



## ■ GENERAL ORTHOPAEDICS

# Fractured neck of femur: a review of three seminal papers and their implications to clinical management

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It is unusual, if not unique, for three major research papers concerned with the management of the fractured neck of femur (FNOF) to be published in a short period of time, each describing large prospective randomized clinical trials. These studies were conducted in up to 17 countries worldwide, involving up to 80 surgical centers and include large numbers of patients (up to 2,900) with FNOF. Each article investigated common clinical dilemmas; the first paper comparing total hip arthroplasty versus hemiarthroplasty for FNOF, the second as to whether 'fast track' care offers improved clinical outcomes and the third, compares sliding hip with multiple cancellous hip screws. Each paper has been deemed of sufficient quality and importance to warrant publication in *The Lancet* or the *New England Journal of Medicine*. Although 'premier' journals, they only occasionally contain orthopaedic studies and thus may not be routinely read by the busy orthopaedic/surgical clinician of any grade. It is therefore our intention with this present article to accurately summarize and combine the results of all three papers, presenting, in our opinion, the most important clinically relevant facts.

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### Introduction

There have recently been three important publications concerning the treatment of the fractured neck of femur (FNOF).<sup>1-3</sup> Each article has been deemed of sufficient quality and importance to warrant publication in some of the most prestigious of journals including *The Lancet* and the *New England Journal of Medicine*. Each article has studied patients and treatments collected worldwide and therefore reflect international results, conclusions and opinions. Clinicians involved in the management of FNOF patients may not routinely read these prestigious but non-orthopaedic journals or indeed have the time to dissect out the key points of these studies relevant to their practice.

We have therefore critically reviewed these articles, summarized their findings and present, in our opinion, the most important clinically relevant facts. We have done this in an attempt to allow the busy orthopaedic clinician a fast track to information and possibly highlight changes they may wish to implement in the management of their own patients with FNOF.

**Paper 1.** The first paper, "Total Hip Arthroplasty or Hemiarthroplasty for hip fracture",<sup>1</sup> published in December 2019 in the *New England Journal of Medicine* compared these two management strategies for hip fracture. The study was funded by the Canadian Institute of health and was coordinated by Bhandari, a well-established and recognized researcher and surgeon from McMaster University in Hamilton. The trial was an international randomized control study and included 80 centres from ten countries around the world (including USA, Canada, UK and South Africa). Patients eligible for study were aged 50 years or older having sustained a low energy displaced FNOF. Importantly patients were, prior to injury, able to walking without the assistance of another. Ethical approval was obtained at each unit and patients randomized to receive either total hip arthroplasty (THA) or hemiarthroplasty. This study involved 523 surgeons, the majority of whom met the author's criteria for a minimal threshold of expertise (277 of 283 (97.9%) undertaking THAs and 369 of 381 (96.9%) hemiarthroplasties). Patients

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were assessed at one and ten weeks post-operation and then at six, nine, 12, 18, and 24 months either by personal interview or telephone. The primary endpoint was any unplanned surgery within the 24 months and secondary endpoints death and/or serious adverse event. Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), EuroQol five-dimension questionnaire (EQ-5D), 12-Item Short Form Survey (SF-12), and Timed Up and Go (TUG) scores were collected. The study recruited for eight years (2009 to 2017) with 1,495 patients randomized, 749 THA and 746 hemiarthroplasty. In all, 1,058 fulfilled all criteria for follow-up of two years, of whom 80% were aged 70 years or older and 70% female. Overall, 54 (7.5%) were assigned to THA but underwent hemiarthroplasty and 21 (2.9%) assigned a hemiarthroplasty but underwent a THA.

At two years a secondary hip procedure occurred in 57 of 718 (7.9%) THA and 60 of 723 (8.3%) hemiarthroplasties ( $p = 0.79$ ). Subgroup analysis showed secondary hip procedures more common with THA within one year but then higher in the hemiarthroplasty group during the second year of follow-up. The most common secondary procedure for THA was reduction for dislocation (33/57) and for hemiarthroplasty, implant revision (36/60). Overall mortality was 13.7% (198 of 1,441 pts) and found not significantly different between the two groups (14.3% THA versus 13.1% Hemi ( $p = 0.48$ )). Serious adverse events occurred in 300 of 718 (41.8%) THA and 265 of 723 (36.7%) hemiarthroplasty ( $p = 0.13$ ). THA 'broadly' led to more cardiac, renal, vascular, neurologic, and respiratory events than hemiarthroplasty. Overall hip-related complications were also more frequent with THA (132 (18.4%) vs 118 (16.3%) hemiarthroplasty), including hip instability/dislocation (34 (4.7%) vs 17 (2.4%) respectively). Lastly, all WOMAC scores (total score, pain, stiffness, and function scores) favoured THA over hemiarthroplasty but the differences fell below the threshold for a minimal clinically importance difference (MCID). All other scores did not differ between groups.

The study concluded that at two years follow-up, there was no significant difference between THA and hemiarthroplasty but THA was associated with a 'modestly better function over 24 months but with a slightly higher incidence of serious adverse events'.

**Paper 2.** The second paper,<sup>2</sup> published in February 2020 in *The Lancet*, compared accelerated versus standard care for patients with FNOF and assessed whether fast tracking such patients reduced mortality and major complications.

Again, this study was prospective, randomized, and international (including Canada, USA, South Africa, Pakistan, and UK). It recruited previously mobile patients aged 45 years or older with low impact displaced FNOF from 17 countries and 69 centres. However, significantly

only patients admitted in 'routine office hours' were randomized centrally to receive either an operation within a median time of six hours from diagnosis (4 to 9) or control patients undergoing 'standard care' with median preoperative time of 24 hours (10 to 42). Six hours was selected as their criteria for 'accelerated care' as it was considered a 'substantial improvement beyond standard care' and 'feasible'.<sup>2</sup> These operations were prioritised and undertaken in the next orthopaedic operating room slot; with any displaced elective orthopaedic or non-emergent trauma patient undergoing delayed surgery in an extra operating room slot facilitated at the end of the day (to avoid cancellations).

All centres obtained ethical approval for the study. Results were assessed at 30 and 90 days of randomization and co-primary outcomes were mortality and a composite of major complications at 90 days from randomization. Secondary outcomes consisted of individual fatal and non-fatal events again at 90 days. A daily troponin was taken for the first seven days and any delirium assessed over the same period. Tertiary outcomes included orthopaedic complications such as implant failure and dislocation.

Although 27,701 patients were screened, only 7,780 were deemed eligible and 2,970 enrolled with 1,487 patients fast-tracked and 1,483 received standard care. Mean age was 79 years. Surgery included internal fixation for 1,877 (63%) or arthroplasty for 1,049 (35%). The primary endpoints include a 90-day mortality of 140 (9%) versus 154 (10%) and complications 321 (22%) versus 331 (22%) accelerated versus standard care respectively.

Secondary outcomes included stroke 5 versus 14 ( $p = 0.047$ , although caution advised due to a low statistical fragility index), delirium 132 versus 175 ( $p = 0.0089$ ), infection 170 versus 207 ( $p = 0.032$ ), and urinary tract infection (UTI) 120 vs 150 (HR 0.78 (95% CI 0.61-0.99)) for accelerated versus standard care. For tertiary outcomes, there were no differences in hip reoperations. Mean time from randomization to discharge was ten days for accelerated care and 11 days for 'standard' care ( $p < 0.0001$ ). Subgroup analysis of those with a raised Troponin prior to randomization surprisingly resulted in a lower risk of mortality for the accelerated over standard care. With regard pain, comment is made of a lower pain score in the accelerated group one day following randomization, but not significant on days two to seven. Fewer accelerated care patients reported moderate/severe pain on days four to seven after randomization.

The authors concluded that compared with standard care, accelerated surgery did not reduce mortality or a composite of major complications. Postoperative delirium and UTI was however reduced, faster mobilization achieved with reduced moderate to severe pain on days four to seven, and an overall one day shortened length of stay for accelerated care.

**Paper 3.** Published in April 2017 in *The Lancet* was again an international prospective multicentre trial comparing the results of patients with low energy FNOF requiring fixation.<sup>3</sup> Randomization was to either a large diameter sliding hip screw (SHS) or multiple cancellous screws. The study was centrally supervised again from McMaster University (Prof Bhandari) and included 81 centres in eight countries (including USA, Canada, Australia, UK and India), all with ethical approval and investigated 1,108 patients aged 50 years or older over a period of six years (2008 to 2014). Although 7,306 patients were screened, 5,463 were deemed ineligible the majority of which through surgeon preference to perform a prosthesis (2,060/5,463, 37.7%) or considered 'unsuitable for fixation' (1,738/5,463, 31.8%). The primary outcome was reoperation within 24 months of surgery, which has previously been quoted to occur as high as 10% to 48% following these procedures. Patients were followed-up at one and ten weeks, then six, nine, 12, 18 and 24 months. Patients were randomized to either multiple cancellous screws (suggested less invasive with better preservation of blood supply, considered the present standard of care) or SHS, without supplemental fixation (greater biomechanical stability especially in an unstable fracture). All surgeons were experienced and used the device manufacturer of their choice. Outcome measures consisted of WOMAC, SF-12 and EQ-5D with intended collection at each review.

Of these 1,108 patients, 557 received a sliding hip screw and 551 cancellous screws. At two years, 923 patients were alive and 844 (91%) reviewed. The primary endpoint (hip reoperation) within 24 months did not differ by type of fixation (SHS 107/542 (20%), cannulated screw 117/537 (22%)). Avascular necrosis occurred in 7% of patients overall and was more common in the sliding screw group (50 (9%) SHS versus 28 (5%) cancellous screws) with 38 requiring reoperation versus 16 cancellous screw patients ( $p = 0.002$ ). The type of reoperation therefore did vary between groups with less frequent metalwork removal in the SHS patients (15/542 (5%) versus 49/537 (9%),  $p = 0.0009$ ), along with less frequent revision to alternative fixation (2 vs 14,  $p = 0.0024$ ). In contrast, revision to total hip arthroplasty was more common in the SHS group (64/542 (12%) vs 40/537 (7%),  $p = 0.0494$ ). There was, however, no difference in nonunion, implant failure, infection, fracture shortening, or quality of life (at 12 or 24 month reviews). Subgroup analysis of low to moderate credibility suggested SHS reduced reoperations in patients with displaced fractures, fractures at the base of the neck and/or current smokers. Although the SHS was associated with a greater incidence of AVN, the authors comment this was at variance with a previous Cochrane review by Parker,<sup>4</sup> which showed despite investigation no difference in AVN in these operations.

In conclusion, the authors suggest that the choice of procedure for fixation is a matter of surgical discretion with no significant increased re-operation rate between groups.

## Discussion

It is unusual to have three very large international randomized studies associated with FNOF, published over a relatively short period of time. Each study has involved admirable effort and careful coordination to achieve central randomization and a review in each study including at least one thousand patients treated in 69 to 81 centres from eight to 17 countries as varied as USA, UK, South Africa and India.

Ethical approval was obtained for all these investigation and treatment options provided by a large number of surgeons (up to 523 in one study<sup>1</sup>) but with care to ensure each surgeon was widely experienced in the operations involved, meeting a minimal threshold of expertise.

Specifically, paper 1<sup>1</sup> compared THA against hemiarthroplasty for a displaced FNOF for death or major complication and documented a mortality of 14.3 versus 13.1 ( $p = 0.48$ ), along with serious adverse events occurring in 300 patients with THA (41.8%) versus 265 (36.7%) with hemiarthroplasty ( $p = 0.13$ ). Somewhat surprisingly, mortality and re-operation rates were not found to be greater for THA despite being the more major procedure. The number of serious adverse events were however greater, approaching statistical significance, with a greater incidence of specifically hip related complications in the THA group (132 (18.4%) vs 118 (16.3%)). THA does require a greater surgical expertise, which can result in a delay either awaiting a THA surgeon and/or cancellation of elective patients. Indeed, one of these papers facilitated this surgery by displacing scheduled elective cases or worse, operating 'out of hours'.<sup>2</sup> In effect this can change any postponed elective procedure to less than ideal conditions and experienced personnel.

The authors concluded that although THA offered slightly better function, this was only revealed within the WOMAC scores with improvements not reaching the MCID and deemed 'clinically unimportant' at 24 months.<sup>1</sup> These results would seem to us to suggest that the more sophisticated procedure of THA should only be undertaken in the ideal patient, with ideal staff and within timely circumstances, otherwise a hemiarthroplasty should be undertaken without delay.

The challenge will always be in identifying who this 'ideal patient' might be to receive a THA? Despite the study selection requirement of patients pre injury able to walking 'without the assistance of another', the overall study mortality was 14.3% at two years with 46.4% (333/718) of those receiving THA aged over 80 years. Endeavouring to identify those with a potentially greater

life expectancy and/or greater functional demand, either of which may be better suited to receive a THA. Attempting to address the identified increased hip related complications, particularly against instability with THA could also prove beneficial. Utilizing options such as larger heads (125/668 (19%) THA received heads < 32 mm), a greater use of dual mobility implants (used in only 5/674 (0.7%) THA) and in utilizing the anterior lateral approach for this group of patients (431/709 (60.8%) THA vs 500/715 (69.9%) hemiarthroplasty patients), may prove beneficial in limiting dislocation. Lastly, study follow-up was only two years and thus there is potential for THA advantage to reveal itself only after this time. Of interest, beyond this 24-month study period, the authors document no difference in the necessity for any subsequent procedures between groups.

Paper 2<sup>2</sup> compared accelerated time to surgery for FNOF with standard care. However, in this study the accelerated time was a median of six hours (4 to 9) and 24 hours (10 to 42) classed as 'standard care'. In our view, an important criticism of this study is that 'standard care' is often defined and nationally accepted as an operation within 48 hours.<sup>5</sup> One could therefore argue this study included accelerated patients within the 'standard' group. This might well account for a 'no difference' in mortality of 9% and 10% and complications of 22% and 22% for accelerated versus so called 'standard' care respectively. Although a lower pain score was identified the day after randomization in the accelerated group, this may merely represent patients awaiting surgery in the standard group. Similarly, the significant one-day improvement in overall length of stay from 11 to ten days would appear to simply represent surgery undertaken one day earlier in the accelerated group. Postoperative delirium and UTI was however reduced, along with reduced moderate to severe pain on days four to seven. Facilitating accelerated surgery for these 'office hour' arrivals is not without challenges and compromise. Interruption to elective lists were required along with the frequently encountered logistical issues such as arranging traction tables and radiology within an otherwise elective orthopaedic list. There is then the aforementioned required 'catch-up', potentially out of hours, for what should be routine elective cases. While the benefits of this accelerated care may seem limited and logistically challenging to achieve, it does however confirm accelerated care is at least not detrimental and when feasible, can be safely undertaken.

Lastly, paper 3<sup>3</sup> compared SHS against multiple cannulated screws with the similar numbers of patients, surgeons and countries involved. These authors concluded that within two years there was no significant difference between groups except incidence of avascular necrosis, diagnosed in 50 (9%) SHS patients and 28 (5%) cancellous screw patients. Advantage of the SHS was proposed in reducing reoperations for displaced fractures, current

smokers and base of neck fractures but this subgroup analysis was reported as of 'low to moderate credibility'. There were no differences in medically related adverse events (including PE, sepsis etc.) or rate of re-operation. It would therefore appear the lesser/quicker procedure would seem appropriate, but this decision be left to the surgeon's own personal preference, experience and expertise. With all else appearing equal, surgeons may wish to select their primary means of FNOF fixation to reflect the differing modes of failure and skill-set required for any subsequent secondary required reconstruction.

Three further studies have since been published by the FAITH investigators. They undertook secondary evaluations of the data collected from this principle study.<sup>6-8</sup> Of most practical value (published in 2019<sup>8</sup>), was their study identifying a 20° posterior tilt on lateral radiograph view as a predictor of failure (with 15/67 (22.4%) requiring arthroplasty within 24 months compared with 58/488 (11.9%) with tilt < 20° ( $p = 0.008$ )). When identified, this posterior tilt, in association with female sex and age > 80 years, the risk of revision reached 42.9% (6/14).

In conclusion, these papers must be admired for collecting a vast amount of important clinical data from many health services, with attempts to reduce the inevitable disadvantage of a large number of operating surgeons with varying ability and experience. We have endeavoured to summarize these major publications for the clinically busy orthopaedic surgeon who might have missed these landmark publications within premier journals not confined to orthopaedics. We have attempted to dissect out from a large amount of clinical data, facts that have practical clinical implications.

It would appear that for the busy orthopaedic department, with time and financial restrictions, that for the majority of patients with a displaced low energy FNOF, a hemiarthroplasty would seem appropriate with regard mortality, function and postoperative complications. A hemiarthroplasty requires less operating time and surgical expertise, particularly, as to quote the authors, "THA proved only an unimportant improvement" at two years.<sup>1</sup> With regard the timing of surgery for a FNOF, accelerated surgery undertaken within six hours of diagnosis did not reduce mortality or a composite of major complications.<sup>2</sup> It did however result in a reduction in postoperative in delirium and UTI and conversely, accelerated surgery was not shown to be detrimental to patient care when it was achieved. When electing for fixation of any FNOF, choice between SHS and cannulated screws appears to remain at the discretion of the attending surgical team with no difference identified in reoperation rate.<sup>3</sup> Although a greater incidence of AVN was identified with the SHS, the technique is proposed as advantageous to the current smoker, the displaced fracture and fractures at the base of neck.

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