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Chapter 1

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)

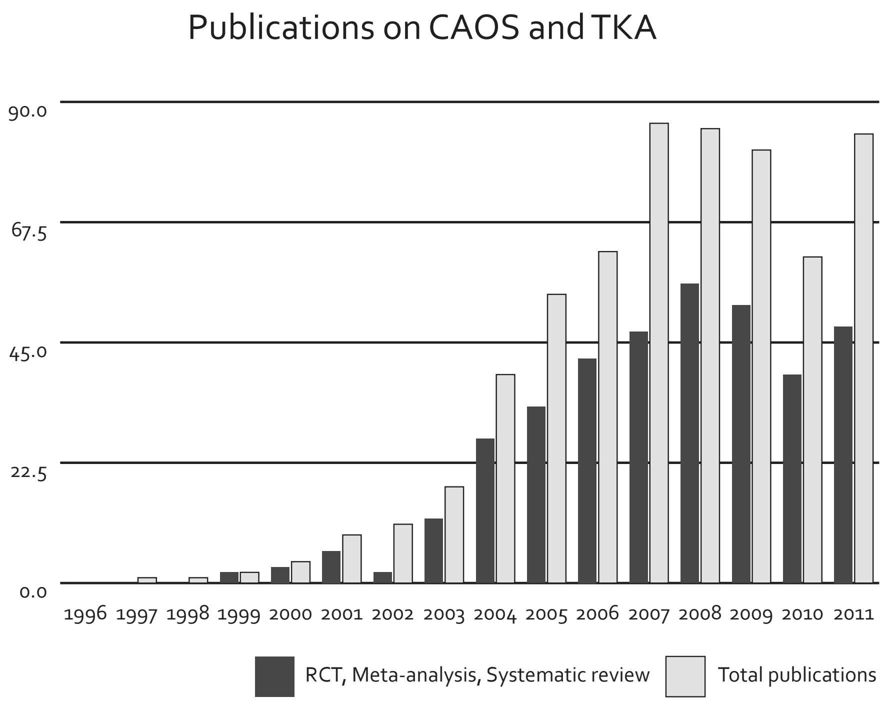

Figure 1. Number of publications a year on CAOS and TKA (for search strategy see appendix).

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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