■ TRAUMA

A randomized controlled trial comparing the Thompson hemiarthroplasty with the Exeter polished tapered stem and Unitrax modular head in the treatment of displaced intracapsular fractures of the hip

THE WHITE 3: HEMI TRIAL

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Aims

This study aimed to compare the change in health-related quality of life of patients receiving a traditional cemented monoblock Thompson hemiarthroplasty compared with a modern cemented modular polished-taper stemmed hemiarthroplasty for displaced intracapsular hip fractures.

Patients and Methods

This was a pragmatic, multicentre, multisurgeon, two-arm, parallel group, randomized standard-of-care controlled trial. It was embedded within the WHiTE Comprehensive Cohort Study. The sample size was 964 patients. The setting was five National Health Service Trauma Hospitals in England. A total of 964 patients over 60 years of age who required hemiarthroplasty of the hip between February 2015 and March 2016 were included. A standardized measure of health outcome, the EuroQol (EQ-5D-5L) questionnaire, was carried out on admission and at four months following the operation.

Results

Of the 964 patients enrolled, 482 died or were lost to follow-up (50%). No significant differences were noted in EQ-5D between groups, with a mean difference at four months of 0.037 in favour of the Exeter/Unitrax implant (95% confidence interval (CI) 0.014 to 0.087, p = 0.156), rising to 0.045 (95% CI 0.007 to 0.098, p = 0.09) when patients who died were excluded. The minimum clinically important difference for EQ-5D-5L used in this study is 0.08, therefore any benefit between implants is unlikely to be noticeable to the patient. There was no difference in mortality or mobility score.

Conclusion

Allowing for the high rate of loss to follow-up, the use of the traditional Thompson hemiarthroplasty in the treatment of the displaced intracapsular hip fracture shows no difference in health outcome when compared with a modern cemented hemiarthroplasty.

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Worldwide, 1.3 million patients sustain a fracture of the hip each year, leading to1.75 million disability-adjusted life years lost, and accounting for 1.4% of the total healthcare burden in established market economies.[1] In the United Kingdom, there are 70 000 such fractures each year which is forecast to increase to 100 000 by 2020.[1,2] Around half of these are intracapsular fractures which are usually treated using a hemiarthroplasty;[3,4] around 19 000 hemiarthroplasties are performed each year in England, Wales and Northern Ireland.[5]

The Thompson prosthesis is a generic monoblock hemiarthroplasty designed 65 years ago and is intended for cemented implantation (Fig. 1).[6] As it is a monoblock, there is limited scope for adjustment of length and offset. At five years, the cemented Thompson stem has a published survival of 95%; the list price, as published and available from trust finance departments, is £327, including United Kingdom Value Added Tax (VAT).

The Exeter hip arthroplasty system (Stryker Ltd., Newbury, United Kingdom) is widely

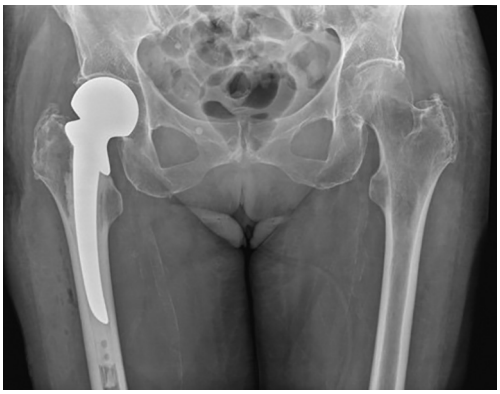

Fig. 1

Plain radiograph of a cemented Thompson monoblock hemiarthroplasty.

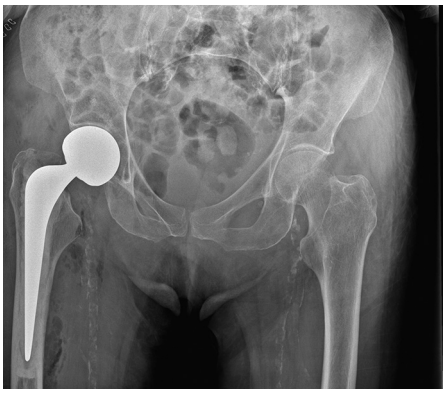

Fig. 2

Plain radiograph of a cemented Exeter polished taper stem with a Unitrax head (modular implant).

used as a total hip arthroplasty (THA) system in arthritis of the hip.[7] Used with the large Unitrax femoral head (Stryker), the Exeter stem may now be used as a hemiarthroplasty; as a modular system, this has the advantage of allowing changes in length and offset following cementation (Fig. 2). While the Exeter stem has excellent long-term survival in THA, no data exists regarding its use as a hemiarthroplasty with the Unitrax head. The list price of this implant combination, as published and available from trust finance departments, is around £1442, including VAT.

The Orthopaedic Device Evaluation Panel (ODEP) produces ratings for THA prostheses used in the United Kingdom, based on length of follow-up and quality of evidence.[8] In the United Kingdom, the National Institute of Health and Care Excellence (NICE) has recommended the use of 'proven' cemented stem designs with an ODEP rating of at least 3B (97% survival at three years) when used as a THA, explicitly advising against the use of the Thompson prosthesis.[9] In the absence of randomised trials, this guidance was based on data from studies of THA and from expert opinion. In fact, no hemiarthroplasty has an ODEP rating, including the Thompson and the Exeter/Unitrax hemiarthroplasty.

The aim of this trial is to compare the change in health-related quality of life of patients receiving a cemented monoblock Thompson *versus* a cemented modular polished taper stem (Exeter/Unitrax) for displaced intracapsular fractures requiring hemiarthroplasty.

Patients and Methods

Study design and participants. This was a multicentre, multisurgeon, two-arm, parallel group, randomized standard-of-care controlled trial.[10] It was embedded within the World (formerly Warwick) Hip Trauma Evaluation (WHiTE) Comprehensive Cohort Study.[11] The trial was approved by the Research Ethics Committee and reported in accordance with the trial protocol and Consolidated Standards of Reporting Trials statement.

The WHiTE Study is a large cohort study examining a range of outcomes including health-related quality of life using EuroQol (EQ-5D-5L) in patients following fracture of the hip, and allows embedding of randomized controlled trials within this patient cohort.[12-15] The WHiTE 3: HEMI trial is an embedded trial that compared the Thompson hemiarthroplasty with the Exeter/Unitrax.[16]

Hypothesis. The null hypothesis was that there is no difference in health-related quality of life at four months post injury between patients over 60 years of age with an AO/OTA type B3 fracture (displaced, intracapsular) of the hip treated with an Exeter/Unitrax compared with those treated with Thompson.[17]

Aims. The primary objective was to compare observed differences in patients' health-related quality of life between the trial treatment groups at four months post-injury. The secondary objectives were to compare mortality, mobility score, reoperation and cause, length of acute ward stay and revision at four months. We also measured radiological leg length discrepancy as per Bidwai and Willett.[18]

Outcome assessment. We augmented the existing National Hip Fracture Database dataset with the United Kingdom Core Outcome Set for Hip Fracture Research.[19] This includes the EQ-5D-5L at baseline (retrospective, prior to fracture) and four months post-fracture.[12] Four months represents a routine follow-up point for the National Hip Fracture Database, and is considered to be the point at which recovery following hip fracture plateaus (Fig. 3).[9,20] The EQ-5D-5L provides a score of 0 in the event of mortality, ensuring patients that die during the follow-up period can be included in the final assessment. EQ-5D correlates strongly with a hip-specific patient-reported outcome measurement, the Oxford Hip Score, and is as responsive to changes over time in patients having hemiarthroplasty.[20]

Radiographs and notes (operation note and discharge summary) were studied in order to capture perioperative complications, length of hospital stay, and discharge address. Radiological neck lengths were calculated using

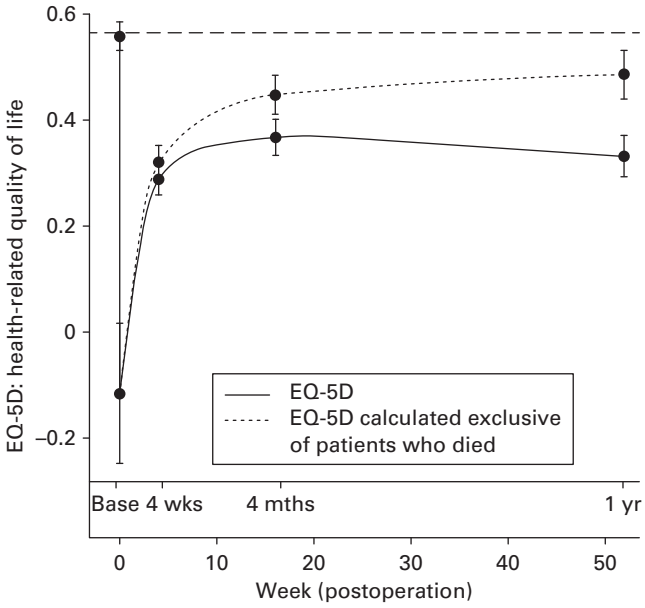

Fig. 3

Postoperative change in EuroQol five domain questionnaire (EQ-5D) following hip fracture surgery. The dashed line indicates the baseline preoperative EQ-5D. (Reprinted from **X. L. Griffin, N. Parsons, J. Achten, M. Fernandez, M. L. Costa.** Recovery of health-related quality of life in a United Kingdom hip fracture population, the Warwick Hip Trauma Evaluation - a prospective cohort study. *Bone Joint J* 2015;97-B:372-382.)[23]

standard hospital-based radiology software and scored by two independent orthopaedic surgeons (see Supplementary material for a full list of the CORNET Collaborators). These measurements were repeated and a mean value identified for each patient. Standardization was achieved using a known value to provide a sizing ratio for radiological measurements (the implant head size).

Inclusion and exclusion criteria. All patients over the age of 60 years, receiving a hemiarthroplasty for a type B3 fracture of the hip were eligible for inclusion. Patients with pre-existing symptomatic hip arthritis were excluded from the trial.

Consent. Consent was conducted under the same conditions as other studies in the WHiTE cohort.[11,21] Where patients lacked capacity, we approached an appropriate consultee. Where a personal consultee was available, they were provided with the study information and their agreement to patient enrolment was recorded. where a personal consultee was not available, a nominated consultee was identified to advise the research team. At the first appropriate time when the patient had regained capacity, informed consent for continuation was obtained from the patient. For those patients with permanent cognitive impairment, a Personal Consultee was asked to give agreement for continuation in the study.

Power and sample size. The sample size was calculated as 964 patients based on standard deviation for EQ-5D at four months' post-surgery of approximately 0.3 points[20] and a minimum clinically important difference for an EQ-5D of 0.08.[22] This assumes an approximately normal distribution (no other distributional assumption has been found to be preferable to normality, based on the authors' experience from previous studies of this outcome measure in this population),[20,23] a 1:1 allocation ratio, a 30% loss to follow-up, a type 1 error rate of 5%, and power of 90%.

Treatment allocation. Allocation sequences were created using a computer-generated random number sequence via an online randomization portal. After registration on the portal, patients were allocated their treatment before surgery and that allocation recorded centrally on the online system. Participants were enrolled by members of the Collaborative Orthopaedic Research Network (CORNET) trainee collaborative or trial research associates.

Blinding. Participants were blinded to the treatment allocation. The operating surgeon could not be blinded to the allocation but took no part in the assessment of the primary outcome measurement. The EQ-5D is a patient-reported measure and was collected independently from the surgical team.

Trial treatments. Participants were randomized to receive either a cemented Thompson hemiarthroplasty or a cemented Exeter/Unitrax. Patients received general or regional anaesthesia at the discretion of the anaesthetist. Surgery was performed under the care of any of the consultant surgeons in the collaborating centres. The large number of surgeons and the wide skill mix was intended to eliminate the 'surgeon effect' such that stratification by surgeon was not required.[24] Pre and postoperative management was as per the standard of care in the unit, according to NICE guidance.[9]

Methods and assessments. Participants were followed up centrally. Techniques used to ensure minimum loss to follow-up included collecting multiple contact addresses, telephone numbers, mobile phone numbers and email addresses during enrolment.

Statistical analysis. The primary outcome measure was health related quality of life according to the EuroQol five domain questionnaire (EQ-5D). Groups were compared on an intention-to-treat basis at four months from the index fracture. In order to avoid overestimating the effects of the intervention or treatment pathway, we used death-adjusted estimates.[25] The differences between treatment groups were assessed using an independent samples *t*-test with p-values less than 0.05 considered significant.

As a sensitivity analysis, regression analyses were performed to adjust for any imbalance between treatment groups in patient baseline (pre-injury) EQ-5D, age and gender. The fixed effects linear regression model was generalized by adding a random effect for recruiting centre to allow for possible heterogeneity in patient outcomes due more generally to the recruiting centre. The mixed-effects regression was the definitive analysis and was undertaken using the specialist mixed-effects modelling functions available in the software package R (R Foundation, Vienna,

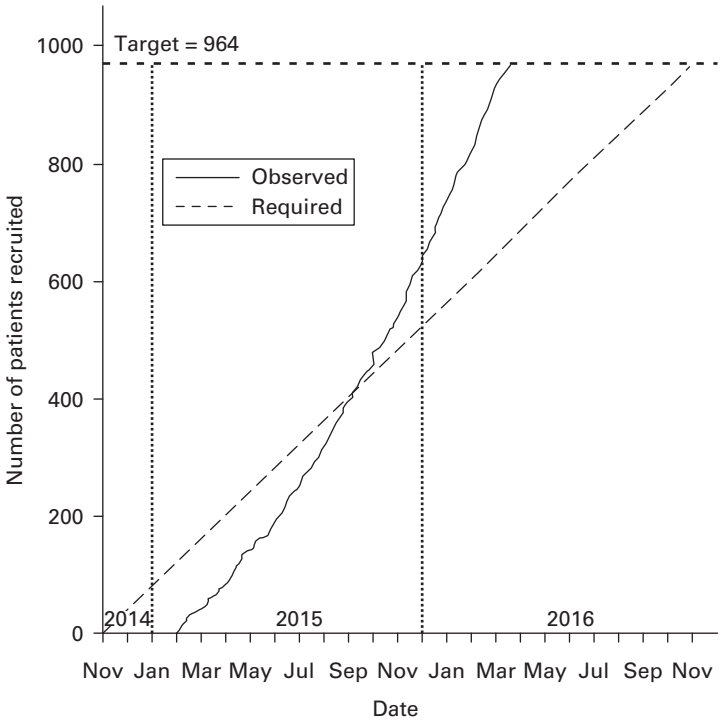

Fig. 4

Graph showing recruitment of patients for this trial. The target, 964 patients, was achieved ahead of schedule.

Austria). EQ-5D data were assumed to be approximately normally distributed.[20,23]

Secondary analyses (mortality, walking ability, length of stay, complications and radiological neck length) were undertaken using the above strategy for approximately normally distributed outcome measures. For dichotomous outcome variables, mixed effects logistic regression analysis was undertaken with results presented as odds ratios (OR) (and 95% confidence intervals (CI)) between the trial groups.

Results

Baseline outcomes. The target of 964 patients was recruited between Feb 2015 and March 2016 (Fig. 4), and was faster than estimated thanks to the efforts of the CORNET trainee research collaborative. Of 964 patients recruited, 704 (73%) were women, and the mean age was 83.7 (7.3) for the Thompsons group and 83.9 (7.9) for the Exeter/ Unitrax group. The mean length of surgery was 80 minutes (42 to 205) for the Exeter/Unitrax and 70 minutes (27 to 197) for the Thompson. A total of 47 patients crossed over to the other treatment group, 15 of whom crossed over to an Exeter/Unitrax and 32 to a Thompson; this generally happened when the alternative implant system was unavailable at the time of surgery (Table I).

Primary outcome

Of the 964 patients recruited, 482 had a valid EQ-5D at four months (50%) (Table I). Of these, 283 self-responded (60%) and 186 were reported by a proxy (40%) (Fig. 5). At four months, including patients who had died, the adjusted mean EQ-5D-5L was 0.321 (SD 0.348, n = 303) in the Thompsons group and 0.379 (SD 0.358, n = 315) in the Exeter group, giving a mean difference of 0.037 (95% CI -0.014 to 0.087, p = 0.156) in favour of the Exeter/Unitrax. Excluding patients who had died, this difference was 0.045 (95% CI -0.007 to 0.098, p = 0.09) (Table II). Dimensions of health at four months are shown in Table III.

Secondary outcomes. Mortality was 15% overall with no difference between the two implants: 73 in the Thompson group and 74 in the Exeter/Unitrax group. The adjusted OR for mortality was 1.02 (95% CI 0.72 to 1.46, p = 0.911).

Walking ability was similar in the two groups: using ordinal logistic regression, the OR for severe walking difficulty was 0.76 (95% CI 0.54 to 1.06, p = 0.107 favouring the Exeter/Unitrax (Table IV).

Mean length of stay was slightly higher in the Thompson group (9.67 days for Thompson, 9 days for Exeter/Unitrax; p = 0.039, Fig. 6). There was no difference in complications between the two groups (Table V). There were three cases of implant revision in each group.

Table I. Patient characteristics

Characteristic	Thompson (n = 482)	Exeter/Unitrax (n = 482)
Female, n (%)	326 (*67.6*)	326 (*67.6*)
Male, n (%)	156 (*32.4*)	156 (*32.4*)
Mean age, yrs (SD)	83.7 (7.3)	83.9 (7.9)
Admitted from, n (%)		
Own home/sheltered housing	271 (*73.2*)	277 (*72.9*)
Residential care	57 (*15.4*)	57 (*15*)
Nursing home	33 (*8.9*)	29 (*7.6*)
Rehabilitation unit	2 (*0.5*)	2 (*0.5*)
This hospital	4 (*1.1*)	6 (*1.6*)
Other hospital within same trust	1 (*0.3*)	9 (*2.4*)
Other hospital trust	2 (*0.5*)	0 (*0*)
ASA,[26] n (%)		
1	1 (*0.3*)	2 (*0.5*)
2	78 (*21.2*)	84 (*22.2*)
3	240 (*65.2*)	230 (*60.7*)
4	49 (*13.3*)	63 (*16.6*)
Mean time from admission to surgery, hrs (SD)	28.2 (23.4)	28.5 (21.0)
Mean preoperation AMTS[19](SD)	6.4 (3.8)	6.6 (3.7)
Mean postoperation AMTS[19](SD)	6.1 (3.8)	6.3 (3.9)

ASA, American Society of Anesthesiologists; AMTS, Abbreviated Mental Test Score (scored from 1 and 10); SD, standard deviation

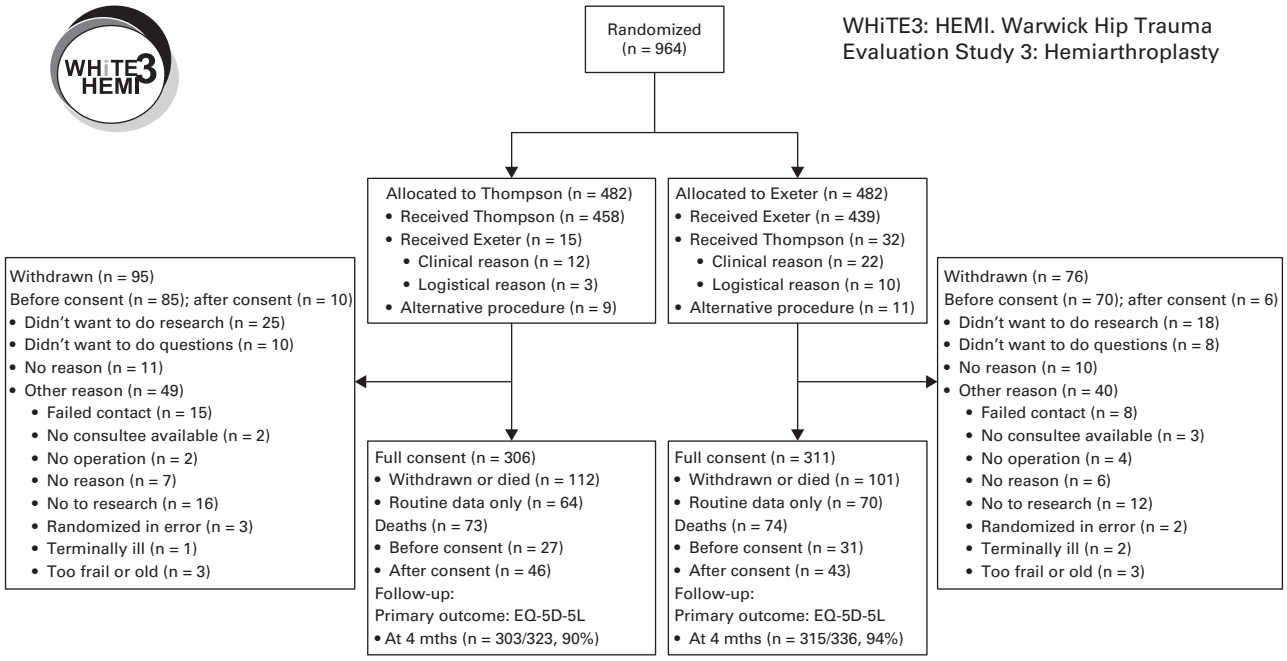

Fig. 5

Consolidated Standards of Reporting Trials (CONSORT) flowchart.

There was no difference in the multivariate mixed-effects regression analysis in radiologically-measured mean neck length between the two prostheses (Thompson, 3.01 mm, standard deviation (SD) 7.26; Exeter/Unitrax, 2.91 mm, SD 7.61, p= 0.834, Fig. 7).

Discussion

This trial found no evidence of a difference in health-related quality of life for patients with displaced intracapsular hip fracture treated with a traditional Thompson hemiarthroplasty compared with a modern cemented modular hemiar-

Table II. Adjusted EuroQol EQ-5D-5L at four months

	Thompson	Exeter/Unitrax	Adjusted difference (95% CI)	p-value*
Mean EQ-5D (SD, n)	0.321 (0.348, 303)	0.379 (0.358, 315)	0.037 (-0.014 to 0.087)	0.156
Mean EQ-5D† (SD, n)	0.420 (0.341, 231)	0.496 (0.332, 241)	0.045 (-0.007 to 0.098)	0.090

*p-value from mixed effects regression analysis, with treatment group, age group, gender and baseline EQ-5D score as covariates (fixed effects) and recruiting centre as a random effect
†EQ-5D calculated exclusive of patients who died (for whom EQ-5D is 0)

Table III. Counts and percentages of four-month EuroQol EQ-5D by domain and level, by intervention group

Domain	Thompson						Exeter/Unitrax					
Level	1	2	3	4	5	Total	1	2	3	4	5	Total
Mobility, n (%)	27 (*11*)	53 (*22*)	77 (*32*)	49 (*20*)	38 (*16*)	244	40 (*16*)	63 (*25*)	73 (*29*)	43 (*17*)	32 (*13*)	251
Self-care, n (%)	85 (*35*)	40 (*16*)	35 (*14*)	18 (*7*)	66 (*27*)	244	112 (*16*)	42 (*25*)	34 (*29*)	10 (*17*)	53 (*13*)	251
Usual activities, n (%)	44 (*18*)	41 (*17*)	44 (*18*)	28 (*12*)	85 (*35*)	242	57 (*23*)	48 (*19*)	50 (*20*)	20 (*8*)	75 (*30*)	250
Pain, n (%)	88 (*37*)	62 (*26*)	52 (*22*)	29 (*12*)	6 (*3*)	237	108 (*44*)	64 (*26*)	54 (*22*)	16 (*6*)	5 (*2*)	247
Anxiety, n (%)	115 (*49*)	53 (*22*)	47 (*20*)	13 (*6*)	8 (*3*)	236	126 (*51*)	52 (*21*)	47 (*19*)	18 (*19*)	5 (*7*)	248

Table IV. Mobility at four months post-fracture

	Thompson (n = 242)	Exeter/Unitrax (n = 252)
Freely mobile without aids, n (%)	15 (*6*)	16 (*6*)
Mobile outdoors with one aid, n (%)	38 (*16*)	47 (*19*)
Mobile outdoors with two aids or frame, n (%)	19 (*8*)	34 (*13*)
Some indoor mobility but never goes outside without help, n (%)	135 (*56*)	123 (*49*)
No functional mobility (using lower limbs), n (%)	35 (*14*)	32 (*13*)

Table V. Complications at four months; estimated raw and adjusted odds ratios based on intention-to-treat analysis

	Thompson (n = 482)	Exeter/Unitrax (n = 482)	OR	Adjusted§	95% CI	p-value
Local complications*	19	28	1.502	1.507	0.828 to 2.741	0.179
Systemic complications†	6	9	1.509	1.513	0.530 to 4.316	0.439
Unrelated adverse events‡	75	72	0.953	0.950	0.665 to 1.358	0.779

OR, odds ratio; CI, confidence interval
*Erythema, serious drainage, purulent drainage, microbiological infection, dehiscence, antibiotics, debridement, implant revision, neurological injury, tendon injury, deep vein thrombosis, wound infection, failure of fixation, dislocation
†Blood transfusion
‡Pneumonia, urinary tract infection, cerebrovascular accident, myocardial infarction, other
§Mixed effects regression based on a complete case analysis with treatment group, age group and gender as covariates (fixed effects) and recruiting centre as a random effect

throplasty. The difference between the two was not statistically significant and did not reach the accepted minimum clinically important difference of 0.08. In terms of secondary outcomes, walking status, mortality and radiological neck length measurements were similar in the two groups. There was a small difference in length of stay favouring the Exeter/Unitrax implant.

This large multicentre randomized controlled trial benefitted from a pragmatic design using the United Kingdom Core Outcome Set for hip fracture research including a patient-reported primary outcome measure (EuroQol (EQ)-5D) that is known to be suitable for proxy use. The benefits of this are that the trial could include the cohort of hip fracture patients with cognitive impairment and is generalizable to this population. Patients were blinded to their treatment allocation.

Recruitment was more rapid than predicted due in part to the involvement of the CORNET trainee collaborative. This group of orthopaedic trainees could ensure that suitable patients were appropriately randomized outside normal office hours, increasing the efficiency of the trial. Use of trainee collaboratives has numerous benefits to clinical

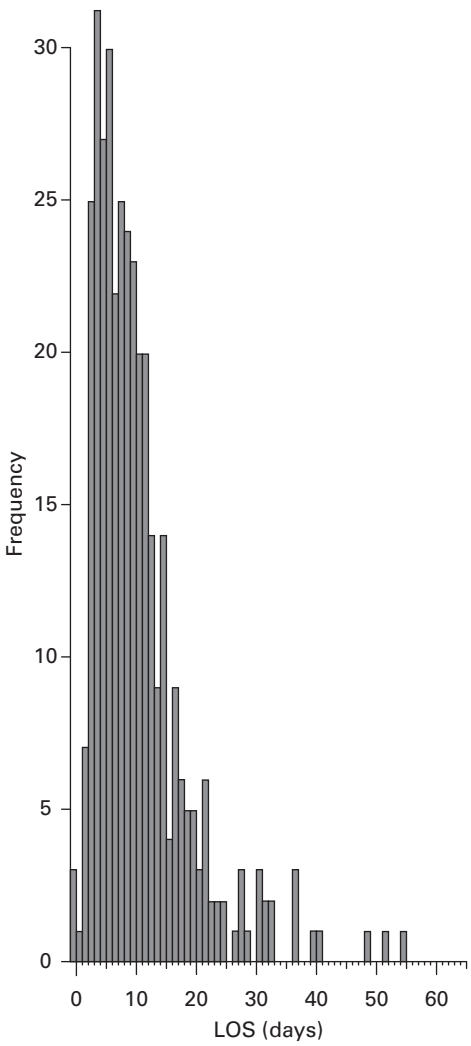

Fig. 6a

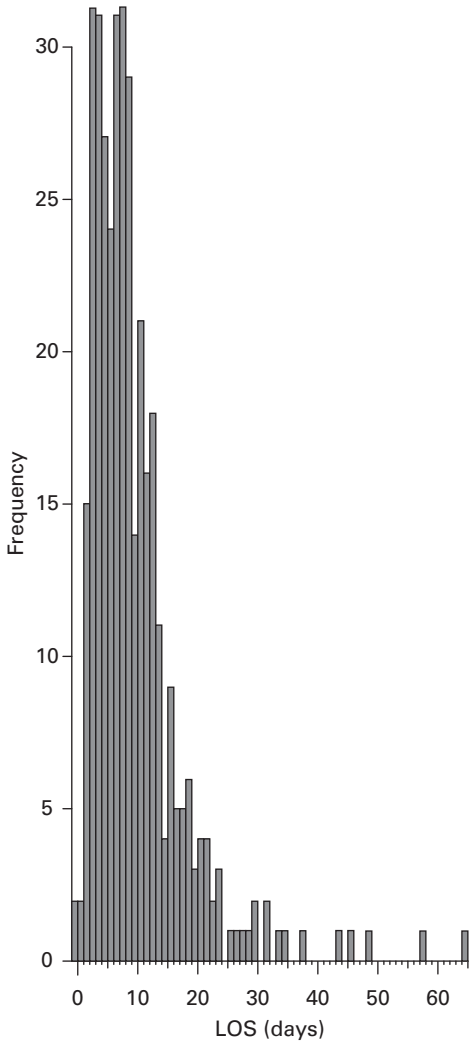

Fig. 6b

Graph showing the length of hospital stay (LOS) in days, from study recruitment to discharge, for a) Thompson and b) Exeter/Unitrax implants. The first column of each graph refers to a LOS of 0 days, the second column refers to a LOS of one day and so on.

research and should be considered carefully during initial trial design.[26]

A limitation of this trial was the large number of withdrawals. As 50% of those enrolled in the trial withdrew, the trial did not quite reach the 90% planned statistical power, which would have required data from 337 patients in each group, but easily passed the sample size required for 80% power (252 in each group). The number of patients who withdrew was higher than anticipated but not wholly unexpected in a trial involving a particularly frail older population. The results of this trial should not be extrapolated to the patients who were excluded because they were having a total hip arthroplasty. THA is generally offered to patients who have higher pre-injury walking status. Recent research suggests that more patients would benefit from total hip replacement than currently receive it.[27]

The follow-up period for this trial was four months. The long-term survival of these implants is not examined. Previously, survival analysis performed on the Thompson stem has demonstrated stem survival of over 95% at five years, and a mortality of 70% at six years, with no revision surgery beyond this point.[28] No comparable data exist on the Exeter/Unitrax prosthesis. More recent evidence from a 12-year follow-up of patients treated with either total hip arthroplasty or hemiarthroplasty has demonstrated a mortality rate of 20% overall with no difference between functional outcomes, mortality or complications.[29]

This trial provides some evidence that the Thompson hemiarthroplasty can offer a comparable outcome with a modern modular stem in this patient group. The Thompson is considerably lower in cost than the more modern hemiarthroplasty implants recommended by NICE.

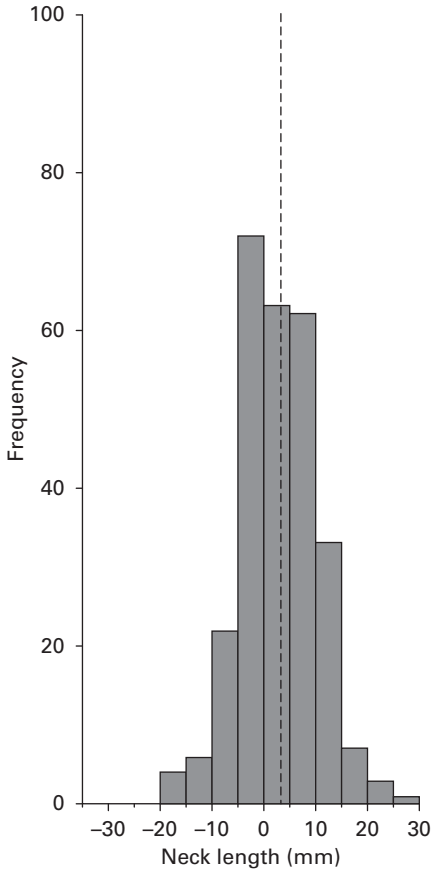

Fig. 7a

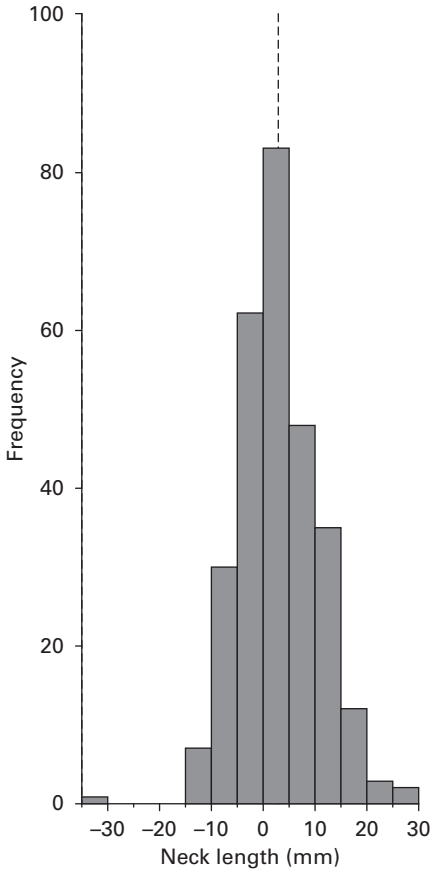

Fig. 7b

Graph showing the distribution of difference in neck length (mm), for a) Thompson and b) Exeter/Unitrax implants, divided into 5 mm categories: -35 mm to -30 mm; -30 mm to -25 mm; -25 mm to -20 mm; and so on. The vertical dashed lines indicate the mean values.

Take home message:

- A cemented Thompson hemiarthroplasty may provide similar health-related quality of life compared with modern implants for patients with a displaced intracapsular fracture of the hip.

Supplementary material

Tables providing further information, along with a full list of the CORNET Collaborators, are available alongside this article at www.bjj.boneandjoint.org.u

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