IRB #: STU00090745 Approved by NU IRB for use on or after 9/8/2017 through 9/7/2018.

Stability of the Medial Pivot Total Knee Prosthesis

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Synopsis

Title	Stability of the Medial Pivot Total Knee Prosthesis
Short Title	Medial Pivot Knee Stability
Protocol Date	04/08/2016
Study Duration	2 years
Study Center(s)	Northwestern Memorial Hospital, Northwestern Memorial Faculty Foundation, Northwestern University
Objectives	To compare objective and subjective measures of knee stability following total knee arthroplasty with a medial pivot design vs. a posterior stabilized design
Number of Subjects	100 (50 in each group)
Diagnosis and Main Inclusion Criteria	Patients requiring total knee arthroplasty that present to Northwestern Memorial Hospital or to Dr. Manning or Dr. Beal's clinic

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1.0 INTRODUCTION - BACKGROUND AND RATIONALE

Several different prostheses are available for use in total knee arthroplasty (TKA) (1). These designs aim to replicate the normal kinematics of the knee joint while maintaining stability throughout a full range of motion. The posterior cruciate ligament (PCL) contributes to these functions in the native knee, and if preserved it can function similarly in the prosthetic knee (2, 3). Prostheses in which the PCL is sacrificed, and its function not replaced by other means, have poorer outcomes (4). However, various problems with preserving the PCL, including PCL deterioration in arthritic knees (5) and difficulties with proper tensioning (6, 7), have led to the development of alternative ways to emulate normal femoral rollback and sagittal plane stability. These posterior-substituted (PS) designs substitute for the PCL with either a cam and post mechanism or a symmetrical ultra-congruent tibial insert (8, 9).

The cruciate-retaining (CR) and PS designs, together with advances in surgical techniques and component materials, have achieved excellent implant survivorship with rates of > 90% at 20 years (10, 11). Reports of functional outcomes, however, have been variable (12). One potential area for improvement in TKA is optimization of implant design to better approximate native knee kinematics. In the normal knee, the medial condyle remains stable in the sagittal plane, functioning like a ball-and-socket, whereas the lateral condyle translates anterior to posterior during flexion (13-15). The designs of the CR and PS knees do not allow for this medial-centered rotation. Analysis has revealed paradoxical anterior sliding of the femur during flexion, abnormal axial rotation, and condylar lift-off (16, 17). Edge loading and increased sagittal plane motion may predispose to accelerated polyethylene wear (18, 19). The posterior stabilized design uses a cam-and-post mechanism in which one piece of the prosthesis has a plastic post that fits into a slot in the other piece of the prosthesis.

A newer design that attempts to address these issues is the medial pivot knee (MP). This design is characterized by an asymmetrical tibial insert in which the medial compartment is ultra-congruent, providing antero-posterior stability and the lateral compartment allows for rollback around a medial axis of rotation i.e uses a ball-and-socket mechanism. (20) This design more accurately recreates normal knee kinematics, reduces anteroposterior instability, and avoids condylar lift-off (21-24). Early studies indicate improved polyethylene wear characteristics (25). Midterm studies report excellent implant survivorship and clinical outcomes (26, 27).

Several randomized trials have compared the MP knee favorably with other designs. Patients with bilateral TKAs with a different prosthesis on each side preferred their medial pivot knee to a PS, CR, or mobile-bearing (MB) design (28). A trial comparing the MP and PS designs found greater range of motion (ROM) and better patient-reported outcomes in the MP group at 2 years (29). There also exists literature reporting poorer outcomes with the MP design. A trial involving 96 patients who had received both an MP knee and an MB knee on contralateral sides found lower ROM, higher complication rates, and worse patient reported outcomes in the MP knee (30).

Given the lack of consensus in the literature, further investigation is warranted to determine the impact of the MP design on outcomes following TKA.

2.0 OBJECTIVES

The goals of this study are to compare subjective and objective measures of knee stability following TKA with a medial pivot design compared with a posterior stabilized design.

3.0 SELECTION OF SUBJECTS

3.1 INCLUSION CRITERIA

- Age 18-85, regardless of gender, ethnicity, or pathology
- Must require a total knee arthroplasty

- All subjects must have given signed, informed consent prior to registration in study.

3.2 EXCLUSION CRITERIA

- Minors
- Any patients that are unable to consent
- Patients with active infection or osseous tumor of the operative extremity
- Patients undergoing revision surgery

4.0 SUBJECT REGISTRATION

The subjects will be recruited by the PI, co-investigator, or other authorized study staff at the orthopaedic surgery clinic at 259 E. Erie, 13th floor. The study will be reviewed with the subjects and they will be consented by the PI, co-investigator, or other authorized study staff.

5.0 STUDY DESIGN & METHODS

50 patients will be recruited over 12-18 months. Half of the patients will receive the Medacta GMK Sphere prosthesis (Ball-and-socket), while the other half will receive the Medacta GMK posterior stabilized prosthesis (Cam-and-post). Patients will be randomized in the operating room through the opening of opaque, study-numbered envelopes prior to skin incision.

Patient-reported outcomes will be administered pre-operatively, immediately post-operatively, 6 weeks post-operatively, 3 months post-operatively, 6 months post-operatively, 12 months post-operatively, and 2 years post-operatively. Patient-reported outcomes will be measured using the Oxford knee score (see appendix 1), Knee Society Score, VR-12 (see appendix 2), the Forgotten Joint Score (FJS) for the knee (see appendix 3), and the Kujala Scoring Questionnaire (see appendix 4) as well as the physical function, pain interference, and pain behavior PROMIS CATs (see appendix 5). These questionnaires will be completed at the routine post-operative clinic visits or over the phone through PROMIS Assessment Center. The Forgotten Joint Score (FJS) will only be administered at the subject's 12 month post-operative time point and the Kujala Scoring Questionnaire will only be administered at the subject's 2 year post-operative time point.

At 3-6 months post-op, the operative knee will be examined by a single Sports Orthopaedics attending surgeon Dr. Terry, who is an expert in assessing knee stability. The attending will grade the stability of the knee in various degrees of flexion according to section 4 of the International Knee Documentation Committee's Knee Ligament Standard Evaluation Form (see appendix 3). KT1000 arthrometer (MEDmetrics, San Diego, CA) measurements will also be taken by a single provider at the 3-month postoperative visit. The patient will also be graded on the get-up-and-go test at this time.

A prospective chart review will be performed starting at the time of enrollment and ending at the study completion date to obtain and verify the following data from NMH Medical records (PRIMES, Cerner PowerChart) and NMFF Medical Records (EpicCare, IDX/GE Centricity):

- EPIC Number
- MRN
- Medical History
- Medications
- Surgical History
- Date of Surgery
- Time taken to complete surgery
- Type of implant

- Post operative quality of prosthesis position/fixation
- Pre and post-operative lab values (Hg, plts, WBC, ESR, CRP, INR, etc)
- Complications/Reoperations
- Knee pathology: Date of onset, age of onset, any associated injuries, radiographic findings, dates and types of prior therapeutic interventions and their effectiveness.
- Physical exam: Specifically, the following information will be obtained: documentation of nerve function, strength, sensation, vascular status, pre-operative stability.
- Outcome data at final follow-up: Ambulatory aid use, orthosis use, job change as result of knee pathology, whether patient went back to work if applicable.

All data collected from chart review will be coded and noted on the Data Collection Form. All patient collected chart data as well as the PROMIS surveys will be coded. The data points will be identified by a random string of five numbers and letters that will be assigned by the PROMIS online database system.

Potential risks involved in this study include the inconvenience of completing questionnaires and stability testing, pain during stability testing, or a fall during the get up and go test. The patient's level of pain will be assessed on the visual analog scale prior to stability testing, and if the degree of pain is felt to be too great by the subject or examiner, the test will be deferred. Inquiry as to the patient's usual level of function will inform the appropriateness of the get up and go test. If the patient does not normally perform transfers into/out of chairs, then those analyses will be deferred. Any ambulation aids that the patient is accustomed to using will be made available.

One possible risk related to the patient's participation in this study is the loss of privacy. To reduce these risks, all of the information collected will be coded (the patient will be assigned a study number and all data will be linked to that number and not the patient's name) and stored in a password-protected file on a password-protected computer. Some of the questions asked may be upsetting, or the patient may feel uncomfortable answering them. If the patient does not wish to answer a question, they may skip it and go to the next question.

Additionally, both knee prostheses included in this study are in common use by orthopaedic surgeons today. Therefore, there are no additional risks involved in the use of these implants for this study.

The subjects are not likely to have any direct benefit from being in this research study. However, the use of the various assessment tools may provide a more accurate assessment of the subject's postoperative pain, function, and satisfaction, and thus help us to better describe and treat any problems that the subject may have after surgery. Beyond these benefits, the subject may benefit from the knowledge that they are helping to improve our understanding of how best to treat future patients that undergo total knee arthroplasty.

6.0 STATISTICAL PLAN

This proposed sample size is small enough to feasibly recruit over the given time period, yet large enough to correlate differences between the two groups.

Data Cleaning and Crosschecking:

Data cleaning and crosschecking will be conducted prior to analyses. These procedures will include: 1) Comparing patient counts with accrual records; 2) Grouping data by assessment and ensuring a match with the designated number of assessments: 3) Cross-checking baseline and follow-up assessment dates; 4) Ensuring correct questionnaire count match to electronic data fields; 5) Summarizing missing data and checking for definable patterns.

Statistical Analysis:
This study has the primary objective of comparing outcome measures between the MP and PS knee prostheses. We will calculate descriptive statistics for the patient characteristics and measures obtained from each group (means, SD, range). We will use the Shapiro-Wilk test to identify whether each continuous variable fits a normal distribution. We will then use a two-tailed Student's t test for parametric data or the Mann-Whitney U test for nonparametric data to compare the two cohorts. The Pearson χ^2 or Fischer's exact test will be used for categorical variables where appropriate. The level of significance will be defined at $p < 0.05$.

7.0 DATA COLLECTION & RECORD KEEPING

All information regarding the nature of the proposed investigation provided to the investigator (with the exception of information required by law or regulations to be disclosed to the IRB, the subject, or the appropriate regulatory authority) will be kept in confidence by the principal investigator. All personal information will be treated as strictly confidential and not made publicly available. All records will be stored in a locked filing cabinet and password-protected computers which are accessed only by the Principal Investigator, co-investigators, and authorized study staff. All identifiable data will be destroyed one year after the study is complete.

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APPENDICES

1. Oxford Knee Score

During the past 4 weeks.. ✓tick one box for every question

1	*During the past 4 weeks.....* How would you describe the pain you usually have from your knee? None ❑ Very mild ❑ Mild ❑ Moderate ❑ Severe ❑
2	*During the past 4 weeks.....* Have you had any trouble with washing and drying yourself (all over) because of your knee? No trouble at all ❑ Very little trouble ❑ Moderate trouble ❑ Extreme difficulty ❑ Impossible to do ❑
3	*During the past 4 weeks.....* Have you had any trouble getting in and out of a car or using public transport because of your knee? (whichever you would tend to use) No trouble at all ❑ Very little trouble ❑ Moderate trouble ❑ Extreme difficulty ❑ Impossible to do ❑
4	*During the past 4 weeks.....* For how long have you been able to walk before pain from your knee becomes **severe**? (*with or without a stick*) No pain/ More than 30 minutes ❑ 16 to 30 minutes ❑ 5 to 15 minutes ❑ Around the house only ❑ Not at all - pain severe when walking ❑
5	*During the past 4 weeks.....* After a meal (sat at a table), how painful has it been for you to stand up from a chair because of your knee? Not at all painful ❑ Slightly painful ❑ Moderately painful ❑ Very painful ❑ Unbearable ❑
6	*During the past 4 weeks.....* Have you been limping when walking, because of your knee? Rarely/ never ❑ Sometimes, or just at first ❑ Often, not just at first ❑ Most of the time ❑ All of the time ❑

1. Oxford Knee Score (Cont.)

During the past 4 weeks... ✓tick one box for every question

7 *During the past 4 weeks.....*
Could you kneel down and get up again afterwards?

Yes, Easily	With little difficulty	With moderate difficulty	With extreme difficulty	No, Impossible
❑	❑	❑	❑	❑

8 *During the past 4 weeks.....*
Have you been troubled by pain from your knee in bed at night?

No nights	Only 1 or 2 nights	Some nights	Most nights	Every night
❑	❑	❑	❑	❑

9 *During the past 4 weeks.....*
How much has pain from your knee interfered with your usual work *(including housework)*?

Not at all	A little bit	Moderately	Greatly	Totally
❑	❑	❑	❑	❑

10 *During the past 4 weeks.....*
Have you felt that your knee might suddenly 'give way' or let you down?

Rarely/ never	Sometimes, or just at first	Often, not just at first	Most of the time	All of the time
❑	❑	❑	❑	❑

11 *During the past 4 weeks.....*
Could you do the household shopping on your own?

Yes, Easily	With little difficulty	With moderate difficulty	With extreme difficulty	No, Impossible
❑	❑	❑	❑	❑

12 *During the past 4 weeks.....*
Could you walk down one flight of stairs?

Yes, Easily	With little difficulty	With moderate difficulty	With extreme difficulty	No, Impossible
❑	❑	❑	❑	❑

2. VR-12

Instructions: This questionnaire asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities.

Answer every question by marking the answer as indicated. If you are unsure how to answer a question, please give the best answer you can.

(Circle one number on each line)

1. In general, would you say your health is:

EXCELLENT	VERY GOOD	GOOD	FAIR	POOR
1	2	3	4	5

2. The following questions are about activities you might do during a typical day. Does **your health now limit you** in these activities? If so, how much?	YES, LIMITED A LOT	YES, LIMITED A LITTLE	NO, NOT LIMITED AT ALL
a. **Moderate activities,** such as moving a table, pushing a vacuum cleaner, bowling, or playing golf?	1	2	3
b. Climbing **several** flights of stairs?	1	2	3

3. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities **as a result of your physical health?**

	NO, NONE OF THE TIME	YES, A LITTLE OF THE TIME	YES, SOME OF THE TIME	YES, MOST OF THE TIME	YES, ALL OF THE TIME
a. **Accomplished less** than you would like.	1	2	3	4	5
b. Were limited in the **kind** of work or other activities.	1	2	3	4	5

4. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities **as a result of any emotional problems** (such as feeling depressed or anxious)?

	NO, NONE OF THE TIME	YES, A LITTLE OF THE TIME	YES, SOME OF THE TIME	YES, MOST OF THE TIME	YES, ALL OF THE TIME
a. **Accomplished less** than you would like.	1	2	3	4	5
b. Didn't do work or other activities as **carefully** as usual.	1	2	3	4	5

5. During the past 4 weeks, how much did **pain** interfere with your normal work (including both work outside the home and house work)?

NOT AT ALL	A LITTLE BIT	MODERATELY	QUITE A BIT	EXTREMELY
1	2	3	4	5

These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling.

6. How much of the time during the past 4 weeks:

	ALL OF THE TIME	MOST OF THE TIME	A GOOD BIT OF THE TIME	SOME OF THE TIME	A LITTLE OF THE TIME	NONE OF THE TIME
a. Have you felt **calm and peaceful**?	1	2	3	4	5	6
b. Did you have **a lot of energy**?	1	2	3	4	5	6
c. Have you felt **downhearted and blue**?	1	2	3	4	5	6

7. During the past 4 weeks, how much of the time has your **physical health or emotional problems** interfered with your social activities (like visiting with friends, relatives, etc.)?

ALL OF THE TIME	MOST OF THE TIME	SOME OF THE TIME	A LITTLE OF THE TIME	NONE OF THE TIME
1	2	3	4	5

Now, we'd like to ask you some questions about how your health may have changed.

8. Compared to one year ago, how would you rate your **physical health** in general now?

MUCH BETTER	SLIGHTLY BETTER	ABOUT THE SAME	SLIGHTLY WORSE	MUCH WORSE
1	2	3	4	5

9. Compared to one year ago, how would you rate your **emotional problems** (such as feeling anxious, depressed or irritable) **now**?

MUCH BETTER	SLIGHTLY BETTER	ABOUT THE SAME	SLIGHTLY WORSE	MUCH WORSE
1	2	3	4	5

3. IKDC Knee ligament standard evaluation form

THE IKDC KNEE LIGAMENT STANDARD EVALUATION FORM*[1]

Name:_____ first name:_____ DOB:__/__/___ med. rec. #:_____
Examiner:____date of examination:__/__/__ date of injury/ies:__/__/__ ; __/__/__ date of surgeries:__/__/__ ; __/__/__
Cause of injury : ☐ ADL*[2] ☐ traff. ☐ non-pivoting non-contact sports ☐ pivoting non-contact sp. ☐ contact sp. ☐ work
Time inj. to surg. : _____(months) ☐ acute (0-2 weeks) ☐ subacute (2-8 weeks) ☐ chronic (>8 weeks)
Knee involved : ☐ r. ☐ l. opposite knee: ☐ norm. ☐ injured exam. under anesthes.: ☐ yes ☐ no
Postop. diagnosis : _____
Surgical proced. : _____
Status menisci : norm ☐ med. ☐ lat. 1/3 removed: ☐ med. ☐ lat. 2/3 removed: ☐ med. ☐ lat. compl. rem. ☐ med. ☐ lat.
Morphotype : ☐ lax ☐ normal ☐ tight ☐ varus ☐ valgus
Activ.level*[3] : preinjury: ☐ I ☐ II ☐ III ☐ IV pretreatment: ☐ I ☐ II ☐ III ☐ IV
present: ☐ I ☐ II ☐ III ☐ IV Eventual change knee-related: ☐ yes ☐ no

GROUPS (PROBLEM AREA)	QUALIFICATION WITHIN GROUPS *[4] A: normal	B: nearly norm.	C: abnormal	D:sev. abnorm.	GROUP QUALIFIC. A	B	C	D*[4]
1. PATIENT SUBJECTIVE ASSESSMENT								
How does your knee function?	☐ normally	☐ nearly norm.	☐ abnormally	☐ sev. abnorm.				
On a scale of 0 to 3 how does your knee affect your activity level?	☐ 0	☐ 1	☐ 2	☐ 3				
2. SYMPTOMS (absence of significant symptoms, at highest activity level known by patient) *[5]								
No pain at activity level*[3]	☐ I	☐ II	☐ III	☐ IV or worse				
No swelling at activity level*[3]	☐ I	☐ II	☐ III	☐ IV or worse				
No partial giving way at activity level*[3]	☐ I	☐ II	☐ III	☐ IV or worse				
No complete giving way at activity level*[3]	☐ I	☐ II	☐ III	☐ IV or worse				
3. RANGE OF MOTION: Flex./ext.: documented side: __/__/___ opposite side: __/__/___ *[6]								
Lack of extension (from zero anatomic)	☐ <3°	☐ 3-5°	☐ 6-10°	☐ >10°				
Δ *[7] lack of flexion	☐ 0-5°	☐ 6-15°	☐ 16-25°	☐ >25°				
4. LIGAMENT EXAMINATION *[8]		3 to 5mm or	6 to 10mm					
Δ *[7] Lachman (in 25°. flex.)*[9]	☐ -1 to 2mm	☐ -1 to-3mm[10]	☐ or <-3mm	☐ >10mm				
idem (alternative measurement, optional)	☐ -1 to 2mm	☐ 3-5 /-1 to-3mm	☐ 6-10/<-3mm	☐ >10mm				
Endpoint: ☐ firm ☐ soft								
Δ *[7] total a.p.transl. in 70° flex.*[9]	☐ 0 to 2mm	☐ 3 to 5mm	☐ 6 to 10mm	☐ >10mm				
idem (alternative measurement, optional)	☐ 0 to 2mm	☐ 3 to 5mm	☐ 6 to 10mm	☐ >10mm				
Δ *[7] post. sag in 70° flex.	☐ 0 to 2mm	☐ 3 to 5mm	☐ 6 to 10mm	☐ >10mm				
Δ *[7] med. joint opening (valgus rotation)	☐ 0 to 2mm	☐ 3 to 5mm	☐ 6 to 10mm	☐ >10mm				
Δ *[7] lat. joint opening (varus rotation)	☐ 0 to 2mm	☐ 3 to 5mm	☐ 6 to 10mm	☐ >10mm				
Pivot shift *[11]	☐ neg.	☐ + (glide)	☐ ++ (clunk)	☐ +++ (gross)				
Δ *[7] reversed pivot shift	☐ equal(neg.) ☐ equal(pos.)	☐ slight	☐ marked	☐ gross				
5. COMPARTMENTAL FINDINGS *[12]								
Δ *[7] Crepitus patellofemoral	☐ none/equal	☐ moderate	☐ painful	☐ severe				
Δ *[7] Crepitus medial compartment	☐ none	☐ moderate	☐ painful	☐ severe				
Δ *[7] Crepitus lateral compartment	☐ none	☐ moderate	☐ painful	☐ severe				
6. HARVEST SITE PATHOLOGY *[13]								
Tenderness, irritation, numbness	☐ none	☐ slight	☐ moderate	☐ severe				
7. X-RAY FINDINGS (DEGENERATIVE JOINT DISEASE) *[14]								
Patellofemoral cartilage space	☐ normal	☐ > 4mm	☐ 2-4mm	☐ < 2mm				
Medial compartment cartilage space	☐ normal	☐ > 4mm	☐ 2-4mm	☐ < 2mm				
Lateral compartment cartilage space	☐ normal	☐ > 4mm	☐ 2-4mm	☐ < 2mm				
8. FUNCTIONAL TEST *[15]								
Δ One leg hop (percent of opposite side)	☐ 90-100%	☐ 76-90%	☐ 50-75%	☐ <50%				
FINAL EVALUATION								

4. Forgotten Joint Score (FJS) – Knee

Patient: _____ Date: ___.___._____

A healthy joint is not something you are aware of in everyday life. However, even the smallest problems can raise one's awareness of a joint. This means that you think of your joint or have your attention drawn to it. The following questions concern **how often you are aware of your affected knee joint in everyday life.**

Please choose the most appropriate answer for each question.

	Are you aware of your knee joint…	**Never**	**Almost never**	**Seldom**	**Sometimes**	**Mostly**
1.	… in bed at night?	O	O	O	O	O
2.	… when you are sitting on a chair for more than one hour?	O	O	O	O	O
3.	… when you are walking for more than 15 minutes?	O	O	O	O	O
4.	… when you are taking a bath/shower?	O	O	O	O	O
5.	… when you are traveling in a car?	O	O	O	O	O
6.	… when you are climbing stairs?	O	O	O	O	O
7.	… when you are walking on uneven ground?	O	O	O	O	O
8.	… when you are standing up from a lowsitting position?	O	O	O	O	O
9.	… when you are standing for long periods of time?	O	O	O	O	O
10.	… when you are doing housework or gardening?	O	O	O	O	O
11.	… when you are taking a walk/hiking?	O	O	O	O	O
12.	… when you are doing your favorite sport?	O	O	O	O	O