AN INSIGHT INTO IMPLANT FAILURE THROUGH INDUCIBLE DISPLACEMENT AND GAIT ANALYSIS IN TOTAL KNEE REPLACEMENTS

by

David Kwadwo Konadu

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ABSTRACT

Knee osteoarthritis is a debilitating disease causing pain and disability in adults. Biomechanical factors including obesity, abnormal magnitude and load distribution have been cited to play a role in its initiation and progression with its definite cause being multi-factorial. Total knee arthroplasty has become the treatment of choice for knee osteoarthritis and although the procedure is mostly successful, there are some patients who experience implant failures which necessitates revision surgery. Revision surgery is more complicated and thus there is the need to monitor patients who have undergone TKA so as ensure better outcomes and also address problems much earlier.

Objective methods like Radiostereometric Analysis (RSA) has proven to be a good tool at diagnosing these implant failures. Inducible displacement with RSA has the potential to serve as a one-time measure to diagnose implant failures. Previous studies have applied loads to induce motion to the knee in various ways- squatting, exercising and weight-bearing on the affected limb. This was not standardized and caused wide variations in the data. This work looked at refining a device used to apply standardized loads to the knee resulting in a more portable and faster way of applying load to the joint.

Gait analysis is used to assess implant function pre and post surgery. Some gait patterns have also been related to implant failure. Previous works have focussed primarily on associations between well-working implants (non-revised patients) and these gait patterns (adduction moments and flexion angles). This work focussed on any differences in the gait patterns between patients who did not undergo revision surgery and those that did. Although most parameter differences did not reach statistical differences, they point to important trends that may explain the causative factors (adduction moments) whiles others may point to the effects of disease progression (external rotation).

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To God be the Glory (Nyame n'ayɛ)

CHAPTER 1: INTRODUCTION

Osteoarthritis (OA) is a degenerative disease of the joint, which leads to loss of function and pain. It is one of the most common causes of disability among North Americans, affecting approximately 20% of all adults in the United States (Lawrence et al., 2008) and approximately 18% in Canada (Perruccio, Power, & Badley, 2006), with the knee being the most likely to be affected (Milner & O'Bryan, 2008). The causes of OA are multifactorial with its initiation and progression being driven by biomechanical factors like malalignment, obesity and abnormal magnitude and distribution of load on the joint (Baliunas et al., 2002; Englund, 2010; D. T. Felson, Anderson, Naimark, Walker, & Meenan, 1988).

Knee OA is most common in the adult population and in women (Lawrence et al., 2008). Obesity is one of the most common risk factors for knee OA (D. T. Felson et al., 1988; D. T. Felson, Zhang, Anthony, Naimark, & Anderson, 1992), and there is increasing incidence of OA due to increasing obesity rates (Lee & Kean, 2012) and decrease in physical activities.

There is no definitive cure for knee OA. The approach with patients has been to control the pain and improve the function and health-related quality of life (D. T. Felson et al., 2000). It is not until advance stages of the disease that total knee arthroplasty (TKA) surgery is considered as an end-stage treatment.

Total knee arthroplasty is a surgical procedure used to treat end stage knee osteoarthritis. TKA has been shown to be successful in reducing pain resulting from OA, correcting deformity and improving the function of the affected limb (McMahon & Block, 2003). Though it is a largely successful procedure (Sharkey, Hozack, Rothman, Shastri, & Jacoby, 2002), there are a fraction of patients who experience implant failure and thus present for revision surgery; about 3% in the first 2 years (Jones & Holt, 2008) and over 12% at 8 years (Lonner, Hershman, Mont, & Lotke, 2000). The reasons for implant failure are multi-factorial with aseptic loosening being dominant (Sharkey et al., 2002). Thus, there is the need to monitor patients post TKA with more objective techniques that can determine these abnormalities (mechanical factors) more accurately and help improve patient outcomes post surgery.

There are various methods of monitoring patient outcomes pre and post TKA. These are through patient questionnaires, conventional radiographic imaging, Radiostereometric Analysis and motion analysis systems. The first two methods are currently being employed clinically with the latter two being more research tools. Questionnaires provide subjective measures of patients' function pre-and post TKA. The other methods give us an objective method of assessment particularly with respect to implant motion. However, conventional x-rays have shortcomings of being 2 planar and detecting deleterious implant motion later on in the post operative years, making remedial treatment very difficult. Radiostereometric analysis (RSA) provide us with an accurate measure of implant micromotion within host bone (Selvik, 1989) and has been proven to diagnose eventual implant failure within 2 years post TKA. Ryd et al. (Ryd et al., 1995) found that patients with implants which showed continuous micromotion of

>0.2mm between 1 and 2 years post TKA did go onto failure resulting in revision surgery.

Conventional RSA though does not give us enough knowledge about the recoverable micromotion occurring at the bone-implant interface during loading and this information is important to understand the stability or otherwise of the implant (Ryd, Lindstrand, Rosenquist, & Selvik, 1986). Inducible displacement, as measured with RSA, gives us such information during loading of the joint and could prove to be another predictor of eventual failure of the implant post TKA (Ryd, 1986). Some work has been done with inducible displacement, though there are generally wide variations in the data reported due to the differences in the way the joints have been loaded and influence of patients' weight (Bragonzoni et al., 2005; Toksvig-Larsen, Ryd, & Lindstrand, 1998; D. A. J. Wilson, Astephen, Hennigar, & Dunbar, 2010). These are primarily from the methods of inducing micromotion. Wilson et al (2010) employed a device to apply loads in a standardized way during an inducible displacement exam. Though variations in the data were reduced, there are other drawbacks to the device that do not benefit its widespread use and accessibility to other research and health centres.

Gait analysis also provides us with a tool that can be used to differentiate pathological gait as compared to normal gait. Patients post TKA have been shown to have improved gait patterns like increased flexion angles and lower flexion and adduction moments, that show improved function and are seen to approach the gait patterns of asymptomatic subjects although most patients do not return to normal patterns

with some still having persistent pre-TKA patterns (Hatfield, Hubley-Kozey, Astephen Wilson, & Dunbar, 2011; Jones & Holt, 2008).

Some studies have also looked at gait patterns seen pre and post TKA and implant migration using RSA. Peak flexion and extension moments were reported to be smaller in implants with good prognosis of eventual stability (Hilding, Lanshammar, & Ryd, 1996; Hilding, Ryd, Toksvig-Larsen, Mann, & Stenstrom, 1999). Astephen Wilson et al (2010) showed that the pre-TKA knee adduction moment, combined with body mass index, was correlated to maximum total point motion (MTPM) at 6 months post TKA. Despite these studies and their findings, the two methods still remain primarily as research tools. This is because most of the studies have not been validated with actual failure cases and thus examining gait patterns in revised cases will help determine any associations between these patterns and failure.

1.2 Thesis Objectives

The purpose of this work was to address some of the challenges seen with the present clinical tools to assess patient outcomes, as stated in the preceding paragraphs. There are 2 main objectives of this work, the first to improve an existing RSA inducible displacement technique, and the second to identify associations between gait mechanics and post-operative implant failure.

1.2.1 Objective 1

To create and validate an improved inducible displacement device for the acquisition of instantaneous TKA tibial implant micromotion.

1.2.1.1 Objective 1 Approach

There is a two-fold approach to accomplish this objective; i) To develop a new inducible displacement device that is portable, user friendly and less intimidating to patients and ii) To investigate the amount of actual loads through the knee and validate the loading protocol when the new device is used. The questions to be investigated here are whether there will be any muscle activation during load application to the knee and to ascertain the amount of actual loads through the knee and validate the loading protocol when the new inducible displacement device is used.

1.2.2 Objective 2

To investigate the pre-revision gait patterns and implant migration/micromotion of revision TKA cases and compare to non-revised not high migrator cases as well as non-revised high migrators.

Sub-objectives under objective 2 are i) To compare the post-operative gait patterns between revised and both non-revised not high and non-revised high TKA subjects post TKA and ii) To determine tibial component micromotion between revised and both non-revised not high and non-revised high TKA subjects post TKA

1.2.2.1 Objective 2 Approach

The gait of patients presenting for revision total knee arthroplasty will be analysed before the surgery. This will help to know whether patients presenting for revision surgery have different gait patterns (both kinematic and kinetic variables) from that of both non-revised not high and non-revised high migration TKA subjects post

TKA. Also Radiostereometric Analysis exams for such revision patients and that of non-revised patients (both not high and high migration cases) will be investigated to find any differences in migration patterns exist.

CHAPTER 2: BACKGROUND

2.1 Knee Osteoarthritis

2.1.1 Cause and Implications

Osteoarthritis (OA) is a major cause of disability in the adult population with about 68% of those affected being women (Public Health Agency, Canada 2010). Osteoarthritis is envisaged to develop when i) the mechanical loads on the joints are excessive in the presence of normal biomaterials of the different connective tissues at the joint or ii) the stresses are normal but the constituent biomaterials at the joint are defective (Brandt, Radin, Dieppe, & van de Putte, 2006).

Knee OA is the most common form of arthritis. It has multiple aetiology and some key factors that have been identified to be associated with its longitudinal development are obesity, joint loading and malalignment (D. T. Felson et al., 1988). Toivanen et al(2010), in a large population study with a follow up of 22years, found that people with a body mass index (BMI) greater than 30 were 7 times more at risk of knee OA than those with BMI less than 25.

The knee adduction moment (KAM) provides a measure of the amount of loading at the knee joint and has been shown to be associated with the progression of knee OA. Patients with higher KAM at baseline did progress from one stage of disease severity to another during 6 years of follow up (Miyazaki et al., 2002). Sharma et al., (1998) also

found that those with severe knee OA had higher adduction moments than those with moderate or less severe knee OA.

Knee OA leads to pain and disability for patients, impacting negatively on the quality of life of patients (Public Health Agency, Canada 2010). Consequently there is also the loss in man hours and revenue to employers that affect the economy of Canada. It is estimated that about $7 billion dollars is lost annually due to loss of productivity and disability (Public Health Agency, Canada 2010).

2.1.2 Knee OA differentiation

Knee OA can be characterized into 2 parts, the illness and disease. The illness part deals with patient-reported symptoms like knee pain, stiffness and limitations in performing functional activities (Lane et al., 2011). Pain is quite common in such patients and it's highly related to activity. It is categorized into two; chronic pain which does not affect the daily activities and stressful/anxiety-provoking pain which flares up without any obvious trigger (G. A. Hawker et al., 2008). Pain is seen to increase with increasing level of progression of the disease (Hurwitz et al., 2000). There are also other patient effects like mood changes, fatigue and overall change in the quality of life (G. Hawker et al., 2011).

The disease part involves the structural changes at the joint that are seen typically with imaging modalities (Lane et al., 2011) and classified using scoring system like the Kellgren and Lawrence score (KELLGREN & LAWRENCE, 1957). This involves the changes in the structure and constituents of bone, synovium and other soft tissues of the

joint (D. Felson, 2009; Hunter et al., 2006). These may result in abnormal biomechanics that contribute to disease progression (Sharma et al., 1998).

Oftentimes, there is poor correlation between the symptoms felt by patients and structural changes seen with the imaging modalities (Manno et al., 2012; Odding et al., 1998). As such it makes early diagnosis of OA difficult.

2.2 Knee OA Treatment Methods

2.2.1 Non-surgical Treatments

Knee OA is often treated in its early stages through the management of pain using pharmacological means. This illness part of OA is commonly treated with non-steroidal anti-inflammatory drugs (Arthritis in Canada, Health Canada, 2003).

Some methods of treatment also aim at slowing progression or preventing development of knee osteoarthritis and may also aid in pain reduction. During walking, the load present at the knee is distributed asymmetrically, with the medial side bearing about 2.5 times that borne by the lateral side (Schipplein & Andriacchi, 1991). Valgus unloader knee braces are sometimes used to try and unload the medial compartment of the knee in a bid to retard the progression of osteoarthritis in that compartment (Krohn, 2005; Lafeber, Intema, Van Roermund, & Marijnissen, 2006). However, a recent study from our laboratory group found this not to be true for all patients. Some had an increase and others had a decrease in knee adduction moment and patients on average had no difference in knee adduction moment between the no-brace and brace conditions with initial application of the brace (Conrad J, 2011).

Weight loss is also another way of reducing the development of osteoarthritis (Christensen, Astrup, & Bliddal, 2005; Messier, Gutekunst, Davis, & DeVita, 2005). Felson et al. (1992), in their study found that a 5.1kg loss of weight over a 10 year period could decrease by 50%, the chance of developing knee OA.

Gait retraining techniques are also being explored as a means to correct abnormal gait present in people with knee osteoarthritis. Noyes et al (1996), presented findings of patients with knee hyperextension thrusting pattern who modified their gait to reduce the knee loads by 22%. Gait retraining enables the reduction of the medial loads at the knee and help to slow down knee OA progression (Fregly, Reinbolt, Rooney, Mitchell, & Chmielewski, 2007). These methods may be difficult to sustain considering some are unnatural or too slow for most patients and the danger is that most patients will revert back to their pre-study gait patterns, once the study is over. A study by Wheeler et al.,(2011) found high variability in the learned gait of each individual subject with all of them showing different variations of the new gait they adopted, through tactile and visual feedback, to reduce the knee adduction moment.

2.2.2 Total Knee Arthroplasty

Arthroplasty, in general, is a reconstructive procedure that alters the structure or function of a joint. Total knee arthroplasty is used when the pharmacological treatments have failed to prevent OA progression (Maillefert et al., 2005). The procedure has evolved over the years since its beginnings in the early 1800s (Steinberg & Steinberg, 2000). Total knee arthroplasty (TKA) has become the primary treatment for end stage knee OA.

It is a considerably low risk procedure with good outcomes but patients do experience trauma and other contraindications may arise afterwards (NIH consensus statement on total knee replacement.2003). TKA is not cheap and also the implants used have a finite lifespan which predisposes patients to secondary TKA further on in their lifetime.

The number of surgeries being done for TKA is on the rise in recent years (CIHI Annual report, 2008-2009). This is expected to continue due to the increasing incidence of osteoarthritis, aging and obese people in the population (CIHI Annual report, 2008-2009). This trend is expected to place a huge burden on surgeons and the hospital resources available to cater for such patients (CIHI Annual report, 2008-2009).

2.3 TKA Outcomes

Most often, the problems with TKA involves the implant with respect to its fixation and/or function.

2.3.1 Implant Failure

TKA is a procedure with mostly good outcomes. However, there are still some patients who do not do so well and present for revision TKA. This typically ranges from 3% to 12% within 2 and 12 years post TKA respectively (Jones & Holt, 2008; Lonner et al., 2000). Due to the increasing numbers of patients presenting for joint replacement, these fractions translate into sizeable numbers of patient (Kurtz, Ong, Lau, Mowat, & Halpern, 2007; Robertsson et al., 2010). Also another trend emerging within the last decade is the sharp increase in the number of young adults (below the age of 60) who are being treated with this surgical procedure (CJRR, 2009; AOANJRR 2010). These

patients are at an increased risk of revision and thus the number of people presenting for revision will consequently increase (AOANJRR 2010). Revision TKA does not have successful outcomes as primary TKA (Jones & Holt, 2008), with the procedure more tedious and leading to more bone loss.

There are many reasons why these implants fail. These include aseptic loosening implant design, infection and surgical approach amongst others (CJRR Annual Report 2013). Infection is reported to account for 14.9% of revisions in Canada between 2010 and 2011 (CJRR Annual Report, 2013). Sharkey et al. (2002), found infection to be the cause for 25.4% of revisions, which were carried out within 2 years of operation. Implants affixed with an alignment less than 3^0 varus are seen to have higher survival rates than those with an alignment of greater than 3^0 varus post TKA (Berend et al., 2004). This malalignment can result in abnormal stresses at the medial side of the underlying bone that can lead to bone collapse (Berend et al., 2004).

Earlier designs of implants that allowed for only flexion and extension, with other motions of the joint not possible, (Coventry, Finerman, Riley, Turner, & Upshaw, 1972) contributed to implant failure during the early years of TKA. Metal on metal implants and poor patellofemoral joint design resulted in lower survival ratios seen at over 5 years post operatively (Berger et al., 2001). The total condylar knee replacement, used by Insall et al. (1979; 1983), paved way for modern TKA with excellent function and durability. Patients who had TKA with a mid-vastus approach had better flexion and knee function when compared to a standard medial parapatellar approach at 1 year post TKA (Floren, Reichel, Davis, & Laskin, 2008).

2.3.1.1 Aseptic Loosening

Aseptic loosening is the most common mode of implant failure (CJRR, 2009; AOANJRR 2010). It can be described as any loosening of the implant in the absence of an infection. Data from the Nordic registries and several registries around the world also highlight this fact. Robertsson et al. (2001) reported a failure rate of 44.1% seen in primary revisions with loosening as the reason for failure during the first 4 years post operatively. Annual data from the Canadian (CJRR, 2008) and Australian (AOANJRR, 2010) joint registries show 25% and 31.1% failure rates due to aseptic loosening respectively. It has a very diverse and intertwined etiology with polyethylene wear, cement degeneration and debonding, failure of implant coatings and bone loss amongst some of its causes (Sundfeldt, Carlsson, Johansson, Thomsen, & Gretzer, 2006). All these phenomena have an underlying factor of joint loading being their precursor (Sundfeldt et al., 2006).

2.3.1.1.1 Wear particles

Wear is manifest in three ways; abrasive, adhesive and fatigue wear (De Baets, Waelput, & Bellemans, 2008). These can occur from a number of sources including debris from cement, polyethylene (PE) wear from articulating surfaces, bone debris and any metal debris that emanate from elsewhere and do have access to the joint space and thus migrate into implant-bone-cement interfaces. This phenomenon is time dependent and usually happens after a considerable number of years of the implant *in situ*.

Also wear from bearing surfaces result from years of motion of the femoral components on the PE insert. Even though highly cross-linked polyethylene is used currently and has improved resistance to wear, they still do show signs of abrasion

especially with longer years and thus multiple loading cycles of the replaced joint. This is known as fatigue wear and occurs due to exceeding the yield stress of polyethylene (Kuster & Stachowiak, 2002). The actions of wear particles normally result in osteolysis and finally gross loosening further down the follow up period.

2.3.1.1.2 Cement degeneration and debonding

Most retrieval studies show either a complete debonding of the implant stem from the cement or partial bonding with some cement degeneration seen around the implant. This occurs because of the changes in the properties of bone cement over time and can be attributed to several processes.

Cement aging of the Polymethylmethacrylate (PMMA), proceeding polymerization, also affects the physical structure of cement. Plasticizing effects are also seen, resulting from residual monomer and water uptake, which remain after incomplete curing of cement. These effects reduce the mechanical strength, thermal stability and glass transition temperature of cement.

Increase in strain, due to cyclic loading of the joint (increase in stress on cement) (Waanders, Janssen, Miller, Mann, & Verdonschot, 2009), also has an effect on the creep of cement. Accumulated damage due to cyclic loading can also lead to cement debonding from the implant causing micromotion to occur at the interface and eventual loosening to result over time.

2.3.1.1.3 Failure of implant coating

The surface layer properties are also important to implant longevity. This is because implants interact with the biological surrounding via these surfaces. There have

been various coatings that have been applied to implants to solicit bony ingrowth and thus better fixation of the implant. The most important characteristics of such coatings are low friction and wear rates, which can help prevent implant failure.

Unfortunately micromotion, between modular parts of an implant, can result in the failure of such coating. It is very difficult to produce most of these coatings with a very strong microstructure because perfect single crystals (which are dense, strong and corrosion resistant) are almost impossible to be grown on most implants (Lappalainen & Santavirta, 2005). Thus third body particles, which can be present even before closure of the incision, can rub against these coatings and trigger delamination of the coating by corrosion via the pin-holes in these coatings (Lappalainen & Santavirta, 2005). This then causes a breakdown of the coating, leading to more particle wear to be present in the joint space resulting in accelerated wear, osteolysis and then loosening of the implant.

2.3.1.1.4 Bone loss

Bone loss can occur either through stress shielding or local osteolysis due to wear particles. The wear particles of small sizes stimulate an inflammatory response which leads to bone resorption (Schmalzried et al., 1992). Stress shielding results from a stiffness mismatch between the implant and cement or bone. Due to the stem being stiffer than the surrounding bone or cement, it tends to carry most of the load borne by the knee joint. This causes the bone to remodel according to Wolff's law (Wolff 1986) resulting in bone resorption. This can lead to bony collapse in the region affected and cause eventual failure of the implant. Thus implant stability is threatened due to the absence of bone to provide a viable support for the implant.

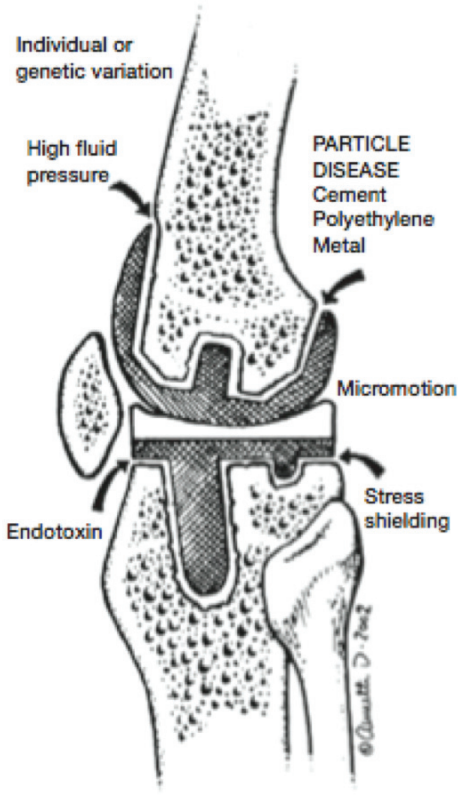


Figure 2.1: Schematic of the various aseptic loosening failure modes (Sundfeldt et al., 2006)

2.4 TKA Assessment Methods

After the surgery, there is the need to assess the effectiveness of the procedure. There are various methods of assessing knee function pre and post TKA. There are the radiographic methods (X Rays, Radiostereometric analysis), patient-reported scoring systems and motion analysis studies (Jones & Holt, 2008).

2.4.1 Patient reported scoring systems

Patient satisfaction with the TKA procedure is assessed through patient reported questionnaires like the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) (Bellamy, Buchanan, Goldsmith, Campbell, & Stitt, 1988), Knee Outcome

Survey-Activities of daily living scale (KOSADLS) (Irrgang, Snyder-Mackler, Wainner, Fu, & Harner, 1998), the medical outcomes survey Short Form-36 (SF-36) (Ware & Sherbourne, 1992) and the Knee Society clinical scale (J. N. Insall, Dorr, Scott, & Scott, 1989). These questionnaires provide us with an overview of the effect of the procedure on the quality of life of patients taking into account the pain levels and function of their affected limbs. The questionnaires are very subjective and also pain has been found to influence patients' opinion on their levels of functional ability after TKA (M. J. Dunbar, Robertsson, Ryd, & Lidgren, 2001; M. J. Dunbar, Robertsson, & Ryd, 2004).

2.4.2 Radiographic Methods

Presently, the extensive use of radiographs is the gold standard to determine instability or otherwise of an implant. Radiolucencies as observed with radiographs are the main indicators of loosening (Ewald & Knee Society, 1989). These zones are as depicted by the knee society total knee arthroplasty roentgenographic evaluation and scoring system (Ewald & Knee Society, 1989). These are uniplanar views and do not capture the 3 dimensional effects of motion of the implant. Also, plane radiographs do not capture the minute micromotions that indicate eventual failure later on in the post-op years (Ryd et al., 1995). Thus, its diagnostic ability is sometimes limited with regards to implant micromotion occurring outside of these planar views**.**

2.4.2.1 Radiostereometric Analysis Longitudinal Migration

Roentgenographic techniques with bone markers have been shown to provide a better method of assessing motion between the bone and the implant as compared to conventional radiography because of its accuracy (Green, Bahniuk, Liebelt, Fender, & Mirkov, 1983; Karrholm, 1989; Mjberg, Hansson, & Selvik, 1984; Ryd, 1986). This

micromotion between the bone and implant in the study of implant fixation is of two kinds; migration and inducible displacement. Migration typifies the relatively slow movement of the implant settling into the host bone whiles inducible displacement describes the immediate reversible motion often due to external loading of the affected limb (Ryd, 1986). Radiostereometric Analysis (RSA) has become one of the best ways of capturing such motion (Selvik, 1989). It has been shown to provide diagnostic information about the long term survival outcomes (up to about 10 years post TKA) of an implant by assessing 1-2 year micromotion data (Grewal, Rimmer, & Freeman, 1992; Ryd, 1992; Ryd et al., 1995). Typically, RSA measurements are computed over a period of time (at least 2 years) where a predictive correlation between implant migration and failure {{8 Ryd,L. 1992}} can be adduced. These measurements are reported as translations and rotations about 3 axes (x-mediolateral, y-proximaldistal and z-anteroposterior) and maximum total point motion (MTPM) (Ryd et al., 1995; Valstar et al., 2005). MTPM is the translation vector of any point on the implant which exhibits the greatest motion (Valstar et al., 2005).

Ryd et al (1992), found that continuous migration of an implant during the second year post-op, exceeding 0.2mm was predictive of eventual failure. Regner et al (Regner, Carlsson, Karrholm, & Herberts, 2000), in a study using cementless implants, found that those coated with hydroxyapatite (HA) migrated less compared to porous coated ones at 5 years post-op. That study reported RSA as subsidence (y-translations) and MTPM. Nilsson et al (Nilsson, Henricson, Norgren, & Dalen, 2006) found two different migration patterns in 2 different kinds of implants. Over two years post TKA, cementless implants had high subsidence, anterior-posterior and varus-valgus rotations within the

first 3 months then stabilize whiles cemented ones showed less migration (albeit continuous) over that same time. Pijls et al (2012), in a follow-up meta-analysis study, found that uncemented and uncoated implants had three times higher revision rate when compared to cemented implants. This confirmed the diagnosis found in an earlier study by Nelissen et al., (1998) where cementless uncoated tibial components exhibited excessive migration and were predicted to experience high failure rate later on in the post operative years.

These studies further strengthen the definite diagnostic ability of RSA. However, conventional (longitudinal) RSA gives us no information about the magnitude of instantaneous micromotion happening at the interface of the implant and bone during loading of the joint of interest. Such information could prove invaluable in understanding the stability or otherwise of the implant.

2.4.2.2 Radiostereometric Analysis Inducible Displacement

Inducible displacement, as measured with RSA, provides us with an instantaneous measure of assessment of the fixation of the implant and the amount of cyclic micromotion (Ryd et al., 1986; Ryd et al., 1986; Ryd et al., 1986; Ryd, 1986) occurring at that interface by evaluating the relative position of an implant under various loading conditions. Thus, it can provide us with an idea of the development (Regner et al., 2000; Toksvig-Larsen et al., 1998) or the quality (Ryd & Linder, 1989) of the implant-bone or cement-bone interfaces.

Ryd and Linder (1989) reported low inducible displacements (MTPM) in 7 knees 2 years post TKA and hypothesized that this may be related to the bony ingrowth at the

bone-implant interface that may have been achieved by the implant used. Fukuoka et al., (2000), applied loads (using a load cell) to the tibial component immediately after they were inserted and found the initial micromovements (both subsidence and lift-off) measured to be correlated to the MTPM at 2 years post surgery. In that study, the mean subsidence, lift off and MTPM was 0.061mm, 0.103mm and 1.29mm respectively. Another study found inducible displacement to be correlated with longitudinal migration at one year post surgery (Toksvig-Larsen et al., 1998). That study also found no difference between inducible displacements observed at one year between cemented and uncemented implants. Wilson et al (2010) found lower inducible displacements in uncemented implants compared to cemented ones at 2 years post op. They reported average MTPM value of 0.20 mm for the uncemented and 0.30 for the cemented groups.

This technique is rarely used with most studies focusing on the traditional longitudinal RSA measurements of migration of prosthesis. This can be attributed to the variations seen in inducible displacement data and the absence of indices that correlate to long term implant failure. These variations stem from the different ways in which recovery motion is induced during the inducible displacement exam and also the different body weights of patients. Most inducible displacement studies have used the supine and statically loaded standing positions (weight-bearing) (Ryd, 1986), exercises (Bragonzoni et al., 2005), an internal or external torque test using a 10Nm torque at the foot (Hilding, Yuan, & Ryd, 1995) and a passive stress test (PST) (D. A. J. Wilson et al., 2010) to quantify the effects of the instantaneous micromotion happening at the interface. Since Inducible displacement highlights the quality of the interface, bone quality can also play a role in the micromotions observed. Ming and Nilsson (2000) found that migration,

measured with RSA within the first 6 weeks after total knee arthroplasty were related to the bone mineral density (BMD) as measured with Dual-energy x-ray absorptiometry (DEXA). They reported more subsidence and lift-off for peri-prosthetic regions with low BMD and vice versa. The association was however not significant at two years. They also reported that pre-operative alignment was significantly related to the amount of BMD. Patients with varus alignment were found to have increased BMD in the medial compartment whiles valgus alignment was related to increased BMD in the lateral region.

2.4.2.2.1 The Passive Stress Test

The Passive Stress Test (PST) (Laende E., 2005) was designed to minimize variation inherent with different loading conditions due to muscle co-contractions and subjects' weights in inducible displacement measurements. The PST is a technique of loading the joint by the placement of known weights on the knee. The procedure is carried out by placing a 20kg weight on the knee in a 90^0 flexed position. This loads the affected lower limb along its longitudinal axis. The procedure has been validated to show minimal co-contraction of the muscles around the joint (Laende E., 2005).

Presently, there is an inducible displacement device in the Radiology suite of the Halifax Infirmary (Figure 2.2). This device has been the apparatus being used to carry out all inducible displacement examinations to date at the facility, developed by Laende et al (Laende E., 2005). It is rectangular in shape with a solid base and support handles on the 3 upper sides for support to the subject. The fourth side is open and serves as the access 'gate' through which subject climb unto the base to have their exams taken. Under the solid base is a wooden disc, which is used to apply internal and external torques, and

the subject is asked to resist these torques. The device is however bulky, not user friendly, not portable and sometimes intimidating to patients.

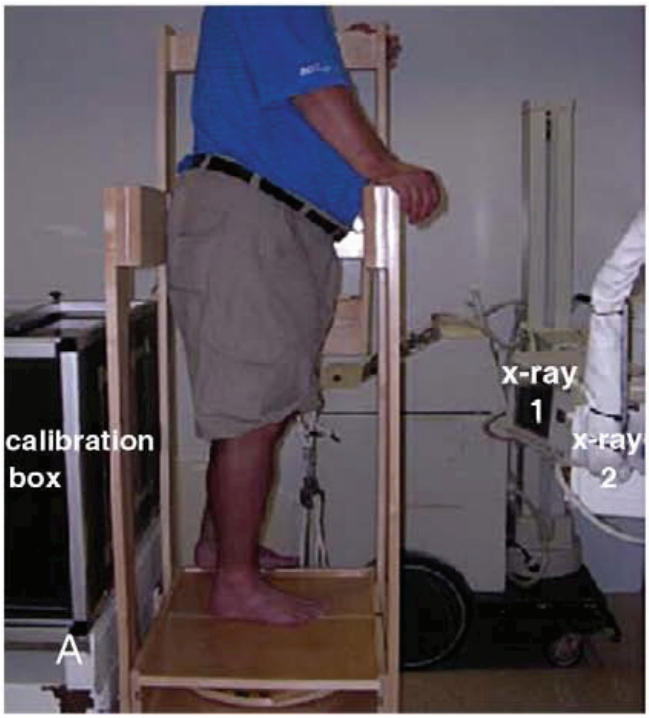


Figure 2.2: The inducible displacement device showing a subject having an exam.

2.4.2.3 Gait Analysis

Gait analysis provides us with an objective way of assessing the kinematic and kinetic joint patterns during walking pre and post total joint arthroplasty. These assessments often involve motion capture equipment coupled with instrumented force plates and infra red markers. Gait analysis enables an understanding of the movement of the joint and the dynamic mechanical loads placed on the joint through the activities of

daily living. Walking is the most common activity of humans that place repetitive loads on the joint (Sharma et al., 1998) and assessing it with gait analysis methods enables the differentiation of pathological gait from normal one. Additional electrodes also enable the recording of electromyographic (EMG) signals from the muscles (C. L. Hubley-Kozey, Hatfield, Wilson, & Dunbar, 2010; D. A. J. Wilson, Hubley-Kozey, Wilson, & Dunbar, 2012). This analysis system is currently being used primarily as a research tool.

Kinematic and kinetic parameters like knee flexion and extension angles, flexion and knee adduction moments and alignment have been shown to improve after TKA. Alnahdi et al (2011) found that there was no difference between the peak knee adduction moment at 1 year between TKA subjects and controls, though the operated limb had higher adduction moments than the non-operated limbs. This can predispose the non-operated limb to knee OA and eventual TKA (Shakoor, Block, Shott, & Case, 2002). Hatfield et al. (2011) found one year post TKA knee flexion and adduction moments improved (compared to pre-op) and were found to approach that of asymptomatic subjects. Abnormal flexion and extension angles during gait highlight the flexion and extension gaps that lead to joint instability in patients, post op (R. L. Mizner et al., 2011). There are general improvements in the degree of alignment, knee flexion and extension angles and as well as decreased knee adduction moment which all point to satisfactory trends post TKA (Bargren, Blaha, & Freeman, 1983; Hatfield et al., 2011; McClelland, Webster, Feller, & Menz, 2011). Some muscle activation patterns have also been associated with changes towards asymptomatic neuromuscular patterns. Hubley-Kozey et al (2010) found increased activity in the gastrocnemius muscles during late stance of

walking with decreased activity in the quadriceps and hamstring muscles in mid to late stance post TKA.

Some studies have combined RSA and gait analysis to try and understand the relationship between biomechanical parameters and implant migration. Astephen Wilson et al. (2010) found that the pre-operative knee adduction moment was correlated to implant migration (using RSA) 6 months post TKA. They reported that Body Mass Index (BMI) and high knee adduction moment was responsible for 45% of the variability in tibial implant migration. Another study found that low magnitude of flexion moment is associated with implants with good prognosis of stability two years post TKA (Hilding et al., 1996). Wilson et al (D. A. J. Wilson et al., 2012) found prolong activation of the lateral gastrocnemius and the vastus medialis muscles pre-operatively to be associated with posterior migration of the tibial component six months post TKA. These studies show that subject-specific gait patterns may be important in diagnosing outcome of TKA. They are few and limited with no studies comparing these patterns to actual TKA failures, an important step towards getting validated models representing failure. Also most of these studies and data show that aseptic loosening is the dominant cause of implants failure. Thus further work needs to be done to understand how gait patterns relate and potentially lead to implant failure (with focus on the mechanical pathways) on an individual basis.

CHAPTER 3: AN IMPROVED INDUCIBLE DISPLACEMENT DEVICE FOR LOADING THE KNEE

3.1 Introduction

Inducible displacement, as measured with RSA, has been around for as long as conventional RSA (Ryd, 1986). This technique provides an insight into the instantaneous interface stability between the bone-implant or bone-implant-cement interface. The technique gives us the added benefits of knowing the quality of the bond between implant and bone interface and the constituent quality of the various materials forming the interface (fibrous, cartilage or bone). Also we can deduce from such inducible micromotions which movements result in what kind of migration (subsidence, tilting or rotation) of an implant and further reduce the time for such diagnosis due to the instantaneous nature of the test compared to longitudinal RSA (at least 2years).

Micromotion of the implant is envisaged to emanate from the bone-implant or bone-implant-cement interfaces (Mann, Allen, & Ayers, 1998; Mann, Werner, & Ayers, 1999; Mann et al., 2004). Miller et al., (Miller, Eberhardt, Cleary, Verdonschot, & Mann, 2010) in a study with sectioned parts of intact bone-cement-implant interfaces found that most of the micromotion, under compressive and tensile loading, occurs between the bone-cement interface. Thus knowing the nature or mechanical integrity of the interface will be very helpful in ascertaining implant stability and thus good TKA outcomes. Ryd et al (1986) found external rotation of the tibial component under various loading conditions (like weight-bearing and pulley application of forces) that corresponded to

MTPM ranging between 0.2-1.0mm over a two year period. They stated that this correlates to the presence of a soft tissue membrane at the interface.

Inducible displacement is achieved by different loading protocols. Ryd et al (1986), used standing and placing most of the body weight on the affected limb (weight-bearing) to solicit recoverable micromotion. Bragonzoni et al (2005) employed plain weight-bearing, rotary stress tests and squatting (to $60\text{-}70^0$ of flexion) to induce micromotion. They found that the biggest displacement was produced by the rotary forces which were similar to the results of a previous study (1986). Some also employ a rotating platform to apply rotary loads to the limb under testing. These use a weight and pulley system to displace the platform either internally or externally and patients are instructed to resist this rotation (Bragonzoni et al., 2005; Hilding et al., 1995; Ryd, 1986).

Most of these studies show wide variations in the data collected, making it difficult to make defining diagnosis from it. These undesirable effects can be attributed to the different weights of the subjects and also the different methods of inducing recoverable micromotion of the implant in the joint. Thus there have been various attempts at addressing this variability with the loading of the joint with a known weight being favoured (D. A. J. Wilson et al., 2010). Pitfalls with this approach are the position of the joint where co-contraction is minimal and determining the optimal magnitude of the weight to be applied to the joint.

There is currently a device (Figure 2.2) employed for inducible displacement exams at our centre (Halifax Infirmary). The present structure of the current device is bulky and not so user-friendly. Due to the size and metal weights used to apply the loads

to the patient, the device can sometimes be intimidating to patients. The present device uses known metal weights that are loaded onto a knee-pad which is then placed on the joint to induce micromotion with simultaneous RSA imaging. The joint is typically in a pose of 90^0 during the loading protocol (also known as the Passive Stress Test). This typically requires at least 2 technicians to set up. The first objective of this study was thus to refine the design of the previously used inducible displacement device by making it more portable and easier to set-up within the RSA radiographic suite, and present an easier way to apply the loading profiles.

Also, since the point of application of the loads are on the outside of the knee joint itself, the influence of surrounding soft tissues in bearing the applied load needs investigating. This is because it is important to determine how much of the loads are borne by the knee joint itself. Pressure sensitive films (Fujifilms) can be employed to detect the amount of forces between two parts in contact with each other. Szivek et al (1995), used fujifilms to determine the contact areas and peak loads in TKA implants affixed in synthetic bones with the knee flexed to 60^0. They found that the film detected accurate contact stresses of range 13-25MPa between 24^0C-37^0C and that the variation observed in the measurements for the 6 different implants was 12% at 60^0 of flexion. They however reported that the Fujifilms (Itochu, Los Angeles, CA) might have underestimated the magnitude of the stresses in comparison to a calibrated electrical resistance contact stress measurements. Morimoto et al (Morimoto, Ferretti, Ekdahl, Smolinski, & Fu, 2009) also employed low and high pressure sensitive film (Fuji Prescale Film; Fujifilm, Valhalla, NY) to measure the mean pressure and contact area respectively of ACL reconstructed cadaveric knees. They reported smaller contact areas

at 30 and 15 degrees of flexion in the lateral and medial compartments of the tibia. They also reported contact stresses in the uninjured knees of approximately 3-3.75MPa that were comparable to that seen in normal knees reported by Fukubayashi et al (1980). Thus the second objective of this study was to determine how much of the forces applied by the new device are transmitted to the inter-condylar surfaces of the knee joint and therefore quantify any attenuations that may happen due to tissue effects.

3.2 Methods

3.2.1 Design of Inducible Displacement Device

During my internship period with Halifax Biomedical Inc., I primarily engaged in designing and making the inducible displacement device. In order to get a robust and versatile design, I used a proven approach called quality functional deployment in the design process (Akao Yoji, 2004).

3.2.2 Design Requirements

The requirement for the new device was primarily to eliminate the drawbacks associated with the current device. The requirements were:

- The device should be able to apply a range of forces (both compression and torsion) to the bone or joint in question.
- Device should not require an external power source.
- There should be an outward and inward torque.

- Torque and load application should be easy for the operator to set.
- It should not allow patient movement to affect the applied loads.
- The device should not allow patient injury due to high torque and or deflection
- The force should be applied along the longitudinal axes of the bone.
- The device should clearly indicate the total load and torque applied.
- The material used for device should be durable, lightweight and there should not be any sharp corners.
- There should be a way to release the load on the subjects when needed quickly.
- The device should not cause degradation of the x-ray image of the implant and/or bone markers by occlusion or other means.
- The dimensions of the device should conform to standard measures of the human extremity and should allow room for variability.
- The device should fit with any RSA suite set-up.
- The device should be easy to transport.
- There should be a way to calibrate the device.

These are captured in the product design document and were used as the guiding principle throughout the design process.

3.2.2.1 Tools for Design Selection: Quality Functional Deployment (QFD)

Quality Functional Deployment (QFD) is a quality system that was introduced in the mid 1960s by Yogi Akao and Mizuno Shigeru (QFD: The Customer-Driven Approach to Quality Planning & Deployment, 1994). QFD is a quality design tool that links the needs of the customer with the technical requirements of the device/equipment. It aims at using the input of the customer (patient) and users (x-ray technicians) to inform the engineering requirements that will go into the design and manufacturing of the device. QFD involves understanding the customer requirements (both technicians and patients), stating the technical requirements needed for device, maximizing the positive qualities that the user inputs will bring to bear on the design, refining your technical requirements with those qualities and finalizing your design to capture these qualities and technical requirement

As is required under the QFD technique, x-ray technicians at the Halifax Infirmary were engaged to find out what they would like to see in a design for an inducible displacement device. The technicians answered questions during a scheduled meeting and also gave their suggestions on what they wanted to see in an improved device. Due to patient privileges and confidentiality, the x-ray technicians were tasked to ask patients what they wanted to see improved in a new device and note the points. The feedback from patients was informal as no specific questionnaire was administered but technicians focused on comfort and improvement. These inputs were then relayed as part of their feedback. The inputs were then used to inform a technical requirements

document. This document specifies the functional and safety attributes of the device taking into account the customer requirements. This process results in a design that is comprehensive and of optimal quality as the needs of customers have been addressed in a systematic way to add value to the product (device).

3.2.3 Validation of the Appropriate Load for the Knee

An electromyographic (EMG) study was conducted to determine the amount of compressive forces through the knee that can be borne by healthy subjects comfortably and with minimal contribution of the muscles around the knee joint. Asymptomatic subjects were used for the validation process because the study was a proof of concept and as such we did not want to endanger any patients should there have been any defects in the operation of the device. Also, it was important to ascertain that the load applied to the joint was the main instigator of micromotion and that any muscle involvement were quantified to verify if they were significant contributors to the motion. Also, this will help in reducing the variations in the data because muscle activity, which is different for different people, was controlled.

3.2.3.1 Subjects

Eleven (11) healthy subjects were recruited for the study. All subjects had no history of knee pain or muscle dysfunction to be included in the study. All subjects were adults (above 20years of age). Informed consent was signed by all of them before taking part in the study. Asymptomatic subjects were preferred because they could provide us with the ability to vary the load to a maximum without causing any adverse event which can easily happen when you use symptomatic patients. Since such studies are few in the

literature, we used a standard deviation of 22 microvolts (Laende, 2005) and assumed an alpha level of 5% and minimum power of 80% to calculate a sample size of 11.

3.2.3.2 Study Procedure

Each study participant had a one-time session at the Dynamics of Human Motion (DOHM) Laboratory for the study. Before undergoing the testing, subjects' anthropometric and demographic data were collected including age, height and weight. Subject preparation included electrode placement at specific muscle sites on the lower limb. These seven muscle sites surrounding the knee were the rectus femoris (RF), vastus lateralis (VL), vastus medialis (VM), medial and lateral hamstrings (MH, LH), medial and lateral gastrocnemius (MG, LG). Electrode placement was done as per the standard described in detail previously (Hubley Kozey, Deluzio, Landry, McNutt, & Stanish, 2006). This involved standard skin preparation (shaving and applying alcohol wipes) over electrode sites. Then silver/silver chloride pellet surface electrodes (.79 mm contact area, Bortec Inc, Calgary) were attached in a bipolar configuration (20 mm centre-to-centre), in line with the muscle fibers using standardized placements based on palpation of specific anatomical landmarks (C. L. Hubley-Kozey & Smits, 1998). A reference electrode was placed over the tibial shaft. Electrode placement was validated by palpation during resisted activations of the selected muscles. The raw EMG signals were pre-amplified (500x) and then further amplified (bandpass 10–1000 Hz, CMRR = 115dB (at 60 Hz), input impedance 10 Gohm) using an eight channel surface EMG system (AMT-8 EMG, Bortec Inc., Calgary, Alberta). The raw EMG signals were digitized at 1000 samples per second, using the analog data capture feature of the Optotrack™ motion analysis system.

Subject biases in which the subject lay supine and then seated with the leg in 90 degrees pose and completely relaxed were recorded prior to data collection. The subject was then seated upright on a plinth with the knee in a flexed position on the inducible displacement device (Figure 3.5). A goniometer was used to ensure the knee is in a 90^0 pose. The knee was then strapped unto the device and loading was applied via the ratchet strap configuration. The forces were applied in an incremental fashion (of 5kgs) from 5kgs until a maximum of 20kgs is reached. Measures of the forces, seen at the foot, were taken to get the percentage of force seen at the base of the foot with the help of a weight scale. The weight scale was calibrated with a known weight of 4.5kgs before every test session. After every increment, subjects rated their level of comfort on a visual analogue scale of comfort (VAS of comfort). They were then asked if they are fine with another increase in load until the maximum load was attained. Additionally, subjects had rotating forces applied to the device which they were be told to resist. The circular disc was turned which extended the spring with every extension corresponding to a known torque. A stop cork was then used to hold the disc in place. Then the subject placed the foot on the disc and velcro straps were used to hold the foot down. This was to minimize 'shuffling' of the feet during exams, thus reducing variability. The stop cork was removed and the subject told to resist the turn of the disc. This provided a measure of how much torque can be resisted by the subjects.

Simultaneously, muscle activity was recorded on an EMG system (Bortec, Calgary, AB) at 1000 Hz for 3 seconds during the loading conditions, which comprised of 3 compressive weight classes (10kg, 15kg, 20kg) and two torque types (5Nm of internal and external rotation).

3.2.3.3 Analysis of data

The EMG data from the test sessions were processed by a custom built Matlab™ code. The code was used to collate the data from all the 7 muscle sites (medial and lateral gastrocnemii (MG, LG), medial and lateral vastii (VM, VL), rectus femoris (RF) and medial and lateral hamstrings (MH, LH)) that were collected through the EMG system at our lab. The raw data was band pass filtered and corrected for bias. The correction was by a mathematical operation in the custom matlab program where the system and subject bias was subtracted from the raw data to get the actual raw activity of the various individual muscles. The corrected data was then rectified and low pass filtered (Butterworth filter, frequency cut-off of 6Hz) to remove any noise in the data (Hubley Kozey et al., 2006). Then a root mean square operator was performed on the data and the RMS data of each muscle for all conditions (rest, 90 degree pose and 4 weight classes) for each subject was compiled in a matrix. The RMS data for each muscle was concatenated into a matrix for all subjects. For example, LG had one matrix for all subjects for all conditions (11x6 matrix). The 6 conditions were rest, 90 degree pose, 5kg, 10kg, 15kg and 20kg. The muscle activation was then analyzed (using a paired Student's t-test) to see whether there were differences between the loaded and unloaded case for each muscle. Muscle activation was considered minimal when they remained below two standard deviations of the supine resting EMG results, during the load application (Hodges & Bui, 1996). Hodges et al. (1996), found that low pass filtering at 50Hz (computer detection) consistently identified muscle onset detection regardless of the background noise and was comparable to visually detected onset.

3.2.4 Force Transmission Validation Study

A force transmission study was performed to quantity the forces seen at the knee when the new device was used during testing with a cadaveric knee. Since the loading in this instance was applied outside of the body, it was pertinent to know how much of the load actually was transmitted through the knee joint.

3.2.4.1 Cadaver

One cadaver of the knee was obtained from the Anatomy Lab at Dalhousie University. The subject was part of the donor program being run by the Lab where explicit consent was sought from the person or relatives for their bodies to be used for scientific research. For confidentially purposes, the particulars of the cadaver were not available for this study. The cadaver had a TKA implant already in situ at time of harvesting of the limb.

3.2.4.2 Study Procedure

The whole limb cadaver was severed from the hip joint. The limb was then draped in a plastic material as a protective cover to contain blood and other fluids. An incision was then made medio-laterally, by a trained laboratory technician using the appropriate surgical tools, to gain access to the implanted knee. The incision spread from the lateral collateral ligament to the medial collateral ligament. The joint area was then cleaned to minimize the amount of fluid present at the joint. The limb was then clamped to a bench and placed in the 90 degree pose on the inducible displacement device (Figure 3.1). The knee was supported rigidly by straps attached to the bench and the device. The pressure sensitive film was composed of two thin parts. Both are base materials with one coated with a colour-forming material (microcapsules) whiles the other had a colour-

developing material coating. The coated sides of each part (color-forming and color-developing) are placed against each other for use. Upon pressure application, the microcapsules are broken and a red colour imprint was generated on the developer material. The pressure film was cut to an appropriate size (rough squares) and placed into a rubber glove to prevent fluids from rendering the film ineffective. It was then inserted into the joint area via the incision in the joint in an anterior-posterior manner. A compressive load of 20kg was then applied via the device and the imprint on the sensitive film was removed and stored to be sent for quantitative analyses.

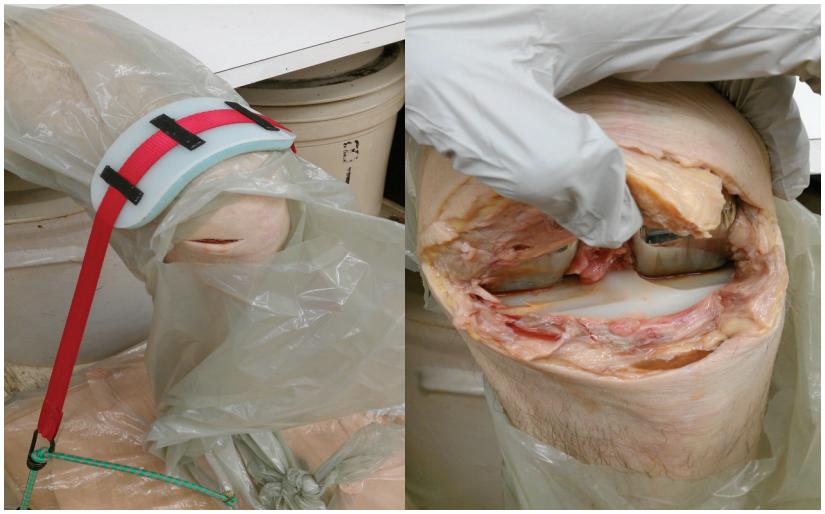


Figure 3.1: Set up of the Cadaver testing.

3.2.4.3 Analysis of Data

The imprinted pressure sensitive film was sent for quantitative analysis. The coloration seen on the pressure sensitive film was scanned and analyzed with the FDP 8010E^{TM} software from PressureMetrics LLC (New Jersey, USA) to get the exact quantity of pressure across a region. This uses a custom algorithm of converting the

pixels of the imprinted coloration into pressure (not available due to company trade policy). The force can then be deduced by the multiplication of the pressure with the area of the region. This corresponds to the force across the area of the tibial condyles in contact with the femur during the load application using the device. The force seen on the pressure sensitive film was compared to that of the weight scale to determine any difference between the weight applied by the device and intercondylar force.

3.3 Results

3.3.1 Device description

The device is a load application apparatus which enables forces to be applied on extremities of the human body and also allows the imaging of such body parts under the loading condition. It is a multi-component device put together in a box (Figure 3.5). These parts are the box, compression and torsion components. The latter two parts enable the application of the forces with the box serving as a platform and storage part. The refined device applies both compression and torsion loads. The compression is applied via ratchet strap, knee cover and weight scale concept whiles the torsion is through a spring and circular disc concept connect by an aircraft thread. The prototype is portable due to its small size and light weight. This allows it to fit into the RSA set-up easily because it does not take up much space. The mode of operation is quite simple in that you place the knee cover over the knee and turn the ratchet up and down to apply compressive force. The torque is applied by turning the wooden disc clockwise or anticlockwise to get internal and external torques. These provide simple and quicker methods of loading the joint. The material (wood) used to fabricate the box is radiolucent

and thus will not affect the RSA images by shielding any marker. There are latches on the box that are used to release the force being applied in the event of any discomfort and they provide quick and immediate load relief (Table 3.1). The new device also accommodates the change of limbs without a change in position of the patient (patient remains seated).

Table 3.1: Summary of Design Requirements and how they are met by new device.

Key Design Requirements	**New Device**
Ease of Set-up	Only one person required for set-up.
Space Required	Small and takes less space.
Set-up Flexibility	Can switch between different limbs with ease.
Multi-Centre Use	Very portable.
Safety	No metal weights and safety release latches.

3.3.1.2 The box

This was rectangular in shape with dimensions of 0.46 x 0.4 x 0.135m (Figure 3.2). The material used was wood due to it being inexpensive, readily available and easy to fabricate. It is very rigid and strong enough to withstand about 3 times the body weight of an average person. The front side of the box is movable via a hinge attached to side of the box. It has a lock on the face that allows one to open the box and access the contents within. The top part is open with a cut-out on the sides upon which the platform for the torsion and compression mechanisms rest. The fasteners used to make the box are wood screws and glue.

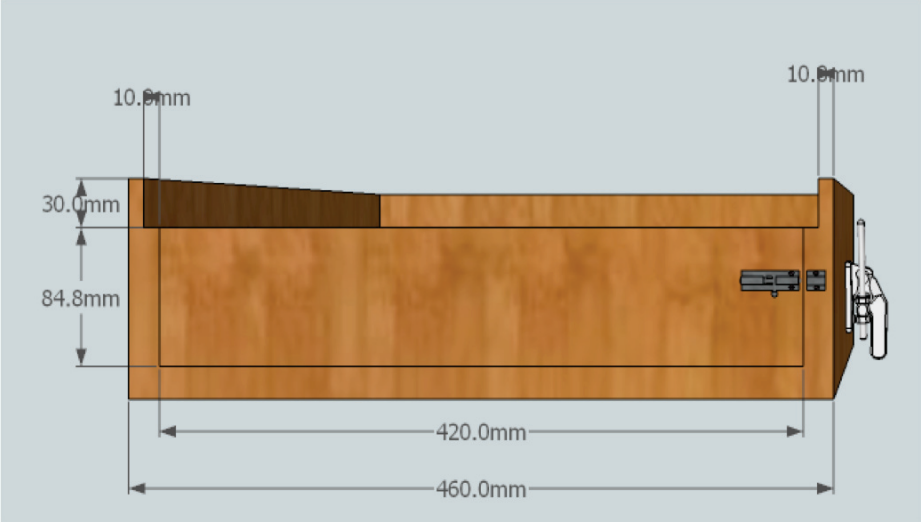


Figure 3.2: The box with dimensions.

3.3.1.3 The mechanism of operation

There are two main mechanisms, compression and torsion.

3.3.1.3.1 Compression

There were two design concepts that were considered. The first was a ‘G-clamp’ metal bar with a padded arm and ratchet straps with padded foam over the knee. In the former, the bar has a turn screw on the side which would be used to lower the padded arm to apply compressional force directly above the knee. The ratchet strap would apply the same force albeit via the use of a ratchet with the ends of the strap attached to the sides of a box.

QFD analysis (Table 3.2) was performed on the 2 design concepts and the latter design was chosen. This was because it had no metal parts that were going to interfere with the RSA rays and it was inexpensive and lighter, making it easily portable.

Table 3.2: QFD Analysis of the 2 design concepts as per the technical and customer requirements.

Technical requirements	Design 1: Straps on rectangular base	Design 2:Solid arm on rectangular base
Design of device	4	3
Space Required	3	4
Standard weight	3	4
Diagnostic capability	4	4
Set up flexibility	5	5
Safety of device	5	5
Ease of Set-up	3	4
Total	27	29

Customer requirements	Design 1: Straps on rectangular base	Design 2:Solid arm on rectangular base
Diagnostic Capability	4	4
Look Professional	4	4
Standard weight	3	4
Low setup time	4	5
Less bulky	4	5
Safety of device	5	5
Multi centre use	5	5
Regulatory Approval	5	5
Ergonomic	4	4
Total	38	41

3.3.1.3.2 The ratchet strap concept

The load is to be applied via the use of ratchet straps, a padded material and latches (Figure 5). The ratchet straps were about 0.025m wide with a length of about 1.5m. This is to cater for any variability in the size of subjects extremities. The straps were made of polypropylene (break strength of 409.1kg) and the ratchet was of metal. The straps were attached via latches to both sides of the box (left and right). The latches are made of metal and are attached by fasteners (screws) to the box.

The padded material (knee cover) was high-density foam glued onto a rectangular flat plastic to provide cover (cushion) for the knees during the application of the loading of the joint via ratcheting of the straps. The flat plastic has curved ends to avoid injury to users and patients. Strap holes were sewn on top of the flat plastic to allow easy movement of the straps over the joint during operation of the ratchet.

A bungee cord was attached to the free side of the ratchet straps and hooked to the latch on the other side. This reduced the amount of weight per turn of the ratchet so patients do not feel large forces being applied to the joint immediately and also aided refinement towards the right amount of load being applied.

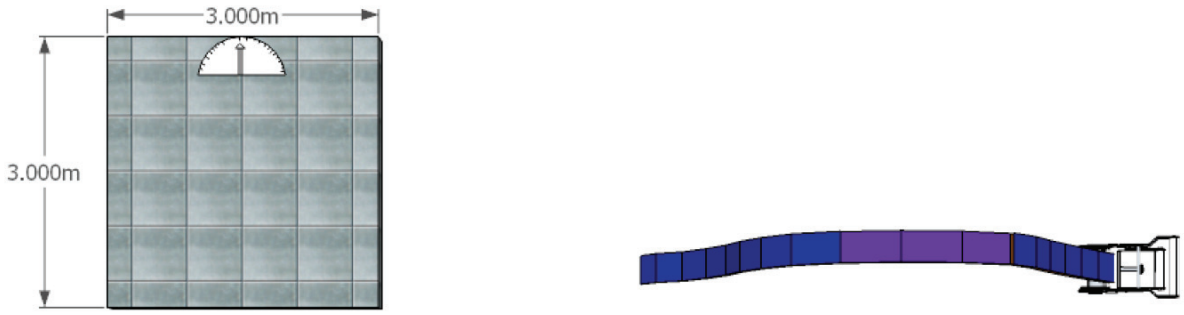


Figure 3.3: The ratchet strap and weight scale.

3.3.1.3.3 Torsion

Two torsion design ideas were considered, the use of a constant force and normal extension spring. The mechanism of operation was by the connection of the springs to two wooden circular discs, connected by a spindle, via a thread so that upon extension of the spring via turning of the disc through known deflections, different amount of torques are applied to the joint in question (Figure 3.4). One disadvantage of the constant force

spring was its inability to vary the torque output with different angles of deflection. Thus the extension spring was chosen because it enabled variation of torque for different angles of deflection.

The parts of the set-up were an extension spring (of appropriate stiffness), a wire thread, two circular discs (of different radii), a lazy susan bearing, a pulley and a circular wooden spindle. The two discs were connected by the spindle with the upper disc (20cm radius), being attached to the lazy susan. The spring was then connected to the second disc (11cm radius) via the wire thread and the required extension was obtained by turning the upper disc through different deflections to produce the required torque. The torque output should not exceed a specified threshold with an acceptable variation of +/-10%. There are clear markings on the bigger disc to indicate the various torques output at different angular displacements. The spring was attached by a bolt and washer system to the underside of the platform on which the disc is fixed. The bolt and washer component were fixed to a wooden block of dimensions (2cm x 5cm x 3cm). This block was fastened to the platform by glue. The bolt was of diameter 6mm and 5cm long. The bolt had a hole near the end through which a key ring was attached. This enabled for easy attachment and removal of the extension spring. The pulley arrangement was at the opposite end of the block and a wire thread from the spring via the pulley was attached to the lower disc.

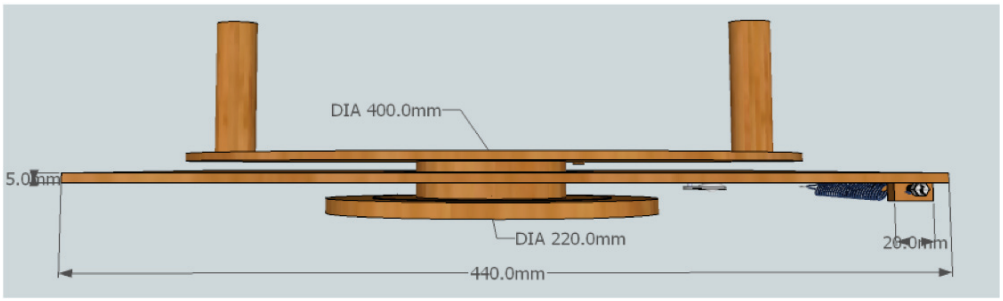


Figure 3.4:Torsion component.

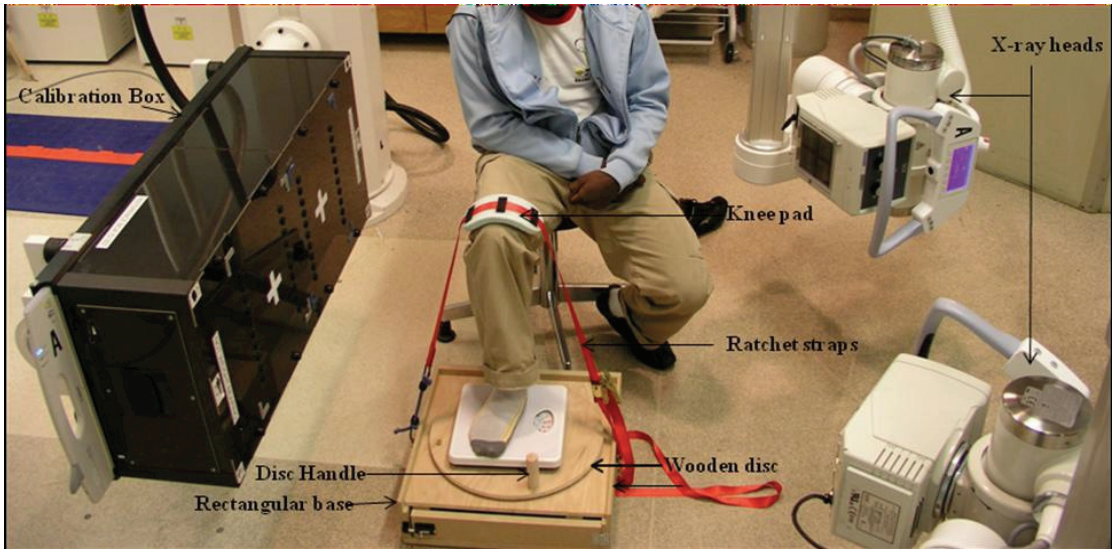


Figure 3.5: Prototype of new device.

3.3.2 EMG Study

For the EMG study, the device was used to load the joint of healthy subjects. Due to the multiple comparisons involved, a Bonferroni correction was applied to the data. This resulted in an adjusted *P*-value of 0.01. Paired t-tests showed no significant differences between root mean square (RMS) muscle activity for all conditions and the supine resting condition for these 11 participants (Table 3.3) ($p>0.01$). Though some of

the EMG activity of certain muscles were close to significance (RF and VM at 20kg and 90degrees, LH at 5kg and 20kg) (Table 3.3), the actual amount of activity falls within 2 standard deviations of the resting muscle activity. Figure 8 below shows the extreme case of the 20Kg test versus the rest and 90 degree positions.

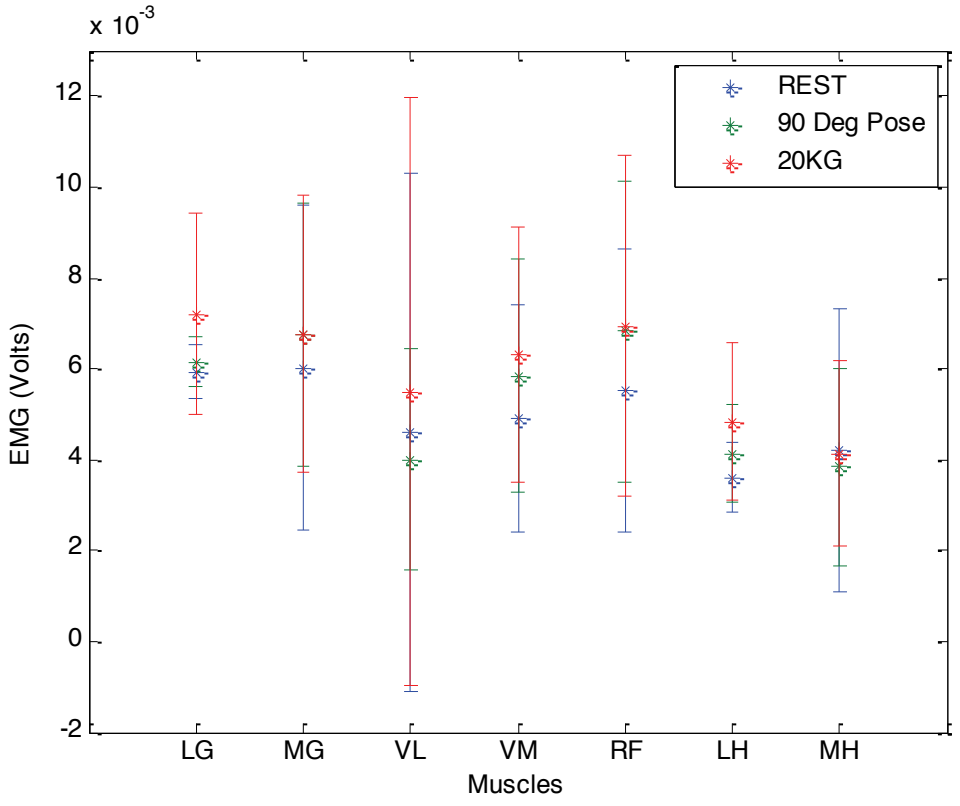


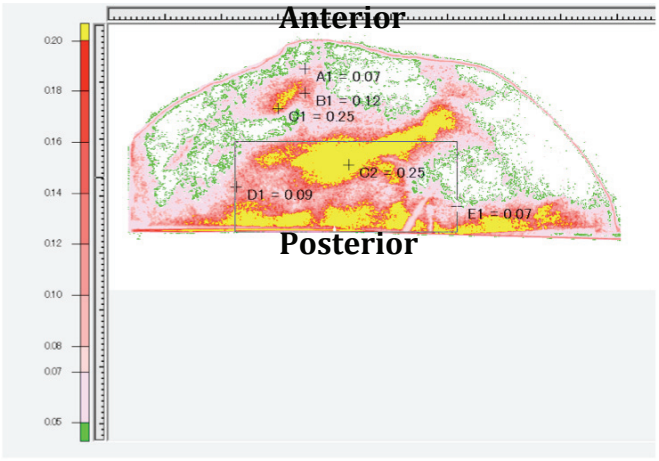
Figure 3.6: Plot of EMG activity of muscles around the knee (mean and standard deviation RMS data) of 11 subjects are shown.

Table 3.3: Summary of p-values and mean (SD) of Paired t-test comparing EMG activity for all muscles for the different conditions compared to the lying supine rest condition.

Conditions (compared to rest)	**Rest**	**90 degree**	**5kg**	**10kg**	**15kg**	**20kg**
LG P-value	N/A	0.400	0.121	0.583	0.087	0.085
Mean (SD) [x10^{-3}]	5.5(0.3)	5.5(0.3)	5.9(0.02)	5.5(0.29)	7.8(3.2)	7.6(3.3)
LH P-value	N/A	0.107	0.025	0.109	0.193	0.050
Mean (SD) [x10^{-3}]	3.87(1.16)	3.8(1.24)	3.9(1.23)	3.8(1.31)	3.7(1.10)	3.6(0.93)
MG P-value	N/A	0.208	0.502	0.166	0.144	0.522
Mean (SD) [x10^{-3}]	2.9(0.29)	3.0(.074)	6.2(4.6)	2.9(0.23)	3.9(1.2)	4.4(1.79)
MH P-value	N/A	0.693	0.748	0.518	0.707	0.935
Mean (SD) [x10^{-3}]	2.6(0.49)	2.4(0.22)	3.1(1.45)	2.4(0.27)	2.6(0.18)	2.4(0.15)
RF P-value	N/A	0.021	0.324	0.184	0.191	0.073
Mean (SD) [x10^{-3}]	3.2(1.27)	2.8(0.89)	8.4(1.9)	2.8(0.77)	2.7(0.64)	2.7(0.67)
VL P-value	N/A	0.722	0.907	0.994	0.638	0.732
Mean (SD) [x10^{-3}]	1.7(0.32)	1.7(0.28)	4.3(0.31)	1.7(0.32)	1.7(0.33)	1.7(0.46)
VM P-value	N/A	0.043	0.103	0.179	0.237	0.024
Mean (SD) [x10^{-3}]	3.2(0.73)	3.2(0.76)	4.6(0.97)	3.1(0.75)	3.1(0.82)	3.2(0.84)

3.3.3 Cadaver Study

Figure 3.7A below is the image analysis as shown by the FPD 8010E scanner and analysis system from Pressure Metrics LLC.



A

B

Figure 3.7: Quantitative analysis showing the pressure distribution (A) and the sample that was sent for analysis (B).

The image (Figure 3.7 above) shows different coloration which correspond to different areas in the joint experiencing different amounts of pressure. The maximum

pressure is seen in the central and posterior regions on the film. This corresponds to the posterior sections on the tibia condyles where the epicondyles of the femur are in contact with the tibia in a 90^0 pose. The central part corresponds to the ridge between the articular surfaces of the tibia. The results show an average force of 199N being felt through the joint and 447.75N being felt in the areas of maximum pressure (Table 3.4).

Table 3.4: Results from the image analysis

Pressed Area (mm^2)	1791
Ave Pressure (MPa)	0.11
Max. Pressure (MPa)	0.25
Measured Area (mm^2)	5699
Load (N)	199
Max Load (N)	447.75

3.4 Discussion

The design technique used to produce the device prototype is quite robust. Quality Functional Deployment (QFD) Analysis is a scientific approach to design that targets meeting the customer needs by having a design product that technically answers those needs. However, QFD does have it shortcomings in that the design person/team should have a clear concept as to what the problem is and what design ideas/concepts can answer the problem. It is then that the tool is very helpful in choosing the best design idea. Though the two design concepts were pretty similar, QFD allowed a quantitative

differentiation between them. The superior design using straps is clearly beneficial as any material that can interfere with the x-rays from the RSA imaging heads will lead to a reduction in the quality of the images produced. This results in different markers being seen in different RSA images that affects the centroid location of markers and introduce inconsistencies. Another requirement for RSA is the minimum markers for analysis which is three, so any occluded marker that can result in this condition not being met, should be avoided.

All design requirements were addressed with the new device to ensure that both customer and user inputs were satisfied (Table 3.1). The new design makes the inducible displacement test much simpler, faster and easy to standardize. With the use of straps instead of weights, patients feel safer when their joint is being loaded because there are no heavy metals that can fall on the legs and cause injury. This also helps in eliminating the intimidating feeling that is sometimes associated with the previous device. The ease of set-up and use of the new device also makes it faster to perform the inducible displacement tests and increases the through-put of the RSA suite allowing more patients to be seen over time. The use of latches also improve the safety mechanism of the test in that whenever a patient feels too much pain from the load application, a one-time loosening of the latch provides enough load-relief and then the knee cover can be removed easily to stop any further weight application. Although the way the load is applied to the joint may not be repeatable in a typical patient population, it is standardized and removes the variations seen with weight-bearing, the mathematical manipulations that is typical in body weight thresholding and danger of symptomatic patients squatting or not being able to squat to a position where enough load is applied to

the joint that can cause recoverable micromotion. Subsidence and tilting (tension on the lateral compartment of the knee) are common observations seen in radiographic measures of implant migration. These speak to two different forces (compression and tension) and as such the device being able to apply a range of forces can help to determine any of these forces that is at play in a particular patient.

The asymptomatic EMG study showed a general increase in the electromyographic signals (EMG) with increase in the load applied though all the data fall within two standard deviation of the resting activity. For most of the muscles, there was a trend of a sharp increase in the activity during the 3rd condition (first loading condition) (Table 3.3) before it then decreases and rises again through the rest of the loading conditions. This might be due to patients maybe contracting because they do not have an idea how the loads being applied by the device will feel like and once they get a sense of that, they are able to relax for the rest of the trials. Though the magnitude of the EMG activity from these healthy subjects were low, there might be more contractions from symptomatic patients (as was seen in some muscles for certain load conditions) but because all the data fell within 2 standard deviations, it should cater for any increased contractions that may be present in symptomatic patients. Also to make the device easily acceptable across hospitals, a clinical trial is important and should be done to make the use of the device reimbursable.

The cadaver study showed an average load of 199N over the contact area, almost the same as the load applied by the device at the top of the joint (approx 200N). The loss of approx 1N (0.5%) might relate to some force/pressure attenuation due to the flesh/skin

tissue around the joint, which is quite minimal. The sample also showed the maximum loads applied by the inducible displacement device was transferred to the posterior regions of the intercondylar surface of the knee joint. This may imply that these regions had maximum contact within the joint between the tibia and femur at 90 degrees of flexion causing direct femoral (metal) to polyethlene insert contact of the implant. This might explain the high forces that implants have to absorb and can be a cause for concern as it can be a source of additional wear to the implant(Kuster, Wood, Stachowiak, & Gachter, 1997). This will be a minimal contribution to wear though as people dynamically load their knee joint with about 3times the body weight during activities of daily living (Kuster et al., 1997; Morrison, 1970). The anterior section of the joint did not experience such high forces during test. This is because the anterior part of the implants do not have much contact in a 90degree flexed pose, as has been shown in asymptomatic subjects (Nagura, Dyrby, Alexander, & Andriacchi, 2002).

Though we only tested one sample, it is quite a promising verification of the loads being applied on top of the knee being actually transmitted through the joint itself. Similar cadaver studies may be performed on different implant designs before wide-scale inducible displacement tests are performed on a particular implant to ensure that this holds for each case.

Generally, the device has shown to be capable of applying loads to the knee in a quicker and safe manner and improves its fit into any RSA suite due to its size. The loads were seen to be tranferred through the joint itself ensuring that recoverable motion is feasible with the use of the device. Also the EMG signals recorded with the device's use

were of low magnitudes and these prove it is a viable alternative to other ways of loading the joint. The Bonferroni correction (adjusted P-value) was used due to the multiple comparisons present, however muscle activity for the five conditions (90deg, 5kg, 10kg,15kg and 20kg) were found not to be different when compared to the resting condition.

For future studies, more samples of imprints from the pressure sensitive films inserted between the cadaver knee joint will have to be looked at to see if the pattern of distribution of the forces will be similar and also verify if the amount of maximum pressure will change. Further investigation into the load distribution between the implant itself and proximal bone/tissues to see if it is sufficient to cause recoverable motion of the implant for inducible displacement testing. Also, it will be desirable if the exact type of implant seen in the cadaver is known so as to ascertain the effects different types of implants will have on load transfer in the joint.

Manual muscle tone checking might have to be performed especially for the muscles that had increased EMG signals (close to significance) so that minimal neuromuscular activity is verified before applying the load to the knee.

Further refinement of the prototype can also be carried out especially with the material used for the fabrication. Fibre glass would be a more durable and robust material to use for the commercial product and also a custom made ratchet that is able to provide very fine tuning of the load being applied would be ideal especially for accuracy.

3.5 Conclusion

The new inducible displacement device prototype is portable and easy to use without any adverse event occuring while performing initial testing in healthy adults. The applied loads via the ratchet straps are shown to be borne mainly by the knee joint itself without the active involvement of the surrounding muscles.

Force transmission proved that these loads are actually passing through the joint itself with minimal losses through skin and soft tissues. The maximum loads were transferred to the posterior regions of the intercondylar joint space.

CHAPTER 4: GAIT AND IMPLANT MICROMOTION OF REVISION PATIENTS

4.1 Introduction

Gait analysis is an objective technique that can be used to differentiate typical walking patterns from abnormal ones. Walking is the most common daily activity performed by humans. This places loads on the knee (Sharma et al., 1998) and gait analysis is a proven tool of characterizing the dynamic mechanical load occurring at the knee joint. Studies have shown differences between patients suffering from knee osteoarthritis and that of healthy subjects. Astephen et al. (Astephen, Deluzio, Caldwell, & Dunbar, 2008), reported decreased stance phase knee flexion angles and decreased peak knee flexion moments between patients presenting with various degrees of severity of knee OA and healthy controls. Patients with knee OA, and increasing BMI, were also found to have decreased peak extension moment than healthy controls (Kaufman et al., 2001). This was attributed to a compensatory mechanism to reduce joint loading. They were also found to have reduced flexion angle during walking though this was not statistically significant (Kaufman, Hughes, Morrey, Morrey, & An, 2001).

The technique has been used to also assess the walking patterns seen in patients who have undergone TKA after their disease severity progresses beyond the level that can be contained with non-surgical treatments. McClelland et al (2011) reported that TKA subjects walked with less knee flexion during stance and swing phases at both

comfortable and fast speeds, 12 months post TKA. The TKA subjects also had less peak knee external rotation in comparison to healthy controls. Brugioni et al (1990) found that patients walked with decreased magnitude of knee adduction that was significant when compared with controls at 1-2 years post TKA. Hatfield et al.(2011), found that flexion angles improved post TKA although the overall range of motion (ROM) showed no difference post-operatively.

Implant migration is an indicator of surgical success post TKA. This is because it provides a direct insight into the movement of the implant in the host bone that can show that it is stable and functioning well. Traditionally, radiographic imaging involving x-rays have been used to assess this motion. Some of the shortcomings that are seen with plain radiographs include lack of 3 dimensional views, higher radiation dosage and longer time to detect deleterious implant motion (Ryd, 1986). Implant migration detected with conventional radiography can take between 5-10 years post TKA by which time revision surgery, considering the age of patients undergoing TKA, becomes more challenging.

Longitudinal Radiostereometric Analysis (RSA) has emerged as a better tool to capture the 3D motion of implants within the host bone with greater accuracy (Selvik, 1989). It also has the diagnostic ability to assess the stability or otherwise of an implant within bone. Ryd et al. (1995) found that RSA can be used to accurately predict the eventual failure of an implant with a predictive power of 82% using micromotion data of 1-2 years post TKA. They reported a maximum total point motion (MTPM) threshold of 0.2mm between 1 and 2 years to be indicative of eventual implant loosening. Another

study found a third of patients being classified as unstable with the rest being stable with the former group having less MTPM at 2years post TKA irrespective of the type of implant they received (1995). They also reported a correlation between longitudinal migration and recoverable micromotion at 2 years post TKA especially with induced rotary forces. Wilson et al (2010) found that uncemented implants had less recoverable micromotions compared to cemented implants that were both stable at 2 years follow-up, using inducible displacement. Ryd and Linder (1989) also found that implants with some bony ingrowth following retrieval had low inducible displacements. Since Inducible displacement captures the recoverable motion that occurs when a joint is loaded and these loads are being highlighted in the literature by the external knee adduction and rotation moments to be possible failure factors, it shows the potential then for the inducible displacement technique to be a good measure of any deleterious motion that can cause eventual loosening in response to these asymmetric and rotation loads.

While previous study has shown that pre and post-operative gait patterns such as high knee adduction moments (Astephen Wilson et al., 2010) and high flexion moments (Hilding et al., 1996) are associated with high migration measured with RSA, there have been no studies to date that have examined the gait patterns of actual failed implants (i.e. TKA revision patients) or those of knees labeled as 'high migrators' according to established RSA criteria (Ryd et al., 1995). These studies compared the gait using patients who were having considerably low micromotions post-TKA. Studies (Sharkey et al., 2002;Jerabek 2011, Fehring et al, 2001) have shown that aseptic loosening is dominant further down the post-operative period with increase in the numbers of patients that fail than was originally screened to be at risk of eventual loosening. This is because

some of the pathways leading to aseptic loosening like wear particles (De Baets, Waelput, & Bellemans, 2008), cement debonding (Waanders, Janssen, Miller, Mann, & Verdonschot, 2009; Nottrott, 2010), bone loss due to aging and osteolysis and failure of implant coating (Lappalainen & Santavirta, 2005) typically take time before they manifest. So it is important to also capture some of the 'high migrating' but not revised patients that are present during the 2 year longitudinal RSA and compare their gait patterns to that observed during failures and get an understanding of the phenomena that may predispose them to eventual aseptic loosening down the years post-TKA. Thus, The purpose of this study was first to examine the knee joint movement and three-dimensional knee joint moments during gait of individuals who are scheduled to receive revision surgery relative to post-TKA gait patterns of both non-revised low and high migrators (according to Ryd's criteria) (Ryd et al., 1995). The second objective was to characterize the inducible displacement RSA migration data of the revision patients relative to the non-revised patients.

4.2 Methods

4.2.1 Patients

This study included 5 patients presenting for revision (secondary) Total Knee Arthroplasty (TKA) and 24 patients who had primary TKA and had stable implants at 2 years post TKA ((Ryd et al., 1995)). The patients were recruited from the Orthopaedic clinic at the Queen Elizabeth II Halifax Infirmary, Nova Scotia. To be eligible for the study, the patients presenting for revision had clinical examination by an orthopaedic

surgeon who assessed their pain, functional difficulties of the involved limb and radiographic signs. The primary TKA subjects had minimal pain and also showed radiographic evidence of the stability of the implant. Exclusion criteria included patients with significant medical condition that affected their ability to ambulate (e.g. congestive heart failure, stroke, pulmonary disease, morbid obesity).

Revision patients are subjected to the same exclusion criteria. Additionally, these subjects were excluded if they were receiving a revision TKA due to infection; patellar revision only, or polyethylene liner exchange. Informed consent was obtained from all patients.

4.2.2 Gait Analysis

Patients scheduled for revision surgery were taken through the Dynamics of Human Motion (DOHM) Laboratory prior to their revision surgery where they performed walking trials to assess their gait patterns. Before beginning the walking trials, demographic and anthropometric data was collected including age, height, weight, thigh and calf circumference. Patient preparation for the walking trials involved the placement of light emitting diodes at certain landmarks of the body. These are the shoulder, greater trochanter, lateral epicondyle, and lateral malleolus. Three-marker triads of infrared light-emitting diodes were placed on the pelvis, thigh, shank, and foot segments. Eight virtual markers (right and left anterior superior iliac spines, medial epicondyle, tibial tuberosity, fibular head, medial malleolus, second metatarsal, and heel) were identified during quiet standing.

Once these were done, the subject then walked along a 6-metre walkway at their self selected walking speeds. A minimum of 5 walking trials with the patient moving at their self selected speed was collected. Exceptions of 3 trials were collected when the patient was feeling too much pain as is common with those presenting for revision surgery. Motion and ground reaction force data were collected from the walking trials. During each walking trial, three-dimensional motion of the affected lower limb was recorded at 100 Hz using 2 Optotrak™ 3020 motion capture camera units (Northern Digital Inc., Waterloo, ON). Ground reaction forces were collected at 2000 Hz using an AMTI force platform (Advanced Mechanical Technology Inc., Watertown, MA).

The foot, shank and thigh were modeled as rigid bodies in order to calculate kinematics and kinetics at the knee joint. The position and orientation of each segment was determined by a least-squares optimization routine with minimal error between the position of each rigid body and the experimental marker data ()(Challis, 1995). The description of angles and moments at the knee joint are done as per the anatomically based joint coordinate system by Grood and Suntay (Grood & Suntay, 1983). Using an inverse dynamics method, implemented through custom Matlab™ (The Mathworks, Natick, MA, USA) software in the Dynamics of Human Motion (DOHM) Lab, net external knee joint moments were calculated from three-dimensional positional data, ground reaction data and from limb segment inertial properties (Costigan, Wyss, Deluzio, & Li, 1992). For this study, the knee flexion/extension angles and the external knee moments in three directions were analyzed. Other stride features like the stance time and speed were also collected and reported.

4.2.3 Inducible displacement

The patients presenting for revision that have RSA beads from previous study were also analysed for implant migration prior to their revision surgery. These patients had Inducible displacement exams taken on them at 12 and 24 months post operatively. Both migration data and gait analysis data were compared to two groups of non-revised patients who were not high migrators and non-revised patients who were high migrators (Ryd et al., 1995). High migrators were defined as patients who had implant migration (measured as Maximum Total Point Motion- MTPM) of more than 0.2mm between 1 and 2 years post surgery. This was done to ensure that, irrespective of the low number of patients presenting at our centre for revision surgery, we could still compare and identify any trends between these groups that might point to a possible failure mechanism.

4.2.4 Data Analysis

Statistical analyses of the data were done using analysis of variance (ANOVA) to determine any differences between the 3 groups of patients (revised, non-revised high migrators and non-revised not high migrators). The goal was to determine any differences between their gait patterns and if not, exploring whether or not differences in gait patterns could be explained by additional clinical or demographic information.

4.3 Results

4.3.1 Patients

There were 5 revision patients, 7 non-revised high migrators and 17 non-revised not high migrators. Demographics, WOMAC and SF-36 for all subjects are included in

Table 4.2. The average age of revised patients, high and not high migrators are 63.5(7.78), 71.5 (0.71) and 66 (1.41) years respectively. The average BMI of the revised patients, high and not high migrators are 34.80 (1.39), 36.23(5.19) and 32.97 (8.95) respectively. There was no difference in the age (P=0.27) and BMI (P=0.312) of the patients in the 3 groups. The WOMAC (Bellamy et al., 1988) and SF-36 scores (Ware & Sherbourne, 1992) reported are the total scores. For the WOMAC the minimum and maximum total scores are 0 and 96 corresponding to "none" and "extreme" discomfort respectively. The SF-36 has minimum and maximum total scores (weighted) of 0 and 100 corresponding to a "poor" and "excellent" health rating. Table 4.1 summarizes the type of primary TKA implant used, the timeline of the revision surgery relative to the primary surgery date, and the relative time of the gait testing pre-revision.

Table 4.1: Timeline to surgery (GTR: Gait session to time of revision; TKATR: Time from primary to revision surgery) and Implant used (PA: Peri-Apatite; TM: Trabecular Metal) for revised subjects.

Patient	**Affected Limb**	**GTR (Days)**	**TKATR (Months)**	**Implant Type**	**Fixation**
Revised					
A	Left	42	25.79	Triathlon PA Coated	Uncemented
B	Left	2	19.57	Nexgen TM	Uncemented
C	Left	1	21.89	Triathlon PA Coated	Uncemented
D	Left	12	61.54	Stryker Scorpio	Cemented
E	Right	3	19.18	Triathlon PA Coated	Uncemented

Table 4.2: Patient information and pain scores

Patient	Age(yrs)	Gender	BMI	WOMAC	SF-36
Revised					
A	58	F	33.82	40	44.85
B	67	M	39.71	60	58.0
C	55	F	39.96	58	38.31
D	64	F	26.45	56	40.69
E	69	F	35.78	75	45.92
Ave (SD)	63.5(7.8)	N/A	34.8(1.4)	57.5(24.8)	45.4(0.8)
Non Revised					
High Migrators					
1YR Post TKA (Ave)	71.5	N/A	36.23	9.5	60.01
1YR Post TKA (SD)	0.71	N/A	5.19	0.71	12.98
Not High Migrators					
1YR Post TKA (Ave)	65.77	N/A	32.18	8	20.39
1YR Post TKA (SD)	6.847	N/A	5.62	9.67	8.88

4.3.3 Subject Gait Patterns

The figures below present the gait variables for the 3 groups. Table 4.3 below presents the peak gait parameters of the 3 groups. All the plots presented are analysed on the stance phase (0-60% of the gait cycle). Also the average 1 year post TKA data used for comparison is made up of revision patients who are not high migrators. These imply patients with MTPM change <0.01 between 1 and 2 years post TKA which is below the threshold of MTPM change of 0.2mm that typifies implants at risk of eventual loosening (Ryd et al., 1995).

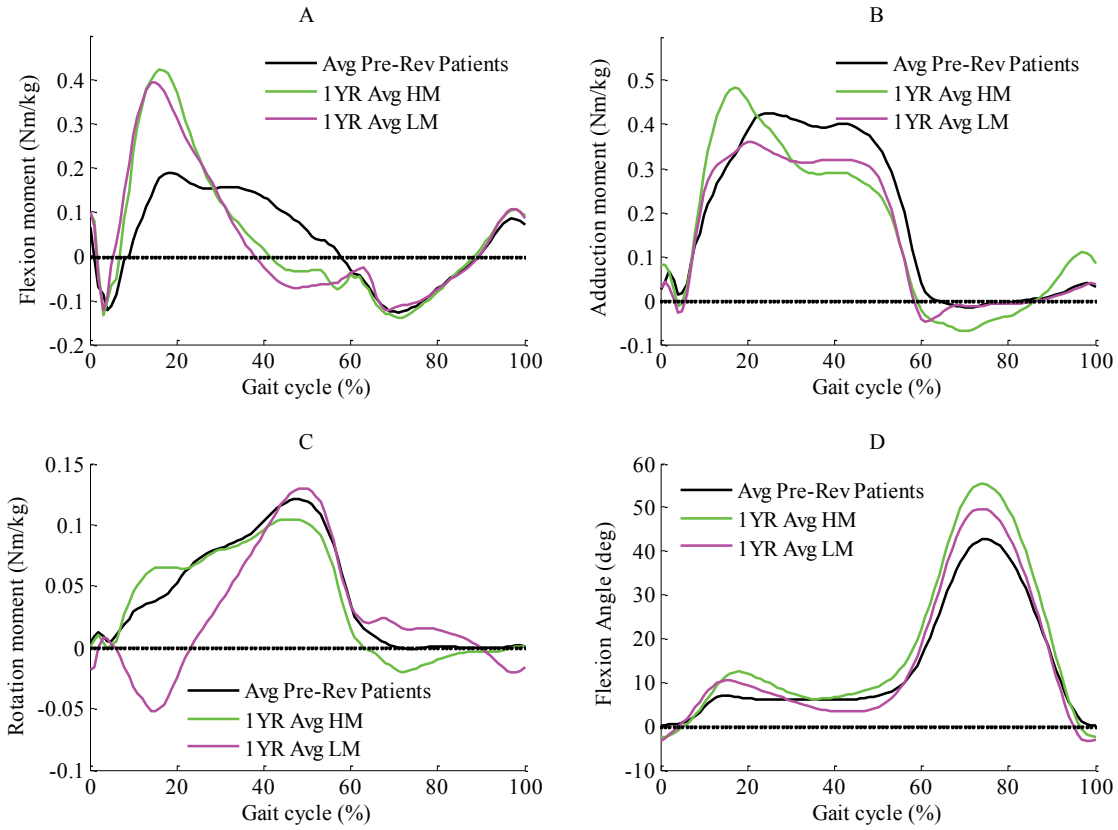


Figure 4.1: Plot showing averages of the gait variables for the 3 different groups. A is the net resultant flexion moment, B is the mean resultant adduction moment, C is the net resultant rotation moment and D is the resultant flexion angles for the 3 groups.

The adduction moment of the revised patients and the high migrator non-revised patients showed high peak magnitudes with the latter having an elevated first peak compared to the non revised not high migrator group. The peak flexion moment, peak extension moment and peak and range of flexion angle of the revised patients are lower than both non revised groups. Analysis of variance (ANOVA) performed on the three groups (revised, non-revised not high migrators and non-revised high migrators) also showed no significant differences (P=0.236, 0.817, 0.164 and 0.185) between the four

knee parameters of adduction, rotation and flexion moments and flexion angle respectively (Table 4.3). Further analyses were done on some parts of the gait parameters to see if any differences exist. The range of motion over the stance phase and entire gait cycle (P=0.369 and 0.543), internal rotation moment (P=0.748), first and second peak knee adduction moment as well as average mid-stance knee adduction moment (P=0.114, 0.402 and 0.278) showed no differences that were significant. External rotation moment and external rotation moment at beginning of mid-stance (20% of gait cycle) did show significant differences (P=0.03 and 0.001) (Table 4.4).

Table 4.3: Gait parameters (values during stance phase).

Patient **Revised**	**Flexion Moment (Nm/Kg)**	**Rotation Moment (Nm/Kg)**	**Adduction Moment (Nm/K)**	**Flexion (Deg)**	**Flexion ROM (Deg)**	**Stance Time (s)**	**Gait Speed (ms^{-1})**
A	0.61	0.21	0.6	20.79	15.16	0.67	1.25
B	0.39	0.13	0.34	9.96	7.39	0.86	0.94
C	0.09	0.12	0.39	5.51	2.64	0.90	0.79
D	0.24	0.06	0.35	4.18	3.62	1.15	0.46
E	0.08	0.13	0.52	5.03	6.17	1.04	0.54
Ave(SD)	0.35(0.3)	0.17(0.06)	0.56(0.06)	12.9(1.1)	10.7(6.4)	0.86(0.3)	0.89(0.5)
Non Revised High Migrators							
F	0.68	0.159	0.44	17.92	12.87	0.76	1.08
G	0.45	0.12	0.45	8.18	6.26	0.64	1.27
H	0.17	0.11	0.59	13.28	12.59	0.78	1.06
I	0.42	0.07	0.57	7.11	3.22	0.72	1.06
J	0.73	0.09	0.62	21.03	19.3	0.62	1.46
K	0.43	0.08	0.27	13.47	6.89	0.84	0.86
L	0.45	0.15	0.69	15.88	7.3	0.65	1.42
Ave (SD)	0.56(0.16)	0.15(0.01)	0.57(0.17)	16.9(1.4)	10.1(3.9)	0.7(0.08)	1.3(0.2)
Non Revised Not High Migrators							
1YR Post TKA (Ave)	0.29	0.12	0.37	9.52	6.45	0.87	1.08
1YR Post TKA (SD)	0.22	0.04	0.15	5.74	5.58	0.06	0.19
P value	0.164	0.817	0.236	0.185	N/A	N/A	N/A

Table 4.4 Additional Gait Parameters

Patient **Revised**	**1st PKAM (Nm/Kg)**	**2nd PKAM (Nm/Kg)**	**Int. Rot. Moment (Nm/K)**	**Ext. Rot. Moment (Nm/Kg)**	**Stance ROM (Deg)**	**Total ROM (Deg)**
A	0.59	0.59	0.21	0.056	13.03	23.1
B	0.34	0.29	0.13	0.08	7.98	18.04
C	0.39	0.36	0.12	0.08	1.49	10.29
D	0.29	0.23	0.06	0.03	4.26	4.07
E	0.51	0.49	0.13	0.004	2.71	13.36
Ave(SD)	0.42(0.13)	0.39(0.15)	0.13(0.06)	0.05(0.03)	5.9(4.7)	13.8(7.3)
Non Revised High Migrators						
F	0.44	0.34	0.16	0.2	12.08	19.57
G	0.45	0.22	0.12	0.01	3.98	14.24
H	0.59	0.47	0..11	0.06	6.04	15.25
I	0.57	0.25	0.07	0.04	1.17	12.36
J	0.22	0.25	0.08	0.06	7.91	18.12
K	0.69	0.34	0.15	0.09	8.23	19.33
L	0.62	0.11	0.09	0.07	15.55	26.24
Ave (SD)	0.5(0.15)	0.28(0.12)	0.11(.04)	0.08(0.06)	7.9(4.83)	17.9(4.6)
Non Revised Not High Migrators						
1YR Post TKA (Ave)	0.38	0.32	0.13	0.03	5.63	14.74
1YR Post TKA (SD)	0.13	0.15	0.06	0.02	4.28	5.33
P value	0.114	0.402	0.748	0.03	0.543	0.369

4.3.5 Case Studies

Due to the lack of statistically significant differences between the revision group and the non-revision group, the high variability and the small sample size, this following section sought to capture and examine the pertinent information relevant to interesting individual cases to determine any potential links between gait patterns, RSA data and clinical/demographic data that would provide insight into potential mechanisms for implant failure for future study. Two such case studies are presented below:

4.3.6.1 Case 1: High joint loading of the knee (Patients A and E)

Patient A was a 58 year old female with a body mass index of 33.82. She had her primary TKA on February 10, 2010 due to degenerative knee OA with some inflammation. She had valgus deformity and antalgic gait. She then had revision surgery due to aseptic loosening and medial subchondral bone collapse a year later. Patient A showed very high adduction moment during the stance phase (Figure 4.3). The actual peak load (0.60Nm/kg) was approximately 62% higher than that of the not high migration non-revised group used as comparison. This may have contributed to the collapse of the medial bone resulting in loosening. Though she walked slightly faster than the non-revised group, speed was found not to cause significant differences in the knee adduction moment, consistent with the results presented by McClelland et al. (2011).

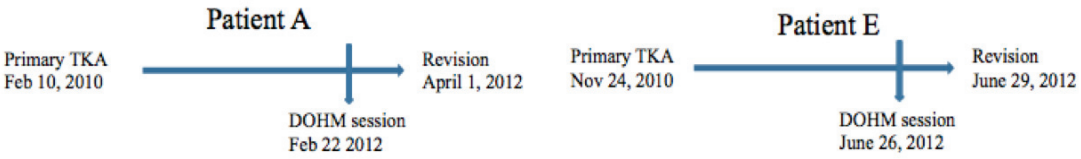


Figure 4.2: Timeline to revision for Patients A and E.

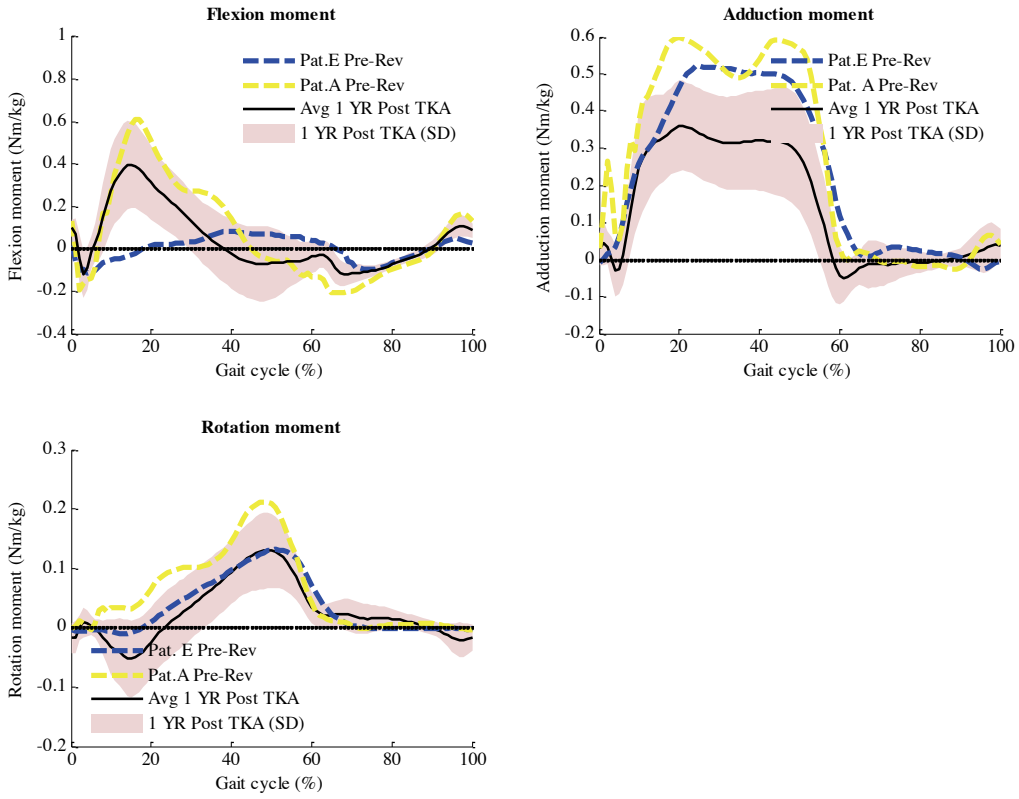


Figure 4.3: All moments for Patients A and E.

The flexion moment pattern seen with Patient A was also different with the usual bimodal pattern of asymptomatic individuals absent (Figure 4.3). Here too, there was a very high moment during stance with a peak value of 0.61Nm/kg which was approximately 110% higher when compared to the average not high non-revised group. This implies high loads during early stance that could have been borne mostly by the

underlying bone as a result of the initiation of the failure process. The lesser extension moment during late stance corresponds to less force for propulsion during late stance.

The rotation moment of Patient A followed a similar pattern to that seen in the not high migration non-revised group but there was a peak moment during stance that is 75% more than the average of the comparison group, again highlighting the abnormal loads that were borne by the implant and the subchondral bone once the failure process has started.

A similar trend was seen in Patient E, who was a 69 year old female with a BMI of 35.78. She had a primary TKA on November 24, 2010 with a revision on August 17, 2012 (Figure 4.2). She showed a peak knee adduction moment of 0.52Nm/kg that was approximately 50% more than the average non-revised group. Although Patient E had excessive pain with a WOMAC score of 75 (the highest amongst the revised group) and walked with the lowest speed (0.54secs) amongst the entire revised group, approximately 50% less than the not high non-revised group. Although Miyazaki et al.(Miyazaki et al., 2002), found patients with high knee adduction moments had more pain, Astephen et al (2011) found no correlation of pain with knee adduction moment. The high pain score and low speed exhibited by this patient cannot be said to be a definite result of the high adduction moment observed. However, reduced speeds has been reported to be a compensatory strategy employed by subjects experiencing knee pain to help reduce the high loads in the medial compartment of the knee (Mndermann, Dyrby, Hurwitz, Sharma, & Andriacchi, 2004).

External knee Moments measured during dynamic tasks give us an idea of the loads being borne by the knee. The knee adduction moment is a surrogate measure of the

amount of loading seen in the medial compartment of the knee during gait (Almouahed, Gouriou, Hamitouche, Stindel, & Roux, 2011; Zhao, Banks, D'Lima, Colwell, & Fregly, 2007). High pre-operative knee adduction moment was found to be associated with high implant migration 6 months post TKA {{196 Astephen Wilson,J.L. 2010}}. Flexion moments were found to capture loading at the knee though their correlation to the internal forces in the joint were not strong (Meyer et al., 2012).

Thus, the high adduction moments in this patient point may point to the causative factors for her TKA being revised with the other moments (flexion and rotation) capturing the debilitating effect seen at the joint once the failure process had set in.

4.3.6.2 Case 2: Stiff knee gait (Patient D)

Patient D was a 64year old female with a BMI of 26.45. She had a car accident which resulted in her being treated for fractures. She did not apparently have a good result after this and eventually had a primary TKA on March 16, 2007 (Figure 4.4). She experienced some pain and stiff knee which resulted in a revision surgery in May, 2012. She had an abnormal knee flexion angle pattern with very minimal flexion during swing (Figure 4.5). Her knee was mostly in flexion all through stance phase which is similar to 'crouch' gait that is exhibited by patients suffering from stiff knee gait (Sutherland & Davids, 1993). The maximum knee flexion angle during stance was 4.18^0 approximately 44% of that of the not high non-revised group whiles swing phase flexion was 9.47^0 approximately 18% of that seen in the not high non-revised group. This indicated a suboptimal outcome following TKA. Knee flexion has been found to improve post TKA

and is indicative of general function and how well patients perform some activities of daily living (Hatfield et al., 2011; Laubenthal, Smidt, & Kettelkamp, 1972; R. L. Mizner et al., 2011). Scar tissues were found in Patient D's knee joint that might have resulted from the trauma she went through during her accident and arthrofibrosis was diagnosed earlier (January, 2010).

Stiff knee gait pattern has been observed in patients who showed decreased knee flexion/extension range of motion throughout the gait cycle. It has been hypothesized that an increased and over-activation of the rectus femoris (RF) muscle can cause this gait abnormality because the RF serves as a bi-articular muscle that produces a flexion and extension moment at the hip and knee respectively(Piazza & Delp, 1996). This keeps the knee in extension during the swing phase and decreases the overall range of motion of the knee that is detrimental to optimal gait outcomes post TKA. Also prolonged activity of the hamstrings has been shown to be present in patients with reduced flexion during swing phase of gait 2 years post TKA (Benedetti et al., 2003).

Patient D exhibits this gait abnormality and the low flexion angles recorded may also be a result of the failure of the TKA. Although arthroscopic arthrolysis was performed to remove the scar tissues, this did not improve the use of the limb as these low angles persisted. This was consistent with the results of Ounpuu et al., (1993) who found that scar tissues present in the quadriceps muscles impeded the function of those muscles as knee flexors during gait.

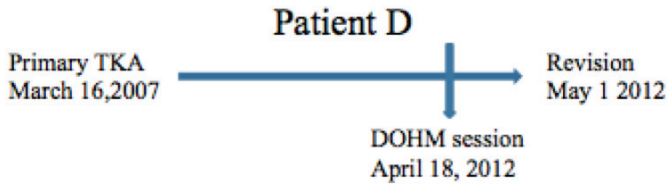


Figure 4.4: Timeline to revision for Patient D.

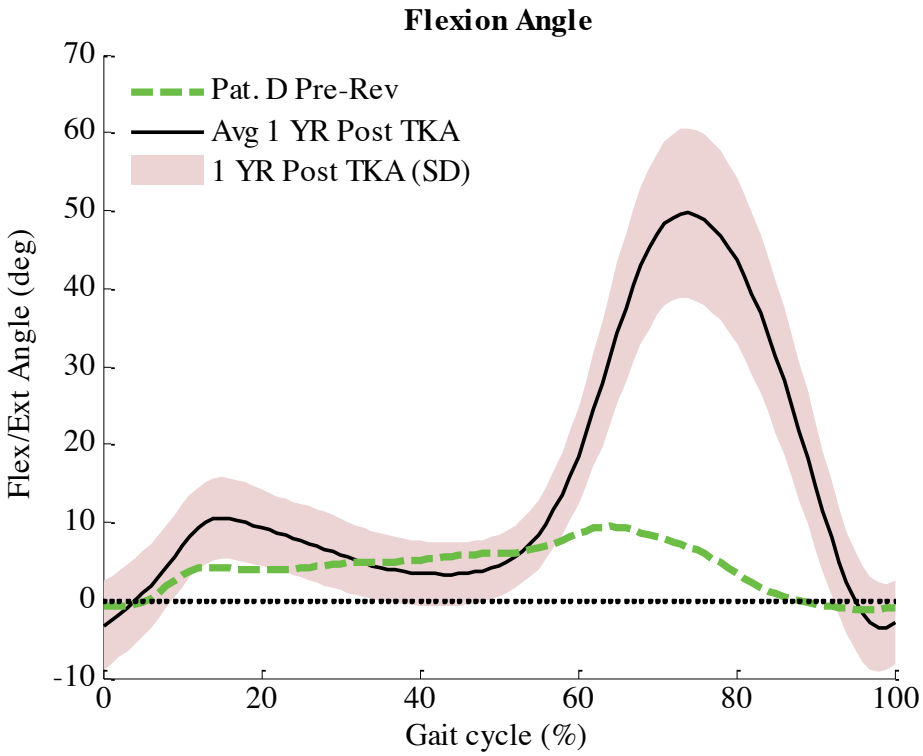


Figure 4.5: Flexion angle for Patient D. Plot shows very low flexion angles for Patient D throughout the entire gait cycle.

4.3.4 Inducible displacement Data

Table 4.5 provides the available Inducible displacement RSA data for the revised, non-revised high and not high migrators. Unfortunately, only one revised patient, patient A, had inducible displacement data at 1 year post-TKA. Patient A's one year MTPM was

excessively higher than values typically seen for either high or low migrators. Generally, the inducible micromotions observed increase in the second year post operatively. Therefore the changes in MTPM are higher than the cut-off for implant stability (Ryd's criteria) (Ryd et al., 1995).

Table 4.5: Patients Inducible Displacement data.

Patient	1YR MTPM (mm)	2YR MTPM (mm)	MTPM Change (mm)
Revised			
A	12.491	N/A	N/A
Non Revised High Migrators			
F	0.959	2.677	1.718
G	0.403	0.855	0.452
H	0.655	0.867	0.211
I	0.307	0.66	0.353
J	4.020	4.3528	0.333
K	0.822	0.602	0.220
L	0.225	0.453	0.228
1YR Post TKA (Ave)	2.122	2.403	0.281
1YR Post TKA (SD)	2.683	2.758	0.074
Non Revised Not High Migrators			
1YR Post TKA (Ave)	0.18	0.208	0.028
1YR Post TKA (SD)	0.021	0.074	0.053

4.4 Discussion

Generally, for the subjective measures of pain (WOMAC) and health status (SF-36) revised patients had higher WOMAC and lower SF-36 than the non-revised groups.

This is consistent with the literature where patients are found to have less pain and better health status post TKA (Hatfield, Hubley-Kozey, Astephen Wilson, & Dunbar, 2011; DUnbar et al, 2004; Dunbar et al., 2001). Gait patterns have been shown to improve, on the average, post TKA. Loads borne by the joint during activities of daily living are captured by the 3D moments with the knee adduction moment being a surrogate measure of knee loads in the medial compartment. The different pattern and magnitudes seen with this parameter (Figure 4.3) may indicate 2 different causes that resulted in revision. The patients (A and E) with higher knee adduction moment (KAM) showed increased loading of the joint that has been associated with implant migration (Astephen Wilson et al., 2010) and lower clinical outcomes (Prodromos, Andriacchi, & Galante, 1985). This may have contributed to their resultant revision. The rest with lower or about average KAM (Patients B, C and D) (Appendix Figure I) seem to be in more pain or had other conditions (stiff knee) or muscle weakness that may have prevented them loading the joint (R. L. Mizner & Snyder-Mackler, 2005; Yoshida, Mizner, Ramsey, & Snyder-Mackler, 2008). The reduced speeds in these patients (revised group) of 0.93 m/s, 0.793m/s and 0.793 m/s was approximately 15%, 27% and 27% (Table 4.3) less than the average speed seen in the not high non-revised group and could possibly be a strategy aimed at reducing pain as a result of the implant failure process that had started in their knees (Astephen Wilson et al., 2011). Though the low KAM should indicate better clinical outcomes (Prodromos et al., 1985), their functional status post-TKA might have been worsened by the other conditions present. The high migrator non-revised group did show higher first KAM peak (Appendix Figure I, Table 4.4) with magnitudes averaging 0.5Nm/kg which is approximately 19% and 31% more than the moments observed in the

revised and non-revised not high migrator group but the considerably reduced second peak (28% and 12.5% less than revised and non-revised not high groups) (Table 4.4) may have contributed in a low cumulative magnitude of loading during stance that may mimic a better mechanical loading environment for the joint/implant (Maly, 2008).

Flexion angles are used to capture the general function of the joint. There was no significant difference observed in this parameter with most patients (revised and non-revised high migrator groups) having comparable levels of flexion during stance (compared to the non-revised not high group). However, the non-revised high migrator group did show elevated levels of flexion during swing. Although this is not significant, it may show that they feel confident in their knee and also it may be that their pre-TKA flexion angles were high and thus after TKA, it increased much more due to the removal of pain and restoration of optimum function of the limb. Flexion moments on the other hand have been shown to correlate to continuous migration which can result in implant failure (Hilding et al., 1995; Hilding et al., 1996; Hilding et al., 1999). Though there were no group differences found (Table 4.3), the higher magnitudes of flexion moments (Figure 4.3) seen in some patients who went onto revision may point to this. The high migration non-revised group had 2 patients (F and J) with higher magnitudes of flexion moments of 0.68Nm/kg and 0.73Nm/kg approximately 135% and 252% more than the average of the non-revised not high migrator group. Though this can be a cause of alarm, it may be cushioned by better muscle support in this group than the general revision group which has resulted in no revision till date. Coupled electromyography analyses should be used in future study to determine this.

The overall rotation moment patterns of the revised patients were similar to the non-revised group with some higher magnitudes (Appendix Figure IV). But a cursory look at the external rotation did show a significant difference between the groups (P=0.03) (Table 4.4). This was even pronounced during mid-stance (around 20% of the gait cycle) with the revised and non-revised high migrator groups having an internal moment (Figure 4.1) altogether. This was just at the end of the loading response stage and may point at the joint not being able to accommodate the rotational load being placed on it resulting in this abnormal rotation moment observed. This may also mean that the patients in these groups were accommodating the loads on undesirable parts of the knee that may worsen the already deteriorating knee. Also, some can be explained by the implants employed (like the Nexgen, Zimmer) that are basically suited to correct flexion abnormalities than allow for rotational support.

Though the moments did show some interesting results, it is important to distinguish between possible causative and non-causative aseptic loosening factors. Because of the study design which further classified the non-revised patients into 2 groups; high and not high migrators, group patterns of the revised patients that tend to mimic that of the non-revised high migrators may explain potential causative factors whiles the cases where the group patterns of the revised patients were different may explain a response to an already failed joint. The knee adduction moment (asymmetric loading) was a possible causative factor because the mean values of the non-revised high migrators are closer to the revised cases (failed TKA patients) and clearly different from the non-revised not high migrators (Figure 4.1). Though this was not statistically significant, it may point to a risk of eventual failure especially for the high migrator

group later on in the post-operative years (Astephen Wilson et al., 2010). Also the external rotation moment showed significant differences and may be a cause of initiation of loosening. However, it may also point to an effect of the already failing knee that may have caused patients to exhibit different patterns. Because the knee is loaded frequently during activities of daily living and moments about the knee give us a measure of the loads borne by the knee, the interesting trends observed in the adduction and external rotation moments may explain some mechanistic pathways to failure in TKA and emphasis should be on them over time to investigate further. The rest of the parameters (flexion moment, flexion angle during stance) analyzed mostly showed lower mean values (and were not statistically significant) for the revised group possibly due to the time of their gait assessment which was closer to their revision implying that patients might have been experiencing too much pain or discomfort with their TKA that loading the knee during stance was very conservative and was a method of managing the dysfunctional knee (Figure 4.1). These may explain the effects of the failure process that had started in the joint and may help in confirming such diagnosis. From the results of the gait patterns, it was observed that the rotational and asymmetric loads (captured by the external rotation and knee adduction moments) may be possible causes of aseptic loosening and thus affirms the design of the Inducible displacement device to be able to apply these two types of loads.

Another point may be the time at which the patients had their gait analysis. Most patients had their gait testing close to their time of surgery so it might be that parameters like flexion angle would be influenced whereby patients would not be able to bend their knee, due to either pain and/or dysfunction, like they would have a bit earlier before their

revision. For the adduction moments, it is quite interesting to see revised patients loading their joints similar to non-revised high migrators who may have better muscle function than them (pointing to possible failure further down the years for the high migrators). The rotation moment showed some different patterns especially during mid-stance with the revised and non-revised high migrator groups showing an internal moment. This may be due to patients changing their patterns to able to accommodate the rotational loads better. Since the external moments are showing interesting associations that may indicate possible failure pathways, it is the imperative that further testing of patients using the improved design of the inducible displacement device will incorporate rotation into the tests. This should not be a hindrance as the improved design can also apply these rotary forces. This will further enhance the data and inferences that can be drawn from such inducible displacements tests.

We compared the data with that of not high migration non-revised patients to remove any conflicts that high migrators might add due to potential failures that could occur within that group (Ryd et al., 1995). Though the high migration non-revised group showed some similarities to the revised group, they have not resulted in failure maybe due to better muscle (quadriceps) strength that aid better functional outcomes post TKA (R. L. Mizner et al., 2011; Yoshida et al., 2008). Further EMG analysis can help throw more insight into the effects of muscle activation on some of these patterns that may have contributed to the revision of the patients. Also, a larger sample size would surely help to get statistically significant differences in the gait parameters analyzed.

Unfortunately, there was only one patient with inducible displacement data. This was because the rest of the patients presenting for revision surgery were referred from out of province. Thus, scheduling of the inducible displacement testing was not possible as that would have interfered with their pre-arranged surgery dates and some routine patient follow-up in the RSA suite. Nevertheless, the available Inducible displacement data showed that the one revised patient had an abnormal maximum total point motion (MTPM) at one year even when compared to the high migrator non-revised group (Table 4.4). The MTPM of 12.491mm was approximately 5.9 times the average migration seen in the high migrator non-revised group and 69.4 times that of the not high migrator non-revised group. This may have been due to the loss of medial bone support for the implant due to the high loads that the subject experienced which resulted in such high continuous migration. The high migrator non revised patients also had increased inducible displacement measurements (Table 4.4) which possibly adds on to the high peak gait parameters (especially the knee adduction moment) seen in that group that might subject them to failure some years later on. They are not revised now possibly due to improved muscle involvement in load attenuation (as seen in the flexion moment in Appendix Figure III) that results in better load share between the implant and proximal bone. This may have reduced the deleterious effect of the implant bearing all the load and failing.

4.5 Conclusion

The revised patients did show varied pathways to revision and although we captured some with gait analysis, there were still some within group differences. Some might be more diagnostic of impending failure especially the pattern observed in patients

much earlier before revision and others, more indicative of the pattern peculiar to patients presenting for revision surgery.

Abnormal implant migration was also observed in the patient with inducible displacement data available that clearly highlighted its risk of eventual failure.

CHAPTER 5: CONCLUSION

5.1 Thesis Summary

Knee osteoarthritis continues to be a debilitating disease that afflicts the older generation in Canada (Perruccio et al., 2006) and North America (Lawrence et al., 2008). Unfortunately, there is no cure to date that relieves patients from this disease. Most patients progress from one stage of severity to another, until joint replacement is the only viable option. Due to the ageing population as a result of increased life expectancy and a newer trend of younger patients (AOAJRR, 2011) electing to undergo this procedure, the numbers presenting for TKA are high and increasing. Resultantly, there is a huge burden on the orthopaedic surgeons with increasing wait times for patients (Wait Time Alliance, 2012). The outcomes seen with TKA are high but due to the aforementioned factors, there is the need to have tools that can help in either slowing the progression of knee OA and/or detect failure in TKA patients much earlier so remedies can be done quicker and improve the outcomes associated with such remedy interventions like revision surgery.

Gait analysis and RSA are two promising research tools that have the potential to fulfill this need. Gait patterns have been shown to correlate to TKA functional outcomes and implant migration predominantly in well functioning implants. This thesis work aimed to address the paucity of such data in the revised patient cohort with focus on the mechanical/aseptic loosening pathway to implant failure. The knee adduction and flexion moments were found to be higher in some patients who went unto revision. This is in agreement with the literature on the effects of loading on TKA implants and may point to

the association between these parameters and definite implant failure. The external rotation moment was also seen to be totally different from what was observed in a non-revised not high patient group, pointing to the possible effects the failure process may have on gait patterns and also possible implant effects. These can help in getting a novel insight into these associations and further enhance our understanding of the biomechanics of implant failure.

RSA has also been predominantly focused on longitudinal migration although inducible displacement is another viable technique. The main pitfall with the latter measure has been the lack of indices which basically stems from the variations seen in the data presented for such exams. These result from the different exams and devices used to induce this recoverable micromotion. This thesis work also looked at designing a new device that could be used to conduct these exams easily and in a standardized way so as to reduce the disparity in the data gathered. The prototype of the new device applies the load in a standardized manner with minimal involvement of the soft tissues around the knee joint. Moreover, it is portable and has the potential for it to be used in multicentre trials and thus reduce the variation associated with using weight bearing poses of the patient to get inducible displacement measures.

This thesis work can serve as a basis for the diagnostic assessment of post operative implant function and implant stability whereby patients who stand the risk of eventual failure can be screened early on and have an opportunity for an appropriate intervention that may prevent revision surgery.

5.2 Limitations

The gait study in this thesis work had some limitations of skin motion artefacts that are present in gait analysis and the modeling of the lower limb as a system of connected rigid bodies (Challis, 1995; Costigan et al., 1992). The skin marker motion errors can be enhanced during dynamic tasks including walking. Fluoroscopy can be an alternative to marker placement but the radiation dosage would have to be checked so that patients are not irradiated to dangerous levels. This would greatly reduce the kinematic errors due to skin motion artefacts especially when most of the patients in the study are obese. However, joint moments (kinetics) are not affected by these errors and since the interesting associations presented in this work were the moments, they were not affected. Also, the use of external moments calculated using the inverse dynamic approach to represent internal contact forces has been shown to be inaccurate (Meyer et al., 2012). Thus there is most often an over or under estimation of the true contact forces at the knee joint.

The Inducible displacement study in Chapter 3 is also limited in that the device and chosen weight class was employed on healthy (asymptomatic) patients and as such the effects on TKA patients are yet to be ascertained. Presently the device is not reimbursable so a planned clinical trial using symptomatic patients will help the device meet the requirements for reimbursement.

In the EMG study in Chapter 3, a limitation is that since the device was used on healthy patients, the EMG activity might be higher in symptomatic patients than healthy ones due to increased co-contraction that occur in such patients. Muscle toning checks

may have to be done to ensure minimum muscle activity before tests are done especially on the muscle sites that showed increased EMG activity.

Due to presence of fluids in the joint area for the cadaver study in Chapter 3, only one sample of pressure film data was done since the fluids rendered the films defective. Getting more samples will definitely paint a better picture of the force distribution seen in the joint.

Statistical analysis performed for most of the gait variables in Chapter 4 did not reach significance due to the lack of power in the gait and RSA studies. There was a small number of revision patients as well as lack of RSA data on them. Thus enough patient numbers may have provided a better idea of the typical patient population. Also we could get more insight into the interface interactions too if Inducible displacement data was available for all revision patients.

5.3 Future Recommendations

The design of the prototype of the new inducible displacement device could be improved. The use of better materials like carbon fibre will make it look very professional for the clinic setting. Also, a custom made ratchet can be used to help make the loading process faster and ease the physical input on the part of the x-ray technician. More samples of the pressure sensitive film can also be done to further strengthen the proof of force transmission through the knee joint.

Fluoroscopy can also be a good complement for the gait trials and help eliminate the skin motion artefacts present in gait analysis especially with regards to obese subjects as was present in this thesis work. This is because the position of the rigid bodies (bone) will be highly enhanced and reduce any possible sources of kinematic errors.

A clinical trial should be done to help transition the device into clinical use. This will help in getting data that is clinically relevant to the specific patient population. This will also help in determining which weight of load can induce recoverable micromotion safely and also be comfortable for patients with TKA. This step will be key in ensuring that the use of the device as a clinical tool will meet reimbursement requirements. Since revision patient numbers are low at our centre, utilizing the portability of the new device, a large multi-centre clinical trial assessing gait and inducible displacement measures pre and post TKA for both non-revised and revised patients can help in building predictive models for implant failure.

APPENDIX

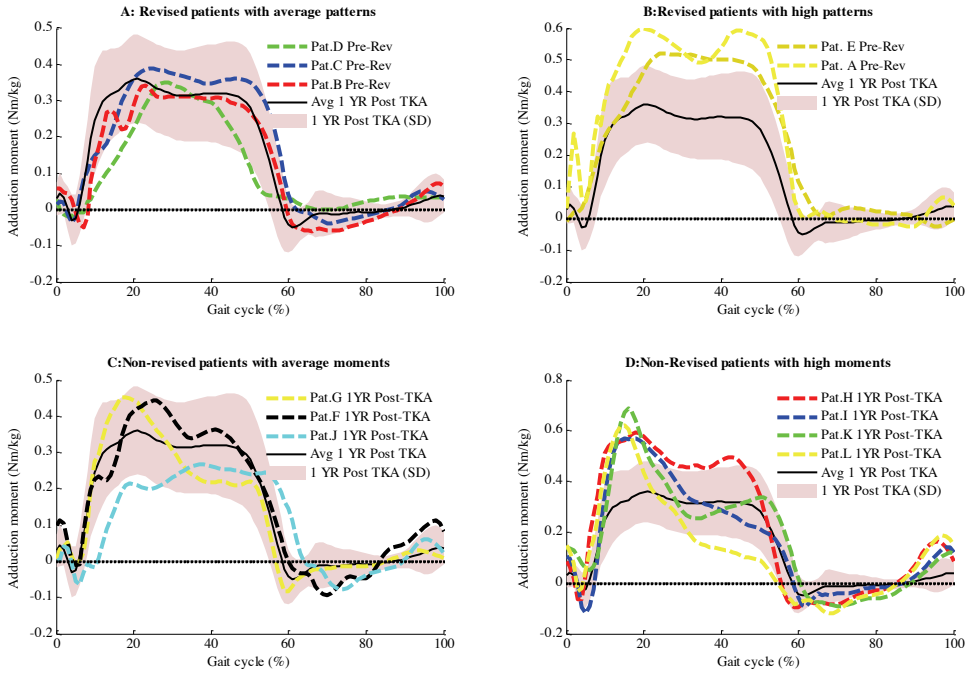


Figure I: Adduction moments for all patients. Plot A shows patients who have average knee adduction moments, plot B are revised patients with higher moments than the average with plot C showing the moments of non-revised high migration patients with average moments and plot D showing non-revised patients with increased first peaks than the average.

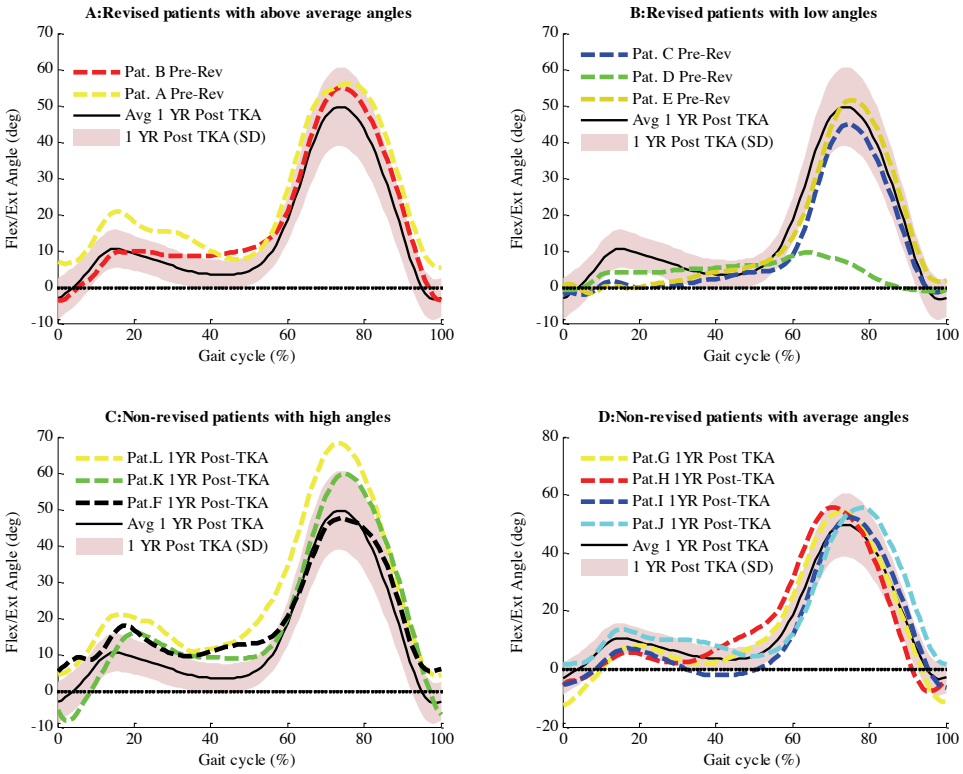


Figure II: Flexion angles for Patient B shows similar flexion to the average group during early stance, however has less extension than what is typical in late stance, indicative of a stiff-kneed gait pattern whiles Patient A shows higher than average peak flexion during early stance (A). Patient D show very small flexion angles during the stance phase, indicative of a stiff-kneed gait pattern as well as minimal flexion during swing phase (B). Plot C shows patients with similar patterns to the not high migrator group with patients having a slightly higher than average flexion magnitude in stance and a lack of extension in late stance (corresponds to higher than average flexion moment in stance shown above, likely indicative of a stiff-kneed gait pattern). Plot D shows patients with average magnitudes and similar patterns to the not high non-revised group.

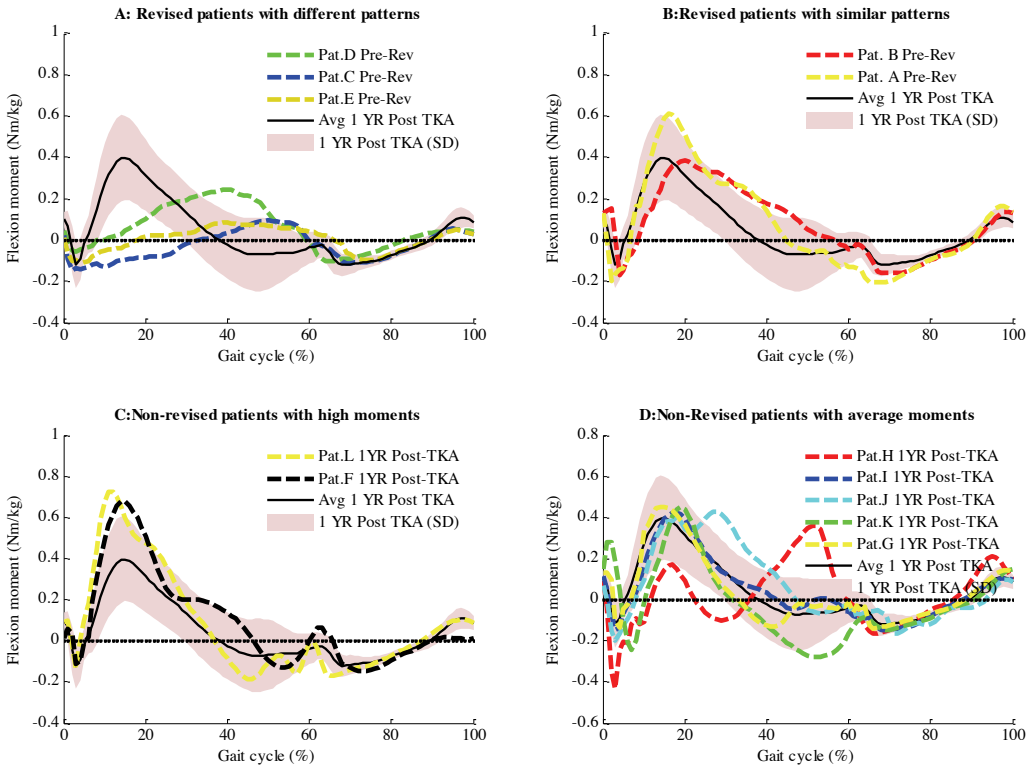


Figure III: Flexion moments for all patients. Plot (A) shows patients with different patterns (a flexion moment in late stance), plot (B) shows patients with similar patterns and magnitude as the non revised group whiles plot (C) shows that of high migrators with similar patterns of flexion/extension moment and higher magnitude to the non-revised not high migratory group with a distinct early stance flexion moment and late stance extension moment. Plot (D) shows non-revised patients with average moments but varying patterns.

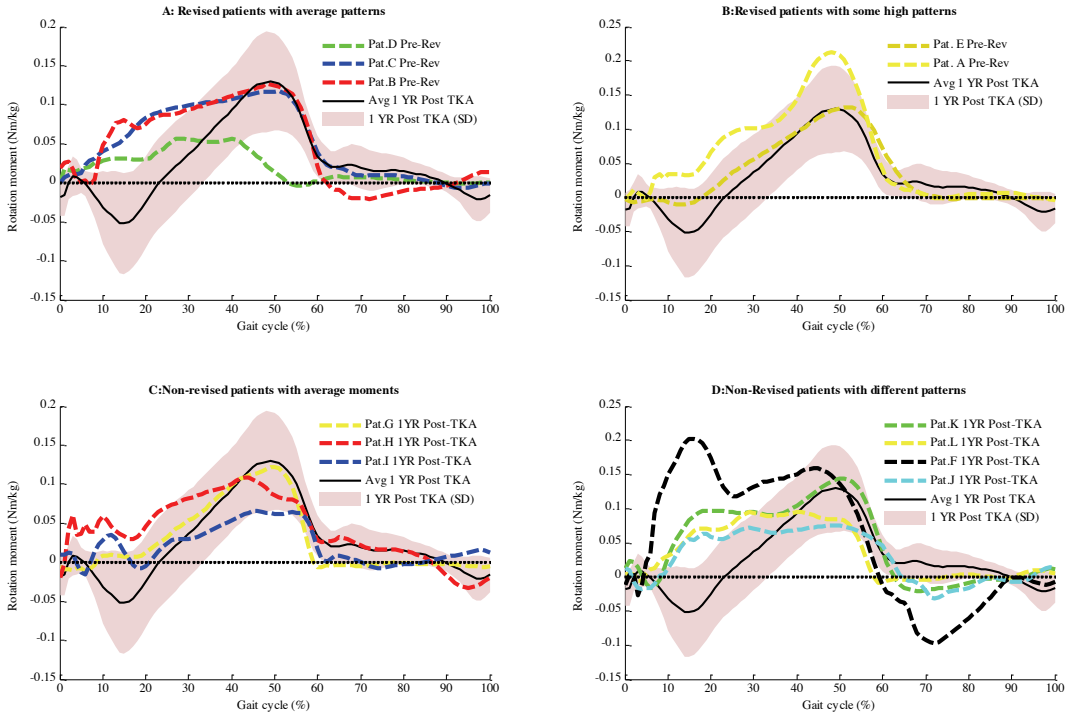


Figure IV: Rotation moments showing Patients B,C,D with distinctly different pattern and lower magnitude of rotation moment during stance, characterized by a lack of early stance external rotation moment and lack of a peak late stance internal rotation moment (A). The patterns of patients A and E (B) are typical but Patient A shows a higher peak internal rotation moment in late stance than what is typical. Plot C shows non-revised patients with very irregular pattern of high internal rotation moment in early stance rather than an external rotation moment, and this moment remains high and internal throughout stance. Plot D shows patients displaying typical rotation moment patterns.

Patient Descriptors

Patient B

Patient B is a 67 year old male and had debridement and arthroscopy in 2008 on his left knee. He eventually had a primary TKA on August 18, 2010. The implant employed was a Nexgen Trabecular metal that was later revised for aseptic loosening on

April 3, 2012. He had a cementless modular tibial component and a cemented femur. Patient has approximately average adduction moment (Figure 4.2) and show either equal or less flexion angle with the knee then being kept at the same level of flexion through mid-stance to toe-off (higher magnitude than the average, Figure 4.5). He walked with a speed of 0.94m/s and no migration data exist yet for this patient as it is less than a year since his revision.

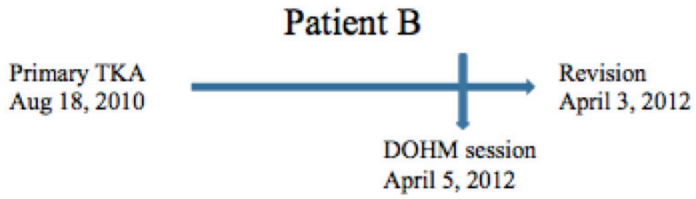


Figure V: Timeline to revision for Patient B

Patient C

Patient C is a 55year old female and had primary TKA on June 16, 2010 on her left leg. The Triathlon Peri-Apatite coated implant used showed malrotation of both components (excessive internal rotation) which was painful (constant pain-10 out of 10). This was concentrated at the posterolateral aspect of the knee and she is non-responsive to oral medication. This resulted in a revision surgery on April 10, 2012. She walked with a speed of 0.79m/s and had a different pattern of flexion moment with a shifted peak (Figure 4.3). She had low flexion angle during weight acceptance (Figure 4.5) and rotation moment that was different from the non-revised patients with low magnitudes (Figure 4.4). There is no RSA data available for this patient as she is not at the required time-point for this measure.

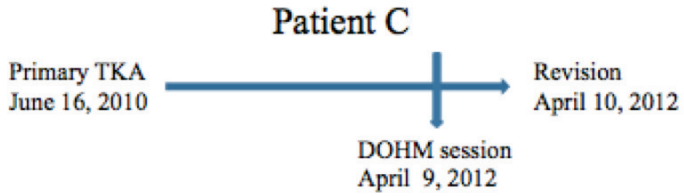


Figure VI: Timeline to revision for Patient C

Patient D

Patient D is 64 years old and had a car crash in 1971 and was operated on for fractures before she had her primary TKA on March 16, 2007 involving her left leg. The implant affixed was the Stryker-Scorpio NRG. She experienced tibial pain and a stiff knee. She was earlier revised in March 2011 for pain and stiffness. She also had some cement injected into the proximal tibia. She also had arthroscopic arthrolysis to remove scar tissues on January 27, 2010. This gave her only 3weeks of pain relief. She experienced an irritated synovum medially and also had her left hip replaced in October, 2009. Patient D showed very low flexion angles especially through the swing phase of gait (Figure 4.5). She had a gait speed of 0.79m/s but migration data at 1 year is not available for this patient.

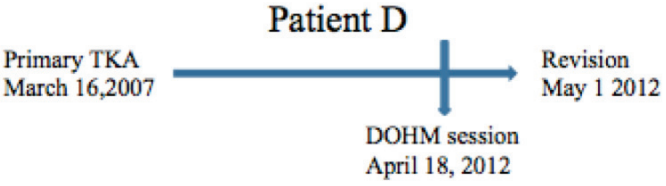


Figure VII: Timeline to revision for Patient D

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