Design improvements in Total Knee Arthroplasty

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in
Total Knee Arthroplasty

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Medische Wetenschappen

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Tout ce qui est incompréhensible ne laisse pas d'être
Alles wat onbegrijpelijk is houdt nog niet op te bestaan
(Blaise Pascal, Pensées)

Contents

Chapter 1

Introduction

Total Knee Arthroplasty (TKA) is the most common surgical procedure in case of osteoarthrosis or rheumatoid arthritis of the knee. Currently, about 750,000 TKAs are performed worldwide each year. About 50% is implanted in the USA[23], and approx. 0.8% (6,000) in the Netherlands. It is a successful procedure: different clinical scores show that TKA reduces pain and increases mobility. Only approximately 5 to 10% of the TKAs need to be revised within the first ten years after surgery[15,18,20,21,32]. However, there are still several thousands of revision TKAs performed each year (35,000 in the US only[23]). With the growing numbers for primary TKAs, the annual number of revision procedures is also growing.

The demands on TKA are growing due to the lasting success. TKAs are, more often, implanted in younger patients. These patients are more active, which is more demanding for TKA. TKAs are also applied in more complicated cases. Furthermore, TKA becomes more and more (financially) available for people from other cultures with different demands. For example, in Eastern cultures there is a demand for increased knee flexion of TKA systems. Hence, the demands on TKAs increase, which makes ongoing development inevitable and necessary.

History

The TKA procedure, as it is currently known, is a condylar total knee which evolved in the 1970's. Before the 1970's there had been various unsuccessful attempts. However, it should be noted, that these attempts were performed in very severe cases where the knee joint was completely destroyed and deformed and where the joint often could not bend anymore. These destroyed knee joints were often a secondary effect of a disease (e.g. tuberculosis, gonorrhoea) or an infection. There have been attempts to transplant entire joints[24]! However, a more popular approach was to remove the original joint surfaces and to reshape the bones into a new joint. This was supplemented by the interposition of soft tissues to prevent bony ankylosis. Over the years, several surgeons tried this approach using different interposition materials, e.g. a flap of joint capsule[39], fat and/or fascia lata[1,24,27,29], chromicized pig bladder[4], prepatellar bursa[7], cellophane[34], sheets of nylon[22] and skin[6]. None of these efforts was very successful. Smith-Petersen[36] was the first to use metal components (Vitallium) in mold arthroplasty of the hip joint. Boyd and Campbell[8,31] introduced this concept in knee arthroplasty. Their solution for the knee evolved into the Massachu-

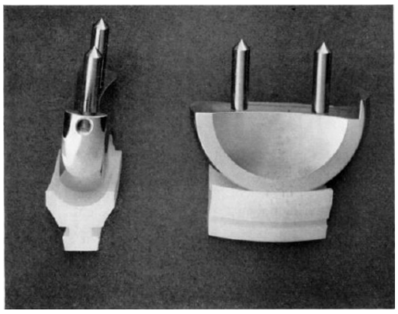

figure 1 (left): hinge type prostheses **figure 2 (right)**: Gunston's Polycentric knee. Reproduced with permission and copyright © of the British Editorial Society of Bone and Joint Surgery. Gunston FH. Polycentric knee arthroplasty. Prosthetic Simulation of Normal Knee Movement. *J Bone Joint Surg* 53-B: 272-277, 1971.

setts General Hospital (MGH) design, which achieved limited success. Hinge designs (figure 1) evolved in the late 1940's and during the 1950's[19,25,35,40]. However, the hinge designs over-simplified the kinematics of the knee joint, as the knee joint is not a simple hinge joint. The biomechanical incompatibility of these simple hinges with the complex motions and loading conditions of the knee, in combination with the negative effects of their metal-on-metal surface contact resulted in unacceptably high failure rates. Important improvements in concepts and materials of (hip) arthroplasty were introduced by Charnley[9] and McKee[26]. These improvements were the introduction of metal on (high-density) polyethylene articulation and the use of acrylic (PMMA) bone cement. Gunston[16] was the first to use these principles in knee arthroplasty. Gunston's Polycentric knee (figure 2) was basically unicompartimental, and consisted of a metal femoral circular runner and a high-density polyethylene tibial component. Finally, in 1970, the basic TKA design as it is still in use today was introduced: the condylar design (figure 3)[33]. This condylar design was a knee resurfacing approach, consisting of a single-piece femoral component and a single-piece tibial component. Furthermore, intramedullary fixation was not the primary mode of fixation. Simultaneously, this approach was introduced by both Freeman and Swanson[13,14], and Kodama and Yamamoto[41]. The first actual posterior cruciate retaining design

figure 3: condylar type prostheses

(Duopatella) was introduced in 1974. In 1977 Buechel and Pappas introduced a solution to achieve lower polyethylene stresses: the first mobile bearing knee design. Since that time, the TKA slowly developed into its current shape and characteristics. It was soon recognized that specialized instrumentation and implant alignment were very important issues. Step by step, the orthopaedic community learned several fundamental features of a good knee implant. It was acknowledged that the femoral design should have an anterior flange, that the tibial PE component should be metal-backed and modular, and that the implant should be available in several compatible sizes. Improvements of the polyethylene (PE) material, improvements of the casting and production processes of the metal and PE components and greater knowledge about the effects of PE sterilization led to significantly improved longevity of the implants.

Components and types

The articulating surfaces of the knee joint are replaced during a TKA procedure. TKA usually consists of a metal on polyethylene articulation. The femoral component is made of metal, and the tibial component typically consist of a polyethylene component which is connected to a metal tray. Resurfacing of the patellar articulating surface with a polyethylene component is optional. The components can either be fixated to the bone with bone cement or with a press-fit bone-to-prosthesis connection. Primary TKAs can, generally speaking, be divided into two types: the posterior cruciate retaining (PCR) type and the posterior sacrificing (PS) type. The posterior cruciate ligament (PCL) is replaced by a post-cam mechanism during the PS procedure. The anterior cruciate ligament (ACL) is sacrificed during both procedures. The advantage of a PCR knee is that less bone has to be resected, which can be of importance during revision surgery. However, although the function of the PCL is to create rollback, it is known that a PCR knee sometimes shows erroneous rollback[12]. Hence, a retained PCL is not always a functional PCL.

A further division between TKAs can be made between fixed bearing and mobile or meniscal bearing TKAs. The mobile or meniscal bearing TKAs also allow articulation between the polyethylene tibial component and the metal tibial tray. The idea behind these TKAs is to reduce polyethylene stresses through an increase in conformity between the components and through a decrease in kinematic constraints.

TKA issues

As indicated above, ongoing development is inevitable and necessary. Knowledge of the weakest part, the type and reason for failure can help to improve TKAs. Furthermore, knowledge of the effects of an increasing demand on TKA can prevent possible failure by foregoing design improvements. There are four major fields, in which continuous development and improvement takes place.

1. **Wear**. The polyethylene (PE) insert and the metal components generally show some amount of abrasive wear, which creates small PE and metal particles. In more exceptional cases, the insert can show delamination or actual breakage. The particles can cause osteolysis (or metalosis), which results in a decrease of bone quality and loosening of the components. Orthopaedic companies are continuously trying to reduce wear by improving the PE and by reducing the surface roughness of the metals (e.g. application of ceramic surfaces).
2. **Kinematics**. Ideally the TKA should restore the physiological kinematics of the knee. Restoring physiological knee kinematics is very difficult, which is shown by the large number of publications about this subject. Femoral rollback, medial- or lateral pivoting, patella tracking and high flexion are hot topics, and not without reason[2,3,5,10,11,17,28,30]. Non-physiological kinematics can lead to problems like post-operative complaints and increased implant wear. High flexion is a different kinematic issue. It causes an increasing demand on TKA, as conventional TKA is not designed for high flexion angles.
3. **Implantation and alignment**. This is affected by the skills of the surgeon, the instrumentation, the implantation technique and possible side effects of the surgery (e.g. infection). Navigation and correct alignment have been very important issues over the last few years. Not without reason, as mal-alignment can neutralize an excellent TKA design. Implantation and alignment are not directly related to implant design and materials, however they bear a significant influence on the longevity of the TKA.
4. **Fixation**. Fixation of the TKA components can be jeopardized by osteolysis (wear particles) and by bone resorption due to a decrease in stress on the bone. Bone resorption often occurs in some areas behind the femoral and tibial components[37,38] as the metallic components are relatively stiff in comparison to the replaced bone. It may lead to loosening of the implant,

which makes TKA revision necessary. Bone defects are a common problem at revision, even for other reasons than loosening of the implant. The fixation of a revision implant becomes more complicated in case of bone defects. The orthopaedic companies put a lot of effort into the improvement of implant fixation and ingrowth of TKAs, and into the prevention of osteolysis due to wear particles. However, instead of prevention of bone resorption, the bone defects are often still filled with metal augmentation.

Questions and structure of this thesis

TKA imposes a lot of changes to the knee joint, which can have negative effects like wear, implant loosening, reduced functionality or post-operative complaints. The main idea behind this thesis is to minimize these adverse effects by decreasing the changes caused by TKA. Hence, to restore the anatomical and physiological situation as close as possible. This main idea was applied to the issues of bone resorption, kinematics and function. The following three questions summarize the topics of this thesis:

1. Are there parameters which can be changed to reduce bone resorption, caused by TKA, without affecting other relevant parameters (chapter 2)?
2. Can the design of the femoral component be changed to obtain more physiological patellar kinematics (chapter 3-7)?
3. Is it possible to increase the range of motion without adversely affecting the mechanical performance in high flexion TKA (chapter 7-8)?

In chapter 2, the bone remodelling behind the femoral TKA component was studied. The stiff femoral TKA component changes the stress pattern in the distal femur, thereby inducing bone remodelling (resorption) in the distal-anterior femur. The objective of this study was to determine whether a different fixation of the femoral component would more closely mimick the pre-operative femoral stress pattern and thereby save femoral bone stock.
The patello-femoral anatomy in relation to kinematics is studied in chapter 3 to 6. It is logical to presume that a more physiological patella tracking after TKA will lead to a reduction in post-operative patellar complaints. The patellar tracking is greatly determined by the direction of the natural trochlea and the prosthetic groove. Therefore, the direction of the natural trochlea was determined in a large series of cadaver femora, in chapter 3. In chapter 4, it was studied whether the direction of the prosthetic groove was similar to the direction of the natural trochlea, and how a truly anatomical prosthetic groove design should look like. The effect of a difference in groove

direction on patellar tracking, was studied in chapter 5, where a comparison was made between pre- and post-operative knee kinematics in an *in vitro* cadaver study. In chapter 6, it was investigated whether the standard medio-lateral alignment of the femoral component introduced a medio-lateral shift of the prosthetic groove relative to the anatomic trochlea. This was studied *in vivo*, during TKA surgery.

The development of a research or a pre-clinical tool was the objective of chapter 7. A mathematical (dynamic finite element) model of the knee was developed, which could be used to simulate kinematic parameters such as patella tracking. Furthermore, it could also be used to simulate kinematic effects of different designs and prosthetic alignments. The principles behind this mathematical model were applied again in chapter 8. The mechanical behavior of high flexion TKA was studied in high flexion. Furthermore, it was investigated whether high flexion TKA resulted in adverse effects within the normal flexion range.

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Chapter 2

A different fixation of the femoral component in Total Knee Arthroplasty may lead to preservation of femoral bone stock

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Abstract

A good femoral bone stock is important for the stability of the femoral component in revision knee arthroplasty. However, the primary total knee may cause significant loss of bone stock in the distal anterior femur. Earlier stress induced bone remodelling simulations have suggested that a completely debonded component may save bone stock in the distal anterior region. However, these simulations did not consider the fixation of a debonded implant and possible secondary effects of micromotions and osteolysis at the interface. The current study tries to combine the preservation of bone stock with an adequate component fixation. Different bone remodelling simulations were performed around femoral knee components with different sizes of the bonding area and different friction characteristics of the debonded area. The fixation of the femoral component with different bonding characteristics is quantified with calculated implant-bone interface stresses. The results show that a bonded femoral component with a debonded inner side of the anterior flange may significantly reduce bone resorption in the endangered distal anterior femur, without jeopardising the fixation of the femoral implant. This effect may be obtained in vivo by using a femoral component with a highly polished inner side of the anterior flange.

Introduction

Bone loss is generally reported behind the anterior flange of the femoral component of a Total Knee Replacement (TKR), but is not regarded as a cause of failure in itself[5]. However, the loss of solid bone stock leads to difficulties in revision arthroplasty. Femoral bone loss in the distal knee, after Total Knee Arthroplasty (TKA), is caused by three major factors: stress shielding (stress induced bone remodelling), wear and implant loosening[10]. It is assumed that stress induced bone remodelling causes an 'osteopenia' type of bone loss, whereas wear causes an 'osteolysis' (soft tissue) type of bone loss. The osteopenia type of bone loss is found in several studies, during the first 1-2 years after TKA, with plain radiographs or DEXA measurements[5,6,9]. The decrease of bone stock behind the anterior flange of the femoral component is significant. Petersen et al.[6] determined an average decrease of 36% in BMD using DEXA, and Mintzer et al.[5] observed bone loss in the distal anterior femur in 68% of the reviewed cases. They used plain radiographs, and a change of at least 20% in bone density is required in the distal anterior femur to be detectable roentgenographically[5]. As no continuation in bone loss is found after 2 years, the stress induced bone remodelling seems to be an initial post-operative problem, which reaches a new equilibrium after a relative short period of time.

A stiff femoral component will alter the strain and stress distribution in the distal femoral femur from a highly stressed region to a relatively low stressed region. The (local) forces on the medial and lateral condyle of the femoral component are redistributed over the implant-bone interface, and the patellar (local) forces are also redistributed over the anterior flange. Stress transfer can be equally distributed over the whole interface, but it is also possible that it only takes place locally at the edges of the prosthesis. It is feasible that this shielding effect is most pronounced in the region behind the anterior flange, as this is the loading area of both tibio-femoral and patello-femoral forces. The region behind the anterior flange is 'shielded' from both of these forces through the anterior flange of the femoral TKA component. The effect of stress shielding is expected to be smaller in case of a debonded implant, as the interfacial situation is less suited to transfer shear stresses over the implant-bone interface. Therefore, interfacial stress transfer has to take place mainly through normal stresses. It is expected that these changes in stress transfer will result in a higher loading of the region behind the anterior flange.

Stress-induced FEM bone remodelling simulations performed by Van Lenthe et al.[8] confirm that the distal femur is subjected to stress shielding to a lower extend in case of a debonded femoral component. These simulations show less bone resorption behind a debonded implant in comparison to a bonded implant. These simulations, however, do not take into account that a debonded implant will not be very stable, that the component-bone interface will therefore show micromotions leading to the generation of a soft tissue layer and early failure of the component.

The research question in this study was whether we were able to reduce bone resorption behind the anterior flange of a femoral TKA component in comparison to the resulting bone stock after a standard bonded TKA, but without jeopardising implant fixation as in case of a debonded TKA. For this purpose, stress induced finite element bone remodelling in the distal femur, around a femoral implant, was simulated with different interface bonding areas and bonding properties (friction), and varying implant material properties.

Materials and Methods

An FE-model of a distal femur with femoral TKA component was developed through adaptation of an existing model[8]. This model was CT-based with a known bone mineral density distribution. The FE-program MARC 7.3 (MSC.Software, Palo Alto, CA, USA) in combination with bone remodelling routines[11] was used to simulate the stress induced bone remodelling. The model consisted of 2328 8-node isoparametric brick elements and 2892 nodes. The material properties were isotropic. The Young's Modulus of the bone was calculated from the known bone mineral density distribution as described by Van Lenthe et al[8]. The modelled femoral TKA component was a CKS cruciate retaining knee prosthesis (STRATEC

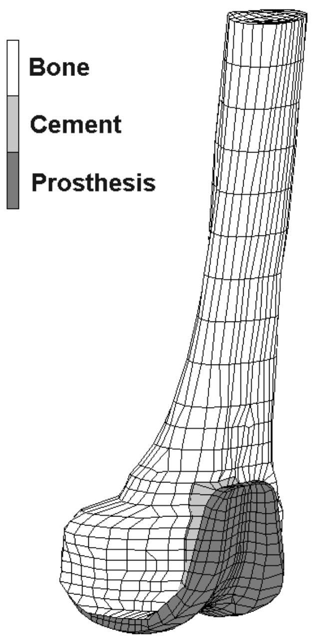


figure 1: finite element model

Medical AG, Oberdorf, Switzerland). The component was positioned onto the distal femur according to instructions from the manufacturer. A cemented femoral component was modelled, but without cement pockets. Therefore, no cement elements were modelled in between prosthesis and bone at locations at which both were in immediate contact. Most cement elements were modelled behind the medial side of the anterior flange and at the edges of the prosthesis around the distal and posterior condyles (figure 1).

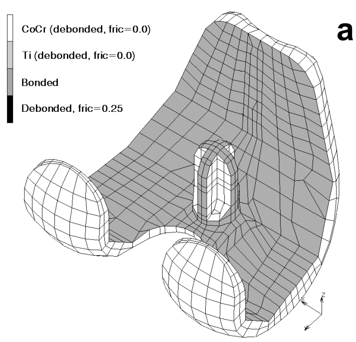
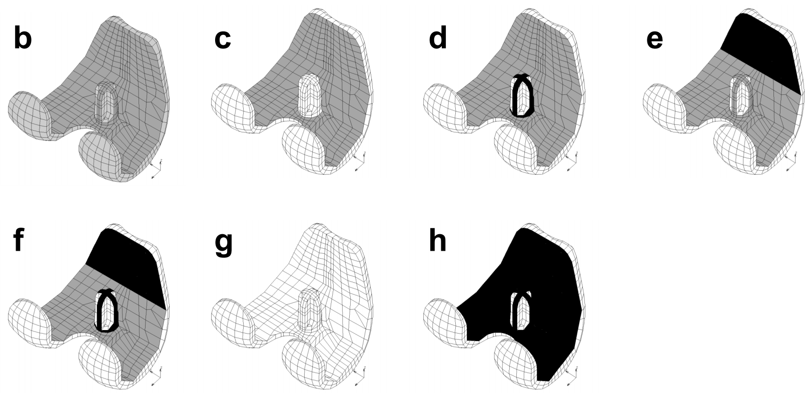


figure 2: **a.** completely bonded implant, **b.** completely bonded titanium implant (E = 110 MPa), **c.** bonded implant with debonded peg (fric. coef. = 0.0), **d.** bonded implant with debonded peg (fric. coef. = 0.25), **e.** bonded implant with debonded anterior flange (fric. coef. = 0.25), **f.** bonded implant with debonded anterior flange and central peg (fric. coef. = 0.25), **g.** completely debonded implant (fric. coef. = 0.0), **h.** completely debonded implant (fric. coef. = 0.25)



Eight different situations were modelled (figure 2):

1. completely bonded CoCr implant (figure 2a, E = 210 GPa),
2. completely bonded Ti implant (figure 2b, E = 110 GPa),
3. bonded CoCr implant with debonded peg (figure 2c, friction coefficient = 0.0),
4. bonded CoCr implant with debonded peg (figure 2d, friction coefficient = 0.25[2,4]),
5. bonded CoCr implant with debonded anterior flange (figure 2e, friction coefficient = 0.25),

6. bonded CoCr implant with debonded anterior flange and central peg (figure 2f, friction coefficient = 0.25),
7. completely debonded CoCr implant (figure 2g, friction coefficient = 0.0),
8. completely debonded CoCr implant (figure 2h, friction coefficient = 0.25)

The debonded- and completely bonded situations were modelled with the CONTACT option. In the partly bonded situations, the opposing nodes of bone and implant were connected using ties. The interface between bone and implant consisted of double nodes with exactly the same coordinates. Bone remodelling was simulated for all cases using the validated adaptive bone remodelling theory[11,13]. The values of the remodelling constants were identical to those used in bone remodelling around hip[12] and knee prostheses[11]. This theory is based on changes in strain energy density between the pre-operative and post-operative situation during activities of daily living. If the post-operative strain energy density is within a defined limit from the pre-operative situation strain energy density (dead zone), then the bone density is left unchanged. If, from the pre-operative to the post-operative situation, the strain energy density increases at a certain location, and the upper limit of the dead zone is crossed, then the bone density will be increased at this location. If the strain energy density will decrease at a certain location, and the lower limit of the dead zone is crossed, then the density of the bone will be decreased at that location. Three load cases during daily living were applied, including muscle forces: heel strike and toe off during normal walking and one load case during cycling (figure 3 and table 1).

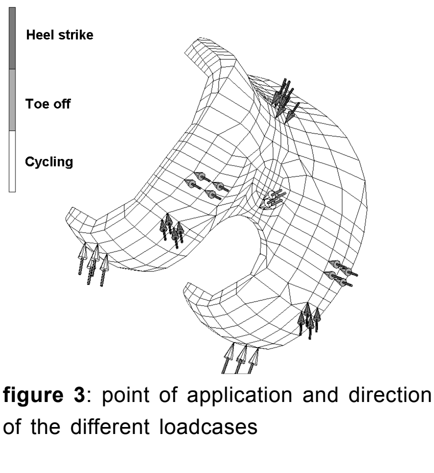


figure 3: point of application and direction of the different loadcases

The changes in bone mineral content (BMC) distribution were visualised using simulated DEXA scans. In different pre-defined regions of interest (ROI), both in frontal and sagittal view, the change in BMC was quantified. Ten ROI's were defined; five in the antero-posterior direction (figure 4a) and five in the medio-lateral direction (figure 5a). The location of the ROI's was chosen in regions which are clinically very suscep-

loadcase	Patello-femoral	Tibio-femoral-medial	Tibio-femoral-lateral
Heel strike	1738.8	1650.8	990.2
Toe off	98.8	714.4	239.3
Cycling	715.4	356.9	228.1

table 1: applied loading cases during bone remodelling simulation

tible to bone resorption or which are just close to the implant-bone interface. To assess the stability of the fixation of the component, shear and tensile stresses were calculated along the interface. Higher interface stresses would indicate a less favourable situation in terms of fixation. To quantify whether the fixation was more or less loaded, the total interface surface area was calculated. The stress level beyond which 2.5 and 5% of the interface surface area was stressed with either tensile or shear stress was calculated. This procedure was performed to reduce the effects of artifacts at singular points in the model and to reduce the influence of just a single peak stress, which may not be so reliable. The interface values were calculated during the initial remodelling phase.

Results

The simulations show a remodelling pattern, which is similar to clinical observations. The distal and distal-anterior regions were most susceptible to bone resorption. ROI 1 and 5 (figure 4) and ROI 6 and 10 (figure 5), show the highest decrease in BMC. ROI 1 and 5 cover the distal condyles. ROI 6 covers the antero-distal region, and ROI 10 the region just posterior of the central peg.

The completely bonded implant and the completely debonded implant (without friction) depict the most extreme cases of bone resorption and bone stock preservation (figure 4 and figure 5). The simulation for a completely bonded implant shows a severe bone resorption within each ROI, resulting in a BMC always in between 3 and 63% of the pre-operative situation. The simulation for the completely debonded implant shows minimum bone resorption, the resulting bone stock is in between 31 and 117 % of the pre-operative BMC.

Debonding the anterior flange, and minimising friction characteristics of the debonded interface were the most effective parameters to preserve bone stock. The situation with the, less stiff, titanium implant showed only a small difference in comparison to the completely bonded implant. Both situations

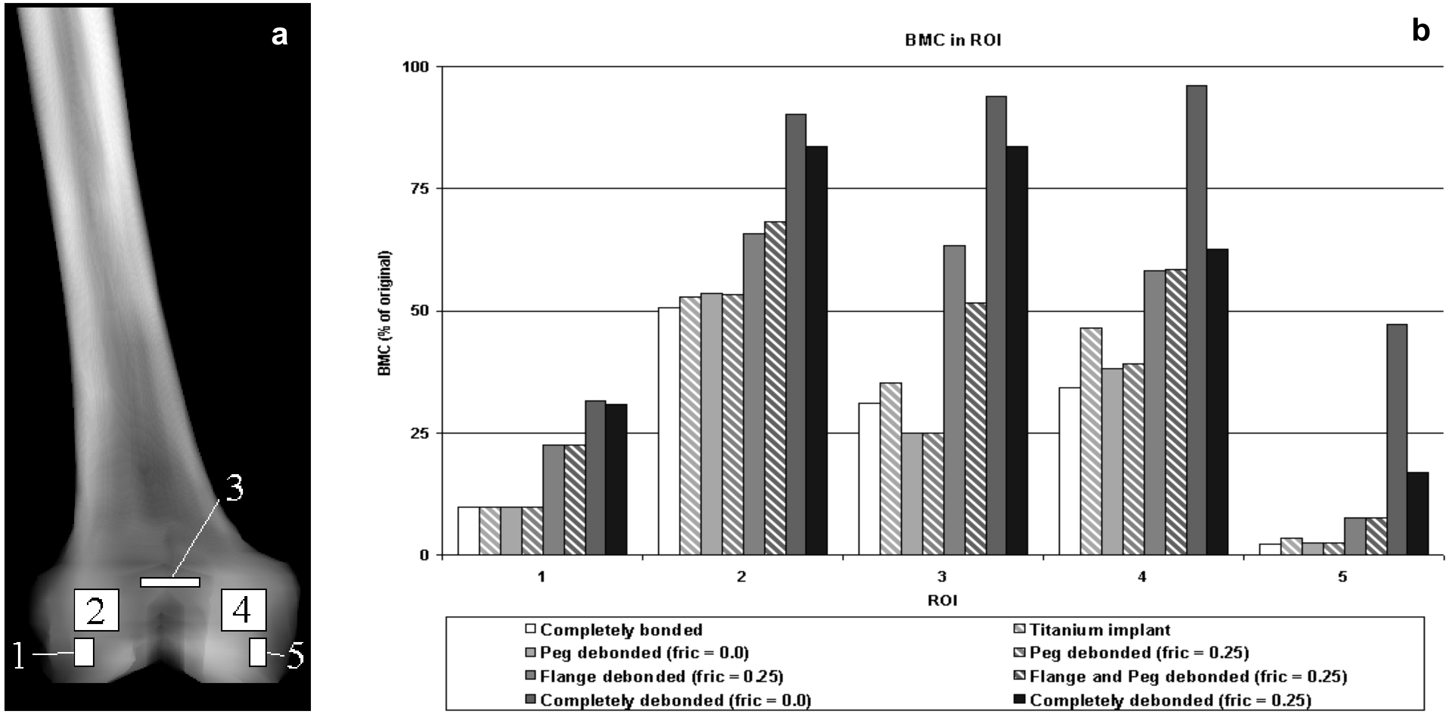


figure 4: **a.** Regions of Interest (ROI) in antero-posterior view. Implant is removed from the bone, **b.** Bone Mineral Content (BMC) as a percentage of the pre-operative BMC, in antero-posterior ROI's (legenda showing the debonded area).

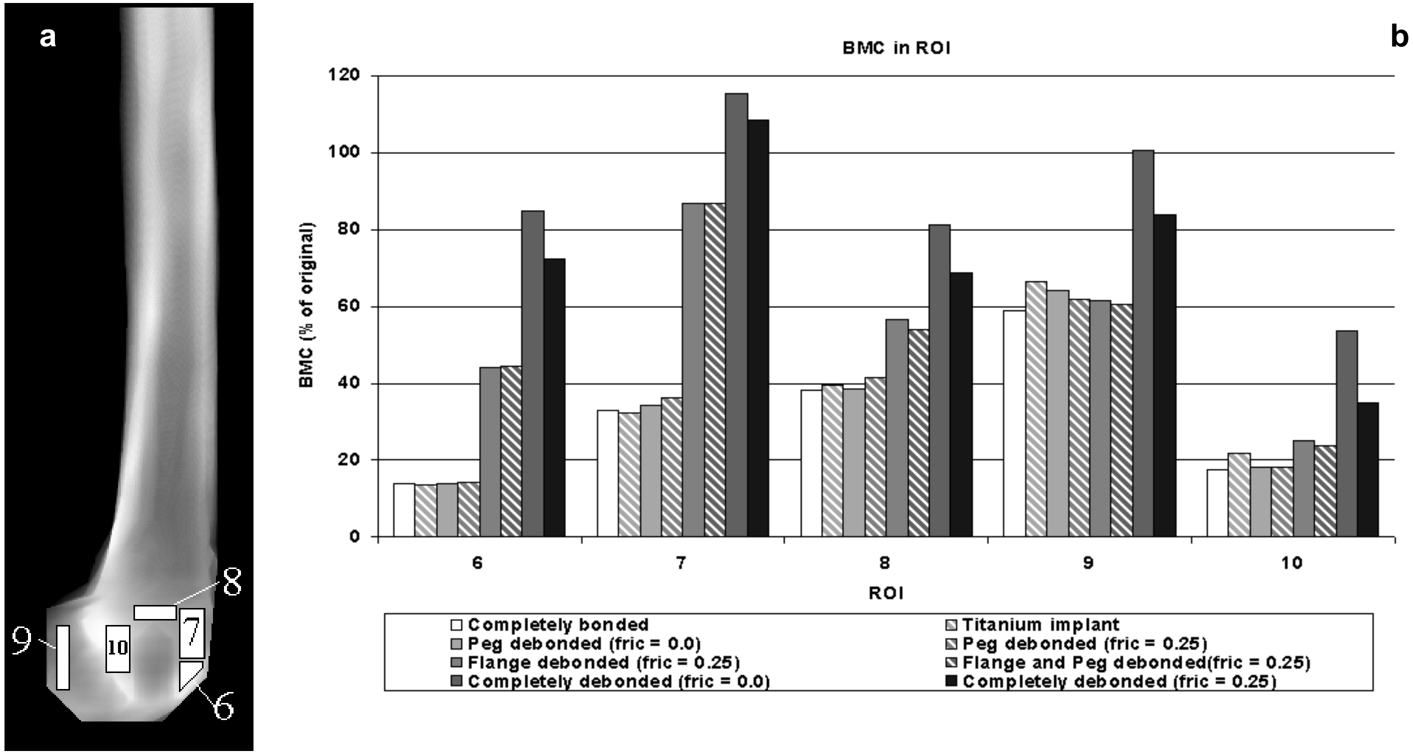


figure 5: **a.** Regions of Interest (ROI) in medio-lateral view. Implant is removed from the bone. **b.** Bone Mineral Content (BMC) as a percentage of the pre-operative BMC in medio-lateral ROI's (legenda showing debonded area).

with the debonded peg also did not show a smaller decrease in bone stock. The situation with the debonded anterior flange performed very well. This option showed, except for region 9, a considerable improvement of bone stock in comparison to the completely bonded situation. There was even a more than 200% increase in the preservance of bone stock in the ROI's 6 and 7, which are the specific bone resorption areas. A combination of a debonded anterior flange and a debonded central peg did not result in a further improvement of the bone stock. The situation of a debonded implant with friction (versus no friction) showed that the addition of friction resulted in considerable differences. The simulation showed more bone resorption in comparison to the debonded situation without friction, but less resorption in comparison to all the other cases.

	Normal tensile stress		**Shear stress**	
	2.5%	**5.0%**	**2.5%**	**5.0%**
Completely bonded	0.600	0.275	2.900	1.975
Titanium implant	1.125	0.400	3.300	2.025
Peg debonded (fric=0.0)	0.500	0.200	2.625	1.875
Peg debonded (fric=0.25)	0.500	0.200	2.625	1.850
Flange debonded (fric=0.25)	0.525	0.200	1.775	1.350
Flange and peg debonded (fric=0.25)	0.300	0.050	1.575	1.050
Completely debonded (fric=0.0)	0.000	0.000	0.000	0.000
Completely debonded (fric=0.25)	0.000	0.000	0.925	0.700

table 2: implant-bone interface normal (tensile) and shear stress (MPa). The table shows lower boundary of the stress distribution above which still 2.5 or 5 % of the surface area is loaded. For each modelling option, a 2.5% interface surface area was determined which suffered from the highest normal or shear stress. The lowest normal or shear stress still found within this 2.5% surface area is displayed in the second and fourth column of this table, respectively. This procedure was repeated for a 5% surface area (third and fifth column).

Debonding the bone-implant interface, or a part of the bone-implant interface, did result in lower interface stresses (table 2). If the different remodelling options were ranked from high to low interface tensile stresses, than the completely bonded titanium implant showed the highest interface tensile stresses. This was followed by the completely bonded implant (none), debonded flange, debonded peg with and without friction, the debonded flange and peg, and totally debonded implant with and without friction. This ranking was only slightly different for the interface shear stresses: completely bonded titanium implant, completely bonded implant, debonded peg without friction, debonded peg with friction, debonded flange, debonded flange and debonded peg, totally debonded implant with friction. The case with a totally debonded implant without any friction obviously produced zero normal tensile and shear stresses.

Discussion

This study consists of two parts: a remodelling simulation with different implant-bone bonding characteristics, and a calculation of the implant-bone interface stresses. The bone remodelling simulations showed similar patterns as observed in clinical practice. The remodelling simulation showed that a cemented femoral component with a debonded anterior flange might save a considerable amount of bone stock in the endangered anterior-distal region. A debonded peg does not result in preservance of bone stock, and a less stiff titanium implant does not seem advantageous either. The calculation of the implant bone interface stresses showed a decrease in interfacial stresses of an implant with a debonded anterior flange, relative to a completely bonded implant. Hence, a debonded (polished) anterior flange produces less bone resorption and lower interface stresses.

It should be noted that this paper presents the results of a bone remodelling simulation, which only takes mechanical factors into account. The model does not show which changes take place at a cellular, (mechano-) biological level. It predicts the result of individual cellular actions at a macro level; bone resorption and -apposition. This kind of simulation cannot predict any osteolysis type of bone loss due to wear particles or micromovements. The bone remodelling process is simulated using the finite element (FE) method. The results of an FE-model should always be approached more in a phenomenological way than in a quantitative way. For this reason, this study does also not present maximum stress values, but certain stress boundary values within the stress distribution. An overall cement layer was omitted in the model. Modelling actual cement pockets would have resulted in very thin cement elements. These elements would then have a bad aspect ratio and give less exact results. Omitting the cement layer represents a worst case scenario for the interface. The stiffness of bone cement is slightly higher than that of trabecular bone, but much lower in comparison to the stiffness of the implant material. For a small part, inclusion of a thin cement layer would therefore have decreased the interface shear stresses. The simulation of the bone remodelling is continued until the strain energy density of the implanted situation 'matches' the pre-operative situation. This definition of taking this 'equilibrium' as the cut-off time of the calculation is not arbitrary, but it is shown to overestimate the bone remodelling result[3]. The 'equilibrium' situation was nevertheless used, as it is the only possibility to make a good comparison between the different situations. The applied loads are activities of daily life. It is not so important for the simulation that, for example, cycling may not be a very common activity for some TKR patients. It should be more or less a typical load in which axial, bending and torsional components are included. The directions of a cycling load will not differ much from the direction of the load in stair climbing.

The results presented in this study are comparable to the results of Tissakht et al.[7]. Tissakht et al. used an FE-model to compare the strain energy density between the intact distal femur, a distal femur with a completely bonded knee prosthesis and a distal femur with a knee prosthesis bonded only at the distal prosthesis-bone interface. Only one loading case was applied and the stiffness of the bone was more simplified in comparison to this study. They concluded that bone resorption can be expected in the anterior distal corner of the distal femur after total knee replacement, even if the fixation was only limited to the distal interface. In their opinion, a straightforward approach towards the reduction of stress-shielding was not apparent in that zone. In that respect, we disagree with Tissakht et al., as their strain energy density calculation with a partly debonded component also shows a huge reduction in stress shielding in comparison to the completely bonded component. This reduction in stress shielding may result in an improved bone stock during revision surgery.

The bone remodelling simulation and determination of the interface stresses with the titanium implant shows similar characteristics as found with titanium hip implants[12], albeit to a lesser extend. A less stiff implant results in less stress shielding and therefore preservance of bone stock. However, it results in higher interfacial stresses. In case of cemented implants, these higher interfacial stresses may lead to earlier failure of the cement-implant interface, which may again lead to earlier failure of the implant or disintegration of the cement layer.

The bonding characteristics of the central peg had no significant influence on the preservance of bone stock. The authors are of the opinion that the central peg is redundant concerning bone preservance and stability, but it may be necessary for design reasons or for a correct medio-lateral placement of the femoral component.

The stability of the implant will change with changes of the fixation principle. It is very difficult to predict whether the stability of the implant with a debonded anterior flange is improving or not. The results showed lower interface stresses for the partly debonded components in comparison to the completely bonded component, which suggests more longevity of the interface. However, the completely debonded component shows the lowest boundary stresses on the interface and that situation is regarded as an unstable fixation or something which is at least clinically unacceptable. As the boundary stresses are lower for the partly debonded situations in comparison to the completely bonded situation, the partly debonded situations have at least a lower risk on further debonding of the implant-cement interface. This may certainly improve implant fixation over a longer time period.
This study shows that a femoral component of a TKA with a debonded anterior flange seems advantageous, but there may be a few difficulties. Wear particles can enter the bone behind the anterior flange, which may induce osteolysis. Micromotions between anterior flange and bone may cause a similar tissue reaction. Both disadvantages may be overcome to some extent with an anterior flange, which is polished at the inner side, which may be initially cemented to the bone. It is known that a cemented highly polished surface will debond almost immediately after insertion. The cement closes the bone to wear particles, and micromotions at the implant-cement interface will not cause a soft tissue reaction. The results of Ezzet et al.[1] suggest that a cement mantle could protect against osteolysis.
In summary; the bone remodelling simulation suggest that a femoral component with a debonded anterior flange saves bone stock at an important clinical location. The calculated implant-bone interface stresses give no reason to assume that the fixation of the implant to the bone will become inadequate because of the debonded anterior flange.

Acknowledgement

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Chapter 3

The trochlea is bilinear and oriented medially

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Abstract

Malfunctioning of total knee replacements often is related to patello-femoral problems. Because the trochlea guides the patella during flexion and extension, its geometry has a major influence. There is a controversy in the literature: relative to the mechanical axis, some authors have found a laterally-oriented trochlea and others have found it to be oriented medially. The groove of implanted prosthetic femoral components always have lateral or neutral orientations. The objectives of the current study were to clarify the controversy found in literature, to determine whether the trochlear orientation is truly linear, and to determine whether the orientation depends on the size of the femur. The trochlea of 100 human femora was measured using a three-dimensional measurement system. Detailed analysis of the results indicated that the trochlea is best described as bilinear, with the distal half oriented 0.2° ± 2.8° laterally and the proximal half oriented 4.2° ± 3.2° medially. Trochlear orientation was not dependent on bone size.

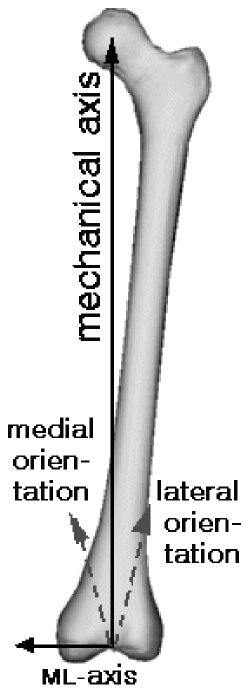
Introduction

The trochlea guides patellar movement during flexion and extension of the knee. It functions as a pulley for the extensor mechanism[9], and the patella protects the anterior knee. According to the Swedish Knee Arthroplasty Register, approximately 5500 total knee replacements are done in Sweden each year[13], and that number is increasing. The survival of total knee replacements is approximately 95% at 7 years, which is good. However, patellofemoral problems are not infrequent. Boyd et al.[2] described problems including: patellar loosening, subluxation, fracture, rupture of the patella tendon, and chronic peripatellar pain. They observed these problems in 4% (patellar resurfacing) and 12% (no patellar resurfacing) of patients with total knee replacement, respectively. In many cases, etiology could not be determined. The problems might be caused by improper tissue balancing, different groove trajectory, or a mismatch between the patella and trochlear geometry.

Most femoral components are implanted in external rotation, and asymmetric femoral components always have neutral or lateral, but never medial, oriented grooves. According to Petersilge et al.[11] the reason for the lateral groove design is based on a theoretic decrease in shear force and an earlier patellar capture.

The current study focuses on the trochlear trajectory. Only two studies were found in which the orientation of the anatomic trochlea was determined. These studies were contradictory regarding the orientation of the trochlea. Eckhoff et al.[4] measured 85 femurs from a Sudanese population. The femur was placed at a 45° angle and the measurements were done with a stereotactic device. The orientation of the intercondylar sulcus was obtained by measuring its deepest point during repeated horizontal passes with the stereotactic device. They found a laterally oriented trochlea (3.6° ± 0.5°), relative to the mechanical axis of the femur. A laterally oriented trochlea means that it is pointed lateral to the mechanical axis of the femur, pointing lateral to the center of the femoral head (figure 1). Feinstein et al.[6] measured the trochlear orientation of 15 femurs. The trochlea was marked using radiopaque wire and its orientation was determined using antero-posterior (AP) radiographs. They found a medially oriented trochlea (1.4° ± 3.7°), relative to the mechanical axis of the femur. Hence, these studies show conflicting results in terms of anatomical trochlear orientation.

The first objective of this study was to settle this controversy by measuring



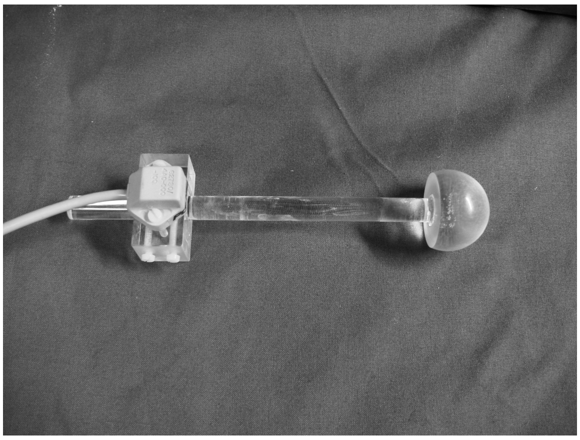


figure 1 (left): the origin of the coordinate system resides at the inferior most AP projection of the trochlea; the mechanical axis connects that point to the center of the femoral head, while the ML axis projects medially and laterally perpendicular to the mechanical axis. Medial orientation projects superiorly and medial to the mechanical axis from the origin while lateral orienation projects superiorly and laterally
figure 2 (top): a polymer measurement probe was used to determine the orientation of the trochlea

a large number of femurs from European individuals to determine the trochlear orientation relative to the mechanical axis of the femur. Patellar tracking might be regarded as an indirect measurement of the trochlear orientation. Because patellar tracking measurements never show a linear path[12,14], the second objective was to determine whether a linear approximation of the trochlear orientation is correct. Anatomic measurements often lack accuracy which is probably caused by the variability in human anatomy. However, variability is also introduced when the bone anatomy is not exactly scaled with bone size. Therefore, the final objective was to determine whether the trochlear orientation is dependent on bone size.

Materials and Methods

One hundred cadaver femurs, which originated from the anatomy department of the university, were measured. No information was available regarding cause of death, age, or gender. The bones were fixed in formaldehyde. The cartilage areas were intact, although many bones suffered from degenerative arthrosis. Femurs showing deformation, trochlear insufficiencies, etc. were excluded from the study.

To measure the three-dimensional geometry, 3SPACE Fastrak (Polhemus, Colchester, VT) was used. This system consists of a source and a sensor. The source generates a known electromagnetic field, of which the strength and direction (Eulerian angles) can be measured by the sensor. Metallic (electroconductive) materials distort the electromagnetic field and were avoided. An, in house made, polymer measurement probe (figure 2) and clamp (figure 3) were used. The sensor was mounted on the probe, which consisted of a rod with a sphere attached to it (figure 2). The center of the sphere was determined by a calibration procedure. The three-dimensional measurement system is able to measure continuously and discontinuously (after keypress). Our measurements showed that Fastrak determines a certain point position, using a probe, with a standard deviation of 0.16 mm. The bone was clamped horizontally, with both condyles in contact with the ground plate of the clamp (figure 3). Three points were measured on the horizontal ground plate of the clamp. The intercondylar notch was measured as one point. It was defined as the posterior endpoint of the floor of the trochlea. The surface of the femoral head was measured continuously. The trochlea also was measured continuously, starting at the notch distally and ending at the anterior cartilage edge proximally.

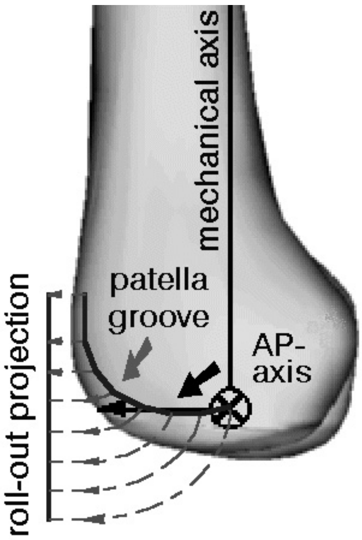


figure 3 (left): the setup of the probe and clamp, which were used during the measurement, is shown

figure 4 (right): the measurement data were transferred to the frontal plane using the roll-out principle

The coordinate system was determined by the bone anatomy. The proximo-distal axis was equal to the mechanical axis: a line between the intercondylar notch and the center of the femoral head. The medio-lateral axis was perpendicular to the mechanical axis and within the plane defined by the mechanical axis and both posterior condyles. The antero-posterior axis was perpendicular to the other two axes.
The measured trochlear points were projected to the frontal plane (defined by the proximo-distal and medio-lateral axes) in a roll-out way (figure 4). This means that the real distance between the points in the sagittal plane (defined by the proximo-distal- and antero-posterior axes) was determined. These real distances were plotted as the proximo-distal coordinate against the medio-lateral offset of the trochlea. A straight line was fitted through these projected points, and the angle between this line and the mechanical axis was determined.
Visual inspection of these measurements did not support a straight linear approximation of the trochlear geometry; two intersecting lines appeared more appropriate. Therefore, in addition to a fit using one straight line, the projected trochlear groove was divided into two equidistant portions and a straight line was fitted through each portion, separately. The phenomenon that the trochlea initially follows a straight (linear) trajectory, then, rather suddenly, changes to a different linear trajectory, is called bilinear (figure 5).
To show that a bilinear approximation was significantly better compared with a linear approximation, the fitting error was determined for five bones chosen arbitrarily.

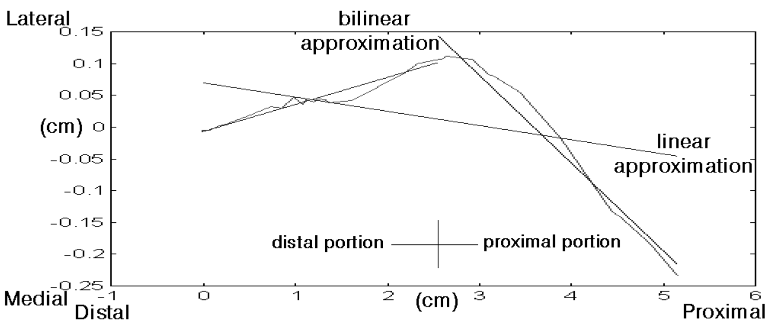


figure 5: the roll-out projection of a trochlear groove with the straight line and the bilinear approximation shown

The same person (SvdG) did all the measurements. To determine reproducibility, one bone was measured 15 times, without reclamping. This resulted in 15 measurements of the four point sets: ground plate, femoral head, notch, and trochlear groove. Sensitivity of the calculated trochlear groove angle to point sets can be estimated by a variation between the 15 measurements of only one point set (for example the three ground plates) and applying only one measurement of the other three point sets (femoral head, notch, and trochlear groove). In case of variation in ground plate or trochlear groove measurements, the variability in trochlear groove angle was determined. In case of the variation in femoral head or notch measurements, the variability in three-dimensional position was determined.
The reproducibility of bone reclamping was tested next. Fifteen measurements of all required points were done, reclamping between each measurement. For each measurement, the trochlear angle was determined.
Next, the actual trochlear angle was determined. To reduce the effects of potential measurement errors, every femur was measured five times without reclamping. To decide between measurement differences and measurement errors, the Chauvenet criterion, as reported by Dally and Riley[3], was applied. Averages and standard deviations of the trochlear angles were calculated for each bone. Finally, the averages and standard deviations of all measured bones were determined.
To analyze whether the trochlear angle was dependent on bone size, the bones were divided into different size groups using the AP sizers for a total knee replacement system (CKS System, STRATEC Medical, Oberdorf, Switzerland).

Results

The reproducibility results (table 1) showed that the variability between the measurement of the trochlear groove point sets is most influential to the determined trochlear angle. The variance in measurements of ground plane point sets least influenced the results. The standard deviation in trochlear angle between 15 trochlear groove point sets was 0.3°. The standard deviation with a variation between 15 ground plane point sets was 0.1°. The standard deviation in femoral head and notch position was 0.7 and 1.3 mm, respectively. If the femur length is approximately 400 mm, then a 0.7 mm medio-lateral position difference will result in a 0.1° trochlear groove angle difference.

Measurement	Average trochlear angle or position	Standard deviation
Groundplane (degrees)	1.1	0.1
Trochlear groove (degrees)	0.9	0.3
Position of femoral head (mm)	1.0	0.7
Position of notch (mm)	2.3	1.3
Reclamping (degrees)	0.3	0.4

table 1: reproducibility measurements

The reproducibility of bone reclamping showed a standard deviation of 0.4° in trochlear angle. With 15 measurements, this means that the 95% confidence interval is within ± 0.23° of the calculated mean value.
The actual trochlear groove orientation measurement of the 100 femurs, using a straight line approximation, showed an average trochlear angle of 1.8° oriented medially (table 2), with a standard deviation of 2.1°. The trochlear angle was oriented medially relative to the mechanical axis of the femur. The standard deviation for each separate bone (n = 5) was never raised above 1.0°. The application of the Chauvenet criterion excluded two femurs.

Femur Size	Trochlear Orientation	Orientation Distal Portion	Orientation Proximal Portion
Extra small and Extra small+ (n=17)	1.3° ± 2.4° (2)	-0.1° ± 3.0° (1)	2.5° ± 3.2° (2)
Small (n = 30)	2.2° ± 2.1°	-0.1° ± 2.8°	5.0° ± 2.4°
Medium (n = 32)	2.4° ± 3.3°	-0.3° ± 3.0° (1)	4.2° ± 3.6° (1)
Large (n = 17)	1.7° ± 2.1° (1)	-0.4° ± 2.3° (1)	5.2° ± 2.5°
Extra large (n = 4)	1.3° ± 0.5°	-0.4° ± 1.7°	3.6° ± 1.1°
All (n = 100)	**1.8° ± 2.1° (7)**	**-0.2° ± 2.8° (3)**	**4.2° ± 3.2° (3)**

table 2: trochlear orientation results. Positive angle is a medial orientation, a negative angle is a lateral orientation. The value between brackets shows the amount of measurements removed with the Chauvenet criterion

For many bones it was found that a bilinear approximation would be an improvement compared with a linear approximation (figure 5). This visual result is supported by the fitting errors shown in table 3. This table shows the total approximation error divided by the number of measured trochlear groove points for the linear approximation and both portions of the bilinear approximation for five arbitrary chosen measurements.
The bilinear approximation showed a decreased approximation error as much as approximately 100%. The actual measurement of the 100 femurs, using two consecutive straight approximations, resulted in a distal average trochlear angle of 0.2° lateral (table 2) and a more proximal average trochlear

angle of 4.2° medial. The Chauvenet criterion was applied, which eliminated two measurement sets in the distal and the proximal portion.

Femur Number	Linear Approximation Error (mm/point)	Distal Portion Bilinear Approximation Error (mm/point)	Proximal Portion Bilinear Approximation Error (mm/point)
1	0.2	0.1	0.0
2	0.4	0.1	0.3
3	0.2	0.1	0.2
4	0.5	0.1	0.5
5	0.2	0.1	0.1

table 3: difference in fitting error between a linear and bilinear approximation in five arbitrary measurements. fitting error = Ó (medio-lateral distance between measured point and approximation)/number of points

No relationship between trochlear angle and size was found. Table 2 also shows the average trochlear angles, with the bones subdivided according to size. The linear approximation showed an average medial trochlear angle between 1.3° and 2.4°. The bilinear approximation showed a distal portion oriented laterally between 0.1° and 0.4°. The proximal portion showed a medial orientation between 2.5° and 5.2°, in which the sizes small and large were almost identical.

Discussion

According to Leblanc[10], adequate patellar tracking depends on proper positioning of the prosthetic components, soft tissue balance, and patello-femoral implant design. Failure to obtain satisfactory patellar tracking will lead to catching, crepitation, excessive wear, lateral subluxation and dislocation, loosening of the prosthesis, and continual patient discomfort. Correct placement of the tibial and femoral components is essential in obtaining proper (anatomic) patello-femoral function. Leblanc[10] reported on resurfaced patellas.

The current study describes the measurement of the trochlear angle, relative to the mechanical axis of the femur. Small standard deviations of several parameters suggested that the method was reproducible and reliable. Fifteen measurements of the same bone, reclamping between measurements, showed a standard deviation of 0.44°. Because the femurs were kept mounted during the real measurement and because the trochlear orientation usually is described in whole degrees, half degrees, or both, this seems to be an acceptable value.

It could be argued that the spherical shape of the probe used is not in agreement with the inner geometry of a patella. The authors hypothesized that the patella is always in contact with both the lateral and medial edges of the trochlear groove (figure 6). Goodfellow et al.[7] and Hehne et al.[8] measured a medio-lateral contact band between 0° and 90° flexion and two-point contact with higher flexion angles. Their results support the applied hypothesis. The size of the probe was not adjusted for various sizes of bones. The sphere of the probe was designed with a radius which always guaranteed two-point contact between the sphere and the femur during flexion and extension. Therefore, the specific size of the probe was not expected to affect the results.

figure 6: two-point contact between the probe and trochlear surface is shown

The linear approximation results showed a medially oriented trochlea, which is in agreement with Feinstein et al.[6], but in disagreement with Eckhoff et al.[4]. Eckhoff et al.[4] used accurate measuring devices, but their measurements principally were two-dimensional and the calculated orientation of the trochlea was fixation dependent. They also used bones from another race and it is possible that this has an effect on the trochlear angle[5]. The method used by Feinstein et al.[6], using AP radiographs, basically resulted in the measurement of the more proximal part of the trochlear groove.

The plotted results clearly show a bilinear trochlea (figure 5), with the intersection point approximately halfway along the sulcus. This visual assessment is supported by fitting errors that were calculated for five arbitrary femurs. The bilinear approximation was an improvement in all cases. The fitting error of the distal half was considerably smaller. The bilinear approximation has, as far as the authors know, never been published before. The measurements of Van Kampen and Huiskes[14] and Rhoads et al[12] measured from 0° to 150° maximum flexion, showed a curved patella tracking result, thereby confirming a bilinear track as found in the current study. The in vitro patella tracking results[1,12,14], are shown from full flexion to extension (figure 7). The trochlear groove measurement described in the current study started near the intercondylar notch, therefore the results also can be seen from flexion to extension. During in vivo and in vitro patella tracking, the patella is not in contact with the trochlea during full extension (patella above proximal cartilage ridge) and greater than 90° to 100° flexion (patellar center has passed the intercondylar notch). The current study only measured the orientation of the trochlear groove. Therefore, the results should be compared with published results of patella tracking in the range of 20° to 90° flexion. At 90° flexion, the patella is located near the intercondylar notch. If the patella tracking results [1,12,14] (figure 7) are considered, they all show a small or clear medial shift extending from 90° to 55° flexion. The results presented in this study show a small lateral or neutral-oriented distal half of the trochlea. Therefore, a slightly lateral or neutral patellar shift would also be expected in this area with patellar tracking measurements. The patella tracking results all show a clear medial shift during extension from 55° to 20° flexion. This medial shift during the final phase of extension is in agreement with the current results of the trochlear orientation.

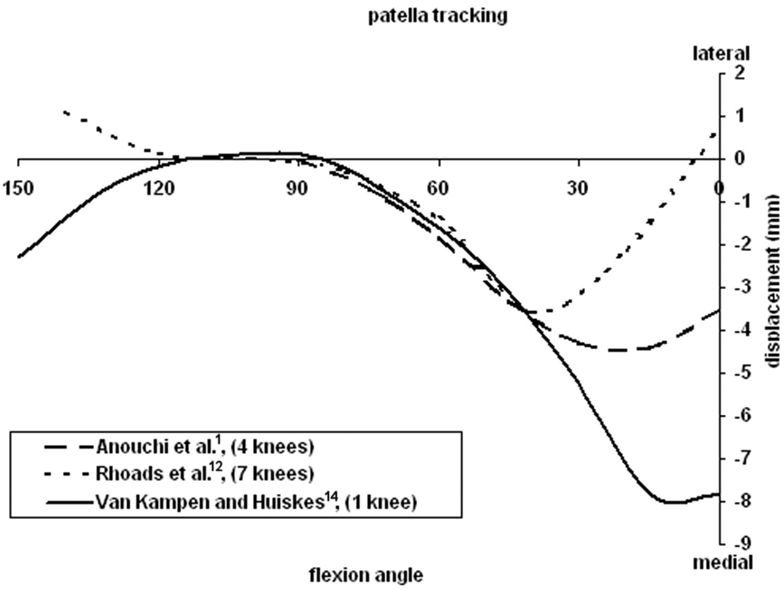


figure 7: patella tracking results, as reported in the literature, are shown from full flexion to extension and the medio-lateral displacement of the patella is zeroed at 90° flexion. This makes it possible to compare figure 5 (trochlear groove measurements) with figure 7 (patella tracking)

The current study provides suggestions for the contradictory results of Eckhoff et al.[4] and Feinstein et al.[6]. In a large series of femurs from European subjects, a medial trochlear angle was measured, using a linear approximation of the trochlear groove. However, the trochlear groove was shown not to follow a linear path. It was shown that the trochlea can better be approximated with a bilinear track. Finally, no relation between femur size and trochlear angle was found.

Acknowledgement

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Chapter 4

The difference in trochlear orientation between the natural knee and current prosthetic knee designs; towards a truly physiological prosthetic groove orientation

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Abstract

The patella groove of Total Knee Replacements has evolved from a groove with a neutral orientation to a groove with a lateral (also referred to as valgus) orientation. In this study the authors questioned whether femoral components with a lateral groove orientation more closely approximate the configuration in the natural knee. The groove orientations of an implanted CKS femoral component, available in different sizes and with different groove orientations, were determined and compared with formerly published measurements of the natural trochlear orientation. It was found that the prosthetic groove orientations differed considerably from human anatomy, up to a maximum deviation of 6.4°. The orientations of the prosthetic grooves were all equal within the area of the natural trochlea. The area of the natural trochlea guides the patella between about 30 and 120 degrees of knee flexion. The orientations of the prosthetic grooves were different in the area of the supracondylar pouch/proximal anterior flange. This area guides the patella between about 0 and 30 degrees of knee flexion. As this study showed a considerable deviation between natural and prosthetic groove orientation, an optimal prosthetic groove orientation, matching the average orientation in the natural knee, was mathematically determined.

Introduction

Most currently available Total Knee Replacements (TKR) show a good to excellent survival. For example, for the Kinematic knee (Howmedica, Rutherford, New Jersey, USA), revision rates of 6.5%[5] and 10%[14] are reported after 10 year follow up. The Swedish Knee Arthroplasty Register, including over 40,000 Total Knee Arthroplasties (TKA's) with different implants[12], shows similar revision rates after 10 year follow up. The main reasons for revision are loosening, infection, progressive radiolucency, wear/mechanical and patellar problems.

Patellar replacement is an optional procedure in TKA; some surgeons resurface all patellae while others decide only to resurface those patellae which show clear signs of degeneration. Both procedures show similar revision rates[8,12], but the reported complications are different. Of the patella related complications, loosening of the patellar component was reported as most common in patellar replaced TKR[2,5]. Pain was reported as major complication in TKR without patellar replacement[2].

Patellar complications can be related to different (interrelated) causes. For example, loosening of a patellar component can be caused by an inferior fixation and patello-femoral pain can be caused by changes in the extensor mechanism or by disease related factors. However, both loosening and pain can also be due to non-physiological patello-femoral forces, which are caused by changes in the tracking pattern. This prosthetic patellar tracking pattern is determined by the alignment and design of the components, but also by releases, scar tissue and the surgery in general. The main determinant within the patello-femoral mechanism is said to be the design of the prosthetic groove[8]. This groove is determined by the geometry and the position/alignment of the femoral component. The geometry of the groove is determined by the groove orientation, depth, shape/congruency and raised ridges.

Conventional prosthetic components have a groove orientation that can either be symmetrical (figure 1a) or asymmetrical (figure 1d). An asymmetrical groove is defined to have a lateral orientation, as the groove turns laterally as it is followed in the superior direction. A symmetrical groove does not turn medially or laterally as it is followed in the superior direction. Apart from the groove orientation, the shape of the anterior flange can also be symmetrical or asymmetrical (figure 1f vs. figure 1c). It should therefore be noted that

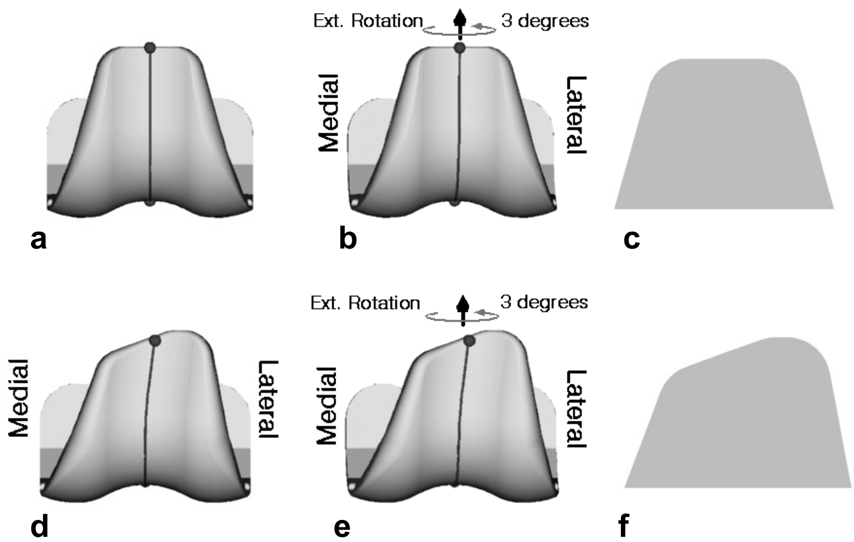


figure 1: **a.** a femoral component of a Total Knee Replacement with a symmetrical patellar groove. The figure shows the groove as a dark straight line. **b.** a femoral TKA component with a symmetrical patellar groove, externally rotated for 3°. **c.** the symmetrical geometry of the anterior flange. **d.** a left femoral component of a Total Knee Replacement with an asymmetrical patellar groove. The figure shows the groove as a dark curved line. **e.** a left femoral TKA component with an asymmetrical patellar groove, externally rotated for 3°. **f.** the asymmetrical geometry of the anterior flange.

it is possible to have a femoral component with an asymmetrical shape of the anterior flange, but with a symmetrical groove orientation. The main purpose of this flange asymmetry is to improve anterior bone coverage.

It is suggested that a femoral component with a laterally oriented patella groove is a more anatomically shaped component[3,4] and would create a more physiological tracking pattern[5,7,10]. However, this is not supported by the literature. A medial orientation of the natural patella groove was measured in a radiological study on a small number (n=15) of femora[6]. The sulcus was physically marked with fine radio-dense wires and the orientation of the wires was measured using multi planar orthogonal radiographs. A medial orientation of the natural trochlea was also found by the current authors, in a large study measuring 100 cadaver femora[1]. Although components with a lateral groove orientation are often called 'anatomical', as there is a left to right difference and as they are thought to be more anatomical, it is questionable whether the term 'anatomical' is appropriate. It seems that the lateral groove orientation of modern femoral TKA implants does not result in a correct approximation of the groove orientation in the natural knee. The first purpose of the present study is therefore to quantify the difference in the groove orientation between the natural knee and conventional prosthetic knee designs, with a special emphasis on a component with an 'anatomical' lateral groove orientation. The second aim is to quantify the design parameters of an optimal prosthetic groove orientation, exactly matching the groove orientation in the average natural knee. The authors applied the assumption that the patella was not resurfaced. Therefore, patellar button placement and design were no parameters in the current study.

Materials & Methods

Cadaver measurements

The groove orientation of the natural knee was measured in a former study[1]. For clarification of the measurement procedure, a global summary of this publication is described. The anatomical orientation of the trochlea was determined from 100 cadaver femora. The trochlear orientation was measured using a 3-dimensional measurement system (3SPACE Fastrak, Polhemus, Colchester, VM, USA) together with a specially designed probe. Figure 2 shows the definition of the trochlear orientation in the cadaver situation. A laterally oriented trochlear orientation means that the trochlea is pointing lateral relative to the mechanical axis of the femur, and therefore pointing lateral to the center of the femoral head. The measurement probe had a spherical head of 34 mm in diameter, which was meant to touch the lateral and medial side of the groove. It was not our aim to measure the orientation of the sulcus, but to measure the direction in which the patella would have to move. The probe was moved through the patella groove, starting distally and ending at the proximal osteochondral ridge. The measurement system measured the 3-dimensional coordinates of the center of the sphere using continuous data acquisition: thereby simulating patellar movement (figure 3). This set of points was projected onto the frontal plane, using a so-called roll-out projection (figure 4). This frontal plane

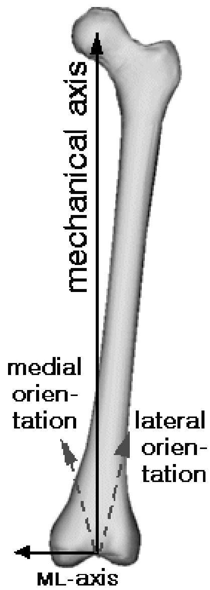
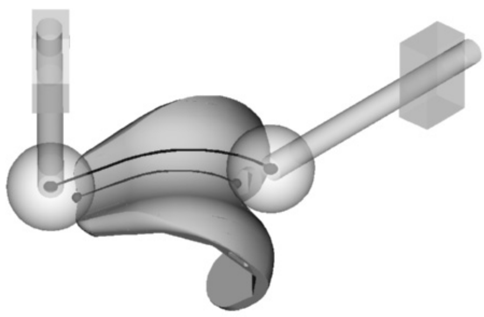


figure 2: definition of the orientation of the patella groove in cadaver femora and virtually implanted situation



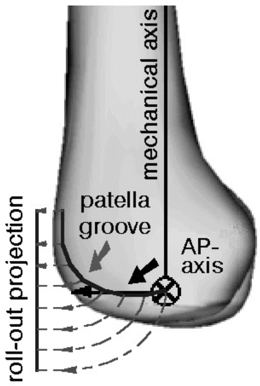


figure 3 (left): ‘measurement’ of groove orientation.
figure 4 (right): Principle of roll-out projection; a projection onto the frontal plane of the femur, which takes the vectorial distance between the groove points into account. The AP-axis is perpendicular to the frontal plane.

was parallel to the mechanical axis of the femur and parallel to the line connecting the most posterior points of both femoral condyles. The authors[1] showed that the natural groove orientation followed a path which could be approximated by two consecutive straight lines: a bilinear approximation. The angle (the groove orientation) was determined between each of the consecutive straight lines and the projected mechanical axis. Figure 5b shows a set of points projected onto the frontal plane, which are fitted by a bilinear approximation.

Prosthetic groove orientation

The same measurement procedure as used for the cadaver measurements was mimicked for the prosthetic knee, applying the procedure in a computer simulation. CAD files of the CKS cruciate retaining femoral knee component (Continuum Knee System. STRATEC Medical AG, Oberdorf, Switzerland) were used. This CKS implant is clinically used and can be regarded as a standard femoral TKA implant. The femoral component has a symmetrical (neutral) groove orientation and a symmetrical anterior flange shape. The manufacturer changed the CAD files of the standard CKS femoral component into CKS prototypes with asymmetrical groove orientations and asymmetrical anterior flange shapes. These CAD files were also used. The groove orientations of a total of 8 different situations were determined in the implanted situation (table 1). Two sizes of the component with a symmetrical groove (Medium and Large) were taken into account, and three sizes of the component with an asymmetrical groove (Small, Medium and Large). These different sizes of the components were taken into account, as manufacturers do not design different sizes of the components just by rescaling. Two versions of the component with an asymmetrical groove were available: version A with a 3.5° laterally orientated groove and version B with a 7° laterally orientated groove. This design orientation is relative to a local prosthetic reference/coordinate system. This reference system is aligned parallel to both the posterior condyles and the distal condyles of the femoral component. It should be noted that the groove orientation of the implanted component is determined relative to the reference system of the femur, which is aligned parallel to both the mechanical axis and the posterior condyles of the femur. External rotation of the femoral component therefore influences the orientation of the prosthetic groove.

	Femoral reference system			**Component reference system**		
	1st part	**2nd part**	**3rd part**	**1st part**	**2nd part**	**3rd part**
Cadaver Measurement[1]	0.2° SD=2.8°	-4.2° SD=3.2°		-4.0°	-8.6°	
Prosthesis						
Asymmetrical -S-3.5	2.9°	2.2°	2.8°	0.0°	0.0°	3.5°
Asymmetrical -S-7.0	2.9°	2.2°	4.4°	0.0°	0.0°	7.0°
Asymmetrical -M-3.5	2.9°	2.2°	2.7°	0.0°	0.0°	3.5°
Asymmetrical -M-7.0	2.9°	2.2°	4.3°	0.0°	0.0°	7.0°
Asymmetrical -L-3.5	2.9°	2.2°	2.8°	0.0°	0.0°	3.5°
Asymmetrical -L-7.0	2.9°	2.2°	4.3°	0.0°	0.0°	7.0°
CKS-M (symmetrical)	2.9°	2.2°	0.4°	0.0°	0.0°	0.0°
CKS-L (symmetrical)	2.9°	2.2°	0.4°	0.0°	0.0°	0.0°

table 1: the bilinear approximation of the determined prosthetic and measured cadaveric groove orientation. Positive angle is a lateral orientation, a negative angle is a medial orientation. S = Small, M = Medium, L = Large

The CAD files were loaded into Mentat (MSC.Software, Palo Alto, USA), a finite element pre- and postprocessor, which has the ability to handle curves and surfaces. The component geometries were positioned as if they were implanted on a distal (virtual) femur. This means that the femoral component was aligned parallel to the mechanical axis of the femur. According to the instructions of the manufacturer, the femoral component was aligned relative to both posterior condyles and was given an external rotation of 3° around the mechanical axis. About 60 equidistant points were generated along the deepest trajectory of the prosthetic sulcus. The trajectory of the center of the measurement sphere was mimicked by a correction of this deepest trajectory using the radius of the measurement sphere. This results in a simulation of the probe center within the cadaveric measurements (figure 3). The points were projected onto the frontal plane of the virtual femur, using a roll-out projection (figure 4), identical to the method used with the cadaver femora. A bilinear approximation was applied to the measurements within the natural knee. Therefore, the authors also applied a bilinear approximation to that part of the prosthetic groove which covered the natural femoral joint surface (articular cartilage). The proximal half of prosthetic groove, the prosthetic anterior flange, does not cover any natural joint surface but covers the area of the supracondylar pouch. A subsequent third linear approximation was applied to that part of the groove exceeding this natural joint surface proximally (figure 6). As three consecutive straight lines are used to define the orientation of the prosthetic patellar groove, we called this a trilinear approximation (figure 5a). The angle between each of these lines and the projected mechanical axis was determined. The third line covers about the same length as the combination of the first two lines. The figures 5 and 6 also give an indication which part of the trochlea or groove guides the patella at a certain knee flexion angle.

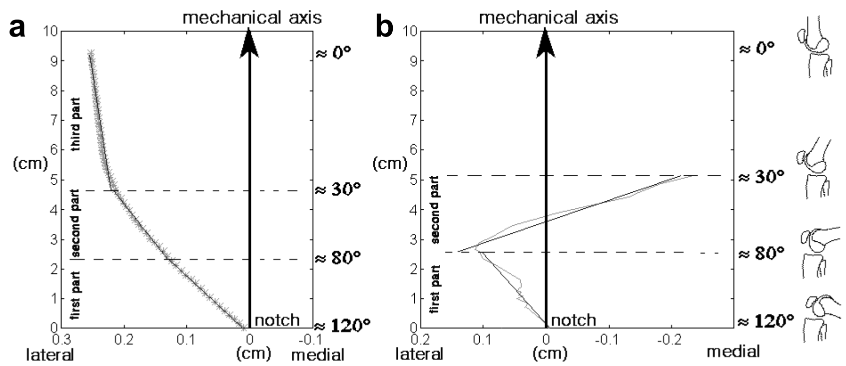


figure 5: **a.** roll-out projection of a prosthetic groove trajectory (CKS-M). **b.** Roll-out projection of a cadaveric trochlear trajectory.

An optimal groove design

To obtain a new patello-femoral design which closely approximated the groove orientation of the natural knee, the described procedure to determine the groove orientation was passed through backwards. This means that the groove orientation of the natural knee was projected onto the external surface of an externally rotated femoral component, which resulted in a design of a 3 dimensional groove trajectory. The roll-out projection of this groove would have matched exactly with the roll-out projection of the natural groove. The externally rotated femoral component with the groove trajectory was rotated back to its neutral position (internal rotation of 3°, posterior condyles of the femoral component set parallel to the posterior condyles of the natural femur). A new roll-out projection was performed within the femoral reference system (which is at this point identical to the prosthetic reference system) which defined the design with the most physiological groove orientation.

There was no optimal groove design determined for the proximal half of the anterior flange, as the measurements within the natural knee did not provide a groove orientation in this area (third part of the trilinear solution).

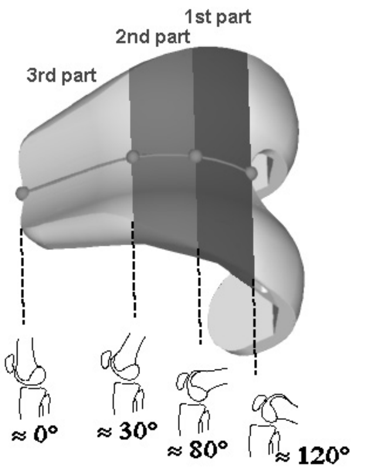


figure 6: visualization of the three areas of the trilinear approximation

Results

The orientation of the physiological groove[1] was considerably different from the orientation of the prosthetic groove. The orientation of the natural or physiological groove resulted in a first part of the groove oriented 0.2° ± 2.8° laterally and a second part of the groove oriented 4.2° ± 3.2° medially, relative to the mechanical axis[1]. The orientation of the groove, determined from femoral components, resulted in a first part of the groove oriented 2.9° laterally and a second part of the groove oriented 2.2° laterally. The prosthetic groove orientation for the first two parts of the trilinear approximation was equal for all simulated components (table 1). Hence, differences between the prosthetic groove orientations only occurred beyond the area originally covered by cartilage. The physiological and prosthetic groove orientation differed 2.7° for the first part of the groove and 6.4° for the second part of the groove. The difference in orientation between the cadaver femora and prostheses for the second part exceeds the values of the standard deviation of the cadaver measurements. The maximum (medio-lateral) difference in millimeters between the prosthetic and the average natural groove orientation was over 4 mm.

The calculations of the prosthetic groove orientation (table 1) showed that the asymmetry of the prosthetic groove is limited to the third part; the most proximal part of the anterior flange. This pattern is embedded within the design of the asymmetrical femoral components as the first two parts of the groove are designed with a neutral (0.0°) orientation and the third part is designed with a neutral- or lateral orientation.

For the new patello-femoral design with physiological groove orientation, an orientation of 4.0° medially for the first part of the groove, and an orientation of 8.6° medially for the second part of the groove was calculated (table 1). The orientation is defined relative to the reference system of the femoral component (the posterior condyles) and not relative to the reference system of a femur. Hence, the proposed design has an orientation of the first two parts that is directed much more medially than commonly used (figure 7).

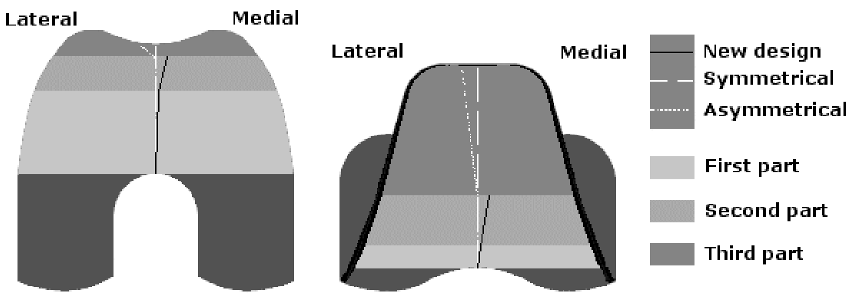


figure 7: visualization of the proposed prosthetic groove orientation (new design) vs. the symmetrical/neutral and asymmetrical/lateral groove orientation. Note that the different groove orientations are visualized on a symmetrical prosthetic component.

Discussion

Patella tracking is influenced by many different factors: the geometry of the groove, the geometry of the posterior side of the patella, soft tissue, extensor mechanism and the orientation of the tibia. As patella and femur can not penetrate one another, the geometry of the groove and the posterior side of the patella could be called 'hard' constraints, particularly at high flexion. The other factors are 'soft' constraints as the effects of these constraints can be overruled by the 'hard' constraints or by external forces.

The trochlea is designed to guide and hold the patella. The use of these 'hard' constraints is the most effective way for the human body to maintain always a basic and necessary patella track. In a healthy knee, 'soft' constraints are only able to enforce small deviations upon this necessary patella track. It is acceptable to assume that the tracking of the patella will be very similar to the orientation of the trochlea. Therefore, the present study applied the hypothesis that the orientation of the groove of a knee prosthesis should be similar to the orientation of the natural trochlea to reproduce this natural patella track.

The knee joint is an example of a very well balanced system. A slight change within this system, affects the whole system. Changes within the patello-femoral joint can have considerable long term effects, as the transmitted forces within this part of the knee joint are relatively high. Total Knee Arthroplasty easily induces changes within the patello-femoral joint.

The present study showed that the groove orientation of TKA components is not conform the natural trochlear orientation. The groove orientation of these implants can easily be redesigned, without the need of necessary changes in hospital or manufacturing stocks, as many currently available TKA implants have already different right and left components. Changes in instrumentation or implantation procedure are also not necessary. There is no reason to assume that this groove design change will influence tissue balancing or the incidence of necessary releases, in case the alignment and all other geometric parameters (e.g. box shape and condylar radii) remain unchanged.

This study was designed from the prospect of not resurfacing the patella, which is common during many total knee arthroplasty. This was done on purpose, as patella resurfacing would have introduced additional variables into the study. In case of resurfacing the patella during TKA, changes in patella tracking are not only influenced by the design of the femoral groove, but also by the design and alignment of the patellar button.

In the former study, the trochlear orientation of 100 cadaver femora was determined. In the present study, the groove orientation was determined of several variations of a typical knee prosthesis. In both studies, the aim was not to determine the orientation of the sulcus. The aim was basically to determine the orientation of the flanks or sides of the groove, as the authors believe that these flanks, and not the sulcus, are guiding the patella. These flanks of the natural trochlea are V-shaped. In the former cadaver study, a spherical probe was used. This probe does not have the geometry of the posterior side of the natural patella nor the geometry of a patellar component. A sphere, with a relatively large radius (34 mm), was used for two reasons. First of all, the measurement is reproducible regardless of the orientation of the probe. In addition, the large radius of the sphere also increases reproducibility, because of guaranteed two-point contact with the groove which 'locks' the position of the probe. With a very deep trochlea, the contact points between probe and trochlea will be located far from the sulcus and more near the edges of the flanks. In case of a shallow trochlea, the contact points will be located close to the sulcus. If V-shape of the natural trochlea is variable, it becomes a parameter which influences the original cadaver measurement. However, this V-shape is almost constant within the area the natural trochlea was measured (first and second part) and only changes significantly within the area of the supracondylar pouch (third part). Therefore, the effect of the V-shape on the cadaver measurements in only secondarily. It should be noted that the V-shape is dependent on the orientation of the femur.

The contact region of the natural patella changes with flexion. At small flexion, the contact is near the bottom of the patella, and as flexion proceeds, the contact moves towards the top of the patella. The geometry of the patellar flanks change slightly from top to bottom. However, this does not introduce an extra parameter within this study, as the effect of the geometry of the patella flanks on patellar tracking is comparable in the pre- and post-operative situation.

The current study showed that the orientation of the prosthetic groove is considerably more laterally than the orientation of the natural groove. The standard deviation of the cadaver measurements was 2.8° and 3.2° for the first and second part of the groove, respectively (table 1,[1]). This standard deviation can be regarded as a natural variation in groove orientation between different subjects. As knees within this natural variation will normally not experience problems, a mismatch of about 3° is probably clinically irrelevant. Nevertheless, the mismatch between the natural and prosthetic groove orientation exceeded 3° in the second part of the groove (4.2° degrees medially vs. 2.2° laterally). The groove of the natural knee was orientated medially. Therefore, the authors expected to find the highest deviation between the natural trochlear orientation and the groove orientation of the asymmetrical femoral components. However, this was not the case. The prosthetic groove of the CKS prosthesis, in the area covering the natural joint surface, is designed with a neutral orientation and only the groove orientation on the anterior flange, which is beyond the cartilage area, is lateralized. The deviation, which was found, is therefore basically caused by the prescribed external rotation of the femoral component. This external rotation is prescribed to obtain a rectangular flexion space and thereby a correct balancing of the ligaments[9]. More or less external rotation of the femoral component may lead to an unbalanced varus or valgus knee and component rotation should therefore not be compromized.

The current study proposes a new anatomical patello-femoral design, with an orientation of 4.0° medially for the first part of the groove and an orientation of 8.6° medially for the second part of the groove. The orientation of the prosthetic groove, after placement of this femoral component, will then result in a first- and second part, which are oriented 0.2° laterally and 4.2° medially (table 1), respectively. Possible disadvantages of a medialized patella groove are higher contact and shear forces on the patella and an increased susceptibility for luxations. On the other hand, no significant differences were found in shear and compressive force between a symmetric and asymmetric femoral component[10]. Therefore, it is questionable whether there will be significant differences in contact forces between the symmetric (neutral orientation of the groove) and the proposed patello-femoral design (medial orientation of the groove).

The prosthetic groove design is not the only parameter which defines the orientation and location of the groove. Alignment of the femoral component (external-internal rotation or medio-lateral placement) highly influences both groove location and orientation. However, this study only shows how the most physiological prosthetic groove should be oriented, assuming a perfect alignment of the TKA components. The proposed prosthetic groove orientation is only defined for the surface which is, in the natural knee, covered with cartilage. The orientation of the third part of the groove (anterior flange) should not be extrapolated from the orientation of the second part of the bilinear approximation measured in cadaver femora. Eckhoff, for example, patented an 'asymmetrical femoral component for knee prosthesis'[3] incorporating a groove orientation, which was measured from Sudanese femora[4]. This patent, incorrectly, assumes that the measured groove orientation can be extrapolated to obtain a prosthetic groove design covering the whole frontal area of the prosthetic anterior flange. The area of the supracondylar pouch/anterior flange is important during the early stage of flexion, as the patella is located there. The contact forces are very low[10] at this stage. However, this initial stage is said to be important regarding the prevention of patellar dislocations, as it is reported that, during flexion, the patella will not dislocate anymore once it has become stable[8]. A laterally oriented prosthetic groove orientation may enhance this stability[10], which can be explained by the more parallel orientation of the quadriceps force and the groove. Patella tracking studies[11,13] also show that the patella moves lateral near extension (after it has been released from the trochlea). Therefore, a lateral orientation of the prosthetic groove on the anterior flange may have some functionality. In our opinion, a lateral groove orientation on the anterior flange should not be designed with the idea or reducing patellar dislocations and subluxations. The lateral groove orientation on the anterior flange is not a replicate of the pre-operative anatomy and the experienced dislocations or subluxations often do not occur pre-operatively. This indicates that these complications are caused by malalignment or a soft-tissue imbalance. Therefore, the authors believe that improved alignment and soft-tissue balancing are the proper ways to actually reduce dislocation and subluxation. Although, it is not expected that a lateral groove orientation on the anterior flange will be an adverse factor, it is also not really anatomical. Therefore, this study proposes to imitate the human anatomy concerning this area. This would probably suggest a flattened third part of the groove with a smooth transfer to the more congruent second part.

This study shows that the groove orientation of femoral TKA implants is not truly anatomic, but deviates up to 6.4° with the trochlear orientation in the natural knee. The authors propose a different, more anatomical, trilinear orientation of the prosthetic patella groove. A flattened third part of the groove is suggested. In case of a prescribed surgical external rotation of the femoral component, the first most posterior part of the groove should have an orientation of 4.0° medial, the second part should have an orientation of 8.6° medial, to mimick natural anatomy as closely as possible.

Acknowledgement

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IGES geometry of the standardized femur was used for figures 2 and 4. Viceconti, std2_3.igs, From: The ISB Finite Element Repository, Istituti Rizzoli, 1997; http://www.cineca.it/hosted/LTM/back2net/ISB_mesh/"

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Chapter 5

Asymmetrical Total Knee Arthroplasty does not improve patella tracking - a study without patella resurfacing

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Knee Surgery, Sports Traumatology, Arthroscopy - accepted for publication

Abstract

It is often suggested that patella tracking after TKA with an asymmetrical patella groove is more physiological than with a symmetrical patella groove. Therefore, this study tried addressed two questions: what is the effect of TKA on patella tracking, and is patella tracking after asymmetrical TKA more physiological than patella tracking after symmetrical TKA? The patellar and tibial kinematics of 5 cadaveric knee specimens were measured in the intact situation, after the incision and suturing of a zipper, and after placement of a symmetrical TKA and asymmetrical TKA, respectively. The patellae were not resurfaced. The flexion-extension kinematics were measured with an internal- and external tibial moment to determine the envelope of motion (laxity bandwidth) of the tibio-femoral and patello-femoral articulation. The kinematics after TKA showed statistical significant changes in comparison to the intact situation: patellar medio-lateral translation, patellar tilt and tibial rotation were significantly affected. No statistical significant differences in knee kinematics were found between the symmetrical and the asymmetrical TKA.

We conclude that conventional TKA significantly changes physiological patello-femoral kinematics and TKA with an asymmetrical patella groove does not improve the non-physiological tracking of the patella.

Introduction

Manufacturers of orthopaedic implants often claim that the design of their total knee implants restores adequate physiological patella tracking. However, the anatomical variations of the patella-femoral joint are considerable and the geometries involved are quite complex. It is therefore not obvious that a Total Knee Arthroplasty (TKA) design reproduces physiological patella tracking even if the components are perfectly aligned.
An important design aspect of TKAs, concerning the restoration of physiological patella tracking, is the groove orientation. The early TKA's were all designed with a neutral or symmetrical patella groove. However, most of the new TKA designs have a laterally oriented or asymmetrical patella groove as this is thought to be more anatomical[16]. However, an improved functional or clinical performance has not been proven up to now[8,11,27]. This raises the question whether an asymmetrical groove design actually results in a more physiological patella tracking.
Patellar kinematics are sensitive to multiple factors. (e.g. design and alignment of the implant, capsular tension, location of the tuberosity). It is therefore difficult to determine the relation between a single parameter and patellar kinematics when other parameters are changed at the same time. This is left under exposed in other studies in which several parameters were changed simultaneously[8,14,28]. In the current study, we developed a procedure to determine the effect of a single parameter on patellar kinematics.
Hence, this study tried to answer two questions. (1) What is the effect of TKA on patella tracking relative to the intact situation, and (2) is the patella tracking after TKA with an asymmetrical patella groove more physiological than the patella tracking after TKA with a symmetrical patella groove, as is often suggested? The authors therefore studied the *in-vitro* kinematics of the knee in detail, before and after TKA, and in case of a symmetrical and asymmetrical groove design.

Materials and Methods

About 15 fresh frozen, right sided, anatomic knee specimens were x-rayed and templated. From these series, five specimens were selected for use with a medium sized femoral knee component. The specimens were obtained from the Department of Anatomy of the hospital. There was no information available regarding cause of death, age, or gender. The specimens were prepared for use in a knee joint motion and loading apparatus (figure 1[25]).

Therefore, the upper and lower leg were transsectioned at about 20 cm from the knee joint centre. The transsectioned ends of the bones were potted in autopolymer to allow fixation into the apparatus. The quadriceps muscle was separated in three parts: rectus femoris, vastus medialis, vastus lateralis/ intermedius.

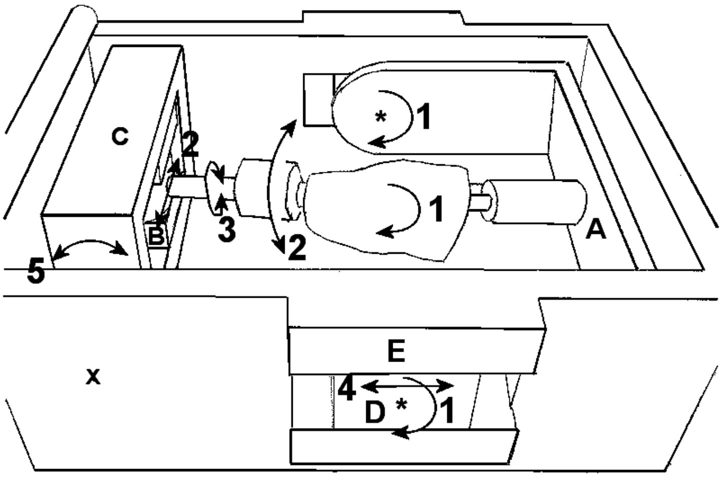


figure 1: knee joint motion and loading apparatus. Flexion (1) is achieved by manual rotation of bracket A around joint *. The tibia is free to move in varus and valgus (2), through translation of block B in slot C. The tibia is also free to rotate internally and externally (3). Joint translations are allowed through translation 4 (block D/Bracket A moving in slot E) and rotation 5 (rotation of block C around joint x)

After these preparations, the knee was inserted into the knee loading and motion apparatus. With this apparatus the knee flexion movement can be applied manually (figure 1: rotation 1) and the tibia and patella have freedom of motion to find their own orientation. The three separated parts of the quadriceps muscle were loaded with 27 N each[26] and a 50 N axial compressive load was applied to the knee[25]. A 3 Nm internal torque was applied to the tibia[12,17,25,26] to obtain the internal rotational pathway (IRP). Nine flexion movements were performed manually with a moderate to slow velocity. An electromagnetic motion tracking system (3SPACE Fastrak, Polhemus, Colchester, VT) was used to measure the patello-femoral and tibio-femoral kinematics of the knee[14]. The source was fixed rigidly onto the femur: one sensor was mounted onto the patella and the other on the tibia. The locations and orientations of both sensors were recorded simultaneously using continuous data acquisition. This test was repeated with a 3 Nm external torque applied to the tibia to obtain the external rotational pathway (ERP). The IRP and ERP represent boundaries (or extremes) of the motion pathway. Hence, the difference between the IRP and the ERP shows the envelope of motion.

After this measurement, a medial incision was used to open the capsula, and a plastic zipper was sewed into it. This zipper replaced the surgical sutures and it made it possible to insert different TKA's and measure the knee kinematics under identical capsular circumstances. The measurements were repeated with only the zipper in situ to assess the individual effect of the incision on the knee kinematics.

A conventional CKS prosthesis (Continuum Knee System, Biomet/ STRATEC, Warsaw, IN, USA) was implanted by an experienced knee surgeon, who also used this implant as the standard primary TKA clinically. The CKS is a posterior cruciate retaining Total Knee Prosthesis with a symmetrical patellar groove. The implantation procedure was similar as performed clinically, according to the instructions of the manufacturer and using the CKS instrumentation. The instructions of the manufacturer included a 3 degrees external rotation (around the mechanical axis of the femur) of the femoral component to balance the flexion gap. The patella was not resurfaced in this study. A medium size of the implant was used for all 5 specimens. The femoral and tibial components were all manufactured from polymer to prevent metal artifacts with the measuring system. The kinematic measurements were repeated with the conventional CKS prosthesis in situ.

After these measurements, the conventional femoral component was replaced with an asymmetrical prototype CKS femoral component. The difference between the prototype and conventional design was that the symmetrical patella groove was replaced with an asymmetrical groove (a groove with a 7 degrees lateral orientation on the anterior flange). The measurements were repeated once more. Both the symmetrical and asymmetrical femoral components were located at the same (medio-lateral) position.

The three-dimensional motion data of the sensors were transformed to anatomic orientations and coordinates. The anatomic coordinate system was based on bony landmarks, which were obtained from pre-operative CT-scans. The calculated parameters for the patella were: flexion, tilt, rotation and medio-lateral translation, and for the tibia; flexion (knee flexion), varus/valgus and internal/external rotation (figure 2).

The main focus in this study was on adaptations in patellar kinematics. To differentiate between the effects of different parameters on the kinematics, the authors compared 4 different situations: 1) intact, 2) after the incision and the suturing of the zipper, 3) after the implantation of the conventional CKS prosthesis and 4) after the implantation of the prototype CKS prosthesis. As the patellar kinematics are also largely dependent on the tibial kinematics both patellar- and tibial kinematics were measured.

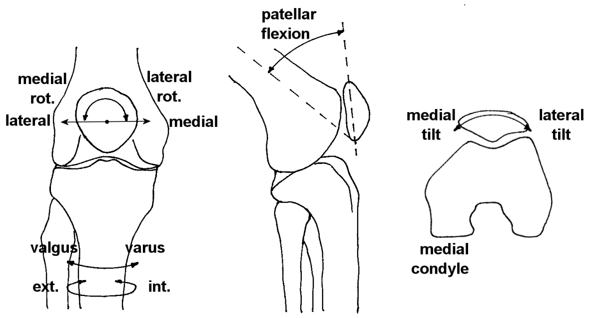


figure 2: definition of patellar- and tibial rotations

A two-way ANOVA with a Tukey test for multiple pairwise comparisons was applied to the data of the 5 specimens at fixed flexion angles (0, 5, 10…,100 degrees) to determine whether differences between the four situations were statistically significant ($p<0.05$). Separate statistical tests were performed for the IRP's and ERP's.

Results

The effect of the incision and the suturing of the zipper

The zipper did not impose statistical significant differences in comparison to the intact situation, except for the patellar rotation. Therefore, the zipper only had a minor effect on the knee kinematics. The patella rotation was not further used for comparison for the remaining part of this study.

The effect of total knee arthroplasty on knee kinematics

Relative to the zipper situation, the symmetrical TKA did impose significant changes to the kinematics of the patella (figure 3). Symmetrical TKA resulted in a significantly more medial position of the patella in flexion (table 1: statistical significant difference between 65 and 90 degrees of flexion for

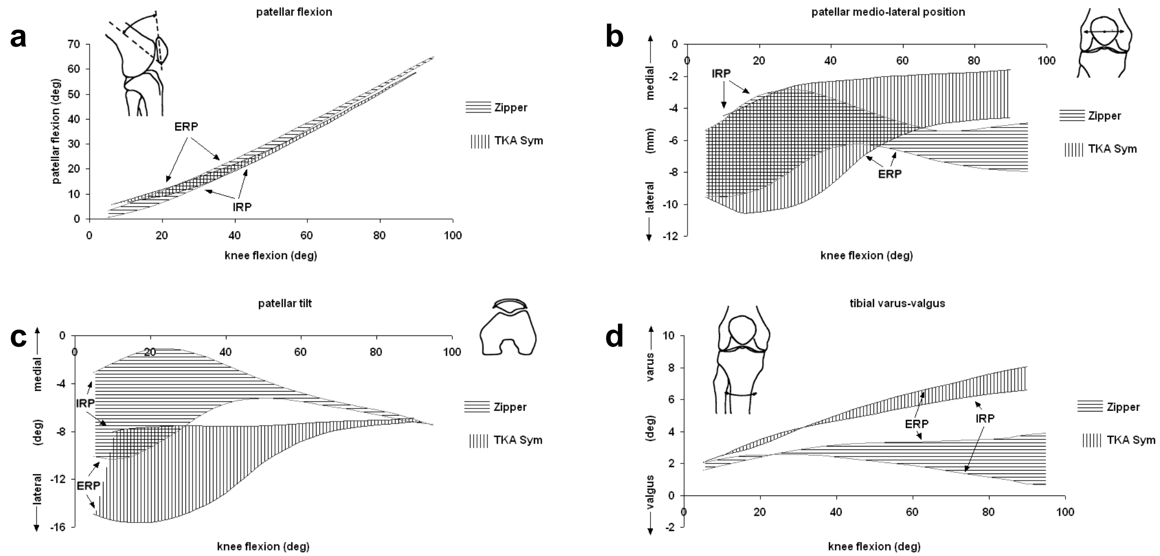
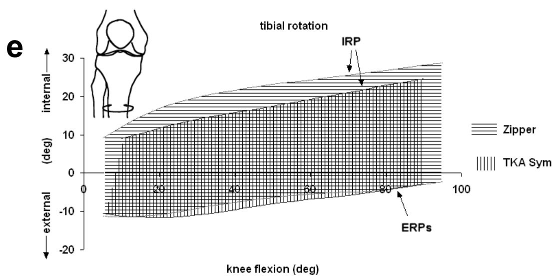
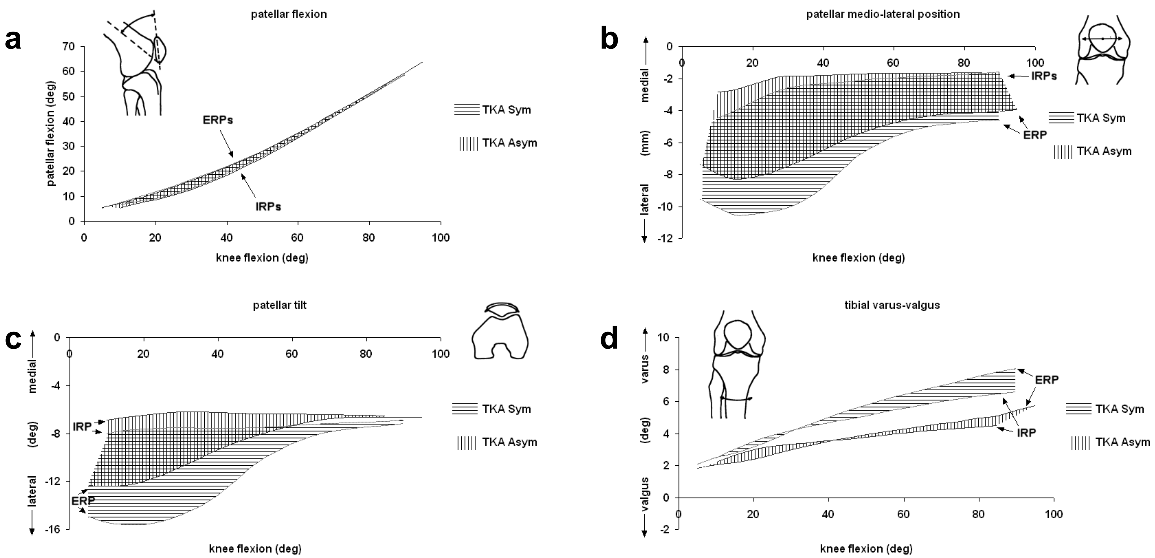


figure 3: the envelope of motion for patella and tibia: the effect of symmetrical TKA. **a.** patellar flexion, **b.** patellar medio-lateral position, **c.** patellar tilt, **d.** tibial varus-valgus, **e.** tibial rotation





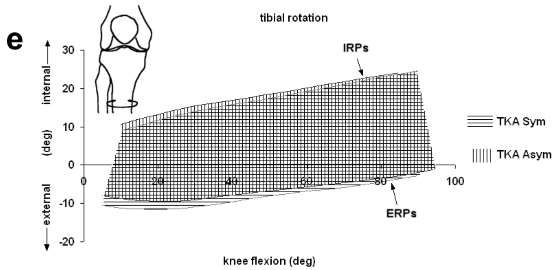


figure 4: the envelope of motion for patella and tibia: the effect of a lateral groove design. **a.** patellar flexion, **b.** patellar medio-lateral position, **c.** patellar tilt, **d.** tibial varus-valgus, **e.** tibial rotation

the IRPs, and between 80 and 90 degrees of flexion for the ERPs). It also resulted in significantly more lateral tilt of the patella at lower flexion angles (table 1a: statistical significant difference between 10 and 30 degrees of flexion for the IRPs, and between 20 and 45 degrees of flexion for the ERPs). Finally, the symmetrical TKA resulted in significantly less internal tibial rotation along the IRP (table 1: statistical significant difference between 45 and 95 degrees of flexion for the IRPs.

The symmetrical TKA also resulted in some more varus angulation of the tibia (figure 3d). However, this difference was not statistically significant (table 1).

			5	10	15	20	25	30	35	40	45	50	55	60	65	70	75	80	85	90	95
Patella	flexion	IRP																			
		ERP																			
	ml-position	IRP																			
		ERP																			
	tilt	IRP																			
		ERP																			
Tibia	varus-valgus	IRP																			
		ERP																			
	rotation	IRP																			
		ERP																			

table 1: statistical significant differences ($p<0.05$) between the situation with the zipper and the situation with symmetrical TKA, for different flexion angles

The difference in kinematics between TKAs with a symmetrical and asymmetrical patellar groove

The symmetrical TKA showed a somewhat more lateral patellar position (figure 4b) and lateral patellar tilt (figure 4c) between 5 and 50 degrees of flexion. Furthermore, it showed more varus angulation (figure 4e) of the tibia. However, the differences between the symmetrical- and asymmetrical TKA were never found to be statistically significant.

Discussion

The results found in the pre-operative situation were generally in good agreement with the results from earlier measurements[6,14,17,19,20,22,23,26].

The trochlea is the main determinant for the patellar position at flexion angles higher than 30 degrees. Hence, the medio-lateral translation of the patella should also correlate with the orientation of the trochlea or groove[5]. The orientation of the natural trochlea is mainly medial[9], which correlates with the medial translation of the patella during knee extension from 90 to 20 degrees of flexion (note that the patella is not located in the trochlea in extension). The orientation of the prosthetic patella groove in the implanted situation is lateral[10], which also correlates with the lateral translation of the patella during extension of the knee as found in this study.

The effect of total knee arthroplasty on knee kinematics

Relative to the situation with the zipper, the patellar flexion pathways did not show significant differences after TKA implantation, except for one individual flexion angle for the ERP (90 degrees). This indicates that the sagittal geometry of the TKA resembled the sagittal geometry of the normal knee relatively well.

At 5-10 degrees of flexion, the medio-lateral position of the patella, after TKA, was close to the medio-lateral position of the patella in the normal knee. This indicated that current alignment and design of the femoral component is able to replicate the patellar position in extension, and that there was no tendency of patellar dislocation. However, at 80-90 degrees of flexion, the pathways of the patellar medio-lateral translation, before and after TKA, were significantly different. The patella was located about 3 mm more medially post-operatively, which increases the Q-angle. Hence, the patella was displaced significantly in high flexion angles, a situation where substantial patellar loading is expected[13,21]. It is therefore expected that this non-physiological patellar position will increase the patellar contact forces. A probable cause for the patellar medialization at 90 degrees of flexion is the alignment of the femoral component. In the intact situation, the medial compartment of the joint is wider, because the medial- and lateral condyle are not parallel[24]. However, the femoral prosthetic component has condyles of equal width. The medio-lateral alignment of the femoral component is based on a compromise between a central placement and good bone coverage (by the anterior flange). It is likely that this may cause the patella groove of the TKA to be located more medially than the anatomic sulcus.

TKA caused the patella to tilt significantly more laterally between 20 and 30 degrees of flexion. This tilt pattern can be explained by the configuration of the distal femur after TKA. The femoral components were placed with 3 degrees of external rotation relative to the femur. These components do not have a raised lateral ridge on the anterior flange. Hence, the medial pros-

thetic condyle reaches more anteriorly than the lateral prosthetic condyle, which leads to a very pronounced lateral tilt at lower knee flexion angles. The patellar tilt in the intact situation can be explained in a similar way by the anatomical configuration of the distal femur, which was already described by Van Kampen et al[26].
TKA did induce a statistical significant difference in the IRP of the tibial rotation between 45 and 95 degrees of flexion. Possible reasons for this behaviour are small changes in knee laxity and the changed curvature of the proximal tibia (a prosthetic condyle running up a slope of the tibial insert). Summarizing, the TKA procedure induced significant changes to the knee kinematics, however the changes are consequences of the design and placement parameters. This suggests that they can consequently be reduced by design improvements, e.g. asymmetrical condylar width to restore the anatomical medio-lateral patellar position and built-in external rotation for the femoral component to restore the anatomical patellar tilt.

The difference in kinematics between TKAs with a symmetrical and asymmetrical patellar groove
The results did not show any statistical significant difference in kinematics between the symmetrical and asymmetrical TKA. Worland et al.[27] and Ashraf et al.[8] also did not find that the asymmetrical TKA improved patella tracking clinically. The asymmetrical groove is apparently not functional, which can be explained by the fact that the difference in prosthetic groove orientation between the symmetrical and asymmetrical TKA only exists on the anterior flange of the femoral component. This is the location of the patella, when the knee is close to extension (0-20 degrees of flexion) and it is the area where the soft tissue structures are the main determinants for the patellar position[17]. This factor apparently overrules the design differences of the anterior flanges. Hence, a more lateral prosthetic groove orientation on the anterior flange of the femoral component does not have the expected influence on the patellar position.

A problem in many patella tracking studies is the high variability within the results and the large number of parameters influencing the results. In this study, the authors have reduced the number of influential parameters by using an intra-specimen comparison, which allowed to use a relatively small group size for the experiments.

Instead of suturing the incision after each variation[7,14,22], a zipper was sutured into the incision[15]. This zipper could be opened to insert or change components and closed to run the tests. The use of a zipper within this study prevents that the differences in soft tissue tension between the tests will affect the results. It allows an intra-specimen comparison, which is a very pure way to assess effects under variable circumstances (human material). This study showed that the incision and the zipper only induced significant changes on the patellar rotation. The other kinematic patterns and trends were not significantly affected, indicating that the zipper had only little influence. It is expected that the effect of the zipper is not very different from the effect of the standard surgical sutures immediately after surgery.

The same order of implantations and measurements was used during all experiments. During testing with cadaver material over time, the knee may have become somewhat more lax. However, the envelope of motion of the asymmetrical vs. the symmetrical TKA did not increase (figure 4). Hence, the results indicate that the order of implantations do not really affect the laxity.

The muscles in this study were loaded equally in their muscle directions. The loads were small and not physiological with regard to the muscle loads *in vivo*. However, in this study the muscle forces were applied to generate tensioning of the capsula and (thereby) joint stability.

Usually, patella-femoral kinematics are measured during flexion-extension motion while applying a general, relatively simple, flexion-extension loading configuration. These kinematics may also be relatively sensitive to small variations in the loading configuration. *In vivo* there are, of course, many different loading configurations with different complexities affecting patellar kinematics. Hence, the patella moves within an area or envelope of motion (laxity bandwidth). In this study, the envelope of motion for the patella and tibia were therefore determined using an internal- and external rotational torque. The value of 3 Nm for this torque is within physiological boundaries and gives a good description of the extremes of the envelope of motion[12].

In this study fresh frozen cadaver specimens were used to enable *in vivo* circumstances as close as possible. The transsection of the femur and the tibia is only expected to have minor influence on the knee kinematics. The transsection of the bones does not affect the actual joint structures. However, the alignment of the prosthetic components becomes somewhat more difficult when the bones are transsected.

The standard procedure within our institution is not to resurface the patella during primary TKA. This is a common procedure during many TKAs in the world (e.g. in England/Wales, Norway, Sweden, Australia and Ontario, the patella is not resurfaced in 63%[4], 95%[18], 89%[1], 57%[3] and 25%[2] of primary TKAs, respectively). Therefore, the patella was also not resurfaced in this study, in contrast to many other patella tracking studies[7,14,22]. Not resurfacing of the patella had an additional advantage concerning the intra-specimen comparison. The alignment and the design of a patellar component are additional parameters which would influence patellar tracking. These additional parameters were excluded in the current situation.

The first question, which we tried to answer in this study, was about the effect of TKA on patella tracking. The results of this study showed that statistically significant changes were induced on the kinematics through symmetrical TKA. These changes could be related to design and alignment. In this way, the patellar medio-lateral translation could be related to the groove orientation[9,10] and to the medio-lateral location of the femoral component. Furthermore, the difference in patellar tilt could be related to the shape of the condyles and the external rotation of the femoral component. The findings can be utilized for improvement for new TKA designs and instrumentation.
The second question, which we addressed, was whether patella tracking after TKA with an asymmetrical groove was more physiological than patella tracking after TKA with a symmetrical groove. The differences between the kinematics of both TKA's were very small and not statistically significant. Therefore, this study does not show a more physiological patella tracking in case of the asymmetrical (lateral) groove orientation.
In conclusion: conventional TKA significantly changes physiological patellofemoral kinematics and TKA with an asymmetrical patella groove does not improve the non-physiological tracking of the patella.

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Chapter 6

The trochlea is medialized by Total Knee Arthroplasty; an intra-operative assessment in 61 patients

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Abstract

A medialization of the femoral component in a TKA causes abnormal patellar tracking, which could result in patellar instability, pain, wear and failure. Previous reports defined medialization in relation to the neutral position of the femoral component, but omitted to compare it to the anatomical position of the trochlea. We assessed intra-operatively whether there is a systematic error of the position of the prosthetic groove relative to the anatomical trochlea.

A special instrument was developed to measure consecutively the medio-lateral position of the anatomical trochlea and the medio-lateral position of the prosthetic groove. Three experienced knee surgeons determined the medio-lateral error of the prosthetic groove in a primary TKA in 61 patients.

There was a significant medial error ($p < 0.001$) of the prosthetic groove relative to the pre-operative position of the trochlea, with a mean medial error of 2.5 mm (SD 3.3 mm)

Our findings indicate that the trochlea is medialized by TKA. Because a conscious medialization of the femoral component in a TKA produces abnormal patellar tracking patterns, which could result in patellar instability, pain, wear and failure, further investigations need to analyze the clinical consequences of this medialization of the trochlea.

Introduction

After implantation of a total knee arthroplasty (TKA), patello-femoral complaints is one of the complications with the highest incidence (1-24%)[4,9,10] and is an important reason for revision surgery. A majority of patello-femoral complications are associated with abnormal patellar tracking[9]. Therefore patella tracking is an important issue in TKA, which is, among other parameters, influenced by the medio-lateral and rotational position of the femoral component. Several studies have shown that small modifications in alignment of the femoral component cause significant changes in patella tracking[1,8,14,17].

In a recent cadaver experiment of TKAs without resurfacing the patella, we observed that the patella in a TKA is displaced to the medial side in a flexed knee, when compared with the pre-operative position[3]. A medialization of the patella results in a higher Q-angle, as the direction of the patella tendon differs more from the vector of the Quadriceps. Because the loads are maximal in a flexed knee[16], one could expect an increase in compressive and shear forces on the patello-femoral joint[13]. Armstrong et al.[2] described that the position of the patella changes with any femoral component malposition, which could result in patellar instability, pain, wear and failure. Furthermore, Rhoads et al.[17,18] concluded that medial femoral displacement produces abnormal patellar tracking patterns with higher stresses on the patella. Although these authors also described problems with medialization of the femoral component and the patella, they defined medialization in relation to the standard or neutral position of the femoral component of a TKA, but omitted to compare it to the pre-operative, anatomical position of the trochlea.

Therefore, the purpose of this study was to assess whether there is a systematic error of the position of the prosthetic groove relative to the anatomical trochlea. We designed a prospective study with participation of three surgeons and analyzed intra-operatively the medio-lateral placement of the trochlea of a TKA.

Materials and Methods

A special instrument was developed to measure intra-operatively the medio-lateral position of the trochlea (figure 1). After preparing the knee for a primary TKA, just before any bone resection took place, this instrument was

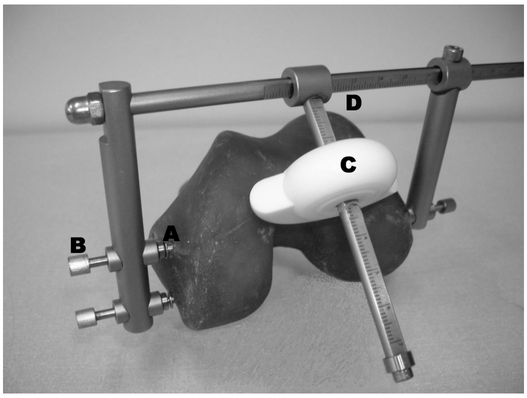

figure 1: Instrument installed on a sawbone of a distal femur to measure the medio-lateral position of the deepest point of the notch. A: hollow cylinder in the epicondyle; B: fixing pin of the instrument; C: probe resting in the deepest point of the notch; D: medio-lateral scale.

placed on the distal femur. Three hollow cylinders with a diameter of 2.7 mm were positioned in the epicondyles as reference points and the three fixing pins of the instrument were slid into those cylinders. Perpendicular to the medio-lateral scale was a sliding part of the instrument with a plastic disc as probe. This probe simulated the articular surface of the patella and had 2 different diameters (33 and 55 mm) to choose the best fitting in the trochlea. Our measurements were performed at the most distal point of the trochlea, because this was a recognizable and reproducible point. When the disc was resting in this most distal point of the trochlea, the pre-operative, anatomical medio-lateral position of the trochlea was determined. After preparing the distal femur and placing the trial component of a TKA, the three pins of the instrument were slid into the three hollow cylinders in the epicondyles again and the medio-lateral position of the most distal point of the prosthetic groove was determined. The difference between both positions was defined as the medio-lateral error of the prosthetic groove relative to the anatomical position of the trochlea, with positive values for medial displacements and negative values for lateral displacements. The most distal point of the trochlea lies approximately at the axis of the femur. Therefore, the amount of rotation of the femoral component does not influence the medio-lateral position of this point of the trochlea. All measurements were performed by the surgeons and were rounded to whole millimeters. The inter- and intra-observer variability of our measure instrument was tested by five observers with five measurements each and the standard deviations were 0.7 mm and 0.4 mm, respectively.

Three surgeons measured the medio-lateral error of the prosthetic groove in a primary TKA in 61 patients. All patients were operated for symptomatic osteoarthritis or rheumatoid arthritis. There were no exclusion criteria. All surgeons were experienced knee surgeons with more than 4 years experience with the implant. None of the patellae were resurfaced. Surgeon A routinely placed a LCS rotating platform prosthesis (DePuy, Warsaw, IN, USA) and determined the medio-lateral error in 21 patients. Surgeon B and C placed a PFC prosthesis (DePuy, Warsaw, IN, USA) and both measured the medio-lateral error in 20 patients each. All three surgeons used their own criteria for the medio-lateral positioning of the femoral component; Surgeon A and B both strived for optimal coverage of both condyles, and surgeon C preferred a flush position of the femoral component relative to the lateral epicondyle. The LCS prosthesis, as used by surgeon A, has a resection guide that is placed on the distal femur after the distal resection is performed. The position of this resection guide is fixed and after the other resections are made, the trial component has exactly the same medio-lateral position. Therefore, the medio-lateral position of the femoral component of the LCS prosthesis (surgeon A) has been based on the distal resection plane. In contrast to the LCS system, within the system of the PFC prosthesis, the trial component can be moved more medially or laterally after all resections are performed. Thus, surgeons B and C can overview the whole distal femur, inclusive the anterior and posterior part, during the positioning of the femoral component.

In addition to the question whether there is a systematic error of the position of the prosthetic groove relative to the anatomical trochlea, we compared the medio-lateral positioning of the trochlea of two different prosthetic designs and three different surgeons, with each their own criteria for medio-lateral positioning of the femoral component. Moreover, we analyzed the influence of difference in prosthetic size on medio-lateral positioning of the prosthetic groove.

Statistics

Statistical analysis to assess whether there was a systematic error of the position of the prosthetic groove relative to the anatomical trochlea was performed with the one sample t-test for all patients together, and for each surgeon and prosthetic design separately. For the assessment of the difference in medio-lateral error between the three surgeons, we used oneway ANOVA with Bonferroni correction for pairwise testing. For the difference in medio-lateral error between the two prosthetic designs a t-test for 2 independent samples was used. The influence of prosthetic size on the medio-lateral error was analyzed with linear regression. P-values less than 0.05 were defined as statistical significant.

Results

There was a significant medial error ($p < 0.001$) of the prosthetic groove relative to the pre-operative position of the trochlea in all sixty-one patients together, with a mean medial error of 2.5 mm (SD 3.3 mm, 95% CI 1.7 – 3.3 mm).

Group	Mean (mm)	Range (mm)	SD (mm)	95% CI (mm)	Significance
All patients	2.5	-4 - 9	3.3	1.7 – 3.3	p < 0.001
Surgeon A	1.5	-3 - 7	2.5	0.3 – 2.6	p = 0.01
Surgeon B	4.4	0 - 9	2.7	3.1 – 5.6	p < 0.001
Surgeon C	1.7	-4 - 8	3.7	-0.1 – 3.5	p = 0.06
LCS Prosthesis (surgeon A)	1.5	-3 - 7	2.5	0.3 – 2.6	p = 0.01
PFC Prosthesis (surgeon B + C)	3.0	-4 - 9	3.5	1.9 – 4.1	p < 0.001

table 1: The medio-lateral error of the prosthetic groove relative to the pre-operative position of the trochlea. The mean, range, standard deviation (SD), 95% confidence interval (CI) and the significance of the error of each group are shown.

Table 1 shows the results of the separate groups. Surgeon B placed the prosthetic groove significantly more medial than surgeon A ($p = 0.01$) and surgeon C ($p = 0.02$). The difference in medio-lateral error between the two prosthetic designs was not significant ($p = 0.08$).

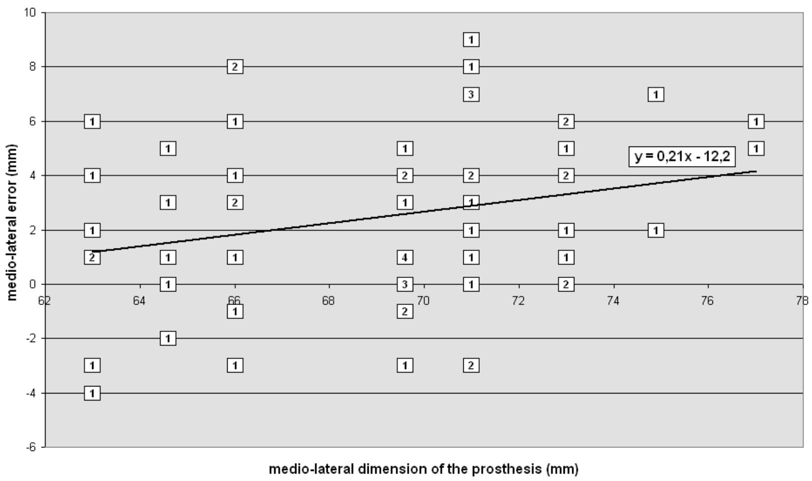

figure 2: The medio-lateral error of the prosthetic groove as a function of the medio-lateral dimension of the prosthesis. The numbers in the squares represent the number of measurements at that position.

Figure 2 shows the medio-lateral error of the prosthetic groove as a function of the size of the femoral component. The correlation between size and medio-lateral error was not significant. ($R = 0.24$, $p = 0.06$).

Discussion

We designed a prospective study to determine whether TKA alters the medio-lateral position of the trochlea compared to the pre-operative position. Our study indicates that there is a systematic medial error of the position of the prosthetic groove. This is in agreement with our cadaver experiment of TKAs without resurfacing the patella, where we observed that the patella in a TKA was displaced to the medial side in a flexed knee, when compared with the pre-operative position[3]. A plausible cause for this medial error could be the difference in distal position of the femoral condyles. Morphological studies of the distal femur showed that in most femurs the medial condyle is positioned more distally[15,20]. This means that the resection area of the medial condyle is greater than the lateral condyle, when the resection is performed in a plane perpendicular to the mechanical axis of the leg. Thus, when an orthopaedic surgeon places a femoral component exactly in the middle of the distal resection, the middle of the prosthesis will be shifted to the wider resection area of the medial condyle and therefore will cause a medial displacement of the trochlea (figure 3).

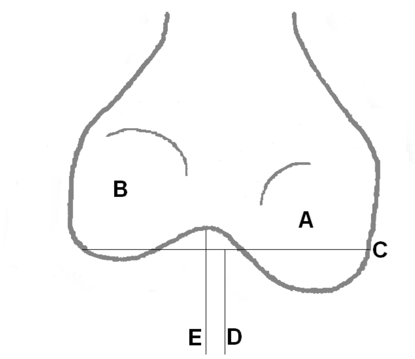

figure 3: schematic illustration of the asymmetric distal femoral resection, with a medial displacement of the middle of the distal resection, relative to the anatomical position of the trochlea. A: medial condyle; B: lateral condyle; C: distal resection; D: middle of the distal resection; E: anatomical position of the trochlea.

Moreover, Eckhoff et al.[6,7] showed that the sulcus of the trochlea is lateral to the midplane between the condyles. This could be another aspect of the asymmetrical distal resection area explaining a medial error of the trochlea in TKA in case of femoral components with equal widths of the medial and lateral condyles. Therefore, it seems more appropriate to develop femoral components, with a wider medial condyle than the lateral condyle, to achieve an anatomical position of the prosthetic groove and good coverage of both condyles as well. To our knowledge, there is only one prosthetic design with a wider medial condyle on the market (3DKnee, Encore Medical, Austin, TX, USA).

Furthermore, we had expected a greater medial error with greater sizes of the femoral components, because greater sizes should give more discrepancy in the widths of the condylar resection area. Moreover, Eckhoff et al.[7] speculated that the sulcus of the anatomical distal femur is more lateral in a wider femur. Although figure 2 showed the tendency that a larger size of the femoral prosthesis had a greater medial error, within this study of 61 patients, the correlation between larger size and more medial displacement was not significant.

Another remarkable result was that surgeon B placed the prosthetic groove significantly more medial than surgeon A and surgeon C. Although surgeon A used another prosthetic design than surgeon B and C, we did not find a significant difference in medio-lateral error between those prosthetic designs. This indicates that surgical judgement may govern medio-lateral positioning, rather than the prosthetic system. Surgeon C preferred a flush position of the femoral component relative to the lateral epicondyle and is consequently less influenced by the asymmetrical distal resection area of the condyles. Surgeon C was the only surgeon of whom the medial error was not significant. Surgeon A and B both strived for optimal coverage of both condyles. Surgeon A had to base the positioning of the femoral component only on the distal resection plane, with the resection guide placed on the distal femur. After all bone resections are performed, surgeon B could view the whole distal femur during the medio-lateral positioning. The exact anatomy seems less obvious after all bone resections, and it appears that with a complete overview of the whole distal femur, surgeon B is more affected by the asymmetrical distal resection area, which causes a shift of the prosthetic groove to the wider medial condyle.

An important issue is the clinical consequence of a displacement of the prosthetic groove in medial direction. Rhoads et al.[17,18] concluded that medial femoral displacement produces abnormal patellar tracking patterns with higher stresses on the patella. Armstrong et al.[2] described that the position of the patella changes with any femoral component malposition. In this study we determined the medio-lateral position of the most distal point of the trochlea, which is assumed to prescribe the position of the patella in flexion of the knee joint. Although we had already observed in a cadaver experiment of TKAs without resurfacing the patella, that the patella in a TKA was displaced to the medial side in a flexed knee[2], we did not analyze the position of the patella in the current study. Furthermore, in case of resurfacing the patella, a conscious medialization of the patella component could compensate for a medially displaced prosthetic groove, and medialization of the patella component has been suggested as a means of improving patellar tracking[5,19]. Although some good initial results of patella component medialization in TKA have been described[11,12], it seems better to strive for an anatomical positioning of TKA, than to compensate a medial error of the femoral component by placing a medially displaced patella prosthesis. The conclusion of our study is that the trochlea is medialized by TKA. Because a conscious medialization of the femoral component in a TKA produces abnormal patellar tracking patterns, which could result in patellar instability, pain, wear and failure, further investigations need to analyze the clinical consequences of this medialization of the trochlea.

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Chapter 7

A three-dimensional dynamic finite element model of the prosthetic knee joint: simulation of joint laxity and kinematics

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Abstract

For testing purposes of prostheses at a pre-clinical stage, it is very valuable to have a generic modelling tool, which can be used to optimize implant features and to avoid poor designs being launched at the market. The modelling tool should be fast, efficient and multi-purpose in nature, a finite element model is very suitable. The question of this study was whether it was possible to develop a mathematically fast and stable dynamic finite element model of a knee joint after Total Knee Arthroplasty that would predict data that are comparable to published data in terms of: 1) laxities and ligament behavior, and 2) joint kinematics. The soft tissue structures were modelled using a relatively simple, but very stable, composite model consisting of a band reinforced with fibers. Ligament recruitment and balancing was tested with laxity simulations. The tibial and patellar kinematics were simulated during flexion-extension. An implicit mathematical formulation was used.

Joint kinematics, joint laxities and ligament recruitment patterns were predicted realistically. The kinematics were very reproducible and stable during consecutive flexion-extension cycles. Hence, the model is suitable for the evaluation of prosthesis design, prosthesis alignment, ligament behavior and surgical parameters on the biomechanical behavior of the knee.

Introduction

There is steady progress in the development of knee implants and surgical procedures around the knee joint. Current technologies are under continuous improvement resulting in the introduction of new products every year. In this respect, it is very valuable to have a generic modelling tool, which can be used during the pre-clinical testing phase to optimize implant features and to avoid poor designs. Such a tool should have two important characteristics: it should be able to answer a variety of design and research questions in a fast and effective way, and it should be able to perform parametric studies starting from the same reference situation every time. It is our aim to develop such a tool, which should be able to determine parameters such as: contact stresses (wear), implant-bone interface stresses, predict bone remodelling and the effects of surgical procedures (e.g. ligament reconstruction) and kinetic and kinematic effects caused by changes in implant design and alignment.

A mathematical computer model is most suitable for this purpose. A finite element (FE) model is a very logical choice, as this model can be used to determine the internal stresses and strains and the kinematics and kinetics. Such a model should only be constrained by physiological boundary conditions, to maximize the physiological freedom of movement. Inertia effects and accelerations (dynamics) should be included, which will improve the multi-purpose nature of the model and are expected to result in more accurate (kinematic) predictions. Finally, the behaviour of the knee ligaments (collateral and cruciate ligaments) should be modelled physiologically, which means that ligaments should be able to slide and wrap around the bone. From the physiological aspect, the ligaments should be modelled with their correct laxity and recruitment patterns. The best way to achieve these characteristics is by modelling the ligaments as actual bands and by testing the laxity and recruitment patterns of the ligaments within the model.

Recently, a small number of knee models have been published which have a moderate multi-purpose nature. D'Lima et al.[10] created a dynamic finite element model of the knee after Total Knee Arthroplasty (TKA), but they did not model the lateral collateral ligament (LCL) or medial collateral ligament (MCL). Beillas et al.[5] developed an explicit finite element model of the human knee in which they modelled the cruciate ligaments only as series of springs in parallel. They also did not model the LCL and the MCL. Halloran et al.[14] also created an explicit finite element model of a TKA, in which the ligaments were modelled as actual bands. The tibio-femoral and patello-femoral kinematics of this model were only verified separately within a constrained environment. These three knee models included ligaments of which the verification of the load-displacement behavior was not mentioned[5,10], or only performed in a tensile stress test[14].

Although these models already included some or more of the necessary features, we have taken an alternative approach to develop and verify our model. First we use an implicit formulation. From a theoretical point of view, an explicit analysis provides a more accurate analysis when high accelerations are involved (impact simulations). If the accelerations are relatively small an implicit formulation produces more accurate predictions. As the accelerations in most common analyses of TKA and ligament issues are relatively small, an implicit formulation is appropriate, despite concerns that implicit models generate more mathematical stability problems[14].

Secondly, to test whether the ligamentous structures behave realistically, the recruitment and laxity of the ligaments were actually tested within the model. The other models have included ligamentous structures but generally considered loading configurations in which these structures were not recruited or activated. Hence, the functionality of the ligaments was not really tested. Therefore, this study also includes the monitoring of ligament recruitment under different circumstances.

The question which we posed in this study were: is it possible to develop a mathematically fast and stable finite element model using an implicit formulation that predicts data comparable to published experimental data in terms of: 1) laxities and ligament behavior, and 2) joint kinematics?

Materials and methods

Model design

A model of a right knee was created, combined with a CKS total knee prosthesis (figure 1a, Continuum Knee System, Biomet/STRATEC). The CKS knee prosthesis is a posterior cruciate retaining total knee prosthesis. The anterior cruciate ligament is sacrificed during surgery. The CKS is a symmetrical design which means that the left and right components are identical. The model (figure 1b) consisted of a distal femur, proximal tibia, total knee prosthesis, several ligaments and a patella. The patella was not resurfaced. The distal femur and proximal tibia were modelled using the geometry of the standardized femur and the standardized tibia (Biomechanics European Laboratory (BEL)Repository[1]), respectively. The distal femur and the femoral component were modelled as rigid bodies. The proximal tibia was modelled as a deformable body of which only the outer surface was modelled with elements, using one layer of brick elements with a constant thickness. The tibial component was also modelled as a deformable body, consisting of a metal base plate and a polyethylene insert. The tibial base plate was modelled as a 2 mm thick flat disc, without a keel. The connection mechanism between insert and plateau was not modelled as this was not the focus of this study. The patella was also modelled as a deformable body and its geometry was derived from CT (Computer Tomography) images. An extra layer of elements was added to the posterior surface of the patella modelling the cartilage layer. The fibula was not modelled. All elements were isoparametric brick elements.

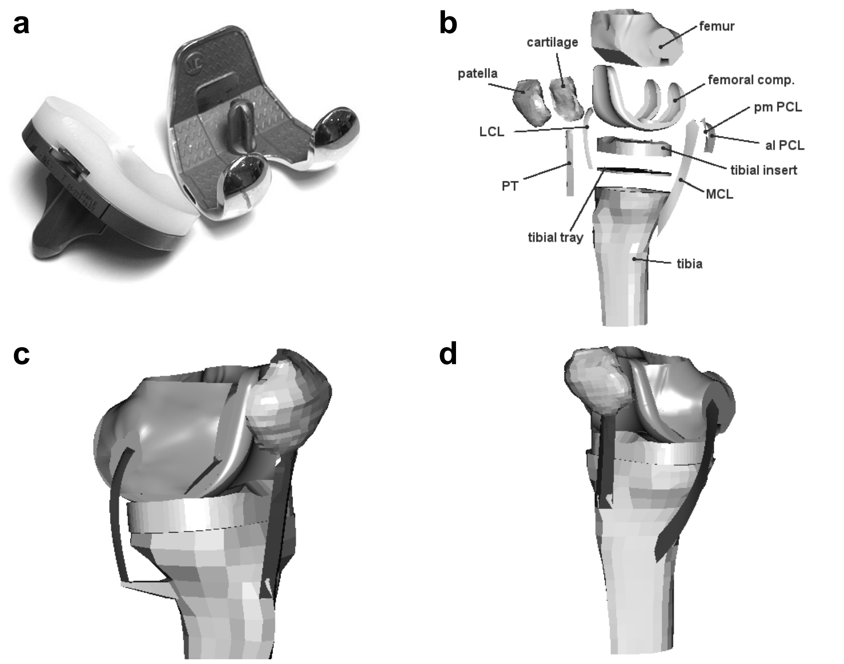

figure 1: the model **a.** CKS posterior cruciate retaining knee prosthesis **b.** exploded view of the prosthetic knee model **c.** lateral view of the model **d.** medial view of the model

Four soft tissue structures were modelled: the medial collateral ligament (MCL), the lateral collateral ligament (LCL), the posterior cruciate ligament

(PCL) and the patella tendon (PT). These structures were modelled as a flexible matrix (interfibrillar matrix) reinforced with stiff trusses (collagen and elastin,[25]). The matrix was modelled with shell elements. The trusses were laid onto those element edges which were aligned parallel to the length direction of the ligaments. These trusses had no bending stiffness. The different insertions of the ligaments were determined using published data[18]. The PCL consisted of a separate antero-lateral and posterio-medial bundle. The fibula was not modelled. Therefore, there was no location for the distal insertion of the LCL. However, the movements of the tibia and fibula are virtually identical. In many cadaver studies, only the knee joint is used and therefore the tibia and fibula are cut halfway between knee and ankle. This allows more relative movement between the fibula and tibia. To restore the original relation between tibia and fibula, a Steinman pin is often used to connect the fibula rigidly with the tibia. This procedure connects the distal insertion of the LCL with the tibia. The lower leg of the model is also cut in half. Therefore, a rigid connection was created to connect to distal insertion of the LCL with the tibia.

The contact option was used within the FE program (MARC, version 2003). All contact definitions within the model were frictionless, but a sensitivity study showed that friction had little effect on the analyses. Contact was simulated between the metallic femoral component and the polyethylene tibial insert, between the femoral component and the patellar cartilage, between the MCL and the femur and between the MCL and the tibia.

Properties

The properties of the different materials within the knee joint model are given in table 1. The elements were modelled linearly elastic and isotropic. The material properties of cortical bone were used for both tibia and patella. Cartilage was assigned an elastic modulus of 15 MPa.

For the ligaments, all the shell elements (the interfibrillar matrix) were modelled with identical stiffness. However, the stiffness of the trusses varied on the ligament modelled. The transverse isotropic characteristics of the ligaments were introduced by modelling these ligaments as a composite structure of shells and trusses. The stress-strain curve of a physiological ligament consists of a ‘toe’-region at low strains followed by a linear relationship at higher strains. The ligaments were modelled linear elastic, because the ‘toe’-region is relatively small.

	elements		Stiffness (MPa)
Tibia	332	bricks	19000
Tibial base plate	273	bricks	210000
Tibial insert	856	bricks	700
Patellar bone	991	bricks	19000
Patellar cartilage	497	bricks	15
MCL	240	shells	shell: 10
	280	trusses	truss: 249[19] *
LCL	240	shells	shell: 10
	280	trusses	truss: 259[7] *
alPCL	96	shells	shell: 10
	112	trusses	truss: 186[20] *
pmPCL	48	shells	shell: 10
	64	trusses	truss: 109[20] *
PT	30	shells	shell: 10
	22	trusses	truss: 482[7] *

table 1: model parameters and properties. *The original stiffness values as reported by Butler[7], Race[20] and Quapp[19] are multiplied by 0.75. The measured stress-strain curves of the ligaments have toe regions. These properties were linearized in the model.

Calculations

Different simulations were performed to determine whether the ligaments were physiologically recruited and balanced and whether the kinematics of the model were valid.

1. The ligament balancing and recruitment was tested by simulations of the varus-valgus, the anterior-posterior and the internal-external rotation laxity. The simulations of the varus-valgus laxities were performed at flexion angles of 0, 30, 60 and 90 degrees (10 Nm). The simulation of the anterior-posterior laxities were performed at 20, 30 and 90 degrees of flexion (100 N). Finally, the simulation of the internal-external rotation laxity was only performed at 90 degrees of flexion (3 Nm).
2. The tibial and patellar kinematics were simulated during two complete flexion-extension cycles (0-90 degrees). This simulation was preceded by a ‘run-in period’ of one flexion movement, in which the kinematics of the different joint segments could converge to a ‘physiological’ track. This was done deliberately, as it was very difficult to position the different joint segments at an exact initial ‘physiological’ location.

Boundary conditions

Flexion was achieved by rotation of the femur in the sagittal plane. Both tibia and patella were not constrained. The tibia was axially loaded with 150 N[6].

The patella was superiorly loaded with 81 N[24] in the direction of action of the quadriceps muscle (The Q-angle, Hungerford et al.[15]).
The medio-lateral translation of the patella and the varus-valgus and internal-external rotation of the tibia were slightly damped. Little force was needed to further improve the stability of the MCL and LCL (0.2 N and 0.1 N, respectively).
The joint laxity calculations started with a flexion-extension simulation which stopped when the knee joint reached the necessary flexion angle. The calculation was then continued with the parameters for the joint laxity simulation.

Coordinate system

Flexion, of both patella and tibia, was defined around the medio-lateral axis of the femur. This medio-lateral axis was parallel to the condyles of the femoral component. Patellar tilt was defined around the superior-inferior axis of the patella. The patella tilted medially when the medial patellar facet rotated towards the medial femoral condyle, and laterally when the lateral patellar facet rotated towards the lateral femoral condyle. Patellar rotation was described around the anterior-posterior axis of the patella, around which the patella described medial patellar rotation when the patellar apex turned towards the medial condyle, and lateral patellar rotation when the patellar apex turned towards the lateral condyle. A local, body-fixed, (Eulerian) patellar coordinate system was used, in which rotations are sequence dependent. The sequence flexion, tilt, rotation was used.
Varus-valgus rotation and internal-external rotation of the tibia were described around the anterior-posterior axis and mechanical axis of the tibia, respectively. The mechanical axis was perpendicular to the tibial base plate. For the tibia, the sequence flexion, varus-valgus, rotation was used.
At the start of the flexion-extension simulation, the knee model was set in extension and the patellar and tibial coordinate systems were aligned parallel to the femoral coordinate system. Therefore, all patellar and tibial rotations originally started at zero.

Flexion angle (°)	**0**	**30**	**60**	**90**
Valgus (°)	5.3	6.3	2.1	0.8
Varus (°)	3.6	5.1	5.5	4.8

table 2: results of the varus-valgus laxity simulations

Results

Ligament balancing/laxities

The predicted varus and valgus laxity was in between 0.8 and 6.3 degrees at all of the four knee flexion angles (table 2). The varus laxity was maximal at 60 degrees of flexion. The valgus laxity was maximal at 30 degrees of flexion. Both varus and valgus laxity were minimal in extension or at 90 degrees of flexion.

The model predicted a posterior laxity of 3.1, 4.3 and 2.0 mm at 20, 30 and 90 degrees of flexion, respectively. The predicted values of the anterior laxity are not of much interest, as only the patellar ligament and the curvature of the tibial insert within the model can function as a restraint for an anterior tibial movement. However, this restraint was insufficient at 20 and 30 degrees as the femoral prosthesis rolled off the tibial platform posteriorly. This restraint was sufficient to prevent the femur from rolling off the platform at 90 degrees of knee flexion,: an anterior displacement of 5.7 mm was predicted. Calculating the rotational laxity of the tibia at 90 degrees of flexion, the model predicted a 10.0 degrees internal rotation. When the tibia was externally rotated, the simulation prematurely terminated. The stresses within the fibers (trusses) of the LCL, MCL and PCL were determined to monitor the recruitment of these ligaments (figure 2). The recruitment patterns were not determined for all laxity tests; only for those which could at least be referenced to other publications. Within the varus-valgus laxity test, at 0 and 30 degrees of knee flexion, the MCL and posterior-medial bundle of the PCL (pmPCL) were recruited during the valgus test and the LCL was recruited during the varus test. The AP-drawer tests, at 30 and 90 degrees of knee flexion, showed a recruited posterior region of the MCL (pMCL) dur-

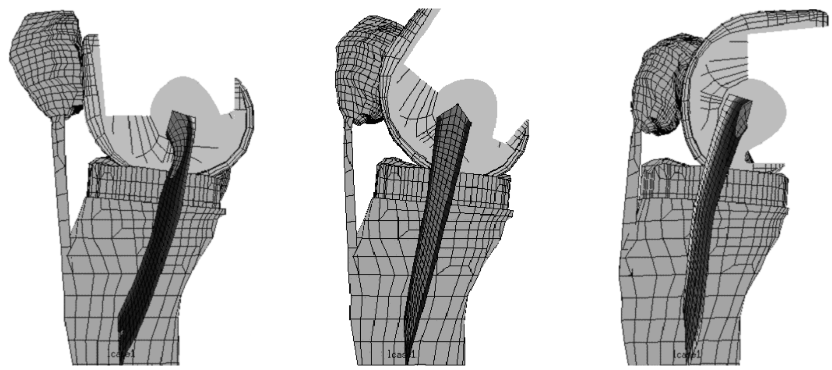

figure 2: an example of ligament recruitment during flexion

ing the anterior drawer at 30 degrees. The pmPCL was recruited during the posterior drawer at 30 degrees of knee flexion. At 90 degrees of flexion, during the flexion-extension simulation, both the anterior region of the MCL (aMCL) and the pmPCL were (already) recruited. The addition of an anterior and posterior drawer at this flexion angle increased this recruitment of both ligaments.

Kinematics

Patellar and tibial kinematics were monitored during a simulation over the 0-90 degrees flexion range. The results from the first flexion movement were omitted, as both tibia and patella were still converging to the equilibrium path. After this run-in cycle, a very stable and reproducible kinematic track was established for both tibia and patella. The patella flexed up to a maximum of 50.8 degrees and extended up to a maximum of 5.6 degrees (figure 3). The flexion of the patella showed a relatively straight line indicating a direct, linear, relation with knee flexion. Relative to the neutral position, the patella was medially tilted during 0-70 degrees of knee flexion, and laterally tilted during 70-90 degrees of flexion. The medial tilt of the patella was decreasing from extension to 20 degrees of flexion. This was followed by a slight increase of the medial tilt from 20 to 45 degrees of flexion. From 45 to 70 degrees of flexion, the medial tilt decreased to zero, and from 70 degrees on, the lateral tilt increased. Although the patella was mostly medially tilted during knee flexion, it should be noted that it was most of the time tilting laterally. The patellar tilting curve also showed a different flexion and extension trajectory (figure 3). Relative to the neutral position, the patella was rotated medially during 0-30 and 65-90 degrees of knee flexion, and was rotated laterally during 30-65 degrees of knee flexion. Starting at extension, the medial rotation of the patella decreased. From 55 degrees of flexion onwards, the medial rotation increased again.
The patella translated 6-7 mm medially over the complete flexion range (figure 4). About 80% of this translation occurred during the first 20 degrees of flexion. The tibia started almost in the neutral position and moved slightly into varus during flexion (figure 5). The tibia rotated also internally during flexion. This internal rotation was more pronounced above 60 degrees of flexion. The curve displaying the tibial rotation also shows a difference in flexion and extension trajectory.

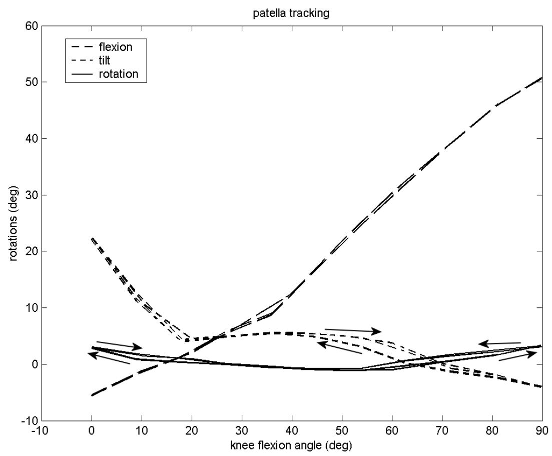

figure 3: patellar rotations (medial patellar tilt and medial patellar rotation are positive)

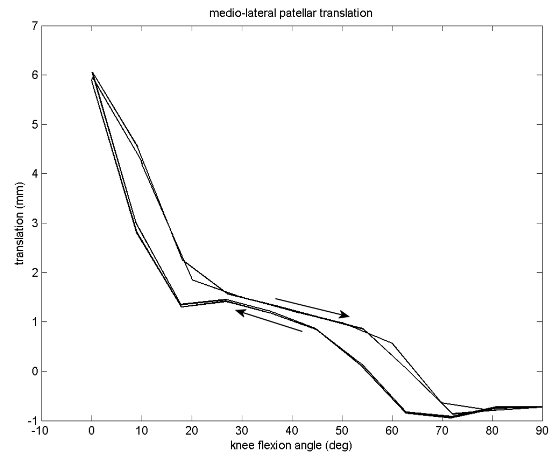

figure 4: patellar medio-lateral translation (lateral translation is positive)

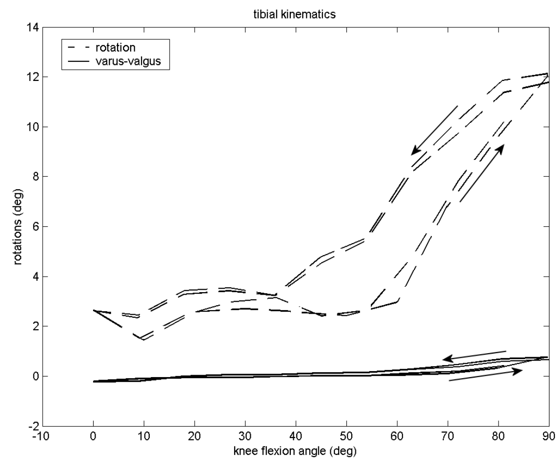

figure 5: tibial rotations (internal tibial rotation and tibial varus are positive)

Discussion

This model offers the ability to perform a single parameter variation analysis with optimal experimental control. It also gives insight into internal phenomena, which are normally difficult to assess with experimental or *in-vivo* studies. However, it is only a valuable tool when its predictions closely mimick *in-vivo* behaviour.

The presented model shows some general strengths and weaknesses. First of all, the model is stable in a mathematical and kinematical sense. Mathematical instabilities were only seen when performing a simulation to determine the laxity of external tibial rotation. The simulations concerning flexion-extension kinematics experienced no instability problems at all. The model was very stable in a kinematic sense as it produced very reproducible kinematics after the first flexion-extension movement. A dynamic simulation of a run-in period followed by two flexion-extension movements, totally 2500 increments, was calculated relatively fast (about 24 hours on a Pentium IV, 2.4 Ghz PC). The contact was modelled frictionless, but a sensitivity study showed that friction had little effect on the analyses. The ligaments were modelled as a reinforced structure which, the authors believe, acts as reliable as a ligament modelled with transverse isotropy. The simplicity of the ligament model is certainly an advantage concerning calculation speed and stability. A linear elastic isotropic material model was used. The stability of the MCL and LCL was further increased by the addition of very small forces which were directed perpendicularly to the ligaments; slightly keeping the ligaments in tension. The element mesh of the presented model is still relatively coarse and several structures are simplified as in most models. In this study we used a mesh of the tibia that only consisted of the cortex, and the patellar cartilage was modelled as a uniform layer of elements. The medio-lateral translation of the patella and the varus-valgus and internal-external rotation of the tibia were slightly damped. Without this damping, patellar and tibia kinematics showed some vibrations. With these adjustments, we were able to produce a mathematically stable and fast model. Hence, the suggestion from Halloran et al. [14] that 'buckling' of the soft tissues will occur and generate stability problems in models that use an implicit formulation can be overcome.

The question arises how closely the current model mimics the *in-vivo* behavior. Therefore, the presented results will be compared to results from published experimental studies. It should be noted that there are always small differences between the model calculations and how the experiments were performed.

Ligament balancing/laxities

The model prediction of the valgus laxity showed a maximum of 6.3 degrees at a knee angle of 30 degrees. The varus laxity showed a maximum of 5.5 degrees at a knee angle of 60 degrees. These laxities were decreasing towards extension and 90 degrees of flexion. The range of the predicted laxities was between 0.8 and 6.3 degrees. Experimentally determined varus-valgus laxities, within cadaver knees,[22] show values within the same range. However, it is perplexing that they observed a significant varus-valgus laxity in extension, as a clinically measured varus-valgus laxity in extension shows no laxity at all. The model also predicts varus-valgus laxity in extension, but this can be attributed to the absence of the posterior capsule. Grood et al.[12] have shown that the restraining moment of the (posterior) capsule to varus-valgus laxity becomes more important in extension.

Within the AP-drawer test, the model predicted a posterior laxity between 2.0 and 4.3 mm. These predictions are comparable with values measured for the posterior laxity in intact knees[8,13]. Note that the PCL is still intact within the model and that it is reported to be the main restraint concerning the posterior laxity[8]. Hence, the laxity constraint generated by the PCL seems to behave realistically within the model. The model predicted an internal rotational laxity of 10 degrees at a knee angle of 90 degrees. Experimentally measured values[26] show about 15 degrees of external and internal rotational laxity, but they were determined with a rotationally unconstrained prosthesis. Hence, these model predictions also seem reasonable for a more constrained prosthesis as used in this study.

The recruitment patterns which were found during the varus-valgus and AP-drawer simulations were in agreement with experimental results of Butler et al.[8] and Grood et al.[12]. They used cadaver knees including all ligamentous restraints. Nevertheless, the sequence of importance concerning the restraining function of the ligaments was similar, taking into account that our model did not include all ligamentous structures.

Hence, the model predictions of the varus and valgus laxity, in addition with the recruitment patterns, indicate that the main varus-valgus constraints (MCL and LCL) are showing physiological behavior. The AP-drawer test shows, in a similar way, physiological behaviour of the PCL.

Kinematics

The patellar kinematics of this study showed a patellar flexion of –5.6 to 50.8 degrees. Argenson et al.[2] measured about 3 degrees of patellar hyper-extension in a TKA kinematics study. Experimental studies in which the patellar kinematics of both normal and TKA knees were measured[2,24] showed a patellar flexion which averaged 60-70 degrees. Therefore, the model seems to slightly underestimate patellar flexion. The values of the rotation angles are determined by the different orientations of the (local) coordinate systems of the patella and femur, respectively. These angles are not necessarily zero in extension and therefore, it is possible to find hyper-extension of the patella. Relative to the neutral position, the patella was tilted medially to a relatively high degree between extension and 20 degrees of flexion. In the normal knee, this medial tilt would have been impossible because of the constraining function of the patellar retinaculum. The patella tilted more and more laterally with increasing flexion. This tendency of the patella is also found in experimental studies[17,21]. The trend is also supported by many *in-vitro* patellar tracking studies of the natural knee[16]. Nevertheless, opposing or different results were also found in experimental studies[3,9]. It should be noted that the standard deviations of patellar tilt within these different experimental studies are in the range of 4 to 8 degrees.

This study showed that, the medial rotation of the patella decreases initially, and that from 55 degrees of flexion onwards, the medial rotation increases again. Studies on TKAs[9,21] showed a patella which was rotating internally with increasing flexion. An internally rotating patella is identical to a laterally rotating patella. Therefore, their results and the results presented in this study are only similar for the first 55 degrees of flexion. A review study of the patellar kinematics of the normal knee[16] concluded that there was a wide variation in patellar rotation and that it was very sensitive to the choice of axes.

The medial shift of the patella with increasing knee flexion, which we found in our model, is also found in experimental studies[3,21]. The predicted medial shift in extension is somewhat high, and is related to the excessive medial patellar tilt in extension.

The tibia within the model started in extension in almost the neutral position and moved slightly into varus during flexion. It also rotated internally during flexion. This is in agreement with some experimental kinematic TKA studies[9,23]. Miller et al.[17] found a similar pattern for tibial varus rotation, but a different pattern for the tibial internal/external rotation. In an experimental study by D'Lima et al.[11], completely opposing results for the tibial kinematics were found. Banks et al.[4] used fluoroscopy to determine tibial rotation of different posterior cruciate retaining TKA's during stair-stepping. They found internal tibial rotation in 92% of the cases and an average internal rotation of 9.4 degrees. The amount of internal rotation, which was predicted by the model (up to 12 degrees), is slightly larger.

In conclusion, the presented results show a knee model which is realistic and stable. Joint laxities and ligament recruitment patterns were predicted realistically with a relative simple, but very stable, composite model for the ligaments. This strongly suggests that the ligament insertion points, zero-length and mechanical properties are correct. The application of the model regarding the evaluation of ligament behavior is limited, as the model only includes the three major ligaments. Several other soft tissues are not included. This model can be used to evaluate the effect of a ligament release or a certain ligament insertion site (in ligament reconstruction), however it should not be applied to situations in which the excluded soft tissues play an important role. It can be a useful tool in many other situations like the evaluation of prosthetic design, prosthetic alignment and surgical parameters on the biomechanical behavior of the prosthetic knee.
The results of this study suggest that predictions of the model will improve with the addition of a (posterior) capsule and a patellar retinaculum. These additions will particularly improve the predictions for the varus-valgus laxity, anterior tibial laxity and the patellar tilt. This will also further enhance the multi-purpose strength of this model concerning patellar kinematics and the effects of ligament reconstruction and surgery.

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http://www.tecno.ior.it/VRLAB/researchers/ repository/BEL_repository.html

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Chapter 8

A mechanical comparison of high flexion and conventional TKA

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Abstract

The question addressed in this study was if high flexion TKA designs improve the mechanical behavior of TKAs in high flexion and whether they maintain the good mechanical performance of conventional TKAs at normal flexion angles?
A finite element study was performed in which the mechanical behaviour of the conventional Sigma RP and the new high flexion Sigma RP-F were compared, during a dynamic simulation of a high flexion squatting activity.
In normal flexion, similar values for the stresses and the plastic deformation of the tibial insert were found. In high flexion, lower values were found for the high flexion Sigma RP-F.
This study confirms that a high flexion design can improve mechanical behaviour at high flexion without changing the performance in normal flexion.

Introduction

Although a decade ago Total Knee Arthroplasty (TKA) patients were satisfied with (a partly) restored mobility and significant pain relief, TKA's are currently subject to higher demands. More often, TKA's are performed in younger patients who are more active and less easy to satisfy. Weiss et al,[26] reported that nowadays, patients experience limitations in important activities like squatting, kneeling and gardening because of their knee replacement. In addition to the traditional western market, the Asian TKA market is rapidly growing. The Asian economy is performing very well and therefore TKA procedures will become affordable to more people in this heavily populated area. High flexion is a key requirement to these people. Asian, including Middle East, people want to be able to kneel, squat or sit in a crossed-leg position because of cultural, social or religious reasons. For example, Muslim people need to be able to squat and kneel because of their way of praying. Similarly, Buddhists use a crossed-leg position[17]. It is common in many places in Asia to sit on the floor during eating or during a conversation. Furthermore, toileting is probably the most important activity performed in squatting[17]. Much of the world's population use a toilet whereby one squats over a hole or bowl embedded in the floor. It is not an activity which can be avoided, and not being able to, will be perceived as a severe handicap.

Mulholland and Wyss[17] have shown that kneeling, squatting and sitting in a crossed-leg position demands flexion angles of 110 to 165 degrees. Current, conventional TKA systems are not designed for these high flexion angles, but for flexion angles up to about 120 degrees. Patients with conventional TKA's may be able to achieve high flexion, as the prosthesis may allow it. However, this takes the prosthesis outside its safe working range and consequent damage may be induced.

Different companies have tried to meet the new demands. In many cases, companies redesigned a clinical successful implant. They combined successful features of the conventional implant with new features which allows the implant to flex up to 150-160 degrees. Stryker developed a TKA for high flexion based on the Scorpio (Scorpio Flex). Zimmer and DePuy did the same for the Nexgen LPS and Sigma RP (Nexgen LPS Flex and Sigma RP-F, respectively).

Considerable research has been performed on the conventional designs. Follow-up and survival studies have shown that these implants perform clinically very well[10-12,22]. *In-vitro* studies with RSA and electromagnetic sensors, and *in-vivo* fluoroscopy studies provided the orthopaedic community with enormous valuable information concerning implant kinematics[3,21]. Implant forces were measured using force transducers[7] and stresses and strains were often calculated using finite element techniques[6,14,23-25]. For the new high flexion implants, however, research and follow-up information is only scarcely available. These implants are designed to function in high flexion, of which it is expected that the transferred loads are much higher. Dahlkvist et al.[8] calculated a maximum tibiofemoral compressive and shear force during a slow ascent from a squat of about 3300 and 2100N, resp. The general pattern observed was that as knee flexion increased, compressive and shear forces also increased considerably. It is therefore questionable whether the excellent mechanical performance of the TKA's, within a flexion range of 0-120 degrees, is maintained at higher flexion angles.

The Sigma RP-F (DePuy, Leeds, UK) is a relatively new TKA design which is specifically designed for high flexion angles. The design is based on the successful conventional Sigma RP design (DePuy, Leeds, UK), which was designed for the normal flexion range (up to 120 degrees of flexion). In this study, the authors compared both designs. The first question in this study was whether the high flexion Sigma RP-F shows an improved mechanical behavior in high flexion (> 120 degrees) as compared to the conventional Sigma RP. The second question was whether the high flexion TKA maintained the good mechanical performance of the conventional TKA at normal flexion angles (< 120 degrees).

Materials and methods

Differences between the conventional Sigma RP design and the new high flexion Sigma RP-F design

The Sigma RP is a rotating platform and cruciate sacrificing or cruciate retaining total knee prosthesis. In this study, only the cruciate sacrificing solution was considered. The condylar sagittal geometry does not have a constant radius, but is designed like a 'J'-curve (figure 1a). In this sagittal plane the prothesis is fully conforming with the insert between 0 and 30 degrees of flexion. The prosthesis has a rounded, fully conforming, condylar coronal design which should maximize the contact area in both perfect alignment and varus or valgus lift off (figure 1b). The posterior articulating aspect of the post on the tibial insert has a slightly built-in curvature which should enhance contact between the femoral cam and the post (figure 1c). The top of the post is pointing slightly posteriorly.

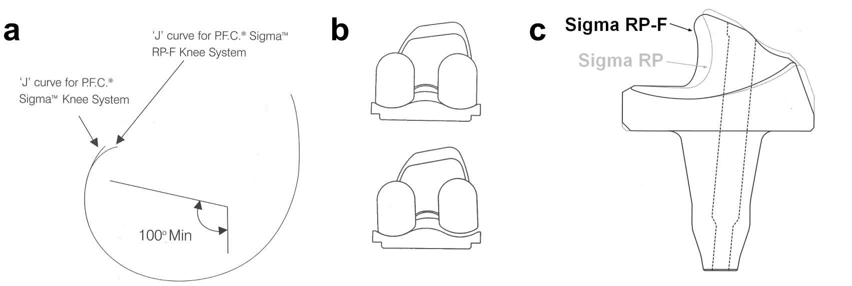

figure 1: **a.** difference in condylar sagittal geometry between the Sigma RP and Sigma RP-F. **b.** the prosthesis has a rounded, fully conforming, condylar design which should maximise the contact area in both perfect alignment and varus or valgus lift off. **c.** difference in post sagittal geometry between the Sigma RP and Sigma RP-F. Figures reproduced with permission of DePuy Orthopaedics, Leeds, UK.

The Sigma RP-F, which is designed to accommodate high flexion angles, has an extended and progressive 'J'-curve in the sagittal plane, which should allow the knee to flex smoothly to 155 degrees (figure 1a). It has an identical articulating geometry to the Sigma RP for the gait cycle and up to 70 degrees of flexion. The tibial post is reinforced with a metal pin and is located 1 to 2-mm more posteriorly (figure 1c). The medio-lateral dimension of the post is constant for the different sizes of the Sigma RP, however the medio-lateral dimension of the post increases, with increasing size, for the Sigma RP-F. Therefore, the medio-lateral dimension of the post of the Sigma RP-F is smaller than the medio-lateral width of the post of the Sigma RP, for size 3 and below. The anterior margin of the tibial insert is cleared to reduce impingement of the extensor mechanism in deep flexion[1].

The models

Two finite element models of the knee were generated. Both knee models were identical, except for the fact that a Sigma RP prosthesis was simulated in one model, and a Sigma RP-F prosthesis was simulated in the other model. The models consisted of a distal femur, tibia, fibula, patella, patellar tendon, femoral component, tibial insert and tibial tray (figure 2). The geometry of the femur, tibia, fibula and patella was taken from a CT-scan and

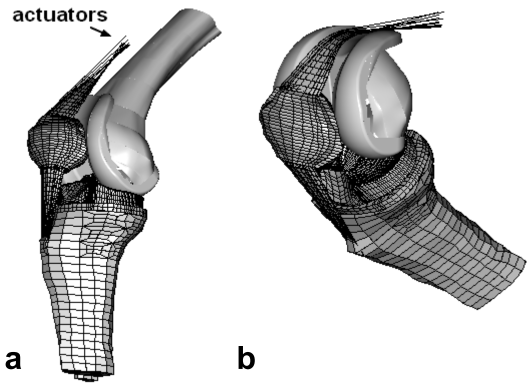

figure 2: **a.** the finite element model at the start of the simulation. **b.** the finite element model during the simulation.

the geometry of the prosthetic components came from CAD models provided by the manufacturer. The patella was not resurfaced. The prosthetic components were aligned according to the instructions of the manufacturer, including a 0 degrees tibial slope. The distal femur and femoral component were modelled as a rigid body. All other components were modelled as deformable bodies, and were meshed using in-house developed software. The tibia, tibial tray, tibial insert, patella and fibula were modelled with 8-node isoparametric brick elements. An elastic-plastic non-linear material model was used to model the material properties of the polyethylene insert[13]. The patellar tendon and the quadriceps tendon were modelled using a composite structure of a linear flexible matrix (shell elements) reinforced with relatively stiff fibers (non-linear line elements)[4].

		Number of elements		Young's Modulus (MPa)
		Sigma RP	**Sigma RP-F**	
Tibia	Insert	5478	4352	* 974
	Metal Pin	-	280	210000
	Tray	1314		210000
	Cortex	462		19000
	Trabecular	737		120
Patella	Cortex	708		19000
	Trabecular	250		120
	Cartilage	648		** 250
	Tendon	437		643
Fibula		60		19000

table 1: model properties. *)[13], **) Cartilage is a very complex material with highly non-linear properties. For use in this model it was modelled in a simplified way as a linear elastic material. To prevent numerical instabilities during the simulations, caused by the high patello-femoral loads, the Young's modulus had to be given a non-physiological value.

Linear elastic material models were used to model the properties of all other materials. Actuator elements were attached to the proximal side of the quadriceps tendon. Material properties for bone, metal and polyethylene were derived from experimental data (table 1). Contact was modelled using the CONTACT option within MARC (MSC.Software Corp., Santa Ana, CA). Glued contact was modelled between the tibia and the tibial tray. Frictionless contact was modelled between the tibial tray and the tibial insert, between the tibial insert and the femoral component, between the femoral component and the patellar cartilage and between the femoral component and the quadriceps tendon. A sensitivity study showed that friction had little effect on the analyses.

Simulations

All finite element simulations were performed using MARC (MSC.Software Corp., Santa Ana, CA). The simulations were all dynamic analyses, using implicit integration. The authors simulated a squatting movement in this study, which started at about 70 degrees of flexion (figure 3). The rotations and translations of the femur and femoral component were constrained. The internal- and external rotation of the tibia was limited to some degree by a torsion spring with a stiffness of 50 N/deg, simulating friction between the foot and the ground. The model was damped to some extent to prevent vibrations and numerical problems. Furthermore, the model was not constrained. Hence, the tibia could rotate into varus or valgus, the tibial insert could rotate within the tibial tray and the patella could rotate and translate. During each simulation, the tibia was loaded at ankle level with a ground reaction force of 350N (simulating a person of about 71 kg). This ground reaction force was the only load which was applied and it loaded the whole model, as the proximal ends of the actuators (quadriceps tendon) were constrained. Hence, instead of applying a quadriceps force as traditional FE simulations do, the actual force produced by the quadriceps was a result from the simulations: a result from the moment equilibrium of the ground reaction force with the quadriceps force.

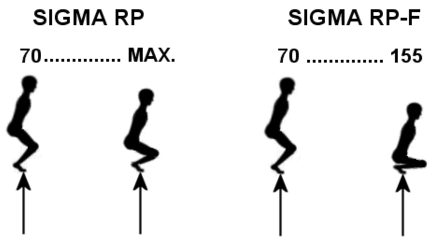

figure 3: simulated stages during squatting

Not the flexion angle was prescribed during the simulations, but the length of the actuator elements. Increasing the length of these actuator elements in time allowed the flexion angle to increase, due to the application of a ground reaction force. To simulate the squatting activity, the length of the actuators was increased uniformly, which resulted in a knee flexion velocity of about 12 degrees per second.

The Sigma RP is designed for flexion angles up to 120 degrees. Therefore, this design was analyzed from 70 to 120 degrees of flexion. In addition, the design was also simulated at flexion angles beyond 120 degrees to obtain an indication of forces and stresses in case the conventional TKA is subjected to high flexion. The Sigma RP-F is designed for flexion angles up to 155 degrees. Therefore, this design was simulated up to 155 degrees of flexion (figure 3).

Outcome parameters

Five outcome parameters were determined. The equivalent Von Mises stress, the accumulated plastic deformation (the total material volume which was plastically deformed) and the contact stresses were determined for the polyethylene insert, as it is often considered as the weakest component of the knee prosthesis. The insert was divided into three areas: both dishes, the post and the remaining area (figure 4). The stresses predicted for the remaining area were relatively low in all cases studied and are therefore not presented.

The contact positions on the dishes (rollback) and the post, and the patella tendon force were assessed as a function of the flexion angle.

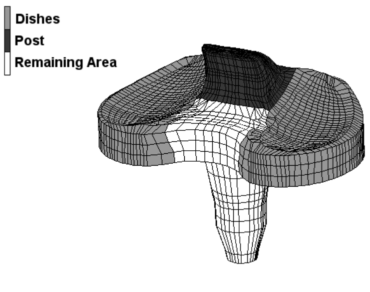

figure 4: different areas of the insert

Results

The Von Mises stress within the insert increased with flexion for both designs (figure 5). The distribution and the maximum values of the Von Mises stress were similar for both TKAs during flexion. The stress patterns also moved in a similar fashion during flexion. These similarities between both TKAs in normal flexion indicated that the Sigma RP-F showed no adverse effects at normal flexion angles.

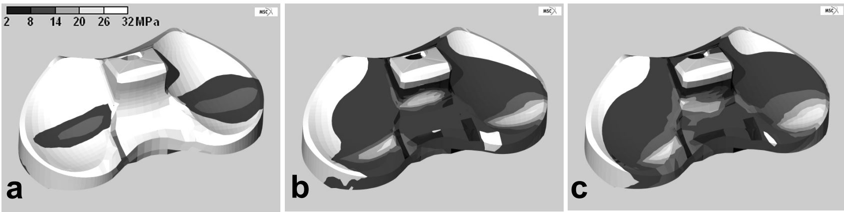

figure 5: equivalent von Mises stress for the Sigma RP-F on: **a.** 90 degrees, **b.** 120 degrees, **c.** 155 degrees of flexion

The maximum material stress was obviously leveled off by plastic deformation of the material. Therefore, the authors also determined the total amount of material volume which is plastically deformed up to the current flexion angle of the simulation (accumulated plastic deformation: figure 6a and figure 6b). Plastic deformation was observed with both TKAs, starting at the same flexion angle. The plastic deformation was about equal for the Sigma RP and Sigma RP-F up to 110 degrees. However, beyond 110 degrees, the Sigma RP-F showed a lower accumulated plastic deformation. Hence, this parameter showed that the Sigma RP-F showed an improved mechanical behavior in high flexion as compared to the conventional Sigma RP design and that this had no adverse effects concerning the normal flexion range.

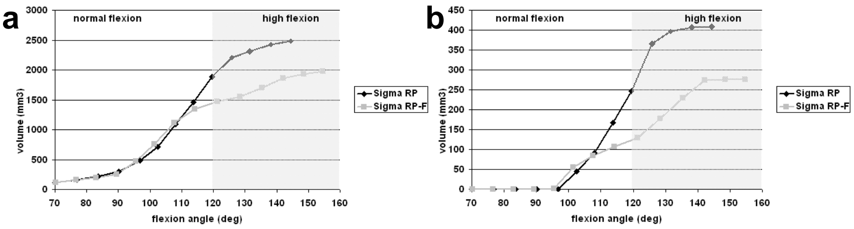

figure 6: accumulated plastic deformation (total volume of the insert which is plastically deformed): **a.** dish, **b.** post

The maximum contact stresses showed a different pattern. The contact stresses on the dish (figure 7a) were clearly lower in high flexion for the RP-F. However, these stresses were slightly higher, or similar, for the RP-F within the normal flexion range (<120 degrees). The contact stresses at the post (figure 7b) were similar or higher for the Sigma RP-F, both in high flexion range and in the normal flexion range. Nevertheless, the Sigma RP-F allowed high flexion whereas the posterior condyles of the Sigma RP started to 'dig in' into the polyethylene insert (>130 degrees). This caused the contact stress on the dish to increase considerably (figure 7a) and even resulted in a complete release of the post-cam contact beyond 140 degrees of flexion (figure 7b).

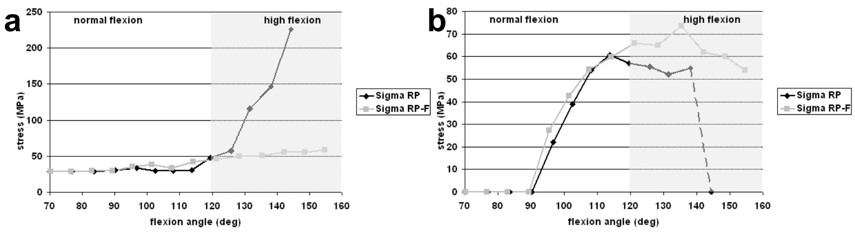

figure 7: maximum contact stresses: **a.** dish, **b.** post

The contact positions between femoral- and tibial component influence the lever arm of the patella tendon and therefore determine the moment equilibrium and the force- and stress transfer. A more posterior contact position on the dish is positive as it increases the effective moment arm of the patella tendon force (figure 8). A more inferior contact position on the post is also positive as it reduces the moment arm of the post-cam contact force on the post. The Sigma RP showed 1.5 mm more rollback in comparison to the Sigma RP-F (figure 9a). At the location of maximum rollback for the Sigma RP, the tibio-femoral contact switched to line contact between the edges of the femoral posterior condyles and the tibial insert. With ongoing flexion, the edges of the femoral posterior condyles of the Sigma RP slid forward over the tibial insert. The Sigma RP-F showed a more inferior contact position at the post for flexion angles beyond 110 degrees (figure 9b).

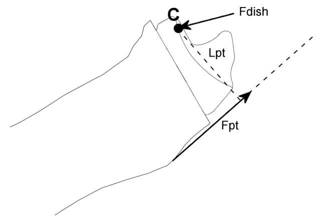

figure 8: the relation between the contact position on the insert and the efficiency of the extensor mechanism

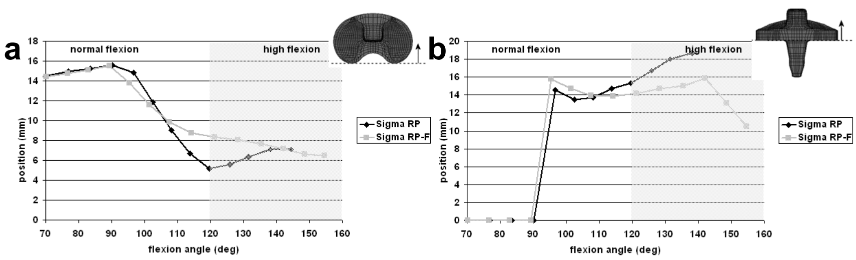

figure 9: contact location on the insert: **a.** dish, **b.** post

The patella tendon force gives an indication of the efficiency with which an activity can be performed. A lower patella tendon force means that less effort is needed for the activity. Hence, the Sigma RP-F showed a lower effectiveness at flexion angles beyond 110 degrees of about 300N, which is about 10% of the total patella tendon force (figure 10).

The simulations also showed that squatting is more demanding at higher flexion angles as compared to normal flexion angles. In general, the simulations showed higher stresses and more deformation in high flexion as compared to normal flexion. Hence, high flexion is more demanding for TKA components.

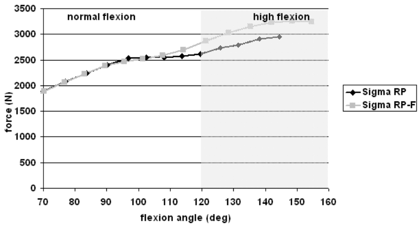

figure 10: patella tendon force

Discussion

The application of conventional TKAs in high flexion may have detrimental effects as these TKAs were not designed for high flexion. This was supported by the simulations of this study which showed that the edges of the posterior condyles of the conventional Sigma RP actually started to 'dig in' into the polyethylene insert at flexion angles beyond 130 degrees. Rollback is a prerequisite for high flexion, because of a later posterior tibio-femoral impingement[2]. Furthermore, it also increases the effectiveness of the extensor mechanism, as it increases the lever arm of the patella tendon force. Between 105 and 140 degrees, the Sigma RP showed more rollback than the Sigma RP-F (figure 9a). Hence, the extensor mechanism appeared to be more effective for the RP design which is also demonstrated by the lower patella tendon force which was found for the Sigma RP (figure 8). A lower patella tendon force may decrease the contact forces.

This study showed a rollback of 8-9 mm during a squatting activity from 70 degrees to maximum flexion. This is comparable with results from Argenson et al.[1] who measured a posterior femoral rollback of at least 4.4 mm (range 0-20 mm), also with a mobile bearing high flexion TKA. Most et al.[16] measured average values for femoral translations up to 20 mm. However, these values were measured for a fixed bearing and cruciate retaining high flexion TKA.

This immediately highlights a disadvantage of a mobile bearing knee in comparison to a fixed bearing knee. The AP-dimension of a fixed bearing insert is larger in case of similar implant sizes. Hence, a fixed bearing TKA allows more rollback theoretically, resulting in lower forces. The advantage of mobile bearing knees, compared to fixed bearing knees, are the reduced contact stresses, due to the higher conformity between the femoral component and the tibial insert. Argenson et al.[1] also advocated the mobile bearing option in high flexion TKA because it is not constrained against substantial axial rotations which sometimes occur in high flexion.
The Sigma RP-F uses an extended curvature of the posterior condyles to obtain high flexion angles without edge loading. This can only be reached with a decrease in condylar radius in the extended part of the curve (figure 1a). This reduces the tibio-femoral conformity beyond 100 degrees of flexion and thereby may be a reason, together with the higher patella tendon force (due to a less effective extensor mechanism), for the slightly higher contact stresses at the dish for the Sigma RP-F between 100 and 120 degrees of flexion.
The contact stresses on the dish for the Sigma RP (70-120 degrees) and the Sigma RP-F (70-155 degrees) reached values up to 60 MPa. Calculated maximum contact stresses of 15-25 MPa are reported during simulations of gait[20,25]. Morra et al.[15] calculated contact stresses at 135 degrees of flexion (kneel rise position) for the Sigma RP-F. They calculated stresses up to 32 MPa, using 3134 N. Chapman-Sheath et al.[5] measured maximum contact stresses of 22-36 MPa. They used a 3600 N load and measured the maximum contact stresses at different flexion angles, up to 110 degrees of flexion. The values of the maximum contact stresses at the dish which were calculated in this study, up to 110 degrees, were close to the range measured by Chapman-Sheath et al.[5].
The contact stresses at the post reached values up to 70 MPa for the Sigma RP and Sigma RP-F. Morra et al.[15] calculated contact stresses at the post up to 32 MPa for the Sigma RP-F, with an anterior load of 279 N. However, they used a lower polyethylene stiffness than was used in this study, which consequently results in lower contact stresses. Nakayama et al.[19] measured contact stresses between the post and the cam at 90, 120 and 150 degrees of flexion, applying only an anterior load of 500 N. They measured contact stresses of 22-34 MPa. The contact stresses calculated in this study were clearly higher. However, the force on the post, which was calculated by the

model itself in this study, exceeded 1000 N. It should be noted that the compressive forces at the dishes also have a posterior component which adds to the force on the post.

In all the studies which were mentioned, TKA components were just pressed against each other and identical loads were applied to different TKAs. In this study, the complete knee joint was modeled and the load transfer between the TKA components was generated within the model through the application of the ground reaction force, which is more realistic. A TKA which exhibits more rollback will show a lower patella tendon force and thereby lower contact forces in this model, similar to what would occur in patients. Simulations with different TKAs will generate different internal forces, which need to be taken into account when analyzing and comparing different designs. Hence, the results of those studies which do not take the kinetic effects of implant specific kinematics into account should be interpreted more carefully.

Argenson et al.[1] argumented that it is preferable to have the contact point of the cam move down the post, during flexion. The rationale is that a more inferior contact position on the post, results in less bending of the post and therefore in a reduced chance of material failure. In this study, the position of post-cam contact for the Sigma RP-F indeed moved downwards on the post after 140 degrees of flexion (figure 9b) indicating the desired post-cam interaction at those higher flexion angles. The downward translation of the post-cam contact of the Sigma RP-F may be positive concerning the Von Mises stresses, however, the calculated contact stresses were still higher due to the lower post-cam conformity. Hence, besides the post-cam contact location, post-cam conformity plays a dominant role as well in material failure. It should be noted that the post-cam design does not only influence the stresses at the post, but also influences the forces and stresses at the dishes, because the post-cam design determines the roll back in flexion.

The maximum contact stress for the Sigma RP-F occurred at 135 degrees of flexion. This maximum value can not be avoided in order to reach 155 degrees of flexion. Hence, there may be a reduced chance of material failure at 155 degrees of flexion, but not during the complete squatting activity. Furthermore, as there are more activities which demand 135 degrees of flexion, the frequency of activities which require lower flexion angles is higher than the frequency of activities which require maximum flexion angles.

Obviously, the model includes several assumptions, which one should realize when interpreting the results.
The effect of collateral ligaments and capsular properties, on the values of joint forces and stresses in high flexion, is unknown. These collaterals, in combination with other soft tissues may constrain kinematics and change kinetics within the joint, but their effect would probably be similar for both designs. It was assumed that these structures would be a minor contributing factor and therefore they were not modeled . The cruciate ligaments are not of interest as these are sacrificed during posterior stabilized TKA.
It was also assumed that no contact would occur between the thigh and the calf in high flexion. However, Nagura et al.[18] described that thigh-calf contact occurred beyond 140 degrees of flexion and Escamilla[9] described that thigh-calf contact typically occurs between approximately 130 and 150 degrees knee flexion. The effect of thigh-calf contact on the joint forces is still unknown and requires further analysis before it can be represented in FE models such as presented in this study.
In conclusion: this study confirms that the high flexion Sigma RP-F shows a better performance in high flexion than the conventional Sigma RP and that it maintains the good mechanical performance of the conventional Sigma RP at normal flexion angles. Hence, a high flexion design can improve mechanical behaviour at high flexion without changing the performance in normal flexion. It should be reminded that high flexion activities, like squatting, are creating high internal forces which create relatively high stress levels in the prosthetic materials, even if the components are optimized for these high flexion activities.

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Chapter 9

summary and general discussion

TKA is one of the most successful procedures in orthopaedic surgery. However, placement of the components imposes many changes to the knee joint (e.g. load transfer and kinematics), which can have adverse effects like wear, implant loosening, reduced functionality or post-operative complaints. Therefore, the main goal of this research was to minimize these adverse effects by restoring the anatomical and physiological situation as much as possible. The subjects of this thesis focus on peri-prosthetic bone resorption, patellar tracking and high flexion TKA and can be summarized by the following three questions:

1. Are there parameters which can be changed to reduce bone resorption, caused by TKA, without affecting other relevant parameters (chapter 2)?
2. Can the design of the femoral component be changed to obtain more physiological patellar kinematics (chapter 3-7)?
3. Is it possible to increase the range of motion without adversely affecting the mechanical performance in high flexion TKA (chapter 7-8)?

Are there parameters which can be changed to reduce bone resorption, caused by TKA, without affecting other relevant parameters (chapter 2)?

In a full grown healthy bone, bone remodelling is a continuous equilibrium of bone resorption and bone apposition. This equilibrium is disturbed after TKA and often leads to more bone resorption than bone apposition due to sub-physiological loading of the bone. This process may lead to loosening of the implant, which may induce pain, and consequently a need for revision. Maybe even more important, bone loss makes a revision operation much more difficult as the fixation and the alignment of the revision implant can become very problematic. Hence, preservation of bone stock around implants is essential.

It is known from earlier bone remodelling simulations that a completely debonded femoral component shows a more physiological load distribution within the bone as compared to a completely bonded femoral component. Hence, these simulations suggest less bone resorption with a completely debonded implant[8]. However, such a type of implant is clinically not acceptable as the implant fixation is not stable. The subject of chapter 2 was whether it would be possible to preserve a considerable amount of bone stock and simultaneously maintain sufficient implant stability, using the compromise of a partly bonded implant. Therefore, bone remodelling simulations were performed, in which femoral bone resorption was simulated, using several different prosthetic bonding characteristics. The interface stresses were calculated as well. The simulations showed that a debonded anterior flange preserves a considerable amount of bone stock without jeopardizing the implant fixation.

One should realize that this result was obtained with a theoretical study. In reality, a debonded part of the interface may be an entrance of wear particles to the surrounding bone tissue and local implant-bone micromotions may promote soft-tissue formation. Therefore, a cemented TKA with an highly polished inner side of the anterior flange was proposed. The cement protects the bone from the entrance of wear particles. Furthermore, the implant-cement interface at the anterior flange is expected to debond quickly after implantation (because of the polishing) and not to result in cement abrasion, similarly to a highly polished cemented femoral hip stem[6].
Whether a polished cemented inner side of the anterior flange actually debonds will have to be tested in the future. Furthermore, it has to be tested whether the simulated effect of a more physiological load distribution within the bone and the subsequent preservation of bone stock will occur. If polishing of the inner side of the anterior flange also sufficiently prevents the generation of cement and metal wear particles, it may be a suitable option in primary TKA. This may be an option, particularly for patients of whom it is expected that they will need a revision in the future, as a good bone stock makes revisions less complicated.
In these simulations bone only remodels due to changes in mechanical signals. Hence, a prosthesis with exactly the same material properties as the bone, would not the change the load transfer and would therefore maintain the current bone quality. This concept of implants with (more) physiological material properties (more flexible) has been applied in Total Hip Arthroplasty (THA) with the introduction of so-called iso-elastic stems. However, it turned out that the interfaces were not strong enough to withstand the increase in interface stresses. The same principle would apply to TKA: the use of an iso-elastic femoral component would increase the interface stresses to such an extent that loosening would be very likely. Even when the material properties of the femoral component were changed from CoCr to Titanium (chapter 2), the interface stresses increased considerably with only a little effect on bone preservation. Hence, a material change offers little perspective.

However, a change in boundary condition, as proposed in this thesis, may preserve bone stock and provide sufficient implant stability.

Can the design of the femoral component be changed to obtain more physiological patellar kinematics (chapter 3-7)?

There are many patients with post-operative patella related complaints. One of the reasons for these complaints may be non-physiological patellar tracking. An important determinant of patellar tracking is the orientation of the pre-operative trochlea, and the orientation of the post-operative prosthetic groove[1]. Therefore, the orientation of the natural trochlea and of the prosthetic groove were compared with each other (chapter 3 and 4). Measurements of the orientation of the natural trochlea showed that the trochlea has two successive orientations. The first part of the trochlea, starting from the intercondylar notch has a 0.2 degrees lateral orientation, with respect to the mechanical axis. The second part of the trochlea has a 4.2 degrees medial orientation (chapter 3). Calculation of the orientation of the prosthetic groove showed a lateral groove orientation of 2.9 and 2.2 degrees for the first and second part, respectively. The prosthetic groove extends much more proximally than the natural trochlea. Hence, the orientation of the prosthetic groove has an additional third part with a lateral orientation between 0.4 and 4.4 degrees (chapter 4). This third orientation depends on the groove design of the anterior flange of the femoral component. The difference in orientation between the trochlea and the prosthetic groove led to a proposal for a more anatomical groove design (chapter 4): a groove design which would mimick the pre-operative medio-lateral patellar translation. This proposed design has a medial orientation of 4.0 and 8.6 degrees for the first and second part, respectively. These orientations are relative to a prosthetic reference frame. The design of current TKAs is often called anatomical. However, they should be called ‘asymmetrical’ rather than ‘anatomical’ as they have laterally oriented or neutral grooves.

An *in vitro* experiment was performed, in which the knee kinematics of a TKA with a lateral and neutral groove orientation were compared with the knee kinematics of the intact situation (chapter 5). The medio-lateral patellar translation, in the intact and in the TKA situation, correlated with the trochlear and prosthetic groove orientation from chapter 3 and 4, respectively. Statistically significant differences in medio-lateral translation of the patella were found between the intact and TKA situations. However, no differences in patellar tracking were found between the TKA with the lateral groove orientation and the TKA with the neutral groove orientation. After TKA, the patella was significantly shifted medially when the knee was in flexion. This could be explained by the alignment of the femoral component. During intra-operative measurements (chapter 6), it was found that the notch of the TKA was located 2-3 mm more medially as compared to the intercondylar notch.

The prosthetic groove extends much more proximally than the natural trochlea. This implies that the proximal part of the prosthetic groove (on the anterior flange of the implant) is an artificial extension of the anatomic trochlea. The reason for this extension is twofold: it prevents that there is otherwise a bone-prosthesis transition within the patello-femoral articulation and it allowed to capture the patella during an earlier stage in flexion (which is thought to prevent patellar subluxation). To additionally support the early capture of the patella, the patella groove on the anterior flange is often designed with a lateral orientation and a raised lateral ridge. However, the attempt to capture the patella during an earlier stage in flexion does not address the actual causes of patellar subluxation and it also does not restore the original physiological situation.
It is thought that the application of a lateral orientation of the patella groove also results in more anatomical patellar tracking[3]. In this thesis, no differences were found between the patellar tracking of both TKAs. It should be noted that the neutral and laterally prosthetic groove design are only different in orientation on the anterior flange (third part): the location of the patella in the extended knee. Extension is a situation with a relatively low patello-femoral load, which makes the groove orientation a less determinating factor. Hence, patellar tracking is not very sensitive to the exact orientation of the patella groove on the anterior flange. The proposed, more medial, groove design is different in orientation for the entire groove as compared to current prosthetic groove designs. The expected physiological patellar tracking of the proposed groove design has to be confirmed by clinical measurements, as only clinical studies can demonstrate the true benefit of the proposed changes in design.
The *in vitro* patellar tracking study (chapter 5) showed that TKA resulted in a more medial position of the patella when the knee was in flexion, which could be explained by the more medial alignment of the femoral component (chapter 6). As the patella is exposed to high forces in flexion, this difference

in patellar position can have considerable clinical consequences. Different possibilities may cause the more medial placement of the femoral component. Studies of Eckhoff et al.[4,5] suggested that the notch is not exactly in the middle of the medial and lateral condyle. Furthermore, after the distal resection, the medio-lateral dimension seems larger for the medial condyle as compared to the lateral condyle. Both condyles are not aligned parallel, but the medial condyle is rotated relative to the lateral condyle. The medial condyle is also positioned more distally. Hence, the distal resection of the femur during TKA surgery removes more bone medially, creating a wider resection area. Thus, when an orthopaedic surgeon aligns a femoral component exactly in the middle of the distal resection, the notch of the prosthesis will be shifted to the wider resection area of the medial condyle and therefore cause a medial displacement of the groove. This can be prevented by the introduction of a TKA with different medio-lateral dimensions for both condyles (a larger medio-lateral dimension for the medial condyle), such as the 3Dknee (Encore Medical, Austin, TX), or with a notch of the groove which is not located centrally. It is surprising to see, that whereas the intact geometry of the distal femur is asymmetrical, many implants are still symmetrical. Simply aligning a femoral component more laterally could have adverse results, as it shifts the whole femur laterally with respect to the tibia. The suggestion to align both the femoral- and tibial component more laterally may change the load transfer adversely, as the majority of the load transfer is through the medial compartment. A design with a wider medial condyle, as proposed, is a better option as it is also more suitable for withstanding the physiological (more medial) load transfer.

The studies of chapter 3-6 were performed assuming that the patella was not resurfaced. One could question whether a patellar surface replacement would neutralize the differences between the pre and post-operative situation. It will probably provide a different but more reproducible pattern: the femoral and patellar component are designed with optimal conformity. However, a patellar surface replacement will not compensate a non-anatomical groove orientation.

A medial placement of the patellar component on the patella could compensate for the more medial position of the prosthetic groove in flexion (chapter 5&6). However, this would treat the effect of the more medial groove position, but not the cause, which seems unnatural.

TKA seems to be a surface replacement mimicking the bone geometry.

However, in reality, there are considerable differences between the normal human anatomy and the prosthetic geometry, which explains some of the clinical complications.

Is it possible to increase the range of motion without adversely affecting the mechanical performance in high flexion TKA (chapter 7-8)?

High flexion TKA was compared with conventional TKA (chapter 8) by comparing a new high flexion Sigma RP-F design with the conventional Sigma RP (DePuy, Leeds, UK). A finite element model of the knee joint was created for both designs. These models were identical, except for the implanted knee prosthesis. The fundamental concepts behind these dynamic finite element models were based on an earlier and more simple model of a TKA knee (chapter 7). A dynamic simulation of squatting was performed with each model and different parameters were calculated. High flexion TKA showed a better performance in high flexion than a conventional TKA while maintaining the adequate mechanical performance of conventional TKAs at normal flexion angles. However, high flexion activities created higher internal forces, which resulted in relatively higher stress levels in the prosthetic materials, even if the components were optimized for these high flexion activities.

High flexion TKA is currently a product for patients with specific demands, within the top segment of the orthopaedic market. It is originally developed for younger, more active patients, and for patients from cultures where high flexion is important for cultural, social or religious reasons. However, if clinical results support the finding of this thesis that high flexion TKA performs just as good as the conventional TKA within the normal flexion range and that high flexion TKA shows improved performance in high flexion, then why should it not become the new gold standard for TKA? This suggestion may seem superfluous as many current TKA patients never reach high flexion or do not require high flexion for their normal daily activities (anymore). However, if high flexion is reached incidentally, high flexion TKA designs are at least more adapted to withstand the effects of it. Furthermore, the knowledge of enhanced flexion of TKA components may lead patients, physiotherapists and surgeons to strive for more flexion during rehabilitation, even if it is currently not demanded. Hence, high flexion capabilities may become an extension of the capabilities of conventional TKA.

Although high flexion TKA shows improved performance in high flexion compared to conventional TKA, high flexion activities still create higher internal forces, which in turn induce higher stress levels. Hence, unless prosthetic materials are improved or new design adaptations further limit the stresses in high flexion, it should be expected that the increase of TKA flexion capabilities will adversely affect longevity.

A high flexion prosthesis does not guarantee that the patient will be able to perform high flexion activities. The pre-operative range of motion (ROM) of a TKA patient largely determines the post-operative ROM[2]. Hence, patients who could reach high flexion pre-operatively, like younger and more active patients, and patients from cultures where high flexion is socially or religiously required, will benefit most.

It was already known that rollback of the femur is a requisite to achieve high flexion angles[2,7]. Rollback also increases the efficiency of the extensor mechanism: the patella tendon force may decrease, as the moment arm of patella tendon increases. Consequently, this may reduce tibio-femoral contact loads and stresses. Hence, rollback is important in high flexion TKA concerning the stresses. The post-cam mechanism of a posterior stabilized TKA ensures rollback of the femoral component. It is known that TKAs which do not have a post-cam mechanism and which consequently retain the posterior cruciate ligament sometimes show erratic rollback behaviour. This would be in favour of applying a post-cam mechanism in high flexion TKAs. Although, it should be noted that the post should be strong enough to prevent failure as the cam transfers substantial loads to the post during rollback.

Closing remarks

With all the focus on changes in TKA design, it should be kept in mind that the surgeon is a more influential parameter than the TKA design. A TKA design may perfectly mimick the anatomy of the knee, however, if the alignment of the TKA components or the balancing of the joint is not correct, the final result will probably be poor. Furthermore, TKA components and instrumentation are designed for the 'perfect' patient. However, at the time of surgery, the joint can already be deformed in such a manner that the joint needs to be realigned and/or correct implant alignment becomes more complicated. This shows that the training and the experience of the surgeon are most important and that surgical navigation and good instrumentation may be of great help for the surgeon to align the prosthetic components as optimal as possible.

Another issue is whether attempting to restore the anatomical and physiological situation is always the best solution, especially in cases where the structures around the knee have completely adapted themselves to the current situation. In some cases, a patient may just be satisfied with a painfree and (limited) functional solution in order to allow his or her daily activities.

In summary, the results of this thesis suggest that the following TKA design changes or issues will improve outcome and functionality:
Concerning bone preservation
· A polished (cemented) back-side of the anterior flange
Concerning patellar tracking
· An anatomical patella groove orientation
· Difference between the medio-lateral dimension of the medial- and lateral condyle
Concerning high flexion
· A post-cam mechanism to ensure rollback

This thesis proposes a combination of both design changes concerning patellar tracking. If only the anatomical groove orientation would be taken into account, without regarding the medio-lateral position of the groove, the patellar tracking could end up being less physiological as compared to current TKAs. Therefore, the application of only a single design change may not have sufficient effect or may even have adverse effects.

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Hoofdstuk 9

samenvatting en algemene discussie

TKA is één van de meest succesvolle procedures in de orthopaedische chirurgie. De plaatsing van de prothesecomponenten brengt, desalniettemin, veel veranderingen teweeg in en rondom het kniegewricht (bijv. ten aanzien van belastingsoverdracht en kinematica). Deze veranderingen kunnen nadelige effecten hebben zoals slijtage, loslating van het implantaat, post-operatieve klachten of een reductie in functionaliteit. Het hoofddoel van dit onderzoek was daarom om de nadelige effecten te minimaliseren door de anatomische en fysiologische situatie zoveel mogelijk te herstellen. De onderwerpen van deze dissertatie richten zich op bot resorptie rondom protheses, patella tracking en TKA voor hoge flexie hoeken. De onderwerpen kunnen worden (samen)gevat door de volgende drie vragen:

1. Zijn er parameters die bot resorptie, veroorzaakt door TKA, kunnen verminderen zonder dat andere relevante parameters hier negatief door worden beïnvloed (hoofdstuk 2)?
2. Kan het ontwerp van de femorale component worden veranderd zodat er een meer fysiologische kinematica van de patella wordt verkregen (hoofdstuk 3-7)?
3. Is het mogelijk om de range of motion te vergroten door middel van high flexion TKA, zonder dat dit een nadelige invloed heeft op de mechanische prestaties (hoofdstuk 7-8)?

Zijn er parameters die bot resorptie, veroorzaakt door TKA, kunnen verminderen zonder dat andere relevante parameters hier negatief door worden beïnvloed (hoofdstuk 2)?

Bot remodellering is een continu evenwicht van bot resorptie en appositie in een volgroeid gezond bot. Dit evenwicht is verstoord na TKA en leidt, vanwege een niet- of minder fysiologische belasting van het bot, in veel gevallen tot meer bot resorptie dan bot appositie. Dit proces kan leiden tot de loslating van de prothese, wat pijn kan veroorzaken en een revisie operatie noodzakelijk maakt. Wat misschien nog wel belangrijker is, is dat bot verlies een revisie operatie veel moeilijker maakt, omdat de fixatie en de uitlijning van de revisie prothese door bot verlies erg problematisch kan worden. Kortom, het behoud van bot rondom implantaten is van essentieel belang. Het is van eerdere botremodellering-simulaties bekend dat een volledig losgelaten femorale component een meer fysiologische belastingsdistributie laat zien dan een volledig vaste (gebonden) femorale component. Kortom, deze simulaties suggereren dat er minder bot resorptie zal optreden bij een volledig losgelaten implantaat[8]. Echter, zo'n type implantaat is klinisch niet acceptabel omdat de fixatie van het implantaat niet stabiel is. Het onderwerp van hoofdstuk 2 was of het mogelijk zou zijn om met een compromis van een gedeeltelijk losgelaten implantaat, een aanzienlijke hoeveelheid van het bot te behouden en tegelijkertijd voldoende stabiliteit van het implantaat te garanderen. Om dit te onderzoeken, zijn er verschillende botremodellering-simulaties uitgevoerd, waarin de femorale bot resorptie werd gesimuleerd in geval van verschillende vormen van fixatie van de prothese. De interface spanningen werden tegelijkertijd uitgerekend. De simulaties lieten zien dat wanneer de verbinding tussen de anterieure flange van de prothese en het bot niet vast is, een aanzienlijk gedeelte van het bot behouden blijft en dat de fixatie van het implantaat niet in gevaar komt.

Dit resultaat werd verkregen door middel van een theoretische studie. In werkelijkheid kan een losse interface een toegang tot het omliggende bot zijn voor slijtage deeltjes en kunnen locale microbewegingen tussen bot en implantaat de groei van zacht weefsel bevorderen. Daarom is er een gecementeerde TKA met een zeer glad gepolijste binnenkant van de anterieure flange voorgesteld. Het cement beschermt het bot tegen penetratie van slijtage deeltjes. Daarnaast is het de verwachting dat de implantaat-cement interface op de anterieure flange snel loslaat na implantatie (vanwege het zeer glad gepolijste oppervlake) en dat deze loslating niet leidt tot abrasieve cement slijtage, vergelijkbaar met zeer glad gepolijste femorale heup protheses[6].
Of een gepolijste en gecementeerde binnenkant van de anterieure flange ook daadwerkelijk loslaat moet worden getest in de toekomst. Daarnaast moet er worden getest of het gesimuleerde effect van een meer fysiologische belastingsdistributie in het bot en het daarbij behorende behoud van bot, optreedt. Het polijsten van de binnenkant van de anterieure flange kan een geschikte optie zijn in primaire TKA, als blijkt dat hiermee het ontstaan van cement en metalen slijtagedeeltjes voldoende wordt voorkomen. Juist voor patiënten waarvan verwacht wordt dat ze in de toekomst een revisieoperatie zullen moeten ondergaan, zal een goede botmassa een revisie operatie kunnen vereenvoudigen.
In deze simulaties remodelleert bot alleen door mechanische signalen. Een prothese met exacte dezelfde eigenschappen als (het vervangen) bot verandert de belastingsoverdracht niet en daarmee verandert de huidige

botkwaliteit ook niet. Dit concept van implantaten met (meer) fysiologische materiaaleigenschappen (minder stijf) is toegepast in Totale Heup Arthroplastiek (THA) met de introductie van zogenaamde iso-elastische stelen. Het bleek echter dat de (prothese-bot/cement) interfaces niet sterk genoeg waren om de toename van de interface stresses te weerstaan. Hetzelfde principe geldt voor TKA: het gebruik van een iso-elastische femorale component zou de interface spanningen in zulke mate doen toenemen dat loslating zeer waarschijnlijk wordt. Zelfs toen de materiaaleigenschappen van de femorale component in de simulatie werden verandert van CoCr in Titanium (hoofdstuk 2) namen de interface spanningen al aanzienlijk toe, met enkel een klein effect op het behoud van het bot. Een verandering van materiaal biedt dus weinig perspectief. Echter, een verandering in randvoorwaarden, zoals voorgesteld in dit proefschrift, kan tot behoud van botmassa leiden en tot het behoud van voldoende stabiliteit voor het implantaat.

Kan het ontwerp van de femorale component worden veranderd zodat er een meer fysiologische kinematica van de patella wordt verkregen (hoofdstuk 3-7)?

Er zijn veel patiënten met post-operatieve patella gerelateerde klachten. Eén van de redenen voor deze klachten is mogelijk een niet fysiologische patella tracking. Een belangrijke bepalende factor bij patella tracking is the oriëntatie van de pre-operatieve trochlea, en de oriëntatie van de post-operatieve groeve van de prothese[1]. Daarom is de oriëntatie van de natuurlijke trochlea vergeleken met die van de prothese groeve (hoofdstuk 3 en 4). Metingen van de oriëntatie van de natuurlijke trochlea lieten zien dat de trochlea twee opeenvolgende richtingen had. Het eerste deel van de trochlea, beginnend bij de intercondylaire notch, heeft een laterale oriëntatie van 0.2 graden ten opzichte van de mechanische as. Het tweede deel van de trochlea heeft een 4.2 graden mediale oriëntatie (hoofdstuk 3). Berekening van de richting van de prothese groeve liet een laterale groeve oriëntatie van resp. 2.9 en 2.2 graden zien voor het eerste en tweede deel. Daarnaast loopt de prothese groeve proximaal verder door dan de natuurlijke trochlea. Daarom is er bij de oriëntatie van de prothese groeve nog een extra derde deel met een laterale oriëntatie tussen 0.4 en 4.4 graden (hoofdstuk 4). Deze derde oriëntatie is afhankelijk van het ontwerp van de groeve op de anterieure flange van de femorale component. Het verschil in oriëntatie tussen de trochlea en de

prothese groeve leidde tot een voorstel voor een meer anatomisch ontwerp van de groeve (hoofdstuk 4): een ontwerp van de groeve dat de pre-operatieve medio-laterale translatie van de patella kan nabootsen. Het voorgestelde ontwerp heeft een mediale oriëntatie van resp. 4.0 en 8.6 graden voor het eerste en tweede deel. Deze oriëntaties zijn ten opzichte van het referentiesysteem van de prothese. Het ontwerp van huidige TKA's wordt vaak anatomisch genoemd. Deze ontwerpen zouden echter beter 'asymmetrisch' dan 'anatomisch' genoemd kunnen worden, omdat ze lateraal of neutraal georiënteerde groeves hebben.
Er is een *in vitro* experiment uitgevoerd waarbij de kinematica van de knie met TKA, met een laterale en met een neutrale groeve oriëntatie, werden vergeleken met de kinematica van de knie in de intacte situatie (hoofdstuk 5). De medio-laterale translatie van de patella, in de intacte en in de TKA situatie, kwamen overeen met de oriëntaties van resp. de trochlea en de prothese groeve uit hoofdstuk 3 en 4. Statistisch significante verschillen in medio-laterale translatie van de patella werden gevonden tussen de intacte en TKA situaties. Echter, er werden geen verschillen gevonden in patella tracking tussen de TKA met de laterale oriëntatie van de groeve en de TKA met de neutrale oriëntatie. Na TKA, bleek de patella significant naar mediaal te zijn verschoven op het moment dat de knie in flexie was. Dit kon worden verklaard door de uitlijning van de femorale component. Tijdens intra-operatieve metingen (hoofdstuk 6) werd gevonden dat de locatie van de notch van de TKA 2-3 mm meer mediaal was dan de locatie van de intercondylaire notch.

De groeve van de prothese loopt proximaal verder door dan de natuurlijke trochlea. Dit betekent dat het proximale deel van de prothese groeve (op de anterieure flange van het implantaat) een artificiële verlenging is van de anatomische trochlea. De reden voor deze verlenging is tweeërlei: het voorkomt een bot-prothese overgang in de patello-femorale articulatie en het laat een vroege opname van de patella in de groeve toe (waarvan wordt gedacht dat daarmee potentiële subluxatie van de patella wordt voorkomen). Ter verdere ondersteuning van een vroege opname van de patella, wordt de patella groeve op de anterieure flange vak ontworpen met een laterale oriëntatie en een verhoogde laterale rand. Echter, de poging om tot een vroege opname van de patella in de groeve te komen behandelt niet de daadwerkelijke oorzaken van patellaire subluxatie en het herstelt ook niet de originele fysiologische situatie.

Er wordt aangenomen dat de toepassing van een laterale patella groeve oriëntatie ook resulteert in een meer anatomische patella tracking[3]. Er werden geen verschillen gevonden in patella tracking van beide TKA's in dit proefschrift. Hierbij moet worden aangemerkt dat het neutrale en laterale groeve ontwerp alleen in oriëntatie verschillen op de anterieure flange van de prothese (derde deel): de locatie van de patella in de geëxtendeerde knie. Extensie is een situatie met relatief lage patello-femorale krachten, wat de groeve oriëntatie een minder bepalende factor maakt. Patella tracking is dus niet erg sensitief voor de exacte oriëntatie van de patella groeve op de anterieure flange. Het voorgestelde, meer mediale, ontwerp voor de groeve verschilt over de hele lengte van de groeve in vergelijking met huidige groeve ontwerpen. De verwachte fysiologische patella tracking van het voorgestelde ontwerp van de groeve zal moeten worden bevestigd door klinische metingen, omdat alleen klinische studies het daadwerkelijke effect van de voorgestelde ontwerpwijzigingen kunnen aantonen.
De *in vitro* patella tracking studie (hoofstuk 5) liet zien dat TKA resulteerde in een meer mediale positie van de patella bij een geflecteerde knie, wat kon worden verklaard door de meer mediale uitlijning van de femorale component (hoofdstuk 6). Dit verschil in patella positie kan aanzienlijke klinische consequenties hebben, aangezien er grote krachten worden uitgeoefend op de patella in flexie. Er zijn verschillende mogelijkheden die deze meer mediale plaatsing van de femorale component kunnen veroorzaken. Studies van Eckhoff et al.[4,5] suggereerden dat de notch niet precies in het midden ligt van de mediale en laterale condyle. Na distale resectie lijkt het verder dat de afmeting van de mediale condyle groter (breder) is in vergelijking met de laterale condyle. Beide condyles liggen niet parallel, maar de mediale condyle ligt geroteerd ten opzichte van de laterale condyle. De mediale condyle ligt ook iets meer distaal. Een distale resectie van het femur tijdens een TKA procedure zal dus meer bot aan de mediale zijde verwijderen, waardoor ook een bredere mediale resectie zal ontstaan. Als een orthopaedisch chirurg de femorale component dus exact in het midden van de distale resectie plaats, zal de notch van de prothese zijn verschoven in de richting van de bredere mediale resectie waardoor er een mediale translatie van de groeve ontstaat. Dit kan worden voorkomen door de introductie van een TKA met verschillende medio-laterale afmetingen voor beide condyles (een grotere medio-laterale afmeting voor de mediale condyle), zoals de 3Dknee (Encore Medical, Austin, TX), of met een

prothese waarbij de notch van de groeve niet precies in het midden ligt. Het is verassend om te zien dat veel implantaten nog steeds symmetrisch zijn, terwijl de geometrie van het intacte distale femur asymmetrisch is. De femorale component simpelweg meer lateraal plaatsen kan mogelijk nadelige gevolgen hebben, omdat dan het hele femur lateraal wordt verschoven ten opzichte van de tibia. De suggestie om zowel de femorale als tibiale component meer lateraal te plaatsen kan mogelijk de belastingsoverdracht nadelig beïnvloeden, omdat het grootste deel van de belastingsoverdracht via de mediale condyle verloopt. Een ontwerp met een bredere mediale condyle, zoals voorgesteld, is een betere optie omdat het ook meer geschikt is ten aanzien van de fysiologische (meer mediale) belastingsoverdracht.

De studies van hoofdstuk 3-6 zijn uitgevoerd in de veronderstelling dat er geen patella component zou worden geplaatst. Men kan zich afvragen of een patella component de verschillen tussen de pre- en post-operatieve situatie niet zal neutraliseren. Het geeft waarschijnlijk een verschillend maar meer reproduceerbaar patroon: de femorale en patellaire component zijn immers ontworpen met een optimale conformiteit. Desalniettemin zal een patella component een niet-anatomische groeve oriëntatie niet (kunnen) compenseren.

Een mediale plaatsing van de patella component op de patella zou mogelijk de meer mediale positie van de prothese groeve in flexie (hoofdstuk 5 & 6) kunnen compenseren. Dit zou echter alleen het resultaat van de meer mediale groeve positie beïnvloeden, maar niet de oorzaak, wat onnatuurlijk lijkt.

TKA lijkt een surface replacement te zijn die de geometrie van het bot nabootst. In werkelijkheid zijn er echter aanzienlijke verschillen tussen de normale menselijke anatomie en de prothese geometrie, wat een aantal van de klinische complicaties kan verklaren.

Is het mogelijk om de range of motion te vergroten door middel van high flexion TKA, zonder dat dit een nadelige invloed heeft op de mechanische prestaties (hoofdstuk 7-8)?

High flexion TKA (TKA geschikt voor hoge flexiehoeken) is vergeleken met conventionele TKA (hoofdstuk 8) door een nieuw high flexion Sigma RP-F ontwerp te vergelijken met de conventionele Sigma RP (DePuy, Leeds, UK). Een eindige elementen model van het kniegewricht werd gemaakt voor beide ontwerpen. Deze modellen waren identiek, behalve met betrekking tot de geïmplanteerde knieprothese. De fundamentele concepten achter deze dynamische eindige elementen modellen waren gebaseerd op een eerder en meer eenvoudig model van een TKA knie (hoofdstuk 7). Een dynamische simulatie van hurken werd uitgevoerd met elk model en verschillende parameters werden berekend. High flexion TKA liet betere prestaties zien in high flexion in vergelijking met conventionele TKA, terwijl de voldoende goede prestaties van de conventionele TKA's bij normale flexiehoeken behouden bleef. High flexion activiteiten creëerden echter hogere interne krachten, die resulteerden in relatief hogere spanningsniveaus in the prothese materialen, zelfs in het geval dat de componenten waren geoptimaliseerd voor high flexion activiteiten.

High flexion TKA is op dit moment een product voor patiënten met specifieke eisen, binnen het topsegment van de orthopaedische markt. Het is in eerste instantie ontwikkeld voor jongere, meer actieve patiënten, en voor patiënten uit culturen waar high flexion belangrijk is vanwege culturele, sociale of religieuze redenen. Als echter klinische resultaten de bevindingen uit dit proefschrift ondersteunen, dat high flexion TKA in normale flexie net zo goed presteert als conventionele TKA en dat het betere prestaties laat zien in high flexion, waarom zou het dan niet de nieuwe gouden standaard voor TKA worden? Deze gedachte lijkt misschien overbodig, omdat veel van de huidige TKA patiënten nooit high flexion bereiken en het ook niet nodig hebben voor hun normale dagelijkse activiteiten. Echter, zelfs als high flexion maar af en toe wordt bereikt, dan zijn high flexion TKA onwerpen ten minste aangepast om de effecten ervan te weerstaan. Verder kan de wetenschap dat hogere flexiehoeken mogelijk zijn, ertoe leiden dat patiënten, fysiotherapeuten en chirurgen gaan streven naar meer flexie tijdens revalidatie, zelfs als dat nu niet wordt verlangd. High flexion mogelijkheden kunnen dus een uitbreiding gaan vormen op de mogelijkheden van conventionele TKA.
Ook al laat high flexion TKA in high flexion betere prestaties zien dan conventionele TKA, toch creëren high flexion activiteiten hogere interne krachten, die op hun beurt hogere spanningsniveaus genereren. Tenzij prothese materialen worden verbeterd of tenzij nieuwe ontwerp aanpassingen verdere beperkingen opleveren van de spanningen in high flexion, moet er worden verwacht dat een toename van de TKA flexie mogelijkheden een nadelig effect zal hebben op de levensduur.

Een high flexion prothese geeft niet de garantie dat de patiënt ook daadwerkelijk high flexion activiteiten kan uitvoeren. De pre-operatieve range of motion (ROM) van een TKA patiënt is grotendeels bepalend voor de post-operatieve ROM[2]. Dus patiënten die pre-operatief high flexion bereikten, zoals jongere en meer actieve patiënten, en patiënten uit culturen waar high flexion vanuit sociaal of religieus oogpunt van belang is, zullen het meeste voordeel hebben.
Het was al bekend dat rollback van het femur een voorwaarde is om high flexion hoeken te bereiken[2,7]. Rollback vergroot ook de efficiëntie van het strek-apparaat: de kracht in de patella tendon kan verminderen omdat de moment arm van de patella tendon toeneemt. Als een gevolg hiervan kunnen de tibio-femorale contactkrachten en –spanningen verminderen. Rollback in high flexion is dus ook belangrijk in verband met de spanningen. Het post-cam mechanisme van een posterior stabilized TKA garandeert de rollback van de femorale component. Het is bekend dat TKA's die geen post-cam mechanisme hebben en die, als een gevolg hiervan, de achterste kruisband behouden, een foutief rollback gedrag vertonen. Dit pleit voor het gebruik van een post-cam mechanisme in high flexion TKA's. Ook al moet daar wel bij worden opgemerkt dat de post sterk genoeg moet zijn om falen te voorkomen, omdat de cam een substantiële belasting overdraagt op de post tijdens rollback.

Afsluitende opmerkingen

Met alle focus op aanpassingen in het ontwerp van TKA's, moet niet uit het oog worden verloren dat de chirurg een meer invloedrijke parameter is dan het TKA ontwerp. De anatomie van de knie kan perfect zijn gekopieerd in een TKA ontwerp, als echter de uitlijning van de TKA componenten of het balanceren van de ligamenten niet correct is, dan is het eindresultaat waarschijnlijk ondermaats.TKA componenten en instrumentarium zijn verder ontworpen voor de 'perfecte' patiënt. Op het moment van operatie kan het gewricht echter al zo gedeformeerd zijn dat de uitlijning van het gewricht moet worden hersteld en dat de juiste uitlijning van de componenten gecompliceerder wordt. Dit laat zien dat de opleiding en ervaring van de chirurg heel belangrijk zijn en dat een navigatiesysteem en goed instrumentarium van groot belang kunnen zijn om de prothesecomponenten optimaal te plaatsen.

Een ander punt is of het herstellen van de anatomische en fysiologische situatie altijd de beste oplossing is, vooral in die gevallen waar de structuren rondom de knie zich hebben aangepast aan de bestaande situatie. In sommige gevallen kan het zo zijn dat de patiënt simpelweg tevreden is met een pijnvrije en (beperkte) functionele oplossing die het weer mogelijk maakt zijn of haar dagelijkse activiteiten uit te voeren.

Samenvattend geven de resultaten van dit proefschrift aan dat de volgende aanpassingen of onderwerpen in het TKA ontwerp het resultaat op langere termijn en functionaliteit zullen verbeteren:

Op het gebied van het behoud van botmassa

· Een gepolijste (gecementeerde) binnenkant van de anterieure flange

Op het gebied van patella tracking

· Een anatomische oriëntatie van de patella groeve

· Verschil in medio-laterale afmetingen van de mediale- en laterale condyle

Op het gebied van high flexion

· Een post-cam mechanisme om rollback te garanderen

Dit proefschrift stelt een combinatie voor van beide ontwerpaanpassingen op het gebied van patella tracking. Als alleen de anatomische oriëntatie van de groeve zou worden toegepast, zonder rekening te houden met de medio-laterale positie van de groeve, dan zou de patella tracking minder fysiologisch kunnen worden in vergelijking met huidige TKA's. Dus de toepassing van een enkele ontwerpaanpassing heeft mogelijk onvoldoende of zelfs nadelig effect.

Referenties

Zie einde "summary and general discussion"

About the author

Marco Barink was born on March 29th 1975 in Hardenberg, the Netherlands, where he also spent his childhood. He left Hardenberg for Enschede when he was 18, to pursue a degree in mechanical engineering at the University of Twente. During his time at the university, he was actively involved within the Christian student union. During his final two years at the university, he specialized in biomedical engineering. He performed a 3-month traineeship at the Hip and Knee Unit of the Robert Jones and Agnes Hunt Orthopaedic and District Hospital (Oswestry, UK), where he worked on the two-phase finite element modelling of cartilage. He graduated in 1998 on a masters assignment entitled ‘the modelling of human walking’, This assignment was concerned with the prediction of joint forces, moments and kinematics within a rigid body model of the human body using an end-point controller.
Two weeks after his graduation, he started to work at the Orthopaedic Research Lab, Nijmegen, The Netherlands. Over the years he performed modelling work (FE), measurements and experiments on many different subjects. Most of these projects were in cooperation with the orthopaedic industry. This PhD thesis is a combination of the studies concerning the knee and knee implants.
Marco Barink is married with Danielle Verhage.

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