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## A Critical Appraisal on Computer Navigation in Total Knee Arthroplasty

Enrike van der Linden – van der Zwaag

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# CAOS & TKA
# A Critical Appraisal on Computer Navigation in Total Knee Arthroplasty

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# General introduction

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## ■ Introduction

Total knee replacement (TKR), also referred to as total knee arthroplasty (TKA), is a surgical procedure where worn, diseased, or damaged surfaces of the knee joint are removed and replaced with artificial surfaces. It is a common treatment in (knee)joints affected by primary or secondary osteoarthritis due to rheumatoid arthritis or trauma.

At the moment about 700.000 people in The Netherlands suffer from knee-osteoarthritis (RIVM). In 2007 20.000 knee replacements were done and it is expected that by 2030 this will increase to 30.000 a year in the Netherlands and 3,5 million a year in the US. (Otten et al 2010, Kurtz et al. 2007).

Since 2008 the registration of total knee and total hip arthroplasties in The Netherlands is centralised in the so-called Landelijke Registratie voor Orthopedische Implantaten (LROI). Already more then 200.000 knee and hip arthroplasties are documented in this registry.

In the Netherlands at this moment, there are over 40 knee replacement designs on the market, the top 5 of TKA compromise 82% of all TKA (Nelissen, NOV 2012).

The choice of prosthesis depends on many factors (including age, level of activity, health, costs of prosthesis and experience/preference of the surgeon). Components are designed so that metal (e.g. cobalt/chromium based alloys) articulates with plastic (ultra high density polyethylene). In general, the best function and outcome in TKA is achieved by restoring mechanical alignment of the leg and soft tissue balance. Knee replacement surgery has improved over the last few decades because of improved insight in knee biomechanics and function, prosthesis materials (i.e. UHMWP inserts) and mainly operating techniques. Besides this growing knowledge, it is also known that there is an association between low volume hospitals and surgeons and the outcome of TKA. (Katz et al 2004). This suggests that a tool to lower the variability in positioning of the TKA in these cases can be of additional value for outcome of TKA. One of these new techniques to assist a surgeon is Computer Assisted Orthopaedic Surgery (CAOS).

## History of TKA

Knee joint replacement has been performed for more than 60 years. Although it was attempted in the 1860's the first artificial implants were not tried until the 1940's. Problems with postoperative pain and loosening limited at that time the success. The success with hip arthroplasty was encouraging but the complexities of the knee joint hindered similar progress. Originally, the simple hinge like prostheses of the 1950s did not take into account the knee mechanics, subsequently high rates of failure with aseptic loosening were seen, due to stresses at the prosthesis-bone interface. Infection also contributed to an unacceptable failure rate. During the late 1960´s a joint which took into account the complex movement between the femoral condyles and tibia was developed by Frank Gunston (a Canadian orthopaedic surgeon from Sir John Charnley's Hip Centre). He designed a metal-on-plastic knee replacement, which was secured to the bone with cement. This was actually the first "metal and plastic" knee and the first with cement fixation (1968). However this one failed through inadequate fixation of the prosthesis. In 1970 Kodama and Yamamoto designed the first total condylar knee prosthesis, which has been used in Japan, re-designed to the Mark II model. In 1974 John Insall, M.D and Carl Burstein (the engineer) in New York City had a similar design which they popularised and became the prototype for current total knee replacements. Both the Kodama-Yamamoto and the Insall-Burstein prostheses were made of three components, in order to resurface all three surfaces of the knee - the femur, tibia and patella (kneecap). They were each fixated with bone cement and the results were outstanding. Since the early '80s TKA surgery improved with the development of specific instrumentation to help with accurate alignment, bone cutting and prosthesis implantation. In the mid and late '80s, metal backing of the UHMWP components (enabling an increased inventory of appropriate sizes of implants) and left and right femoral components were introduced, besides better instruments to perform the procedure. Knee arthroplasties results have equaled or surpassed those of hip arthroplasties in survival analysis (i.e. mean survival at 10 years 96% in Sweden and 94% in Australia (Carr et al. 2012).

However, considering the results in terms of satisfaction, Robertsson et al. 2000 and Nilsdotter et al. 2009 showed that patients have high preoperative expectations concerning activities which could be performed as well as reduction of pain. These expectations are not met at three years after surgery. To a considerable extent, these expectations are fulfilled after one year. Expectations concerning demanding physical activities are not fulfilled to the same degree. The (lack of) accuracy of TKA placement could be of influence in this effect.

## History of Computer Assisted Orthopaedic Surgery in TKA

Besides developments in knee prostheses design and materials, and more attention to patient's (higher) demands and expectations, there are new surgical techniques introduced in knee replacement surgery, which might influence the patient related outcome measures. One of them is Computer Assisted Orthopaedic Surgery or CAOS.

This new generation of surgical tools, also known as surgical navigation systems, has been developed to try to help surgeons place implants more accurately and in a reproducible way. CAOS applications have a history rooted in the desire to link imaging technology with real-time anatomic landmarks. The first field of application of computer assistance was neurosurgery. After the application of computer guided spinal surgery, the navigation of total hip and knee joints became available. It has improved significantly over the last years, being transformed from an experimental, and laboratory procedure into a procedure available to every orthopaedic surgeon.

The earliest and most complex systems were active robotic systems, in which a robot performed some surgical task, such as drilling, without the direct intervention of the surgeon (Picard et al. 2004). One of the first active robotic systems for TKA used a pre-operative CT scan of the patient to plan the surgery. The use of the first commercial European robotic system for total knee arthroplasty resulted in improved accuracy during clinical trials (Siebert et al.,2002); however, active systems have not been widely used for TKA because of the cost and complexity associated with using active robots in the operating room. Therefore more focus came on the development of non-robotic systems, where navigation systems helps the surgeon and does not take over some actions. The first (image-free) navigation system that was used in the operating room was described and evaluated by Leitner (Saragaglia et al. 1997). Image-free navigation systems have become the most common navigation technique, and will be described in chapter 2.

In the development of CAOS systems for TKA, different philosophies for knee replacement can be used:

1. Alignment: the TKA should be positioned in a specific relationship to the anatomical landmarks of the limb
2. Soft tissue balance: to obtain minimal and even wear, tensions at the peri-prosthetic soft tissues should be evenly distributed around the joint in all positions
3. Kinematics: to obtain a near anatomical performing TKA, thus mimicking the kinematics of a normal knee

Most of the time surgeons adhere to two philosophies, and the majority of the surgeons adopt a hybrid of the first two philosophies. The first generation of CAOS in TKA was also primarily alignment driven. Nowadays more attention is paid to the soft tissue balance and kinematics of the knee during flexion and extension. The ability of the navigation systems to record quantitative information such as joint range of motion, laxity, and kinematics intra-operatively is getting more attention because of research goals.

## ■ CAOS potential benefits / limitations

According to the developers of navigation systems, it has the potential to address the main challenge for TKA: consistent TKA replacement with excellent outcome. In general it is advocated that outcome is (directly) related to accuracy of positioning of TKA. While the system gives the orthopaedic surgeon real time feedback and registration of surgical techniques and the time needed to make adjustments or check the precision of a proposed cut, the accuracy can still improve. The data given by the system give feedback with respect to achieved rotation of the components, soft tissue balance, bi-planar assessment of the position of the components and thus its relation to normal knee anatomy.

This might also improve the reproducibility of placing the TKA by the surgeon, thus giving less variance in the position of the prosthesis with respect to the bone.

Last but not least, it can also be used as an educational tool to assist less experienced surgeons in interpreting prosthesis position and their precision related to predefined anatomic landmarks.

**Potential advantages / benefits of CAOS in TKA:**

1. Uniform (computer organised) and directed surgical work flow
2. Improved reliability of sizing, positioning of joint implants and limb alignment
3. Information about ligament and muscle balancing
4. Data storage of intra-operative limb/joint anatomy and deformity
5. No intramedullary guiding instruments: decreased intra- and post-operative blood loss and tissue damage

**Potential disadvantages / limitations of CAOS in TKA:**

1. Learning curve of the surgeon using CAOS
2. Increased time required to perform the operation
3. Additional incisions (wounds) required for attachment of the reference arrays for CAOS, which are attached to the femur and tibia
4. A potential for initial stress fractures at these former pinholes of the marker trees or infection related to these incisions
5. Increased hospital costs due to the additional equipment, software and surgical time

## ■ CAOS results so far

Using a search strategy (Pubmed, Embase and Cochrane (see appendix for search strategy)), a significant increase in publications on CAOS and TKA is seen from 1996 till 2011, as shown in Figure 1.

All publications: 617 hits

- PubMed: 545
- Embase: 531 (63 unique)
- COCHRANE: 97 (9 new)

Only RCTs / Systematic Reviews / Meta Analysis: 378 hits

- PubMed: 338
- Embase: 216 (18 unique)
- COCHRANE: 82 (22 new)

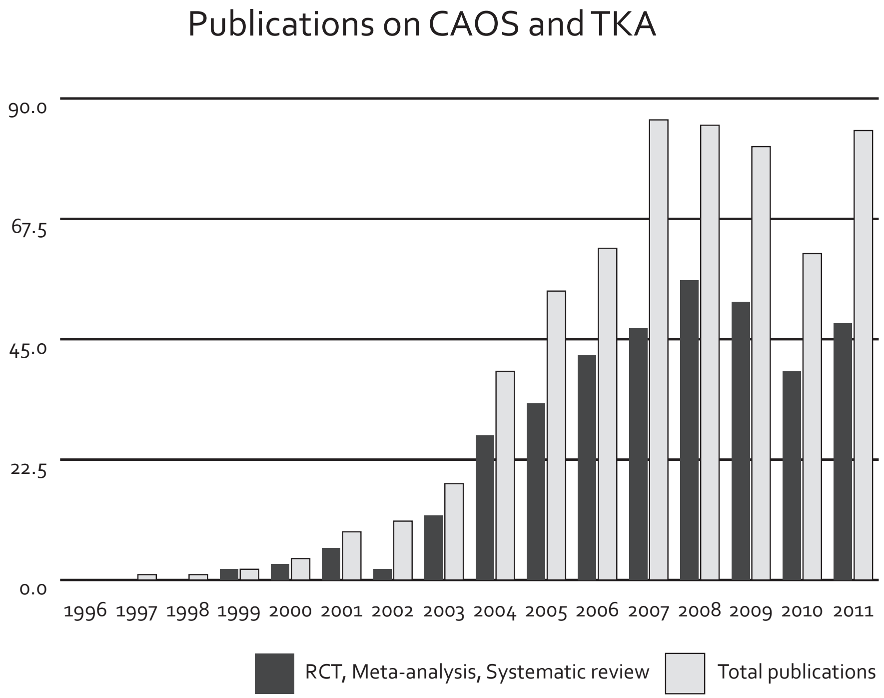


**Figure 1.** Number of publications a year on CAOS and TKA (for search strategy see appendix).

The first meta-analysis on Robotics and CAOS was done by Specht et al. in 2001. Since then the number of RCT's, meta-analysis and reviews increased rapidly till a maximum of publications around 2007. However, the last 5 years there is no further increase and even a decrease in the number of new published articles on CAOS and TKA is observed.

## ■ Aims of this thesis

The premise of CAOS is improvement of intra-operative positioning of a TKA. The above resulted in three research questions addressing the validity of a CAOS system, on the accuracy of placement of TKA with such a CAOS system with respect to outcome.

Thus the following research questions were posed:

1. **Is CAOS useful in achieving an accurate TKA positioning TKA?**
   *(Chapter 3,4,5)*
   Background. Knowledge of the anatomy of the knee is essential in achieving an optimally positioned TKA. Since rotational malalignment is a matter of concern in TKA, the inter-individual anatomical landmarks are studied in cadaver femora. The postoperative position of the components (e.g. rotation with respect to femur) can be measured on postoperative CT scans, this can be related to the intra-operative required data by the navigation system.
2. **Does CAOS lead to accurate component sizing and patella tracking?**
   *(Chapter 6,7)*
   Background. Size of the TKA components is of importance to the functional outcome. Anterior knee pain is a common reason for revision of a TKA, patellar maltracking plays an important role.
3. **What is the clinical and radiographic (migration) outcome of TKA using CAOS?**
   *(Chapter 8)*
   Background: TKA positioning is related to outcome. The latter is defined by TKA alignment, clinical outcome and migration of the prosthesis (migration analysis by roentgen stereo photogrammetric analysis, RSA).

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# Chapter 2

# CAOS & TKA

- Computer Navigation systems: the components
- Types of navigation
- Available Computer Navigation systems
- CAOS system used in this thesis

## ■ Computer Navigation systems: the components

Surgical Computer Navigation Systems allow the surgeon to perform surgical actions in real time using information conveyed through a virtual world, which consist of computer-generated models of surgical instruments and the virtual representations of the anatomy being operated on. The navigation systems currently in use can be characterized by three major components: the surgical object, the virtual object, and the navigator (figure 1, table 1 &2). The surgical objects are the bones and surrounding tissues in the surgical field. The virtual object is the virtual representation of this surgical object. Finally, the navigator establishes a coordinate system in which the location and orientation of the target as well as "end-effectors" are expressed. The "end-effectors" can be surgical instruments or active devices.

| Components | Definition | Procedure | Definition |
|---|---|---|---|
| Surgical Object | Surgical anatomy | End-Effectors Calibration | Establish correct representation of the shapes and geometry of surgical instruments/ devices in the coordinate system |
| Virtual Object | Virtual representation of the surgical object (i.e. data from CT, fluoroscopy, biomechanical model or image-free tracking system) | Registration | Establish correspondence between the surgical and the virtual object through identification of anatomical structures at the bony surface and corresponding features in the image data |
| Navigator | Establish a coordinate system for the accurate correspondence between the surgical and virtual object | Dynamic Referencing | Establish local coordination system to detect and accommodate for possible motion of the navigator and/or surgical object during the operation |

**Table 1.** The major components and procedures of Computer Navigation Systems

Three major procedural requirements are essential to successful navigation. First, end-effectors must be calibrated for correct representation of their shapes and geometry in the coordinate system established by the navigator. Second, "registration" establishes correspondence between the surgical and the virtual object, which is essential to the display of the end-effectors' locations in the virtual representation. Finally, "dynamic referencing" using dynamic reference bases establishes a local coordinate system that compensates for possible motion of the navigator or the surgical object during surgical actions. Examples of dynamic reference bases are optical markers.

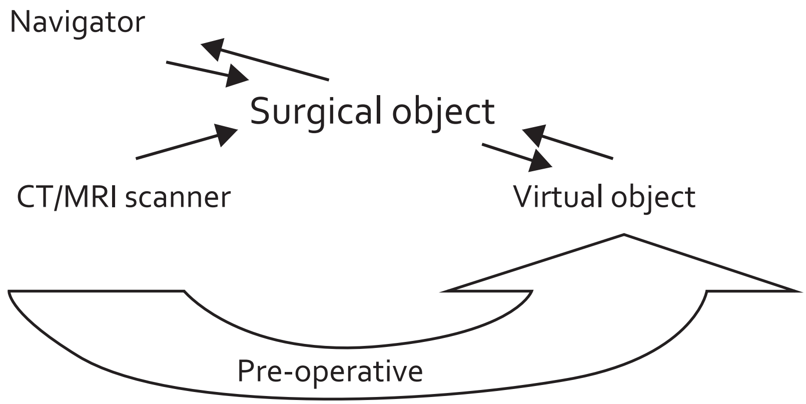


**Figure 1.** Schematic situation of the elements of navigation

The aforementioned virtual representations can be generated from data obtained through images (e.g. important from CT) or based on biomechanical models (i.e. image-free). The navigation systems thereby differ in the way this information of the surgical object is acquired.

## ■ Types of navigation

Overall the systems are divided in ´**image free**´ and ´**image based**´.

´**Image free**´ strictly means, the software does not need any image of the joint in its algorithms. However the ´image free´ system such as the BrainLAB Vector Vision have a pre-installed library of anatomical knee images which are adapted with intra-operative acquired patient specific biomechanical and dimensional data of the joint. These data are used to construct a knee model seen on the work screen, thus 'augmented image free' is a better term.

The basic concept of this image-free surgical navigation is to create virtual representation of the surgical object using a tracking system defining various anatomical structures. No pre- or intra-operative radiological images are used, instead, the virtual representation is biomechanical, "surgeon-defined", based on anatomical axes and dimensions. There are various image-free navigation systems, with the most-advanced forms utilizing "bone-morphing technologies". While image-free navigation could avoid some errors that are present in CT-based and fluoroscopy-based navigation, the surgeon-defined virtual representation is subject to other pitfalls. The accuracy of the virtual representation cannot be verified with recorded information unless the online view at the screen is grossly distorted according to the surgeon. Moreover, atypical anatomy may not be accurately represented by the generated representation, due to the limited recording of intra-operative data from the bony surface.

In ´**Image based**´ systems an image, usually a CT scan or a set of fluoroscopic radiographs are acquired and these pictures are incorporated into a model, which is then patient specific. The additional preoperative planning for this procedure takes about twenty minutes more (Minekus et al.2005). These systems also deal exclusively with the bony alignment and do not correct for soft tissue imbalances. At present the new image based systems (2012) using real time CT data are promising compared to the older which were time consuming to use and added little tot the validity of the intra-operative process of TKR (Cheng et al. 2011). Two types of "image based" navigation can be distinguished:

**1. CT-based navigation**

A CT-scan is used to pre-operatively acquire data of the surgical object. The data is then loaded into a navigation system. During the surgery, the CT-images must be matched with the patient's anatomy through registration. CT-based navigation systems have the advantage of providing detailed 3D images. However, a CT-scan exposes the patient to radiation. A potential error can be made during the registration process.

**2. Fluoroscopy-based navigation**

Mobile fluoroscopic devices provide real-time feedback on the surgical objects and the end-effectors. Patients are placed in the "C" of the C-arms during the surgery (see picture below). Since 1999, 3D fluoroscopy-based surgical navigation is available. The 3-D image is reconstructed from a series of 2-D images taken in different orientations. Fluoroscopy has the advantage of providing real-time information of the surgical objects as well as the end-effectors. Thus, changes in the anatomy of the patient due to surgical actions can be visualized. However, the C-arm must be carefully calibrated to ensure the accuracy of the acquired images.

| Types of Navigation | CT-based | Fluoroscopy-based | Image-free based |
|---|---|---|---|
| Devices used | CT scanner | Mobile Fluoroscopic devices (C-arm) | Varies, including anatomy land-marks and statistical models. |
| Advantages | Allow pre-operative planning on detailed 3D images | Real-time images of the surgical field. | No errors similar to those of CT-based and Fluoroscopy -based systems |

**Table 2.** Comparing types of navigation systems

## ■ Available Computer Navigation systems

A large number of articles have been published on CAOS in TKR using different systems [3]–[7]. Computer-assisted surgical systems can be divided into three categories: active robotic systems, semi-active robotic systems, and passive systems (Picard et al., 2004).

Current available systems (table 3) for TKR can be basically categorized into four groups (Figure 2) :

(1) Fluoro-based systems using fluoroscopic images to navigate;
(2) Image-less systems using bone morphing;
(3) Image-less systems using landmarks;
(4) CT-based systems.

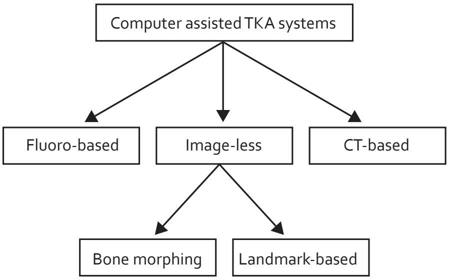


**Figure 2.** Categories of navigation systems

| Company | System name | Classification and description |
|---|---|---|
| Acrobot (The Acrobot Company Ltd) | Acrobot, MI Navigation | Semi-active robotic assistant, planning software, resurfacing |
| Aesculap | Orthopilot | Image-less, planning and navigation hip and knee |
| Amplitude | | Image-free hip and knee navigation |
| BrainLAB | Vector Vision | Image-free and CT-based planning and navigation |
| CAS Innovations | | Fluoro Navigatie en integratie van de Iso C 3D C-arm |
| CASurgica Inc. | HipNav, KneeNav | CT-based, preop planning, RoM simulation, acetabular placement for hips, navigation for TKA |
| DePuy | iOrthopaedics Ci System | Image-less TKA and THA planning and navigation |
| GE Healthcare | FluoroTrack/Flexiview | Fluoroscopy navigation system mobile C-arm |
| Integrated Surgical Systems (ISS) | ROBODOC/ORTHODOC | Active robotic system / associated planning system |
| Medacta | | Image-free hip and knee navigation |
| Medtronic SNT (Surgical Navigation Technology) | StealthStation | Image-based navigation system, working with various third party C-arms, CT or MRI |
| OmniLife Group | Praxim | Originally started with bone morphing, image-free navigation hip and knee |
| Northern Digital Inc | Optptrak Aurora | Generic IR tracking systems Electromagnetic tracker |
| PI Systems | PiGalileo | Image-free navigation system TKA and THA, plus electromechanical positioning ´mini-robot´for TKA |
| Siemens Medical Solutions | SIREMOBIL Iso-C | 2D/3D C-arm fluoroscopy working with various third party navigation systems |
| Stryker Orthopaedics | Knee Navigation System | Image-free THA/TKA with wireless tracking technology |
| Universal Robot Systems (URS) | CASPAR | Active robotic system for bone preparation in TKA |

**Table 3.** Commercially available CAOS systems and components

The studies in this thesis used the BrainLAB's Vector Vision system (version 1.5.1, BrainLAB, Munich, Germany), both image-free and image (CT) based. This is a camera-based navigation system, onto which these two navigation approaches were implemented. The CT-based CAOS uses a preoperative CT scan of the hip, knee, and ankle from which a 3D model is reconstructed. A preoperative planning of the size and position of the femoral and tibial component can be made with the created virtual model. During surgery this preoperative planning is adapted to the patient by matching bony landmarks to the virtual data set, which is based on the CT data. In the other, more frequently used, approach (CT-free CAOS), all patient specific data are collected during surgery. The software calculates the optimal prosthesis size and position based on several anatomical reference points (i.e. anatomical dimensions and biomechanical axes) identified by the surgeon. In this way, a 3D bone model is adapted to the specific patient.

### Hardware

The BrainLAB computer navigation system consists of a tracking unit linked to a computer and display screen. The tracking unit uses infrared light emitting diodes, surrounding the sensor lens of an infrared camera. The diodes flood the field of view with infrared light. This is reflected from spheres which are attached to reference arrays. Each position and each tool has a specific configuration of spheres which make them recognizable. The camera receives the signals and the position of the object(s) in space is calculated and the orientation of the reflecting object is defined.

### Intra-operative localization of anatomical landmarks and registration

The positioning of the patient and draping is conventional. Only at the side of the ankle care should be taken not to wrap too much sterile draping material as this may make identification of the malleoli and centre of the talus, both input for the intra-operative model, difficult.

Reference arrays or marker trees have to be attached to the bone, in order to have both input for the biomechanical model as well as control for intra-operative change of position of the knee (leg). These marker trees are inserted through the same median incision or through separate small stab incisions, they are rigidly to the femur and tibia by a screw mechanism.  As the technology has improved, the pin diameter has been decreased, and most of the frames use two pins for greater stability. The arrays have passive reflectors which should be arranged perpendicular to the tracking unit to enable tracking by the camera during surgery.

The passive reflective arrays have to be within a certain spatial distance o the tracking unit. All of the reflecting arrays have to be within this space and have a clear line of sight to the camera to be seen. The characterization of the used system shows that overall volume root-mean-square distance error by stepping a single marker though the measurement volume is less than 0.35 mm. This however does not necessarily translate to an equivalent accuracy during use in surgery. The accuracy of tracking systems used in navigation is related to the combination of the tracking camera and associated reference frames and can range from approximately 0.5–3mm (Khadem et al.,2000). Potential errors might be higher in an operation theater environment, due to bumps against marker arrays, occluding reflectors by blood etc. Users should be aware of this and run calibration programs regularly.

The registration process consists of three phases which are shown as on screen workflows:

- identification of anatomical landmarks and biomechanical centers, these determine the reference planes and axes
- mapping of the articular surfaces of femur and tibia by the surgeon, using a probe with markers
- morphing parts of femur and tibia to augment the model that is created

The accuracy of this registration determines the overall accuracy of the intra-operative navigation process.

The surgeon is able to create its own profile utility to perform the same steps in the same order every operation, like Whiteside line referencing or epicondylar referencing etc.

**After registration**

The optical tracking system monitors the (virtual) location of surgical instruments relative to patients' virtual bony anatomy. A real-time verification of bone resections at every step of the procedure can be made, with visual and numeric (e.g. mm resected bone, deviations from mechanical axes).

Finally, after implantation of trial components a kinematic analysis can be made to support the surgeon in achieving optimal leg alignment balance. It provides absolute (virtual) values on varus/ valgus, joint gap sizes and flexion and extension positions, and thereby enables a "before and after" analysis of the biomechanical situation.

Overall, the whole workflow takes on average 20 minutes more operating time (thesis Minekus, Cerha et al 2009, Stiehl et al 2009).

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# Chapter 3

## The inter- and intraindividual anatomical relationship of the femoral anteversion and distal femoral rotation. A cadaveric study on the femoral anteversion angle, posterior and inferior condylar angle using Computed Tomography

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submitted

## ■ Abstract

Malrotation following total knee arthroplasty (TKA) is directly related to poor outcome. Knowledge of the rotational axes (torsion) and angles is therefore important. The aim of the study was to determine whether an association existed between the Femoral Anteversion Angle (FAA) Posterior Condylar Angle (PCA) and the Inferior Condylar Angle (ICA) in individuals. A CT scan of 50 (25 paired) cadaver femora was made. The FAA, PCA and ICA were measured. Statistical analysis of comparative relationships between these different angles was examined by calculating Pearson correlation coefficients and a paired t-test. The mean FAA, PCA and ICA for the whole group were respectively 11.7° (range 0-32, SD 8.2), 5.18° (range 0-12, SD 2.4) and 4.4° (range 0-10, SD 2.1). A correlation of 0.82 ($p=0.01$) of the FAA was found between left versus right. For the overall group a correlation coefficient between the PCA of the left and right femur was $r=0.59$, $p=0.01$). The Pearson correlation between the FAA and PCA in the whole group was $r=0.27$, $p=0.06$. In females this was $r=0.54$ ($p=0.03$). Although the difference of the mean ICA and PCA was very small (0.7°), there was no correlation between these angles ($r=0.14$, $p=0.23$). In conclusion, one should be aware that, considering the weak correlation of the FAA and PCA, an individual rotational variation exists. Furthermore, no correlation was found between the PCA and ICA. Therefore, for now, this angle cannot be assumed to be helpful in TKA. A more individual approach in total knee arthroplasty seems essential for future TKA.

**Keywords:** knee; femoral anteversion angle; posterior condylar angle; inferior condylar angle; computed tomography

## ■ Introduction

Knowledge of the anatomy of the femur is essential in positioning, and thereby outcome and survival of, hip (THA) and knee arthroplasty (TKA). Since malrotation problems can only be objectivised in extreme cases (i.e. patella dislocations and hip dislocation), less severe malrotations usually go unnoticed, but these patients may have clinical symptoms. These symptoms might even necessitate revision surgery (Berger et al., 1993; Berger et al., 1998; Miller et al., 2001; Soong et al., 2004; Sikorski 2008). Recognition of not only the ideal coronal and sagittal plane position but also transverse plane position of a joint preoperatively might prevent less optimal prosthesis position. Thus knowledge on anatomic morphology is important and might be useful in determining the position of a prosthesis within a patient. In general, only weight bearing AP and lateral views of the knee are made, thus information on torsion of the distal femur of the knee with respect to the proximal femur cannot be determined and therefore the position of the femoral component of a TKA can not be determined from plain radiographs of the knee (with or without weight bearing. During surgery, the three most common references for setting the rotational (sagittal) position of the femoral component are (a) the posterior femoral condyles (b) the epicondylar axis and (c) the Whiteside's line, which is the alignment of the AP axis as estimated from the trochlear groove (Siston et al., 2005). Neither one is superior. The PCA (figure 3) is the most common used rotational reference for TKA (Berger et al., 1993; Laskin 1995; Poilvache et al., 1996; Griffin et al., 1998; Berger et al., 1998). The torsion of the distal femur differs inter- and intraindividual in many studies (Yoshioka et al., 1987; Berger et al., 1993; Poilvache et al., 1996; Nagamine et al., 1998; Griffin et al., 2000; Tanavalee et al., 2001). Since most measurement are out-of-plane with respect to the conventional AP and lateral knee and hip radiographs, measurement of torsion of the femur has to done at CT scans. Contrary, the inferior condylar angle (ICA) (figure 4) can be measured at a conventional radiograph. Thus if the ICA is highly correlated to the PCA one could have a tool to estimate the distal femoral rotation on a conventional AP radiograph. Thus, the aims of this study are 1. to see if there is a relation between femoral anteversion and either the posterior condylar axis or the inferior condylar axis, and 2. to see if the posterior condylar axis and the inferior condylar angle can be used interchangeably for alignment of a femoral component of a TKA.

## ■ Materials and Methods

At the anatomy department of the Leiden University Medical Center (LUMC), 50 Caucasian femora were available after use for medical education. Exclusion criteria were: signs of prior trauma or surgery (e.g. prosthesis of the hip, knee) or signs of osteoarthritis. In total 25 paired cadavers (11 men, 14 female) were studied. The average age at time of death was 79 years (men: mean 74 yrs; SD 11); female: mean 84 yrs; SD 7). The whole group ranged from 57 to 94 years.

All soft tissues were removed before scanning. A multislice CT scan was made according to a standard protocol. The CT scans were made on a 64-slice scanner (Aquilion, Toshiba, Otawara, Japan), scanning parameters were beam collimation 64x0.5 mm and pitch 0.828; images were reconstructed using a standard kernel with 1 mm slice thickness and 1 mm reconstruction index. The labelled femora were scanned per pair and the data were separated into single femurs. The measurements were done at random using a three-dimensional software system (OsiriX version 3.5.1, California, USA) and the same workstation (Apple, Mac OS X, California, USA).

## ■ CT Measurements

For all anatomical measurements we used the in literature most common used / described and reproducible methods. The measurements were done twice by the same observer (LCDK) at two different occasion (3 weeks apart) in a random order. All measurements of the Femoral Anteversion Angle (FAA) (figure 2) are based on the ORTHODOC protocol (Lee et al., 2006). The differences and/or correlation of the most commonly used proximal and distal femoral angles (FAA and PCA) were analysed (a) within individuals, (b) between right/left and (c) gender, while these are most important in arthroplasties. We also analyzed the ICA to see whether there is a relationship between the ICA and PCA/FAA.

Measurements of the PCA were done as an adapted version of the measurements recommended by Yoshioka et al (Yoshioka et al., 1987). The same adapted method was applied for the inferior condylar angle using the Trans Epicondylar Line (TEL) and the most distal bony axes in AP view (figure 2, 3, 4).

*Femoral Anteversion Angle measurement*

The FAA was defined as the angle between the line through the centre of the femoral neck and head (FHNL) and the posterior condylar line (PCL). We used a 5-step procedure, as a guideline:

1. A three-dimensional-overview was made. A so called thick slice was used showing the view through the middle of the femoral head and the middle of the femoral neck. The centre of the femoral head was measured by drawing the longest line through the head, perpendicular at the femoral neck line. The middle of this line was used as the centre of the head. The proximal line was drawn by starting a line through centre of the femoral head. The line parallel to both collum borders was used as femoral neck axis. In an anteroposterior

and axial view it was checked if the figure (and FHNL) was through the centre of the femoral neck and head (See black line in figure 1).

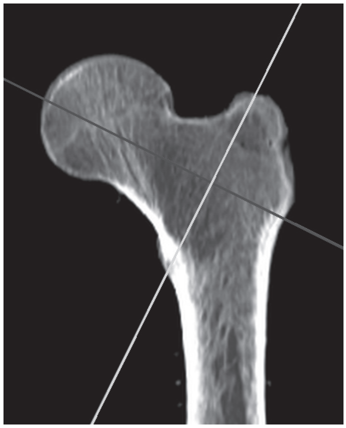

**Figure 1.** Step one in FAA measurement. CT thick slab image of the hip in coronal view to check whether the image is through the centre of the collum and centre of head. Black line: femoral head-neck axis.

2. The second image was from the distal femur. The guidelines to make this figure were to have a view of the PCL and the TEL. The PCL is the line drawn along the most posterior edge of both femoral condyles. The TEL is defined as the line between the femoral medial (most prominent point) and lateral epicondyles.
3. Both images were made using the 'thick slice' option in Osirix. Using this option the outer margins of the femoral bone and consequently the maximum diameter of the bone was visible. The thickness of all slices was set on 40 mm.
4. The Osirix images were converted to DICOM-images and these two images were superimposed (figure 2), making the FHNL and the PCL visible in one view and measurements could therefore be performed without changing the slides.
5. For final measurement of the FAA, the 'dynamic angle' option in the Osirix software was used. The usage of this 'dynamic angle' option allows the researcher to indicate two separate lines in different slides. Therefore, this option makes it possible to use the same baseline angle, which has been measured once, in different slices.

The FAA was calculated by identifying the femoral head and neck centre. This FHNL was referenced to the PCL.

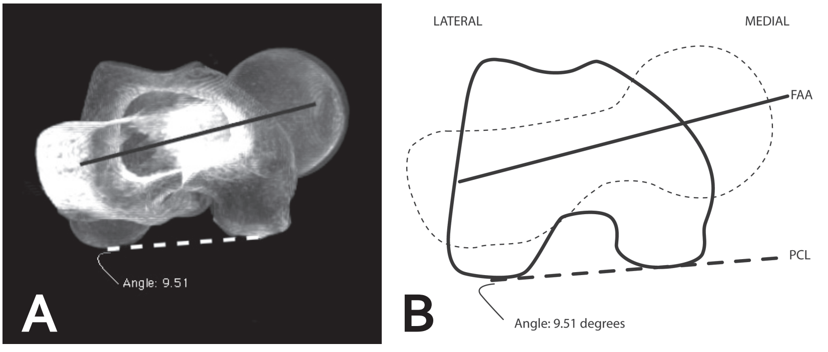


**Figure 2.** Measurement of the Femoral Anteversion Angle (FAA).

*Posterior Condylar Angle measurement*

The PCA is the angle between the posterior condylar line (PCL) and the anatomical or clinical transepicondylar axis (TEL) (figure 3), in literature also called condylar twist angle (CTA) (Yoshino et al., 2001).

The measurement of the PCA was done in a two-step procedure:

1. The PCA was measured on the figure of the distal femur used for measurement of the FAA, as described above. Using the ´thick slap´ option we optimised determination of the PCL.
2. The PCA was measured using the dynamic angle option (figure 3). The PCA was noted positive when medially opened (external rotation).

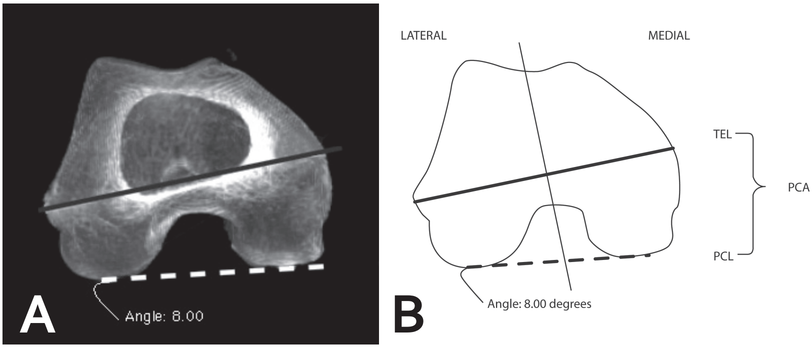


**Figure 3.** Measurement of the Posterior Condylar Angle (PCA).

*Inferior Condylar Angle measurement*

The ICA is based on the inferior condylar line (ICL) and the TEL in the AP plane (figure 4). This measurement is also performed in a two-step procedure:

1. An image in the coronal plane of the distal femur was made created. A thick slice was made of the figure showing the TEL and the most inferior borders of the femoral condyles. In the sagittal view was checked that the inferior borders of the condyles were visible.
2. The dynamic angle option was used. The ICA had a positive denominator if the angle opened medially (figure 4).

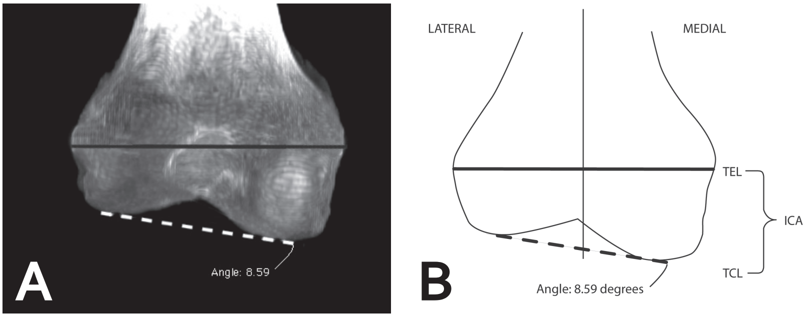


**Figure 4.** Measurement of the Inferior Condylar Angle (ICA).

## ■ Statistical analysis

To estimate the reliability of the measurements the Intraclass Correlation Coefficient (ICC) and also the Standard Error of Measurements (SEM ) were calculated. Descriptive analysis were performed to analyse the normal values and distributions of these angles, values are given as mean, standard deviation and range. Unpaired t-tests were applied to analyse the differences in these angles between males and females paired t-tests were used for comparison of the left to right difference. Correlation coefficients of the FAA, PCA and ICA (rho) were calculated for the whole group of femora and for gender (male and female) and side (left and right). To investigate if the PCA could be predicted, a regression model was build: both univariate and multivariate with FAA, ICA, gender and side as possible predictors. Statistical significance was set at a p-value of ≤ 0.05. All data were analysed using SPSS (SPSS for Windows Release 17.0; SPSS Inc, Chicago, Illinois).

## ■ Results

The descriptive values are displayed in table 1. Important to note is the wide range in both ICA and PCA, although the mean is used in clinical practice, the difference from this mean value could reach more than 6 degrees. Although the mean value for PCA is used in clinical practice, we found that PCA can differ substantially with a range from 0 to 12 degrees. When we would use an arbitrary cut-off of plus or minus three degrees from the mean value, 23% of the femora are outside this range. This is shown in figure 5.

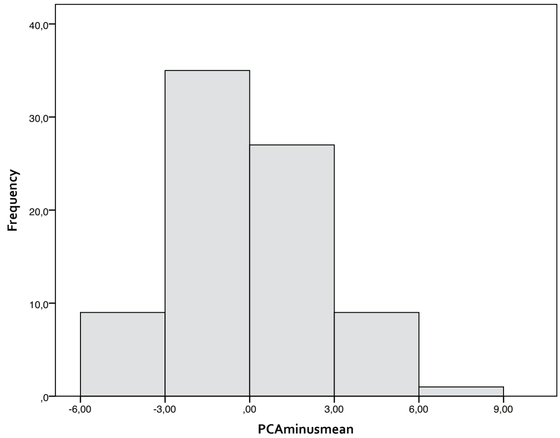


**Figure 5.** Histogram showing the distribution of the deviation of the mean PCA.

## Reliability

The Intraclass Correlation Coefficient of the two measurements of the FAA, PCA and ICA (Table 1), were respectively 0.90, 0.91 and 0.93. Rating the ICC > 0.80 as good, the measurements are reliable. The SEM was low, namely for the FAA 0.94°, for the PCA 0.79°, and ICA 0.67°.

| Angle | Mean | SD | Range |
|---|---|---|---|
| **FAA** | 11.7 | 8.2 | 0-32 |
| **ICA** | 4.4 | 2.1 | 0-10 |
| **PCA** | 5.1 | 2.4 | 0-12 |

**Table 1.** The measured angles of all femora.
FAA = femoral anteversion angle; PCA = posterior condylar angle; ICA = inferior condylar angle. For all these angles the observed difference was not statistically significant for male versus female (FAA p=0.46, PCA p=0.74, ICA p=0.15) and right versus left (FAA p=0.71, PCA p=0.40, ICA p=0.47).

## Correlations

When we compare the FAA, PCA and ICA between males and females, only the ICA is different, 3.8 degrees (SD 1.8) for females and 5.0 degrees (SD 2.2) for males (p=0.009). We found no difference in a paired t-test when comparing the left and right knee: the observed differences were 1.2 degrees for the FAA (p=0.27), 0.4 degrees for the ICA (p=0.30) and 0.4 degrees (p=0.30) for the PCA.

Though the mean difference between the ICA and PCA was very small, 0.3 degrees (SD 2.9), there is no correlation between these two measurements; Rho is 0.14 (p=0.23).

When we compare the FAA, PCA and ICA between males and females, only the ICA is different, 3.8 (SD 1.8).

When comparing the correlation values of the FAA, PCA and ICA, only three correlations were found to be statistically significant;

1. For correlation measurements of the total group for the FAA, a strong correlation was found between the right and left FAA (r = 0.82; p = 0.01).
2. A weaker correlation was found for the right and left PCA (r = 0.59; p = 0.01) and not for the right and left ICA (r=0.26, p=0.11).
3. When the FAA compared to the PCA is subdivided in sexes, there is a moderate correlation for the female group only (r = 0.54; p =0.01).

The other correlations were not statistically significant and very weak (Table 2). We used the FAA, ICA, gender and side as predictors for the PCA. It was not possible to predict the PCA with these mentioned factors as predictors.

| | FAA vs PCA | FAA vs ICA | PCA vs ICA |
|---|---|---|---|
| **Whole group** | 0.27 | 0.16 | 0.14 |
| **Male** | 0.02 | 0.30 | 0.12 |
| **Female** | 0.54* | 0.05 | 0.12 |

**Table 2.** Correlations between the different angles (rho, * = p < 0.05)

## ■ Discussion

The aims of this study were 1. to see if there is a relation between femoral anteversion and either the posterior condylar axis or the inferior condylar axis, and 2. to see if the posterior condylar axis and the inferior condylar angle can be used interchangeably for alignment of a femoral component of a TKA.



Malrotation is one of the most important errors following TKA, and is directly related to poor outcome (Berger et al., 1993; Berger et al., 1998; Miller et al., 2001; Soong et al., 2004; Sikorski 2008). The aim of our study was therefore to analyse anatomical torsion differences of human femora using CT. Therefore the study was designed to determine whether an association existed between the FAA, PCA and the ICA and whether the ICA could be used as estimation for the PCA and FAA. Only a moderate correlation was found for the FAA and PCA in female, for all other combinations no significant correlation was found. Though the mean difference between the ICA and PCA was very small, we did not find a correlation between the ICA and PCA ($r = 0.14$) or FAA as well ($r = 0.16$).

Considering all potential anatomical measurements presented in literature, we used the most common used CT based method of Lee et al. As also shown by Sugano et al 1998, there is no gold standard, they compared three CT measurement protocols and found different values. However, the ICC of all three angles in our used measured CT protocol was > 0.80, thus they can be considered reliable measurements.

More than 60 papers have been published on measurements of the FAA from 1878 till now. Mikulicz et al. were the first describing measurements of the FAA (Mikulicz J 1878). Anatomic measurements, biplane radiography, axial tomography, ultrasonography, fluoroscopy and eventually multi-resonance imaging (MRI) and CT imaging have been used.

We only included published CT and MRI measurements to compare our results with (table 3) We are aware of the fact that our measurements were only done by CT. However, we do believe that we could use the results of both MRI and CT for comparison of our results.

Especially gender differences in femoral anatomy are studied and discussed in literature (Chin et al., 2002; Hitt et al., 2003; Conley et al., 2007; Dargel et al., 2011). Dargel et al also concluded that implant design should focus inter-individual variations in knee joint anatomy (Dargel et al., 2011).

Differences in FAA are common in literature, especially the range of this angle shows variability. Most of current research is based on the axis through the femoral head-neck axis and a base-axis (Hoiseth et al., 1989; Miller et al., 1993; Schneider et al., 1997; Kuo et al., 2003). However for this base-axis different reference lines are used. Toogood et al. use the transepicondylar axis of the distal femur (Toogood et al., 2009).Yoshioka et al used the transverse functional axis of the distal femur which is referenced to the transepicondylar line (z-axis) as a reference to measure the values of FAA (Yoshioka et al., 1987), however they did not use X rays but an osteometry table for there measurements. The lowest variability (i.e. Method 3.95% confidence limits of ± 0.4°) is shown when surgeons use the PCL as reference line (Kirby A.S. et al., 1993).

Therefore, this PCL was used for measurement of the FAA. The differences in measurement methods may reveal the differences in FAA noted in table 3, showing a variability from 0 to 40° (table 3), which demonstrates a large standard deviation and differences between observers and methods (Hoiseth et al., 1989; Ruwe et al., 1992). We found comparable results for the FAA.

| Angle | Authors (year) | n | Mean (degrees) | SD (degrees) | Method of measurement |
|---|---|---|---|---|---|
| FAA | Høiseth et al. (1989) | 33 | 11.4 | 3.5 | CT |
| | Miller et al. (1993) | 24 | 11.4 | - | CT |
| | Schneider et al. (1997) | 98 | 10.4 | 6.2 | MR |
| | Kuo et al. (2003) | 10 | 12.4 | 3.8 | CT |
| | Current study (2010) | 50 | 11.86 (total)<br>10.75 (M)<br>12.69 (F) | 8.25 (total) | CT |
| PCA | Nagamine et al. (1998) | 40 | 5.8 | 2.7 | CT |
| | Matsuda et al. (1998) | 30 | 6.03 | 3.6 | MR |
| | Griffin et al. (2000) | 104 | 3.11 (total)<br>2.75 (M)<br>3.33 (F) | 1.75 (total)<br>1.61 (M)<br>1.82 (F) | MR |
| | Current study (2010) | 50 | 4.69 (total)<br>4.86 (M)<br>4.56 (F) | 2.36 (total) | CT |
| ICA | Lustig et al. (2008) | | 3.1 | 2.1 | CT |
| | Current study (2010) | 50 | 4.55(total)<br>3.81 (M)<br>5.1 (F) | 2.07 (total) | CT |

**Table 3.** English Language Literature Review of FAA and PCA and ICA:
FAA = femoral anteversion angle; PCA = posterior condylar angle; ICA = inferior condylar angle.

Femoral anteversion can influence the stresses on a TKA but alignment of the TKA components is not based on the FAA, solely on the mechanical axis and the rotational axis (PCA, etc). Vice versa, an abnormal FAA is not corrected by adjustment of the TKA position but should, if necessary, be corrected extra-articularly.

Similar limitations in current literature on measurement exist for the distal femoral (PCA) measurements. The protocols differ in the listed studies. For example, Griffin et al used the surgical TEL and used the cartilage surface of the knee (Griffin et al., 2000). Tanavalee et al have made a comparison of the anatomical TEL and the surgical TEL, and there has been proven that the anatomical TEL is more reliable. Therefore, we used the anatomical TEL as a reference line to measure PCA and ICA (Tanavalee et al., 2001).

In perspective of the older knee joint, and more specific knees with osteoarthritis, there could be a difference in the PCL as reference line (Griffin et al., 2000). For example Aglietti et al showed that posterior condyles can be worn off because of cartilage erosion (Aglietti et al., 2008), influencing the PCL. However, macroscopically in our femora there was no cartilage loss on the posterior condylar region.

Analysis of the FAA, PCA and ICA showed a broad range of measurements and only a weak correlation between the proximal (FAA) and the distal femur (PCA). A more individual approach in total knee arthroplasty is getting more attention and our study results suggest that awareness of anatomical differences is needed to plan an individual arthroplasty.

When FAA and PCA were subdivided in sexes, we found only correlation in females (r=0.54) compared to no correlation (r=0.02) in males. The anatomical difference in varus/valgus alignment of the femur and shape of the pelvis between men and women, also reflecting probably a difference in shape of the femoral condyles in men and women and could be an explanation.

We did not find many correlations between all possible combinations of the FAA, PCA and ICA which were statistically significant. Thus an estimation of a easy to measure ICA line at the AP radiograph cannot be used to determine the epicondylar rotation. A wide range and variability was seen, supporting the hypothesis that considering alignment an individual, patient specific approach might be needed.

Based on our results, the ICA measured on a CT is not useful in estimating the PCA and thereby gives no information on the distal femoral rotation.

Others found lack of correlation between PCA and ICA (called DCA in their study) as well (Lustig et al., 2008).

Along with this a new development is the usage of computer assisted orthopaedic surgery or/and preoperative MRI or CT planning combined with special patient specific manufactured intra-operative saw molds (Spencer et al., 2009). These methods tend to to enhance visibility of surgical anatomy and improve accuracy by means of robotic devices or navigation systems (Pearle et al., 2009).

Nevertheless, there is no complete uniformity about the accuracy of these methods (Galaud et al., 2008). For example, it has been shown that individual position of the femoral component using a Computer Assisted Orthopaedic Surgery system differs significantly from the position on the postoperative CT scan (van der Linden-van der Zwaag HM et al., 2010). However, debate exists on the value of CAOS for improvement of TKA placement.

It is possible that the morphology of the proximal femur determines the distal femur and vice versa (Wolff J. 1869) during growth, however no (further) studies on this topic have been performed. Therefore it is of interest and probably important to examine the relationship of the distal femur to the hip for knee arthroplasty and other knee pathologies. This requires more time, technological and radiological effort.

## ■ Conclusion

Based on our results we conclude that the most frequently used proximal and distal femoral angles (FAA and PCA) differ within individuals, and between the right and left leg. There is only a correlation between FAA within individuals and in females there is a weak correlation of the FAA with the PCA. The ICA showed no correlation with the other measurements and was not useful to estimate the rotation of the distal femur. Current guidelines to determine rotation in TKR show great variation between individuals. Therefore, a more individual approach would be recommended to be implemented in these currently used guidelines.

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# Chapter 4

## Transepicondylar axis accuracy in computer assisted knee surgery. A comparison of the CT-based measured axis versus the CAS determined axis.

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## ■ Abstract

Rotational malalignment is recognized as one of the major reasons for knee pain after total knee arthroplasty. Although computer assisted orthopedic surgery systems (CAOS) have been developed to achieve more accurate and consistently aligned implants, it is still unknown if they significantly improve the accuracy of femoral rotational alignment as compared to conventional techniques.

We evaluated the accuracy of the intra-operatively determined transepicondylar axis with that from postoperative CT-based measurement in twenty navigated total knee arthroplasties (TKA). The intraoperatively determined axis during CAOS was marked with tantalum (RSA)-markers. Two observers measured the posterior condylar angle (PCA) on postoperative CT scans.

The PCA measured using the intraoperatively pointed axis showed an interobserver correlation of 0.93 between the two observers. The intraobserver correlation was slightly better than using the CT based angle, being 0.96. The PCA had a range of -6 (internal rotation) to 8 (external rotation) degrees with a mean of 3.6 degrees for observer 1 (SD 4.02) and 2.8 degrees for observer 2 (SD 3.42). The maximum difference between the two observers was 4 degrees. All knees had a patellar component inserted with good patellar tracking and no anterior knee pain. The mean postoperative flexion was 113 degrees (SD 12.9).

The mean difference between both epicondylar line angles was 3.1 degrees (SD 5.37 degrees), with the CT based PCA being bigger.
During CT-free navigation in TKA, a systematic error of 3 degrees was made in determining the transepicondylar axis. It is emphasized that the intraoperative epicondylar axis is different from the actual CT based epicondylar axis.

## ■ Introduction

The outcome of a total knee arthroplasty (TKA) depends on several factors, both patient and surgery related. It is known that the size of the components and especially their position and alignment are of great influence on the clinical outcome (1). Primary malalignment and inadequate positioning of in particular the femoral component may lead to an unsatisfactory outcome, including patella maltracking, anterior knee pain, flexion instability (2-4). Malalignment is a common indication for revision and can be the underlying reason for failure PE wear, loosening and instability (5). The revision rate because of malalignment may therefore be higher than already stated in literature.

External rotation of the femoral component of 3 to maximum of 5 degrees with respect to the posterior condylar line or 0 degree placement with respect to the transepicondylar line is thought best for optimal functionality (6). Using the conventional and bony reference point methods, rotation of the femoral component can be determined intra-operatively by the use of the transepicondylar line, the posterior condylar line and/or the Whiteside line (7;8).



Whilst many opinions are expressed in the literature as to which axes are the most reliable and/or show the least intra-/inter-observer variability, none seems to be superior (9).

Several studies have shown improvement in AP alignment using Computer Assisted Orthopaedic Surgery (CAOS) (10-12), but little is known about the attainment of better rotational alignment of the components when using CAOS (13-15).

Although these systems have been developed in an attempt to align implants more accurately and more consistently, it is unknown if navigation systems can improve the accuracy of femoral rotational alignment as compared to traditional techniques using mechanical guiding devices. Since postoperative knee prosthesis problems are related to rotational mal-alignment, CAOS systems should reduce these errors. We studied the accuracy of intraoperative axis determination by the surgeon. To this end the accuracy of the intra-operatively palpated and digitized TEA was compared to the postoperatively CT-based epicondylar axis in twenty navigated total knee arthroplasties (TKA).

## ■ Materials and Methods

### Patients

Twenty navigated TKAs in 18 patients – 9 female and 9 male – were studied with a mean age of 69 years (range 46 – 85 years). Half of them had primary osteoarthritis; the others had secondary osteoarthritis due to rheumatoid arthritis. In all patients the NexGen Legacy Total Knee Prosthesis (Zimmer, Warsaw, IN, USA) was implanted with the use of cement, and in all cases the patella was resurfaced. All TKAs were performed by one single surgeon (HMJvdL). All patients participated in a prospective roentgenstereophotogrammetric (RSA) study on possible postoperative migration of the knee prostheses in CAOS TKA after informed consent, including marker insertion and postoperative CT scans. To this end tantalum (RSA) markers were inserted in the bone. Postoperatively a CT scan was made to measure component position.

Preoperatively the AP (anterior-posterior) leg alignment was measured on long-leg standing radiographs using the hip-knee-angle (HKA) and the femoral-tibial-angle (FTA). The mean preoperative HKA was 181 degrees (SD 4.1) with a range of 172 to 188 degrees; the mean FTA was 176 degrees (SD 7.2) with a range of 166 to 180. The mean extra time needed for navigation during the surgery was twenty minutes.

**Computer Navigation**

We used the Vector Vision CT free computer navigation system, software version 1.5.2 (BrainLAB, Feldkirchen, Germany). During surgery two infrared receivers are fixed on the leg; one on the femur and one on the tibia. Identification of the anatomical landmarks, bony surfaces and axes of the knee and leg was undertaken initially. A blunt pointer with an infrared receiver was used. The femoral localization points consisted of identifying the medial and lateral epicondyles (Figure 1), the anterior sulcus, the femoral mechanical axis and posterior condyles.

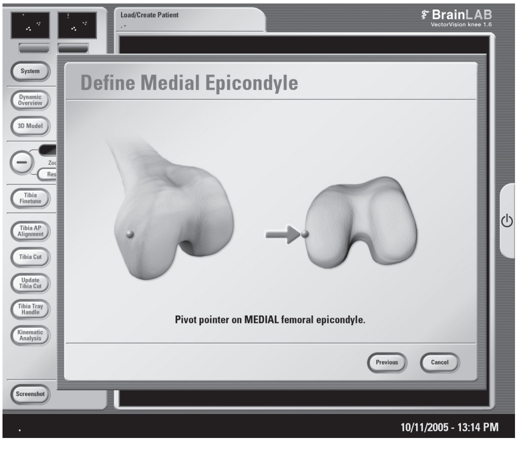


**Figure 1.** Screen of the navigation system during registration of the epicondyles of the femur.

Before identification of the bone and rotational centres of the leg and knee, the surgeon chose which reference axis was to be used for determining the correct position (i.e. rotation) of the femoral component. These reference axes in the BrainLAB system are the epicondylar line, the posterior condylar line or the Whitesides line (16). After the localization is completed, the software calculates the ideal position of the femoral and tibial component based on the pointed axes and surfaces. With regard to rotation, the system uses the chosen rotational axes and but does not take into account all three. Hence, it shows the displacement of the component compared to all three axes (Figure 2).



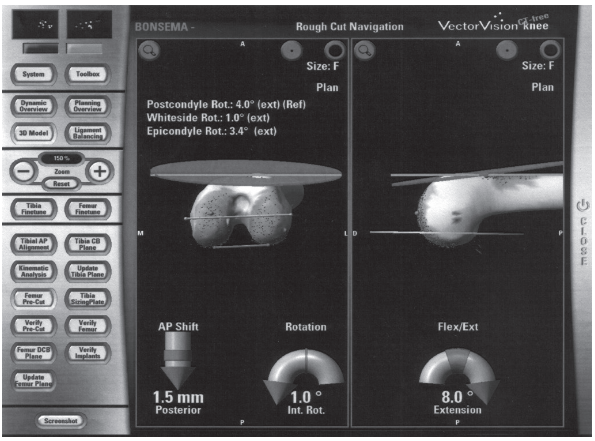


**Figure 2.** The position of the femoral component, showing the calculated position to the rotation axis.

The selected rotational reference line was in all of our cases the epicondylar axes. To be able to postoperatively identify the pointed and registrated epicondylar points on CT, the digitized lateral and medial points on the epicondyles were marked by a 1-milimeter diameter tantalum marker. These markers can be assessed highly accurately on CT scans and radiographs.

## CT scanning

Postoperatively, prosthesis placement was checked by multislice CT. Based on availability, either a 16-slice (9 patients) or 64-slice (9 patients) machine was used (Aquilion, Toshiba, Otawara, Japan). CT protocols were developed based on recommendations by the BrainLAB company. For 16-slice

CT, scanning parameters were beam collimation 16x1mm and pitch 0.938; images were reconstructed using a medium-smooth kernel with 1mm slice thickness and 1mm reconstruction index. For 64-slice CT, scanning parameters were beam collimation 64x0.5mm and pitch 0.828; images were reconstructed using a standard kernel with 1mm slice thickness and 1mm reconstruction index.

Images were interactively viewed on a workstation (Vitrea2, Vital Images, Minnetonka, MN, USA) using an extended window scale (16-bit deep, up to a window width and level of 65,500. Therefore, no dedicated metal artefact reduction filtering techniques needed to be employed.

After aligning the markers into a single plane by thin MPR, thin-slice (1-2mm) images of the distal femur were used to measure the postoperative rotational axes (Figure 3). If necessary, thick MPR may be employed to help visualize both tantalum markers at the same time.

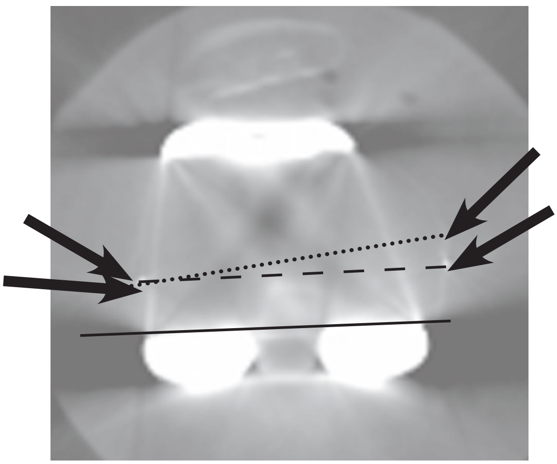

**Figure 3.** Example of a CT slice (1 mm) of the distal femur (dotted line = CT based Transepicondylar Line, dashed line = Pointed and marked line by tantalum markers, solid line = Posterior condylar line). The angle between these CT Based line and Pointed line to the posterior condylar line was measured.

On the postoperative CT scan, the most prominent part of the epicondyles was used to draw a line, the CT-based Transepicondylar line (CTB-TEL). The other reference line was drawn between the tantalum markers; the so-called marker based transepicondylar line (MB-TEL). The reference posterior condylar line (PCL) was drawn following the inner border of the posterior part of the femoral component, being the posterior condylar femoral osteotomy. We measured the posterior condylar angle (PCA): this is the angle between the PCL and the transepicondylar line (figure 3) (17). This was done for the CTB-TEL and the MB-TEL separately: the CT Based Angle (CTBA) and the marker-based Angle (MBA), respectively. In both instances the same PCL was used. The CTBA and the MBA were measured twice by observer 1 (HMJvdL) and by observer 2 (RGHHN) separately.

Since the true TEL is not known, the mean of the two PCAs (CTBA and MBA) can be used as the best estimate (limits of agreement). The difference in the two measurements for each observer of the PCA was statistically evaluated by the method of Bland and Altman (18), a non-parametric approach to compare two methods of clinical measurement. Cohen's Kappa is calculated to assess the agreement between the two observers, where kappa is 1.0 implies perfect agreement and kappa is 0 suggests that the agreement is no better than that which would be obtained by chance.



## ■ Results

The mean measured CTBA was 3.6 degrees for observer 1 (95% confidence interval between 1.72 and 5.48) and 2.8 degrees (95% confidence interval between 1.21 and 1.59) for observer 2.

The mean measured MBA was 0.55 degrees for observer 1 (95% confidence interval between -1.18 and 2.28) and 0.95 degrees (95% confidence interval between -0.76 and 2.66) for observer 2. So, overall a bigger PCA was found using the CTB-TEL as compared with the MB-TEL (figure 4).

The interobserver relationship between measurement of the CTBA by observer 1 and 2 was calculated and showed a linear pattern with a correlation coefficient of 0.95. The intraobserver correlation was kappa = 0.93 for the CTBA and 0.96 for the MBA (Cohen's Kappa is good if > 0.80).

The mean difference found between both epicondylar line measurement methods was 3,1 degrees (range 0,5 to 8 degrees, SD 5,37 degrees) (figure 4).

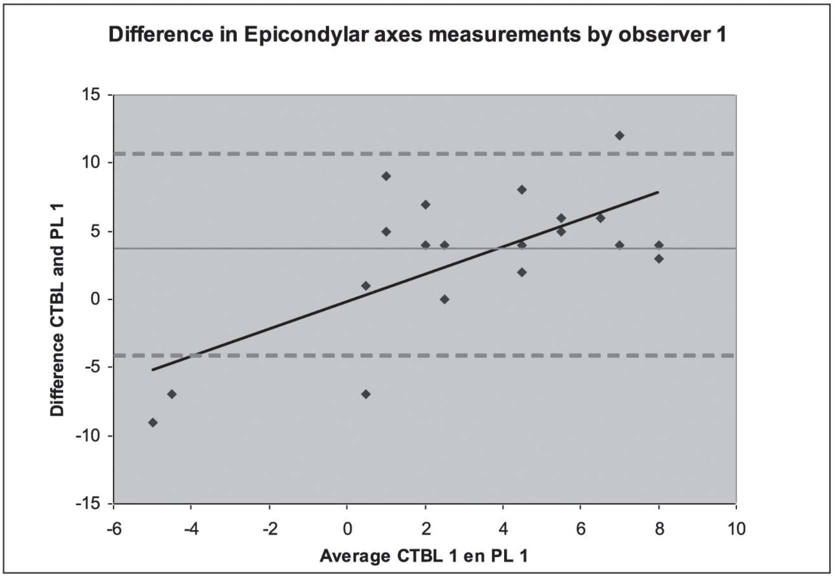


**Figure 4.** A plot of the differences in measurements between the two PCA methods (line = average difference of 3,18 degrees, upper dashed line = +2 standard deviation, lower dashed line = -2 standard deviation (SD = 3,67))

All knees had a patellar component with good patellar tracking and no anterior knee pain. The mean postoperative maximum flexion was 113 degrees (SD 12,9).

## ■ Discussion

Determination of the TEA during surgery is reproducible, however comparison of the intraoperatively determined axis with a postoperative CT scan showed a systematic error of 3 degrees. In general, determining the accurate rotation of the femoral and tibial component is difficult. However correct component rotation is very important in total knee arthroplasty in order to optimize patellofemoral and tibiofemoral kinematics. We studied the accuracy of intraoperative axis determination by the surgeon using CAOS and found an inaccuracy of 3 degrees.

There are three methods for determining femoral rotation based on bony landmarks: (1) posterior condyles with 3 degrees of external rotation, (2) anterior-posterior axis according to Whiteside and (3) the TEA.

The TEA approximates the flexion axis of the knee. Alignment of the femoral component parallel to the epicondylar axis results in the most normal patellar tracking and minimized patellofemoral shear forces early in flexion according to Miller et al. (19). But Kinzel et al. stated that even in experienced hands clinical estimation of the epicondylar axis is inaccurate and should not be relied upon as the sole determinant of femoral rotation (20).



The goal of CAOS in TKA is assisting the surgeon in determining the optimal rotational position of the components. Although accuracy in the coronal (AP) alignment is improved by CAOS (21-23), less is known about the influence on (or improvement in) rotational alignment as compared to that achieved with more traditional techniques involving mechanical guides (24-26).

Identification of the transepicondylar line during navigation is performed using a blunt pointer that the surgeon places on the palpated medial and lateral epicondyle(s) (27).

However, the shape and the soft tissue coverage of the epicondyles make these points difficult to assess, even more so due to the different shape of the medial and lateral epicondyles. The most prominent point of the medial epicondyle appears to be more easy detectable than the medial sulcus (28;29).

Since the most prominent point medially and the centre of the sulcus are on a line 2 degrees different, an error may be introduced, explaining the systematic error in this study between the CT and markers based measurement. RSA markers have not been used previously although Jerosch et al. used digital analysis by video registration (30).

Intraobserver error in obtaining the TEA has been found to be considerable (Yau et al. (31) and Jenni et al. (32)). The CT free navigation software does not take into account the difference in shape of the epicondyles. The users tend to use the most prominent and thus most easily palpable point to identify the landmarks. In developing computer assisted surgical techniques, one must be certain of the validity of measurements, inter-rater reliability, and reproducibility. The current method of localization of the epicondyles therefore is not ideal.

The PCA can best be measured on CT-scans (33). This 'gold' standard was compared with the intraoperative determined angle. The reproducibility of this measurements and the observer agreement between the PCA using both CTB-TEL and MB-TEL, is very good. Further, reproducibility was evaluated for observer 1 showing an equally good result (0.93 respectively 0.96).

We found that, overall, a larger PCA is measured using the CTB-TEL of 3 degrees. Thus, the current localization procedure of the epicondyles in CAOS could lead to less external rotation of the femoral component when based on the epicondylar line. One should be aware of this difference and possible relative internal rotation.

In general using CAOS, besides trying to achieve an adequate position of the sawing block, one must be aware of cutting errors and errors made while cementing. Because of partially sclerotic bone in an arthritic knee, the saw can divert from the bone and change the direction of the surface. Therefore, after cutting the bone the surface must be checked. But by using a computer-assisted technique, the surgeon becomes aware of cutting errors and therefore will be able to correct these (34).

Using the current software in CAOS in TKA, one should check the rotational alignment of the components using the 'conventional' techniques, using ligament balancing. A combination of the Whiteside's line and PCA provides a visual rotational alignment check during primary arthroplasty (17).

Using only the posterior condylar line is not reliable also. Hypoplasia and/or distorsion of the lateral condyle are described in the valgus knee (35) thereby influencing the PCA (36). There is also a tendency for the PCA to increase with age, causing a variation of the posterior condylar angle in knees (37). Hence the posterior condyles are potentially unreliable reference points for femoral component rotation in some knees (38), with wide interindividual variability of the PCA (39).

Lastly, all three bony landmarks have the disadvantage that they will not create a symmetric flexion gap in all cases. The balanced flexion gap method has the disadvantage that the femoral component may not be aligned parallel to the epicondylar axis in some cases. However, Olcott et al. stated that the TEA most consistently recreated a balanced flexion space (40). It is not known which of the two methods will produce better clinical results.

## ■ Conclusion

During navigation in total knee arthroplasty using the CT-free BrainLAB system, a systematic error is made between the intra-operatively transepicondylar pointed axis and CT based bony axis.

We believe that a need exists for a more accurate method to determine the epicondyles / rotation axes, thereby improving the position of the femoral component. It is necessary to be aware of a systematic error whilst using a navigation system. Determination of the best fit axis may require that a combination of all rotational axes or a cloud of points at the epicondyles be used in the software to improve the accuracy of rotation.



The operating surgeon should be aware that the computer is only providing information based on the software flow of the program. Thus, "expecting the computer to recognize the epicondylar axis when we have no ' iron clad' way ourselves exposes the true limitations of any computer assisted surgery" (DiGioia 2002).

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# Chapter 5

## A computed tomography based study on rotational alignment accuracy of the femoral component in total knee arthroplasty using computer-assisted orthopaedic surgery.

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Does navigation improve the rotation of the femoral component in TKA?
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International Orthopaedics. 2011 June; 35(6): 845–850.

## ■ Abstract

Rotation of the femoral component in total knee arthroplasty (TKA) is of high importance in respect of the balancing of the knee and the patellofemoral joint. Though it is shown that computer assisted surgery (CAOS) improves the anteroposterior (AP) alignment in TKA, it is still unknown whether navigation helps in finding the accurate rotation or even improving rotation.

Therefore the aim of our study was to evaluate the postoperative femoral component rotation on computed tomography (CT) with the intraoperative data of the navigation system. In 20 navigated TKAs the difference between the intraoperative stored rotation data of the femoral component and the postoperative rotation on CT was measured using the condylar twist angle (CTA). This is the angle between the epicondylar axis and the posterior condylar axis. Statistical analysis consisted of the intraclass correlation coefficient (ICC) and Bland-Altman plot. The mean intraoperative rotation CTA based on CAOS was 3.5° (range 2.4–8.6°). The postoperative CT scan showed a mean CTA of 4.0° (1.7–7.2). The ICC between the two observers was 0.81, and within observers this was 0.84 and 0.82, respectively. However, the ICC of the CAOS CTA versus the postoperative CT CTA was only 0.38.

Though CAOS is being used for optimising the position of a TKA, this study shows that the (virtual) individual rotational position of the femoral component using a CAOS system is significantly different from the position on a postoperative CT scan.


## ■ Introduction

Total knee arthroplasty (TKA) malalignment is related to an unsatisfactory outcome, including patella maltracking, anterior knee pain, flexion instability and early loosening [24]. Furthermore, inadequate positioning particularly of the femoral component is a common indication for revision [2, 8]. Using the conventional and bony reference point methods, rotation of the femoral component can be determined intraoperatively by the use of the transepicondylar line, the posterior condylar line and/or the Whiteside line [5, 23]. With the need for more accurate alignment as an important outcome determinant in TKA, prosthesis positioning has been facilitated in recent years by computer assisted orthopaedic surgery (CAOS). The (intraoperative) value of CAOS on coronal plane alignment of knee prostheses has been discussed in literature [27]. Some showed improved alignment using

CAOS [12, 21, 22, 26], while others showed little difference in alignment [3, 31] and no significantly better results during follow-up [16]. The reason for the differences are both surgical and related to the intraoperative navigation using predetermined anatomical landmarks; furthermore, the CAOS software program may be relevant. In CAOS, the planned rotational position of the components can be determined using the transepicondylar, the posterior condylar and the Whiteside line. Although the CAOS systems have been developed in an attempt to align implants more accurately and more consistently, it is unknown if navigation systems improve the accuracy of femoral rotational alignment as compared to the traditional techniques using mechanical guiding devices [10, 11, 28]. Whether the intraoperative positions of the knee prosthesis components, as shown on the CAOS screen, reflect the actual position of the knee prosthesis has not been evaluated. The goal of this study was to determine the validity of the intraoperative CAOS position of knee prostheses compared to the postoperative rotational position of the knee prosthesis using a postoperative CT scan evaluation method [7, 15].



## ■ Materials and methods

Twenty imageless navigated total knee arthroplasties were performed at the department of orthopaedic surgery at the Leiden University Medical Centre. In a former study by Van Strien et al. [31], the CAOS system was evaluated using postoperative radiographs and CT scans as well as RSA. The protocol was approved by the institutional medical ethics committee. All patients gave informed consent. The average age was 69 years (SD 9 years). The groupconsisted of eight male and 12 female patients. Fourteen of these 20 patients had primary osteoarthritis of the knee. Five patients had secondary osteoarthritis due to rheumatoid arthritis and one secondary to haemophilia. In 11 patients the left knee was operated upon, in nine the right knee. In all patients a NexGen LPS flex prosthesis (Zimmer Inc.,Warsaw) was implanted. The Vector Vision CT free computer navigation system, software version 1.6 (BrainLAB, Feldkirchen, Germany) was used in all operations. Before identification of the bone and rotational centres of the leg and knee, the surgeon chooses in the software which reference axis will be used for determining the correct rotational position of the femoral component. These reference axes in the BrainLAB system are the epicondylar line, the posterior condylar line or the Whitesides line [32]. During surgery, anatomical landmarks are used to build a virtual image of the tibia and femur in the Brainlab system. After attaching reference markers to the tibia and femur, hip rotations are made to determine centre of rotation of the hip. The intraoperative femoral anatomical registration points are: the most prominent points of the medial and lateral epicondyles, the anterior sulcus (Whitesides line), the femoral mechanical axis, a cloud of points of the anterior distal femur and a cloud of points of the posterior condyles. After localisation of the landmarks is completed, the software calculates the ideal position of the femoral and tibial component based on the anatomical data input of axes and surfaces (i.e. femur and tibia). With respect to the rotation reference axes, the system uses one of the preoperative selected axes (in this study the epicondylar axis); it does not take into account all three axes. However, the CAOS software displays the displacement of the component with respect to all three axes on the screen (figure 1).

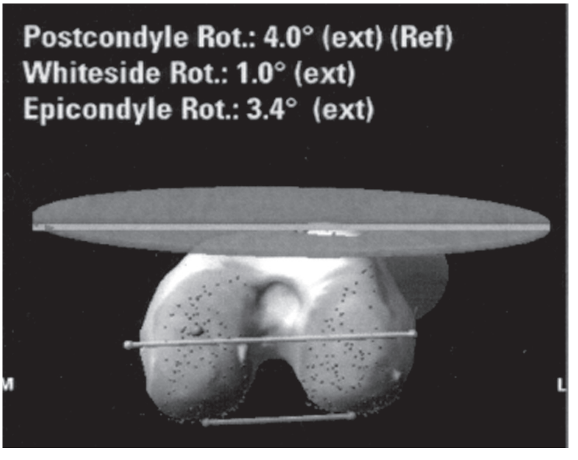


**Figure 1.** Screenshot of the CAOS system with intra-operative data showing the deviation of the planned femoral component position compared to the rotational axis.

Thus data is available for off-line analysis. The definite femoral component was positioned as proposed by the navigation system, being the optimal CAOS femoral position. In these 20 cases we did not adjust the rotation as suggested by the navigation system. The anterior cut was verified with a plane-verifying marker tree after the bone cut so that there was no change in rotation caused by the saw blade. This plane was then stored in the Brainlab system (figure 2).

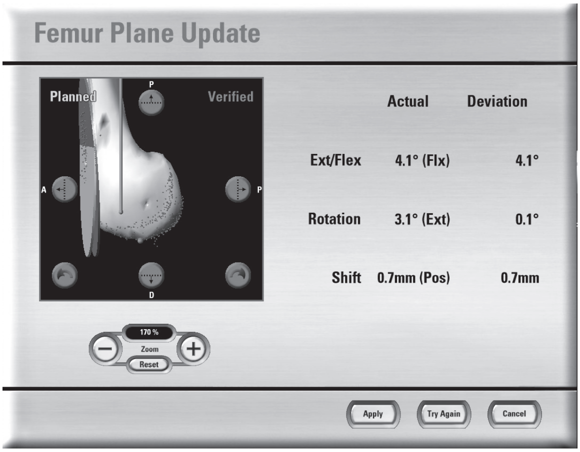


**Figure 2.** Screendump of the CAOS system showing intra-operative information on the actual femoral cut.



Thus the postoperative measured bone cut along the femoral component is the same as made intraoperatively. The postoperative multi-slice CT scan was made between six weeks and three months after the operation, according to a standard protocol. Based on availability, either a 16-slice (nine patients) or 64-slice (11 patients)machine was used (Aquilion, Toshiba, Otawara, Japan). CT protocols were developed based on recommendations by the BrainLAB company. For 16-slice CT, scanning parameters were beam collimation 16 x 1 mm and pitch 0.938; images were reconstructed using a mediumsmooth kernel with 1-mm slice thickness and 1-mm reconstruction index. For 64-slice CT, scanning parameters were beam collimation 64×0.5 mm and pitch 0.828;images were reconstructed using a standard kernel with 1-mm slice thickness and 1-mm reconstruction index. Postoperative CT images were interactively viewed on a workstation (Vitrea2, Vital Images, Minnetonka, MN, USA) using an extended window scale (16-bit deep, up to a window width and level of 65,500). Therefore, no dedicated metal artefact reduction filtering techniques were needed. Thin-slice (1-2 mm) images of the distal femur were used to measure the postoperative rotational axes. The senior author (RN) performed all the operations and was not involved in the postoperative measurements of component position. We used the condylar twist angle (CTA) to measure the rotational position of the femoral component. This is the angle between the epicondylar axis and the posterior condylar axis. This epicondylar line was drawn between the most prominent point of the medial epicondyle and the most prominent point of the lateral condyle of the distal femur. The most prominent point of the medial epicondyle which is required for the CTA is easier to identify than the medial sulcus which is required for the posterior condylar angle. Both are registered at the same time during the navigation registration process. The posterior condylar line was drawn along the posterior femoral cut (i.e. the inner border of the metal posterior condyles of the femoral component). At the CT scan viewer (Sectra workstation) two points were identified at the medial and lateral epicondyles for angle measurement (CTA). These points were marked at the CT workstation and were thus visible at the different CT slices (figure 3).

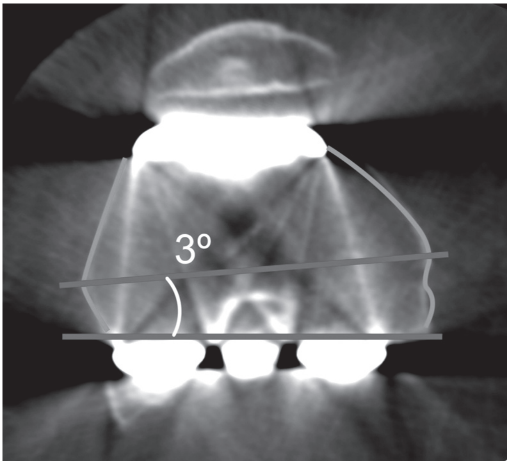


**Figure 3.** Postoperative CT example showing the measured condylar twist angle (CTA).

Therefore, the angle between the medial and lateral epicondyle could be measured accurately without reconstructing a thick slice to visualise both most prominent epicondylar points at the same time. The CTAwas independently measured by two observers, at two separate time intervals two weeks apart. The observers were blinded for the intraoperative measured rotation. These measurements were compared to the intraoperative registered rotation of the femoral component; the latter is stored in a therapy report by the CAOS system. This report is an overview of all registered femoral and tibial points, which are needed to register the specific morphology of both tibia and femur as well as the centre of the hip joint and the ankle joint. Furthermore, this report saves, during the several steps of the COAS procedure, final steps after bone cuts have been made (i.e. tibial cut, femoral bone cuts).

Statistical analysis was performed using repeated measure analysis (ANOVA). The intraclass correlations were calculated for the CT measurements for the different observers. The epicondylar axis which was obtained from the CAOS system was compared to the CT measurements of the femoral component using an intraclass correlation coefficient. Limits of agreement were obtained for the different comparison according to Bland and Altman [6], a graphical tool to measure agreement between two methods. The interpretation of the ICC is similar to that of the Cohen's Kappa, such that ICC=0.40–0.59 is moderate interobserver reliability, 0.60–0.79 substantial and 0.80 outstanding [17]. For statistical analysis, SPSS 16.0 was used and the level of significance was set as 0.05.

## ■ Results



The rotational alignment of the femoral component was expressed with the CTA. The rotational alignment of the femoral component which was saved in the registry report of the CAOS system was 3.5° (range 2.4–9.6°). In none of the knee prostheses was a cement layer of more than 1 mm detected at the lateral radiograph on the anterior, posterior and/or distal cut. The mean CTA measured on the postoperative CT scan was 4.0° (range 1.7–7.2°) for observer 1 and 4.4° (range 1.2–9.9, SD 1.5) for observer 2. The measured CTA on the CT scan showed an intraclass correlation of 0.81 (p<001) between the two observers. The intraclass correlation coefficient for differences within the observers was 0.84 and 0.82 (p<0.001), respectively. However, when we compared the angles obtained from the CAOS navigation system with the CTA measurements by both observers on the postoperative CT scans, we found an intraclass correlation of only 0.38 (p=0.15).

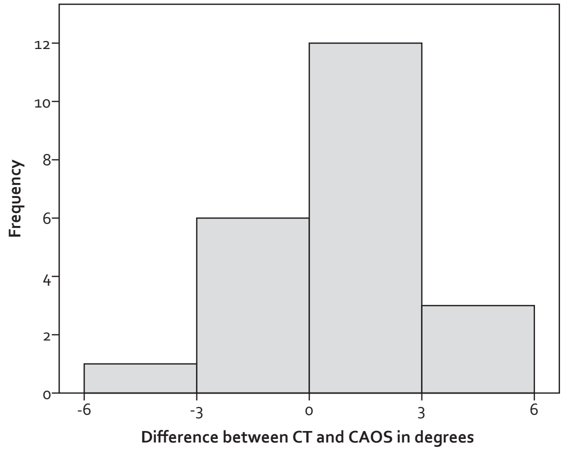


**Figure 4.** Histogram shows the measured difference in rotation (CTA) of the femoral component between the intra-operative data and the postoperative CT.

In figure 4 a histogram shows the difference between the CAOS and the postoperative CT scans. From this histogram we can see that all differences were between −6 and 6°, and 80% between −3 and 3°. The Bland-Altman plot (figure. 5) shows no monotonic drift between the two measurements nor a systematic increase in error related to the value of the measurement. The 95% limits of agreement were −4.3 to 5.7°; thus, not only no correlation between CAOS and CT position could be found, but the differences between the two values were also relatively large.

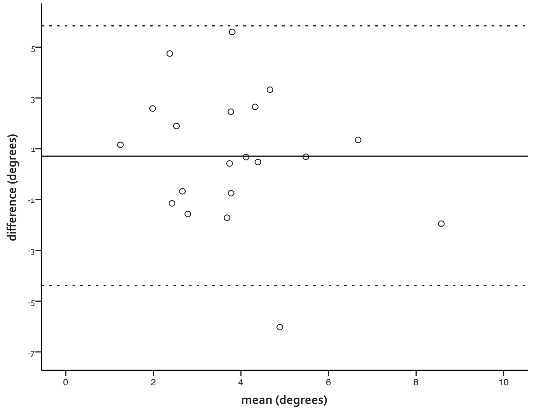


**Figure 5.** Bland Altman plot shows the difference between intra- and postoperative CT data against the average of the intra-and postoperative measurement values for each sample. The middle line is the mean difference and the two extreme lines are the +2 and -2 standard deviation.

## ■ Discussion

The intraoperative position of the femoral component of the knee prosthesis, as determined by the CAOS system, differs from the actual position of the knee prosthesis as measured on a postoperative CT scan. This difference between the intraoperative rotation registered by the navigation system and the actual postoperative CT position has not been published before. Accurate positioning of the components in TKA is very important. The rotation of the femoral component especially influences the final outcome due to its role in flexion stability, kinematics and patellar tracking. The use of navigation in TKA showed more accurate AP alignment; however, little is known about the effect of CAOS navigation systems on rotational alignment [19]. Furthermore, little is known about whether the intraoperative knee component angles are indicative for the actual postoperative component positions. Therefore, the purpose of this study was to evaluate the difference between this intraoperative computer guided femoral rotational alignment with the actual postoperative femoral position, measured using CT scans. So far, only Han et al. performed a study on rotation and the use of navigation [14]. They found no difference in rotational alignment between CAOS and conventional placement of the femoral component. However, they used a Mann-Whitney U-test to compare the groups, and this test only analyses the mean and standard deviation of the two groups and not the agreement. We used an intraclass correlation coefficient in which the agreement is more important than the mean value of the two groups. Furthermore, in their patients treated with the conventional technique, the PCA was used, and in the navigation group a combination of the epicondylar axis and the flexion gap with the use of laminar spreaders was used; thus, two different techniques were applied.



In general, external rotation of the femoral component of 3° to a maximum of 5° with respect to the posterior condylar line or 0° placement with respect to the transepicondylar line is considered an optimal femoral component position [1, 18]. In this study, the mean intraoperative rotation of the femoral component was 3.5° according to the navigation software, and the mean postoperative rotation measured on CT was 4.2°. Taking this into account, as well as the mean rotational positions at first sight, suggests that there was no significant difference between the intraoperative data and the postoperative situation. However, comparison of each single measurement showed no correlation. Besides, there was still a considerable range of the measurements (2.4–9.6°) in this group of navigated TKAs. There are several factors that could cause the difference between the intraoperative registered position and the definite postoperative measured position of the femoral component. These can be related to the navigation system, the intraoperative events after the bone cuts have been made and factors related to CT measurement errors. With respect to the CAOS system, errors can occur during registration and during surgery by, for example, displacement of the markers.

To achieve a precise rotational position, the determination of the epicondylar axis, posterior condylar line and Whiteside's line is crucial. Whilst many opinions are expressed in the literature as to which axes are the most reliable and/or show the least intra-/inter-observer variability, neither one seems to be superior [25]. This supports our finding that CAOS provides information though does not replace clinical judgement. Benjamin et al. [4] compared the different axes and showed that the posterior condylar axis matched within 1° in 64% of the patients in contrast to epicondylar (32%) and Whitesides line (26%). In this navigation module, the planned position of the femoral component was based on the epicondylar axis Yau et al. [33] also stated that landmark referencing of the axes shows variation because of intraobserver errors and anatomical differences, and thereby leads to variation of the navigation planned implant positioning. This variation is, for example, described for the epicondylar axis. An average random error of 3° was found using the same navigation module by Van der Linden et al. [30]. Several authors [13, 20] concluded that, because of this problem, preoperative CT scanning is a more appropriate method because of the fact that using computer navigation, rotation is still based on a controversial intraoperative identification of the axes. Also, averaging the different alignment axes will not solve this problem. This was studied by Siston [25]; it will reduce the number of rotational alignment outliers, but they are still present.

To measure the postoperative position of the femoral component we used computed tomography. The most prominent point of the medial epicondyle is required for the CTA. This is much more easily identifiable than the medial sulcus which is required for the posterior condylar angle [29]. By measurement of the ICC within and between the observers, which was 0.84 and 0.82, respectively, it is shown that the measurements using CT had very good reproducibility. Prosthesis placement might be changed after the bone cuts have been made due to small cement layers. To measure this alignment deviation caused by standard impaction of the components following bone resections, Catani et al. [9] measured the alignment of the bone resections during surgery. The alignment measure was repeated after final tibial and femoral component implantation with cement. The alignment deviation was >1° in the frontal plane of the femur in 20%. However, the rotational position was not evaluated and the influence of the thickness of the cement layer on femoral component position is therefore still unknown. Thus, the positioning of the components in total knee arthroplasty, which mainly involves cementation and impaction of the final components, can introduce an error in alignment, regardless of how accurately the resection planes are made.

In conclusion, the intraoperative CAOS measured rotation of the femoral component differs from the postoperative CT measured position and is therefore not reliable as an absolute value. CAOS can probably help to achieve the optimal position of the femoral component but continuous improvement in methods to accurately identify the rotational position and establish the ideal rotation of the components in total knee arthroplasty is still needed.

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# Chapter 6

## Computer assisted orthopedic surgery; its influence on prosthesis size in total knee replacement

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The Knee, Vol 15 (2008) 281–285

## ■ Abstract

Improvement of alignment and position of the components in TKAs using Computer Assisted Orthopaedic Surgery (CAOS) has been described. However, much less is known about the accuracy of CAOS in determining the size of the components. The purpose of this study was to evaluate the size of the femoral and tibial component using the CAOS system from Brainlab. The component sizes were compared to pre-operative templating and post-operative scoring the adequateness of size. Forty TKAs (NexGen) were evaluated: 20 using CAOS and 20 conventional. Statistical analysis of the templated and implanted size indicated a fair agreement for the femur (kappa 0.38) and the tibia (kappa 0.35). In the CAOS group significantly more oversizing occurred for the femoral component ($p=0.020$). No significant difference was found for the tibial component. We conclude there is a risk of oversizing the femoral component of the NexGen system when using CAOS.


## ■ Introduction

The outcome of primary total knee arthroplasties (TKA) has improved during the last decade, as a result of better prosthesis design, new materials and optimization of surgical techniques. However, the functional result depends on patient factors and complications, but is also related to the position and the size of the prosthesis.

Both oversizing and undersizing of the components can cause pain or functional impairment. Oversizing of the femoral component can lead to a too narrow flexion space and/or overstuffing of the patellofemoral joint and diminish the knee function. [1–4]. Pre-operative templating is a common method to estimate the optimal size and position of the components in total knee replacements. The definitive implant sizes are determined during surgery using measuring instruments from the manufacturer and ligament balancing. Recently, several studies have shown that computer assisted orthopaedic surgery (CAOS) can improve the placement of the knee prosthesis [5–7]. In particular the anteroposterior alignment has been shown to be less variable [8–10]. Less is known about the process that leads to the selection of the optimal component size using CAOS. Matsumoto [11] reported the risk of oversizing the femoral component in a study of 60 posterior stabilized knees. The anteroposterior dimension of the femoral condyle and prosthesis size was significantly larger in the navigated group. While using the Brain LAB system for TKA (Vector Vision, version 1.5.2 Brain LAB, Feldkirchen, Germany), we also had the impression that oversizing (of especially the femoral component) occurred more frequently using navigation than in conventional surgery. Therefore the aim of our study was to assess whether the size of the total knee components using CAOS differed from the size pre-operatively templated, and if this influenced the functional outcome in case of oversizing.

## ■ Patients and methods

From a series of 117 patients with a NexGenTKA(Zimmer,Warsaw, Indiana, USA), which were operated by two surgeons (HMJL and RGHHN) at the Leiden University Medical Center, a group of 40 TKA operated by one surgeon (HMJL) was selected for this study. A single surgeon approach was used to reduce confounding on prosthesis placement by surgeon's preference. The first five CAOS TKA performed by that surgeon were excluded from analysis. Thus 20 prostheses implanted with a computer navigation system with CT free software (Vector Vision, version 1.5.2 Brain LAB, Feldkirchen, Germany) were compared to 20 prostheses implanted by a conventional technique. The latter group was matched with respect to degree of radiological destruction and diagnosis. Four patients had bilateral TKA, all in the conventional group. There were six males and fourteen females in the navigated group versus four males and sixteen females in the conventional group. In both groups, the major indication for a TKA was osteoarthritis secondary to rheumatoid arthritis (14 in both groups), the other patients suffered from primary osteoarthritis. The mean age of the patients in the navigated group was 66 years (range 33 to 82 years), in the conventional group 69 years (range 38 to 86 years). Both groups had the same degree of pre-operative radiological destruction (Kellgren 3 to 4) [12]. The mean preoperative hip knee angle (HKA) was 181 in the navigated group (range 168 to 192 ) and 179 in the conventional group (range 166 to 190).

## ■ Functional and radiological evaluation

Of all the 40 TKAs the pre- and post-operative range of motion and the anteroposterior alignment were assessed. In all patients anteroposterior weight bearing radiographs, a lateral non-weight bearing knee radiographs and a long leg standing anteroposterior radiograph were made pre- and post-operatively, using the same protocol in order to standardize the magnification.

The size of the femoral and tibial components was assessed using templates and instructions provided by the manufacturer (Nexgen templates, Zimmer, Warsaw, USA). The templates had a magnification factor of 115% as usual for templating in hip and knee surgery. The two observers (HMJL, RGHHN) were double-blinded for surgical technique (i.e. CAOS or conventional and component size used) and the post-operative radiograph (i.e. correct, too small, too large) before templating and scoring each radiograph. First the series pre-operative radiographs in a random order, second the post-operative radiographs. Three weeks later a randomized series (different from the first evaluation) from the pre-operative and a randomized series from the post-operative radiographs were scored. Considering the component sizes it is important to realise that the NexGen knee system has an unusual sizing system such that both size 3 and size 4 have the same mediolateral diameter but increase in size in the anteroposterior diameter.

Therefore on the AP Xray the next size up from a size 3 is a size 5. Thus, the following schedule sizes of all 40 TKA femoral and tibial components were available for analysis:

1. Pre-operative templated tibial and femoral component size, based on AP and lateral radiographs by the two observers
2. The intraoperatively proposed size by the navigation system
3. The actually placed size of the TKA implants
4. Post-operative score on femoral and tibial component size. The two observers used the following score: too big (oversized), correct or too small (undersized, for criteria see Table 1)

| | Femur AP view | | Femur Lat view | Tibia AP view | | Tibia Lat view |
|---|---|---|---|---|---|---|
| Too big | Medial and/or lateral overhang of the posthesis | and/ or | Anterior and/ or posterior overhang | Medial and/ or lateral overhang of the posthesis | and/ or | Anterior and/ or posterior overhang |
| Too small | Medial and/or lateral no complete coverage of the prosthesis of the distal femur cut | and/ or | Anterior notching and/ or no complete coverage of the prosthesis over the posterior condyle cut | Medial and/or lateral no complete coverage of the prosthesis of the tibia cut | and/ or | Insufficient coverage of the prosthesis over the tibia cut |

**Table 1**. Criteria sizing of femoral and tibial component.

## ■ Statistics

We measured the inter-observer agreement by a weighted kappa coefficient. The agreement is considered poor when b0.20, fair between 0.21 and 0.40, moderate if 0.41 and 0.60, good 0.61 and 0.80 and very good if between 0.81 and 1.00. To assess the homogeneity between the differences in size (too big or too small) observed by the two observers a Pearson Chi Square test (with one degree of freedom) was used (Exact sig. 2-sided). The overall reliability of the pre-operative templated size of the components versus actually implanted component sizes was evaluated for each of the two observers. An unpaired t-test was used to evaluate the pre- and post-operative functional outcome. The null hypothesis was that the mean difference between the pre- and post-operative flexion and pre- and post-operative extension were the same in both groups.

## ■ Results

The overall reliability of the pre-operative templated size of the 40 components versus the actually implanted component sizes showed agreement between the templated and actual TKA in 40–60% for the femoral component and in 48–55% for the tibial component for the two observers (Table 2).

6

| Templated versus definitive implant size | Femur | | Tibia | |
|---|---|---|---|---|
| | Observer 1 | Observer 2 | Observer 1 | Observer 2 |
| Same size | 24 / 40 | 16 / 40 | 22 / 40 | 19 / 40 |
| One size bigger or smaller | 39 / 40 | 36 / 40 | 37 / 40 | 38 / 40 |
| Agreement (kappa) | 0,38 | | 0,35 | |

**Table 2**. The templated component size versus the definitive implanted size.

In 14 of the 40 TKAs a different femoral component size was implanted than pre-operative templated by both observers. Eleven of these where in the navigated group and in 10 of these a larger femoral component was implanted than that suggested/calculated by navigation. Ten implanted tibial components differed from the pre-operative templated size; in three of these a smaller size was implanted. The latter was equally distributed between the CAOS and conventional group. In five knees both the implanted femoral and tibial components differed (in one for femur to two sizes for the tibia) compared to the pre-operative templated size. For both the tibial and femoral component the size suggested by CAOS was compared to the templated size by either of the two observers (Table 3).

| | Femur | | Tibia | |
|---|---|---|---|---|
| CAOS determined size was | Observer 1 | Observer 2 | Observer 1 | Observer 2 |
| 3 sizes larger | - | - | - | 1 |
| 2 sizes larger | 2 | 2 | 1 | - |
| 1 size larger | 2 | 4 | 4 | 4 |
| Same size | 14 | 11 | 9 | 8 |
| 1 size smaller | 1 | 2 | 3 | 5 |
| 2 sizes smaller | 1 | 2 | 2 | 2 |
| 3 sizes smaller | - | - | 1 | - |
| than templated by observer | | | | |

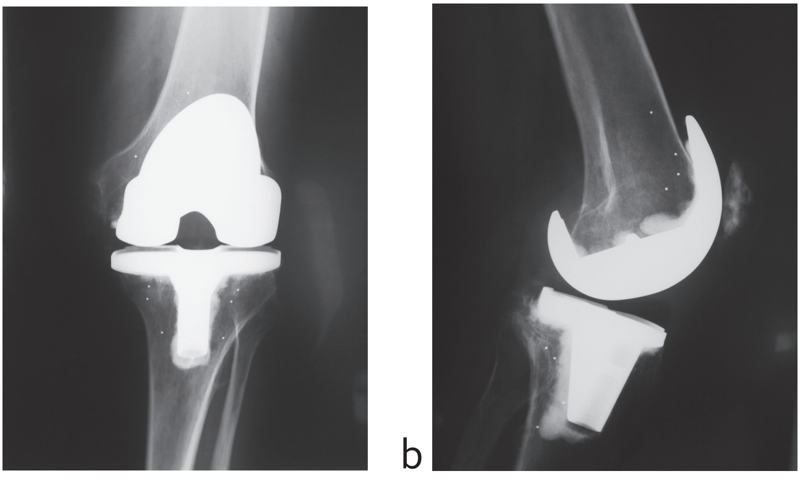
**Table 3**. Agreement between observer's templated size and CAOS determined size (see text for details of sizing).

If including a CAOS determined component size within one size larger or smaller, than 17 out of the 20 femoral components were within this correct size range according to both observers. Using the same definition, 16 tibia components were correct according to observer 1 and 17 out of 20 were within correct size range for observer 2. Evaluating the post-operative radiographs, six femoral components were considered 'too large' by at least one, and four by both observers. All these "too large" components were in the CAOS group. Furthermore, the actual implanted femoral component size was in four of these six already one size smaller than the CAOS system had proposed (i.e. the surgeon had overruled the CAOS proposition, as could be concluded from the surgical report). Three femoral components were scored 'too small' by at least one observer, two of them in the CAOS group.

Taking into account all 'too small' and 'too big' scored femoral components by both observers, , the Chi square test showed a value of 7.059 (p=0.020). A similar significant result is obtained when we take into account the by at least one of the observers 'too big' scored femoral components. The tibial component was scored as 'too small' by one or both observers in six knees. This was equally distributed in both groups. Combining 'too small' and 'too big’ scored tibial components by both observers into an inadequate size group, the Chi Square was 0.229 (p=1.000).

## ■ Functional outcome

The pre-operative range of motion of the knee showed a mean flexion of 109 (range 70 to 130 , SD 15) and a mean extension of −10 (range −40 to 0 , SD 13) in the navigated group. In the conventional group the mean flexion was 110 (range 80 to 130 , SD 16) and the mean extension also −10 (range −30 to 0 , SD 9). No statistical difference was found between the two groups (flexion p=0.881, extension p=0.62). At 12 months follow up, the mean flexion and extension were respectively 113 (range 90 to 140 , SD 14) and −3 (range 0 to −20, SD 5) in the navigated group. The conventional group showed a post-operative flexion of 114 (range 90 to 130 , SD 13) and −1 (range 0 to −5 , SD 1) extension. The estimated differences between the two means of the two groups for flexion and extension were 0.05° and 0.4° respectively. The 95% confidence interval for the difference between the pre- and postoperative flexion ranges from −10.3 to 10.3°, for the difference between the pre- and post-operative extension the range was −5.4 to 6.1°. Two of the 40 patients with a TKA needed manipulation under anesthesia because of a flexion range of less than 90 , both were present in the navigated group. In one an over sized femoral component had been implanted (Figure 1a, b). However, at 12 months follow up, flexion was 110 and 120 in these two patients which was comparable to the overall mean flexion.



a b

**Figure 1 a.** Anteroposterior radiograph of an example of a left TKA with an oversized femoral and tibial component in the navigated group. The medial overhang of the tibia component is visible. **1 b**. Mediolateral radiograph of the same knee. The anterior and posterior overhang of the femoral component is visible.

## ■ Discussion

## ■ Pre-operative templating

We found a fair agreement between the templated and postoperative size scoring for both components. In 19 out of 40 knees a different size of femoral and/or tibial component was used. The agreement increased to very good when one size smaller or bigger was also included. In two of the oversized femoral components a bigger size was implanted than templated. The use of template systems has aided the pre-operative selection of correct prosthetic size during routine arthroplasty. It has been recommended mainly in uncemented hip joint arthroplasty [13]. Previous studies on uniand total knee arthroplasties, showed a bigger and significant intra- and interobserver variability, regardless of the surgeon's experience, with a reliability of 49–53% for the femoral component to 53–67% of the tibial component [14,15].

Thus, limited reliability of pre-operative templating in TKA exists, but the current system of templating has to be used as an approximate guide for the surgeon during the intraoperative procedure and probably limits oversizing the femoral component [16]. One limitation to the templating is reflected to the (small) differences in magnification between the templates and the actual radiograph. The current increased use of digital radiographs (PACS systems) may afford correction of the magnification factor yielding more accurate pre-operative planning. The et al. [17] found a good inter-observer reliability for the planning of TKA using digital radiographs. Their procedure proved to be accurate (0.1–0.4 size too small on average) while analog planning of TKA systematically underestimated the component sizes (1.1 size on average). However, White et al. [18] concluded that surgeons should be aware that digital radiographs may reduce the magnification of the film and, therefore, reduce the accuracy of pre-operative templates supplied by the manufacturers of implants, resulting in incorrect selection of implants.

## ■ CAOS and component size

We found significantly more oversized femoral components in the navigated group than in the conventional group scored by both observers. The result was the same when taking into account both observers. This additionally suggests that the use of CAOS tends to oversize the proposed femoral component. There are two intraoperative methods used to determine the appropriate femoral component size: size matched resection using an AP sizing guide (measured resection) versus a flexion space balancing method. Incavo et al. [19] reported that the flexion space balancing method yielded a smaller size selection than the size matched resection in about 50% of the cases. The CT free navigation system selects the femur size comparative to a 'size matched resection method'. A single point on the anterior sulcus is acquired for the definition of the anterior femoral cut and the size of the implant. It also uses the distance to the acquired posterior condylar axis [20]. Such a CT free system based on bone model morphing, provides geometric and morphologic three-dimensional information without any preoperative or intraoperative imaging. It relies on data collected with a three-dimensional optical localizer in a relative coordinate system, attached to femur and tibia. Errors can arise when registration is not performed accurately and thereby also influence the estimated size of the components [21]. These findings are supported by the findings of Matsumoto et al. These occurred mostly in the earliest performed navigated TKAs and may reflect the learning curve, especially in identifying the correct refer ence points on the femur.

## ■ Manipulation of TKA in case of oversizing

Two patients in the navigated group needed manipulation under anesthesia; one of them did have an oversized femoral component. There are multiple factors that affect the postoperative range of motion (or stiffness) after total knee arthroplasty [22] indeed; Several authors [23] found that the pre-operative range of motion was the only significant predictor of post-operative range of motion. A too small flexion space/gap (compared to extension) may create a poor range of motion in flexion and/or excessive posterior polyethylene wear. Several authors have described the relationship between oversizing of the femoral component and the need of manipulation under anesthesia [24]. Daluga et al. [25] stated that an increase of the AP dimension of the knee by 12% or more is a critical independent variable that significantly predisposes the patient to manipulation and may increase the likelihood of failure of the implant. Considering the functional outcome we have insufficient evidence to reject the null hypothesis that the mean difference between the pre- and post-operative flexion and pre- and post-operative extension were the same in both groups. Although the number of knees needing manipulation is small, awareness of the risk of oversizing is necessary.

## ■ Conclusion

This study confirms that pre-operative templating in NexGen TKA shows a considerable inter-observer variability, with a fair agreement for the femoral and tibial component. Especially considering the femoral component a different size was template compared to that proposed or calculated by CAOS using Vector Vision from Brainlab.We conclude that oversizing of the femoral component occurs significantly more in NexGen TKA using this CAOS system. This stresses the importance that the surgeon should have knowledge and interpretation of which data are used by a CAOS system for plane and ultimate component size definition. The latter enables the surgeon to adapt intra-operatively to potential mismatch between conventional and CAOS techniques.

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# Chapter 7

## Accuracy of Computer Navigated Patellar Tracking in Total Knee Arthroplasty. The influence of velocity of movement and marker occlusion on validity

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submitted

## ■ Abstract

*Objectives*

Complications after total knee arthroplasty (TKA) often involve the patellofemoral joint. Computer assisted surgery has been advocated to address these problems intra-operatively, in order to have the possibility to correct directly during surgery. This study measured the changes of the virtual patellofemoralkneekinematics during different velocities of an flexion-extension cycle (FE-EF) to validate tracking on a CAOS system.

*Methods*

An experimental knee set-up was used, which allowed single axis tibiofemoral and patella movement. The patellar kinematics was measured during active EF and FE motions at different velocities. Measurements obtained during flexion-extension movements were modeled using second-order polynomials based on least squares estimation in order to estimate means per time cycle. One way analysis of variance by ranks was performed using (non-parametric) Kruskal–Wallis test.

*Results*

The patellar motion was significantly different between the different EF-FE motion velocities. The measurements per time cycle were highly reproducible and excellent model fits were obtained; $R^2 > 0.95$ in all cases and $R^2 > 0.99$ for 90% of cases.

One way analysis of variance by ranks for the values at 20, 45 and 70 degrees of flexion showed significant differences per F and E motion at the different velocities. It is also shown that the positions in flexion and extension differ in a timecyclus and this difference gets larger at higher velocities.

*Conclusions*

The pattern of patellar tracking as presented during CAOS was influenced by the velocity of movement during a EF-FE cycle. One should be aware of this phenomenon when using this patella tracking system.

## ■ Introduction

Anterior knee pain following knee arthroplasty (TKA) is a common complaint, and is often related to abnormal tracking behaviour of the patellofemoral joint (maltracking).[1,2] Several factors influence patellar tracking, including prosthetic design, surgical technique and placement of the components.

Patellofemoral complications are a major cause of poor function in the prosthetic knee. There is good experimental and clinical evidence that poor femoral component rotational alignment can adversely affect patellar tracking and kinematics Intra-operative monitoring and evaluation of the patellar tracking during total knee arthroplasty gives intraoperative feedback to the surgeon on potential (mal)alignment of the kneeprosthesis. The patello femoral motion is a six degree-of-freedom motion, with translations along and rotations about an axis. Four of these motions can be related to the clinical shift, tilt, flexion, and rotation of the patella. In knee arthroplasty these patellar movements are the end result of the kneeprosthesis position. If the rotation of either the femoral or tibial component is too far off, the end result will be an dislocating patella. By adding the patellar component position and its movement within a CAOS system, might give the surgeon feedback on the ultimate component position. More subtle corrections in patellar maltracking (e.g. change of rotation of the tibial component) will be possible by soft tissue releases if visualized by CAOS compared to the normally considered "rule-of-no-thumb". The latter indicating intraoperative good patellar tracking while flexing the knee without pushing the patella in place. It is obvious that this method can only judge gross patellar maltracking (i.e. dislocation) and not subtle differences in patellar maltracking.



Computer assisted orthopaedic surgery (CAOS) systems are potentially valuable in giving intraoperatieve feed back on this patellar tracking to surgeons. Thus adjustments to patella position with respect to femoral and tibial component (or vice versa) might give an optimal patellar tracking. Futhermore since data are stored in the CAOS system, offline analysis is possible with subsequent evaluations of associations between clinical symptoms and dynamic patellar tracking. However, before such analyses can be performed, the validity of intra-operative patellar tracking during TKA surgery has to be evaluated. As was shown earlier, validity of CAOS systems is determined by the CAOS software as well as by the operator (i.e. surgeon).[3]

The aim of this study was to evaluate the validity of the patellar tracking software which is present in a CAOS system.

## ■ Materials and Methods

The patellofemoral and tibiofemoral joint kinematics are inter-related via the femoral component after TKA. Thus, an alteration of one factor alters the kinematics of the other joint.[4,5] Therefore, a phantom knee model was used in an experimental setup, in which a femoral and tibial sawbone were connected to each other with a hinge (figure 1), The clinical situation is confused by the variable relationship between the tibiofemoral and patellofemoral articulations thus only a single plane (extension and flexion) movement was allowed in the experimental set-up. In order to evaluate only the effect of a flexion and extension motion on patellar tracking motions the femoral and tibial sawbone were attached with a hinge. Thus the knee joint could only make motions in the sagittal plane (i.e. flexion and extension). The patellar sawbone was connected to the femur with a hinge, thus only movement in again a single, sagital plane was possible.

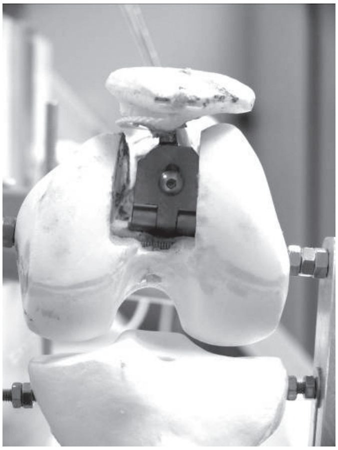
The patellar tendon was simulated with a length of non-elastic rope, thus coupling the motions of the patella to the motions of the tibia. The femur was fixed with the most-posterior parts of the femoral condyles horizontal. The component of the quadriceps was loaded with hanging weights using cables and pulleys with a total of 5N, according to the physiological directions of the quadriceps muscles relative to the femoral axis. From the upper pole of the patella, a second non-elastic rope was aligned with the center of the hip by a pulley wheel and loaded with a 0.5 kg weight, hanging downwards, thus imitating the quadriceps pull. The two hinges eliminated medio-lateral and tilting motions of the patella (figure 2). Thus, only rotation of the patella around the 'epicondylar axis' during flexion and extension was possible.

Data from the patellar tracking, which were analysed off line from the CAOS system, were: the patellar medio-lateral shift and, the medio-lateral tilt during the FE motion of the knee, and the off-circle distance with respect to the EF-FE velocity and knee flexion. All tracking results are also saved in a.text-file created by the software module.

The file contained information at certain points in time during testing of:

- Flexion: TF flexion in degrees.
- Shift: Medial-lateral patella shift in mm.
- yRot: Tilt, rotation around patella AP direction in degrees.
- zRot: Internal/External patella rotation in degrees.
- OffCircleDistance: Distance between patella and initial patella circle in mm.

The patellar tracking functionality of the CAOS system of Brainlab ( BrainLAB CT Free Vector Vision navigation system, Version 1.6, BrainLAB, Heimstetten, Germany) was used throughout the experiments. This system was used according to the manufacturer's manual, it requires the use of two marker-trees next to the patellar tracking marker tree, which are attached to the femur and the tibia using a two-pin fixation device. For the registration of the patellar motion a third marker-tree is attached to the anterior surface of the patella (figure 1). Each marker-tree has three retro-reflective (passive) markers. All three marker trees are registered within the CAOS system and matched to the dimensionsof the phantom knee model during a registration process by manually indicating  landmarks at the femur, tibia, and patellar saw bones. This matching process is guided through the Brainlab software according to a guided visual flow at the CAOS screen. To this purpose, the femoral head has to pivot in a ball and socket construction to determine the centre of rotation of the hip joint. This point is used for the virtual reconstruction of limb axes. After registration, the femur was fixed in a neutral horizontal position.



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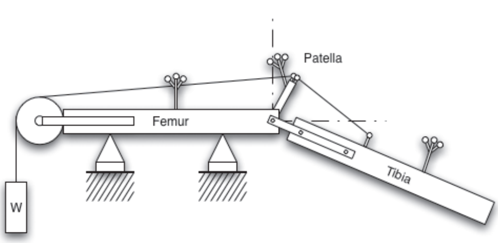
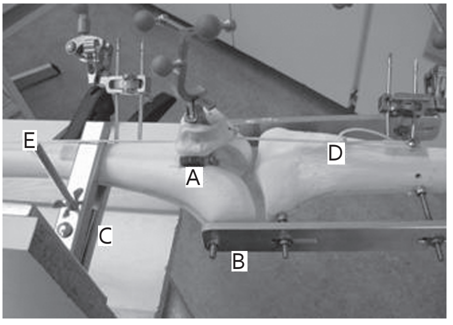



b.

c. 

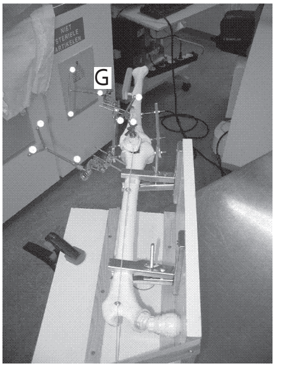

d. 


**Figure 1.** showing the model of the knee used to evaluate the patella tracking navigation module.

1a: detailed AP view of bended knee showing the hinge on which the patella is attached
1b: schematic view of the model
1c.d: model in full extension from lateral and AP view showing the separate parts:
A: Patella fixed at a hinge
B: External tibial hinge
C: Femur clamp
D: Patellar tendon
E: Quadriceps
F: Hip joint
G: Lateral malleolus

The knee was moved into two cycles of flexion–extension, against the extending moment of the quadriceps tension, using a rod held transversely against the anterior surface of the distal tibia.

Data collected during knee extension and flexion were saved in the Brainlab system for analysis.

For patellar lateral translation (or shift), the position in extension of the knee was designated as 0 mm. Lateral patellar tilt was defined as a rotation about the longitudinal axis of the patella (figure 2) with positive values indicating that the lateral patella approached the femur. Positive patellar lateral rotation means that the distal patella moved laterally relative to its centre.

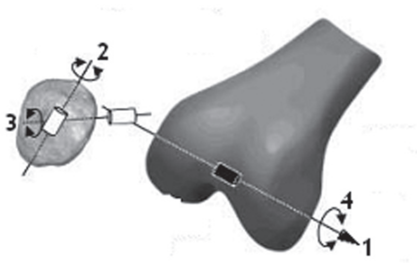



**Figure 2.** Patellar motion. A three cylinder open-chain-representation of the PF-joint. 1: Shift 2: Tilt 3: Rotation 4: Flexion. Because of the hinge, only patella motion in flexion/extension was possible.

In order to validate the (virtual) data produced by the patella tracking software of the CAOS system, matching was performed with the actual movements of the patella and knee in the sagittal plane. Data of patellar tracking were recorded by the COAS system during extension / flexion (EF) and reverse motion of the knee. Data were analysed off-line from the research module in the BrainLab CAOS.

Three effects were studied: First the effect of the extension / flexion (EF) and reverse movement (FE) on virtual patellar tracking. Each flexion motion ranged from 0° extension to 90° of knee flexion and vice versa and was repeated 10 times. Secondly, the influence of the velocity of flexion and extension movement was evaluated by applying a range of different flexion / extension cycle times: 60, 30, 10, and 2 seconds to this knee motion. Thus, a total of 4 series of 10 flexion-extension (FE) motion measurements of the knee were collected.

Finally, the influence of partial occlusion of the marker trees on patellar tracking visualisation was evaluated. The effect of marker occlusion on patellar tracking registration was tested by separately occluding the marker-tree of the femur, patella and tibia. Each of the three marker trees were occluded once during one cycle of EF and FE in 10 seconds.

## ■ Statistical analysis

Patella position data (medio-lateral shift, off circle distance, tilt etc.) were recorded from the FE and EF curves, for analysis maximum values at predetermined intervals of flexion angles (i.e. 0, 10, 20, 30, 45, 60, 70, 90 degrees) were used. These values correspond to knee flexion angles used in patellar motion.

Measurements obtained during individual flexion-extension movements were modeled using second-order polynomials based on least squares estimation in order to estimate means per time cycle (5 repeats per time cycle). The measurements per time cycle were highly reproducible and excellent model fits were obtained; $R^2 > 0.95$ in all cases and $R^2 > 0.99$ for 90% of cases. One way analysis of variance by ranks was performed using the (non-parametric) Kruskal – Wallis test for flexion values of 20, 45 and 70 degrees.

## ■ Results

Overall there is a curved motion visible of the "hinged" patella during the extension-flexion-extension motion of the hinged knee joint. There was a difference in motion pattern seen between a slow (60 sec) and fast (2 sec) speed flexion motion. A fast motion caused a far more visible difference between the path followed during flexion motion and the way back during the extension motion. The motion patterns are shown in figure 3. The maximum difference of the measured patella position during the flexion versus the extension motion are shown in table 1a,b.

| Patellar motion | | | | |
|---|---|---|---|---|
| Degr of flexion | Shift (mm) | Tilt (mm) | Rotation (mm) | Circle distance (mm) |
| 0 | 0.2 | 0.3 | 0.4 | 0.2 |
| 10 | 2 | 7 | 2 | 2 |
| 20 | 4 | 8 | 5 | 6 |
| 30 | 5 | 10 | 7 | 8 |
| 40 | 6 | 13 | 10 | 10 |
| 50 | 6 | 10 | 11 | 10 |
| 60 | 5 | 7 | 10 | 7 |
| 70 | 5 | 5 | 10 | 5 |
| 80 | 4 | 3 | 5 | 4 |
| 90 | 2 | 1 | 3 | 2 |

a.

| Knee | Patellar motion | | | |
|---|---|---|---|---|
| Degr of flexion | Shift (mm) | Tilt (mm) | Rotation (mm) | Circle distance (mm) |
| 0 | 0.3 | 0.1 | 0.2 | 0.3 |
| 10 | 0.3 | 0.6 | 0.4 | 0.4 |
| 20 | 0.5 | 0.8 | 0.5 | 0.6 |
| 30 | 0.7 | 0.9 | 0.6 | 0.7 |
| 40 | 0.8 | 0.9 | 0.6 | 0.8 |
| 50 | 1.0 | 0.9 | 0.7 | 0.9 |
| 60 | 0.8 | 0.8 | 0.8 | 0.9 |
| 70 | 0.7 | 0.7 | 0.7 | 0.8 |
| 80 | 0.5 | 0.5 | 0.6 | 0.6 |
| 90 | 0.1 | 0.3 | 0.4 | 0.5 |

b.

**Table 1 a**. Maximal difference in measured patella position during a fast (2 sec) flexion vs extension motion **b**. Maximal difference in measured patella position during a slow (60 sec) flexion vs extension motion

The patellar motion had an initial medial translation of 5.8mm ± 2 mm from 0º to 40º flexion ($P < 0.05$) followed by lateral translation of 5 ± 2 mm ($P < 0.001$) by 90º flexion. After TKA, the patella was 4 ± 3 mm ($P < 0.01$) more medial than in the native knee at 0º flexion. A significant difference was not shown between 5º and 60º. (Table 2)

2 sec

60 sec

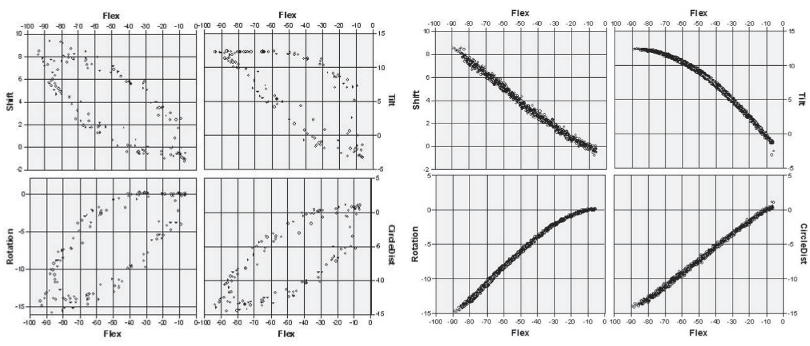


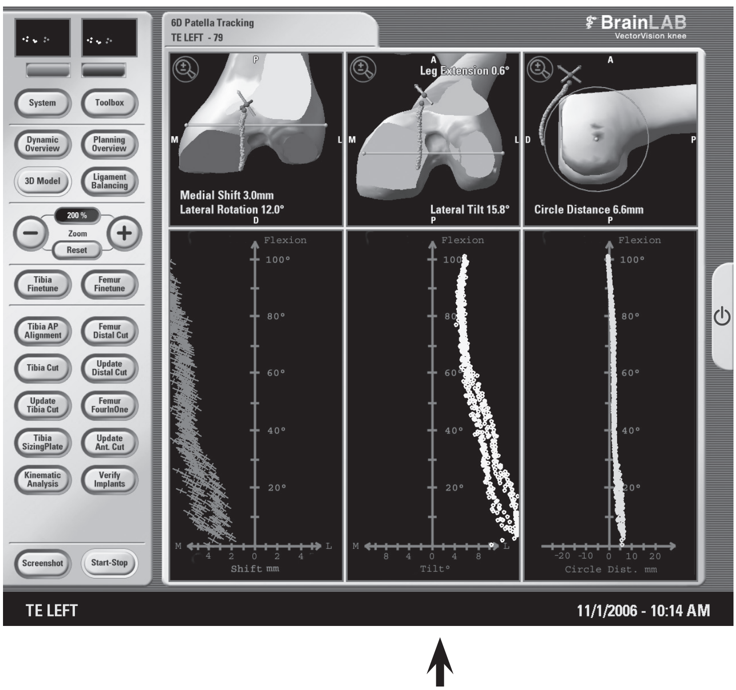

**Figure 3.** Registration of patellar position during flexion and extension at a extension-flexion and flexion-extension time of 2 and 60 seconds

| | | Shift | | y-Rotation | | z-Rotation | | Off circle | |
|---|---|---|---|---|---|---|---|---|---|
| Motion | Time cycle | During flexion (0° - 90°) | During extension (90° - 0°) | During flexion (0° - 90°) | During extension (90° - 0°) | During flexion (0° - 90°) | During extension (90° - 0°) | During flexion (0° - 90°) | During extension (90° - 0°) |
| At 20° flexion | 2 | -0.63 (0.16) | 2.78 (0.67) | -1.35 (0.60) | 7.00 (1.39) | 0.28 (0.22) | -4.33 (1.13) | 0.48 (0.26) | -5.43 (1.09) |
| | 5 | 0.15 (0.04) | 1.21 (0.08) | 0.88 (0.18) | 3.83 (0.09) | -0.59 (0.07) | -1.61 (0.08) | -0.91 (0.09) | -2.69 (0.10) |
| | 10 | 0.26 (0.04) | 1.03 (0.02) | 1.27 (0.17) | 3.28 (0.06) | -0.62 (0.09) | -1.32 (0.08) | -1.13 (0.10) | -2.28 (0.07) |
| | 20 | 0.49 (0.07) | 0.92 (0.07) | 1.79 (0.13) | 2.91 (0.07) | -0.71 (0.04) | -1.14 (0.05) | -1.36 (0.06) | -2.05 (0.06) |
| | 30 | 0.54 (0.06) | 0.86 (0.04) | 1.92 (0.05) | 2.81 (0.04) | -0.77 (0.15) | -1.06 (0.07) | -1.45 (0.01) | -1.92 (0.05) |
| | 45 | 0.61 (0.03) | 0.83 (0.03) | 2.03 (0.06) | 2.76 (0.02) | -0.84 (0.04) | -1.04 (0.05) | -1.51 (0.04) | -1.89 (0.03) |
| | 60 | 0.67 (0.04) | 0.85 (0.04) | 2.11 (0.06) | 2.66 (0.19) | -0.83 (0.04) | -1.04 (0.04) | -1.52 (0.02) | -1.85 (0.02) |
| p | | < 0.001 | < 0.001 | < 0.001 | < 0.001 | < 0.001 | < 0.001 | < 0.001 | < 0.001 |
| At 45° flexion | 2 | 0.73 (0.47) | 6.02 (0.92) | 3.26 (1.04) | 11.04 (0.70) | -1.03 (0.67) | -10.15 (1.73) | -2.16 (0.84) | -10.47 (1.26) |
| | 5 | 2.61 (0.14) | 4.00 (0.13) | 6.97 (0.18) | 9.18 (0.12) | -3.99 (0.13) | -6.40 (0.29) | -5.33 (0.16) | -7.49 (0.27) |
| | 10 | 2.77 (0.12) | 3.71 (0.10) | 7.26 (0.19) | 8.87 (0.09) | -4.16 (0.18) | -5.80 (0.13) | -5.55 (0.15) | -7.00 (0.14) |
| | 20 | 3.00 (0.08) | 3.60 (0.08) | 7.56 (0.05) | 8.51 (0.08) | -4.36 (0.04) | -5.37 (0.13) | -5.81 (0.05) | -6.72 (0.11) |
| | 30 | 3.04 (0.04) | 3.49 (0.06) | 7.66 (0.08) | 8.50 (0.06) | -4.46 (0.20) | -5.21 (0.15) | -5.93 (0.04) | -6.57 (0.11) |
| | 45 | 3.13 (0.06) | 3.41 (0.04) | 7.77 (0.07) | 8.38 (0.06) | -4.63 (0.04) | -5.06 (0.07) | -6.00 (0.06) | -6.47 (0.06) |
| | 60 | 3.16 (0.06) | 3.40 (0.06) | 7.82 (0.07) | 9.29 (0.47) | -4.71 (0.09) | -5.15 (0.05) | -6.09 (0.04) | -6.53 (0.05) |
| p | | < 0.001 | < 0.001 | < 0.001 | < 0.001 | < 0.001 | < 0.001 | < 0.001 | < 0.001 |
| At 70° flexion | 2 | 3.61 (0.60) | 8.14 (0.83) | 8.05 (1.11) | 12.75 (0.56) | -5.96 (1.27) | -13.91 (1.43) | -7.05 (1.13) | -13.51 (1.11) |
| | 5 | 5.54 (0.18) | 6.78 (0.10) | 10.93 (0.26) | 12.00 (0.11) | -9.27 (0.16) | -11.56 (0.16) | -9.90 (0.21) | -11.62 (0.21) |
| | 10 | 5.72 (0.18) | 6.56 (0.13) | 11.02 (0.25) | 11.93 (0.19) | -9.38 (0.25) | -11.04 (0.16) | -10.08 (0.19) | -11.30 (0.22) |
| | 20 | 5.91 (0.11) | 6.45 (0.12) | 11.16 (0.10) | 11.60 (0.09) | -9.65 (0.08) | -10.80 (0.20) | -10.37 (0.11) | -11.21 (0.19) |
| | 30 | 5.92 (0.10) | 6.40 (0.13) | 11.22 (0.16) | 11.78 (0.06) | -9.91 (0.23) | -10.76 (0.26) | -10.54 (0.06) | -11.15 (0.13) |
| | 45 | 6.05 (0.13) | 6.31 (0.15) | 11.35 (0.18) | 11.66 (0.17) | -10.24 (0.13) | -10.68 (0.22) | -10.68 (0.15) | -11.14 (0.05) |
| | 60 | 6.09 (0.08) | 6.30 (0.19) | 11.35 (0.16) | 11.52 (0.81) | -10.16 (0.22) | -10.70 (0.07) | -10.76 (0.09) | -11.21 (0.05) |
| p | | < 0.001 | < 0.001 | 0.001 | 0.001 | < 0.001 | < 0.001 | 0.001 | 0.001 |

**Table 2.** Relation between velocity and motion of the patella during flexion and extension cycle.

Occlusion of one of the three marker trees  showed that:

1. Occlusion of the tibial marker tree stopped recording of patellar tracking
2. Occlusion of the femoral markertree resulted in no changes in output of the patellar tracking data. After ending the occlusion, the patellar tracking recordings followed the original tracking pathways. However, when the position in the room of the test-setup was changed during the time that the femoral marker was occluded by moving the table on which the model stands on,  the pathways shifted when the occlusion ended. (figure 4a)
3. Occlusion of the patella marker tree resulted in false data output as well: patella motion was visualised (i.e. resgitered) as a straight line during the range of motion. After the occlusion was ended, the registration was restored and followed the original pathways. (figure 4b)




a.

b.

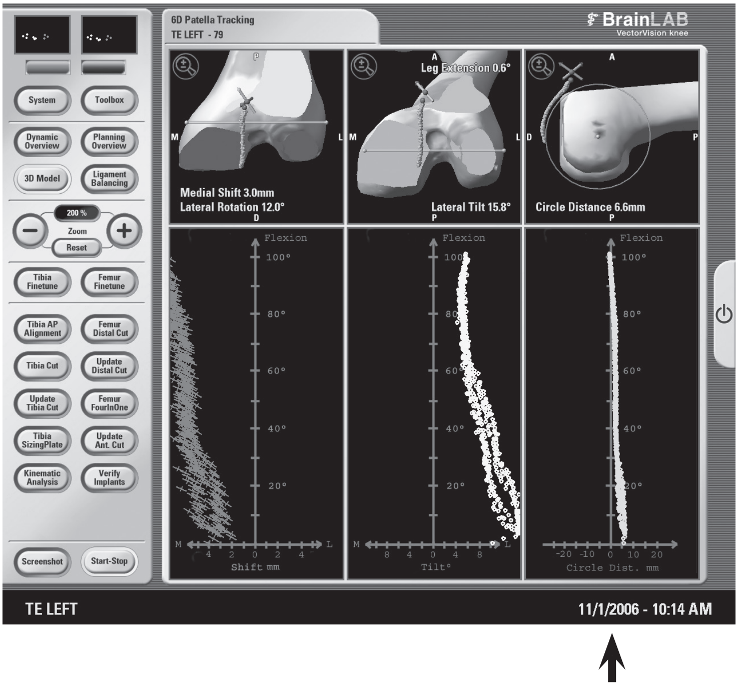



**Figure 4.** Print screen of the registration of the patella tracking during flexion-extension **a.** Occlusion femoral markertree shows shifted pathway (arrow) **b.** Occlusion patella marker tree shows straight line (arrow)

## ■ Discussion

This study showed that the velocity of movement within a flexion-extension cycle influenced the amount and degree of patellar tracking as registered and visualized on a CAOS screen: a low velocity resulted in an equal track during flexion and extension where a high velocity resulted in a significantly different path. The direction of motion (extension to flexion or flexion to extension) showed also that a different patellar pathway is seen between flexion and extension motion. Occlusion of one of the marker trees was also of influence on this patellar tracking pathway and resulted in erratic patellar pathways.

The use of navigation in TKA is of high interest. An additionally developed feature in the software at this moment is the patellar tracking module. A good patellar tracking is considered important for the success of TKA, since complications at the patellofemoral joint represent one of the main causes of failure and are the end result of malrotation of either the femoral or tibial or both components.[1,6,7] This indicates that further research concerning this compartment is of importance in order to evaluate the end result of a TKA.

The ideal in vivo patellar tracking in kneeprotheses has been studied, but a wide range of patellar tracking patterns are reported, probably reflecting the different study methods used. Only few have evaluated patellar tracking in vivo[4,8,9], and even then most have used static positions of flexion, thus making extrapolation of the dynamic range of motion difficult. Analysis of patellar tracking has been done by the use of many different techniques: from active or passive markers, a 2D or 3D images (CT, MRI)[10,11,12] to fluoroscopy, X-ray photogrammetry and recently CAS.[13,14,9]

The occurrence of outliers in our data can completely explained by the (partially) occlusion of marker trees during the phantom experiment. Erratic behaviour occurs as soon as one or more markers are occluded. Depending on which marker tree is partly occluded different outliers occur, all of which are highly undesirable.

Especially occlusion of the femur markertree caused recording of a false patella tracking pattern.

Obviously, the navigation system should give an indication of possible false data. In our case, simply beeping and excluding data points that were acquired during occlusion of one or more markers would be sufficient.

The sawbone experiment with two hinge, one between the femur and tibia and one between the femur and the patella showed a clear difference between the flexion and extension pathways at the higher FE motion speeds. This hysteresis was correlated with the FE velocity and became clearest at the fastest FE speed (2sec) (Figure 3). This resulted in a maximal difference in the medio-lateral translation of >6 mm and >10º difference on patellar tilt between the flexion and extension pathways. During a slow FE speed (60 seconds) the results given by the Vector Vision Brainlab system showed no difference in the flexion and extension pathways. These differences in flexion and extension pathways of the patella were seen in all three motions; mediolateral shift (red), tilt (yellow) and circular distance (blue).

In the literature different tracking patterns of the patella during flexion and extension are described (hysteresis).[15,16] However, we found that the patterns also differed considerably depending on the speed of our manually applied flexion and extension.

A general explanation for the difference in tracking patterns during flexion and extension at different velocities can be attributed to elastic hysteresis. An example of elastic hysteresis is a rubber band with weights attached to it: hung on a hook and weights attached at the end will lengthen the band. More weights will extend the band but unloading will shorten it less. This is because the band does not obey Hooke's law perfectly. An example of such a hysteresis loop is shown in figure 5. We used a cord of unknown elasticity in our model, but this material also shows this phenomenon. In vivo muscle (and tendon) lengthening in a movement cycle is higher than during shortening; one should be aware of this hysteresis when performing patella tracking measurements.

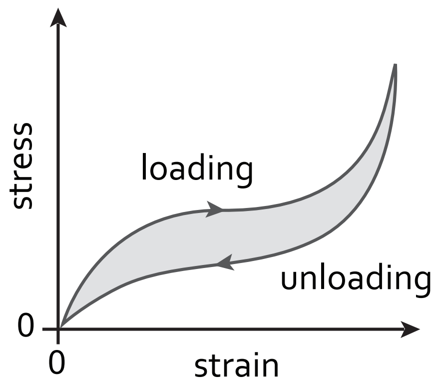



**Figure 5.** Example of an hysteresis loop.

A second possible explanation for hysteresis is that the positions of the marker trees are not measured simultaneously. If the patellar marker tree is sampled slightly later than the tibial and femoral maker tree, then hysteresis would occur. According to the manufacturer the software of the system calculated the tracking data with the patella location at one sample step back in time. This confirms our possible explanation and is supported by our measurements that the hysteresis increases with higher velocity times for the extension-flexion motion.

When further adjustments in the software are made and the patellar tracking module is valid and accurate during the registration, the discussion rises which method is most reliable to register 'normal' patellar tracking. Patellar tracking is influenced by several factors such as muscle loading, range and direction of knee motion, use of static or dynamic measurement techniques, and last but not least femoral component rotation[8,17] will all affect the results obtained. Strachan et al.[18] used this module to evaluate staged releases of the patella. The effect of the release is clearly visible but what the optimal patellar track should be is yet not known.

Belvedere et al.[13] used another navigation system to evaluate patellar tracking in vitro. They found approximately similar motion as reported in earlier studies[19,20].

Replication of the original patellofemoral motion in the intact knee was not fully accomplished in the replaced knee. However, the original patellofemoral motion could be influenced by osteoarthritis and secondary soft tissue contractures and therefore normal motion will not be captured either.

When normal patella tracking in future is defined, maybe showing individual differences, the navigation system might help in the decision whether to resurface the patella or not and where a patella component is ideally placed. However, tracking abnormalities of the patella are mostly resembling a malpositioned knee prosthesis.

There are strengths and limitations of this in vitro study which influence its clinical relevance. An important strength of this study is that it's shown that the use of a new tool/module should be tested before using in clinical practice to be able to know it's limitations and pitfalls.

One of the limitations is that the quadriceps components were loaded in physiological directions, however tibiofemoral rotation was not allowed in the hinged joint, in order to reduce variabilty on the patellar tracking motion pattern. Thus we could not study the effect of tibiofemoral rotation on patellar motion.



## ■ Conclusion

Overall, the new patellar tracking functionality in the navigation system appeared to be a relatively easy instrument to evaluate the patella kinematics before, during, and after total knee arthroplasty.

Apart from attachment of the patellar marker tree and a small amount of extra time for the patella tracking registration it needs no special preparation in navigated TKA.

However, the velocity of movement and partial marker tree occlusion gives a misinterpretation of absolute values of the patella movement. One should be aware of the hysteresis phenomenon when analyzing patellar tracking.

Overall, monitoring the patello-femoral kinematics gives the surgeon a more complete prediction of the performance of the final implant and it is therefore a valuable support in TKA. Patellofemoral complaints might be related to the patellar tracking. However, the technique to monitor tracking needs to be further developed before clinical symptoms can be related to it.

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# Chapter 8

## Computer assisted versus conventional cemented total knee prostheses alignment accuracy and micromotion of the tibial component.

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International Orthopaedics 2009 Oct;33(5):1255-61.

## ■ Abstract

We evaluated the influence of CT-free or CT-based computer assisted orthopaedic surgery (CAOS) on the alignment of total knee prostheses (TK) and micromotion of tibial components. This randomised study compared 19 CT-free, 17 CT-based CAOS TK, and a matched control group of 21 conventionally placed TK. Using Roentgen stereophotogrammetric analysis (RSA) the migration was measured. The alignment and component positions were measured on radiographs. No significant difference in leg and tibial component alignment was present between the three groups. A significant difference was found for micromotion in subsidence, with the conventional group having a mean of 0.16 mm, compared to the CT-free group at 0.01 mm and the CT-based group at -0.05 mm. No clinical significant difference in alignment was found between CAOS and conventionally operated TK. More subsidence of the tibial component was seen in the conventional group compared to both CAOS groups at two year follow-up.

## ■ Introduction

Alignment has been shown to be an important factor in survival of total knee prostheses (TK) [1, 10, 22]. Varus or valgus alignment of more than three degrees is associated with aseptic loosening, decrease of the prosthesis survival, and could impair the range of motion [1, 10]. In conventional surgical techniques, the position of the TK is determined by alignment rods, which only achieve correct alignment in 75% of cases even if performed by experienced surgeons [18].

Recently, several studies have shown improved alignment of knee prostheses when using either CT-free or CT-based computer assisted orthopaedic surgery (CAOS) [1, 2, 4, 6, 13, 17, 24]. Although the placement accuracy has been proven to be higher using this technique, ultimately initial progressive micromotion of a TK as measured with RSA is of more importance, since this is indicative of future prosthesis survival [13, 23, 26].

The primary goal of this study was to determine whether postoperative TK alignment was improved when comparing the two CAOS techniques with the conventional alignment instruments.

A secondary goal was to assess whether the two existing CAOS techniques reduced micromotion of the TK during a two year follow-up.

## ■ Materials and methods

A prospective, randomised study using two different modalities of CAOS (CT-based and CT-free) in 40 cemented Nexgen total knee prostheses (Zimmer, Warsaw, Indiana, USA) was performed. Four TK (one CT-free and three CT-based) were lost after randomisation due to problems with the CAOS system. In three instances (one CT-free and two CT-based TK), the CAOS intraoperative attachment trees loosened from the tibial or femoral bone during the bone saw cuts. In one other instance the CT-based COAS software could not section the femoral or tibial bones separately, thus making navigation impossible. Thus 36 TK remained for evaluation. The control group was a conventionally operated TK group, matched for preoperative deformity (i.e. varus or valgus), BMI (body mass index), and age, of 21 cemented Nexgen TK. All operations were performed by either of two CAOS experienced surgeons. The study protocol was approved by the medical ethics committee and all patients gave informed consent. The study was blinded for evaluation of the clinical, radiological, as well as the micromotion measurements.

The Brainlab's Vector Vision system (version 1.5.1, Brainlab, Munich, Germany) was used. This is a camera-based navigation system, onto which two navigation approaches were implemented. The CT-based CAOS uses a preoperative CT scan of the hip, knee, and ankle from which a 3D model is reconstructed. According to this model and CT data, preoperative planning can be achieved, and during surgery this preoperative planning is registered with the patient by matching bony landmarks. In the other approach (CT-free CAOS), all patient specific data are collected during surgery. The software calculates the optimal prosthesis size and position based on several anatomical reference points identified by the surgeon. In this way, a 3D bone model is adapted to the specific patient.

Randomisation was by means of a randomisation list generated by a computer program. The randomisation number was revealed the day before surgery, since a CT scan had to be made if the patient was allocated to the CT-based group. Nineteen TK were performed using CT-free CAOS and 17 using CT-based CAOS. In neither of the two applications was the CAOS ligament balancing option used.

The mean age was 71 years (SD 11.5 years; $p = 0.2$), body mass index (BMI) 28 kg/m2 (SD 3.8 kg/m2; $p = 0.5$), preoperative leg alignment (hip knee ankle angle [HKA]) 180° (SD 8.9°; $p = 0.3$), and preoperative destruction of the knee according to the Kellgren & Lawrence scale 4 points (SD 0.4 points; p = 0.1) [8, 15]. For the preoperative Clinical Knee Society score, the mean preoperative functional score was 34 points (SD 21.9 points; p = 0.8) and the mean preoperative knee score was 24 points (SD 19.9 points; p=0.9).

No significant differences between the three groups were present preoperatively.

A cemented Nexgen total knee prosthesis was implanted by a median incision and medial parapatellar approach. All knees had a fluted tibial base plate (either fixed or mobile bearing insert). All patients received a patellar component.

## ■ Radiographic measurements

Pre- and postoperatively, a weight-bearing long-leg AP radiograph and a lateral radiograph of the knee were taken and the preoperative extent of articular destruction was scored.

The pre- and postoperative mechanical axis (HKA), the frontal femoral component angle (FFC), and the frontal tibial component angle (FTC) were measured and are depicted in figure 1. The aim of the surgery was to achieve an HKA angle of 180°. In the coronal plane, the medial angle of the components to the mechanical axes should be 90° for the tibial and femoral component.

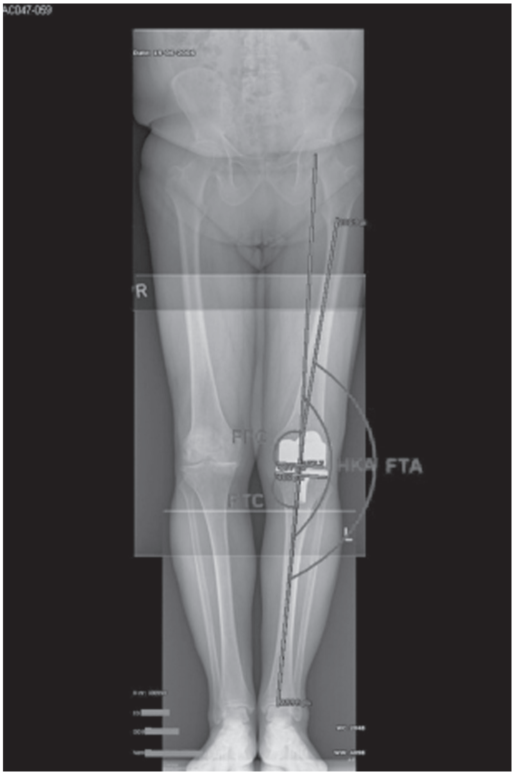


**Figure 1.** Radiograph showing the measured angles in the coronal plane. Depicting the angle between the femoral and mechanical axis (the hip knee angle [HKA]), the angle between the anatomical femoral and tibial axis (the femoral tibial angle [FTA]), the angle between the tangent to the most distal part of the femoral condyles and the mechanical axis (the frontal femoral component angle [FFC]), and the angle between the tangent to the tibial base plate and the mechanical axis (the frontal tibial component angle [FTC])

On the lateral radiographs, the lateral tibial component angle (LTC) was measured, as depicted in figure 2. The LTC was determined by measuring the posterior angle between a line parallel to the posterior cortex of the tibia and a line parallel to the tibial base plate. The tibia slope (TS) is expressed as 90° minus the LTC; the target of this angle was 7° as advised by the manufacturer. All of these radiographs were checked for the appearance of radiolucent lines.


**Figure 2.** Radiograph depicting the measured angle in the sagittal plane between the tangent to the tibial base plate and the tangent to the posterior cortex of the tibia (the lateral tibial component angle [LTC]).

Clinical (knee society score [KSS]) and radiological evaluations were performed preoperatively, within one week postoperatively, at six weeks, three months, six months, one year, and two years postoperatively. RSA analysis was performed using the Model Based RSA (MBRSA) (version 3.02, Medis Specials, Leiden, The Netherlands) technique [14, 27]. The analogue stereo radiographs were scanned with a Vidar VXR-12 scanner (Vidar, Lund, Sweden) at a resolution of 150 dots per inch.

The *x* axis represents the medio–lateral axis (lateral movement taken as positive), the *y* axis the caudal–cranial axis (cranial movement taken as positive), and the *z* axis the posterior–anterior axis (anterior movement taken as positive). Translations of the centre point of the tibia are presented. The error in migration calculation with MBRSA was measured using 44 double examinations and, presented as standard deviations, is 0.06 mm for translations in the *x* and *y* directions and 0.16 mm for the out of plane *z* direction. For rotations about the *y* axis, the standard deviation was 0.3° and for rotations about the *x* and *z* axis 0.2°. Since migration is highly dependent on the type of implant, only the fluted fixed based tibial components were analysed for micromotion (11 CT-free CAOS, 9 CT-based CAOS, and 19 conventional TK).

## Statistical methods

The statistical analysis was performed using the statistical software package SPSS (version 12.0.1, SPSS Inc., Chicago, USA). Mean values and standard deviations of the measured angles and the clinical scores were calculated for each group. A one-way ANOVA was used on the data to determine the differences between the three groups with respect to the continuous variables. A Levene's test was used to determine whether the group variances were equal for the tested parameters. If the variances were unequal a Kruskal-Wallis test was used instead of a one-way ANOVA. To determine the effect of deviation from the ideal HKA on micromotion, the radiographic angle measurements were categorised: well aligned (within 3° deviation of the ideal positioning) and mal-aligned (more than 3° deviation from the ideal positioning). The chi-square test was used to analyse the categorical data. The Pearson's correlation test was used to detect any correlation between micromotion and component alignment.

## Results

### Radiographic results

*Hip knee ankle angle*

No significant difference was found between the three TK groups (figure 3, chi-squared $p = 0.2$) with respect to deviation from ideal alignment. While the CT-based CAOS group had more valgus malaligned knees (mean 179°, SD 3.0°), the conventional group had more varus malaligned knees (mean 181°, SD 2.7°), as can be seen in figure 3. The CT-free CAOS group (mean 181°, SD 1.9°) showed the least variance (Levene's test $p = 0.07$), but no significant difference was seen between the mean of the three groups (ANOVA $p = 0.07$) (see Table 1 and figure 3).

| Angle (º) | Desired range (º) | Conventional (n=21) | CT-free (n=19) | CT-based (n=17) | P-value |
|---|---|---|---|---|---|
| HKA | | | | | |
| Mean (SD) | 177-183 | 181 (2.7) | 181 (1.9) | 179 (3.0) | 0.07 |
| Within range (n) | | 14 | 17 | 12 | 0.2 |
| FTA | | | | | |
| Mean (SD) | | 175 (2.8) | 176 (2.7) | 174 (3.6) | 0.3 |
| FTC | | | | | |
| Mean (SD) | 87-93 | 89 (2.4) | 89 (1.5) | 89 (1.7) | 0.8 |
| Within range (n) | | 20 | 18 | 16 | 1.0 |
| FFC | | | | | |
| Mean (SD) | 87-93 | 90 (1.8) | 90 (1.3) | 91 (2.8) | 0.6 |
| Within range (n) | | 20 | 19 | 13 | 0.03 |
| TS | | | | | |
| Mean (SD) | 4-10 | 5.4 (3.8) | 5.0 (2.9) | 5.2 (2.6) | 0.9 |
| Within range (n) | | 12 | 14 | 13 | 0.4 |

**Table 1** Number of TK aligned within the ideal range (within 3°) for the different limb and component angles. HKA= Hip Knee Angle; FTA= Femoral Tibial angle; FTC= Frontal Tibial Component angle; FFC= Frontal Femoral Component angle; TS= Tibial Slope

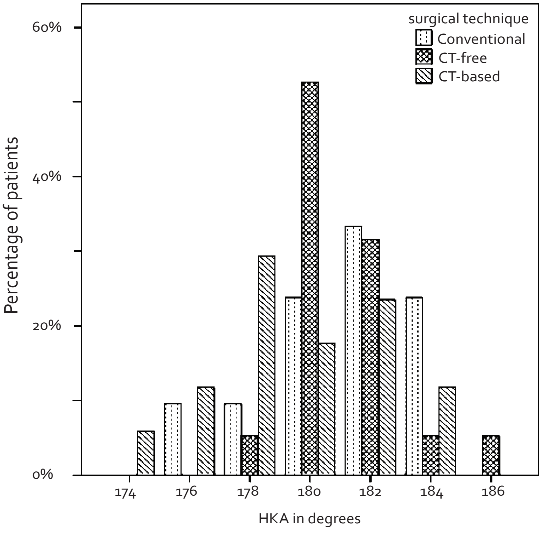


**Figure 3.** Chart depicting the distribution of the hip knee angle (HKA) for the three groups of surgical technique. No significant difference was found between the three groups (chi-squared $p$ = 0.2)

*Frontal component angles*

With respect to alignment, the tibial implants were all very well aligned (chi-squared $p = 1.0$) (see Table 1 and figure. 4).

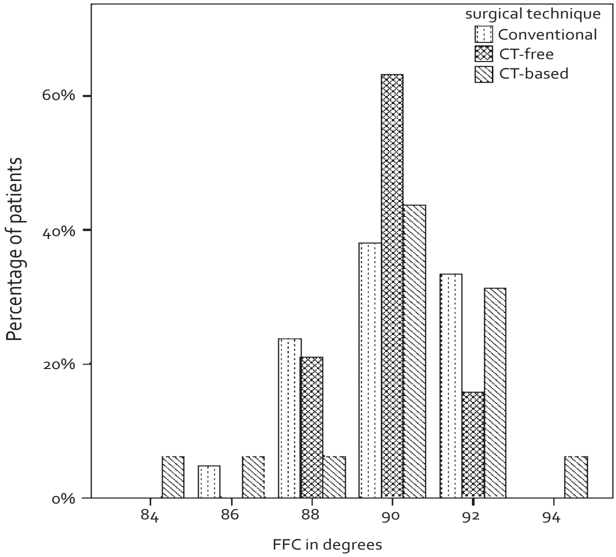


**Figure 4.** Chart depicting the distribution of the frontal femoral component angle (FFC) for the three surgical technique groups. The CT-free group had significantly more well aligned components than the CT-based group (chi-squared $p = 0.03$)

With regard to the femoral implants, the conventional group had 20 out of 21 well aligned knees, the CT-free CAOS group had all 19 out of 19 knees well aligned, and the CT-based had 13 out of 17 well aligned knees. This difference was significant (chi-squared $p = 0.03$).

*Tibial slope*

A satisfactory slope within 3° of the optimum was achieved in 12 of the 21 implants in the conventional group, 14 of the 19 implants in the CT-free CAOS group, and in 13 of the 17 implants in the CT-based CAOS group. These differences were not significant ($p = 0.4$) (Table 1).

## ■ RSA results

*Translations*

At six months follow-up, the mean migration along the *y* axis (i.e. subsidence) of the tibial component was 0.08 mm (SD 0.089) for the conventional group, −0.033 mm (SD 0.144) for the CT-free group, and −0.035 mm (SD 0.259) for the CT-based group. At one year follow-up these values were 0.12 mm (SD 0.193) for the conventional group mean, −0.014 mm (SD 0.189) for the CT-free group mean, and −0.028 mm (SD 0.408) for the CT-based group mean (see figure. 5). These differences were not significant (ANOVA $p = 0.1$ and ANOVA $p = 0.2$, respectively) between the groups.

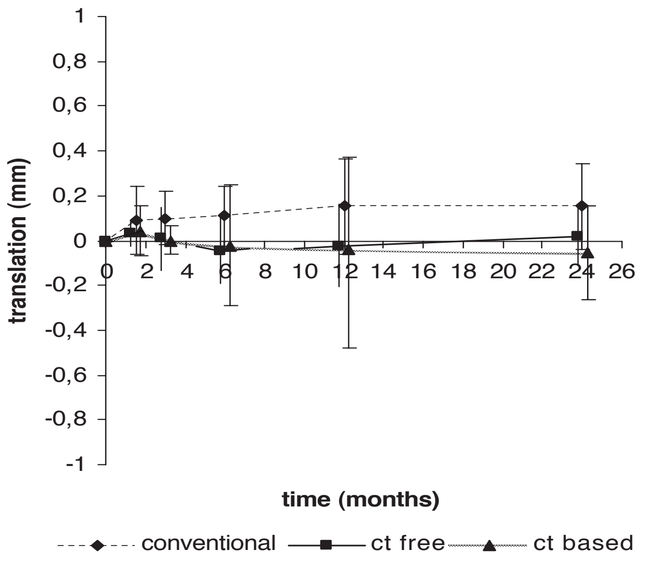


**Figure 5.** Graph depicting the migration along the caudal–cranial axis (subsidence). The values are given as mean and standard deviation and are positive if the translation was in the cranial direction. Significantly more micromotion was seen in the conventional group

| | Direction | Conventional n=19 | CT-free n=11 | CT-based n=9 | P-value |
|---|---|---|---|---|---|
| Translation (mm) | Lateral-medial | **0.04** (-0.057, 0.142) | **0.07** (-0.039, 0.173) | **0.04** (-0.182, 0.259) | 0.9 |
| | Caudal-Cranial | **0.16** ( 0.065, 0.250) | **0.01** (-0.069, 0.097) | **-0.05** (-0.213, 0.107) | 0.01 |
| | Posterior-anterior | **-0.14** (-0.371, 0.099.) | **-0.02** (-0.256, 0.217) | **0.43** (-0.822, 1.680) | 0.3 |
| Rotation (degrees) | Anterior tilt | **0.02** (-0.370, 0.403) | **-0.02** (-0.654, 0.608) | **0.67** (-1.055, 2.398) | 0.4 |
| | Internal rotation | **-0.14** (-0.442, 0.171) | **-0.30** (-0.790, 0.186) | **0.05** (-1.057, 1.163) | 0.7 |
| | Lateral tilt | **-0.09** (-0.268, 0.095) | **-0.17** (-0.421, 0.086) | **-0.18** (-0.507, 0.142) | 0.8 |

**Table 2.** Mean translations (95% confidence interval) and mean rotations (95% confidence interval) of the tibial component at two years follow-up

At two-year follow-up, a significant difference was present (ANOVA $p$ = 0.01) for micromotion along the caudal–cranial $y$ axis (i.e. subsidence), with the conventional TK group showing more micromotion (mean 0.16 mm, SD 0.191 mm) compared to the CT-free group (mean 0.01 mm, SD 0.123 mm) and the CT-based group (mean −0.05 mm SD 0.208 mm) (Table 2, figure. 5). The CT-based group showed more variance (Levene's test $p$ = 0.04) with a large variation in translation in the posterior–anterior $z$ axis.

*Rotations*

The mean rotations along the three axes were not significantly different between the three groups. No correlation with any of the measured angles (e.g. HKA, FFC, LTC, and FTC) was found.

There was one outlier in each group. They showed large migrations in the posterior–anterior direction (conventional 1.20 mm, CT-free 1.38 mm, and CT-based 1.00 mm) and anterior tilting (1.82°, 2.66°, and 2.08°, respectively). One of these patients (CT-based, BMI 30 kg/m$^2$) had a broken tibial cam and the implant had to be revised. This caused the large SD in this group. Migration of the tibial component from a patient of the CT-free group seemed to stabilise during the follow-up, another migrating tibial component from the conventional group showed continuous micromotion during the study follow-up. Neither were severely obese (BMI = 26 kg/$m^2$ and 27 kg/$m^2$ respectively) but were outliers with respect to the HKA and FTA. The patient showing the continuous migration had a varus malalignment of 6°, while the other patient was 4° with respect to the HKA.

## ■ Clinical results

In the clinical evaluations no differences were seen between the three groups in postoperative knee society score. The knee society scores and the flexion and extension of the knee are listed in Table 3.

| Parameter evaluated | Conventional (n=21) | CT-free (n=17) | CT-based (n=15) | P-value |
|---|---|---|---|---|
| **KSS knee** | **65** (13.8) | **66** (17.6) | **61** (6.7) | **0.6** |
| **KSS function** | **66** (33.5) | **80** (16.9) | **70** (23.1) | **0.5** |
| **Flexion (°)** | **116** (11.4) | **117** (12.6) | **115** (11.9) | **1.0** |
| **Extension (°)** | **-1** (7.5) | **-3.4** (6.5) | **-1** (6.8) | **0.8** |

**Table 3.** Postoperative clinical scores at 1 year follow-up (mean (SD))

The mean surgical time was 137 (SD 43.3) minutes in the conventional group, 148 (SD 25.0) minutes in the CT-free CAOS group, and 159 (SD 33.3) minutes in the CT-based group (Kruskal-Wallis $p$ = 0.1).

## ■ Discussion

The necessity to align the limb correctly after total knee arthroplasty has been stressed by others [1, 10, 22, 25]. Malpositioning in any of the anatomical planes of the knee can cause problems such as early loosening and excessive polyethylene wear. The aim should be a restoration of the mechanical axis of the leg (HKA of 180°) where a valgus malalignment is more forgiving than a varus malalignment [1, 22]. To optimise TK placement CAOS has been promoted. After its introduction several authors noted significant improvement in prosthesis position with CAOS compared to the conventional technique with alignment guides [1–4, 5, 7, 11, 17, 19, 20]. At present, no long-term results in comparison to conventionally placed TK are available. Continuous micromotion during the first two postoperative years is a warning for probable aseptic loosening at ten years [23]. Thus, RSA micromotion measurements will relate best to the value of a new CAOS technique for knee prosthesis placement with respect to longevity of the implant [23]. This study compared two CAOS techniques to the conventional method of TK replacement. Only four studies have used a CT-based CAOS technique and compared it to the conventional technique [1, 3, 11, 20].

We were unable to perform a sample size calculation because the expected proportion of micromotion of the navigated TK was unknown due to lack of previous studies.

Since TK malalignment is considered a key factor for excessive TK micromotion with consequent failure at late follow-up, the overall alignment (i.e. HKA) in the three groups was within one degree of the ideal alignment. Ideal alignment of the tibial component in the sagittal plane was present in only 57% of the conventional TK and 74–76% in the two CAOS TK groups. Since the study's population was small and inaccuracy of radiographs is rather high [9], data from our study might not have reached significance.

The mean caudal–cranial translation of the "conventional" tibial component was clinically small (0.16 mm) at two-year follow-up, but it was significantly larger than in the two CAOS groups. As early migration of this component is considered to be predictive for early loosening, this value indicates that in the long run the "conventional" tibial component might perform worse than the two "CAOS" components in terms of early loosening.

This study showed a significantly better alignment ($p = 0.03$) in the FFC for the CT-free compared to the CT-based group. Although the difference of one degree was clinically not relevant, this result is similar to the study of Matziolis et al. in which the alignment of the femoral component was improved by CT-free CAOS [21]. The comparison in other outcome measures between CT-free and CT-based CAOS showed similar results to the study of Bäthis et al., with no significant difference but a better performance of CT-free CAOS [1].

A potential error in CT-based CAOS originates during the preoperative planning, where detection of the border of bone is dependent on the settings of the threshold of the grey values. Therefore visualisation of severely damaged bone is extremely difficult. Ironically, these severely damaged knees are the ones one would like to be able to plan in advance because of their potential difficulty during surgery.

The mean duration of the surgical procedure was prolonged as well, with the CT-free procedure lasting nine minutes and the CT-based procedure 22 minutes longer. Though no significant difference existed, this could potentially lead to a higher infection rate. Another disadvantage is the additional radiation dose because of the preoperative CT-scan.

In both techniques the same reference trees are attached to the femur and tibia. No complications of these markers were seen pre- or postoperatively so far. However, there are some case reports describing a femoral stress fracture related to the hole of the reference tree [12, 16].

In this study a significant difference in micromotion in caudal–cranial direction between the groups at two years was found, with more micromotion in the conventional group. CT-free CAOS showed a significantly better performance in FFC than CT-based CAOS, though clinically similar results for limb and TK alignment were found.

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# Chapter 9

# General discussion & summary

- Introduction
- Is CAOS useful in achieving an accurate position of the TKA?
- Does CAOS lead to accurate component sizing and patella tracking?
- What is the clinical and radiographic (migration) outcome of TKA using CAOS?
- Future directions
- Conclusion and recommendations

## ■ Introduction

Over the last decade, CAS has been an active development and research area within several surgical fields (e.g. Ear-Nose-Throat, Neurosurgery, Orthopaedics). Within Orthopaedics, most research is oriented on the applicability and precision of CAOS in knee surgery. Especially the TKA is of interest because of the increase of the number of TKA's performed annually and the premise that CAOS would improve implant positioning. Thus improving clinical outcome and prosthesis fixation with subsequent better survival of the implant.

Orthopaedics is a challenging area for CAS, as many orthopaedic surgeons consider the outcomes of conventional procedures like THA and TKA generally successful. The latter is substantiated by good survival results of these prostheses from registries. Thus, improving the current surgical techniques with subsequent even better success at long term follow up in TKA is therefore challenging. It is shown that 20 to 30% of the TKA patients are 'not happy' with their replaced joint (Robertsson et al., Nilsdotter et al.). Furthermore TKA's are implanted in younger patients with known lower survival rates compared to patients of 65 years and older. These two facts support the need for an optimal intra-operative positioning of the prosthesis which is also patient specific.

Policymakers as well as hospital administrators demand efficient and cost effectiveness for new procedures. As CAOS is supposed to improve positioning and thereby to be of major influence on outcome, longevity of the prosthesis and thus chance for revision, the extra costs of CAOS should be worthwhile on short term, as well as for long term results. Whether COAS is improving accuracy of TKR was evaluated in this thesis. Thus the following research questions posed were:

1. **Is CAOS useful in achieving an accurate position of the TKA? (Chapter 3,4,5)**
2. **Does CAOS lead to accurate component sizing and patella tracking? (Chapter 6,7)**
3. **What is the clinical and radiographic (migration) outcome of TKA using CAOS? (Chapter 8)**

## ■ Is CAOS useful in achieving an accurate position of the TKA? (Chapter 3,4,5)

*This thesis: adequate registration is essential in achieving an accurate position of the TKA. CAOS does not (yet) lead to an accurate rotational position of the femoral component.*

### Anatomical torsion of the (distal) femur (Chapter 3)

The position of the TKA, especially the rotational position of the components with respect to the bone and with respect to the femoral and tibial component is determining the outcome of a TKA. The most common reason for revision is malrotation (Sharkey et al. 2002). To be able to analyse the rotation accuracy of a CAOS system in TKA, information on the anatomic torsion / rotation axes of the proximal and distal femur is necessary.

These rotational axes and angles of the femur were studied to identify the anatomical differences in order to aid in planning the optimal position of a TKA. In this anatomical study the most used proximal and distal femoral angles (femoral anteversion angle (FAA) and posterior condylar angle (PCA)) were analyzed using CT, within individuals, between right, left side and gender. Also the 'inferior condylar angle' was studied for a method to measure the distal femoral rotation. In general, the measured FAA, PCA and inferior condylar angle (ICA) were comparable with earlier studies. Strong correlation of the FAA was found within the total group and left versus right and only weak for the PCA measurements. A weak correlation between the FAA and PCA existed for the female group. No correlation was found between the ICA and PCA, although the mean difference of these two was very small. Considering the weak correlation of the FAA and PCA within the group and PCA within individuals, the importance of development of more individual approaches for determining the optimal rotation of the components in total knee surgery seems essential. So the ´ideal´ rotational position of the femoral component varies between individuals and is not always 3 degrees of external rotation. CAOS could, when there is a higher accuracy of the method, create the opportunity to individualize the (rotational) position of the TKA, better than with conventional instruments.

## Intra-operative registration of the rotation (Chapter 4)

When performing a bony reference technique to determine the rotational position of a TKA, the surgeon uses the posterior condylar line, epicondylar line and Whiteside's line as reference lines. An accurate registration of these three lines/axes intra-operatively by the surgeon determines the correct rotational position of the components also during CAOS.

A study on the accuracy of intra-operative axis determination by the surgeon was done comparing the trans-epicondylar axis intra-operatively (marked by tantalum beads) with postoperatively CT measured epicondylar axis in the navigated TKA. It was concluded from this study that during the registration process using the image-free CAOS system, a random error was found between the intra-operatively registered and postoperatively measured trans-epicondylar axis.

Debate exists on which axis is the most reliable for determination of intra-operative rotation of the femoral component, and which has the least intra- and inter-observer variability. Moon et al. 2010 studied the variability of three reference axes; the angles from the posterior condylar line to the proximal tibia resection plane showed the smallest range of variance. They found the posterior condylar axis to be a reliable landmark for the rotational orientation of the femoral cutting-guide during bone-cuts.

Though there is a lot of literature on AP alignment, very little is published on rotational alignment. Therefore, debate still exists as to whether a CAOS system will (Chauhan et al., 2004;Stöckl et al., 2004) or will not (Siston et al., 2005) improve rotational alignment of the femoral component in the transverse plane. Using conventional techniques, an external rotation of the femoral component of 3 to a maximum of 5 degrees with respect to the posterior condylar line, or 0 degrees with respect to the trans-epicondylar line, is considered to be the optimal femoral component position. This would supposedly be essential for a good functionality of the knee.

Little studies on position of the tibial component are published. Most studies have concluded that the alignment in the sagittal plane (slope) did not improve with CAOS. Also Yaron et al. 2010 found significant deviations of the coronal angle using a COAS system in vitro (saw bones). A major cause for anatomical reference errors is made due to the registration process of the tibia.

## Postoperative rotation of the components (Chapter 5)

When we rely on the accuracy of registration of the distal femoral and proximal tibial anatomical points, the CAOS system shows the degrees of (external) rotation of the knee prosthesis components.

A validation study on this registration process was done. In conclusion, it was found that although the mean intra-operative rotation by the CAOS system was comparable to the postoperative CT scan measured position (3.5° vs 4.0°), the ICC of the intra-operative versus the postoperative position was only 0.38. This indicated only a weak association between the intra-operative CAOS value and the postoperative CT value. A correlation greater than 0.8 is generally described as *strong*, whereas a correlation less than 0.5 is generally described as *weak.* Even more a relatively large (and significant) difference between the intra- and postoperative position is found. The definition of what correct rotational alignment is, varies. Some authors advocate an individual, patient specific approach with respect to rotation (for example Michaut et al.2008). They use preoperative CT scans to measure the individual distal femoral torsion and analyzed whether CAOS provided a reproducible rotational alignment. Measured with the use of a postoperative CT, 77% of the CAOS knees had good rotational alignment (i.e. +/- 2 degrees difference with the preop planned rotational position). Others ( Walde et al. 2010) used the same technique of anatomical landmarks to determine rotation and compared this  to a navigated ligament tension-based tibia-first technique. Using the anatomical landmarks technique, the rotation ranged from 12.2° of internal rotation to 15.5° of external rotation from parallel to the tibial resection.

In conclusion, until recently it was not known what correct alignment is of a knee component with respect to the anatomy, nor how a CAOS will reproduce this intra-operatively. These factors will probably be addressed in newer CAOS systems.

## ■ Does CAOS lead to accurate component sizing and patella tracking? (Chapter 6,7)

*This thesis: Beware of oversizing of especially the femoral component. The data collected by the patellar tracking module is significantly influenced by velocity and different marker tree occlusions.*

### Sizing (Chapter 6)

After the registration process in CAOS, the navigation system suggests not only an optimal position but also an optimal size for the TKA components. Adequate sizing of the femoral and tibial component is important in the outcome of a TKA. Both oversizing and undersizing can cause pain or functional impairment or prosthesis subsidence. The effect of CAOS on TKA size was studied.

Pre-operative templating is a common method to estimate the optimal size of the components. The definitive sizes are determined intra-operatively. In the study, the component sizes using CAOS were compared to pre-operatively templated sizes, a second aim was to see whether oversizing influenced functional outcome. It was confirmed that pre-operative templating shows a considerable inter-observer variability, with a fair agreement for both the femoral and the tibial component. But different femoral sizes were found between preoperative templated and intra-operatively "calculated" by the CAOS system. Oversizing of the femoral component occurred significantly more often. As a result manipulation under anesthesia was performed in some of these cases. This stresses knowledge of the surgeon on the software algorithm which decides on when a size-up or size down is chosen. Furthermore, in the CAOS used this study, it is still a an aid and not a replacement in the workflow of the surgeon.

### Patellar tracking (Chapter 7)

Error in component rotational alignment is one factor that contributes to patella-femoral complications, a major cause for revision surgery following total knee arthroplasty (Berger et al. 1993, 1998; Bindelglass et al. 1998). Others (Stiehl et al., 1995, 2001; Komistek et al., 2000, Hsu et al., 1996; Miller et al., 2001; Jenny et al., 2002) stress importance of patella-femoral kinematics in association with patello-femoral problems in TKA. To be able to evaluate the patellar tracking and possibly detect maltracking, a special patellar tracking module is added to the CAOS system software. This was evaluated.

The patellar motion was influenced by different velocities of flexion and extension in the motion arc. Occlusion of the marker trees affected the collection of the patellar tracking data and gave misinterpreted data of the analysed the patellar motion, without giving an error output. However, this study also shows that the reliability and accuracy of the CAOS system should be carefully checked before but also during intra-operative use; the surgeon remains responsible.

## ■ What is the clinical and radiographic (migration) outcome of TKA using CAOS? (Chapter 8)

This thesis: Despite some evidence that there are less outliers in alignment, the clinical benefit is (still) not proven.

If the position of the knee prosthesis is essential for the performance and thus outcome of the TKA, as such CAOS would improve clinical and radiological outcome. The effect of on outcome by CAOS was studied between CT-free and CT-based CAOS TKA, compared to conventional (non CAOS) surgery.

### Alignment

Although the (potential) benefit of CAOS in TKA is a better alignment of the TKA, in this study there was no significant difference in alignment between CT free, CT based and conventional surgery, but less variability and thus outliers in the CT free group.

Traditional instrumentation aligns approximately 75% of knees within 3 degrees of neutral alignment, leaving a significant number of outliers with more than 3 degrees deformity. (72% Jenny et al. 2003, 78% Bäthis et al.2004). CAOS in TKA should, according to the developers, decrease these number of outliers.

In literature there is no consensus on whether CAOS improves alignment. Novicoff et al. (2010) analyzed 22 randomized controlled studies and showed an advantage in alignment for CAOS versus conventional surgery. Bäthis et al. (2006) also did a meta-analysis on alignment using CAOS. The same safe zone of +/-3 from neutral alignment was defined and in the conventional group, 75% of TKA were implanted within the safe zone compared to 94% in the CAOS group ($p<0.0001$). A systematic review by Mason JB et al. in 2007 described twenty-nine studies of CAOS versus conventional TKA, where mechanical axis malalignment of more than 3 degrees occurred in 9% of CAOS vs 32% of conventional surgery. This was a significant improvement. On the contrary, a recent meta-analysis on the potential of CAOS to increase the precision of the component placement was done by Bauwens et al. 2007. CAOS was compared with conventional TKA in thirty-three studies. In this analysis the alignment of the mechanical axes did not differ between the CAOS and conventional group. It was concluded that navigation lengthened the mean duration of surgery by 23% and provides few advantages over conventional surgery on the basis of radiographic end points.

Focusing on alignment, a bias is introduced by different definitions of alignment between the different studies, thus making comparisons difficult (i.e alignment of the limb as a whole or alignment of components, Sikorski JM. 2008). Despite discussion on norm values, navigation reduces the number of outliers of the femoral component in both the coronal and sagittal plane to predefined values.

## Clinical outcome

Neither a difference in alignment nor a difference in clinical outcome (Knee Society Score) was found between CT-free navigation, CT-based navigation and conventional non CAOS (Chapter 8). One would expect that if CAOS leads to less outliers and enables the surgeon to improve alignment, this would result in a better clinical outcome. There are only a few studies on clinical results of CAOS. Bäthis (2006) and Stiehl (2007) did a meta-analysis and in these comparative studies overall there was no difference in clinical outcome, there were only few advantages on radiographic end points. A comparative conclusion was drawn by Dattani (2009); he also included radiographic results and CAOS didn't show any significant benefits based on both radiographic and clinical outcome.

Maybe an even more important factor for clinical outcome is not the frequently studied coronal alignment but the rotational alignment of the kneeprosthesis. A recent study of Hoffart et al. 2012 compared difference in clinical outcome between total knee replacement (TKR) using computer navigation and that of conventional TKA. At 5 years follow up, the navigated TKA resulted in a better mean Knee Society Score. No significant difference in the frequency of malalignment was seen between the two groups. Given the comparability in AP alignment between the groups, this supports the hypothesis that another factor e.g. rotational alignment may be a better method of identifying differences in clinical outcome after navigated surgery.

Since small differences in alignment might influence prosthesis fixation, evaluation of prosthesis migration with respect to the bone (by the use of rontgenstereophotogrammetry) might be a better evaluation method.

A difference in micromotion in caudal–cranial direction (y-axis) between the groups at two years was found (Chapter 8), with more micromotion in the conventional group, despite similar results for limb and TK alignment. Since micromotion, as measured by RSA, is indicative of future prosthesis survival (Ryd 1995, Nelissen 2012) the use of RSA in the evaluation of CAOS TKA is important. So far this is the only study which evaluates CAOS with RSA measurements.

## Minimally Invasive Surgery

In Orthopaedics, minimally (or less) invasive surgery could potentially enhance patient recovery and function following surgery. Especially in TKA this implies decreased pain and increased quadriceps muscle strength. CAOS may aid in performing these procedures by guiding the surgeon when visual feedback is lost because of the smaller incision and surgical exposure.

However, although specific clinical parameters reflect an early increased rate of functional recovery in association with minimally invasive TKA within the first postoperative months, this effect disappears after 6 months.

Bonutti et al.2008, 2011 / Cheng 2010 evaluated minimally invasive TKAs performed with and without navigation. The mean operative time for navigation was twice as long. Blood loss, pain as well as functional scores and mean component alignments were similar. Complication rate was higher using CAOS. No distinct advantage of navigation was demonstrated when combined with a minimally invasive approach. Thus, the higher incidence of complications in addition to the longer operative time in the navigated group may outweigh any potential radiographic benefits. Navigated and minimally invasive TKAs are emerging technologies having distinct strengths, but also weaknesses.

## Costs

The first meta-analysis on Robotics and CAOS was done by Specht et al. (2001) He concluded that only a clear understanding of the goals, applications, and limitations of these systems will result in an appropriate use for the patients as well as a cost effective use for the hospital.

More recently, Slover (2006) and Dakin (2012) stated that total knee replacement surgery is a clinically successful and a cost-effective intervention and

CAOS could be a potentially cost-effective technique in TKA. However, effectiveness is sensitive to variability in costs of the systems, the accuracy of alignment, and probability of revision TKA.

CAOS systems are expensive, and it may take 5 up to 10 cases before the surgeon feels comfortable with the system and can reliably establish the anatomical coordinate systems that are the basis of the procedure (Minnekus, Stulberg et al., 2002; Bolognesi and Hofmann, 2005). However, variability in published clinical outcomes introduces uncertainty in determining the exact cost-effectiveness. Novak et al. 2007 evaluated the cost-effectiveness of CAOS and concluded that CAOS was both more effective with respect to mechanical alignment systems but also more expensive than these systems. The incremental cost of using CAOS was calculated to be $45,554 per quality-adjusted life-year gained. Cost-savings is achieved if the added cost of CAOS is $629 or less per operation. Considering the acquisition expenses of various navigation systems, the annual costs for maintenance and software updates as well as the accompanying costs for every surgical procedure, a decrease of the incremental costs between 50 and 100 procedures per year (Cerha et al. 2009) was found, with incremental expenses amounting to 300-395 Euro per TKA. Beringer et al. 2007 showed contradictive financial incentives existed between surgeons and hospitals (who buy the system), which might interfere with the adoption of the use of CAOS techniques.

Besides these costs, the most important question is not whether CAOS is saving costs on the long term but whether CAOS leads to less complaints and better function for the patient and eventually to less revisions. However these questions are still not answered. Despite attempting to use computer-assisted surgical techniques to improve TKA positioning and outcome, so far it is also known that this technique significantly increases surgical time and some complications may exist.

## ■ Future directions

Future research and development of validated CAOS systems should address three major challenges in total knee arthroplasty:

- Kinematics: consistent postoperative outcome (i.e. intra-operative kinematics)
- Revision: an aid in difficult knee revision surgery
- Patient Specific Surgery: improvement of patient specific positioning of the knee prosthesis components

### Kinematics

The intra-operative recorded kinematics with a navigation system may challenge total knee design assumptions and may potentially add important information for a design of a new generation of implants. However, a limitation of using a CAOS system to characterize knee kinematics is that data are acquired under passive manipulation conditions. Knee kinematics during activities of daily living are different from those measured passively due to high forces generated by muscles and by interactions with the external environment. If intra-operative kinematic measurements could be visualized, a sound placement of a knee prosthesis is possible.

### Revision

It has been suggested that the most common cause of revision TKA is an error in surgical technique from malpositioning of the components. The study in Chapter 8 showed less micromotion of the CAOS total knee prosthesis compared to conventional surgery. Considering micromotion as a predictor for early loosening, this could affect the number of revisions because of aseptic loosening in CAOS TKA. However, recent evaluation of outcome of primary total knee replacements between 2005 and 2008 in the Norwegian registry ( Furnes et al. showed a slightly higher risk of revision in the CAOS group. The adjusted Cox regression analysis showed a higher risk of revision in the CAOS group (RR = 1.7, 95% CI: 1.1–2.5; p = 0.02), but no data on differences of case mix were available. Furthermore, the system can also be used as a teaching instrument in knee reconstruction or revision surgery (Stulberg et al. 2007).

## Patient Specific Instruments

Recently a different technique is being promoted in TKA: Patient Specific Instruments (PSI). These are based on a pre-operative CT or MRI scan; an intra-operative sawing mold can then be used by the surgeon to achieve the planned position of the TKA.

TKAs performed with these PSI should restore the mechanical leg axis, however results between conventional and PSI instruments are comparable, some studies show better alignment, some slightly worse alignment (Nunley et al 2012, Ng et al 2012) of the positioning guides compared to the more classic manual instrumentation. Maybe the ideal situation is to incorporate PSI in CAOS.

A parallel exists between PSI and the introduction of CAOS: although it is evident that these patient specific instruments add cost, it is uncertain whether they will improve TKR alignment and thus outcome. Furthermore, the discussion on the ideal position of the components is still open.

## Future on the use of CAOS

With improvements in validity and cost effective analysis (i.e. revision burden, younger patients) the importance of reproducibility with a system (COAS or PSI or a combination) is evident. Another development is patient empowerment and direct patient self management.

Actual examples of patient information on CAOS are:

*"What are the actual developments in Orthopaedics? ... Another development is the increase of number of surgeries performed using computernavigation. Before surgery a scan is made. The orthopaedic surgeon marks which structure he is going to operate on and how. The computer calculates where this structure exactly is. In this way, the orthopaedic surgeon can intra-operatively check on a screen if he is cutting too deep or too shallow and whether the prosthesis is placed in the bone in the right way." (Zorgvoorbeweging.nl)*

and *"TomTom. The new navigationsystem is a real expansion for the Orthopaedic Staff. In this way prostheses can be placed with an accuracy within a millimeter." (WFgasthuis)*

and *"The Orthopaedic Staff is also involved in international research, allowing the application of the newest technology. Hip and knee surgeries are, if necessary, performed with computernavigation, allowing more accuracy, less complications and better results."(StadUtrecht.nl)*

The patient absorbs this biased information as "the Truth" and asks for this 'new' technique before validation is performed. A comparison can be made with the 'hype' on the (metal-to-metal) resurfacing hip prostheses. Although CAOS and PSI are not prostheses but a tool to implant the prosthesis, the effect on patients  is the same.

This rapid progress of modern computerised capabilities and expectations have not been paralleled by a similar progress in the use of CAOS in the operating room. It would seem logical that most surgeons would want to embrace this technology in TKA. However, at the moment CAOS is still not the standard procedure.

According to the Swedish Knee Arthroplasty Registry 2011, only 0.7% of the cases were reported as having been operated on with CAOS, more often for TKA than UKA (Unicondylar Knee Arthroplasty). According to the annual report of the Norwegian arthroplasty register, 19% of the TKA were performed using CAOS in 2009, decreasing compared to 21% in 2008.

How many TKAs in the Netherlands are performed with navigation was evaluated in 2010; 22 of the 83 hospitals participating in the questionnaire on CAOS actually used these CAOS systems. Of these 22  16 used CAOS in TKA. In Germany, 30% of the orthopaedic surgeons who perform TKA have used navigation. However, most orthopaedic surgeons still avoid using computer-navigation surgical techniques. Friederich et al. performed a survey among the more than 3000 members of the European Society of Sports Traumatology Knee Surgery and Arthroscopy (ESSKA) and the Swiss Orthopedic Society (SGO-SSO) in 2007. 52% was equipped with a navigation system. 50% used CAOS in less than 25% of the TKA and only 25% in more than 75% of the cases. The potential for improving the alignment was the strongest cited reason, while increasing operation times and risk of infections were reasons for not using it. Half of respondents believed CAOS was a real innovation contributing to the improvement of TKA.

Why does the implementation of CAOS procedures meet so many hurdles and obstacles? Currently there are three considerations that have slowed down computer navigation's wider acceptance: evidence (i.e. technological), human and financial. It takes additional time and a learning curve to do the procedure and there are significant financial costs to purchase and utilize this technology, and finally evidence for improved position is on debate. CAOS still requires an experienced surgeon and additional costs are made. And again, last but definitely not least, it is still not known whether this new technique improves the longevity and outcome of TKA. As long as these issues (a clear effect on outcome, revisions, costs etc.) are not answered yet, the use of CAOS will still be on debate.

## ■ Conclusion and recommendation

COAS in TKA is a promising tool to improve the accuracy of positioning the total knee prosthesis if the considerations from this thesis are addressed.

The answers on the three questions on which this thesis is based, namely considering 1. positioning, 2. size of the TKA and patellar tracking and 3. outcome, support to the following conclusion:

CAOS in the future might help the surgeon to perform a TKA with more accuracy. The combination of the current design of CAOS, the in this thesis performed studies, and the in literature published results considering positioning, outcome and costs, leeds to the conclusion that CAOS needs more 'fine tuning' and will not become the standard of care in TKA in short term.

To be able to optimally use this tool, which can eventually lead to an accurate, reproducible and reliable position of the TKA, determination of what's the accurate position of the total knee prosthesis for that specific patient should be the main focus: should the knee be in a "neutral" position for that specific patient, but what is neutral? This may be slight varus for one and slight valgus for another patient. What rotation should we aim for? Should the ligament balancing be equal in extension and flexion or asymmetric in flexion? These anatomical and kinematic inputs are needed into a CAOS system which has good validity, and which has to reduce human (i.e. surgeons) error. To ensure its validity in daily practice, also CAOS, like any new technique or prosthesis has to be evaluated within a model of phased introduction before mass introduction to the market (Nelissen et al 2012). This will ultimately improve outcome for the patient, thereby answering the question whether CAOS is a tool or a toy.

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# Chapter 10

## Samenvatting

## ■ Samenvatting

Het aantal totale knieprotheses (TKP) dat per jaar geplaatst wordt stijgt naar verwachting tot 30.000 per jaar in Nederland in 2030. Momenteel worden alle TKP geregistreerd in de zogeheten Landelijke Registratie Orthopaedische Implantaten (LROI). Er zijn veel verschillende TKP op de markt, welke specifieke prothese gebruikt wordt is afhankelijk van o.a. de kosten en de ervaring van de chirurg met een bepaalde prothese.

Sinds 1860 is de TKP in ontwikkeling. Van een eenvoudig metalen scharnier is uiteindelijk in de tachtiger jaren de huidige vorm van een combinatie van metaal en polyethyleen op de markt gekomen. Naast deze ontwikkeling wat betreft design zijn ook de chirurgische technieken verder ontwikkeld om de plaatsing van de prothese en daarmee de uitkomst te verbeteren. Vanaf 1997 is computer navigatie toegepast en het gebruik hiervan bij het plaatsen van een TKP geënt op: verbeteren van alignment, nauwkeuriger plaatsen van de TKP, balancing van de weke delen en de kinematica van de knie. Door de Computer Assisted Orthopaedic Surgery (CAOS) ontwikkelaars worden deze voordelen beschreven, maar er worden ook nadelen genoemd, zoals o.a. langere operatieduur en kosten.

Vanaf 1995 tot 2007 is een flinke stijging te zien wat betreft het aantal publicaties over CAOS en TKP, dat na 2000 ook gevolgd is door randomized-controlled trials, meta-analyses en systematic reviews. Echter, na 2007 is er geen stijging, maar zelfs een daling van de publicaties betreffende CAOS en TKP waar te nemen. Uit een enquête in 2010 blijkt dat 22 van de 83 ziekenhuizen navigatie gebruikt, waarvan 16 het gebruiken bij TKP. Het Zweedse Register laat zien dat slechts 0.7% van de TKP met behulp van CAOS wordt geopereerd, waar in het Noorse Register 19% van de TKP geregistreerd zijn als geplaatst met CAOS. Bij beiden neemt het gebruik af. Al met al speelt CAOS dus (nog) geen standaard rol bij de Orthopaedie in Europa wat betreft de TKP.

Naast de ontwikkeling van TKP wat betreft vorm, materialen en chirurgische techniek is de positie van de prothese nog steeds essentieel voor de uitkomst.

Om de potentiele voordelen van CAOS bij het plaatsen van een TKP te toetsen zijn in dit proefschrift 3 vragen opgesteld:

1. Leidt CAOS tot het nauwkeuriger plaatsen van een TKP?
2. Leidt CAOS tot een juiste maatvoering van de TKP en patella tracking?
3. Wat is de klinische en radiologische uitkomst van een TKP geplaatst met CAOS?

Allereerst is een anatomische studie gedaan naar de rotatie van het femur (Hoofdstuk 3). Hierin zijn de meest gebruikte rotatie assen (femur anteversie (FAA), posterieure condylaire as (PCA) en de inferieure condylaire as (ICA)) van het femur vergeleken. Daaruit blijkt dat er inter- en intraindividuele verschillen tussen rechts en links bestaan met daarbij een grote spreiding. Er was alleen een duidelijke correlatie tussen de FAA links en rechts. De inferieure condylaire as bleek niet betrouwbaar om op een voorachterwaartse knieopname de rotatie van het distale femur te beoordelen.

Het registreren van de anatomische (rotatie)referentiepunten peroperatief is de basis om tot een nauwkeurige plaatsing van de TKP te kunnen komen. Uit de studie beschreven in Hoofdstuk 4 blijkt echter dat het registreren van de epicondylaire as door de chirurg peroperatief onderhevig is aan grote variatie. De aangewezen transepicondylaire as blijkt niet dezelfde te zijn als die gemeten op de postoperatieve CT scan.

Wanneer met behulp van CAOS daadwerkelijk de TKP geplaatst is, kan postoperatief een CT scan gemaakt worden om de definitieve stand van de TKP te evalueren. Dat de peroperatief door het CAOS systeem weergegeven rotatie van de femurcomponent significant verschilt met de postoperatieve stand, bleek uit de studie beschreven in Hoofdstuk 5. CAOS leidt dus voor wat betreft de rotatie van de femurcomponent (nog) niet tot een nauwkeuriger plaatsing van de TKP.

Naast de stand van de TKP is de maatvoering van de componenten belangrijk voor de functionele uitkomst. Een te grote femurcomponent bijvoorbeeld leidt tot flexiebeperking. Om te beoordelen of CAOS ook tot een juiste maatvoering van de femur- en tibiacomponent leidt, is een studie gedaan waarbij de tevoren (op basis van de röntgenfoto bepaalde maat), uiteindelijk juist, te groot of te klein was. In Hoofdstuk 6 wordt geconcludeerd dat er met gebruik van CAOS de neiging is om een te grote femurcomponent te plaatsen. Dit leidde in dergelijke gevallen ook daadwerkelijk tot een flexiebeperking waarvoor doorbuigen onder anaesthesie noodzakelijk was.

Om de beweging van de patella over de knie (zogeheten patella tracking) te analyseren bevat het CAOS systeem een patella-tracking module. Door op de patella een markertree te bevestigen kunnen de bewegingen van de patella in alle richtingen gevisualiseerd worden. De studieresultaten in Hoofdstuk 7 laten echter zien dat registratie sterk beïnvloed wordt door de snelheid van flecteren/extenderen van de knie en dat bij occlusie van 1 van de markertrees de registratie onjuiste waarden weergeeft.

Tot slot is een vergelijkende studie gedaan naar de radiologische uitkomst en migratie van de TKP. Hiervoor is een studie gedaan betreffende 3 groepen: CT vrije, CT gebaseerde navigatie en conventionele chirurgie. Als uitkomstmaten is gekeken naar de klinische scores, radiologische evaluatie (alignment) en de microbeweging (migratie) van de TKP met behulp van röntgenstereophotogrammetrische analyse (RSA), beschreven in Hoofdstuk 8. Er werd geen verschil gevonden in klinische scores en alignment. Alleen in de conventionele groep werd een significant verschil in caudale-craniale migratie gevonden na 2 jaar, en hoewel er aanwijzingen zijn dat het aantal outliers wat betreft het alignment van de TKP met CAOS afneemt, was er geen verschil in klinische score.

Bovenstaande leidt tot de volgende antwoorden op de 3 eerder gestelde onderzoeksvragen:

1. **Leidt CAOS tot het nauwkeuriger plaatsen van een TKP?**
   Op basis van bovengenoemde studies en analyse van de huidige literatuur is geconcludeerd dat juiste registratie tijdens CAOS essentieel is voor het bereiken van een goede stand van de TKP. CAOS leidt (nog) niet tot het nauwkeuriger plaatsen van de TKP wat betreft de rotatie van de femurcomponent.
2. **Leidt CAOS tot een juiste maatvoering van de TKP en patella tracking?**
   Geconcludeerd wordt dat men uit moet kijken voor het plaatsen van met name een te grote femurcomponent. De data die verkregen wordt middels het gebruik van de patella tracking module worden significant beinvloed door de snelheid van flecteren/extenderen van de knie en occlusie van een markertree.

3. **Wat is de klinische en radiologische uitkomst van een TKP geplaatst met CAOS?**
   Hoewel er aanwijzingen zijn dat het aantal outliers wat betreft het alignment van de TKP met CAOS afneemt, kan er geen relatie aangetoond worden met de klinische uitkomst van de prothese.

## ■ Conclusie

Op basis van de hierboven beschreven vraagstelling, onderzoek en antwoorden kan geconcludeerd worden dat CAOS een bruikbare techniek is voor de orthopaedisch chirurg om meer inzicht te krijgen in/tijdens plaatsing van een TKP. Met de huidige resultaten en in de huidige vorm heeft het op korte termijn (nog) geen standaard plaats op de operatiekamer.

Er is nog geen consensus over wat de optimale stand van de TKP zou moeten zijn. Is een bony referenced of ligament balanced techniek de aangewezen methode, welke stand of balancing zou je dan moeten nastreven? Om COAS te kunnen gebruiken als techniek om tot nauwkeurige plaatsing van de TKP te komen is deze informatie dus allereerst nodig. Wanneer de ideale stand van de TKP gedefinieerd en behaald kan worden is verbetering in de klinische uitkomst en survival van de TKP te verwachten.

Momenteel is CAOS een bruikbare techniek voor onderzoeksdoeleinden, zoals de chirurgische techniek, kinematische analysen, en als onderwijsinstrument. Verder onderzoek is nodig om de exacte plaats van CAOS bij het plaatsen van TKP te bepalen. Tot die tijd moet men kritisch blijven wat betreft de toepassing van nieuwe technieken in de Orthopaedische Chirurgie, deze gefaseerd invoeren en de vraag stellen of iets een 'tool' of een 'toy' is.

# Appendix

- Curriculum Vitae
- List of publications
- Search strategy on CAOS and TKA

## Curriculum Vitae

Henrica Maria Jannetta (Enrike) van der Linden - van der Zwaag was born on the 17th of May, 1972 in Haarlem, The Netherlands. In 1990, she graduated from the VWO-B programme at the ¨Eerste Christelijk Lyceum¨ in Haarlem. In that same year she started the study of Biomedical Sciences at the Leiden University. In 1991 she switched to the study of Medicine at the Leiden University. She graduated in 1997 and before starting the Orthopaedic speciality training she worked from july 1997 till februari 1998 at the Ministry of Immigration and Naturalisation as medical examiner.

In 1998 she commenced her speciality training program at the Department of Surgery, Leiden University Medical Center (Head: Prof.Dr. O.T. Terpstra). Her orthopaedic training started in the year 2000 at the Department of Orthopaedic Surgery at the Leiden University Medical Center (Head: Prof. Dr. P.M. Rozing). The peripheral training was conducted in the Rode Kruis Ziekenhuis, The Hague (Head: Dr. C.F.A. Bos) and in 2004 she graduated.

Since 2004 she is one of the staff members of the Orthopaedic Department at the Leiden University Medical Center (Head: Prof.Dr. R.G.H.H. Nelissen). It was here where she was inspired to embark on this thesis.

## List of Publications

1. HMJ van der Linden - van der Zwaag, T Siebelt, PW de Bruin, BL Kaptein, RGHH Nelissen. Accuracy of Computer Navigated Patellar Tracking in Total Knee Arthroplasty. The influence of velocity of movement and marker occlusion on validity. Submitted.
2. HMJ van der Linden – van der Zwaag, L Konijn, T van der Steenhoven, HJ van der Heide, M de Ruiter, RGHH Nelissen. The inter- and intraindividual anatomical relationship of the femoral anteversion and distal femoral rotation. A cadaveric study on the femoral anteversion angle, posterior and inferior condylar angle using Computed Tomography. Submitted.
3. LJ van Baardewijk, JB Ponten, IB Schipper, HMJ van der Linden, R Haas, P Krijnen, E Krug. Indicatiestelling voor intensieve revalidatie na een heupfractuur. Conditionally accepted Injury May 2012.
4. N Wolterbeek, EH Garling, HMJ van der Linden, RGHH Nelissen, ER Valstar. Integrated assessment techniques for linking kinematics, kinetics and muscle activation to early migration: a pilot study. Gait posture may 2012, Epub ahead of print.
5. K Beenakker, B Duijnisveld, H van der Linden, C Visser, R Westendorp, G Butler-Browne, R Nelissen, A Maier. Muscle characteristics in patients with chronic systemic inflammation. Accepted Muscle and Nerve, Epub ahead of print april 2012.
6. B Pijls, HMJ van der Linden, RGHH Nelissen. Poly-Ethylene thickness is a risk factor for wear necessitating insert exchange. International Orthopaedics (2012) 36:1175–1180.
7. BG Pijls, OM Dekkers, S Middeldorp, ER Valstar, HJ van der Heide, HM van der Linden - van der Zwaag, RGHH Nelissen . AQUILA: Assessment of QUality In Lower limb Arthroplasty: An expert Delphi consensus for total knee and total hip arthroplasty. BMC Musculoskelet Disord 2011; 12(1):173.
8. T van Strien, J Dankelman, J Bruijn, Q Feilzer, V Rudolphy, H van der Linden - van der Zwaag, HJ van der Heide, E Valstar, R Nelissen. Efficiency and safety during Knee Arthroplasty Surgery. Journal of Bone and Joint Surgery - British Volume, 2011 Vol 93-B, Issue SUPP_II, 115.
9. SM Pasha, HMJ van der Linden. Nieuwe anticoagulantia ter preventie van veneuze trombo-embolie in de orthopedische chirurgie. Hart Bulletin, jaargang 42, nr. 2, april 2011.
10. HMJ van der Linden - van der Zwaag, J Bos, HJ van der Heide, RG Nelissen. A computed tomography based study on rotational alignment accuracy of the femoral component in total knee arthroplasty using computer-assisted orthopaedic surgery. International Orthopaedics 2010.
11. HMJ van der Linden - van der Zwaag. Conservatieve behandelmogelijkheden bij artrose. Modern Medicine nr. 9, (september)2010; 34:303-305.
12. E Krug, HMJ van der Linden, R Haas, K de Vos. Sneller uit het verkeerde bed. Medisch Contact. 5 ed. 2010. 225-227.
13. T van Strien, HMJ van der Linden-van der Zwaag, B Kaptein, A van Erkel, ER Valstar, RGHH Nelissen. Computer assisted versus conventional cemented total knee prostheses alignment accuracy and micromotion of the tibial component. International Orthopaedics (SICOT) (2009) 33:1255–1261.

14. HMJ van der Linden – van der Zwaag. Behandeling van heup en knie artrose. Reuma en huisartsenvademecum april 2008.

15. HMJ van der Linden-van der Zwaag, R Wolterbeek, RGHH Nelissen. Computer assisted orthopedic surgery; its influence on prosthesis size in total knee replacement. The Knee. 2008 Aug;15(4):281-5.

16. HMJ van der Linden – van der Zwaag. Welke knieprothesen zijn er en wat is hun gemiddelde levensduur? Huisartsen Vademecum nummer 21 F-19 mei 2009.

17. HMJ van der Linden - van der Zwaag, ER Valstar, AJ van der Molen, RGHH Nelissen. Transepicondylar axis accuracy in computer assisted knee surgery: a comparison of the CT-based measured axis versus the CAS-determined axis. Comput Aided Surg. 2008 Jul;13(4):200-6.

18. HMJ van der Linden - van der Zwaag, GJ Onvlee. Massive osteolysis (Gorham's disease) affecting the femur. Acta Orthop Belg, 2006, 72, 261-268.

19. HMJ van der Linden - van der Zwaag, RGHH Nelissen, JB Sintenie. Results of surgical versus non-surgical treatment of achilles tendon rupture. International Orthopaedics, 2004, 28(6), 370-373.

20. PDS Dijkstra, HMJ van der Linden. Comparison of torsional strength reduction of cortical defects in femora estimated by surgeons using radiographs and CT and measured by in vitro experiments. Westeinde Ziekenhuis Den Haag, Thesis 1999.

21. HMJ van der Zwaag, R Brand, WR Obermann, PM Rozing. Glenohumeral osteoarthrosis after Putti Platt repair. J Shoulder Elbow Surg, Volume 8, Issue 3, 252-258 (May 1999).

## Search strategy on CAOS and TKA

### PubMed

http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?otool=leiden

(“Arthroplasty, Replacement, Knee”[Majr] OR “total knee”[ti] OR “knee arthroplasty”[ti] OR “knee arthroplasties”[ti] OR “Knee Prosthesis”[Majr] OR “knee prosthesis”[ti] OR “knee prostheses”[ti] OR tka[ti]) AND (“Surgery, Computer-Assisted”[Majr] OR Caos[ti] OR “computer assisted”[ti] OR “computer-assisted”[ti] OR navigation[ti] OR “computer-navigated”[ti] OR “computer navigated”[ti]) AND (randomized controlled trial OR controlled clinical trial OR randomized controlled trials OR random allocation OR double-blind method OR single-blind method OR “latin square” OR placebos OR placebo* OR random* OR “Research Design”[MeSH:noexp] OR comparative study OR evaluation studies OR follow-up studies OR prospective studies OR cross-over studies OR prospective* OR volunteer* OR randomised controlled trial OR randomised controlled trials OR randomized active control trials OR randomized active control trial OR randomised active control trials OR randomised active control trial OR RaCT OR RaCTs OR RCT OR RCTs OR “Evaluation Studies “[Publication Type] OR “Evaluation Studies as Topic”[Mesh] OR metaanalysis OR metaanalyses OR meta-analysis OR meta-analyses OR systematic[sb])

### EMBASE

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(exp *knee prosthesis/ OR exp *total knee replacement/ OR exp *knee arthroplasty/ OR (”total knee” OR ”knee arthroplasty” OR ”knee arthroplasties” OR ”Knee prosthesis” OR ”knee prostheses” OR tka).ti) AND (exp *computer assisted surgery/ OR (Caos OR ”computer assisted” OR ”computer-assisted” OR navigation OR ”computer-navigated” OR ”computer navigated”).ti) AND (exp randomized controlled trial/ OR exp meta analysis/ OR exp evidence based medicine/ OR (controlled clinical trial* OR randomized controlled trial* OR random allocation OR double-blind method OR single-blind method OR ”latin square” OR placebos OR placebo* OR random* OR comparative stud* OR evaluation stud* OR follow-up stud* OR prospective stud* OR cross-over stud* OR prospective* OR volunteer* OR randomised controlled trial* OR randomised controlled trial* OR randomized active control trial* OR randomized active control trial* OR randomised active control trial* OR randomised active control trial* OR RaCT OR RaCTs OR RCT OR RCTs OR metaanalysis OR metaanalyses OR meta-analysis OR meta-analyses OR systematic review*).af)

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Cochrane Reviews [1]

Other Reviews [6]

Trials [82]

Technology Assessments [5]

Economic Evaluations [3]

("knee replacement" OR "total knee" OR "knee arthroplasty" OR "knee arthroplasties" OR "Knee prosthesis" OR "knee prostheses" OR tka) AND (computer assisted surgery OR Caos OR "computer assisted" OR "computer-assisted" OR navigation OR "computer-navigated" OR "computer navigated")

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