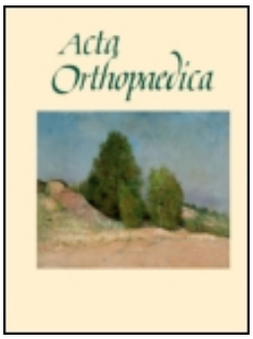

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Outcome after treatment of complications of Gamma nailing

A prospective study of 554 trochanteric fractures

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Background **A high reoperation rate has been the main reason why Gamma nailing should not be recommended for routine use in the treatment of trochanteric fractures. We compared the outcome after reoperation to the outcome after primary surgery with Gamma nailing.**

Methods **In a series of 554 patients, we compared the outcome in 52 patients who were reoperated with that in 502 patients who had no reoperations. We assessed mortality, pain, walking ability and habitat at follow-up.**

Results **The most common reason for reoperation was new fracture around the implant (17), local pain after healed fracture (11), nonunion (9) and cut-out (8). A second reoperation was required in 9/52 patients. The mortality was significantly lower in the reoperated cases at 30 days and at 1–5 years, but not at 120 days, and there were no significant differences in the other outcome parameters.**

Interpretation **Reoperation did not lead to a worse clinical outcome, nor to increased mortality.**

The Gamma nail has been widely used for the treatment of trochanteric fractures. However, a complication rate of 3–12%, including perioperative fractures around the implant, have led to the recommendation that the Gamma nail should not be used routinely (Parker and Pryor 1996, Parker and Handoll 2005). However, little is known about the outcome after revision surgery for complications of the Gamma nail. We assessed the outcome in patients who had revision surgery because of complications after Gamma nailing for a trochanteric fracture. The outcome was compared to that in patients who did not have any complications.

Patients and methods

We studied 52 patients who had a reoperation after having been treated with a Gamma nail for a trochanteric fracture (reoperated cases). The outcome in these patients was compared to that in 502 fracture cases who were also treated with Gamma nailing but were not reoperated, and who did not have secondary surgery during the study period.

The 554 patients were treated at our hospital between September 1, 1998 and August 31, 2003. During this 5-year period, all hip fracture patients were included in a prospective observational study in which we recorded data pertaining to living conditions, walking ability, and general health as measured by ASA scores (American Society of Anesthesiologists) (Michel et al. 2002), as well as information about the surgery. We recorded all reoperations until August 31, 2004 and all deaths until December 31, 2004. Thus, data for survival studies were censored on December 31, 2004.

A proportion of patients did not attend follow-up appointments, mostly due to poor health conditions. We were able to examine 38 of 52 reoperated cases after a mean of 1 (0.3–3) year and 347 of 502 cases who were not reoperated after 0.9 (0.1–4.1) years. All hospital records, including those

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Table 1. Background information at index operation showing age at surgery and proportion of patients in each category

	Cases reoperated (52) Age: 78 (43–97) [a]			Cases not reoperated (502) Age: 81 (33–103) [a]		
	n	Proportion	95% CI	n	Proportion	95% CI
Sex						
Male	22	0.42	0.29–0.56	146	0.29	0.25–0.33
Female	30	0.58	0.44–0.71	356	0.71	0.67–0.75
Habitat						
Own home [b]	45	0.87	0.77–0.96	320	0.64	0.60–0.68
Sheltered living**	2	0.04	0.00–0.09	79	0.16	0.13–0.19
Nursing home	5	0.10	0.02–0.18	98	0.20	0.16–0.23
Other	0	0.00	0.00–0.00	5	0.01	0.00–0.02
Walking						
Outdoors alone [b]	38	0.73	0.61–0.85	253	0.50	0.46–0.55
Outdoors with company [b]	2	0.04	0.00–0.09	61	0.12	0.09–0.15
Indoor dweller	12	0.23	0.12–0.35	188	0.37	0.33–0.42
ASA						
Healthy	1	0.02	0.00–0.06	16	0.03	0.02–0.05
Asymptomatic disease	27	0.56	0.42–0.69	242	0.48	0.44–0.53
Symptomatic disease	22	0.42	0.29–0.56	222	0.44	0.40–0.49
Serious disease	0	0.00	0.00–0.00	22	0.04	0.03–0.06

[a] Mean (range). T-test (unequal variances assumed) p = 0.07.
[b] Significant difference as evidenced by nonoverlapping confidence intervals.

Table 2. Type of surgery and indication for primary surgery in cases that were not reoperated (n = 502) and in reoperated cases (n = 52)

	SG without locking screw	SG with locking screw	LG without locking screw	LG with locking screw
Cases not reoperated				
Stable trochanteric (n = 254)	232	20	1	1
Unstable trochanteric (n = 248)	28	196	6	18
Cases reoperated				
Stable trochanteric (n = 18)	16	2	0	0
Unstable trochanteric (n = 34)	11	21	2	0

SG: short Gamma nail. LG: long Gamma nail

of neighboring hospitals, were inspected in order to ensure that no reoperation had been missed by the investigators, even though the patient did not attend follow-up.

The fractures were classified as stable or unstable according to the classification of Evans, as modified by Jensen (Jensen and Michaelsen 1975). Fractures with two fragments were considered stable, whereas fractures with more than two fragments or a reverse oblique fracture line were considered unstable. Stable fractures were mostly treated with a short nail with no distal locking screw, whereas unstable fractures were treated with a short nail with distal locking screw (Table 2).

Osteosynthesis was performed on a fracture table in standard fashion. The diaphysis was overreamed by 2 mm before the insertion of an 11-mm/135-degree nail. All nails were inserted by force of hand only; the use of a hammer was prohibited. All patients had oral antibiotics and also prophylaxis against thromboembolism with a low molecular weight heparin.

The characteristics of patients who were reoperated or not reoperated are shown in Table 1.

Table 3. Reason for reoperation in reoperated cases and type of surgery including revisions

Reason for reoperation	Type of reoperation	Second reoperation	Third reoperation	Fourth reoperation
Fracture disocation (1)	Hemiarthroplasty (1)			
Cut-out (8)	Removal of implant (1)			
	Hemiarthroplasty (4)	Drainage (1)		
	Reosteosynthesis (3)			
New fracture around the implant (17)	Reosteosynthesis (17)	Removal of implant (1)		
		Reosteosynthesis (1)	Hemiarthroplasty	
Nonunion (9)	Hemiarthroplasty (8)	Reduction of dislocation (1)	Reduction of dislocation	D [a]
	Total hip replacement (1)			
Necrosis of femoral head (1)	Removal of implant (1)	Hemiarthroplasty (1)		
Local pain, healed fracture (11)	Removal of implant (11)	Hemiarthroplasty (2)		
Infection (2)	Drainage (2)	Drainage (1)		
		Girdlestone (1)		
Hematoma (2)	Drainage (2)			
Unsatisfactory primary osteosynthesis (1)	Reosteosynthesis (1)			
	52	9	2	1

[a] Deepening of acetabulum

Statistics

For comparing rates and proportions, the chi-squared test was used. The t-test of independent samples was used for comparing means. A p-value of less the 0.05 was considered significant. For comparison of proportions in the two groups, the 95% confidence interval for proportions is given. When determining the confidence intervals, the standard error (SE) of a proportion was calculated using the formula $\sqrt{p(1-p)/n}$ where p is the proportion and n is the number of persons at risk. The 95% confidence interval was then calculated by adding and subtracting 1.96 × SE (Altman 1991).

Data were entered into a Cox regression model using SPSS v.12 software. In this analysis, we entered presumed risk factors in order to evaluate the importance of revision as a possible predictor of increased mortality.

Results

The revision rate in the entire material was 52/554 (9.4%) (Table 1). The fracture was classified as stable in 18/52 (0.3) of reoperated cases and in 254/502 (0.5) in the cases that were not reoperated (p = 0.03; chi-square) (Table 2). The most common reason for reoperation in the 52 reoperated cases was a postoperative fracture around the implant (17), local pain after healed fracture (11), nonunion (9) and cut-out (8) (Table 3). Of the 52 reoperated cases, 9 had a second reoperation (17%). As compared to the revision rate in the entire material, this result is not significant (p = 0.07; chi-squared test).

Comparing the cases who were reoperated and those who were not, there was no difference in the proportion of patients living in their own home after surgery, or in the proportion of patients who had retained their ability to be independent outdoor walkers. The proportion of patients experiencing no or slight hip pain was equal in the two groups (Table 4).

Mortality at 30 days and at 1–5 years was significantly lower in the reoperated patients than in the patients who were not reoperated, but not the mortality measured at 4 months (Tables 5 and 6; Figure). Cox regression analysis revealed that revision after primary surgery and female sex reduces the risk of mortality, whereas increasing age, ASA group 3–4, and living away from one's own home increased the risk of dying in this model.

Table 4. Number and proportion of patients who resided in their own home and were independent walkers at surgery and at the follow-up examination. Presented as proportions with 95% confidence interval of proportions

	At FU/ at surgery	Proportion	95% CI
Reoperated (38)			
Own home	22/27	0.81	0.67–0.96
Walking outdoors alone	14/14	1.00	1.00–1.00
Slight or no pain in the hip	30/38	0.79	0.66–0.92
Not reoperated (347)			
Own home	206/320	0.64	0.59–0.70
Walking outdoors alone	139/253	0.55	0.49–0.61
Slight or no pain in the hip	271/347	0.78	0.74–0.82

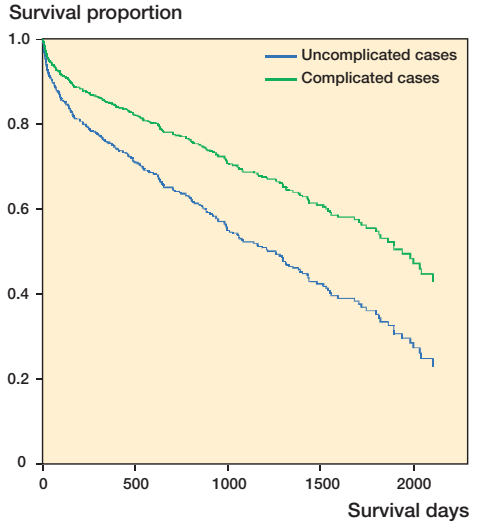
Table 5. Estimated change in risk of mortality. Risk below 1 indicates less risk. All risks are significant, as confidence interval does not encompass 1

	Risk	95% CI
Age (per year)	1.05	1.03–1.07
Reoperation	0.58	0.35–0.96
ASA 3–4	2.14	1.68–2.73
Female	0.65	0.51–0.83
Habitat [a]		
Sheltered living	1.46	1.06–2.03
Nursing home	2.25	1.71–2.97
Other	2.45	1.27–4.70

[a] Own home is reference

Table 6. Mortality in the cases that were reoperated and not reoperated, and p-values for the difference between the groups as determined by chi-square test

	Reoperated (n = 52)		Not reoperated (n = 502)		
	n	Percent	n	Percent	P-value
30 days	1	2	52	10	0.05
120 days	5	10	93	19	0.11
1 year	8	15	147	29	0.03
2 years	13	25	199	40	0.04
3 years	17	33	236	47	0.05
4 years	17	33	259	52	0.01
5 years	18	35	272	54	0.01



Survival of cases that were reoperated and not reoperated, adjusted for age, sex, ASA class and habitat.

Discussion

Several authors have reported a lower rate of complications using a screw-plate system, which is currently considered to be the gold standard, compared to a Gamma nail (Parker and Pryor 1996, Osnes et al. 2001, Parker and Handoll 2005). Also, a higher rate of fracture around the implant has been cited as the main reason why the Gamma nail should not be used for routine treatment of trochanteric fractures. However, the goal of the treatment is to assist the patient in regaining the best possible function and well-being, while keeping cost and suffering at the lowest possible level. It is therefore important to know how reoperations affect the ultimate outcome in patients. In this study, we attempted to determine whether revision of the primary Gamma nailing is detrimental to the final outcome.

The revision rate was 52/554 (9%) which is somewhat higher than in previously published reports (Parker and Pryor 1996, Adams et al. 2001, Miedel et al. 2005). The reason for this is at least in part due to the fact that we have chosen to include patients who had removal of hardware (11/554) after the fracture had healed. Although removal of hardware is undoubtedly a reoperation, it might not be considered a complication. The threshold of recommending hardware removal may vary between surgeons, as well as between institutions. Even so, using an implant that requires a high rate of removal

after fracture healing would not be beneficial to the patient—nor to the health care system—unless the implant has advantages that outweigh this. In our study, 2 of the 11 patients in the group of patients who had elective hardware removal had a second reoperation, both with hemiarthroplasty. One sustained a new fracture after a fall and the other patient was diagnosed with a nonunion 2 weeks after hardware removal. This patient might have been more correctly classified among the nonunions. This rate of complication after hardware removal is similar to what was found in a previous report (Hesse and Gächter 2004), in which 4 of 30 patients who had their nail removed sustained a new proximal femoral fracture.

Clinical outcome after surgery, as assessed by calculating the proportion of patients who lived in their own home both at the time of surgery and at follow-up, did not reveal any differences between the patients who were reoperated and those who were not. Likewise, there was no difference in the proportion of patients who retained their ability to be independent outdoor walkers after surgery; nor was there any difference in the pain score. These results must be interpreted with caution, as the proportion of patients returning for follow-up was only 70%. However, the results lend some support to the notion that a higher rate of reoperations among the reoperated cases did not result in a worse outcome. This is in accordance with findings in reports investigating the impact of revision surgery after osteosynthesis for intracapsular hip fracture, in which the authors did not find any increase in morbidity or mortality after revision surgery (Palmer et al. 2000).

Mortality expressed as the proportion of patients who died within 30 days, 4 months, or 1–5 years, was lower in the reoperated cases—which does not imply a worse outcome after reoperation, a finding which is also supported by previous studies (Sipila et al. 2004). In the Cox regression model, it appears that revision surgery reduced the risk of mortality even after correction for sex, age, habitat, and ASA group. In any case, it seems that revision surgery does not represent a major setback to the health of the patients.

Even though the rate of complications is important in evaluating an implant, the outcome after revision surgery should also be taken into account. Any complication or reoperation is an undesirable event, both in terms of individual suffering and in the cost to society. It appears, however, that correctional surgery after complications with the use of the Gamma nail does not significantly worsen outcome.

Contributions of authors

KB: designed the study, collected and analyzeded the data and wrote the manuscript in collaboration with OR. OR: assisted in analyzing and preparing data for publication and revised the manuscript.

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