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Statistical Analysis Plan (SAP)

Prospective, Randomized, Multi-center Post-Market study of Anterior Advantage Surgical Approach in Total Hip Arthroplasty with and without the KINCISE™ Surgical Automated System.

Protocol Version: REV 2

SAP Revision: 2

SAP Revision Date: 15JUN2022

Prospective, Randomized, Multi-center Post-Market study of Anterior Advantage Surgical Approach in Total Hip Arthroplasty with and without the KINCISE™ Surgical Automated System.

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The following individuals have reviewed this version of the Statistical Analysis Plan and are in agreement with the content:

Signature Page

Study Biostatistician:

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(Print) (Sign) Date

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(Print) (Sign) Date

Franchise Clinical Study Lead:

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Revision History

Revision Number	Revision Date (DD/MMM/YYYY)	Reasons for Revision
Version 1	02APR2021	Initial Version
Version 2	15JUN2022	• Removal of exploratory endpoint • Extension added to the calculation of ROM in the Harris Hip Score • Patient accounting table revised • Primary and secondary endpoint analyses to be conducted on the per protocol analysis set, as specified in the CIP.

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1 Study Design

This study is designed as a Prospective, Randomized, Multi-center Post-Market study of Anterior Advantage Surgical Approach in Total Hip Arthroplasty with and without the KINCISE™ Surgical Automated System.

The primary objective of this study is to demonstrate that the mean femoral broaching time with KINCISE™ is non-inferior to the mean femoral broaching time with manual instruments when used in THA with Anterior Advantage. If non-inferiority is successfully demonstrated then the study will be deemed successful, and a test for superiority for mean femoral broaching time will be conducted.

2 Treatment Assignment

After the subject is consented, it must be verified that the subject meets all eligibility criteria. Once confirmed, the subject will receive a planned treatment assignment, 'KINCISE' or 'MALLET', as described in section 3.
The treatment received, the actual treatment, will be recorded in the Operative eCRF and will be the basis for all safety and per-protocol analyses. If it is recorded on the Operative eCRF that KINCISE was used at any time during the study for femoral broaching and/or stem impaction then the treatment received will be KINCISE. If KINCISE was neither used for femoral broaching nor for stem impaction and if a mallet was used then the treatment received will be MALLET.

3 Randomization and Blinding Procedures

Sticker sheets were created, one set for up to 30 sites, containing treatment assignments for 120 subjects using a fixed block size of 4 and a treatment allocation ratio of 1:1. On the face of each sticker is a character in the sequence A, B, C, …., X, Y, Z, AA, AB, AC, ……AX, AY, AZ, BA, BB, BC, etc…., BX, BY, BZ, CA, etc...

The stickers should be removed sequentially to reveal the randomization code and treatment group ('Study (Kincise)' or 'Control (Mallet)') for each consecutive consented subject that meets eligibility criteria. Peeled sticker should be placed on the screening log to document that randomization was unbiased. The planned randomization group should then be documented in the applicable source document and on the Randomization eCRF (eCRF RDM) in the database.

The assigned treatment will remain secret to site personnel until subject is found to meet all eligibility criteria; No other blinding is implemented in this study.

4 Interval Windows

The study includes the following periods: Pre-op, Operative, Immediate post-op, 6 Week, 24 Week. Intervals related to each are shown in Table 3, below.

Table 3 Interval Windows for Non-Radiographic Study Visits

Visit	Minimum Day	Maximum Day	Midpoint Day
Pre-Op	**-180**	**0**	
Operative	**0**	**0**	**0**
Immediate post-op	**0**	**Discharge**	
6 week	**14**	**60**	**37**
24 week	**61**	**200**	**130**

Time point specific data collected to satisfy the primary and secondary efficacy-related objectives will be assessed for compliance with these intervals. Only data which can be attributed to the visit intervals in Table 3 will be used in the analysis of primary and secondary endpoints. This visit will be hereafter referred to as the Analysis Visit and the originally recorded visit as the Nominal Visit. If multiple measurements fall into the pre-operative window, or into the 'Immediate post-op' post-operative window, the result collected most proximate to surgery will be utilized. For the '6 week' and '24 week' visits, if multiple measurements fall into the window then the last value within the window will be utilized for analysis.

5 Levels of Significance

The level of significance is 95%. Primary endpoint analyses, further described in section 8.7, and secondary endpoint analyses with hypotheses, further described in 8.8, will use 1-sided 95% confidence intervals and associated p-values. Data summaries of secondary endpoints without hypotheses and of exploratory endpoints will use 2-sided 95% confidence intervals and associated p-values.

6 Analysis Sets

The following analysis sets are defined:

- **Enrolled** – The Enrolled population set will consist of all subjects who sign the informed consent document.
- **Safety** – The Safety population set will consist of all subjects in the Enrolled population set for whom treatment was attempted, according to the actual treatment received.
- **Per Protocol** – The Per Protocol population set will consist of all subjects in the Enrolled population set who successfully received the planned treatment, who met all inclusion/exclusion criteria, who were seen at least once at a post-operative visit, and who did not have any protocol deviations which were prospectively determined to potentially have influence on the scientific validity of the data (such as inclusion/exclusion criteria).

7 Sample Size Justification

Primary endpoint Non-Inferiority (NI) analysis: Based upon input from key opinion leaders (KOLs) and data from other studies, typical femoral broaching time with manual instruments is anticipated to have a range of 5 to 15 minutes, which implies a standard deviation of approximately 2.5 minutes (1/4 of the range). Moreover, KOLs suggest that a difference of 10 minutes in femoral broaching time (increase for a single patient) is clinically meaningful. The non-inferiority margin of 1.25 minutes was established because it

is ½ of the anticipated standard deviation and is much less than a clinically meaningful difference. Under a 1-sided test with 5% alpha, a sample size of N=88 per group would be sufficient to demonstrate non-inferiority with 95% power. A sample of size N=200 per group (N=400 total) was chosen as feasible by the sponsor and desirable for providing further data for both KINCISE and Anterior Advantage; this sample size would provide more than 99% power to demonstrate non-inferiority for the primary endpoint analysis.

Primary endpoint supplemental superiority analysis: It is not known if there will be a true difference in means between groups. However, if there is a true difference of 1 minute between group means (lower time favoring KINCISE), and assuming an SD as stated above (2.5 minutes), then a sample of N=200 per group (N=400 total) would provide approximately 99% power to demonstrate superiority.

Secondary endpoint analyses:

- Non-inferiority of skin-to-skin OR time

  Based upon input from KOLs and data from other studies, skin-to-skin OR time is anticipated to have a typical range from 60 to 90 minutes, which implies a standard deviation of approximately 7.5 minutes (1/4 of the range). The non-inferiority margin of 3.75 minutes was established because it is ½ of the anticipated standard deviation and is much less than the 10 minute clinically meaningful difference in femoral broaching time (a subset of skin-to-skin OR time). Under a 1-sided test with 5% alpha, a sample size of N=200 per group would be sufficient to demonstrate non-inferiority with greater than 99% power.

- Non-inferiority of optimal acetabular cup abduction

  The percent of subjects within +/- 10 degrees of planned cup abduction for an anterior approach (AA) is anticipated to be between 90% and 95% (based on studies presented by Hamilton[1] and Rathod[2], respectively). These are a clinical improvement from percentages exhibited with a posterior approach (PA), which were 79% and 86% in [1] and [2], respectively. A NI margin of 10% was chosen because it is less than the improvement from PA to AA observed by Hamilton[1] and

Rathod[2]. With this margin and a 1-sided test with 5% alpha, a sample size of N=200 per group would be sufficient to demonstrate non-inferiority with approximately 95% power.

- Non-inferiority of optimal acetabular cup abduction

  The percent of subjects within +/- 10 degrees of planned cup version for an anterior approach (AA) is anticipated to be between 91% and 92% (based on studies by Rathod[2] and Hamilton[1], respectively). These are a clinical improvement from percentages exhibited with a posterior approach (PA), which were 64% and 77% in [1] and [2], respectively. A NI margin of 10% was chosen because it is less than the improvement from PA to AA observed by Hamilton[1] and Rathod[2]. With this margin and a 1-sided test with 5% alpha, a sample size of N=200 per group would be sufficient to demonstrate non-inferiority with approximately 95% power.

In summary, with a sample size of N=400 (200 with KINCISE; 200 without KINCISE), the anticipated overall likelihood of demonstrating the primary endpoint non-inferiority analysis, followed by the three stated secondary endpoint non-inferiority analyses in the specified gate-keeping order, is at least (99%)(99%)(95%)(95%) ≈ 88%.

8 Analyses to be Conducted

8.1 General Conventions

All statistical analyses will be performed using SAS® Version 9.4 or higher, unless otherwise noted. Standard descriptive summaries for continuous data include the number of subjects with non-missing observations (n), mean, standard deviation (SD), median, minimum, and maximum values. For categorical data, the count and percentage will be provided. Percentages will be based on the number of subjects without missing data. If exploratory tests of hypotheses are performed, t-tests will be performed for continuous variables, and Fishers' Exact Test will be performed for categorical variables. Baseline for the Forgotten Joint Score is 6 weeks. Baseline for all other endpoints is the pre-operative

measurements collected before surgery. Unless specifically stated otherwise, all endpoints will be analyzed first by treatment then combined.

8.2 Disposition of Study Subjects

Counts of the following categories of subjects by treatment and in total will be provided: All Enrolled dataset, Safety, major inclusion/exclusion protocol violations, Per Prototol, non inclusion/exclusion major protocol violations, deaths, withdrawals, study completion, ongoing in the study.

A subject accounting table using the Safety set will also be provided to account for the following at each follow-up interval:

- Treated: the count of subjects treated; This should not vary per visit;
- Not Yet Due: the count of subjects who do not have an evaluation at the visit (Harris Hip or Forgotten Joint) and who, based on date of surgery and date of data extract, are not yet in-window for the visit;
- Theoretical Due: the count of subjects treated and not counted in Not Yet Due;
- Death: the count of theoretical subjects who died after the start of the window and who do not have data (Harris Hip or Forgotten Joint) at the visit;
- Revision: the count of subjects theoretically due, without data at the visit, who were revised and withdrawn from the study;
- Not Yet Overdue: count of theoretical subjects within the evaluation time window; Do not count subjects who have data at the visit or subjects who are counted in Death or Revision;
- Expected: the count of subjects theoretically due who are not counted in Death, Revision, Not Yet Overdue;
- Actual data on file (records with a date): the count of subjects with a record with a date for each of the following endpoints: RSA measured subsidence, cup positioning at 6 weeks, Harris Hip, HOOS Jr., Forgotten Joint score, and Linear head penetration. A count of subjects with a record with a date in any of the listed

endpoints will also be provided and a follow-up rate will be calculated using the number of expected subjects in the interval as denominator;

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- Any data on file: the count of subjects with any record with a date for the endpoints listed in “Actual data on file”
- Follow-up rate calculated as 100*(Any data on file)/Expected

8.3 Demographic and Baseline Characteristics

Descriptive statistics will be summarized for the subjects in the Safety Analysis Population and for the subjects in the Per Protocol population (both in total and by treatment):

- Age at consent (in years);
- Sex;
- Child’s bearing potential if Sex is Female;
- Hispanic/Latino;
- Race;
- Height (cm);
- Weight (kg);
- BMI (kg/m^2).

8.4 Operative details

Operative details will be summarized for the subjects in the Safety Analysis Population and for the subjects in the Per Protocol population (both in total and by treatment group):

- Primary diagnosis;
- Occurrence of Intraoperative complication(s) (Y/N);
- ASA Risk;
- Surgical time (Duration) (min);
- Anesthesia time (Duration) (min);

- Femoral broaching time (Duration) (min);
- Surgical approach;
- Use of Hana table
- Use of standard table if Hana table was not used
- Use of intraoperative fluoroscopy to position the cup
- Starting broach size;
- Ending broach size;
- Skipped any broach size (Y/N); If any broach sizes were skipped then provide a listing of which sizes were skipped;
- Use of KINCISE (Yes/No);
- Listing of steps taken when KINCISE was used;
- Use of a mallet;
- Listing of steps taken when mallet was used;
- Use of wires/cables (Y/N);
- Use of screws (Y/N);
- Listing of additional details when screws were used;
- Cup need to be repositioned after the initial impaction (Y/N);
- Use of KINCISE when cup was needed to be repositioned after the initial impaction (Y/N);
- Established preoperative target(s) for inclination during the surgery was changed (Y/N);
- New target in degrees if established preoperative target(s) for inclination during the surgery was changed;
- Established preoperative target(s) for version during the surgery was changed (Y/N);
- New target in degrees if established preoperative target(s) for version during the surgery was changed;
- Acetabular bone graft;
- Acetabular bone class;

- Acetabular osteophytes removed (Y/N);
- Femoral bone graft;
- Femoral bone class proximal;
- Femoral bone class distal;
- Femoral DORR class;
- Femoral stem component present (Y/N);
- Femoral head component present (Y/N);
- Acetabular shell (cup) component present (Y/N);
- Acebabular liner (insert) component present (Y/N);
- EMG data uploaded to Athos (Y/N).

8.5 Post-operative details

Post-operative details will be summarized for the subjects in the Safety Analysis Population and for the subjects in the Per Protocol population (both in total and by treatment group):

- Subject taking any narcotic pain medication to manage study hip pain (Y/N);
- Hospital stay less than 24 hours (Y/N);
- Length of hospital stay in days (date of discharge minus date of surgery);
- Location of discharge;
- Narcotics prescribed for pain management (Y/N).

8.6 Device Deficiencies and Protocol Deviations

Listings of device deficiencies and protocol deviations will be provided.

8.7 Primary Endpoint and Associated Hypotheses

The primary endpoint analysis is to demonstrate that femoral broaching time (in minutes)

with KINCISE is non-inferior to femoral broaching time with manual instruments (not using KINCISE) under a non-inferiority margin of 1.25 minutes.

Hypotheses for this non-inferiority analysis are as follows:

- Null Hypothesis: H_0: $\mu_I \geq \mu_C + 1.25$
- Alternative Hypothesis: H_A: $\mu_I < \mu_C + 1.25$

whereμ_I and μ_C are mean femoral broaching times with and without KINCISE, respectively, and 1.25 is the NI margin. The null hypothesis will be rejected and non-inferiority will be concluded if the 1-sided upper 95% confidence limit for the $\mu_I - \mu_C$ difference (based upon a 2-sample t-test) is less than 1.25. The study will be deemed to be successful if this analysis demonstrates non-inferiority of femoral broaching time.

If non-inferiority is successfully demonstrated, then a test for superiority will be conducted to assess if femoral broaching time with KINCISE is less than femoral broaching time without KINCISE with statistical significance (1-tailed t-test with 5% alpha).

The primary endpoint analysis and all associated hypotheses will be conducted on the Per Protocol Analysis Set.

8.8 Secondary Endpoints and Associated Hypotheses

All secondary endpoint analyses and associated hypotheses will be conducted on the Per Protocol Analysis Set.

If the primary endpoint analysis successfully demonstrates non-inferiority of femoral broaching time, regardless of whether the above test of superiority was successful or not, then the following three secondary endpoint analyses will be conducted under a gatekeeping strategy, in this specified order, where testing is performed in sequence and continues until a null hypothesis is not rejected or all hypotheses have been tested, each with a 1-sided alpha of 0.05:

8.8.1 Skin-to-skin OR time

- Skin-to-skin OR time in minutes will be summarized as a continuous variable for both treatments and combined
- A non-inferiority test of skin-to-skin OR time will be conducted with a non-inferiority margin of 3.75 minutes, using a 2-sample t-test:
  - Null Hypothesis: H_0: $\mu_I \geq \mu_C + 3.75$
  - Alternative Hypothesis: H_A: $\mu_I < \mu_C + 3.75$
  - where μ_I and μ_C are mean skin-to-skin OR times with and without KINCISE, respectively. The null hypothesis will be rejected and non-inferiority will be concluded if the 1-sided upper 95% confidence limit for the $\mu_I - \mu_C$ difference (based upon a 2-sample t-test) is less than 3.75
  - The 1-sided upper 95% confidence limit for the difference and the p-value will be presented.

8.8.2 The percent of subjets with acetabular cup abduction angle within +/- 10 degrees of plan

- The proportion of subjets with acetabular cup abduction angle within +/- 10 degrees of plan will be summarized for both treatments and combined
- A non-inferiority test of the percent of subjects with acetabular cup abduction angle within +/- 10 degrees of plan under a NI margin of 10% will be conducted:
  - Null Hypothesis: H_0: $P_I \leq P_C - 10\%$
  - Alternative Hypothesis: H_A: $P_I > P_C - 10\%$
  - where P_I and P_C are the percentages of subjects with acetabular cup abduction angle within 10% of plan with and without KINCISE, respectively. The null hypothesis will be rejected and non-inferiority will be concluded if the 1-sided lower 95% confidence limit for the $P_I -$

P_C difference (based upon a normal approximation method) is greater than -10%

- The 1-sided lower 95% confidence limit for the difference and the p-value will be presented.

8.8.3 The percent of subjects with acetabular cup version angle within +/- 10 degrees of plan

- The proportion of subjets with acetabular cup version angle within +/- 10 degrees of plan will be summarized for both treatments and combined
- A non-inferiority test of the percent of subjects with acetabular cup version angle within +/- 10 degrees of plan under a NI margin of 10% will be conducted:
  - Null Hypothesis: H_0: $P_I \leq P_C - 10\%$
  - Alternative Hypothesis: H_A: $P_I > P_C - 10\%$
  - where P_I and P_C are the percentages of subjects with acetabular cup version angle within 10% of plan with and without KINCISE, respectively. The null hypothesis will be rejected and non-inferiority will be concluded if the 1-sided lower 95% confidence limit for the $P_I - P_C$ difference (based upon a normal approximation method) is greater than -10%.
  - The 1-sided lower 95% confidence limit for the difference and the p-value will be presented.

8.8.4 The percent of subjects with both acetabular cup abduction angle within +/- 10 degrees of plan and acetabular cup version angle within +/- 10 degrees of plan will be summarized for both treatments and combined.

8.8.5 Harris Hip Score at Pre-Op, 6 week, 24 week

Harris hip scores are assessed at the Pre-Op visit and at 6 week and 24 week. Results within each visit window will be summarized and changes from baseline will be provided using the Per Protocol Analysis Set. Standard continuous summaries will be supplemented with 95% confidence intervals using the t distribution.

8.8.6 Forgotten Joint Score (FJS-12) at 6 week, and 24 week

FJS-12 scores are assessed at 6 week, 24 week. Results within each visit window will be summarized and the change at 24 week from 6 week will be provided using the Per Protocol Analysis Set. Standard continuous summaries will be supplemented with 95% confidence intervals using the t distribution.

8.8.7 EQ-5D-5L at Pre-op, Week 6, and Week24

The EQ-5D-5L US index values and EQ-VAS values are assessed at Pre-op, 6 week, and at 24 week. Results within each visit window will be summarized and the change from Pre-op will be provided using the Per Protocol Analysis Set. Standard continuous summaries will be supplemented with 95% confidence intervals using the t distribution.

8.8.8 Hip Evaluation at Pre-op, 6 week, 24 week

All questions on the Pre-op hip evaluation CRF will be summarized: (“How satisfied do you anticipate you will be with this procedure?”, “Groin pain”, “Buttock pain”, “Leg length”, “Can you walk without an aid?”, “Do you drive?”, “Can you perform basic activities of daily living (bathing, getting in and out of bed, etc)?”, “Can you perform light household duties? (cooking, dusting, etc.)”, “Can you perform moderate/heavy household duties (cleaning floors, moving heavy boxes, etc.)?”, “Can you go up and down a flight of stairs using a handrail?”, “Can you put on socks/stockings without someone's assistance?”, “Can you bend down to pick up an object on the floor?”, “Can you stand up from a chair without assistance?”, “Can you participate in leisure recreational activities (swimming, gardening, bowling, etc)?”, “Do you work?”) as categorical data using the Per Protocol Analysis Set.

All questions on the Post-op hip evaluation CRF will be summarized: “How satisfied are you with this procedure?”, “Would you have this procedure again?”, “Groin pain”, “Buttock pain”, “Leg length”, “How long did you take narcotics after your surgery?”) as categorical data using the Per Protocol Analysis Set.

8.8.9 Hip Evaluation Functional Recovery Outcomes

All questions on the hip evaluation functional recovery outcomes will be summarized as categorical data using the Per Protocol Analysis Set in the following fashion: recovery time will be the first week (Week 1 – After Week 12) recovery was achieved; Otherwise, recovery time will be “Still cannot do” or “Not Applicable/I never do this” if subject selected these options at the last visit subject was seen.

8.8.10 Radiographic Outcomes (based upon: AP Hip, AP Pelvis, and Lateral) at week 6, week 24

The following radiographic endpoints will be summarized at week 6 and at week 24: Acetabular cup version – Hip, Acetabular cup version – Pervis, Acetabular cup Inclination, Acetabular cup migration, Acetabular cup radiolucency, Acetabular cup osteolysis, Acetabular cup scerotic lines, Acetabular cup porous coating integrity, Femoral stem position, Femoral stem tilt, Femoral stem subsidence, Femoral stem radiolucency, Femoral stem osteolysis, Femoral stem osteolytic lines, Femoral stem coating integrity, Calcar resorption, Calcar fracture, Heterotopic ossification, Proximal femur, Pelvis vertical alignment, Device/anatomy condition.

8.8.11 Narcotic Drug Usage

A listing of narcotic drug use will be provided using the Safety population set which will include: treatment group, subject id, time point, name of medication, 24 hour dose, dose, and whether drug usage is ongoing.

8.9 Safety Analyses

Adverse Events (AE) will be coded according to the Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. Analyses will be conducted for all subjects in the Safety Analysis Set.

All AEs from the start of device placement until subject finishes participation in the study will be summarized by treatment group and combined with frequencies, number of subjects with at least one AE, and percentages for the following categories:

- Overall
- Device related (AE marked Possible, Probable, or Causal Relationship by investigator)
- Procedure related (AE marked Possible, Probable, or Causal Relationship by investigator)
- Serious (SAE)
    - led to death

The number (%) of subjects with adverse events will be presented by MedDRA system organ class (SOC) and preferred term (PT) for all AEs, and for all SAEs separately for each treatment group and combined. In these summaries, AEs will be sorted by decreasing frequency within each MedDRA SOC and PT in the combined cohort. A subject-level listing will be provided to display details of all reported AEs.

A listing of device deficiencies will also be provided.

8.10 Plans for Interim Analysis

There are no formal interim analyses that are designed to potentially stop or change the study design. An interim summary analysis of the EMG data may take place when approximately 15 subjects in each treatment group have been treated for the purpose of a publication. Along with the BMG data, key demographic and operative endpoints will be

summarized. There is no intention to utilize this interim analysis as a means to justify stopping the study early.

8.11 Handling of Missing Data

Only subject data which is collected in the study will be utilized in analyses; there will be no imputation of missing data.

8.12 Adjustment for Multiplicity

A gatekeeping strategy will be utilized to ensure the family-wise type I error rate does not exceed 5% for all pre-specified hypotheses: the test of non-inferiority of the primary endpoint will be performed at the 95% confidence level and all subsequent hypotheses in the order specified in sections 8.7 and 8.8 will be tested only if the prior null hypothesis was rejected. P-values and confidence intervals for analyses which were not tested will not be adjusted for multiplicity and may only be provided to facilitate clinical judgement.

8.13 Sensitivity Analyses

No sensitivity analyses will be conducted.

8.14 Subgroup Analysis

Although no additional subgroup analyses are prospectively planned, post-hoc analyses may be conducted.

8.15 Assessment of Site Homogeneity

No formal assessment of site homogeneity will be conducted.

9 Data Monitoring Committee (DMC)

A DMC will not be used to monitor safety or efficacy in this study.

10 Changes from the Study Protocol

The basis of this Statistical Analysis Plan (SAP) is the Clinical Investigation Plan (CIP). Changes have been made to address any typographical errors and improve clarity and consistency of terminology. In addition, substantive changes are presented in the following table:

Table 10.1 Summary of Substantive Changes

Content	Modification	Justification
Pain (Groin, Thigh, and Buttock) as a secondary endpoint	Thigh pain is removed	Thigh pain data is not collected on the hip evaluation CRF
Section 10.5.2 of the study protocol: "…gatekeeping strategy, in this specified order, where testing is performed in sequence and continues until an **alternative** hypothesis is not rejected"…	"**alternative**" is replaced with "**null**"	We continue testing endpoints as long as the null is rejected. We stop as soon as the null hypothesis is not rejected.

11 Appendix A – Questionnaire Scoring

11.1 Harris HIP Score

The Harris Hip Score was developed for the assessment of the results of hip surgery, and is intended to evaluate various hip disabilities and methods of treatment in an adult population. Scores range from 0 (worse disability) to 100 (less disability).
To calculate the overall score, score each answer according to table;, then sum up those scores to obtain the total score. Do not allow score to be greater than 100. If a question was left unanswered then the total score cannot be calculated. [Source: https://www.orthopaedicscore.com/scorepages/harris_hip_score.html].

11.1.1 HHS Scoring

Item	HHS Question	Response Scoring
1	Pain	None = 44 Slight = 40 Mild = 30 Moderate = 20 Marked = 10 Totally disabled = 0
2	Limp	None = 11 Slight = 8 Moderate = 5 Severe = 0 Unable to walk = 0
3	Support	None = 11 Cane long walk = 7 Cane full time = 5 Crutch = 3

		Two canes = 2 Two crutches/Walker = 0 Unable to walk = 0
4	Distance Walked	Unlimited = 11 6 blocks (600 meters) = 8 2-3 blocks (200-300 meters) = 5 Indoors only = 2 Bed and chair = 0
5	Activities: Stairs	Normally = 4 Normally with banister = 2 Any method = 1 Not able = 0
6	Activities: Socks/Shoes	With ease = 4 With difficulty = 2 Unable = 0
7	Activities: Sitting	Any chair, 1 hour = 5 High chair, ½ hour = 3 Unable to sit, ½ hour, any chair = 0
8	Activities: Public Transportation	Able to enter = 1 Unable to enter = 0
9	Deformity	If subject did not respond then missing **else** If Fixed adduction >= 10 degrees **or** Fixed internal rotation (in extension) >= 10 degrees **or**

		Leg length discrepancy > 3.2 cm or 1.25 in. **or** Fixed flexion >= 30 degrees **Then 0** **Else 4**
12	Flexion + Extension + Abduction + Adduction + External rotation + Internal rotation	Sum all ranges then score as following: Sum >= 161 = 5 101 <= Sum < 161 = 4 61 <= Sum < 101 = 3 31 <= Sum < 61 = 2 0 <= Sum < 31 = 1 Sum < 0 = 0 *Do not* Exceed Range Boundaries Associated with Each Variable; e.g. Flexion measured as 130 º = 120 º. Allowables ranges: Flexion: 0 to 120 Extension: 0 to 20 Abduction: -15 to 90 Adduction: -20 to 90 External Rotation: -20 to 100 Internal Rotation: -30 to 90

11.2 Forgotten Joint Score (FJS-12)

For scoring the FJS-12, all responses are summed (never, 0 points; almost never, 1 point; seldom, 2 points; sometimes, 3 points; mostly, 4 points) and then divided by the number of completed items. This mean value is subsequently multiplied by 25 to obtain a total score range of 0 to 100. Finally, the score is subtracted from 100, to change the direction of the final score in a way that high scores indicate a high degree of “forgetting” the artificial joint, that is, a low degree of awareness.

If more than 4 responses are missing, the total score should not be used.

[Source: The “Forgotten Joint” as the Ultimate Goal in Joint Arthroplasty: The Journal of Arthroplasty Volume 27, Issue 3 , Pages 430-436.e1, March 2012 H Behrend et al.]

11.2.1 FJS-12 Scoring

FJS-12 Question	Item	Response Scoring
…in bed at night	1	Never = 0 Almost never = 1 Seldom = 2 Sometimes = 3 Mostly = 4
…when you are sitting on a chair for more than one hour?	2	Never = 0 Almost never = 1 Seldom = 2 Sometimes = 3 Mostly = 4
... when you are walking for more than 15 minutes	3	Never = 0 Almost never = 1 Seldom = 2 Sometimes = 3

		Mostly = 4
... when you are taking a bath/shower	4	Never = 0 Almost never = 1 Seldom = 2 Sometimes = 3 Mostly = 4
... when you are traveling in a car	5	Never = 0 Almost never = 1 Seldom = 2 Sometimes = 3 Mostly = 4
... when you are climbing stairs	6	Never = 0 Almost never = 1 Seldom = 2 Sometimes = 3 Mostly = 4
... when you are walking on uneven ground	7	Never = 0 Almost never = 1 Seldom = 2 Sometimes = 3 Mostly = 4
... when you are standing up from a low-sitting position	8	Never = 0 Almost never = 1 Seldom = 2 Sometimes = 3 Mostly = 4
... when you are standing for long periods of time	9	Never = 0 Almost never = 1 Seldom = 2

		Sometimes = 3 Mostly = 4
... when you are doing housework or gardening	10	Never = 0 Almost never = 1 Seldom = 2 Sometimes = 3 Mostly = 4
... when you are taking a walk/hiking	11	Never = 0 Almost never = 1 Seldom = 2 Sometimes = 3 Mostly = 4
... when you are doing your favorite sport	12	Never = 0 Almost never = 1 Seldom = 2 Sometimes = 3 Mostly = 4

12 References

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2. Rathod PA, Deshmukh AJ, Rodriguez JA. Does Intraoperative Fluoroscopy Improve Component Positioning in Total Hip Arthroplasty? Orthopedics 2016;39(2):71.

13 Tables, Listings and Graphs Shells

Provide, or reference the document that contains the tables, listings and graphs shells.

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