PROTOCOL TITLE:

Comparison of clinical and radiographic results of collared and collarless femoral stems in total hip arthroplasty

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REVISION HISTORY

Revision #	Version Date	Summary of Changes	Consent Change?
1	10/16/2025	Added device and 510(k) information	No
2	11/12/2025	Added risk of randomization	Yes
3	12/10/2025	Included option for electronic consent with Interlace	Yes

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1.0 Study Summary

Study Title	Comparison of clinical and radiographic results of collared and collarless femoral stems in total hip arthroplasty
Study Design	Randomized controlled trial
Primary Objective	SA1: Prospectively assess clinical outcomes in patients undergoing primary total hip arthroplasty with a collared versus collarless femoral stem of the same design.
Secondary Objective(s)	SA2: Evaluate serial radiographs to quantify differences in subsidence between collared and collarless implant groups. SA3: Report and compare incidence rates of intraoperative and postoperative periprosthetic fractures and aseptic loosening following primary total hip arthroplasty with use of either a collared or collarless stem.
Research Intervention(s)/ Investigational Agent(s)	N/A
IND/IDE #	N/A
Study Population	Adults (≥18 years) undergoing primary total hip arthroplasty with use of collared or collarless femoral stem.

Sample Size	100
Study Duration for individual participants	Preoperative consent to completions of postoperative followup (up to 1 year per patient)
Study Specific Abbreviations/ Definitions	THA – Total Hip Arthroplasty PPF – Periprosthetic Fracture

2.0 Objectives*

SA1: Prospectively assess clinical outcomes in patients undergoing primary total hip arthroplasty with a collared versus collarless femoral stem of the same design.

SA2: Evaluate serial radiographs to quantify differences in subsidence between collared and collarless implant groups.

SA3: Report and compare incidence rates of intraoperative and postoperative periprosthetic fractures and aseptic loosening following primary total hip arthroplasty with use of either a collared or collarless stem.

Hypothesis: The addition of a collar to the same designed triple-taper primary hip stem will lead to a reduction in subsidence and incidence of perioperative and periprosthetic femur fractures.

3.0 Background*

Total hip arthroplasty (THA) is a widely successful and common orthopedic intervention used to replace damaged hip joints with artificial components; however, femoral component-related complications such as early subsidence, aseptic loosening, and periprosthetic femoral fractures (PPFs) continue to challenge long-term outcomes. Recent attention has focused on femoral stem design modifications—particularly the addition of a collar—to enhance primary stability and reduce the risk of early failure. The rationale for collar usage lies in its theoretical ability to provide mechanical support at the calcar, thereby preventing stem migration and improving load transfer in uncemented femoral stems.

The release of the ACTIS Hip Stem (DePuy Synthes, 2018) has contributed to a resurgence in the use of collared stems, prompting renewed clinical inquiry into their comparative performance. Despite encouraging early results, the current evidence remains incomplete. Notably, most data derive from retrospective series or registry-based analyses, which are inherently subject to selection bias and inconsistent reporting standards, particularly concerning intraoperative PPFs and stem revisions. Additionally, DePuy Synthes has recently released the exact same stem without a collar for similar use in primary THA.

Recent studies suggest that collared stems may indeed reduce the incidence of PPFs. Favroul et al. observed a significantly lower 90-day PPF rate in the collared stem group (0.4%) compared to the collarless group (1.6%) in a cohort of 1,623 THAs ($p = 0.048$). Aseptic loosening, a leading cause of THA failure, may also be mitigated by the use of a collared design. In a Swiss National Joint Registry study of over 30,000 THAs, collared Corail™ stems had a significantly lower revision rate for aseptic loosening (0.47%) than collarless stems (0.73%; $p = 0.022$). Perhaps most compelling is the growing body of evidence linking collared stems to reduced femoral stem subsidence—an early indicator of mechanical instability and a predictor of later aseptic loosening. A randomized controlled trial using radiostereometric analysis (RSA) found that collared stems exhibited significantly less subsidence than collarless stems at two weeks postoperatively (mean difference 2.23 mm; $p = 0.023$), although the difference diminished by one year. Additional studies using non-invasive EBRA (Ein-Bild-Röntgen-Analyse) confirm that collared stems consistently demonstrate lower average subsidence over 6 to 18 months.

Despite promising preliminary data, several gaps in the literature persist. For example, intraoperative PPFs are typically treated intraoperatively and may lead to a change in the femoral component type that is utilized. Oftenly, this is not captured in retrospective reviews or during chart assessment even with prospectively collected data. Such arguments support the necessity of a controlled, prospective study directly comparing collared and collarless stems with standardized measurement of femoral stem subsidence and documentation of associated complications such as aseptic loosening and PPF. Furthermore, the clinical significance of early migration differences observed with various imaging modalities has not been fully elucidated, nor has their correlation with long-term outcomes been firmly established.

This proposed randomized controlled trial seeks to address these gaps by comparing the clinical and radiographic outcomes of collared versus collarless femoral stems in THA, using femoral stem subsidence as the primary endpoint and incidence rates of PPF, aseptic loosening, and PROMs as key secondary endpoints. By employing standardized radiographic measurements and robust follow-up, this study will offer high-quality evidence to inform implant selection and optimize surgical outcomes. It will also contribute to the development of clinically relevant thresholds for subsidence that can serve as early predictors of implant failure.

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4.0 Study Endpoints*

Study Endpoints

- Primary: Measurement of femoral stem subsidence at 6 weeks, 6 months, and 1-year post-operation

- Secondary: Incidence rates of periprosthetic fractures, incidence rates of aseptic loosening, and patient-reported outcome measures (PROMs)– collected in OBERD.

Safety Endpoints – N/A

5.0 Study Intervention/Investigational Agent - N/A

	Applicable to:		
FDA Regulation	***IND Studies***	***IDE studies***	***Abbreviated IDE studies***
21 CFR 11	***X***	***X***	
21 CFR 54	***X***	***X***	
21 CFR 210	***X***		
21 CFR 211	***X***		
21 CFR 312	***X***		
21 CFR 812		***X***	***X***
21 CFR 820		***X***	

The collared and collarless femoral stem implants that will be used in this study are FDA-approved for standard use in primary THA. The 510(k) number for the collared hip stem is K150862 and for the collarless version is K21058. Thus, both hip prosthetics are not HUDs and do not have IDE or HDE numbers. No other investigational drugs or devices will be administered.

6.0 Procedures Involved*

This study is a prospective, randomized controlled trial comparing the clinical and radiographic outcomes of a collared versus collarless femoral stems of the same design in primary THA. A total of 100 participants undergoing elective, uncemented primary THA for degenerative hip disease will be enrolled. Participants will be randomized in a 1:1 ratio to receive either a collared femoral stem or a collarless femoral stem. All patients indicated for a cementless primary total hip arthroplasty will be offered enrollment. Once consented, they will be randomized into the collared or collarless stem groups. Study participants will be informed about the risk of randomization due to removing the elements of choice from the clinician, as outlined in the informed consent form.

The primary endpoint is femoral stem subsidence, measured at postoperative 6week, 6-month, and 1-year clinical visits, which coincide with standard of care routine follow-up. Secondary endpoints include the incidence of PPF and aseptic stem loosening within the first postoperative year. Again, all research procedures are designed to align with standard perioperative and postoperative care for THA, minimizing burden for study participants. Additionally, the ACTIS Hip Stem (DePuy Synthes, Warsaw, IN) is routinely used by the participating surgeons for the last 3-4 years. The following outlines the specific protocol steps and time points:

Preoperative (Day -30 to 0):

- Obtain written informed consent either in person or via Interlace.
- Confirm eligibility criteria (inclusion/exclusion).
- Record baseline demographic data, diagnosis, and Dorr classification (from preop imaging).
- Randomization and group assignment.

Operative Day (Day 0):

- THA performed using the allocated femoral stem type (collared or collarless), via a standard surgical approach.
- Per standard practice, intraoperative documentation of any complications, including intraoperative PPFs, will be recorded by the surgical team.

Postoperative Follow-Up:

- Routine anterior-posterior (AP) pelvic and lateral hip X-rays will be obtained at 6 weeks, 6 months, and 1 year.
- Subsidence will be quantified using standardized radiographic measurement techniques. Typically, radiographs are obtained at 6 weeks, 6 months and annually thereafter. Calibration will be performed with the known femoral head size and subsidence measured by standard techniques on these serial radiographs.

Adverse Event Monitoring (Ongoing):

- Any PPFs or aseptic loosening will be identified through clinical assessment, imaging review, and/or surgical reports, and reported by trained investigators or study staff.
- Participants will be advised to report any fall or unusual hip symptoms. Any clinically indicated imaging or intervention will be reviewed for endpoint classification.

Risk Minimization:

- All surgeries will be conducted by experienced orthopaedic surgeons within the MedStar Health System (MedStar Georgetown University Hospital and MedStar Washington Hospital Center) to minimize procedural variability.

- Standard sterile technique and perioperative protocols will be followed.
- Follow-up visits coincide with routine care to minimize patient burden.
- Radiographic measurements will be conducted by independent reviewers to reduce measurement error and bias.
- There is no additional physical risk to participating in this study beyond standard of care.
- The primary risk is a potential breach of confidentiality. To minimize this risk, all data will be de-identified and stored on password-protected, HIPAA-compliant platforms. Participants will be assigned a unique study ID (SID), and any linkage to identifiable information (e.g., MRN) will be stored separately in a secured, password-protected file. No patient names or identifiers will be recorded on any data collection forms.
- Study participants will be made aware about the risk of randomization for the implant they will receive. By participating in the study, the surgeons will not be able to choose the implant.

Devices Used:

- Collared and collarless femoral stems, both commercially available and FDAcleared for primary THA use–the ACTIS Hip Stem that comes in both a collared and collarless variation, will be used.
- Both stem types are used in current clinical practice and do not represent investigational use.

Source Records:

- 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 MedStar for collecting PROMs

Data Collected:

- Demographics and clinical variables: age, sex, BMI, comorbidities, Dorr classification.
- Operative data: stem type, surgical approach, intraoperative complications.
- Primary endpoint: femoral stem subsidence at 6 weeks, 6 months, and 1 year, measured in millimeters from standardized serial radiographs.
- Secondary endpoints:
    - PPF incidence (confirmed radiographically or operatively).
    - Aseptic loosening (evidenced by radiolucent lines, implant migration, or revision surgery).
- Other outcomes: functional scores (PROMs), adverse events, and reoperation rates.

Data Collection Methods:

- Radiographic analysis performed by independent reviewers blinded to group allocation.
- Adverse events recorded by research staff at each visit and during any interim visits.

Long-Term Follow-Up — Patients will follow standard protocol for follow-up, offering the possibility of more longitudinal reporting potentially 5-10 years postop.

Humanitarian Use Device (HUD) — N/A
This study does not involve any HUDs. All devices used (collared and collarless femoral stems) are FDA-approved for standard use in primary THA and do not require an Investigational Device Exemption (IDE). The 510(k) number for the collared hip stem is K150862 and for the collarless version is K21058.

7.0 Data and Specimen Banking – N/A

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

8.0 Sharing of Results with Subjects*

Study results relating to the participant's individual subsidence measurements or clinical outcomes may be shared at their discretion. This will be done privately and confidentially; results of any other participants will not be shared.

9.0 Study Timelines*

Each participant will be involved in the study for approximately 1 year, from the time of surgery through standard postoperative care. Data will be collected at preop, 6 weeks, 6 months, and 1-year post-op, coinciding with already scheduled clinic visits. The anticipated amount of time to enroll all subjects is 1 year, with the total duration of the project estimated to be 2 years.

10.0 Inclusion and Exclusion Criteria*

Potential participants will be identified from the MedStar Orthopaedic Surgery clinics at MGUH and MWHC. Screening will occur during routine preoperative consultation visits for patients scheduled to undergo primary, uncemented THA due to osteoarthritis or other non-inflammatory degenerative joint disease. Patients will be screened by the study investigator or trained research coordinator. Screening will involve review of the EMR for clinical and radiographic eligibility,

verification of surgical plan, preoperative radiographic assessment, and assessment of patient capacity to provide informed consent. Patients who meet all inclusion criteria and none of the exclusion criteria will be approached for informed consent and formally enrolled after confirming eligibility.

Inclusion Criteria:

- Adults (≥ 18 years old) scheduled for primary, uncemented THA using a cementless femoral stem.
- Diagnosis of primary osteoarthritis or other non-inflammatory degenerative joint disease.
- Ability and willingness to comply with study procedures and follow-up schedule.
- Ability to provide written informed consent.

Exclusion Criteria:

- **Patients not indicated for a cementless THA**.
- Prior surgery on the ipsilateral hip (e.g., prior THA, internal fixation, osteotomy).
- Use of cemented or hybrid femoral components.
- Revision THA or conversion THA.
- Active or prior infection of the hip joint.
- Severe osteoporosis (T-score ≤ −2.5) or known metabolic bone disease.
- Inability to complete follow-up or anticipated relocation out of the area.

Special Populations:
The following special populations will be excluded from participation in this study: adults unable to provide consent, anyone under the age of 18, and pregnant women.

11.0 Vulnerable Populations* - N/A

12.0 Local Number of Subjects

For this study we aim to enroll 100 participants (50 per group) undergoing primary, cementless THA across two MedStar sites, MedStar Georgetown University Hospital and MedStar Washington Hospital Center. All participants will be screened at the time of surgical scheduling and enrolled if they meet the criteria and consent to participate. This target number of 100 participants accounts for any dropouts throughout the study. Based on our power calculation (assuming 80% power, significance of 0.05, and a SD of 0.45 mm based on prior studies), a sample size of at least 20 subjects per group (40 in total) would be needed to complete the research procedures.

13.0 Recruitment Methods

Recruitment will occur during standard preoperative clinic visits at the Department of Orthopedic Surgery at MGUH and MWHC. Potential subjects will be identified weekly by IRB-approved research staff by screening cinic appointments. Patients scheduled for primary, uncemented THA will be approached during these visits. Recruitment will begin after IRB approval and continue until the target enrollment of 100 participants is reached. Each potential participant will be approached in-person by a study investigator or trained research coordinator prior to surgery, typically 2–4 weeks in advance.

The study will be described in detail, and eligible patients will be provided with a written informed consent form and ample time to ask questions. If interested, they may sign the consent form at that time or take it home and return it during a subsequent visit. Patients may also choose to complete an electronic consent form

that can be sent to their emails through a secure MedStar consenting platform, Interlace.

All subjects will be under the routine clinical care of orthopaedic providers at the study institution and will be recruited without deviation from the standard clinical pathway for surgical planning and follow-up. Recruitment will occur entirely through face-to-face interaction during clinic visits, with no use of public advertisements, social media, or media broadcast. No posters or flyers regarding the study will be distributed.

No monetary compensation will be provided to participants for their involvement in this study.

14.0 Withdrawal of Subjects*

A subject may choose to withdraw from the study at any time. Withdrawal of a subject will have no effect on their clinical care or clinical decision making.

Subjects may also be withdrawn from the study without their consent under the following circumstances:

- Intraoperative change in surgical plan, such as conversion to a cemented or hybrid femoral stem, revision THA, or significant intraoperative complications rendering the assigned study implant unusable.
- Failure to attend postoperative follow-up appointments necessary for primary or secondary outcome data collection.
- Medical conditions or complications (e.g., infection, stroke, malignancy) that significantly impact the participant's ability to safely continue study participation or follow the protocol.
- Protocol violation identified by the research team that invalidates study participation (e.g., unintentional enrollment of an ineligible subject).

In all such cases, the reason for withdrawal will be documented in the subject's research file and medical record.

15.0 Risks to Subjects*

Since this study aligns with standard of care for THA procedures, and no investigational devices or additional interventions are introduced beyond routine care, participation in the research carries minimal risk. However, the following potential risks and inconveniences apply:

Physical Risks:

- Radiation exposure from X-rays: Although all imaging is part of routine clinical follow-up and not performed solely for research purposes, participants will

- undergo three radiographic evaluations (6 weeks, 6 months, and 1 year). The radiation dose is low and well within accepted clinical safety standards.

  Standard surgical risks: These include pain, infection, dislocation, periprosthetic fracture, implant loosening, nerve or vascular injury, and deep vein thrombosis (DVT). However, these risks are inherent to any THA procedure and are not elevated by study participation.
- Increased awareness of complications: Participation may involve increased attention to postoperative outcomes, which could potentially lead to increased anxiety regarding complications.
- Risk of randomization: This study removes the elements of choice from the practicing surgeon. Currently, there is no definitive data based on prospective studies that suggests that one is better than the other. While improvement of symptoms is expected for both implants for all patients, there may be general differences in the clinical and radiographic results between the two.

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 followup imaging results.
- Privacy risks are minimal due to the use of secure, HIPAA-compliant data systems and appropriate de-identification of research data.

16.0 Potential Benefits to Subjects*

There is no guaranteed direct benefit to participants for taking part in this research study. The primary goal of this study is to generate knowledge that may improve care for future patients undergoing THA. While this research study is designed primarily to gather knowledge on the comparative outcomes of collared versus collarless femoral stems in total hip arthroplasty (THA), there may be limited, indirect benefits to individual participants. These potential benefits include:

- Increased clinical oversight: Study participants may experience enhanced monitoring through standardized radiographic follow-up and evaluation by trained research staff, which could aid in early identification of implant-related complications.
- Educational benefit: Participants may gain a greater understanding of their surgical procedure and postoperative course through discussions with the study team.

17.0 Data Management* and Confidentiality

Femoral stem subsidence will be the primary outcome, measured in millimeters at 6 weeks, 6 months, and 1 year postoperatively. Differences in mean subsidence between the collared and collarless groups will be assessed using independent samples t-tests or nonparametric alternatives if assumptions of normality are not met. Incidence of PPF and aseptic loosening will be compared using chi-square tests or Fisher's exact tests. Logistic regression or Cox proportional hazards modeling will be used to adjust for covariates such as age, BMI, Dorr classification, and surgical approach if sample size allows. A sample size of 20 participants per group (40 total) provides 80% power to detect a difference of 0.4 mm in mean stem subsidence, assuming a standard deviation of 0.45 mm (based on prior RSA-based studies), with $\alpha = 0.05$. A proposed target enrollment of 100 participants is set to account for unforeseen dropouts.

All study team members will be trained in HIPAA compliance and Good Clinical Practice (GCP). Electronic data will be stored in a secure, password-protected, encrypted research database hosted on institutional servers. Subject identifiers (e.g., name, MRN) will be stored separately from study data and linked only via a unique coded identifier. Transmission of data between team members or collaborators will occur via encrypted institutional email or secure file-sharing platforms. No data will be shared externally without IRB and institutional approval.

Information Included:

- Demographic data, medical history, surgical details, implant type, radiographic images and measurements, and clinical outcomes (e.g., fracture, loosening, revision surgery).

Storage Location and Method:

- Data will be stored on secure, password-protected, encrypted institutional servers.
- Only authorized members of the research team listed on the IRB application will have access.
- The PI will oversee access and approve any data sharing requests.

18.0 Provisions to Monitor the Data to Ensure the Safety of Subjects – N/A

This proposed research study does not involve more than minimal risk to subjects, since it aligns with standard of care for THA procedures.

19.0 Provisions to Protect the Privacy Interests of Subjects

The following steps will be taken to respect and protect the privacy interests of all participants:

- Recruitment and consent discussions will occur in private clinic rooms during routine preoperative visits. Discussions will be conducted in a quiet, confidential setting to ensure that participants are comfortable and not overheard by others.
- Personal and health-related information will be obtained only by authorized research staff who are trained in HIPAA and human subjects research protections.

  Subjects will be informed that their participation is entirely voluntary and that they may decline to answer any questions or withdraw at any time without affecting their care.
- Only the minimum necessary identifiable information will be collected to achieve the study aims.
- Identifiers will be removed or replaced with coded subject IDs during data analysis and publication to prevent disclosure of personal information.

To help subjects feel comfortable and reduce any sense of intrusiveness during research interactions:

- Study procedures are designed to align with routine clinical care, minimizing additional burden or deviation from normal patient experiences.
- The research team will introduce themselves clearly, explain the purpose of the study, and emphasize that participation is optional and will not affect their surgical care or relationship with providers.
- Written and verbal information will be provided in clear, respectful language. Ample time will be given for questions.
- Subjects will be reminded that they can decline to answer any questions or stop participation at any time.
- Follow-up assessments rely on clinical imaging and observations already performed as part of standard care, eliminating the need for sensitive questioning or intrusive examinations.

The research team will access subject information through the following authorized and IRB-approved means:

- MedConnect (EMR): Used to review demographic data, surgical details, imaging, clinical outcomes, and follow-up attendance.
- Study-Specific Forms and Surveys: Any forms collected directly from subjects will be securely stored and managed by the study team. Access will be limited to IRB-approved personnel listed on the protocol, and all team members will be trained in HIPAA compliance and institutional data security protocols.

20.0 Compensation for Research-Related Injury – N/A

21.0 Economic Burden to Subjects – N/A

22.0 Consent Process

Written informed consent will be obtained from all study participants prior to enrollment in the research study. The consent process will take place in a private clinical examination room during a preoperative orthopedic clinic visit, prior to the subject's scheduled THA procedure. Participants may also elect to sign consent forms electronically via Interlace. Participants will be given the opportunity to review the consent form during their clinic visit, with a minimum waiting period of 24 hours offered before they decide whether to participate. If a subject prefers, they may take the consent form home for further review and return at a subsequent visit to provide consent.

At each study visit (6 weeks, 6 months, 1 year), the research staff will reaffirm the subject's willingness to continue participation. Any changes to the study protocol or new risk information will be communicated to participants with an IRBapproved amended consent process if applicable. The research team will follow SOP: Informed Consent Process for Research (HRP-090) as required by the IRB and institutional policy.

Only the PI or designated, IRB-approved study coordinators will conduct the consent process. Participation will be presented as completely voluntary, with emphasis that declining to participate will have no impact on clinical care or the surgeon-patient relationship. For the study we will only consent patients who speak English, are not cognitively impaired, and are able to provide consent on their own.

23.0 Process to Document Consent in Writing

Yes, this study will follow SOP: Written Documentation of Consent (HRP-091). Informed consent will be documented using an IRB-approved written consent form, which includes all required elements of informed consent per 45 CFR 46.116. The consent form will be signed and dated by the participant and the member of the study team obtaining consent.

Although this research study is minimal risk and aligns with standard clinical care, it involves allocation to different standard-of-care implants and radiographic assessments used to measure the primary endpoint. Therefore, written documentation of informed consent will not be waived.

The study team believes that full written consent is appropriate and necessary for transparency and to maintain subject trust. A written consent document will be

- submitted with this application using the institution's template consent document (HRP-502).

24.0 HIPAA Authorization – N/A

25.0 Setting

All research activities will be conducted at MedStar Health-affiliated institutions specifically within the Department of Orthopedic Surgery at MGUH and MWHC. These institutions are fully equipped for conducting prospective clinical research involving surgical procedures and are HIPAA-compliant with IRB oversight. Subjects will be identified and recruited during preoperative orthopedic clinic

visits, which are part of routine care for patients scheduled to undergo primary uncemented THA.

26.0 Resources Available

We anticipate screening approximately 100 patients in order to enroll at least 50 participants in adherence to our power calculation. MGUH and MWHC sees an ample number of patients for THA that should allow us to reach our target number within the stated timeframe (approximately 1 year). The total allotted timeframe we are devoting to conducting and completing this research is 2 years. Additional research members can be recruited as needed from the Georgetown School of Medicine and will be updated to the IRB.

27.0 Multi-Site Research – N/A