Cemented all-polyethylene and metal-backed polyethylene tibial components used for primary total knee arthroplasty: a systematic review of the literature and meta-analysis of randomized controlled trials involving 1798 primary total knee implants

Voigt J, Mosier M

CRD summary
The authors concluded that the evidence supported the use of all-polyethylene tibial components in place of cemented metal-backed tibial components as part of a total knee implant. This was a generally well conducted review, but the paucity of data and questionable quality of the trials suggest the authors’ conclusions should be interpreted cautiously.

Authors’ objectives
To compare the clinical efficacy of lower-cost cemented all-polyethylene tibial components to more expensive metal-backed tibial components for total knee arthroplasty.

Searching
MEDLINE, EMBASE, EBSCO and CINAHL were searched up to 2011; search terms were reported. The Cochrane Central Register of Controlled Trials (CENTRAL) was also searched. No date or language restrictions were applied. Primary authors were contacted for relevant information or unpublished data. Reference lists of retrieved studies were checked and relevant journals, medical association and society websites, health technology assessment websites and ClinicalTrials.gov were scanned for additional studies.

Study selection
Eligible randomised controlled trials (RCTs) compared any brand cemented all-polyethylene tibial components to cemented or non-cemented metal-backed tibial components for primary total knee replacement in patients of any age. The outcomes of interest were durability and functionality of the implant, and adverse events that occurred during the procedure. Where RCTs were lacking, quasi-randomised trials (as defined in the review) were included.

Included trials compared cemented all-polyethylene stemmed or non-stemmed tibial components versus cemented metal-backed stemmed non-porous-coated and modular or non-modular tibial components at two, 10 or 15 years. The mean or median age of patients was at least 67 years. The methods used to measure durability and functionality varied between studies and included: radiostereometric analysis, survival and movement or migration of the tibial component for durability; and use of the Knee Society scoring system, Oxford Knee Score and the Western Ontario and McMaster Universities Osteoarthritis Index for functionality.

Two reviewers screened studies for inclusion. Discrepancies were resolved by discussion or referral to a third reviewer.

Assessment of study quality
Two reviewers independently assessed the risk of study bias according to the Cochrane Collaboration tool; including criteria that related to randomisation, allocation concealment, blinding and reporting of incomplete outcome data. Each trial was given a risk of bias score of low, unclear or high for each criteria assessed. Discrepancies were resolved by discussion.

Data extraction
One reviewer extracted dichotomous outcome data to calculate risk ratios (RRs) and 95% confidence intervals (CIs), and this was checked for accuracy by a second reviewer. Continuous outcome data were extracted to calculate mean differences and 95% confidence intervals. When necessary, primary authors were contacted for additional data.

Methods of synthesis
A fixed-effect model, or random-effects model where there was evidence of statistical heterogeneity, was used to pool risk ratios, mean differences and their 95% confidence intervals. Where trials included multiple intervention groups, control patients were split between the different groups.
Statistical heterogeneity was assessed using $I^2$. Sensitivity analyses were undertaken to assess the effects of trial quality, use of a random-effects or fixed-effect model, and the choice of treatment effect measures on the results.

Publication bias was assessed through visual inspection of a funnel plot.

**Results of the review**

Twelve RCTs (1,798 patients; range 23 to 409) were included in the review. The overall quality of the trials was average. Trials were at high risk of bias for lack of blinding, selective reporting and other bias. None of the trials were based on intention-to-treat analysis.

**Durability**

There were no statistically significant differences between all-polyethylene versus metal-backed components in the risk of abject failure at two years (three RCTs), 10 years (two RCTs) or 15 years (one RCT). There was no statistically significant difference in risk of failure defined by maximal total point motion, at two years (three RCTs).

**Functionality**

There were no statistically significant differences between all-polyethylene versus metal-backed components for patient assessed Oxford Knee Score at two years or SF-12 measure at two years (one RCT). The authors stated that there was a statistically significant difference in the Knee Society clinical score at two years in favour of the all-polyethylene tibial component (mean difference 2.20, 95% CI -1.95 to 2.45). The figures in the text and forest plot differed and the forest plot indicated a non-significant result.

There were no statistically significant differences between the two types of implants for functional status at eight or 10 years (one RCT each).

**Adverse Events**

There were no statistically significant differences in adverse events (as defined in the review) between cemented all-polyethylene tibial components versus cemented metal-backed components (11 RCTs).

There was no evidence of significant statistical heterogeneity for any outcome.

There was no evidence of significant publication bias for durability at two and 10 years or adverse events.

**Cost information**

Three RCTs indicated that all-polyethylene tibial components were $470 to $1,650 less costly than metal-backed components.

**Authors’ conclusions**

The evidence supported the use of all-polyethylene tibial components in place of cemented metal-backed tibial components as part of a total knee implant.

**CRD commentary**

The review question was clearly stated and supporting inclusion criteria reported. Several sources were searched for relevant studies, which included a search for unpublished data. The authors acknowledged that foreign language articles were not identified, but no language restrictions were applied to the search. Formal assessment of publication bias did not identify evidence of bias for some outcomes, but the robustness of these findings were questionable given the small number of trials that assessed some outcomes. Trial quality was assessed using appropriate criteria, but there was some risk of bias. Each stage of the review process was undertaken in duplicate, which reduced the potential for reviewer error and bias.

There was no evidence of statistical heterogeneity, but there was evidence of methodological variability in terms of outcome definitions and outcome measurement tools so it may have been more appropriate to present the data as a narrative synthesis. Outcome results were only reported for a small number of RCTs, particularly in the longer term.
There was also some uncertainty surrounding the results for functionality using the Knee Society score at two years. This was a generally well conducted review, but the paucity of data and questionable quality of the trials, suggest the authors' conclusions should be interpreted cautiously.

**Implications of the review for practice and research**

**Practice:** The authors stated that the less expensive implants (all-polyethylene tibial components) performed equally well as more expensive cemented metal-backed tibial components and could be used in many cases, which would reduce healthcare costs.

**Research:** The authors stated that studies should be undertaken to compare the use of all-polyethylene tibial components versus non-cemented porous-coated tibial components as part of total knee prostheses in younger patients.

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