

PROTOCOL TITLE: A Randomized Controlled Trial Comparing Reoperation Rates and Clinical Outcomes of Rotating Hinge Versus Condylar Constrained Knee Implants in Revision Total Knee Arthroplasty

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A Randomized Controlled Trial Comparing Reoperation Rates and Clinical Outcomes of Rotating Hinge Versus Condylar Constrained Knee Implants in Revision Total Knee Arthroplasty

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REVISION HISTORY

Revision #	Version Date	Summary of Changes	Consent Change?
1	10/6/25	MHRI Monitoring Removed, SANE score added	N
2	11/05/25	Conflict of interest added	Y
3	12/09/25	Modified study duration table, removed a statement regarding withdrawal of subjects	Y

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Study Summary

Study Title	A Randomized Controlled Trial Comparing Reoperation Rates and Clinical Outcomes of Rotating Hinge Versus Condylar Constrained Knee Implants in Revision Total Knee Arthroplasty
Study Design	Prospective, randomized study
Primary Objective	To assess if rotating hinge knee (RHK) implants have similar revision rates as condylar constrained knee (CCK) implants in patients undergoing a revision total knee arthroplasty (rTKA)
Secondary Objective(s)	To assess if RHK implants have similar rates of aseptic loosening and clinical outcomes as CCK implants in patients undergoing rTKA. Determine if patient satisfaction, range of motion and knee stability are similar between the two types of implants.
Research Intervention(s)/ Investigational Agent(s)	Rotating hinge knee (RHK) implant, condylar constrained knee (CCK) implant.
IND/IDE #	Not applicable
Study Population	Adults ages 18- 80 years undergoing RTKA requiring full revision of both the tibial and femoral components.
Sample Size	186 subjects (93 subjects per group)

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Study Duration for individual participants	10 years
Study Specific Abbreviations/ Definitions	RHK: rotating hinge knee CCK: condylar constrained knee rTKA: revision total knee arthroplasty

Objectives*

The primary purpose of this study is to compare reoperation rates for rotating hinge knee implants versus condylar constrained knee implants when used in revision total knee arthroplasty. The secondary purposes are to compare patient satisfaction, loosening rates and clinical outcomes for RHK implants compared to CCK implants in rTKA. Additionally, knee range of motion and stability will be assessed and compared at all follow-up time points.

We hypothesize that RHK implants provide patients undergoing rTKA with similar reoperation rates to those of patients who receive a CCK implant. We also hypothesize that patients who receive an RHK implant will have similar loosening rates and clinical outcomes compared to patients who receive a CCK implant. Lastly, knee stability and patient satisfaction may improve with the use of a rotating hinge device.

Background*

Revision total knee arthroplasty (rTKA) is an increasingly common procedure performed in the setting of a failed prior implant, often due to issues such as infection, instability, mechanical loosening and/or general polyethylene wear.¹ Patients undergoing rTKA often present with intraoperative challenges such as bone loss, ligamentous instability, and soft tissue compromise. As a result, more constrained implants are necessary to restore knee function and joint stability, compared to those used in a primary total knee arthroplasty (TKA).

Currently, two types of constrained implants are used in clinical practice: condylar constrained knee (CCK) implants and rotating hinge knee (RHK) implants. CCK implants provide stability in the coronal plane (with minimal means for component rotation) with less constraint and have traditionally been used for cases with moderate instability or bone loss. In contrast, RHK implants feature a hinge mechanism that allows for axial rotation, offering a greater level of constraint and are typically reserved for the most complex revision cases involving severe instability, significant bone loss and/or deficient extensor mechanisms.

Although both implant types are well-established in orthopedic practice, there is currently no consensus on their relative effectiveness in similar

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clinical situations. Almost all of the current data is retrospective in nature and consists of small sample sizes only. Retrospective studies suggest that RHK implants may be associated with slightly higher rates of aseptic loosening and reoperation^{2,3} when compared to CCK implants⁴, but this may be due to differences in case complexity rather than intrinsic differences of the implant itself, as CCK implants are often used in less complex cases. Additionally, some data suggests that the opposite is true, with CCK implants having reduced survivorship compared to RHK implants.⁵

One of the most common reasons for revising a CCK implant is recurrent or new onset instability. Using more constrained implants provides greater stability, while maintaining a high level of function. Thus, using an RHK implant in more moderate cases in place of a CCK could potentially eliminate this frequent cause of re-revision and increase the longevity of the rTKA. One of the theories behind the potential lower re-revision rate is the use of adjunct fixation (porous cones) that allows enhanced fixation to prevent loosening, the freedom of rotation which may be just as important as the anterior-posterior constraint of the hinge and the modern design of the components are more advanced than prior versions.

Based on this idea that the limited rotational freedom of a CCK may be more important than the anterior-posterior constraint of an RHK; it is imperative to settle this debate in like scenarios. Historically, the RHK was used in only the worst revision cases that were deemed too unstable for a CCK device. If given the chance in the so-called easier revision cases it is likely that it will perform similar to or better than CCK constructs.

Currently, there are no prospective randomized trials directly comparing these two implant types in patients with similar clinical scenarios. This study aims to fill a crucial gap in the literature by directly comparing RHK and CCK implants in a prospective randomized, controlled study. The focus will be on implant survivorship, functional outcomes, patient-reported outcome measures and complication rates at an early time point 1-2 years and again at long-term follow-up. By enrolling patients with comparable revision indications, the study seeks to isolate implant-related performance from patient or surgical factors that may be confounding.

The findings from this study have the potential to significantly influence clinical decision-making, implant selection and future practice guidelines in revision total knee arthroplasty. Generating high-level evidence through this randomized controlled trial will contribute meaningfully to orthopedic literature and may inform surgical practices for years to come.

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Study Endpoints*

The primary endpoint is reoperation rates. The secondary endpoints are rates of aseptic loosening and clinical outcomes (range of motion, KOOS JR score, knee society score (KSS), PROMIS score, UCLA activity score, EQ5D, SANE score and radiographic assessment of fixation, any post-operative complications).

Safety endpoints include incidence of adverse and serious adverse events, reoperation rates, implant-related mechanical complications and infection rates.

Study Intervention/Investigational Agent

- 1.1 Potential subjects undergoing an rTKA procedure and require revision of both the tibial and femoral components and indicated to receive a CCK implant with one of the study investigators will be invited to participate in the study. Subjects will be randomized to one of two groups:

Group 1 (control group) will receive a condylar constrained knee device

Group 2 (treatment group) will receive a rotating hinge knee device.

The implants for both groups will be stored at the site of surgery where device implants for all patients undergoing a knee replacement are stored.

Both the RHK implant and the CCK implant are FDA approved and indicated for rTKA and manufactured by the same implant company. **Procedures**

Involved*

This study is a prospective, randomized controlled trial comparing rotating hinge knee (RHK) implants with condylar constrained knee (CCK) implants in patients undergoing revision total knee arthroplasty. All potential subjects visiting one of the study investigators, who elect to undergo a revision total knee arthroplasty, meet all inclusion criteria and no exclusion criteria, will be invited by the research staff to participate in the study. Potential subjects will be offered to participate by the research team during an office visit, by phone or by video conferencing. Potential subjects will be consented in person, by remote consent or by eConsent. A signed consent form will be obtained prior to enrollment and randomization. Potential subjects will be offered enrollment at the time of their clinic visit and will have up to two weeks before their scheduled surgery date to decide if they want to participate. Study participation will be documented in MedStar EMR. The trial will be conducted at MedStar Georgetown University Hospital (MGUH) and Medstar Montgomery Medical Center and will enroll a total of 186 patients. Subjects will attend follow-up visits that are consistent with standard of care practices for all patients undergoing rTKA. Follow-up visits will occur at 6

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weeks, 6 months, 1 year and then annually thereafter. The study is expected to last 8-10 years.

Both RHK implants and CCK implants are normally used for these type of surgeries and the choice between them is based purely on surgeon discretion. For the purposes of this study, the implant will be randomly chosen - either an RHK or a CCK implant. Randomization will be computer-generated with a random number generator. Due to the nature of the surgical intervention, the study will be single-blinded; the investigators will not be blinded but the subject will be blinded to the implant they receive until their 6-month follow-up visit. Additionally, outcome assessors and data collectors will be blinded to the implant type.

The research data will be collected using a MedStar issued, encrypted and password-protected device (research iPad, desktop, or laptop) and stored in the secure, encrypted and password-protected OBERD database. Research data includes baseline information (date of visit, age at the time of surgery, gender, race/ethnicity, BMI at the time of surgery, medical comorbidities, revision etiology) and study specific questions asked preoperatively and at each post-operative visit. The research staff will be responsible for collecting and recording the research data in OBERD.

Study evaluation	Baseline	Post-op^a				
	Within 90 days of surgery	6 weeks	6 months	1 year +/- 3 months	3, 4, 5, 6 & 7 yrs	8-10 yrs
Informed consent	X					
Physical exam	X	X	X	X	X	X
X-ray	X	X	X	X	X	X
Clinical follow-up assessing outcome measures	X	X	X	X	X	X

^AAll listed visits are the current standard of care for follow-up. Additional visits may be necessary based on the surgeon's discretion.

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On the day of surgery, study participants will follow all standard day of surgery procedures. Study participants will have their surgery performed under regional or general anesthesia, based on the anesthesiologist's and patient's discretion. All routine protocols for a patient undergoing rTKA will be followed before, during and after the surgery.

The devices that will be used are:

NexGen® Legacy® Constrained Condylar Knee by Zimmer Biomet (Group 1)

NexGen® Rotating Hinge Knee by Zimmer Biomet (Group 2)

Both devices are FDA approved and indicated in patients undergoing rTKA.

Source documentation will include:

- Electronic medical records (EMR)
- Operative reports
- Imaging records (X-rays)
- Clinic visit notes
- Patient-reported outcome forms—collected in OBERD, the standard platform at MGUH for collecting PROMs

The primary outcome of this study is reoperation rates. Secondary outcomes include loosening rates and clinical outcomes assessing patient satisfaction and functional ability. The following information will be obtained for the study pre- and post-operatively.

1. Reoperation for any reason
2. Range of motion
3. KOOS JR score
4. Knee society score (KSS)
5. PROMIS score
6. UCLA activity score
7. EQ5D
8. SANE score
9. Radiographic assessment of fixation at 1 year follow-up and then at long-term follow-up occurring 8-10 years after surgery date

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10. Any post-operative complications

Chart review will be conducted by the research staff to collect the following baseline information for the study:

1. Date of visit
2. Age at the time of surgery
3. Gender
4. Race/ethnicity
5. BMI at the time of surgery
6. Medical comorbidities
7. Etiology of revision

Follow-up visits will follow current standard of care timelines for all patients who undergo rTKA. Follow-up visits will occur at 6 weeks, 6 months, 1 year and then annually thereafter. The study is expected to last 8-10 years. All long-term data that will be collected is discussed in 6.4.

Data and Specimen Banking*

This study does not involve the banking of specimens or long-term data storage for future unrelated research.

Sharing of Results with Subjects*

Participants will be informed of the type of implant they received during their 6-month follow-up visit. Upon completion of data collection, aggregate study results may be shared with participants who submit a written request.

Study data will be disseminated to the scientific community through peer-reviewed publications and/or conference presentations. All data will be reported in aggregate, and no individual identifiers, including dates, will be included in any shared or published materials.

If study findings emerge that are determined to be clinically relevant to a participant's health, the investigators will communicate this information to the participant in a timely and appropriate manner.

Study Timelines*

The study will start following approval by the Institutional Review Board (IRB). After approval, enrollment will begin. Participants will consent to participation. Each participant will be followed from the time of enrollment through a period of 8 to 10 years postoperatively.

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Following surgery, participants will be required to attend clinical follow-up visits at approximately 6 weeks, 6 months, 1 year, and annually thereafter for the duration of the study. Clinical follow-up visits align with the current standard of care for patients who have undergone rTKA.

Intermittent analysis of the data will take place at 25, 50 and 100 cases to make sure that there are no significant differences between the two procedures.

Enrollment is expected to be completed within approximately 2 years. We anticipate full study completion by 2036-2038.

Inclusion and Exclusion Criteria*

All potential subjects visiting one of the study investigators, who elect to undergo a revision total knee arthroplasty will be screened for eligibility by a study investigator.

Potential subjects must meet all of the inclusion criteria and none of the exclusion criteria. Potential subjects who do not meet the study eligibility criteria will not be enrolled.

Inclusion criteria: Potential subjects MUST meet all of the following criteria:

1. Age 18-80 years.
2. Undergoing a revision total knee arthroplasty for any etiology
3. Requires full revision of both the tibial and femoral components

Exclusion criteria: Potential subjects MUST NOT meet any of the following criteria:

4. Undergoing a primary total knee arthroplasty
5. Candidate for only a RHK implant
6. Diagnosed with an active infection
7. Under 18 years of age
8. Over 80 years of age
9. Pregnant or breastfeeding
10. Non-independent dweller (prisoner)
11. Unable to consent

10.3 The study will not include adults unable to consent, individuals who are not yet adults, pregnant women or prisoners.

Vulnerable Populations*

Not applicable

Local Number of Subjects

We will enroll 186 subjects in the study, 93 per group.

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Any patient seeing one of the study investigators who is a candidate for rTKA will be screened. We anticipate about 20% of those screened and eligible will not participate and approximately 5-10% will drop out.

Recruitment Methods

All potential subjects visiting one of the study investigators, who elect to undergo a revision total knee arthroplasty, meet all inclusion criteria and no exclusion criteria, will be invited by the research staff to participate in the study. Potential subjects will be offered to participate by the research team during an office visit, by phone or by video conferencing. Potential subjects will be consented in person, by remote consent or by eConsent. A signed consent form will be obtained prior to enrollment and randomization. Potential subjects will be offered enrollment at the time of their clinic visit and will have up to two weeks before their scheduled surgery date to decide if they want to participate. Study participation will be documented in MedStar EMR.

The subjects are patients who are presenting to the clinic to discuss their total knee replacements.

The study investigators will determine if the patient meets the inclusion criteria and does not meet exclusion criteria during their clinic visit.

Not applicable. The subjects are patients who are presenting to the clinic on their own accord because of concerns about their current knee replacement.

No payment will be offered to the subjects.

Withdrawal of Subjects*

A subject might be withdrawn from the study without their consent if:

1. They meet any of the exclusion criteria.
2. The subject fails to complete any of the study procedures.
3. Any new information becomes available that might be harmful to the subject or may influence their willingness to continue participation in the study.

Subject(s) will be notified in person or via telephone the reason for their withdrawal from the study.

The IRB will be notified of any subject withdrawals at the time of continuing review. If a participant voluntarily withdraws or is withdrawn from the study at the discretion of the investigator, they will continue to receive standard clinical care under their treating surgeon. Partial data may be used for analysis from participants who

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have withdrawn voluntarily, been removed from the study by the investigator, or demonstrated non-compliance with study-related scheduled visits.

Risks to Subjects*

Physical risks:

Subjects will be randomized to receive one of two implant types. While both are appropriate for use in rTKA, it is possible that one implant may ultimately prove more beneficial than the other. This uncertainty presents a low but unavoidable risk that a subject may not receive the implant that, in hindsight, would have offered them the best outcome.

There are inherent surgical risks associated with undergoing a total knee replacement. These risks are related to the procedure itself and not caused by participation in this study.

Surgical procedures, in general, carry risks which may include infection, bleeding, undesirable cosmetic results, allergic reactions, cardiac arrest and even death.

Expected risks associated with this procedure include but are not limited to swelling, pain, discomfort and a visible scar. Common risks also include bleeding and hematoma.

Uncommon risks include infection of the incision, joint or bone; dislocation of the kneecap or the knee joint; damage to nerves or vascular structures; fractures caused by surgical instruments, hardware or implants during the procedure; undesirable cosmetic effects including limb length discrepancies; the prosthesis may loosen, move, break or wear out; venous thrombosis (blood clot) and pulmonary embolism (clot in the lungs) any of which may require additional treatments, procedures or surgery.

Subjects will be required to attend clinical follow-ups and receive imaging at certain time points. However, the physical risks associated with the clinical follow-ups and imaging are not increased by study participation as these are standard of care for any rTKA. The radiation dose is low and well within accepted clinical safety standards.

Psychological and Social Risks:

There are no direct psychological risks anticipated, but some participants may experience mild anxiety related to study participation, data monitoring, or follow-up imaging results.

Privacy risks are minimal due to the use of secure, HIPAAcompliant data systems and appropriate de-identification of research data.

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Any surgical procedure can have unforeseen risks such as adverse or allergic reaction, or even death in rare circumstances. These events will be documented and reported to the IRB as per “Adverse Event Evaluation and Reporting” policy.

As with any surgery, undergoing an rTKA may pose indirect risks to a pregnant woman or developing fetus due to physiologic stress, anesthesia, or potential postoperative complications. We do not plan to enroll pregnant women, women who are planning to become pregnant while enrolled in the study, or women who are breastfeeding.

Not applicable.

Potential Benefits to Subjects*

Potential benefits include increased stability in the subjects randomized to Group 2 (treatment group) thereby decreasing the risk of revision and increasing quality of life.

All participants have the potential and are likely to benefit from receiving an rTKA regardless of the treatment group that they are in.

We expect that the procedure, regardless of the implant type, will lead to increased range of motion and knee functionality, and decreased pain for most subjects.

Data Management* and Confidentiality

Biostatistics support will be provided by MedStar Health Research Institute (MHRI). Power analysis was performed by the biostatistical support group to determine the sample size needed so that the study would be adequately powered to detect a clinically relevant difference. Based on a 5% equivalence margin and powered at 80% with a two-sided significance level (α) of 0.05, the study will enroll 186 patients to sufficiently detect equivalence in reoperation rates between groups.

All statistical analyses will be conducted using validated software such as R. All nominal variables (e.g., sex, race, comorbidities) will be compared between groups using chi-squared or Fisher’s exact tests. Baseline continuous variables (e.g., age, BMI) will be compared using independent samples t-tests or Wilcoxon rank-sum tests, as appropriate.

Continuous clinical and patient-reported outcomes (e.g., KOOS JR, KSS, PROMIS, ROM) will be analyzed using linear mixed-effects models to account for repeated measures across timepoints. Ordinal outcomes such as radiographic assessments and UCLA activity scores will be assessed using proportional odds models. Binary

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outcomes (e.g., loosening, complications) will be modeled using generalized estimating equations (GEE) or mixed-effects logistic regression to account for intra-subject correlation and repeated assessments.

Time-to-event variables (e.g., time to reoperation) will be analyzed using Kaplan-Meier survival estimates and Cox proportional hazards models to evaluate between-group differences in event timing.

Research staff will collect and record the data in its data center on secure servers operated behind the MedStar firewall. All research data will be entered into the secure OBERD database and MedStar electronic systems, all of which require user ID and password authentication. Access to research data will be restricted to IRB-approved study personnel only. Any physical documents will be kept in locked offices or cabinets with limited access. When necessary, research data and protected health information (PHI) will be transmitted via secure, MedStar-authorized email systems.

The research staff will review the data periodically to ensure that it is being generated, collected, and handled per the protocol. Intermittent analysis will occur at 25, 50 and 100 cases. Data will also be reviewed for integrity and completion.

Research records will be maintained the longer of Federal regulation, state statute, sponsored contract terms, or institutional policy. Research data and records will be destroyed as per MedStar Health Corporate Policy "Record Retention and Destruction Policy".

Provisions to Monitor the Data to Ensure the Safety of Subjects*

Research staff will periodically review the study data to ensure accuracy, completeness, and participant safety. If a significant reoperation rate is observed in Group 2 (the treatment group), the study will be suspended.

To protect participant confidentiality, all paper records will be securely stored in locked offices or cabinets. Electronic data will be maintained in secure, password-protected platforms, including OBERD and the MedStar EMR systems (MedConnect and PACS).

Any adverse events, serious adverse events, or protocol deviations will be promptly reported to the IRB in accordance with the institutional "Adverse Event Evaluation and Reporting" policy.

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Provisions to Protect the Privacy Interests of Subjects

19.1 Potential subjects will be approached privately during their scheduled clinical visits. Only study team members with IRB approval and appropriate training in human subjects research will be permitted to approach potential participants and discuss study details.

19.2 Informed consent will be obtained in a private setting where participants can freely ask questions without being overheard. At no point will personal health information be discussed in public or non-clinical areas. They will be given as much time as needed to ask questions. They will also have time between enrollment and the procedure to have further questions answered.

Once a participant is enrolled, medical records will be reviewed to collect baseline information. Study participants will be asked certain routine and study related questions pre-operatively and at their routine post-operative follow-ups at 6 weeks, 6 months, 1 yr and annually thereafter. Routine x-rays, collected preoperatively and 1-2 years post-operatively or at the discretion of the treating physician, will be reviewed for the purposes of the study. Medical records will not be reviewed for any information beyond the study specific requirements. Other than the routine and research related questions, participants will not be required to complete additional study forms/procedures during their enrollment period.

19.3 All study team members working with the study have completed the appropriate CITI training. Research staff is obligated to comply with MedStar's policy on breach of data security notification and mitigation and will utilize only MedStar assigned user ID and password protocols to access study data.

Research data will be stored in secure password protected OBERD and MedStar EMR (MedConnect) databases. The research staff will record study information in OBERD using a MedStar issued, encrypted and password-protected device (research iPad, desktop, or laptop). No identifiable health information will be shared outside of the research team. Subjects will be informed that participation is voluntary and that they may decline to answer any questions they are not comfortable with, or withdraw from the study at any time, without affecting their clinical care.

Compensation for Research-Related Injury

Participants will not be compensated for any medical or psychological adverse events or serious adverse events.

Economic Burden to Subjects

Participation in this study is not expected to result in any additional costs beyond those associated with standard medical care. Any expenses

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incurred by participants, such as co-pays or out-of-pocket costs, will be determined by their individual insurance coverage. All preoperative and postoperative clinic visits, including imaging studies, are considered routine components of care for rTKA.

Consent Process

The study Will be following “SOP: Informed Consent Process for Research (HRP-090)”. A written informed consent will be obtained prior to enrollment and randomization. Potential subjects will be offered enrollment at the time of their clinic visit and will have up to two weeks before their scheduled surgery date to decide if they want to participate.

Potential subjects will be provided with the contact information of the principal investigator, study investigators, and the study coordinator(s) in case they have any study-related questions or concerns. Potential subjects will be invited to participate by the research team during an office visit, by phone or by video conferencing. Potential subjects will be consented in person as per MG.O-004.01 or by remote consent or eConsent (MHRI approved method) as per MG.O-004.06. A signed informed consent (MG.O004.01 or MG.O004.06) will be obtained prior to enrollment and randomization. In the event we are not able to obtain documentation of consent at the time of a phone conversation, we will document the conversation using the institutional approved attestation form. If the subject agrees, we will ask them to sign either a paper consent or eConsent prior to the subject taking part in research procedures. Informed consent forms will be stored in locked cabinets/offices. Participants can opt out of the study at any time.

Process to Document Consent in Writing

23.1 The study will follow “SOP: Written Documentation of Consent (HRP-091)” or (MG.O-004.06 / MG.O-004.06 FM1) Remote Informed Consent Process. A copy of the informed consent form will be provided to subjects.

HIPAA Authorization

Request for a Partial Waiver of HIPAA Authorization: regardless of IRB review category, for a chart review study involving Protected Health Information (PHI) a Waiver of HIPAA Authorization for the use or disclosure of PHI needs to be requested and obtained. The following elements from 45 CFR 164.512 (i) (1) (i) must be met for the IRB to waive the requirement:

Protected health information (PHI) will never be shared outside the research team, nor will it be used for analysis, reporting or publication. Each subject will be de-identified, and access to data will be limited to the research team.

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PHI will be destroyed at the conclusion of data collection. These are only collected to verify age, and to ensure that no subject is enrolled more than once.

Research data will be retained for 2 years after publication, or longer, depending on institutional, state, or federal guidelines at the time. Then, they will be removed by permanent deletion. Paper ICFs will be discarded into the shredding service contracted by MedStar Health at the time.

This study involves reviewing non-sensitive data. The only risk to this study is confidentiality risk, which is minimized through using standard HIPAA provision and data security. All MedStar HIPAA policies will be followed. Study documents are saved on password protected drives, no identifiable data will be transferred from the covered entity and access is restricted to personnel listed on the IRB-approved study.

We request a partial waiver of written consent, so that we may review medical records to identify potentially eligible subjects. Requiring consent prior to screening will pose unnecessary difficulties for both the potential subjects and the research team.

Names, dates of birth, and medical record numbers will be used to ensure that no duplicate enrollments occur. Dates of birth will also be used to verify a subject's age. Without access to PHI, the research team may have difficulty tracking subjects, and duplicate enrollments may occur, compromising data integrity.

Setting

Research participants will be identified and recruited at MedStar sites where the principal investigator and the sub-investigators practice: Medstar Georgetown University Hospital and Montgomery Medical Center. The surgical procedures will be performed at MGUH and Medstar Montgomery Medical Center. Follow-up visits will take place at MGUH and Medstar Montgomery Medical Center. Research data will be collected at MGUH and Medstar Montgomery Medical Center. No outside regulatory bodies will be involved. No community advisory board will be used.

Resources Available

Potential subjects will be identified and recruited through high-volume orthopedic practices affiliated with the study investigators. At MedStar Georgetown University Hospital (MGUH), approximately 60 to 100 patients per year are expected to meet eligibility criteria for the study. Based on this projection, we estimate that enrolling 186 subjects will require approximately two years.

The total duration of the study is anticipated to be 8 to 10 years, which includes data collection, reconciliation, analysis, and

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dissemination of findings through scientific presentations and/or publications.

All research data will be collected and managed using a MedStar issued, encrypted, and password-protected device (e.g., research iPad, desktop, or laptop), ensuring compliance with institutional data security standards.

Research staff will be fully trained in all study protocols and procedures. Only IRB-approved study personnel will be involved in study activities. These individuals will be provided with the IRB approved protocol, consent forms, and study materials for review. Regular meetings and oversight by the principal investigator will ensure adherence to the protocol and consistent application of research procedures.

All study procedures will be conducted within the facilities of MGUH and Montgomery Medical Center, which include outpatient orthopedic clinics, operating rooms, and imaging services necessary for routine pre- and post-operative care. Should any unanticipated clinical issues arise, appropriate medical and psychological support services are available on-site through the institution's comprehensive care network.

Multi-Site Research*

Not applicable.

Conflict of Interest Disclosure

Dr. Brett Levine serves as a paid consultant for Zimmer Biomet, the manufacturer of the NexGen® Legacy® Constrained Condylar Knee and the NexGen® Rotating Hinge Knee devices used in this study. However, this study is not sponsored or funded by Zimmer Biomet. The research will be conducted independently within MedStar hospitals. No study data, analyses, or results will be shared with Zimmer Biomet at any point during or after the study.

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