

Supplementary Appendix

This appendix has been provided by the authors to give readers additional information about their work.

Supplement to: The HEALTH Investigators. Total hip arthroplasty or hemiarthroplasty for hip fracture. N Engl J Med. DOI: 10.1056/NEJMoa1906190

SUPPLEMENTARY APPENDIX



Hip Fracture Evaluation with Alternatives of
Total Hip Arthroplasty Versus Hemi-Arthroplasty

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S2.0 SUPPLEMENTAL APPENDICES

S2.1 Eligibility Criteria

Inclusion Criteria	
1) Adult men or women aged 50 years and older (with no upper age limit).	
2) Fracture of the femoral neck confirmed with either anteroposterior or lateral hip radiographs, computed tomography, or magnetic resonance imaging (MRI).	
3) Displaced fracture that is not, in the judgment of the attending surgeon, optimally managed by reduction and internal fixation.	
4) Operative treatment within 3 days (i.e. 72 hours) of the patient being medically cleared for surgery.	
5) Patient was ambulatory prior to fracture, though they may have used an aid such as a cane or a walker.	
6) Anticipated medical optimization for arthroplasty of the hip.	
7) Provision of informed consent by patient or proxy.	
8) Low energy fracture (defined as a fall from standing height).	
9) No other major trauma (defined as an Injury Severity Score <17*).	
10) Assurance that surgeons with expertise in both total hip arthroplasty and hemi-arthroplasty were available to perform surgery. Note: Surgeons do not need to be experts in both techniques.	
<p>*The Injury Severity Score (ISS) is an anatomical scoring system that provides an overall score for patients with multiple injuries. Each injury is assigned an Abbreviated Injury Scale (AIS) score and is allocated to one of six body regions (Head, Face, Chest, Abdomen, Extremities (including Pelvis), and External). Only the highest AIS score in each body region is used. The 3 most severely injured body regions have their score squared and added together to produce the ISS score.</p>	
Exclusion Criteria	
1) Patient not suitable for hemi-arthroplasty (e.g. inflammatory arthritis, rheumatoid arthritis, pathologic fracture (secondary to cancer), or severe osteoarthritis of the hip).	
2) Associated major injuries of the lower extremity (i.e., ipsilateral or contralateral fractures of the foot, ankle, tibia, fibula, knee, or femur; dislocations of the ankle, knee, or hip; or femoral head defects or fracture).	
3) Retained hardware around the affected hip that will interfere with arthroplasty.	
4) Infection around the hip (soft tissue or bone).	
5) Patients with a disorder of bone metabolism other than osteoporosis (i.e., Paget's disease, renal osteodystrophy, osteomalacia).	

6) Patients with a previous history of frank dementia that would interfere with assessment of the primary outcome (i.e., secondary procedures at 2 years).

7) Likely problems, in the judgment of the investigators, with maintaining follow-up (i.e., patients with no fixed address, report a plan to move out of town, or intellectually challenged patients without adequate family support).

8) Patients whose fracture occurred as a result of an act of violence.

* For Item 6 above, patients with a history of frank dementia were unlikely to survive to 2 years, which would cause problems with assessment of the primary outcome.

* Exclusion of a patient because of enrolment in another ongoing drug or surgical intervention trial was left to the discretion of the attending surgeon, on a case-by-case basis.

S2.2 American Society of Anesthesiologists Physical Status Classification

Last approved by the ASA House of Delegates on October 15, 2014¹

ASA Classification	Definition
ASA I	A normal healthy patient
ASA II	A patient with mild systemic disease
ASA III	A patient with severe systemic disease
ASA IV	A patient with severe systemic disease that is a constant threat to life
ASA V	A moribund patient who is not expected to survive without the operation
ASA VI	A declared brain-dead patient whose organs are being removed for donor purposes

S2.3 Threshold Performance for Expertise in Total Hip Arthroplasty and Hemi-Arthroplasty

Surgeons participating in the HEALTH trial were required to meet both of the following two criteria for expertise for either THA or HA:

1. Surgeons must have performed at least 50 procedures (either THA or HA) in their career (including residency experience in which they assumed responsibility for the procedure).
2. Surgeons must have continued to perform at least five procedures (either THA or HA) in the year prior to trial start date, as well as each year for the duration of the study.

Surgeons who met the threshold for both THA and HA could perform either procedure based on randomization if no overwhelming bias in favour of one procedure was evident. A surgeon was considered biased for an approach if he/she had performed less than five cases of either procedure in his/her last 50 procedures for a displaced femoral neck fracture. One question on the surgical forms asked surgeons to indicate whether they met the expertise threshold for the procedure the patient received. No other methods were implemented to ensure that surgeons met the expertise criteria listed above.

Residents and fellows were able to perform the procedures under the supervision of a participating attending surgeon. The surgeon most responsible for the case must have met threshold expertise criteria and must have been present in the operating room for the critical aspects of the procedure.

The critical aspects of THA procedures that required the presence of an expert surgeon were:

- Trial component insertion and verification of hip stability
- Implant insertion to ensure correct alignment of femoral and acetabular components
- Cement procedure, if used
- Final assessment of hip stability after implant insertion

The critical aspects of HA procedures that required the presence of an expert surgeon were:

- Trial component insertion and verification of hip stability
- Implant insertion to ensure correct version)
- Cement procedure, if used
- Final assessment of hip stability after implant insertion

S2.4 Trial Interventions and Standardization of Peri-Operative Care

A. Total Hip Arthroplasty (THA)

To optimize feasibility and applicability of results, this study did not standardize the surgical approach, the use of cemented components, the implant manufacturer, or femoral head size. Surgeons used the manufacturer specific implant guides and jigs for insertion of the total joint arthroplasty. Prescribed approaches included no use of minimally invasive total hip arthroplasty (i.e., 2 incision approaches) and hinged prostheses or capture cups.

Surgeons documented the following:

1. Augmentation of the acetabular liner
2. Type of acetabulum implant used
3. Fixation of the acetabular component to the acetabulum with screw fixation
4. Acetabular component modularity
5. Material of acetabular liner
6. Manufacturer

B. Hemi-Arthroplasty (HA)

Surgeons used modern implants for HA excluding non-modular, non-canal filling unipolar implants such as Moore's and Thompson's prostheses. The choice of modular unipolar versus bipolar HA were not standardized. This study did not standardize whether implants were inserted with cement or with a press-fit design. Surgeons used the manufacturer specific implant guides and jigs for insertion of the total joint arthroplasty.

Surgeons documented the following:

- Type of HA performed
- Manufacturer
- Implant material
- Bearing surface of the implant

C. Standardization of Procedures and Peri-Operative Care

Given the inherent variability in practice patterns among orthopaedic surgeons, it was important to ensure that surgeons adhered as closely as possible to the surgical management protocol and to current accepted practice.

Peri-Operative and Post-Operative Treatment Common to Both Groups

To ensure similar peri-operative regimens, it was recommended that participating centers standardize key aspects of pre- and post-operative care.

Pre-Operative Care

1. Pre-operative antibiotic prophylaxis (i.e., cephalosporin, Ancef, or equivalent coverage).
2. Thromboprophylaxis (i.e., Thromboembolic Disease Stockings (TEDS), pneumatic compression boots, or medical prophylaxis to be discontinued in sufficient time to allow surgery as guided by International Normalized Ratio (INR) / Partial Thromboplasty Time (PTT)).
3. Medical consultation to optimize condition prior to surgery.

Post-Operative Care

1. Antibiotic prophylaxis (i.e., cephalosporin or equivalent) for 24 hours.
2. Thromboprophylaxis with unfractionated heparin, Low Molecular Weight Heparin (LMWH), warfarin, anti-platelet agents, or intermittent pneumatic compression boots.
1. Weightbearing as tolerated was allowed as patients autoprotect the affected hip during rehabilitation. Post-surgery, patients were weightbearing as tolerated, and then advanced according to the attending surgeon's best judgment (i.e., touch weightbearing was permitted, and then advanced according to the surgeon's best judgment).
2. Calcium 600 mg by mouth (PO) daily and vitamin D 1,000 International Units (IU) per day (provided there were no contraindications) and further investigation and treatment of osteoporosis as recommended by a local osteoporosis expert/consultant.
3. Appropriate nutritional assessment with administration of oral micronutrient feeds as needed.

Other Care

Due to a lack of evidence favouring a particular approach, the following was recorded, but not standardized:

1. Use of pre-operative traction.
2. Surgical delay.
3. Type of anesthetic (i.e., general or regional).
4. Physiotherapy and rehabilitation programs.

S2.5 Follow-up Processes

Time-point	Assessment Procedures	Data Collection
1 week (Up to 3 months)	In Person/Hospital/Clinic (if prior to discharge)	•Follow-up Form •Secondary Procedures, AE Forms •SF-12, WOMAC, EQ-5D (self-administered*) (asking about patient function prior to surgery)

1 week (Up to 5 weeks)	In Person/Hospital/Clinic (if prior to discharge)	•TUG Test
10 weeks (5 weeks to 4 months)	In Person/Hospital/Clinic (if prior to discharge) or Telephone	•Follow-up Form and TUG Test •Secondary Procedures, AE Forms •SF-12, WOMAC, EQ-5D (self-administered*) •Radiographs
6 months (4 to 7.5 months)	In Person/Hospital/Clinic or Telephone	•Follow-up Form and TUG Test •Secondary Procedures, AE Forms •SF-12, WOMAC, EQ-5D (self-administered*)
9 months (7.5 to 10.5 months)	In Person/Hospital/Clinic or Telephone	•Follow-up Form •Secondary Procedures, AE Forms •SF-12, WOMAC, EQ-5D (interview-administered)
12 months (10.5 to 15 months)	In Person/Hospital/Clinic or Telephone	•Follow-up Form and TUG Test •Secondary Procedures, AE Forms •SF-12, WOMAC, EQ-5D (self-administered*) •Radiographs
18 months (15 to 21 months)	In Person/Hospital/Clinic or Telephone	•Follow-up Form •Secondary Procedures, AE Forms •SF-12, WOMAC, EQ-5D (interview-administered)
24 months (21 to 30 months)	In Person/Hospital/Clinic or Telephone	•Follow-up Form and TUG Test •Secondary Procedures, AE Forms •SF-12, WOMAC, EQ-5D (self-administered*) •Radiographs •Planned revision surgery after 24 months

* Interview-administered data collection done if patient was unable to complete self-administered forms.

AE = Adverse Event, EQ-5D = EuroQol-5D, SF-12 = Short Form-12, TUG = Timed Up and Go, WOMAC = Western Ontario McMaster Osteoarthritis Index.

S2.6 Outcome Definitions

Primary Outcome

Outcome	Definition
Unplanned Secondary Hip Procedure (study event)	Unplanned secondary procedures that were classified as study events included: <ul style="list-style-type: none"> ○ Closed reduction of hip dislocation ○ Open reduction of hip dislocation ○ Open reduction of fracture ○ Soft tissue procedure ○ Insertion of antibiotic spacer ○ Full implant exchange ○ Partial implant exchange – stem only ○ Partial implant exchange - head only ○ Partial implant exchange - liner only

Outcome	Definition
	<ul style="list-style-type: none"> ○ Partial implant exchange - head and liner ○ Partial implant exchange – acetabular component only ○ Partial implant exchange – acetabular component and head ○ Implant adjustment – re-orientation of the stem ○ Implant adjustment – re-orientation of the acetabulum component ○ Implant removal with no replacement ○ Excision heterotopic ossification ○ Supplementary fixation ○ Other
Reason for Unplanned Secondary Procedure	<p>Classification of the reason for unplanned secondary procedures included:</p> <ul style="list-style-type: none"> ○ Treat a peri-prosthetic fracture ○ Treat hip instability or dislocation ○ Treat infection – superficial ○ Treat infection – deep ○ Treat wound necrosis ○ Treat another wound healing problem ○ Remove heterotopic ossification ○ Manage abductor failure ○ Manage another soft tissue problem (i.e. pseudotumor) ○ Correct implant failure –loosening or subsidence ○ Correct implant failure - breakage ○ Treat implant wear ○ Treat osteolysis ○ Treat implant corrosion ○ Improve function ○ Relieve pain

Secondary Outcomes

Outcome	Definition
Mortality	Mortality was adjudicated by the Central Adjudication Committee and it was considered to be an event if it occurred within 24-months of the initial hip fracture surgery.
Serious Adverse Events	Serious adverse events, as diagnosed by physicians at the clinical sites, were documented. A serious adverse event was defined as any adverse event that is fatal, life threatening, requires or prolongs hospital stay, results in persistent or significant disability or incapacity, a congenital anomaly or birth defect, or an important medical event, symptom, sign, illness, or experience that develops or worsens in severity during the study.
Hip-Related Complication	The Central Adjudication Committee reviewed hip-related complications including peri-prosthetic fracture, hip instability or dislocation, implant failure (loosening/subsidence and breakage), wound healing problems (including superficial/deep infection, wound necrosis), soft tissue problems (i.e. pseudotumor), heterotopic ossification, abductor failure, implant wear

Outcome	Definition
	and corrosion, osteolysis, neurovascular injury, decreased function, and pain.
Functional Outcomes and Quality of Life	<p data-bbox="459 304 1421 493">Functional outcome and quality of life were measured using self-administered and interview-administered questionnaires. Functional outcome questionnaires included a generic health status measurement instrument (SF-12), a hip function and pain questionnaire (WOMAC), a health outcome measure (EQ-5D), and a functional mobility test (TUG).</p> <p data-bbox="459 525 1421 745">The SF-12 Health Survey is a standardized instrument to measure health-related quality of life. This self-administered, 12-item questionnaire covers eight main health domains that make up the Physical and Mental Health Composite Scores (PCS & MCS). Each domain consists of one or two questions and is scored separately from 0 (lowest level) to 100 (highest level).</p> <p data-bbox="459 766 1421 1060">The WOMAC is a self-administered questionnaire that assesses the three dimensions of pain, disability and joint stiffness in knee and hip osteoarthritis, and consists of 24 questions. This questionnaire uses a Likert scale, consisting of responses including: none, mild, moderate, severe, and extreme. Specifically, for the WOMAC questionnaire, the Likert scale is in reverse order. Therefore, a higher score indicates worse pain, stiffness, and functional limitations. The ranges for each dimension are: 0-20 for pain, 0-8 for stiffness, and 0-68 for physical function.²</p> <p data-bbox="459 1081 1421 1449">The EQ-5D is a standardized instrument that measures quality of life in five dimensions (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression). Each dimension has three response options: 1=no problems, 2=some problems, and 3=extreme problems. Each response corresponds with a one-digit number that can then be combined into a 5-digit number to describe the participant's state of health. The participant's state of health is then translated into a corresponding utility score.² The EQ-5D also includes a visual analogue scale (VAS) that assesses the individual's health today on a scale from 0-100, with the endpoints being 'worst imaginable state of health' and 'best imaginable state of health'.^{3,4}</p> <p data-bbox="459 1480 1421 1701">The TUG test is a standardized, physical test to assess balance and mobility in the participants. The participant is timed while they perform simple physical movements, such as rising from an arm chair, walking 10 feet, walking back to the chair, and sitting down. A faster time indicates that the participant has greater functional performance, while a lower score may identify participants who are at risk for increased falls in the community.⁵</p> <p data-bbox="459 1722 1421 1812">The SF-12, WOMAC, and EQ-5D were asked at 10 weeks, 6, 9, 12, 18, and 24-month visits. The TUG was performed at 1 and 10-week 6, 12, and 24-month visits.</p>

S2.7 Overview of Adjudication

Adjudication Processes

The following information was excerpted from the HEALTH Adjudication Charter, which documents the responsibilities of the Central Adjudication Committee and the adjudication processes for the HEALTH trial.

1) Fracture Eligibility

The Central Adjudication Committee adjudicated fracture eligibility for all patients based on available pre-surgery and post-surgery x-rays, and completed case report forms. If the fracture did not meet all inclusion criteria or met one of the exclusion criteria, the fracture was deemed ineligible.

2) Technical Placement of Prostheses

The Central Adjudication Committee adjudicated the technical placement of the prosthesis based on available pre-surgery and post-surgery x-rays to determine if the quality of the implant placement was acceptable or unacceptable. This was unrelated to fracture eligibility.

3) Additional Surgical Procedures

The Central Adjudication Committee adjudicated additional surgical procedures that occurred within two years of initial surgery after the participant had completed their 24-month visit (or following early withdrawal) to determine if they were study events. Planned surgeries were not considered study events. If a participant had multiple unplanned surgeries for one indication, each unplanned surgery was considered a study event in addition to the first. Any unplanned surgery after the initial fixation that satisfied the criteria below was considered to be a study event:

- Treat a peri-prosthetic fracture
- Treat hip instability or dislocation
- Treat infection – superficial
- Treat infection – deep
- Treat another wound healing problem
- Treat another soft tissue problem
- Remove heterotopic ossification
- Manage abductor failure
- Correct implant failure – loosening or subsidence
- Correct implant failure – breakage
- Treat implant wear and corrosion
- Treat osteolysis
- Treat neurovascular injury
- Improve function
- Relieve pain

The Central Adjudication Committee reviewed all available x-rays, and data from the patient's completed case report forms.

4) Hip-Related Complications

The Central Adjudication Committee adjudicated adverse events related to the patient's randomized hip as reported by the clinical site after each participant had completed their 24-month follow-up (or following early withdrawal). The Central Adjudication Committee also reviewed all available x-rays (scheduled visits and unscheduled visits) to look for radiographic evidence of hip-related complications that were not reported by the clinical site. The Central Adjudication Committee was responsible for determining when the hip-related adverse event was first diagnosed/evident on participant x-rays. Hip-related complications that were considered study events included:

- f) Peri-prosthetic fracture
- g) Hip instability or dislocation
- h) Implant failure (loosening/subsidence and breakage)
- i) Wound healing problems (including superficial/deep infection, wound necrosis)
- j) Soft tissue problems (i.e. pseudotumor)
- k) Heterotopic ossification
- l) Abductor failure
- m) Implant wear and corrosion
- n) Osteolysis
- o) Neurovascular injury
- p) Decreased function
- q) Pain

The Chair of the Central Adjudication Committee independently reviewed all cases of heterotopic ossification that were identified by the Central Adjudication Committee. For each participant that was identified as having radiographic evidence of heterotopic ossification, the Chair independently reviewed the x-rays from each post-operative assessment and determined the severity of heterotopic ossification using the classification system developed by Brooker and colleagues:

- Stage I: Islands of bone within soft tissues of any size of the hip
- Stage II: Bone spurs from pelvis or femur, leaving at least 1 cm between opposing bone surfaces
- Stage III: Bone spurs from pelvis or femur reducing the space between opposing bone surfaces to less than 1 cm
- Stage IV: Ankylosis of the hip

The Central Adjudication Committee reviewed all available x-rays, and data from the patient's completed case report forms.

5) Mortality

The Central Adjudication Committee adjudicated mortality as required following a patient's early withdrawal. The Central Adjudication Committee reviewed all data from the patient's completed case report forms, available clinical notes, and/or x-rays to confirm the cause of death. They also commented on the relation to the treatment arm.

S2.8 Statistical Analyses for Primary and Secondary Outcomes

Analyses included patients in the groups to which they were assigned. Patients were censored at 24 months of follow-up or at the time of their last follow-up for patients lost to follow-up. The primary analysis was a proportional hazards model using a competing risk analysis (death as the competing risk) with time to the HEALTH primary study endpoint as the outcome. The independent variable was THA versus HA, and the following covariates were used: age (50-80 years or >80 years), pre-fracture living setting (institutionalized or not institutionalized), pre-fracture functional status (using assistive device for ambulation or able to ambulate without assistive device), and ASA Class (Class I/II or III/IV/V). For these covariates, we used values that were entered into the minimization system at time of enrollment. For our competing risk analyses, we used the method described by Zhou et al. to account for clustering within surgeons.⁶ The estimates from the competing risk analysis for clustered data analyses were marginal estimates. We report the treatment effects as hazard ratios (HRs) with 95% confidence intervals (CIs). No adjustment for multiplicity was made and the 95% CIs do not adjust for multiplicity. Kaplan-Meier curves were constructed for the primary outcome.

Cox proportional hazards modeling was used to estimate the relative effect of THA versus HA on time to mortality, serious adverse events, and hip-related complications, separately, and included the same independent variables as listed for the primary analysis as well as including surgeon as a random effect. The hip-related complications analysis was a competing risk analysis with death as the competing risk. The estimates from the competing risk analysis for clustered data analyses were marginal estimates. We report the HRs and 99% CIs for the proportional hazards models. We performed proportional hazards regressions only for hip-related complications in which there were at least 50 events. Using multi-level models, the effect of THA versus HA on quality of life (SF-12, EQ-5D), function (WOMAC), and mobility (TUG) were estimated separately. Randomized treatment, visit (entered as a categorical variable) were also included as independent variables. We accounted for death via joint modelling, using the method described by Rizopoulos.⁷ The SF-12, WOMAC, and EQ-5D were summarized using mean difference (MD) and 99% CIs. We analyzed the TUG as a dichotomous outcome with the following categories: a) patients who complete the test in ≤ 12 seconds, and b) those who require >12 seconds to complete the test or were unable to complete the test. We selected 12 seconds as the cut-off because this was the threshold used by the Centers for Disease Control and Prevention.⁸ The TUG was summarized using odds ratios and 99% CIs. For our multi-level analyses of quality of life, function, and mobility, all available data were used with no imputation performed. The models do not require that a patient have valid scores at all follow-up visits. We chose alpha levels of 0.05 and 0.01 for the primary and secondary outcomes, respectively. When scoring the WOMAC domains, we used the mean of the items that were answered in our calculation if at least 4 of the 5 pain items were answered, at least 1 of the 2 stiffness items were answered, and if at least 14 of the 17 function items were answered. If there were less items answered, the domain was set to missing. To calculate the WOMAC total score, we required non-missing scores for all 3 domains.

When scoring the SF-12, we required at least half of each of the items in each domain to be answered to use the mean of the non-missing items as the domain score. The physical

component summary score and the mental component summary score were only calculated if all 8 domains were non-missing.

All 5 questions of the EQ-5D were required to calculate the utility score.

S2.9 Subgroup Analyses and Hypothesized Effects

At the trial onset, we specified in the trial protocol that no subgroup analyses would be conducted. However, towards the end of the trial, prior to unblinding, the following subgroup analyses were decided upon and were conducted to investigate the following prognostic factors as possible effect modifiers. The HEALTH primary endpoint was the dependent variable for these analyses. For these subgroup analyses, we used the data from our database. What was captured in the database reflects the true values for these factors, which may be different than what was originally entered into the minimization system at time of enrollment.

1. Age (i.e., 50-80 years or >80 years): Hypothesized that THA will be better relative to HA in the younger subgroup than in the older patients.
2. Pre-fracture living setting (i.e., institutionalized or not institutionalized): Hypothesized that THA will be better relative to HA in those not institutionalized than those institutionalized.
3. Pre-fracture functional status (i.e., using assistive device for ambulation or able to ambulate without assistive device): Hypothesized that THA will be better relative to HA in those able to ambulate without an assistive device than in those using an assistive device for ambulation.
4. American Society for Anesthesiologists (ASA) Class (i.e., Class I/II or III/IV/V): Hypothesized that THA will be better relative to HA in Class I/II than in Class III/IV/V.

These subgroup analyses were performed (separately) by including the subgroup factor as an independent variable in our proportional hazards regression model along with an interaction term between it and randomized treatment. We used the criteria suggested by Kasenda et al. to guide inferences about the credibility of our subgroup analyses.⁹

After unblinding, we identified three post hoc subgroup analyses and performed them as follows:

1. Added a three-category age (50 to 70 years or 71 to 80 year or ≥ 81 years) as an independent variable in our proportional hazards regression model along with an interaction term between it and randomized treatment. We hypothesized that THA will be better relative to HA in the youngest subgroup than in the older patient subgroups.
2. Added a three-category age (50 to 70 years or 71 to 80 year or ≥ 81 years) as an independent variable and interaction of age with treatment group into our final WOMAC total score model. We hypothesized that THA will be better relative to HA in the youngest subgroup than in the older patient subgroups.
3. Added country (Canada or Netherlands or USA or Australia or Norway or Spain or UK or Finland or New Zealand or South Africa) as an independent variable in our proportional hazards regression model along with an interaction term between it and randomized treatment. We hypothesized no difference across countries in treatment effects.

S2.10 Sensitivity Analyses

At the trial onset, we did not specify in the trial protocol that any sensitivity analyses would be conducted. However, towards the end of the trial, prior to unblinding, we decided to conduct the following sensitivity analyses, with the HEALTH primary endpoint as the dependent variable:

- a) The primary analysis without including surgeon as a random effect
- b) The primary analysis with country included as an independent variable
- c) A per-protocol analysis
- d) An as-treated analysis
- e) Unstratified proportions analyses where we made varying assumptions about risk of event in those who were lost to follow-up

S2.11 Interpretation of Blinded Data

Hypothesis: We hypothesize that THA will have similar or lower rates of secondary procedures and higher functional outcome scores at 24 months compared with HA.

Here, we present alternative interpretations of blinded preliminary results. Blinded data interpretation may decrease the frequency of misleading data interpretation. Widespread adoption of blinded data interpretation with a minimum set of recommendations should be widely adopted.¹⁰

Secondary procedures over two years did not differ between treatment groups X and Y. The Kaplan Meier curve for the primary outcome suggests that the hazard ratios (HRs) remain constant up to 1 year (HR=1.30, 95% CI 0.86-1.95, $p=0.217$; non-significant estimates favoring treatment Y) and suggested estimates favouring treatment X after 1 year (up to 2 years) (HR=0.24, 95% CI 0.08-0.73; $p=0.011$).

Deaths did not differ between treatment groups X and Y over a 2-year period ($p=0.493$).

Serious adverse events ($p=0.052$) and hip-related complications ($p=0.277$) between treatment groups X and Y did not differ over a 2-year period.

Treatment X demonstrated significantly better overall WOMAC and EQ-5D utility scores ($p<0.05$) compared to Treatment Y (and trended towards better SF-12 PCS scores) over a 2-year period. TUG scores (cut-off 12 seconds) did not differ between treatment groups ($p=0.181$).

Subgroup analyses did not show any differences in the treatment effect between different subgroups ($p>0.05$).

Given the above preliminary findings, the more plausible hypothesis follows. Treatment X is THA and Treatment Y is HA. THA does not result in a statistically significant difference in secondary procedure rates over a 2-year period compared to HA; however, our findings suggest THA may have more secondary procedures earlier (less than 1 year, possibly driven by higher dislocations *results still blinded*) and HA may have more secondary procedures after 1-year post-fracture in those who did not have a secondary procedure during the first year. Functional outcome scores over 2 years favour THA compared to HA. These differences in function are small (although statistically significant). A lack of difference in secondary procedures, hip-related complications, and deaths, a lack of subgroup effects, and modest improvements in function render THA mildly superior to HA over 2 years. It's not unreasonable to consider the two treatments similar given

small differences in functional scores. The extra cost of THA to the modest benefits in function may not render it the primary implant of choice in this patient population.

If treatment X is HA and treatment Y is THA, then HA does not result in a statistically significant difference in secondary procedure rates over a 2-year period compared to THA. However, our findings suggest HA may have more secondary procedures earlier (less than 1 year) and THA may have more secondary procedures after 1-year post-fracture, in those who did not have a secondary procedure during the first year. Further, functional outcome scores over 2 years favour HA compared to THA. These differences in function are small (although statistically significant), and somewhat unexpected. A lack of difference in secondary procedures, hip-related complications, and deaths, a lack of subgroup effects, and modest improvements in function render HA mildly superior to THA over 2 years. It's not unreasonable to consider the two treatments similar given small differences in functional scores. However, the extra cost and added complexity of THA may not render it the primary implant of choice in this patient population.

S3.0 SUPPLEMENTARY FIGURES

Figure S1: Patient Flow Diagram

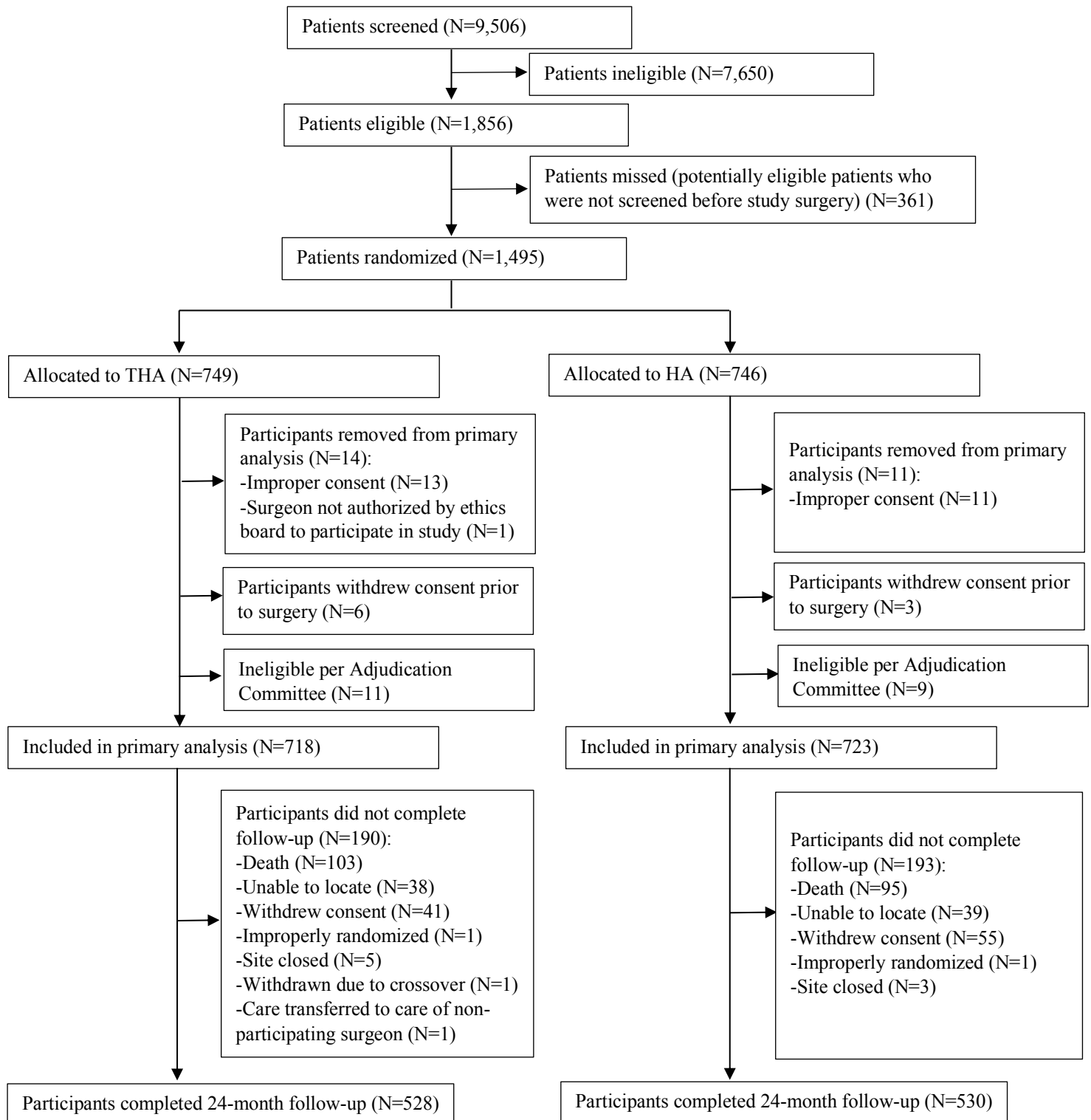
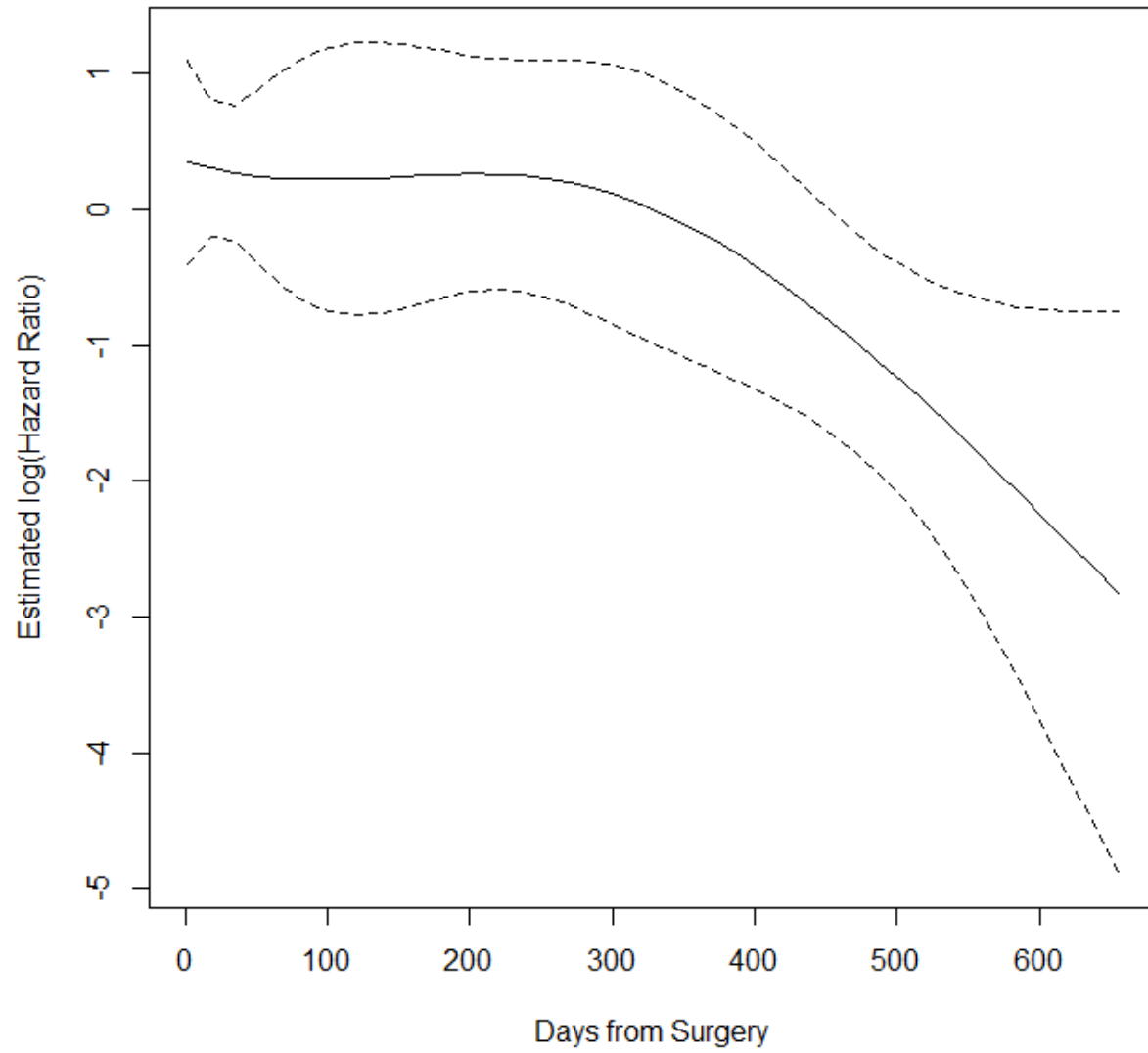


Figure S2: Plot of the Estimated $\log(\text{Hazard Ratio})$ Over Time



S4.0 SUPPLEMENTARY TABLES

Table S1: Reasons Patients Were Excluded Before Randomization

Reasons for Exclusion	Number of Patients Excluded N=7,650
The patient is not at least 50 years or older (no upper age limit), n (%)	202 (2.6)
The patient does not have a fracture of the femoral neck confirmed with either anteroposterior and lateral hip radiographs, computed tomography, or magnetic resonance imaging (MRI), n (%)	100 (1.3)
The patient does not have a displaced fracture that is not repairable via reduction and internal fixation, in the judgement of the attending surgeon, n (%)	1,107 (14.5)
Operative treatment will not take place within 3 days (i.e. 72 hours) of the patient being medically cleared for surgery, n (%)	219 (2.9)
The patient was not ambulatory prior to the fracture, though they may have used an aid such as a cane or walker, n (%)	301 (3.9)
The patient does not have anticipated medical optimization for arthroplasty of the hip, n (%)	144 (1.9)
The patient does not have a low energy fracture (defined as a fall from standing height) , n (%)	106 (1.4)
The patient has other major trauma (defined as an Injury Severity Score >17), n (%)	53 (0.7)
The surgeons with expertise in both total hip arthroplasty and hemi-arthroplasty are not available to perform the surgery, n (%)	226 (3.0)
The patient has a condition that makes them unsuitable for HA (e.g. inflammatory arthritis, rheumatoid arthritis, pathologic fracture (secondary to cancer), or severe osteoarthritis of the hip, n (%)	315 (4.1)
The patient has associated major injuries of the lower extremity (i.e. ipsilateral or contralateral fractures of the foot, ankle, tibia, fibula, knee, or femur; dislocations of the ankle, knee or hip; or femoral head defects or fracture) , n (%)	29 (0.4)
The patient has retained hardware around the affected hip that will interfere with arthroplasty, n (%)	25 (0.3)
The patient has an infection around the hip (i.e. soft tissue or bone), n (%)	5 (0.1)
The patient has a bone metabolism disorder other than osteoporosis (i.e. Paget's disease, renal osteodystrophy, or osteomalacia), n (%)	37 (0.5)
The patient has a previous history of frank dementia that would interfere with assessment of the primary outcome (secondary procedure at 2 years), n (%)	1,921 (25.1)
There are problems, in the judgement of the investigators, with maintaining follow up (i.e. patients with no fixed address, report a plan to move out of town, or intellectually challenged patients without adequate family support), n (%)	451 (5.9)

The fracture occurred as a result of violence, n (%)	6 (0.1)
The attending surgeon believes this patient should be excluded because they are enrolled in another ongoing drug or surgical intervention trial, n (%)	51 (0.7)
Patient has a condition and/or a comorbidity that makes them unsuitable for HEALTH, n (%)	417 (5.5)
Unable to obtain consent due to a language barrier, n (%)	63 (0.8)
The attending surgeon does not participate in HEALTH, n (%)	74 (1.0)
The attending surgeon prefers THA, n (%)	181 (2.4)
The attending surgeon prefers HA, n (%)	571 (7.5)
The attending surgeon prefers another treatment, n (%)	334 (4.4)
The reason for exclusion is unspecified by site, n (%)	21 (0.3)
The patient has an old fracture making them unsuitable for HEALTH, n (%)	13 (0.2)
Other reason for exclusion from HEALTH, n (%)	1 (0.01)
The patient or proxy has not provided informed consent, n (%)	677 (8.9)

HA=Hemi-arthroplasty; THA=Total hip arthroplasty;

*Please note, some patients were excluded for more than one reason. We present one reason per patient based on order of reason for exclusion in table

Table S2: Reasons for Exclusion after Adjudication Committee Review

Reasons for Exclusion*	Number of Patients Excluded Following Adjudication	
	THA	HA
The patient is not at least 65 years or older (no upper age limit) (UK age criteria)	1	1
The patient does not have a fracture of the femoral neck confirmed with either anteroposterior and lateral hip radiographs, computed tomography, or magnetic resonance imaging (MRI)	2	3
The patient does not have a displaced fracture that is not repairable via reduction and internal fixation, in the judgement of the attending surgeon	2	1
The patient does not have a low energy fracture (defined as a fall from standing height)	5	4
The fracture occurred as a result of violence	1	0
Total	11	9

HA=Hemi-arthroplasty; THA=Total hip arthroplasty;

*Guided by the recommendations of Fergusson et al who maintain that including ineligible patients in the analyses for clinical trials adds random error and therefore decreases the power of the trial to answer the question(s) being addressed.¹¹

Table S3: Patient Demographics

Characteristic	THA N=718	HA N=723
Age, mean (SD)	N=718 79.1 (8.3)	N=722 78.6 (8.6)
Age, n (%)	N=718	N=722
50 to 70 years	136 (18.9)	149 (20.6)
71 to 80 years	249 (34.7)	247 (34.2)
≥81 years	333 (46.4)	326 (45.2)
Sex, n (%)	N=718	N=722
Male	208 (29.0)	223 (30.9)
Female	510 (71.0)	499 (69.1)
Ethnicity, n (%)	N=716	N=721
Native/Aboriginal	2 (0.3)	1 (0.1)
South Asian	3 (0.4)	6 (0.8)
East Asian	7 (1.0)	7 (1.0)
Hispanic/Latino	7 (1.0)	6 (0.8)
White/Caucasian	683 (95.4)	684 (94.9)
Black (African/Caribbean)	12 (1.7)	15 (2.1)
Middle Eastern	2 (0.3)	2 (0.3)
Body Mass Index (BMI) (kg/m ²), n (%)	N=697	N=705
Underweight <18.5	35 (5.0)	38 (5.4)
Normal weight 18.5-24.9	357 (51.2)	336 (47.7)
Overweight 25-29.9	217 (31.1)	243 (34.5)
Obese 30-39.9	77 (11.0)	83 (11.8)
Morbidly Obese ≥40	11 (1.6)	5 (0.7)
Pre-Fracture Living Status, n (%)	N=718	N=723
Institutionalized	30 (4.2)	27 (3.7)
Not Institutionalized	688 (95.8)	696 (96.3)
Pre-Fracture Functional Status, n (%)	N=718	N=723
Uses assistive device for ambulation	187 (26.0)	182 (25.2)
Able to ambulate without assistive device	531 (74.0)	541 (74.8)
Employed at the Time of Fracture, n (%)	N=601	N=602
Yes	38 (6.3)	38 (6.3)
No	563 (93.7)	564 (93.7)
Retired	506 (84.2)	528 (87.7)
Homemaker	36 (6.0)	18 (3.0)
Doctor Advice/Disabled	14 (2.3)	8 (1.3)

Characteristic	THA N=718	HA N=723
Student	4 (0.7)	1 (0.2)
Unemployed	1 (0.2)	8 (1.3)
Volunteer	2 (0.3)	0 (0.0)
Taking Time Off	0 (0.0)	1 (0.2)
Current Medications, n (%)	N=715	N=722
None	114 (15.9)	127 (17.6)
NSAIDs	91 (12.7)	90 (12.5)
Analgesics: Opioid	63 (8.8)	55 (7.6)
Glucocorticoids	26 (3.6)	23 (3.2)
Anabolic Steroid Therapy	3 (0.4)	1 (0.1)
Hormone Replacement Therapy	30 (4.2)	34 (4.7)
Bisphosphonates	50 (7.0)	47 (6.5)
Other Osteoporosis Medications	28 (3.9)	15 (2.1)
Anti-hypertension Medications	407 (56.9)	402 (55.7)
Pulmonary (Respiratory System) Medications	81 (11.3)	87 (12.1)
General Cardiac Medications	296 (41.4)	278 (38.5)
Calcium	140 (19.6)	139 (19.3)
Calcitonin (Mialcalcin)	2 (0.3)	1 (0.1)
Vitamin D	165 (23.1)	160 (22.2)
Prior Surgery to Affected Hip, n (%)	N=714	N=722
	2 (0.3)	1 (0.1)
Major Comorbidities, n (%)	N=715	N=722
Osteopenia	28 (3.9)	30 (4.2)
Osteoporosis	114 (15.9)	110 (15.2)
Lung disease	127 (17.8)	122 (16.9)
Diabetes	135 (18.9)	145 (20.1)
Ulcers or stomach disease	49 (6.9)	67 (9.3)
Kidney disease	71 (9.9)	67 (9.3)
Anemia or other blood disease	48 (6.7)	55 (7.6)
Depression	70 (9.8)	84 (11.6)
Cancer	65 (9.1)	80 (11.1)
Osteoarthritis, degenerative arthritis	111 (15.5)	91 (12.6)
Back pain	64 (9.0)	71 (9.8)
Rheumatoid arthritis	13 (1.8)	21 (2.9)
Heart disease	247 (34.5)	249 (34.5)
High blood pressure	434 (60.7)	443 (61.4)

HA=Hemi-arthroplasty; THA=Total hip arthroplasty; SD = Standard deviation; NSAIDS = Nonsteroidal anti-inflammatory drugs

Table S4: Fracture Characteristics

Characteristic	THA N=718	HA N=723
Fractured Hip, n (%)	N=715	N=722
Left	386 (54.0)	386 (53.5)
Right	329 (46.0)	336 (46.5)
Level of the Fracture Line, n (%)	N=715	N=722
Subcapital	434 (60.7)	456 (63.2)
Midcervical	251 (35.1)	230 (31.9)
Basal	30 (4.2)	36 (5.0)
Garden Classification, n (%)	N=715	N=722
Garden III (displaced)	311 (43.5)	320 (44.3)
Garden IV (displaced)	404 (56.5)	402 (55.7)
Pauwels' Classification, n (%)	N=714	N=721
Type I	70 (9.8)	47 (6.5)
Type II	404 (56.6)	367 (50.9)
Type III	240 (33.6)	307 (42.6)
Mechanism of Injury, n (%)	N=715	N=722
Fall from standing	696 (97.3)	700 (97.0)
Spontaneous fracture	16 (2.2)	14 (1.9)
Fall from small height	3 (0.4)	8 (1.1)
Additional Fractures, n (%)	N=714	N=722
Upper extremity	34 (4.8)	25 (3.5)
Lower extremity	0 (0.0)	1 (0.1)
Spine	0 (0.0)	1 (0.1)
Pelvis	2 (0.3)	0 (0.0)
Chest	2 (0.3)	1 (0.1)
Sternum	0 (0.0)	1 (0.1)
Additional Injuries, n (%)	N=714	N=722
Pneumothorax	0 (0.0)	2 (0.3)
Minor Facial or Neck Injury	8 (1.1)	11 (1.5)
Minor Bruising/Contusion	2 (0.3)	6 (0.8)
Minor Laceration/Abrasion	10 (1.4)	6 (0.8)
Dislocation	0 (0.0)	2 (0.3)
Head Trauma	3 (0.4)	4 (0.6)
Sprain	1 (0.1)	0 (0.0)
Hematoma	2 (0.3)	1 (0.1)
Other Orthopaedic Injury	4 (0.6)	0 (0.0)

HA=Hemi-arthroplasty; THA=Total hip arthroplasty;

Table S5: Summary of Pre-Operative Care Details

Characteristic	THA N=718	HA N=723
Pre-operative Traction, n (%)	N=714 661 (92.6)	N=722 666 (92.2)
Pre-operative Antibiotic Prophylaxis, n (%)	N=715 640 (89.5)	N=722 654 (90.6)
Pre-operative Thromboprophylaxis, n (%)	N=714	N=718
Heparin	41 (5.7)	38 (5.3)
Warfarin	16 (2.2)	21 (2.9)
Low Molecular Weight Heparin	348 (48.7)	342 (47.6)
Mechanical	110 (15.4)	109 (15.2)
Acetylsalicylic Acid (ASA)	7 (1.0)	5 (0.7)
Other	14 (2.0)	8 (1.1)
Medical Consultation Provided to Optimize Condition Before Surgery, n (%)	N=715 640 (89.5)	N=721 642 (89.0)

HA=Hemi-arthroplasty; THA=Total hip arthroplasty;

Table S6: Surgical and Peri-Operative Management

Surgery Characteristic	THA N=718	HA N=723
Time from Injury to Surgery, mean (SD) (hours)	N=663 54.9 (79.0)	N=674 52.5 (80.3)
Length of Procedure, mean (SD) (minutes)	N=710 92.6 (41.5)	N=711 81.0 (37.6)
Procedure Performed, n (%)	N=716	N=719
THA	657 (91.8)	0 (0.0)
HA	0 (0.0)	694 (96.5)
Internal Fixation	5 (0.7)	4 (0.6)
Crossover from THA to HA*	54 (7.5)	0 (0.0)
Crossover from HA to THA**	0 (0.0)	21 (2.9)
Who Performed Majority of Procedure, n (%)	N=714	N=719
Attending	541 (75.8)	417 (58.0)
Fellow	46 (6.4)	76 (10.6)
Resident	127 (17.8)	226 (31.4)
Expert Surgeon's Position, n (%)	N=714	N=713
Attending	689 (96.5)	665 (93.3)
Fellow	25 (3.5)	48 (6.7)
Surgeon Meets the Expertise Threshold for the Procedure Patient Received, n (%)	N=711 699 (98.3)	N=715 696 (97.3)
Expert Surgeon Present in Operating Room for Critical Aspects of Procedure, n (%)	N=716 712 (99.4)	N=719 709 (98.6)
ASA Physical Class System, n (%)	N=657	N=672
Class I	22 (3.4)	20 (3.0)
Class II	280 (42.6)	275 (40.9)
Class III	305 (46.4)	326 (48.5)
Class IV	50 (7.6)	51 (7.6)
Class V	0 (0.0)	0 (0.0)
Type of Anaesthesia, n (%)	N=716	N=719
General	262 (36.6)	273 (38.0)
Regional	484 (67.6)	469 (65.2)
Sedation	10 (1.4)	4 (0.6)
Neurolept	9 (1.3)	7 (1.0)
Total Blood Loss, mean (SD) (mL)	N=672 329.2 (207.4)	N=683 257.2 (152.4)
Surgical Approach Used, n (%)	N=709	N=715
Direct Anterior	26 (3.7)	10 (1.4)
Anterolateral/Lateral	431 (60.8)	500 (69.9)
Posterior	229 (32.3)	191 (26.7)

Surgery Characteristic	THA N=718	HA N=723
Anteromedial	1 (0.1)	1 (0.1)
Posterolateral	22 (3.1)	13 (1.8)
Femoral Head Implant Company, n (%)	N=711	N=715
Stryker	295 (41.5)	296 (41.4)
DePuy	97 (13.6)	89 (12.5)
Wright Medical	0 (0.0)	1 (0.1)
Smith & Nephew	73 (10.3)	90 (12.6)
Biomet	36 (5.1)	37 (5.2)
Zimmer	127 (17.9)	103 (14.4)
Other	83 (11.7)	99 (13.9)
Femoral Stem Implant Company, n (%)	N=711	N=715
Stryker	297 (41.8)	295 (41.3)
DePuy	98 (13.8)	90 (12.6)
Wright Medical	0 (0.0)	1 (0.1)
Smith & Nephew	71 (10.0)	90 (12.6)
Biomet	35 (4.9)	37 (5.2)
Zimmer	122 (17.2)	104 (14.6)
Other	88 (12.4)	98 (13.7)
Material of Femoral Head Component, n (%)	N=709	N=715
Stainless Steel	201 (28.4)	209 (29.2)
Oxinium	5 (0.7)	3 (0.4)
Ceramic	63 (8.9)	8 (1.1)
Cobalt-Chrome	434 (61.2)	479 (67.0)
Aluminum	3 (0.4)	0 (0.0)
Titanium	3 (0.4)	10 (1.4)
Vitalium	0 (0.0)	6 (0.8)
Material of Femoral Stem Component, n (%)	N=708	N=715
Stainless Steel	261 (36.9)	276 (19.4)
Cobalt-Chrome	190 (26.8)	241 (33.7)
Titanium	257 (36.3)	198 (27.7)
Vitalium	0 (0.0)	0 (0.0)
Femoral Implant Porous Coated, n (%)	N=707	N=710
No Porous Coating	458 (64.8)	470 (66.2)
Grit Blasted Fully Porous Coated	28 (4.0)	28 (3.9)
Grit Blasted Partially Porous Coated	39 (5.5)	52 (7.3)
HA Fully Porous Coated	58 (8.2)	52 (7.3)
HA Partially Porous Coated	91 (12.9)	74 (10.4)
HA Porous Coating Not Specified	0 (0.0)	2 (0.3)
Other Fully Porous Coated	2 (0.3)	0 (0.0)

Surgery Characteristic	THA N=718	HA N=723
Other Partially Porous Coated	30 (4.2)	32 (4.5)
Other Porous Coating Not Specified	1 (0.1)	0 (0.0)
Bone Grafting of Femur, n (%)	N=710	N=715
Autograft	12 (1.7)	10 (1.4)
Allograft	2 (0.3)	3 (0.4)
Type of Femoral Stem, n (%)	N=711	N=715
Cemented	432 (60.8)	486 (68.0)
Press-Fit	276 (38.8)	229 (32.0)
Hybrid	1 (0.1)	0 (0.0)
Fully Porous Coated	1 (0.1)	0 (0.0)
N/A – Internal Fixation	1 (0.1)	0 (0.0)
Offset of the Chosen Stem, n (%)	N=593	N=594
Standard	453 (76.4)	499 (84.0)
High	129 (21.8)	80 (13.5)
Reduced	11 (1.9)	15 (2.5)
Other Surgical Procedures or Secondary Procedures Planned for Patient's Fractured Hip, n (%)	N=716	N=719
	1 (0.1)	1 (0.1)

HA=Hemi-arthroplasty; THA=Total hip arthroplasty; SD=Standard deviation

*Reasons for crossover from THA to HA included: error, surgeon decision, surgeon with THA expertise not available, patient preference for HA

**Reasons for crossover from HA to THA included: error, surgeon decision, patient preference for THA

Table S7: THA Surgical Management

THA Characteristic	THA N=678
Manufacturer of Acetabular Implant, n (%)	N=676
Stryker	212 (31.4)
DePuy	163 (24.1)
Smith & Nephew	73 (10.8)
Biomet	37 (5.5)
Zimmer	122 (18.1)
Waldemar LINK GmbH & Co. KG	22 (3.3)
JRI Orthopaedics Ltd	31 (4.6)
Lima Corporate	1 (0.2)
Mathys Ltd Bettlach	4 (0.6)
Medacta International	2 (0.3)
OMNIlife science™, Inc.	1 (0.2)
Symbios Orthopaedics	6 (0.9)
United Orthopedic Corporation	1 (0.2)
Plus Orthopedics	1 (0.2)
Type of Acetabular Implant, n (%)	N=677
Cemented	231 (34.1)
Both Porous and HA Coated Press-Fit	7 (1.0)
Porous Coated Press-Fit	252 (37.2)
HA Coated Press-Fit	178 (26.3)
Trabecular Metal	2 (0.3)
Screw Cup	7 (1.0)
Acetabular Implant Augmented with Screw Fixation, n (%)	N=677
	270 (39.9)
Number of Screws Used for Any Acetabular Implant Augmented with Screw Fixation, n (%)	N=269
One	123 (45.7)
Two	121 (45.0)
Three	24 (8.9)
Four	1 (0.4)
Acetabular Component Modular, n (%)	N=676
	287 (42.5)
Material of Acetabular Liner, n (%)	N=675
Highly cross-linked Polyethylene	379 (56.2)
Metal	26 (3.9)
Ceramic	9 (1.3)
Polyethylene	255 (37.8)
Polymetal	2 (0.3)
ZCA Allpoly Acetabular	2 (0.3)

Modular Dual Mobility	2 (0.3)
Augmentation of the Acetabular Liner, n (%)	N=674
Neutral	415 (61.6)
10 Degree	168 (24.9)
15 Degree	1 (0.2)
20 Degree	75 (11.1)
Offset	9 (1.3)
Constrained	1 (0.2)
Dual Mobility	5 (0.7)
Diameter of Acetabular Shell, mean (SD) (mm)	N=626 50.2 (5.9)
Diameter of the Femoral Head, n (%)	N=668
22 mm	10 (1.5)
28 mm	115 (17.2)
32 mm	354 (53.0)
34 mm	2 (0.3)
35 mm	1 (0.2)
≥36 mm	186 (27.8)

THA=Total hip arthroplasty; SD=Standard deviation

Table S8: HA Surgical Management

HA Characteristic	HA N=748
Type of HA, n (%)	N=746
Bipolar HA	404 (54.2)
Modular monopolar HA	311 (41.7)
Non-modular monopolar HA	31 (4.2)
Outer Diameter of Bipolar Shell, mean (SD) (mm)	N=401 47.3 (4.3)
Inner Diameter of Bipolar Shell, mean (SD) (mm)	N=395 29.7 (5.4)
Length of the Bipolar Head, mean (SD) (mm)	N=227 15.9 (16.7)
Offset of the Chosen Bipolar Head, mean (SD) (mm)	N=349 0.2 (2.9)
Diameter of the Chosen Bipolar Head, mean (SD) (mm)	N=392 29.8 (6.6)
Offset of the Chosen Modular Monopolar Head, mean (SD) (mm)	N=213 1.0 (6.2)
Diameter of the Chosen Modular Monopolar Head, mean (SD) (mm)	N=305 48.0 (4.4)
Implant Size of Non-Modular Monopolar HA, n (%)	N=31
Standard	30 (96.8)
Narrow	1 (3.2)

HA=Hemi-arthroplasty; SD=Standard deviation

Table S9: Summary of Post-Operative Care Details

Characteristic	THA N=718	HA N=723
Post-Operative Antibiotic Prophylaxis, n (%)	N=711 606 (85.2)	N=716 597 (83.4)
Post-Operative Thromboprophylaxis, n (%)	N=710	N=715
Heparin	41 (5.8)	42 (5.9)
Warfarin	42 (5.9)	44 (6.2)
Low Molecular Weight Heparin	587 (82.7)	596 (83.4)
Mechanical	66 (9.3)	81 (11.3)
Acetylsalicylic Acid (ASA)	17 (2.4)	14 (2.0)
Other	17 (2.4)	18 (2.5)
Weightbearing, n (%)	N=712	N=717
Full weightbearing	424 (59.6)	438 (61.1)
Partial weightbearing	271 (38.1)	271 (37.8)
Non-weightbearing	17 (2.4)	8 (1.1)
Prescribed Post-operative Calcium, n (%)	N=711 394 (55.4)	N=717 420 (58.6)
Prescribed Post-operative Vitamin D, n (%)	N=712 431 (60.5)	N=716 444 (62.0)
Received Nutritional Assessment Prior to Hospital Discharge, n (%)	N=707 421 (59.6)	N=716 442 (61.7)
Discharge Location, n (%)	N=713	N=719
Home	253 (35.5)	267 (37.1)
Aging and Long-Term Care Facility/Skilled Nursing Facility	136 (19.1)	133 (18.5)
Rehabilitation Facility	282 (39.6)	283 (39.4)
Community Hospital	16 (2.2)	18 (2.5)
Transitional Care	8 (1.1)	6 (0.8)
Patient Deceased	17 (2.4)	9 (1.3)
Other	1 (0.1)	3 (0.4)
Aids at Hospital Discharge, n (%)	N=696	N=708
Bedridden	16 (2.3)	19 (2.7)
Wheelchair	90 (12.9)	86 (12.2)
Walker	562 (80.8)	604 (85.3)
Cane	16 (2.3)	15 (2.1)
One Crutch	13 (1.9)	6 (0.9)
Two Crutches	102 (14.7)	72 (10.2)
Assisted by Person	17 (2.4)	15 (2.1)
Mobility Scooter	0 (0.0)	1 (0.1)
Two Canes	0 (0.0)	2 (0.3)
None (Participant is ambulatory)	4 (0.6)	6 (0.9)

Table S10: Procedure Performed by Country

Procedure Performed, n (%)	THA N=718	HA N=723
Canada	N=169	N=178
THA	155 (91.7)	3 (1.7)
HA	12 (7.1)	174 (97.8)
Internal Fixation	2 (1.2)	1 (0.6)
The Netherlands	N=103	N=106
THA	92 (89.3)	3 (2.8)
HA	8 (7.8)	100 (94.3)
Internal Fixation	3 (2.9)	3 (2.8)
USA	N=113	N=112
THA	104 (92.0)	4 (3.6)
HA	9 (8.0)	108 (96.4)
Internal Fixation	0 (0.0)	0 (0.0)
Australia	N=34	N=38
THA	27 (79.4)	1 (2.6)
HA	7 (20.6)	37 (97.4)
Internal Fixation	0 (0.0)	0 (0.0)
Norway	N=85	N=84
THA	83 (97.6)	0 (0.0)
HA	2 (2.4)	84 (100.0)
Internal Fixation	0 (0.0)	0 (0.0)
Spain	N=107	N=103
THA	94 (87.9)	6 (5.8)
HA	13 (12.1)	97 (94.2)
Internal Fixation	0 (0.0)	0 (0.0)
UK	N=71	N=67
THA	68 (95.8)	4 (6.0)
HA	3 (4.2)	63 (94.0)
Internal Fixation	0 (0.0)	0 (0.0)
Finland	N=27	N=24
THA	27 (100.0)	0 (0.0)
HA	0 (0.0)	24 (100.0)
Internal Fixation	0 (0.0)	0 (0.0)
New Zealand	N=4	N=4
THA	4 (100.0)	0 (0.0)

Procedure Performed, n (%)	THA N=718	HA N=723
HA	0 (0.0)	4 (100.0)
Internal Fixation	0 (0.0)	0 (0.0)
South Africa	N=3	N=3
THA	3 (100.0)	0 (0.0)
HA	0 (0.0)	3 (100.0)
Internal Fixation	0 (0.0)	0 (0.0)
Total	N=716	N=719
THA	657 (91.8)	21 (2.9)
HA	54 (7.5)	694 (96.5)
Internal Fixation	5 (0.7)	4 (0.6)

Table S11: Primary Endpoint by Treatment Group Per Year

Primary Endpoint	THA N=718	HA N=723	Hazard Ratio** (95% CI)	P-Value
Unplanned Secondary Procedure (Total composite)*	57 (7.9)	60 (8.3)	First year: 1.23 (0.82, 1.86) Second year: 0.23 (0.08, 0.69)	0.32 0.01

* Treatment does not meet the assumption of proportional hazards

** Regression modeling of subdistribution hazards. The minimization factors are included as covariates in the regression: age (50-80 years or >80 years), pre-fracture living setting (institutionalized or not institutionalized), pre-fracture functional status (using assistive device for ambulation or able to ambulate without assistive device), and ASA Class (Class I/II or III/IV/V). Surgeon is included as a random effect.

Table S12: Sensitivity Analyses – Unstratified Proportions Analyses

	Patients with 24-month follow-up or experienced the primary outcome prior to being withdrawn or died	Early withdrawal prior to experiencing the primary outcome	All Patients	p-value for difference between THA and HA*
	Primary outcome n/N (%)	Primary outcome n/N (%)	Primary outcome n/N (%)	
Excluding those without complete follow-up				
THA	57/638 (8.9)	-/80 (-)	- (-)	0.77
HA	60/631 (9.5)	-/92 (-)	- (-)	
Assume missing patients have a) HA: same event rate as nonmissing, and b) THA: same event rate as nonmissing				
THA	57/638 (8.9)	7/80 (8.8)	64/718 (8.9)	0.72
HA	60/631 (9.5)	9/92 (9.8)	69/723 (9.5)	
Increase the event rate in THA				
Assume missing patients have a) HA: same event rate as nonmissing, and b) THA: 2x the event rate as nonmissing				
THA	57/638 (8.9)	14/80 (17.5)	71/718 (9.9)	0.86
HA	60/631 (9.5)	9/92 (9.8)	69/723 (9.5)	
Assume missing patients have a) HA: same event rate as nonmissing, and b) THA: 3x the event rate as nonmissing				
THA	57/638 (8.9)	21/80 (26.3)	78/718 (10.9)	0.43
HA	60/631 (9.5)	9/92 (9.8)	69/723 (9.5)	
Assume missing patients have a) HA: same event rate as nonmissing, and b) THA: 4x the event rate as nonmissing				
THA	57/638 (8.9)	29/80 (36.5)	86/718 (12.0)	0.15
HA	60/631 (9.5)	9/92 (9.8)	69/723 (9.5)	
Increase the event rate in HA				

Assume missing patients have a) HA: 2x the event rate as nonmissing, and b) THA: same event rate as nonmissing				
THA	57/638 (8.9)	7/80 (8.8)	64/718 (8.9)	0.29
HA	60/631 (9.5)	17/92 (18.5)	77/723 (10.7)	
Assume missing patients have a) HA: 3x the event rate as nonmissing, and b) THA: same event rate as nonmissing				
THA	57/638 (8.9)	7/80 (8.8)	64/718 (8.9)	0.07
HA	60/631 (9.5)	26/92 (28.3)	86/723 (11.9)	
Assume missing patients have a) HA: 4x the event rate as nonmissing, and b) THA: same event rate as nonmissing				
THA	57/638 (8.9)	7/80 (8.8)	64/718 (8.9)	0.01
HA	60/631 (9.5)	35/92 (38.0)	95/723 (13.1)	

* Fisher's Exact Test.

Those who died without experiencing the primary outcome are included in these analyses as not having the outcome.

Table S13: Sensitivity Analyses Using Competing Risk Analyses

Endpoint	THA N=718	HA N=723	Hazard Ratio (95% CI)	P-Value
Primary Analysis with Surgeon Removed as a Random Effect*				
Primary Outcome	N=718 57 (7.9)	N=723 60 (8.3)	0.95 (0.66, 1.36)	0.77
Primary Analysis with Country Added as a Fixed Effect*				
Primary Outcome	N=718 57 (7.9)	N=723 60 (8.3)	0.94 (0.64, 1.39)	0.77
Per-Protocol Analysis**				
Primary Outcome, n (%)	N=658 55 (8.4)	N=694 57 (8.2)	1.01 (0.68, 1.50)	0.97
As-Treated Analysis**				
Primary Outcome, n (%)	N=679 57 (8.4)	N=747 59 (7.9)	1.05 (0.71, 1.55)	0.80

HA=Hemi-arthroplasty; THA=Total hip arthroplasty; 95% CI=95% Confidence Interval

*Using competing risk analysis (death as a competing risk)

**Using competing risk analysis (death as a competing risk) and accounting for clustering by surgeon

Note that the competing risk analysis methods do not allow for the inclusion of a random effect.

Table S14: Participants who did and did not contribute to the Health-Related Quality of Life, Function or Health Outcomes Analyses

Characteristic	THA		HA	
	N=718		N=723	
	Participants who contributed NO data to any HRQL or function analysis N=54	Participants who contributed ANY data to any HRQL or function analysis N=664	Participants who contributed NO data to any HRQL or function analysis N=63	Participants who contributed ANY data to any HRQL or function analysis N=660
Age, mean (SD)	N=54 83.4 (7.1)	N=664 78.7 (8.2)	N=63 79.9 (9.6)	N=659 78.4 (8.5)
Sex, n (%)	N=54	N=664	N=63	N=659
Male	20 (37.0)	188 (28.3)	21 (33.3)	202 (30.7)
Female	34 (63.0)	476 (71.7)	42 (66.7)	457 (69.3)
Ethnicity, n (%)	N=52	N=664	N=63	N=658
Native/Aboriginal	0 (0.0)	2 (0.3)	0 (0.0)	1 (0.2)
South Asian	0 (0.0)	3 (0.5)	0 (0.0)	6 (0.9)
East Asian	0 (0.0)	7 (1.1)	2 (3.2)	5 (0.8)
Hispanic/Latino	0 (0.0)	7 (1.1)	0 (0.0)	6 (0.9)
White/Caucasian	49 (94.2)	634 (95.5)	59 (93.7)	625 (95.0)
Black (African/Caribbean)	3 (5.8)	9 (1.4)	2 (3.2)	13 (2.0)
Middle Eastern	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.3)
Body Mass Index (BMI) (kg/m ²), n (%)	N=45	N=652	N=58	N=647
Underweight <18.5	3 (6.7)	32 (4.9)	5 (8.6)	33 (5.1)
Normal weight 18.5-24.9	29 (64.4)	328 (50.3)	36 (62.1)	300 (46.4)
Overweight 25-29.9	10 (22.2)	207 (31.7)	12 (20.7)	231 (35.7)
Obese 30-39.9	2 (4.4)	75 (11.5)	5 (8.6)	78 (12.1)
Morbidly Obese ≥40	1 (2.2)	10 (1.5)	0 (0.0)	5 (0.8)
Pre-Fracture Living Status, n (%)	N=54	N=664	N=63	N=660
Institutionalized	3 (5.6)	27 (4.1)	4 (6.3)	23 (3.5)
Not Institutionalized	51 (94.4)	637 (95.9)	59 (93.7)	637 (96.5)
Pre-Fracture Functional Status, n (%)	N=54	N=664	N=63	N=660
Uses assistive device for ambulation	26 (48.1)	161 (24.2)	24 (38.1)	158 (23.9)
Able to ambulate without assistive device	28 (51.9)	503 (75.8)	39 (61.9)	502 (76.1)
Any Major Comorbidities, n (%)	N=51 49 (96.1)	N=664 582 (87.7)	N=63 58 (92.1)	N=659 572 (86.8)

Table S15: Subgroup Analyses for Primary Endpoint Using Competing Risk Analyses

Characteristic	Hazard Ratio* (95% CI)	P-Value for the interaction
A Priori Subgroup Analyses**		
Age, 50 to 80 years >80 years	1.02 (0.63, 1.66) 0.85 (0.48, 1.49)	0.59
Pre-Fracture Living Status Institutionalized Not Institutionalized	2.67 (0.25, 28.04) 0.92 (0.62, 1.37)	0.39
Pre-Fracture Functional Status Uses assistive device for ambulation Able to ambulate without assistive device	0.73 (0.37, 1.42) 1.05 (0.66, 1.68)	0.37
American Society of Anaesthesiologists Physical Class System Class I/II Class III/IV/V	1.06 (0.63, 1.80) 0.86 (0.50, 1.47)	0.57
Post Hoc Subgroup Analyses**		
Age 50 to 70 years 71 to 80 years ≥81 years	0.44 (0.15, 1.29) 1.30 (0.75, 2.26) 0.84 (0.48, 1.49)	0.17
WOMAC Total Score: Age 50 to 70 years 71 to 80 years ≥81 years	Mean Difference (99% CI)*** -3.22 (-8.69, 2.25) -0.70 (-4.16, 2.75) -3.34 (-6.82, 0.15)	0.33
Country Canada Netherlands USA Australia Norway Spain UK Finland	0.51 (0.21, 1.25) 1.30 (0.55, 3.06) 0.90 (0.33, 2.49) 1.63 (0.42, 6.26) 0.47 (0.18, 1.26) 1.77 (0.77, 4.06) 1.36 (0.38, 4.86) 0.17 (0.02, 1.32)	

Characteristic	Hazard Ratio* (95% CI)	P-Value for the interaction
New Zealand	Not estimated****	
South Africa	Not estimated*****	

95% CI=95% Confidence Interval; 99% CI=99% Confidence Interval

*Hazard ratio presented as total hip arthroplasty relative to hemi-arthroplasty

**Using competing risk analysis (death as a competing risk) and accounting for clustering by surgeon

***Total hip arthroplasty minus hemi-arthroplasty

**** There are only 8 patients from New Zealand, 4 in each group. There is one event in the hemi-arthroplasty group, none in the total hip arthroplasty group.

***** There are only 6 patients from South Africa, 3 in each group. There is one event in the total hip arthroplasty group, none in the hemi-arthroplasty group.

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