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■ HIP

Thompson hemiarthroplasty *versus* modular unipolar implants for patients requiring hemiarthroplasty of the hip

A SYSTEMATIC REVIEW OF THE EVIDENCE

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Objectives

The objective of this study was to assess all evidence comparing the Thompson monoblock hemiarthroplasty with modular unipolar implants for patients requiring hemiarthroplasty of the hip with respect to mortality and complications.

Methods

A literature search was performed to identify all relevant literature. The population consisted of patients undergoing hemiarthroplasty of the hip for fracture. The intervention was hemiarthroplasty of the hip with a comparison between Thompson and modular unipolar prostheses.

Pubmed, Embase, CINAHL, Web of Science, PROSPERO and the Cochrane Central Register of Controlled Trials.

The study designs included were randomised controlled trials (RCTs), well designed case control studies and retrospective or prospective cohort studies. Studies available in any language, published at any time until September 2015 were considered. Studies were included if they contained mortality or complications.

Results

The initial literature search identified 4757 items for examination. Four papers were included in the final review. The pooled odds ratio for mortality was 1.3 (95% confidence Interval 0.78 to 2.46) favouring modular designs. The pooled odds ratio for post-operative complications was 1.1 (95% CI 0.79 to 1.55) favouring modular designs. Outcomes were reported at 12 or six months. These papers all contained potential sources of bias and significant clinical heterogeneity.

Conclusion

The current evidence comparing monoblock *versus* modular implants in patients undergoing hemiarthroplasty is weak. Confidence intervals around the pooled odds ratios are broad and incorporate a value of one. Direct comparison of outcomes from these papers is fraught with difficulty and, as such, may well be misleading. A well designed randomised controlled trial would be helpful to inform evidence-based implant selection.

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Keywords: Hemiarthroplasty, Hip, Fracture, Monoblock, Modular

Article focus

- To assess all evidence comparing the Thompson monoblock hemiarthroplasty with modular unipolar implants for patients requiring hemiarthroplasty of the hip.
- To use pooled data to assess the effect of common outcomes by implant type.

Key messages

- Current evidence is weak.
- Confidence intervals around the pooled odds ratios are broad and incorporate a value of one.

Strengths and limitations

- Strength: Rigorous methodology.

- Strength: Broad search criteria.
- Weakness: Heterogeneity between papers.

Introduction

Fractures of the hip can generally be subdivided into intra- and extracapsular. Where a fracture is extracapsular, the blood supply to the femoral head usually remains intact. This provides an opportunity to preserve the femoral head using a surgical procedure to fix the fracture, commonly using a dynamic hip screw, intramedullary device, or cannulated screws. Where a fracture is intracapsular, the blood supply to the femoral head may be damaged. In the event of an intracapsular displaced fragility fracture, the native femoral head is likely to progress to malunion or avascular necrosis, necessitating a procedure to replace the femoral head. The NICE hip fracture guidance¹ recommends total hip arthroplasty for patients able to walk independently out of doors with no more than the use of a stick, who are not cognitively impaired and who are medically fit for anaesthesia and for the procedure. For those who do not meet these criteria, the recommended procedure of choice is hemiarthroplasty of the hip.

The National Institute of Health and Care Excellence (NICE)¹ has made recommendations regarding the choice of hemiarthroplasty (hip arthroplasty) prosthesis: "Use a proven femoral stem design rather than Austin Moore or Thompson stems for arthroplasties." In producing this guidance, NICE have used evidence from primary total hip arthroplasty and expert opinion. "This recommendation was based on NICE guidance on selection of prosthesis for primary total hip replacement and expert opinion. In the light of such good evidence being available for the adequacy of femoral stem designs for patients with degenerative change it was thought that specific research in the fracture group would not be appropriate."¹ This guideline was published in 2011. Since then, there has been an opportunity for progress in research and a greater understanding of the outcomes that are important to this patient cohort.

The aim of undertaking this systematic review was to assess current evidence comparing the use of a Thompson monoblock implant with a modular implant for treatment of femoral neck fractures. The Thompson implant has been used for many decades and continues to enjoy popularity particularly for older, less active patients due to low cost and good results.² There is, however, variation in usage and a trend for decreasing use of monoblock stems including the Thompson. The number of such procedures reported in the Australian Joint Registry annual report was 12.6% lower in 2014 than in 2013 and is down 60.1% from 2003.³

Other considerations for hemiarthroplasty implant design include the use of cement and use of bipolar or monopolar designs. A Cochrane review published in 2010 concluded that hemiarthroplasty should be performed with cement. NICE hip fracture guidance supports this.⁴ A

recent meta-analysis has shown no evidence of benefit of bipolar over unipolar hemiarthroplasty. It is also noted that a bipolar hemiarthroplasty is generally a more expensive prosthesis.⁵

A monoblock prosthesis is, as the name suggests, manufactured as one piece. The sizing of this implant depends on the measured dimensions of the native femoral head. The Thompson prosthesis is collared, meaning that the implant rests on the femoral neck at a fixed point, controlled by the osteotomy site and this should be on the superior aspect of the lesser trochanter. As such, there is minimal control over leg length or offset. This means that this prosthesis will not necessarily accurately reproduce the patient's own anatomy. A modular prosthesis is manufactured using a separate stem, neck and head. This provides the opportunity for the surgeon to attempt to replicate more efficiently the patient's own anatomy. Whether these aspects of modular design translate into a clinically relevant difference is unknown.

The objective of this study was to assess all evidence comparing the Thompson monoblock hemiarthroplasty with modular unipolar implants for patients requiring hemiarthroplasty of the hip with respect to mortality and complications.

Materials and Methods

A systematic review was conducted in line with PRISMA-P guidance.⁶ A literature search was performed to identify all relevant literature.

Search strategy. The study designs included were randomised controlled trials, well designed case control studies and retrospective or prospective cohort studies. Studies available in any language, published at any time, were considered. A search using the PROSPERO and Cochrane databases was performed to ensure no duplication of efforts. This systematic review was registered on PROSPERO (CRD42015024512).

The search included the following resources: Pubmed, Embase, CINAHL, Web of Science and the Cochrane Central Register of Controlled Trials. Search terms were used to identify studies examining the hip, or synonyms thereof, and prosthesis categories. The Pubmed search strategy used is provided as an example: (((((monoblock) OR mono-block) OR mono block) OR modular*) OR hemiarthroplasty)) AND (((hip*) OR femur neck) OR femoral neck) OR neck of femur).

Where authors did not report data in a form that could be analysed in this review, authors were contacted to provide relevant information.

Study selection. The population consisted of patients undergoing hemiarthroplasty of the hip for fracture. The intervention was hemiarthroplasty of the hip with a comparison between Thompson and modular unipolar prostheses. Studies were included if they reported outcomes of mortality and complications. Although the Exeter Trauma Stem implant is a monoblock implant, due

Table I. Summary of included papers

Title	Inclusion	Intervention*	Design	Risk of bias score	Size
Parker et al ⁷ (2012) Cemented Thompson hemiarthroplasty versus cemented Exeter Trauma Stem (ETS) hemiarthroplasty for intracapsular hip fractures: A randomised trial of 200 patients.	Admitted to one UK trauma centre with intracapsular hip fracture between 2006-2009, patients with dementia were excluded.	Exeter trauma stem (monoblock) vs Thompsons (monoblock)	Randomised Controlled Trial	Low/ unclear (Cochrane risk of bias tool)	200 Thompson 100 ETS 100
Bauer et al ² (2010) Cemented Thompson versus cemented bipolar prostheses for femoral neck fractures.	Patients admitted to Australian Hospitals undergoing hemiarthroplasty for hip fracture between 1 January 2000 and 31 December 2003 were reviewed	Thompson vs cemented bipolar modular prosthesis in patients with intracapsular hip fracture	Retrospective cohort study	17/22 (TREND statement checklist)	303 Thompson 206 bipolar modular 97
Dawe et al ⁸ (2014) Does using a modular variable offset hemiarthroplasty reduce length of stay after hip fracture? Early experience with the Exeter Unipolar hemiarthroplasty.	Patients admitted to one UK trauma centre Nov 2010-Aug 2011 undergoing hemiarthroplasty for hip fracture	Exeter Unipolar with Unitrax Head (modular) vs Thompson hemiarthroplasty (monoblock)	Retrospective Cohort Study	16/22 (TREND statement checklist)	123 Thompson 68 Exeter Unipolar with Unitrax Head (modular) 55
Rogmark et al ⁹ (2012) Monoblock hemiarthroplasties for femoral neck fractures – A part of orthopaedic history? Analysis of national registration of hemiarthroplasties 2005–2009.	Patients undergoing hemiarthroplasty for hip fracture in Sweden 2005 to 2009	Austin-Moore prosthesis vs Thompson /ETS prosthesis vs modular implants	Swedish Joint Registry paper	17/22 (TREND statement checklist)	20 391 Thompson 753 ETS 371 Modular 18 959

*Thompsons = Monoblock, monopolar implant with a collared design; Exeter trauma stem (ETS) = Monoblock, monopolar implant with a tapered stem, amenable to intra-operative stem height adjustment; Austin-Moore = Older monoblock design, not examined within our data pooling

to the nature of the implant design facilitating variation in offset, it was included under the banner of modular implant.

Screening of studies was performed in two stages and by two independent reviewers currently practising within the field of trauma and orthopaedic surgery. Stage 1 involved the selection of studies for full document review. All items disagreed upon were retrieved in full for further examination. Stage 2 involved selecting studies for inclusion in the final analysis. This was performed following the assessment of suitability according to the criteria outlined above. There was an independent review of all full-text studies and a consensus was reached on papers to be included.

Data extraction and risk of bias assessment. Endnote software (Clarivate Analytics, London, United Kingdom) was used for data management and de-duplication of study reports.

Relevant data from each study were tabulated into two tables according to the following headings: (Table I) Title, Intervention, Design, Risk of Bias Score, Size and Inclusion; and (Table II) Title, Outcome Measures, Length of Follow-up and Findings.

Risk of bias was examined for RCTs using the Cochrane Risk of Bias Tool,¹⁰ for case-control studies using the Newcastle-Ottawa Scale¹¹ and for other non-randomised designs the TREND Statement Checklist was used.¹²

Statistical analysis. Assessment for clinical heterogeneity was performed with comparison of the various implants studied in each paper.

MetaLight V.1.2.0 (Social Science Research Unit, UCL, London, United Kingdom) statistical software was used for analysis. Odds ratios for binary outcomes were

calculated. Forest plots were constructed to examine these data, and pooling of data where there were common outcomes was conducted using a random effects model.¹³ Where feasible, the heterogeneity statistic was calculated using this software.

Results

Following an initial literature search, 4757 papers were identified from all combined sources. After de-duplication, 3170 references remained. Two independent reviewers reviewed abstracts for each paper. Reviewer 1 identified eight abstracts to be obtained as full text and reviewer 2 identified five abstracts. After review, four papers including 21 017 patients were selected for inclusion.^{2,7-9} (Fig. 1, Tables I and II).

The nine rejected papers included studies comparing bipolar and unipolar prostheses,^{14,15} a conference abstract relating to an included paper¹⁶ and Scandinavian and Australian Joint Registry studies examining epidemiological factors not relevant to this study.¹⁶⁻¹⁸ The remaining studies were excluded due to duplication.

Rogmark et al⁹ combined the results of Thompson stems and Exeter Trauma Stems (ETS), however, following a written request, the authors helpfully provided the data breakdown according to prosthesis type. This study was used for both mortality and complications pooling.

Dawe et al⁸ predicted mortality at 12 months with a Kaplan-Meier analysis, rather than following up the patient cohort for this period of time. An estimate of mortality was therefore used to calculate an odds ratio of mortality for this cohort.

Study methods and bias. Three different research methods were employed across the four studies. Overall,

Table II. Summary of included papers

Title	Outcome Measures	Length of follow-up	Findings T = Thompsons E = Exeter	Odds ratio
Parker et al ⁷ (2012) Cemented Thompson hemiarthroplasty versus cemented Exeter Trauma Stem (ETS) hemiarthroplasty for intracapsular hip fractures: A randomised trial of 200 patients.	Pain scores, mobility scores, perioperative complications and mortality	1 year	Mean degree of residual pain (1 year) T = 1.6, E = 1.5, p = 0.8 Mean change in mobility score (1 year) T = 1.1, E = 1.7, p = 0.05 Mortality (1 year) T = 25, E = 36, p = 0.12 No statistically significant difference in medical complications	<u>Mortality</u> T = 25/75; E = 36/64 0.59 (95% CI 0.32 to 1.09) <u>Complications</u> T = 10/90; E = 6/94 1.36 (95% CI 0.46 to 4.08)
Bauer et al ² (2010) Cemented Thompson versus cemented bipolar prostheses for femoral neck fractures.	Mortality, mobility, perioperative complications	6 months	Mortality (6 months); (T) 27 (13%) vs bipolar 6 (6%) p = 0.078 Post-operative mobility; Independently indoor (T) 82/206 vs bipolar 88/97 p = 0.001 Independently outdoor (T) 67/ 206 vs bipolar 65/97 p = 0.001 Prosthesis complication; (T) 13/ 206 vs bipolar 5/97 p = 0.799	<u>Mortality</u> T = 27/179; bipolar = 6/91 2.29 (95% CI 0.91 to 5.74) <u>Complications</u> T = 19/187; bipolar = 9/88 1.11 (95% CI 0.48 to 2.54)
Dawe et al ⁸ (2014) Does using a modular variable offset hemiarthroplasty reduce length of stay after hip fracture? Early experience with the Exeter Unipolar hemiarthroplasty.	Length of Stay, median time to discharge from rehabilitation, Mortality, early complications	1 year	Length of stay was (E) Median 5.72 days vs 6.99, p = 0.048. Median time to discharge from rehabilitation, (E) 13.6 days vs (T) 21.7 days, p = 0.0003 Kaplan–Meier estimate of survival at 1 year showed no significant difference p = 0.153. Estimated mortality T = 15/68, E = 7/55. OR 1.94 (95% CI 0.73 to 5.16) There was no significant difference in early complications	<u>Mortality</u> T = 15/53; E = 7/48 1.94 (95% CI 0.73 to 5.16) <u>Complications</u> T = 6/62; E = 1/54 3.38 (95% CI 0.37 to 31.11)
Rogmark et al ⁹ (2012) Monoblock hemiarthroplasties for femoral neck fractures – A part of orthopaedic history? Analysis of national registration of hemiarthroplasties 2005–2009.	Re-operation, mortality.	1 year	Risk of re-operation was increased twice for the Austin-Moore prosthesis (2.0; 95% CI 1.5 to 2.8). Thompson /ETS prosthesis did not influence the risk of re-operation compared with modular implants (0.7; 95% CI 0.5 to 1.2). One-year mortality in the Thompson1/ETS group was 338 (30%) and in the modular group 4 239 (23%)(p < 0.001)	<u>Mortality</u> T = 247/505; ETS = 94/277; Modular = 4239/14 420 1.66 (95% CI 1.42 to 1.94) <u>Complications</u> T = 26/726; ETS = 1/370; Mod = 655/18 004 0.98 (95% CI 0.66 to 1.47) Note: for subgroup separation see forest plot (Fig 4, Fig 5)

the methods were of medium or low quality. Two were retrospective cohorts^{2,8}, one was a prospective randomised controlled trial⁷ and one was a Swedish Joint Registry paper.⁹

There is no evidence that an attempt at prospective sample size calculations was made in any of the papers identified. Risk of bias assessment indicated that there was likely to be bias in all papers, particularly selection bias and confirmation bias.

Sample sizes were variable. The joint registry paper had examined records of over 20 000 patients over a period of four years. The remaining papers had sample sizes of between 123 and 303 patients.

Clinical heterogeneity. The prostheses under review in two of the studies do not strictly fit into the criteria; Parker⁷ compared a Thompson stem with an Exeter Trauma Stem. The ETS is a monoblock stem and a non-collared implant with a modern tapered design which provides a greater choice of offset. Although not identical, it shares some of the key features of modular cemented implants and so this direct comparison with a Thompson implant was considered informative and therefore included in the review. The Parker study⁷ was the only randomised controlled trial included in this review.

Bauer et al² used a retrospective cohort to compare the Thompson stem with an Exeter stem with a bipolar

head, rather than unipolar as specified. The paper was selected due to relevance to our study question. Although a bipolar head was used, the implant was a modular cemented implant. This implant provides flexibility over offset and is very similar to modular cemented implants. This paper provides a direct comparison between a modular and a Thompson stem. The strong similarities between this paper and the inclusion criteria were felt to warrant its inclusion in this review. This paper identified no difference between the two prostheses in terms of functional outcome, complications or mortality rates.

Dawe et al⁸ found no statistically significant differences in mortality or complications rates. The modular unipolar prosthesis reduced the length of stay (p = 0.048) and duration of rehabilitation (p = 0.0003) after hip fracture (two-tailed non-parametric *t*-test.)

The study from Rogmark et al⁹ is a joint registry study and, as such, outcomes are dependent on the quality of data capture. Similarly to Bauer et al² and Dawe et al,⁸ this study is observational; factors influencing implant choice may impact on outcomes.

Mortality and complications were identified as the only common outcome measures.

Mortality. In a paper by Dawe et al,⁸ mortality at 12 months was taken from the Kaplan-Meier estimates of

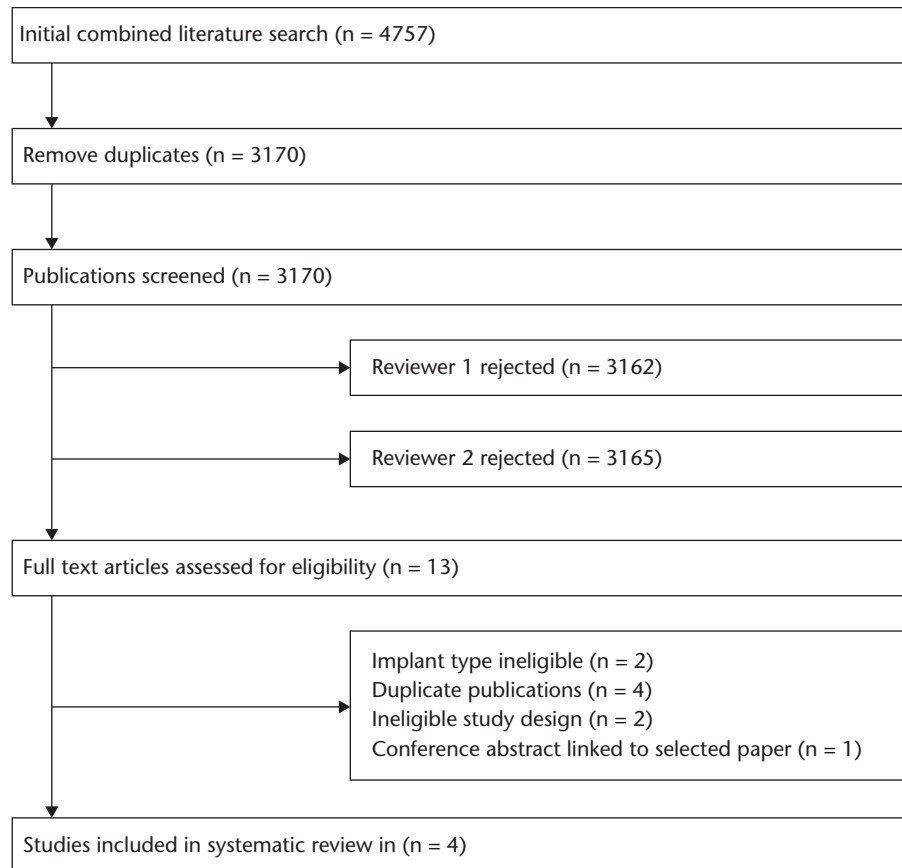


Fig. 1

Flowchart to demonstrate literature review process.

relative survival because follow-up time in this study was insufficient for 12-month mortality. Bauer et al² recorded mortality at six months. Pooled mortality using a random effects model of data derived from papers showed an odds ratio of 1.38 (95% CI 0.78 to 2.46), favouring modular/ ETS (Fig. 2). Author provision of raw data from Rogmark et al⁹ allowed direct comparison of mortality between Thompson and ETS (OR 1.44, 95% CI 1.09 to 1.91) and between Thompson and modular implants (OR 1.66, 95% CI 1.42 to 1.95) (Figs 3 and 4).

Complications. An estimate of the difference in surgical complications (including infection, dislocation, fracture and acetabular wear) was calculated using a random effects model. Rogmark et al⁹ collected data on patients undergoing further surgery only; those patients sustaining dislocation and requiring closed reduction were not included. An odds ratio of 1.1 (95% CI 0.79 to 1.55), favouring modular/ ETS (Fig. 5), was identified. Author provision of raw data from Rogmark et al⁹ allowed direct comparison of complications between Thompson and ETS (13.25, 95% CI 1.79 to 98.03) and between Thompson and modular implants (0.98, 95% CI 0.66 to 1.47) (Figs 4 and 5).

Discussion

This paper reports a review of comparisons of Thompson hemiarthroplasty with modular, monopolar hemiarthroplasty. We found weak evidence in favour of modular implants, against the background of clinical heterogeneity and methodological weakness.

A large number of papers were initially identified following a literature search (3170) but after an independent review process, the majority were removed. This was to be expected following the use of a search strategy which was designed to be broad. Many of those excluded were focused on basic science or total hip arthroplasty, perhaps reflecting a paucity of evidence relating to hemiarthroplasty of the hip for trauma.

One paper excluded was Bidwai and Willett.¹⁹ Although this paper did meet some of the inclusion criteria, mortality was not used as an outcome. This has been an influential paper. It did not find statistically significant differences in complications between the two types of implants.

There is clinical heterogeneity throughout the selected papers, as well as differences in methods used, sample sizes, implant selection and outcome measures. Risk of

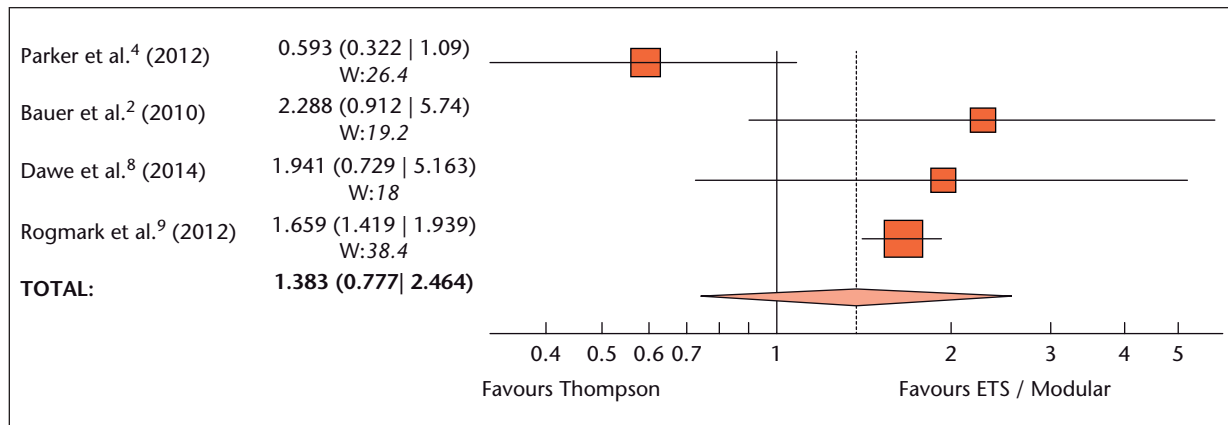


Fig. 2

Mortality Forest Plot (1.38 (95% CI 0.78 to 2.46), favouring modular/ ETS) ($I^2 = 65\%$). Dawe et al⁸ mortality estimated from Kaplan-Meier-predicted survival graph. Rogmark et al⁹ shows Thompson *versus* Exeter Trauma Stem (ETS) and modular implants.^{2,7} W, Weight %.

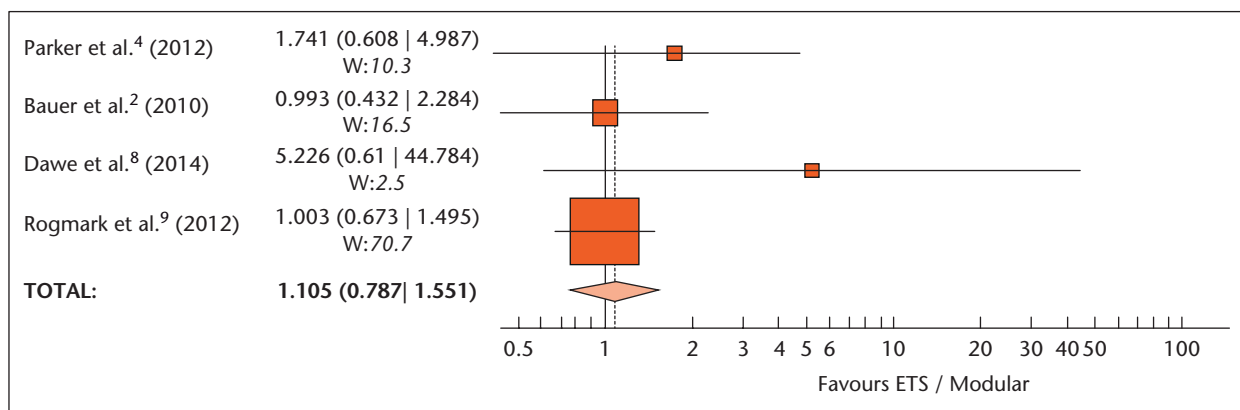


Fig. 3

Complications Forest Plot (1.1 (95% CI 0.79 to 1.55), favouring modular/ ETS) ($I^2 = 0.48\%$). Rogmark et al⁹ complications include only complications requiring operative management and exclude closed joint reduction. Rogmark et al⁹ shows Thompson *versus* ETS and modular.^{2,7,8} W, Weight %.

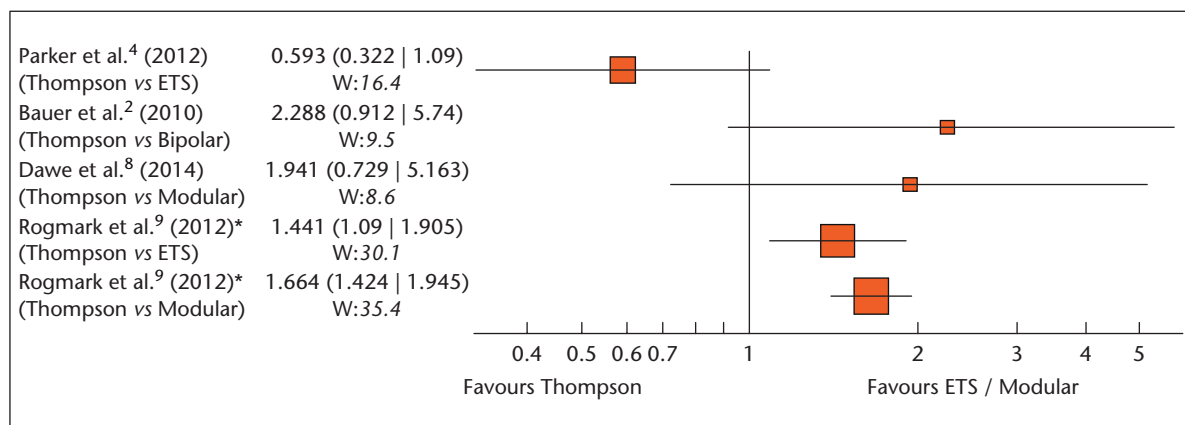


Fig. 4

Mortality Forest Plot (1.66 (95% CI 1.42 to 1.95) ($I^2 = 65\%$) (Rogmark et al⁹ data separated). Dawe et al⁸ mortality estimated from Kaplan-Meier-predicted survival graph (ETS, Exeter Trauma Stem).^{2,7} W, Weight %.

bias assessment indicated bias is likely in all papers assessed. All papers were likely to have been influenced by bias due to prosthesis selection. The Thompson

prosthesis is often used in elderly patients with reduced mobility due to good results and low cost. We may expect to see increased mortality and complications in older, less

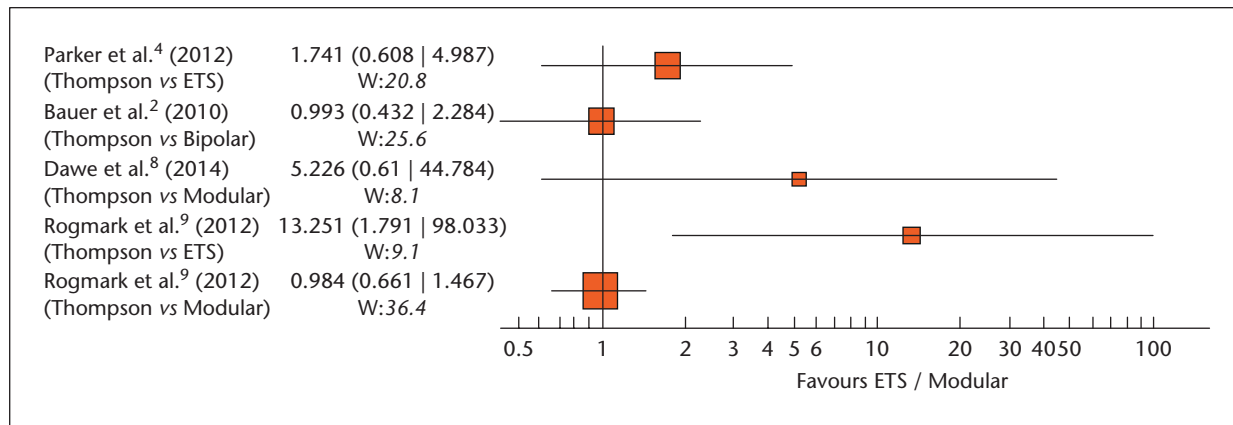


Fig. 5

Complications Forest plot (0.98 (95% CI 0.66 to 1.47) ($I^2 = 55.2\%$) (Rogmark et al⁹ data separated). Rogmark et al⁹ complications include only complications requiring operative management and exclude closed joint reduction (ETS, Exeter Trauma Stem).^{2,7,8} W, Weight %.

mobile patients. Prosthesis cost, availability and ease of use could all impact on the surgeon's choice of implant. Parker's study⁷ was a randomised trial, however, patients with dementia were excluded and this may effect external validity.

Two papers recorded mortality at 12 months and one at six months, and one paper estimated differences in survival at 12 months with a Kaplan-Meier curve. No statistically significant difference was found. The appropriateness of mortality as an outcome for this procedure is questionable; this cohort is known to have a high mortality rate and, as such, it could be argued that quality of life would be more appropriate as an outcome.

Complications were reported in a number of ways through each of the included papers. While Rogmark et al⁹ examined re-operations, Bauer et al² separate "prosthesis complications" and general complications encountered during a six-month follow-up. Complications are a relatively infrequent event: four out of 200 patients required "further surgery" in Parker's study⁷ and there was a 5% to 6% rate of "prosthesis complication" in Bauer et al's paper.² Data pooling does not show a significant effect of prosthesis type on complications. Considering the heterogeneity in gathering and presenting complications data between papers, this result should be treated with caution.

Dawe et al⁸ found a reduced length of stay in patients treated with a modular design.⁸ However, this could be due to selection bias in the retrospective nature of the study. It is possible that the frailer patients or those with lower demands will have been treated with the less expensive prosthesis.

In the study from Parker,⁷ patients were excluded for a number of reasons such as when the patient had dementia and consent of next of kin could not be obtained, or when the lead trialist was not available. Using the *t*-test, the ETS was found to present fewer operative difficulties ($p = 0.005$).

Despite the relative lack of evidence on the performance of the prostheses, there is evidence of change in global trends for choice of hemiarthroplasty prosthesis. The Swedish Joint Registry has shown a decrease in the use of monoblock implants from 18% to 0.9% between 2005 and 2009, in favour of modular implants.¹⁶ This would suggest that changes in practice are underway, despite a lack of evidence.

The strengths of this study were the deliberately broad selection criteria and therefore likelihood of identifying all relevant papers and the fact that there are no other systematic reviews examining these two types of implants which enjoy widespread clinical use. There was substantial heterogeneity between papers examined and, as such, direct comparison was challenging. Selection criteria were relaxed slightly where it was felt the paper closely approximated requirements. There are subtle variations in implant comparison between papers; ideally implant choice would be homogenous. These variations are discussed in the current study.

This systematic review attempted to examine evidence on selection of hip hemiarthroplasty implants, given national recommendations based on expert opinion. There is weak evidence in favour of modular implants, against the background of clinical heterogeneity and methodological weakness. A well designed randomised controlled trial could improve decision making for hip fracture patients. Agreement upon the best choice of outcome measure in combination with a rigorously designed randomised controlled trial would enable an optimum choice of implant to be recommended. This would impact directly on patient care and have economic implications for health providers.

In conclusion, evidence comparing the Thompson monoblock hemiarthroplasty with modular unipolar implants for patients requiring hip hemiarthroplasty is weak. Direct comparison of outcomes from these papers is fraught with difficulty and, as such, may well be

misleading. A randomised controlled trial designed with a rigorous methodology and a prospective sample size calculation would likely prove beneficial to evidence-based implant selection.

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Author Contributions

- A. L. Sims: First author, writing the paper, editing the paper, data collection, statistical analysis.
- A. J. Farrier: Co-author, editing the paper, data collection.
- M. R. Reed: Co-author, editing the paper.
- T. A. Sheldon: Senior author, editing the paper, statistical analysis.

Conflicts of Interest Statement

- None declared

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