Appendix 2. Data Extraction Form

ARTICLE

First author ……………………………………

Date of publication (year) [|__|__|__|__|]

Was there a statistician or a methodologist among the authors (see in the affiliation)? □ Yes □ No

INTERVENTIONS

Study Group

☐ Total Hip Replacement
   ☐ standard technique
   ☐ minimally invasive
   ☐ computer assisted

☐ Total Knee Replacement
   ☐ standard technique
   ☐ minimally invasive
   ☐ computer assisted

Control Group

☐ Total Hip Replacement
   ☐ standard
   ☐ minimally invasive
   ☐ computer assisted

☐ Total Knee Replacement
   ☐ standard technique
   ☐ minimally invasive
   ☐ computer assisted

DEMOGRAPHIC DATA

Study design

☐ Randomised control trial

☐ Nonrandomised study
   ☐ Comparative cohort study
Prospective  ✔  Retrospective  ❌  Unclear  ❌  Historically controlled study  ❌  Case-control study  ❌  Other  ❌

Number of arms  □ □
Sample size  □ □ □ □ □ hips/knees
□ □ □ □ □ patients

In case of nonrandomised study, was the reason for the design chosen justified?
☐ Yes  ☐ No

Evaluation of internal validity

1. CREATION OF TREATMENT GROUPS

Were the patients in the different intervention groups recruited from the same population?
☐ Yes  ☐ No  ☐ Unclear

IF YES, were groups comparable at baseline?
☐ Yes  ☐ No  ☐ NA (characteristics at baseline not reported)

Was there any attempt to balance groups by design to control selection bias?
☐ Yes  ☐ No  ☐ Unclear  ☐ NA

IF YES, what was the method used for this purpose?
☐ Matching (includes studies with only bilateral procedures)
☐ Stratification
☐ Restriction to particular subgroups
☐ Other

For NRS, did study groups consist of consecutive series of patients?
☐ Yes  ☐ No  ☐ Unclear

Was the method of assignment of patients to different prostheses described?
☐ Yes  ☐ No  ☐ Unclear

IF YES, was it:
- randomised:  ☐ Yes  ☐ No
- according to period of time:  ☐ Yes  ☐ No
- according to clinicians or patients preference: □ Yes □ No
- according to care provider: □ Yes □ No
- according to centre: □ Yes □ No

For RCT, was the generation of allocation sequences adequate?
□ Yes □ No □ Unclear

For RCT, was the treatment allocation concealed?
□ Yes □ No □ Unclear

2. DATA COLLECTION

What were the main outcomes assessed?
□ Composite
□ Multiple
□ Simple (there is a single primary endpoint)

Did the main outcomes include:
□ PRO (Patient-Reported Outcomes)
□ Physician reported outcome
□ Functional questionnaire
□ Clinical event (eg revision of the implant, complications)
□ Radiographic findings (eg implants’ positioning)
□ Other complementary tests (other than radiographic findings)
□ Other outcomes (operative time, blood loss, hospital stay, …)

Was the outcome assessment blinded to the intervention of participants (when possible)?
□ Yes □ No □ Unclear

In case the outcome assessor was not blinded, was there an independent outcome assessor?
□ Yes □ No □ Unclear

Was there a monitoring procedure reported?
□ Yes □ No □ Unclear

Was there a quality control of data collection reported?
□ Yes □ No □ Unclear

3. FOLLOW-UP

Was the length of follow up reported?
□ Yes □ No □ Unclear

IF YES, how long? □ ≤ 3 months □ ≤ 6 months □ ≤ 12 months
Were there patients excluded from the analysis?

- Yes
- No
- Unclear
- Not reported

IF YES, was the percentage of excluded patients reported?

- Yes
- No
- Unclear

➢ when reported for HIPS / KNEES:
  - the global percentage: □ □ □ %
  - the percentage by group: □ □ □ %

➢ when reported for PATIENTS:
  - the global percentage: □ □ □ %
  - the percentage by group: □ □ □ %

Was the rate of missing data reported?

- Yes
- No
- Unclear
- Not reported

IF YES, indicate:

➢ when reported for HIPS / KNEES:
  - the global percentage: □ □ □ %
  - the percentage by group: □ □ □ %

➢ when reported for PATIENTS:
  - the global percentage: □ □ □ %
  - the percentage by group: □ □ □ %

4. ANALYSIS

Was there a sample size calculation or power calculation?

- Yes
- No
- Unclear

Were important confounders managed in the analysis?

- Yes
- No
- Unclear

IF YES, what was the method of analysis used?

- Stratified analysis
- Regression modelling with covariates
- Regression modelling with propensity scores
Were the missing data dealt with in statistical analysis?
☐ Yes  ☐ No  ☐ Unclear

Evaluation of applicability

PATIENTS

Recruitment
Were the dates defining the period of recruitment reported?
☐ Yes  ☐ No

Selection of patients
Were eligibility criteria reported?
☐ No
Were criteria used to decide to operate patients reported?
☐ Yes
Was the number of eligible patients reported?
☐ No
IF YES N=  ____  ____  ____

-Were the reasons for exclusion participation reported?
☐ Yes

- Were baseline data on excluded patients reported?
☐ Yes

Characteristics of patients
Were the baseline clinical characteristics of patients reported?
☐ Yes
☐ No
IF YES, did these data concern:
☐ Age  ☐ Activity level
☐ Sex  ☐ Measure of functional status
☐ Weight / Height / BMI  ☐ Level of pain
☐ Race  ☐ Description of radiographic deformity
☐ Diagnostic  ☐ Coexisting diseases or co-morbidities

Number of data reported to describe the population at baseline N=  ____  ____  ____

SETTING AND CENTRES
Country
Were the countries where the trial took place reported?
☐ Yes clearly in the text  ☐ Yes in the affiliation  ☐ No

IF YES, indicate the number of countries participating: N= __________

Intervention centre
Was the number of centres reported?
☐ No

IF YES N= __________

Were details of the centres reported?
☐ Yes  ☐ No

IF YES how?
- number of interventions performed ☐ Yes  ☐ No
- reported as "expert" with no details ☐ Yes  ☐ No

CARE PROVIDER
Were data on care providers reported?
☐ No

IF YES:
- Were they reported as "experts" with no details ☐ Yes  ☐ No
- Were data on years of practice reported? ☐ Yes  ☐ No
- Were data on number of experimental interventions performed reported? ☐ Yes  ☐ No

Was the number of care providers reported?
☐ Yes  ☐ No

IF YES N= __________

INTERVENTION (experimental group)
Was the surgical approach reported?
☐ Yes ☐ No

Was the length of the incision reported?
☐ Yes ☐ No

Was the number of surgical assistants reported?
☐ Yes ☐ No

Was the operative time reported?
☐ Yes ☐ No

Was the blood loss reported?
☐ Yes ☐ No

Were the prosthesis implanted described?
☐ Yes ☐ No
Was the brand name of the experimental device reported? [ ] Yes [ ] No

Was the type of fixation reported? [ ] Yes [ ] No

Was the information provided to patients reported? [ ] Yes [ ] No

Was the preoperative care reported? [ ] Yes [ ] No

Was the anesthesia protocol reported? [ ] Yes [ ] No

Was the thromboprophylaxis protocol reported? [ ] Yes [ ] No

Were the anti-infective prophylaxis protocol reported? [ ] Yes [ ] No

Was the postoperative pain management protocol reported? [ ] Yes [ ] No

Was the postoperative rehabilitation program described? [ ] Yes [ ] No

Was the length of the hospitalization stay reported? [ ] Yes [ ] No

**Minimally invasive technique**

Was the instrumentation used described? [ ] Yes [ ] No

IF YES:
- Was it reported as specific? [ ] Yes [ ] No

IF YES:
- Was its trademark (or brand name) reported? [ ] Yes [ ] No

**Computer-assisted technique**

Was the type of computer navigation system described? [ ] Yes [ ] No

IF YES:
- Was its trademark (or brand name) reported? [ ] Yes [ ] No

IF YES:
- Was it reported as: [ ] image based\(^1\) OR [ ] imageless (bone morphing)\(^2\)

- Was it reported as: [ ] open OR [ ] closed\(^3\)?

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\(^1\) Pre-operative image sets are required

\(^2\) Also called CT free computer-assisted system

\(^3\) Specific to a particular trademark of prosthesis
HARM

Were adverse events/complications reported?
☐ Yes  ☐ No  ☐ Unclear
   IF YES, were they reported:
      - for peri-operative and early post-operative complications ☐ Yes  ☐
      No
      - for post-operative complications ☐ Yes  ☐ No

Were severe adverse events defined?
☐ Yes  ☐ No  ☐ Unclear
   IF YES, were they defined:
      - for peri-operative and early post-operative complications ☐ Yes  ☐
      No
      - for post-operative complications ☐ Yes  ☐ No

DISCUSSION

Was applicability discussed in the discussion section?
☐ Yes  ☐
No