Total Hip Replacement Versus Open Reduction and Internal Fixation of Displaced Femoral Neck Fractures

A Randomized Long-Term Follow-up Study

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**Background:** Clinical trials with short and intermediate-term follow-up have demonstrated superior results for total hip replacement as compared with internal fixation with regard to hip function and the need for secondary surgery in elderly patients with a displaced intracapsular femoral neck fracture. The aim of the present study was to compare the results of total hip replacement with those of internal fixation over a long-term follow-up period of seventeen years.

**Methods:** We enrolled 100 patients who had sustained a femoral neck fracture in a single-center, randomized controlled trial; all patients had had a healthy hip before the injury. The study group included seventy-nine women and twenty-one men with a mean age of seventy-eight years (range, sixty-five to ninety years). The subjects were randomly assigned to either total hip replacement (the arthroplasty group) \( n = 43 \) or internal fixation (the control group) \( n = 57 \). The primary end point was hip function, evaluated with use of the Harris hip score. Secondary end points included mortality, reoperations, gait speed, and activities of daily life. Follow-up evaluations were performed at three months and at one, two, four, eleven, and seventeen years.

**Results:** The Harris hip score was higher in the total hip arthroplasty group, with a mean difference of 14.7 points (95% confidence interval, 9.2 to 20.1 points; \( p < 0.001 \) [analysis of covariance]) during the study period. We found no difference in mortality between the two groups. Four patients (9%) in the total hip replacement group and twenty-two patients (39%) in the internal fixation group had undergone a major reoperation (relative risk, 0.24; 95% confidence interval, 0.09 to 0.64). The overall reoperation rate was 23% (ten of forty-three) in the total hip replacement group and 53% (thirty of fifty-seven) in the internal fixation group (relative risk, 0.44; 95% confidence interval, 0.24 to 0.80). The results related to gait speed and activities of daily living favored the arthroplasty group during the first year.

**Conclusions:** Over a period of seventeen years in a group of healthy, elderly patients with a displaced femoral neck fracture, total hip replacement provided better hip function and significantly fewer reoperations compared with internal fixation without increasing mortality.

**Level of Evidence:** Therapeutic Level I. See Instructions for Authors for a complete description of levels of evidence.

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A commentary by J.L. Marsh, MD, is linked to the online version of this article at jbjs.org.
from the short to intermediate-term perspective, there is now sufficient evidence to recommend replacement rather than internal fixation for elderly patients with a displaced intracapsular femoral neck fracture. This is based on several well-conducted randomized controlled clinical trials showing that, for a relatively healthy, active, and lucid patient, primary total hip replacement is superior to internal fixation with regard to hip function, quality of life, and the need for secondary surgery. However, the follow-up periods in these trials have, with few exceptions, been limited to the short and intermediate term (up to four years).

The long-term reoperation rate following total hip replacement for the treatment of degenerative hip disease is approximately 20% after twenty years, but the long-term reoperation rate following replacement for the treatment of a femoral neck fracture is less well described. Because of the high prevalence of osteoporosis, periprosthetic fractures and aseptic loosening have been assumed to be one major reason for the failure of total hip replacement in patients with hip fractures. As the number of elderly patients over the age of ninety years is continually increasing, it is important to evaluate outcome over a longer period of time.

The short-term (four-year) results from the current study were previously reported in a thesis but not in the peer-reviewed literature, and we now present the long-term follow-up results at eleven and seventeen years after the initial operation. We hypothesized that total hip replacement in healthy elderly patients would yield significantly better functional results and fewer reoperations than internal fixation over the long term.

Materials and Methods

Settings and Location

This prospective, randomized, controlled trial was performed between February 1990 and June 2010 (inclusion period, February 1990 to December 1994) at the Orthopaedic Department of Danderyd Hospital, Stockholm, Sweden. Danderyd Hospital is an emergency regional teaching hospital affiliated with the Karolinska Institute and, at the start of the study, had a catchment area of approximately 350,000 inhabitants.

Registration

The study is registered at ClinicalTrials.gov: NCT01344772

Study Subjects and Eligibility Criteria

All patients with a femoral neck fracture who were admitted to Danderyd Hospital during the inclusion period were screened for participation in the study. Those who agreed to participate gave their informed consent and were included. The inclusion criteria were an acute displaced femoral neck fracture (Garden stage III or IV) that had been sustained within the previous thirty-six hours, an age of sixty-five years or more, and admission from home with no concurrent joint disease (such as osteoarthritis of the hip) or previous fracture involving the lower extremities. The inclusion criteria also included a healthy status or only mild systemic disease (ASA [American Society of Anesthesiologists] grade 1 or 2), intact cognitive function (no diagnosis of dementia, with the patient being lucid and fully oriented), and the ability to carry out all activities of daily living (Katz index A). In addition, all patients had had intact hip function, with a Harris hip score of 100 points, prior to the injury. The Harris hip score was obtained retrospectively when admitted to the hospital. All patients gave their informed consent and had the ability and willingness to participate in the study. Patients with a pathological fracture, those who were deemed not suitable for a total hip replacement by the anesthesiologist, and those who were unsuitable to participate in the trial for any other reason were excluded.

Intervention

Total Hip Replacement

Total hip replacement was performed with use of a cemented femoral stem manufactured from a titanium alloy (Ti-6Al-4V; Biometric, Biomet UK, Brigend, South Wales, United Kingdom) and a 28-mm chromium-cobalt head. The acetabular component was also cemented (Müller; Biomet UK). A posterolateral approach without repair of the capsule or external rotators was used. On the basis of postoperative radiographs, the total hip replacement was determined to be good (minimum circumferential cement mantle around cup and stem, 2 mm; abduction angle of the cup, ≥35° and ≤55°; antversion angle of the cup, ≥10° and ≤25°; varus/valgus angle of the stem, ≤3°; postoperative limb-length difference, ≤10 mm), fair (at least four of the five categories graded as good), or poor (three categories or fewer graded as good).

Internal Fixation

Internal fixation was carried out with the patient on a fracture table. The fracture was reduced closed, with the aid of an image intensifier, and was fixed with two cannulated screws (Olmed; DePuy/Johnson & Johnson, Sollentuna, Sweden). Capsulotomy or joint aspiration was not performed. In the anteroposterior projection, the distal screw was aimed to the level of the lesser trochanter to rest on the medial inferior cortex of the femoral neck. The proximal screw was positioned parallel to and at least 1 cm from the distal screw. The screws were parallel and were positioned in the central or posterior third of the femoral head and neck. The reduction and position of the screws was categorized, in accordance with the recommendations of Tidermark et al., as good (displacement, <2 mm; Garden angle, 160° to 175°; posterior angulation, <10°), fair (displacement, <5 mm; Garden angle, 160° to 175°; posterior angulation, <20°), or poor (displacement, >5 mm; Garden angle, <160° or >175°; posterior angulation, >20°). The position of the screws was good if the tips of the screws were <5 mm from the subchondral bone.

All operations were performed on the day of admission or the following day. All patients were managed with dextran (Macrodex; Meda, Sweden) for thromboprophylaxis one hour preoperatively and postoperatively daily for four days. Antibiotic prophylaxis with cloxacillin (Ekaacillin; Meda, Sweden) was given on the day of surgery.

Under the supervision of a physiotherapist, all patients were mobilized to full weight-bearing on the first postoperative day. In the total hip replacement group, the patients were allowed to sit on a high chair and could stop using crutches at their own discretion. After six weeks, there were no restrictions.

Sample Size and Power Analysis

At the time of initiation of the study, no formal power analysis had been performed. An interim analysis (two-sided, $p = 0.05$) was performed after one year on the primary end point, and we tested the null hypothesis that the mean Harris hip scores for the two groups would be equal. We assumed that a mean difference of 10 points (standard deviation, 15 points) in the Harris hip score was the smallest effect that would be clinically relevant. Taking into consideration the difference in the number of patients included in the two groups, we calculated that a total of ninety patients with one year of follow-up (forty in the total hip arthroplasty group and fifty in the internal fixation group) would have a power of 87.5% to yield a significant result. A total of 100 patients (forty-three in the total hip replacement group and fifty-seven in the internal fixation group) would have a power of 87.5% to yield a significant result. A total of 100 patients (forty-three in the total hip replacement group and fifty-seven in the internal fixation group) were recruited to allow for any loss to follow-up.

Randomization and Blinding

The randomization process for the first twenty patients was conducted with use of sealed opaque envelopes. No stratification was used. Because
of hospital economic and logistic reasons related to the lack of operating room staff with total hip replacement experience during weekends, a change in allocation routines was implemented during the study. Thus, the following eighty patients were allocated to treatment according to which weekday they were admitted. Patients who were admitted on Monday to Thursday were managed with total hip replacement, whereas those who were admitted from Friday to Sunday were managed with internal fixation.

The patients, surgeons, and staffs were not blinded to choice of treatment.

**Outcome Measurements**

**Primary End Point**
The primary end point was hip function as evaluated with the Harris hip score in subjects who were managed with total hip replacement as compared with those who were managed with internal fixation during a seventeen-year period, with follow-up evaluations being performed at three months and one, two, four, eleven, and seventeen years.

**Secondary End Points**
Secondary end points included mortality, hip complications, reoperations, gait speed (measured as the time [in seconds] to walk 30 m with a comfortable velocity), pain in the involved hip (measured with a visual analogue scale ranging from 0 [no pain] to 10 [extreme pain]), and the ability to carry out activities of daily living. Anteroposterior and lateral radiographs were examined at all follow-up visits. We identified all major hip reoperations (revision of total hip replacement components, open reduction and osteosynthesis due to periprosthetic fracture, total hip replacement as a secondary or tertiary procedure, and excision arthroplasty) and all other reoperations of the hip for any reason (all major reoperations, closed reduction, screw removal, and surgical debridement). We used the unique Swedish civic registration number for all patients to verify mortality in the Swedish Death Register. We also used the Swedish Hip Arthroplasty Register to search for patients who had undergone reoperation elsewhere in Sweden. No such case was found.

In the total hip replacement group, we examined the radiographs for radiolucent lines around the stem in the zones of Gruen et al. and around the cup in the zones of DeLee and Charnley. Any circumferential radiolucent lines around the implants were defined as loosening.

In the internal fixation group, healing of the fracture was defined as the presence of visible trabeculations across the fracture line and no signs of osteonecrosis. The absence of radiographically visible trabeculations across the fracture line and progressive or early displacement was defined as a nonunion.

The patients were followed for seventeen years or until death. Patients who could not return to the hospital for follow-up were visited in their own homes for an interview and a clinical examination.

**Statistical Analysis**
Analyses of outcome were based on the intention-to-treat principle, and all patients remained in the group to which they had been randomized, regardless of any later surgical intervention. Patients with missing data at any of the follow-up evaluations were analyzed with the last observation carried forward. For the clinical outcome variables (Harris hip score, gait velocity, and VAS), we used a one-way repeated measures analysis of covariance (ANCOVA) to detect an overall difference between the two treatment arms throughout the study period, with use of estimated marginal means to adjust for the difference between the two groups in terms of sample size. Age, sex, and surgeon (registrar or consultant) were included in the analysis. The Bonferroni correction was used to adjust for multiple comparisons. The Pearson chi-square test was used to compare categorical variables between the groups. Kaplan-Meier curves with the log-rank test were used for the analysis of patient and implant survival. The level of significance was set at \( p \leq 0.05 \). We used SPSS 18.0 for Windows (IBM, New York, NY) for all analyses.

**Ethics**
All patients gave informed consent prior to inclusion in the study. The study was conducted in accordance with the ethical principles of the Declaration of Helsinki. The Ethics Committee of the Karolinska Institute approved the study.

**Source of Funding**
No outside funding was received for this study.

**Results**

**Patient Flow and Baseline Data**
Between February 1990 and December 1994, 1172 patients with a femoral neck fracture were admitted to the Orthopaedic Department at Danderyd Hospital, Stockholm, Sweden. Of these, 100 patients met the inclusion criteria and were recruited to participate in the study (Fig. 1). The study group included seventy-nine women and twenty-one men with a mean age of seventy-eight years (range, sixty-five to ninety years). All subjects received their allocated treatment. The characteristics of the groups were similar at baseline (Table I).

**Operative Data**
A total of eighteen surgeons performed all of the surgical procedures, and a greater proportion of internal fixation procedures were performed by registrars; specifically, consultants performed forty-one total hip replacements and forty-seven internal fixation procedures, whereas registrars performed two total hip replacements and ten internal fixation procedures. The duration of surgery and the amount of blood loss were greater in the total hip replacement group. The total hip replacement was graded as good in forty patients (93%) and fair in three (7%). In the internal fixation group, closed reduction was categorized as good in fifty-one patients (89%) and fair in six patients (11%). The positioning of the

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**Table I: Patient Characteristics**

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<thead>
<tr>
<th></th>
<th>Total Hip Replacement (N = 43)</th>
<th>Internal Fixation (N = 57)</th>
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<tbody>
<tr>
<td>Sex (no. of patients)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>5 (12%)</td>
<td>16 (28%)</td>
</tr>
<tr>
<td>Female</td>
<td>38 (88%)</td>
<td>41 (72%)</td>
</tr>
<tr>
<td>Age* (yr)</td>
<td>78 (65 to 90)</td>
<td>79 (66 to 90)</td>
</tr>
<tr>
<td>Side (no. of patients)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Left</td>
<td>20 (47%)</td>
<td>31 (54%)</td>
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<tr>
<td>Right</td>
<td>23 (53%)</td>
<td>26 (46%)</td>
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</table>

*The values are given as the mean, with the range in parentheses.*
screws was considered good in fifty-six patients (98%) and fair in one patient (2%). We found no correlation between the incidence of failed fracture-healing and the reduction or the positioning of the screws.

**Primary End Point**

The Harris hip score was higher in the total hip replacement group, with a mean difference throughout the study period of 14.7 points (95% confidence interval [CI], 9.2 to 20.1 points;
p < 0.001 [ANCOVA]), with the greatest difference between the groups during the first two years (Fig. 2).

Secondary End Points

Mortality

The mortality was high, regardless of treatment. At eleven and seventeen years, 25% and 13% of the patients, respectively, were still living. The mortality rate did not differ between the groups during the study period.

Hip Complications and Reoperations

During the study period, forty hips (40%) required at least one reoperation. Four patients (9%) in the total hip replacement group and twenty-two patients (39%) in the internal fixation group underwent a major reoperation (relative risk [RR], 0.24; 95% CI, 0.09 to 0.64; p = 0.001) (Table II). The overall rate of reoperation was 23% (ten of forty-three) in the total hip replacement group and 53% (thirty of fifty-seven) in the internal fixation group (RR, 0.44; 95% CI, 0.24 to 0.80; p = 0.003) (Table II). The majority of failures in the internal fixation group occurred early; within two years after primary surgery, twenty of fifty-seven patients had undergone conversion to a total hip arthroplasty. The major reoperations in the arthroplasty group occurred late; four of the forty-three patients needed major surgery between four and nine years. Two of these reoperations were revision arthroplasties that were performed because of aseptic loosening, and two were open reduction and internal fixation procedures that were performed for the treatment of one Vancouver type-B1 and one Vancouver type-C fracture (at four to twelve years after primary surgery) (Table II and Fig. 1) (see Appendix).

The median time to the first reoperation was thirty-three months (range, 0.5 to 114 months) in the total hip replacement group and ten months (range, 0.5 to forty-seven months) in the internal fixation group. Twelve patients underwent more than one surgical procedure (range, one to four procedures); ten of these patients were in the internal fixation group. The most frequent complications in the total hip replacement group were dislocations (n = 9, with one hip dislocating four times and five hips dislocating once), late-presenting periprosthetic fractures (n = 2), and aseptic loosening (n = 2). In the internal fixation group, osteonecrosis (n = 17) and nonunion/mechanical failure (n = 14) were the two most common hip complications. At the time of the eleven-year follow-up, eighteen of twenty living patients in the arthroplasty group still had the primary hip replacement and eight of sixteen living patients in the internal fixation group still retained the natural hip. The corresponding numbers at the time of the seventeen-year follow-up were four of six patients in the arthroplasty group and five of eight patients in the internal fixation group.

Gait Velocity, Pain, and Activities of Daily Living

Gait velocity was significantly faster in the total hip replacement group than in the internal fixation group at three months (mean time required to walk 30 m, thirty-seven compared with fifty seconds; p = 0.005) but did not differ between the groups at the later follow-up evaluations.

Patients in the total hip replacement group had less pain in the involved hip throughout the study period. The mean difference was 1.2 points (95% CI, 0.4 to 2.0 points; p < 0.001 [ANCOVA]) on the 10-point VAS. A greater proportion of patients in the total hip replacement group

![Fig. 2](image-url)
were fully independent in terms of activities of daily living during the first year of the study. At the later follow-up visits, there was no difference between the groups (see Appendix).

Discussion

In the present trial of healthy, cognitively intact patients with an age of at least sixty-five years, a displaced femoral neck fracture, and excellent preinjury hip function, primary total hip replacement provided, in the long term, better hip function and significantly fewer reoperations than internal fixation, without increasing mortality.

These results were obtained despite the fact that a less-than-optimal cemented femoral component with a titanium-alloy stem was used. Studies have shown superior results for cobalt-chromium as opposed to titanium-alloy stems when used with bone cement \(^{23,24}\), and this femoral stem is no longer used at our institution.

The strengths of the present study include its prospective, randomized, controlled design, the long-term follow-up of seventeen years, and the use of intention-to-treat analysis. During the last fifteen years, numerous reports have been published on the subject of displaced femoral neck fractures, but a lack of long-term follow-up still exists. This continuing follow-up is important because of the increasing lifespan of patients with a femoral neck fracture.

Our primary end-point variable is widely used and recently was validated for patients with a femoral neck fracture \(^{25}\). When the present study was initiated, neither the HOOS (Hip disability and Osteoarthritis Outcome Score) \(^{26}\) nor the WOMAC (Western Ontario and McMaster Universities Osteoarthritis Index) \(^{27}\) scoring systems were available or in clinical use at our department. As the patient-inclusion criterion regarding hip function was a Harris hip score of 100 points, the difference in Harris hip score on follow-up visits represented an absolute difference between the groups at subsequent follow-up visits. It is obvious that the patients’ ability to correctly record their prefracture status when waiting for acute surgery may be questioned. However, it is impossible to collect these data in a prospective manner, and this method is regularly used in trauma studies on patients with hip fractures \(^{1,2,4}\).

A limitation of the present study was the two different types of allocation. When the study was designed approximately twenty years ago, the allocation of the patients was accepted as a randomization procedure; however, today this would be considered more a stratification rather than a randomization. This could have introduced inequalities between the groups and could have resulted in fewer patients receiving total hip replacement. It also resulted in a greater proportion of patients being allocated to internal fixation performed by registrars. However, we analyzed our primary end point with ANCOVA.

<table>
<thead>
<tr>
<th>TABLE II Hip Complications and Reoperations up to Seventeen Years According to Allocated Treatment*</th>
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<tr>
<td><strong>Total Hip Replacement (N = 43)</strong></td>
</tr>
<tr>
<td><strong>Hip complications</strong></td>
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<tr>
<td>Dislocation†</td>
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<tr>
<td>Nonunion/mechanical failure</td>
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<tr>
<td>Osteonecrosis</td>
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<tr>
<td>Deep infection</td>
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<tr>
<td>Lateral pain</td>
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<tr>
<td>Aseptic loosening</td>
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<tr>
<td>Periprosthetic fracture</td>
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<tr>
<td>Total number of hip complications</td>
</tr>
<tr>
<td>Number of hips with any complication‡</td>
</tr>
<tr>
<td><strong>Hip reoperations</strong></td>
</tr>
<tr>
<td>Closed reduction†</td>
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<tr>
<td>Screw removal</td>
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<tr>
<td>Excision arthroplasty (Girdlestone)</td>
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<tr>
<td>Hip arthroplasty as a secondary or tertiary procedure</td>
</tr>
<tr>
<td>Open reduction and internal fixation of periprosthetic fracture</td>
</tr>
<tr>
<td>Revision of total hip replacement due to aseptic loosening</td>
</tr>
<tr>
<td>Surgical debridement due to deep infection</td>
</tr>
<tr>
<td>Total number of hip reoperations</td>
</tr>
<tr>
<td>Number of hips with any major reoperation§</td>
</tr>
<tr>
<td>Number of hips with any reoperation#</td>
</tr>
</tbody>
</table>

*All complications and reoperations are counted, so more than one event may apply for each hip. The values are given as the number of hips. †In the total hip replacement group, one hip dislocated four times and five hips dislocated once. ‡RR = 0.39 (95% CI, 0.23 to 0.68; p < 0.001). §RR = 0.24 (95% CI, 0.09 to 0.64; p = 0.001). ††RR = 0.44 (95% CI, 0.24 to 0.80; p = 0.003).
and included covariates (age, sex, and surgeon experience) to adjust for these inequalities. In addition, the radiographic results in the internal fixation group were no worse following operations performed by registrars as compared with consultants.

It is also important to note that our trial focused on a very select group of healthy, cognitively intact patients with a femoral neck fracture. More than eleven patients were screened for each patient who was included in the study. The reason for these strict inclusion criteria was to study only the function of the intervention; we therefore excluded all patients who had had diminished walking ability due to comorbidities or other degenerative joint disease before the fracture.

Our short-term results are consistent with the results of previous studies in which patients who were allocated to total hip replacement had lower reductions of both hip function and quality of life as compared with those who were allocated to internal fixation14,15. Beyond four years, the difference in clinical outcome was less, probably because of the natural aging of the patients and because a large proportion of patients in the internal fixation group later underwent conversion to a total hip replacement (Table II). To our knowledge, there have been only two previously published studies with long-term follow-up of more than ten years16,17 and there have been no studies with a follow-up period as long as seventeen years.

The study by Leonardsson et al.9,10 and the study by Ravikumar and Marsh18 both included a greater number of patients than our study did. Ravikumar and Marsh evaluated hip function with use of the Harris hip score and found that total hip replacement yielded a superior result over internal fixation at thirteen years. Leonardsson et al., in their ten-year follow-up study, did not use a standardized form to evaluate function but drew the conclusion that there was no significant long-term difference between the groups in terms of hip pain, reduction of mobility, the need for walking aids, and the ability to return to or remain in their prefracture accommodations. In terms of complications and revision surgery, Ravikumar and Marsh and Leonardsson et al. reported revision rates of 6.8% and 8.8%, respectively, for total hip replacement and of 33% and 46.6%, respectively, for internal fixation. These results are consistent with our findings.

We found no significant difference between the groups in terms of mortality. The mortality rate in both groups was high. However, we did confirm that the overall rate of complications and reoperations over a longer time period was significantly higher in the internal fixation group. Our other secondary end points, such as gait velocity and activities of daily living, at least during the first year of the study, favored the total hip replacement group. Most importantly, patients who were managed with total hip replacement had less pain in the involved hip over the long term.

Dislocation was the most common complication in the total hip replacement group. When the study was initiated, the posterior surgical approach was used routinely at our institution. In other trials on femoral neck fractures and arthroplasties in which the posterolateral approach has been used, the dislocation rate has been similar to ours17,19. Since the early 1990s, there have been multiple improvements that can reduce the dislocation rate for this group of patients, such as different surgical approaches20, capsular repair, and bigger femoral head sizes.

In the present study, the incidence of aseptic loosening of the prosthesis or periprosthetic fracture after primary total hip replacement was no greater than the rates in previously reported long-term studies of patients with degenerative joint disease20,21.

In conclusion, we recommend total hip replacement for healthy, elderly patients with a displaced femoral neck fracture. This procedure will provide better hip function and will lead to fewer reoperations compared with internal fixation in the long term.

Appendix
A table showing the proportion of patients who were fully independent in activities of daily living and a figure showing the cumulative percentage of patients who were still alive without a major reoperation are available with the online version of this article as a data supplement at jbjs.org.