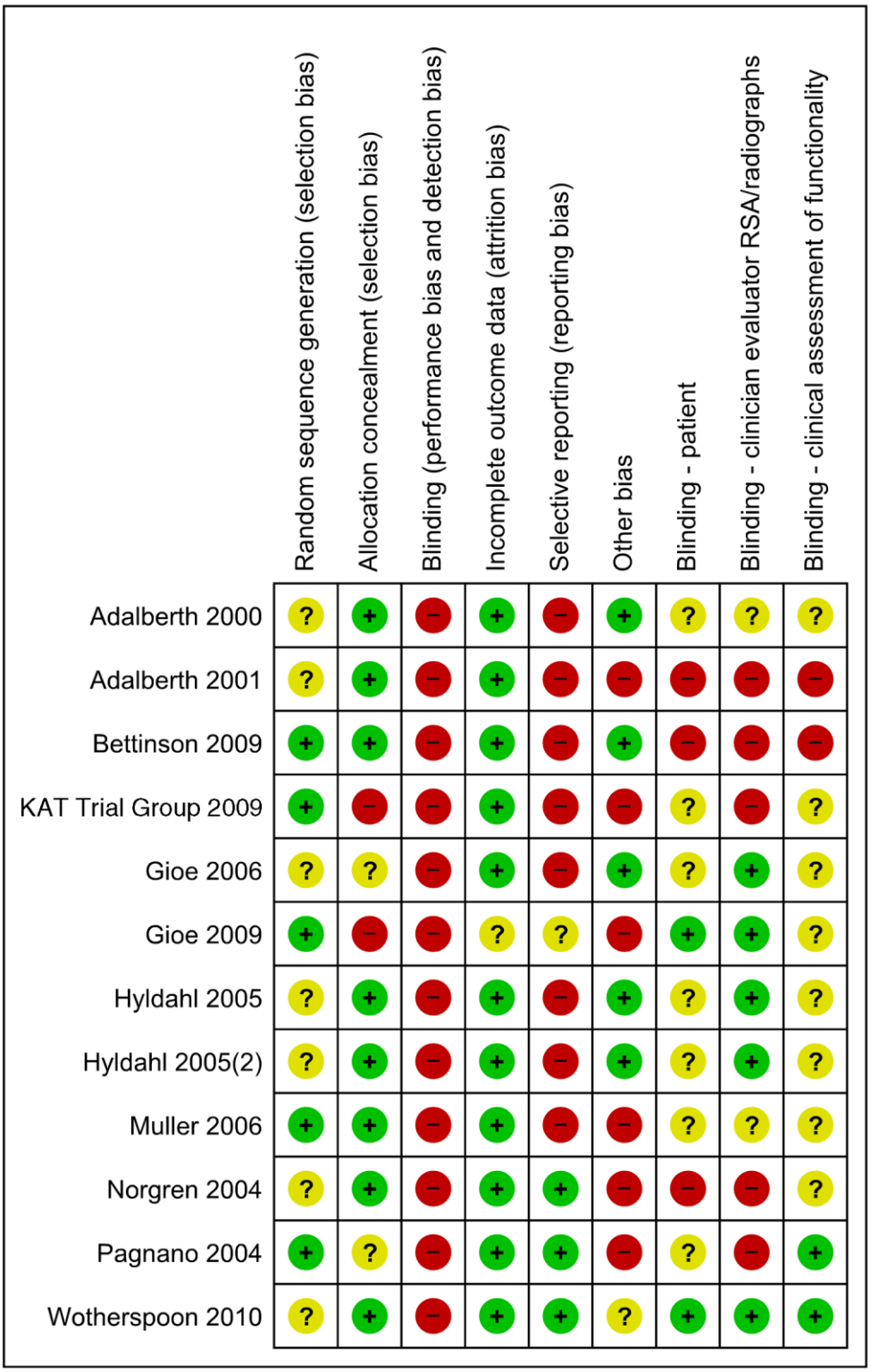

Fig. E-1
Illustration summarizing the risk of bias by trial. RSA = radiostereometric analysis.

TABLE E-1 Number of Participants

Study	Participants
Adalberth[54] (2000)	34
Adalberth[19] (2001)	40
Bettinson[7] (2009)	293
KAT Trial Group[8] (2009)	409
Gioe[26] (2006)	200
Gioe[9] (2009)	312
Hyldahl[32] (2005)	40
Hyldahl[33] (2005)	40
Muller[39] (2006)	40
Norgren[56] (2004)	23
Pagnano[45] (2004)	240
Wotherspoon[58] (2010)	127
Total	1798

TABLE E-2 Data on Ages and Ranges from Trials

	Age *(yr)*	
Study	Mean or Median	Range*
Adalberth[19] (2001)		
Metal-backed	70 (median)	52 to 78
All-polyethylene	69 (median)	54 to 83
Bettinson[7] (2009)		
Metal-backed	68.9 (mean)	N/A
All-polyethylene	67.6 (mean)	N/A
KAT Trial Group[8] (2009)		
Metal-backed	69 (mean)	22 to 93
All-polyethylene	70 (mean)	43 to 90
Gioe[26] (2006)		
Metal-backed	69 (mean)	60 to 91
All-polyethylene	69 (mean)	60 to 91
Gioe[9] (2009)		
Metal-backed	72.62 (mean)	NA
All-polyethylene	71.79 (mean)	NA
Hyldahl[32] (2005)		
Metal-backed	73 (median)	58 to 81
All-polyethylene	73 (median)	45 to 82
Hyldahl[33] (2005)		
Metal-backed	70 (median)	51 to 82
All-polyethylene	73 (median)	55 to 78
Muller[39] (2006)		
Metal-backed	74 (mean)	66 to 89
All-polyethylene	73 (mean)	63 to 75
Norgren[56] (2004)		
Metal-backed	74 (median)	63 to 79
All-polyethylene	71 (median)	63 to 75
Pagnano[45] (2004)		
Metal-backed	67 (mean)	41 to 80
All-polyethylene	67 (mean)	41 to 80
Wotherspoon[58] (2010)		
Metal-backed	76.3 (mean)	NA
All-polyethylene	75.9 (mean)	NA

*NA = not available.

Appendix 1: Complete Definition of Maximum Total Point Motion (MTPM)

Longitudinal radiographic analysis has been used increasingly over time as an accurate tool for assessing micromotion in orthopaedic implants and is highly predictive of clinical loosening and revision[1], especially when measured relatively early in the life of the implant (one to two postoperatively). It has been found that continuous migration represents defective fixation, which manifests very early. Maximum total point motion (MTPM) is a three-dimensional vector, with the vectors being (1) the x plane (transverse, flexion-extension), which corresponds with medial migration of component; (2) the y plane (longitudinal, internal-external rotation), which corresponds with proximal migration; and (3) the z plane (sagittal, varus-valgus rotation), which corresponds with posterior migration. A maximum total point motion of >0.2 mm at two years implies that revision due to loosening can be predicted.

Appendix 2: Search Strategies

The Cochrane Central Register of Controlled Trials (CENTRAL)

#1 MeSH descriptor Arthroplasty, Replacement, Knee explode all trees
#2 MeSH descriptor Randomized controlled trial explode all trees
#3 MeSH descriptor polyethylene explode all trees
#4 (#1 OR #2 OR #3)

A modified search strategy was adapted to search Ovid MEDLINE (with slight modifications for Ovid EMBASE and EBSCO CINAHL):

#1 exp Arthroplasty, Replacement, Knee/ (8056)
#2 knee arthroplasty.tw. (7369)
#3 (knee adj3 replace*).tw. (4756)
#4 or/1-3 (12906)
#5 exp Polyethylene/ (2101)
#6 polyethylene.tw. (23805)
#7 or/5-6 (24229)
#8 4 and 7 (993)
#9 randomized controlled trial.pt. (292935)
#10 controlled clinical trial.pt. (81735)
#11 randomized.ab. (207387)
#12 placebo.ab. (122690)
#13 clinical trials as topic.sh. (148909)
#14 randomly.ab. (153261)
#15 trial.ti. (89204)
#16 or/9-15 (696249)
#17 (animals not (humans and animals)).sh. (3403497)
#18 16 not 17 (645735)
#19 8 and 18 (56)

Orthopaedic Journal Web Sites Searched

The Journal of Bone and Joint Surgery (American Volume) (1990 to present); *The Journal of Bone and Joint Surgery (British Volume)* (1990 to present); abstract presentations from major orthopaedic meetings, including the American

Academy of Orthopaedic Surgeons (AAOS); *Clinical Orthopaedics and Related Research* (1990 to present).

Medical Society Web Sites Searched

American Academy of Orthopaedic Surgeons (AAOS) and British Orthopaedic Association Clinical Guidelines sections.

Technology Assessment Web Sites Searched

Health technology assessment web sites, including Agency for Healthcare Research and Quality (AHRQ); National Institute for Health and Clinical Excellence (NICE) and the National Institute for Health Research (NIHR) Technology Assessment Programme (UK); Canadian Agency for Drugs and Technologies in Health (CADTH); California Technology Assessment Forum (CTAF); Blue Cross Blue Shield (BCBS) Technology Assessment.

Appendix 3: Data Collection and Analysis Detail

Selection of Studies

Two review authors screened the titles and abstracts of all studies that were identified in the search strategy. Full-text versions were obtained for all studies that were identified as being potentially relevant. Those studies were assessed by two review authors for inclusion with use of an eligibility pro forma screening document that was based on prespecified inclusion/exclusion criteria. Any disagreement between the two review authors was resolved by discussion or was adjudicated by an independent third party.

Data Extraction and Management

A data extraction/collection form was developed to aid in the collection of details from included studies. One review author independently extracted the data, and a second review author validated the extracted data (see Appendix 4).

If more than one publication arose from the same study, all versions were considered in order to maximize data extraction and the primary publication was identified along with the secondary references.

Assessment of Risk of Bias in Included Studies

Two review authors independently assessed each included study with use of the Cochrane Collaboration tool for assessing risk of bias[1]. This tool addresses six specific domains, namely, sequence generation, allocation concealment, blinding, incomplete outcome data, selective outcome reporting, and other issues (e.g. extreme baseline imbalance) (see Appendix 5 for details on the criteria on which the judgment was based). Blinding and completeness of outcome data were assessed for each outcome separately. A risk-of-bias table was completed for each eligible study.

Any disagreement among all review authors was discussed to achieve a consensus.

An assessment of risk of bias with use of a "risk-of-bias summary figure," which presents all of the judgments in a cross-tabulation of study by entry, was evaluated. This display of internal validity indicates the weight that the reader may give the results of each study.

Studies other than randomized controlled trials (i.e., quasi-randomized controlled trials) were assessed with use of the same criteria. We incorporated the results of the risk-of-bias assessment into the review through systematic narrative description and commentary about each of the domains, leading to an overall assessment of the risk of bias of included studies and a judgment about the internal validity of the results.

Measures of Treatment Effect

Each study is reported separately. The results of binary outcomes (e.g., revision or not) is presented as risk ratios (RR) with corresponding 95% confidence intervals (CI). For continuous data, we used the mean difference if outcomes were measured in the same way between trials. We used the standardized mean difference to combine trials that measured the same outcome but used different methods. Furthermore, if pooling of data was not possible, we used the statistics utilized in the study for analyzing treatment effect; in most cases, the Mann-Whitney U test was used (for nonparametric data).

Unit of Analysis Issues

If trials include multiple intervention groups (e.g., different types of tibial implants), we split the shared control group into two or more groups with smaller sample sizes, depending on the number of interventions, and included two or more comparisons.

Dealing with Missing Data

For binary primary outcome variables, it was not anticipated that there would be missing data for determining percentages. In cases in which data were missing, we attempted to contact the authors and requested the data. In the case of abstracts, we attempted to contact the authors to see if a report has been published in a peer-reviewed journal. If a paper had been generated from an abstract but was unpublished, we attempted to obtain it from the author.

Assessment of Heterogeneity

Assessment of statistical heterogeneity was made with use of the I^2 statistic in order to determine appropriateness for meta-analysis. If the I^2 statistic was $\leq$60%, the heterogeneity was considered moderate and meta-analysis was appropriate. If the value was >60%, sensitivity analysis was undertaken in an attempt to identify which studies were most likely causing the problem. If there were only a few such studies, and they could be identified, the reasons for their difference were explored and the appropriateness of removing these studies was determined. When appropriate, the meta-analysis was performed with the exclusion of any such studies.

Assessment of Reporting Biases

We used a funnel plot to assess reporting bias. Each primary outcome was reported separately. Furthermore, we performed an assessment of publication bias (including a review of unpublished studies), location bias (types of journals), and language bias.

Data Synthesis

When possible, we grouped similar studies together. In the absence of heterogeneity (I^2 = 0%) or in the presence of low heterogeneity (I^2 <40%), a fixed-effect model was used. If heterogeneity

was moderate (I^2 ≥40% and ≤60%) a random-effects model was used.

Sensitivity Analysis

A sensitivity analysis was performed to determine the effect of study quality on the results. Studies were classified as high quality if allocation was concealed, if bias due to nonblinding was unlikely (blinding of patient/caregiver/outcome assessor), and if incompleteness of outcome data was addressed. Additionally, sensitivity analyses were conducted to assess the effect of the choice of meta-analysis methods and the choice of treatment effect measures (such as relative risk ratio, odds ratio, or absolute risk difference).

Appendix 4: Data Collection Form

Name of person/reviewer extracting data:

Author of article:

Title:

Source (e.g., Journal title):

Date of study:

Study location (geographical):

Care setting (e.g., hospital):

Inclusion/exclusion criteria (list of patient inclusion and exclusion criteria)

Inclusion:
Exclusion:

Sample Size:

Number in each arm of trial
A priori power calculation? **YES NO NOT STATED**
Trial powered adequately?

Patient baseline characteristics:

Age range:
Gender:
Medical condition(s):

Trial Design Details:

Single center/multicenter trial?

Study Type

Randomized controlled trial/matched control/unmatched concurrent control/historic control:

Allocation

Was it random? **YES NO NOT STATED**
Method of randomization:
Was it concealed? **YES NO NOT STATED**

Intervention Details

Care setting:
Treatment group(s):

Control(s):
Co-interventions:
Duration of intervention:
Who delivered intervention?
Was the provider performing the procedure blinded? **YES NO NOT STATED**
Was the patient blinded? **YES NO NOT STATED**

Outcome Measures
What were they?
Methods of assessing outcome measures:
Blind assessment? **YES NO NOT STATED**
When were they measured?
Validity of assessment:
Length of follow-up:

Costs
Considered? **YES NO NOT STATED**
Cost-effectiveness details:
Results:

Analysis:
Description of analysis employed:
Statistical methods:
Comparisons made:
Intention-to-treat analysis?
Adjustment for confounding?
Subgroups considered:
Exploration of heterogeneity:

Results:
Missing data:
Length of follow up:
Withdrawals/drop-outs--are proportion and characteristics of participants lost to follow-up comparable for the study groups at the end of the trial?
Reasons for withdrawal:
Loss to follow-up:
Number of implants requiring revision (primary outcome):
Intervention arm (1):

Intervention (or control) arm (2):
Intervention arm (if more than 2 intervention arms are included in the trial):
Intervention arm (if more than 2 intervention arms are included in the trial):
Number of adverse events:
Intervention arm (1):
Intervention (or control) arm (2):
Intervention arm (if more than 2 intervention arms are included in the trial):
Intervention arm (if more than 2 intervention arms are included in the trial):

Conclusions:

Implications (e.g., for practice):

Other comments:
Methodological quality of study:
Comparability of intervention:
Baseline comparability:
Informed consent:
Country of origin:

Appendix 5: Risk-of-Bias Assessment

Criteria for a judgment of "yes" for the sources of bias

1. Was the allocation sequence randomly generated?

Yes, low risk of bias

The investigators describe a random component in the sequence generation process, such as referring to a random number table, using a computer random-number generator, coin tossing, shuffling cards or envelopes, throwing dice, drawing of lots.

No, high risk of bias

The investigators describe a nonrandom component in the sequence-generation process. Usually, the description involved some systematic, nonrandom approach; for example, sequence generated by odd or even date of birth, sequence generated by some rule based on date (or day) of admission, sequence generated by some rule based on hospital or clinic record number.

Unclear

Insufficient information about the sequence generation process to permit judgment of "Yes" or "No."

2. Was the treatment allocation adequately concealed?

Yes, low risk of bias

Participants and investigators enrolling participants could not foresee assignment because one of the following, or an equivalent method, was used to conceal allocation: central allocation (including telephone, web-based and pharmacy-controlled randomization); sequentially numbered drug containers of identical appearance; sequentially numbered, opaque, sealed envelopes.

No, high risk of bias

Participants or investigators enrolling participants could possibly foresee assignments and thus introduce selection bias because allocation was based on the use of an open random

allocation schedule (e.g., a list of random numbers); because assignment envelopes were used without appropriate safeguards (e.g., envelopes that were unsealed, non-opaque, or not sequentially numbered); or because allocation was based on alternation or rotation, date of birth, case record number. or any other explicitly unconcealed procedure.

Unclear

Insufficient information to permit judgment of "Yes" or "No." This was usually the case if the method of concealment was not described or was not described in sufficient detail to allow a definite judgment; for example, if the use of assignment envelopes was described but it remained unclear whether envelopes were sequentially numbered, opaque, and sealed.

3. Was knowledge of the allocated interventions adequately prevented during the study?

Yes, low risk of bias

Any one of the following:

- No blinding, but the review authors judged that the outcome and the outcome measurement were not likely to be influenced by lack of blinding
- Blinding of participants and key study personnel was ensured, and it was unlikely that the blinding could have been broken
- Either participants or some key study personnel were not blinded, but outcome assessment was blinded and the nonblinding of others was unlikely to introduce bias

No, high risk of bias

Any one of the following:

- No blinding or incomplete blinding, and the outcome or outcome measurement was likely to be influenced by lack of blinding

- Blinding of key study participants and personnel attempted, but it was likely that the blinding could have been broken
- Either participants or some key study personnel were not blinded, and the nonblinding of others was likely to introduce bias

Unclear

Any one of the following:

- Insufficient information to permit judgment of "Yes" or "No"
- The study did not address this outcome

4. Were incomplete outcome data adequately addressed?

Yes, low risk of bias

Any one of the following:

- No missing outcome data
- Reasons for missing outcome data were unlikely to be related to true outcome (for survival data, censoring was unlikely to be introducing bias)
- Missing outcome data balanced in numbers across intervention groups, with similar reasons for missing data across groups
- For dichotomous outcome data, the proportion of missing outcomes compared with observed event risk was not enough to have a clinically relevant impact on the intervention effect estimate
- For continuous outcome data, plausible effect size (difference in means or standardized difference in means) among missing outcomes was not enough to have a clinically relevant impact on observed effect size

- Missing data were imputed using appropriate methods

No, high risk of bias

Any one of the following:

- Reason for missing outcome data were likely to be related to true outcome, with either imbalance in numbers or reasons for missing data across intervention groups
- For dichotomous outcome data, the proportion of missing outcomes compared with observed event risk was enough to induce clinically relevant bias in intervention effect estimate
- For continuous outcome data, plausible effect size (difference in means or standardized difference in means) among missing outcomes was enough to induce clinically relevant bias in observed effect size
- "As-treated" analysis done with substantial departure of the intervention received from that assigned at randomization
- Potentially inappropriate application of simple imputation

Unclear

Any one of the following:

- Insufficient reporting of attrition/exclusions to permit judgment of "Yes" or "No" (e.g., number randomized not stated, no reasons for missing data provided)
- The study did not address this outcome

5. Were reports of the study free of suggestion of selective outcome reporting?

Yes, low risk of bias

Any of the following:

- The study protocol was available and all of the study's prespecified (primary and secondary) outcomes that were of interest in the review were reported in the prespecified way
- The study protocol was not available but it was clear that the published reports included all expected outcomes, including those that were pre-specified (convincing text of this nature may be uncommon)

No, high risk of bias

Any one of the following:

- Not all of the study's pre-specified primary outcomes were reported
- One or more primary outcomes was reported using measurements, analysis methods, or subsets of the data (e.g., subscales) that were not pre-specified
- One or more reported primary outcomes were not pre-specified (unless clear justification for their reporting was provided, such as an unexpected adverse effect)
- One or more outcomes of interest in the review were reported incompletely so that they could not be entered in a meta-analysis
- The study report failed to include results for a key outcome that would be expected to have been reported for such a study

Unclear

- Insufficient information to permit judgment of “Yes” or “No.” It is likely that the majority of studies will fall into this category

6. Was the study free of other sources of potential of bias?

Yes, low risk of bias

The study appeared to be free of other sources of bias.

No, high risk of bias

There is at least one important risk of bias. For example, the study:

- Had a potential source of bias related to the specific study design used
- Was stopped early because of some data-dependent process (including a formal stopping rule)
- Had extreme baseline imbalance
- Has been claimed to have been fraudulent
- Had some other problem

Unclear

There may be a risk of bias, but there was either insufficient information to assess whether an important risk of bias existed or insufficient rationale or evidence that an identified problem will introduce bias.

Appendix 6: Characteristics of Included Studies

Adalberth[54] (2000)

Methods	Randomized controlled trial (RCT); patients randomized to either cemented all-polyethylene (AP) or cemented metal-backed (MB) group via the opening of a sealed envelope just before implantation of the component with use of an AGC (Anatomic Graduated Component) cemented total knee arthroplasty (TKA) (Biomet, Warsaw, Indiana); single-center trial
	Blinding: No
	Intention-to-treat analysis: No
	A priori power calculation: No
	Reliable primary outcomes: Yes
Participants	Male and female. MB group: median age, 69 yr (range, 61-79 yr); 5 male, 12 female. AP group: median age, 73 yr (range, 60-84 yr); 7 male, 10 female. Patients undergoing total knee arthroplasty for osteoarthritis. Approved by ethics committee at hospital and informed consent obtained
	Exclusion criteria: age, <60 years; body weight, >100 kg; prior ipsilateral knee surgery
	Total randomized to trial: 34
Interventions	Group MB: (n = 17): cemented metal-backed non-porous-coated and stemmed metal tray
	Group AP (n = 17): cemented all-polyethylene stemmed component
Outcomes	Durability of tibial fixation as measured by radiostereometric analysis (RSA) at 7 to 10 days, 4 months, 12 months, and 24 months. Movement or migration of the tibial component measured as rotations of the tibial component in relation to the tibia, maximum subsidence (greatest distal migration), maximum lift-off as greatest distal migration, and maximum migration (maximum total point motion [MTPM]) as the greatest three-dimensional translation of the part of the tibial tray that moved the most
	Functionality measured with use of the Knee Society scoring system before implantation and at 4, 12, and 24 months postoperatively
	Adverse events: intraoperative and postoperative complications including the need for additional surgery
Notes	Disclosures: none noted
	Three patients from MB arm and 3 from AP arm excluded from RSA analysis and were not part of the intention-to-treat analysis because of inappropriate marking of the prosthesis or tibial bone; thus, not able to determine quality of fixation using RSA
	Country of origin: Sweden
	Adverse events included two complications in MB group (infection and trauma to anterior part of implant causing pain, unrelated to procedure) and three in AP group (deep-vein thrombosis, pulmonary embolism, mobilization with patient under anesthesia to increase knee flexion)

Adalberth[19] (2001)

Methods	RCT; patients randomized to either cemented all-polyethylene (AP) or cemented metal-backed (MB) groups via the opening of a sealed envelope just before implantation of the component with use of a Freeman-Samuelson (Sulzer Orthopaedics AG, Zug, Switzerland); single-center trial
	Blinding: No
	Intention-to-treat analysis: No
	A priori power calculation: No

	Reliable primary outcomes: Yes
Participants	Male and female. MB group: median age, 70 yr (range, 52-78 yr); 3 male, 15 female; AP group: median age, 69 (range, 54-83 yr); 4 male, and 16 female. Patients undergoing total knee arthroplasty for osteoarthritis. Approved by ethics committee at hospital and informed consent obtained.
	Exclusion criteria: body weight >100 kg, age <50 yr, prior ipsilateral knee surgery
	Total number of patients randomized to trial:38
Interventions	MB group (n = 18): cemented metal-backed non-porous-coated and stemmed metal tray
	AP group (n = 20): cemented all-polyethylene nonstemmed component
Outcomes	Durability of tibial fixation as measured by radiostereometric analysis (RSA) at 7-10 days, 4 months, 12 months, and 24 months. Movement or migration of the tibial component measured as rotations of the tibial component in relation to the tibia, maximum subsidence (greatest distal migration), maximum lift-off as greatest distal migration, and maximum migration (MTPM) as greatest three-dimensional translation of the part of the tibial tray that moved the most
	Functionality measured with use of the Knee Society scoring system before implantation and at 4, 12, and 24 months postoperatively
	Adverse events: intraoperative and postoperative complications, including the need for additional surgery
Notes	Disclosures: study supported by grants from the Research Funds of Umeå University, the Swedish Association of Rheumatoid Diseases, and Sulzer Orthopedics
	Country of origin: Sweden
	Two patients from MB arm excluded from RSA analysis and were not part of the intention-to-treat analysis because of inappropriate marking of the prosthesis or tibial bone; thus, not able to determine quality of fixation with use of RSA
	Adverse events included four complications in the MB group (deep-vein thrombosis [DVT], manipulation with patient under anesthesia to increase knee flexion, and two complications unrelated to implant procedure [femoral neck fracture, car accident]) and one in the AP group (DVT)

Bettinson[7] (2009)

Methods	RCT; patients randomized to either cemented all-polyethylene (AP) or cemented metal-backed (MB) modular component (identical designs) on the basis of a set of computer-generated random codes (a block of 30) via a sealed envelope and in the operating room just before implantation of the component with use of the Kinemax Plus Total Knee Prosthesis (Stryker Orthopaedics, Mahwah, New Jersey); single-center trial UK
	Blinding: No to clinician performing the procedure, no to patients
	Intention-to-treat analysis: No
	A priori power calculation: No
	Reliable primary outcomes: Yes
Participants	Male and female. Group MB: mean age (and standard deviation), 68.9 ± 8.6 yr; 59% female, 41% male. Group AP: mean age, 67.6 ± 9.3 yr; 57% female, 43% male. Patients undergoing total knee arthroplasty for osteoarthritis (81%) and rheumatoid arthritis (19%). Approved by ethics committee at hospital and informed consent obtained

	Exclusion criteria: history of infection, refusal to provide consent for trial, unstable knee requiring a constrained or semi-constrained prosthesis
	Total number of patients randomized to trial: 510 (566 knees)
Interventions	MB group: (n = 304 knees): cemented metal-backed modular non-porous-coated and stemmed metal tray
	AP group (n = 262 knees): cemented all-polyethylene stemmed component
Outcomes	Implant survival at 10 years (with revision for any reason or the time at which patients were documented as requiring revision but were unfit for surgery as the end point)
	Adverse events: intraoperative and postoperative complications including the need for additional surgery
Notes	Disclosures: none noted
	Country of origin: UK
	149 knees in MB group could not be followed for various reasons: death (121 knees), patient moved (4), amputation because of vascular reasons (2), patient declined to attend clinic review (1), patient unable to return because of other illness (10), patient lost to follow-up (9), last review at 9 years (2)
	124 knees in AP group could not be followed for various reasons: death (97 knees), patient moved (6), patient declined to attend clinic review (1), patient unable to return because of other illness (4); patient lost to follow up (14); last review at 9 years (2)
	Adverse events: 2 infections in the MB group and 7 in AP group
	Patellar resurfacing not performed for any of the patients

KAT Trial Group[8] (2009)

Methods	RCT; patients randomized to either cemented all-polyethylene (AP) or metal-backed (MB) component, randomized to patellar resurfacing or no patellar resurfacing; and/or with or without a mobile-bearing tibial surface. Randomization to more than one comparison was allowed. Randomization occurred via an automated centralized telephone randomization service, which the patient called and, after basic identification had been given over the phone, the patient was allocated to the relevant comparison or combination of comparisons. Randomization was stratified by surgeon. Unclear as to types/manufacturer/brands of implants used. Also unclear if metal-backed component was modular, stemmed, or cemented. Multicenter trial in the UK
	Blinding: No to clinician performing the procedure; unclear to patients; unclear to clinicians performing follow-up assessment
	Intention-to-treat analysis: No
	A priori power calculation: yes for difference in Oxford Knee Score (OKS) of 3 points for comparisons involving tibial metal-backed components and the mobile bearing (350 participants providing 80% statistical power and 470 participants providing 90% power to identify this difference [$p<0.05$]). Difference sought was 1.5 points for patellar resurfacing comparison, with 1400 participants providing 80% power to detect this difference ($p<0.05$).
	Reliable primary outcomes: Yes
Participants	Male and female. MB group: mean age, 69 ± 9 yr (range, 22-93 yr); 51% female, 49% male; AP group: mean age, 70 ± 8 yr (range, 43-90 yr); 53.6% female, 46.4% male. Patients undergoing total knee arthroplasty for osteoarthritis (95%) and rheumatoid

	arthritis (5%). Approved by ethics committee at hospitals and informed consent obtained
	Exclusion criteria: clinician considered a particular type of operation and implant to be clearly indicated
	Total number of patients randomized in trial comparing metal-backed to all-polyethylene: 409
Interventions	MB group (n= 202 knees): metal-backed component
	AP group (n=207 knees): cemented all-polyethylene stemmed component
Outcomes	Functional status as measured with the Oxford Knee Score (OKS), quality of life as measured with the Short-Form (SF-12) and the EuroQol-5D (EQ-5D)
	Adverse events: intraoperative and postoperative complications, including need for additional surgery
Notes	Numerous disclosures were noted in the trial regarding affiliations with industry
	Twenty-two patients subsequently randomized in error: fourteen were randomized twice, three were not eligible, three were managed by surgeons not registered to participate in the trial, and two were excluded for other reasons
	Adverse events (short-term complications): one patient in each arm had a proven infection, four patients in metal-backed arm had suspicion of infection, and eight patients in AP arm had suspicion of infection. Three patients in MB arm had DVT, five patients in AP arm had DVT

Gioe[26] (2006)

Methods	RCT; patients randomized to either cemented all-polyethylene (AP) or cemented metal-backed (MB) component of the same articular design and geometry; randomization scheme unclear. The DePuy PFC total knee implant was used (DePuy, Warsaw, Indiana). Single-center trial in US
	Blinding: No to clinician performing procedure; unclear as to patient; yes to clinicians performing follow-up radiographic evaluation
	Intention-to-treat analysis: No
	A priori power calculation: Yes, 80% power to detect a 5-point difference in Knee Society Score
	Reliable primary outcomes: Yes
Participants	279 male, and 11 female. Mean age, 69 ± 6 yr (range, 60-91 yr). Mean body weight, 96 ± 14 kg. Mean body-mass index (BMI), 36. Preoperative diagnosis: osteoarthritis (92%), inflammatory arthritis (5%), posttraumatic arthritis (3%). Approved by ethics committee at hospital, and informed consent obtained. Patient characteristics not broken out by implant type but authors state that there was no substantial difference between the two study groups with regard to age, weight, sex, comorbidities, diagnosis, preoperative range of motion, or Knee Society score (KSS)
	Exclusion criteria: need for bone grafting, modular stems or augments, or more constrained designs
	Total number of patients randomized to trial: 290 (316 total knee implants)
Interventions	MB group (n = 70): cemented metal-backed non-porous-coated and stemmed metal tray
	AP group (n = 97): cemented all-polyethylene stemmed component
Outcomes	Implant survival at 10 yr (i.e., no need for revision)
	Radiographic failures (impending revision)

	Functionality using Knee Society score and Short Form-36 (SF-36) was assessed preoperatively and at 1, 5, and 10 yr
	Adverse events: intraoperative and postoperative complications including the need for additional surgery
Notes	Disclosures : none noted
	Country of origin: US
	Twelve patients declined enrollment. An additional twenty-nine patients were not candidates for study according to exclusion criteria (exclusion criteria not noted).
	At 10-yr follow-up, 120 patients had died, 22 had revision surgery, and one was lost to follow-up, leaving 147 patients (167 implants: 97 all-polyethylene, 70 metal-backed)
	Adverse events: 3 late infections in each group were noted and were indications for revision surgery
	Adverse events (surgical complications) included 4 infections at a mean of 15 months in the metal-backed group and 4 infections in the all-polyethylene group at a mean of 12 months of follow-up. 3 reoperations for patellofemoral problems in the all-polyethylene group at a mean of 21 months. Additionally, one reoperation was performed in the all-polyethylene group and one was performed in the metal-backed group because of late varus or valgus instability; these required trade-out of the components or augmentation with additional surgery

Gioe[9] (2009)

Methods	RCT; patients randomized to either cemented all-polyethylene (AP) or cemented rotating platform metal-backed (MB) groups with use of a computer-generated randomization schedule. The Sigma DePuy total knee implant was used (DePuy, Warsaw, Indiana). Single-center US trial
	Blinding: No to clinician performing procedure; yes to patient receiving implant; yes to clinicians performing follow-up radiographic evaluation
	Intention-to-treat analysis: No
	A priori power calculation: Yes; 80% power to detect a 5-point difference in the Knee Society score
	Reliable primary outcomes: Yes
Participants	MB group: mean age, 72.62 ± 7.2 yr; 96 male, 4 female. AP group: mean age, 71.79 ± 6.8 yr; 98 male, 2 female. Patients undergoing total knee arthroplasty for osteoarthritis (97.1%), inflammatory arthritis (1.3%), and posttraumatic arthritis (1.6%). Approved by ethics committee at hospital and informed consent obtained.
	Exclusion criteria: Patients with substantial angular deformity that clearly required an osteotomy or use of a more constrained design, patients in whom bone loss necessitated structural grafting or modular augmentation, patients whose mental function precluded them from responding to standard questionnaire, patients with age of <60 or >85 yr
	Total number of patients/knees randomized to trial: 358/400
Interventions	Rotating-platform MB group (n = 176 knees): cemented metal-backed non-porous-coated and stemmed metal tray
	AP group (n = 136 knees): cemented all-polyethylene stemmed component
Outcomes	Durability assessed via radiographic outcomes
	Functionality measured with Knee Society score (KSS), Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), SF-36

	Adverse events: intraoperative and postoperative complications including the need for additional surgery
Notes	Disclosures: one or more of the authors received, in any one year, outside funding or grants in excess of $10,000 from DePuy
	18 patients who consented to be enrolled in trial were excluded at time of surgery when intraoperative findings dictated the use of modular augmentation, stems, or a more constrained design
	16 patients (17 knees) died before the minimum follow-up period of 2 years had elapsed
	1 patient lost to follow-up
	40 patients (42 knees) had been followed for less than a minimum of 2 years at the time of data analysis and 10 knees in 10 patients had been revised

Hyldahl[32] (2005)

Methods	RCT; patients randomized to either cemented all-polyethylene (AP) (proximal cementing only, leaving the stem uncemented) or cemented metal-backed (MB) (proximal cementing only, leaving the stem uncemented) via the minimization method using the AGC total knee prosthesis (Anatomic Graduated Component; Biomet, Warsaw, Indiana); single-center trial
	Blinding: No to clinician performing operation; unclear to patient; yes to independent radiologist evaluating radiograph for postoperative period up to 2 years; unclear to clinicians evaluating functionality via Hospital for Special Surgery (HSS) score
	Intention-to-treat analysis: No
	A priori power calculation: No
	Reliable primary outcomes: Yes
Participants	MB group: median age, 73 yr (range, 58-81 yr); 4 male, 16 female. AP group: median age, 73 yr (range, 45-82 yr); 4 male, 16 female. Patients undergoing total knee arthroplasty for grade III-V primary arthrosis were included. Approved by ethics committee at hospital and informed consent obtained.
	Exclusion criteria: None
	Total number of patients randomized to trial: 40
Interventions	MB group (n = 20): proximally cemented metal-backed non-porous-coated non-modular stemmed metal tray
	AP group (n = 20): proximally cemented all-polyethylene stemmed component
Outcomes	Durability of tibial fixation as measured by radiostereometric analysis (RSA) of tantalum marker balls in the tibial implant component and the proximal tibial metaphysis. RSA measured at 3-4 days postop, 3 months, 12 months, and 24 months. Movement or migration of the tibial component measured as rotations of the tibial component in relation to the tibia, maximum subsidence (greatest distal migration), maximum lift-off as greatest distal migration, and maximum migration (MTPM) as the greatest 3-dimensional translation of the part of the tibial tray that moved the most.
	Functionality measured using the Hospital for Special Surgery (HSS) score after 2 years
	Adverse events: intraoperative and postoperative complications including the need for additional surgery
Notes	Disclosures: None noted
	Country of origin: Sweden
	Four patients from MB arm excluded from RSA analysis and were not part of the

	intention-to-treat analysis because of inability to visualize tantalum markers at RSA examination
	Patients stratified according to age (<65 yr, ≥65 yr), body weight (<75 kg, ≥75 kg), degree of deformity (<10°, ≥10°), and sex
	No adverse events noted in study

Hyldahl [33] (2005)

Methods	RCT; patients randomized to either cemented all-polyethylene (AP) (completely cemented component including cemented stem) or cemented metal-backed (MB) (completely cemented component including cemented stem) via the minimization method using the AGC total knee prosthesis (Anatomic Graduated Component; Biomet, Warsaw, Indiana); single-center trial
	Blinding: No to clinician performing operation; unclear to patient; yes to independent radiologist evaluating radiograph for postoperative period up to 2 years; unclear to clinicians evaluating functionality via HSS score
	Intention-to-treat analysis: No
	A priori power calculation: No
	Reliable primary outcomes: Yes
Participants	Male and female. MB group: median age, 70 yr (range, 51-82 yr); 2 male, 18 female. AP group: median age, 73 yr (range, 55-78 yr); 4 male, 16 female. Patients undergoing total knee arthroplasty for grade III-V primary arthrosis were included. Approved by ethics committee at hospital and informed consent obtained
	Exclusion criteria: None
	Total number of patients/knees randomized to trial: 39/40
Interventions	MB group (n = 20): completely cemented metal-backed non-porous-coated non-modular stemmed metal tray
	AP group (n = 20): completely cemented all-polyethylene stemmed component
Outcomes	Durability of tibial fixation as measured with radiostereometric analysis (RSA) of tantalum marker balls in the tibial implant component and the proximal tibial metaphysis. RSA measured at 3-4 days postoperatively, 3 months, 12 months, and 24 months. Movement or migration of the tibial component measured as rotations of the tibial component in relation to the tibia, maximum subsidence (greatest distal migration), maximum lift-off as greatest distal migration, and maximum migration (MTPM) as the greatest 3-dimensional translation of the part of the tibial tray that moved the most.
	Functionality measured with us of the Hospital for Special Surgery (HSS) score after 2 years
	Adverse events: intraoperative and postoperative complications, including the need for additional surgery
Notes	Disclosures: none to declare
	Country of origin: Sweden
	Four patients from MB arm excluded from RSA analysis and were not part of the intention-to-treat analysis because of inability to visualize tantalum markers at RSA examination
	Patients stratified according to age (<65 yr, ≥65 yr), body weight (<75 kg, ≥75 kg), degree of deformity (<10°, ≥10°), and sex

	No adverse events noted in study.

Muller[39] (2006)

Methods	RCT; patients randomized to either cemented all-polyethylene (AP) (completely cemented component including cemented stem) or cemented metal-backed non-modular (MB) (completely cemented component including cemented stem) by means of a sealed envelope block randomization employing blocks of eight. The cruciate-retaining condylar PFC-Sigma (Σ) (DePuy, Johnson & Johnson, Leeds, United Kingdom) was used; single-center trial. Implant configuration/shape identical between the 2 tibial components.
	Blinding: No
	Intention-to-treat analysis: No
	A priori power calculation: No
	Reliable primary outcomes: Yes
Participants	Male and female. MB group: mean age, 74 yr (range, 66-89 yr); 11 male, female. AP group: mean age, 73 yr (65-82 yr); 9 male, 12 female. Patients undergoing total knee arthroplasty for a primary diagnosis of osteoarthritis or rheumatoid arthritis were included. Approved by ethics committee at hospital and informed consent obtained.
	Exclusion criteria: renal disease, bone deficiencies detected intraoperatively; <65 years of age
	Total number of patients/knees randomized to trial: 39/41
Interventions	MB group (n = 20): completely cemented metal-backed non-porous-coated non-modular stemmed metal tray
	AP group (n = 21): completely cemented all-polyethylene stemmed component
Outcomes	Durability of tibial fixation as measured by radiostereometric analysis (RSA) of tantalum marker balls in the tibial implant component and in the proximal tibial metaphyseal bone. RSA measured at 0, 3, 6, 12, and 24 months. Movement or migration of the tibial component measured as rotations of the tibial component in relation to the tibia, maximum subsidence (greatest distal migration), maximum lift-off as greatest distal migration, and maximum migration (MTPM) as the greatest 3-dimensional translation of the part of the tibial tray that moved the most.
	Functionality measured using the modified WOMAC, SF-12 scoring system, and Oxford Knee scores after 2 years.
	Adverse events: intraoperative and postoperative complications, including the need for additional surgery
Notes	Disclosures: author or one or more of the authors have received or will receive benefits for personal or professional use from a commercial party related directly or indirectly to the subject of this article
	Country of origin: United Kingdom
	Four patients in the AP arm of the trial who were randomized to receive this type of implant were not allocated to the intervention because the appropriate sized implant was not available.
	Six patients in the MB arm of the trial who were randomized to receive this type of implant were not allocated to the intervention because the appropriate sized implant was not available.
	One patient in the MB arm was excluded from the analysis because of an inability to

	visualize the RSA beads on radiography
	No adverse events were noted

Norgren[56] (2004)

Methods	RCT; patients randomized to either cemented all-polyethylene (AP) or cemented metal-backed modular (MB) tibial components via the opening of a sealed envelope just before implantation of the component using a Profix cemented TKA (Smith & Nephew, Memphis, Tennessee); single-center, single-surgeon trial
	Blinding: No
	Intention-to-treat analysis: No
	A priori power calculation: No
	Reliable primary outcomes: Yes
Participants	Male and female. MB group: median age, 74 yr (range, 63-79 yr); 3 male, 8 female. AP group: median age, 71 yr (range, 63-75 yr); 2 male, 10 female. Patients undergoing total knee arthroplasty for osteoarthritis. Approved by ethics committee at hospital and informed consent obtained
	Exclusion criteria: body weight >120 kg, age <60 years, prior ipsilateral knee surgery
	Total number of patients randomized to trial: 21 (however, 23 knees treated as 2 patients had bilateral knee implant)
Interventions	MB group (n = 11): cemented titanium metal-backed non-porous-coated and 5-cm stemmed metal tray
	AP group (n = 12): cemented all-polyethylene 5-cm keeled stemmed component
Outcomes	Durability of tibial fixation as measured with radiostereometric analysis (RSA) at 5-9 days, 3 months, 12 months, and 24 months. Movement or migration of the tibial component measured as rotations of the tibial component in relation to the tibia, maximum subsidence (greatest distal migration), maximum lift-off as greatest distal migration, and maximum migration (MTPM) as the greatest 3-dimensional translation of the part of the tibial tray that moved the most
	Functionality measured using the Knee Society scoring system before implantation and at 12 and 24 months postoperatively
	Adverse events: intraoperative and postoperative complications including the need for additional surgery
Notes	Disclosures: study funded by grants from the Faculty of Medicine, Umeå University, and from Smith & Nephew, Memphis, Tennessee
	Country of origin: Sweden
	One knee in the AP arm could not be analyzed with RSA at 3 months because of stereoradiographs of inferior quality. However, this knee was analyzed at 12 and 24 months. One woman with an AP component could not attend the 24-month follow-up because of mental illness
	Adverse events: one woman with an AP tibial component had a deep knee infection just prior to the 2-year follow-up

Pagnano[45] (2004)

Methods	RCT; patients randomized to one of 3 arms: (1) cemented mobile-bearing knee with metal-backed tray and posterior stabilizing polyethylene insert (modular tibial component); (2) cemented fixed-bearing knee with metal-backed tibial tray (modular

	tibial component); and (3) fixed-bearing knee with an all-polyethylene tray; (Sigma Press-Fit Condylar Knee System; DePuy, Warsaw, Indiana). Single-center trial. Randomization performed with a computer program developed by Dept of Biostatistics, which balanced the patients on basis of age, weight, and surgeon to limit the introduction of selection bias among each of 3 arms in the study.
	Blinding: Clinicians performing procedure were not blinded, clinicians evaluating radiographs were not blinded (they also performed the procedure); unclear if patients were blinded to type of implant received; per communication with one of the authors, clinicians evaluating for function were blinded.
	Intention-to-treat analysis: No
	A priori power calculation: Yes, 80% power to detect a 10^{o} difference in mean maximum knee flexion among the 2 fixed-bearing groups and the rotating-platform group.
	Reliable primary outcomes: Yes
Participants	167 women and 73 men with a mean age of 67 yr (range, 41-80 yr). Mean weight, 91 kg (range, 53-162 kg). Distribution of patient age, sex, and weight was not different between the groups. Patients undergoing total knee arthroplasty for degenerative joint disease. Approved by ethics committee at hospital and informed consent obtained.
	Exclusion criteria: prior upper tibial osteotomy; patellectomy; age <40 yr or >75 yr; severe deformity (20 varus, valgus malalignment); osteomyelitis, septicemia, or other active infections; presence of infections or highly communicable diseases; evident neurological or musculoskeletal disorders; metastatic disease; any congenital, developmental, or other bone disease; presence of previous prosthetic knee replacement; arthrodesis; patients not requiring patellar resurfacing
	Total number of patients randomized to trial: 240
Interventions	Modular MB implant group: (n = 80): cemented cobalt-chromium metal-backed non-porous-coated and stemmed metal tray; with modular polyethylene insert
	Rotating-platform MB group (n = 80): cemented cobalt-chromium metal-backed non-porous-coated and stemmed metal tray; with modular rotating-platform polyethylene insert
	AP group (n = 80): cemented all-polyethylene 5-cm keeled stemmed component
Outcomes	Functionality assessed with use of the Knee Society score (KSS) and the SF-12 preoperatively and at 3 and 12 months
	Adverse events: intraoperative and postoperative complications, including the need for additional surgery
Notes	Disclosures: One or more authors received funding from DePuy, a Johnson & Johnson company, Warsaw, IN, and from Zimmer Inc., Warsaw, IN.
	Country of origin: US
	Adverse events: 5 in AP group (2 patients with limited range of motion [ROM] in early postop. period, 1 patient with serous wound drainage for 1 week postop., 1 patient with a small area of marginal skin necrosis, and 1 patient with a partial tear of the quadriceps tendon at 4 months postop.), 8 in modular MB group (2 patients with limited ROM, 1 patient with DVT, 1 patient with a patellar clunk, 1 patient with a minimally displaced fracture of the inferior pole of the patella, 1 patient with an intraoperative fracture of the medial condyle, and 1 patient with intraoperative fracture of the proximal tibia), 5 in the rotating-platform MB group (2 patients with limited ROM postop., 1 patient with DVT,

	1 patient with wound hematoma, 1 patient with serous wound drainage for one week postop.)

Wotherspoon[28] (2010)

Methods	RCT; patients randomized to either cemented all-polyethylene (AP) or cemented modular metal-backed (MB) component with use of sealed envelope opened just prior to surgery. The Genesis I system was used (Smith & Nephew, Memphis, Tennessee). . Multicenter trial in Canada
	Blinding: No to clinician performing procedure, yes to patient receiving implant, and yes for clinicians (research nurses) evaluating patients postoperatively for duration of follow-up on functional assessment (per e-mail from author).
	Intention-to-treat analysis: No
	A priori power calculation: Yes, per e-mail from author
	Reliable primary outcomes: Yes
Participants	Patients >70 years of age with debilitating arthritis (osteoarthritis, rheumatoid arthritis) treated with primary total knee arthroplasty. Approved by ethics committee at hospitals and informed consent obtained. MB group: mean age, 76.3 ± 4.2 yr; BMI, 28.2 ± 4.3; 49 female, 19 male. AP group: mean age, 75.9 ± 3.8 yr; BMI, 28.1± 4.4; 30 female, 29 male.
	Exclusion criteria: revision knee arthroplasty, history of knee infection, life expectancy <5 years, contralateral knee replacement inserted >5 years prior, patellectomy, deformity >20° in varus, valgus or flexion contracture, ROM <90°, previous high tibial osteotomy, bone deficiency necessitating augmentation
	Total number of patients/knees randomized to trial = 126/127
Interventions	MB group (n = 68): completely cemented metal-backed non-porous-coated non-modular stemmed metal tray
	AP group (n = 59): completely cemented all-polyethylene stemmed component
Outcomes	Durability as measured with survivorship analysis of implant
	Knee Society clinical rating system, WOMAC SF-12 (physical and mental)
	Adverse events: intraoperative and postoperative complications, including the need for additional surgery
	Cost-effectiveness analysis
Notes	Disclosures: unclear at time of study. Dr. Bourne, one of the authors, is currently a consultant and designer for Smith & Nephew
	Country of origin: Canada
	Adverse events: 3 superficial infections in MB group treated with oral antibiotics and 2 superficial infections in AP group also treated with oral antibiotics. One deep infection in AP group necessitated revision. 1 DVT in MB group and 2 DVTs in AP group treated with anticoagulation therapy
	Cost savings noted with AP Genesis knee system of $800 Canadian when compared with the MB Genesis knee system. Noted that when comparing the manufacturer's list price of a number of different tibial components, the AP component is approximately

	50%-65% the cost of the MB equivalent, with a difference in cost between the 2 components of anywhere from $470-$1650

Appendix 7: Characteristics of Excluded Studies

Study	Reason for Exclusion
Agiletti[20] (2005)	Study performed with use of metal-backed tibial components only
Baker[21] (2007)	Study performed with use of metal-backed tibial components only
Beaupré[22] (2007)	Study performed with use of metal-backed tibial components only
Carlsson[23] (2005)	Study performed with use of metal-backed tibial components only
Gicquel[24] (2000)	Study performed with use of metal-backed tibial components only
Gioe[25] (2000)	Follow-up study to this appears in the included study section (see Gioe 2006). Thus, this study was not included so as to not double-count data. However, the early surgical complication info included in this study was added to the data in the Gioe 2006 study
Grodzki[27] (2001)	Study performed with use of metal-backed tibial components only
Hansson[28] (2005)	Study performed with use of metal-backed tibial components only
Hanusch[29] (2010)	Study performed with use of metal-backed tibial components only
Harato[30] (2008)	Study performed with use of metal-backed tibial components only
Harrington[31] (2009)	Study performed with use of metal-backed tibial components only
Khaw[34] (2002)	Study performed with use of metal-backed tibial components only
Kim[35] (2009)	Study performed with use of metal-backed tibial components only
Laskin[36] (2000)	Study performed with use of metal-backed tibial components only
McCalden[37] (2009)	Study performed with use of metal-backed tibial components only
McCaskie[38] (1998)	Study performed with use of metal-backed tibial components only
Nelissen[40] (1998)	Study performed with use of metal-backed tibial components only (also see study by Pijls below, which is the 16-year follow-up to this study)
Nilsson[41] (1992)	Study performed with use of metal-backed tibial components only
Nilsson[42] (1993)	Study performed with use of metal-backed tibial components only
Nilsson[43] (1999)	Study performed with use of metal-backed tibial components only
Nilsson[44] (2006)	Study performed with use of metal-backed tibial components only
Pijls[46] (2010)	Study did not evaluate all-polyethylene and cemented tibial components. Evaluated the use of metal-backed polyethylene tibial components that were porous-coated (non-cemented); porous coated with hydroxyapatite spray (non-cemented), and non-porous-coated. All metal-backed components were composed of a cobalt-chromium alloy material. This is the 16-year follow-up to a study originally published in JBJS in 1998 entitled “The Effect of Hydroxyapatite on the Micromotion of Total Knee Prostheses” (80-A:11;1665-72)
Redha[53] (2005)	Study performed with use of metal-backed tibial components only
Saari[47] (2003)	Study performed with use of metal-backed tibial components only
Tanzer[48] (2002)	Study performed with use of metal-backed tibial components only
Toksvig-Larsen[49] (1998)	Study performed with use of metal-backed tibial components only
Uvehammer[50] (2001)	Study performed with use of metal-backed tibial components only
Vasdev[51] (2009)	Study performed with use of metal-backed tibial components only
Wotherspoon[57] (2008)	Abstract only; complete results of unpublished manuscript were included in the analysis
Wylde[52] (2008)	Study performed with use of metal-backed tibial components only

Yang[55] (2008)	Study performed with use of metal-backed tibial components only

Appendix 8: References to Studies Broken Out as Included and Excluded

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