Displaced Femoral Neck Fractures

A prospective randomized study of clinical outcome, nutrition and costs

Torsten Johansson

Division of Orthopaedics and Sports Medicine
Department of Neuroscience and Locomotion
Faculty of Health Sciences, Linköpings Universitet
Linköping, Sweden

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"Bättre en protes i höften än två skruvar åt skogen"
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ABSTRACT

Displaced femoral neck fractures comprise more than a third of all hip fractures. There is controversy as to the optimal treatment. Despite attempts to improve the methods for internal fixation, complication rates have been almost unchanged: 20-40% non-union and late segmental collapse in another 10-20%. Internal fixation has been the preferred treatment in Scandinavia, whereas primary hemi- or total arthroplasty have been more prevalent in the rest of Europe and North America.

In this study, patients 75 years or older, including those with mental impairment, were randomized to either internal fixation or cemented primary total hip arthroplasty (THA). A total of 146 hips in 143 patients were followed for two years. After one year 23% had died, and after two years 29%. Mortality was about the same in both groups. The accumulated mortality was pronounced among the mentally impaired patients.

In the internal fixation group, 44% underwent further surgery. In the THA group, 18% dislocated. The dislocation rate was higher for the mentally impaired patients. The Harris hip scores were higher in the THA group, whereas pain was more common in the internal fixation group.

The first 50 patients in each treatment group were studied concerning heterotopic ossification (HO), a well-known complication after THA. The incidence of HO in the THA group was similar to what is found after THA due to osteoarthritis. However, only 1/39 developed severe symptoms.

A subgroup of 100 patients was included in a study concerning nutritional status and functional capacity using the Modified Norton scale, Katz index of ADL and a questionnaire measuring instrumental activities of daily living. The THA group fared better concerning weight change over time, locomotion and pain. The nutritional intervention did not show any measurable effects.

All patients were followed until two years postoperatively and all fracture-related hospital costs, including reoperations, were calculated. We found no difference in total costs between the treatment groups. Costs to the municipality were calculated comparing the baseline cost before surgery with the average cost per month during the first postoperative year. No difference was found between the treatment groups.

On the basis of our results, we recommend arthroplasty for patients in this age group with normal mental function and high functional demands.
LIST OF PAPERS

This thesis is based on the following papers, which will be referred to in the text by their Roman numerals.


STATEMENT

Description of contribution

Study I
Design: Johansson T, Jacobsson SA, Ivarsson I, Wahlström O
Examination of patients: Johansson T, Jacobsson SA, Ivarsson I, Wahlström O
Review of radiographs: Knutsson A
Data collection and analysis: Johansson T
Manuscript writing: Johansson T
Manuscript revision: Jacobsson SA, Ivarsson I, Wahlström O

Study II
Design: Johansson T, Risto O
Review of radiographs: Knutsson A
Data collection and analysis: Johansson T
Manuscript writing: Johansson T, Risto O
Manuscript revision: Wahlström O

Study III
Design: All authors
Examination of patients: Bachrach-Lindström M
Data collection and analysis: Bachrach-Lindström M, Johansson T
Manuscript writing: Bachrach-Lindström M, Johansson T
Manuscript revision: Unosson M, Ek AC, Wahlström O

Study IV
Design: Johansson T, Bachrach-Lindström M, Jonsson D, Wahlström O
Data collection and analysis: Johansson T
Manuscript writing: Johansson T
Manuscript revision: Bachrach-Lindström M, Aspenberg P, Jonsson D, Wahlström O
# ABBREVIATIONS

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tr>
<td>ADL</td>
<td>Activities of daily living</td>
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<tr>
<td>AMC</td>
<td>Arm muscle circumference</td>
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<tr>
<td>BMI</td>
<td>Body mass index</td>
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<tr>
<td>HA</td>
<td>Hemiarthroplasty</td>
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<tr>
<td>HO</td>
<td>Heterotopic ossification</td>
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<tr>
<td>I-ADL</td>
<td>Instrumental activities of daily living</td>
</tr>
<tr>
<td>MAC</td>
<td>Mid-arm circumference</td>
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<tr>
<td>MNS</td>
<td>Modified Norton Scale</td>
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<td>THA</td>
<td>Total hip arthroplasty</td>
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<td>TSF</td>
<td>Triceps skinfold</td>
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INTRODUCTION

For more than a hundred years the optimal treatment of femoral neck fractures has been sought. The first surgical treatment is attributed to von Langenbeck, who used a silver pin for internal fixation in 1878. It failed due to infection. Non-operative treatments were preferred until the modern era of surgical fracture treatment started some 70 years ago. Soon the term "The unsolved fracture" was introduced by Speed in 1935 and is still alive due to ongoing controversy concerning the ideal treatment.

Different classification systems for femoral neck fractures have been proposed. The system according to Pauwels (1936) relates to the shearing angle of the fracture surface. However, it has not been shown to offer any predictive value for the incidence of non-union (Parker 1998). The AO classification has been criticized for being too complicated, having poor intra- and interobserver reliability and being of limited predictive use for the outcome of treatment (Blundell et al. 1998). The most accepted and widespread classification is that by Garden (1961). Originally, only an anteroposterior radiogram was used, but in its modified form it is complemented with a lateral view. Also the Garden classification system has been criticized for inter-observer variation, although less pronounced between stages I-II and III-IV (Frandsen et al. 1988). In essence, the most reliable subdivision of femoral neck fractures seems to be undisplaced, displaced and basal fractures. This simplified classification corresponds well to secondary complications after internal fixation such as non-union and segmental collapse (Alberts and Jervaeus 1990, Barnes et al. 1976, Frandsen and Andersen 1981, Nilsson et al. 1993).

In Scandinavia internal fixation has been the treatment of choice for the vast majority of cervical fractures. In the rest of the world primary arthroplasty is more often the preferred treatment, especially for displaced fractures. It is well known that patients with a displaced femoral neck fracture comprise a heterogeneous group. Some are essentially healthy, come from independent living and have long life expectancies, whereas others are living in institutions, have other compromising diseases and short life expectancies. Thus, it seems logical that the optimal treatment algorithm includes different treatment methods. In order to eventually "solve the fracture", prospective and randomized studies are needed.

The goal of modern fracture treatment is to enable the patient to return to the original activity level and living conditions as soon as possible, with a minimum of risks and pain and with the least expense for society. This thesis focuses on the choice of fracture treatment, the value of nutritional support, and an evaluation of the clinical results in relation to hospital and municipality costs.

Internal fixation
The modern era of surgical treatment of this fracture started in the 1930s with open reduction and internal fixation using the Smith-Peterson nail (Smith-Peterson 1931). Improvements were made in the surgical technique using
closed reduction (Watson-Jones 1936) and cannulated devices (Johansson 1932).

During the past 70 years attempts have been made to improve the results. The combination of closed reduction and percutaneous fixation has made surgery minimally invasive. Furthermore, the use of biplane fluoroscopy has enhanced the surgical procedure. A number of new internal fixation devices have been invented. There is one publication with excellent outcomes, but those results have proven difficult to reproduce (Rehnberg and Olerud 1989). Despite attempts to improve the prerequisites for internal fixation, the failure rates have been almost unchanged in clinical materials, with a 20-40% non-union rate and late segmental collapse in another 10-20% (Lu-Yao et al. 1994).

Complications following internal fixation
There are three main local complications: Non-union, segmental collapse and lateral local pain. Non-union is a condition when bone continuity has not been restored. A subgroup of non-union is redisplacement, meaning a loss of contact between the fracture fragments early in the postoperative period, usually within weeks. In those cases, the osteosynthesis device is dislocated, and it is obvious that healing is impossible. In its more chronic form, patients with non-union have persistent pain during activity and sometimes at rest. Eventually a radiogram shows a radiolucent area at the fracture site. Non-union is usually apparent within six months postoperatively.

The second major local complication is late segmental collapse. The primary cause is ischemia of the femoral head, presumably due to an injury to the local blood vessels at the initial trauma. Later in the process, revascularization is followed by partial resorption of the femoral head leading to deformation. The patients sometimes have none or only mild symptoms and only 30-50% of them require secondary hip replacement (Nilsson et al. 1989, Skinner and Powles 1986, Strömqvist et al. 1984, Strömqvist et al. 1992). Shortening at the fracture site may cause further penetration of the screw or pin ends laterally into the soft tissue. This may cause pain at walking or from local pressure, a condition that sometimes necessitates a secondary operation when the osteosynthesis device is removed.

Prerequisites for a successful osteosynthesis
In a regression analysis by Alberts and Jervaeus (1990), the single most important factor for fracture healing was the quality of reduction, followed by the type of fracture, and the position of the internal fixation material. In a series of 446 consecutive cases treated by internal fixation, reduction in lateral and in anteroposterior views was of equal importance. Reduction in a valgus position was more favorable than in anatomical or, the worst, a varus position (Nieminen et al. 1981).

The incidence of non-union can be reduced if the quality of reduction and placement of fixation devices is improved by allowing only surgeons with special interest to operate (Johansson et al. 1986, Strömqvist et al. 1992). In contrast, the incidence of late segmental collapse seems not to be influenced by the quality of surgery.
Rigid osteosynthesis with the Deyerle device was proposed to lower the non-union rate (Deyerle 1959, Hernefalk and Messner 1996). This advantage was not found in other materials (Ryan et al. 1979). Due to technical difficulties in using the device as well as higher rates of segmental collapse and infection, this method has been abandoned (Swiontkowski 1986).

In a meta-analysis of 25 randomized trials, no major differences were detected between screws, pins and implants with a side-plate (Parker and Blundell 1998). The authors also recommended further studies with a large number of patients (>400) treated at centers where the devices had not been developed.

Secondary treatment after failed internal fixation
The results after secondary THA were good regarding pain, walking capacity, and function, and THA was considered to be the salvage operation of choice (Hägglund et al. 1984, Tabsh et al. 1997). Secondary THA in patients with healing complication following primary internal fixation resulted in better long-term functional capacity than that obtained with a primary hemiarthroplasty (Nilsson et al. 1994). A well-positioned secondary THA was more stable than a secondary HA, resulting in fewer dislocations (Johansson et al. 1984). Five years or more after primary pin fixation or secondary total hip replacement, patients with healed fractures had fewer problems with sleep, housework and hobbies, and thus functioned better than patients who had required a secondary total hip replacement (Nilsson et al. 1991).

Hemiarthroplasty (HA)
The original and simplest design is an uncemented stem with a unipolar head to be fit in a preserved acetabulum. The stem can also be cemented or hydroxyapatite-coated. A later invention is the bipolar head.

Descriptive studies of primary HA after a femoral neck fracture
One of the most influential papers that popularized HA was published in 1976 and described 82% satisfactory 3-year results with cemented Thompson prostheses (D’Arcy and Devas 1976). In contrast, a 2-year follow-up of a consecutive series of elderly patients with displaced femoral neck fractures, who were treated with uncemented Moore prostheses, showed that more than 1/3 of the survivors needed conversion to THA due to pain. When only active patients living in their own homes were considered, 55% were found to need total hip replacements (Kofoed and Kofod 1983). In another series with a ten-year follow-up, 24/78 patients with a cemented Thompson hemiarthroplasty had been converted to THA. Of the remaining prostheses, 23/54 appeared loose on radiographs. There was severe protrusion of the metal head in 25 cases. The clinical result was excellent or good in only 17 of 78 cases (Kuokkanen et al. 1990).

Comparative studies between cemented and uncemented HA stems in fracture treatment
In a retrospective study, comparing cemented and uncemented Bateman bipolar hemiarthroplasties, the cemented group had less pain (13% versus 46 %) and higher Harris Hip Scores (Lo et al. 1994). Similar findings were seen in three
prospective randomized studies, one comparing cemented and uncemented bipolar HA (Emery et al. 1991), the other cemented versus uncemented Moore prostheses (Sonne-Holm 1982) and the third comparing THA versus cemented and uncemented HA (Dorr et al. 1986). A hydroxyapatite-coated stem showed superior functional results compared to an uncemented bipolar prosthesis (Livesley et al. 1993). Non-cemented Moore prostheses and cemented Christiansen HA had equally inferior survival of the prosthesis compared to cemented Hastings HA (Eiskjaer and Ostgård 1993). In a meta-analysis of 15 publications, there was support in favor of cemented HA (Khan et al. 2002).

**Comparative studies between unipolar and bipolar prosthesis**

The bipolar head was designed to make the movement take place in the implant instead of between the head of the prosthesis and acetabulum, thereby reducing the erosion of the acetabulum. The distribution of the movement has been shown to vary between different brands (Brueton et al. 1993). A retrospective study from the Mayo clinic, consisting of 1,001 hip hemiarthroplasties, showed that the acetabular erosion as well as the reoperation rate was higher in the unipolar group (Yamagata et al. 1987). A prospective randomized study on octogenarians with displaced fractures, comparing Thompson unipolar and Monk bipolar heads, showed no major differences. Both groups received identical cemented Thompson stems. At follow-up after 1-2 years 45-47% of the patients had pain (Calder et al. 1996).

**Total hip arthroplasty (THA)**

**Descriptive studies of primary THA after a femoral neck fracture**

Primary THA can be performed with an acceptable mortality and good clinical outcome, with dislocation being the most prominent complication (Cartlidge 1981, Coates and Armour 1979, Gregory et al. 1992). Based on results from a retrospective study, THA was recommended for previously active elderly patients (Sim and Stauffer 1980).

Dislocations after operation for fracture were more common than for osteoarthritis, but few revision operations were required (Taine and Armour 1985). In a long-term follow-up study from the Mayo clinic, the probability of survival of the prosthesis without revision was 95% (95% CI 91-99 %) at five years and 94 % (95% CI 88-98 %) at ten years (Lee et al. 1998). In contrast to the reports showing favorable results after THA, a retrospective study of 37 patients, 70 years or younger, showed a reoperation rate of 49% after 4-5 years (Greenough et al. 1988).

**Comparative studies between HA and THA**

At follow-up after almost four years in a retrospective study consisting of socially independent patients, none of the THAs had required revision, whereas 38% of the HA (mixed cemented/uncemented unipolar) had required conversion to THA. Six percent of THAs had dislocated. The modified Harris Hip score rated 86% of THAs as "good or excellent", compared with 12% of the remaining HA. Of the patients who had received a THA, 77% estimated that they could walk more than a mile, compared with 27% of the remaining HA (Squires and Bannister 1999).
THA may be avoided due to its assumed increased risk of dislocation. However, in a review of the literature, the dislocation rates after a fracture appeared to be the same for THA and HA if the first dislocation was disregarded (Papandrea and Froimson 1996).

Comparative studies between internal fixation and arthroplasty

The first prospective randomized study was published in 1979 by Söreide et al., who compared von Bahr screws with primary THA using the Christiansen prosthesis. The postoperative mortality rate was similar in the two groups, but general complications were more common in the THA group. THA was associated with earlier postoperative mobilization, and fewer reoperations, and showed better results at one-year follow-up. The Christiansen prosthesis used in the study was later found to have catastrophic long-term results.

Sikorski and Barrington (1981) performed a study with three treatment groups: internal fixation using Garden screws and Thompson cemented hemiarthroplasty through either a posterior or an anterolateral approach. After internal fixation the revision rate was 38% within two years. Patients with the anterior approach had better survival, but mobilization was best achieved with the posterior approach. The authors' conclusion was that hemiarthroplasty, using an anterolateral approach, is the safest operation in this group of patients.

Bray et al. (1988) compared reduction and pinning (Knowles or Neupold) or HA (cemented, bipolar) in a pseudo-randomized study without any significant differences in functional results.

In 1989 Skinner et al. published the one-year results comparing internal fixation with a sliding compression screwplate, uncemented Moore HA and THA (Howse semicaptive prosthesis). One year after operation there was little difference between the three groups in mortality (25%) or general complications. The revision rate within the first year was 25% for internal fixation. Dislocation after HA was 11%, and after THA 12.5%. THA resulted in the least pain and most mobility at one year, whereas hemiarthroplasty was worst in these respects. The authors concluded that internal fixation and, particularly, primary THA were the methods of choice.

Ravikumar and Marsh (2000) made a long-term follow-up on the same patients studied by Skinner et al. The 13-year results showed that there was no statistical difference in the mortality between the three groups (81%, 85% and 91% respectively). Internal fixation and hemiarthroplasty groups fared poorly, with a revision rate of 33% and 24%, respectively, compared with 6% in the THA group. Internal fixation and hemiarthroplasty resulted in a poor outcome with respect to pain and mobility. Despite high early complications, the authors recommended THA for physiologically active patients.

Van Vugt et al. 1993 compared HA and sliding-plate osteosynthesis (DHS). No difference could be demonstrated in the mortality rates, fracture- or operation-related complications or in the need for secondary intervention. Reintervention
could be carried out without additional risk in both groups and did not lead to poor end results. Comparable results were obtained with both methods up to 24 months.

THA showed superior results to internal fixation with hook pins and was recommended for healthy individuals (Jonsson et al. 1996).

Primary THA was recommended for healthy patients over 65 years due to better functional results and fewer reoperations (Neander 2000).

A recent randomized study by Parker and Pryor (2000) studied internal fixation using three parallel cannulated screws versus an uncemented HA (Austin Moore). Functional assessment of survivors at one, two and three years from injury showed no significant difference between groups. The reoperation rate was higher after internal fixation.

In a somewhat younger age group, 65-79 years, the revision rate was 30% after internal fixation versus 3-5% in the HA groups after a minimum of two years. The subjective assessment of outcome, made by the patients, showed the highest level of dissatisfaction in the internal fixation group despite equal mean Harris hip scores at annual reviews (Davison et al. 2001).

Only one prospective study has compared osteosynthesis and arthroplasty for demented patients (van Dortmont et al. 2000). In that study 60 patients were randomized to either osteosynthesis or cemented HA. The results were very poor; 28% were able to walk at four months and the one-year mortality rate was 57%, without any significant difference between the groups. The authors concluded that demented people should not be treated with major surgery like HA. Unfortunately, the prevalence and magnitude of pain was not assessed in that study.

A Finnish study that compared internal fixation and cemented HA in a randomized fashion in patients 75 years or older was discontinued since the primary results indicated that it would have been unethical to continue due to the poor results in the internal fixation group (Puolakka 2001).

The most recently published paper, comparing internal fixation and arthroplasty following a displaced femoral neck fracture, came from a Swedish prospective randomized multicenter study. 409 patients, 70 years or older, were included if not confused, bedridden or living in nursing homes. Hansson hookpins or Olmed screws were used for internal fixation. The arthroplasty group comprised a mixture of THA, cemented and uncemented HA. The authors recommended primary arthroplasty for displaced fractures of the neck of the femur in patients over 70 years of age (Rogmark et al. 2002).
Heterotopic ossification
Heterotopic ossification (HO) is a well-known complication after arthroplasty due to osteoarthritis (Ahrengart et al. 1991, Hu 1991, Nilsson 1998). To our knowledge, it has not been described and commented on after a hip fracture, except for a report by Rosendahl et al. (1977). Non-steroidal anti-inflammatory drugs (NSAIDs) are known to prevent the development of HO (Gebuhr et al. 1991, Persson et al. 1998, Wahlström et al. 1991). The value of such medication following primary arthroplasty due to a femoral neck fracture has not been described nor debated.

Nutritional status and intervention
Patients with hip fractures are more malnourished than age-matched controls (Galvard et al. 1996, Hillier et al. 2000, Meyer et al 1995). Hip fracture patients have been shown to deteriorate in nutritional status and functional condition after a fracture (Galvard et al. 1996, Koval et al. 1998, Unosson et al. 1995). It would be of great value if the fracture event, including its treatment, did not accelerate the deterioration of these patients.

Dietary supplementation during an average of 32 days postoperatively lowered the rates of complications and mortality, and shortened the hospital stay (Delmi et al. 1990). Another report from the same Swiss hospital showed that protein supplementation improved the clinical course (Tkatch et al. 1992).

A Swedish study demonstrated that elderly patients consumed the same volume of food despite the energy content, and that increased density of energy in the food resulted in a 3.4% increase in body weight which was reversible in a six-week cross-over design (Olin 1996).

The value of nutritional supplementation after hip fractures has been presented in a Cochrane review (Avenell and Handoll 2002). They found that the strongest evidence for the effectiveness of nutritional supplementation exists for oral multinutrient feeds, but the evidence is very weak.

The importance of the choice of surgical method for the nutritional status has not been studied previously.

Cost analyses
Displaced femoral neck fractures comprise more than one third of all hip fractures. This, in combination with high complication rates, constitutes enormous expenses. The number of hip fractures in Sweden is approximately 18 000 - 20 000. Worldwide, the number of hip fractures is expected to grow rapidly mainly due a growing number of elderly people (Gullberg et al. 1997). It is obvious that the economic aspects are important and that any improvement in a treatment algorithm can be beneficial for the patients as well as for society.

Different methods have been used to calculate the total cost of a hip fracture. The potential savings of preventing a fracture have been estimated (Autier et al. 2000, De Laet et al. 1999, Zethraeus et al. 1997). Others have compared different osteoporotic fractures (Randell et al. 1995), whereas some have tried
to describe the total costs of a hip fracture (Brainsky 1997, Reginster et al. 1999) with respect to social and physical functions (Sernbo and Johnell 1993). The estimated costs for a fracture ranged, in those studies, from USD 10 000 - 40 000. None of the studies reported the complication rates, and the follow-up time was not longer than one year.

The only prospective randomized study comparing THA versus internal fixation published so far showed that the hospital costs for THA were 2.4 times higher when counting only the primary treatment. When secondary procedures were included with a one-year follow up, THA was 1.6 times more expensive (Söreide et al. 1980).

Iorio et al. (2001) made an analysis where the 2-year clinical results from three other reports (Koval and Zuckerman 1994, Lu-Yao et al. 1994, Swiontkowski 1994) were used in combination with the costs at the authors’ hospital for primary and secondary treatments. They found THA to be the least expensive treatment, USD 20 000, and internal fixation the most expensive, USD 24 000. The results for unipolar and bipolar HA were in between those two figures.

**Summary of introduction**

Despite more than a century-long search for the optimal treatment of displaced femoral neck fractures, there is no consensus. Surgical techniques and implants have been developed to the point where major further improvements cannot be expected. The different surgical methods are fairly well documented but rarely compared in prospective randomized studies.

When comparing different methods, not only the surgical aspects are of interest. Function, pain, effects on nutritional status and economic consequences are other factors that deserve to be elucidated. This has motivated us to compare those different outcomes after a displaced femoral neck fracture treated with either internal fixation or THA. The overall goal has been to bring different results together and present a treatment algorithm.
AIMS OF THE STUDY

To compare the clinical outcome of displaced femoral neck fractures treated with internal fixation versus total hip arthroplasty when performed as routine procedures.

To relate the clinical outcome to the surgical performance through analyses of radiographs.

To analyze the occurrence of heterotopic bone formation and its clinical importance following internal fixation and THA for femoral neck fractures.

To compare the effects of internal fixation and THA on nutritional status and functional capacity within one year postoperatively.

To evaluate the effects of nutritional support postoperatively.

To compare the total hospital costs in relation to surgical methods and mental function including all complications within a two-year follow-up.

To compare the municipality costs for displaced femoral neck fractures treated with internal fixation versus THA within a one-year follow up.

To formulate a treatment algorithm concerning the treatment of displaced femoral neck fractures.
PATIENTS AND METHODS

Patients and randomization procedure
From September 1994 to May 1998, patients 75 years or older who were admitted with displaced and acute femoral neck fractures were included in the study. Further inclusion criteria were: ability to walk prior to the fracture, absence of any known malignancy of significance and rheumatic joint disease, and no contraindications to major surgery.

The randomization was carried out at the emergency department by a method described by Zelen (1979), primarily only asking the patients in the experiment group (THA) to participate. The patients were postoperatively asked to participate in the second study concerning nutritional intervention. In the nutritional study, the control group comprised the first 50 patients and the experiment group the following 50. All patients randomized were eventually asked to participate in the follow-up.

A total of 157 hips were randomized as outlined in Figure 1. After exclusions, 146 hips (143 patients) were included in the main study. Those three patients who were randomized twice were thought to be fully recovered after the first fracture treatment. After randomization, 141 patients were invited to participate in the nutritional study. Randomization to the main study was discontinued when the goal of 100 patients in the nutritional study was reached. All patients were consecutively randomized with the exception of short periods during the summers.

Figure 1. Randomization and study procedures. Paper I+II are based on the results from the first 50 patients in each treatment group. Paper III comprises 100 patients included in the nutritional study. In paper IV, all patients are included.
Surgical procedures and follow-up
All patients in this study were operated on the day after admittance in order to eliminate bias due to different delays before surgery. Surgery was performed all days of the week as routine procedures. Internal fixation was performed by 25 different surgeons (1-8 operations each) and THA by 22 surgeons (1-7 operations each). After closed reduction, internal fixation was performed with two parallel and percutaneously inserted screws (Olmed®, Olmed Medical AB, Uppsala, Sweden) and with the aid of two-plane fluoroscopy. Total hip arthroplasty was performed with a cemented prosthesis (Lubinus IP®, Link, Hamburg, Germany) using a dorsolateral approach.

Outpatient visits including radiographic examination were performed at three months, one and two years postoperatively.

Nutritional intervention and follow-up
The control group received standard hospital food (2200 kcal per day) and pursued their normal habits at home. The intervention group was given protein- and energy-enriched, and more frequent, meals at the hospital (2400 kcal per day). In addition, individual nutritional advice was given before discharge. The patients were examined the first time (baseline) 3-6 days postoperatively. Follow-up was performed at one and three months in the patients’ homes and at one year as an outpatient visit.

Evaluation methods
Mental state
The patient's mental state was classified according to the modified Norton scale (Ek 1987, Ek and Bjurulf 1987) as either 4 = fully oriented, 3 = occasionally confused, 2 = cannot answer adequately, or 1 = no contact (I+III+IV). Only those with grade 4 were referred to as being "lucid"; those with grade 3 and below were classified as having mental impairment or dysfunction. Two independent researchers (M Bachrach-Lindström and T Johansson) assessed all patients in paper III with an agreement level of 90%. The additional patients, who were not included in the nutritional study, were assessed by T Johansson (I+IV). When necessary, additional information was collected from medical records or from a close relative or caregiver. In the total material 38% (55/146) were classified as mentally impaired. The lucid patients were on average 83.6 years old compared with 84.9 for the mentally impaired (NS).

Radiological assessment (I+II)
All radiograms were reassessed by one radiologist (Anders Knutson). After internal fixation, reduction of displacement was classified as “good” when the residual angulation in the lateral projection was less than 15 degrees, when there was no varus angulation and when there was good alignment in the calcar area. Screw position was considered “good” when the distal screw was supported by the medial cortex, when there was less than 10 degrees deviation of the screws, when the screw tips were less than 5 mm from the subchondral bone and when there were no signs of penetration. The fracture was considered healed when trabeculae were observed crossing the fracture line.
In the THA group, the placement of the cup was considered “good” if there was a 30-50 degree lateral opening in the anteroposterior view and a 10-30 degree anteversion in the lateral view. The stem position was classified as “good” in the absence of a varus position.

The first 50 patients in the internal fixation and THA groups were studied for the presence of heterotopic ossification (HO). HO was classified according to Brooker et al.:

Grade I: Islands of bone within the soft tissues about the hip.
Grade II: Bone spurs from the pelvis or proximal end of the femur, leaving at least one centimeter between opposing bone surfaces.
Grade III: Same as II but less than one centimeter.
Grade IV: Apparent ankylosis of the hip.

**Anthropometry and Biochemistry (III)**
Body weight was measured to the nearest 0.1 kg on a digital electronic wheelchair scale or on a portable scale. The height was measured to the nearest 0.1 cm in supine position on a flat bed. Triceps skinfold (TSF) was measured on the posterior side of the non-dominant upper arm. Mid-arm circumference (MAC) was measured on the same side. Venous sampling of serum proteins was performed in the fasting state.

**Functional capacity and pain**
The Harris Hip Score was used to measure functional capacity and pain at the outpatient visits at three months, one and two years (I+III+IV) (Harris 1969). In study III, three other questionnaires were used as well; The Modified Norton Scale (Ek 1987, Ek and Bjurulf 1987), which also includes an assessment of food and fluid intake; Katz index of ADL (Katz 1963); Instrumental Activities of Daily Living (I-ADL) (Hamrin 1982). Pain was assessed using that specific part in the Harris Hip Score (0-44 points). The patients were dichotomized as having no pain (40-44 points) or pain (<40 points) (III+IV).

**Calculation of hospital costs**
The direct costs for surgical procedures, hospital stay, radiographic examinations, home rehabilitation, emergency and outpatient visits were calculated (Table 1). The set up cost for anesthesia and the operating room was estimated to be SEK 5,310, the variable cost (SEK per minute): 13 for the surgeon, 36 for anesthesia and 46 for the operating room. The average time consumption in minutes was estimated to be 40 for an osteosynthesis, 100 for a THA, 30 for screw removal, 15 for closed reduction of a dislocated THA and 45 minutes for a Girdlestone procedure. These estimates correspond to the normal operating time at our clinic for each procedure. The costs at different wards included all standard services including drugs and physiotherapy.

All costs included the overhead costs for the hospital, including those for auxiliary departments. The number of days at the hospital was calculated counting the day of admittance but not the day of discharge.
All recorded costs represented the real consumption. When closed reduction of a dislocated hip prosthesis was carried out in the patient’s bed, only the radiography costs were counted. One outpatient visit was planned approximately three months after surgery and was included in “the initial treatment”. Outpatient visits for scientific purposes were not included.

**Table 1. Specifications of hospital costs (SEK year 2000).**

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Cost (SEK)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Emergency visit</td>
<td>1 000</td>
</tr>
<tr>
<td>Out-patient visit</td>
<td>700</td>
</tr>
<tr>
<td>Radiograph of the hip:</td>
<td></td>
</tr>
<tr>
<td>- planned outpatient</td>
<td>384</td>
</tr>
<tr>
<td>- emergency</td>
<td>531</td>
</tr>
<tr>
<td>- in-patient planned</td>
<td>599</td>
</tr>
<tr>
<td>- in-patient/emergency</td>
<td>746</td>
</tr>
<tr>
<td>Internal fixation</td>
<td>9 930</td>
</tr>
<tr>
<td>Screw removal</td>
<td>8 175</td>
</tr>
<tr>
<td>THA</td>
<td>26 176</td>
</tr>
<tr>
<td>Closed reduction of THA</td>
<td>6 743</td>
</tr>
<tr>
<td>Girdlestone</td>
<td>9 608</td>
</tr>
<tr>
<td>Cost per day:</td>
<td></td>
</tr>
<tr>
<td>- orthopaedic clinic</td>
<td>3 800</td>
</tr>
<tr>
<td>- clinic for infectious dis.</td>
<td>3 800</td>
</tr>
<tr>
<td>- geriatric clinic</td>
<td>2 500</td>
</tr>
<tr>
<td>Home rehabilitation</td>
<td>1 100</td>
</tr>
<tr>
<td>Gastroscopy</td>
<td>1 850</td>
</tr>
<tr>
<td>Flebography</td>
<td>2 033</td>
</tr>
<tr>
<td>Radiograph of lungs</td>
<td>704</td>
</tr>
<tr>
<td>CT head</td>
<td>1 551</td>
</tr>
<tr>
<td>Radiogr.abdomen</td>
<td>1 056</td>
</tr>
</tbody>
</table>

**Cost analyses part 2 (municipality-based services)**

Nursing homes with 24-hour surveillance and support as well as group residences were classified as institutional living. The average cost for institutional living was SEK 925 per day. For those living in their own homes, the cost for municipal home help was SEK 243 per hour (personal communication from the Linköping Municipal Office). These represent the direct costs for the community. The incremental costs were calculated comparing the baseline costs representing the level of community service consumption immediately before the fracture and the average consumption during the first postoperative year. If a patient died before one year, the final level of municipal support was extrapolated to one year. The baseline and the accumulated costs during the postoperative year were expressed in average SEK/month (year 2000).

**Statistical methods**

Parametric data were tested by Student’s paired or unpaired two-tailed t-tests. Non-parametric unpaired data were tested with Chi²-test, Fisher’s Exact test or the Mann-Whitney U-test. For non-parametric paired data, Friedman’s test or Wilcoxon’s signed rank test was used. Median values in study IV were complemented with interquartile range (Iqr) representing the 25th and 75th percentile. For correlation between data, Pearson’s correlation analysis and simple regression were performed. ANOVA for repeated measures and logistic regression were used when appropriate. P-values below 0.05 were considered significant.

**Ethical considerations**

The studies were approved by the local ethics committee of the Faculty of Health Sciences, Linköping University and conducted in accordance with the Declaration of Helsinki. Verbal and written information was given to all participants and it was made clear that participation was voluntary. If the patient was mentally impaired, information was also given to a legal guardian who decided about participation.
RESULTS

Mortality and general complications
The accumulated mortality with reference to mental function is shown in table 2. There was no difference between lucid and mentally impaired patients at three months, but the difference was highly significant at 1, 2 and 3 years. Mortality in relation to the type of primary surgery did not show any statistically significant differences at any time (Table 3).

Table 2. Accumulated mortality in relation to mental state. Percentage in brackets. At one year and thereafter, the mortality rate was significantly higher for the mentally impaired.

<table>
<thead>
<tr>
<th>Mental state</th>
<th>3 months</th>
<th>1 year</th>
<th>2 years</th>
<th>3 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lucid n=91</td>
<td>3 (3)</td>
<td>10 (11)</td>
<td>13 (14)</td>
<td>19 (21)</td>
</tr>
<tr>
<td>Impaired n=55</td>
<td>7 (13)</td>
<td>23 (42)</td>
<td>30 (55)</td>
<td>35 (64)</td>
</tr>
<tr>
<td>Total</td>
<td>10 (7)</td>
<td>33 (23)</td>
<td>43 (29)</td>
<td>54 (37)</td>
</tr>
</tbody>
</table>

Table 3. Accumulated mortality in relation to surgical method. Percentage in brackets. There was no difference between internal fixation and THA.

<table>
<thead>
<tr>
<th>Treatment</th>
<th>3 months</th>
<th>1 year</th>
<th>2 years</th>
<th>3 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Internal fixation n=78</td>
<td>7 (9)</td>
<td>17 (22)</td>
<td>23 (29)</td>
<td>28 (36)</td>
</tr>
<tr>
<td>THA n=68</td>
<td>3 (4)</td>
<td>16 (24)</td>
<td>20 (29)</td>
<td>26 (38)</td>
</tr>
</tbody>
</table>

In the internal fixation group, general complications were seen in 8% (6/78) of the patients: Two died after reoperation with a THA, one due to a stroke and the other due to fat embolism to the lungs verified by autopsy. There were also 1 gastrointestinal bleeding, 1 deep venous thrombosis, 1 renal insufficiency and 1 cardiac failure, all with non-fatal outcome.

In the THA group 22% (15/68) had general complications. One patient died 4 days postoperatively due to a myocardial infarction verified by autopsy. Non-fatal complications included 5 patients with gastrointestinal bleeding, 3 cases of pneumonia, 2 renal failures, 2 cases of pulmonary edema, 1 cardiac arrest during surgery (minor myocardial infarction) and 1 minor stroke.

Local complications after internal fixation
Clinical findings
A total of 54% (42/78) of the patients had complications noted at radiographic or clinical examinations (Figure 2). This figure does not include those with local pain that were not reoperated on with screw removal. One patient with a deep infection was reoperated with a Girdlestone procedure. Another patient with a superficial infection was successfully treated with antibiotics and local drainage. One potentially life-threatening complication occurred in a woman with intrapelvic screw penetration. She was successfully reoperated on with a THA.
Secondary surgery after internal fixation
At two years, 34 patients had been reoperated on. With a present follow-up time of 4-8 years, only one more patient has experienced secondary surgery (screw removal). The total reoperation rate so far is 45% (35/78). THA was the most common type of secondary surgery (n=26), followed by screw removal (n=7) and a Girdlestone procedure (n=2) (Figure 2).

The different types of complications, if and how they were treated, are shown in figure 2. Two patients with pain from the joint were successfully reoperated on with a THA although the radiographic examination showed no obvious signs of segmental collapse or non-union. Only half (6/12) of the patients with segmental collapse have been reoperated on. Of the 7 patients who underwent screw removal, 3 had non-union and 2 had segmental collapse.

![Figure 2. Local complications after internal fixation and how they were treated.](image)

Local complications after THA
The most predominant complication so far in this group is dislocation of the prosthesis, which has been seen in 18% (12/68) of the patients in the primary THA group (Table 4). One patient dislocated for the fifth time after two years. Closed reduction required spinal or general anesthesia in 18/25 dislocations. The only other type of local complication in the THA group was superficial wound infection seen in 3 patients. They were all successfully treated and only one needed reoperation with local debridement. 10 patients dislocated their hips within 11 days postoperatively, the other two after 19 and 31 days, respectively.
Table 4. Number of patients with one or more dislocations after primary THA. Most patients, who experienced a dislocation, had it only once or twice.

<table>
<thead>
<tr>
<th>Number of dislocations</th>
<th>Patients (n)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>6</td>
</tr>
<tr>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td>5</td>
<td>1</td>
</tr>
<tr>
<td>Total: 12 (18%)</td>
<td></td>
</tr>
</tbody>
</table>

Mental function in relation to local complications
Reoperation after internal fixation was more common among the lucid. After THA, dislocations were common among those with mental impairment (Figure 3).

Radiographic findings
Internal fixation and outcome
Four postoperative radiograms could not be retrieved for reevaluation. 3 of those patients were reoperated with a THA, 2 due to redisplacement and 1 due to joint pain. The fourth patient underwent a Girdlestone procedure.
Six fractures were unsatisfactorily reduced, which resulted in poor screw fixation and very unsatisfactory results. All in that group were reoperated on, except one patient who died a few months after primary surgery. When the fractures were well reduced, the rate of redisplacement, non-union and segmental collapse was 9/26 for those with good screw fixation versus 11/21 for those with bad fixation (NS).
THA and outcome
Also in this group four postoperative radiographs could not be retrieved for reevaluation. No stem was put in a varus position. The cup position was classified as good in 33 cases. Eight of those dislocated their hips compared to 4/31 with poor cup position (NS).

Heterotopic ossification (II)
After a drop-out of 16 patients, 84 hips were radiographically examined at least once with a minimum of three months postoperatively (Figure 5). HO in the THA group was found in 71% (32/45) of the patients in at least one of the investigations. In the internal fixation group, only one patient 3% (1/39) developed HO (p<0.0012). All ten men in the THA group developed HO compared with 63% (22/35) of the women (p<0.02). There was no difference in age between those who developed HO compared with those who did not.

Severe HO (grade III+IV) was seen in 9% (4/45) in the THA group. The three patients with grade III HO were pain-free two years postoperatively and had acceptable ranges of motion (flexion 90, 95 and 110 degrees). Their Harris Hip Scores at two years were 71-85. Severe clinical symptoms in the THA group were limited to one mentally impaired patient, who developed complete stiffness of the hip due to grade IV HO.

Figure 5. Heterotopic ossification after THA. The numbers within brackets indicate those who were not examined at 3 months but at 1 and/or 2 years.
Function and pain

*Comparative functional results of internal fixation and THA (I+IV)*

The Harris Hip Scores are presented in Table 5. “Failures” is a subgroup of the “poor” group and consists of all patients with radiographic evidence of redisplacement, non-union, two patients with joint pain that were operated with a secondary THA, but only those with segmental collapse that underwent secondary surgery. Local pain due to screw ends was not considered a failure.

Primary THA showed more favorable results compared to internal fixation. When the number of patients scoring in the excellent and good categories, was compared with the fair and poor groups, the differences were highly significant at 3 months and 1 year (p<0.0001) as well as at 2 years (p<0.001).

**Table 5. Number of patients within different Harris hip score groups at 3 months, 1 and 2 years.** Once a patient scored as “poor” due to a failure, she remained classified as such despite reoperation with a good result. Local pain due to screw ends was not considered a failure.

<table>
<thead>
<tr>
<th></th>
<th>Internal fixation</th>
<th>THA</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>3 months</td>
<td>1 y</td>
</tr>
<tr>
<td>Excellent (90-100)</td>
<td>0</td>
<td>3</td>
</tr>
<tr>
<td>Good           (80-89)</td>
<td>5</td>
<td>3</td>
</tr>
<tr>
<td>Fair           (70-79)</td>
<td>8</td>
<td>8</td>
</tr>
<tr>
<td>Poor           (&lt; 69 (failures))</td>
<td>51</td>
<td>40</td>
</tr>
<tr>
<td>Diseased</td>
<td>7</td>
<td>17</td>
</tr>
<tr>
<td>Missing</td>
<td>7</td>
<td>7</td>
</tr>
</tbody>
</table>

*Comparisons of pain between internal fixation and primary THA (IV)*

Table 6 shows absolute and relative prevalence (%) at follow-up. The groups were dichotomized as having pain (<40 points) or no pain (40-44 points) determined by the Harris Hip Score.

The prevalence of pain, in relation to the primary treatment, was significantly higher in the internal fixation group despite the fact that those figures include those who had reoperated with a secondary THA (intention-to-treat). For the mentally impaired patients, the relative prevalence of pain after was higher at 3 months after internal fixation, but not at 1 and 2 years (Table 7).
Table 6. *Number of patients with pain at 3 months, 1 and 2 years. Percentage in brackets. Intention-to-treat, thus the internal fixation group here includes secondary THA. Primary THA was clearly better.*

<table>
<thead>
<tr>
<th></th>
<th>Internal fixation</th>
<th>THA</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>3 months</td>
<td>29/56 (52)</td>
<td>3/54 (6)</td>
<td>0.0001</td>
</tr>
<tr>
<td>1 year</td>
<td>12/45 (27)</td>
<td>2/48 (4)</td>
<td>0.007</td>
</tr>
<tr>
<td>2 years</td>
<td>10/38 (26)</td>
<td>0/41 (0)</td>
<td>0.002</td>
</tr>
</tbody>
</table>

Table 7. *Pain in mentally impaired patients. At 3 months, pain was more common after internal fixation.*

<table>
<thead>
<tr>
<th></th>
<th>Internal fixation</th>
<th>THA</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>3 months</td>
<td>7/14 (50)</td>
<td>0/22 (0)</td>
<td>0.001</td>
</tr>
<tr>
<td>1 year</td>
<td>1/9 (9)</td>
<td>1/17 (4)</td>
<td>0.08</td>
</tr>
<tr>
<td>2 years</td>
<td>1/5 (20)</td>
<td>0/12 (0)</td>
<td>0.2</td>
</tr>
</tbody>
</table>

Nutritional intervention, nutritional status and functional capacity

*Nutritional intervention (III)*

The nutritional intervention had no effect on nutritional status. Factors studied were total body weight, body mass index (BMI), triceps skinfold (TSF), arm muscle circumference (AMC) and serum albumin.

*Nutritional status, functional capacity and comparisons between treatment groups (III)*

Compared with the THA group, the internal fixation group lost significantly in weight during the one-year follow-up period (p<0.05). At one month the I-ADL score “locomotion” was significantly worse compared with the preoperative scores in the THA and internal fixation groups (p<0.001). The only group that improved in locomotion between one month and one year was the primary THA group. The need of help at one year (Katz index of ADL) did not differ between the treatment groups.
Hospital costs
The total average cost for all patients including complications and reoperations performed at two years was SEK 117 000 (range 27 000-519 000). The median cost was SEK 97 300 (Iqr 70 800 – 145 300). These costs were mainly normally distributed, but with a right-hand tail (Fig 6).

The right-hand tail in Figure 6 comprises the high-cost patients. The total treatment costs exceeded SEK 200 000 in 12 cases. 8 of these were patients with an internal fixation who were reoperated on with a THA (7/8 lucid), 3 were patients with mental dysfunction with recurrent dislocations after a primary THA, and one was a patient with mental impairment who had a long rehabilitation period after internal fixation.

The total average number of bed-days was 26 (4-120), of which 55% were at the orthopedic ward, the remainder mainly at the geriatric ward. There was no difference between internal fixation and primary THA; the mean costs were SEK 118 000 and SEK 115 000 respectively. 73% of the total cost was derived from the hospital bed-day costs, 20% from surgery, 4% from home rehabilitation, and 1% from radiographic examinations, out-patient and emergency visits respectively.

Mental function in relation to hospital cost
The average total cost for the lucid patients and for those with mental impairment was SEK 118 000 and SEK 114 000 respectively.

For the lucid patients, the average cost appeared higher after internal fixation than after THA, but the opposite was found for the patients with mental impairment (Table 8).
For the lucid patients, the 95% confidence interval for the comparison between treatment groups ranged from internal fixation being SEK 4300 cheaper to SEK 42 500 more expensive than a THA. Thus, only with a 2.5% probability, will a THA in a lucid patient be more than SEK 4300 more expensive than an internal fixation and will most likely be cheaper. For patients with mental impairment the 95% confidence interval for the comparison between treatment groups ranged from THA being SEK 68 000 more expensive to SEK 18 800 cheaper.

Table 8. Total costs after internal fixation and THA dichotomized by mental function (SEK, year 2000). Each number represents the accumulated average cost including all fracture-related complications, e.g. reoperations and readmissions, within two years after the fracture.

<table>
<thead>
<tr>
<th></th>
<th>Lucid patients</th>
<th>Mental impairment</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Internal fixation</td>
<td>THA</td>
<td>Internal fixation</td>
</tr>
<tr>
<td>Bed-days</td>
<td>n=53</td>
<td>n=37</td>
<td>n=25</td>
</tr>
<tr>
<td></td>
<td>27</td>
<td>20</td>
<td>27</td>
</tr>
<tr>
<td>Surgery</td>
<td>22548</td>
<td>27118</td>
<td>15165</td>
</tr>
<tr>
<td>Care cost</td>
<td>92032</td>
<td>68481</td>
<td>80732</td>
</tr>
<tr>
<td>Emergency</td>
<td>1415</td>
<td>1135</td>
<td>1320</td>
</tr>
<tr>
<td>Outpatient</td>
<td>1162</td>
<td>605</td>
<td>476</td>
</tr>
<tr>
<td>Radiography</td>
<td>2039</td>
<td>1343</td>
<td>1614</td>
</tr>
<tr>
<td>Home rehab.</td>
<td>7057</td>
<td>8414</td>
<td>616</td>
</tr>
<tr>
<td>General comp.</td>
<td>52</td>
<td>88</td>
<td>0</td>
</tr>
<tr>
<td>Total</td>
<td>126300</td>
<td>107200</td>
<td>99900</td>
</tr>
<tr>
<td>CI (95%) kSEK</td>
<td>106-147</td>
<td>96-118</td>
<td>72-128</td>
</tr>
<tr>
<td>Initial treatment</td>
<td>74700</td>
<td>101500</td>
<td>81100</td>
</tr>
<tr>
<td>% initial/total</td>
<td>59%</td>
<td>95%</td>
<td>81%</td>
</tr>
</tbody>
</table>

Initial versus total cost

The costs for the initial treatment, including primary surgery, hospital stay and one outpatient visit to the hospital averaged SEK 88 000, which accounted for 75% of the total costs (Table 8). For the lucid patients the initial treatment costs were lower in the internal fixation group but the secondary costs were inversely higher (p<0.001).

45 patients were readmitted to the hospital after the initial treatment: 37/78 after internal fixation versus 8/68 after THA (p<0.0001). Only 2 of 37 lucid patients who had undergone THA were ever readmitted, one due to a wound infection and one due to recurrent dislocations. When secondary surgery was performed, the total costs doubled for both treatment groups (Table 9).
<table>
<thead>
<tr>
<th></th>
<th>Internal fixation</th>
<th>THA</th>
</tr>
</thead>
<tbody>
<tr>
<td>no reoperation</td>
<td>81 n=44</td>
<td>100 n=57</td>
</tr>
<tr>
<td>CI (95%)</td>
<td>65-98</td>
<td>91-109</td>
</tr>
<tr>
<td>secondary surgery</td>
<td>165 n=34</td>
<td>194 n=11</td>
</tr>
<tr>
<td>CI (95%)</td>
<td>144-186</td>
<td>155-232</td>
</tr>
</tbody>
</table>

Municipality costs
Preoperatively, 45/146 (31%) of the patients lived in institutions. All survivors in that group were discharged back to their original institution, thus not adding any additional costs to the municipality. Of the surviving patients who came from independent living, 91/100 (91%) could return to their homes (Figure 7). During the year of observation, the costs remained unchanged for 83/142 (58%) of the patients. Another 5 patients had had an emergency alarm device installed but received no other municipal support. For the 59 patients with incremental costs the average increase was SEK 11 765 per month, median 8 900 (Iqr 2 300 – 20 100). At the end of the year, 37/113 (33%) survivors lived in institutions, whereas 32 (28%) still had independent living without any formal home help.

There was no difference in the change of average costs per month between the THA and internal fixation groups, nor in the subgroup analysis between lucid and mentally impaired patients in both treatment groups.

Figure 7. Types of living before the fracture, after discharge from hospital and at one year. Deaths (†) and changes in types of living during the first year are illustrated. At one year, 76/113 (67%) lived independently.
GENERAL DISCUSSION

Clinical outcome
Patients who have sustained a hip fracture are generally different from age-matched controls. They are malnourished to a greater extent, and dementia is more common. However, the group is heterogeneous. Some have severe diseases, may be bedridden, live in institutions and have short life expectancies. Others are generally healthy individuals with independent living, high activity levels and long life expectancies.

Thus, the goals for the treatment are different. A basic goal for all patients should be relief from pain. Ambulatory patients should regain their walking ability. The long-term outcome is important for those with long life expectancies.

The controversy on the treatment of a dislocated femoral neck fracture has resulted in numerous scientific articles and debates. Great efforts have been made in trying to optimize surgical procedures. Many internal fixation devices have been invented but have only had a marginal effect on the results. Different brands of prostheses have been designed and followed-up for many years. The cementing technique has been improved. It seems doubtful that any further major improvements are possible in the near future. The best approach may be to use what we have, but use it wisely.

When treating this heterogeneous group of patients, one can have different strategies: Either one primary treatment for all, or diversified treatments depending on the patients' assessed future potential. The only possible primary surgical method that can be used for everybody is internal fixation. Some authors have recommended this approach with the main argument being the avoidance of unnecessary prosthetic replacement (Strömqvist et al. 1984, Nilsson et al. 1989). Secondary arthroplasty as a salvage procedure has been reported not to be as successful as a primary healed osteosynthesis (Nilsson et al. 1991). When six skilled surgeons performed the osteosynthesis, the complication rate, including early dislocation, non-union and segmental collapse was, 30% compared to 41% when 35 surgeons were involved on a routine basis (Strömqvist et al. 1992). When we planned our study, we decided to make it reflect routines at most hospitals, where a large number of surgeons perform these operations.

When reevaluating the radiograms, we found bad reduction in 8% of the cases and consequently badly positioned screws, with catastrophic results for those patients. However, this was a relatively small fraction of the patients, and those isolated results do not influence the overall outcome. The positioning of the screws seemed less important. Overall, the outcome after internal fixation in our study, 32% early dislocation/non-union and 15% segmental collapse, is within the range of what can be expected (Lu-Yao et al. 1994). In our study we had one potentially life-threatening complication by an intrapelvic penetration of a screw. This complication is rare, but has been previously reported (Sundgren and Persson 1994, Adolphson 1995).
Arthroplasty as the overall treatment method seems dubious. First of all, in younger patients the benefit of having a preserved femoral head is obvious since there is a risk of a revision arthroplasty later on in life. For patients with compromising diseases, the surgical trauma has to be kept to a minimum due to risks of complications, thus making closed reduction and internal fixation the method of choice. In our study, the mortality rate was not higher in the primary THA group, which corresponds well with other studies (Søreide et al. 1979, Rogmark 2002). In our material, three patients died after THA, one after a primary THA and two after secondary THA. The direct relation between surgery and death could only be clearly demonstrated in one case with pulmonary fat embolism. The cementing of the stem has been shown to be a crucial moment in the surgical procedure (Parvizi et al. 1999). Fat embolism to the pulmonary circulation is known to occur. Moreover fat and air bubbles may enter the systemic circulation via a patent foramen ovale or through pulmonary circulation. Cerebral microembolization has been shown intraoperatively by transcranial Doppler assessment. The clinical significance of these findings is not known (Edmonds et al. 2000). Cementation has been shown to produce a transient reduction in cardiac output and stroke volume, but the mechanism behind it is still unclear (Clark et al. 2001).

It is obvious that THA is more dangerous than internal fixation, with more frequent and potentially lethal general complications. Notorious intra- and postoperative surveillance is a prerequisite for good outcome. The disparity between general complications and mortality indicates that modern health care is effective in treating secondary complications.

Another argument against primary arthroplasty is that the benefits of the operation may be questionable for patients with low functional demands and limited survival. However, the term "benefit" in the orthopedic literature is often limited to the absence of major complications such as mortality or need for secondary surgery. Secondary surgery as a single outcome measure is crude and may be misleading (Alho et al. 1998). For example a dislocation after THA ought to have lower dignity than secondary THA after a failed internal fixation, considering the magnitude of surgery and the suffering for the patient before and after the secondary operation. Furthermore, secondary complications presented in percentages tend to make us compare incomparable entities. When functional scores are used as a measure of benefit, we must acknowledge that the scores are based on examinations at different time intervals, usually months and years. Those scores may only indirectly tell us how a patient performed before and between those examinations. A good example is the postoperative period after an internal fixation that eventually heals. That patient probably has more pain during the first three months than after a THA, although it is seldom measured. Pain is disabling and undoubtedly, even when life is limited to a few months postoperatively, treatment that eliminates pain has to be considered beneficial.

The predominant local complication after THA was dislocation. In our study, 12 patients (18%) dislocated, but it was only a major clinical problem for three of them who dislocated 4 or 5 times. The dislocation rate of 8% for the lucid
patients in our study may seem high, but should be compared to an average of 10% in other studies (Lu-Yao et al. 1994, Papandrea and Froimson 1996). Almost 1/3 of the mentally impaired patients dislocated their hips. However, this category of patients has not been included in any comparable study, thus making comparison impossible.

A dislocation may be painful, but after reduction the patient is basically free of pain and the time lapse between dislocation and reduction can usually be kept to a minimum. Recurrent dislocations may, on the other hand, frighten the patient and compromise normal rehabilitation. The radiographic reevaluation did not show any totally aberrant positions of the cups or stems in those cases, but we have to accept that standard projections, especially the lateral view, may be difficult to measure (McCollum and Gray 1990). There are also other major factors that contribute to an increased rate of dislocation compared to THA due to osteoarthritis; a greater range of motion preoperatively (Gregory et al. 1991, Ekelund et al. 1992), muscle weaknesses, dementia and confusion.

Nutritional status and intervention

In a longitudinal study, a cohort of 70-year old Swedes was followed during 25 years. Mean body weight decreased 3.2 and 5.1 kg; mean height decreased 4 and 4.9 cm in males and females, respectively. Due to the decrease in both height and weight over time, body mass index (BMI) was less affected (Dey et al. 1999). Whether this is a natural part of the aging process is not known. Others postulate that as long as elderly people stay healthy and do not have other serious risk factors, they keep good food habits and nutritional status up into their eighties and nineties (Rothenberg et al. 1993).

Hip fracture patients are on average more malnourished than age-matched controls and more vulnerable to further deterioration (Galvard et al. 1996). In our study, patients in the internal fixation group lost significantly more weight during the one-year follow-up compared with the THA group. Hypothetically, this may be due to a less favorable postoperative period, with more pain and subsequently more use of analgesics that may cause indisposition. Pain may also have influenced general well-being, including the appetite.

The value of oral supplementation is uncertain (Avenell and Handoll 2002). One can speculate whether the positive results in the studies by Delmi et al. (1990) and Tkatch et al. (1992) were, at least partially, due to a very low calorie intake in the control groups, thus making the supplementation crucial for survival and recovery. The nutritional intervention in our study had no measurable effects, indicating that it was not efficient or needed. Obviously, the type of surgery had a greater impact than the nutritional intervention, which may indicate that there may be other factors that were more important for the nutritional status than the food available. The patients in our control group had the possibility to consume at least 2 200 kcal per day at the hospital. The basal metabolic rate for a 75-year old woman weighing 55 kg is approximately 1 200 kcal per day. With limited physical activity level she requires approximately 1 850 kcal per day, which should make the food supplied at our hospital sufficient. That should not deter us from trying to improve the nutritional status, or at least strive to minimize the deterioration. This should not only be
emphasized during the hospital stay, but rather as a general issue for the elderly, at home and in institutions. More energy-enriched diets and frequent meals might be beneficial. More importantly, however, factors that contribute to make people loose their appetite or their ability to eat should be sought and fought.

Cost analyses
The variety of methods and purposes for cost analysis contribute to make comparisons of studies difficult. Some authors have compared a hip fracture group with an age-matched control group (Autier 2000, De Laet 1999). The main shortcoming of this method is that the control groups were a selection of healthier individuals. This was clearly demonstrated in those studies by a different mortality in the observational and control groups.

To avoid the dilemma of having a healthier control group, patients can be used as their own controls. Brainsky et al. (1997) compared the costs for medical, formal and non-formal care during six months before a hip fracture with the costs during the first postoperative year. Zethraeus and Gertham (1998) and Zethraeus et al. (1997) compared the direct costs in the health care and social welfare systems during one year after the fracture with the year before. There are two main objections to this method. The incremental cost may not only be attributed to the fracture but may as well be due to concomitant diseases, often connected with the aging process in these patients (Cooney 1997). Secondly, a hip fracture may call to attention a fragile home situation that is unsuitable for a patient even in the pre-fracture period. A change of living or intensified formal care may be thought to be a result of the fracture, and there is a risk for overestimation of costs.

The chosen follow-up time is crucial in any cost analysis. From a scientific point of view, a genuine cost analysis can only be made with a life-long follow-up of all patients. For practical purposes this follow-up can be replaced by a reasonably long follow-up combined with a qualified assessment of future complications. After internal fixation, most complications are apparent within two years (Alho et al. 1999, Barnes et al. 1976, Nilsson et al. 1989). In our study 71% (25/35) of the reoperations after internal fixation occurred within the first year and 26% (9/35) during the second postoperative year. So far, only one reoperation, a screw removal, has been performed after two years. The majority of failures after THA, such as dislocations and infection, are usually apparent within weeks or months. However, the risk for aseptic loosening remains until death. So far, we have not yet seen any aseptic loosening of prosthesis in our patients. The combination of a high natural mortality for this group of patients and high probability of survival of the prosthesis indicates that few, if any, future hip revisions will be needed.

In some studies that describe the costs the year after a hip fracture, only the primary treatment was included (Sernbo and Johnell 1993). That must be considered insufficient, since reoperations are common and expensive. In study IV, secondary procedures and readmittances accounted for 25% of the total hospital costs. This was most prominent for the lucid patients, where 41% of the total costs were due to secondary treatments.
Complications are costly. Fracture complications after internal fixation were found to triple the hospitalization costs, excluding surgery costs (Holmberg and Thorngren 1988). In our study the hospital costs doubled.

In the literature, only two studies have compared the costs for internal fixation versus THA. Only one was prospective and randomized (Söreide et al. 1980). They used the basic costs of a hospitalization day as a unit, and found the total costs, including reoperations, for THA and internal fixation were equivalent to 29.8 and 18.55 days, respectively. Those results recalculated by use of our present cost per day would correspond to SEK 113 000 for THA and SEK 70 000 for internal fixation, figures almost identical to ours with the exception of internal fixation being cheaper in their study. This, however, may be due to the fact that Söreide et al. followed these patients only one year, and the local complication rate was lower for their internal fixation group compared to ours.

The second study that compared internal fixation with THA (Iorio et al. 2001) was based on results collected from the literature, including reoperations within two years. They calculated that a fracture treatment cost between USD 20 000-24 000, and cost about the same for internal fixation, HA and THA. Their costs were higher than ours, which may be explained by the exchange rate and different unit costs. Their results were, however, similar to ours in the sense that the total costs for different treatments did not differ. It also showed that the benefit of low costs for primary internal fixation is lost when secondary surgery is included in the calculus.

Limitations and weaknesses of our studies
The primary randomization procedure, used to allocate the patients to either internal fixation or THA, was performed according to Zelen. Many ethical committees would probably not allow this procedure today, but we consider that it has advantages. First of all, it is practical since only half of the study population has to be informed in connection with the randomization. Secondly, the major advantage is when a certain treatment or non-treatment has well-known poor results. Then the patients may be less willing to participate and demand an untested treatment. When and if that happens, the risk of a selection bias may become considerable and the results difficult to interpret. The disadvantage of the Zelen randomization procedure is that some patients allocated to the experiment group may decline participation, which is less likely to happen if the patients have consented to participation before randomization. In our study five patients declined participation after having been randomized to THA, but we consider this number of patients too small to affect the overall results.

After the randomization, 7% (11/157) of the hips were excluded, which should eliminate systematic selection bias at this stage. In the nutritional study, 29% declined to participate before inclusion was completed, but an analysis showed no difference between participants and non-participants concerning, age, gender and mental state.
In the nutritional study 20 patients died and another 25 dropped out before one year making a complete follow-up possible in only 55% of the patients. This may have affected the results. In the clinical follow-up, some patients did not show up on different occasions for planned follow-up, although not to the extent that we believe that it had any radical effect on the results or conclusions.

In a perfect world, an independent person, blinded to the treatment, should perform all investigations. This was not planned, nor done in any of our studies. The different types of operations were obvious at clinical and radiographic evaluations. A bias in this type of studies cannot be eliminated. However, many of the outcome variables were objective, such as death, complications and reoperations, while some were semi-objective such as range of motion and anthropometric parameters.

In a majority of the patients, two independent investigators dichotomized mental state, with a 90% agreement level. We did not use any mental tests, which could have been useful for scientific clarity. However, the use of mental tests in the post-fracture and postoperative period may not be reliable due to a high incidence of temporary confusion (Lundström et al. 1999).

Assessment of pain in mentally impaired patients may be questioned. In some cases it may be difficult to assess whether the discomfort expressed by the patient is related to the hip. In most cases the combination of a physical examination, observation and information from a relative or caregiver gives a good picture. A mentally impaired patient does not have any interest in an over- or underestimation of the symptoms and perhaps these patients may even be more reliable than the lucid. The use of a proxy (close relative or caregiver) as a source of information concerning demented people has, for obvious reasons, rarely been evaluated. According to the literature, the proxy-subject agreement is best concerning observable symptoms and manifestations but poorer when dealing with less observable and potentially embarrassing conditions (Magaziner 1997, Østbye et al. 1997).

Assessment of costs is difficult. It is impossible to measure every single item and every minute spent by all employees in a hospital. To make calculation possible, rather rough assessments have to be made. These calculations should not be translated to another hospital or another country without careful examination. When describing the hospital costs in study IV, we made efforts to describe the calculation methods and assessments. The reader can make alternative calculations based on our results but using different unit costs. It would have been simpler to use the DRG system in counting the hospital costs, but that method is associated with risks of over- and underestimation (Reinhardt 1997, Vickrey 1987).

The calculation of municipality costs was based on unit costs multiplied by the number of units consumed. The unit cost for a patient at an institution is an average cost for all individuals living there. Thus, our calculation of costs does not reflect the true consumption nor does it reflect any differences or changes.
after the fracture treatment. For those living in their own homes, non-formal help from relatives, neighbors and friends was not included in the calculation. Obviously there is a risk that the actual costs may be underestimated. We found no difference between internal fixation and THA, which may be due to this methodological shortcoming. It is likely that a group with pain, as the internal fixation group, would require more attention and help, and thus higher unmeasured costs.

Treatment algorithm
When we started this project, we wanted to create a treatment algorithm based on clinical outcome, function, nutrition and costs. The decision on treatment has to be made without delay after a patient arrives at the emergency department. It seems logical that the treatment should be diversified and that the chosen method preceded by an analysis of the potential goals and possibilities for each patient. This may be difficult if sufficient data concerning the patient are lacking. The patient may be senile, confused or generally impaired by concomitant trauma or its cause, e.g. a stroke or heart attack. Further information from medical records, relatives and other caregivers may have to be obtained.

If the patient is a high-risk patient from the anesthetist's point of view and if the functional level is low, an internal fixation carries the lowest risk of life threatening complications. The operation may also provide enough fracture stability to enable patients to return to their normal functional level without pain. For the young patient, below an arbitrary age of 70-75 years, internal fixation should be preferred due to the benefit of having a preserved femoral head.

With no doubt, arthroplasty should be offered to those with joint diseases and the elderly with high functional demands. Our studies show that lucid patients benefit from being operated on with an arthroplasty due to fewer readmittances, better locomotion and function, less pain and less nutritional deterioration, without being more expensive than when operated on with internal fixation.

Our clinical results from Paper I do not differ from the compiled material in this thesis. Our results were later confirmed by Rogemark et al. (2002). However, there are some notable differences (Table 10). In their study, patients with confusion were not included. How this distinction was done is not defined in the paper. One should expect their patients to be similar to our patients defined as lucid. Their study included a diversity of prostheses, of which 46% (89/192) were HA. Some of those were uncemented, but the number is not stated in the paper. The dislocation rate for this mixture of prostheses was 8%, the same as for the lucid patients in our study. This may be a little high, considering that almost half of the prostheses were HA, which usually has a lower dislocation rate compared to THA. The failure rate after internal fixation was similar to ours. The mortality was almost identical at one year, but at two years it was 21% compared to 14% for our lucid patients. This difference is not statistically significant (Chi² p=0.19), but may raise some suspicion that their patients were somewhat unhealthier than our lucid patients, despite a
lower average age, 81.5 versus 83.6 years. It is difficult to compare the functional outcomes since they did not use the same evaluation methods as we did. However, at four months 61% in their internal fixation group reported pain at walking, which is similar to 52% at three months in our study. In their arthroplasty group pain was noted in 34% at four months, which is higher than the 6% found by us. This could be explained by the use of HA in their study. Unfortunately, THA and HA were not reported separately.

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<td></td>
<td>Lucid</td>
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<tr>
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<td>Age (mean)</td>
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<td>Failure (%)</td>
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<td>- arthroplasty</td>
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<td>Dislocations arthrop.</td>
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<td>Pain at 3-4 mo (%)</td>
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<tr>
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<td>- arthroplasty</td>
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Table 10. Comparison between our results and those by Rogmark et al. (2002). In this table, failure after internal fixation was defined as early redisplacement, non-union, segmental collapse or deep infection. In the arthroplasty group, failure was defined as two or more dislocations, loosening, deep infection or fractures adjacent to the prosthesis. In both studies, failures and pain were common after internal fixation. A higher percentage had pain after arthroplasty in the study by Rogmark et al.

Our studies do not address to what extent HA is a good option. According to the literature, uncemented stems should be avoided. A cemented HA does not offer good long-term results compared to THA. For patients with long life expectancy, THA is recommended. For the patients in the "gray zone", e.g. senile but active patients or those with medium anesthetic risks, we should have a generous attitude toward arthroplasty. We must not forget that almost all patients that have been successfully operated on with an arthroplasty (THA or cemented HA) have little or no pain. So far, only one prospective study has compared internal fixation and arthroplasty (HA) for demented patients (van Dortmont et al. 2000). The functional outcome was bad without difference between the groups. For patients with low functional capacity prior to the fracture, small changes and differences are to be expected in a randomized study. Overall, the prevalence and magnitude of pain may be the most
important outcome measure which, unfortunately, was not assessed in their study. Our study showed that half of the mentally impaired patients who were operated on with internal fixation had pain at three months.

A major reoperation, such as a secondary THA after a failed osteosynthesis, means another life-threatening event for the patient and a new rehabilitation period in a deteriorated nutritional state, at double the cost for the hospital and with a major impact on the patient’s life in general and that on the relatives. It is obvious that we should strive to solve the problem once and for all with one single operation.

When looking for the optimal treatment, the failure of one method does not automatically mean that the other method would have been successful. We may have to accept that for some patients there may not be any successful surgical treatment. For those patients a displaced femoral fracture will always be “The Unsolved Fracture”.

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CONCLUSIONS

The functional outcome is better after THA than after internal fixation.

Pain is less frequent after THA than after internal fixation.

Weight loss during the first year after a displaced femoral neck fracture is more pronounced after internal fixation than after THA.

Dislocation is the most common local complication after THA and more so among mentally impaired patients. In most cases it only occurs once or twice early in the postoperative period.

The cup position may not have an obvious correlation to dislocation after THA. This indicates the involvement of other contributing factors for dislocation.

The quality of reduction before internal fixation is the most important factor for fracture healing, whereas the quality of the screw positioning appears less important.

Heterotopic bone formation is rare following internal fixation but common after THA. Severe clinical symptoms are very rare.

Nutritional intervention showed no positive effects.

There is no major difference between internal fixation and THA in hospital costs if reoperations are included. For lucid patients, THA may even be cheaper than internal fixation.

The total hospital costs double when reoperations are performed.

There is no difference in the increase of municipality costs after internal fixation and THA.

Mentally preserved patients, 75 years or older, should be treated with an arthroplasty after a displaced femoral neck fracture.

For other patients, closed reduction and internal fixation is the treatment of choice. When in doubt, an arthroplasty should be generously considered.
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