The Effectiveness of Medial Pivot Knee Arthroplasty Implants at Improving Gait in Patients with Knee Osteoarthritis: An Interim Analysis of an RCT

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LIST OF ABBREVIATIONS

ADL	Activities of Daily Living
ANCOVA	Analysis of Covariance
ASIS	Anterior Superior Iliac Spine
BMI	Body Mass Index
KL	Kellgren-Lawrence
KOOS	Knee Injury and Osteoarthritis Outcome Score
OA	Osteoarthritis
PCL	Posterior Cruciate Ligament
PRO	Patient Reported Outcome
PROM	Patient Reported Outcome Measures
PSIS	Posterior Superior Iliac Spine
RCT	Randomized Control Trial
ROM	Range of Motion
TKA	Total knee arthroplasty
VAS	Visual Analogue Scale
WOMAC	Western Ontario and McMaster Universities Osteoarthritis Index

ABSTRACT

Background: Over 47,000 total knee arthroplasty (TKA) procedures are performed in Canada annually, the majority being for knee osteoarthritis (OA). These procedures use various designs to maximize outcomes and restore knee motion, but the safety and effectiveness of the implants are not thoroughly tested. Furthermore, it is not clear which TKA implants can restore normal knee motion. The medial pivot design is a novel design that is hypothesized to restore normal knee motion; however, it is more expensive, and outcomes are not well established. **Objectives:** 1) To compare knee kinematics and spatiotemporal measures during gait and step up/down tasks 1 year after TKA between patients who received the medial pivot implant and patients who received the traditional posterior stabilized implant. 2) To compare patient reported outcomes measures (PROMs) (pain, symptoms, stiffness, function in daily activity, sport, and recreation, and quality of life) between patients who received the medial pivot implant and patients who received the traditional posterior stabilized implant 1-year after surgery. 3) To examine relationships between participants' ratings of perceived change (using PROMs) and biomechanical measures (kinematic data). **Methods:** This was a double-blind randomized control trial in which 22 adult participants were placed into two groups either receiving a medial pivot or a posterior-stabilized implant. Outcomes included knee angles and spatiotemporal variables during gait and step up/down tasks. These were measured using 3D motion capture and force plates pre-operatively, and at 1-year post-surgery. Analysis of covariance, effect sizes, post-hoc power analyses were used to compare results between the groups while adjusting for their baseline visits and speed. Analysis of covariance was also used to analyze the results of the PROMs (pain, symptoms, stiffness, function in daily activity, sport, and recreation, and quality of life) at 1-year after surgery. Spearman correlations were run

to identify relationships between the biomechanical and self-reported changes. **Results:** No significant differences were found in knee angle variables during gait. The medial pivot group was significantly faster (p=0.03) with large effect size (d=1.10). In the step-up analysis, the posterior-stabilized group had significantly greater peak knee flexion (p=0.03, d=-1.31). Step-down analysis showed that the medial pivot group had significantly greater peak knee flexion and knee rotation ROM (p=0.03, d=1.68; p=0.04, d=1.65, respectively). Clinically, the medial pivot group scored higher in activities of daily living and had better perceived changes (p=0.019, d=1.18; p=0.039, d=0.79, respectively). However, all analyses yielded low power. There were no significant correlations between perceived changes and biomechanical measures, with weakest r coefficients being -0.032 and strongest being 0.383. **Discussion:** Based on these results, the medial pivot might have some slight advantages compared to the posterior-stabilized implant. However, these results are preliminary and as such the RCT must continue as the sample size is still too small to fully grasp the differences between the implants. Addressing this gap will help physicians improve decision-making and patient care with the best TKA implant.

ABERGÉ

Introduction: Plus de 47 000 arthroplasties totales du genou (ATG) sont effectuées chaque année au Canada, la majorité d'entre elles pour traiter l'arthrose du genou. Ces interventions font appel à diverses conceptions pour maximiser les résultats et restaurer le mouvement du genou, mais la sécurité et l'efficacité des implants ne sont pas testées de manière rigoureuse. En plus, il n'est pas clair quels implants d'ATG peuvent restaurer le mouvement normal du genou. La prothèse à pivot médial est une nouvelle prothèse dont on estime qu'elle rétablit le mouvement normal du genou ; cependant, elle est moins économique et ses résultats ne sont pas bien établis. **Objectifs:** 1) Comparer la mécanique du genou et les mesures spatiotemporelles pendant la marche et les tâches de montée/descente un an après l'ATG entre les patients ayant reçu les différents implants. 2) Comparer les résultats rapportés par les patients (douleur, symptômes, raideur, fonction dans les activités quotidiennes, sportives et récréatives, et qualité de vie) entre les patients ayant reçu les différents implants un an après l'intervention chirurgicale. 3) Examiner les relations entre les évaluations du changement perçu par les participants (à l'aide des rapportés par les patients) et les mesures biomécaniques (données kinématiques). **Méthodes**: Cette étude randomisée en double aveugle a consisté à regrouper 22 participants adultes en deux groupes, l'un recevant un implant à pivot médial et l'autre un implant à stabilisation postérieure. Les résultats comprenaient les angles du genou et les variables spatiotemporelles pendant la marche et les tâches de montée/descente. Ces variables ont été mesurées à l'aide d'un système de capture de mouvement 3D et de plaques de force avant l'opération et un an après l'opération. L'analyse de la covariance et les tailles d'effet ont été utilisées pour comparer les résultats entre les groupes tout en tenant compte des visites et de la vitesse de départ. L'analyse de covariance a également

été utilisée pour analyser les résultats des rapportés par les patients (douleur, symptômes, raideur, fonction dans les activités quotidiennes, sportives et récréatives, et qualité de vie) au départ et 1 an après l'opération. Des corrélations de Spearman ont été effectuées pour identifier les relations entre les changements biomécaniques et les changements déclarés. **Résultats**: Aucune différence significative n'a été trouvée dans les variables de l'angle du genou pendant la marche. Le groupe à pivot médial était significativement plus rapide (p=0,03) avec une taille d'effet importante (d=1,10). Dans l'analyse de la montée, le groupe postéro-stabilisé avait un point de flexion maximal du genou significativement plus élevé (p=0,03, d=-1,31). L'analyse descendante a montré que le groupe à pivot médial présentait une flexion maximale du genou et une rotation du genou ROM significativement plus importantes (p=0,03, d=1,68 ; p=0,04, d=1,65, respectivement). Sur le plan clinique, le groupe pivot médial a obtenu de meilleurs résultats dans les activités de la vie quotidienne et a mieux perçu les changements (p=0,019, d=1,18 ; p=0,039, d=0,79, respectivement). Il n'y avait pas de corrélation significative entre les changements perçus et les mesures biomécaniques. Il n'y avait pas de corrélation significative entre les changements perçus et les mesures biomécaniques, les coefficients r les moins forts étant de -0,032 et les plus forts de 0,383. **Discussion**: D'après ces résultats, le pivot médial pourrait présenter de légers avantages par rapport à l'implant à stabilisation postérieure et devrait donc être utilisé plus souvent. Cependant, ces résultats sont préliminaires et, en tant que tels, l'essai clinique randomisé doit se poursuivre car la taille de la population est encore trop petite pour que l'on puisse saisir pleinement les différences entre les implants. En cherchant à répondre à cette insuffisance, les médecins pourront améliorer la prise de décision et les soins prodigués aux patients en leur proposant le meilleur implant pour l'arthroplastie totale du genou.

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Dr. Robbins was responsible for the study design and obtaining ethics approval. Dr. Robbins also created code for MATLAB and Visual 3D that was used during data processing. Dr. John Antoniou, Dr. Olga Huk, Dr. David Zukor, and Dr. Adam Hart performed the surgeries and referred participants to the study. Anthony Teoli, Maria do Carmo Correia de Lima, and Isabella Sierra assisted with data collection, data processing, and participant recruitment. I, Nicolas Herrera, was the main contributor and lead author of the content of this thesis. My contributions included the screening of participants, data collection, data processing, statistical analysis, interpretation of findings, figures/tables/appendices, translating the abstract to French, and formulation of conclusions and clinical implications. Dr. Robbins reviewed the thesis and provided feedback.

CHAPTER 1: BACKGROUND

1.1. OSTEOARTHRITIS & TOTAL KNEE ARTHROPLASTY

1.1.1 Definition and prevalence

Knee osteoarthritis (OA) is described as cartilage damage, a formation of a bony osteophyte, and subchondral sclerosis that affects the three compartments of the knee joint (medial, lateral, and patellofemoral joint) (Lespasio et al., 2017). It is among the top 10 causes of disability worldwide (Lespasio et al., 2017). Knee OA is one of the most common health conditions with a lifetime prevalence of 44.7% (Murphy et al., 2008; Vos et al., 2012). This debilitating chronic condition is of a progressive nature which leads to substantial negative impact on the patient's physical function, quality of life, and pain levels (Gignac et al., 2006; Gupta et al., 2005; Salaffi et al., 2005). Along with all the negative impacts the disease has on these individuals, it also creates a massive economic burden for both the patient and the healthcare system (Gignac et al., 2006; Gupta et al., 2005; Salaffi et al., 2005).

1.1.2 Description of TKA

The end-stage treatment for knee OA is a total knee arthroplasty (TKA). In Canada alone, over 47,000 TKA procedures are performed annually, with the majority of these procedures performed on patients with knee OA (CJRR, 2022). TKAs are used as an effective treatment for end stage knee OA (CJRR, 2022; Lavernia et al., 1997; Lespasio et al., 2017). The TKA procedure involves removing the damaged articular surfaces of the knee and replacing them with prosthetic components made of either metal, polyethylene, or both (Lavernia et al., 1997).

1.1.3 Post TKA

Following TKA, individuals have demonstrated enhanced physical capability. However, 10% of these patients express dissatisfaction, particularly younger patients seeking vigorous recreational pursuits post-TKA (CJRR, 2022; DeFrance & Scuderi, 2023). In Canada, approximately 7% of TKAs are revision surgeries, primarily attributed to aseptic loosening and instability due to excessive shear forces within the prosthesis (CJRR, 2022; Dennis et al., 2003; Schmidt et al., 2003).

1.1.4 Description of implants

Manufacturers have made design changes to the implants to maximize outcomes and limit revisions. The primary objective in the design TKA implants is to restore knee motion and function. It has been suggested that abnormal motion patterns within the implant, such as excessive shear, may contribute to loosening and eventual failure (Dennis et al., 2003; Schmidt et al., 2003). Normal knee motion is crucial when looking at knee OA as it has a significant impact on the overall function of the knee joint. Normal knee flexion is characterized by the lateral femoral condyle translating posteriorly with respect to the lateral tibia plateau, while the medial femoral condyle undergoes minimal translation (Feng et al., 2016). This results in a coordinated external rotation of the femur with respect to the tibia during knee flexion.

In order to achieve such movement, different types of implants have been designed and constructed. Some of these knee implants include the ultracongruent prosthesis, mobile bearing prosthesis, cruciate ligament prosthesis, posterior stabilized (PS), medial pivot (MP), and others (Dall'Oca et al., 2017; Hoskins et al., 2022). Each type of implant design has a different influence on functionality, joint stability, and survivorship due to the differences in geometries and techniques. The posterior-stabilized is a commonly used implant design that uses a post-cam

mechanism which serves as a substitute for the posterior cruciate ligament (PCL) (Sekeitto et al., 2022). This mechanism allows for femoral rollback which in turn allows for more flexion however, high flexion angles may lead to increased risk of dislocation (Dennis et al., 2003; Schmidt et al., 2003).

The medial pivot implant has a bigger medial compartment compared to more traditional implant designs. These implants feature a congruent, ball-and-socket configuration for the medial compartment, with the lateral femoral condyle having a cylindrical shape (Moonot et al., 2009; Shimmin et al., 2015). This design is theorized to replicate normal knee kinematics by limiting anterior-posterior translation at the medial femoral condyle and allowing posterior sliding at the lateral femoral condyle during knee flexion which in turn, enables internal rotation of the tibia during knee flexion (Moonot et al., 2009; Shimmin et al., 2015). The anterior edge of the tibial insert provides stability to the knee from fully extended to deeply flexed positions, limiting anterior movement with a stronger anterior restriction. The outer side of the tibial insert offers a moderate level of conformity. The lateral femoral condyle is smaller and cylindrical, designed to move with greater freedom along a curved trajectory (Moonot et al., 2009; Shimmin et al., 2015). The medial pivot TKA implant aims to mimic normal knee movement with the intent to improve range of motion (ROM) and increase patient satisfaction, as well as reduce the rates of revision (Moonot et al., 2009). However, ongoing research and clinical studies continue to highlight the lack of randomized control trials to fully understand the long-term outcomes, durability, and potential complications associated with medial pivot implants. Surgeons and researchers continue to investigate factors such as implant survivorship, patient satisfaction, and the impact of different surgical techniques on the performance of these implants. It is essential to know the

full scope of literature about these implants if the goal is to utilize this design over other types of implants.

CHAPTER 2: LITERATURE REVIEW

2.1. EFFECTS OF OSTEOATHRITIS

2.1.1. Gait impairments due to OA

Knee OA affects and alters the gait patterns of those with the disease, including kinetic and kinematic parameters. A systematic review found that patients with severe OA exhibit the most alterations, while lower severity levels (i.e. mild and moderate) exhibit fewer differences than healthy adults (Mills et al., 2013). The same review found that values for internal rotation moments were notably reduced in patients with severe OA compared to moderate and mild levels of OA as well as a healthy group (Mills et al., 2013). Likewise, patients with moderate and severe OA also commonly exhibit decreased peak flexion moments ($p<0.05$) (Esrafilian et al., 2013; Mills et al., 2013; Naili et al., 2017). Another study found that individuals with severe OA have even further reductions in knee extension moments. (Astephen, Deluzio, Caldwell, & Dunbar, 2008). In terms of joint angles, there is a significant reduction in knee flexion-extension ROM, smaller joint ROM, and reductions in peak knee flexion angles in patients with severe knee OA compared to healthy adults (Astephen, Deluzio, Caldwell, & Dunbar, 2008; Mills et al., 2013; Naili et al., 2017). Additionally, comparing individuals with moderate OA and severe OA, those with severe levels exhibit lower magnitudes of knee flexion angles during both the swing and stance phases of gait (Astephen, Deluzio, Caldwell, Dunbar, et al., 2008). Spatiotemporal alterations in gait have also been reported. A meta-analysis demonstrated that patients with severe knee OA have increased stride duration and a notable reduction in walking speed and cadence compared to healthy counterparts (Mills et al., 2013). These findings highlight the

impact that severe knee OA has on gait patterns, revealing significant alterations in joint mechanics and movement dynamics.

2.1.2. Step up/down impairments due to OA

Stairs are a common obstacle that is encountered almost daily which requires more range of motion and knee moments than walking (Guccione et al., 1990; Hicks-Little et al., 2011). During stair climbing activities for healthy adults, there is a larger angular displacement in knee flexion and greater knee flexion moment compared to walking (Hicks-Little et al., 2011). The demands placed on the knee joints during stair-related activities take an even bigger toll on those with OA than healthy individuals.

Studies indicate that the impact of stair climbing activities on patients with knee OA is significantly more pronounced than on those with heart disease or other medical conditions. (Hicks-Little et al., 2011). The impact of knee OA on biomechanics during stair activities has been extensively studied, revealing a range of compensatory movements. Typically patients with mild to moderate knee OA adjust to minimize the knee extensor moment and thus reduce the loading on the knee joint while ascending stairs (Hicks-Little et al., 2011). Additionally, during the swing phase of stair ascent, patients with mild to moderate knee OA have demonstrated smaller peak knee flexion angles (88.2°± 6.7°) than healthy adults (93.7°± 6.2°) (Hicks-Little et al., 2011). These compensative mechanisms are also usually seen in the hip joint and typically take the form of greater hip extension moments and increased hip flexion angles in stair ascension in patients with knee OA (Esrafilian et al., 2013; Heiden et al.; Komnik et al., 2015; Naili et al., 2017). A study determined that patients with mild to moderate knee OA will, on average, exhibit less hip abduction angles (3.7°± 3.8°) compared to a healthy population (7.1°± 4.9°) during stair climbing (Hicks-Little et al., 2011). The study also discovered that during stair

descent, patients with knee OA exhibited greater knee abduction angles in the frontal plane and smaller peak knee flexion angles compared to healthy individuals (Hicks-Little et al., 2011). It has been hypothesized that such compensatory mechanisms are due to increased knee stiffness and pain (Hicks-Little et al., 2011). Another study compared the time required to climb either 10 or 12 steps in individuals with severe knee OA and healthy adults (Bade et al., 2010). Patients with severe OA (23.1±17.3 seconds) were significantly slower than healthy adults (8.9±1.7 seconds) (Bade et al., 2010). Therefore, it is crucial to address these compensative mechanisms and limitations through surgery (TKA) and rehabilitation (physiotherapy), as such mechanisms have been linked to the progression of OA in the contralateral limb (Alnahdi et al., 2011; Esrafilian et al., 2013; Heiden et al., 2009; Komnik et al., 2015; Naili et al., 2017).

2.1.3. Effects of OA on patient-reported outcomes

Patient-reported outcomes (PROs) are directly reported by the patient and relate to the patient's own sense of health, pain, quality of life, and physical functional status associated with the treatment, while patient-reported outcome measures (PROMs) are the tools used in the assessment (Weldring & Smith, 2013). When considering the effects of knee OA on the results of PROMs, an exploratory study (n=18) looking at the differences between patients with moderate knee OA and healthy adults used the Knee Injury and Osteoarthritis Outcome Score (KOOS) and the European Quality of Life–5 Dimensions (EQ-5D-5L) (Sparkes et al., 2019). This study found that patients with OA reported significantly lower scores in all aspects of the KOOS questionnaire, indicating more pain and lower quality of life than healthy adults ($p<0.005$) (Sparkes et al., 2019). Additionally, in the EQ-5D-5L patients with OA (mean=81/100) reported lower overall current health than the healthy adults (mean=97/100) (Sparkes et al., 2019). One study looking at the relationship between the severity of OA using the Kellgren-Lawrence (KL)

scale and PROMs (Oxford Knee Score) found that there was a weak but significant correlation between OA severity and PROMs, meaning patients with severe OA typically had reduced PROM scores (Innmann et al., 2023). This study also highlighted that patients with severe OA indicated higher pain severity on a visual analogue scale than patients with lower OA severity levels (Innmann et al., 2023). Another study found that individuals with knee OA had high concerns about instability, reporting that they often feel "locking" and "catching" of the joint leading to a decrease in activities (Van Der Esch et al., 2012). Furthermore, a review found that patients with lower self-efficacy had lower abilities to navigate stairs (Whitchelo et al., 2014). These findings highlight the necessity for interventions, such as TKAs, to improve self-efficacy and reduce pain in patients with knee OA, ultimately restoring their quality of life.

2.2. TOTAL KNEE ARTHROPLASTY

2.2.1. TKA effects on gait in OA patients

TKA procedures tend to partially alleviate gait impairments resulting from OA however, it has been shown that results are rarely at the same level as non-operated limbs. Previous studies have demonstrated differences between the knee that underwent TKA and the other non-operated knee within the same patients (Alnahdi et al., 2011). Specifically, non-operated knees show larger knee adduction angles during gait compared to knees that have undergone TKA (Alnahdi et al., 2011; Naili et al., 2017). Kinetic parameters vary between operated and non-operated limbs. Two studies showed that there were lower peak knee adduction moments on the operated knee compared to the non-operated knee (Alnahdi et al., 2011; Naili et al., 2017). The study performed by Naili et al. (2017) used a posterior cruciate-retaining, fixed tibial component, while the Alnahdi et al. (2011) did not specify. Spatiotemporal variables such as step length have also

been found to be significantly different between the operated and non-operated limbs, where the operated limbs had a larger step length than the non-operated limbs (Bączkowicz et al., 2018). Though comparing the operated limb to the non-operated contralateral limb may not be the best method due to potential compensatory mechanisms in the non-operated limb, there is still some significance and aids in highlighting the impact of TKA on joint function. Therefore, it can be said that while TKAs can improve gait patterns to some extent, differences between the operated and non-operated limbs may persist.

Gait metrics have also been compared between patients that had a TKA and healthy adults. A systematic review using a variety of implants where most were PCL-retaining implant designs (some studies did not specify), showed that patients who underwent a TKA showed less total ROM than healthy controls while walking (McClelland et al., 2007). Additionally, it was found that patients who underwent a TKA had reduced flexion ROM during the loading phase and reduced knee flexion during the swing phase of their gait cycle (McClelland et al., 2007). Additionally, a study showed the step length post-surgery was comparable to the healthy controls that participated in the study (Bączkowicz et al., 2018). Therefore, it can be said that full restoration of knee function during gait to pre-OA level is unlikely; however, improvements can be seen post-TKA and thus this surgery is beneficial to patients.

When comparing patients pre- and post-TKA, there are significant differences in gait parameters. A study found that gait speed was significantly slower pre-TKA (one day before surgery) compared to post-TKA (15 weeks post-surgery) in patients who received a posterior cruciate-retaining fixed tibial component (Bączkowicz et al., 2018). Another study using posterior-stabilized and medial pivot implants found that during gait, knee flexion ROM was not different between pre-TKA (one week before surgery) and one-year post-TKA (Hatfield et al.,

2011). However, post-operatively patients exhibited higher magnitudes of knee flexion throughout the entire gait cycle particularly in the swing phase (Hatfield et al., 2011). These findings indicate that TKAs can improve gait, typically leaving the patient better than they were before.

2.2.2. TKA effects on step up/down in OA patients

TKAs have also been shown to improve an individual's ability to perform stair-climbing activities; however similar to gait, full restoration is improbable. A review conducted by Standifird et al. (2014) studied a variety of implants and found that the majority of studies reported a knee flexion angle reduction at contact and a lower ROM for patients who underwent a TKA compared to healthy adults during stair ascension (Standifird et al., 2014). Some studies in the review reported a reduction in the maximum external flexion moment among the TKA group compared to the healthy group (Standifird et al., 2014). Six studies reported frontal plane variables, primarily focusing on either the maximum external knee adduction moment or maximum internal knee abduction moment, but no consensus was reached among them (Standifird et al., 2014). However, a study using fixed-bearing TKA implants found that flexion ROM was improved significantly post-TKA compared to pre-TKA (Murakami et al., 2018). Another study examined patients' biomechanics pre-operatively and 1 year post-operatively in stair ascent and stair descent using three implants with varying degrees of congruency and PCL management (Komaris et al., 2021). This study showed that peak adduction angles and sagittal ROM also increased from pre-surgery to post-surgery (Komaris et al., 2021). Additionally, this study showed that post-operatively, patients had faster cadence and stride times than pre-operatively (Komaris et al., 2021). Therefore, it can be said that like gait, improvements can be seen from pre- to post-surgery however it is not a full restoration to pre-OA levels.

While TKAs have been shown to improve an individual's ability to perform stair-climbing activities, the literature on stair descent in TKA patients is comparatively limited and results vary (Standifird et al., 2014). A review demonstrated that there was a reduction in knee flexion/extension ROM in patients post-TKA compared to healthy controls (Standifird et al., 2014). It was also reported that patients post-TKA exhibited a lower maximum knee extension angle during the swing phase than the control group (Standifird et al., 2014). In the frontal plane, there were no significant differences in the maximum external knee adduction angle between groups (Standifird et al., 2014). Though there is a limited quantity of literature on stair descent, it seems that there are generally some reductions in performance for patients post-TKA when compared to healthy individuals.

2.3. TOTAL KNEE ARTHROPLASTY IMPLANTS

2.3.1. Role of TKA implants

TKA implants play a pivotal role in restoring mobility and relieving pain in patients with knee OA (Akbari Shandiz et al., 2016; Alnahdi et al., 2011; Sekeitto et al., 2022). Multiple TKA designs exist with the aim of optimizing results and minimizing the need for revisions. TKA revision surgeries are primarily due to aseptic loosening and instability caused by excessive shear forces within the prosthesis (Dennis et al., 2003; Schmidt et al., 2003). Thus, implant manufacturers have implemented design alterations to optimize results and minimize the need for revisions. The posterior stabilized implant is one that is commonly used in TKA procedures. This implant design is unique as it has a post-cam mechanism that substitutes the PCL, consequently facilitating femoral rollback, hindering tibial subluxation, and improving ROM (Sekeitto et al., 2022). The posterior stabilized implant has been greatly accepted in the field, however, recently

there has been a decline in its usage. An explanation for such a decline could be due to the increased long-term risk of revisions (Hoskins et al., 2022). It has been shown that there is an increased risk of dislocation at high knee flexion angles due to femoral rollback (Dennis et al., 2003; Schmidt et al., 2003). A systematic review and meta-analysis done by Hoskins et al. (2022) showed that the medial pivot and posterior stabilized implants may have similar long-term revision risks. However, a meta-analysis performed by (Shi et al., 2022) found that overall complication rates are higher in the posterior stabilized implants than the medial pivot devices.

The medial pivot TKA implant is theorized to mimic normal knee movement and thus may lead to more favourable outcomes. However, postoperative knee kinematics for these implants have yet to fully replicate those of a healthy non-arthritic joint (Hoskins et al., 2022). A study focusing on confirming the stability and mobility of medial pivot design TKAs used fluoroscopy to measure knee motion during constrained movements such as kneeling and lunges (Shimmin et al., 2015). This study found that the posterior translation of the lateral femoral condyle during knee flexion, coupled with internal rotation of the tibia was similar to healthy knees only at a reduced magnitude (Shimmin et al., 2015). The medial pivot implant has also shown heightened conformity compared to the posterior stabilized design. However, it could result in component impingement and potentially restrict femoral rollback and flexion in some patients (Hoskins et al., 2022). These findings suggest that while medial pivot implants show promise in mimicking normal knee movement, improvements are still needed to fully replicate the kinematics of a healthy, non-arthritic joint.

A systematic review comprised of nine studies highlighted some kinetic and kinematic differences between the two implants during gait (Risitano et al., 2023). Kinetic results were found by reviewing three studies using 3D motion capture (Risitano et al., 2023). One study had

a sample size of ten TKA patients (n=4 posterior stabilized, n=6 medial pivot) and found that the medial pivot group showed lower peak knee flexion moments than the posterior stabilized group at 25% of the gait cycle (2.34%BW*Ht and 3.78%BW*Ht respectively) (Ghirardelli et al., 2021). Another study included in the review had a sample size of 40 post-TKA participants split equally into a medial pivot group and a posterior stabilized group (n=20 per group) (Esposito et al., 2020). This study found similar results as the previous study, as well as lower max extension moment in the medial pivot group compared to the posterior stabilized group (0.21 Nm/kg and 0.27 Nm/kg, respectively) (Esposito et al., 2020). The final study to report on kinetics in the review had a sample size of 46 (medial pivot group: n=24, posterior-stabilized group: n=22), and found no statistical differences in knee moments between the implants (Papagiannis et al., 2016). These findings suggest that the medial pivot implant may offer the slight advantage of lower knee flexion and extension moments during gait, potentially reducing joint stress and improving implant longevity, though findings are not entirely consistent across all studies. Kinematic results were identified by reviewing six studies (Risitano et al., 2023). One of the studies included in the review found that in the posterior stabilized group (7.95°), the knee was generally more flexed than the medial pivot group (3.07°) during the heel-strike portion of gait (Ghirardelli et al., 2021). Another study reported greater max knee flexion angle during the swing phase of gait in the posterior stabilized group than the medial pivot group (55.6° and 47.3°, respectively) (Esposito et al., 2020). These findings would indicate that the posterior-stabilized implant may provide better flexion however, another three studies in the review found no statistical differences in the knee flexion kinematics between the two implants (Gray et al., 2020; Papagiannis et al., 2016; Tan et al., 2021). Three studies in the review reported that the posterior stabilized design exhibited higher anterior femoral roll and anterior translation on both the

medial and lateral condyles during knee flexion during gait (Risitano et al., 2023). Conversely, the medial pivot demonstrated a more pronounced external rotation of the tibia compared to the posterior stabilized (Risitano et al., 2023). The posterior stabilized implant also exhibited greater knee flexion at toe-off, higher knee flexion peak in the swing phase, and increased adduction angle than the medial pivot design (Risitano et al., 2023). These findings highlight the performance of the implant designs. They suggest that each has its own advantages and limitations such as increased risk of dislocation for the posterior-stabilized and component impingements in the medial pivot.

In addition to kinetics and joint kinematics, it is important to also understand differences in spatiotemporal parameters between the implants. A systematic review found six articles that mentioned various spatiotemporal parameters (e.g. cadence, walking speed, step length, and stride length) (Risitano et al., 2023). The review found that there were no statistically significant differences reported in any of the spatiotemporal parameters between the posterior stabilized prosthetic design and the medial pivot (Risitano et al., 2023). Furthermore, consistent benefits may not always be observed, and thus more studies must be done to identify the true level of difference between the implants (Hoskins et al., 2022). Additionally, there is a need for more literature comparing the implants in stair-related tasks. Currently, there are no randomized control trials (RCTs) comparing the two implants in stair-related tasks and further research is needed to identify if one of these implant's results can result in improved kinematics during stair ascent and descent.

2.3.2. Patient-reported outcomes and TKA

A meta-analysis performed by Hoskins et al. (2022) using the Western Ontario and McMaster Universities Arthritis Index (WOMAC) and the Oxford Knee Score compared medial pivot implants to the posterior stabilized design. The meta-analysis identified that four studies used the Oxford Knee Score and there was no significant difference in PROMs when comparing medial pivot and posterior stabilized implants, with a mean difference of 0.26 favouring the medial pivot (95% CI -2.12 to 1.60, p = 0.69) (Hoskins et al., 2022). The meta-analysis also identified two studies using the WOMAC and there was no significant difference between medial pivot and posterior stabilized implants, with a mean difference of 0.24 favouring the medial pivot (95% CI -31.23 to 31.71, p = 0.94 (Hoskins et al., 2022). However, they acknowledged that their sample size of RCTs (n=5) was small and more RCTs are required (Hoskins et al., 2022).

Another crucial relationship that needs to be understood when evaluating the success of TKAs, is between PROMs and objective clinical measures. A systematic review highlighted the potential for a correlation between PROMs and objective clinical measures post-surgery (Ramkumar et al., 2015). However, despite the emphasis on PROMs as crucial indicators of treatment success and patient satisfaction, there are no current studies with this type of analysis (Ramkumar et al., 2015). The review underscored the need for further exploration into the alignment between subjective patient experiences and objective clinical assessments following TKA (Ramkumar et al., 2015).

Though there are theoretical claims of superiority in the medial pivot implants, there seems to be little evidence to support such claims (Hoskins et al., 2022). Considering the intention is to further expand the implementation of these medial pivot TKA implant designs, it

is vital not to rely on this narrow scope of data and continue to test their effectiveness (Hoskins et al., 2022).

2.4. KNOWLEDGE GAPS

The existing body of research on the medial pivot implant of interest (Zimmer Medial Pivot Persona) is notably constrained in its scope, as it has yet to comprehensively scrutinize the biomechanical outcomes in direct comparison to those of traditional implants. A review concluded that there is inadequate testing of recently designed Medial Pivot Persona implants from only 10 participants, and therefore more research is required (Sabatini et al., 2018). Other meta-analyses were done in recent years for medial pivot designs from different manufacturers including works from Shi et al. (2022), Hoskins et al. (2022), and Risitano et al. (2023) where all recognized that there was a small number of RCTs in their reviews (n=8, n=5, and n=4, respectively) and thus more RCTs must be done to confirm or refute their findings. The lack of RCTs comparing the medial pivot implants to the posterior stabilized implants in terms of functionality during daily activities such as walking and stair climbing makes it impossible to provide any claims about whether one implant is superior. It is crucial to further analyze knee kinematics during tasks that are more functionally pertinent, such as walking or stair negotiation, to ascertain whether the medial pivot implant effectively enhances knee motion. There is a lack of research comparing PROMs between patients receiving medial pivot or posterior stabilized implants. Exploring factors such as pain, function, and quality of life can enhance our understanding of how the medial pivot and the posterior stabilized implants influence the subjective experiences of TKA recipients. Furthermore, comparing subjective experiences to objective measures may broaden our understanding of the complex relationship between the

implant and the person receiving the implant. Acknowledging the low quantity of research present comparing the medial pivot and posterior stabilized implants, it is crucial to perform a study that thoroughly investigates the differences.

2.5. RELEVANCE

The Canadian healthcare system is investing greatly in new and more expensive TKA implants, without having enough evidence to support the claims of efficacy and safety. This study will provide novel data in the treatment of knee OA, as there is a lack of research when looking at the joint kinematics in medial pivot implants during functional tasks (e.g., stair climbing). Addressing this lack of published knowledge will also inform orthopaedic surgeons so that they may use the data and their judgment for the best possible patient care. Utilizing the most optimal TKA implants is crucial to optimizing patient outcomes, minimizing revisions, reducing financial expenses, alleviating the strain on the healthcare system, and ensuring greater patient satisfaction.

2.6. STUDY OBJECTIVES

The purpose of this study was to compare two TKA implant designs (medial pivot or posterior stabilized) before the surgery and one year after. The primary objectives of this thesis were:

1) To compare knee kinematics and spatiotemporal measures during gait and step up/down tasks 1 year after TKA between patients who received the medial pivot implant and patients who received the traditional posterior stabilized implant.

2) To compare patient-reported outcomes (pain, symptoms, stiffness, function in daily activity, sport and recreation, and quality of life) between patients who received the medial pivot implant and patients who received the traditional posterior stabilized implant 1-year after surgery.
3) To compare participant's ratings of perceived change (using PROMs) and biomechanical measures (kinematic data) to understand the relationship between perceived and biomechanical changes.

As such, we hypothesized:

1) The medial pivot group will have greater internal rotation knee angle motion during gait and stairs at 1 year. There will be an increase in step length, walking speed, and single support time in both implants. However, we suspect that the increase will be greater in those who received the medial pivot implant.
2) Those with the medial pivot implant will have better scores in the PROMs at 1-year post-surgery.
3) A moderate positive relationship between patients' self-reported outcomes and their objective measures, suggesting that those with superior self-reported outcomes would also demonstrate better results in objective assessments.

CHAPTER 3: METHODS

3.1. STUDY DESIGN AND PARTICIPANTS

3.1.1. Study design

This was a double-blind randomized control trial in which both participants and researchers participating in the data collections were blinded, while orthopaedic surgeons were not. Participants were randomly assigned to two groups using a random number generator in blocks based on the four surgeons performing the TKA surgeries. One group received a medial pivot design (Zimmer Medial Pivot Persona), while the other groups received a posterior-stabilized design (Zimmer Persona Knee-PS). The study was approved by the CIUSSS West-Central Montreal Research Ethics Board and the trial was registered (ClinicalTrials.gov NCT036819770) (Appendix 1). TKAs were performed by one of four surgeons participating in the study (Dr. Antoniou, Dr. Hart, Dr. Huk, and Dr. Zukor).

3.1.2. Study participants

Participants under the age of 80 years with a diagnosis of either medial, lateral, or patellofemoral knee OA in accordance with the American College of Rheumatology guidelines were recruited by one of the four orthopaedic surgeons. (Altman et al., 1986). Knee OA severity from radiographs were assessed using the KL global rating scale (Kellgren & Lawrence, 1957). All participants had KL scores of three or four, reflecting moderate to severe osteoarthritic joint changes. All participants were scheduled for TKA surgery. The exclusion criteria included previous arthroplasties for other lower extremity joints (not including the contralateral knee), severe hip OA, lower extremity trauma within 1-year, inflammatory arthritis, or neurological

conditions. Patients were recruited from the Jewish General Hospital and the Montreal General Hospital in Montreal, Quebec.

Contact information was provided by the hospital's research coordinator, the participants were then contacted by the lab and further information about the project was given to the participant. An initial screening was done over the phone based on the inclusion/exclusion criteria, and the eligibility screening form. Given that the participant was eligible and interested, baseline testing was then scheduled approximately one month prior to their surgery date. A second visit was scheduled one-year post-operation.

3.2. SAMPLE SIZE

In this study, a sample size of 22 participants was utilized. It is important to note that this sample size was chosen for the interim analysis of a larger RCT. Sample size and power calculations deemed that the RCT would need a sample size of 108 with 54 participants per group assuming p=0.05, power=0.80, and 20% dropout (Borm et al., 2007). Data for this analysis were derived from published findings on a metric representing knee rotation range of motion, with a standard deviation of 26.79 and an r^2 of 0.43 (between repeated measures) (Robbins et al., 2013). A moderate difference of 12.06 (40% of one standard deviation) was assumed, as a significant change is necessary for clinical relevance. Given the ongoing nature of the RCT, it was deemed unnecessary to conduct a formal sample size calculation prior to data collection for this specific interim analysis.

3.3. DEMOGRAPHICS

Demographic data encompassing age, sex, height, weight, and other relevant details regarding total knee arthroplasty (TKA) surgery, including the type of implant used, severity of OA, the date of the procedure, and the performing surgeon, were gathered from both medical records and self-reported information.

3.4. SURGICAL INTERVENTION

Four surgeons performed the TKA procedures with either the medial pivot or a traditional design. The surgeons completed the required training for the TKA systems. Both TKA implant designs were PCL sacrificing with fixed polyethylene inserts and used the medial parapatellar approach. The PCL was resected for better access to the knee and to enable full motion. Pre-operative radiographs were utilized with templates to determine implant size, although the final choice of component size was decided during surgery. The tibia was initially prepared, followed by the femur, using either the distal or anterior technique based on the surgeon's preference. After resecting the native bone, a tibial spacer was employed along with the corresponding femoral spacer to assess soft tissue tensioning and laxity. A polyethylene insert was selected to balance the extension gap while allowing for full flexion and maintaining stability. Cemented fixation of the tibia and femur components was then performed after bone preparation. Patella resurfacing was performed only if deemed necessary by the surgeon. Post-surgery, participants underwent a standard inpatient and outpatient rehabilitation program conducted by a registered physiotherapist.

3.5. PATIENT-REPORTED OUTCOME MEASURES

Patient-reported outcome measures included the KOOS, EQ-5D-5L (EuroQol Group), and the Global Rating of Change. Baseline assessment was done using only the KOOS and the EQ-5D-5L, while the one-year visit included all three questionnaires.

3.5.1. KOOS questionnaire

The KOOS is a self-report, disease specific questionnaire that looks at an individual's perception of their knee and potential associated problems. The KOOS consists of 41 items: symptoms (7 items; 5 for other symptoms and 2 for stiffness), pain (9 items), function in daily activity (17 items), function in sport and recreation (5 items), and quality of life (4 items). The answers are based on five standardized answer options for each question and were scored from 0 to 4 (0 = none to 4 = extreme). The subscales were transformed to a scale of 0-100, where higher scores meant better outcomes. Among patients with TKA, the KOOS has exhibited satisfactory test-retest reliability (ICC > 0.78), convergent validity with SF-36 (r > 0.48), and responsiveness (response mean > 0.81) (Roos & Toksvig-Larsen, 2003).

3.5.2. EuroQol questionnaire

The EQ-5D-5L (EuroQol) is a self-report questionnaire comprised of five parts: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. These sections consisted of five standardized answer statements that were evaluated on a scale from 1 to 5 (1= no problem to 5 = unable/extreme). The dimension scores created a five-digit profile that represented the individual's health which was used alongside the Canadian-specific values to calculate a utility score (Xie et al., 2016). Health utilities varied from -0.148 for the worst EQ-5D-5L state (55555) to 0.949 for the best state (11111) (Xie et al., 2016). The EQ-5D-5L was used to capture a general idea of the individual's perceived health at the time of the visit. The final section of the

questionnaire is the EQ VAS which required the participant to rate their overall health on the day of the visit on a scale from 0 to 100, where 0 meant the worst possible health while 100 meant the best health possible. Among patients awaiting TKA, the EQ-5D demonstrated good reliability (ICC = 0.61 to 0.87) (Conner-Spady et al., 2015).

3.5.3 Global Rating of Change

In the global rating of change questionnaire, participants assessed the extent of their changes in comparison to the pre-operative baseline visit using a 15-point scale (-7 = Worse, 0 = No change, and +7 = Better) (Salaffi et al., 2005).

3.6. BIOMECHANICAL DATA COLLECTION

Biomechanical data was gathered by using Qualisys track manager (Qualisys AB, Gothenburg, Sweden, version 2021.2) software. Kinematic data were collected using an eight-camera, three-dimensional, marker-based motion capture system (Oqus 3+, Qualisys AB, Göteborg, Sweden) sampled at 100 Hz. Eighteen markers were attached on bony landmarks bilaterally including the first and fifth metatarsal heads, calcaneus, lateral malleolus, lateral femoral epicondyle, greater trochanter, posterior superior iliac spine (PSIS), anterior superior iliac spine (ASIS), and the acromion (Figure 1) (Collins et al., 2009). Furthermore, four rectangle-shaped marker clusters were placed bilaterally on the thigh and shank to track the segments. Each cluster consisted of four markers for a total of sixteen cluster-based markers. Additionally, six markers were placed bilaterally on the medial malleolus, second metatarsal head, and the medial femoral epicondyle. These six additional markers were used only for the static trials and were then removed for the remainder of the data collection.

Kinetic data were acquired through two floor-embedded (Advanced Mechanical Technology, Inc. Watertown, USA, model BP400600-2000, excitation voltage of 10V and an amplification of 1000 mV) and one step-mounted force plates (Advanced Mechanical Technology, Inc. Watertown, USA, model BP400600NC-2000, excitation voltage of 10V and an amplification of 1000 mV) sampled at 2000Hz. The floor-embedded force plates were placed along an eight-meter walkway. The step-mounted force plate was embedded on a 20 cm step and moved beside the floor force plates during step up/down tasks. All three force plates were synchronized and aligned to the global coordinate system used by the motion capture system.

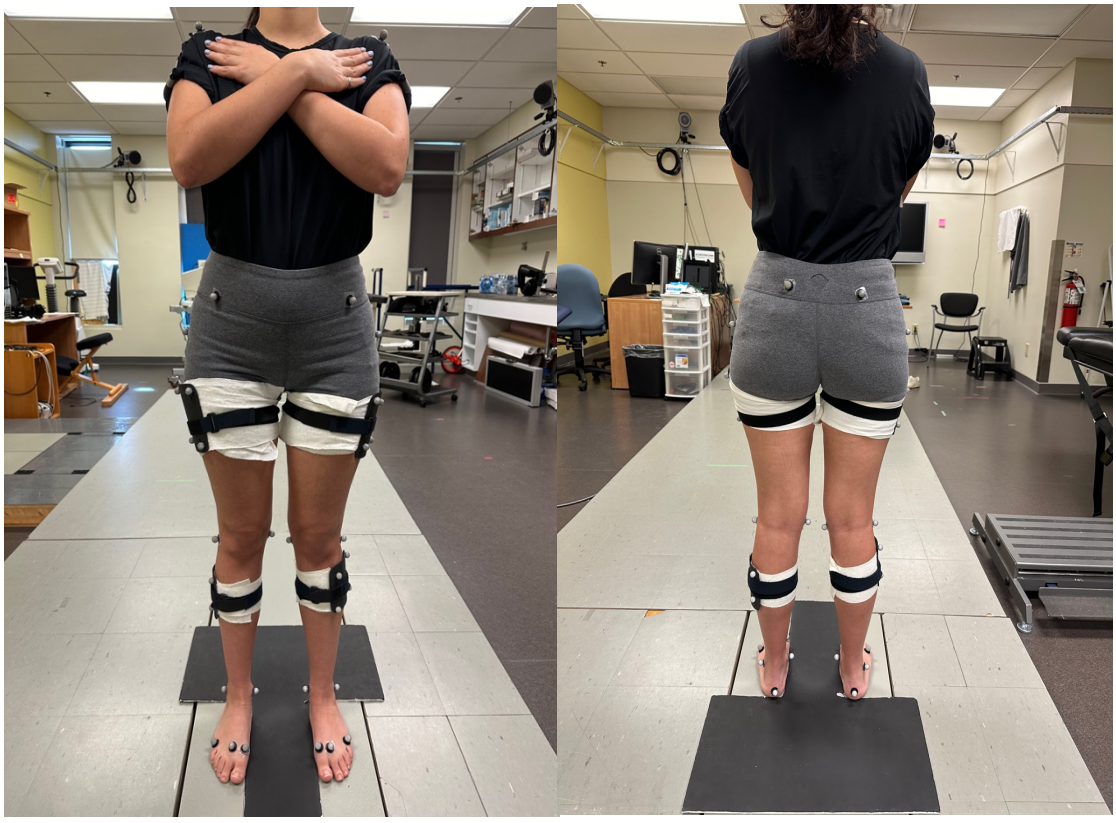

Figure 1. Placement of reflective markers

3.6.1. Test protocol

Calibration of the equipment occurred prior to data collection and consisted of zeroing the force plates, setting the reference coordinate system using an L-frame reflective marker reference system, and calibrating the motion capture using a calibration wand of length 750mm around the area of interest. Reflective markers were placed on the participants as described above (Figure 1). Data collection began with a static trial using a standing template to ensure that lower extremity rotation was consistent while standing still on one of the floor force plates (Figure 1). This static trial lasted 5 s and was used as an anatomic calibration for determining ankle, knee, and pelvic joint centres and to measure body mass. Participants were then asked to perform bilateral hip swing trials, in which they performed pendular like flexion, extension, abduction, and adduction motions. This trial lasted 15 s and was used to identify the functional hip joint centres (Schwartz & Rozumalski, 2005).

Participants were directed to a sequence of step up/down trials, utilizing a standardized 20 cm step, in accordance with the maximum step height set forth by the National Building Code of Canada. The order of initiating either the step up or down was randomized. Prior to the formal trials, participants were allowed two practice trials to familiarize themselves with the task. During the step-down trials, both limbs started on the step, after which the non-study limb descended, making contact with the floor first, followed by the study limb. By leading with the non-study limb, participants were forced to use the study limb to descend the step and thus, we were able to determine the joint angles throughout the movement. Conversely, in the step-up trials, participants initiated the task with both limbs on the ground. The participants were instructed to raise the study limb to the step followed by straightening the study knee and subsequently placing the non-study limb onto the step. By leading with the study limb,

participants were forced to use the study limb to perform the task rather than relying on the non-study limb. To ensure the reliability of the gathered data, participants underwent five trials for each step movement, thereby affirming the quality and usability of the acquired information for analysis. The participants then performed the gait trials starting with at least two warm-up trials to allow them to acclimatize to the task. Gait trials required participants to ambulate at self-selected speeds over 8 meters, however, only the strides that struck the force plates were analyzed. Similar to the step up/down tasks, at least five trials were done at self-selected speeds to ensure proper data. Furthermore, participants were required to perform all tasks barefooted in order to nullify any potential difference in footwear between the two visits.

3.7. BIOMECHANICAL DATA PROCESSING

Five trials for step up, step down, and gait for each leg were first selected on the criteria of a complete marker set and a clear foot contact with the force plate. Data were initially processed on Qualisys Track Manager (Qualisys AB, Gothenburg, Sweden, version 2021.2) where gap-filling through a polynomial spline interpolation function (maximum 10 frames) was done when necessary. Raw kinetic and kinematic data were further processed and analyzed using custom pipelines in Visual 3D (v5, C-motion Inc., Germantown, USA).

Marker paths were filtered using a low-pass, fourth-order Butterworth filter with an 8Hz cut-off frequency. Force plate data used a low-pass, fourth-order Butterworth filter with a cut-off frequency of 20Hz. A local coordinate axis system was established as described by Collins et al. (2009). Static trials were also used to help identify the local coordinate system using a six degrees-of-freedom linked segment model. The centers of the knee and ankle joints were determined as the midpoint between the epicondyle and malleolus markers, respectively. Hip

joint centers were found using the functional hip trials in accordance with previous methods (Schwartz & Rozumalski, 2005). Knee joint angles were calculated using an XYZ Euler sequence (positive values were flexion, adduction, and medial rotation). A MATLAB (version R2023a, MathWorks Inc., Natick, USA:4) function was created to extract the biomechanical outcome variables (peak knee flexion and rotation angles, knee flexion and rotation ROM angles, and spatiotemporal gait variables).

3.7.1. Step up/down event detection

Step-up events were identified by using kinematic and kinetic waveforms. The start of the trial corresponded to the instance when the knee started to bend. This was identified by using the event onset function in Visual3D, which uses the last minimum value before the knee flexion angle increase. This was found using the appropriate knee flexion angle waveform. Kinetic data from force plate contact identified when the participant contacted the force plate and exceeded the minimum threshold of force set at 20N. The end of the event corresponded to when the heel velocity of the trailing limb reached a threshold of -0.5m/s in the vertical direction.

Similar to the step-up events, the start of the step-down trial corresponded to the moment when the non-study knee began to bend passing the last minimum value before the knee flexion angle increased using the event onset function in Visual3D. The “OFF” event corresponded to when the force plate detected 0 N, meaning the participant had fully stepped off the force plate. The conclusion of the step-up task occurred when the participant finished the stepping motion, and the heel velocity of the trailing limb attained a vertical threshold of -0.5 m/s.

3.7.2. Gait event detection

Gait events (initial contact and toe-off) were identified using force plate contact and the same minimum force threshold of 20N as the step up/down trials. Subsequent gait events not on

the force plate were identified using a kinematic based method (Stanhope et al., 1990). This method uses data from the motion capture system and force plates to identify the first heel strike and toe-off on the force plate and match the axial and anteroposterior trajectory of an anatomically fixed point on a subject's body to determine subsequent gait events not on the force plate (Stanhope et al., 1990). Additionally, the researchers checked all gait events visually. The gait cycle was described as the time frame spanning from one ipsilateral initial contact to the next initial contact from the same foot.

3.7.3. Knee angle dependent variables

From knee angles, the following discrete parameters were extracted: peak flexion, peak internal rotation, flexion ROM, and internal rotation ROM angles in both stance and swing phases of gait. During the step up and down task, parameters from knee angles included peak flexion, peak internal rotation, flexion ROM, and internal rotation ROM. Only the study limb was considered when calculating these variables.

3.7.4 Spatiotemporal dependent variables

Speed was identified for both gait and step up/down tasks by averaging the speed of the posterior superior iliac spine markers over the gait and step up/down cycle. Swing time is the phase of the gait cycle when the leg is not in contact with the ground and is measured from toe-off until heel strike. Stance time refers to the portion of the gait cycle when the leg is in contact with the ground and is calculated as the time from that foot's heel strike event to its toe-off event. Both stance and swing times were measured in seconds as well as %stride to account for differences in walking speeds. Step length refers to the distance from when the study leg makes its first contact to when the non-study leg makes its first contact. Meanwhile, stride length is the distance between two successive initial contacts of the study leg. Both step length and stride

length were normalized to height (m/height) to adjust for height differences among participants. These variables were calculated for the study limb only.

3.8. TEST PROCEDURE

Testing began with the participant reviewing and signing the consent form (Appendix 2). Following, basic demographic information was obtained using the demographic sheet. Participants were then asked to complete the self-reported surveys which included the KOOS, EQ-5D-5L, and the global rating of change. Afterward, participants were asked to change into tight-fitting clothing provided by the lab so that markers could be placed as close to the landmarks as possible, and the markers would not shift throughout the study. These markers were placed by the researchers performing the data collection, which were not always the same thus the importance of identifying the landmarks properly. Participants then proceeded to the calibration process (static trials and functional hip swing trials), followed by the step up/down, and then the gait trials. Upon completion of the gait trials, the height of the participant was taken and noted.

3.9. STATISTICAL ANALYSIS

Descriptive statistics were provided for demographic characteristics such as age, weight, height, body mass index (BMI), KL scores, and sex, as well as clinical outcomes, gait variables, step up/down variables, and spatiotemporal measures. Independent t-tests were performed to compare group demographics.

Analysis of covariance (ANCOVA) was used to compare biomechanical outcome values (peak knee flexion angle, knee flexion and rotation ROM, etc.) during gait as well as step up and

down tasks at the 1-year visit between the medial pivot and posterior stabilized groups while adjusting for their respective baseline and speed values. Speed was adjusted in the statistical analysis, rather than controlled by a metronome, to ensure the most natural gait and step tasks possible. Differences in spatiotemporal measures were also determined using ANCOVA between the two groups at the 1-year visit, while adjusting for their respective baseline values. An ANCOVA was also used to compare clinical outcomes (KOOS and EQ-5D-5L) between the two groups at the 1-year visit, while adjusting for their respective baseline values. An independent t-test was employed for the analysis of the global rating of change values. Cohen's d effect sizes were calculated for the ANCOVA values after adjusting for unequal sample size, and interpreted as small (d = 0.2), medium (d = 0.5), and large (d = 0.8) based on previously set standards (Cohen, 2013; Rosnow et al., 2000). Missing data for 1-year visit was analyzed by simple imputation of the data based on the mean of the dataset (Bell et al., 2014). This was done due to the large differences between the first and second visit for those without missing data, therefore employing a technique such as previous observation carried forward would not be truthful to what would have been seen.

To satisfy the third objective, a Spearman correlational analysis examined relationships between PROMs and biomechanical variables (peak knee flexion and ROM) during gait tasks. Through this analysis, we sought to elucidate whether subjective perceptions align with objective measures of change in the context of the studied variables.

An evaluation to ensure adherence to statistical assumptions, encompassing assessments of linearity, normality, homogeneity, homoscedasticity, multicollinearity, and influential cases, utilizing techniques such as examining skewness and the Shapiro-Wilk test, as well as scrutinizing normality plots and histograms was performed. To assess the statistical power of our

findings retrospectively, post-hoc power analyses were conducted. This allowed for a comprehensive evaluation of the robustness of the results obtained from the sample size chosen for this interim analysis. The statistical analyses were performed using SPSS version 29 (IBM Corp., Armonk, USA).

CHAPTER 4: RESULTS

4.1. CHARACTERISTICS OF THE STUDY SAMPLE

A total of 38 participants were recruited, 14 participants were screened out for reasons including unwillingness to participate, medical reasons, or not meeting the inclusion criteria, and two dropped out after baseline testing, ultimately leaving 22 participants to be included in the study (see Figure 2). Participants in both groups were similar in age and height; however, significant differences were observed where the posterior-stabilized group had greater weight ($p = 0.02$) and BMI ($p = 0.03$) than the medial pivot group. This may be due to the fact that the posterior-stabilized group had more males than the medial pivot group. The medial pivot group comprised of four right knee TKAs and six left knee TKAs, where seven participants had predominantly medial compartment OA and three had predominantly lateral compartment OA. While the posterior-stabilized group consisted of six right and six left TKAs, of which eight had predominantly medial compartment OA and three had predominantly lateral compartment OA. One participant in the posterior-stabilized group had severe patellofemoral OA and had KL scores of one in the medial compartment and two in the lateral compartment. KL scores and descriptive statistics for the participant demographics are presented in Table 1.

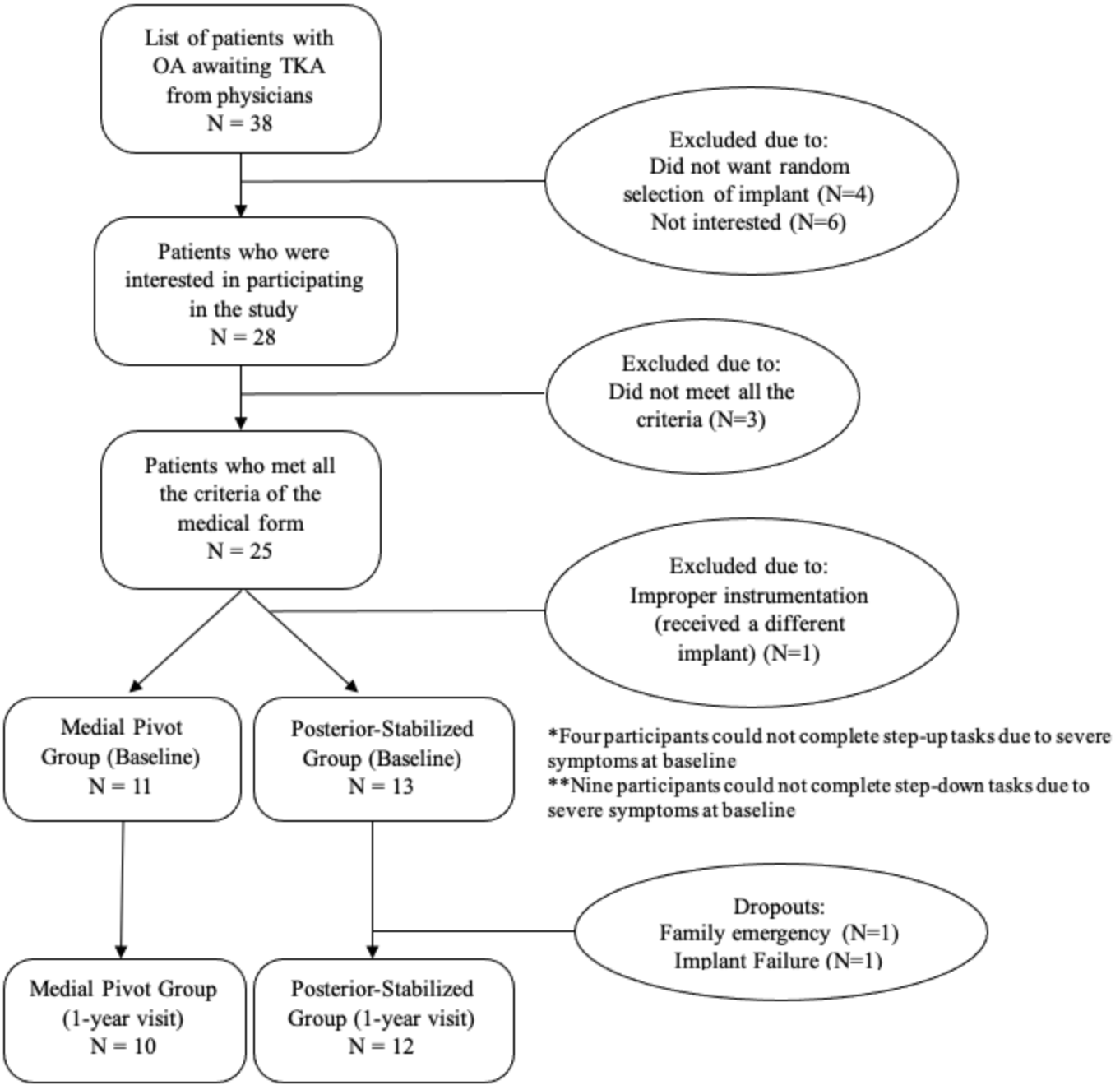

Figure 2. Consort diagram of participants in the study

Table 1. Mean (standard deviation) values for participant demographics and corresponding p-values. Frequency is provided for KL scores in both compartments, and sex.

Variable	Medial Pivot Group	Posterior-Stabilized Group	p-value
Age (years)	66 (8)	66 (4)	0.80
Height (m)	1.65 (0.10)	1.67 (0.11)	0.65
Weight (kg)	75.65 (12.07)	91.59 (15.59)	0.01
BMI (kg/m^2)	27.91 (4.21)	33.05 (5.94)	0.03
KL scores (frequency)			
2 (mild)	0	0	-
3 (moderate)	2	1	-
4 (severe)	8	11	-
Sex (frequency)	8 women	8 women	-
	2 men	4 men	-

BMI = body mass index.

4.2. ANALYSIS OF COVARIANCE

4.2.1. Gait analysis

The results showed no statistically significant differences in the knee angle variables (e.g., peak knee flexion) between groups during both the stance and swing phase of gait (Table 2). Effect sizes via Cohen's d suggested meaningful differences with medium effect size in knee flexion ROM and knee rotation ROM angles during stance favouring the medial pivot group (d=0.54 and 0.56, respectively), and knee rotation angle in the swing phase favouring the posterior-stabilized group (d=-0.73). However, the post-hoc power analysis revealed low power for all analyses (0.05 to 0.31; Table 2). Unadjusted values for baseline and year 1 visits are shown in Appendix 3. Group means for the baseline and 1-year post-surgery knee flexion and knee internal rotation waveforms during gait can be observed in Appendix 4.

Table 2. Mean (standard deviation) for the adjusted 1-year visit, and the corresponding ANCOVA p-values, effect size, and observed power for joint angles for gait tasks.

Joint Angles (°)	Medial Pivot Group	Posterior-Stabilized Group	p-value	Effect Size	Observed Power
Peak knee flexion-stance	35.59 (4.34)	32.79 (9.28)	0.730	0.17	0.06
Peak knee flexion-swing	55.24 (3.32)	54.50 (6.64)	0.987	-0.01	0.05
Knee flexion ROM-stance	37.80 (5.34)	31.24 (8.13)	0.272	0.54	0.19
Knee flexion ROM-swing	59.87 (5.00)	55.78 (6.73)	0.771	0.14	0.06
Peak knee rotation-stance	-5.16 (9.95)	-3.02 (5.25)	0.352	-0.45	0.15
Peak knee rotation-swing	-9.05 (8.46)	-5.90 (4.39)	0.142	-0.73	0.31
Knee rotation ROM-stance	13.88 (5.10)	10.76 (2.53)	0.256	0.56	0.20
Knee rotation ROM-swing	14.02 (3.97)	14.12 (2.19)	0.961	-0.02	0.05

Note: Values are adjusted by baseline scores and speed.

For spatiotemporal variables during gait (Table 3), the medial pivot group was significantly faster than the posterior-stabilized group (p=0.03) with a large effect size (d=1.10) but low power (0.62). No other statistically significant differences were observed between the groups however, Cohen's d values indicate that both stride length and step length had medium effect sizes favouring the medial pivot group (d=0.64 and 0.68, respectively). Additionally, power was 0.26 and 0.30 respectively (Table 3). The unadjusted values for the baseline and year 1 visits can be found in Appendix 5.

Table 3. Mean (standard deviation) for the adjusted 1-year visit, and the corresponding ANCOVA p-values, effect size, and observed power for spatiotemporal variables for the affected limb during gait tasks.

Spaciotemporal Variables	Medial Pivot Group	Posterior-Stabilized Group	p-value	Effect Size	Observed Power
Speed (m/s)	1.21 (0.13)	1.06 (0.16)	0.027	1.10	0.62
Swing time (s)	0.36 (0.13)	0.30 (0.19)	0.374	0.42	0.14
Swing time (%stride)	35.17 (12.42)	28.06 (17.04)	0.282	0.51	0.18
Stance time (s)	0.57 (0.20)	0.51 (0.31)	0.535	0.29	0.09
Stance time (%stride)	54.83 (19.30)	46.94 (28.38)	0.472	0.34	0.11
Stride length (m)	1.13 (0.41)	0.84 (0.54)	0.179	0.64	0.26
Step length (m)	0.53 (0.20)	0.37 (0.28)	0.157	0.68	0.30

Note: Values are adjusted by baseline scores and speed.

4.2.2. Step-up analysis

During step up, a total of 18 participants were included in the analysis (n=9 per group) (Table 4). Not all participants were able to complete the task at baseline due to pain and/or safety concerns. The posterior-stabilized group had significantly greater peak knee flexion than the medial pivot group (p=0.03), which had a large effect size (d=-1.31) and low power (0.63). No other statistically significant differences were observed between the groups. However, Cohen's d values indicate that knee flexion ROM angle had a medium effect size (d=-0.54) favouring the posterior-stabilized group. However, low power was reported at 0.16. The effect size for step-up speed was large favouring the medial pivot group (d=0.98) yet power was low (0.43). Baseline and year 1 visit unadjusted values are presented in Appendix 6. Appendix 7 presents the group

means for knee flexion and knee internal rotation waveforms during step-up at baseline and 1-year post-surgery.

Table 4. Mean (standard deviation) for the adjusted 1-year visit, and the corresponding ANCOVA p-values, effect size, and observed power for joint angles for step up tasks

Joint Angles (°)	Medial Pivot Group	Posterior-Stabilized Group	p-value	Effect Size	Observed Power
Peak knee flexion	73.05 (10.68)	76.47 (7.53)	0.028	-1.31	0.63
Knee flexion ROM	73.56 (11.23)	74.67 (3.93)	0.333	-0.54	0.16
Peak knee rotation	-4.65 (7.85)	-2.29 (5.37)	0.501	-0.37	0.10
Knee rotation ROM	13.94 (3.67)	11.05 (4.80)	0.751	0.17	0.06
Speed (m/s)	0.24 (0.02)	0.23 (0.01)	0.076	0.98	0.43

Note: Values are adjusted by baseline scores and speed.

4.2.3. Step down analysis

Similar to step up, not all participants were able to complete the step-down task at baseline, thus only 13 participants were included in the analysis (n=7 for the medial pivot group, and n=6 for the posterior-stabilized group) (Table 5). The medial pivot group had significantly greater peak knee flexion (p=0.03, d=1.68, power=0.61) and knee rotation ROM (p=0.04, d=1.65, power=0.59) than the posterior-stabilized group, which were large effect sizes. Knee flexion ROM angle was found to be not statistically significant; however, it did yield a medium effect size favouring the medial pivot group (d=0.67) with low power of 0.15. Additionally, step-down speed had a large effect size favouring the medial pivot group (d=0.96) but yielded low power of 0.29. Appendix 8 includes the unadjusted values for the visits at baseline and year 1.

The group means for baseline and 1-year post-surgery knee flexion and internal rotation waveform during step-down are provided in Appendix 9.

Table 5. Mean (standard deviation) for the adjusted 1-year visit, and the corresponding ANCOVA p-values, effect size, and observed power for joint angles for step down tasks.

Joint Angles (°)	Medial Pivot Group	Posterior-Stabilized Group	p-value	Effect Size	Observed Power
Peak knee flexion	86.50 (4.21)	81.77 (3.12)	0.033	1.68	0.61
Knee flexion ROM	82.75 (6.54)	79.91 (2.97)	0.345	0.67	0.15
Peak knee rotation	-2.01 (10.16)	-1.48 (4.49)	0.505	-0.46	0.10
Knee rotation ROM	15.73 (4.15)	12.12 (3.73)	0.036	1.65	0.59
Speed (m/s)	0.21 (0.03)	0.19 (0.02)	0.161	0.96	0.29

Note: Values are adjusted by baseline scores and speed.

4.2.4. Post-Hoc analysis of BMI as covariate

Due to the significant difference in BMI between groups, post-hoc analyses were conducted adding BMI as a covariate, alongside speed and baseline scores, for knee angle variables during gait and step up/down tasks. The gait analysis yielded no change in significance for all variables but had small reductions in effect sizes (Appendix 10). For the step-up analyses, peak knee flexion was not statistically significant (p=0.07) when BMI was entered as a covariate compared to the analysis without BMI as a covariate (p=0.03) (Appendix 11). For step-down, there were differences in the peak knee flexion analysis where statistical significance changed from p=0.03 to p=0.01, effect size increased from 1.68 to 2.43, and power increased from 0.61 to

0.85 when BMI was entered as a covariate (Appendix 12). All other step-down variables had no changes in statistical significance (Appendix 12).

4.2.5. Analysis of clinical variables

For the KOOS in the activities of daily living subscale, the medial pivot group had statistically significant higher values than the posterior-stabilized group, which had a large effect size but low power (Table 6; p=0.019, d=1.18, power=0.68). Higher values in the KOOS indicate better functional outcomes. No other subscale was found to be statistically significant however, the pain subscale had a large effect size in favour of the medial pivot group (d=0.79) and low power (0.37). The analysis for the EQ5D5L also resulted in no statistically significant differences, however, the health utility scores did have a large effect size favouring the medial pivot group (d=0.82) but a lower power (0.40). Unadjusted values for baseline and year 1 visits are shown in appendix 13.

Table 6. Mean (standard deviation) values for adjusted 1 year visit, and the corresponding ANCOVA p-values, effect size, and observed power for clinical outcomes.

Clinical Outcomes	Medial Pivot Group	Posterior-Stabilized Group	p-value	Effect Size	Observed Power
KOOS					
Pain	89 (9)	81 (16)	0.101	0.79	0.37
Symptoms	75 (19)	76 (19)	0.327	0.46	0.16
ADL	96 (5)	83 (14)	0.019	1.18	0.68
Sport & recreation	65 (20)	57 (23)	0.446	0.36	0.12
Quality of life	77 (16)	69 (21)	0.204	0.62	0.24
EQ 5D 5L					
Health utility score	0.89 (0.04)	0.86 (0.05)	0.092	0.82	0.40
VAS	82 (11)	70 (11)	0.221	0.60	0.14

Note: Values are adjusted by baseline scores. ADL – activities of daily living; VAS – visual analogue scale

4.3. ANALYSIS OF GLOBAL RATING OF CHANGE

The analysis of the global rating of change indicated that participants in the medial pivot group had greater perceived change in a positive manner than those in the posterior-stabilized group, although the difference was only 1 point (p=0.039) (Table 7). However, this was a large effect size, but low power (d=0.79, power=0.42). Additionally, the minimal clinically important difference in this case is 0.5 according to previous literature (Jaeschke et al., 1989).

Table 7. Independent t-test of global rating of change between groups, and the corresponding p-value, effect size, and observed power.

Clinical Outcome	Medial Pivot Group	Posterior-Stabilized Group	p-value	Effect Size	Observed Power
Global rating of change	6 (1)	5 (3)	0.039	0.79	0.42

4.4. CORRELATIONAL ANALYSIS

The results for the correlational analysis of participant's ratings of perceived change (global rating of change and KOOS pain subscales) and biomechanical measures (knee angles during gait; Table 2) are shown in table 8. The was no statistically significant relationships between PROMs and biomechanical measures. All relationships had weak correlation coefficients, with the strongest being between knee flexion ROM in the swing phase and the KOOS pain subscale (r = 0.383) (Figure 3).

Table 8. The r coefficient (p value) between participant's ratings of perceived change and biomechanical measures during gait.

Patient reported outcomes	Biomechanical measures	
	KOOS – Pain	Global rating of change
Peak knee flexion-stance	-0.097 (0.355)	-0.221 (0.196)
Peak knee flexion-swing	-0.032 (0.451)	-0.278 (0.140)
Knee flexion ROM-stance	0.124 (0.317)	0.214 (0.205)
Knee flexion ROM-swing	0.383 (0.065)	0.292 (0.127)
Peak knee rotation-stance	0.092 (0.362)	0.073 (0.390)
Peak knee rotation-swing	0.193 (0.229)	0.091 (0.364)
Knee rotation ROM-stance	-0.308 (0.115)	0.170 (0.257)
Knee rotation ROM-swing	-0.373 (0.070)	-0.036 (0.445)

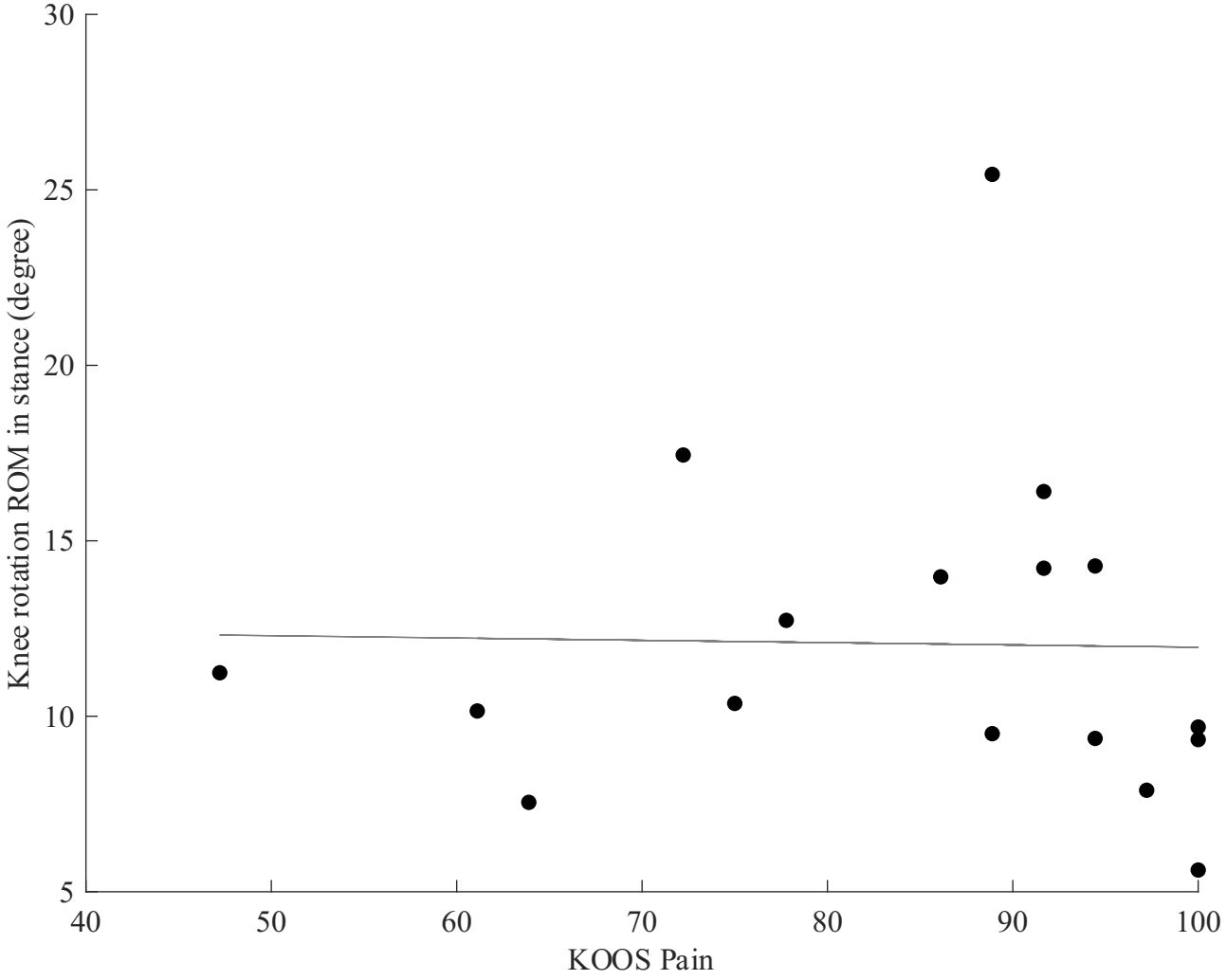

Figure 3. The relation between the KOOS pain subscales and biomechanical measure gait knee rotation ROM in the stance phase at 1 year.

CHAPTER 5: DISCUSSION

5.1. OVERVIEW

Some differences in 1-year outcomes existed between the TKA medial pivot and posterior stabilized groups. The medial pivot group demonstrated faster gait speeds, greater peak knee flexion and rotation ROM during step-down activities, higher KOOS ADL scores, and improved global rating of change scores. Overall, our hypothesis was partially confirmed as the differences between the two implants were marginal. While the posterior-stabilized group demonstrated greater step-up peak knee flexion angle. Finally, we hypothesized that those with better subjective reports would also demonstrate superior objective performance; however, this was not seen in our results. Ultimately, these results need to be further investigated as this study was underpowered.

5.2. GAIT

5.2.1. Gait knee angles

The hypothesis stated that the medial pivot group would exhibit a greater internal rotation knee angle during gait. Though the medial pivot group did have a greater internal rotation knee angle during both the stance and swing phases of gait, neither was statistically significant nor did it yield a large effect size. Thus, our hypothesis was rejected. As for the rest of the knee parameters during gait, medium effect sizes were found for knee flexion ROM and knee rotation ROM angles during stance favouring the medial pivot group, and knee rotation angle in the swing phase favouring the posterior-stabilized group. The observed effect sizes in this study suggest that there are nuanced differences that did not reach statistical significance and were

underpowered. Still, these minor differences could be explained by the medial pivot implant's shape which resembles a more natural knee motion which enhances knee flexion, while the posterior-stabilized's cam and post mechanism theoretically provides additional stability (Hoskins et al., 2022). Although the differences between the implants did not reach statistical significance in the current study, based on effect sizes they were different from the findings of the previously mentioned systematic review by Risitano et al. (2023). The review analyzed six studies using different implant manufacturers, and found that the posterior stabilized knee design generally exhibited greater knee flexion during various phases of gait compared to the medial pivot design (Risitano et al., 2023). This is important to keep in mind, as clinical decisions should not be made solely on medium effect sizes. Furthermore, the post-hoc power analysis illustrates that the results of this study may be underpowered to detect the true effects between the implants. Comparing the findings from this study to those of the systematic review further highlights the need to continue investigating these implants as there is still no clear winner between the two.

5.2.2. Spatiotemporal parameters

In alignment with our hypothesis, the medial pivot group had faster gait speeds than the posterior-stabilized group. However, despite reaching statistical significance ($p=0.03$) and large effect ($d=1.10$), the post-hoc power was below the 0.80 threshold (0.62), suggesting the potential for overestimating the effect size. Furthermore, no other statistically significant differences were observed between the groups in terms of other spatiotemporal parameters. These results are reflective of the findings from the systematic review, which also reported no statistically significant differences in spatiotemporal parameters between the posterior-stabilized and medial pivot implants (Risitano et al., 2023). However, this current study did find medium effect sizes

for stride length and step length favouring the medial pivot group suggesting that this implant design might have some small benefits in these specific spatiotemporal parameters. Similar to knee mechanics, these findings suggest that there may be subtle differences which, although not statistically significant and underpowered, could still be worth further exploring.

5.3. STAIR TASKS

The posterior-stabilized group demonstrated significantly greater peak knee flexion compared to the medial pivot group during step-up, although there were no differences in the knee internal rotation. Even though other measures did not yield statistical differences, knee flexion ROM had a medium effect size favouring the posterior-stabilized group. This suggests that though there might not be major differences, the posterior-stabilized may have minor benefits compared to the medial pivot group during stair ascent. However, the difference between the groups was only one degree which is less than the measurement error for the system, as error for peak flexion values for functional tasks are typically between 3 and 4 degrees (Robbins et al., 2013). Furthermore, a larger sample size is needed to understand the full effect of these findings.

Conversely, during the step-down task, the medial pivot group performed better exhibiting significantly greater peak knee flexion and knee rotation ROM angles than the posterior-stabilized group. Additionally, knee flexion ROM in the medial pivot group was greater than the posterior-stabilized group (MP=82.75, PS=79.91) however; statistical difference was not reached. Additionally, no step-down variable reached the 0.80 power threshold, thus the findings are not sufficiently powered to draw conclusions. Due to the lack of previous literature on this topic, it is difficult to compare these results to previous studies.

Overall, the findings suggest that the posterior-stabilized implant may offer some benefits in knee flexion during step-up tasks, however, the medial pivot implant provides better overall knee mechanics during step-down tasks. These differences could be due to the medial pivot following a more natural knee motion which would enhance knee flexion, while the posterior-stabilized implant has the cam and post mechanism that provides additional stability to the knee (Hoskins et al., 2022). Nonetheless, the lack of power reached in this study and lack of previous knowledge emphasizes the need for more research studying knee implants during functional movements such as step up and down.

5.4. BMI POST-HOC ANALYSIS

Given the significant difference in BMI between groups, post-hoc analyses were performed adding BMI as a covariate in the ANCOVAs, to examine its impact on knee angles during gait and step up/down tasks. Research indicates that BMI can significantly influence joint angles during dynamic activities like gait, stepping, and stair navigation (Harding et al., 2012; Messier et al., 2014). However, in the gait analysis, no changes in significance occurred and only minor reductions in effect sizes were seen. Therefore, it can be said that BMI difference did not have a big influence on the gait analyses for this study. Meanwhile, the post-hoc analysis of step-up indicated that BMI might have impacted peak knee flexion angles, as this variable was no longer statistically significant when BMI was entered as a covariate. This aligns with previous studies stating that higher BMI can restrict knee flexion (Law et al., 2021). The most notable change was observed in peak knee flexion during the step-down task, which increased power (0.85), achieved a larger effect size (2.43), and continued to be statistically significant with a lower p-value ($p=0.01$). This finding suggests that accounting for BMI may have had a

significant influence on this particular task. This finding aligns well with current literature stating that individuals with higher BMIs, in this case the posterior-stabilized group, have greater difficulties during stair descent (Law et al., 2021). Overall, these findings emphasize that some activities are more affected by BMI than others, as such BMI statistical analyses should be run with and without BMI as a covariate in studies where body composition varies between groups.

5.5. PATIENT REPORTED OUTCOMES

There were a few differences in the PROMs. The medial pivot had better function at 1 year, as indicated by higher KOOS daily activities subscale scores at one-year post-surgery. This was a new finding, as previous explorations of this area used mostly other types of self-assessment questionnaires resulting in no significant differences between the medial pivot and posterior stabilized implants (Hoskins et al., 2022). Another noteworthy result is the larger effect size in the pain subscale favouring the medial pivot implant however, it was not statistically significant. This result indicates a trend towards a reduction of pain found more in the medial pivot group than the posterior-stabilized group. The rest of the results were similar to those found previously in the literature with all other subscales of the KOOS not showing statistically significant differences between the groups (Hoskins et al., 2022). Similarly, the EQ-5D-5L group exhibited no statistical difference in the health utility scores between the groups. However, there was a large effect size favouring the medial pivot group which can be interpreted as better perceived health status in this group. This result is backed by the analysis of the global rating of change questionnaire that found a statistically significant difference between the two groups in perceived change one-year after surgery. This finding aligns with the hypothesis, indicating that patients with the medial pivot implant perceived a more significant improvement in their

condition post-surgery. Additionally, the mean group difference for the global rating of change was one point, which should be considered as the minimal clinically important difference in this case is 0.5 based on previous literature (Jaeschke et al., 1989). However, these findings may not be indicative of the true effect as the study is underpowered, further illustrating the need for more research to solidify these findings. The lack of statistically significant differences in several subscales suggests that while there may be benefits to the medial pivot implant design, these advantages might not be universally experienced across all dimensions of patient-reported outcomes. Additionally, it is important to consider that the global rating of change questionnaire was administered at one time point. Future studies should implement this questionnaire multiple times to get a true depiction of what the patient feels. These outcomes are similar to those of a review by Hoskins et al. (2022), where they highlighted the need for more studies to fully understand the complex relationship between patient and implant and see which is the better implant based on the patient's perception.

5.6. RECOMMENDATIONS & FUTURE DIRECTIONS

Considering the results of the current study, it would appear that the medial pivot has certain advantages over the posterior-stabilized implant. The medial pivot group has demonstrated faster gait speeds, greater peak knee flexion and rotation ROM during step-down activities, higher KOOS ADL scores, and improved global rating of change scores than the posterior-stabilized group. Though the study is underpowered, the results lead us to believe that with more participants differences between the implants may be present in favour of the medial pivot design. These slight advantages may be the result of the mimicking of normal knee motion that is caused by the implant's shape. However, it is imperative to continue this study as part of

the RCT with larger sample sizes, particularly focusing on joint kinematics in medial pivot implants during functional tasks like stair climbing to better understand the differences between TKA implants and increase generalizability. Additionally, further research exploring longer-term outcomes beyond one year assessing the durability and longevity of these implants could help better understand whether one implant should be used over the other. Investigating subgroups, such as sex, could also provide insights into which patients might benefit most from each implant design. Finally, an economic evaluation should take place while considering the outcomes of these studies. It is known that the medial pivot implant is more costly than the posterior-stabilized therefore if no differences exist or if the differences are negligible, it may be better financially to use the cost-effective posterior-stabilized implant. Overall, further research is crucial for optimizing TKA outcomes and enhancing patient care in the future.

5.7. CORRELATION BETWEEN PATIENT-REPORTED AND BIOMECHANICAL OUTCOMES

By collecting patient-reported outcomes and objective biomechanical data, we aimed to examine the relationships between individuals' subjective experiences with measurable objective parameters of joint function. However, the results showed no correlation between self-reported assessments of change and objective biomechanical data. These findings could shed light on what Ramkumar et al. (2015) found in their review, which stated that there may be some significant relationships between biomechanical variables and patient-reported outcomes. Though the purpose of the review was not to identify relationships between the two variables, they mentioned that some of the studies had highlighted the potential for correlation between the two and that future studies should take that into consideration. Considering the lack of statistical

significance of our findings, we would have to disagree with the review. However, our results may be due to a small sample size which could be affecting the power of our results. Therefore, further research with a larger sample size is needed to truly identify whether or not there is any correlation between self-reported assessments of change and objective biomechanical data.

5.8. LIMITATIONS

The main limitation of this study is the sample size, which makes it difficult to generalize the results to a larger population. The post-hoc power analysis further exemplified this limitation as even some statistically significant results had low power, meaning a larger sample size was needed. However, this is an interim analysis of an RCT and thus results should be interpreted as such. Another limitation is the distribution of sex among the groups. The medial pivot group only had two men while the posterior-stabilized group had four men. This is a limitation as sex differences have been seen between males and females with knee OA (McKean et al., 2007). Additionally, body composition is different between the sexes which might have contributed to another limitation in this study. This study saw a significant difference in BMI between groups. BMI was not used as a covariate in the main analyses because controlling for too many variables can reduce the ability to effectively assess and compare the two groups. However, a post-hoc analysis using BMI as a covariate was done and found that BMI had very small changes in the results, with only one major difference in step-down peak knee flexion. Lastly, while efforts were made to blind participants and assessors to the type of implant received, factors such as patient expectations and potential biases in reporting subjective outcomes cannot be entirely ruled out, potentially influencing the interpretation of patient-reported data.

CHAPTER 6: CONCLUSION

6.1. CONCLUSION AND SUMMARY

Overall, the findings underscore several minor advantages associated with the medial pivot implant design over the posterior stabilized design. The medial pivot implant group had faster gait speed, greater peak knee flexion and rotation ROM during step-down activities, higher KOOS ADL scores, and improved global rating of change scores; however, the posterior stabilized implant group demonstrated greater peak knee flexion angle during the step-up task. The implications of these preliminary results are that the RCT must continue as the sample size is still too small to fully grasp the differences between the implants. By addressing this gap, orthopaedic surgeons can enhance their decision-making for optimal patient care using the most effective TKA implant.

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Appendix 1. Ethics approval certificate.

Centre intégré universitaire de santé et de services sociaux du Centre-Ouest-de-l'Île-de-Montréal
Québec

CENTRE GÉRIATRIQUE DONALD BERMAN MAIMONIDES GERIATRIC CENTRE
CENTRE D'HÉBERGEMENT FATHER-DOWD RESIDENTIAL CENTRE
CENTRE D'HÉBERGEMENT HENRI-BRADET RESIDENTIAL CENTRE
CENTRE D'HÉBERGEMENT SAINT-ANDREW RESIDENTIAL CENTRE
CENTRE D'HÉBERGEMENT SAINT-MARGARET RESIDENTIAL CENTRE
CENTRE MIRIAM HOME AND SERVICES
CENTRE DE RÉADAPTATION CONSTANCE-LETHBRIDGE REHABILITATION CENTRE
CENTRE DE RÉADAPTATION MAB-MACKAY REHABILITATION CENTRE
CHSLD JUIF DE MONTRÉAL JEWISH ELDERCARE CENTRE
CLSC DE BENNY FARM
CLSC DE CÔTE-DES-NEIGES
CLSC MÉTRO
CLSC DE PARC-EXTENSION
CLSC RENÉ-CASSIN
HÔPITAL CATHERINE BOOTH HOSPITAL
HÔPITAL GÉNÉRAL JUIF JEWISH GENERAL HOSPITAL
HÔPITAL MOUNT SINAI HOSPITAL
HÔPITAL RICHARDSON HOSPITAL

Integrated Health and Social Services University Network for West-Central Montreal

Montreal, November 16, 2018

Shawn Robbins
Constance Lethbridge Rehabilitation Centre, Room 2-247
7005 de Maisonneuve Boulevard West Montreal, QC, H4B 1T3

Subject:

Support to the project "The Influence of Medial Pivot Knee Arthroplasty Implant Design on Joint Mechanics, Muscle Activation and Clinical Outcomes" (2018-821, 17-162)

Dear Dr Robbins,

We have evaluated your research project titled: **The Influence of Medial Pivot Knee Arthroplasty Implant Design on Joint Mechanics, Muscle Activation and Clinical Outcomes**. This innovative project corresponds to our research orientations and meets the needs of our clientele of the Integrated Health and Social Services University Network for West-Central Montreal.

In support of the project, we are happy to grant you access to the CLIMB lab at Constance Lethbridge Rehabilitation Centre.

In order to contribute to the development of evidence-based practices in our institution, we also hope you will agree to present your results in our clinical programs and to our clinical staff.

If needed, Josianne Crête, clinical research coordinator, will help you with the implementation of the project in our center.

Sincerely yours,

Felicia Guarna
Director of Rehabilitation PD, ID-ASD
Integrated Health and Social Services University Network for West-Central Montreal

Appendix 2. Participant consent form (English).

CONSENT TO PARTICIPATE IN THE RESEARCH STUDY
The Influence of Medial Pivot Knee Arthroplasty Implant Design on Joint Mechanics, Muscle Activation and Clinical Outcomes

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Study doctors	**Study coordinators:**
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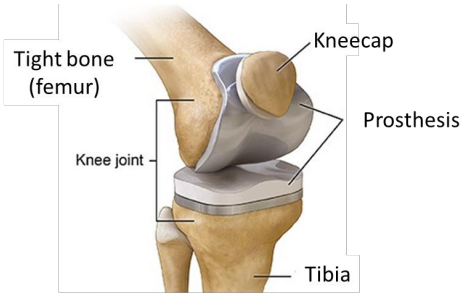
Introduction

You are being asked to consider participating in this research study because you need a total knee replacement for your knee joint.

Before deciding if you wish to participate in this study, you should clearly understand its requirements, potential risks and benefits. This document provides information about the study and it may contain words you do not fully understand. Please read it carefully and ask the study personnel any questions you may have. The study personnel will discuss the study with you in detail. You should not sign this form until you are sure you understand the information and your role in the study. You may also wish to take this form and discuss the study with anyone else before making any decision. You do not have to take part in this study if you do not want to. If you decide to participate in this study, you will be asked to sign and date this form and a copy will be given to you.

Purpose of the Study and Background

You and your study doctor have decided that you need to have a total knee replacement (TKR) surgery.



During a TKR, the surgeon removes the end of the femur (the long bone in the thigh) and places a metal shell. The end of the tibia (the larger of the two bones in the lower leg) is also removed and replaced with a channeled plastic piece (polyethylene insert) with a metal stem. Depending on the condition of the kneecap portion of the knee joint, a plastic "button" may also be added under the kneecap surface. The artificial components of a total knee replacement are referred to as the *prosthesis*.

An important factor in the way a knee implant performs is the way the parts of the prosthesis move when you bend your knee. Over time implant companies have developed and improved different prosthesis designs to ensure that the patients have a comfortable, natural feel and function during knee movement. The purpose of this study is to compare two types of Zimmer knee prostheses and determine which one performs better allowing you to have a walking pattern closer to a healthy knee. Both implants used in this study are approved for use by the FDA and Health Canada.

The study will last for two years and will follow 108 patients requiring TKR like you. Approximatively 80 patients will be enrolled at the Jewish General Hospital, 40 of whom will receive Zimmer Medial Pivot Persona and 40 Zimmer Persona Knee-PS implants, while 28 patients will be recruited at the Montreal General Hospital 14 of whom will receive Zimmer Medial Pivot Persona and 14 Zimmer Persona Knee-PS implants. Another 54 healthy participants will be enrolled so that normal knees can be compared to the knees of the participants receiving the knee replacements used in this study.

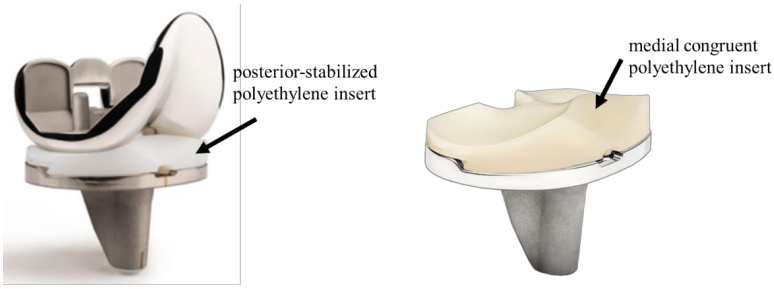
Description of the Study

Participation in this study will not prevent or delay your surgery.
If you decide to participate in this study, before surgery you will be assigned at random, that is, by a method of chance (like a flip of a coin), to receive one of the two prostheses:

- Zimmer MP Persona TKA
- Zimmer Persona Knee-PS TKA

You will have a 1 in 2 chance of being treated with Zimmer Medial Pivot Persona TKA and 1 in 2 chance of being treated Zimmer Persona Knee-PS. This means you have a 50/50 chance of being assigned into each one of the two groups. You will not be able to choose what type of treatment you will receive in this study because it will be determined by chance.

Zimmer Persona TKA prosthesis was created to tailor each patient's knee anatomy making the surgery easier for you and your doctor. It uses four different polyethylene inserts with different surface geometries for the same metal tibial stem. This study aims to compare two of the most current design of these inserts, the traditional posterior-stabilized polyethylene insert called **Persona Knee-PS** to the medial congruent polyethylene insert called **MP Persona**. The company claims that the surface of the MP Persona insert should permit more natural knee movement. This study will test this claim that has not been tested before.



Zimmer Persona Knee-PS **Zimmer MP Persona**

Both prostheses used in the study are approved to be used in Canada and Quebec since 2013 but they are not currently used at the Jewish General Hospital and the Montreal General Hospital because they cost more than typical prostheses.

Prior, during and following your operation, the hospital will follow standard procedures and you will receive normal and routine (standard) care that is the same whether you choose to take part in this study or not.

During the study, you will have several evaluations as indicated in Table 1:

1. a clinical evaluation, which is the routine (standard) care provided for all patients with total knee replacement and
2. an evaluation of your walking pattern, overall mobility, and symptoms.

Table 1. Examinations and Assessments

Event/Visit	Location of Collection	When Collected				
		Pre-op	Operative	6 Wk.	1 Yr.	2 Yr.
Obtain Informed Participant Consent	JGH/MGH	x				
Medical history*	JGH/MGH	x				
Surgery*	JGH/MGH		x			
Clinical evaluation*	JGH/MGH	x	x	x	x	x
Normal Evaluation with Doctor						
X-ray						
Lab evaluation†	LLMRC	x			x	x
Walking pattern					x	x
Mobility Tests (stairs, walking, sit to stand)						
Self-Assessment questionnaires						

* standard care required only for participants requiring total knee replacement (TKR)
† required for both groups, healthy participants and the participants with total knee replacement (TKR)

Clinical evaluation

You will see your study doctor in his office before your surgery and then again at 6 weeks, 1 year and 2 years following your surgery. This schedule of follow-up visits is what you would normally expect after your surgery and are standard of care at the Jewish General Hospital and the Montreal General Hospital, which you would receive even if you choose not to participate in this study.

- At each visit, your study doctor will examine your knee and take routine knee X-rays.
- You will be asked to complete a one-page form to share how your knee is functioning and the level of physical function before your surgery and then at regular intervals following your surgery.

You do not need to bring anything to the clinic during these follow up appointments and you don't have to change any part of your normal routine or daily living during the periods between assessments.
The study team will also consult your medical records to collect information such as your medical history and demographics (e.g., gender, birth year) and take notes of the relevant information (data) for this research study.

Lab evaluation

You will go the Lethbridge-Layton-MacKay Rehabilitation Centre in Montreal for data collection. This visit should take 3 hours, and will be completed pre-operative, and 1 and 2 years after surgery.

Firstly, you will complete three surveys that will ask you how you feel about your knee as well as how it affects you in your daily activities. Next you will change into shorts and a t-shirt. You will perform three mobility tests. The first one will be a sit to stand action repeated over 30 seconds; the second is an 11-stair climbing and descending test; and the third is a test requiring you to walk for 6 minutes. You will be asked about your pain level before and after each of these tests. You can stop these tests or rest at any time if you feel your pain is getting worse. After that, small devices will be placed on your skin over your leg muscle using stickers. We will shave the area and clean it with alcohol prior to attaching the devices. These devices will measure when your muscles are being used. You will be required to do some exercises to ensure the devices are

working properly. Next, reflective markers will be applied to your skin with adhesive tape. Cameras around the room can measure the position of the markers. This information will be used to analyze your walking pattern. You will then be asked to step up one step (20 cm in height) and then step down this step. Next you will walk along an 8-meter platform at your usual walking speed. Each task (step up, step down, walking) will be repeated 5 to 7 times. Finally, you will be required to complete a series of five exercises requiring you to use your maximum strength. Each exercise will be held for 5 seconds and repeated three times.

Your participation in these follow-up visits is *very* important. The study team will contact you to schedule these visits. **It is most important that you come to clinic at your scheduled visits.**

Risks and Discomforts: Your study doctor will discuss with you all the usual problems associated with a total knee replacement surgery.

As with any major operation, there are risks associated with total knee replacement surgery. Risks or problems related to any total knee replacement surgery may include:

- early or late infection possibly causing the implant to be removed;
- damage to nerves and blood vessels;
- a break in the bone surrounding the implant;
- the implant may break, crack or loosen;
- bone may not grow around the implant enough to hold it in place and it may become loose;
- you may not be able to move your knee as much or get around as easily as before;
- long-term swelling of your leg or knee
- the wound may take longer to heal;
- you may develop phlebitis (blood clots) which could cause lung problems;
- the knee implant may need to be replaced with a different kind of implant;
- the knee implant may separate or move (dislocation);
- the knee implant may come apart (disassociation);
- the bone or tissue may grow across the joint (arthrofibrosis);
- the length of your legs may feel or not be equal (limb length inequality);
- loss of knee joint alignment;
- early or late local and/or systemic reaction to the implant materials;
- bone resorption (bone disappears) caused by particulate wear debris from the implant and/or bone cement.

Nerve, heart, and breathing problems are also risks with anesthesia during and after surgery. Others may cause prolonged illness, hematoma (swelling or mass of blood under the skin caused by a broken blood vessel); draining wounds, the need for blood transfusions and/or further surgeries, increased or permanent pain, deformity, inconvenience or longer healing time. Rarely, some complications may be fatal.

There may also be some risks associated with total knee replacement surgery that are unknown.

X-rays expose you to radiation. The radiation dose depends on the part of your body that is being examined. For X-rays of the extremities (knee in this case), the dose is about 0.01 mSv per view, which is about the same as the average person receives from background radiation in less than 1 day. Since you are having 3 such X-rays at the office visits outlined above, the exposure is about the same as you would get from normally occurring background radiation in three days at the

beach or in one sunny day skiing. Stated another way, it is less than the amount of radiation exposure that one would experience in a round trip flight between New York and Chicago.

During the knee evaluation, a few small areas of skin will be shaved before positioning electrodes and markers. As such, strict hygiene measures (razor, hypoallergenic adhesive tapes, cleaning skin with alcohol) will be respected. Skin reaction where electrodes or markers are fixed is an uncommon risk but could occur. You might feel some discomfort when removing the electrodes or markers. You will be required to complete walking tests and strength tests. There is a small risk of injury, pain, or discomfort during the walking and strength tests. You will be asked for feedback during testing to make sure you are not uncomfortable.

Potential Benefits: You should not expect any direct benefits from participating in this study. The knee replacement itself will hopefully provide you relief from symptoms. However, your participation will help us to determine if one of the prostheses may be better than the other and this could help future patients who need knee replacement.

The information collected during the study will be used to increase medical community knowledge on knee prostheses and could influence future thinking on the best implant design used in knee surgery. We believe that the information obtained from this study will benefit future patients and allow surgeons to make informed decisions about which prostheses to use based on real evidence.

Alternatives to Participation: You do not have to participate in this study to receive a total knee replacement. If you decide not to participate in this study, the surgeon will treat your knee as he would normally do, as per standard care. He will discuss with you all treatments available and their risks and benefits. Full standard care and treatment will be provided to you regardless of your involvement in this study. However, you can't receive the Zimmer MP Persona or the Zimmer Persona Knee-PS TKA without participating in this study. Being too costly, these prostheses are not currently used at the Jewish General Hospital and the Montreal General Hospital for total knee replacement. Zimmer, the company that makes these prostheses, will supply them at no charge for this study.

Should you suffer any harm: Should you suffer harm of any kind following the implantation of the study device, or following any other procedure related to the research study, you will receive the appropriate care and services as required by your state of health.

By agreeing to participate in this research study, you do not give up any of your legal rights nor discharging the doctor in charge of this research study, the sponsor or the institution, of their civil and professional responsibilities.

Voluntary participation/withdrawal: Your participation in this research project is voluntary. Therefore, you may refuse to participate. You may also withdraw from the project at any time, without giving any reason, by informing the doctor in charge of this research study or a member of the research team.

Your decision not to participate in the study, or to withdraw from it, will have no impact on the quality of care and services to which you are otherwise entitled, or on your relationship with the doctor in charge of this research study or the clinical team.

The doctor in charge of this research study, the WCMH MBM Research Ethics Committee, the funding agency, or the Sponsor may put an end to your participation without your consent. This may happen if new findings or information indicate that participation is no longer in your interest,

if you do not follow study instructions, or if there are administrative reasons to terminate the project.

However, before you withdraw from the study we suggest, that you return to the clinic for a final evaluation, for safety reasons.

If you withdraw or are withdrawn from the study, the information collected during the study will nonetheless be stored, analyzed or used to protect the scientific integrity of the research project.

Any new findings that could influence your decision to stay in the research project will be shared with you as soon as possible.

Study Results: The results of this study may be presented at conferences, seminars or other public forums, and published in journals, but no information will be used in these presentations that would disclose your identity as a study participant. No information from this study will be released or printed that would disclose your personal identity without your permission unless required by law. At the end of the study, if you so wish, you may contact the study doctor to obtain results of the study.

Confidentiality: During your participation in this study, the study doctor and their team will collect and record information about you in a study file. They will only collect information required to meet the scientific goals of the study.

The study file may include information from your medical records concerning your past and present state of health, your lifestyle, as well as the results of the tests, exams, and procedures that you will undergo during this research project. Your research file could also contain other information, such as your name, sex, and date of birth.

Your surgical information (e.g. implant type) and measures from your x-rays will be transferred from Jewish General Hospital and the Montreal General Hospital to the Lethbridge-Layton-MacKay Rehabilitation Centre (to the researcher- Shawn Robbins). This data will be conserved for 25 years for the exclusive objectives of this study and then destroyed.

All the information collected during the research project will remain confidential to the extent provided by law. You will only be identified by a code number. The key to the code linking your name to your study file will be kept by the researcher in charge of this research study (CLIMB Lab, Lethbridge-Layton-MacKay Rehabilitation Centre).

To ensure your safety, a copy of this information and consent form will be placed in your medical chart. As a result, any person or company whom you give access to your medical chart will have access to this information.

The study doctor will forward your coded data to the sponsor or their representatives. The Sponsor may share the coded study data with their commercial partners. However, the sponsor and any international partners will respect the confidentiality rules in effect in Quebec and Canada, regardless of the country to which your data may be transferred. The study data will be stored for 25 years by the researcher in charge of this research study. The gait study information will be added permanently to the database of the Lethbridge-Layton-MacKay Rehabilitation Centre and may be used for other reasons related to the study or to help in the development of future studies. This data will be coded and will not contain identifying information (e.g. name, date of birth, hospital number). This data will be kept confidential, stored, and locked in a secure place in Dr. Robbins office that only the study personnel will be able to access.

The data may be published or shared during scientific meetings; however, it will not be possible to identify you.

For monitoring, control, safety, security, your study file as well as your medical charts may be examined by a person mandated by the Research Ethics Committee. All these individuals and organizations adhere to policies on confidentiality.

You have the right to consult your study file in order to verify the information gathered, and to have it corrected if necessary. However, in order to protect the scientific integrity of the research project, accessing certain information before the project is ended may require that you be withdrawn from the study. While you take part in this research study, the researcher in charge and study staff will collect and store personal identifiable information about you in a file for the research study. Only information necessary for the research study will be collected.

A copy of this consent form will be placed in your medical record file and a copy will be given to you. Only information necessary for the research study will be collected.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by Canada and Quebec Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Costs and compensation: You will be compensated $30 for each visit to the Lethbridge-Layton-MacKay Rehabilitation Centre to cover the cost of travel.

Possible benefits of taking part: If you participate in the study you will receive one of the most recent protheses designed by Zimmer. The information from this study might help researchers to come up with new tests or treatments to help others in the future.

Who is funding the research? This study is sponsored by the Arthritis Society. The medical services (surgery and clinical evaluation) are supported by Jewish General Hospital and the Montreal General Hospital as part of your medical standard of care. Zimmer is providing the study prosthesis at no cost. The sponsored amount is sufficient to cover the costs of conducting the study. No additional funds or compensation will be available at the end of the study.

Study Contacts and Emergency Contact: If you have any questions about this study, or if you feel you have experienced a study-related injury, please contact Dr. John Antoniou or any of the study doctors listed on the first page of this document.
In case of an emergency, please go to the nearest emergency department.

Information Resource: If you have any questions regarding your rights as a person taking part in this study, you may contact the Jewish General Hospital's Local Commissioner of Complaints & Quality of Services, Rosemary Steinberg, at (514) 340-8222 ext. 25833 or the Patient Ombudsman of the Montreal General Hospital at (514) 934-1934 ext. 44285.

CONSENT SIGNATURE PAGE

I have reviewed the information and consent form. Both the research study and the information and consent form were explained to me. My questions were answered, and I was given sufficient time to make a decision. After reflection, I voluntarily consent to participate in this research study in accordance with the conditions stated above.

I authorize the research study team to have access to my medical record for the purposes of this study.

I do not give up any of my legal rights by signing this consent form.

I agree to take part in this study.

_____	_____	_____
Printed Name of Participant	Signature of Participant	Date

Signature of person obtaining consent

I have explained the research project ant the terms of this information and consent form to the research participant, and I answered all his/her questions.

_____	_____	_____
Name of the person obtaining consent	Signature	Date

Signature of Principal Investigator

I certify that this information and consent form were explained to the research participant, and that the questions the participant had were answered.

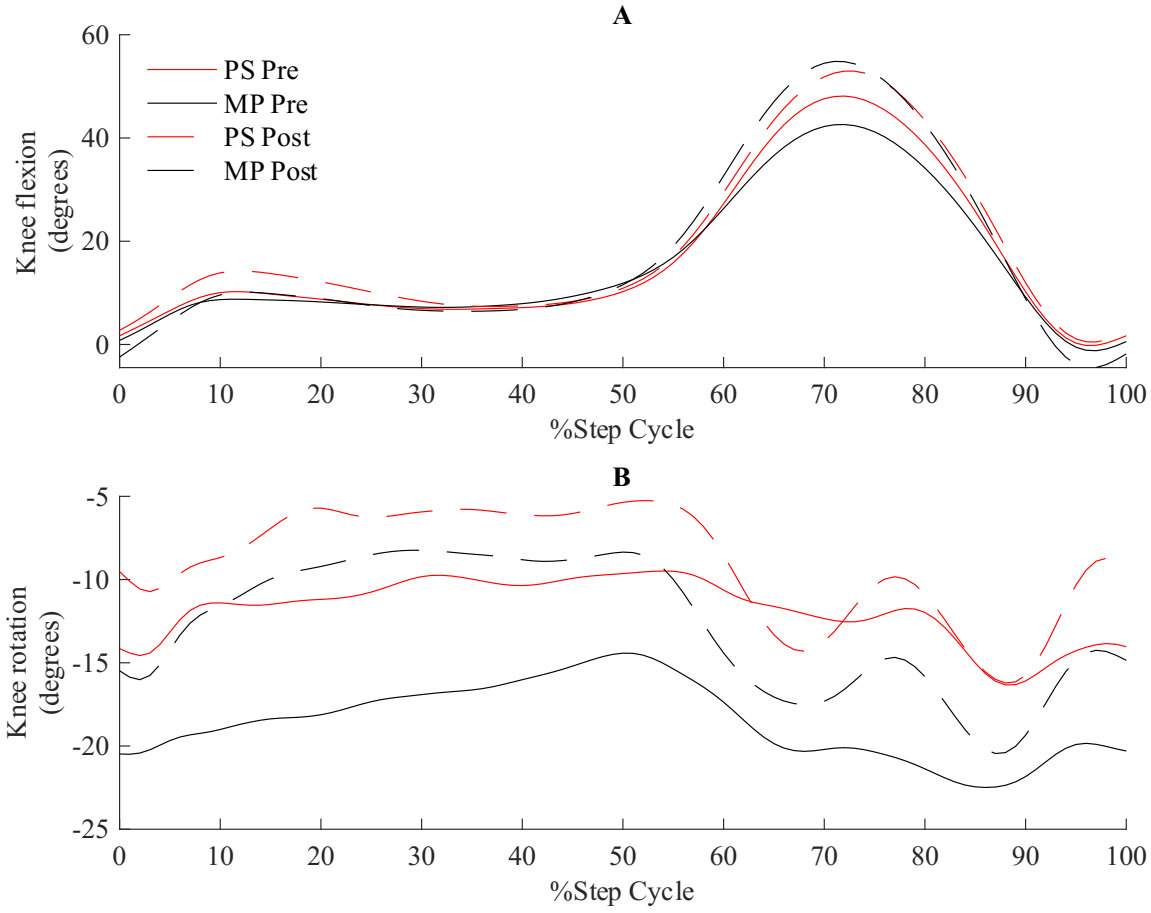
I undertake, together with the research team, to respect what was agreed upon in the information and consent form, and to give a signed and dated copy of this form to the research participant.

_____	_____	_____
Name of the principal investigator	Signature	Date

Appendix 3. Unadjusted values for baseline and 1-year visits for joint angles during gait tasks.

Joint Angles (°)	Medial Pivot Group		Posterior-Stabilized Group	
	Pre	Post	Pre	Post
Peak knee flexion-stance	27.88 (8.11)	35.59 (4.34)	29.73 (7.01)	32.79 (9.28)
Peak knee flexion-swing	42.80 (13.48)	55.24 (3.32)	49.18 (10.65)	54.50 (6.64)
Peak knee flexion ROM-stance	26.79 (9.62)	37.80 (5.34)	28.86 (7.50)	31.24 (8.13)
Peak knee flexion ROM-swing	43.96 (17.05)	59.87 (5.00)	50.56 (11.32)	55.78 (6.73)
Peak knee rotation-stance	-12.74 (11.57)	-5.16 (9.95)	-4.74 (10.28)	-3.02 (5.25)
Peak knee rotation-swing	-14.47 (11.17)	-9.05 (8.49)	-5.96 (8.92)	-5.90 (4.39)
Peak knee rotation ROM-stance	9.02 (2.56)	13.88 (5.10)	10.23 (4.21)	10.76 (2.53)
Peak knee rotation ROM-swing	10.32 (3.43)	14.02 (3.97)	11.28 (3.95)	14.12 (2.19)

Appendix 4. Group means for the baseline (Pre) and 1-year post-surgery (post) A) knee flexion and B) knee internal rotation values during gait for the posterior-stabilized (PS) and medial pivot (MP) groups. Positive values knee angles are represented by knee flexion and internal rotation.



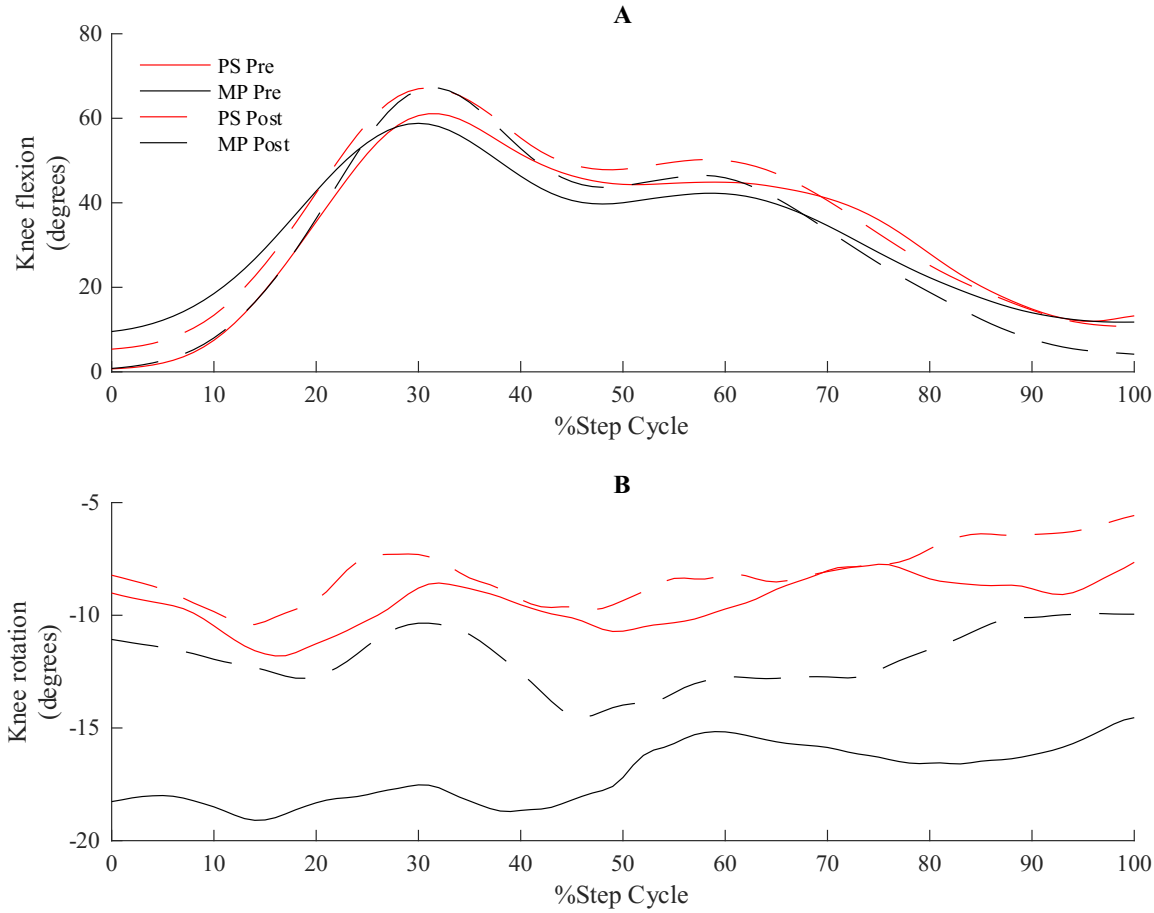
Appendix 5. Unadjusted mean values (standard deviation) for baseline (pre) and 1-year (post) visits for spaciotemporal variables of the affected limb during gait tasks.

Spaciotemporal Variables	Medial Pivot Group		Posterior-Stabilized Group	
	Pre	Post	Pre	Post
Speed (m/s)	1.05 (0.25)	1.21 (0.14)	0.99 (0.19)	1.07 (0.17)
Swing time (s)	0.43 (0.04)	0.36 (0.14)	0.43 (0.05)	0.29 (0.19)
Stance time (s)	0.69 (0.09)	0.56 (0.21)	0.69 (0.08)	0.50 (0.32)
Stride length (m)	1.15 (0.19)	1.11 (0.44)	1.10 (0.20)	0.83 (0.56)
Step length (m)	0.61 (0.09)	0.53 (0.21)	0.54 (0.07)	0.35 (0.28)

Appendix 6. Unadjusted mean values (standard deviation) for baseline (pre) and 1-year (post) visits for joint angles during step-up tasks.

Joint Angles (°)	Medial Pivot Group		Posterior-Stabilized Group	
	Pre	Post	Pre	Post
Peak knee flexion	64.70 (21.25)	73.05 (10.68)	69.00 (12.53)	76.47 (7.53)
Knee flexion ROM	59.10 (20.51)	73.56 (11.22)	68.54 (13.54)	74.67 (3.92)
Peak knee rotation	-10.89 (11.76)	-4.65 (7.85)	-2.15 (8.08)	-2.29 (5.37)
Knee rotation ROM	12.39 (3.06)	13.94 (3.67)	13.17 (6.30)	11.05 (4.80)

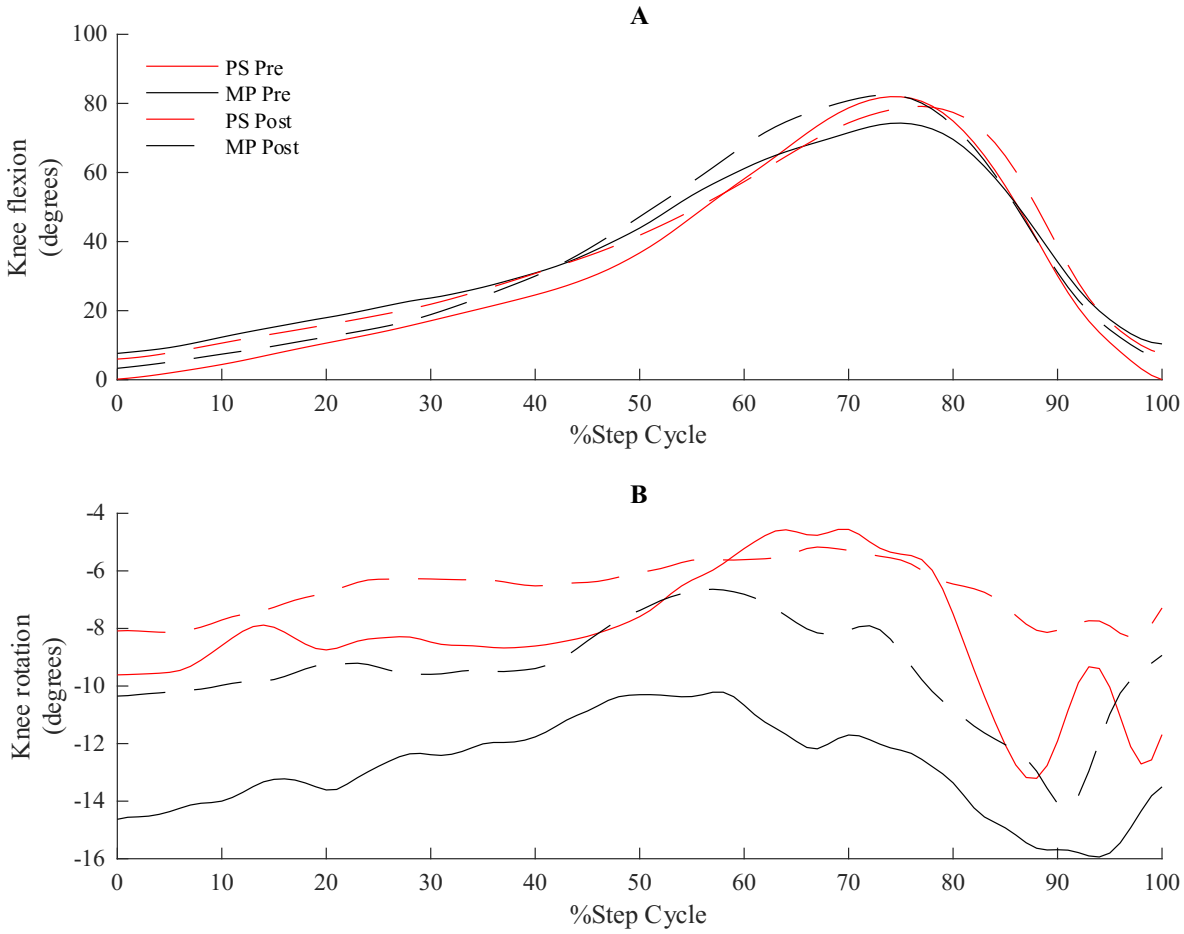
Appendix 7. Group means for the baseline (Pre) and 1-year post-surgery (post) A) knee flexion and B) knee internal rotation values during step-up tasks for the posterior-stabilized (PS) and medial pivot (MP) groups. Positive values knee angles are represented by knee flexion and internal rotation.



Appendix 8. Unadjusted mean values (standard deviation) for baseline (pre) and 1-year (post) visits for joint angles during step-down tasks.

Joint Angles (°)	Medial Pivot Group		Posterior-Stabilized Group	
	Pre	Post	Pre	Post
Peak knee flexion	81.52 (11.20)	86.50 (4.21)	83.87 (8.47)	81.78 (3.12)
Knee flexion ROM	75.51 (13.31)	82.75 (6.54)	84.57 (6.24)	79.91 (2.97)
Peak knee rotation	-7.23 (11.02)	-2.01 (10.16)	-1.14 (7.70)	-1.48 (4.49)
Knee rotation ROM	12.44 (2.04)	15.73 (4.15)	16.17 (6.73)	12.12 (3.73)

Appendix 9. Group means for the baseline (Pre) and 1-year post-surgery (post) A) knee flexion and B) knee internal rotation values during step-down tasks for the posterior-stabilized (PS) and medial pivot (MP) groups. Positive values knee angles are represented by knee flexion and internal rotation.



Appendix 10. Mean (standard deviation) for the 1-year visit data adjusted by baseline scores, speed, and BMI, and the corresponding ANCOVA p-values for joint angles for gait tasks.

Joint Angles (º)	Medial Pivot Group	Posterior-Stabilized Group	p-value	Effect Size	Observed Power
Peak knee flexion-stance	35.59 (4.34)	32.79 (9.28)	0.659	-0.22	0.07
Peak knee flexion-swing	55.24 (3.32)	54.50 (6.64)	0.830	-0.11	0.06
Knee flexion ROM-stance	37.80 (5.34)	31.24 (8.13)	0.827	0.11	0.06
Knee flexion ROM-swing	59.87 (5.00)	55.78 (6.73)	0.966	-0.02	0.05
Peak knee rotation-stance	-5.16 (9.95)	-3.02 (5.25)	0.299	-0.52	0.17
Peak knee rotation-swing	-9.05 (8.49)	-5.90 (4.39)	0.104	-0.84	0.34
Knee rotation ROM-stance	13.88 (5.10)	10.76 (2.53)	0.534	0.31	0.09
Knee rotation ROM-swing	14.02 (3.97)	14.12 (2.19)	0.405	-0.42	0.13

Note: Values are adjusted by baseline scores, speed, and BMI

Appendix 11. Mean (standard deviation) for the 1-year visit data adjusted by baseline scores, speed, and BMI, and the corresponding ANCOVA p-values for joint angles for step-up tasks.

Joint Angles (º)	Medial Pivot Group	Posterior-Stabilized Group	p-value	Effect Size	Observed Power
Peak knee flexion	73.05 (10.68)	76.47 (7.53)	0.073	-1.08	0.44
Knee flexion ROM	73.56 (11.23)	74.67 (3.93)	0.177	-0.79	0.26
Peak knee rotation	-4.65 (7.85)	-2.29 (5.37)	0.560	-0.33	0.09
Knee rotation ROM	13.94 (3.67)	11.05 (4.80)	0.268	0.64	0.19

Note: Values are adjusted by baseline scores, speed, and BMI.

Appendix 12. Mean (standard deviation) for the 1-year visit data adjusted by baseline scores, speed, and BMI, and the corresponding ANCOVA p-values for joint angles for step-down tasks.

Joint Angles (º)	Medial Pivot Group	Posterior-Stabilized Group	p-value	Effect Size	Observed Power
Peak knee flexion	86.50 (4.21)	81.77 (3.12)	0.009	2.43	0.85
Knee flexion ROM	82.75 (6.54)	79.91 (2.97)	0.298	0.79	0.17
Peak knee rotation	-2.01 (10.16)	-1.48 (4.49)	0.186	-1.03	0.25
Knee rotation ROM	15.73 (4.15)	12.12 (3.73)	0.082	1.41	0.42

Note: Values are adjusted by baseline scores, speed, and BMI.

Appendix 13. Unadjusted mean values (standard deviation) for baseline (pre) and 1-year (post) visits for clinical outcomes.

Clinical Outcomes	Medial Pivot Group		Posterior-Stabilized Group	
	Pre	Post	Pre	Post
KOOS				
Pain	43 (10)	89 (9)	46 (8)	81 (16)
Symptoms	40 (15)	75 (19)	50 (7)	76 (19)
ADL	50 (14)	96 (5)	45 (9)	83 (14)
Sport & recreation	17 (9)	65 (20)	15 (13)	57 (23)
Quality of life	19 (14)	77 (16)	25 (16)	70 (21)
EQ 5D 5L				
Health utility score	0.59 (0.23)	0.89 (0.04)	0.66 (0.15)	0.87 (0.04)
VAS	82 (11)	85 (10)	70 (11)	78 (7)