevertheless, for the first knee, which showed irregularly damaged cartilage, the rotational error in the sagittal plane was higher than the threshold of 3°. This could be due to the fact that the contrast fluid was not dispersed evenly in the entire knee joint, making it necessary to interpolate the cartilage thickness in the regions where the contrast fluid was missing.

Rotational errors of the cutting plane may lead to under- or overstuffing, maltracking of the patella, a decrease of the patellofemoral contact areas and concomitantly an increase of the patellofemoral contact pressures,[22,23] which was confirmed in the current study. The variation in the observed differences between the native and replica condition could at least partly be explained by the rotational errors of the cutting planes. Therefore, when investigating the influence of a pathological geometry, the pathological condition should always be compared to a replica condition instead of the native condition to rule out the influence of the confounding effect of rotational errors.

Besides the rotational errors, the material properties of the implants can also affect the behaviour of the model in the cadaver experiments. To date, not all the material properties of the RPT material are provided by the supplier. Important properties of the RPT materials, namely the friction coefficient, Young’s modulus and Poisson’s ratio should be further investigated by performing additional material testing.

These rotational errors and differences in material properties are not an issue in the earlier studies of

Amis and colleagues, where the articulating material is preserved.[7,8] The current method however allows simulating an unrestricted variety of geometrical characteristics, inherent to the appearance of trochlear dysplasia. Moreover, the proposed method allows future testing of multiple abnormalities by replacing one type of trochlear implant by another on one single cadaver specimen.

To conclude, this study shows that skeletal geometry can be simulated by 3D-modelling and RPT, including simulation of the cartilage layer. The influence of the material properties and possible rotational errors of the implants can be countered by using a replica implant as a control condition instead of the native condition. Simulating a variety of isolated joint deformities can lead to better understanding of the specific biomechanical effects of the deformities.

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Figure Captions

Figure 1. Planning and placement of the implants : (a) Orientation of the cutting plane (knee 1). (b) Guiding instrument to resect the cadaveric trochlea: 3D model (left) and intraoperative image (right). (c) Guiding instrument to ream a socket for the fixation component: 3D model of the guide, the reamer is guided through the cylindrical part (left), RPT guide placed on a cadaver and fixed with one screw (right). (d) Placement of the implant on the fixation component; the metal fixation component is cemented in the reamed socket (left), the RPT implant is fixed on the fixation component (right)

Figure 2. Patellofemoral kinematics

Figure 3. Post-operative CT scan: axial and sagittal view on the cutting plane

Figure 4. Implanted trochlea of knee 4 with a colour plot representing the distance (in mm) between the planned and actual cutting plane

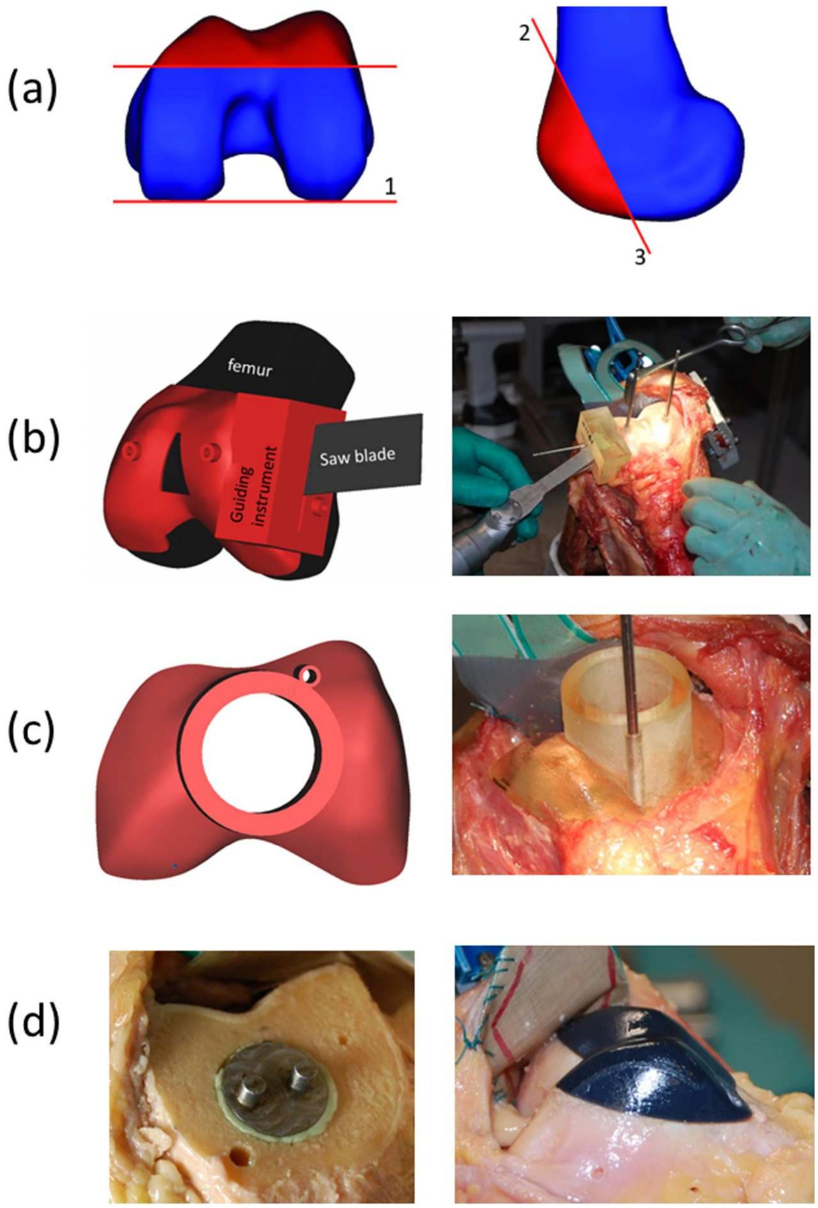
Figure 5. Bland-Altman plots for the kinematic parameters of the four knees during the squat (a) and open chain (b) simulation with average differences (solid lines) and ± 2 SD (dashed lines). The dots represent the patellar rotation, tilt and mediolateral translation with respect to the femur during the squat and open chain with an interval of 5° of knee flexion

Figure 6. Bland-Altman plots for kinetic parameters of the four knees during the squat (a) and open chain (b) simulation with average differences (solid lines) and ± 2 SD (dashed lines). The dots represent the patellofemoral contact pressure and contact area during the squat and open chain with an interval of 5° of knee flexion

Table Captions

Table 1. Rotational error between the planned and actual cutting plane and the mean absolute errors (± SD) for each of the four knees and maximal difference between the planned and actual cutting plane for each of the four knees

Table 2. Paired samples correlations (r) between the biomechanical parameters measured in the native knee and replica condition showing the relation between the two conditions and paired samples correlations (r) between the average ([native + replica]/2) and the difference (native - replica) of the biomechanical parameters of the native and replica condition, which shows if the differences between the conditions were related to the magnitude of the parameters. Statistically significant correlations with a p-value < 0.05 are indicated by (*)



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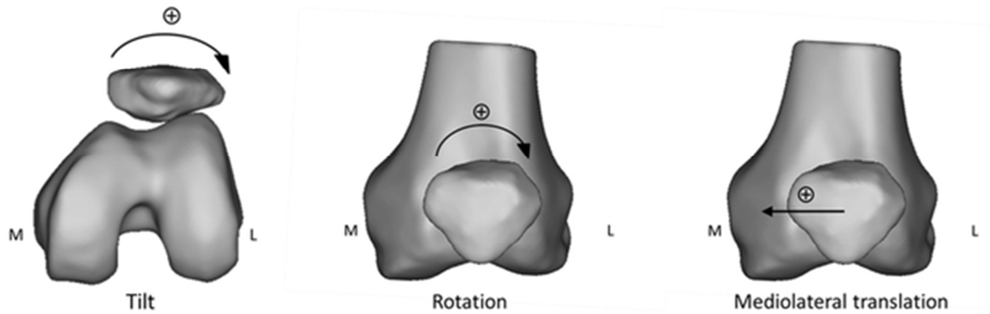

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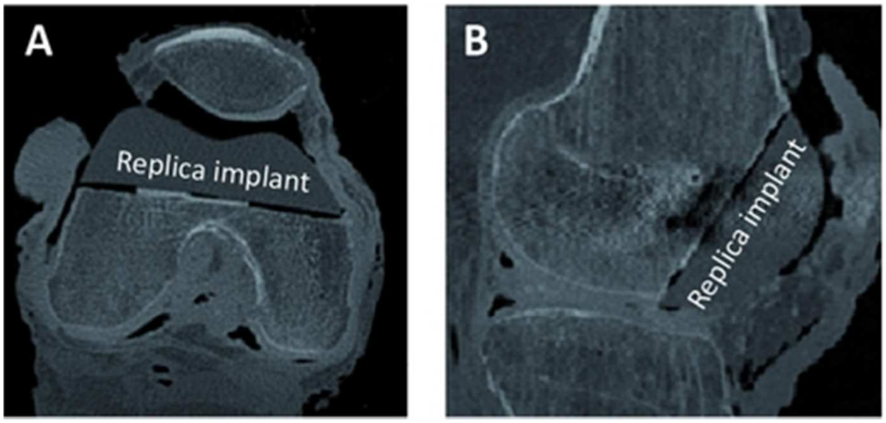

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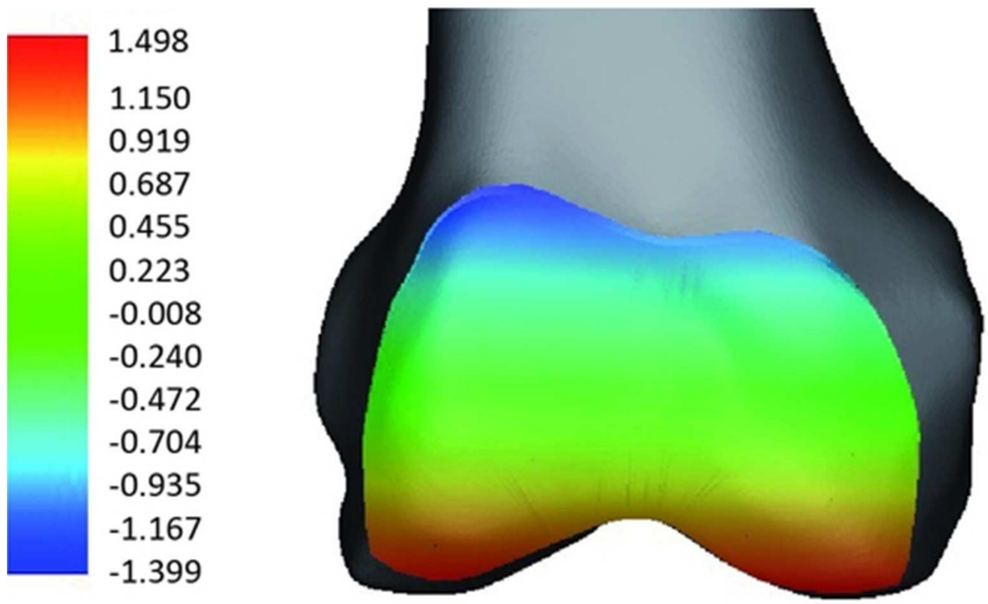

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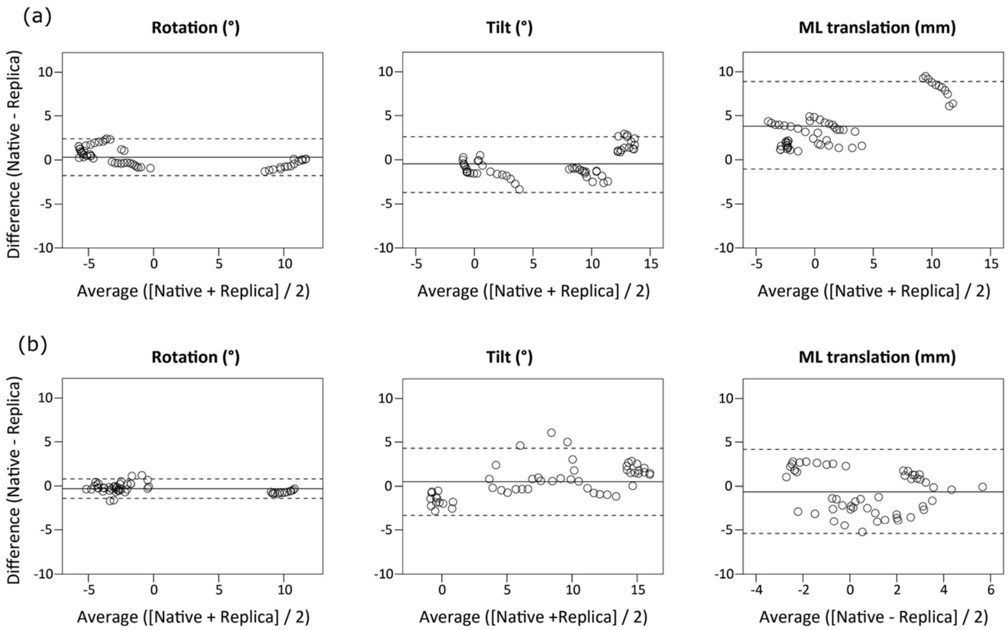
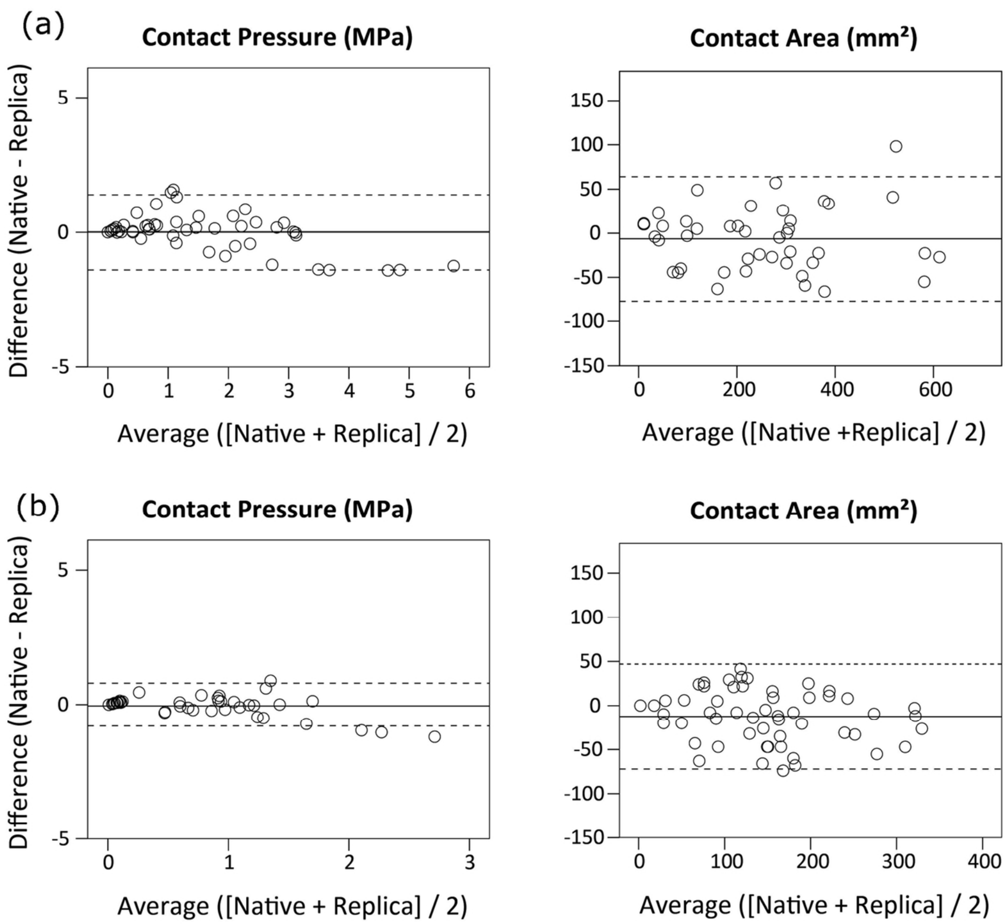


120x76mm (300 x 300 DPI)



117x108mm (300 x 300 DPI)

	Rotational errors		Maximal distance	
	Axial (°)	Sagittal (°)	Proximal (mm)	Distal (mm)
Knee 1	-1.88	-3.97	-2.59	2.46
Knee 2	1.16	-2.71	-0.14	2.82
Knee 3	-1.35	-2.74	-1.51	1.32
Knee 4	-0.36	-2.63	-1.4	1.5
Mean absolute error ± SD	1.18 ± 0.63	3.01 ± 0.64	1.41± 1.00	2.03 ± 0.73

	Squat		Open chain	
	Native - Replica	Average - Difference	Native - Replica	Average - Difference
Rotation	0.992*	-0.577*	0.996*	-0.367*
Tilt	0.970*	0.472*	0.965*	0.580*
ML translation	0.953*	0.810*	0.532*	-0.216
Contact Area	0.977*	-0.008	0.938*	-0.205
Contact Pressure	0.915*	-0.552*	0.877*	-0.541*