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Component Placement in Hip and Knee Replacement Surgery: Device Development, Imaging and Biomechanics

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Component Placement in Hip and Knee Replacement Surgery: Device Development, Imaging and Biomechanics

by

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A THESIS

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Abstract

Total joint replacement replaces the worn surfaces of arthritic joints with artificial components. This usually results in significant pain relief, but problems persist in some patients. An important contributor to postoperative complications following joint replacement is component malalignment. The goal of the work described is to improve component placement in total hip and knee arthroplasty. As one of the main objectives in this work, an adjustable mechanical device, called Optihip, was developed and tested to improve the accuracy of acetabular cup alignment in hip replacement surgery. An *ex vivo* study reported in this thesis, demonstrated the accuracy and feasibility of the device for guiding orientation and depth of the acetabular cup.

With respect to knee replacement surgery, preoperative and postoperative weightbearing patellofemoral and tibiofemoral kinematics throughout the range of motion, using calibrated sequential-biplanar radiographic imaging at 8 flexion angles, are reported for nine subjects before and at least one year after total knee arthroplasty (TKA).

Changes in the articular geometry of knee joints for the same nine subjects are also investigated by matching the three-dimensional (3D) implant models to the 3D bone-implant volume from computed-tomography (CT) imaging. Relationships between the subjects' quality of life (QOL) and changes in knee articular geometry and kinematics are also evaluated. There were significant differences between pre-TKA and post-TKA kinematics in this pilot study, although not for all degrees of freedom. Patellofemoral and femoral analyses showed that the knee shape and geometry changed in numerous significant ways as a result of the TKA. There

were also significant correlations between shape, kinematics and QOL parameters. Postoperative QOL in this cohort was better for a more lateralized proximal femoral groove, smaller changes in femoral condylar dimensions, more lateralized patellofemoral mediolateral translation and shift, less patellar tilt, more internal TF internal-external rotation and fewer individual shape and kinematic high/low values. Postoperative patellar tracking followed the femoral component groove more closely than the original preoperative tracking, suggesting that the femoral groove has more control over patellar tracking than the soft tissues.

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Successful completion of this project would not have been possible without the assistance and guidance of many people. I take this opportunity to express my sincere thanks and appreciation to them.

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List of publications and co-authors

Conference presentations

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M. Ehlke, T. Frenzel, H. Ramm, H. Lamecker, C. Perka, **M. Akbari Shandiz,** C. Anglin and S. Zachow, *Robust measurement of natural acetabular orientation from AP radiographs using articulated 3D shape and intensity models*, 14th Annual Meeting of the International Society for Computer Assisted Orthopaedic Surgery (CAOS International), Milan, 18-21 June 2014. Podium presentation.

M. Akbari Shandiz, S. K. Saevarsson, P. Boulos and C. Anglin, *Investigating knee kinematics differences due to total knee arthroplasty*, 60th Annual Meeting of the Orthopaedic Research Societies (ORS), New Orleans, 15-18 March 2014. Podium presentation.

M. Akbari Shandiz, S. K. Saevarsson, P. Boulos and C. Anglin**,** *Investigating knee shape differences due to total knee arthroplasty*, 60th Annual Meeting of the Orthopaedic Research Societies (ORS), New Orleans, 15-18 March 2014. Poster presentation.

M. Akbari Shandiz, S. K. Saevarsson, S. Yoo and C. Anglin, *Kinematic differences before and after total knee arthroplasty*, 13th Annual Meeting of the International Society for Computer

Assisted Orthopaedic Surgery (CAOS International), Orlando, 13-15 June 2013. **Best poster award.**

Publications

M. Akbari Shandiz, J.R. MacKenzie, S. Hunt and C. Anglin, *Accuracy of an adjustable patient-specific guide for acetabular alignment in hip arthroplasty (Optihip)*, Proceedings of the Institution of Mechanical Engineers, Part H: Journal of Engineering in Medicine, Vol. 228(9), 876–889, 2014. *[See Chapter 2]*

M. Akbari Shandiz, P. Boulos, S. K. Saevarsson, S. Yoo and C. Anglin, *Investigating knee kinematics before and after total knee arthroplasty to explore the influence of prosthesis shape and placement*, Bone & Joint Journal, Orthopaedic Proceedings Supplement, 96-B (SUPP 11), 4, 2014.

Submitted manuscripts:

M. Akbari Shandiz, P. Boulos, S.K. Saevarsson, S. Yoo, S. Miller, C. Anglin, *Impact of total knee arthroplasty on knee kinematics. [See Chapter 3]*

M. Akbari Shandiz, P. Boulos, S.K. Saevarsson, H. Ramm, C. Fu, S. Miller, S. Zachow, C. Anglin, *Impact of total knee arthroplasty on knee shape and geometry. [See Chapter 4]*

M. Akbari Shandiz, P. Boulos, S. Miller, C. Anglin, *Relationships between shape, kinematics and quality of life before and after total knee arthroplasty. [See Chapter 5]*

Intellectual Property

C. Anglin, **M. Akbari Shandiz**, J. Mackenzie, B. Wylant, J.G. Person, K.C.T. Ho, *Apparatus and method for positioning of acetabular components during hip arthroplasty procedures.* PCT application filed on October 21, 2013 (PCT/CA2013/000895). US provisional patent applications filed on October 22, 2012 and March 1, 2013. Applicant: UTI Limited (Innovate Calgary).

Dedication

To my family for their love and support through both the good and the hard times.

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List of Symbols, Abbreviations and Nomenclature

Abbreviations	Definition
2D	Two-dimensional
3D	Three-dimensional
ACL	Anterior cruciate ligament
AP	Anteroposterior
APP	Anterior frontal plane of the pelvis
ASIS	Anterior superior iliac spine
ASSIM	Articulated statistical shape and intensity model
BMI	Body mass index
CAS	Computer assisted surgery
CMM	Coordinate measuring machine
CT	Computed tomography
DLA	Device landmark angle
DOF	Degree of freedom
HA	Helical axis
HKA	Hip-knee-ankle (angle)
HSS	Hospital for Special Surgery
IE	Internal-external
KSS	Knee Society Score
QOL	Quality of life
MCS	Mental component summary

MRI	Magnetic resonance imaging
ML	Mediolateral
OA	Osteoarthritis
PCL	Posterior condylar line
PCS	Physical component summary
PF	Patellofemoral
Postop	Postoperative
Preop	Preoperative
SD	Standard deviation
ROM	Range of motion
TAL	Transverse acetabular ligament
TEA	Transepicondylar axis
TF	Tibiofemoral
THA	Total hip arthroplasty
TJA	Total joint arthroplasty
TKA	Total knee arthroplasty
WOMAC	Western Ontario and McMaster Universities Osteoarthritis Index

Chapter One: **General Introduction**

Osteoarthritis (OA) is a common degenerative condition in older adults, characterized by worn and damaged joints. It is the most common type of arthritis in Canada, affecting one in every ten Canadians (Hatfield et al., 2010). The cartilage on the joint surface wears away; the joint may not move easily; and the muscles surrounding it become stiff, all of which make movement very painful. It is estimated that 27 million Americans have OA, and this number is expected to grow to 67 million by 2030, if the progression rates of obesity and other co-morbidities remain unchanged (Flegal et al., 2010; Yaemsiri et al., 2011)

In severe cases of OA or other degenerative diseases such as rheumatoid arthritis, fractures/injuries, and avascular necrosis, the joint is usually treated with total joint arthroplasty (TJA). TJA replaces the worn surfaces of the joint with artificial components. This usually results in significant pain relief, enhancing joint stability and improving functional range of motion (ROM), which in general improves the patient's quality of life (QOL).

With the aging of the population as well as advances in medical technology and surgical development, TJA is becoming an increasingly important and common orthopaedic procedure. In the US, over 1 million TJA procedures were performed in 2009 alone (Wier et al., 2011). Due to the increase in the number of obese people, and the extension of the surgery to younger patients as a result of longer implant longevity, the incidence of TJA has grown dramatically. In Canada, 24000 hip replacement surgeries and 38000 knee replacement surgeries are performed every year, of which 2600 hip and 4000 knee replacements are performed in Alberta (Canadian Institute for Health Information, 2008) . In the US, the current rate is 293,000 THA, and 655,000 TKA per year (DeFrances et al., 2007; Kurtz et al., 2007). Around 4.2% of adults over the age of 50 in the US have a TKA (Inacio et al., 2011). It is estimated that the number of TKAs in the US increased by 50% from 2000-2006, and this number is expected to increase even faster in the future (Kurtz et al., 2007). Younger patients in Canada also contributed to the increasing numbers (Greene et al., 2008). In the latest report from the Canadian Joint Replacement Registry, total knee arthroplasty (TKA) rates more than doubled over the past decade for individuals aged 45-54 (Canadian Institute for Health Information, 2009; Smith et al., 2003). In the US, the number of patients younger than 65 years old, candidates for primary or revision TKA, increased from 25-32% to 40-46% of the cases from 1993 to 2006 (Severson et al., 2012). The increasing incidence of procedures is expected to continue.

It has been estimated that the incidence of THA surgery will increase by 120% to 512,000 and the incidence of TKA surgery will increase by 190% to 1.38 million procedures, from 2005 to 2020 (Kurtz et al., 2014).

Although THA and TKA are normally excellent treatments for patients with severe osteoarthritis or other degenerative diseases of the hip and knee joints, there are still large numbers of patients who have pain after their joint replacement and who do not have their functional expectations met (Kurtz et al., 2007; Mannion et al., 2009). An important contributor to postoperative complications following joint replacement is component malalignment, which can cause major postoperative complications such as ligament imbalance, uneven load distribution, impingement, early wear, loosening of the components impingement, and reduced range of motion (Callaghan et al., 2004; De Haan et al., 2008; Hart et al., 2011; Hofmann et al., 2011; Langton et al., 2010; Lewinnek et al., 1978; Loughead et al., 2008; Mahoney et al., 2003; Morlock et al., 2008; Seil et al., 2011; Victor, 2009; Widmer, 2007). Component malalignment in joint arthroplasties can occur due to the surgical technique used by the surgeon or because the optimal component position for each individual patient is unknown.

Due to postoperative complications, revision THA and TKA surgeries are estimated to increase by 55% and 170% respectively, from 2005 to 2020 (Kurtz et al., 2014). The cost to the health care system for revision surgeries to correct the postoperative complications following THA and TKA can be substantial. It has been estimated that the cost savings of a 1% decrease in revision surgeries in the US could range from $42.5 million to $112.6 million for THA and from $53.5 million to $98.4 million for TKA, in addition to having a major impact on the lives of many individuals.

The main motivation for my thesis is therefore to improve component placement in THA and to understand the role of individual component placement in TKA.

1.1 Hip study

The hip joint is a ball-and-socket type joint where the ball consists of the femoral head and the socket is known as the acetabulum (Figure 1-1). This type of joint offers some stability and a large ROM. Joint stability is obtained by the bony configuration combined with a complex system of muscles and ligaments around the joint.

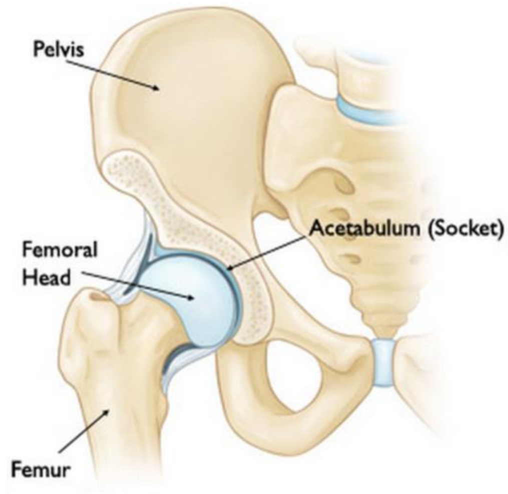


Figure 1-1. Anatomy of the hip joint (**Reproduced with permission from *OrthoInfo.* © American Academy of Orthopaedic Surgeons. http://orthoinfo.aaos.org.**).

The hip joint is one of the most common joints to experience OA (Figure 1-2). In severe cases the hip joint is usually treated with total hip arthroplasty (THA).

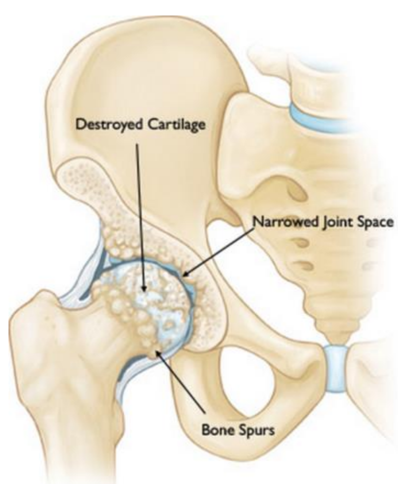


Figure 1-2. Osteoarthritis (OA) of the hip joint (**Reproduced with permission from OrthoInfo. © American Academy of Orthopaedic Surgeons. http://orthoinfo.aaos.org.**).

THA replaces the worn surfaces of the hip joint with an acetabular cup and a femoral head and stem (Figure 1-3). The two most common surgical methods for THA are the posterior and anterolateral approaches.

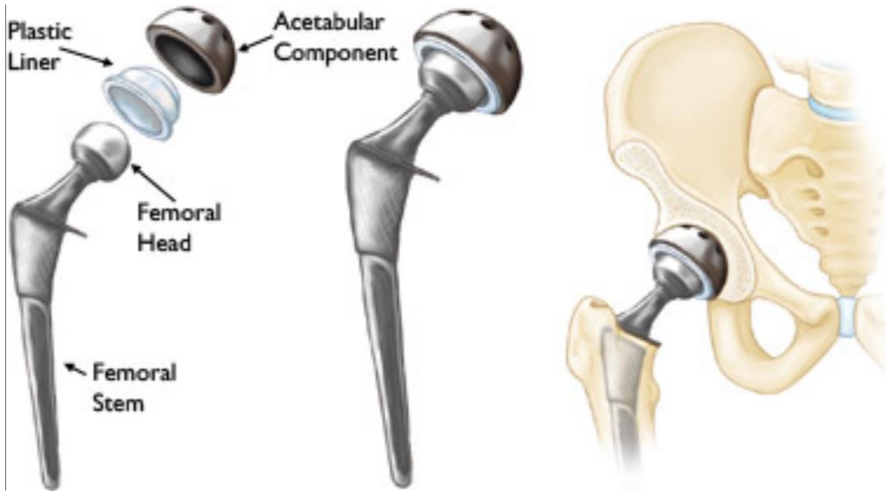


Figure 1-3. Total hip arthroplasty (THA) (Reproduced with permission from OrthoInfo. © American Academy of Orthopaedic Surgeons. http://orthoinfo.aaos.org.).

Postoperative stability or instability of THA is the consequence of multiple factors, including acetabular orientation, soft tissue balancing, and restored leg length and offset (Chen et al., 2006; McCollum et al., 1990); of these, proper cup orientation has the largest influence (Ybinger et al., 2007). Hip instability is the single greatest reason for revision THA in the US, accounting for 23% of all revisions in the US Medicare population resulting in $504 million annually (Bozic et al., 2009). Therefore, the cost to the health care system for revision surgeries to correct for implant malpositioning following a THA can be substantial.

Malplacing the acetabular component in THA has been shown to increase the rate of revision surgery due to problems with hip instability, wear, impingement, aseptic loosening and osteolysis and higher metal ion levels (De Haan et al., 2008; Desy et al., 2011; Gawkrodger, 2003; Hart et al., 2011; Langton et al., 2010; Lewinnek et al., 1978; Mahoney et al., 2003; Morlock et al., 2008; Widmer, 2007).

It has been shown that the risk of postoperative problems following hip surgery such as dislocation is minimized if the acetabular implant is oriented within a particular range of values (Babisch et al., 2008; Lewinnek et al., 1978). The anatomical range within which placement of the acetabular cup is considered acceptable is commonly referred to as the "safe zone" (Lewinnek et al., 1978). Although there have been updates to this definition (Babisch et al., 2008), acetabular orientation values are still usually referenced to the anterior frontal plane of the pelvis (APP), which is formed by the most prominent aspects of the right and left anterior superior iliac spines (ASIS), and the right and left pubic tubercles. The safe range of cup alignment or 'safe zone' was defined as an abduction or inclination angle of 40° ± 10° and an anteversion angle of 15° ± 10° (Lewinnek et al., 1978).

The technique used to place the acetabular component is important for proper cup orientation. Surgeons use one of several techniques to determine cup orientation. Current manual methods rely on impacting the cup in line with an alignment guide relative to the operating table, which is assumed to be perpendicular to the patient's APP. However, the resulting cup angles have been shown to differ significantly from the desired orientation, due to the unknown and variable orientation of the patient's pelvis on the operating table (Digioia III et al., 2000; Wixson, 2008).

Concerns regarding the accuracy of conventional alignment systems led to the development of computer-assisted surgery (CAS) techniques. Although CAS systems dramatically improve the accuracy of acetabular cup placement (Nolte et al., 2004), they are currently rarely used, generally due to increased operative time, extra cost and complexity, and the need to flip the patient from a supine to lateral position after digitizing the APP. Although recent developments have addressed some of these issues (Haimerl et al., 2012), there are still a number of barriers to use. As a result, CAS is not currently the standard of care. Recently, rapid-prototyped patient specific guides have been invented for cup placement (Hananouchi et al., 2010; Kunz et al., 2010), constructed from computed tomography (CT) scans before surgery. They are quick to use and reduce the total number of instruments required for the surgery. However, they require removing more soft tissue around the acetabular rim, which adds to the length of the surgery, and still have challenges to achieve good accuracy. Other disadvantages include: the cost for the rapid-prototyping service, the time-delay for ordering the patient-specific jig, patient exposure to additional radiation, and the difficulty to change the plan during the surgery. Another recent instrument, an adjustable patient-specific mechanical device called the Hip Sextant, provides good accuracy, even better than CAS in the author's series, in much less time since no intraoperative imaging is required and intraoperative changes to the preoperative plan are allowed (Steppacher et al., 2010). However, it requires a preoperative CT, additional costs and time to acquire the settings for the adjustable instrument, and requires two small additional incisions. An accurate, fast, inexpensive and non-invasive device for acetabular placement is still needed.

1.1.1 Optihip

As discussed above, each of the current techniques has advantages and disadvantages. We have developed a device that takes advantage of these techniques while minimizing or eliminating their disadvantages. We created an adjustable mechanical device, called Optihip, that can be preset to the correct orientation based on preoperative imaging of the pelvis (X-rays or CT scans) and intraoperatively sets a guide pin showing the desired orientation of the acetabular cup.

This technique takes advantage of the preoperative planning capabilities of the CAS and patient-specific methods, while being faster and less expensive than current CAS systems, and more flexible than rapid-prototyped instruments. For less invasiveness and to maintain the current surgical workflow, we limited our device to mount within the standard incision size of surgery, on recognizable landmarks near the acetabular rim. This was the desire of our collaborating orthopaedic surgeon and co-inventor, Dr. Jim MacKenzie, whose goal was to transfer his preop plan for acetabular orientation to the patient.

A PCT application was filed on October 21, 2013 (PCT/CA2013/000895) (Anglin, Akbari Shandiz, et al., 2013), with a priority date of October 22, 2012 from the provisional filing.

My thesis included both the design of the device and validation testing of the device in cadaveric specimens.

1.1.2 Hip imaging

While the Optihip device is designed to achieve the desired acetabular orientation, the question remains as to what that desired orientation should be. Some authors have emphasized that postoperative problems such as dislocation may occur even with well-oriented implants (Nishihara et al., 2003). For instance, patients who demonstrate a more flexed or extended pelvic orientation during standing or sitting before THA may require a specific adjustment in acetabular cup alignment to maximize stability and permissible hip range of motion (ROM). Therefore, a recommended safe zone taken as one standard for all patients may not be sufficient in addressing the dynamic issue of implant stability for each individual. Also, it has been shown that the functional behaviour of the pelvis influences the orientation of the acetabulum during daily activities such as sitting, standing, or lying supine (DiGioia et al., 2006; Lazennec et al., 2011).

These variations maximize the natural range of motion of the hip (e.g., maximize flexion in sitting or extension in supine positions), can affect acetabular cup alignment after THA, and should be taken into consideration during hip replacement surgery because they may interfere with postoperative stability in routine daily activities.

To address this problem, we originally planned to study differences between patients who have experienced problems (dislocation, impingement, edge loading, wear, higher metal ion levels, or reduced range of motion) following hip surgery and those who have not, to see whether patient factors, particularly pelvic flexion and acetabular orientation, affect the outcome, and whether we can use these patient factors to plan a better, more individualized acetabular orientation. The goal was to study a cohort of identified patients with good and poor results both radiographically and functionally to provide guidelines regarding how component orientation must be adjusted to each individual patient's anatomy and posture. Unfortunately, after obtaining ethics approval to access the large database of retrospective X-ray data for the Alberta Bone and Joint Health Institute (ABJHI) metal-on-metal study (ABJHI, 2006) , with known outliers as well as individual surgeon data, and after Karen Phillips and Pam Railton from ABJHI kindly and laboriously identified the appropriate patient numbers and clinical data, followed by anonymization, a large number of the relevant plain film X-rays had recently been discarded and of the remaining patients, only 6/100 had clinical issues, with different complications (elevated ion levels, dislocation, revision). While this was too few from which to create guidelines or to perform functional testing, we continued our valuable collaboration with the Scientific Visualization Group at the Zuse Institute Berlin (ZIB) to develop a novel technique to match a three-dimensional (3D) model of the pelvis to 2D X-rays, to make such retrospective studies possible in the future.

1.1.3 Measuring pelvic flexion and natural acetabular orientation

To measure pelvic flexion and natural acetabular orientation in various postures, both X-ray images and a 3D model of the patient's pelvis are needed. If CT or MRI images of the patient are available, a patient-specific 3D model can be registered to the X-ray. However, for most THA patients, only preoperative and postoperative X-ray images are available, which provide little information about the pelvis.

As an alternative technique, we worked with researchers at ZIB to develop a novel articulated statistical shape and intensity model-based (ASSIM) 2D/3D reconstruction method to address such a limitation. In this method, a patient-specific 3D model is reconstructed from the 2D X-ray image, by expressing the variance in anatomical shape and bone density of the pelvis and proximal femur between individual patients, while modeling the articulation of the hip joint, thus eliminating the requirement of having a CT of the patient (Figure 1-4) (Ehlke et al., 2014).

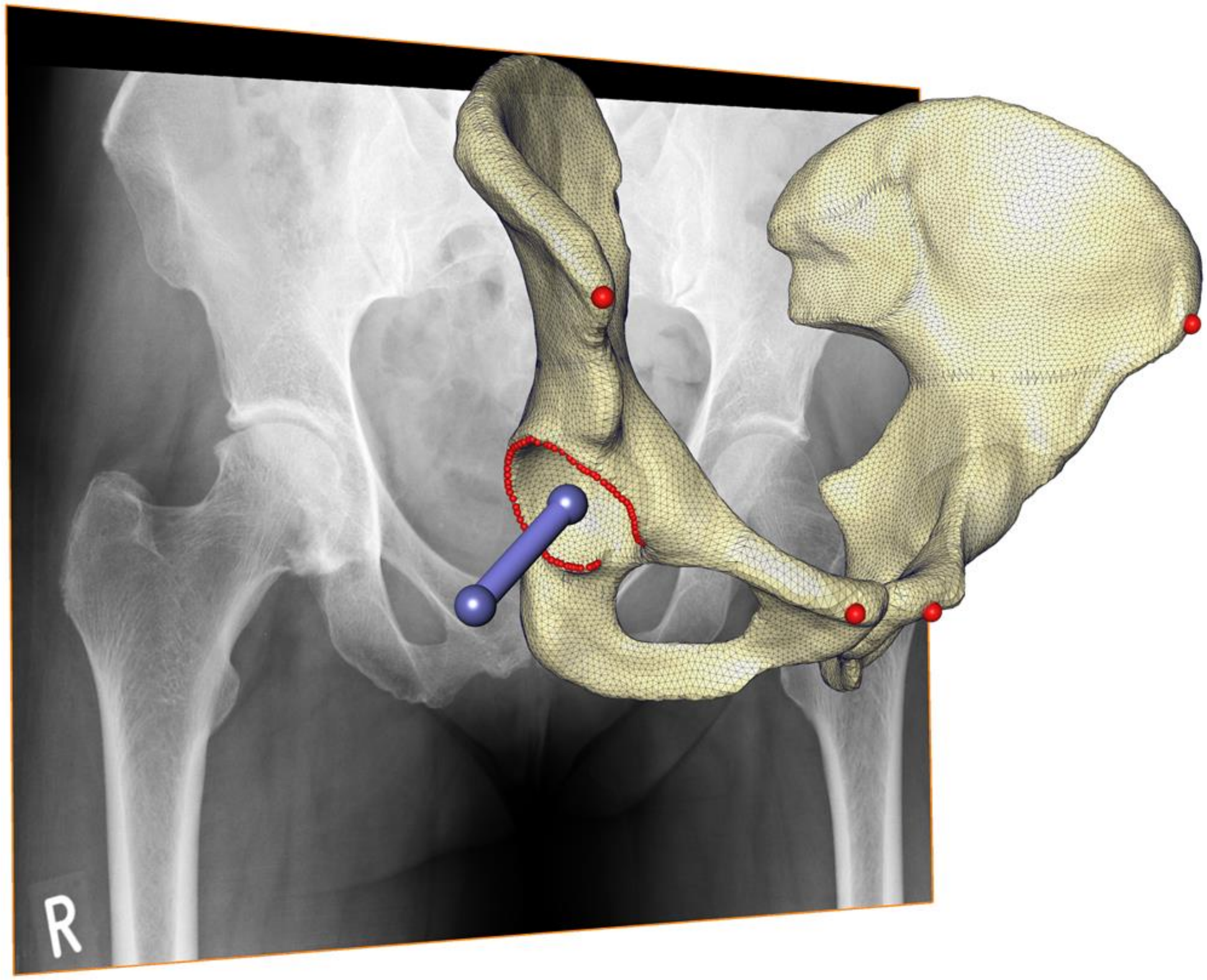


Figure 1-4. A 3D pelvis model is reconstructed from an AP radiograph using a novel articulated statistical shape and intensity model-based (ASSIM) 2D/3D reconstruction method (Ehlke et al., 2014).

Statistical shape models (SSM) derive from statistical shape analysis, which is an important tool for understanding anatomical structures from medical images (Small, 1996). Statistical shape models determine the normal variations in pelvic shape (e.g. wider and narrower), based on a large collection of sample data, and match these standard variations to find a suitable fit to the patient's individual X-ray. The first step is to extract the pelvic bone contours automatically from the radiographic images. These are then used together with the initial estimation of the scale as the input to the statistical shape model software, to create the corresponding 3D model. The ASSIM-based reconstruction technique considers the density of the pelvis and proximal femur as well as the anatomical shape of the pelvis, in order to use as much information contained in the X-ray as possible, to improve the accuracy of the 2D/3D reconstruction.

The remaining thesis work constituted a comprehensive study of knee kinematics, shape and quality of life of nine individuals before and after TKA.

1.2 Knee study

The knee joint is a complex synovial hinge-type joint, where a membrane encapsulates three articulating bones, consisting of the femur, tibia and patella. The articulating surfaces are covered with cartilage and menisci, in order to reduce the friction and distribute the loads between the articulating bones. The capsule is filled with synovial fluid, which lubricates the joint and also provides nutrients to the articular cartilage. The main knee movements consist of flexion and extension, along with rolling and internal-external rotation.

The knee is the most common joint to experience OA, a condition that can affect the articulating surfaces of the knee and cause destruction to the articular cartilage. In severe cases of osteoarthritis or other degenerative diseases such as rheumatoid arthritis the joint is usually treated with TKA (Badley et al., 2003; Mizner et al., 2011).

TKA replaces the worn surfaces of the femur, tibia and patella with metallic and plastic components (Figure 1-5). During surgery the anterior cruciate ligament (ACL) is sacrificed; the posterior cruciate ligament may be preserved (cruciate retaining) or not (posterior sacrificing or posterior stabilized). Both medial and lateral collateral ligaments are preserved.

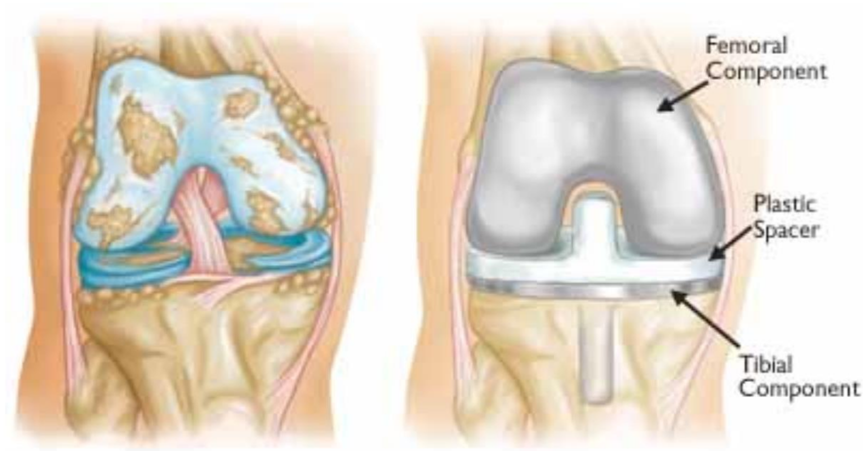


Figure 1-5: Total knee replacement (Reproduced with permission from OrthoInfo. © American Academy of Orthopaedic Surgeons. http://orthoinfo.aaos.org.).

TKA is usually considered a successful operation because only 5-10% of the patients will have a revision surgery within 10 years of the operation (Robertsson et al., 2001). Despite this success, TKA patients often comment that their knee does not feel “normal”; in other words, it does not feel like their natural knee.

Unfortunately, 57% of patients continue to have knee pain after TKA (Mannion et al., 2009), almost always worse than expected preoperatively, and fully 70% of patients do not have their functional expectations met (Mannion et al., 2009). Given the large and growing number of knee replacements each year (Kurtz et al., 2014), the proportion with moderate or severe pain postop (12%) or with moderate or severe functional limitations (13%) (Mannion et al., 2009) translates to a large number of individuals. In total, around 18% of patients are not satisfied with the outcome of their surgery (Baker et al., 2007; Dunbar et al., 2013). Even those who are satisfied with their knee replacement and are glad to have the pain reduced or eliminated, are aware daily that they have a knee replacement.

The increase in the number of younger recipients of TKA supports the need for implant designs that provide greater stability, better functional outcomes, and longer survivorship. Ideally, the goal should be to reproduce normal kinematics as closely as possible – a challenge given the altered joint state both before and after surgery.

1.2.1 Knee kinematics

An important factor affecting pain, function, satisfaction and revision is knee kinematics. Many factors can affect knee kinematics following TKA, including implant design, component position and soft tissue tensions (Harman et al., 2012; Matsuzaki et al., 2013; Mikashima et al., 2013), as well as the preoperative kinematics (Lizaur et al., 1997; Ritter et al., 2003; Schurman et al., 1998). In a study of 5 subjects with persistent postop pain compared to 25 subjects without, three showed abnormal kinematics (Saevarsson, 2012).

Although the general goal is to achieve ‘normal’ kinematics, neither the average nor the range of normal *in vivo* kinematics before and after TKA are known, especially for the patellofemoral (PF) joint and some DOF of tibiofemoral motion, nor are the changes due to TKA for individual patients known. *Ex vivo* studies (Belvedere et al., 2007; Bull et al., 2008) cannot fully replicate the physiological situation. The few *in vivo* studies reporting kinematics of osteoarthritic knees (Hamai et al., 2009; Nagao et al., 1998) and post-TKA knees (Yue et al., 2011) did not include PF kinematics nor do they provide insight into the changes due to TKA for an individual person. Although several studies have shown that post-TKA knee kinematics are different from the normal, healthy knee (Dennis et al., 2003; Harman et al., 2012; von Eisenhart-Rothe et al., 2007), these do not examine the direct influence of TKA on the same population and generally do not include all six DOF. Passive supine kinematics have been compared before and after arthroplasty intraoperatively (Anglin et al., 2008; Casino et al., 2009; Siston et al., 2006), but the influence of muscles, gravity and weightbearing during functional activities are not considered. A more recent study compared knee kinematics before and after TKA *in vivo* and under weightbearing, but did not study patellofemoral kinematics (Yue et al., 2011).

Full 6 DOF TF and PF kinematics are needed before and after TKA on the same individuals. Studying the same individuals before and after surgery increases the power of the study, and if one or more of the subjects presents a problem or is dissatisfied after the surgery, we are able to examine both their preop and postop kinematics to identify potential causes. Identifying such causes could help improve implant design or surgical technique.

1.2.2 Knee shapes

Another important factor which can affect QOL of TKA patients is the changes in knee shape after TKA, which has a direct impact on the knee kinematics as well (Bull et al., 2008; Clary et al., 2013; Digennaro et al., 2014; Harman et al., 2012; Matsuzaki et al., 2013; Mikashima et al., 2013; Stoddard et al., 2014; Whiteside et al., 2003). Patients who receive a knee replacement usually have malaligned legs (varus or valgus), malshaped knees (worn cartilage, osteophytes) and may have abnormal kinematics (patellar maltracking, poor range of motion) that require alteration during the surgery. Therefore, the knee shape will inevitably be changed as a result of the surgery. Furthermore, only a limited number of shapes and sizes of implants are typically available for each patient, necessitating compromises in the fitting of the components to the bones, and, as mentioned, one or both cruciate ligaments are removed during the surgery. As a result, the implanted knee has a different shape than the original natural knee. These changes can affect patellar tracking, range of motion, stiffness, stability, and pain. Implant designs are usually based on existing anatomy, without taking into consideration the changes that are made to the joint during surgery.

TKA component malalignment can cause major postoperative TKA complications such as ligament imbalance, uneven load distribution, early wear and loosening of the components (Callaghan et al., 2004; Hofmann et al., 2011; Loughead et al., 2008; Seil et al., 2011; Victor, 2009).

We are unaware of any studies that have compared the shape of the knee joint before and after arthroplasty comprehensively. A better understanding of the changes in knee shape and geometry could aid implant design as well as patient-specific planning using computer-assisted surgery or patient-specific instrumentation, to improve patient outcomes and satisfaction.

1.2.3 Quality of life data

Evaluating the outcome of TKA usually depends on the judgment of the surgeon, and is evaluated from postop clinical and medical image analysis and from talking with the patient at clinical visits. However, the patient's own perception and concerns may differ from the surgeon's, and not all information can be captured at the clinic visit. Therefore, methods of measuring the patient's satisfaction and quality of life after TKA are required. Different health-related quality-of-life questionnaires exist to document outcomes of TKA.

1.2.4 Relationships

Improvements in surgical techniques and implant design, such as appropriate use of lateral release, proper sizing of components, and external rotation of the femoral components all can help to decrease the incidence of post-TKA complications and to improve patient QOL. However, to our knowledge, a comprehensive study that evaluates the relationships between these clinically-relevant parameters related to knee shape and kinematics and correlates them with QOL of the TKA patients is lacking in the literature. A better understanding of the relationships between the knee shape and kinematics, and how their changes following TKA surgery affect patient QOL, could aid implant design as well as patient-specific planning using computer-assisted surgery or patient-specific instrumentation, to improve patient outcomes and satisfaction.

The purpose of our knee study was therefore to answer the following research questions, in a sample population of nine subjects:

(1) How do the knee kinematics differ before and after TKA surgery?

(2) How does the knee shape differ before and after TKA surgery?

(3) How do the changes in knee kinematics correlate with changes in knee shape? In particular, is patellar tracking affected by groove location?

(4) Does postop QOL correlate with changes in knee kinematics?

(5) Does postop QOL correlate with changes in knee shape?

(6) Do individuals with worse QOL differ from those with better QOL?

Our hypothesis was that significant differences and correlations do exist for these parameters.

1.3 Chapter outline

This thesis consists of the following chapters, prepared in manuscript format. There is necessarily some repetition of motivation and methods related to the commonalities between the studies; these were largely left in so that each chapter retains its independence. Chapter 2 has been published in the Journal of Engineering in Medicine (Institution of Mechanical Engineers, Part H). Chapters 3-5 have been submitted as manuscripts to peer-reviewed journals.

Chapter Two presents the cadaveric validation experiment for the device, Optihip, which we developed to improve the accuracy of acetabular cup alignment in hip replacement surgery.

Chapter Three investigates the impact of TKA on weightbearing *in vivo* knee kinematics of patients with severe OA, for all 6 DOF patellofemoral and tibiofemoral kinematics, tibiofemoral contact and helical axes of motion.

Chapter Four evaluates how the knee shape and geometry change after TKA, including color-coded maps of the distance between the original bone surface and the bone-implant surface, as well as numerical differences between key geometrical parameters.

Chapter Five creates and implements methods to correlate specific changes in knee articular geometry to the changes in knee kinematics and QOL of patients following TKA.

Chapter Six provides an overall discussion of the previous four chapters, including the novelty and contributions of the present work, conclusions, and future directions.

Chapter Two: **Accuracy of an Adjustable Patient-Specific Guide for Acetabular Alignment in Hip Replacement Surgery (Optihip)**

2.1 Introduction

Suboptimal placement of the acetabular component in total hip arthroplasty (THA) can lead to hip instability, impingement, increased wear, and reduced range of motion (De Haan et al., 2008; Hart et al., 2011; Langton et al., 2010; Lewinnek et al., 1978; Mahoney et al., 2003; Morlock et al., 2008; Widmer, 2007). Traditional manual instrumentation is based on the incorrect assumption that the patient's pelvis is perpendicular to the operating table. It also assumes that a single acetabular goal exists, regardless of individual patient variance. The clinical outcome can be compromised by the resulting improper placement.

Traditionally, the risk of postoperative problems is considered reduced if the acetabular component is oriented within a particular range of values called the "safe zone" (Callanan et al., 2011; Lewinnek et al., 1978). Although variations from this exist, the most common reference is still the anterior frontal plane of the pelvis (APP), which is formed by the most prominent aspects of the right and left anterior superior iliac spines (ASIS), and the right and left pubic tubercles. The accuracy of cup orientation is affected by the technique used to place the acetabular component (Wixson, 2008).

Surgeons use one of several techniques to determine cup orientation. Current manual methods rely on impacting the cup in line with an alignment guide relative to the operating table, which is assumed to be perpendicular to the patient's APP. However, the resulting cup angles have been shown to differ significantly from the desired orientation, due to the unknown and variable orientation of the patient's pelvis on the operating table (Digioia III et al., 2000; Wixson, 2008). Concerns regarding the accuracy of conventional alignment systems led to the development of computer-assisted surgery (CAS) techniques. Although CAS systems dramatically improve the accuracy of acetabular cup placement (Nolte et al., 2004), they are currently rarely used, generally due to increased operative time, extra cost and complexity, and the need to flip the patient from a supine to lateral position after digitizing the APP. Although recent developments have addressed some of these issues (Haimerl et al., 2012), there are still a number of barriers to use. As a result, CAS is not currently the standard of care. Recently, rapid-prototyped patient specific guides have been created for cup placement (Hananouchi et al., 2010; Kunz et al., 2010), constructed from computed tomography (CT) scans before surgery. They are quick to use and reduce the total number of instruments required for the surgery. However, they require removing more soft tissue around the acetabular rim, which adds to the length of the surgery, and still have challenges to achieve good accuracy. Other disadvantages include: the cost for the rapid-prototyping service, the time-delay for ordering the patient-specific jig, patient exposure to additional radiation, and the difficulty to change the plan during the surgery. Another recent instrument, an adjustable patient-specific mechanical device called the Hip Sextant, provides good accuracy, even better than CAS in the author's series, in much less time since no intraoperative imaging is required and intraoperative changes to the preoperative plan are allowed (Steppacher et al., 2010). However, it requires a preoperative CT, additional costs and time to acquire the settings for the adjustable instrument, and requires two small additional incisions. An accurate, fast, inexpensive and non-invasive device for acetabular placement is still needed.

An important aspect of all of the image-based methods is that the goal can be tailored to each individual. The safe zone definition has remained the same since its inception (Lewinnek et al., 1978), yet was based on a very limited dataset and does not take into account the large inter-individual variations in natural acetabular orientation (Murtha et al., 2008), or the differences in functional pelvic orientation between standing, sitting and supine (Dardenne et al., 2009; DiGioia et al., 2006), nor the relationship to other parts of the body, particularly the spine, that may impact how the hip can and will react to the new prosthesis orientation (J. Y. Lazennec et al., 2007; J.-Y. Lazennec, Boyer, et al., 2011; J.-Y. Lazennec, Brusson, et al., 2011). Although more research is required to determine what the acetabular orientation should be for each individual, an acetabular orientation device should be adaptable to any desired patient-specific goal, unlike current manual instrumentation.

We developed an adjustable mechanical device, called Optihip, that can be preset to the correct orientation based on preoperative imaging of the pelvis (X-rays or CT scans) and intraoperatively sets a guide pin showing the desired orientation of the acetabular cup. This technique takes advantage of the preoperative planning capabilities of the CAS and patient-specific methods, while being faster and less expensive than current CAS systems, and more flexible than rapid-prototyped instruments. For less invasiveness and to maintain the current surgical workflow, we limited our device to mount within the standard incision size of surgery, on recognizable landmarks near the acetabular rim.

In some situations, surgeons may wish to have guidance only for inclination, choosing to set the version based on intraoperative parameters since the version of the natural acetabulum, which can affect the chosen cup version, cannot currently be determined reliably from the standard anteroposterior (AP) X-ray (Thomas Kalteis et al., 2006) and there are more anatomical landmarks for version than for inclination (Abe et al., 2012; McGann, 1999; Pearce et al., 2008; Viste et al., 2011). Our mechanical device was designed so that it can focus on guiding the inclination angle only, if desired, which simplifies both the planning and the execution. For these cases, only a standard anteroposterior (AP) radiograph is required.

Full seating of the cup within the acetabular socket is also important to ensure bone ingrowth in the case of uncemented cups, and to avoid changes in femoral leg length and offset with lateralization of the component. In most cases, the first evidence of a poorly seated cup is on the postoperative X-ray. Repeating the depth of the trial cup, for which there is good visibility of the bone, in the final cup is particularly difficult for solid cups since there is no visibility of the bone through the holes, and other cases where visibility is compromised, including obese patients and minimally-invasive surgery. Although computer-assisted surgery (CAS) is well suited to guide the depth of insertion (Haaker et al., 2003), its use is not widespread. We are unaware of any mechanical instrumentation to address cup depth.

The aim of the current cadaveric study was to validate the accuracy of this mechanical device in guiding the acetabular cup orientation in total hip arthroplasty and to compare its results with historical control groups of THA from previous reports. We chose not to perform the conventional technique in comparison to the new technique because it was not possible to provide optimal conditions for using the manual method with cadaveric specimens. It was more valuable to have twice as many acetabular cups placed with the proposed device, to gain more experience and for better statistical power. Our hypothesis was that using an adjustable patient-specific mechanical device, preset to the correct orientation based on the preoperative images and planning, results in fewer outliers in acetabular cup orientation compared to current conventional techniques.

2.2 Methods

A total of 12 acetabular cups were placed in six fresh-frozen cadaveric specimens (three male, three female; average age 78) (Table 2-1) by two orthopaedic surgeons, using the adjustable device. The specimens were truncated from mid-femur to mid-spine. The two surgeons had very different experience levels - one was a surgical trauma fellow, the other an expert arthroplasty surgeon - and used different surgical approaches based on what they were most familiar with, allowing two different approaches to be tested. The expert surgeon, with experience of more than 2000 THAs, used a posterior approach whereas the surgical fellow, with 150 THAs at the time of testing, used a Modified Hardinge direct lateral approach. Our institutional review board approved the study.

Table 2-1. Specimen details.

Specimen #		**#1**	**#2**	**#3**	**#4**	**#5**	**#6**
Age		71	92	67	65	90	88
Gender		Female	Male	Male	Male	Female	Female
Arthritic State	Right	None	None	None	Mild	Mild	Mild
	Left	None	None	None	Mild	Mild	Mild

The device was first verified on artificial pelvis models, confirming the accuracy and experimental protocol and providing training for the surgeons. Functional and geometric testing of the device was then performed on cadaveric specimens (separate from those used in this study) to confirm the design dimensions and use before conducting the full testing.

Using the device involves: preoperatively planning the desired orientation relative to identified landmarks; preparing the hip joint surgically; marking the defined landmarks; placing the device on defined landmarks; inserting a guide pin at the desired orientation; aligning the cup impactor parallel to the guide pin; and finally implanting the component, matching the depth between the trial and final. Each of these is described in detail below.

2.2.1 Preoperative planning

The device is set based on preoperative 2D or 3D imaging. Inclination-only guidance requires only a standard AP X-ray. If both inclination and version guidance are desired, as for this validation experiment, then the third dimension of the pelvis is required. The easiest and most accurate way to do so is to CT scan the pelvis. Other possibilities, pending accuracy validation for this purpose, include: magnetic resonance imaging (MRI), 3D pelvis models derived from single-plane imaging (Ehlke et al., 2013) or 3D models derived from biplanar imaging, including EOS low-dose simultaneous-biplanar imaging (J. Y. Lazennec, Rousseau, et al., 2011). CT images can either be fully segmented to create a 3D model, or can simply be rotated to align with the APP, to acquire the two key slices, parallel and perpendicular to the APP.

For this experiment, CT scans were taken of each of the six specimens before the experiment to obtain the preoperative 3D pelvic model, and after the experiment to obtain the postoperative implant positioning. A 64-slice scanner (General Electric, Norwalk, Connecticut, USA), was used with the following parameters: 0.6 mm slice thickness, 0.4 mm increments, 120 kV, 700 mAs, 100 mm field of view, bone reconstruction kernel. The preoperative images were automatically segmented using statistical shape and intensity models developed at the Zuse Institute Berlin, followed by manual refinement, to create an accurate 3D model (Ho et al., 2012; Seim et al., 2008). The postoperative analysis is described below.

The key to templating from the preoperative imaging and replicating the desired angles on the patient anatomy was to identify repeatable, reliable landmarks as corresponding points on both the preoperative hip images and the patient anatomy. Four specific landmarks were selected as our device landing points: the teardrop and superior landmarks for guiding inclination, and the anterior acetabular notch and posterior landmark for guiding version (Figure 2-1).

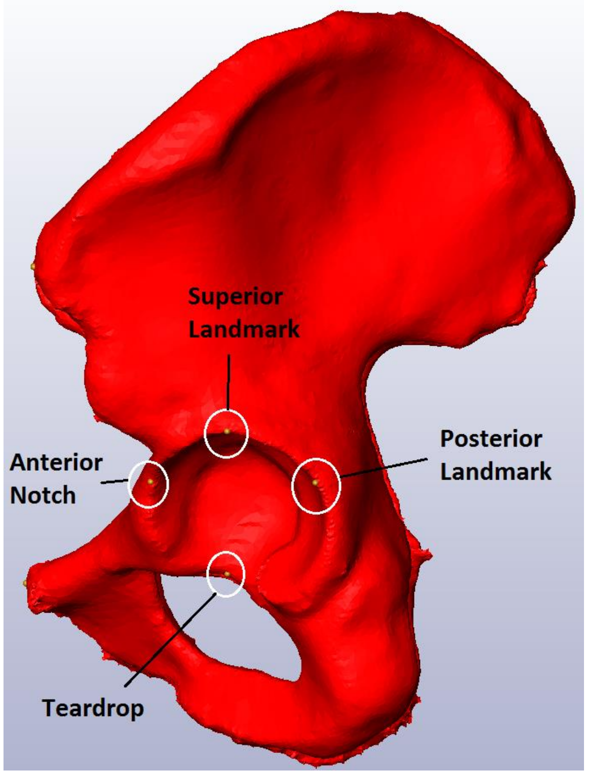


Figure 2-1. Four device landing landmarks : deepest point of the teardrop & superolateral point diametrically opposite within the plane parallel to the APP; deepest point of the anterior notch & posterior point diametrically opposite within the plane perpendicular to the APP.

On a standard AP X-ray, the teardrop (so named because it forms the shape of a teardrop on the AP image) and the lateral-most superior aspect of the acetabulum are routine clinical landmarks that are confidently identifiable around the acetabulum (Figure 2-2).

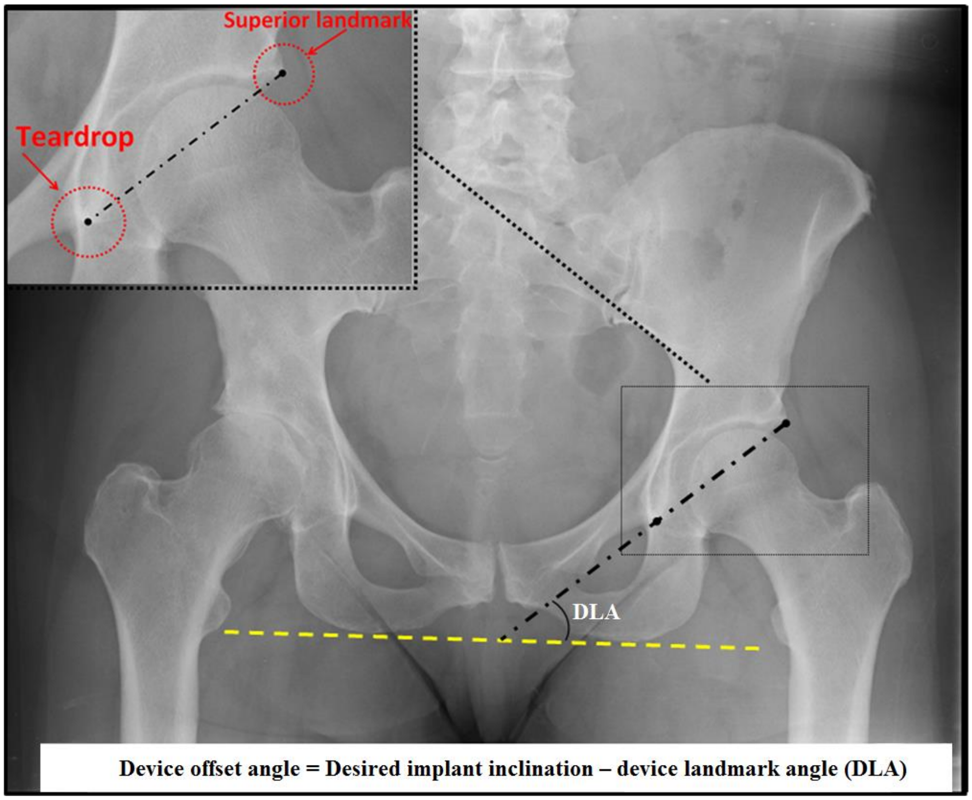


Figure 2-2. Preplanning the cup inclination angle and device offset on a standard AP X-ray when only inclination guidance is desired.

On 3D imaging, the teardrop and anterior acetabular notch are likewise identifiable (Ha et al., 2012) and the superior and posterior landmarks are found diametrically opposite, as described below.

Although we guided both inclination and version in this experiment, the inclination-only procedure, based on the AP X-ray, will be described first, for greater clarity. The device landmark angle (DLA) is measured as the angle of the line passing from the superolateral edge of the acetabulum (superior landmark) to the teardrop of the acetabulum relative to the pelvic horizon, defined by connecting the medial and lateral ischial tuberosities or teardrops (Figure 2-2). This value averaged 36° for our specimens. Note that the device landmark angle is less than the acetabular plane angle since the notch corresponding to the teardrop drops below the plane of the natural acetabulum.

The next step is for the surgeon to decide the desired angle for the implant, relative to the pelvic horizon. This may be a standard number for all patients (e.g. 40º, as defined for the safe zone) or can be templated individually to any value (e.g. 34º). The device is then set according to the difference between the desired implant inclination and the measured DLA inclination:

Device offset angle = Desired implant inclination – device landmark angle (DLA) (Eqn 1)

Using the example numbers given above, this results in: device offset angle = 40º- 36º = +4º, i.e. more ‘open’, or device offset angle = 34º-36º = -2º, more ‘closed’.

If both inclination and version guidance are desired, then the 3D pelvis model or unsegmented CT scan is oriented parallel to the APP, after which slices are created through the teardrop, parallel to the APP (similar to a standard AP X-ray) and transversely perpendicular to the APP through the anterior notch (Figure 2-3). The DLA is defined separately for inclination and version, based on the angle of the landmarks relative to the two plane perpendicular to the APP (Figure 2-3).

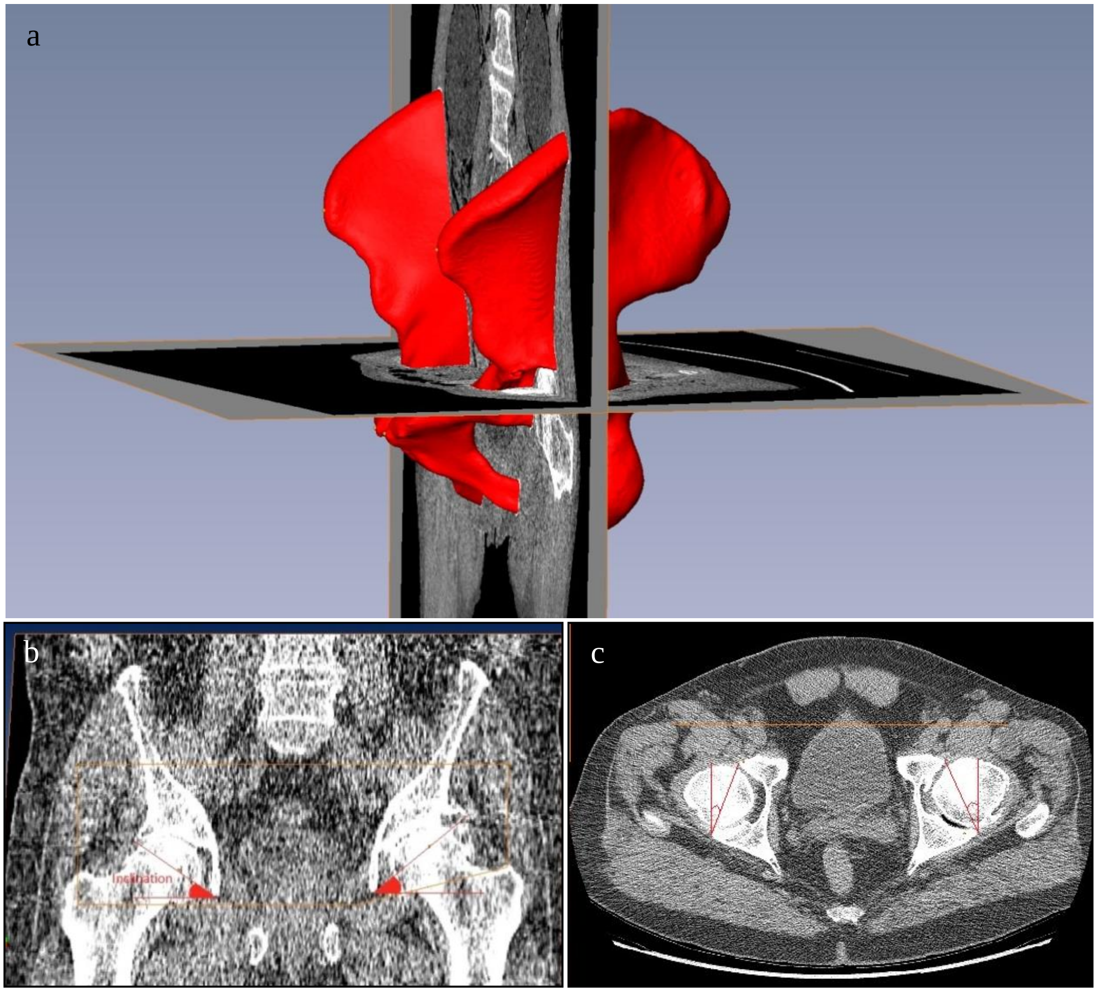


Figure 2-3. Preplanning the inclination and version offsets on a pelvis CT scan.

The surgeon then defines the desired implant angle for both inclination and version using either a consistent or individualized goal, e.g. 40º inclination/15º version for all subjects or, for example, 34º inclination/19º version for a particular subject. Equation 1 is applied to establish the device settings for both inclination and version. For our experiment, we generally had 2º increments available from -10º to +10º, with multiple offset options per slider. The nominal goal was 40º inclination and 20º version, which is the senior surgeon's normal goal. Based on the preop planning, we chose the closest offset angle within 2º, favouring less than 20º for version, to approach the typical safe zone goal of 15º. If the nominal offset angle was not available, a different offset was selected and the preop plan adjusted accordingly since our purpose was to test how closely we achieved the intended goal rather than to target a single goal for all specimens.

To determine the inter-observer repeatability of selecting the four landmarks, two observers selected the landmarks on all six specimens and the inclination and version DLA were measured. To determine the intra-observer repeatability, one of the observers performed three repetitions on all of the specimens and five repetitions on one, performing the repetitions in random order to avoid memorizing the landmarks. The other observer performed four repetitions on one of the specimens. The experimental settings were based on the first set of landmarks measured.

2.2.2 Device description

The Optihip device consists of an elongated base with a V-shaped landing surface (edge), a perpendicular slider with multiple positioning openings along its length, and a handle to position the base onto the landmarks (Figure 2-4) (Anglin et al., 2013). The V-shape of the base secures the device placement on the acetabular rim and also allows easy rocking of the device to align in the other dimension, as explained below. Each of the positioning openings on the slider corresponds to a predetermined positioning angle setting (e.g. +4º or -2º) such that, when a bone pin (k-wire) is inserted into the slider it points in the direction of the planned cup orientation. In other words, the bone pin is angled relative to the acetabular landmark line to align with the desired implant angle. It has been shown that surgeons can achieve appropriate alignment of implants when holding the cup impactor parallel to a given line (Murphy et al., 2011).

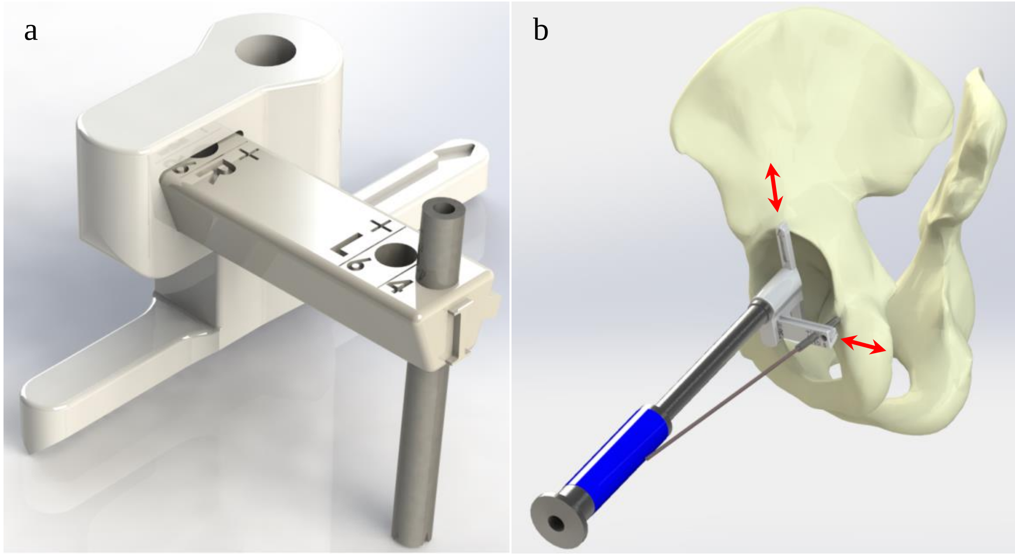


Figure 2-4. An adjustable patient-specific mechanical guide (Optihip)for guiding acetabular cup orientation in hip replacement surgery: (a) V-bottomed landing base, slider with selection of offset holes and sheath for the bone pin; (b) mounted on the pelvis to insert a bone pin for inclination guidance, posterior approach.

A special effort was made to consider human factors such that the device was more ergonomic to use, both to ease the learning curve for our users and to prepare for clinical implementation. Specific features include: a dovetail keyway feature on opposite sides of the inclination and version sliders (marked I and V, respectively) as well as R(ight)/L(eft) marks on the sliders to ensure the correct positioning on the right and left acetabula (Figure 2-5). Two different sizes of the device were available to accommodate different sizes of acetabula. The models used in this experiment were rapid-prototyped using an acrylic-based material (Objet Connex500 3D printer, VeroClear transparent material). Future models could be made from metal or plastic.

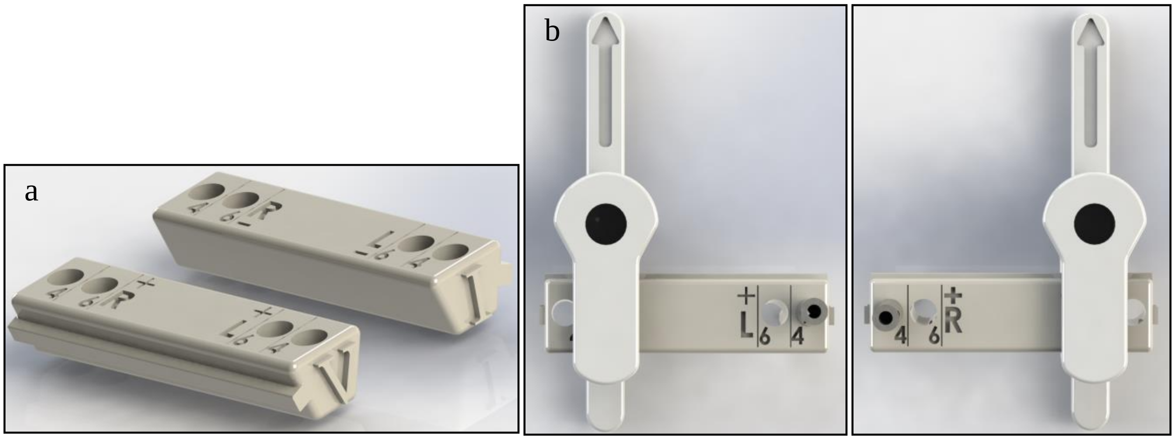


Figure 2-5. (a) The keyway and (b) R(ight)/L(eft) marks help the surgeon to select the appropriate direction when inserting different sliders, to guide inclination and version correctly.

Locating the device landmarks precisely during surgery is also important. To help the surgeon transfer the preoperatively planned sets of landmarks accurately to the patient, we developed a set of crosshairs – at fixed angles for the experiment, subsequently made into an adjustable device (Figure 2-6). This step is not essential, but was used in our experiments to improve accuracy and certainty regarding the points selected, and is recommended for future use of the device. In the previous imaging step, four virtual landmarks were identified, two each on the acetabular slices parallel and perpendicular to the APP, for inclination and version, respectively.

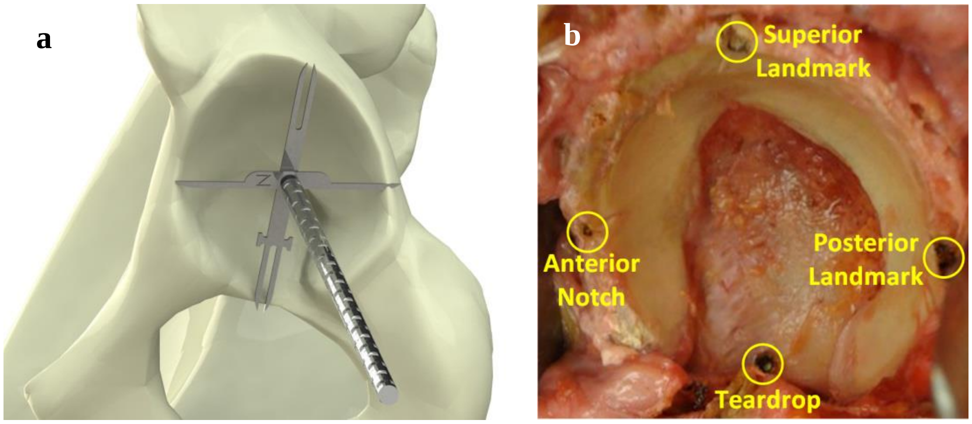


Figure 2-6. Crosshairs.(a) The crosshairs help the surgeon to define the device landmarks around the acetabular rim. The angle of the crosshairs is templated on the 3D model of the pelvis (Figure 2-7), in the plane of the acetabulum. (b) The surgeon then positions the crosshairs on the acetabular rim to mark the four device landmarks around the rim. The T-shaped arm is placed at the deepest point of the teardrop notch; the N-marked arm is placed within the anterior notch; the superior and posterior landmarks are then identified automatically based on where the crosshairs land on the acetabulum.

To determine the crosshair angles, a 2D projection view is created perpendicular to the best-fit plane to the four virtual landmarks (Figure 2-7). Although these two lines belong to two perpendicular planes, the angles of the landmarks are typically less than 90º to each other (averaging 74º in our series) because the projection plane is oblique to the APP (Figure 2-7). Custom software was created to find the best-fit acetabular plane and extract the crosshairs angle automatically. The crosshairs device is either placed over a printed image of the projected acetabular plane with landmarks, or over a goniometer with the designated angle, after which the tightening mechanism on the handle is rotated to lock the angle in place. The T-shaped end is used for the teardrop, the N-marked arm for the anterior notch.

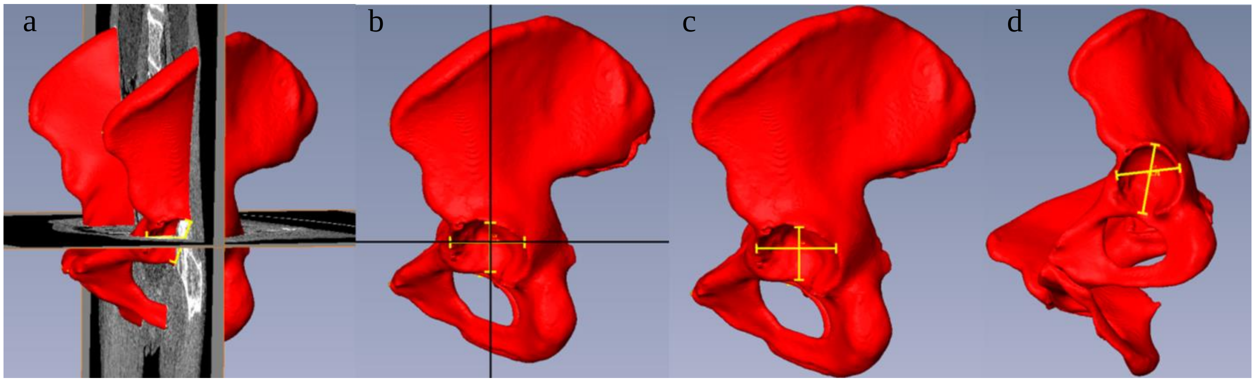


Figure 2-7. Templating the crosshairs on the 3D model of the pelvis.(a) The legs of the crosshairs point in the directions of two lines in space, belonging to two planes, parallel and perpendicular to the APP, seen (a) in an oblique view of the pelvis; (b) the direct lateral view shows the perpendicular planes; (c) virtual landmarks are created where the planes cut the acetabulum; (d) the resulting crosshairs angles are projected onto the best-fit plane to the four virtual landmarks (range 70.8º to 80.4º) for our specimens. The angle is no longer 90º due to the obliquity of the acetabular plane to the APP. This step is not essential to use of the device, but decouples version and inclination when rocking the device, and simplifies the landmark localization during the surgery.

To complete the guidance of the acetabular cup placement, we also created a depth gauge: a rigid flag with 1 mm horizontal parallel slots, spaced 2 mm apart (Figure 2-8). This was attached to the bone pin and then juxtaposed against the impactor, to match the final cup depth to the trial cup depth (Anglin, Akbari Shandiz, et al., 2013). To our knowledge, this technique has not been used previously. A similar system was developed for the situation in which the trial and final impactors are different (Anglin, Akbari Shandiz, et al., 2013). Although the depth gauge was used in our experiments, the accuracy of depth matching was not measured quantitatively.

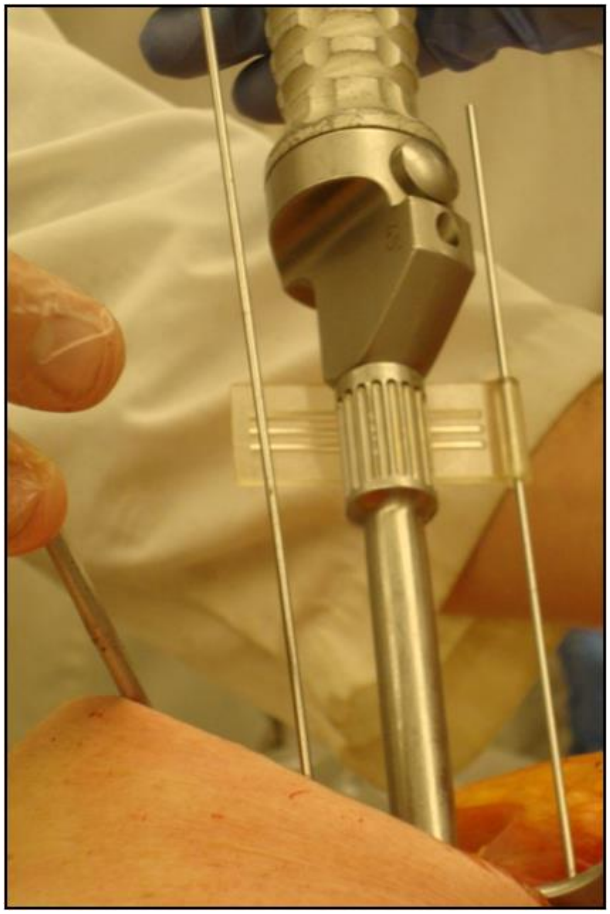


Figure 2-8. Depth gauge mounted onto the bone pin. Depth gauge mounted onto the bone pin. After inserting the trial component, the depth gauge is slid up or down on the bone pin such that one of the slots aligns with a chosen landmark on the impactor. The final cup is then inserted until the chosen landmark aligns with the slot again.

All specimens were thawed at room temperature for at least 24 hours prior to testing. The selected specimen was then placed in the lateral position and attached to a custom mounting via screws to ensure stability. The surgeon used his standard surgical approach, posterior or direct lateral, after which he removed the femoral head, acetabular labrum and transverse acetabular ligament (TAL). The device can be used with the TAL in place, but both surgeons typically remove the TAL clinically for better visibility, so this was repeated in the experiments. The specimens had primarily normal anatomy, without major osteophytes or deformed geometry, with no arthritis to mild arthritis (Table 2-1). If osteophytes were present clinically, they would be left in place until the guide pin is placed, after which they can be removed.

Once the acetabulum was ready, the crosshairs were positioned on top, with the key landmarks being the deepest point on the teardrop and anterior notch, and the remaining two, the superior and posterior points, being defined across the acetabulum by the crosshairs angle. The four landmarks were then marked with a soldering iron (clinically a cautery tool would be used) for easy reference when placing the device (Figure 2-6).

2.2.3 Placing the device on the landmarks and inserting a guide pin at the desired orientation

The version slider was selected with the appropriate offset angle (e.g. +4º or -2º), and inserted into the Optihip base with the appropriate R/L side extended out from the base. To minimize bending of the pin, a 3.5 mm outer-diameter, 2.5 mm inner-diameter, 2.5 cm long sheath, extending from above the slider down to the bone, was inserted into the appropriate hole. The device was then placed onto the version landmarks, translated back and forth and the slider moved in and out until a convenient location was found above the superior rim (Figure 2-9).

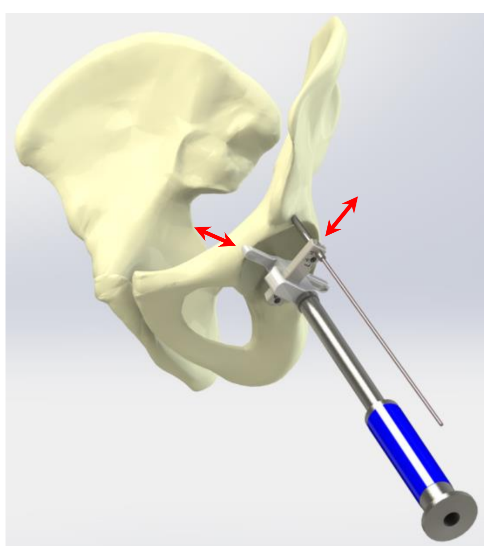


Figure 2-9. *Version pin* placed above the superior rim for both surgical approaches.

The device was then rocked towards the rough direction of inclination (to simplify later visualization), and a 2.5 mm diameter bone pin inserted through the sheath. (Alternatively, inclination could be set first). The pin was drilled into the bone and the device removed. The appropriate inclination slider was then selected and inserted into the device, together with the sheath, after which the device was placed onto the inclination landmarks, translated as needed, and the slider adjusted as needed to achieve a convenient location either on the ischial saddle (posterior approach) (Figure 2-10a) or above the superior rim close to but separate from the version pin (direct lateral approach) (Figure 2-10b). It was then rocked to align visually with the version pin and a second 'combined' bone pin inserted that could now guide both inclination and version (Figure 2-10c). Due to the crosshairs landmark positions, the inclination and version directions are decoupled and no changes occur in inclination when matching the version angle. The first pin could be removed at this point, but was left in for the experiment.

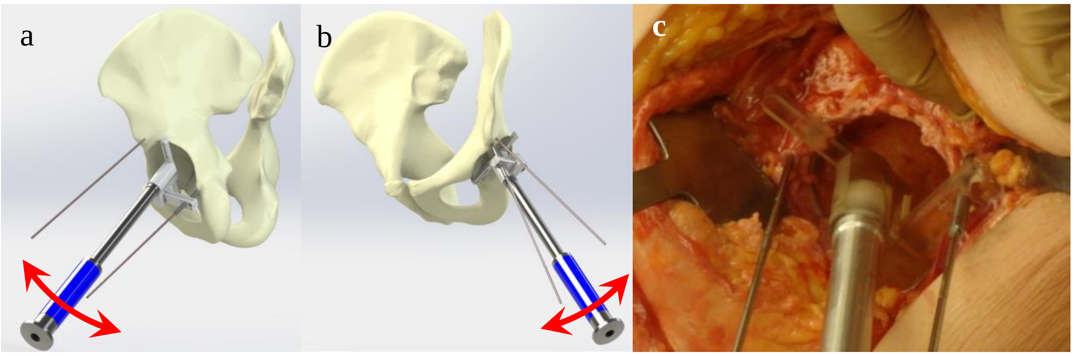


Figure 2-10. (a) Combined pin inserted into the ischial saddle for the posterior approach, and (b) into the superior rim for the lateral approach, using the device on the teardrop and superior landmark, while (c) matching the version of the version pin. A metal sheath (c) was inserted into the slider hole to create a more rigid line to the bone surface.

2.2.4 Reaming, trial component and final component impaction parallel to the combined pin

The surgeon reamed roughly parallel to the combined inclination+version pin and then inserted the trial cup, carefully aligning the impactor handle visually parallel to the combined pin. After inserting the trial cup (sized line-to-line with the reaming to avoid press fitting), the surgeon confirmed his satisfaction with the depth and orientation. The surgeon then slid the depth gauge onto the bone pin, aligned one of the gradations (slots) on the flag to an identifiable point on the impactor handle, replaced the trial cup with the final cup on the impactor, and impacted the final cup until the same point on the impactor was aligned with the same slot. Reaming was typically 2 mm under-sized, allowing a press-fit on the final uncemented cup. Although the surgeon could sometimes recognize that the cup was not exactly parallel with the pin after placement, the cup was not repositioned, in order to maintain a good press-fit. Clinically the pins would be removed at this point, but were left in for the experiment. The cup positioning was then complete (Figure 2-11).

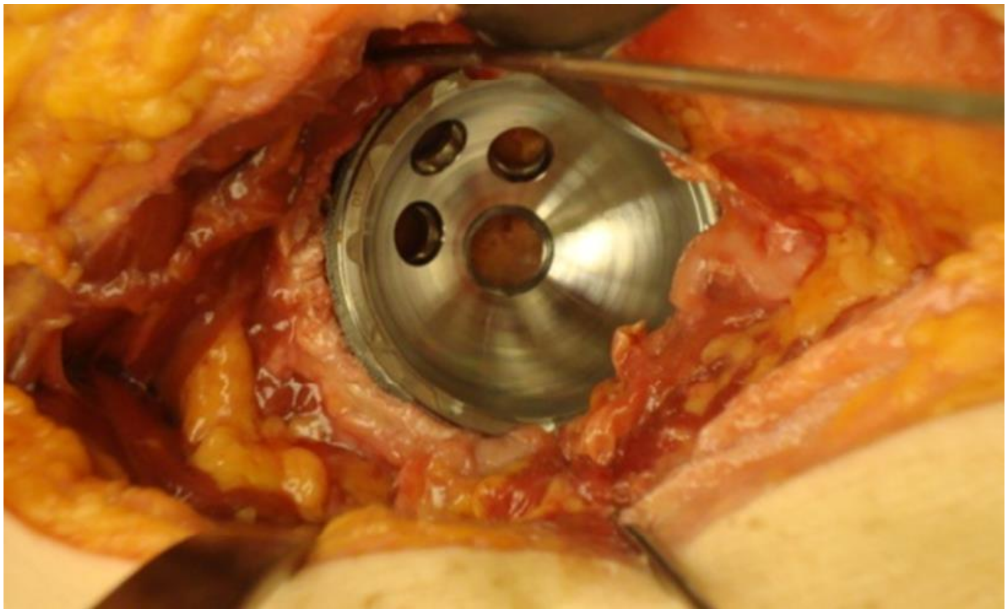


Figure 2-11. Cup insertion using the Optihip adjustable patient-specific mechanical device. The implant is impacted parallel to the final guide pin.

2.2.5 Summary of procedure

In summary, the intraoperative steps are: mark the four landmarks, select the sliders with the appropriate offset angle, use the device to insert a first pin (either inclination or version), use the device to insert a second combined pin by rocking it to align with the first pin, and then insert the cup by aligning with the combined pin. If only inclination guidance is desired, then only one pin needs to be inserted and the surgeon can set the version according to their current method.

2.2.6 Simulation of inclination-only option and investigation of pelvic tilt effects

Since we could not test the option of guiding inclination-only (in which the surgeon chooses their own version intraoperatively) without more specimens, we simulated the inclination-only accuracy by determining the device landmark angle from pseudo-X-rays, digitally created from the pelvis CT scans using image analysis software (ZIBAmira, version

2012-rc8; Zuse Institute Berlin, Berlin). We were unable to obtain X-rays directly of the specimens due to the equipment available and the biohazard risk.

Interpretation of plain pelvic radiographs is typically complicated by the wide variability in individual pelvic position relative to the X-ray plate (Anda et al., 1990). We therefore performed a study to evaluate the effect of pelvic tilt on the device landmark angle based on AP pelvic radiographs created from the CT models at different pelvic orientations. The pelvis was tilted around the interacetabular axis with 2^{o} increments (Figure 2-12). Tilt ranged from -10º posterior tilt to +12º anterior tilt, based on the variability of pelvic orientation in the literature (J.-Y. Lazennec, Brusson, et al., 2011; Tannast et al., 2005). We thus obtained a total of 12 digitally reconstructed radiographs (DRR) for each specimen in this study. We measured the inclination DLA and compared the results with our 3D CT-based measurements as the ground truth. Based on previous analysis, pelvic rotation has a negligible impact on the DLA: 0.3º±0.3º, across a full range of 9º rotation in either direction, with a maximum effect of 1.0º.

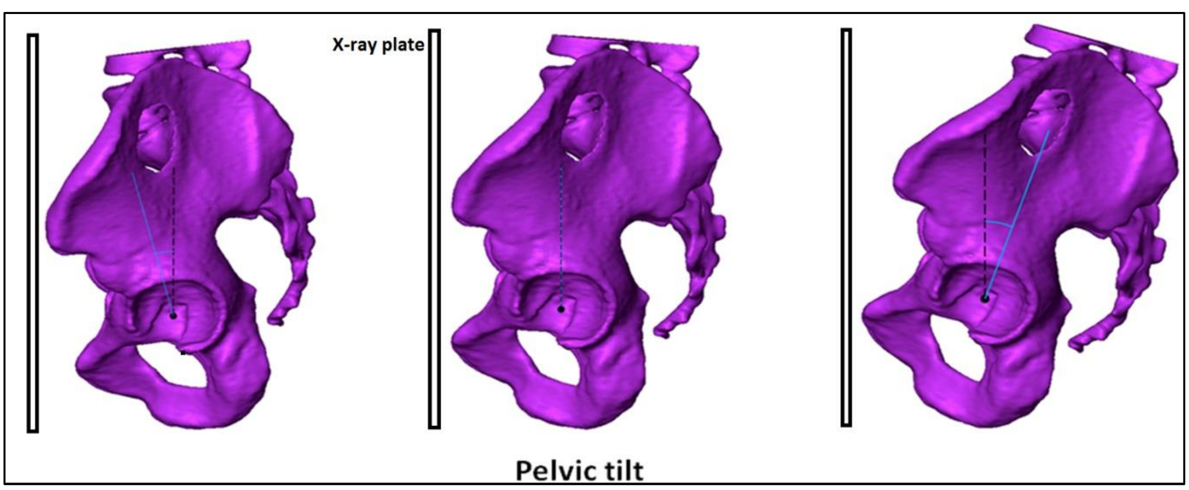


Figure 2-12. Pelvic tilt around the interacetabular axis, to evaluate the effect of pelvic tilt on the landmark measurements when made on a standard anteroposterior X-ray. A range of angles from -10º to +12º was evaluated.

2.2.7 Postoperative analysis

Cup orientation of the implanted components was determined relative to the APP from the postoperative CT scans. Using the unsegmented CT scan, the edge of the acetabular cup was easily identified on each slice, creating an ellipse for the cup edge from which the orientation was calculated. The operator was blinded to the preoperative plan when determining the postoperative cup orientation. The preoperative plan and the postoperative cup orientation were then compared to determine the mean absolute difference for each specimen as well as the range across specimens. The desired vs achieved cup orientation were compared statistically using a Student's t-test, with alpha = 0.05, to determine whether the difference was significant. The number of outliers greater than 10º, if any, and the average error were compared to literature reports for surgeons using conventional techniques, CAS systems and patient-specific guides.

2.3 Results

Mean absolute difference between the preoperatively planned acetabular inclination and the measured cup inclination from CT data was 2.5º (SD: 1.2º). Maximum deviation from the preoperatively planned angle was 4.7º (Table 2-2). Therefore there were no outliers greater than 10º.

Mean absolute difference between the preoperatively planned acetabular version and the measured cup version from CT data was 2.5º (SD: 2.2º). Maximum deviation from the preoperatively planned angle was 6.8º with 75% of the cups having a version angle within 2.5º (Table 2-2). There were no outliers greater than 10˚. Although the difference in cup inclination from the preoperative plan was small (averaging 2.5º absolute), the difference was significant ($p=0.02$) because the cup position was higher than planned in 10/12 hips. The difference in cup version was not significant (p=0.72). There were no significant differences based on surgeon (p=0.20 for inclination, p=0.87 for version).

Table 2-2. Preoperative planning vs. postoperative results of 12 acetabular cup placements.

Specimen #		**Device Landmark Angle (DLA) (º)**		**Device Offset (º)**		**Preop Planned Angle (º)**		**Postop Cup Angle (º)**		**Error (deviation from preop plan)**	
		Inc	Vers	Inc	Vers	Inc	Vers	Inc	Vers	Inc	Vers
1	Right	41.6	20.5	-2	-2	39.6	18.5	37.9	20.0	-1.7	1.5
	Left	41.3	16.9	-2	0	39.3	16.9	40.0	23.7	0.7	6.8
2	Right	37.0	15.0	+4	+4	41.0	19.0	43.3	17.0	2.3	-2.0
	Left	36.0	12.3	+4	+4	40.0	16.3	42.1	17.3	2.1	1.0
3	Right	34.1	17.0	+6	+2	40.1	19.0	44.1	19.4	4.0	0.4
	Left	34.0	21.7	+6	0	40.0	21.7	42.4	23.2	2.4	1.5
4	Right	29.3	20.7	+10	-2	39.3	18.7	41.2	14.1	1.9	-4.6
	Left	31.4	11.3	+6	+8	37.4	19.3	42.1	13.0	4.7	-6.3
5	Right	37.2	23.6	0	-4	37.2	19.6	40.9	19.6	3.7	0.0
	Left	32.8	18.3	+8	+2	40.8	20.3	44.1	18.0	3.3	-2.3
6	Right	36.3	22.8	+4	-4	40.3	18.8	37.7	16.7	-2.6	-2.1
	Left	37.3	22.2	2	-2	39.3	20.2	40.1	22.0	0.8	1.8
									Mean abs	**2.5**	**2.5**
									SD	**1.2°**	**2.2°**
									Max	**4.7º**	**6.8º**

By comparison, based on the review of historical case controls *in vivo* (Table 2-3, extended from a previous review (Hananouchi et al., 2010)), average inclination errors ranged from 3.7º to 6.3º for the conventional technique, 1.6º to 4.2º for CAS and 1.3º to 3.2º for patient-specific guides; average version errors ranged from 5.1º to 13.0º for the conventional technique, 0.2º to 5.3º for CAS, and 1.0º to 3.7º for patient-specific guides (Table 2-3). The percentage of outliers greater than 10º ranged from 20% to 83% for conventional techniques, 0% to 25% for CAS, and 0% for patient-specific techniques.

Table 2-3. Comparison of clinical studies on accuracy of the cup placement (where Conv. = conventional = mechanical guide aligned with the operating table).

Study	Method	Type	Incid. outliers	# Hips	Imaging method	Inclination accuracy (˚)	Version accuracy (˚)
DiGioia et al. , 2002	Conv.	*in vivo*	78.0%	74	CT	—	—
Saxler et al. 2004	Conv.	*in vivo*	83.8%	105	CT	—	—
Callanan, et al., 2011	Conv.	*in vivo*	49.7%	1823	X-ray	—	—
Kalteis et al. 2006	Conv.	*in vivo*	53.0%	30	CT	6.1 (0–16)	13.0 (0–38)
	Image-free navigation		10.0%	30	CT	3.6 (1–12)	4.2 (0–10)
	CT-based navigation		25.3%	30	CT	4.2 (0–11)	5.3 (0–14)
Bosker et al., 2007	Conv. (surgeons)	*in vivo*	19.7%	85	X-ray	4.1 (SD, 3.9)	5.1 (SD, 4.5)
	Conv. (residents)		36.5%	115	X-ray	6.3 (SD, 4.6)	5.7 (SD, 5.0)
Parrate et al., 2007	Conv.	*in vivo*	57.0%	30	CT	—	—
	Image-free navigation		20.0%	30	CT	—	—
Perlick et al., 2007	Conv.	*in vivo*	53.0%	30	CT	3.7° (SD,7.3°)	7.2° (SD,14.2°)
	Image-free navigation		7.0%	30	CT	3.2° (SD,4.0°)	0.2° (SD, 5.5°)
	CT-based navigation		17.0%	30	CT	1.6° (SD,4.0°)	4.3° (SD, 5.3°)
Sugano et al., 2007	Conv.	*in vivo*	27.9%	111	X-ray	—	—
	CT-based navigation		0%	59	X-ray	—	—
Babisch et al., 2008	Image-free navigation	*in vivo*	3%	98	CT	—	—
Hananouci et al., 2009	CT-based navigation	*in vivo*	0%	40	CT	—	—
Hananouci et al., 2010	Conv. + 3D planning	*in vivo*	23.7%	38	CT	5.1 (0.3–13.9;SD, 3.7)	5.2 (0.1–17.1; SD, 4.0)
	Tailor-made guide		0%	31	CT	3.2 (0.4–8.0; SD, 2.3)	3.7 (0.1–9.3; SD, 2.7)
Steppacher et al., 2010	CT-based navigation	*in vivo*	9.6%	146	2D/3D matching HipMatch	3.5 (-12.7–6.9; SD, 4.2)	3.0 (-11.8– 19.6; SD, 5.8)
	Adjustable mechanical guide		0%	70		1.3 (-6.6– 8.2; SD,3.4)	1.0 (-8.8–9.5; SD, 4.1)
Current study	Adjustable patient-specific mechanical guide	*ex vivo*	0%	12	CT	2.5 (0.7-4.7; SD, 1.2)	2.5 (0-6.8; SD, 2.2)

For selecting the four image landmarks, the intra-observer repeatabilities (standard deviations) of the inclination DLA and version DLA were 0.4º and 0.3º, respectively. The inter-observer repeatabilities (standard deviations) of the inclination DLA and version DLA were 0.9º and 0.7º, respectively, with maximum deviations of 1.9º in inclination and 1.6º in version.

Pelvic tilt with respect to the X-ray plane only had a small impact on the DLA compared to the 3D model (Table 2-4): the maximum error added to the inclination, averaged across specimens, was 0.7º (SD, 0.6º), maximum 2.3º across the full range of tilt angles; the maximum error subtracted from the inclination, averaged across specimens, was 1.0º (SD, 0.6º), maximum 2.4º.

Table 2-4. Effect of pelvic tilt on device landmark angle in inclination-only option from AP X-ray.

Specimen #	Average error added to true inclination		Average error subtracted from true inclination	
	Right	**Left**	**Right**	**Left**
1	0.1 (Max 0.3)	0.0 (Max 0.0)	-0.3 (Max -0.7)	-0.4 (Max -1.0)
2	0.4 (Max 0.7)	0.2 (Max 0.3)	-0.7 (Max -1.5)	-0.5 (Max -1.5)
3	0.1 (Max 0.1)	0.3 (Max 0.8)	-0.8 (Max -1.1)	-0.6 (Max -1.6)
4	1.3 (Max 2.3)	0.5 (Max 1.0)	-0.2 (Max -0.2)	0.0 (Max 0.0)
5	0.6 (Max 0.9)	0.2 (Max 0.6)	-0.5 (Max -0.5)	-0.3 (Max -0.8)
6	0.2 (Max 0.6)	0.8 (Max 1.3)	-1.2 (Max -2.4)	-0.3 (Max -0.6)
Average	**0.4±0.3 (Max 0.7±0.6)**		**-0.5±0.3 (Max -1.0 ± 0.6)**	

2.4 Discussion

This study demonstrated the accuracy and feasibility of an adjustable patient-specific mechanical device for guiding orientation and depth of the acetabular cup. The results were more accurate on average, and with a smaller standard deviation, than those reported *in vivo* for conventional hip arthroplasty, and comparable to those reported *in vivo* for current computer-assisted surgical techniques and patient-specific guides (Table 2-3). Note that most literature reports are from expert surgeons. The 0% outliers in the present experiment is a better result than both the conventional and CAS approaches, and matches the other patient-specific techniques. While clinical testing is required to confirm these experimental results, the positive *ex vivo* accuracy suggests good potential with this device. Furthermore, the similar results between the two surgeons suggest there is no effect with experience or surgical approach unlike the conventional approach (Bosker et al., 2007), which could reduce one of the highest risk factors for malpositioning, between high and low volume surgeons (Callanan et al., 2011). Since device use is independent of pelvis position, it is also well-suited to obese patients, another major risk factor for malpositioning (Callanan et al., 2011).

Our simulated inclination-only investigations show good potential for guiding inclination from an AP X-ray, demonstrating that 2D/3D projection and pelvic tilt have only a small effect on the DLA measurements on radiographs. The ability to guide only inclination is a unique feature of the device that led to its simplification.

There is increasing awareness that the surgical plan should be patient-specific, and that functional pelvic tilt and native acetabular orientation, amongst other factors, should be taken into consideration (DiGioia et al., 2006; J. Y. Lazennec, Rousseau, et al., 2011; J.-Y. Lazennec, Brusson, et al., 2011; Tang et al., 2000). This is coupled with greater availability of imaging and software planning tools, and more sophisticated image analysis algorithms. These make preoperative planning both desirable and possible. Implementing a patient-specific plan is very difficult with conventional instrumentation, hence the adaptability of newer techniques.

We note several limitations of our study. It was limited by the small number of specimens, with largely normal anatomy, and by having only two surgeons. Also, we did not record the extra time required for using this device to guide acetabular cup placement, since it was not a typical clinical situation; we therefore cannot compare our mechanical guide with other conventional or navigation systems in terms of time efficiency, although we anticipate good efficiency due to the small number of intraoperative steps required. A further limitation is that we compared the results of our study with historical control groups, which had different setups and were performed *in vivo*, but we achieved more power to our study by using the Optihip device on all 12 hips, and a comparison to the standard technique would not have been realistic in the anatomy lab setting. Clinical testing on a larger cohort of patients with multiple surgeons is in preparation.

Overall, these experiments demonstrated that an adjustable patient-specific mechanical device can be a viable tool for guiding the insertion of the acetabular cup, thereby reducing postoperative complications in hip arthroplasty and improving patient quality of life. The device is independent of pelvis position and can adapt to individualized goals. Clinical studies are needed to evaluate the safety and efficacy of this technology before adoption as a standard operative practice in THA.

Chapter Three: **Impact of Total Knee Arthroplasty on Knee Kinematics**

3.1 Introduction

Two major goals of total knee arthroplasty (TKA) are to treat severe osteoarthritic pain and to restore knee function. Unfortunately, 57% of patients continue to have knee pain after TKA (Mannion et al., 2009), almost always worse than expected pre-operatively, and fully 70% of patients do not have their functional expectations met (Mannion et al., 2009). Given the large and growing number of knee replacements each year (Kurtz et al., 2014), the proportion with moderate or severe pain postop (12%) or with moderate or severe functional limitations (13%) (Mannion et al., 2009) translates to a large number of individuals. In total, around 18% of patients are not satisfied with the outcome of their surgery (Baker et al., 2007; Dunbar et al., 2013b). Even those who are satisfied with their knee replacement and are glad to have the pain reduced or eliminated, are aware daily that they have a knee replacement (Noble et al., 2005).

An important factor affecting pain, function, satisfaction and revision is knee kinematics. Patellar maltracking and pain are often indicative of component malrotation or an incorrect resection, and abnormal tibiofemoral (TF) contact patterns can result in excess wear (Baldini et al., 2007; Barrack et al., 2001; Nishikawa et al., 2013). Many factors can affect knee kinematics following TKA, including implant design, component position and soft tissue tensions (Harman et al., 2012; Matsuzaki et al., 2013; Mikashima et al., 2013), as well as the preoperative kinematics (Lizaur et al., 1997; Ritter et al., 2003; Schurman et al., 1998). In a study of 5 subjects with persistent postop pain compared to 25 subjects without, three showed abnormal kinematics (Saevarsson, 2012).

The general goal is to achieve 'normal' kinematics, but neither the average nor the range of normal *in vivo* kinematics before and after TKA are known, especially for the patellofemoral (PF) joint and for all DOF of tibiofemoral motion, nor are the changes due to TKA for individual patients known. *Ex vivo* studies (Belvedere et al., 2007; Bull et al., 2008) cannot fully replicate the physiological situation. The few *in vivo* studies reporting kinematics of osteoarthritic knees (Hamai et al., 2009; Nagao et al., 1998) and post-TKA knees (Yue et al., 2011) did not include PF kinematics nor do they provide insight into the changes due to TKA for an individual person. Although several studies have shown that post-TKA knee kinematics are different from the normal, healthy knee (Dennis et al., 2003; Harman et al., 2012; von Eisenhart-Rothe et al., 2007), these do not examine the direct influence of TKA on the same population and generally do not include all six DOF. Passive supine kinematics have been compared before and after arthroplasty intraoperatively (Anglin et al., 2008; Casino et al., 2009; Siston et al., 2006), but the influence of muscles, gravity and weightbearing during functional activities are not considered. A more recent study compared knee kinematics before and after TKA *in vivo* and under weightbearing, but did not study patellofemoral kinematics (Yue et al., 2011). Full 6 DOF TF and PF kinematics are needed before and after TKA on the same individuals.

The tibiofemoral contact path and the helical axis of motion during different phases of flexion deepen the understanding of how the femur moves relative to the tibia before and after TKA. The relative movement can indicate or influence ligament tensions, how the knee feels to the individual, stability, range of motion and wear and provides further clues regarding the changes in kinematics resulting from TKA (Colle et al., 2012; Dennis et al., 2005; Varadarajan et al., 2008). TF contact studies do exist before and after TKA (Li et al., 2006; Varadarajan et al., 2008), but lack a clear consensus, even about the direction of pivoting, due to the small number of subjects and variety of prosthesis designs studied. Additional data are needed.

The helical axis of rotation (HA) is both a mathematical and geometrical method that provides insight into the nature of the knee motion by representing the 6 DOF motion of the tibiofemoral kinematics as a rotation about and translation along an axis, independent of the choice of anatomical coordinate system (Woltring et al., 1987). Due to the complex knee kinematics, the HA in the knee is not a fixed point in the sagittal plane, as would occur for a pure hinge joint (Freeman et al., 2003). The location and orientation of the helical axis differentiates sliding and rolling components of the movement, indicating the interaction between the femoral and tibial surfaces at each flexion phase. When the helical axis is close to the epicondylar axis of the knee, the knee acts primarily as a hinge, with the femur sliding against the tibia (Hollman et al., 2003). When the helical axis is close to the tibial surface, the knee is pivoting about that point indicating a rolling action. The anteroposterior location of the helical axis relative to the tibial plateau in general indicates where the femur is contacting the tibia.

The helical axis has been used to study the kinematics of osteoarthritic knees (Colle et al., 2012), post-TKA knees (Karrholm et al., 1994), and more recently during passive motion of the knee within the operating room before and after implantation of knee components (Wilson et al., 2013). However, we are unaware of any study that examines the position and movement of the helical axis on the same population before and after TKA *in vivo* and under weightbearing.

Studying the same individuals before and after surgery increases the power of the study, and, by prospectively measuring their kinematics before surgery, if one or more of the subjects presents a problem or is dissatisfied after the surgery, we are able to examine both their preop and postop kinematics to identify potential causes. Identifying such causes could help improve implant design or surgical technique. If all of the subjects were to have good results, this provides us with a database of normal, ‘good’ results, which can be used for later comparison to ‘poor’ results, or for building an accurate musculoskeletal model.

The purpose of this study, therefore, was to compare the detailed weightbearing kinematics of a group with debilitating osteoarthritis awaiting TKA to the same individuals a minimum of one year after surgery to determine their comprehensive preop kinematics, postop kinematics and changes in kinematics due to TKA.

3.2 Methods

3.2.1 Subjects

We imaged the knees of nine OA subjects (5 male, 4 female, ages 44 to 82) (Table 3-1) before and at least one year after TKA, using unique radiographic and computed tomography (CT) protocols that allow both PF and TF 6 DOF kinematics to be studied under weightbearing throughout the range of motion, with clinically available imaging systems (Ho et al., 2012; Sharma et al., 2012). Eleven patients agreed to participate in the study during the preoperative recruitment period; nine of the subjects agreed to return for the postoperative evaluation.

Table 3-1.Demographic data for the nine preop-postop subjects.

Subject #		#1	#2	#3	#4	#5	#6	#7	#8	#9	AVG
Age (years)		65	56	75	71	82	67	44	75	82	**68.6 yrs**
Gender		Female	Male	Male	Female	Male	Male	Female	Male	Female	**4F,5M**
BMI (kg/m^2)		38.1	22.7	30.5	27.2	23.6	31.5	38.3	31.6	20.4	**29.3**
Side		Right	Left	Right	Right	Right	Right	Right	Right	Right	**8R,1L**
Implant sizes	**Femoral**	3	4	6	3	4	3	3	4	2.5	**3.6**
	Tibial	3	4	5	3	3	4	2.5	5	2	**3.5**
	Patellar (mm)	35	41	41	38	35	41	35	41	32	**37.7**
	Insert (mm)	12.5	10	10	10	10	12.5	12.5	10	12.5	**11.1**

All subjects had a primary, cemented rotating-platform posterior-stabilized, multi-radial prosthesis (PFC® Sigma™ Mobile Bearing; DePuy Synthes Joint Reconstruction, Warsaw, IN), with a resurfaced all-polyethylene patella, and were operated on by a single expert surgeon. The surgeon used a femur-first, ligament-balancing technique, and used the manufacturer's patellar resection guide. After TKA, all subjects had good function and were satisfied with their TKA, judged on the basis that no further follow up or revision surgery were planned, and based on a question about satisfaction (see Chapter 5 for further details regarding quality of life). Our institutional review board approved the study and written informed consent was obtained from all subjects.

3.2.2 Sequential-biplanar sagittal radiographs

Two sequentially-biplanar radiographic images were acquired with an AXIOM Luminos dRF flat-bed fluoroscopy unit (Siemens; Berlin, Germany) at 8 knee flexion angles: 0^o, 15^o, 30^o, 45^o, 60^o, 75^o, 90^o and maximum flexion. Weightbearing at the different flexion angles was achieved by having the subject 'just about' step up onto steps of different customized heights. One image was taken with the X-ray source directly horizontal (sagittal) and the other with the source 10º below horizontal, with less than 5 seconds between the two orientations. Having two images from two different angles provided out-of-plane information. The two-dimensional (2D) images were calibrated using a calibration frame around the subject's knee and custom software (Sharma et al., 2012).

3.2.3 Obtaining 3D knee geometry

CT imaging of the subject's preop knee was used to create a 3D model of the preop knee bones (Ho et al., 2012). Images were acquired using a SOMATOM 64-slice CT machine (Siemens; Berlin, Germany) with the following parameters: slice thickness: 0.6 mm; slice increment: 0.4 mm; in-plane resolution: 0.35 mm × 0.35 mm. The CT images were then automatically segmented using statistical shape models developed at the Zuse Institute Berlin, with minor manual refinement, to generate femoral, tibial and patellar bone models (Figure 3-1a).

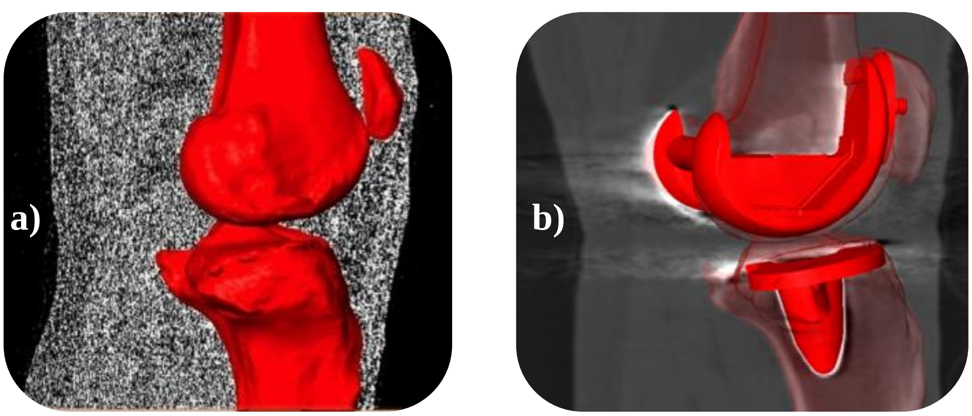


Figure 3-1. (a) 3D models of the femur, tibia and patella were segmented from preop CT images using statistical shape models followed by manual refinement; (b) 3D implant models, provided by the manufacturer, were fit automatically to the postop CT, allowing the relative bone-prosthesis positions to be determined.

A direct comparison between the preop and postop knee geometry and bone/implant positioning was achieved by CT imaging the subject's postop knee, with the leg raised using a custom knee rig to reduce the effect of the metal artifact through the patella. Coordinate systems were assigned to the manufacturer-provided prosthesis models using features on each component (Figure 3-2).

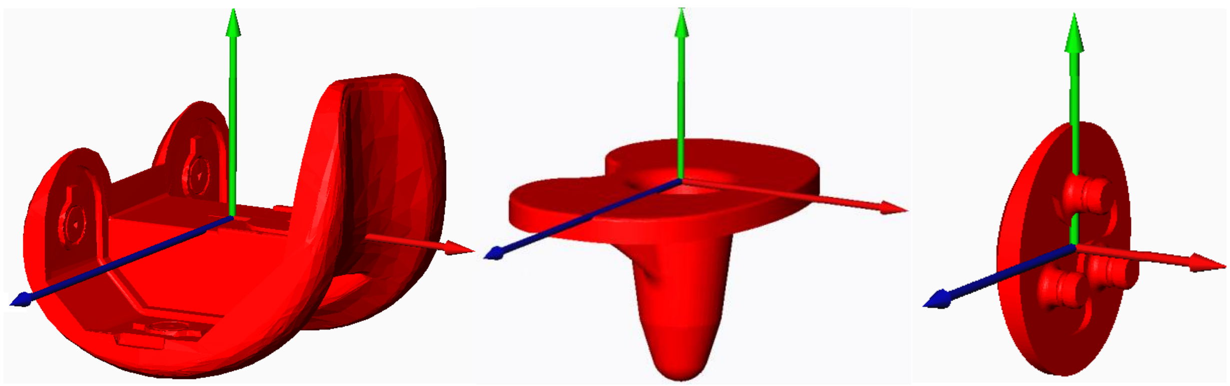


Figure 3-2. Post-TKA coordinate systems were defined using features on each prosthesis component. Preoperative kinematics in the bone coordinate systems were transformed to the prosthesis coordinate systems to allow for a direct comparison between preop-postop kinematics.

3.2.4 Image analysis

By performing the 3D-3D image matching using Amira software, the 3D preop knee bones models and component CAD models were matched to the postop CT scans to determine the postop placement of the femoral, tibial and patellar components relative to the bone models (Figure 3-1b) (Ho et al., 2012). In this way, a rigid transformation was determined between the coordinate system of the subject's natural knee (Ho et al., 2012) and the coordinate system of the subject's prosthesis components using ZIBAmira image analysis software. By knowing this transformation matrix, and in order to judge changes in kinematics accurately, both preop and postop kinematics were reported relative to a single coordinate system. For this study, the preop kinematics were reported with respect to the postop coordinate frame.

To determine the kinematics through the range of motion, the 3D bone or implant models were matched to each set of two 2D calibrated images using JointTrack Biplane open-source software (sourceforge.net/projects/jointtrack/) (Figure 3-3) (Acker et al., 2011).

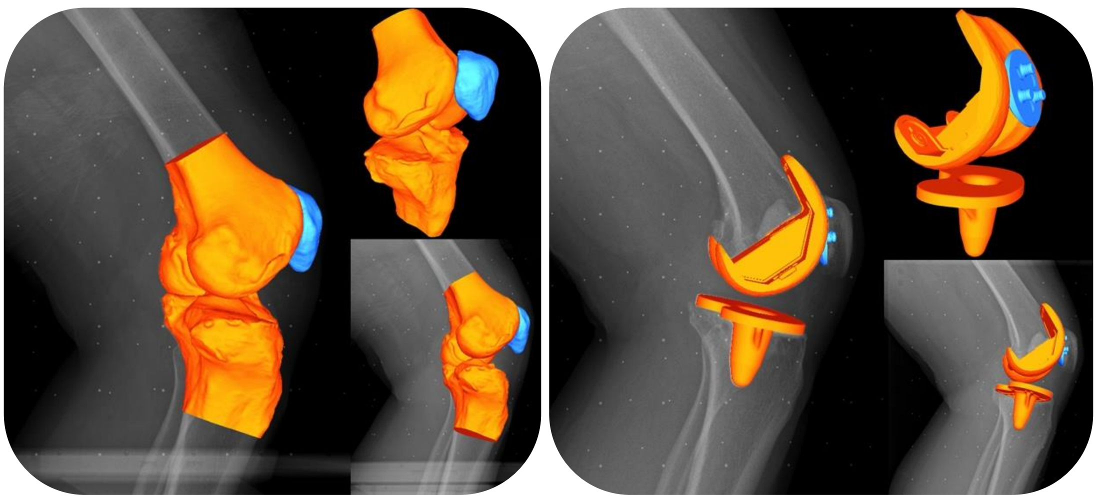


Figure 3-3. 2D/3D image matching was performed with JointTrack Biplane software to determine the knee kinematics before and at least one year after TKA.

To address slight patient movement between the two images, the 3D models were matched to each image separately, using the second image as a reference when matching to the first image, to aid 3D perception, and vice versa when matching to the second image. The results for each individual image were then averaged for better accuracy. The method can detect differences within 3 mm for translation and 3^{o} for rotation in preoperative analysis, except the 7^{o} error for PF spin, and 2 mm for translation and 2^{o} for rotation in the postoperative analysis, based on an analysis of intra- and inter-observer repeatability.

Three types of analyses were performed with the resulting 3D data: (1) preop and postop kinematics for each PF and TF degree of freedom (DOF), with TF flexion as the input parameter; (2) closest tibiofemoral contact points, to examine the relative motion of the femur and tibia; and (3) helical axis of rotation between each flexion angle.

3.2.5 Preop and postop kinematics for PF and TF degree of freedoms

Preop and postop kinematics were calculated using a custom Matlab program (version 7.14.0739 (R2012a), The Mathworks Inc., Natick, Massachusetts), based on the method described by Grood and Suntay (Grood & Suntay, 1983).

To provide a reference point, normal kinematics for healthy individuals were determined from the literature (Gill et al., 2009; Nha et al., 2008; Qi et al., 2013), with 7-8 subjects in each study and the average plotted against the present results. Although many studies reportedly compare to normal 'kinematics' this usually refers only to TF contact location or limited TF degrees of freedom, resulting in a paucity of complete normal data. Results for 25 subjects with a fixed bearing design (Zimmer NexGen LPS) (Saevarsson et al., 2013), using the same protocol as the present study, were included for a comparison of postoperative results. The exception in both cases is for the degrees of freedom in which differences in coordinate systems would have made a comparison misleading, primarily the anteroposterior and inferosuperior translations.

3.2.6 Tibiofemoral contact points

The closest proximity points between the femur and tibia on the surface of the medial and lateral condyles were determined for 0º, 45º, 90º and maximum flexion angle (using ZIBAmira), based on the 3D models matched to the biplanar 2D images (Figure 3-4). Only four out of the total eight flexion angles were chosen for better clarity. These contact points were projected down onto the tibial plateau to track the contact between the femur and the tibia, for both pre-TKA and post-TKA knee joints.

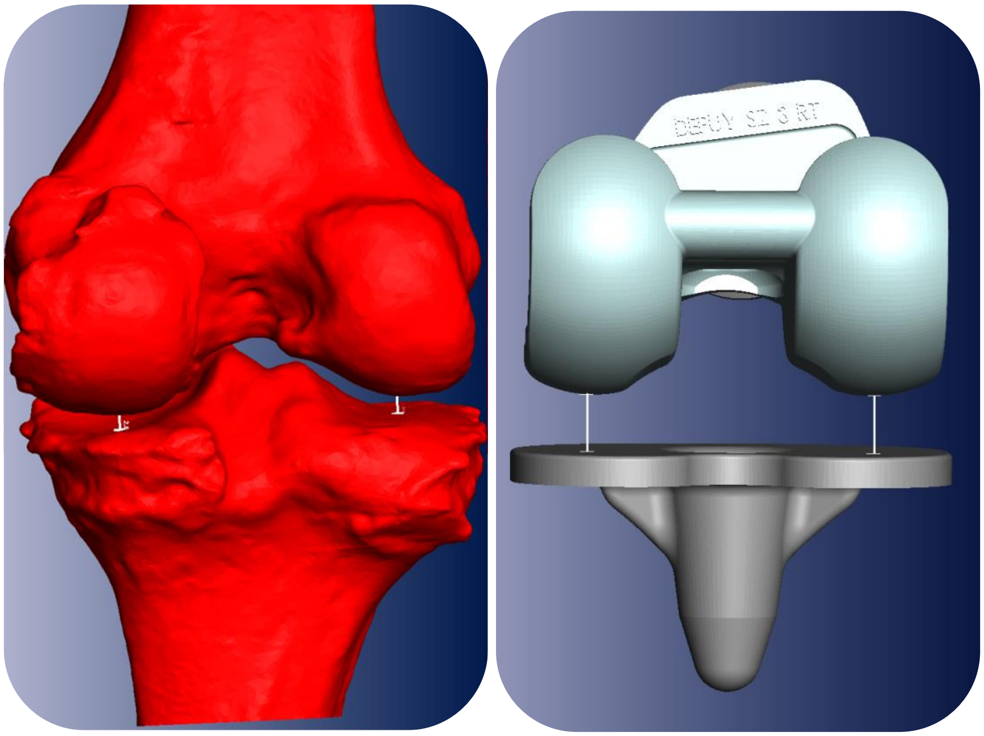


Figure 3-4. TF contact points were calculated and plotted using the closest distances between the femur and tibia on the surface of the medial and lateral condyles, excluding the cartilage and meniscus (preop) or tibial insert (postop).

Lines were drawn between the medial and lateral contact points for clarity, and to help define the pivoting location of the femur on the tibia: medial pivoting occurred when the lines connecting the contact positions at full extension and max knee flexion, visually intersected on the medial one-third of the tibia-superimposed line, lateral pivoting when they intersected on the lateral one-third, and central pivoting within the central one-third, corresponding roughly with the limits of the rotating bearing axis hole in the postop knee; there was no pivoting, just translation, when the lines remained parallel to each other and did not cross (Dennis et al., 2005).

3.2.7 Helical axis of rotation

The location of the helical axis of knee motion, i.e., the axis in space about which the tibia rotated, pre and post-TKA, was calculated and compared between each set of consecutive flexion angles (0-15º, 15-30º, 30-45º, 45-60º, 60º-75º, 75-90º, and 90º to maximum flexion). The axis was defined with respect to the coordinate system of the tibia, to be most consistent with the literature (Dennis et al., 2005; Karrholm et al., 1994; Wilson et al., 2013). For visualization purposes, the representative helical axis (HA) for each flexion interval was superimposed on femoral bone and component models with the median sizes among nine subjects, shown from the anterior, distal and lateral perspectives. Intersections of the HA with the medial and lateral sagittal planes (located at the femoral condyles) were also plotted to show the changes in position of the HA during each flexion interval.

3.2.8 Statistical analyses

Statistical comparisons were made between the preop and postop kinematics of the 9 subjects using an ANOVA for each degree of freedom; if significant, paired Student's t-tests were performed to examine differences at each flexion angle, with $p<0.05$ considered significant. TF contact was evaluated based on the number of knees with medial, lateral, central or no pivoting. Helical axes were evaluated based on the medial and lateral locations of the axes as well as their intersection with the sagittal plane.

3.3 Results

There were clear differences between pre-TKA and post-TKA kinematics for the nine subjects for all types of analyses performed. Post-TKA kinematics were in general closer both to normal and to those of the other implant (Figure 3-5, Figure 3-6). Even when group preop-postop differences were not significant, individual subjects showed substantial changes.

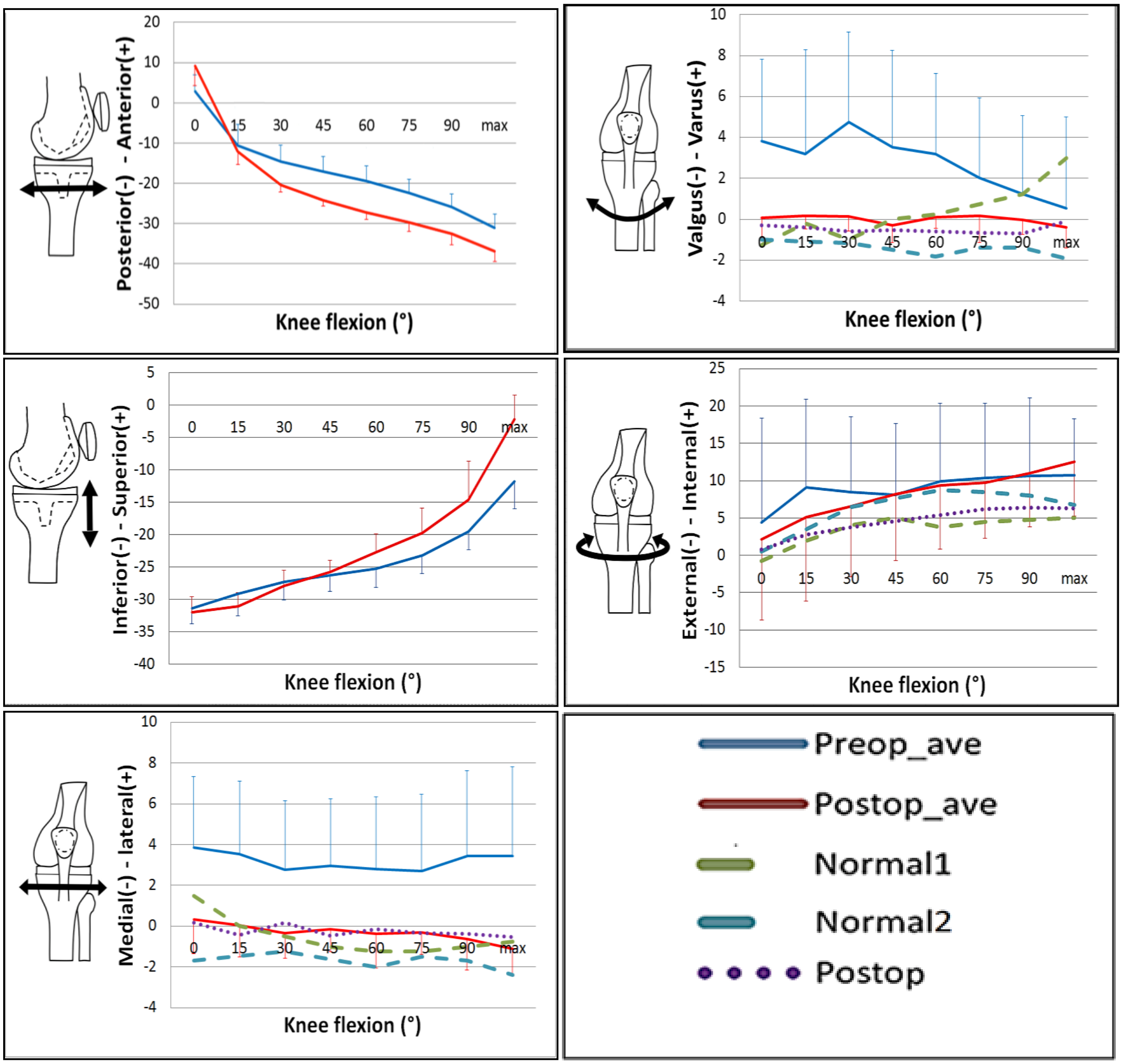


Figure 3-5. Tibiofemoral kinematics across the range of knee flexion. Blue = preop, red = postop (mean and standard deviation across the 9 subjects). Normal healthy data from the literature (7-8 subjects each). Green dashed line = (Qi et al., 2013), blue dashed line = (Gill et al., 2009). Data for 25 subjects with another prosthesis design are provided for comparison. Purple dotted line = (Saevarsson et al., 2013).

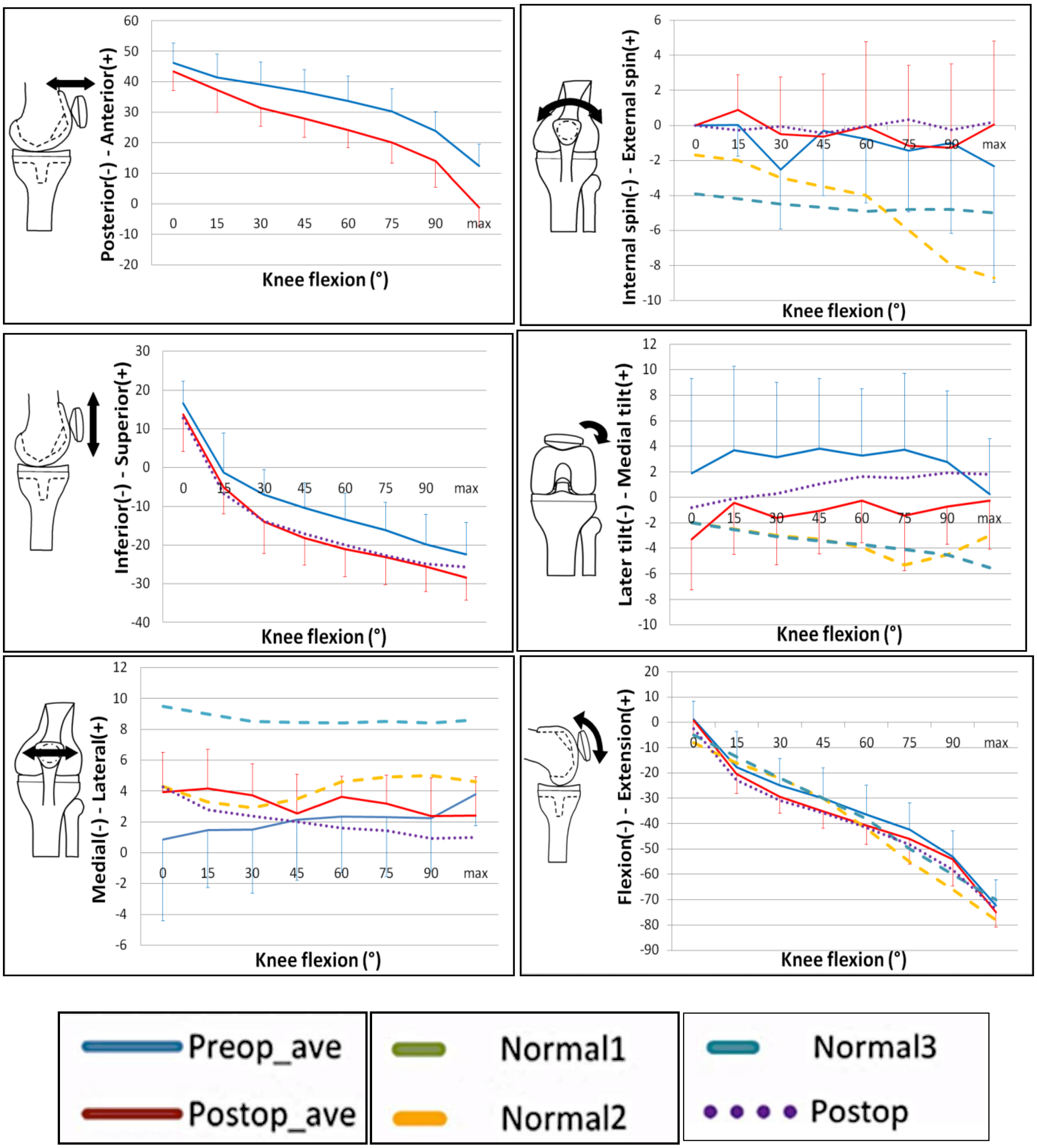


Figure 3-6. Six DOF patellofemoral kinematics across the range of knee flexion. Blue = preop, red = postop (mean and standard deviation across the 9 subjects). Normal healthy data from the literature (7-8 subjects each). Green dashed line = (Qi et al., 2013), blue dashed line = (Gill et al., 2009), yellow dashed line = (Nha et al., 2008). Data for 25 subjects with another prosthesis design are provided for comparison. Purple dotted line = (Saevarsson et al., 2013).

The largest differences were for TF varus/valgus in which the knee was more neutrally aligned postop ($p<0.004$ up to 60º flexion, based on the absolute difference) and for TF mediolateral translation, in which the knee was more centrally aligned postop ($p<0.03$). The tibia was more anterior postop in full extension ($p=0.01$) and more posterior from 30º onwards ($p<0.002$) as well as more superior from 75º onward ($p<0.05$).

Individual subjects demonstrated substantial preop-postop changes for TF medial/lateral translation, varus/valgus, and internal/external rotation. For TF mediolateral translation, in three subjects, a large difference exists (>4 mm) between pre and post-TKA kinematics with the tibia more lateral preop (Figure 3-7).

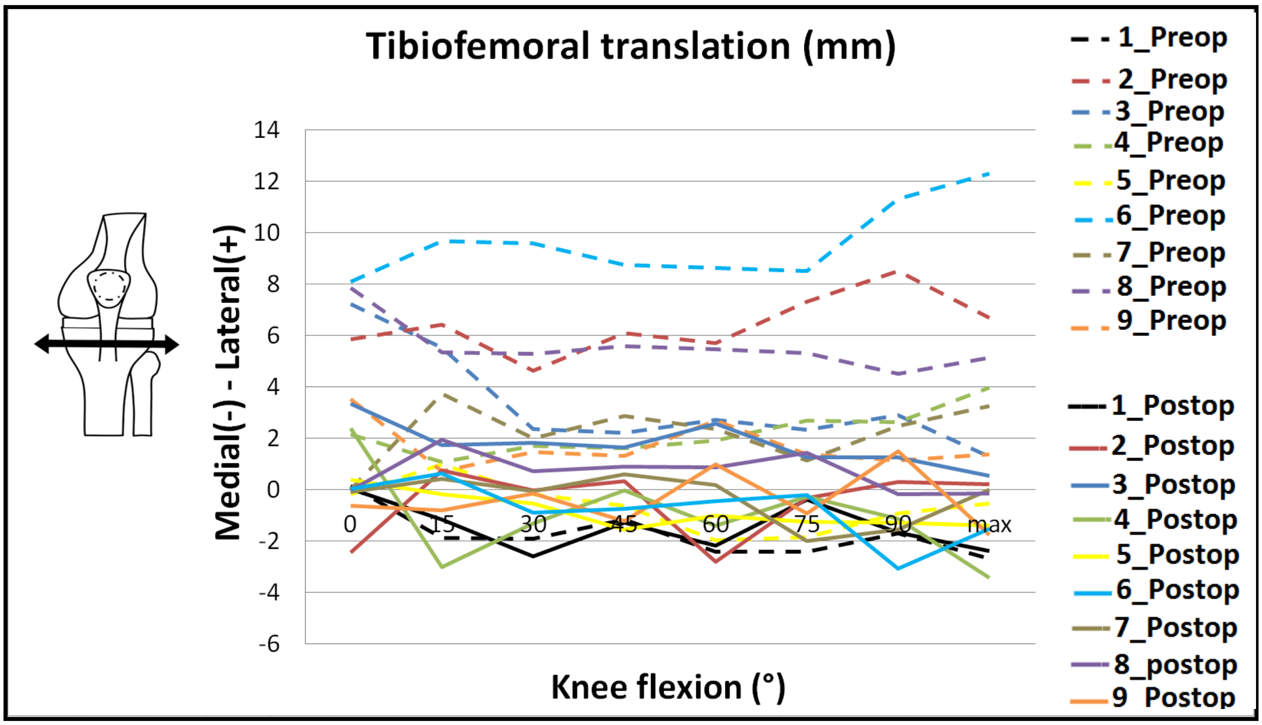


Figure 3-7. Detailed tibiofemoral medial/lateral translation for the 9 subjects pre and postoperatively showing that some subjects had negligible change (e.g. #1 black) whereas some had a large change (e.g. #6, blue), with all subjects clustering near neutral postoperatively.

For TF varus/valgus alignment, only one subject had valgus alignment preop, compared to the 8 other subjects with a varus knee preoperatively (Figure 3-8).

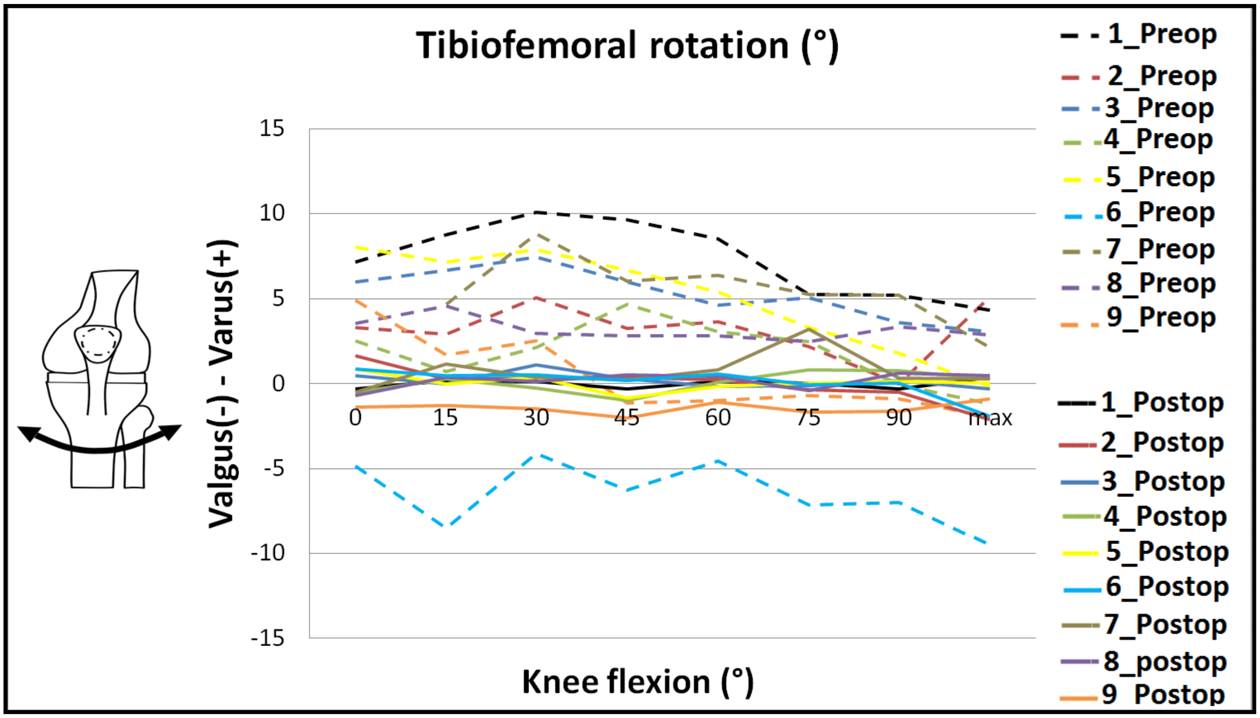


Figure 3-8. Detailed tibiofemoral varus/valgus alignment for the 9 subjects pre and postoperatively, showing that one subject changed from valgus to neutral whereas the remaining changed from different amounts of varus to neutral.

For the TF internal/external rotation, although the range of values amongst subjects is large, the postop kinematics follow the preop kinematics with less than 10º differences for each of the 9 subjects individually (Figure 3-9).

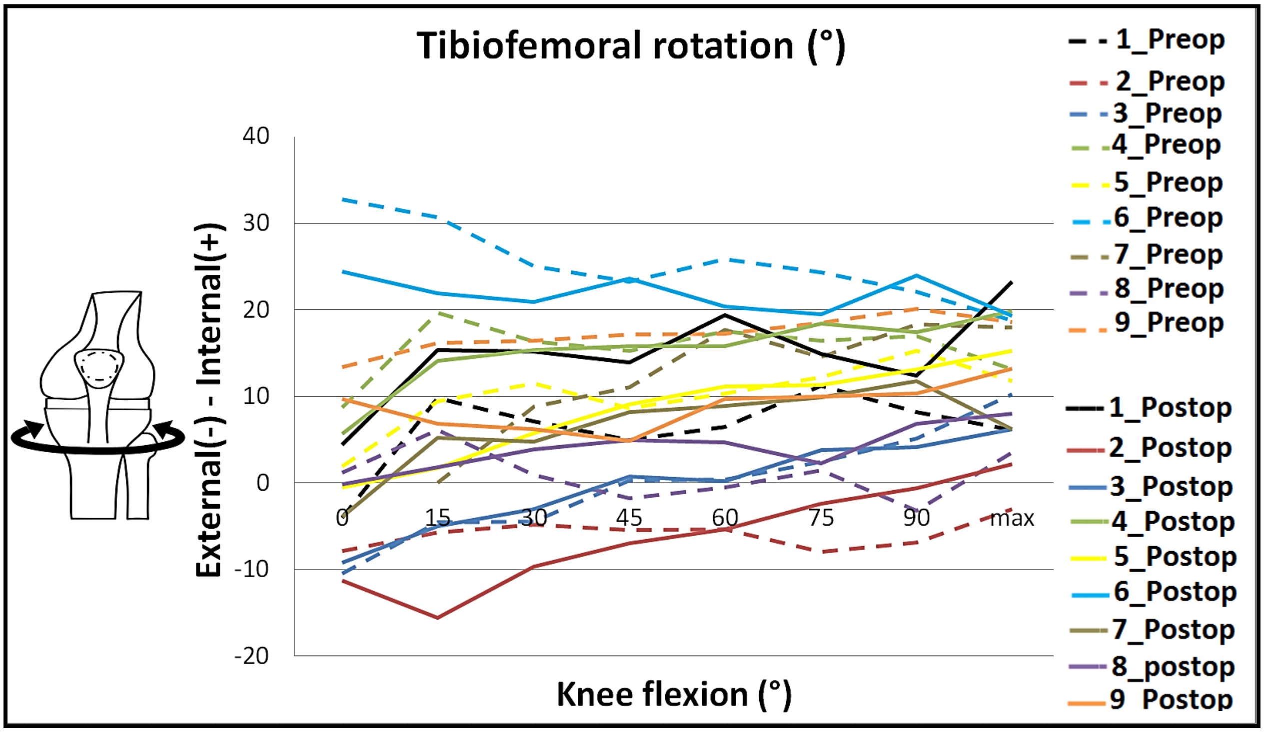


Figure 3-9. Detailed tibiofemoral internal/external rotation for the 9 subjects pre and postoperatively, showing a wide range of rotation values amongst subjects, but relative consistency preop-postop for each individual subject.

For the PF joint, directions of change were less consistent amongst individuals, leading to fewer preop-postop statistical differences (Figure 3-6). Individual results for mediolateral translation and tilt are presented to show the individual preop-postop changes (Figure 3-10, Figure 3-11). Considering all subjects as a group, the patella was more posterior postop beyond 30º ($p<0.03$), more inferior in mid-flexion ($p<0.05$), and tilted more laterally in mid-flexion postop ($p<0.05$). The other degrees of freedom showed no overall significant differences ($p>0.1$). However, individually, patellar translation changed by 0.2 to 13.2 mm (mean, 3.5 mm), and patellar tilt changed by 0.1º to 18.7º (mean, 5.5º) preop to postop.

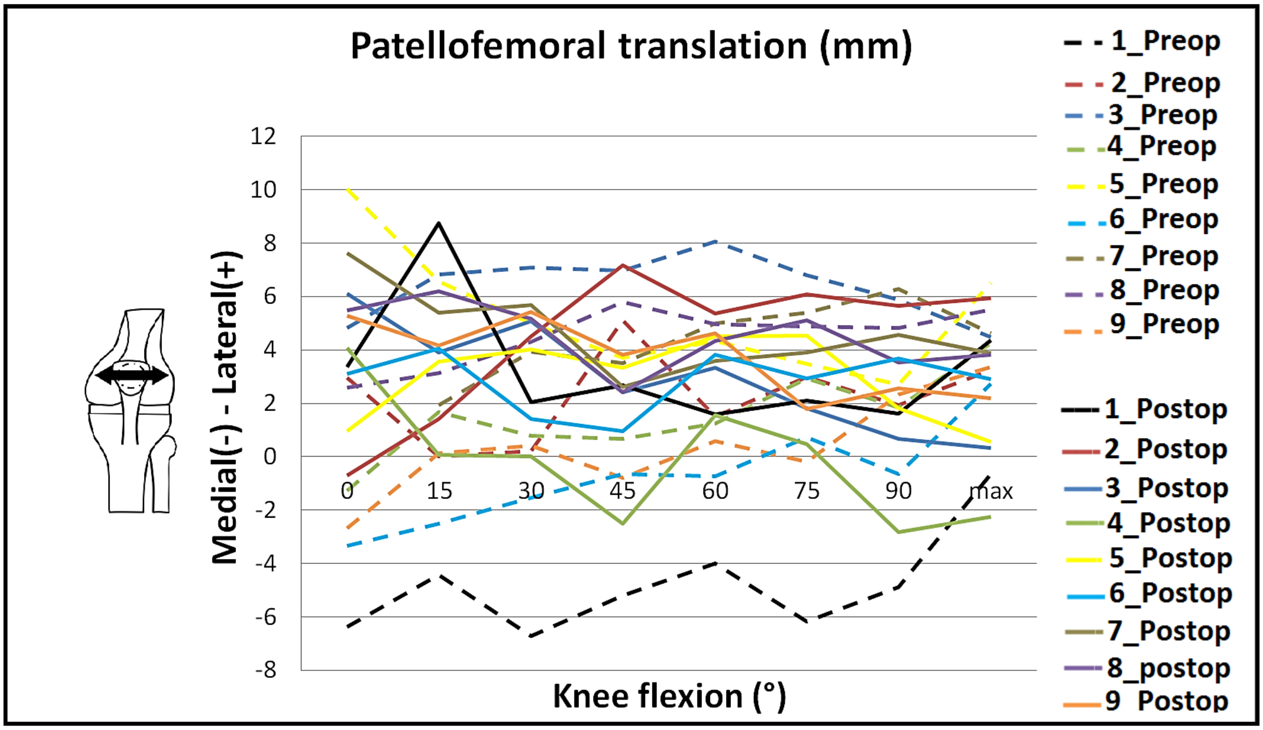


Figure 3-10. Detailed patellofemoral ML translation for the 9 subjects pre and postoperatively, showing that some subjects translated more medially and some translated more laterally. Both preop and postop showed a large range amongst the subjects. The translation is measured relative to the femoral coordinate system.

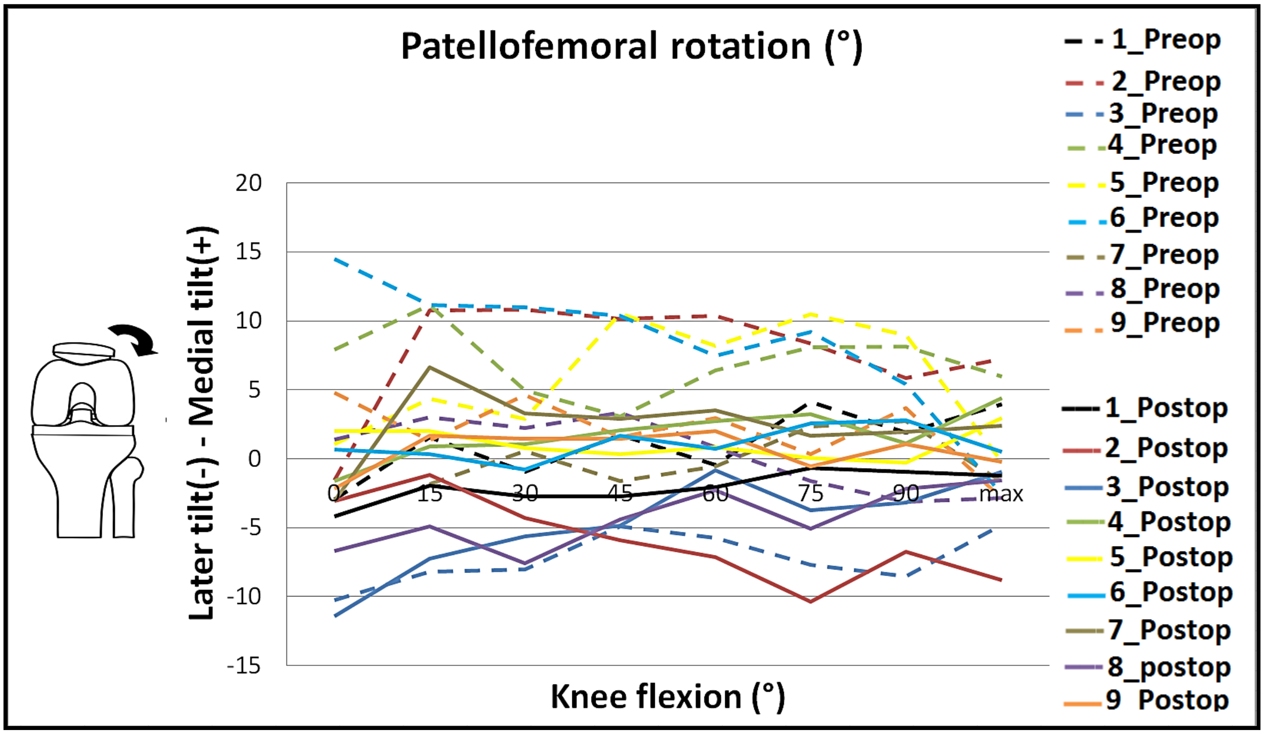


Figure 3-11. Detailed patellofemoral tilt for the 9 subjects pre and postoperatively, showing generally greater tilt preop and more neutral tilt postop, but with changes apparent in both directions.

Although pre-TKA knees on average displayed medial pivoting of the femur on the tibia (Figure 3-12), there was considerable variability. One of the knees displayed medial pivoting; two showed lateral pivoting; one had central pivoting; and five showed just translation. Contact location was often quite medial or lateral on the bone surface. In some cases, the knee reversed direction, e.g. between 90° and maximum flexion. Postop knees on average had central pivoting: pivoting was central in five subjects, medial in two and lateral in two. In all cases, the contact points remained within the central condylar surfaces. In most cases, the direction of pivoting continued in the same direction, but in two cases pre-TKA and one case post-TKA, this direction reversed between 90° and maximum flexion. All subjects showed substantial changes in preop-postop pivoting behaviour. The preop-postop ML translation to a more central mediolateral alignment, as reported in the degree-of-freedom analyses, can be seen in the TF contact plots (Figure 3-12). Postop contact was mostly posterior to the centreline, compared to a wide range of anteroposterior contact locations preop, both within and between subjects.

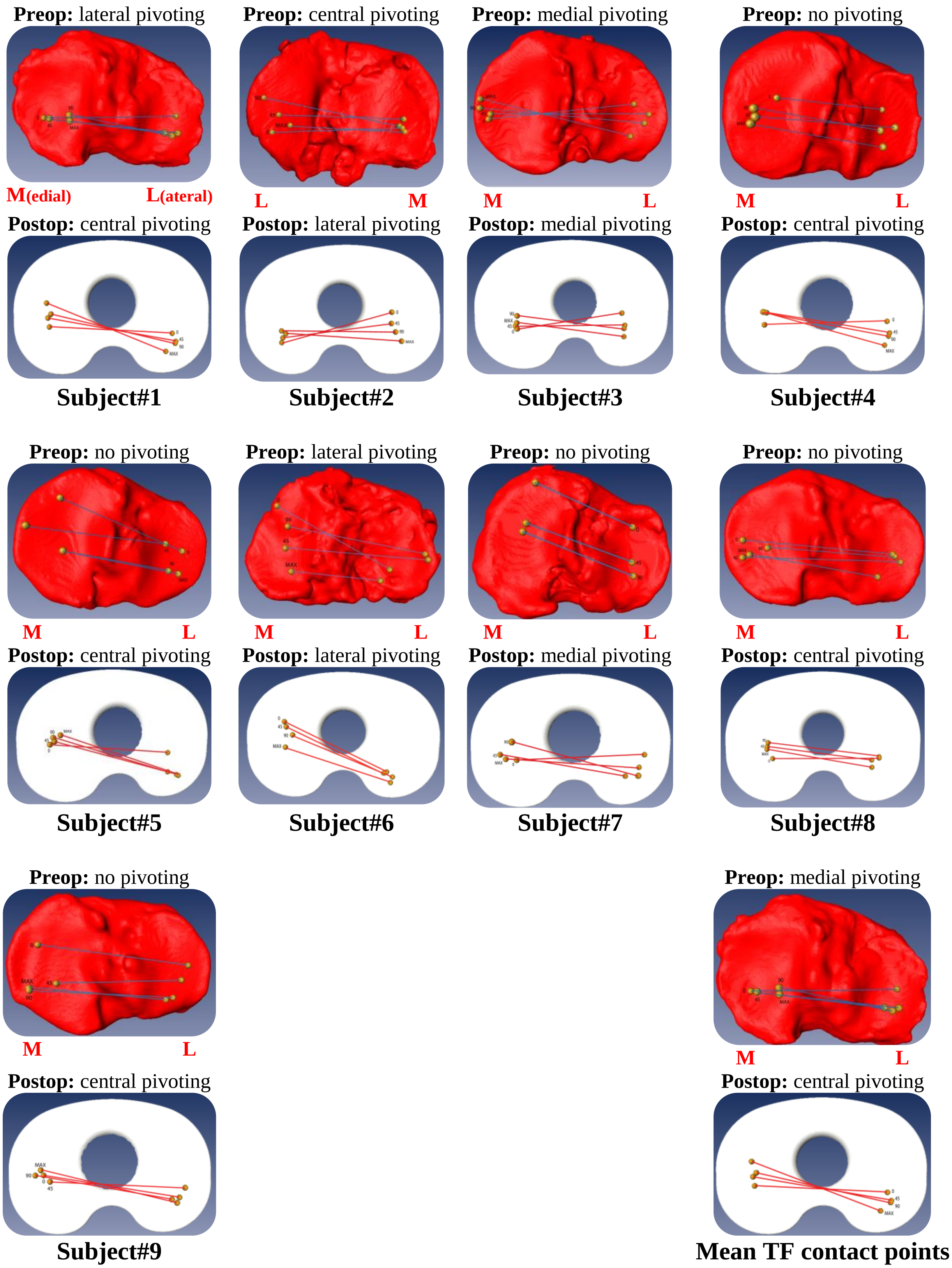


Figure 3-12. Tibiofemoral contact points for the nine subjects pre and post-TKA.

The helical axes were more scattered preop than postop, in all planes (Figure 3-13), showing greater variability in tibiofemoral mechanics. Medially the postop helical axes are reasonably focused close to the epicondyle suggesting more hinge-like movement on the medial side, and therefore sliding at the interface. Medially the preop helical axes are quite widely distributed, generally distal to the epicondyle, particularly in mid flexion (interval #3, 30-45º), which is close to the tibial surface, indicating a mostly rolling action. Laterally both the preop and postop helical axes are more distal to the epicondyle, showing more rolling in mid-flexion, with clear differences amongst the flexion intervals. Both preop and postop, the HA is generally anterior on the medial side and posterior on the lateral side, relative to the tibial coordinate system, with the preop being more anterior, indicating that medial contact on the tibia is more anterior, as can also be seen from the TF contact plots.

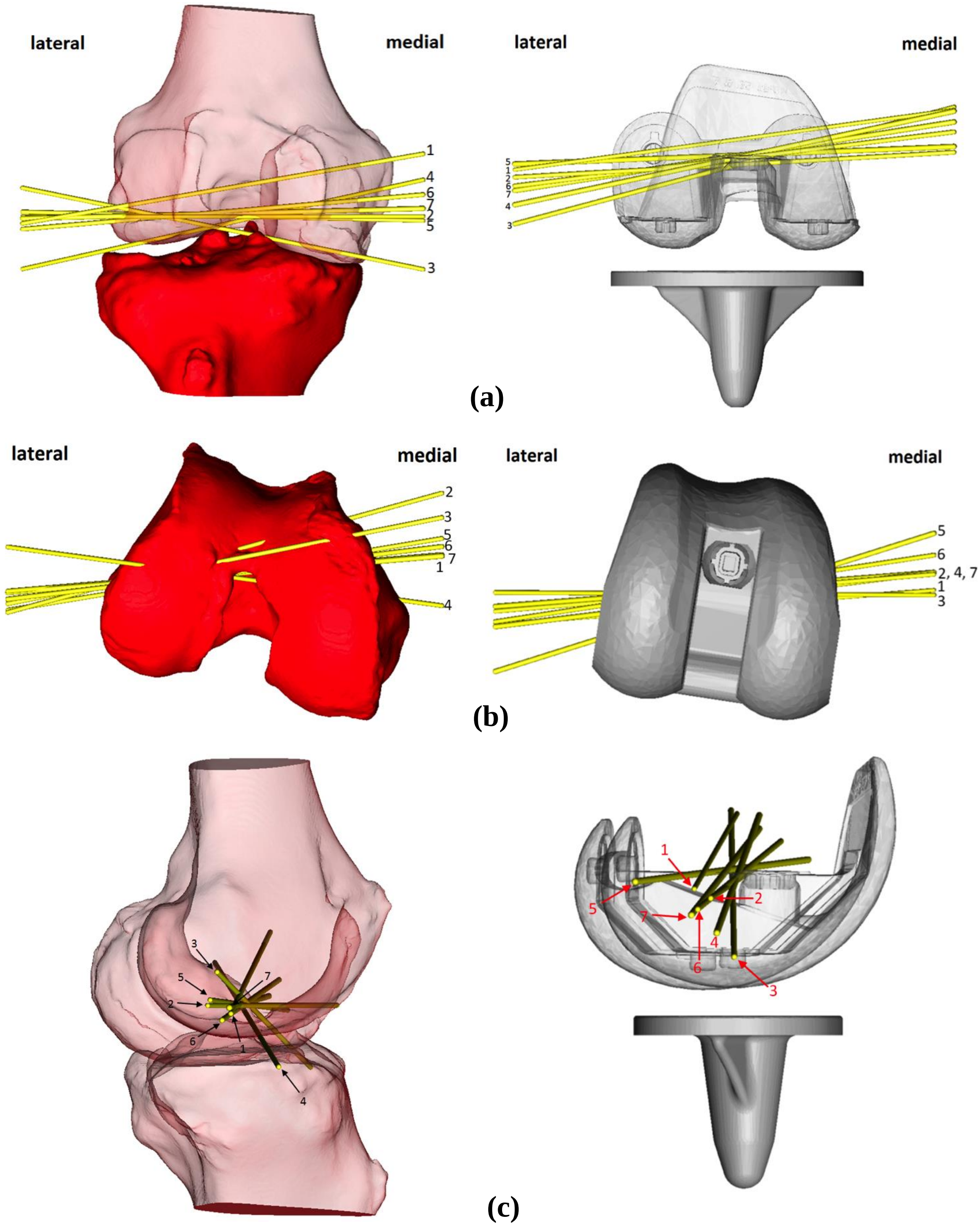


Figure 3-13. Mean helical axes of rotation : (a) anterior view; (b) distal view; (c) lateral view. Numbers 1-7 refer to the seven flexion intervals, from 0-15^o (#1) to 90^o to max flexion (#7).

The average preop intersections of the HA with the sagittal plane on the lateral side of the knee were closely clustered, versus more scattered and anterior on the medial side (Figure 3-14). Postop, the average intersections on the medial side showed a large change from the preop, with the HA intersections being closely clustered while being more anterior and superior to the TEA than preop. However the mean intersections were more similar on the lateral side between the preop and postop knees, with the postop intersections being slightly superior and closer to the TEA.

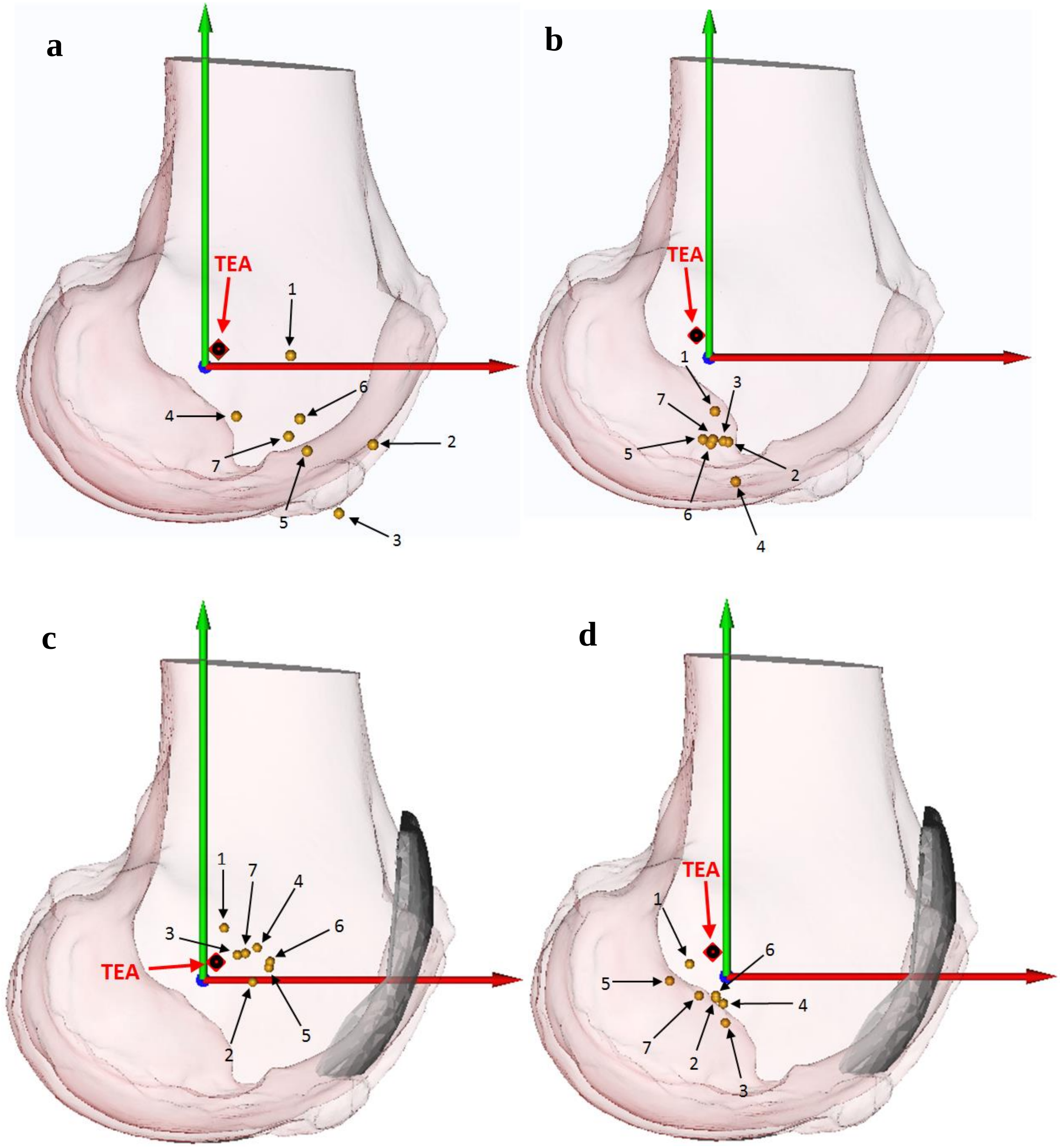


Figure 3-14. Mean intersections of the HA with the medial and lateral sagittal planes (located at the femoral condyles) show the changes in position of the HA during each flexion interval: (a) preop medial intersections; (b) preop lateral intersections; (c) postop medial intersections; (d) postop lateral intersections. Numbers 1-7 refer to the seven flexion intervals, from 0-15^{o} (#1) to 90^{o} to max flexion (#7). Note that for images (c) & (d), the rest of the implant is hidden inside the bone and therefore does not appear.

3.4 Discussion

The purpose of this study was to investigate pre- and post-TKA weightbearing kinematics throughout the range of motion, including all 6 DOF tibiofemoral and patellofemoral, tibiofemoral contact and helical axes. For all types of analyses and for all individuals, substantial changes were seen.

For the nine subjects studied, the arthroplasty procedure corrected the varus/valgus and mediolateral malalignments observed in the pre-TKA knees. The anteroposterior positioning of the tibia depends on the component positioning, component design and the state of the soft tissues. Our results are consistent with other reports of posterior tibial translation in post TKA knees (Li et al., 2002). The more medial contact point of the femur on the tibia and ML translation of the tibia is likely due to the varus alignment of 8 of the 9 knees.

For the PF joint, the TKA on average modified and corrected the medial tilt observed in the pre-TKA knees to a more neutral, slightly lateral tilt postop. The more inferior and posterior patella postop is likely due to the change in joint line (by 3.8 mm on average in extension and by 2.6 mm on average in 90^{o} flexion) resulting in the patella tracking farther down on the femoral groove. This likely caused the significant preop-postop differences in PF AP and IS translations. Substantial individual changes were seen in the most clinically-relevant degrees of freedom, namely mediolateral tilt and translation. Patellar tracking is sensitive to implant geometry and placement for all three components (patellar, femoral and tibial) and changes in the soft tissue structures (Anglin et al., 2008). Maltracking, in terms of tilt or translation is often associated with pain (Saevarsson, 2012); a future study of subjects with postop maltracking could evaluate outliers relative to this established database to determine potential causes. The interrelationships between shape and kinematics are the subject of a separate study [Chapter 5].

Our results also showed that there are discrepancies between the pre- and post-TKA HA of rotations for our nine subjects. Post-TKA had more sliding movements on the medial side. However, a more rolling action was apparent in the pre-TKA knees medially. Laterally both the preop and postop knees showed more rolling action in mid-flexion. For the HA rotations, our results correlate reasonably well with another recent study, except for greater rolling action on average in the present study on the medial side of the post-TKA knees (Wilson et al., 2013).

This study was limited by the small number of subjects from a single surgeon with a single implant design. It is therefore important to recognize that different patients, different surgical techniques or different implant designs could have different results. Nonetheless the similarity in average postop results with a different implant design from patients operated on by two other surgeons, suggests reasonable postop consistency (Saevarsson et al., 2013). For the tibiofemoral contact point, because the articular cartilage and meniscus in pre-TKA radiography, and the polyethylene tibial inserts in post-TKA radiography, are radiotransparent and hence difficult to segment, the contact points were defined as the closest distances of the femoral condyles with the tibial plateau surface; although an approximation, this was likely sufficient to define the direction of pivoting and translation. Out-of-plane accuracy was improved with the sequential-biplanar approach over single-plane radiography, but uncertainty remains leading to the uneven graphs. Despite this, the preop-postop differences were usually greater than the level of uncertainty, leading to the same overall conclusions. The other limitation of this study is that knee function was only evaluated during static step-up activity. However, the static kinematics with this protocol were shown to be comparable to dynamic kinematics during a step up in all but one DOF for one subject (out of 12 DOF for ten subjects) (Saevarsson et al., 2013). We did not have a control group of normal healthy subjects for ethics reasons, and there is only a small amount of literature detailing normal, healthy data for comparison. More data on normal, healthy subjects are needed.

This study provides data previously unavailable concerning preop/postop changes and provides the basis for a full analytical model. Six DOF tibiofemoral data are rarely reported, and we are unaware of any 6 DOF patellofemoral data throughout the range of motion postop. The results of our proposed broader study with more subjects, from more surgeons, and different implants designs will be used for a better understanding of the changes between preoperative and postoperative kinematics. Using this protocol to analyze patients with a poor clinical outcome or with kinematics that are substantially different than normal in comparison to the changes seen for patients with a good outcome could help improve surgical techniques, implants or instruments, leading to improved patient outcomes and satisfaction.

Chapter Four: **Impact of Total Knee Arthroplasty on Knee Shape and Geometry**

4.1 Introduction

Changes in knee articular geometry after total knee arthroplasty (TKA) can affect knee pain, function, stability and range of motion as well as tibiofemoral and patellofemoral kinematics (Bull et al., 2008; Clary et al., 2013; Digennaro et al., 2014; Harman et al., 2012; Matsuzaki et al., 2013; Mikashima et al., 2013; Stoddard et al., 2014; Whiteside et al., 2003). Changes in knee articular geometry compared to the preoperative knee occur both intentionally (e.g. due to correcting the preoperative malalignment) and unintentionally (e.g. due to standardized component sizing and component malplacement). The impact of TKA on the geometrical dimensions of the knee has not been documented previously to our knowledge, except for joint line changes (Anglin et al., 2008).

Patients who receive a knee replacement usually have malaligned legs (varus or valgus), malshaped knees (worn cartilage, osteophytes) and may have improper kinematics (patellar maltracking, poor range of motion) that require alteration during the surgery. Therefore the knee may be intentionally changed during the surgery to correct these complications, resulting in a different shape of the implanted knee compared to the original natural knee. Unintentional changes may occur due to the fact that only a limited number of shapes and sizes of implants are available for each patient, necessitating compromises in the fitting of the components to the bones. Furthermore, one or both cruciate ligaments are removed during the surgery. As a result of these inevitable changes, the implanted knee has a different shape and geometry than the original natural knee.

Clinically-relevant geometrical parameters include: *dimensional changes in the distal condyles* as these can affect varus/valgus alignment, femoral groove orientation, and stability in extension; *changes in the posterior condyles* as these can affect stability in flexion, patellar tracking, range of motion and kinematics (Malviya et al., 2009); *changes in intercondylar gap location*, reflecting mediolateral component placement, affecting the femoral groove location and possible overhang or undercoverage of the knee medially or laterally; *changes in patellofemoral distance* as this can affect over- or understuffing of the joint, range of motion and pain and reflects the anteroposterior component design and positioning (Mihalko et al., 2006); *changes in patellar thickness* for similar reasons, but with a closer focus on the cause (Bengs et al., 2006; Dennis, 2006; Merican et al., 2014); *changes in hip-knee-ankle (HKA) angle* as correcting HKA is one of the primary goals of the surgery (Daniilidis et al., 2013), and coronal alignment of the knee is a major determinant of load distribution through the knee (Moyer et al., 2010), preoperatively influencing disease progression of osteoarthritis (OA) (Colebatch et al., 2009) and postoperatively having a direct impact on the survivorship and function of TKA (Longstaff et al., 2009)); *femoral component rotation*, since internal rotation can cause patellar maltracking, pain and complications (Berger et al., 1993; Matsuda et al., 2001; Rhoads et al., 1990; Victor, 2009) whereas excessive external rotation can cause mechanical overload on the medial side of the joint and also increased shear forces on the patella (Hanada et al., 2007; Miller et al., 2001); and *medial and lateral joint line changes* to detect whether the TKA tended to make the joint tighter or looser, since small changes to the joint line post-TKA can have a considerable effect on joint stability, range of motion, and patellofemoral mechanics (Bellemans, 2004; Martin et al., 1990; Romero et al., 2010; Rouvillain et al., 2008; Ryu et al., 1993).

A better understanding of the changes in knee shape and geometry could aid implant design as well as patient-specific planning using computer-assisted surgery or patient-specific instrumentation, to improve patient outcomes and satisfaction. The more that orthopaedic engineers and surgeons can visualize and think about these shape differences when designing and implanting TKA components, the closer the postop knee joint may be to the desired goals. The purpose of the present study was therefore to investigate the changes in articular shape and geometry resulting from TKA, visually and numerically, both individually and as a group, in a sample population.

4.2 Methods

4.2.1 Image acquisition

To evaluate three-dimensional (3D) changes in knee shape and geometry, CT scans were obtained of 9 OA subjects (Table 3-1) before and at least one year after TKA, using a unique, validated CT protocol (Ho et al., 2012).

The supine subjects experienced partial loadbearing by pushing their heel against a 9-kg weighted pedal mounted on a custom knee rig (9 kg was chosen to provide partial loadbearing without pain). Following a pelvis-to-foot topogram (scout scan), sections at the hip, knee and ankle were imaged with the knee in full extension, using a SOMATOM 64-slice CT machine (Siemens, Berlin, Germany) using the imaging parameters in Table 4-1.

Table 4-1. CT imaging parameters.

	FOV (mm)	kVp	Knee (cm)	Knee (mAs)	Slice width (mm)	Slice thickness (mm)
Preop	180	120	20	160	0.6	0.4
Postop	180	120	20	180	1.0	0.7

To evaluate the joint line shift at 3 flexion angles (extension, 45º flexion and 90º flexion), sequential-biplanar, calibrated radiographs were obtained of the same subjects preop and postop, using a sagittal view and 10º below sagittal (Sharma et al., 2012). These views were chosen for good patellofemoral visibility for a broader study of knee kinematics before and after TKA [Chapter 3].

4.2.2 Prosthesis components and surgical technique

All subjects had a cemented, rotating platform posterior-stabilized prosthesis (PFC® Sigma^{TM} Mobile Bearing; DePuy Synthes Joint Reconstruction, Warsaw, IN) with a resurfaced all-polyethylene patella, operated on by a single surgeon. All subjects had good function and were satisfied with their TKA, judged on the basis that no further follow up or revision surgery was planned, and based on a question about satisfaction (Chapter 5). Our institutional review board approved the study and written informed consent was obtained from all subjects.

The surgeon performed a primarily ligament-balancing technique, resecting the femur first (distal, 6º valgus cut first) and setting the tibial cuts to achieve good medial/lateral ligament balance. He typically took 11-13 mm off the distal femur rather than the standard 9 mm, to leave more room, and then took slightly less off of the tibial side, aiming for a slightly looser rather than slightly tighter joint. He positioned the femoral component as posteriorly as possible without notching anteriorly. He chose the largest tibial tray that can fit on the tibial plateau without any part of the tray overhanging the cut surface, and within one size of the femoral component, as required. The tibial tray was rotated on the plateau to cover the maximum surface possible without overlap. This rotation can be compensated for by the mobile bearing liner. He put an emphasis on achieving full extension to aid descending stairs. The standard femoral instrumentation builds in 3º external component rotation relative to the posterior condyles, although if he thought one condyle was more worn, he would leave a small gap. The external rotation promotes better patellar tracking and a better flexion gap. He typically preferred to leave the patella thicker than normal to avoid patellar fracture, and ensured good tracking prior to closure. If medial release is warranted, he performs some distal release of the medial collateral ligament; if lateral release is warranted, he releases just the synovium if it is pulling the patella laterally rather than a full lateral release; there were no specific comments in the operating room reports. The surgeon prefers the mobile bearing knee design so that the components can find their own best rotational alignment after the surgery.

4.2.3 Image segmentation and prosthesis model fitting

The preoperative CT scans were segmented automatically using statistical shape models developed at the Zuse Institute Berlin (ZIB), with minor manual refinement, to generate 3D femoral, tibial and patellar bone models (Ho et al., 2012) (Figure 4-1a).

The postoperative CT scans were used to define the relative positions of the bones and prosthesis components after the surgery. Manufacturer-provided 3D prosthesis models were matched automatically to the CT images using custom software developed within ZIBAmira (version 2011.2-rc6, Zuse Institute Berlin, Berlin) (Figure 4-1b). Previous analysis demonstrated good accuracy and repeatability with this technique (Ho et al., 2012). On the tibial side, due to the radiotransparency of the polyethylene and the unknown rotation of the mobile bearing insert, only the metal tibial tray was matched. Matching the preop segmentations to the prosthesis-matched postop CT scans allowed combined bone-implant models to be created for the femur, tibia and patella (Figure 4-1c).

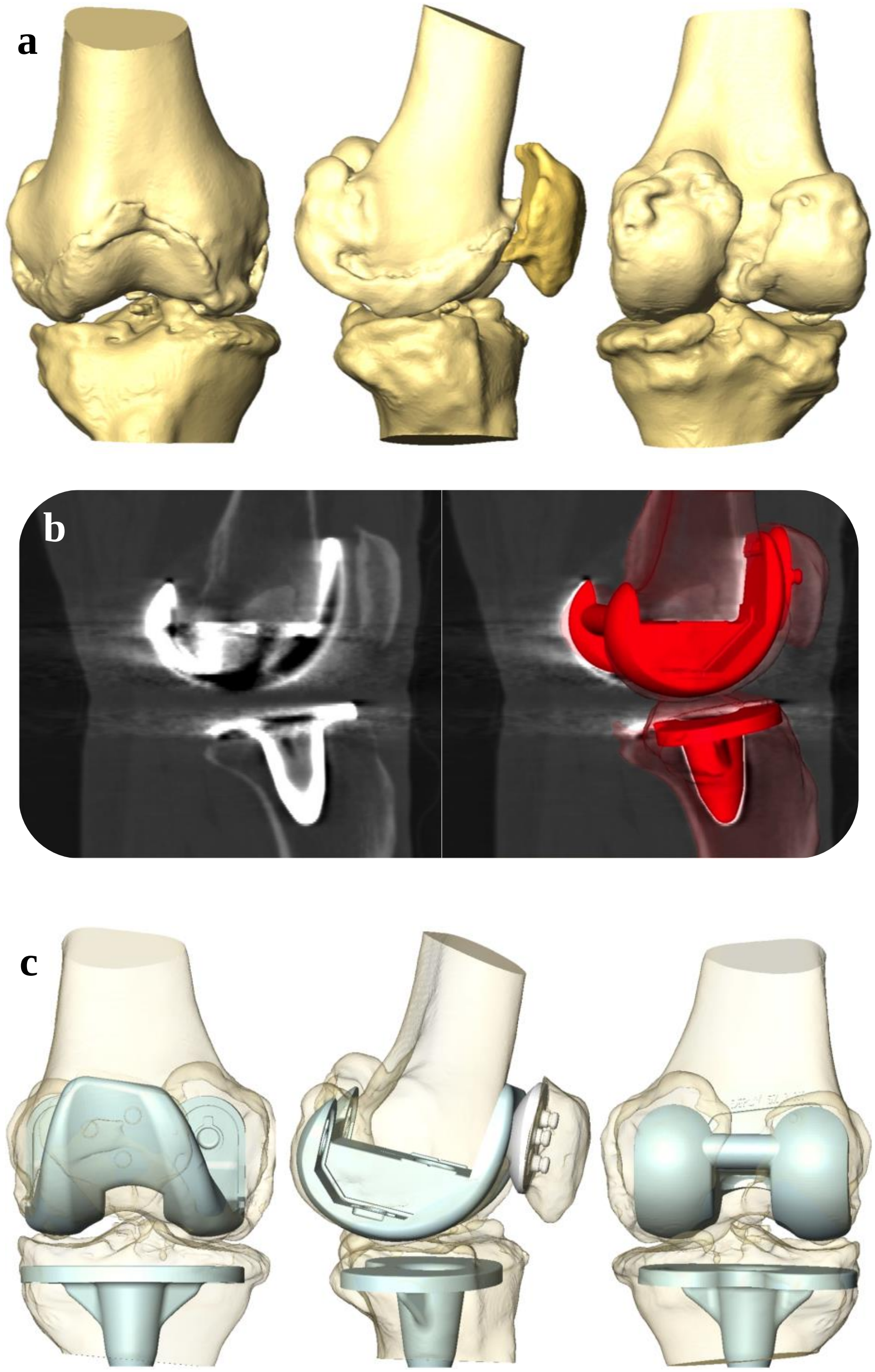


Figure 4-1. Image segmentation and prosthesis model fitting(a) Segmented preoperative bones; (b) accurate 3D-3D matching of the manufacturer-provided implant models to the CT volume despite substantial metal artifact; (c) implants overlayed on preoperative bones (tibial insert not shown due to radiotransparency of the polyethylene).

For the joint line analysis, the bone or prosthesis models were fit to the preop and postop biplanar radiographs, respectively, using JointTrack Biplane open-source software (sourceforge.net/projects/jointtrack/) (Acker et al., 2011) (Figure 4-2). See Chapter 3 for details.

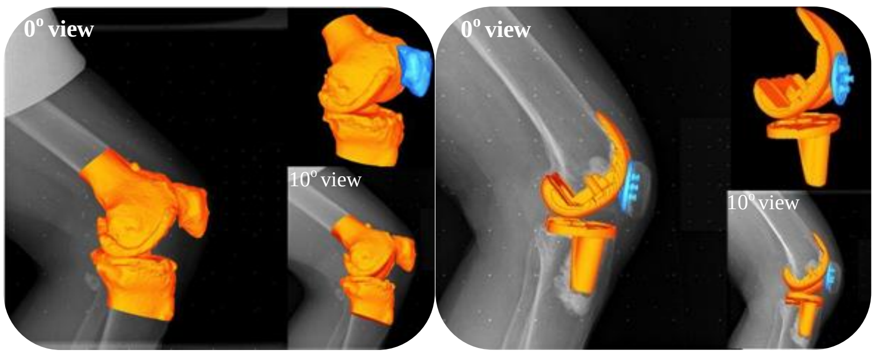


Figure 4-2. Performing the 2D-3D image matching to the biplanar (pure sagittal and 10º below sagittal) radiographs for the joint line calculations at 0º, 45º and 90º knee flexion.

4.2.4 Femoral and patellar colour maps and tibial coverage

Colour maps were created between the preop segmentations and the postop combined femoral and patellar bone-implant models, to visualize the overall preop-postop shape changes in the knee joint, using ZIBAmira. For better clarity of the clinically-relevant femoral condylar regions, the intercondylar region was excluded. Spectrum ranges were defined from -8 to +8 mm for the femur, and from -5 and +5 mm for the patella; values outside this range were shown at maximum colour intensity. For prosthesis surfaces inside the preoperative bone surface, distances are shown in blue; for prosthesis surfaces outside the preoperative bone surface, distances are shown in red.

Colour maps were not relevant for the polyethylene tibial surface due to the mobile bearing insert, but images were created showing the coverage of the metal tibial baseplate on the cut surface and the sagittal baseplate positioning within the bone.

4.2.5 Condylar and patellofemoral dimensions

To quantify the key regions, the following preop and postop parameters and changes due to the TKA were measured: (1) *medial and lateral prosthesis-bone distances* (i.e. excluding cartilage) *for the distal condyles*; (2) *medial and lateral prosthesis-bone distances for the posterior condyles*; (3) *preop, postop and change in intercondylar gap location* (defined as the mediolateral distance between the intercondylar gaps in bone and component models overlaid on postop CT scans); (4) *preop and postop patellofemoral distances* (defined as the distance between the origin of the patellar bone coordinate system and the origin of the femoral bone coordinate system) with the knee in full extension, and at 45º and 90º knee flexion; and (5) *preop and postop patellar thickness*, in which preop patellar thickness was measured as the thickest part of the patellar bone and postop thickness was measured from the apex of the patellar component on the combined bone-implant model (Figure 4-3), using ZIBAmira.

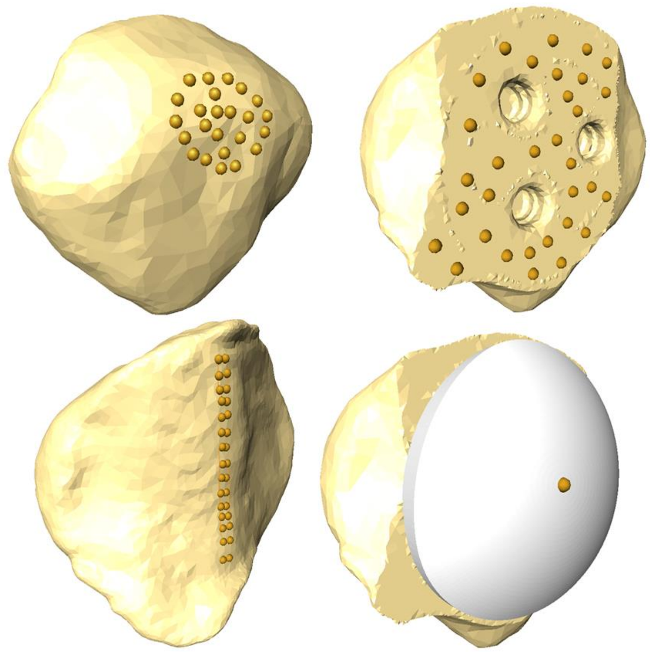


Figure 4-3. Preop and postop patellar thickness. Preop patellar thickness was measured as the distance between two planes: one fit to the anterior surface and the other to the posterior ridge. Postop patellar thickness was measured as the distance between a plane fit to the anterior surface and the patellar component apex.

4.2.6 Hip-knee-ankle angle

To evaluate varus/valgus alignment changes for our subjects, the HKA angle was measured from the preop and postop CT topograms. This was possible because the subject's leg was well-aligned due to the foot position on the custom knee rig while CT scanning; it was also preferred to a 3D analysis in order to provide a straightforward comparison to the clinical standard. The HKA angle was computed as the angle between two lines: one connecting the femoral head centre to the knee centre, the other from the knee centre to the ankle centre (Figure 4-4) (Cooke et al., 2007). The femoral head and knee centres were determined by selecting the centre points on fitted circles to the femoral head and the intercondylar notch on the

CT topogram, respectively. The ankle centre was defined as the midpoint of the articular surface between the malleoli, on the tibia and talus bone.

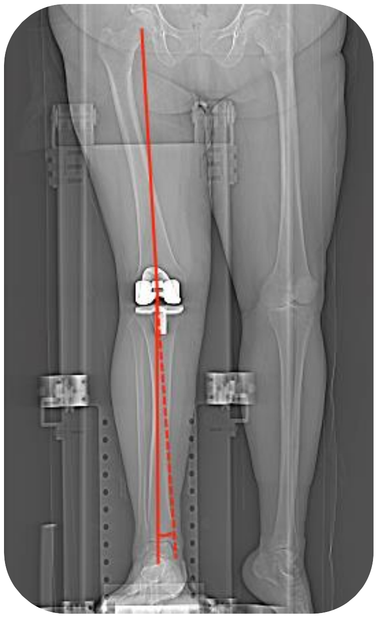
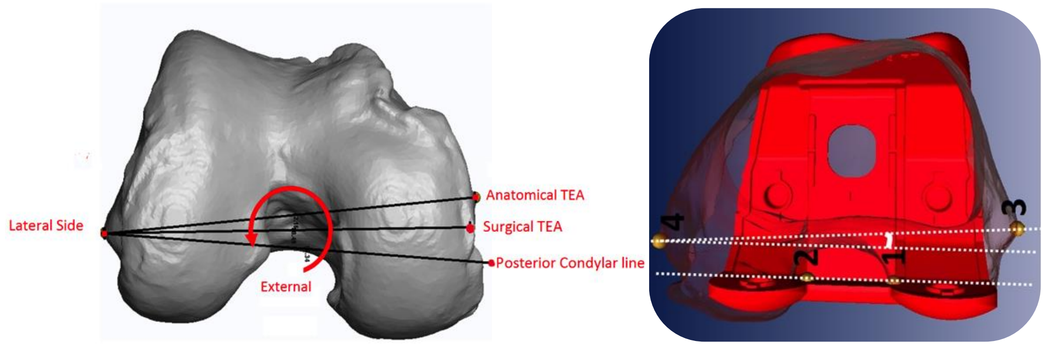


Figure 4-4. Hip-knee-ankle angle measured from the CT topogram with the leg mounted in a custom knee rig. The subject pressed against a pedal, resisting a 9-kg load.

4.2.7 Condylar axes and femoral component rotation

To evaluate the transepicondylar axis (TEA) and assess femoral component rotation, we first compared the anatomical and surgical TEA lines relative to the preop posterior condylar line (PCL) and then compared the femoral component-PCL to the bone-PCL and the surgical TEA. The anatomical transepicondylar axis (TEA) is a line drawn between the medial and lateral epicondylar prominences, whereas the surgical TEA is drawn between the medial sulcus and the lateral epicondylar prominence (Figure 4-5) (Barrack et al., 2001; Berger et al., 1993; Berger et al., 1998; Victor, 2009). Tibial component rotation was not measured, as it is not relevant for a mobile bearing prosthesis.



(a) (b)

Figure 4-5. Condylar axes and femoral component rotation. a) Preop anatomical and surgical TEA relative to the PCL; b) Postop anatomical (line 3-4) and surgical TEA, relative to the femoral component posterior condylar line (line 1-2).

4.2.8 Joint line shift

To measure tibiofemoral (TF) joint-line alterations, we used two recently-reported methods (Amiri et al., 2013; Sato et al., 2007). The first method fits the prosthesis components to the preoperative images (“preoperative-based registration”) to determine the total changes in TF joint line, taking preoperative cartilage thickness into account; the second method fits the preoperative bones to the postoperative images (“postoperative-based registration”) to determine the tibial and femoral joint line shifts separately, relative to the bone (not cartilage) surfaces.

Preoperative-based registration (Amiri et al., 2013)*:* In this method, the combined 3D bone-implant model created above was overlaid on the preoperative lateral radiographs at 0º, 45º and 90º of flexion using 2D-3D image matching using the JointTrack Biplane software. A cutting plane perpendicular to the tibial tray was created, through the medial and lateral condyles of the femoral component using ZIBAmira. The distance between the most distal point on the condyle of the femoral component and the most proximal point on the tibial tray was measured as the joint line shift (Figure 4-6). Due to radiotransparency of the polyethylene, we added the insert thickness at its lowest point manually to our calculation. *Interference* between the components, defined as a positive joint line shift, suggests a tighter knee post-TKA. *Separation* of the components, defined as a negative joint line shift, suggests a looser knee post-TKA. Since the combined femoral-tibial distance is measured, the thickness of the combined femoral and tibial cartilage is taken into account.

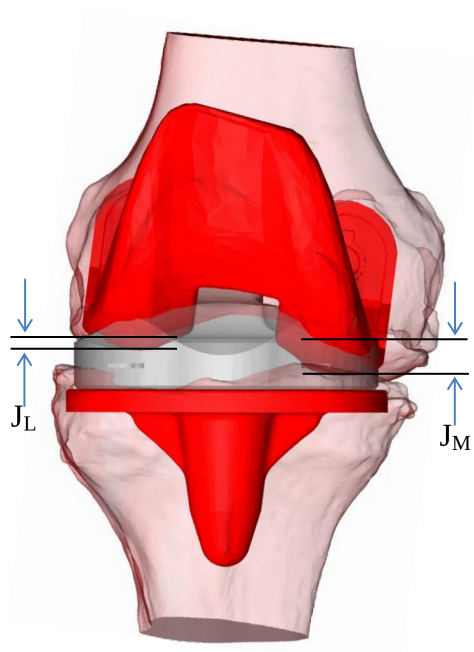


Figure 4-6. Total tibiofemoral joint line shift using preop-based registration method (J_L:lateral joint line shift; J_M:medial joint line shift); this method takes the preop cartilage into account. Interference suggests a tighter joint postop; separation suggests a looser joint postop.

Postoperative-based registration (Sato et al., 2007)*:* In this method, the cross-section through the bone-implant 3D models matched to the 0º, 45º and 90º radiographs were used for the joint line analysis. Medial and lateral femoral joint line changes were defined as the distances between the most distal points on the femoral component condyles and the most distal points on the preop femoral condyles (Figure 4-7.a). The corresponding tibial joint line changes were defined as the distances between the most proximal points of the tibia and the tibial component in the cross-sectional slice (Figure 4-7.b). Positive values were given to the joint line measures when the component added thickness to the bone (more distal femoral component or more proximal tibial component). The total joint line shift was defined as the sum of the tibial and femoral joint line changes, excluding cartilage thickness.

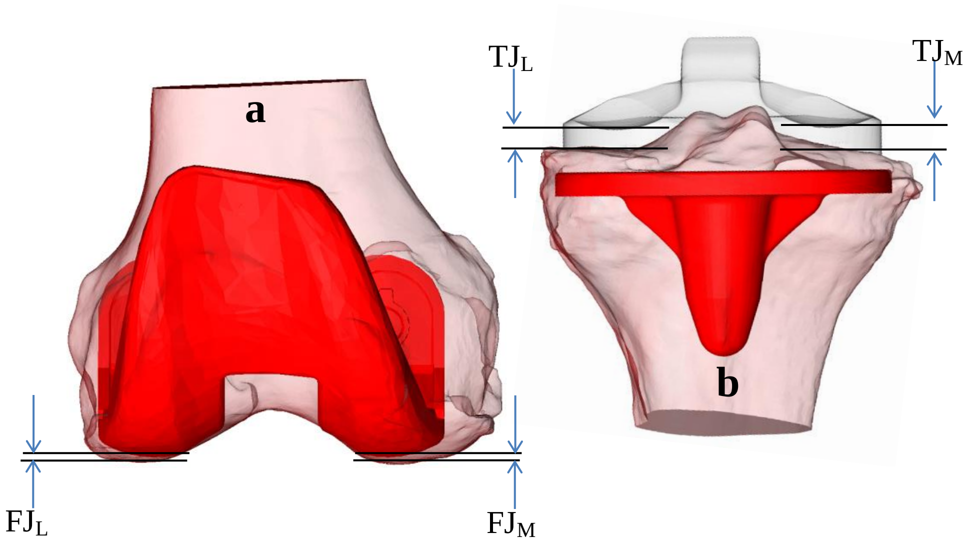


Figure 4-7. Separate femoral and tibial joint line changes relative to the bone surface using the preop-based registration method (FJ$_L$: lateral femoral joint line; FJ$_M$: medial femoral joint line; TJ$_L$: lateral tibial joint line; TJ$_M$: medial tibial joint line), excluding cartilage. The insert thickness at its lowest point, i.e. the presumed contact point, was added to the distance to the tibial baseplate to account for the radiotransparent insert in the joint.

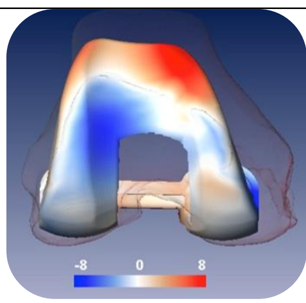
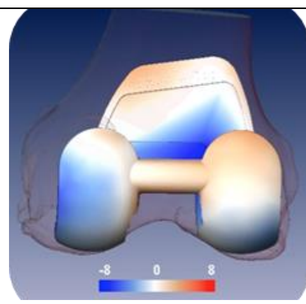
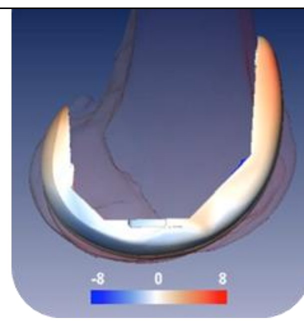
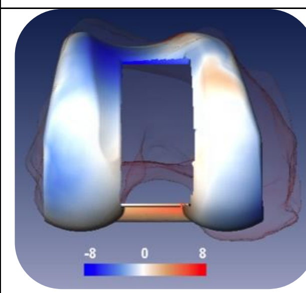
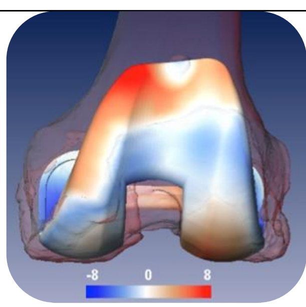
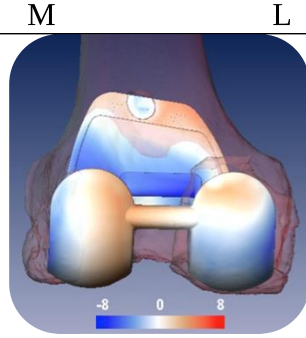
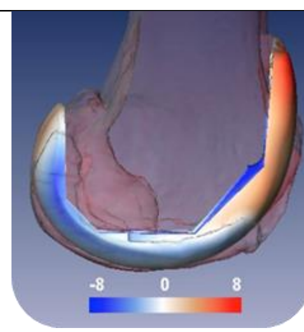
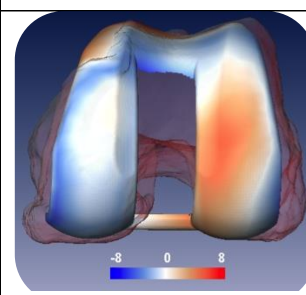
4.2.9 Statistical analyses

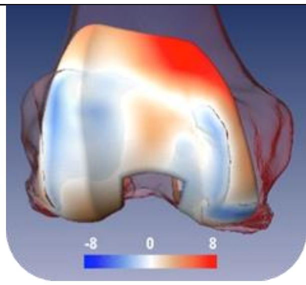
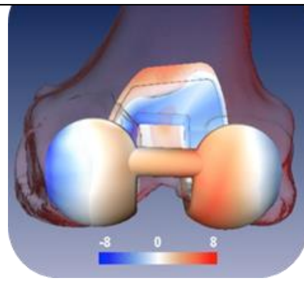
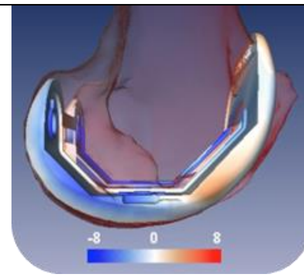
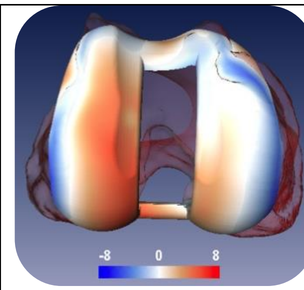
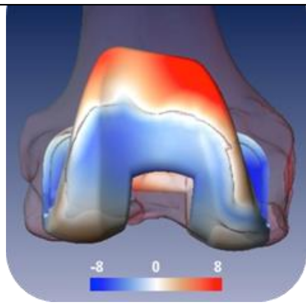
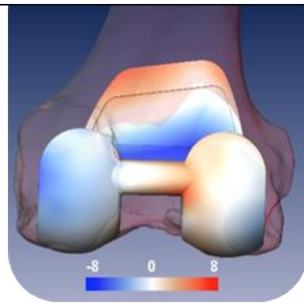
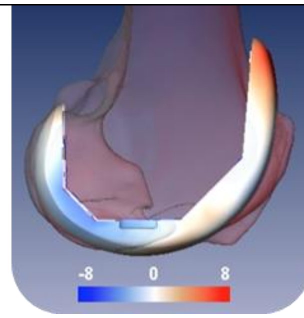
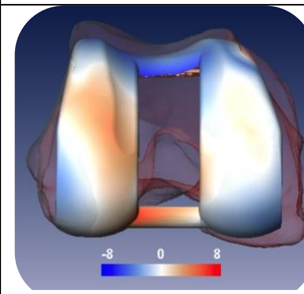
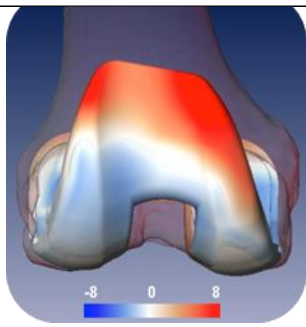
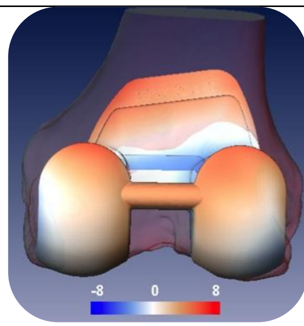
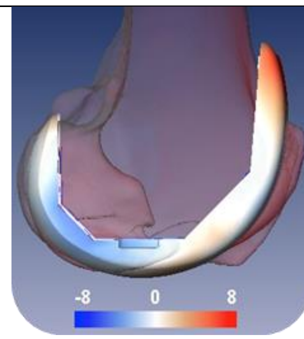
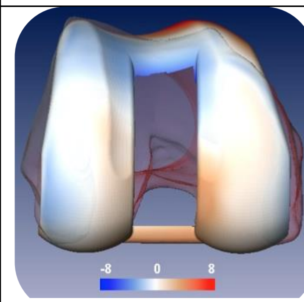
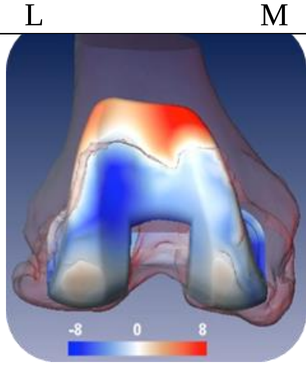
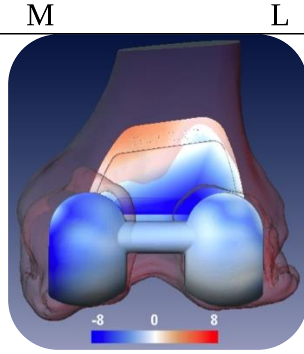
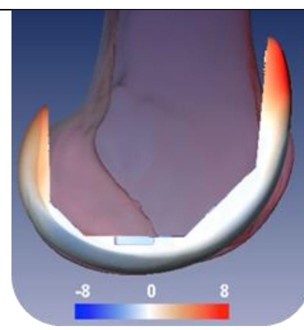
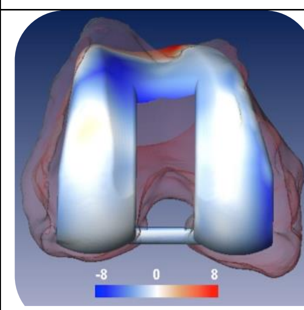
Statistical comparisons, for our nine subjects with a single implant design and surgeon, were made on the measured geometrical parameters using paired Student's t-tests to examine differences between preop and postop knee shapes, with $p<0.05$ considered significant, whereby the null hypothesis was that the measured knee geometrical parameters do not change following

TKA. Although using alpha=0.05 could overestimate the number of significant results, this threshold provides directions for future research beyond the present pilot study. We only performed the statistical analysis on the geometrical parameters in which the cartilage was taken into account to avoid falsely concluding a difference; these parameters included the preop/postop PF distance changes and the HKA angle.

4.3 Results

Knee shape and geometry changed in numerous ways as a result of the TKA. This can be seen from the postop components overlaid on the preop bones (Figure 4-1c) and the colour maps for each subject (Figure 4-8 to Figure 4-10) as well as the dimensional changes (Table 4-2 to Table 4-12).

Subject #	Frontal (Anterior)	Frontal (Posterior)	Sagittal	Coronal from below
1	 L M	 M L		 L M
2	 M L	 L M		 M L

3	 L M	 M L		 L M
4	 L M	 M L		 L M
5	 L M	 M L		 L M
6	 L M	 M L		 L M

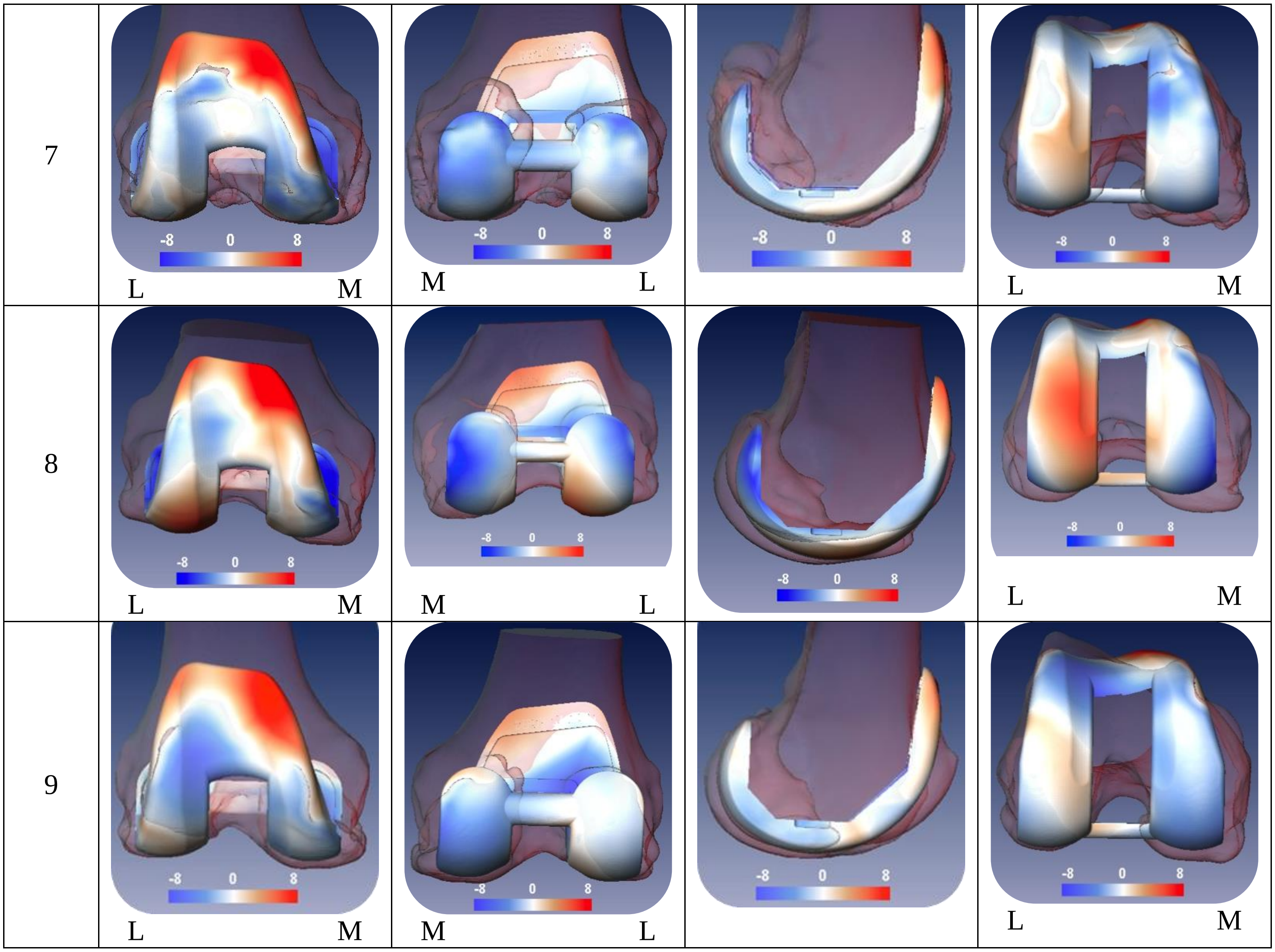


Figure 4-8. Colour maps of each individual subject's femur, showing the distance of the femoral prosthesis from the preop bone surface (excluding cartilage). Red indicates that the prosthesis is outside of the bone; blue indicates that the prosthesis is inside the bone. Note that all subjects except S2 had TKA on their right leg and all subjects except S6 had varus alignment preop.

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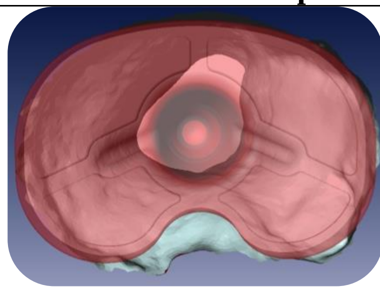
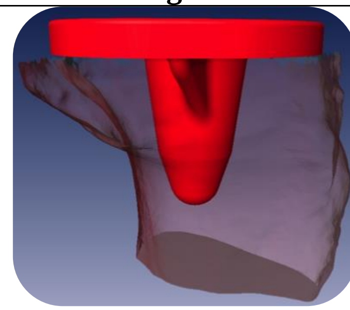
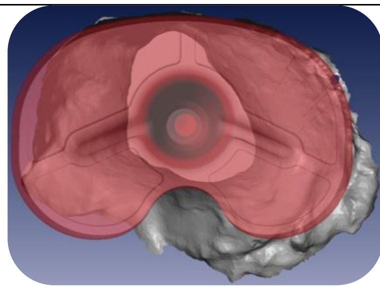
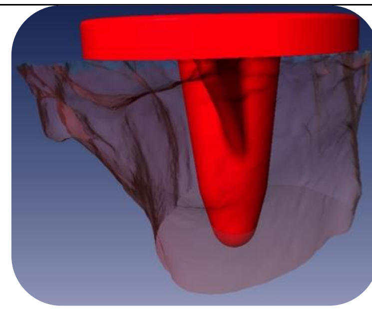
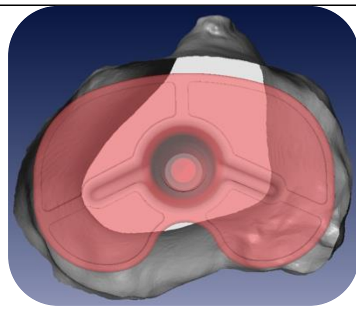
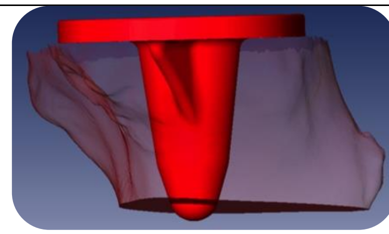
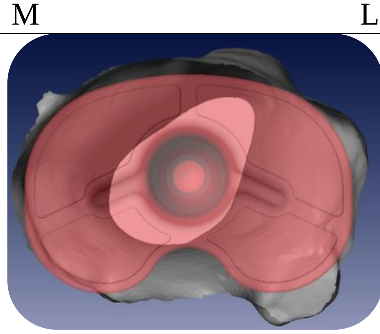
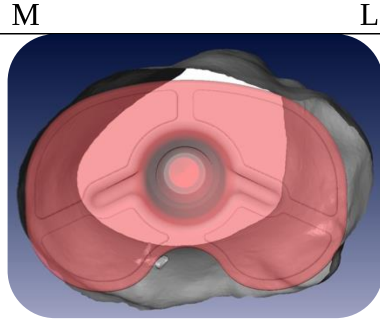
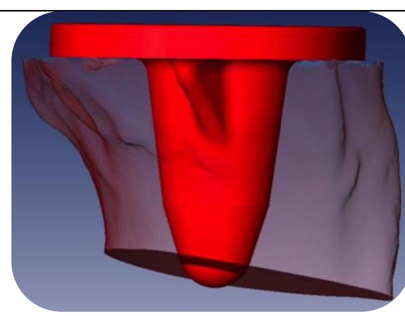
1	 M L	
2	 L M	
3	 M L	
4	 M L	
5	 M L	

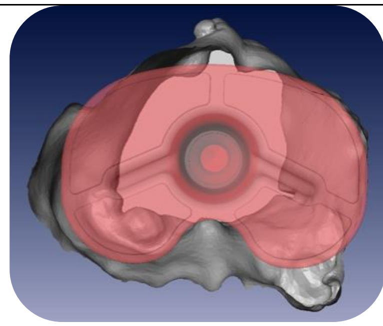
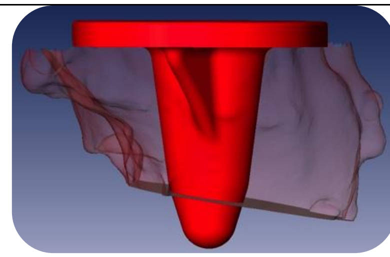
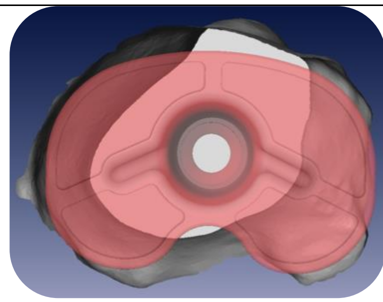
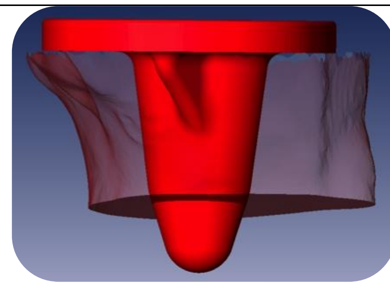
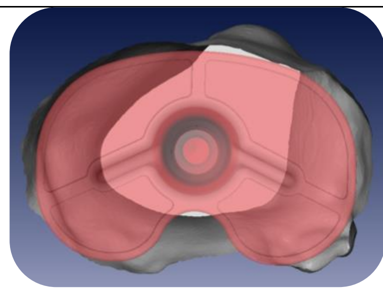
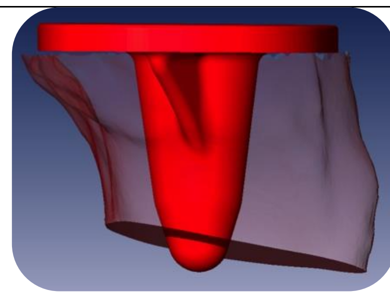
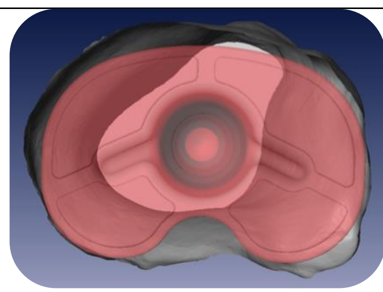
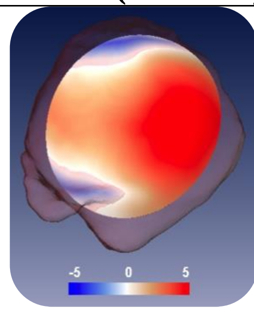
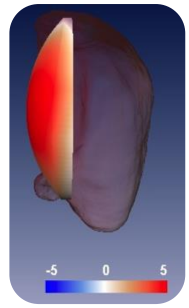
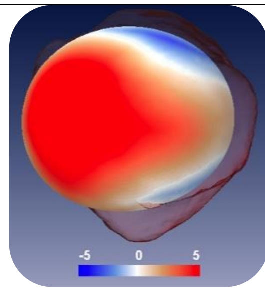
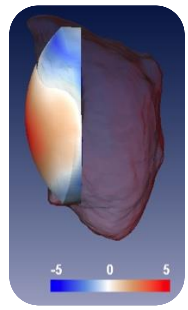
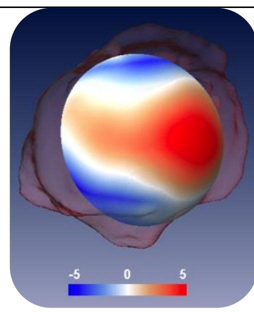
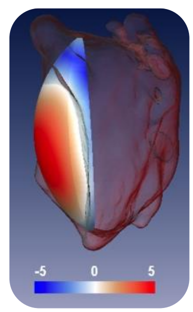
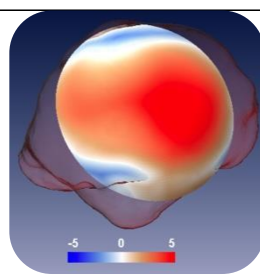
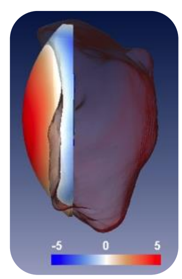
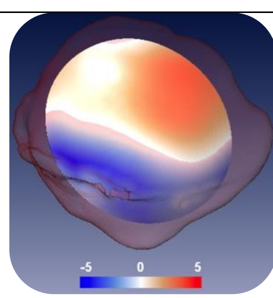
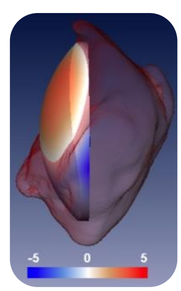
6	 M L	
7	 M L	
8	 M L	
9	 M L	

Figure 4-9. Overlays of the tibial component on the bone, showing bone coverage. Colour maps were not created for the tibia because of the mobile bearing insert; nonetheless, it is important to remember that TF joint changes are affected by changes on both sides, and to note that joint line changes in this study were larger on the tibial side than the femoral side (Table 4-10 & Table 4-11).

Subject #	Frontal (Posterior)	Sagittal
1	 M L	
2	 L M	
3	 M L	
4	 M L	
5	 M L	

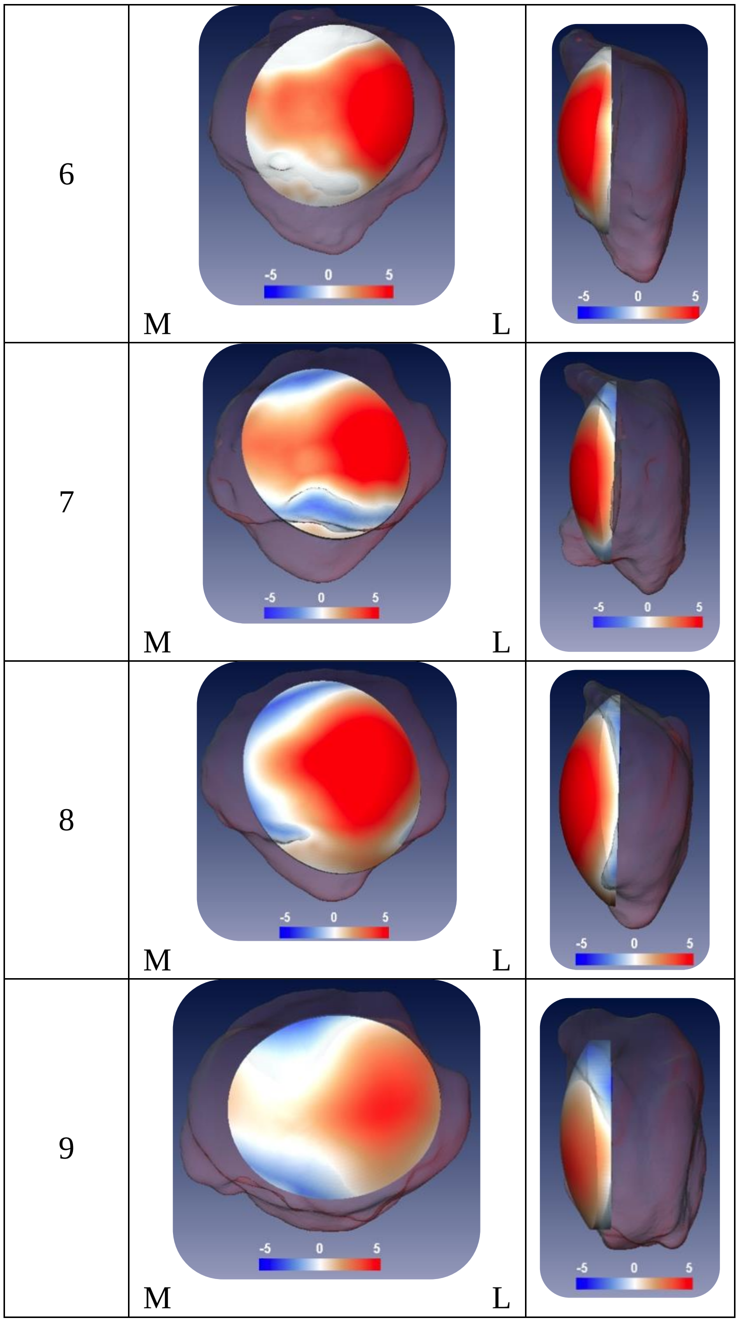


Figure 4-10. *Colour maps* of each individual subject's patella, showing the distance of the patellar prosthesis from the preop bone surface (excluding cartilage).

On average the distal condyles were higher (i.e. inside the preop bone) by 1.2 mm medially (range: -4.4 mm to 0.9 mm) and lower (outside the preop bone) by 0.6 mm laterally (range: -1.5 mm to 4.5 mm) for the subjects in this study, excluding the cartilage thickness (Table 4-2)

Table 4-2. Medial and lateral prosthesis-bone distances (mm) (i.e. excluding cartilage) for the *distal condyles*. Positive refers to the femoral component being outside the preop bone; negative is inside the preop bone. Average femoral cartilage thicknesses in healthy knees are approximately 2.7 mm and 2.2 mm on the lateral and medial distal condyles, respectively (Koo et al., 2003). Refer to Figure 4-8 for related colour maps.

Prosthesis-bone distances (mm) (distal condyles)	#1	#2	#3	#4	#5	#6	#7	#8	#9	Ave	SD
Medial	-0.8	-0.8	0.4	0.2	0.9	-4.4	-3.5	-1.1	-2.1	**-1.2**	**1.8**
Lateral	-1.4	1.9	1.4	0.6	-0.4	-0.7	-1.5	4.5	0.9	**0.6**	**1.9**
Ave	**-1.1**	**0.6**	**0.9**	**0.4**	**0.3**	**-2.6**	**-2.5**	**1.7**	**-0.6**	**-0.3**	**1.8**

The posterior condyles were smaller by 1.3 mm medially (range: -6.0 mm to 6.4 mm) and 0 mm laterally (range: -3 mm to 2.7 mm), with positive referring to the femoral component being outside the preop bone and negative being inside the preop bone (Table 4-3).

Table 4-3. Medial and lateral prosthesis-bone distances for the *posterior condyles* (mm). Positive refers to the femoral component being outside the preop bone; negative is inside the preop bone. Average femoral cartilage thicknesses in healthy knees are approximately 2.4 mm and 2.1 mm on the lateral and medial posterior condyles, respectively (Koo et al., 2003). Refer to Figure 4-8 for related colour maps.

Prosthesis-bone distances (mm) (posterior condyles)	#1	#2	#3	#4	#5	#6	#7	#8	#9	Ave	SD
Medial	-2.9	0.0	-1.0	-2.8	1.8	6.4	-4.3	-6.0	-3.1	**-1.3**	**3.7**
Lateral	0.0	0.0	1.0	0.0	2.7	2.7	-2.0	-3.0	-1.0	**0.0**	**1.9**
Ave	**-1.5**	**0.0**	**0.0**	**-1.4**	**2.3**	**4.5**	**-3.2**	**-4.5**	**-2.1**	**-0.6**	**2.8**

The intercondylar gap moved 0.3 mm laterally on average (range: -2.7 mm to 2.5 mm) (Table 4-4).

Table 4-4. Change in *intercondylar gap location* (mm). Positive indicates more lateral intercondylar gap location postop.

Changes in intercondylar gap location	#1	#2	#3	#4	#5	#6	#7	#8	#9	Ave	SD
Magnitude (mm)	2.5	-2.7	-0.3	0.4	1.2	1.3	1.3	-0.4	-0.5	**0.3**	**1.5**
% of femoral component's width	4%	-4%	0%	1%	2%	2%	2%	-1%	-1%		

Patellofemoral distance increased by 1.8 mm (range: -0.5 to 4.6 mm), 3.8 mm (range: 0.1 to 7.2 mm) and 3.5 mm (range: -0.3 to 8.1 mm) at 0º, 45º and 90º, respectively and were significantly larger postop ($p<0.05$) than preop (Table 4-5).

Table 4-5. Preop and postop *patellofemoral distances* (mm) (defined as the distance between the origin of the patellar bone coordinate system and the origin of the femoral bone coordinate system) with the knee in full extension, and at 45º and 90º knee flexion. Refer to Figure 4-10 for related colour maps.

Patellofemoral distance (mm)		#1	#2	#3	#4	#5	#6	#7	#8	#9	Average	SD
0 degree flexion	**Preop**	29.9	33.5	36.1	31.7	32.1	28.4	32.5	30.8	31.5		
	Postop	32.9	33.0	36.9	32.2	33.6	33.0	33.7	33.9	33.5		
	Diff	3.0	-0.5	0.8	0.5	1.5	4.6	1.2	3.2	2.0	1.8	1.5
45 degree flexion	**Preop**	29.0	34.1	35.7	32.6	31.4	28.0	30.9	30.9	31.8		
	Postop	35.4	34.3	40.1	33.1	35.3	35.1	34.8	34.5	35.9		
	Diff	6.4	0.1	4.4	0.5	3.9	7.2	3.9	3.6	4.2	3.8	2.3
90 degree flexion	**Preop**	29.6	34.7	36.2	33.6	34.5	27.8	32.6	31.4	33.2		
	Postop	36.4	34.6	42.0	33.3	35.6	35.9	35.7	35.5	36.2		
	Diff	6.8	-0.1	5.8	-0.3	1.1	8.1	3.2	4.1	3.0	3.5	3.0

Patellar thickness increased by an average of 2.9 mm (range: 0.7 to 5.2 mm), excluding the preop cartilage (Table 4-6). Judged visually, the patellar resection was mainly symmetric in both the mediolateral and inferosuperior directions.

Table 4-6. ***Patellar thickness*** **(mm), before and after TKA. Note: Preop thickness does not include cartilage; average patellar cartilage thickness is approximately 2.5 mm (Iranpour et al., 2008). Refer to Figure 4-3 for measurement method.**

Patellar thickness (mm)	#1	#2	#3	#4	#5	#6	#7	#8	#9	Average	SD
Preop bone	20.5	22.4	25.3	20.1	20.0	24.5	20.4	20.6	20.3	21.6	2.0
Postop total	23.2	26.6	26.4	23.6	22.8	27.7	23.3	25.9	21.0	24.5	2.2
Difference	**2.7**	**4.2**	**1.0**	**3.5**	**2.8**	**3.2**	**2.9**	**5.2**	**0.7**	**2.9**	**1.4**

In all cases: the proximal anterior flange of the femoral component was outside the preop bone (Figure 4-8), especially medially; the lateral portion of the anterior femoral condyle was inside the preop bone, cutting off the lateral prominence of the femoral groove; and the postop patella remant+component was thicker laterally compared to the preop patellar bone (Figure 4-10). Other changes varied from individual to individual, sometimes inside, sometimes outside the preop bone. In general, tibial trays fit better medially (Figure 4-9). Three tibial components demonstrated slight lateral overhang and there was less tibial coverage anteriorly for all subjects. Two tibias showed less coverage posterolaterally, and two posteromedially.

With respect to HKA angle, there were 8 varus knees and 1 valgus knee preoperatively. Postoperatively the knee was brought closer to neutral alignment in all cases ($p<0.01$), and within +/-3º in 7/9 cases (which is considered as neutral alignment) (Table 4-7). The average correction was 2.6º (SD: 4.0º) and the average postop HKA was 1.7º varus (SD: 2.7º).

Table 4-7. *Hip-knee-ankle (HKA) angle*, before and after TKA. Positive indicates valgus alignment. Refer to Figure 4-4 for measurement method.

HKA angle (°)	#1	#2	#3	#4	#5	#6	#7	#8	#9	Average	SD
Preop	-6.3	-7.7	-8.7	-5.3	-4.9	6.6	-3.0	-6.4	-2.5	**-4.2**	**4.5**
Postop	**2.6**	**-3.0**	**-4.0**	**-1.2**	**-0.7**	**1.6**	**-3.0**	**-6.1**	**-1.0**	**-1.7**	**2.7**
Change	**-9.0**	**-4.8**	**-4.7**	**-4.1**	**-4.1**	**5.0**	**0.1**	**-0.3**	**-1.5**	**-2.6**	**4.0**

With respect to the posterior-condylar lines (PCLs) and transepicondylar axes, preoperatively the anatomical transepicondylar axis (TEA) was externally rotated by a mean of 6.3º (SD: 1.6º) relative to the bone-PCL whereas the surgical TEA was externally rotated by a mean of 1.9º (SD: 2.0º) relative to the bone-PCL (Table 4-8) resulting in an average difference between the two TEAs of 4.4º (SD: 1.0º), with the anatomical TEA more externally rotated than the surgical TEA ($p<0.01$). Postoperatively, the femoral component was slightly externally rotated by 0.8º on average (SD: 1.8º) relative to the surgical TEA, and externally rotated by 2.7º on average (SD: 1.4º) relative to the preop PCL.

Table 4-8. *Anatomical and surgical TEA* relative to the preop PCL and femoral component PCL relative to the bone PCL and surgical TEA (º). Positive indicates external rotation. Refer to Figure 4-5 for definitions.

Pre/postop	Ref Line	#1	#2	#3	#4	#5	#6	#7	#8	#9	Average	SD
Preop	Anatomical TEA w.r.t. PCL (º)	9.2	4.1	6.0	7.0	5.1	5.6	8.3	5.6	5.5	**6.3**	1.6
	Surgical TEA w.r.t. PCL (º)	5.2	0.4	1.8	3.3	0.5	2.3	4.0	0.3	-1.0	**1.9**	2.0
	Difference (º)	**4.0**	**3.7**	**4.2**	**3.7**	**4.6**	**3.3**	**4.3**	**5.3**	**6.5**	**4.4**	1.0
Postop	Fem. Comp. w.r.t. Bone-PCL (º)	4.1	0.7	2.6	3.7	0.2	4.1	2.6	3.2	3.0	**2.7**	1.4
	Fem. Comp. w.r.t. Surg-TEA (º)	**-1.1**	**0.3**	**0.8**	**0.4**	**-0.3**	**1.8**	**-1.4**	**2.9**	**4.0**	**0.8**	1.8

Total joint line shift using the preoperative-based registration method, taking cartilage into account, showed that the joint line was changed by 0.7 mm on average (SD: 2.4 mm) in extension, -1.3 mm (SD: 2.9 mm) in 45º flexion and -1.5 mm (SD: 3.1 mm) in 90 º flexion (Table 4-9), suggesting a slightly tighter joint in extension and a slightly looser joint in flexion. There was a significantly larger joint line shift, in extension, on the medial side than the lateral side due to the varus knees preop (P<0.01).

Table 4-9. *Total tibiofemoral joint line changes* (mm), taking cartilage into account (preoperative-based registration). Positive refers to an equivalent interference fit, suggesting a tighter joint postop; negative refers to an equivalent separation, suggesting a looser joint postop.

Joint line (preoperative-based) (mm)		#1	#2	#3	#4	#5	#6	#7	#8	#9	Average	SD
0 degree flexion	Medial	5.9	8.8	1.7	0.0	3.6	2.1	0.4	3.1	2.9	3.2	2.7
	Lateral	-3.6	2.1	-3.5	-4.7	-2.9	4.7	-3.6	-1.0	-2.9	-1.7	3.1
	Average	1.1	5.4	-0.9	-2.3	0.3	3.4	-1.6	1.1	0.0	**0.7**	**2.4**
45 degree flexion	Medial	7.1	7.1	1.0	-2.4	0.7	-0.4	1.5	-2.2	-1.1	1.2	3.6
	Lateral	-3.7	-0.8	-3.6	-9.3	-5.0	2.5	-5.4	-7.1	-2.7	-3.9	3.4
	Average	1.7	3.1	-1.3	-5.9	-2.2	1.0	-1.9	-4.6	-1.9	**-1.3**	**2.9**
90 degree flexion	Medial	5.4	5.9	1.2	-4.4	-0.3	-1.9	-2.0	-2.6	-2.1	-0.1	3.6
	Lateral	-1.8	1.2	-1.9	-7.0	-2.6	1.8	-5.4	-7.2	-3.6	-2.9	3.2
	Average	1.8	3.6	-0.4	-5.7	-1.4	-0.1	-3.7	-4.9	-2.9	**-1.5**	**3.1**

Using the postoperative-based registration to identify the source of these changes, we found that the femoral joint line was raised by 0.3 mm on average relative to the bone surface (SD: 1.5 mm) in extension, 1.5 mm (SD: 1.4 mm) in 45º flexion and 1.5 mm (SD: 2 mm) in 90º flexion (Table 4-10). The tibial joint line was raised by 4.1 mm relative to the bone (SD: 2.3 mm) at 0º, 45º and 90º flexion (Table 4-11).

Table 4-10. Individual *femoral joint line shifts* relative to the bone surface (mm). Positive refers to the femoral component being outside the preop bone; negative is inside the preop bone; average femoral cartilage thicknesses in healthy knees are approximately 2.7 mm and 2.2 mm on the lateral and medial posterior condyles; and 2.4 mm and 2.1 mm on the lateral and medial posterior condyles (Koo et al., 2003). Refer to Figure 4-7.a for definitions.

Femoral Joint line (postoperative-based) (mm)		**#1**	**#2**	**#3**	**#4**	**#5**	**#6**	**#7**	**#8**	**#9**	**Ave**	**SD**
0 degree flexion	Medial	-0.8	-0.8	0.4	0.2	0.9	-4.4	-3.5	-1.1	-2.1	-1.2	1.8
	Lateral	-1.4	1.9	1.4	0.6	-0.4	-0.7	-1.5	4.5	0.9	0.6	1.9
	Average	-1.1	0.6	0.9	0.4	0.3	-2.6	-2.5	1.7	-0.6	**-0.3**	1.5
45 degree flexion	Medial	-2.5	-2.0	0.0	-2.7	0.6	-5.4	0.8	-5.5	-4.1	-2.3	2.4
	Lateral	-1.8	-0.3	1.6	-1.1	-0.6	-0.8	-1.7	-1.3	-1.1	-0.8	1.0
	Average	-2.2	-1.2	0.8	-1.9	0.0	-3.1	-0.5	-3.4	-2.6	**-1.5**	1.4
90 degree flexion	Medial	-3.1	0.0	-0.5	-0.8	1.2	-6.7	-3.7	-6.6	-3.0	-2.6	2.8
	Lateral	0.0	-0.3	2.6	-0.6	0.9	-2.2	-1.0	-1.8	-0.9	-0.4	1.4
	Average	-1.5	-0.2	1.0	-0.7	1.1	-4.5	-2.4	-4.2	-2.0	**-1.5**	2.0

Table 4-11. Individual *tibial joint line shifts* relative to the bone surface (mm). Positive refers to the tibial component being outside the preop bone; negative is inside the preop bone; average tibial cartilage thicknesses in healthy knees are approximately 2.8 mm and 2.2 mm on the lateral and medial anterior tibial plateau, respectively; and 3.3 mm and 2. 4 mm on lateral and medial posterior tibial plateau, respectively (Koo et al., 2003). Refer to Figure 4-7.b for definitions.

Tibial Joint line (postoperative-based) (mm)	**#1**	**#2**	**#3**	**#4**	**#5**	**#6**	**#7**	**#8**	**#9**	**Ave**	**SD**
Medial	10.3	7.7	4.4	1.5	3.8	8.5	3.8	5.4	4.6	5.6	2.8
Lateral	4.2	4.5	1.0	-0.4	2.1	5.8	2.3	0.6	3.8	2.6	2.1
Average	7.3	6.1	2.7	0.5	3.0	7.2	3.1	3.0	4.2	**4.1**	2.3

Total joint line shift using the postoperative-based registration method, excluding the cartilage, showed that the joint line was changed by 3.8 mm on average (SD: 2.0 mm) in extension, 2.6 mm (SD: 2.3 mm) in 45º flexion and 2.6 mm (SD: 2.4 mm) in 90º flexion (Table 4-12).

Table 4-12. *Total tibiofemoral joint line changes (mm), excluding cartilage* (postoperative-based registration). Positive refers to the implant being outside the original bone; negative refers to the implant being inside the original bone.

Joint line shift (postoperative-based) (mm)		#1	#2	#3	#4	#5	#6	#7	#8	#9	Ave	SD
0 degree flexion	Medial	9.4	7	4.7	1.9	4.5	4.1	0.4	4.2	2.4	4.3	2.7
	Lateral	2.7	6.3	2.4	0.1	1.7	5.5	0.9	4.8	4.7	3.2	2.2
	Average	6.1	6.7	3.6	1.0	3.1	4.8	0.7	4.5	3.6	**3.8**	2.0
45 degree flexion	Medial	8	5.7	4.5	-1.4	4.5	3.1	4.7	-0.4	0.6	3.3	3.1
	Lateral	2.5	4.2	2.8	-1.5	1.5	4.7	0.8	-0.6	2.8	1.9	2.1
	Average	5.3	5.0	3.7	-1.5	3.0	3.9	2.8	-0.5	1.7	**2.6**	2.3
90 degree flexion	Medial	7.2	7.6	3.8	0.6	5.2	1.8	0.0	-0.8	1.5	3.0	3.1
	Lateral	4.1	4.2	3.5	-1.0	2.9	3.5	1.1	-1.0	2.8	2.2	2.0
	Average	5.7	5.9	3.7	-0.2	4.1	2.7	0.6	-0.9	2.2	**2.6**	2.4

The average differences between preoperative- and postoperative-based joint line shift measurements in extension was 1.1 mm on the medial side and 4.9 mm on the lateral side (Table 4-13). For the 45 º flexion, these measures were about 2.1 mm and 5.8 mm for the medial and lateral sides, respectively. For the 90 º flexion, these measures were about 3.1 mm and 5.1 mm for the medial and lateral sides, respectively.

Table 4-13. Differences between preoperative and postoperative- based joint line shift measurements (mm).

Joint line shift (preop vs postop) (mm)		#1	#2	#3	#4	#5	#6	#7	#8	#9	Ave	SD
0 degree flexion	Medial	3.5	-1.8	3	1.9	0.9	2	0	1.1	-0.5	1.1	0
	Lateral	6.3	4.2	5.9	4.8	4.6	0.8	4.5	5.8	7.6	4.9	-0.9
	Average	5	1.3	4.5	3.3	2.8	1.4	2.3	3.4	3.6	**3.1**	-0.4
45 degree flexion	Medial	0.9	-1.4	3.5	1	3.8	3.5	3.2	1.8	1.7	2.1	-0.5
	Lateral	6.2	5	6.4	7.8	6.5	2.2	6.2	6.5	5.5	5.8	-1.3
	Average	3.6	1.9	5	4.4	5.2	2.9	4.7	4.1	3.6	**3.9**	-0.6
90 degree flexion	Medial	1.8	1.7	2.6	5	5.5	3.7	2	1.8	3.6	3.1	-0.5
	Lateral	5.9	3	5.4	6	5.5	1.7	6.5	6.2	6.4	5.1	-1.2
	Average	3.9	2.3	4.1	5.5	5.5	2.8	4.3	4	5.1	**4.1**	-0.7

4.4 Discussion

The aim of this study was to investigate changes in knee geometry due to TKA. Changes in geometry can have a profound impact on the patient, yet these changes have not been documented previously, to our knowledge. The surgeon changes the knee shape both intentionally, to correct the joint, and unintentionally, due to uncertainties in the component positioning as well as standardized component sizing. Component design and placement can impact HKA angle, joint line height, patellofemoral thickness and femoral groove location. These in turn can influence alignment, stability, range of motion, pain, patellar tracking and patellar fracture. Since all subjects had good to excellent clinical results based on patient-assessed questionnaires, these findings represent a range of normal results.

The surgery corrected the varus/valgus malalignment observed in the pre-TKA osteoarthritic knees to 4° or less, except in one knee, which remained at 6° varus. This malalignment correction has a number of repercussions. Varus knees (which were 8/9 of our subjects) typically have greater wear on the medial side of the knee; correction to neutral alignment therefore requires cutting less off the medial side or more off the lateral side on the femur and/or tibia. The surgeon aims to achieve a balanced knee during flexion and extension to maintain both stability and range of motion. Due to the severe knee deformation and worn cartilage in arthroplasty patients, the surgeon may decide not to restore the preoperative joint line (Amiri et al., 2013). Given that the medial side had a 3.2 mm 'tighter' joint line on average postop in full extension (0.1 mm 'looser' at 90º flexion), with 1.7 mm 'looser' on the lateral side in full extension (2.9 mm at 90º flexion), the surgeon generally chose to add more thickness on the medial side (mostly on the tibial side), to restore the joint closer to its pre-arthritic state, while allowing more flexibility medially and laterally in flexion. 'Tight' refers to having the femur and tibia pushed farther apart in the postop vs preop joint due to an interference fit, but this may or may not be a tighter joint depending on the state of the ligaments before and after surgery. The femoral vs. tibial changes are consistent with the surgeon's planned technique of taking 2-3 mm more bone off the distal femur. Some of the variation between individuals may be due to differences in cement thickness.

The two joint line methods both have value and limitations and are best used together. The second method, comparing the prosthesis surface to the bone surface has been routinely used but is inaccurate for comparing the preop/postop shapes due to the lack of cartilage. This led to an average error of 3.1 mm, 3.9 mm and 4.1 mm for 0º, 45º and 90º flexion, respectively (Table 4-14), when estimating joint line changes. The first method accurately considers the preop cartilage thickness, but benefits from the second method to identify the source of changes in the joint line.

Patellofemoral geometry changed substantially. Patellar thickness increased in all subjects relative to the bone surface, particularly laterally. Even if a typical cartilage thickness of 2.5 mm (for healthy subjects) is added to the bone surface (Iranpour et al., 2008), the total thickness likely increased in all but two of the subjects; the cartilage thickness of subjects with severe arthritis is likely much less. The surgeon preferred a thicker resurfaced patella to avoid patellar fracture. However, the increase in patellar thickness could cause excessive tightness leading to patellar tilt laterally (Merican et al., 2014). Lateral release of the retinaculum (not performed for these subjects) can correct this patellar tilt partially, but it can also cause abnormal tibial rotation externally (Merican et al., 2014) and is generally avoided due to other morbidities and complications. Postoperatively, patellofemoral distance was increased significantly which can cause the PF overstuffing. It was also changed by the knee flexion angle. This shows that the changes in PF distance were not just because of the change in the patellar thickness postop, and could be due to the variations in the anterior aspects of the femur, which change the arc that the extensor mechanism must travel, and thereby cause different amounts of tightness.

Femoral component rotation can impact patellar tracking, tibiofemoral kinematics, pain, stability and range of motion (Berger et al., 1998, Barrack et al., 2001). In TKA, surgeons mostly aim to position the femoral component in the "correct" alignment rather than the normal alignment of the distal femur (Victor, 2009). Since the normal tibial plateau has an average 3º varus orientation (Moreland et al., 1987), the standard perpendicular coronal tibial cut changes the natural angle. Matching the femoral component to the natural alignment can therefore cause problems during flexion. Furthermore, in most femoral components, the posterior condylar line is parallel to the anterior cut. Therefore, usually a 3º external rotational compensation is recommended on the femoral side to correct the tibial cut and symmetric component design. In knees with a perpendicular tibial cut, internal femoral component rotation negatively affects knee stability, patellar tracking, and patellofemoral contact points; a small external rotation improves both of these (Poilvache et al., 1996). In our study, we found that the femoral component was 2.7º externally rotated on average from the posterior condylar line, as desired, or 0.8º externally rotated from the surgical TEA. Nonetheless, the wide range between individuals and possibly between women and men (Victor, 2009) suggests that an individualized plan could be beneficial. For example, most instrumentation builds in 3º external component rotation and references from the posterior condyles, but the angular difference between the surgical TEA (an approximate functional goal) relative to the posterior condylar line (PCL) in our subjects ranged from -1.0º to 5.2º. Furthermore, variations in cartilage thickness can affect the normal relationships between the PCL and TEA. The average difference of 4.4º between the anatomical and surgical TEA, which is similar to that found in other studies (Yoshino et al., 2001), emphasizes the importance of identifying the correct landmarks during surgery. Optimizing coverage of the tibial plateau is an important consideration in total knee arthroplasty (TKA). This will provide the best overall knee stability and load transfer to the proximal tibia and may avoid complications such as postoperative bone bleeding, subsidence, and loosening (Wernecke et al., 2012).

Individual changes are as important as the average results described above, to understand the range of values possible, and to link the various factors together (Table 4-14). It is also important to realize that individuals are different coming into the surgery, including the state of their bones and cartilage, the state of their ligaments, the existence of flexion contractures and the normality of their bone shapes. For example, S6 had a very tight knee intraop, which required the surgeon to cut more off the distal femur in order to access the joint; this was later compensated with augments. The relationships between individual shape and kinematics are explored in Chapter 5.

Table 4-14. Individual subject high/low values for the main parameters evaluated.

Item	Distal condyles	Post. condyles	Inter. gap	PF distance	Pat. thick.	HKA postop	Fem. rotn.	Med joint change	Lat joint change
Subject with max value	S3	S6	S2	S3	S8	S8	S9	S2	S6
Subject with min value	S7	S8	S1	S9	S9	S5	S7	S4	S4

This pilot study was limited by the small number of subjects with a single implant design and surgeon. It is important to recognize that results may be different for different implant designs and surgical techniques. A larger study with multiple surgeons and implant designs, including patients with good and poor results, would be beneficial. Another major limitation is that we only had information on the bone surface, not the cartilage surface due to the CT and radiographic methods used. Nonetheless, wherever the prosthesis is inside the bone, it will be even more inside the cartilage surface, and average cartilage thicknesses (provided with the tables) can be added to the bone surface calculations to gauge the changes and the preop-based method was included to address this issue for the tibiofemoral joint line and patellofemoral distance. The primary purpose of this study was to highlight that such changes in knee geometry do exist. Although a more complete study would include magnetic resonance imaging (MRI) to evaluate the cartilage surface as well, MR image acquisition is considerably more expensive; preop segmentation is considerably more time-consuming; and postop metal artifact is considerably worse. Therefore postop CT is still preferred.

Based on the results of this shape and geometry study, the anterior flange of the femoral component should be thinner and the patellar resection thickness should be carefully controlled.

More femoral size options would allow a better match to the original geometry and fewer compromises. Our results also showed that the intercondylar gaps are located more laterally on average postop, although the total distances were small. Implant shape and size should be designed based on how the prosthesis will be implanted, not on the original anatomical bone shape, since more will be cut off one side than the other to realign the leg. Component placement plays a critical role in clinical outcome and should be accurately controlled. A previous study of 5 patients with poor results each revealed that component placement or patellar thickness (too thick or too thin) was the most likely cause for their clinical outcome (Saevarsson, 2012). Better patellar resection techniques are needed to achieve the correct thickness (Anglin, Rex, et al., 2013). Patellar non-resurfacing is also an option, but can be more likely to lead to anterior knee pain and functional deficits (Helmy et al., 2008; Johnson et al., 2012). Given all of the inter-related factors in component placement, residents could benefit from computer-based training to understand the consequences, interactions and corrective actions for each step, e.g. femoral component rotation, flexion vs extension gaps, anteroposterior and mediolateral component positioning, and patellar thickness.

Changes in knee shape and geometry depend on a combination of surgical technique, implant design, implant selection and component positioning. This pilot study is the first that we are aware of to investigate these changes. Existing databases as well as future prospective studies could exploit this new way of looking at the knee joint to determine shape differences between patients with good vs. poor results after TKA to identify intraoperative interventions or changes in implant design to improve surgical outcome and patient satisfaction. The protocol that was developed in this study can be used for comparisons of surgical plans with surgical outcomes and to create a feedback loop that keeps track of and augments the surgeon's learning experience for continual improvement.

Chapter Five: **Relationships between Shape, Kinematics and Quality of Life Before and After Total Knee Arthroplasty**

5.1 Introduction

Important factors affecting quality of life, pain, function, satisfaction, ligament balance, wear and revision after total knee arthroplasty are postoperative knee kinematics and knee geometry, which are influenced by implant design and implant placement (Berger et al., 1993; Hanada et al., 2007; Ho et al., 2012; Matsuda et al., 2001; Miller et al., 2001; Nishikawa et al., 2013; Noble et al., 2005; Rhoads et al., 1990). Although specific design factors and their effect on kinematics or quality of life have been investigated previously, the inter-relationships between preop-postop changes in kinematics, knee geometry and the resulting quality of life have not been studied to our knowledge. These are essential to understand the interplay between the different factors, and to determine which factors implant manufacturers and surgeons should focus on when designing and implanting knee prostheses. Furthermore, the majority of TKA studies focus on the tibiofemoral (TF) joint, although the patellofemoral (PF) joint is routinely the source of postoperative complications; the PF joint is difficult to study due to the radiotransparency of the polyethylene component and because the patella is obscured by the femoral component from most directions.

In Chapters 3 and 4, we studied the preoperative and postoperative PF and TF kinematics and articular geometry of nine subjects before and at least one year after TKA. In the present study, we evaluate relationships between the subjects' health-related quality of life, based on patient-assessed clinical scores, and the changes in knee shape and kinematics, to determine whether shape impacts kinematics and whether shape or kinematics affect QOL. Given the extensive dataset for each individual subject, which has not previously been available, but the limited number of subjects for a single implant design and surgeon, the goal of this pilot study was not to provide definitive relationships for all surgeons and implant designs, but to identify the presence or lack of relationships for this selection of patients, which can then be explored further and hypotheses tested in a larger series. In addition to our own further work, our goal is motivate other clinical and technical researchers, developers and surgeons to think about these relationships, both experimentally and through computer modeling, in relation to implant design (both standardized and custom) and implant placement (including preoperative planning, intraoperative execution and postoperative diagnosis), ultimately to improve patient quality of life and the clinical success of TKA.

The purpose of the present study was to correlate specific changes in knee articular geometry, over which the implant designers and surgeons have some control, to changes in kinematics and postop QOL for a sample population, with a particular focus on the patellofemoral joint, to answer the following research questions: (1) Do changes in knee shape affect knee kinematics? In particular, is patellar tracking affected by the groove location? (2) Do changes in knee kinematics affect quality of life? (3) Do changes in knee shape (resulting from implant design and placement) affect quality of life? (4) Do individuals with worse quality of life differ from those with better quality of life?

5.2 Methods

5.2.1 Subjects and prosthesis

A group of nine osteoarthritis (OA) subjects participated in the current study (5 male, 4 female, ages 44 to 82) (Table 3-1). We studied the affected knee of the subjects before and at least one year after TKA. All but one of the subjects had a varus knee preop; subject #6 had a valgus knee. All subjects were implanted with a cemented, rotating-platform posterior-stabilized, multi-radius prosthesis (PFC® Sigma^{TM} Mobile Bearing; DePuy Synthes Joint Reconstruction, Warsaw, IN) with a resurfaced patella, and were operated on by a single expert surgeon. The surgeon uses a femur-first, ligament-balancing technique. After TKA, all subjects were satisfied with their TKA. Our institutional review board approved the study and written informed consent was obtained from all subjects.

5.2.2 Kinematic analyses

To evaluate the impact of TKA on weightbearing knee kinematics, we determined the 6 degree-of-freedom (DOF) PF & TF kinematics, TF contact point and TF helical axis of rotation before and after TKA using calibrated sequential-biplanar radiographic imaging at 8 flexion angles (Sharma et al., 2012). There were significant differences between pre-TKA and post-TKA kinematics for all types of analyses performed, although not for all degrees of freedom [Chapter 3]. The DOF selected from this larger analysis for the present study, based on their high clinical relevance, were: *PF mediolateral translation, patellar shift within the groove* and *patellar tilt* (together representing patellar tracking), *TF anteroposterior (AP) translation* (closely tied to TF contact, wear, range of motion and stability), and *TF internal-external (IE) rotation* (particularly relevant for the mobile bearing design and tied to patellar tracking, TF contact and stability). In the kinematic analysis, both preop and postop kinematics are referenced to the postop coordinate system, so that changes reflect the true change rather than a change in the coordinate system [Chapter 3].

5.2.3 Shape analyses

To investigate changes in articular geometry, we compared the overall shape (using colour-coded maps to visualize the difference between the original and resurfaced knee) and specific geometric parameters, matching the three-dimensional (3D) implant models to the generated 3D bone-implant volume from computed-tomography (CT) imaging (Ho et al., 2012). The following clinically-relevant geometric features were evaluated numerically [Chapter 4]: *changes in patellofemoral distance,* as this can affect over- or understuffing of the joint, range of motion and pain, and reflects the anteroposterior component design and positioning (Mihalko et al., 2006); *femoral component rotation relative to the bone*, since internal rotation can cause patellar tracking, pain and complications whereas excessive external rotation can cause mechanical overload on the medial side of the joint and increased shear forces on the patella (Victor, 2009); *changes in the distal condylar dimensions,* as this can affect varus/valgus alignment, femoral groove orientation, and stability in extension; and *changes in the posterior condylar dimensions,* as these can affect stability in flexion, patellar tracking, range of motion and kinematics (Malviya et al., 2009). On the tibial side, due to the unknown rotation of the mobile bearing insert, only the metal tibial tray was matched and changes in tibial geometry were not calculated. Our patellofemoral and femoral analyses showed that the knee shape and geometry changed in numerous significant ways as a result of the TKA [Chapter 4].

For the present relationships study, we also evaluated the following kinematically-relevant geometrical parameters: preop and postop *patellar height*, a factor over which the surgeon and implant designers do not have control, but which can cause patellar maltracking, anterior knee pain, and bony impingement and is particularly important since patella baja is more commonly encountered following TKA and can lead to decreased range of motion, extensor lag, decreased lever arm, and patellar tendon rupture (Chonko et al., 2004); and *changes in femoral groove orientation*, as this can cause patellar maltracking, poor knee extension function and increased medial–lateral shear force on the patellar button (Petersilge et al., 1994). In newer implants, femoral groove orientation has evolved from a symmetrical design to having a proximal–lateral angle, with the groove aligned proximal–lateral to distal–central (Stoddard et al., 2014). Preop and postop patellar height (Figure 5-1), was calculated using the Insall–Salvati ratio (Equation 1) with 1.02 considered as the normal ratio, values below 0.8 defined as patella baja and values above 1.2 defined as patella alta (Laskin, 1998; Phillips et al., 2010).

patellar height =(patellar tendon length)/(patellar bone length) *(Eqn. 1)*

Figure 5-1. Patellar height. Patellar height was calculated using the Insall–Salvati ratio (patellar height =patellar tendon length / patellar bone length), with 1.02 considered as the normal ratio, values below 0.8 defined as patella baja and values above 1.2 defined as patella alta.

5.2.4 Patellar tracking & femoral groove location

The location of the patella within the femoral groove was determined in 3 steps: (1) the location of the preop or postop femoral groove was determined relative to the femoral component coordinate system, at the 8 flexion angles, as described below; (2) the location of the preop or postop patellar apex was determined relative to the femoral component coordinate system, at the 8 flexion angles; and (3) patellar tracking within the groove was defined as the difference between the two. Spline-fitting a curve to the groove locations and patellar apex locations and determining the difference was considered more reliable than directly measuring the shift within the groove at the individual flexion angles. The femoral groove was defined by taking a cross-section through the epicondylar axis of the femur and the patellar apex and selecting the landmarks on the deepest point within the femoral groove relative to the femoral component coordinate system. To solve the more challenging problem of defining the groove within the intercondylar gap (due to the lack of contact of the patellar apex with the notch cut-out in the femoral component), a curved surface was fit to the two side-surfaces and then the turning points of the curved surface selected as the groove line (Figure 5-2).

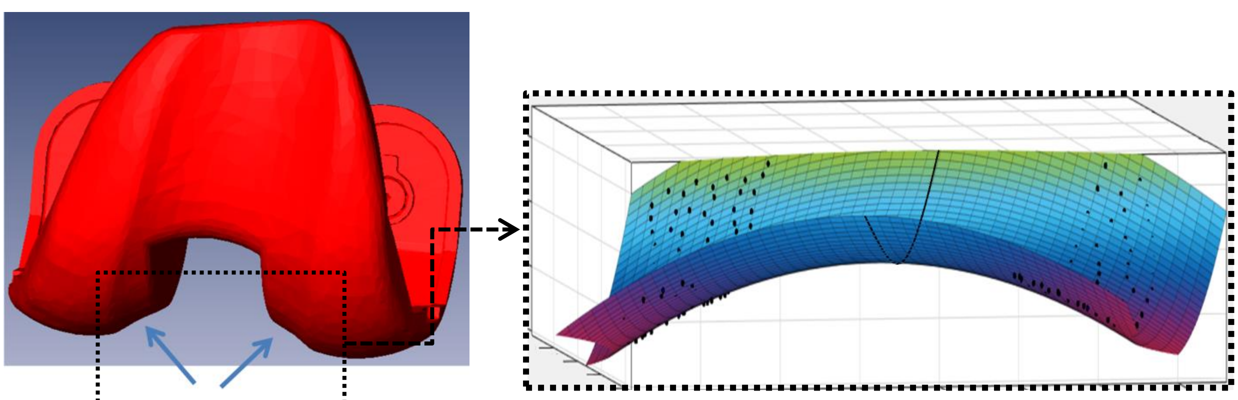


Figure 5-2. Defining the femoral groove within the intercondylar gap. Curve surface fitting was performed to define the groove location in the cut-out part within the intercondylar gap; a curved surface was fit to the two side-surfaces and then the turning points of the curved surface were selected as the groove line.

The preop patellar apex was defined as the midpoint of the patellar ridge relative to the femoral component coordinate system, measured on the 3D reconstructions derived from the biplanar radiographs. The postop patellar apex was chosen as the most prominent point on the posterior surface of the patellar component, relative to the femoral component coordinate system. Patellar tracking relative to the groove was then calculated as the difference between patellar tracking relative to the femoral component coordinate system and the femoral groove relative to the femoral component coordinate system.

5.2.5 Quality of life data

To determine the subjects' health-related quality of life before and after TKA, they completed a set of validated questionnaires. These were used to identify patients with lower QOL after the surgery, to determine whether the physical changes in shape and kinematics had a clinical impact. The QOL data also provided a more global view of the subjects' health beyond the radiographic analyses. The following standard QOL scores were collected at the time of the imaging sessions: Hospital for Special Surgery (HSS) Patella Score (Baldini et al., 2006), Knee Society Score (KSS) (Insall et al., 1989), Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) score (Bellamy et al., 1988), Oxford score (Dawson et al., 1998), and SF-12 physical component summary (PCS) and mental component summary (MCS) (Gandek et al., 1998). Each score has its own unique features (Dowsey et al., 2013): for example the HSS Patella Score emphasizes anterior knee pain, which is not addressed by the other scores although it is a common source of dissatisfaction; this score was previously used to identify worse QOL with an asymmetric patellar resection (Baldini et al., 2006). By contrast, the SF-12 score evaluates general health and can be useful for identifying issues unrelated to the knee prosthesis.

5.2.6 Relationships between kinematics, shape and QOL

Analyzing the effect of TKA on knee shape, kinematics and QOL allowed us to investigate the inter-relationships amongst these parameters. In particular, we were interested in the influence of these changes on patellofemoral kinematics. We investigated the inter-relationships amongst the kinematics parameters (patellar mediolateral translation, PF shift, PF tilt, TF AP translation, and TF IE rotation), the geometrical parameters (changes in patellofemoral distance, femoral component rotation, posterior and distal condylar dimensions, and mediolateral femoral groove location), and the collected QOL scores. The SF-12 physical and mental scores, which evaluate general health and can therefore be affected by issues unrelated to the knee prosthesis, were excluded from the correlation analysis since the surgeon is unlikely to be able to affect these scores through implant design or surgical technique. While we recognize the limitations of investigating numerous correlations with a small number of subjects, this pilot study will provide the basis for future studies, both in our group and in others, using advanced imaging and analysis techniques to produce a quicker analysis of a larger dataset.

5.2.7 Statistical analyses

The relationships between the different kinematics, shape and QOL parameters were assessed by calculating a two-tailed Pearson's correlation coefficient (ρ), with $p<0.05$ considered significant (approximately $\rho > 0.7$), using SPSS ver. 21 (SPSS Inc., Chicago, IL, USA). Preop-postop comparisons were made for the newly evaluated parameters: patellar height, patellar tracking within the femoral groove and the QOL data of the 9 subjects using paired Student's t-tests, with $p<0.05$ considered significant. Although a lower significance threshold could be selected due to the multiple comparisons, this threshold was chosen to identify trends for further study. Conversely, to avoid missing potential trends for clinically-significant correlations due to the small number of subjects, a power analysis was performed for those parameters in which $p>0.05$.

5.2.8 Analysis of individuals with lower QOL

In addition to the group analyses, we evaluated each individual subject's parameters to identify subjects with high or low values for each parameter. A high/low value was defined when the result was more than one standard deviation worse than the average for the group, except for patellar height/tilt/shift and femoral component rotation. For patellar height, ratios greater than 1.2 or less than 0.8 were considered as high/low values, as these have previously been recognized as problematic (Laskin, 1998; Phillips et al., 2010). For the femoral component rotation, values less than 3º external rotation from the posterior condyles were considered problematic (Poilvache et al., 1996). A maltracking patella was defined as a patella shifted more than 5 mm relative to the femoral groove or tilted > 5° (Shih et al., 2004). High/low values for the same parameter at multiple flexion angles were treated as a single value.

5.3 Results

5.3.1 Overview

There were significant correlations between numerous kinematics parameters, shape parameters and QOL of the subjects with TKA (Figure 5-3). Details are provided below.

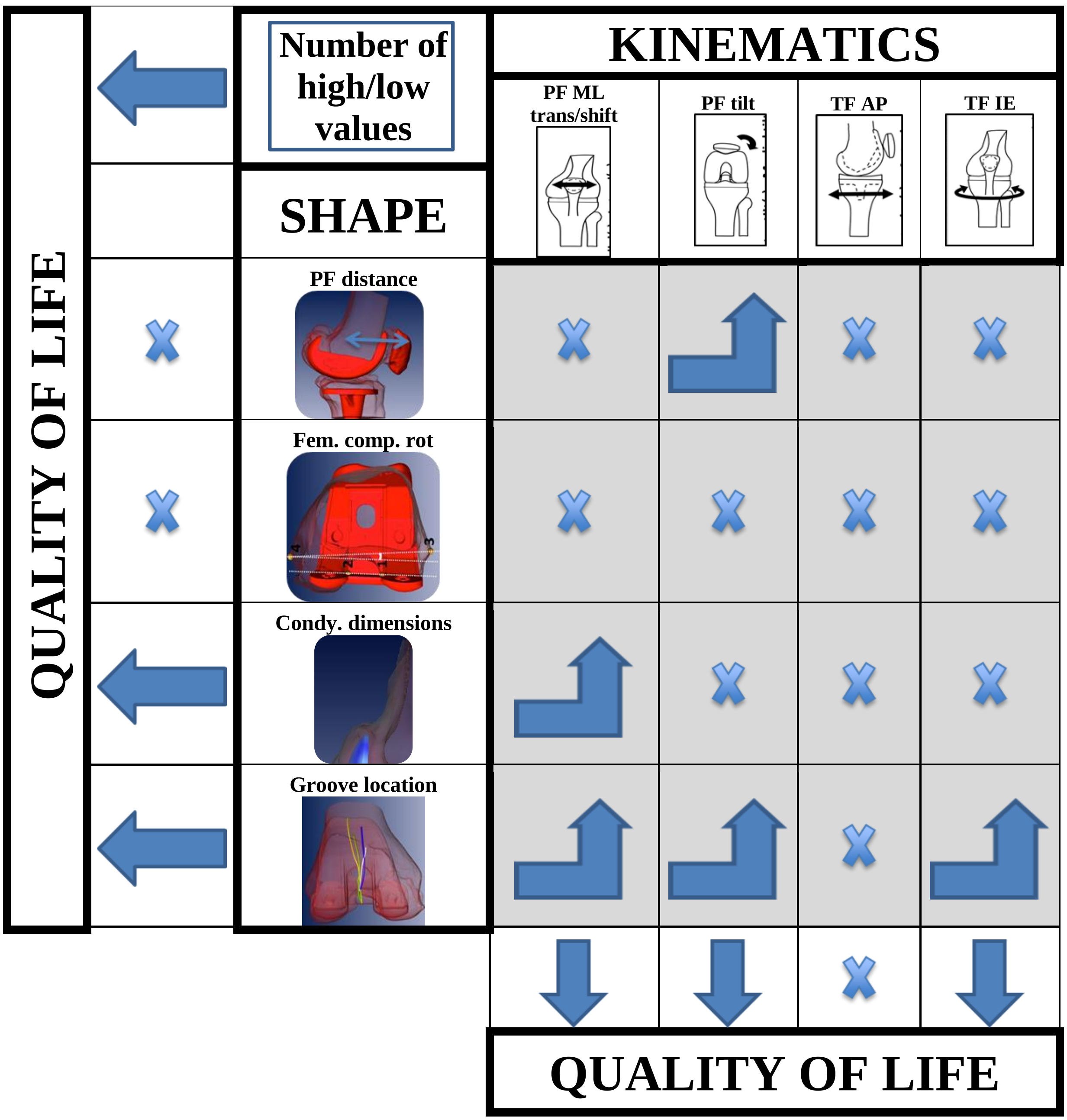


Figure 5-3. General overview of correlations found between different kinematics, shape , and QOL parameters. See tables for specific correlation values and flexion angles.

5.3.2 Preop-postop quality of life, patellar height and femoral groove

Quality of life improved for all subjects ($p<0.01$), to varying degrees (Table 5-1 & Figure 5-4).

Table 5-1. Average pre and postop QOL. Note that a lower WOMAC score is better.

QOL	HSS patella score	KSS knee score	WOMAC score	Oxford score	SF-12 PCS	SF-12 MCS
Avg - Preop	**49**	**56**	**51**	**19**	**30**	**55**
SD - Preop	17	18	21	11	10	14
Avg - Postop	**86**	**89**	**12**	**39**	**47**	**52**
SD - Postop	14	11	10	7	13	13

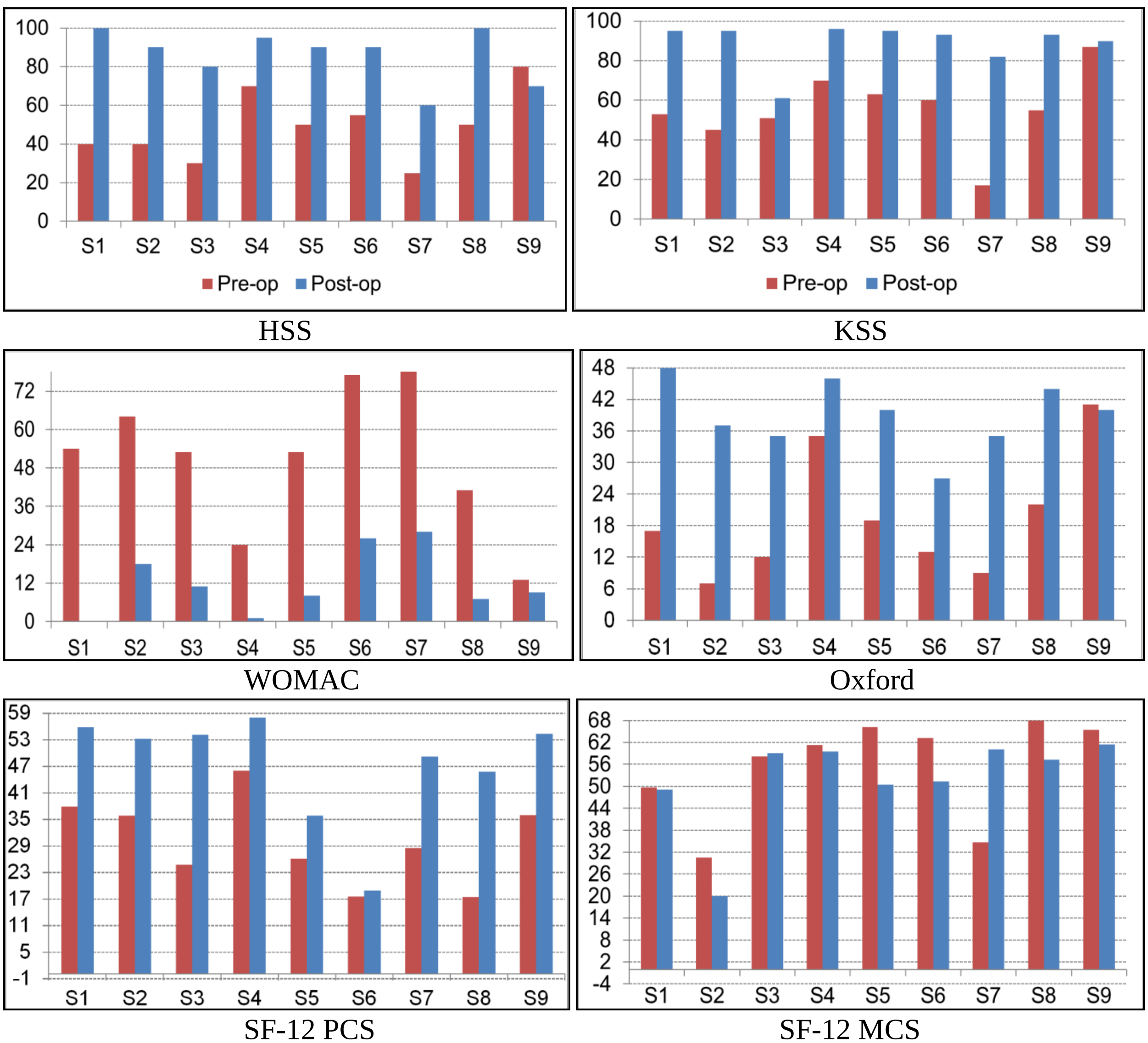


Figure 5-4. Preop vs postop QOL. Red bars= preop; blue bars= postop.

In general, patellar height was unchanged preop-postop (p=0.8) (Table 5-2), but three subjects had patella alta (>1.2) and 1 had patella baja (<0.8).

Table 5-2. *Patellar height*. 1.02 ratio is considered as the normal ratio; values below 0.8 are defined as patella baja; values above 1.2 are defined as patella alta.

Patellar height	#1	#2	#3	#4	#5	#6	#7	#8	#9	t-test
Pre-op	**1.21**	1.13	**1.26**	0.91	1.17	**0.64**	0.96	1.14	**1.35**	0.8
Post-op	**1.22**	0.89	**1.26**	0.91	1.13	**0.70**	0.91	1.20	**1.33**	

Patellar tracking with respect to the femoral groove (PF shift) was unchanged on average (p=0.4), but individual changes were up to 6 mm (Table 5-3), in some cases becoming more medial, in other cases more lateral.

Table 5-3. *Patellar shift* with respect to the femoral groove (mm). Positive refers to the patella being more lateral relative to the femoral groove; negative is medial.

Patellar shift (medial/lateral) (mm)		#1	#2	#3	#4	#5	#6	#7	#8	#9	Ave	SD	Max lateral	Max medial
0º flexion	Preop	2.9	-2.9	-2.4	-6.9	2.8	-3.9	-1.3	0.8	-0.3	-1.2	3.2	2.9	-6.9
	Postop	-3.1	1.9	-0.3	-1.4	0.2	-2.6	-0.2	-2.6	-5.5	-1.5	2.2	**1.9**	**-5.5**
	difference	-6.1	4.7	2.1	5.5	-2.6	1.2	1.2	-3.4	-5.3	**-0.3**	**4.2**		
45º flexion	Preop	-0.9	-0.3	1.8	-3.2	-0.8	-0.5	2.0	-1.6	-4.0	-0.8	2.0	2.0	-4.0
	Postop	0.7	1.3	-1.2	-1.1	1.3	-0.4	1.1	-0.8	1.2	0.2	1.1	**1.3**	**-1.2**
	difference	1.6	1.7	-2.9	2.2	2.1	0.1	-1.0	0.8	5.1	**1.1**	**2.2**		
90º flexion	Preop	-1.6	-1.6	-0.1	-0.5	-1.6	1.9	3.0	-3.4	-2.0	-0.7	2.0	3.0	-3.4
	Postop	2.5	0.3	0.1	0.7	1.1	-0.1	2.9	0.2	1.5	1.0	1.1	**2.9**	**-0.1**
	difference	4.1	1.9	0.1	1.2	2.8	-2.1	-0.2	3.6	3.5	**1.7**	**2.1**		

5.3.3 Relationships between shape and kinematics

Significant relationships were found between changes in each of the shape parameters (except femoral component rotation), and changes in at least two of the five kinematic parameters (Table 5-4). The Pearson correlation coefficients for the parameters are shown in the tables. The results of the power analysis, as well as the required sample size to detect a possible correlation are added for the parameters with no significant correlation (p>0.05). Note that in cases where no correlation was found for these well-functioning subjects, there could be a correlation for subjects with poor clinical results.

Table 5-4. Changes in shape vs. changes in kinematics. Significant relationships are highlighted in green; non-significant relationships are shown in red. PF ML-translation is determined relative to the femoral coordinate system whereas PF shift is determined within the femoral groove. These were combined in Figure 5-3.

		KINEMATICS				
		Change in PF ML-trans	**Change in PF shift**	**Change in PF tilt**	**Change in TF AP**	**Change in TF IE**
SHAPE	**Change in patellofemoral distance**	*ρ =-0.5 Power=30% Sample size=30*	*ρ =-0.6 Power=40% Sample size=20*	ρ =0.7 at 90° flexion	ρ =-0.8 at 45° & 90° flexion	*ρ =0.2 Power=8% Sample size=195*
	Femoral component rotation	*ρ =0.5 Power=30% Sample size=30*	*ρ =-0.4 Power=20% Sample size=48*	*ρ =-0.65 Power=50% Sample size=17*	*ρ =-0.6 Power=40% Sample size=20*	*ρ =0.4 Power=20% Sample size=48*
	Changes in condylar dimensions	ρ =-0.7 at max flexion pos. cond. M&L	ρ =-0.9 at max flexion pos. cond. M&L	*ρ =0.6 Power=40% Sample size=20*	*ρ =-0.6 Power=50% Sample size=20*	*ρ =0.6 Power=50% Sample size=20*
	Change in groove location	ρ =0.8 at 15° flexion	ρ =-0.8 at 15° flexion	ρ =0.7 at 45° flexion	*ρ =-0.4 Power=20% Sample size=48*	ρ =0.7 at 0° flexion

5.3.4 Relationships between patellar tracking and femoral groove location

The postop patella (green line) in most cases tracked more closely to the postop femoral groove (yellow) than to the original preop tracking (white), whereby the preop patellar tracking (blue) generally followed the preop femoral groove (white) (Figure 5-5). In all cases, the proximal portion of the postop femoral groove was more lateral after TKA, and extended more proximally (Figure 5-5). In 8/9 cases, patellar tracking was more posterior postoperatively.

On average, the patella tracked very closely within the groove both preop and postop, as desired (Table 5-3). Only one subject experienced shift within the groove greater than 5 mm (in this case, 5.5 mm in full extension where the patella is less constrained) indicating that none of the subjects had a maltracking patella.

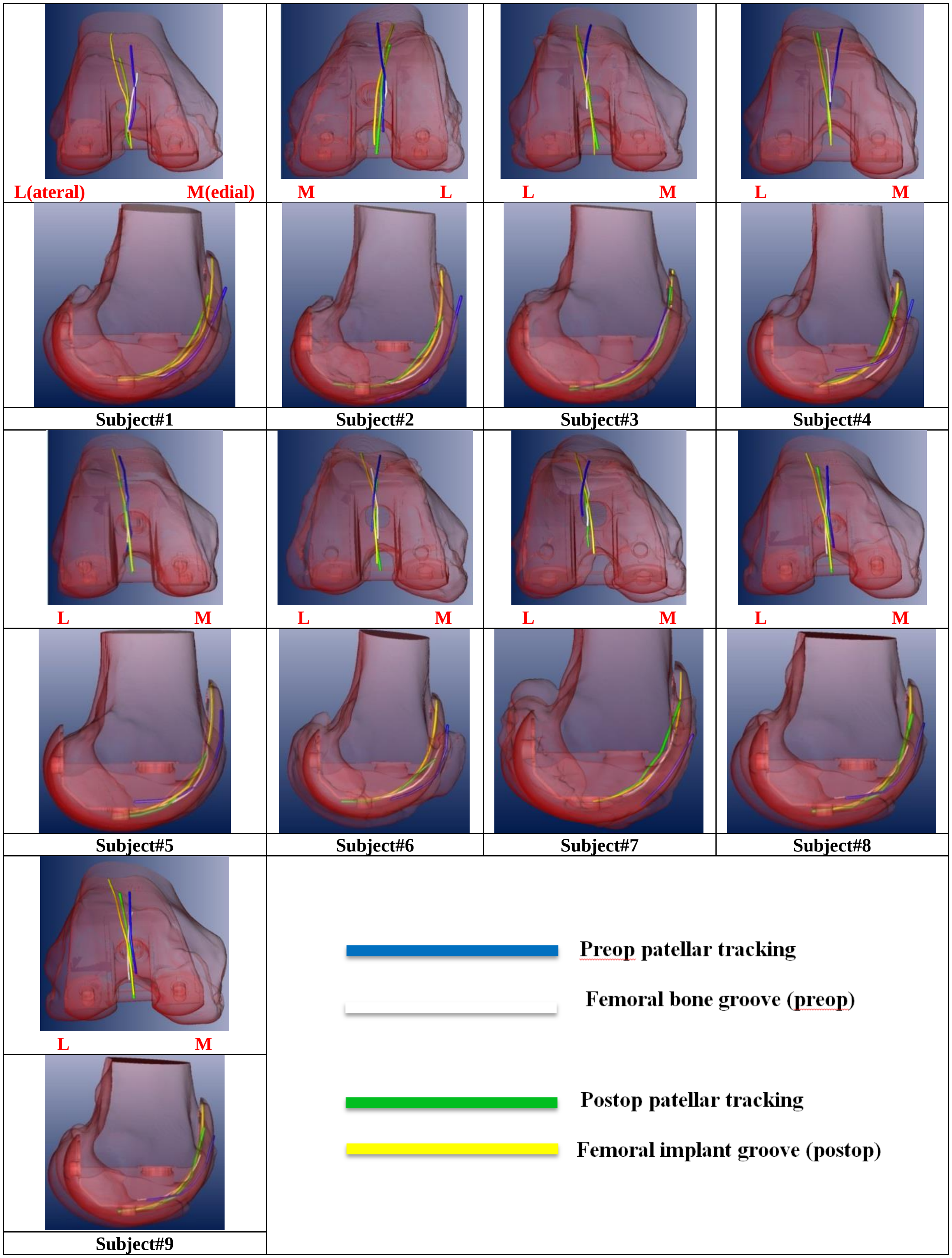


Figure 5-5. Patellar tracking and femoral groove orientation.

5.3.5 Relationships between changes in kinematics and postop QOL

Preop-postop changes in kinematics parameters, except for TF AP translation, correlated with at least two of the QOL scores at at least one flexion angle (Table 5-5). The WOMAC and Oxford scores correlated with changes in PF ML translation, PF shift and TF IE rotation. The HSS Patella Score correlated with changes in PF tilt and TF IE rotation. The KSS correlated with changes in PF shift.

Table 5-5. Postop QOL vs. change in kinematics.

	KINEMATICS				
	Change in PF ML-trans	**Change in PF Shift**	**Change in PF tilt**	**Change in TF AP**	**Change in TF IE**
QOL	ρ = -0.7 (WOMAC) at 45^o -90^o flexion ρ = 0.7 (Oxford) at 45^o -max flexion	ρ =0.7 (KSS) at 45 ^{o} flexion ρ = -0.7 (WOMAC) at 90^o flexion ρ = 0.7 & 0.8 (Oxford) at 75^o -90^o flexion	ρ = -0.8 (HSS) at 15 ^{o} flexion ρ =-0.7 (KSS) at 90 ^{o} flexion	*ρ =0.6 Power=40% Sample size=20*	ρ =0.8 (HSS) at 45^o-max flexion ρ = -0.7 (WOMAC) at max flexion ρ = 0.7 (Oxford) at 0^o flexion

5.3.6 Relationships between changes in shape and postop QOL

Changes in groove location and condylar dimensions correlated with at least one QOL score at at least one flexion angle, whereas changes in PF distance and femoral component rotation did not (Table 5-6).

Table 5-6. Postop QOL vs. changes in knee shape.

	SHAPE			
	Change in PF distance	**Femoral component rotation**	**Changes in condylar dimensions**	**Change in groove location**
QOL	*ρ =-0.6 Power=50% Sample size=20*	*ρ =0.5 Power=30% Sample size=30*	ρ = -0.7 (WOMAC) medial distal ρ = -0.6 (Oxford) medial posterior	ρ =0.7 (Oxford) at 0^o flexion

5.3.7 Analysis of individuals with lower QOL

The QOL, kinematics and shape results of each individual subject are summarized in Table 5-7, Table 5-8, and Table 5-9, respectively. High/low values worse than one standard deviation from the average results (or as defined in the Methods for the patellar height/tilt/shift and femoral component rotation) have been highlighted.

Although all subjects had good to excellent QOL, subjects 2, 3, 6, 7 and 9 exhibited values more than one SD below the average on at least one score, with subject 6 having three high/low values (Table 5-7).

Table 5-7. Subjects with lower QOL data. QOL scores more than one standard deviation lower than the average of this cohort are highlighted in bold.

Postop Quality of Life Scores:		**Subject number**								
	Average ±SD	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**
HSS patella score	86±14	100	90	80	95	90	90	**60**	100	**70**
KSS knee score	89±11	95	95	**61**	96	95	93	82	93	90
WOMAC score	12±10	0	18	11	1	8	**26**	**28**	7	9
Oxford score	39±7	48	37	35	46	40	**27**	35	44	40
SF-12 PCS	47±13	56	53	54	58	36	**19**	49	46	54
SF-12 MCS	52±13	49	**20**	59	59	50	51	60	57	61
# High/low values		0	1	1	0	0	**3**	2	0	1

All of the subjects had at least one and up to four kinematic high/low values (Table 5-8) and all subjects had at least one and up to five shape high/low values (Table 5-9).

Table 5-8. High/low values in the kinematics analysis. A high/low value was defined when the results were more than one standard deviation worse than the average for all scores except for patellar tilt and shift for which the high/low values were defined according to the criteria explained in the Methods.

Kinematics Parameters:			**Subject number**								
	Positive sign	**Average ±SD**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**
PF ML translation 0° (mm)	Lateral	5.1±3.4	4.4	8.0	**8.9**	7.2	6.1	**0.0**	7.8	4.4	**-0.3**
45° (mm)		2.1±1.6	1.4	**4.9**	2.8	1.3	2.6	**0.4**	**4.0**	**-0.2**	2.0
90° (mm)		2.1±1.5	2.5	1.5	1.6	2.8	0.9	**0.6**	**4.9**	**0.7**	**3.8**
PF shift 0° (mm)	Lateral	-1.5±2.2	-3.1	1.9	-0.3	-1.4	0.2	-2.6	-0.2	-2.6	**-5.5**
45° (mm)		0.2±1.1	0.7	1.3	-1.2	-1.1	1.3	-0.4	1.1	-0.8	1.2
90° (mm)		1.0±1.1	2.5	0.3	0.1	0.7	1.1	-0.1	2.9	0.2	1.5
PF tilt 0° (°)	Medial	-3.3±4.0	-4.2	-3.0	**-11.4**	-1.6	2.0	0.7	-3.0	**-6.7**	-2.2
45° (°)		-1.1±3.4	-2.7	**-5.9**	-4.8	2.1	0.3	1.7	2.9	-4.4	1.4
90° (°)		-0.7±3.0	-1.0	**-6.7**	-3.2	1.1	-0.3	2.8	2.0	-2.2	1.1
TF AP translation 0° (mm)	Anterior (tibia relative femur)	9.2±4.9	**3.7**	12.3	6.8	**16.8**	**2.9**	7.0	**15.1**	11.1	6.7
45° (mm)		-24.2±1.4	-24.9	-24.5	**-26.5**	**-22.2**	-23.7	-24.6	**-22.0**	-24.1	-25.3
90° (mm)		-32.6±2.7	-34.0	-34.6	**-37.3**	**-27.5**	-32.5	-32.5	-31.3	-32.1	-31.2
TF IE rotation 0° (°)	Internal (tibia relative femur)	2.1±10.8	4.4	**-11.3**	**-9.2**	5.7	-0.5	**24.4**	-4.0	-0.2	9.7
45° (°)		8.2±8.9	13.9	**-7.0**	0.7	15.8	9.1	**23.6**	8.1	5.0	4.9
90° (°)		11.0±7.2	12.3	**-0.7**	**4.1**	17.4	13.1	**23.9**	11.8	6.8	10.3
# High/low values			1	3	4	1	1	2	2	2	2

Table 5-9. High/low values in the shape analysis. A high/low value was defined when the results were more than one standard deviation worse than the average for all scores except for patellar height and femoral component rotation, for which high/low values were defined according to the criteria explained in the Methods.

Shape Parameters:			**Subject number**								
	Positive sign	**Average ±SD**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**
Change in PF distance 0° (°)	Postop larger than preop	1.8±1.6	3	**-0.5**	0.8	0.5	1.5	**4.6**	1.2	3.2	2
Change in PF distance 45° (°)		3.8±2.3	**6.4**	**0.1**	4.4	**0.5**	3.9	**7.2**	3.9	3.6	4.2
Change in PF distance 90° (°)		3.5±3.0	**6.8**	**-0.1**	5.8	**-0.3**	1.1	**8.1**	3.2	4.1	3
Fem. comp. rotation w.r.t. bone-PCL (°)	External	2.7±1.4	4.1	**0.7**	2.6	3.7	**0.2**	4.1	2.6	3.2	3
Implant-bone distance - distal condyle (mm)	Comp. outside bone	-0.3±1.5	-1.1	0.55	0.9	0.4	0.25	**-2.5**	**-2.5**	**1.7**	-0.6
Implant-bone distance - post. condyle (mm)	Comp. outside bone	-1.0±3.2	-2.2	0	-0.5	-2.1	2.05	**5.4**	**-3.7**	**-5.25**	-2.6
Patellar height (mm)	NA	1.1±0.2	**1.22**	0.89	**1.26**	0.91	1.13	**0.70**	0.91	1.2	**1.33**
Change in femoral groove location 0° (mm)	Lateral	5.4±4.2	**11.6**	**0.9**	5.2	6.0	1.8	**-0.4**	4.6	8.3	**10.3**
Change in femoral groove 45° (mm)		0.2±1.7	**2.7**	**-3.1**	1.4	1.7	-1.0	-0.3	0.5	-0.2	-0.3
Change in femoral groove 90° (mm)		-1.6±1.5	**0.2**	**-3.9**	**-3.2**	-0.3	-2.2	**0.5**	-2.3	-1.8	-1.7
# High/low values			3	3	2	1	1	5	2	2	2

In summary, subjects 2, 3, 6, 7 and 9 exhibited the lowest QOL (although their QOL was still not low); subjects 2 and 3 showed the most high/low values in the kinematic parameters; subjects 1, 2 and 6 showed the most high/low values in the shape parameters; and subjects 2, 3 and 6 showed the most total (kinematic + shape) high/low values (Table 5-10). The anomaly is subject 7, with two lower QOL scores, but not a large number of high/low values amongst the parameters studied.

Table 5-10. Summary of high/low values.

# High/low values:	**Subject number**								
	1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**
Postop QOL scores	0	1	1	0	0	3	2	0	1
Kinematic parameters	1	3	4	1	1	2	2	2	2
Shape parameters	3	3	2	1	1	5	2	2	2
Total: Kinematics+shape	4	6	6	2	2	7	4	4	4

5.4 Discussion

This study investigated relationships between changes in knee shape, kinematics and quality of life for nine TKA patients.

Postoperative QOL in this cohort was better for a more lateralized proximal femoral groove, smaller changes in femoral condylar dimensions, more lateralized PF ML translation and shift within the groove, less lateral patellar tilt, more internal TF IE rotation, and fewer individual shape and kinematic high/low values. The more lateralized proximal femoral groove favours a greater angle to the femoral component groove. Smaller changes in condylar dimensions favour either more sizing options or customized implants, as well as accurate component placement. More lateralized PF ML translation/shift (but still less than 5 mm within the groove, for example by changing from medial to lateral) and less lateral patellar tilt shows the importance of addressing factors that could affect patellar kinematics, such as groove location and soft tissue constraints. More internal tibial rotation shows the importance of correct placement of the tibial component in fixed bearing implants and avoiding internally-rotated placement of the tibial plate, which could cause external TF IE rotation postop. This correlates with the results of another study which showed that TKA patients with internal rotation of the tibial component are more likely to experience anterior knee pain following TKA (Barrack et al., 2001).

The subjects in this study with lower QOL (although not low QOL) generally had a higher number of high/low values. Subject 6, for instance, had the worst postop QOL scores and also had the largest number of high/low values in his knee shape and kinematics analysis; his high/low value parameters included: larger posterior and distal condylar changes, larger changes in patellofemoral distance, less change in femoral groove location, patella baja, more central patellar translation, and a more internally rotated tibia; he also had the most severe preoperative arthritis. Subject 9 had a lower HSS Patella Score than the other subjects whereas all of her other QOL were within the normal range. She had several patellar anomalies: medial patellar translation at full knee extension and a more lateral translation at 90º knee flexion, greater than 5 mm patellar shift within the femoral groove, patella alta, and 10 mm translation of the femoral groove; the HSS Patella Score may have been the only instrument sensitive enough to detect the effects of these differences. Exceptions to the high/low value/QOL trend amongst these subjects could be due either to the selection of parameters defining the high/low values, the lack of any subjects with poor QOL requiring revision, or the fact that for some individuals large changes are beneficial to their knee joint. The present study is the first that we are aware of to focus on the individual data and provide evidence towards a link between QOL and kinematics or shape high/low values; a larger study can evaluate these links further. The value of counting the number of high/low values is that the source of pain or reduced function is different for each individual and may be a combination of factors. The individual knee data can also be used to develop an accurate musculoskeletal model to probe other relationships between shape and kinematics. Our ultimate goal is to identify characteristics of groups and individuals with poor QOL.

Preop and postop imaging should therefore be routine for patients with good and poor results. Newer imaging modalities and techniques (Dubousset et al., 2007; Ehlke et al., 2013; Trozzi et al., 2008), may provide sufficient accuracy and parameter calculation speed at a low radiation dose by fitting a 3D model to 2D biplanar data for the purposes of identifying key outliers, preop planning and postop diagnosis, especially if this leads to a large database of patients with good and poor results.

Several links between shape and kinematics were found. In most cases, the postop patella seems to be guided more by the prosthesis groove than by the original preop tracking (recognizing that the numerous changes to the joint during TKA means that the patella would not necessarily be expected to follow the original path), suggesting that the femoral groove has more control over patellar tracking than the soft tissues. Based on the correlation analyses, changes in the groove location also affect the patellar tilt and TF internal/external rotation. The positive correlation with TF IE means that, by increasing the external rotation of the femoral component relative to the tibia, the femoral groove moves more laterally postop, which in turn affects the PF ML translation, shift and tilt. This should be taken into consideration if a patient has a maltracking patella preoperatively. The more the groove moved laterally (at the proximal end of the femoral component, where the patella contacts in full extension), the higher the quality of life as judged by the Oxford knee score. Therefore, in general a more lateral proximal groove, by design or placement, appears to be beneficial.

An increase in patellofemoral distance, generally due to increased patellar thickness in this series, but also potentially from a thicker anterior flange, correlated with more medial PF tilt and a more posterior tibia. Overstuffing of the PF joint could increase tension in the medial retinaculum and cause the medial PF tilt.

There was no significant correlation between femoral component rotation and any of the selected PF or TF kinematics and QOL, contrary to expectations. Although no correlation was detected for this well-functioning group, there could be correlations for subjects with poor clinical results.

Based on the correlation analysis, changes in condylar dimensions affect the PF ML translation and shift at max knee flexion. The negative correlation of changes in the posterior condyle with patellar tracking means that the more the femoral component is outside the bone posteriorly, the more the patella tracks medially, at max flexion. The more the femoral component is outside the bone posteriorly, the lower the quality of life as judged by the Oxford score. However, the more the femoral component is outside the bone at the medial distal condyle, the higher the quality of life as judged by the WOMAC score. This could be due to the varus alignment of the knees in 8/9 of our subjects; therefore correction to neutral alignment requires cutting less off the medial side or more off the lateral side on the distal femoral condyles.

The preop-postop changes in PF ML translation, shift, tilt and TF IE rotation also affect the QOL. A more lateralized PF ML translation or PF shift improved the quality of life. A more medial PF tilt lowered the HSS and KSS knee scores. A more internal tibia rotation also improved the QOL.

This pilot study was limited by the small number of subjects with a single implant design and surgeon. It is important to recognize that results may be different for different implant designs and surgical techniques. Small number of subjects could also mean that the significant correlations found in our study may not truly exist in the general population, or may mean that we did not have the power to detect a difference when these truly exists. Statistical power analysis demonstrated that at least 48 subjects were required to detect significant correlations between all studied parameters, except for the relationship between changes in PF distance and changes in TF IE, which requires 195 subjects (Table 5-4). However, scaling the number of subjects to 195, in a future study, is not recommended as the measured correlation coefficient (ρ) of 0.2 shows that, probably, there is no correlation between changes in PF distance and changes in TF IE.

Since all subjects had good to excellent clinical results based on patient-assessed questionnaires, these findings represent a range of normal results and the differences in most parameters that were studied are relatively minor. A larger study with multiple surgeons and implant designs, including patients with good and poor results, would be beneficial. Another major limitation is that the contribution of soft tissues around the knee was not evaluated in this study, nor was information on the preop cartilage surface available due to the CT and radiographic methods used. Nonetheless, CT and radiographs are readily available modalities that provided substantial insight into the effect of TKA on the knee joint. The other limitation of this study is that we only studied the knee function during static step-up activity and did not evaluate the other functional capabilities, e.g. gait, sit-to-stand, strength and etc. In this study several clinically important knee shape and kinematics parameters were studied. However, there are several other parameters that can contribute to post-TKA complication, which were not studied such as: patellar cut asymmetry (Anglin et al., 2009), tibial slope (Callaghan et al., 2004) and femoral component overhang (Hofmann et al., 2011). Furthermore a number of studies have shown the important role of patient expectations to postop satisfaction (Bourne et al., 2010;

Drexler et al., 2013; Dunbar et al., 2013a; Fisher et al., 2007; Lingard et al., 2007; Noble et al., 2006).

This study provides data previously unavailable concerning the relationships between knee shape and kinematics parameters with TKA and their correlation with quality of life. These normal, ‘good’ results can be used for later comparison to subjects with ‘poor’ results. Identifying implant and surgical factors that contribute to a poor clinical outcome, using the presented approach, could help to improve surgical techniques, implants or instruments, leading to improved patient outcomes and satisfaction.

Chapter Six: **Chapter Six: Discussion and Conclusions**

6.1 Summary and overview

Although joint replacement operations such as THA and TKA are the preferred treatments for patients with severe osteoarthritis or other degenerative diseases of the hip and knee joints, there are still large numbers of patients with ongoing pain or who do not have their functional expectations met (Kurtz et al., 2007; Mannion et al., 2009). One of the major contributors is component malalignment, which can lead to ligament imbalance, uneven load distribution, impingement, early wear, loosening of the components impingement, and reduced range of motion. Component malalignment in joint arthroplasties can occur due to the surgical technique used by the surgeon or due to a lack of knowledge about the optimal component position for each individual patient. Other mechanical factors that can affect the patient's QOL are different implant designs and surgical techniques.

Suboptimal placement of the acetabular component in total hip arthroplasty (THA) is one of the most recognized surgical problems after hip replacement. Although there exists an acceptable range of values for acetabular cup orientation, called the "safe zone", the accuracy of cup placement is affected by the technique used to place the acetabular component. As one of our main objectives in this thesis, we developed and tested an adjustable mechanical device, called Optihip, that is set to angles within the "safe zone" or to a patient-specific goal preoperatively and is independent of pelvis position intraoperatively, to improve the accuracy of acetabular cup alignment in hip replacement surgery. We evaluated Optihip's accuracy on 12 cadaveric hip joints. The results were more accurate on average, and with a smaller standard deviation, than those reported *in vivo* for conventional hip arthroplasty, and comparable to those reported *in vivo* for current computer-assisted surgical techniques and patient-specific guides. The 0% outliers in the present experiment is a better result than both the conventional and CAS approaches, and matches the other patient-specific techniques. While clinical testing is required to confirm these experimental results, the positive *ex vivo* accuracy suggests good potential with this device. Furthermore, the similar results between the two surgeons who performed the testing suggest there is no effect with experience or surgical approach unlike the conventional approach (Bosker et al., 2007), which could reduce one of the highest risk factors for malpositioning, between high and low volume surgeons (Callanan et al., 2011). Since device use is independent of pelvis position, it is also well-suited to obese patients, another major risk factor for malpositioning (Callanan et al., 2011).

Our simulated inclination-only investigations showed good potential for guiding inclination from an AP X-ray, demonstrating that 2D/3D projection and pelvic tilt have only a small effect on the DLA measurements on radiographs. The ability to guide only inclination is a unique feature of the device that led to its simplification.

Component malalignment can cause major postoperative complications in TKA too, which could be due to the fact that it alters the knee shape and geometry following TKA. Other intentional and unintentional reasons for changes in the knee shape post-TKA include correcting the preoperative malalignment, different implant designs and standardized component sizing. Changes in the knee shape and geometry can affect tibiofemoral and patellofemoral kinematics. Patellar maltracking and abnormal tibiofemoral (TF) contact patterns can result in post-TKA complications as well, since TF and PF kinematics can indicate or influence ligament tensions, how the knee feels to the individual, stability, range of motion and wear. To our knowledge, the impact of TKA on weightbearing *in vivo* knee kinematics has not been previously reported for all

6 DOF PF and TF kinematics, nor the impact of TKA on the shape and geometry of the knee joints, nor relationships between shape, kinematics and QOL.

We used clinically available computed tomography and radiography imaging systems to compare PF and TF kinematics of OA patients before and at least one year after TKA. For the TF joint, substantial changes were seen for most DOFs between pre and post-TKA knees. For the PF joint, substantial individual changes were seen in the most clinically-relevant degrees of freedom, namely mediolateral tilt and shift. Our results also showed that there are differences between the pre- and post-TKA helical axis of rotations and TF contact points for our nine subjects.

Based on the results of this shape and geometry study, the anterior flange of the femoral component should be thinner and the patellar resection thickness should be carefully controlled. More size options would allow a better match to the original geometry and fewer compromises. Our results also showed that the intercondylar gaps are located more laterally on average postop, although the total distances were small. Implant shape and size should be designed based on how the prosthesis will be implanted, not on the original anatomical bone shape, since more will be cut off one side than the other to realign the leg. Component placement plays a critical role in clinical outcome and should be accurately controlled. Better patellar resection techniques are needed (Anglin, Rex, et al., 2013). Patellar non-resurfacing is also an option, but can be more likely to lead to anterior knee pain and functional deficits (Helmy et al., 2008; Johnson et al., 2012). Given all of the inter-related factors in component placement, residents could benefit from computer-based training to understand the consequences and corrective actions for each step, e.g. femoral component rotation, flexion vs. extension gaps, anteroposterior and mediolateral component positioning, and patellar thickness.

In addition to the kinematics and shape data, we collected quality of life (QOL) data pre- and postoperatively, to see if the changes in the kinematics and knee shape would affect the subjects' QOL and anterior knee pain. Analyzing the effect of TKA on knee shape, kinematics and QOL allowed us to investigate the inter-relationships amongst these parameters. In our study we found significant relationships between numerous knee kinematic parameters, shape parameters and QOL of the subjects with TKA. The patella seems to be guided more by the prosthesis groove than by the original preop tracking, which indicates that the femoral groove has more control over the patella tracking than the soft tissues. The results of our knee analyses for each individual subject show that there is an apparent relationship between the number of high/low values in the main kinematics and geometrical parameters and subject's QOL, as the subjects with lower QOL had the higher number of high/low values. Whereas the preop-postop group analyses help to identify the overall trends of the inter-relationships between the knee shape, kinematics and QOL, the individual knee analyses for each subject and defining the high/low values for the main kinematics and geometrical parameters help to identify causes for the pain or functional limitations.

6.2 Novelty and contributions

Optihip: The developed hip device has many novel features that were covered in the description and claims of the patent application (PCT/CA2013/000895) (Anglin, Akbari Shandiz, et al., 2013). Optihip is an accurate, fast, inexpensive and non-invasive device for acetabular placement, which is adaptable to any desired patient-specific goal, unlike current manual instrumentation. This technique takes advantage of the preoperative planning capabilities of the CAS and patient-specific methods, while being faster and less expensive than current CAS systems, and more flexible than rapid-prototyped instruments. We limited our device to mount within the standard incision size of surgery, on recognizable landmarks near the acetabular rim, for less invasiveness and to maintain the current surgical workflow. It was designed so that it can focus on guiding the inclination angle only, if desired, which simplifies both the planning and the execution. For these cases, only a standard AP radiograph is required.

Depth gauge: To complete the guidance of the acetabular cup placement, we also created a depth gauge which addresses full seating of the cup within the acetabular socket to ensure bone ingrowth in the case of uncemented cups, and to avoid changes in femoral leg length and offset with lateralization of the component. We are unaware of any mechanical instrumentation to address cup depth.

Knee kinematics before and after TKA: This thesis compared the full 6 DOF TF and PF kinematics before and after TKA on the same individuals. The impact of TKA on weightbearing *in vivo* knee kinematics has not been previously reported for all 6 DOF PF and TF kinematics. It also examined the position and movement of the helical axis on the same population before and after TKA *in vivo* and under weightbearing. Studying the same individuals before and after surgery allows us to make much finer comparisons of changes with TKA rather than comparing group statistics.

Knee shape before and after TKA: This thesis also investigated the changes in articular shape and geometry resulting from TKA, visually and numerically, both individually and as a group, in a sample population; these changes have not been documented previously, to our knowledge. The colour maps were created between the preop segmentations and the postop combined femoral and patellar bone-implant models, to show the preop-postop changes in knee geometry relative to the bone surface.

Knee relationships: In this thesis, we also created and implemented methods to correlate specific changes in knee articular geometry to the changes in knee kinematics and QOL of patients following TKA, which were unavailable previously. The results of our knee analyses for each individual subject show that there is an apparent relationship between the number of high/low values in the main kinematics and geometrical parameters and subject's QOL, as the subjects with lower QOL had the higher number of high/low values. This is an exciting finding, as the high/low values for the main kinematics and geometrical parameters could help to identify causes for the pain or functional limitations. Using this protocol in the future to compare patients with a poor clinical outcome with patients with a good outcome could help to improve surgical techniques, implants or instruments, leading to improved patient outcomes and satisfaction. Also, the protocol that was developed in this study can be used for comparisons of surgical plans with surgical outcomes and to create a feedback loop that keeps track of and augments the surgeon's learning experience for continual improvement.

6.3 Limitations

Hip study: We note several limitations of our accuracy analysis of the hip device. It was limited by the small number of specimens, with largely normal anatomy, and by having only two surgeons. Also, we did not record the extra time required for using this device to guide acetabular cup placement, since it was not a typical clinical situation; we therefore cannot compare our mechanical guide with other conventional or navigation systems in terms of time efficiency, although we anticipate good efficiency due to the small number of intraoperative steps required. A further limitation is that we compared the results of our study with historical control groups, which had different setups and were performed *in vivo*, but we achieved more power to our study by using the Optihip device on all 12 hips, and a comparison to the standard technique would not have been realistic in the anatomy lab setting.

Knee study: There are several limitations for the knee study of this thesis. It was limited by the small number of subjects from a single surgeon with a single implant design. It is therefore important to recognize that different patients, different surgical techniques or different implant designs could have different results. Since all subjects had good to excellent clinical results based on patient-assessed questionnaires, these findings represent a range of normal results. Therefore we could not identify the cause of low QOL after TKA. Also differences in most of the parameters that were studied were relatively minor.

In our kinematics analysis, out-of-plane accuracy was improved with the sequential-biplanar approach over single-plane radiography, but uncertainty remains leading to the uneven graphs. Despite this, the preop-postop differences in knee kinematics were usually greater than the level of uncertainty, leading to the same overall conclusions. We did not have a control group of normal healthy subjects for ethical reasons, and there is only a small amount of literature detailing normal, healthy kinematic data for comparison. More data on normal, healthy subjects are needed.

The other limitation of this study is that we only studied the knee function during static step-up activity and did not evaluate the other functional capabilities, e.g. gait, sit-to-stand, strength and etc. Static kinematics with this protocol were shown to be comparable to dynamic kinematics during a step up in all but one DOF for one subject (out of 12 DOF for ten subjects) (Saevarsson, Romeo, et al., 2013)

Another major limitation is that we only had information on the bone surface, not the cartilage surface, because the articular cartilage and meniscus in pre-TKA radiography, and the polyethylene tibial inserts in post-TKA radiography, are radiotransparent and hence difficult to segment. For the tibiofemoral contact point, the contact points were defined as the closest distances of the femoral condyles with the tibial plateau surface; although an approximation, this was likely sufficient to define the direction of pivoting and translation. For the shape analysis, wherever the prosthesis is inside the bone, it will be even more inside the cartilage surface, and average cartilage thicknesses can be added to the bone surface calculations to gauge the changes. Although a more complete study would include magnetic resonance imaging (MRI) to evaluate the cartilage surface as well, MR image acquisition is considerably more expensive; preop segmentation is considerably more time-consuming; and postop metal artifact is considerably worse. Therefore postop CT is still preferred.

6.4 Future directions

Optihip: As the next step of development, we are aiming to perform a clinical study to evaluate the safety and efficacy of our device before adoption as a standard operative practice in THA. Prior to clinical testing, the design will be subjected to a thorough risk analysis and appropriate design changes made. Performing preop planning on a larger dataset of AP X-rays is needed to determine the required slider and device size. The dimensions will also be tested by inserting Optihip into the acetabulum of the larger number of patients during clinical testing. The accuracy of our depth gauge method also needs to be tested.

In addition to Dr. Jim Mackenzie and Dr. Steve Hunt, who performed the cadaveric testing and are co-authors on our paper from Chapter 2, several other local surgeons have offered to test our device clinically. Our eventual goal is to license the technology to an orthopaedic company to improve acetabular cup placement in patients.

HipTouch: During testing of our device on artificial bones and cadaveric specimens, we used an inexpensive 3D digitizer, called Microscribe (www.3d-microscribe.com), to perform several analyses such as measuring the orientation of inserted cups on the artificial bones, and creating 3D surface models from the cadaveric acetabula by tracing over the contours of the pelvic socket. We then generated the idea for a computer-assisted system for acetabular component placement in THA using a 3D digitizer. The 3D digitizer can be used to register the AP plane landmarks along with an inertial measurement unit (IMU) to track the pelvic movements. Using the preoperatively determined transformation between the AP plane and the desired acetabular landmarks around the rim, as for the Optihip device, the desired orientation of the reamer or cup impactor, attached to the kinematic chain of the Microscribe, can be displayed for real-time feedback. Therefore there is no need to flip the patient from a supine to lateral position after digitizing the APP, which is one of the main barriers to using the current CAS systems. This navigation system has no *line-of-sight* requirement, a major frustration in optically-based systems, is relatively inexpensive, and is compact in size. If only a double-check of the cup orientation is desired, the surgeon can use the 3D digitizer to measure the orientation of the acetabular cup relative to the AP plane landmarks intraoperatively, with no need for preoperative imaging. This 3D digitizer can also be used for recreating femoral leg length and offset intraoperatively. Further development of this technique is required.

Hip imaging and optimal positioning: There is increasing awareness that the surgical plan should be patient-specific, and that functional pelvic tilt and native acetabular orientation, amongst other factors, should be taken into consideration (DiGioia et al., 2006; J. Y. Lazennec, Rousseau, et al., 2011; J.-Y. Lazennec, Brusson, et al., 2011; Tang et al., 2000). This is coupled with greater availability of imaging and software planning tools, and more sophisticated image analysis algorithms. These make preoperative planning both desirable and possible. The purpose of a future study is to provide guidelines regarding how component orientation must be adjusted to each individual patient's anatomy, by evaluating the influence of patient factors, particularly pelvic flexion, on the outcome of THA. The range of motion (ROM) following hip surgery also needs to be investigated, to analyze how acetabular components should be oriented to achieve a maximized and stable ROM.

Knee shape, kinematics and QOL - experiments: Our knee study provides data previously unavailable concerning the relationships between the knee shape and kinematics parameters with TKA and their correlation with QOL of the TKA patients. The results are useful for investigating relationships for future hypothesis-testing. Since all subjects had good to excellent QOL, these findings represent a range of normal results and provide us with a database of normal, ‘good’ results, which can be used for later comparison to ‘poor’ results. A larger study with multiple surgeons and implant designs, including patients with good and poor results, would be beneficial. Using this protocol to compare patients with a poor clinical outcome with patients with a good outcome, adapted to a faster analysis technique (see below) to analyze a larger cohort, could help to improve surgical techniques, implants or instruments, leading to improved patient outcomes and satisfaction. In Chapter 4 we have evaluated several clinically important knee shape and geometry parameters. Other parameters that can contribute to post-TKA complications could also be considered, including: patellar cut asymmetry (Anglin et al., 2009), tibial slope (Callaghan et al., 2004) and femoral component overhang (Hofmann et al., 2011).

Knee shape, kinematics and QOL – imaging systems: Although out-of-plane accuracy in our PF kinematics analysis was improved with the sequential-biplanar approach over single-plane radiography, uncertainty remains leading to the uneven graphs. The biplanar fluoroscopy unit now available in the McCaig Institute for Bone and Joint Health can be used to improve the major limitations of our fluoroscopy method as well as opening up the opportunity for dynamic evaluations. The recently-acquired EOS imaging system, to be located at the Mobility and Joint Health Facility at the McCaig Institute, capable of simultaneously capturing two orthogonal AP and lateral images of the full body in both standing and sitting positions, can be used to acquire many of the parameters required for our analyses (Dubousset et al., 2007), including semi-automated parameter calculation if integrated into the system. This system reduces the patient's exposure to X-ray dose and has the capability of creating 3D reconstruction volumes. Taking the full body radiographs enables us to study the effect of whole body posture on the knee kinematics. The reconstruction program needs further development to perform implant model fitting.

Knee shape, kinematics and QOL - musculoskeletal modeling: For further analysis of the relationships between knee shape and kinematics and to test changes in individual parameters, one option is to build an accurate musculoskeletal model. The results of our study provide useful inputs and can be used for the validation of the musculoskeletal model. The musculoskeletal model can be used to find the optimum knee component placement for each individual patient. The resulting patient-specific planning can be incorporated into computer-assisted surgery systems or custom instrumentation to achieve greater accuracy, with the goal of reducing pain and restoring more normal kinematics.

6.5 Conclusion

Our overall goals were to improve component placement in hip arthroplasty and to understand the role of component placement in knee arthroplasty. Our *ex vivo* hip study demonstrated the accuracy and feasibility of our adjustable patient-specific mechanical device for guiding orientation and depth of the acetabular cup. Preparations for clinical testing are underway. Our pilot study of nine knee subjects revealed the potential effects of malpositioned implants and the effects of different design features and surgical techniques. A larger study of subjects with good and poor results, using the developed analysis techniques and conceptual approaches to the issues, should help identify causes for pain and reduced function, and thereby guide individualized planning and implant placement.

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