**Hemiarthroplasty of the Hip with and without Cement: A Randomized Clinical Trial**

Fraser Taylor, BSc, MBChB, FRACS, Mark Wright, MBChB, FRACS, and Mark Zhu, BHB

*Investigation performed at Auckland City Hospital, Auckland, New Zealand*

**Background:** Controversy exists regarding the use of cement for hemiarthroplasty to treat a displaced subcapital femoral neck fracture in elderly patients. The primary hypothesis of this study was that use of cement would provide better visual analog pain scores following this procedure in an elderly patient population.

**Methods:** Elderly patients (at least seventy years of age) without severe cardiopulmonary compromise who presented to one institution with a displaced subcapital femoral neck fracture were offered inclusion in the study. One hundred and sixty patients (mean age, eighty-five years) with an acute displaced femoral neck fracture were randomly allocated to hemiarthroplasty with either a cemented Exeter or an uncemented Zweymüller Alloclassic component. Clinical and radiographic follow-up was performed for two years and the outcomes were recorded by a blinded assessor. The main clinical outcome measures were pain, mortality, mobility, complications, reoperations, and quality of life measured with use of validated instruments.

**Results:** The mean visual analog pain score at rest did not differ significantly between the groups. The total number of complications was greater in the uncemented group (sixty-three compared with twenty-eight in the cemented group). Subsidence was significantly more common in the uncemented group (eighteen compared with one in the cemented group). Intraoperative or postoperative fracture was also significantly more common in the uncemented group (eighteen compared with one in the cemented group). The mortality rate did not differ significantly between the groups at any time point (thirty-five deaths in the uncemented group compared with thirty-two in the cemented group at two years). The Oxford hip score was significantly poorer in the uncemented group at six weeks (38.8 compared with 35.7 in the cemented group), and it was also poorer or similar at later follow-up time points although the differences were not significant. There was also a trend toward poorer mobility and greater dependence on walking aids in the cemented group. The postoperative Short Musculoskeletal Function Assessment and Mini-Mental State Examination scores did not differ significantly between the groups.

**Conclusions:** In elderly patients (seventy years or older) without severe cardiopulmonary compromise who were treated with hemiarthroplasty for a displaced femoral neck fracture, use of a cemented Exeter implant and use of an uncemented Alloclassic implant provided a comparable outcome with regard to pain. However, implant-related complication rates were significantly lower in the group treated with a cemented implant. Trends toward better function and better mobility in the cemented group were observed. These trends reached significance in particular functional scores at some postoperative time points.

**Level of Evidence:** Therapeutic Level II. See Instructions for Authors for a complete description of levels of evidence.
Hemiarthroplasty is the recognized treatment for displaced subcapital femoral neck fractures in elderly patients. However, controversy still exists regarding whether cemented or uncemented implant fixation is preferable in this patient population. Evidence suggests that cementing prevents loosening by improving prosthesis anchorage to the bone. This is an advantage since a loose prosthesis can cause pain, delay patient mobilization, and require further surgery. However, the use of cement can complicate revision surgery and has been reported to cause rare but severe cardiovascular complications.

Several past studies on this topic were summarized in a 2010 Cochrane Systematic Review. These studies were criticized for their size, inclusion criteria, poor randomization, limited reporting of outcomes, inadequate follow-up, and exclusion of patients. The Cochrane review concluded that patients with cemented prostheses experienced less pain at one year or later and had improved postoperative mobility. Furthermore, no differences in mortality or complications between the groups were found at any time point. The authors of the review acknowledged that the majority of the included studies evaluated traditional prostheses such as the cemented Thompson and uncemented Austin Moore prostheses. Thus, despite its conclusion in favor of cementing, the review raised the need for further comparisons between cemented prostheses and more advanced uncemented prostheses.

The results of recent studies involving hydroxyapatite-coated uncemented prostheses suggest that these implants can achieve the same functional outcome as cemented prostheses. Unfortunately, those studies did not present the results of radiographic follow-up. Given the cognitive challenges that are often faced by members of this patient group, radiographic analysis is a useful tool for assessing the prosthesis performance.

The present blinded, randomized controlled trial compared two well-documented and relatively modern unipolar designs, cemented Exeter implants (Stryker Orthopaedics, Mahwah, New Jersey) and uncemented Zweymüller Alloclassic implants (Centerpulse, Zurich, Switzerland). The aim of the study was to gather clinically meaningful data on the relative merits and shortcomings of cementing of hemiarthroplasty implants. The primary hypothesis of this study was that use of a cemented hemiarthroplasty component would provide an improvement in the visual analog pain score compared with use of an uncemented component in an elderly patient population.

Materials and Methods

This randomized controlled trial included 160 patients with an acute displaced femoral neck fracture (Garden stage III or IV) and was registered with the Australian New Zealand Clinical Trials Registry. All patients presented to Auckland City Hospital between May 2006 and November 2008. The inclusion criteria were an age of at least seventy years and an acutely displaced fracture deemed by the admitting surgeon to be suitable for hemiarthroplasty. Patients with a previous fracture of the same hip or with a pathological fracture were excluded. In addition, one patient deemed by the admitting surgeon to be suitable for total hip arthroplasty was excluded. The suitability of each patient for receiving a cemented component was assessed by the charge anesthetist, and patients whose risk of mortality was deemed unacceptable were excluded from the study. As there are no established criteria for the risk of mortality due to implantation of cemented components, the assessment was based on the patient’s age, preexisting cardiovascular or respiratory disease, and/or a history of bone cement implantation syndrome.

One hundred and sixty of the 301 patients who received hemiarthroplasty during the study period were included in the trial (Fig. 1). All patients gave informed consent, and the research protocol was approved by the Northern Regional Ethics Committee and the Auckland Hospital Ethics Committee. The patients were randomized with use of a computer-generated, sequentially numbered, sealed and opaque envelope. The envelope was opened in the operating room.

Patients randomized to the cemented group received a modular Exeter stem with an appropriately sized UniTrax head (Stryker). The cementing technique was standardized and involved use of a cement restrictor, lavage of the intramedullary canal, and retrograde introduction of the cement with use of a cement gun; the cement was not further pressurized after insertion. Patients randomized to the uncemented group received an uncemented Alloclassic stem with an appropriately sized head. The implant was inserted according to the manufacturer’s instructions, and a template was used preoperatively to determine the level of the femoral neck osteotomy. Care was taken to ensure that the femoral entry point was lateralized to avoid varus malpositioning. A box chisel was used to gain entry to the femoral canal, a canal finder was used to define the femoral canal, and progressive rasping was used to prepare the canal for the definitive component. Once the pitch of the impactor changed from low to high, confirming contact with the cortical bone, a final ras corresponding to the implant size was used. The definitive implant was then inserted and its stability was confirmed. The group allocation was revealed to the study coordinator (M.W.) immediately after the operation.

Efforts were made to standardize the procedures. The anesthetist, who was not blinded to the type of hemiarthroplasty performed, was given specific instructions regarding fluid management for patients in either group, and treatment of intraoperative hypotension was the responsibility of the anesthetist. Hemiarthroplasty was carried out with use of the modified Harding surgical approach with the patient in the lateral decubitus position. All patients received a dose of 1 g of cefazolin (Kefzol; Eli Lilly, Indianapolis, Indiana) intraoperatively and two further doses at eight and sixteen hours postoperatively unless a preoperative allergy existed. A radiograph was obtained immediately after the operation. Each patient received routine observation, analgesia, and prophylaxis against deep venous thromboembolism. Patients in both groups were allowed to mobilize with full weight-bearing as tolerated.

The majority of the patients (110 of 160, 69%) were female, and the mean age was 85.2 years (range, seventy to 99.4 years). Operations were performed under the supervision of one of twelve consultant surgeons experienced with both procedures. The majority of procedures were performed by registrars in training. The mean duration of surgery was 4.5 minutes shorter in the uncemented group than in the cemented group. The groups did not differ significantly with regard to intraoperative blood loss, duration of hospitalization, Charlson Comorbidity Index, or American Society of Anesthesiologists (ASA) grade (Table I).

Clinical and radiographic examinations were performed at approximately six weeks, six months, twelve months, and twenty-four months postoperatively. All clinical variables were assessed by an unbiased observer (a research nurse who was not involved in the surgery or clinical decisions and who was blinded to the treatment group). Complications, the Mini-Mental State Examination (MMSE) score, the Timed Up and Go (TUG) score, the use of walking aids, the Short Musculoskeletal Function Assessment (SMFA) score, a visual analog scale pain score, the Oxford hip score, and the ability to live independently were recorded at each follow-up visit.

Pain, assessed with use of a visual analog scale, was the primary outcome measured in the study. The Oxford hip score, a widely used instrument that has been validated in patients with osteoarthritis and in patients who have undergone hip replacement surgery, was utilized to assess clinical hip function. Use of the Oxford hip score following hemiarthroplasty is less well documented, but this instrument was selected in the absence of a more suitable measure. The Oxford hip score was determined with use of the original Oxford questionnaire, in which a low
score implies a better outcome. The TUG test is a validated measure of mobility in which the patient is asked to rise from a seated position, walk around a cone placed 5 m away, and return to the original seat. The SMFA questionnaire is derived from the original Musculoskeletal Function Assessment questionnaire and contains forty-six questions related to the quality of life of the patient.

A sample size of eighty in each group was required to give an 80% probability of detecting a significant difference (p < 0.05) in the primary outcome measurement (the visual analog pain score) between the two groups. A total of 160 patients were therefore enrolled. In the outcome analysis, all patients who had been included in the study received the treatment to which they had been randomized, in accordance with the intention-to-treat principle. All complications related to the hip were recorded at each follow-up appointment.

All relevant radiographs made on or after the date of admission were reviewed by two experienced orthopaedic surgeons. Each immediate postoperative radiograph was evaluated to identify perioperative fractures and the varus/valgus angulation and size of the femoral implant. Implants that deviated by more than 3° from the anatomical axis of the femur were classified as being in either varus or valgus. Filling of the femoral medullary canal was measured by means of a modification of the technique of Garcia-Cimbrelo et al. The width of the implant relative to that of the canal was measured at the middle of the implant stem and at 3 cm from its distal tip, and the component was considered to be undersized if the average of the two ratios was <0.8 (<80% filling of the canal). All subsequent radiographs were studied for fractures and for implant subsidence. Measurements were made from the tip of the implant to the tip of the greater trochanter, and an implant was classified as having subsided if it had moved in the caudad direction by >5 mm.

Patients who did not attend a follow-up visit were sent a standardized letter thanking them for their participation and asking them to complete the visual analog pain score, SMFA, Oxford hip score, and mobility assessment instruments.

Statistical Methods
Binary variables were analyzed with use of the Fisher exact test, and continuous outcomes were analyzed with use of the Student t test (two-tailed). Survival and the duration of hospitalization were further analyzed with use of the Kaplan-Meier method. A p value of <0.05 was considered significant for all analyses.

Source of Funding
Funding for this study was provided by the New Zealand Orthopaedic Association (NZOA) and the Wishbone Trust. Funding from the Accident Compensation Corporation (Wellington, New Zealand) was also used for the study.

Results
All patients received the allocated treatment. In the uncemented group, one patient later underwent revision to a cemented hemiarthroplasty, two later underwent conversion to a total hip arthroplasty, and one later underwent a Girdlestone procedure because of an unresolved deep infection. In the cemented group, two patients later underwent a Girdlestone procedure because of a deep infection.
Complications

Five deaths occurred within forty-eight hours of surgery in each group. In the cemented group, one of these deaths was due to acute renal failure, two were due to a respiratory infection, and two were due to generalized sepsis. In the uncemented group, one of these deaths was due to cardiovascular arrest, three were due to a respiratory infection, and one was due to sepsis. Intraoperative hypotension was not assessed but the total number of cardiovascular complications was comparable in the two groups, with seven in the cemented group and six in the uncemented group. The rates of nonfatal respiratory, urinary tract, and wound infections were comparable in the two groups (Table II).

Six intraoperative fractures occurred in the uncemented group compared with none in the cemented group; this difference was significant. All of these fractures were identified intraoperatively and treated with cerclage wires. Twelve additional fractures occurred postoperatively in the uncemented group; none of these required further surgery.

Mortality did not differ significantly between the groups at any follow-up time point. A large number of patients withdrew prior to completing the study (Table III), but these

<table>
<thead>
<tr>
<th>Complication</th>
<th>Cemented (N = 80)</th>
<th>Uncemented (N = 80)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cardiovascular</td>
<td>7</td>
<td>6</td>
<td>0.999</td>
</tr>
<tr>
<td>Respiratory infection</td>
<td>7</td>
<td>8</td>
<td>1</td>
</tr>
<tr>
<td>Superficial or deep wound infection</td>
<td>4</td>
<td>5</td>
<td>0.999</td>
</tr>
<tr>
<td>Urinary tract infection</td>
<td>3</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>Subsidence</td>
<td>1</td>
<td>18 (includes fracture subsidence)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Postoperative fracture</td>
<td>1</td>
<td>12 (6 greater trochanter fractures)</td>
<td>0.0023</td>
</tr>
<tr>
<td>Intraoperative fracture</td>
<td>0</td>
<td>6</td>
<td>0.028</td>
</tr>
<tr>
<td>Reoperation</td>
<td>2</td>
<td>4</td>
<td>0.50</td>
</tr>
<tr>
<td>Dislocation</td>
<td>2</td>
<td>0</td>
<td>0.50</td>
</tr>
<tr>
<td>Other</td>
<td>1 peroneal nerve palsy</td>
<td>1 retroverted implant</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>1.3 (0.2-6.8)</td>
<td>1.3 (0.2-6.8)</td>
<td></td>
</tr>
</tbody>
</table>

*Values are given as the percentage, with the 95% confidence interval in percent in parentheses.
patients were included in the mortality analysis. The reasons cited for withdrawal were similar in the two groups; in many cases, the patient was not healthy enough to attend the follow-up visit. The total number of complications was greater in the uncemented group (sixty-three compared with twenty-eight in the cemented group).

**Radiographic Results**

In the uncemented group, seven implants were in varus and two were in valgus relative to the anatomical axis of the femur. In the cemented group, one implant was in varus and one was in valgus. As noted, six intraoperative fractures occurred in the uncemented group compared with none in the cemented group. Subsequently, eighteen cases of loosening and subsidence occurred in the uncemented group compared with one in the cemented group. Twelve postoperative fractures, including six fractures of the greater trochanter (Vancouver type AG), were noted in the uncemented group compared with one in the cemented group. One Vancouver type-B1 fracture occurred in the cemented group as a result of a documented fall; this patient was treated conservatively because of frailty. None of the fractures in the uncemented group were attributable to falls. Radiographically observed complications are summarized in Table II.

**Clinical Outcomes (See Appendix)**

Subjective outcomes included the visual analog pain score, SMFA, and Oxford hip score. The mean visual analog pain score and the mean SMFA score were better in the cemented group than in the uncemented group at each follow-up time point, although none of the differences reached significance. The mean Oxford hip score was significantly better in the cemented group than in the uncemented group at six weeks postoperatively (p < 0.05). The Oxford hip score was also better or similar in the cemented group at later follow-up time points although the differences were not significant.

Objective outcomes included the ability to flex the hip to 45° without pain, the Independence Grade, the use of walking aids, and the TUG test. The patients in the cemented group performed the TUG test significantly faster than the patients in the uncemented group at six months and one year postoperatively (p = 0.01 for both). A significantly greater proportion of the patients in the cemented group compared with patients in the uncemented group were able to flex the hip to 45° without pain at six weeks postoperatively (p = 0.007). No other significant differences in outcomes between the groups were observed.

A decline in independence was noted in both groups at the time of hospital discharge. At the time of admission, 50% of the patients allocated to receive a cemented prosthesis and 59% of those allocated to receive an uncemented prosthesis had been living in their own home; this decreased to 32% and 34%, respectively, on discharge. Twenty-nine of the patients in the cemented group and twenty-eight of the patients in the uncemented group who had not required private hospital-level care before the surgery were subsequently able to return to their previous level of independence.

**Discussion**

Previous studies on the treatment of femoral neck fractures in the elderly have focused on comparisons between the cemented Thompson and uncemented Austin Moore implants. However, these prostheses do not correspond well with the prostheses used in current clinical practice. The present study involved the cemented Exeter stem and the uncemented Alloclassic stem. Both of these implants have been proven to be effective in total hip arthroplasty.

The primary rationale for avoiding the use of cement comes from previous studies linking cementing to perioperative death and the occurrence of pulmonary embolism. The exact mechanism responsible has not been established, but it is believed to be attributable to either direct cement toxicity or embolism of bone marrow contents. In our study, no deaths in either group were directly attributable to embolism. Furthermore, the patients in the cemented group did not experience more cardiopulmonary complications. Forty-six patients with cardiovascular comorbidities were excluded from receiving a cemented implant, and thus from the study, by the anesthetist. This represents a weakness of our study, as we were unable to include all patients for randomization. It is important to point out that the study did not have the statistical power to evaluate the potential adverse health effects of cement. However, the lack of any significant difference in complications or mortality reported in the Cochrane review suggests that

<table>
<thead>
<tr>
<th>Time Point</th>
<th>Followed</th>
<th>Withdrawn</th>
<th>Died</th>
<th>Uncemented</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Cemented</td>
<td>Uncemented</td>
<td>Cemented</td>
<td>Uncemented</td>
</tr>
<tr>
<td>6 weeks</td>
<td>63</td>
<td>62</td>
<td>7</td>
<td>8</td>
</tr>
<tr>
<td>6 months</td>
<td>36</td>
<td>48</td>
<td>24</td>
<td>15</td>
</tr>
<tr>
<td>1 year</td>
<td>29</td>
<td>38</td>
<td>26</td>
<td>29</td>
</tr>
<tr>
<td>2 years</td>
<td>21</td>
<td>27</td>
<td>24</td>
<td>21</td>
</tr>
</tbody>
</table>

*Values are given as the percentage, with the 95% confidence interval in percent in parentheses.*
the risk of cementing is minimal. The rate of intraoperative hypotension was not recorded in the present study, and this may be of interest in future studies on this topic.

The broad eligibility criteria used in the present study did not exclude patients on the basis of mental status. Because of the age of the study cohort (mean, eighty-five years), a considerable proportion of the patients had cognitive deficiencies (47.5% of the patients in each group, as indicated by the MMSE score). We did not wish to exclude these patients because they reflect the realities of treating femoral neck fractures in the community and their inclusion made our conclusions more generally applicable. However, including these patients did introduce considerable difficulties during the follow-up period.

Because of patient deaths and withdrawals, twenty-one patients in the cemented group and twenty-seven in the uncemented group completed the full two years of follow-up. Despite the efforts that were made to keep the patients in the study, many were unable to continue because of marked declines in health and mental capability. Withdrawals can often cause bias if the trends over time in each group are analyzed. However, the effect of withdrawals on the results of our study will have been minimal because outcomes were compared between groups at each time point. To further investigate the effects of the withdrawals on our results, we conducted a secondary analysis of the patients who had a full two years of follow-up. No significant differences were found between the outcomes in these patients and the outcomes in the entire study cohort.

The methods used to evaluate functional outcomes included both subjective and objective measures. The Oxford hip, SMFA, and visual analog pain scores are all subjective scores and depend greatly on the subject's perceptions of pain and recovery. Only one significant difference in subjective functional outcomes between the groups was found: the better Oxford hip score in the cemented group at six weeks postoperatively. That difference may indicate that patients in the cemented group regained hip function faster than those in the uncemented group.

The functional outcome scores were very similar to those of previous studies. Our primary outcome measure, the visual analog pain score, did not differ significantly between the groups. Similarly, in 2009, Figved et al. reported no significant differences in pain and function between patients treated with cemented Spectron and uncemented Corail implants. A large study conducted by Parker et al. did indicate significantly better Charnley pain scores from three weeks to two years postoperatively in the group treated with a cemented Thompson prosthesis compared with the group treated with an uncemented Austin Moore prosthesis. However, the follow-up in that study was conducted by telephone only.

The most relevant finding of our study was the substantial difference between the groups in the rate of complications. In the two years after the index procedure, eighteen patients in the uncemented Alloclassic group had subsidence related to fracture compared with one in the cemented Exeter group. Many factors may have contributed to this large difference, including the suitability of each implant for hemiarthroplasty, the familiarity of the operating surgeons with each implant, and the margin of error tolerated by each prosthesis. Our results suggest that, considering fracture and subsidence risk, the cemented Exeter implant is superior to the uncemented Alloclassic implant in our study population. This is especially important in hemiarthroplasty as reoperations are often unrealistic because of the age of the patients. Our follow-up was limited to two years and we had a low revision rate at that time point. Supporters of uncemented components note the ease of revision of these components compared with cemented components, and we acknowledge that this is a consideration in implant choice for many surgeons.

Few previous studies evaluating hip hemiarthroplasty have included detailed radiographic analysis, so it is difficult to evaluate their implant-related complication rates. However, a study that examined the longevity of the Austin Moore implant in slightly younger patients showed an average subsidence rate of 29% compared with 22.5% in our study, which used the same criteria for assessing the occurrence of subsidence. Figved et al. also reported an intraoperative fracture rate of 1.9% and a postoperative one-year fracture rate of 3.7% for the uncemented Coral implant compared with 7.5% and 15% in the uncemented group in our study. They also reported similar functional outcomes for the Coral implant compared with the cemented Spectron implant. This study, along with others, raises the possibility that hydroxyapatite-coated uncemented implants may result in better functional outcomes with fewer prosthesis-related complications.

In summary, hemiarthroplasty with the cemented Exeter implant provided a comparable outcome with regard to pain compared with hemiarthroplasty with the uncemented Alloclassic implant in our study of elderly patients with a displaced femoral neck fracture and without severe cardiovascular compromise. However, the secondary outcomes in our study favored the cemented Exeter implant, although most differences were not significant. More importantly, there was a significant difference in the rate of implant-related complications in favor of the cemented proximal femoral hemiarthroplasty implants.

Appendix
A table showing the patient outcome scores at each time point is available with the online version of this article as a data supplement at jbjs.org.


