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Development and evaluation of a new method for sagittal knee movement reproduction

- An external approach for application in knee distracting devices –

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Knee osteoarthritis affects up to 10% of adults in Western societies. Estimations on prevalence show over five times more patients in 2030. Conventional therapy does not provide sufficient and cost effective therapy. Joint distraction is currently considered as new treatment option. Preliminary studies explored the feasibility of knee joint distraction with experimental setups. Further evolvement of distractors should include accurate joint motion reproduction to improve circumstances for tissue recovery, to prevent joint damage, and to reduce immobilization of patients. A method was developed for patient specific joint motion reproduction. Evaluation was performed on cadaver joints and delivered a proof of principle. Within 40 degrees of flexion, a prototype was successfully evaluated for loadings present during natural joint loading.
Application of the method can provide clinical and economic advantages by reducing invasiveness of procedures and by reducing costs with low complexity therapy and reduction of treatment time.

Keywords: External; Osteoarthritis; Knee; Reproduction; Kinematics

1. Introduction

Knee osteoarthritis (OA) is one of the most challenging diseases of the near future. Currently it influences 6-10% of the adults in Western societies [1, 2]. Estimations on occurrence in the near future show an increase of knee OA patients up to 565% until 2030 [3, 1].

The limited possibilities of conventional therapy make it difficult to provide adequate solutions for a treatment period of multiple decades, which is needed since the age of OA patients becomes lower with the growing number of obese patients and the longer life expectation, demanding for therapy for a longer period [1]. Moreover, conventional therapy is not able to stop tissue degeneration, not to speak about regeneration of affected tissue [4].

A combination of different techniques is currently used to provide therapy for the longest period possible. The first stage of treatment often exists of use of pain relieving medicine, which reduces the main symptoms of OA in the begin stage. This kind of treatment does not take away any of the causes. During the next stage, invasive procedures are used to provide partial or even full arthroplasty. The impact of such procedures is spread over

the rest of a patient's life. The limited lifespan of prosthesis [5] used for arthroplasty, results in the need for revision of the prosthesis for about 7% after about 10 years for patients under 60 years of age [6], which increases the costs of therapy.

New treatment options are needed to reduce the number of failing prosthesis, reduce implementation of expensive treatment, and deliver adequate treatment for the large number of expected OA patients over a longer treatment period.

1.1. Knee joint anatomy and kinematics

The knee is the largest joint in the human body and consists of more than two bony components: the femur part, the patella and the tibia, see figure 1. Joint ligaments connect the bones and strongly influence the dynamic behaviour. Natural movement of the human knee joint is therefore complex and not a pure rotation, but a combination of translation and rotation. The composition of the joint makes that movement of the bones is rather difficult to describe, and differs per patient. Different joint loadings also result in different knee kinematics. Most of the models which are used for description of the knee movement consider the knee to move in a two dimensional plane, without considerations of torsion or variation in varus and valgus [13, 12, 5]. Simplification of the model into a two dimensional model has proven to deliver applicable models for design of prosthesis and braces. These simplifications concerning kinematics are commonly accepted, although they obviously do influence the characteristics of knee motion.

1.2. Joint distraction as treatment option

An interesting evolvement in treatment of OA encloses the recovery of the joint tissues by the human body itself.

Studies during the last decades linked joint loading to the progress of OA. Active unloading of joints by application of distracting devices resulted in delayed progress of tissue damage and recovery of affected joint tissue.

Literature provides indications that the human body is able to recover the damaged cartilage tissue without the use of contributing medicine, when a stimulating environment is created. Multiple studies showed a significant increase in clinical improvement after joints which were affected by OA, were actively unloaded [7, 8, 9, 5]. Postponing conventional therapy seems to be reachable with therapy based on joint distraction [10, 2, 8]. Some even raised the possibility of joint distraction as permanent treatment of OA [9].

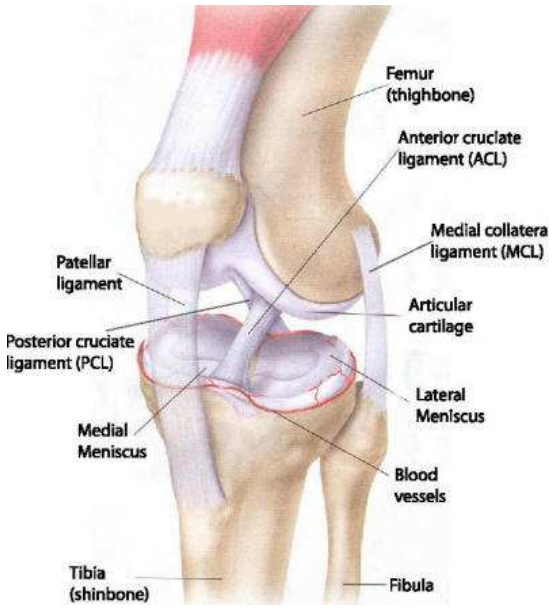


Figure 1. Schematic figure of knee anatomy showing bones and ligaments of the human knee joint [11].

1.3. Clinical evaluation of knee joint distraction and relevant devices

First medical evaluation on human knee joints was performed with experimental, non-commercial, knee distracting setups and showed promising results. A distinction in use of available mechanisms was made: mechanisms used for stabilization of a knee joint, like brace mechanisms, and mechanisms for actual replacement of the function of a knee joint. With joint preservation as motivation for knee joint distraction, the focus is on

the first type of products, and especially on products that support the knee joint while externally and rigidly fixated to the patient's leg with e.g. bone pins or Kirschner-wires (K-wires).

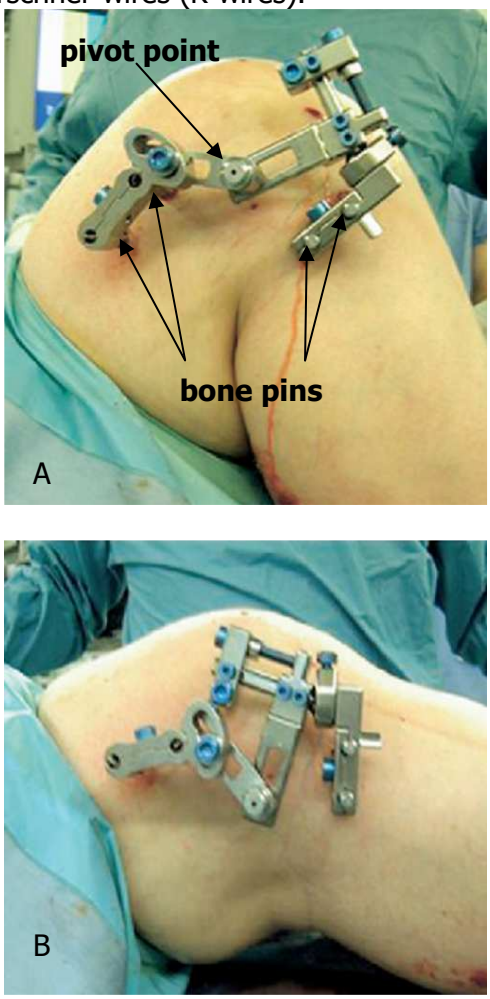


Figure 2. Adapted from figures 1 and 2 of Deie et al. (2007) [5] of a clinically evaluated external knee distractor. The used bone pins and the assumed pivot point are denoted. A: flexed joint. B: extended joint.

In that specific category, three systems were found with relevance for development of an external knee distractor (EKD). Two systems result from scientific studies ([5, 12]), and one mechanism is commercially available, see figures 2, 3 and 4, respectively (Knee Hinge by Orthofix®). Only one system was actually designed for knee distraction, others primarily for knee stabilization.

All systems use bone pins in the femur and tibia for fixating the device and need specific alignment relative to the anatomy of the knee joint with help of K-wires [5, 12]. After placement of each device, a movement trajectory is prescribed in a two dimensional plane, the sagittal plane (defined as in figure 10), of the leg. The principle of the movement prescribing mechanism is different for every system and varies between hinges with one point of rotation [5] to more complex four bar linkages, which are able to deliver a polycentric movement trajectory [12].

All three mentioned systems have principally fixed configurations and prescribe movement based on generalized models. None of them is able to deliver a true reproduction of the motion of a specific patient's knee.

Due to the generalized character of the movement delivered by the existing devices, it is unlikely that the movement of the joint after placement of such device is sufficient accurate for obtaining a constant amount of distraction during flexion and extension of the joint for every patient. The risk of contact between the joint surfaces, which is undesirable during distraction therapy, is assumed to increase. Moreover, the movement of the joint after placement of any existing device does rely on alignment of that device relative to the anatomy of a patient's knee since kinematics are generalized.

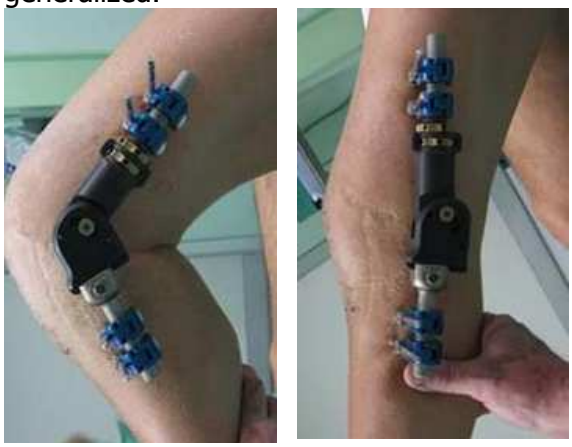


Figure 3. External knee joint fixator which allows joint flexion, adapted from figure 2 of Zaffagnini et al. (2008) [12].

During placement, bony landmarks medial and lateral from the joint are used to determine the imaginary 'axis of rotation'

of the knee joint, which functions as reference during the alignment procedure. Through these landmarks, a K-wire is drilled, where after any of the mentioned devices can slide along the K-wire, followed by fixation to the femur and tibia. This procedure might deliver undesirable movement of the joint, since the deviation in motion from the natural movement due to the generalized character of the mechanisms is added to the possible deviation from the optimal line for fixation of the device relative to the knee. No details about this possible error are known.

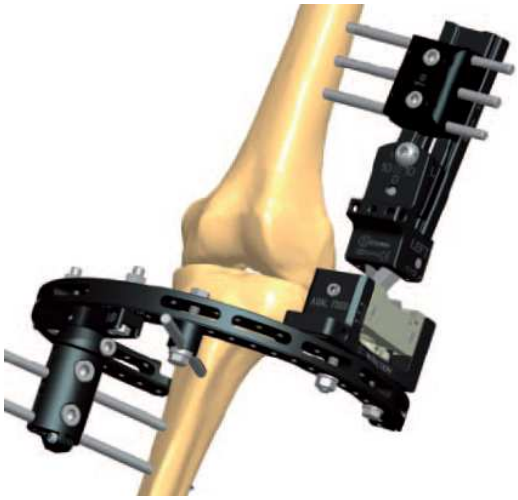


Figure 4. Knee Hinge by Orthofix® [14].

Although the joint is able to withstand certain variation from the natural trajectory, pain might result when the joint is forced to move along another trajectory, and damage to the joint tissues is thinkable [12].

Together with the complexity of the alignment procedure and the damage to the joint during the alignment, a better solution for reproducing knee joint movement for every patient might reduce the risk of damage.

Among the fixating devices which were used for external knee distraction during previous studies, is a setup originating from the UMCU [8]. The results of the research done with that device were motivating and led to the demand of an improved version of the device for further research on the treatment of knee OA with help of EKD in the UMCU.

Different from other devices, Intema et al. [8] introduced a resilient distracting setup for the knee joint, resulting in a dynamic distraction method, which is illustrated in figure 5. This feature allows small variations in the distraction distance and thereby in variations of the intra-articular fluid pressure; the pressure in the joint fluids. Variations of that pressure are considered to be important for the process of cartilage recovery [7, 8].

A limitation of the setup as used by Intema et al. [8], is the fact that the joint was rigidly distracted, and joint flexion was thereby impossible. Besides the obvious benefit of joint flexion on the mobility of patients, is joint flexion expected to be of influence on effectiveness of treatment since circulation of intra-articular fluids might increase due to joint flexion.

Existing devices are not suitable for knee distraction therapy since the distance between the joint surfaces is not controlled, and stimulation of cartilage tissue by variation in intra-articular fluid pressure cannot be combined with joint flexion. The UMCU started the development of a new device for knee distraction which should combine the features of joint distraction, motion (flexion/extension) and resilience. First technical development of such device started with this graduation project, which should deliver better insight in the reachability of an external knee distractor for clinical application.

The goal of the project is to develop better insight in the reachability of an external knee distractor for clinical application by development of a proof of principle for accurate knee motion reproduction.

2. Design

2.1. Introduction

The development of an EKD can be divided in three separate design challenges. In the first place, a rigid connection between the patient and the

distractor is required. Next, the motion of the knee joint should be reproduced, and finally the joint needs to be distracted.

In order to be able to dynamically distract the human knee joint, the first step is to reproduce the movement of the knee joint before the joint surfaces are distracted from each other, and knowledge about the natural movement of the joint is therefore essential.

When joint flexion cannot be prescribed by a system for dynamic joint distraction, other features of a new system will not be needed since technical solutions are available for stiff joint distraction, e.g. the Stryker Triax Monotube® system as used by Intema et al. (2010) [8]. The actual distraction of the joint, together with the connection of the system with the patient, is considered to be less complicated compared to the movement describing mechanism of the system. Incorrect movement might result in contact between the cartilage surfaces, which should be prevented during the distraction therapy in order to provide a stimulation environment for recovery of the damaged cartilage tissue.

Determination of the actual pathway which should be reproduced is essential in the development of a device for EKD. This motion needs to be accurately tracked to maintain a constant amount of distraction. Constant distraction prevents contact between the joint surfaces, which is assumed to be essential for proper treatment, and makes abrupt movements impossible, reducing the risk of e.g. ligament rupture [12, 13]. Special attention to the problem of joint movement reproduction was therefore needed.

Special motion descriptions for distracted knee joints are not provided by literature. Reasons for this might be of different grounds. One of them is that movement of a sufficiently distracted knee might become less critical compared to the movement of the natural trajectory, making the existing models of the knee movement applicable for knee distraction. Another reason might be the fact that small deviations from the natural trajectory are compensated by laxity of the soft tissues in the joint, as is reasoned by Walker et al. (1985) [13].

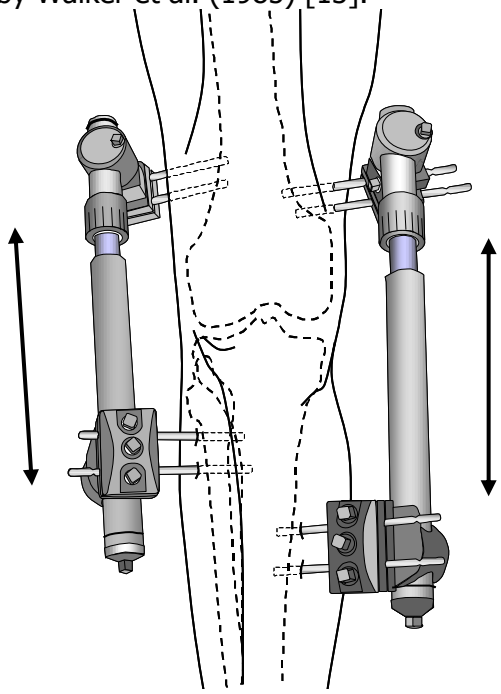


Figure 5. Schematic use of the Stryker Triax Monotube® system. The resilience option is denoted with arrows. Adapted from figure 1 of Intema et al. (2010) [8].

2.2. Design requirements for a motion reproducing mechanism

External vs. internal approach

When minimal limitation in patients' mobility is demanded, the basic functionalities of the knee joint should not be affected drastically during therapy [5]. Movement and loading of a distracted joint should remain possible in order to keep patients mobile. A device for EKD should therefore allow certain movement of the leg in order to do so.

The UMCU aims on an approach with minimal impact to the joint. Infections, scar tissue and other consequences of joint procedures might limit the options for conventional therapy, which might be needed when new therapy fails. When a distinction between internal and external devices is made, these consequences are important factors in the choice for the type of system. For internal systems, the joint cannot stay unaffected,

which brings additional risks when compared to external devices. Furthermore, therapy is based on joint distraction, according to current insights, only needed for a relative short period of two to three months [5, 8], and patients will relatively quickly be helped. This short period of distraction makes external devices more suitable compared to internal devices since for example no radical intervention will be needed to remove the device after the period of treatment. Waller et al. [9] supports this vision concerning the use of external devices.

Loading of an EKD

Although no information is available on loadings of the knee joint for patients that are immobilized due to the placement of an external knee joint distractor, an estimation was made based on the loadings of normal gait and loading by a healthy subject. Two aspects were of importance for generating insights on the loadings of a knee joint. Combining information about knee flexion over a normal gait cycle with loadings during normal gait, provided critical knee flexion angles and their corresponding peak loadings, as illustrated by figure 6. Two critical angles were found at 0 degrees and 15 degrees of joint flexion. Both flexion angles correspond with approximately equal peak loadings which can be related to the body weight of a patient. A factor of three times the body weight is the maximal axial load on the knee joint which can be expected during normal gait, resulting in an axial load of 3000N for a patient with 100kg body mass, which is chosen as baseline.

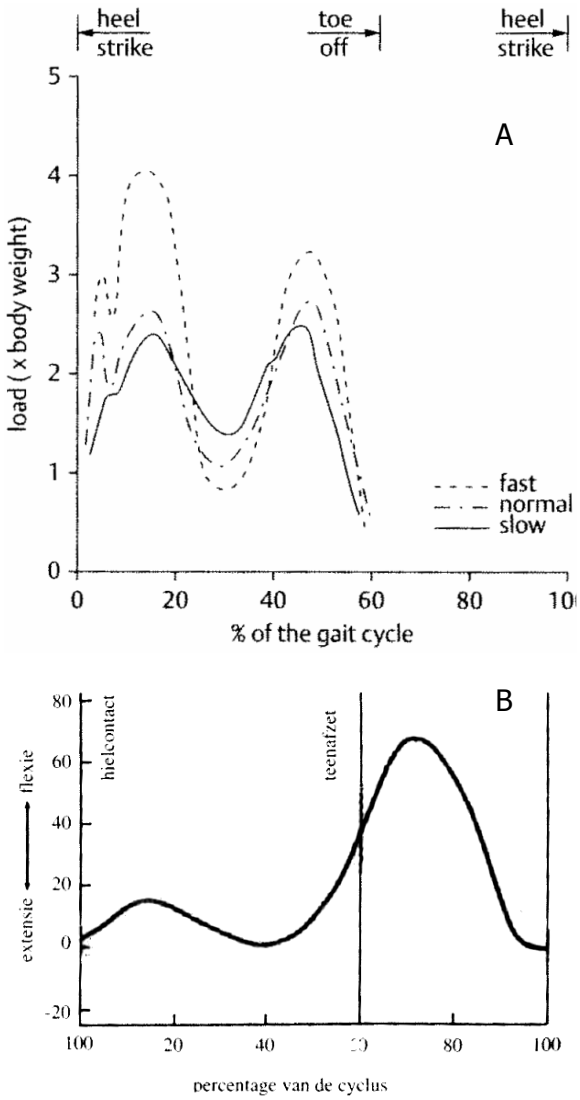


Figure 6. A: Gait cycle with corresponding axial knee joint loading in units of body weight [15]. B: Knee flexion and extension angle in degrees over percentage of the gait cycle [16].

Patients are not expected to walk with a normal gait cycle due to aspects of the treatment method like the awareness of the external device, pain during walking and limited freedom of motion of the device compared to the natural situation without a harmed joint. Peak loadings are expected to be lower compared to the loadings during normal gait, providing a safety factor with unknown magnitude, to be determined during clinical trials.

The force required for distracting the knee joint for a certain amount of distance, is considered to be significantly lower compared to the peak loadings which are present during normal gait. The peak values of axial load will for that

reason be used as guideline. Other joint loadings than axial load are more difficult to determine. No information was found providing details about torsion load between femur and tibia, nor about load in transversal direction.

By using a bilateral approach for the external device, the torsion and transversal loadings are expected to be within a range which can be controlled in a safe way.

Range of motion

The amount of allowed motion of the joint after attachment of the EKD will be limited compared to the normal range of motion (ROM) of the knee joint. Like other devices which reproduce knee motion, the focus is on reproduction in one plane; the sagittal plane of the leg, which is a commonly accepted simplification which neglects small torsional variations which are present during natural movement.

Within the sagittal plane, motion of a by OA affected knee will be limited due to pain during flexion and extension. The ROM of the device will be lower compared to the natural situation.

With the EKD attached to the knee, patients are assumed to move the treated joint, and stimulate damaged tissue to recover. Limitations during activities of daily living should be minimal. The aspect of mobility is considered to be essential. Knee movement during normal gait requires a ROM of 30 to 40 degrees during the period the joint is loaded in the gait cycle, as is presented in figure 6. Reduction of the ROM to 30 degrees of joint flexion is considered to be sufficient for initial evaluation of the method since the gait cycle of the patient is expected to be different from normal gait while the EKD is attached.

Reproduction

Contact between the joint surfaces during distraction therapy is undesirable. Motion prescription by the device should be accurate to prevent contact. A constant and controllable amount of distraction distance is essential. Natural motion is different for every person and depends on joint loading [17]. A device for EKD requires the option to adapt to different motion trajectories and should be able to approach the natural pathway of the knee joint of any patient. The ability to reproduce different motion trajectories for one single patient during different activities is not expected to be essential. Reproduction of one single trajectory per patient should suffice for different loading.

Alignment

Existing devices need complex and invasive procedures for correct alignment relative to the knee joint. The use of K-wires and radiographic help for alignment are undesirable and should be avoided where possible. Especially intervention with the affected joint brings risks for infections.

2.3. Cadaver tests dog: methods

Before developing an improved mechanism which overcomes previous named limitations of existing devices, better insight in knee movement was needed. Especially analysis of the commonly accepted approach based on movement of knee joints in one (sagittal) plane was needed. An interesting aspect of this type of external devices is found in the feature of a rigid connection between the device and the patient since the device is directly attached to the bones of the patient's leg, providing opportunities for accurate motion tracking. Experiments on cadaver dog knees, which have anatomy and kinematics roughly comparable to the human knee joint, were performed to get insight in measuring knee movement.

A device was developed for digital registration of motion in an arbitrary chosen plane near the sagittal plane of the joint, while fixated to the femur and tibia of that joint.

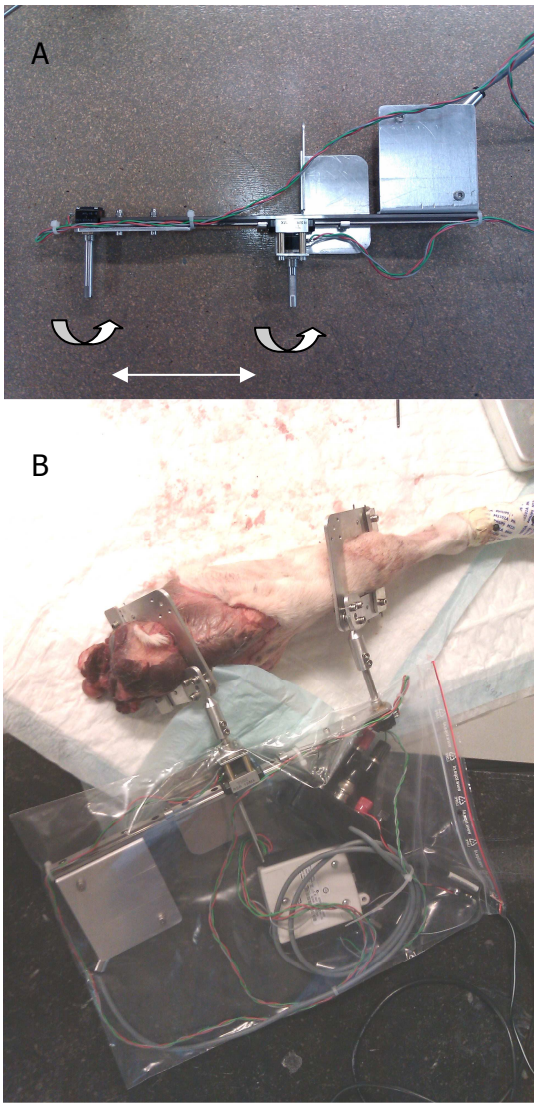


Figure 7. A: digital measurement device for joint motion registration in the sagittal plane. Two rotations and one translation can simultaneous be measured. B: measurement performed on dog cadaver knee.

The used measurement principle is based on two fixation points which are needed to describe motion in one plane. One fixation point on both the femur and tibia are arbitrary chosen, and movement of the knee is analysed without a descript relation to the anatomy of the measured knee. Analysis is done by measuring the distance between the chosen fixation points while rotation of the bones around the points in the chosen plane is measured. The used measurement device is shown in figure 7, together with an impression of a measurement on a cadaver dog knee. The measured parameters are schematically represented in figure 7 and further details are given in appendix B. This approach is able to track any motion of one body relative to another body in one plane.

Two cadaver dog knees where used for acquiring data and evaluation of the measurement principle. Based on an acquired dataset during movement of the joint, description of movement of any point in the chosen plane relative to a chosen fixation point becomes possible, since relative changes in rotation and position are available. The measured data can therefore be reproduced with a cam following system with cam follower positions defined as points relative to one of the fixation points, and cam curvatures defined as motion of the defined cam follower positions over time.

2.4. Cadaver dog knees: results

Software was developed which translated datasets to a graphic file format representing a cam following mechanism for reproduction of the measured movement. With such a file, a CNC-milling machine was programmed to produce the defined cam curvatures. Application of the method delivered a cam follower system, which is shown in figure 8. In order to evaluate the obtained motion of the mechanism which was based on direct measurement on a cadaver dog knee, a setup was configured to attach on the cadaver dog. The motion that was prescribed by the mechanism was evaluated by attaching the cadaver dog knee to the setup to find out if the knee joint was able to follow the prescribed motion and to get confirmation on the working principle. The knee joint was able to move along the prescribed motion trajectory without noticeable deviations from motion that was present without the mechanism attached.

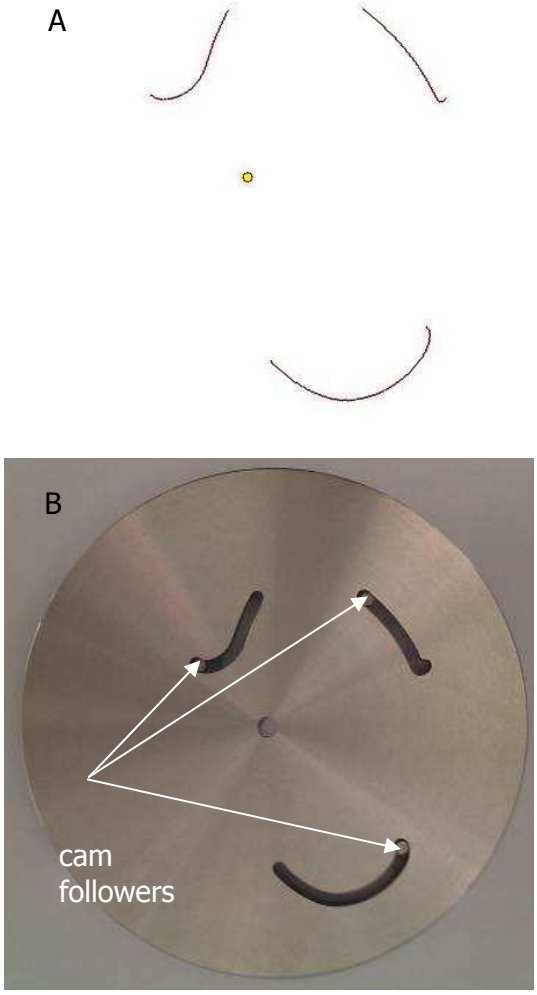


Figure 8. A: By software defined cam follower trajectories created around a position used for angular measurement (yellow dot). B: Cam following mechanism based on motion of cadaver dog knee, corresponding with trajectories above.

No digital measurement of motion was performed due to limitations of the setup for proper measurement conditions with the developed device attached. Separate measurements can with this measurement principle only be compared in case alignment is exactly equal during different measurements or when exact alignment of the measurement device relative to the analysed joint is known. Combining the initial orientation of the measurement device with the fabricated device for evaluation of motion was due to design limitations no option. Exact analysis of the motion with and without the mechanism was therefore not possible, and only indicative results about the method were obtained.

2.5. Human cadaver tests: method

After first evaluation of the reproduction principle on dog knees, conformation was needed on the effectiveness when the mechanism is scaled to the size of a human knee joint. Since a rigid connection to a human knee was needed, evaluation on a human knee was only reachable if patients with bone pins would be available. In the limited time span, no tests on patients could be managed. Instead of evaluation on living patients, human cadaver tests were done. Due to rigor mortis, deterioration of tissue, and lack of tension in the soft tissues of cadavers, the kinematics of a cadaver joint are different from the kinematics in a living knee joint, but expected to provide sufficient inside of the feasibility of the method. These effects were reduced were possible by using an untreated joint (no conservation) whereby all tissues that contribute to the kinematics remain undamaged. For that reason, the evaluation was performed on a whole human cadaver leg.

Besides registration of the knee motion, reproduction of that motion was realized by producing motion prescribing parts which was assembled in the used device, and evaluation of the obtained motion was verified. Conversion from the initial measurement to the motion prescribing part was done within one working day and limited the duration the cadaver leg was needed for each test, reducing undesired deterioration of the joint tissues.

Three separate tests were performed on one human cadaver leg. Between the tests, the leg was frozen. One day before a next test, the leg was placed in an environment at room temperature.

Attachment of the setup to the cadaver was initially performed by an orthopaedic surgeon with help of a conventional ring fixation mechanism

(Ilizarov) and bone pins. After placement of the required bone pins, adaptation in the orientation of the device remained possible.

Measurement

Other than the measurements on dog knees, an analog approach was chosen. This change in measurement approach was chosen for a few reasons. First of all, exclusion of digital components increases the opportunities for proper cleaning of instrumentation after the tests. Secondly, in case measurements on living patients are desired, any simplification of the measurement device decreases the chance of failure.

The working of the analog measuring device was based on the earlier developed cam following mechanism, where the movement of multiple cam followers was recorded during knee flexion and extension in an arbitrary chosen plane. Different from the digital approach, is the fact that the position of the cam followers was chosen before the measurement was performed, and the cam surfaces thereby directly depended from those positions. The resulting movement of the mechanisms is equal for both approaches with those cam follower positions.

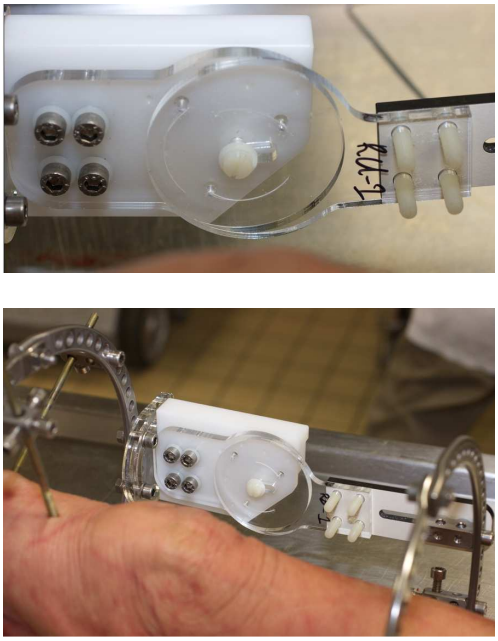


Figure 9. Analog measurement setup as used during human cadaver test. Notice the PMMA plates with recorded motion curves.

During analog measurements, movement was recorded by scratching the trajectory of the cam follower positions with scribers in PMMA (Perspex) plates. The configuration of the analog measurement setup is given in figure 9. Further details concerning measurement are given in appendix C.

Reproduction of motion

The scratched trajectories were coloured with black ink, for maximum contrast, where after the curves were digitalized with help of a conventional photo scanner at a resolution of 600dpi (0.04 mm per pixel) (Brand, type: Xerox, Workcentre 245). A conversion of the obtained digital image into a STP-file format was the final step before a movement prescribing part could be manufactured.

Reproduction of motion with motion prescribing parts was aimed for after bilateral and unilateral measurements, whereby reproduction of the bilateral measurement was considered to be most valuable.

Alignment and positioning

Separate from the patient-specific approach of this movement reproducing mechanism, an important aspect in the measurement procedure is the choice of the plane in which movement is prescribed. In line with the desired ease of the method, alignment by complex methods is not desirable. Instead of that, a self-aligning system will be aimed on during further evaluation of the principle. After attachment of the mechanism onto the patient, the movement of the knee joint while limited to movement in one plane, will be determined in an experimental way. When the mechanism is free to find a plane of movement at a small angle to the sagittal plane of the joint, it will be able to find an orientation of preference. The angle of preference is related to the amount of friction during movement, and within the range of motion, an optimal angle will be found during joint movement. Fixation of the

mechanism at the found angle will be needed to obtain sufficient stiffness for joint distraction during movement.

Position of the device in the chosen flexion-extension plane relative to joint was arbitrarily chosen. Construction of the device allows certain variation in the position; no strict alignment is required but a certain region for positioning can be used, as is illustrated by figure 10.

Evaluation of the reproduction principle on a human cadaver knee was performed three times with the same experimental setup on the same cadaver knee joint. The procedure for placement of the device on the joint was for every test repeated, whereby the procedure was slightly adapted to the changing conditions of the test. Conditions changed primarily due to the deterioration of the cadaver, and the limited options for bone pin placement bringing the need for using identical connections for different orientations of the device relative to the joint. Alignment of the device to the bone pins was different for each test.

For the first two tests, the placement of the device was performed by an orthopaedic surgeon specialized in placement of ring fixators as used during the tests. Positioning of the device and the quality of the bone pin connections with the bone were thereby secured. A first indication on the ease of use of the mechanism also became available.

2.6. Human cadaver test: results

The results of the tests were in first place based on the functioning of the mechanism after placement of the patient-specific part. For the chosen configuration of the device relative to the joint, a reproducing mechanism had to be manufactured. Movement of the joint while motion is prescribed by the mechanism, was analysed in multiple ways. In the first place, the friction during flexion and extension was judged by an orthopaedic surgeon in order to detect incorrect movement or an undesirably amount of friction during motion. Secondly, the prescribed motion of the mechanism was recorded and compared with the initial measurement of motion without a prescribing mechanism attached.

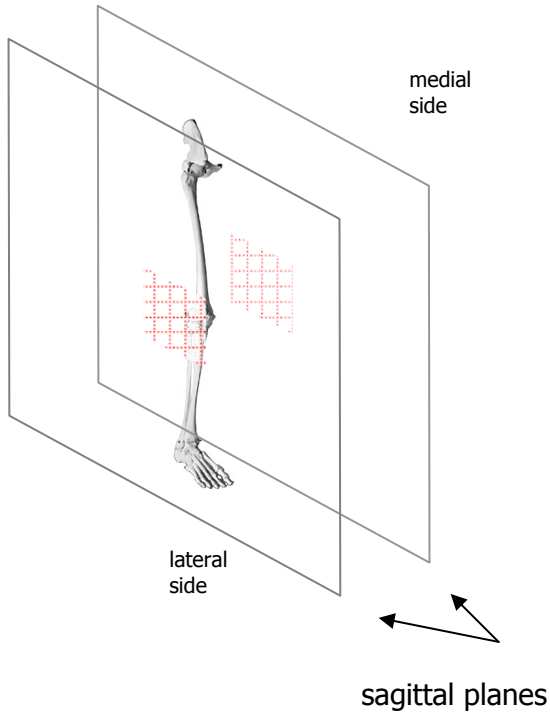


Figure 10. Sagittal plane for reproduction of flexion and extension of the knee joint [18].

A few limitations were found during evaluation, which clearly influenced the outcome of the tests. An important limitation of the chosen attachment method became visible during every test. The used ring fixation mechanism could only be properly attached to bone pins while placed parallel to each other, since parts for attachment leaved no deviation from that orientation. In the movement reproducing parts of the prototype, no option for angle correction was built in since no fixed orientation relative to a joint can be determined before attaching the mechanism to a leg. After the initial connection to a leg, the angle of the experimental setup relative to the sagittal

plane could not be changed without choosing new bone pin locations.

During the second test, the motion prescribing parts that were produced could not be used for evaluation. The dimensions of the parts were such, that motion within the device was not possible. Enclosure of those parts by the casing was thereby not possible as well, and a reliable connection between the part and the casing was thereby not present. These effects are related to the area where reproduction of the knee motion can be arranged by the device, as is shown in figure 10.

2.7. Technical hinge test: method

Axial load

With small adaptations to the design after the cadaver tests, a prototype was made for evaluation of the design requirements concerning loading and ROM. The prototype was constructed out of a stainless steel casing, with a brass motion prescribing part which reproduces motion that was measured during the first cadaver test. The reproduced motion is arbitrarily chosen; any of the measured trajectories during cadaver tests would suffice. Figure 11 gives an impression of the prototype.

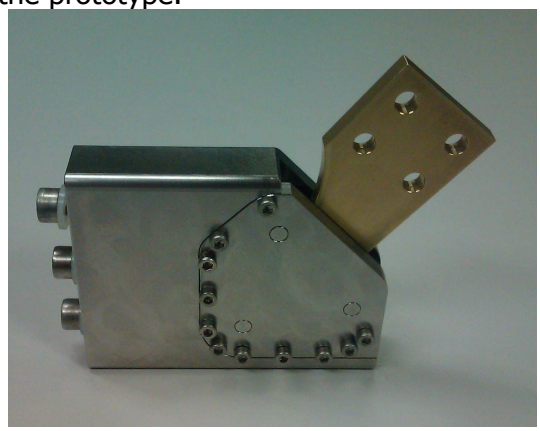


Figure 11. Prototype made of a stainless steel and brass (rotated 90 degrees clockwise).

Use of the device in a bilateral arrangement is considered. The maximal axial load, or load in the sagittal plane, which the prototype should withstand are for sake of experiment simplicity equally divided over two hinges, resulting a maximal loading to be evaluated of 1500N at the defined critical angles.

Since motion of the device is different for every position of the device, or every measurement, a dynamic evaluation whereby axial load is dynamically evaluated over the flexion angle, is hard to perform. The geometry of the motion prescribing part will be different every time the device is used due to changes in alignment relative to the joint, and kinematics will thereby vary as well. Comparison between the performance of different motion prescribing parts was with current setup not reachable due to those differences.

Besides limited knowledge about the loading profile during joint movement of the joint under distraction, does application of such a loading profile to the prototype require a complex test setup. Instead of a fully dynamic evaluation, a quasi-static evaluation was for that reason performed.

The defined maximal loading of 1500N was evaluated for defined critical flexion angles. At 15 degrees and 30 degrees of flexion, the maximal loadings are expected. Besides those angles, the initial orientation at 0 degrees, and an angle outside the required range, at 40 degrees of joint flexion, were chosen for evaluation. All angles were evaluated for the maximal loading of 1500N, although lower values are expected at the last two angles.

A setup was created for loading the prototype at different flexion angles. Load was directly applied in axial direction to the casing, varying from 250N to 1500N, applied with masses from 25kg to 150kg. For each load, all four angles were evaluated, as indicated by figure 12. The evaluation angle was set by adjusting the angle of the motion prescribing part, as represented by figure 13. Dynamic variation of this angle was possible, delivering a constant axial joint load while the hinge was slightly flexed and extended.

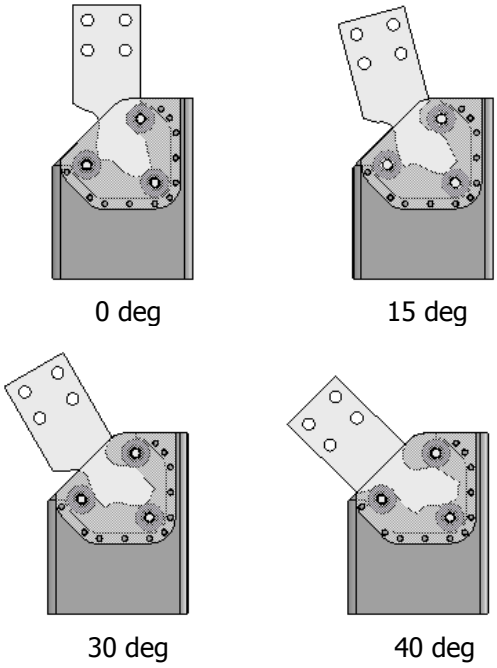


Figure 12. Evaluated flexion angles.

During every loading condition, small variation in the angle was applied by swinging the attached mass in the flexion-extension plane of the hinge. The angle deviation was not constant, since the swing was limited by the size of the attached mass. In every orientation movement in the hinge was generated, providing information about friction within the hinge. Any noticeable indication of failure of any of the components was reason to stop testing.

An indication of the required force which was needed to initiate joint motion was obtained with help of spring suspension, consequently attached at a certain point between the load and the hinge. Results of the measurements are only indications for judging performance of the hinge and are not reproducible for several reasons. The alignment of the applied forces, both the mass loadings and the force required for joint flexion, were not controlled, delivering certain errors compared to alignment in the exact orthogonal planes. These errors are neglected due to the reason that the prescribed motion of the hinge is variable, and consists of a translation and a rotation. The translation within the device changes the distance between the centre of mass of the applied loading relative to the hinge, and thereby changes the moment of inertia of the mass. Measurement of the force required for flexion of the joint is directly coupled to that inertia, and no relation between the load and the force required for movement of the hinge can be found in such a way that accurate description of friction within the hinge can be given. This effect is emphasized by the differing size of the mass for different loadings, resulting in other centres of rotation. The error which is present in the alignment of the loadings is for that reason not considered to be relevant, and results will only be used for better understanding of the behaviour of the hinge.

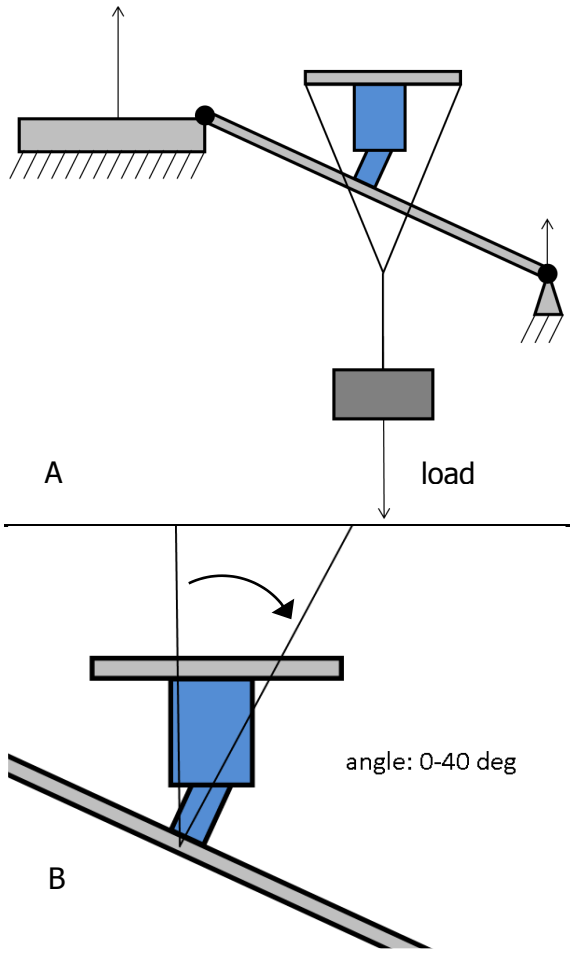


Figure 13. Schematic representation of the setup for evaluation of axial loading (side view). The hinge is shown in blue. A: load is applied in direction of the adjacent arrow. The evaluated angle is set by adapting the left platform. B: flexion angle of the hinge.

Transversal and torsion load

Although axial load is expected to be significantly higher compared to other loadings that an EKD needs to resist, and loadings in the transversal plane can be transferred into axial load in a bilateral setup, an evaluation of the limitations of the prototype with respect to those loadings was performed. No reference values for those loadings that can be expected during use of an EKD were known or could be determined within the available time span. Evaluation only provided an indication of the limitations of the prototype.

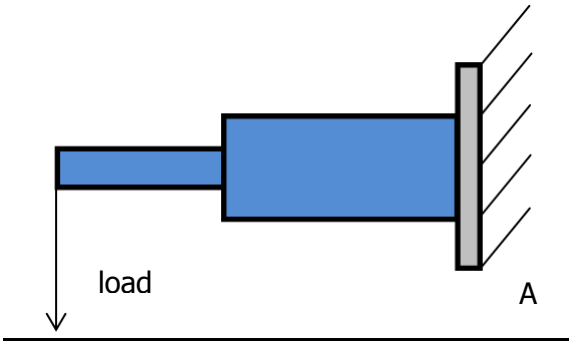
Both load types will be present during use of an EKD but those should not influence flexion and extension of the hinge in such a way that discontinuous motion occurs, that the ROM of the device is reduced, or that the device fails.

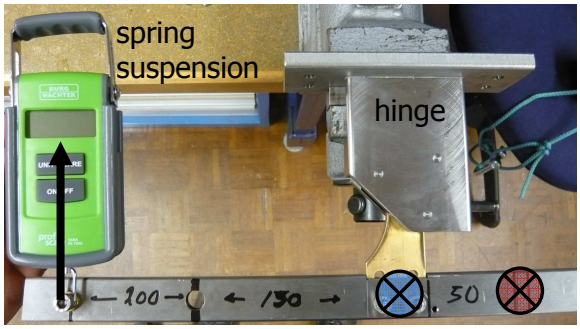
Friction in the hinge as result of transversal load was evaluated by applying a load by directly attaching mass in orthogonal direction to the flexion-extension direction as is shown in figure 14.

Transversal load was applied to the hinge, varying in magnitude from 100N to 400N with aid of masses from 10kg to 40kg. Although no pure transversal loading is created since torsion is present in the hinge, this type of loading was considered as transversal loading while no torsion occurred around the length axis of the device.

Orthogonal to the load direction and in line with the initial hinge angle, a spring suspension was used to measure an indicative force required to initiate motion at 0, 15 and 30 degrees of flexion for every load step.

The choice for motion initiation in line with the hinge angle is arbitrary. Initiation in e.g. orthogonal direction to every point on the motion trajectory during flexion, requires a complex setup. Comparison of different motion trajectories is hard without such a setup, making the performed measurement nothing but an indication. The fact that the direction of the applied force for motion initiation is not controlled in an exact way is thereby not considered to be relevant for this evaluation.





transversal load direction

torsion load direction

B

Figure 14. A: schematic representation of the used setup for evaluation of transversal load (side view). The prototype of the hinge is represented by the blue structure. Load is separately applied in direction of the arrow. B: direction of indicative friction measurement with spring suspension. The arrow indicates the direction of initial motion.

Torsion load was evaluated with a similar approach as the transversal load. Different is the attachment point of the load, which is shifted in orthogonal direction, delivering torsion around the length axis of the device.

2.8. Technical hinge test: results

ROM

The defined angle of 30 degrees of flexion was reached by the evaluated prototype. Motion of a human cadaver knee was used whereby measurement of 90 degrees of flexion was obtained. The prototype was designed to track a measured trajectory along 45 degrees of flexion. No

discontinuities or backlash was noticeable during manual flexion and extension of the hinge within the range of 30 degrees.

Axial load

Evaluation of the expected maximal axial load to the knee joint was performed at angles of 0, 15, 30 and 40 degrees. For every load step between 25 and 150kg, little motion of the hinge was obtained by applying little angular variations. No noticeable complications occurred. For certain combinations of loading and initial angles, vibrating behaviour was visible during flexion and extension. No visual indications of hinge failure were present during loading.

Figure 15 provides an indication of the ratio between the forces that were required to initiate motion at different angles for every load step. The indicative force required for initiating hinge motion was quite consistent for the different load steps.

After all loading steps were performed, the device was taken apart and the components were inspected for damage. One radial bearing was affected by the applied loadings. The outer ring of the bearing was squeezed, and loading was directly taken by the inner ring. Although the failure of one part, motion of the joint remained possible with slight changes of kinematics. No further damage to the prototype was noticed.

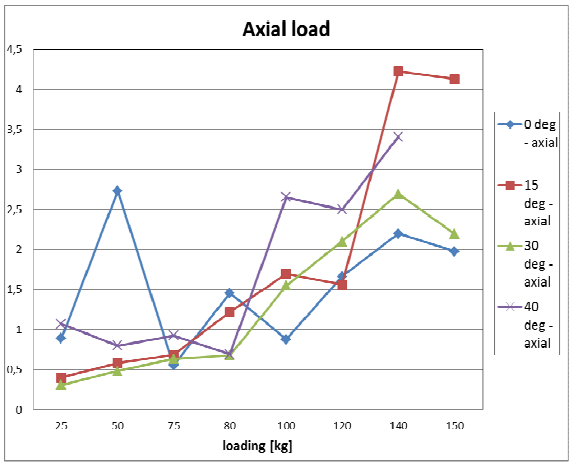


Figure 15. Plot of axial load at 0, 15 and 30 degrees of flexion. Attached mass is given horizontally in kg. Vertically a ratio is given for the force needed for motion initiation.

Transversal and torsion load

No damage or reduced functionality of the hinge occurred after transversal or torsion loading. The ability of the hinge to prescribe relative motion between the hinge parts remained.

After load of 400N was applied transversal, the motion prescribing brass plate slightly deflected. Deformation was not measured and only observed. No plastic deformation occurred.

The amount of friction increased with the amount of load for both configurations in a linear way, as might be expected. The initial angle influences the amount of friction minimally.

Application of torsion load orthogonal to the axial direction of the hinge showed reduced friction during motion compared to transversal loading.

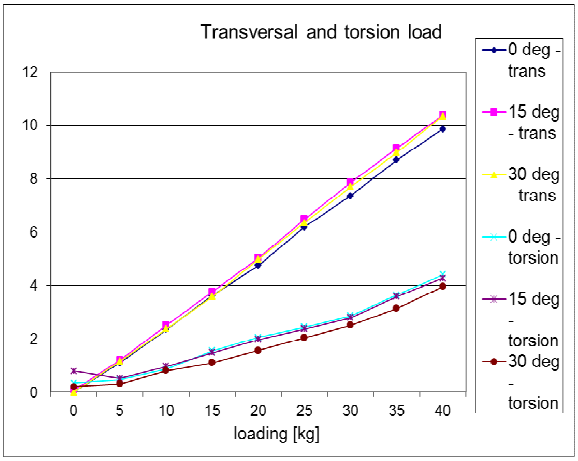


Figure 16. Plot of transversal and torsion load at 0, 15 and 30 degrees of flexion. Attached mass is given horizontally in kg. Vertically a ratio is given for the force needed for motion initiation.

3. Evaluation

3.1. Evaluation dog cadaver tests

Measurements with the developed device provided initial information about cam following possibilities for the reproduction of knee joint motion. The insight that variation in cam follower positions enables optimization of the mechanism to withstand loadings in an optimal way within a certain range of device dimensions turned out to be essential.

Figure 8 gives an impression on the differences in motion trajectories when different cam follower positions are chosen.

The area of measurement strongly influences the outcome of the measurement. Positioning of a system near the joint enables reproduction of movement with a smaller mechanism. Alignment of measurement system relative to the knee joint is for that reason desirable, for example with help of palpation of bony landmarks. Exact alignment is not required, since the method certainly enables little variation in the placement position.

Digital registration of the motion provides the option of optimization of a motion prescribing mechanism to the expected loadings of a certain joint. When information is digitally available, processing data can be accelerated and automatic production of corresponding parts becomes more accessible.

The ability of a joint to be forced into a certain plane of motion was relatively easy for the small knee joint of a dog. It is uncertain how critical the choice of the motion plane is for a larger, and stiffer, human knee joint. This can only be evaluated during clinical tests on patients.

3.2. Evaluation human cadaver test

Alignment

Correct alignment of the test setup in the sagittal plane was found to be difficult. Due to the use of ring fixators, adjustment in the chosen plane relative to the sagittal plane of the knee joint was limited and difficult. Adjustments were needed during two of the three tests since initial alignment deviated from the plane of preference of the joint. Natural motion of the knee joint is known to be at an angle relative to the sagittal plane. The limitations in the settings of the test setup became visible during the measurements of the motion. Recorded trajectories showed to be inconsistent at the lateral side of the cadaver leg. Deviation from the optimal angle of the motion plane delivers an additional motion in varus/valgus direction when the attached device has limited stiffness. This effect was clearly present since the used PMMA plates slightly bend during joint flexion. A stiffer setup with the option to change the orientation of the plane of motion of the device might prevent this effect.

No procedure for correct positioning of the device relative to the joint anatomy was used during the tests. Alignment was done by eye. During one of the three tests (second), positioning failed in two ways. The chosen angle of the plane of motion did not deliver reproducible motion on both sides of the joint (only medial). The position of the device in the plane seemed to be incorrect as well. The measurement was performed at the tibia side of the joint, which increased the length of the recorded trajectories, and required larger parts for reproduction of those.

For optimal reproduction, both hinges need to be aligned in the same plane. No special option for ensuring alignment of the medial and the lateral side of the joint was available in the used setup, which probably contributed to motion recording with little deviations for every joint motion.

Attachment

Limited by the use of an existing fixation mechanism, placement of bone pins and connection to those bone pins, could not be managed in an ideal way. Per bone, only two bone pins were available. The orientation of the bone pins was restricted by medical limitation, which resulted in a small angle between the planes of the bone pins. Stiffness of the connection became directly dependent on the connections between the bone pins and the ring fixator. This effect became visible during the last of the three tests when little motion of the setup along the leg became possible.

Deterioration of soft tissues

The last cadaver test showed less consistent movement of the knee joint.

Every joint stroke delivered motion trajectories with little variation in the recorded motion. This effect was not present during the first test. Joint manipulation by hand clearly showed more flexibility in the tissues. Motion of the joint was not consistent and the reproduced trajectories are therefore less representative for natural knee motion compared to the first test.

3.3. Evaluation technical hinge test

Axial load

Three interesting effects can be distilled from the plot in figure 15. The outlier at zero degrees while loaded with 500N indicates misalignment of the hinge, resulting in possible pretension in the hinge. Secondly, no value is available at 40 degrees for a load of 1500N due to insufficient motion reproduction at that angle, which can be seen for all loads of 800N and higher. The last remark concerns loads above 1200N at an angle of 15 degrees, where the required force for motion initiation increased to over three times the initial force at lower load steps.

Loading of the prototype resulted in damage of one of the three radial bearing in the hinge. The indicative values of the force required for initiation of hinge movement showed increasing values at a loading angle of 15 degrees from a load of 1200N and more. At that specific angle and at that angle alone, all loadings were transferred completely by the affected bearing. The outer shell of the used bearing type was not suitable for the type of loading; the known specifications were valid for loading of the inner ring while the outer ring is surrounded by a casing.

A clear difference of the prototype for the loadings tests compared to the previously used (plastic) hinges, is the stiffness of the device. Small deviations from the exact contour of the motion prescribing part, which is required to have contact with all bearings, can be compensated by low stiffness of materials in such a setup. A device for clinical application is expected to be rigid and provide certain stiffness. The accuracy in the production of the motion prescribing part becomes more critical for such applications.

Transversal and torsion load

Torsion load delivered less friction compared to transversal load. Slight tilting of the motion prescribing plate relative to the casing plausibly changed the contact surface between the bearing plates and the brass plate. Adaptation of that plate might result in reduced friction during transversal loading as well, e.g. by rounding edges and reducing the contact surface area.

Stiffness of the hinge parts is considered to be the first aspect to improve the transversal and torsion load capacity of the hinge. The chosen bearing principle needs further evaluation for a stiffer device in case higher transversal loadings need to be sustained.

4. Conclusions

A new method was developed for external knee motion reproduction, and a proof of principle was arranged. The patient specific approach reduces the impact of treatment since the joint will not be affected during placement, and true reproduction of motion is obtained, instead of general knee motion. Focus on the development of the hinge was required since joint distraction cannot be reliable without accurate motion prescription by the hinge. In order to reduce the impact of the distraction to the knee joint, the amount of distraction should be minimized, which increases the need for such accurate motion reproduction method.

In order to improve robustness and accuracy of the reproduction principle, accurate motion recording is required to ensure accurate motion reproduction.

Further development of the proof of principle is required before clinical evaluation is reachable. Especially the interaction of the hinge mechanism with

the attachment method requires attention. Options for (non-invasive) realignment are essential for correct functioning of a knee motion reproducing mechanism. Application of a hinged device could already be used for accurate stabilization of a knee joint.

When the principle is used for treatment of knee OA, the option of joint distraction needs further evolvement. Distraction with option of resilience in the axial direction of the tibia is expected to be reachable, delivering a new joint distraction method which allows joint motion.

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Sagittal plane for flexion and extension of the knee joint. Last visit February 8, 2012 Adapted from http://prohealthcareproducts.com/images/leg-skeleton-model-lafayette.jpg

Appendices

Appendix A: Nomenclature

Appendix B: Measurements on dog cadaver knees

Appendix C: Measurements on human cadaver knees

Appendix D: Load evaluation of prototype

Appendix E: Journal choice and requirements

Appendix A: Nomenclature

Abbreviations:

OA: Osteoarthritis
EKD: External Knee Distractor
DOF: Degrees Of Freedom
ROM: Range Of Motion
UMCU: University Medical Centre Utrecht
TUD: Delft University of Technology

Definitions:

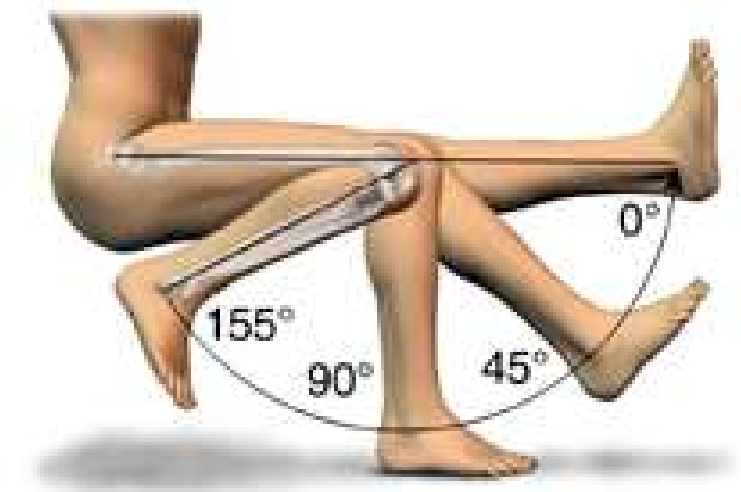


Figure I. *Definition of the knee flexion angle. Adapted from http://www.shalby.org/images/knee_joint_replacement/knee_flexion.jpg Last visit February 8, 2012*

Osteoarthritis:
'A degenerative joint disorder characterized by progressive cartilage damage and loss, changes in bone and other peri-articular tissues, and commonly also secondary joint inflammation. These changes in tissue structure are associated with pain, stiffness, and functional disabilities.' (Intema et al., 2010) [8]

Appendix B: Measurements on dog cadaver knees

Measurement principle

Measurement of joint motion in an arbitrary chosen plane near the sagittal plane of a dog cadaver knee joint was performed based on the principle as shown in figure II. At both sides of the joint, a rigid connection to the bones (femur and tibia) was created with help of crossed Kirschner-wires (K-wires) through the bones. Every connection was used to measure rotation of the attached bone relative to that point. Together with measurement of the distance between both connection points it is possible the track motion of one body relative to another body within a certain region in one plane.

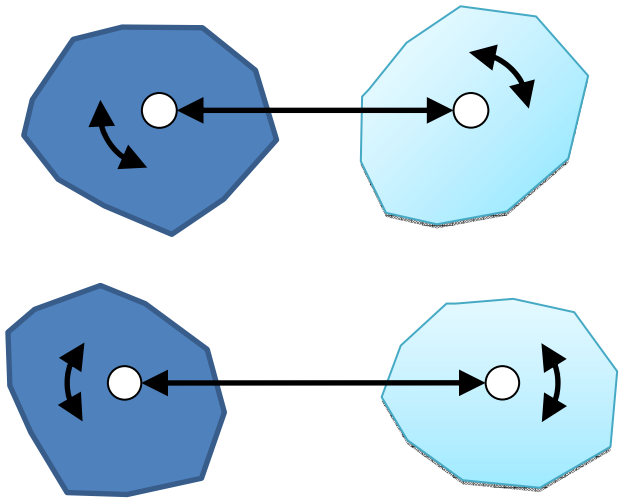


Figure II. Schematic explanation of measurement principle. The white circles represent the rigid connections to the bodies. The arrows denote the measured parameters.

Measurement device

The measurement principle was used in the development of a device for measurement of relative motion between the femur and tibia of a dog cadaver knee. The left picture in figure III shows the device. The device was built of two potentiometers for registration of the rotation at both fixation points, and a laser distance sensor (Brand, type: Feteris, optoNCDT1300) for measurement of the relative changes in distance between the fixation points. All data was acquired with an A/D converter (Brand, type: National Instruments, USB 6008) and processed with help of developed scripts for simulation software (Software: Matlab 2011b).

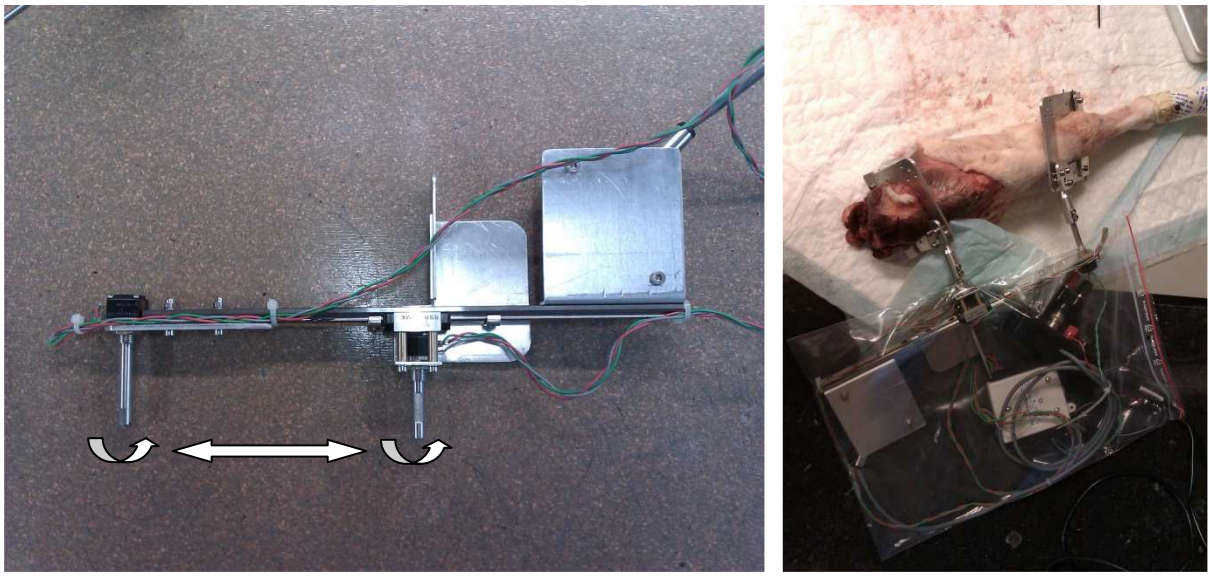


Figure III. Measurement device for registration of movement in an arbitrary chosen plane near to the sagittal plane of a dog knee joint. Left: not attached to a cadaver dog knee with measured parameters denoted by arrows. Right: device attached to a cadaver knee for registration of movement.

The three measured parameters were used to describe the recorded motion. Although motion of any point in the plane of measurement can be used as basis for a motion description, one of the two fixation points was used for sake of simplicity.
Around such a chosen point, the motion of another point relative to that initially chosen point can be calculated from the measured parameters. When multiple points around one point are 'followed', a set of curves can be created. A combination of at least two of such curves prescribes a one degree of freedom motion, as is illustrated by figure IV.

Translation of a set of curves into an exact motion reproducing mechanism was straight forwardly done by using the created curves in a cam following mechanism. Optimization of the curve selection was during this stage of the project no point of attention, and should be considered during later research in order to minimize loads and complexity of the mechanism. Since exact reproduction is aimed for, and no referencing between the joint anatomy and the device is desired, an approach based on fitting a general knee model on the measured data was not chosen. Such general models do not compensate for differences in patients anatomy and require accurate data for optimization in the first place, and an accurate alignment procedure for correct placement in the second place. All those aspects are not desirable and increase the complexity of the procedure to make an accurate motion reproducing mechanism.

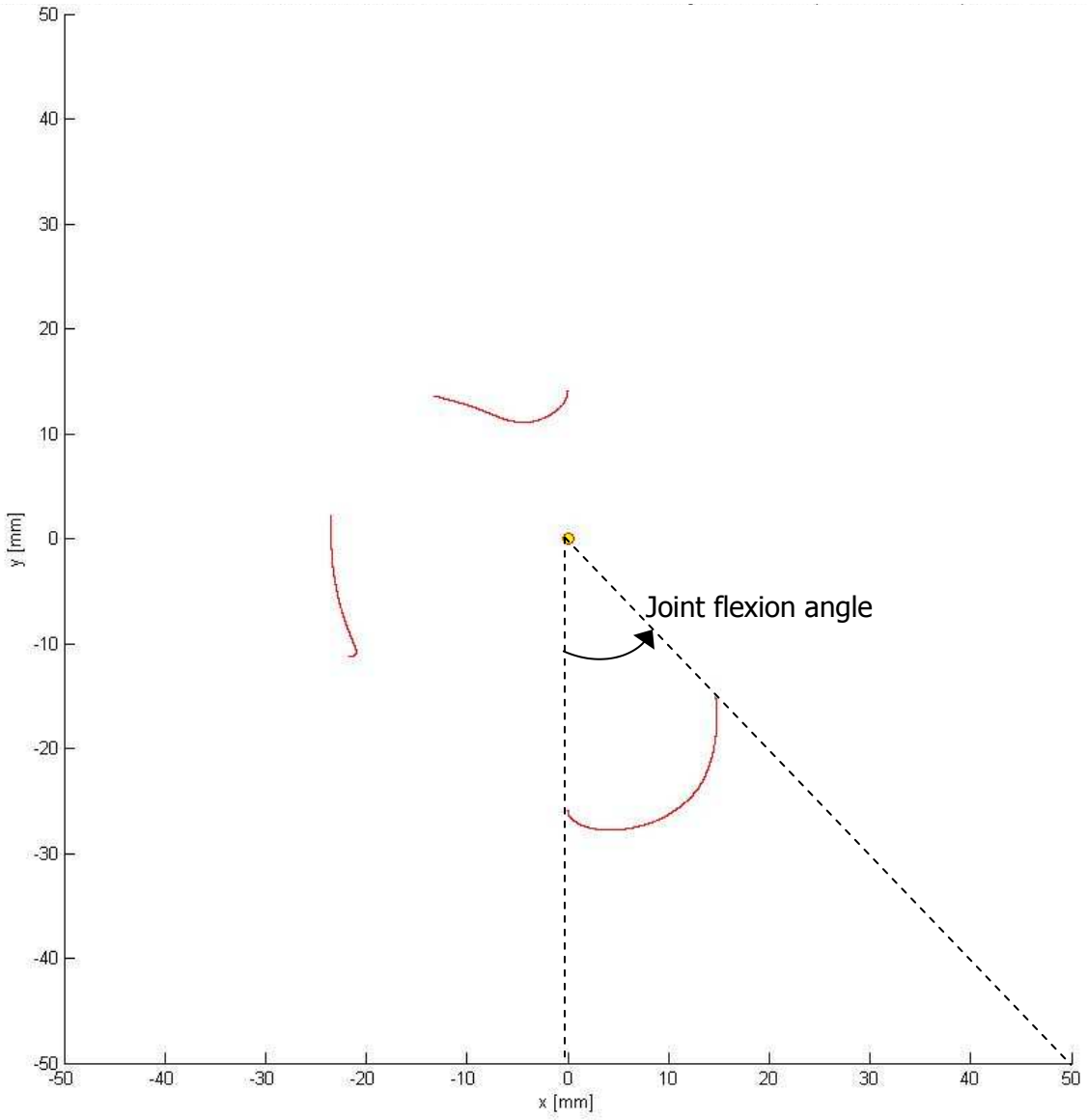


Figure IV. A set of curves around one arbitrary chosen point (during this measurement equal to the axis of one of the two connection points at the femur side of the joint). The dashed lines indicate the flexion angle wherein motion was registrated.

Appendix C: Measurements on human cadaver knees

The used setup enabled coupling and decoupling of motion prescription and motion registration. Initial motion measurements were performed by scratching motion with help of scribers in PMMA (Perspex) plates. Since those scribers were for this setup aligned with the axis of the radial bearings, only compensation for the bearing diameter was required in the process of creating a corresponding motion prescribing part. Motion of the device after placement of the motion prescribing part was measured in order to compare the measurement of 'free' motion in the sagittal plane with the prescribed motion.

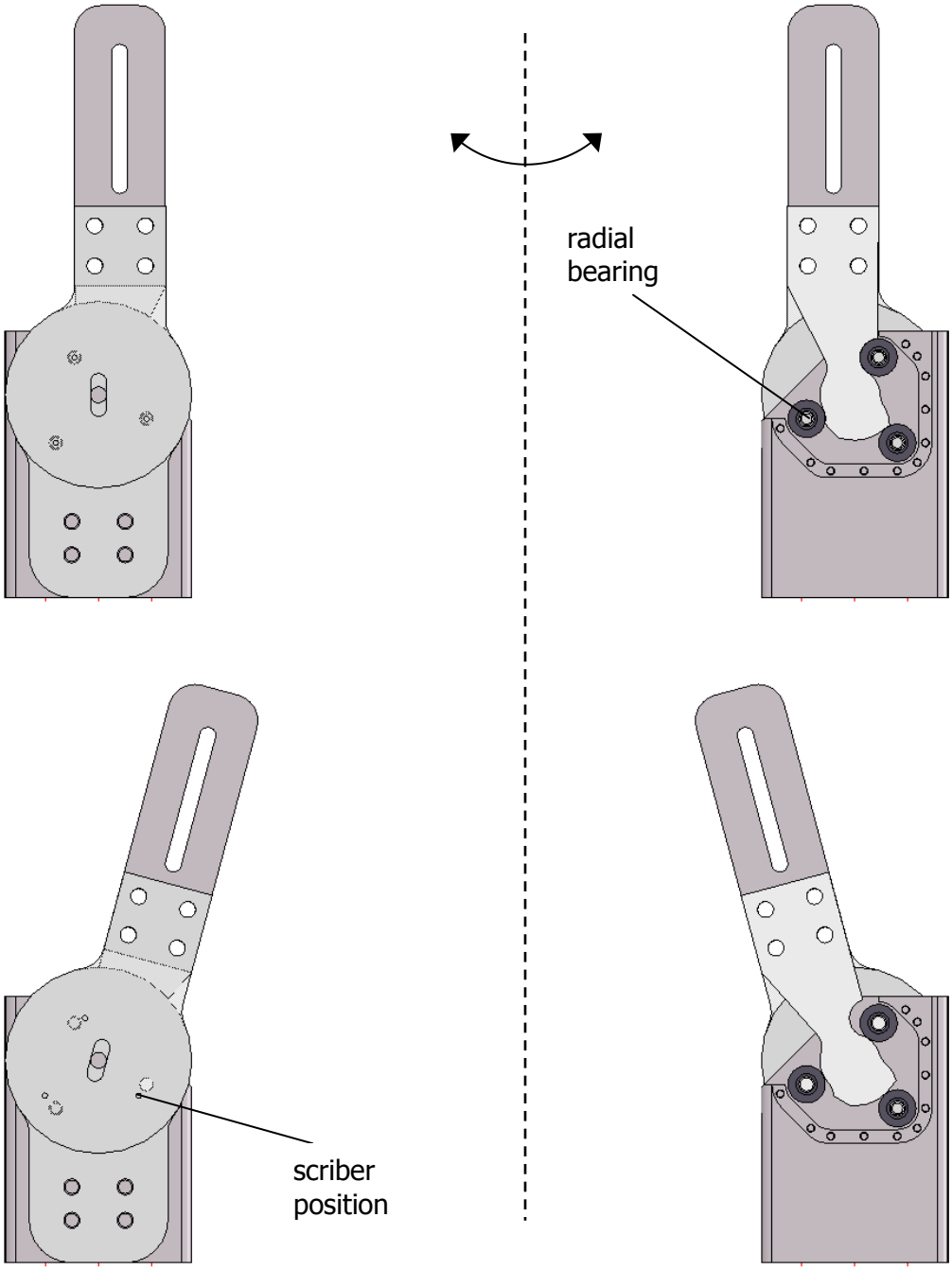


Figure V. Impression of the measurement device as used during analog measurement on a human cadaver knee. Left: scriber positions in line with the axis of the radial bearings at 0deg and 15deg of flexion. Right: mirrored view showing the position of the corresponding motion prescribing part.

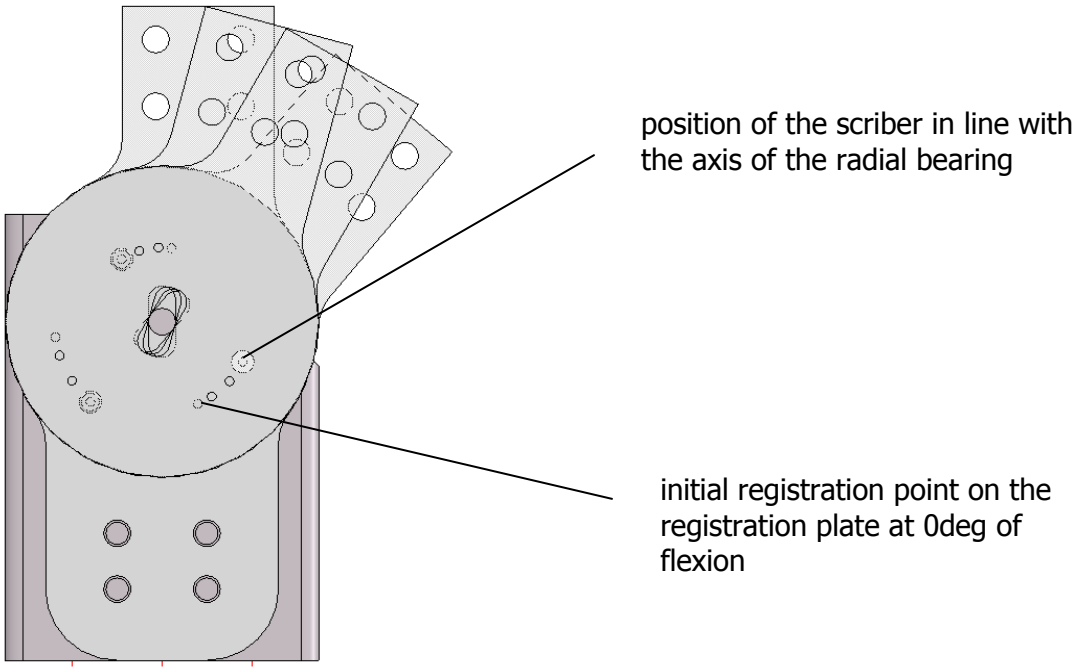
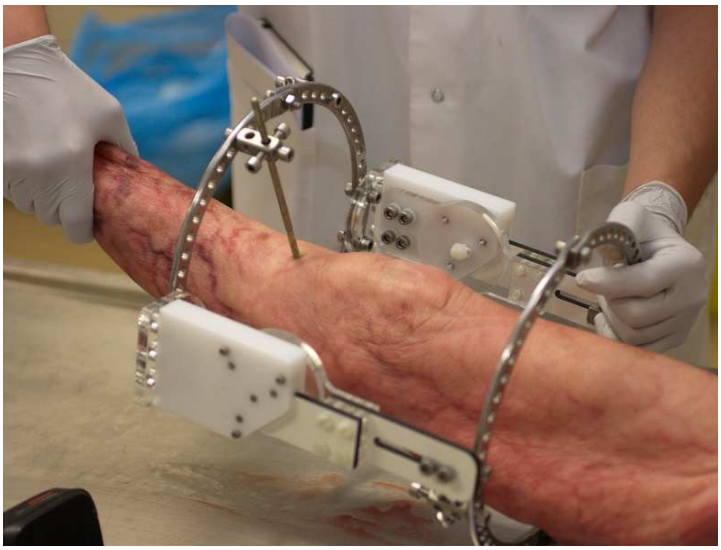


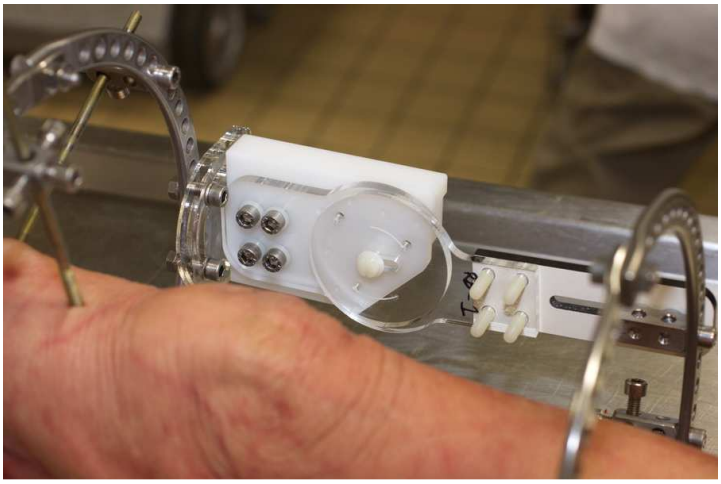
Figure VI. Measurement device with the position of the registration plate at 0, 15, 30 and 40 degrees of flexion. Three measured trajectories are generated in line with the axis of the radial bearings. Notice that the motion of the registration plate above is no a pure rotation.

Figure VII. Registration plates resulting from measurements. (left: medial side of the joint, right: lateral side of the joint). The black lines show the recorded motion trajectories.



Evaluation of joint motion after placement of motion prescribing parts. Motion was reproduced bilateral.

Position of a motion prescribing part at the lateral side of the joint.



Motion registration at the lateral side of the joint.

Figure VIII. Human cadaver knee used for evaluation of the movement reproduction principle.

Appendix D: Load evaluation of prototype

Test setup for axial load evaluation

Figure IX. Impression of setup for evaluation of axial loadings.

Results

One radial bearing failed during the axial load test after. The outer shell of the bearing was unfolded after axial loading as is shown in the figure below. The applied load method was not according to the specifications of the bearing.

Figure X. Impression of the failed radial bearing. The motion prescribing part is positioned in the upper-right corner.

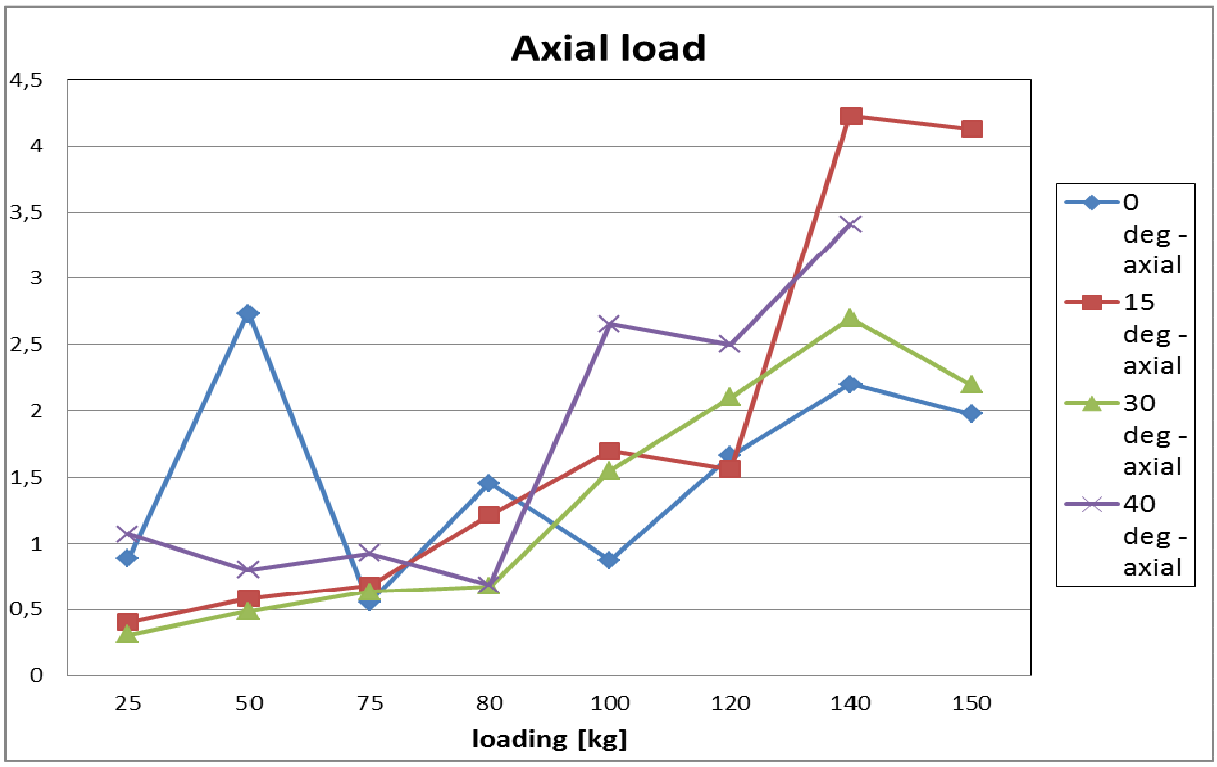


Figure XI. Enlarged plot of figure 15.

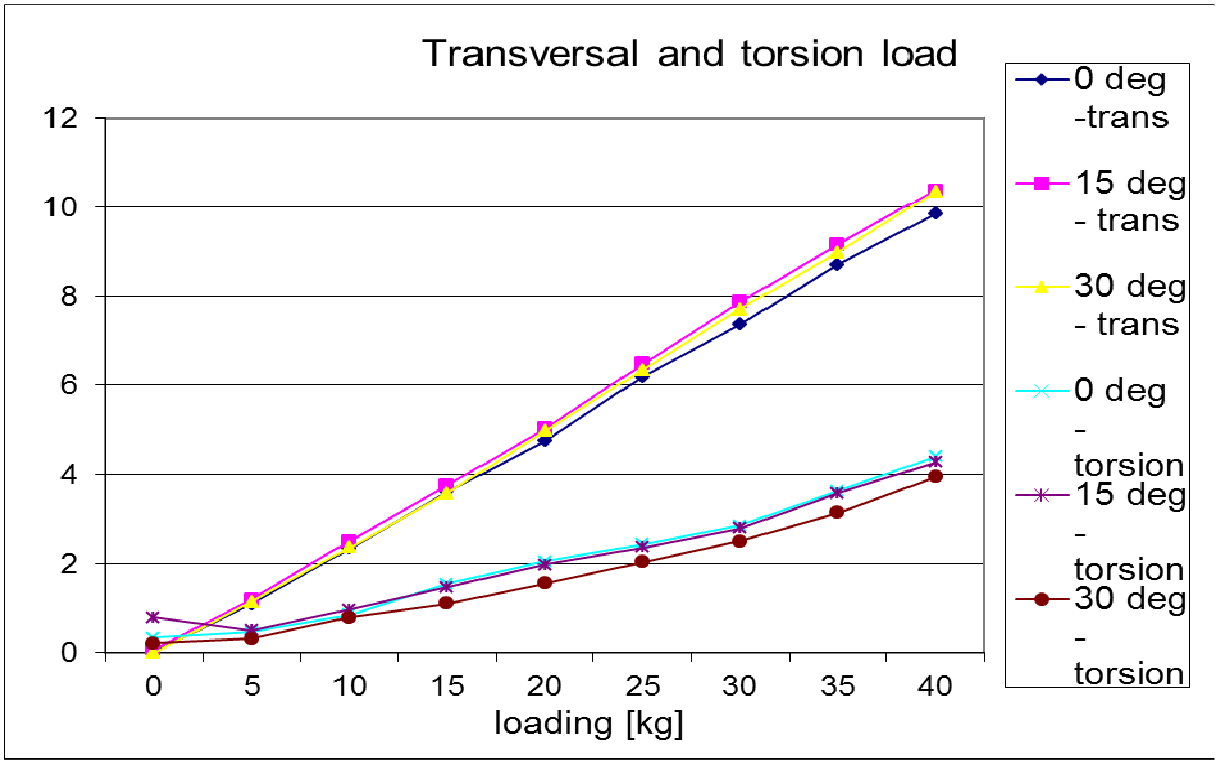


Figure XII. Enlarged plot of figure 16.

Appendix E: Journal choice and requirements

The chosen journal for publication is the International Journal of Medical Engineering & Technology (IJMET). Reasoning for choosing this journal is based on several aspects. In the first place, no clinical evaluation has been performed yet, and only a technical evaluation of the prototype was done. Medical journals are therefore less relevant in this stadium. Another motivation is that the only commercially available product for treatment of knee osteoarthritis, the KineSpring® by Moximed, although this product has an internal approach, was evaluated in the IJMET.

Instructions for authors are given in the next five pages, delivering information concerning the required format.

Journal of Medical Engineering & Technology

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Conference proceedings: [3] Irvin AD, Cunningham MP, Young AS, editors. Advances in the control of Theileriosis. International Conference held at the International Laboratory for Research on Animal Diseases; 1981 Feb 9-13; Nairobi. Boston: Martinus Nijhoff Publishers; 1981. 427 p.

Dissertations or Thesis: [4] Mangie ED. A comparative study of the perceptions of illness in New Kingdom Egypt and Mesopotamia of the early first millennium [dissertation]. Akron (OH): University of Akron; 1991. 160 p. Available from: University Microfilms, Ann Arbor MI; AAG9203425.

Journal article on internet: [5] De Guise E, Leblanc J, Dagher J, Lamoureux J, Jishi A, Maleki M, Marcoux J, Feyz M. 2009. Early outcome in patients with traumatic brain injury, pre-injury alcohol abuse and intoxication at time of injury. *Brain Injury* 23(11):853-865. http://www.informaworld.com/10.1080/02699050903283221. Accessed 2009 Oct 06

Webpage: [6] British Medical Journal [Internet]. Stanford, CA: Stanford Univ; 2004 July 10 - [cited

2004 Aug 12]; Available from: http://bmj.bmjjournals.com

Internet databases: [7] Prevention News Update Database [Internet]. Rockville (MD): Centers for Disease Control and Prevention (US), National Prevention Information Network. 1988 Jun - [cited 2001 Apr 12]. Available from: http://www.cdcnpin.org/

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