A randomised feasibility study comparing total hip arthroplasty with and without dual mobility acetabular component in the treatment of displaced intracapsular fractures of the proximal femur

THE WARWICK HIP TRAUMA EVALUATION TWO: WHITE TWO

Aims
The optimal treatment for independent patients with a displaced intracapsular fracture of the hip remains controversial. The recognised alternatives are hemiarthroplasty and total hip arthroplasty. At present there is no established standard of care, with both types of arthroplasty being used in many centres.

Patients and Methods
We conducted a feasibility study comparing the clinical effectiveness of a dual mobility acetabular component compared with standard polyethylene component in total hip arthroplasty for independent patients with a displaced intracapsular fracture of the hip, for a 12-month period beginning in June 2013. The primary outcome was the risk of dislocation one year post-operatively. Secondary outcome measures were EuroQol 5 Dimensions, ICEpop CAPability measure for Older people, Oxford hip score, mortality and re-operation.

Results
Only 20 patients were recruited during this time. The baseline demographics were similar in the two groups and no patient suffered a dislocation. Differences in secondary outcomes were not analysed due to the small sample.

Conclusion
This feasibility study suggests that any trial investigating the effectiveness of total hip arthroplasty for fracture of the hip might not be deliverable within the constraints of current systems of care in the United Kingdom.

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Fractures of the hip are one of the greatest challenges facing the medical community. In 1990, a global incidence of 1.31 million was reported and was associated with 740 000 deaths.1 These fractures constitute a heavy socioeconomic burden worldwide. The cost of this clinical problem is estimated at 1.75 million disability adjusted life years lost, 1.4% of the total healthcare burden in established market economies.1

The accepted treatment of a displaced intracapsular fracture is arthroplasty.2 This includes both hemiarthroplasty (HA) and total hip arthroplasty (THA). Recently, an increasing body of evidence has shown that for selected, comparatively healthy and independent patients, THA offers a functional benefit and a reduced risk of revision surgery over HA.3

Recent National Institute of Health and Clinical Evidence (NICE) guidance in the United Kingdom suggests that for this fitter subgroup of patients a THA should be considered.2

The principal additional clinical concern with THA is the risk of dislocation. Dislocation often requires admission to hospital for closed reduction and may require revision procedures with the consequent risks and costs. Alternative acetabular components are available with dual mobility (DM) bearing surfaces that may reduce the risk of dislocation, yet provide the functional benefit of standard THA.4

The aim of this feasibility study was to investigate the risk of dislocation of a DM acetabular component compared with a standard polyethylene component in THA for independent patients with a displaced intracapsular fracture of the hip.
Patients and Methods
The full details of the protocol for the trial have been previously published. A summary of the methodology is provided here and a report of the findings of the process evaluation elsewhere. This was a single centre, multi-surgeon randomised feasibility study embedded within the WHiTE Comprehensive Cohort Study. The trial was registered (ISRCTN90544391) and included within the National Institute for Health Research Portfolio (ID14785). Ethical approval was granted on 1 May 2013 by the National Research Ethics Service Committee West Midlands - Coventry and Warwickshire (13/WM/0110).

Most patients with a fracture of the hip are a priority for urgent surgical treatment. In this emergency situation the focus is on obtaining consent for surgery (where possible) and informing the patient and any next of kin about the immediate clinical care. It is not possible for the patient and surgeon to review all the trial documentation, weigh the information and communicate an informed decision about whether they would wish to participate. Conducting research in this ‘emergency setting’ in England and Wales is regulated by the Mental Capacity Act 2005. Where the urgent nature of the treatment limited access to, and thus appropriate discussion with, Personal Consultees, we identified an appropriate Nominated Consultee to advise the research team. At the first opportunity, this Nominated Consultee provided written consent for entry into the study.

All patients aged > 60 years with a displaced intracapsular fracture of the hip were eligible for inclusion during a one-year period beginning 19 June 2013. Patients were

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**Figure 1**

**Flow of participants through the study (THA, total hip arthroplasty; DM, dual mobility).**
excluded if they had chronic cognitive impairment, or in the opinion of the Consultant Trauma Surgeon the patient would not benefit from a THA, or were treated non-operatively.

Patients were randomly allocated to treatment groups in a 1:1 ratio using variable block sizes. Randomisation was administered via an online service administered by an independent Clinical Trials Unit. Patients and research associates, but not the operating surgeon, were blinded to the allocation of treatment.

Pre-operative assessment, anaesthetic technique and post-operative rehabilitation was similar to that used for other patients recruited into the larger WHiTE Comprehensive Cohort Study. They received antibiotic and venous thromboembolic prophylaxis in accordance with local protocols. THA was undertaken with the patient in the lateral position according to the preferences of the operating surgeon. They were randomly allocated to receive either a standard bearing or DM THA. The surgeon selected the prosthesis for those receiving a standard bearing arthroplasty; for those receiving a DM bearing, an uncemented Novae DM acetabular component (SERF Dedienne Santé, Lyon, France) was used.

Patients were reviewed at one, four and 12 months. The primary outcome measure was dislocation. Secondary measures included EuroQol 5 Dimensions Score\(^9\) (York A1 value set)\(^{10}\), ICEpop CAPability measure for Older people\(^11\), Oxford Hip score\(^12\) (OHS), mortality and re-operation.

No formal sample size calculation was performed for this feasibility study. The primary outcome measure, the proportion of patients sustaining a dislocation within one year of the fracture, was analysed using a chi-squared test for differences between THA-S (control) and THA-DM (test) on an intention-to-treat basis. Treatments were considered to differ significantly if p-values were < 0.05. The distributions of secondary outcome measures were reported for the whole sample, such was the small size of the study. Subsidiary analyses using regression and health economic models as described in the protocol\(^5\) were not deemed appropriate given the sample recruited. The number and temporal pattern of adverse events were investigated to assess whether they differed between treatment groups.

Insufficient data were available to support a cost-effectiveness analysis.

**Results**

A summary of the flow of patients through the study is shown in Figure 1. In total 26 patients (20%) admitted with a displaced intracapsular fracture of the hip during the period of the study, were assessed to be eligible for inclusion. In total, 21 patients were randomised, of whom one withdrew. One patient died. Thus, the proportion available for analysis was 90%.
Baseline characteristics were similar in both groups (Table I).

There were no dislocations in either group. The distribution of outcome scores is shown in Figures 2 to 4. There were no significant differences, and no complications were reported.

**Discussion**

We have reported the findings of a feasibility study investigating two types of THA for patients with a fracture of the hip in the setting of the NHS. The principal finding was that the size of the population of interest was insufficient to support any future definitive trial addressing this research question. No significant differences in any outcomes were found between treatments.

This was a pragmatic study. No specific modifications were made to local practices, nor were surgeons required to change their normal preferences. Other authors have successfully delivered trials investigating the clinical effectiveness of THA versus HA as well as other forms of arthroplasty.13-19 Some of these trials have been criticised.20 For example, the different interventions in the trial reported by Keating et al15 were delivered by substantially differently qualified and experienced surgeons. This implies that to a degree some alterations were made to the service delivered during the trial. Our study was designed specifically to test how successfully a large, multicentre, pragmatic trial might be delivered.

The current NICE Guidance for the Management of Hip Fracture in Adults2 suggests future research comparing THA using a large femoral head with HA. The guidance suggests that a research network might deliver a study including 500 patients within two years if ten centres recruited 20 patients per month. Our centre has been extensively involved with such research networks and has contributed actively to several multicentre trials21-23 that have recruited on schedule. Experience of recruitment between different centres has shown two to three times the rates of recruitment in lead centres (unpublished data). Therefore, our reported recruitment of approximately two patients per month, is highly unlikely to be repeated across ten centres. This study thus suggests that such a trial might not be deliverable.

We have conducted a mixed-methods study of the trial processes in parallel with this study.6 We hope that these findings will help explore the reasons underlying the poor recruitment into this trial.

**Take home message:**

A definitive clinical trial exploring the clinical effectiveness of any type of total hip arthroplasty for the management of hip fracture is not currently feasible in the United Kingdom.

**Author contributions:**

X. L. Griffin: Conception and experimental design, Data interpretation, Manuscript preparation.

J. Achten: Experimental design, Manuscript proofing.

N. Parsons: Experimental design, Data analysis, Manuscript proofing.

M. L. Costa: Conception and experimental design, Data interpretation, Manuscript proofing.
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References