Objective clinical performance outcome of total knee prostheses. A study of mobile bearing knees using fluoroscopy, electromyography and roentgenstereophotogrammetry

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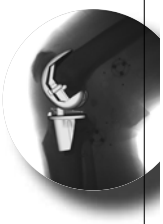
Chapter 12

General discussion and conclusion

12.1 Discussion

The original hinge and surface replacement knee prostheses have evolved to the modern fixed and mobile-bearing designs. However, past experience has demonstrated that so-called design improvements may not always result into clinical success. Therefore, every surgeon should base implant selection on well-controlled, long-term follow-up studies using objective outcome parameters. The frequency of implantation of contemporary total knee arthroplasty designs in progressively younger patients makes a critical review of longevity and durability of total knee arthroplasty devices all the more important. In addition, the higher demands placed on these implants by the younger, typically more active patient population emphasizes the importance for prostheses that show consistent long-term results. The constant introduction of new modifications of older knee designs can make this process complex. It is not uncommon that satisfactory clinical results are obtained in the short term (5 years). However, longer follow-up (>10 years) often demonstrates shortcomings and reveals designs that actually have stood the test of time (Mc Bride et al., 2000).

These factors have lead amongst others to an important new directive from the European Commission. On August 11, 2005, a long-anticipated Reclassification Directive for hip, knee and shoulder joint replacements was published (Official Journal, 2005/50/EC). This Directive reclassifies these implants from Class IIB to Class III, the highest risk category for medical devices in the European Union (EU). The Directive must be transposed into the national laws of all EU Member States by 1 March 2007 and will apply to all new products being launched on the market from 1 September 2007. The upward classification of joint replacements renders them subject to a more burdensome set of regulatory requirements, most importantly, requiring direct scrutiny of pre-market clinical data used to support performance claims. Before the Reclassification Directive for Class IIB devices, a notified body needed only to assess the orthopaedic device manufacturer's procedures for evaluating its clinical data (post-market surveillance) when introducing new or modifications to implant designs. The Global Harmonization Task Force (founding members: EU, United States, Canada, Japan and Australia) is responsible for the international



harmonization in the regulation of medical devices. It is expected that the members of this task force will follow the EU's Reclassification Directive in the near future. In order to reduce costs and decrease timelines when introducing new products on the market from September 2007 onwards, joint replacement manufacturers will need objective outcome measurement tools that will deliver reliable clinical results evaluating device performance in a short period of time. RSA, fluoroscopy and gait analysis will become more important measurement tools for the short term evaluation of (new) total joint replacements.

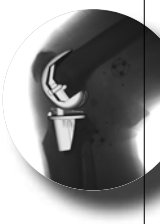
Due to the high accuracy, RSA studies on the fixation of joint prostheses can be performed in small study groups with a short follow-up period, while maintaining the sensitivity to accurately assess the fixation of these implants (Chapters 8, 9 and 10). However, more prospective RSA studies are needed that correlate the short-term results of implants with specific design characteristics (e.g. material, coating, geometrical shape etc.) with the long term clinical results. It is expected that many of these RSA studies will be published the coming years since RSA has been widely used after introduction of digital RSA analysis systems in the mid nineties (Börlin et al., 1997; Gill et al., 1998; Vrooman et al., 1998) so that more long-term clinical data can be collected and related to the short-term RSA results.

A very important development in RSA is the Model-based RSA technique (Kaptein et al., 2003; Kaptein et al., 2004). The methodology used by Model-based RSA is based on matching virtually projected boundaries (contours) of a 3D model of the prosthesis onto the actually detected contours of the prosthesis in an RSA radiograph. The position and orientation of the prosthesis are calculated by changing the orientation and position of this model such that the virtually projected contours form an optimal match with the actual contours. The reported accuracy of Model-based RSA for a total knee prosthesis (95% confidence interval) ranges between 0.1 and 0.3 mm for translations and between 0.1° and 0.2° for rotations (Kaptein et al., 2003). With the Model-based RSA technique the position and orientation of prostheses can be highly accurately assessed, without the demand for specific manufacturing adjustments to these prostheses. It is therefore relatively easy, cost effective and time efficient to set-up RSA studies. It is expected that Model-based RSA will be used by the industry and clinicians as being the golden standard for

the evaluation of joint prostheses. In addition to the Reclassification Directive, initiatives from our group towards the International Standardisation Organisation Working Group 4, should lead for a standard of pre-market clinical evaluation using (Model-based) RSA (CEN/TC 285/WG4).

The 2D/3D matching technique used in Model-based RSA can also be applied in fluoroscopy studies (Chapters 3, 4 and 5). The main difference between RSA and fluoroscopy is the use of a single focus set-up and dynamic image acquisition. Since the Model-based RSA technique is commercialized (Medis specials b.v., Leiden, The Netherlands) and initiatives from the group of Banks (University of Florida) to make fluoroscopy software on-line available will lead to a wider use of these techniques. When efforts are made to standardize fluoroscopy protocols and experimental set-ups including an agreement about coordinate systems, the goal should be to build a knowledge base of knee prostheses kinematic behaviour. Using this information the next step for research would be to focus on the development of knowledge based software capable of providing orthopaedic surgeons involved with knee arthroplasty with the ability to simulate pre-operatively, and intra-operatively assess the optimal prosthetic configuration and position in order to maximise the effectiveness of the procedure and therefore to offer the best possible surgical outcome for the patient.

However the use of the fluoroscopy technique has several pitfalls and limitations that one should be aware of when interpreting fluoroscopy results and when one would like to start fluoroscopy studies. Although many studies have been published using the fluoroscopy technique (Banks, et al., 2003; Callaghan et al., 2000; Dennis et al., 1998; Fantozzi et al., 2003; Saari et al., 2003; Stiehl et al., 1997; Walker et al., 2002) not always a thorough validation of the technique precedes or joins these publications (Dennis et al., 1998, Stiehl et al., 1997, Komistek et al., 2000). The accuracy of the technique (like for Model-based RSA) is mainly dependent on the geometrical characteristics of the prosthesis, accuracy of the CAD or RE model, and the pincushion distortion of the image (Chapter 3; Kaptein et al., 2003). Especially the out-of plane accuracy of the fluoroscopy technique is very sensitive for measurement errors and limits therefore the applicability of the technique and interpretation of results. A validation study about the accuracy of the technique applied to the specific implant(s) used in a fluoroscopy study should therefore always be preceded by a



validation study or at least be included in the 'Materials and Methods' section of the publication.

Only recently flat-panel detectors have been introduced that nullifies measurement error caused by image distortion. Also large flat panel detectors have been introduced increasing the diameter of the field of view from about 25cm to 40cm. However, the fluoroscopy studies always involve dynamic tasks related to daily activity. For these activities the field of view is still too limited and restricts the subject's movement pattern. Therefore, one actually needs a system that is able to follow the joint over a movement trajectory. Several systems are currently under development that will allow the assessment of knee kinematics during gait and/or other complex tasks. A research group in Zürich developed a mobile fluoroscopy unit that follows the knee joint during level walking using an external marker registration system (Zihlmann et al., 2006). Another and more flexible approach is the use of a robot arm to track the knee joint (Banks et al., 2006). By real time tracking of the joint, the robot arm that holds the fluoroscopic system is able to follow the knee in 3D space. This fluoroscopic approach also allows the postoperative functional assessment of other joints and other complex joint movements. As mentioned, the out-of plane direction is very sensitive for measurement errors. To overcome this error component, the group of Tashman in Detroit has developed a stereo fluoroscopic system which allows high speed assessment of kinematics by using high speed film camera's instead of image intensifiers. The accuracy when using this kind of set-up approaches that of RSA (Bey et al., 2006).

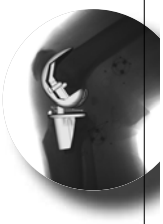
Accurate and easy to use software needs to be developed that is not only applicable in a research setting but also in the clinical setting. Surgeons need easy to use and objective tools beyond the patient's experience to tell them whether the surgical technique or approach worked as intended and whether the patient risks new or additional damage. Gait analysis, with skin mounted marker tracking and force plates, is a well-established objective method for the acquisition of kinematic and kinetic data of total knee arthroplasty *in vivo* and for non-invasive estimation of joint function. However, joint rotations and resultant moments at the knee joint are inaccurate with this method, due to large skin movement artefacts (Chapter 5). Therefore, methodologies need to be developed by which patient specific data

(anthropometry, ankle centre, knee flexion axis etc.) can be integrated and related to the fluoroscopy knowledge base. The development of accurate dynamic models that mathematically correct for skin artefacts by using patient's specific data will allow the development of easy to use gait analysis systems for the clinical setting to postoperatively monitor functional outcome.

In addition to that, real time feedback and visualization of dynamic joint motion is essential to make a clinician work with these advanced measurement tools and consequently apply the techniques in a clinical setting.

It has been shown that there is a strong relation between pre- and post operative function of total knee arthroplasty patients (Nelissen, 1995). Therefore, it is also important to assess both the preoperative kinematics as well as possible kinematic changes over time. A new technique that is under development for RSA and fluoroscopy uses digital reconstructed radiographs of CT datasets to reconstruct the position and orientation of the registered segments. This technique will provide accurate data of the *in vivo* kinematics of healthy subjects and preoperative kinematics of patients with joint disorders and accurate dynamic models made with accumulated data will provide detailed insight in skeletal kinematics (de Bruin et al., 2006; Mahfouz et al., 2005). The aim is to pre-, and intra-operatively assess the optimal prosthetic configuration and position in order to maximise the effectiveness of surgery.

The integration of RSA, fluoroscopy and EMG, preferably in combination with other imaging modalities like CT and MR for visualisation, results in a more or less holistic research approach. More insight into the relation between parameters can be obtained when measurement techniques are combined and when many parameters are assessed. One should aim to set-up randomized clinical studies that will combine fluoroscopy and gait analysis including electromyography. Electromyographic data provides also important information about total knee replacement functioning, co-contraction and control of movements (Chapter 6 and 7). Including the micromotion data assessed by RSA with this data will complete the variables related to the outcome of the specific total knee replacement and relations between the different outcome parameters can be established. Using this holistic approach where also CT could be included as imaging modality, even controversies like the rotational positioning of



the tibial component can be studied and the optimal orientation of the components in relation to functional outcome can be assessed (Barrack et al., 2001; Berger and Rubash, 2001; Uehara et al., 2002). Dual energy X-ray absorptiometry (DEXA) was not used in the studies of this thesis. This technique is an established standard for measuring bone mineral density and adds important information about bone remodelling or bone loss to prosthesis fixation studies and should also be included to complement the holistic approach.

A rotational mismatch between the tibial and femoral components may lead to patellar complications. It must be noted that almost no attention has been given towards the kinematics of the patella in this thesis. Due to practical issues with a fluoroscopy set-up applied to patellar kinematics like the out-of plane inaccuracy and visualisation of the patella during the range of motion there are no validated publications of *in vivo* patellar kinematics after total knee replacement. However, the patellofemoral joint is a major source of problems after total knee replacement. As many as one-half of all re-operations are done for extensor mechanism or patellar-related problems (Price et al., 2006). Patellofemoral geometry and orientation has a significant effect on knee kinematics (Barink et al., 2006). Especially the quadriceps moments in the joint are dependent of the orientation of the prosthesis relative to the patella (Chapter 7; Andriacchi et al., 1997). Forces several times body weight are transferred across the patellofemoral joint when one climbs stairs or rises from a chair. Future research using fluoroscopy should clarify the *in vivo* kinematics of the patella in different femoral component designs in both patella resurfacing or non-resurfacing variants.

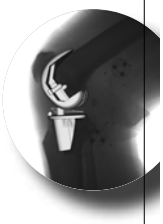
12.2 Conclusion

The goal of this thesis was to assess with accurate and objective methods the function and fixation of current total knee prostheses concepts, in particular of mobile bearing total knee designs. Some methods like marker-based fluoroscopy were validated to determine its feasibility and accuracy. Subsequently the *in vivo* clinical performance of several total knee prostheses was reported. Already established methods like RSA

were used in randomized trials to assess the differences in micromotion between total knee prostheses.

Findings from kinematic studies of knee prostheses have been variable and have sometimes given conflicting kinematic patterns. Various studies have indicated posterior-medial rollback, posterior-lateral rollback, anterior translation with flexion, and both internal and external tibial rotation (in Chapter 4). Analysis of the presence of femoral-tibial anterior/posterior mobility in the literature reveals a wide range of constraints in prostheses, with unconstrained designs prevailing. Also mobile bearings have shown controversial kinematic patterns or limited motion (Chapter 4). Therefore, an alternative design would be a mobile bearing prosthesis that is not hindered by a locking mechanism (pivot point or curved tracks) which may also lead to polyethylene on metal impingement and increased wear (Chapter 11). Highly conformed geometries of the tibial polyethylene, matched with appropriately sized condyles, have less focal contact stress and therefore less wear. Also has been shown that low conformity knee prostheses as well as a higher conformity mobile bearing knees give less variability in the migration data compared to fixed bearing posterior-stabilised prostheses (Chapter 10; Nelissen et al., 1998). Therefore a highly congruent bearing-femur articulation (in both media-lateral as posterior-anterior direction) in combination with a tibia-bearing articular surface that is flat-on-flat would on theoretical grounds be a good solution. This articulation would provide the needed axial rotation and translations needed to avoid unnecessary constraint without preventing congruent flexion. In order to achieve joint stability with a lower level of constraint, competent soft tissue, including balanced collateral ligaments and the posterior cruciate ligament are necessary. Therefore soft tissue deficiency together with an uncorrectable extensor mechanism deficiency would be an absolute contra-indication for this type of knee prostheses since mobile bearing prostheses are more demanding for the soft tissue surrounding the knee compared to fixed bearing prostheses (Chapter 6 and 7). This might limit patient selection of this type of prosthesis towards the younger patient with less deterioration of the joint.

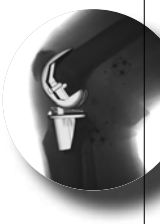
Although, ultra-high molecular weight polyethylene is the current material of choice for use as a bearing surface in total joint replacement, the recently introduced cross-linked polyethylene is currently marketed as the material of choice based on



initial wear tests and short term-results of congruent articulating surfaces (Chapter 11). However, this type of polyethylene might also be too brittle in the knee joint during focal loading of the surface or in less congruent ranges of motion. Despite all the mechanical tests and wear simulation studies, long-term clinical results should clarify the benefits of this new type of polyethylene.

Cemented total knee arthroplasty is still accepted as the gold standard. However, apatite coated implants show excellent mid-term (RSA) results and offers the advantage of bone preservation in the event of need for revision. Based on the results from Chapters 8 and 9 and the publications of others (Nelissen et al., 1998; Onsten et al., 1998), a calcium coating augmented with a plasma spraying process or a porous coated surface consisting of multiple layer beads showed to be an excellent and promising alternative to cemented fixation. It was concluded that this type of fixation would benefit survival of any total knee design. However, uncemented fixation of components requires the necessity for a precise fit of the component. Computer assisted surgery systems (CAS) are being developed to improve the precision of prosthesis placement. Recently, several studies have shown improved alignment of the leg and orientation of the components compared to the conventional technique when using computer navigation (Bathis et al., 2004; Decking et al., 2005; Luring et al., 2006; Sparmann et al., 2003). However, there has not yet been any prove of better patient outcome, function or longevity of the implant (Luring et al., 2006; Sikorski and Chauhan, 2003). Also minimal invasive techniques have been introduced in an effort to reduce tissue damage and shorten rehabilitation period. A prospective randomized trial comparing CAS in combination with minimal invasive surgery and conventional techniques should clarify the benefits when using these methods.
The benefits offered by total knee arthroplasty in terms of pain relief and restoration of function have resulted in ever increasing demand for this surgery during the past 2 decades. Satisfactory knee function is usually restored following total knee arthroplasty, and the majority of patients are able to return to low-impact sporting activity. The focus of total knee arthroplasty and the development of new implants has shifted from pain relief towards functional restoration of normal kinematics for the growing and more demanding (younger) population. However, one should question what are 'normal kinematics' of patients and in particular of rheumatoid

patients? In addition to that, it is doubtful to aim at restoring 'normal kinematics'. From kinematic studies we may generally conclude that knee kinematics after total knee arthroplasty do not replicate 'normal knee kinematics' (Chapter 4, Chapter 7). The gain in survival of total knee prostheses can only be marginal with survival rates of 91-96% at 14-15 years follow-up. However, technological advances in materials, operative procedures, product design and manufacturing processes will always drive to new prosthesis development. Nearly every orthopaedic device manufacturer has introduced new (mobile bearing) knee prostheses within the last years. Many orthopaedic device manufacturers are marketing something new claiming it to be better. However, surgeons as well as patients should be critical towards the evidence and the used methods and be aware that new is not always better.



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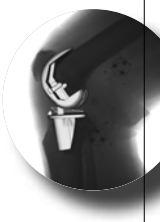

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