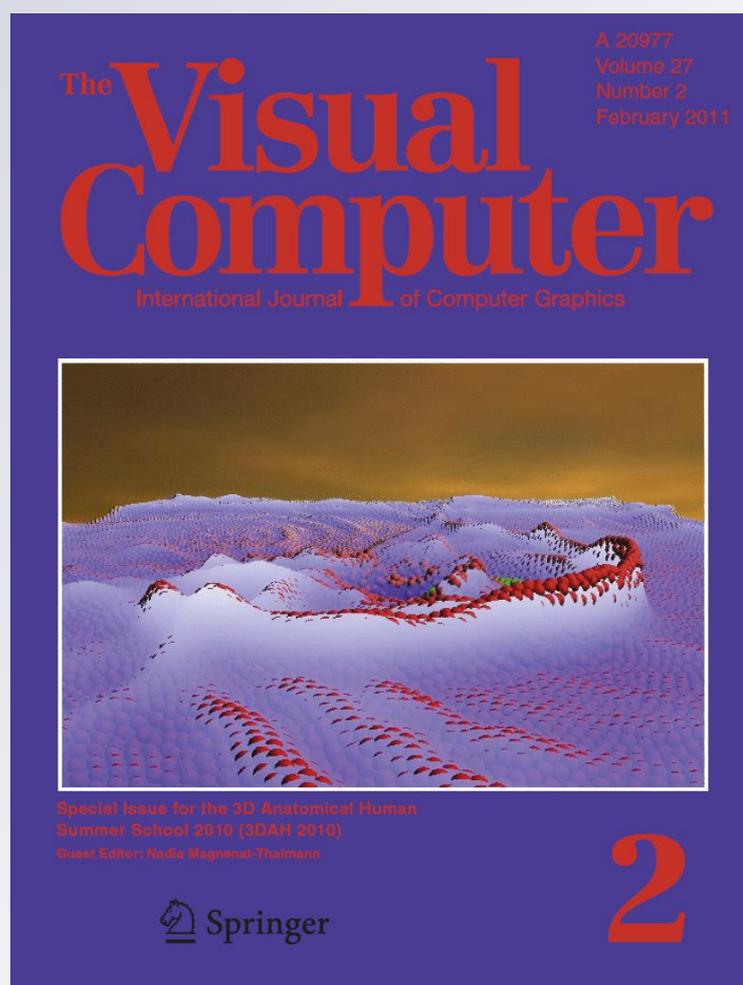


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Subject-specific knee joint model: Design of an experiment to validate a multi-body finite element model

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Abstract The availability of a validated subject-specific model of the knee joint would be extremely useful for the orthopaedic surgeon in evaluating the biomechanics of the joint of a patient, especially when suspecting an injury of one or more components.

The aim of this paper was to describe a procedure designed and developed to validate a subject-specific model of the human knee. The proposed approach considers the use of clinical images to create a multi-body finite element model of a healthy knee. The same joint must undergo an experimental test aimed at collecting the data necessary to validate the model predictions. Therefore, the experimental set-up must be designed to monitor all the degrees of freedom of the joint, allowing the replication of the loading conditions *in silico* with a finite element (FE) model.

At the moment, an animal model is used to verify the accuracy and repeatability of the developed procedure.

Keywords Knee joint · FE model · Subject-specific · Experimental validation

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1 Introduction

There are many studies about knee biomechanics. However, there is still a need to better understand the mechanism of healthy knees to be later able to define with accuracy the damage occurred in the joint following an injury and the best way to repair or reconstruct injured joint components.

The healthy knee joint mainly behaves as a single degree of freedom mechanism in passive motion [1]. The relative motion of the tibia to the femur is determined by the joint anatomy and the passive structures, i.e. ligaments and menisci. However, while the main role of the menisci is to transfer the joint load and better distribute the pressure on the cartilage, the role of the knee ligaments is primarily to ensure the stability of the joint all through its range of motion.

In the literature, there are many studies referring to the development of a knee joint model [2–4]. Depending on the aim of each study (e.g. describing joint kinematics, estimating strain within individual ligaments and predicting joint contact stresses), different approaches have been used in modelling the components of the joint. All models represent the only way to get estimated quantitative data about the effective stress-strain fields that may occur *in vivo* in the components of a healthy joint. However, due to knee joint complexity, it is difficult to model accurately each single component, taking into account also the interaction between structures. Therefore, model validation is extremely important, not only to ensure that the results are coherent with the whole response of the joint, but also to evaluate prediction accuracy.

The problem of model validation is generally addressed trying to investigate experimentally a simple, and therefore repeatable and accurate, loading condition. However, due to the difficulties in multi-axis motion control setups, generally, in the literature simplified setups have been developed

to solve specific problems reducing the degrees of freedom [5–7] and/or focusing only on one or a few components [8, 9]. Furthermore, even though several studies [10–13] measured translations, rotations and loading conditions, not all reproduced the dynamic loading condition that the knee is mechanically exposed to. The works aimed at replicating such dynamic loading tend to do so by applying loading by hand rather than using a more systematically controllable and repeatable methodology [14, 15]. The use of a robotic arm [16–18] does, however, enable the application of dynamic, repeatable and physiological loading. Nevertheless, these types of test required resection of specimens above and below the level of the knee capsule. Such resection is common as it produces a specimen that is more convenient for testing procedures. Conversely, a system that enables testing of full, unresected, lower limbs under systematically repeatable and dynamic loading conditions is not currently available. Consequently, a subject-specific model, of the human knee joint, which simulates the contribution of the passive structures during passive motion, has not been experimentally validated, yet.

This paper describes the design of an experiment to validate a subject-specific numerical model of the healthy knee. The present study addresses the problem of defining the subject-specific geometry of both bones and passive structures of the knee. Additionally, the designed experiment tries to determine both the contribution of the passive structures to joint stability, testing the whole knee under controlled loading conditions, and furthermore, the material properties of the single structures.

2 Design of the validation experiment

2.1 Samples

The validation experiment must be designed to provide data to be used in verifying the accuracy of the model predictions. The data have to be measured on the modelled joint. Therefore, human lower limbs must be used in the validation experiment. The lower limbs must be collected from donors with no reported history of musculoskeletal diseases. Furthermore, the lower limbs have to be visually checked for scars and other indications of surgery and/or malalignments before testing. Only samples without any of these signs can be accepted since exclusively healthy knees are investigated.

If *ex vivo* biomechanical tests are designed to reflect as close as possible the conditions in life, specimens should be removed from the body as soon as rigor mortis has passed and tested immediately in the fresh state [19]. However, human specimens are not readily available. Hence, storage/fixation of human samples before testing is unavoidable. Among the different storage methods available (e.g. freezing, alcohol and formalin fixation) freezing should have less

effect on the tissue. Even though freezing significantly affects the mechanical properties of muscles [19], it has been found that ligaments and tendons are relatively unaffected [20–23]. Since the experimental test designed replicates a passive motion of the lower limb, the muscles are consequently only working passively and thus freezing the samples was considered acceptable.

2.2 Joint geometry

The geometry of the knee joint must be acquired to enable the identification of the subject-specific anatomy of each sample. Therefore, three-dimensional images of the knee must be acquired. Computed Tomography (CT) and Magnetic Resonance Imaging (MRI) scans of the whole lower limb are performed. CT scans are useful for imaging bone-structures within the lower limb whereas MRI scans are better suited for soft tissue imaging. Since the two image datasets, acquired from the same limb, must be aligned, the problem of image registration occurs. If a set of corresponding points—fiducial points—can be visible in both views, then the transformation which aligns the fiducial point pairs can be used for all points of the view. Anatomical landmarks can be used as fiducial points. However, the use of markers visible in both CT and MRI should reduce the error in the localisation of fiducial points. If markers are used, their dimensions must be greater than the image voxel size. The marker must be fixed to the bone segments, to avoid skin artefacts. Placing a cube with three orthogonal markers attached to each bone segment enables the 3D image alignment of each segment. However, this approach would not allow minimising the registration errors. Therefore, it may be necessary to place more than one coordinate-system marker set per long bone segment, trying to maximise the distance between the markers, to reduce registration errors.

2.3 Experimental design

The *in vitro* test is designed to test the knee joint with a protocol that afterwards can be replicated *in silico* with the finite element (FE) model. However, the loading conditions have to be kept simple to assure the feasibility and repeatability of the test.

The experimental setup must allow testing of the whole lower limb. Since the relative motion occurring in the knee joint must be measured, the proximal and distal parts of the limb must be rigidly fixed to the device (robot manipulator or testing machine) used to apply/measure motion/forces. Therefore, the experimental setup must consider a rigid fixation of femur and tibia, to avoid soft tissue compliance.

2.4 Specimen alignment

Alignment is necessary if both segments are fixed. The challenge is to determine suitable criteria by which considering

the alignment as 'suitable'. Alignment has not always been defined experimentally. Furthermore, older 'by hand' experiments tend to fix the thigh in place, and allow free tibial movement [14]. This is feasible because the tibial component can be left free and then rotated (e.g. flexion–extension, or intra-extra rotation), or translated (e.g. drawer test) by hand [15]. An alignment method using Roentgen Stereophotogrametric analysis (RSA) has been defined [24]. However, using such a technique would depend on the availability of such equipment. Physiologically, it is logical that the configuration leading to lowest resistance for flexion–extension is that in which the bone segments are appropriately aligned. One method to reduce the likelihood, or extent, of misalignment is to align the thigh/femoral component and fix this segment initially while allowing the tibial component to remain free. Subsequently, fixing the tibial component in the position it naturally remains in. This method requires the centre of rotation of the knee to be assessed; i.e. the femoral epicondyles [25, 26].

Even if the centre of rotation is well defined, it is still difficult to assure experimentally the perfect alignment between this axis and the axis of the frame—which allow the flexion of the joint—used to fix the limb. The degrees of freedom of the setup will zero any force or moment by allowing a relative motion of the knee. This would introduce an unknown displacement/rotation from the presumed initial position of the thigh or lower leg. Therefore, it is necessary to define the relative position of the segments on the testing machine/robot manipulator. This information is essential to obtain more accurate data for the validation of the model.

3 Procedure implementation

An experimental set up to test full human lower limbs was designed, developed, and further improved, using a porcine lower limb model. This is part of the development process, and an important step in preparing and assessing an experimental system for experiments on human specimens.

3.1 Samples

Human lower limb specimens are expensive, in high demand, and are not readily available. Using them during the development process of an experimental set up is not a viable option. Porcine lower limbs, however, are readily available (as the rest of the limb often enters the food chain). Furthermore, as the animal enters the food chain there are no ethical issues or biological risks to consider. The geometry of a porcine lower limb model, although smaller, approximates that of a human lower limb, at least at the level of the knee. In fact, it has been demonstrated that there are some similarities between human and porcine knees [27]. However, it has to be taken into consideration that there are also

some differences between the two species, which has to be considered in the experimental model. For example, porcine lower limbs do not have the range of flexion–extension that human lower limbs have. However, the main aim was firstly to verify the feasibility of the setup and secondly its repeatability. Therefore, the outcome is not affected by such differences.

3.2 Markers

MR pinpoint markers (Beekley Corporation, Bristol, CT, USA) with a conic shape and a 1.27 mm diameter hole have been selected for use as markers. These are suitable for both CT and MRI images, and are designed specifically for CT–MRI image co-registration.

3.3 Geometry acquisition

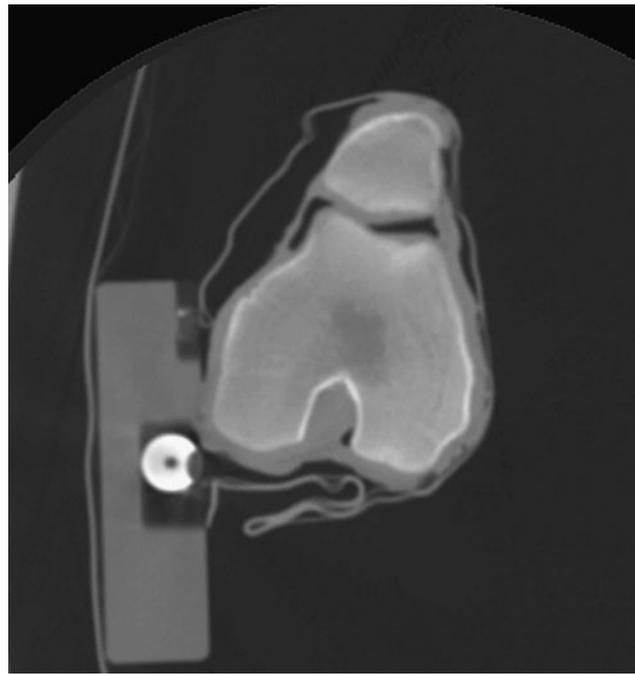
In order to establish the feasibility of lower limb reconstruction using both the marker coordinate system and the markers, preliminary scans of porcine lower limbs were performed (Fig. 1). The preliminary scans were employed to determine the feasibility of the methodology, rather than producing high resolution scans (see below). Therefore, a 0.23 T MRI scanner (Outlook Proview) was used to obtain the images. The *Soft tissue* scanning sequence was employed, with a slice thickness of 3.5 mm being acquired. The distance between slices was of 0.5 mm for coronal and sagittal planes; transverse plane slice thickness was reduced to 3 mm with a gap of 0.5 mm. The acquisitions led to a resolution of 1.423 pixels per mm for final images. A CT scanner (GE Medical systems) was used to obtain CT images using a Helical scanning mode. Images were reconstructed using the Bone convolution kernel and a body filter. The field of view was of 25 mm (i.e. small). The slice thickness was of 1.25 mm with a pixel spacing of 0.884766/0.884766. The resultant resolution was of 1.130 pixels per mm.

3.4 Experimental design

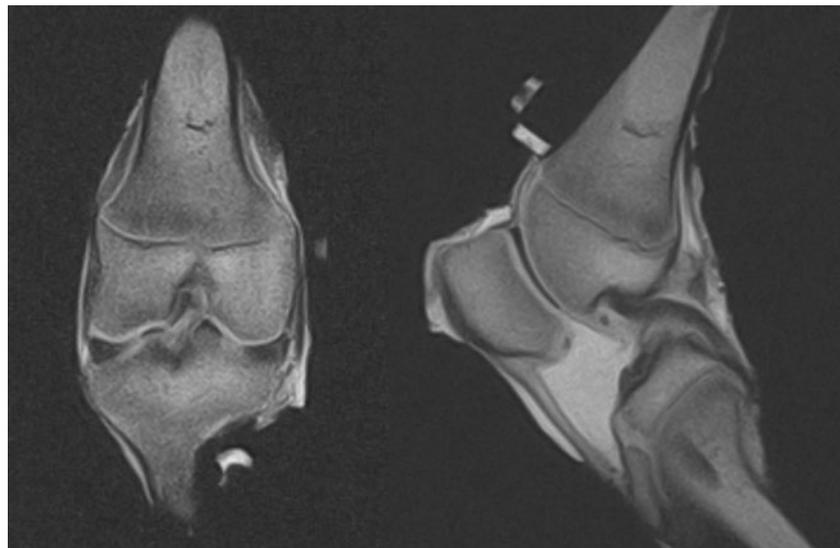
The in vitro test is designed to test the knee joint with a protocol that afterwards can be replicated in silico with the FE model. However, the loading conditions have to be kept simple to assure the feasibility and repeatability of the test. The chosen experimental design simulates drawer tests at different flexion angles (Fig 2(a)), which provide simple, but clinically relevant measures of the knee function.

The degrees of freedom of the knee are shown in Fig 2(b). The provisional design (Fig 2(c)), enables testing of full lower limbs, and consists of two frames: a femoral and a tibial one. The concept of fixation is derived from the use of external fixators. This is preferred to the use of pins being inserted into the bone canal (along their long

Fig. 1 Sample porcine (a) CT (transverse plane) and (b) MRI images (coronal and sagittal planes)



(a)



(b)

axis), as it does not require the resection of the lower limb.

In terms of validating the FE model, the key design requirements include:

- The ability to vary the relative position of the two frames so as to adjust the flexion angle between 0° (fully extended leg) and 90° of knee flexion;
- The tibial segment requires the ability to rotate around its own axis (intra-extra rotation), this angle requires measurement. Such a measurement can be achieved using a rotary variable differential transformer (RVDT);
- The tibial segment requires free displacement along the anterior–posterior and medial–lateral axes of the joint. One possibility is the use of orthogonal cross-rails. These displacements can be measured with linear variable differential transformers (LVDTs);
- The tibia and femur require displacement perpendicular to the orientation of the long axis of the tibia. The displacement also requires measurement. It is possible to achieve this by using a biaxial material testing machine. Alternatively, if required, the machine can allow free displacement, with the application of a known load at a set rate,

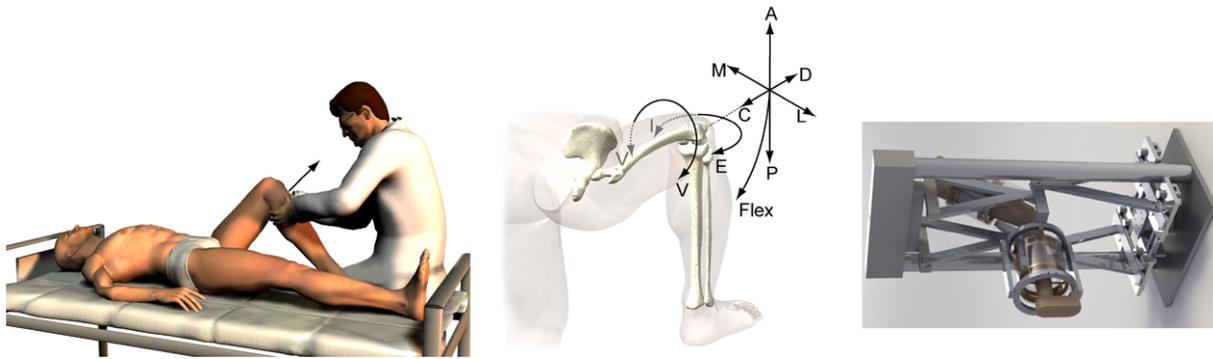


Fig. 2 (a) Drawer test; (b) the degrees of freedom in the knee: medial-lateral displacement (M-L), anterior-posterior displacement (A-P), cranial-distal displacement, (C-D), flexion (flex), varus-valgus rotation (V-V) and intra-extra rotation (I-E); (c) preliminary design of the

experimental set up. The preliminary design shows the placement of a sample, full lower limb, within a testing machine. The components of the experimental apparatus are all visible, including the tibial and femoral frames



Fig. 3 Digitising. The markers used, can be easily digitised, a sample reference frame cube is shown, mounted on a porcine model within the experimental set up

along the axis of displacement. This displacement should be measurable, which is feasible by use of the machine's LVDT;

- Varus-valgus rotation should be accounted for and measured. Use of the biaxial testing machine allows the application of a torque or, if necessary, a free movement in the remaining rotational axis. This rotation should be measurable, which is possible by use of the machine's RVDT;
- Any applied load and/or torque should be measured. The load cell mounted on the testing machine allows the measurement of load and/or torque applied along or around the actuator axis.

The above criteria are critical because they define the translation and rotation undergone during an experimental test by a specimen, and provide the applied loading conditions. Thus, if all translations, rotations and loading conditions are known, it should be possible to experimentally

assess the accuracy of predictions by an FE model which simulates these conditions.

3.5 Digitising

To replicate the experimental test in silico it is necessary to determine the exact position of the bone segments in relation to the axes of the testing machine. This is done using a mechanical digitising device (Gage-Plus-V1.5, Faro-Europe, Stuttgart-Weilimdorf, Germany). The points collected with the digitiser are the markers (i.e. fiducial points, used to register CT and MRI images) and the three axes and center of rotation of the setup, mounted onto the testing machine. Consequently, this enables the experimental and computational environments to be registered.

3.6 Mechanical testing of knee ligaments

After the experimental testing of the knee joint, the mechanical properties of each single ligament are determined, using a previously published protocol [28]. The constitutive equations determined are used as an input (i.e. material properties of the ligaments) in the numerical model.

3.7 Numerical model

The geometry of femur, tibia, articular cartilage, menisci, and ligaments (two collateral and two cruciate ligaments) is extracted from the images using a combination of automatic and interactive segmentation methods. The resulting surfaces of menisci and ligaments are converted to volumetric, tetrahedral meshes for finite element (FE) simulation. Bones and articular cartilage are considered as rigid. A transversely isotropic, hyperelastic material model is used to simulate the ligaments. The required fibre directions are estimated automatically from the geometry of the ligaments.

For the menisci, a standard hyperelastic model is used. Rheological parameters for all structures are taken from the collected data or the literature. The simulation is set up using the SOFA software with an implicit solver. For further details on the numerical model, the reader is referred to [29].

4 Conclusion

In order to validate predictions from an FE model, it is necessary to know the specimen geometry, boundary conditions applied (including magnitude and rate), the constraints, and the subsequent displacements and rotations. Our developed design intends to provide these by replicating a clinically relevant procedure; thus, enabling evaluation of a subject specific FE model, as this is currently missing in the literature.

The experimental set-up has been developed and manufactured. At the moment, it is under investigation using a porcine model to verify its accuracy and repeatability. Tests on knee joints from human cadaver samples are planned.

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