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Implant-Related Complications and Mortality After Use of Short or Long Gamma Nail for Intertrochanteric and Subtrochanteric Fractures

A Prospective Study with Minimum 13-Year Follow-up

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Investigation performed at Østfold Hospital Trust, Norway

Background: The purpose of this study was to evaluate the rates of implant-related complications and mortality after treatment of an intertrochanteric or subtrochanteric fracture with a short or long Gamma nail.

Methods: Between September 1998 and August 2003, 644 patients at 2 centers treated with a long or short Gamma nail for a hip fracture were prospectively enrolled in this study. These patients were followed until they reached 1 of the study end points, which included death, a reoperation directly related to the Gamma nail, or the end date of the study.

Results: The average age (and standard deviation) of the patients included in the study was 81.3 ± 8.6 years at the time of the operation, and 28.3% of the patients were male. The rate of implant-related complications was 9.9%. The most common complications included peri-implant fracture (4.2%), proximal lateral thigh discomfort requiring extraction of the implant (2.0%), and lag-screw cutout (1.1%). Interestingly, more than half (56%) of the 27 peri-implant fractures occurred >1.5 years after the index operation. The median time from the operation to death was 2.9 years (range, 0 to 17.1 years). The 30-day mortality rate after treatment was 9.5%. Patients with American Society of Anesthesiologists (ASA) class-3 or 4 physical status had a significantly higher risk of mortality than ASA class-1 patients.

Conclusions: Gamma nails are effective in the treatment of intertrochanteric and subtrochanteric fractures. However, 9.8% of patients had complications requiring additional surgery. The most common serious complications include peri-implant fracture and lag-screw cutout. Several peri-implant fractures occurred long after the index procedure. Patients had a high rate of mortality (27%) after 1 year, and higher preoperative ASA class was found to be a predictor of increased risk of mortality. Therefore, clinicians must carefully consider patients' preoperative comorbidities when counselling patients on the risks of surgery.

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

Hip fractures place a large strain on health-care systems and are associated with a substantial rate of mortality in the elderly population[1]. Surgical management of hip fractures is usually recommended unless the patient is unfit for surgery[2]. Nevertheless, patients with hip fracture often have many comorbid conditions that place them at elevated risk for postoperative complications and even death. Higher American Society of Anesthesiologists (ASA) physical status scores have been shown to be a predictor of an increased risk of mortality after hip fracture surgery[3].

The Gamma nail was introduced into clinical practice in the late 1980s for the treatment of hip fractures. Use of short and long Gamma nails has been well established in the literature[4,5]. One of the key features of Gamma nails is that the construct allows for immediate weight-bearing postoperatively[6]. Early weight-bearing is key for elderly patients as it helps to prevent secondary medical complications such as pneumonia and ulcers as well as loss of patient independence[7]. Furthermore, the Gamma nail allows a minimally invasive exposure relative to other constructs such as the sliding hip

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screw, although meta-analyses have not shown any significant difference in outcomes between these 2 techniques[8].

A number of relatively common complications, including trochanteric pain, lag-screw cutout, malunion, nonunion, and infection, can occur after use of Gamma nails[9]. Furthermore, patients with a Gamma nail are at higher risk for femoral shaft fractures with future falls[10,11]. The current study builds on previous studies of the complications and mortality associated with the use of Gamma nails for the treatment of hip fractures[12] by assessing these outcomes after a longer follow-up time (minimum, 13 years) and in a larger sample of patients.

The purpose of this study was to determine the long-term rates of implant-related complications and mortality associated with the treatment of hip fractures with either a short or a long Gamma nail at 2 institutions. A secondary goal was to determine whether there was a significant difference in rates of implant-related complications between short and long Gamma nails or between Gamma nails with and those without a distal locking screw. Our hypotheses were that patients treated with a Gamma nail would have a relatively low complication rate but, despite this, high 30-day and 1-year postoperative mortality rates as a result of older age and higher rates of comorbidities in this population. We also anticipated that there would be no significant difference in complication rates between short and long Gamma nails or between nails implanted with and those implanted without a distal locking screw.

Materials and Methods

All patients at 2 centers in Norway (Fredrikstad and Moss sites of the Østfold Hospital Trust) who were living in Østfold county and were treated with a long or short Gamma nail for a proximal femoral fracture between September 1998 and August 2003 were prospectively enrolled in this study. The research question as well as the primary and secondary outcomes were all formulated a priori. We prospectively recorded data pertaining to living conditions, walking ability, and general health as measured with ASA scores as well as information about the surgery. The primary outcomes were mortality and a reoperation due to (1) fracture around or distal to the implant, (2) pain related to the implant, (3) implant failure, (4) nonunion or malunion, (5) cutout, or (6) infection. Patient age was not a criterion for inclusion in this study. The decision to use a long or short Gamma nail was based on surgeon discretion. All short Gamma nails were inserted with a distal locking screw except for those used for stable 2-part intertrochanteric fractures, for which the decision to use a distal locking screw was left to surgeon discretion. The long Gamma nails used to treat subtrochanteric fractures always included a distal locking screw, but the surgeons decided whether to use a distal locking screw when treating intertrochanteric fractures with a long Gamma nail. Patients with a pathologic hip fracture, those with a high-energy mechanism of injury such as a motor-vehicle accident or a fall from a height, and those with fractures in >1 long bone in the lower extremities were also excluded. Patients were followed until they reached 1 of the study end points, which included death, a reoperation directly related to the Gamma nail, or the end date of the study (August 2016). Electronic health records were used to determine the patients' status as of August 2016, including whether they had died, had any perioperative or postoperative implant-related complication, had a fracture of the ipsilateral femur, and/or had a reoperation. We considered only major implant-related complications that involved the Gamma nail—i.e., those requiring a reoperation or causing substantial morbidity. Malunion was defined as healing of the fracture in a non-anatomic position requiring a reoperation. Demographic information as well as the details of the operations, such as the type of Gamma nail, duration of the operation, and estimated blood loss, were also documented. All participants gave informed consent, and the study was approved by an institutional review board.

Statistical Analysis

All statistical analysis was performed using Stata, general purpose statistical software, and Microsoft Excel. Data are presented either as the mean and standard deviation or as the median and range. Statistical comparison, when relevant, was performed using a Fisher exact test for categorical data. The 2-sample t test was used to determine whether 2 groups differed with respect to the means of continuous dependent variables. A p value of <0.05 was considered significant. A Cox

TABLE I Demographic Characteristics

Characteristic	No. (%) of Patients*
Males	182 (28.3%)
Age *(yr)*	81.3 ± 8.6 (68-101)
Follow-up *(yr)*	3.5 ± 3.7 (0-17.1)
Right femur	341 (53.0%)
Operation	
Short Gamma nail	558 (86.6%)
With distal locking screw	297 (46.1%)
Without distal locking screw	261 (40.5%)
Long Gamma nail	86 (13.4%)
With distal locking screw	72 (11.2%)
Without distal locking screw	14 (2.2%)
Type of fracture	
2-part intertrochanteric	285 (44.3%)
Multipart intertrochanteric	301 (46.7%)
Subtrochanteric	58 (9.0%)
ASA class	
1	21 (3.3%)
2	307 (47.7%)
3	289 (44.9%)
4	27 (4.2%)

*With the exception of age and follow-up, which are given as the mean and standard deviation with the range in parentheses.

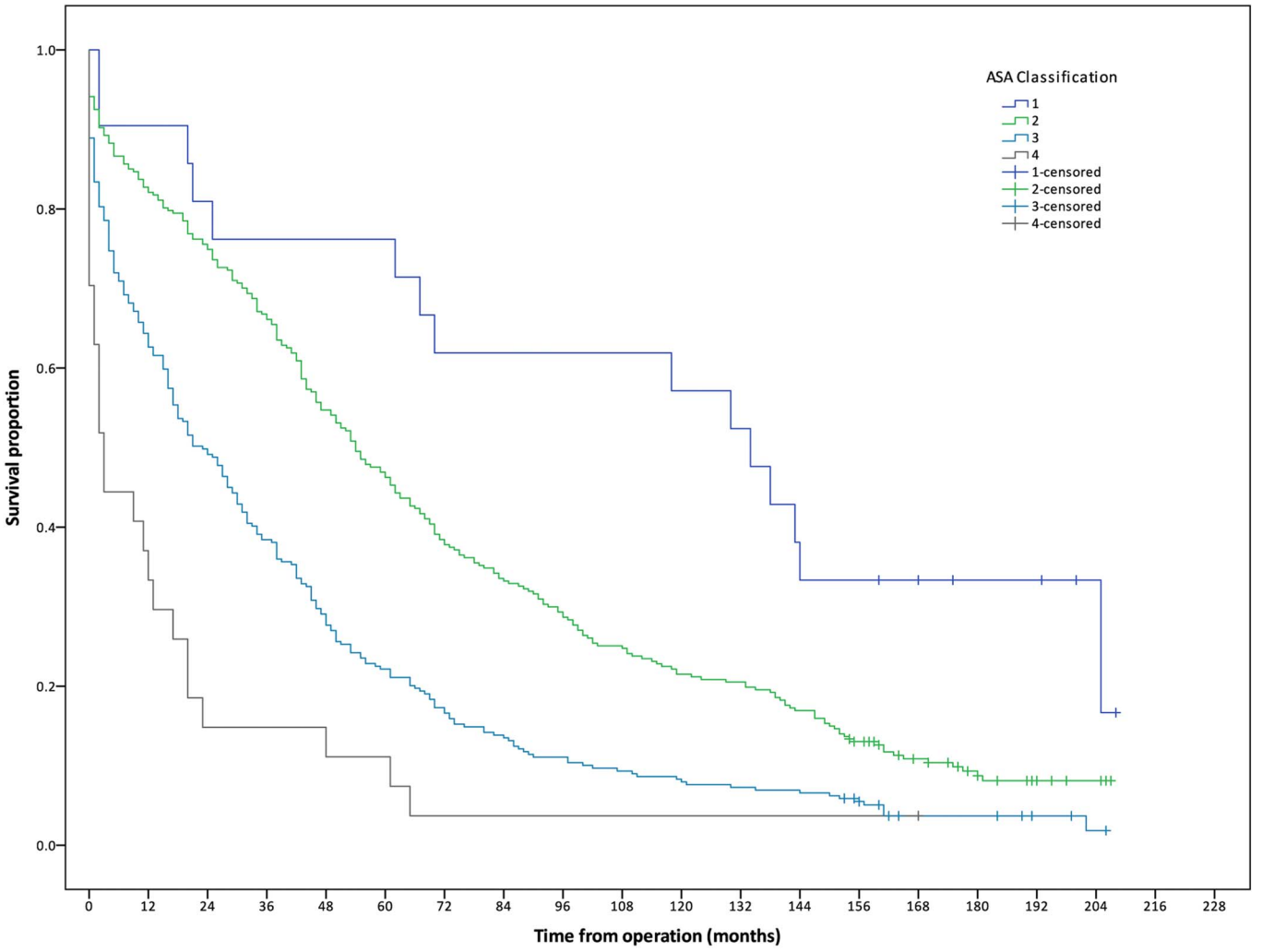

Fig. 1

Survivorship curves after treatment with a Gamma nail for each ASA class.

regression analysis was used to determine the effect of ASA class on patient mortality. All statistical analysis was performed in consultation with a statistician.

Results

The study included 644 patients, 558 (86.6%) treated with a short Gamma nail and 86 (13.4%) treated with a long Gamma nail. Of the 558 short Gamma nails, 432 were first-generation and 126 were second-generation. Only 1 (0.2%) of the 644 patients was lost to follow-up, having moved out of the county in March 2005, and we were unable to determine the long-term outcome for this patient. The follow-up duration was a minimum of 13 years and a mean of 3.5 ± 3.7 years. The average age was 81.3 ± 8.6 years at the time of the operation, and 28.3% of the patients were male. Demographic data on the included patients are summarized in Table I.

At the study end date of August 2016, only 48 (7.5%) of the 644 patients were still alive. The median time from the operation to death was 2.9 years (range, 0 to 17.1 years). The overall mortality rate after treatment with a Gamma nail was 9.5% after 30 days and 27% after 1 year. Figure 1 shows the postoperative survivorship curves according to ASA class. The hazard ratio (HR) for mortality relative to patients in ASA class 1 was not significantly higher for those in ASA class 2 (HR = 1.7; 95% confidence interval [CI] = 0.98 to 2.8; p = 0.06), but was significantly higher for patients in ASA class 3 (HR = 2.4; 95% CI = 1.4 to 4.0; p = 0.002) and ASA class 4 (HR = 3.7; 95% CI = 1.9 to 7.1; p < 0.001).

The overall rate of surgical implant-related complications was 9.9%. The most common complications included peri-implant fracture (4.2%), proximal lateral thigh discomfort requiring extraction of the implant (2.0%), and lag-screw cutout (1.1%). A peri-implant fracture was defined as a new fracture around or distal to the Gamma nail. The rates of specific complications are shown in Table II. Three (0.5%) of the patients had complications during the operation, including 1 intraoperative proximal femoral fracture, 1 case in which the distal locking screw was not correctly inserted into the nail, and 1 death during the surgery.

TABLE II Complications

Complication	No. (%) of Patients
Proximal lateral femoral discomfort	13 (2.0%)
Periprosthetic femoral shaft fracture	12 (1.9%)
Periprosthetic distal femoral fracture	12 (1.9%)
Lag-screw cutout	7 (1.1%)
Nonunion	6 (0.9%)
Deep surgical site infection	4 (0.6%)
Periprosthetic subtrochanteric fracture	3 (0.5%)
Lag-screw penetration	2 (0.3%)
Malunion	1 (0.2%)
Broken nail	1 (0.2%)
Intraoperative fracture	1 (0.2%)
Missing distal locking screw	1 (0.2%)
Intraoperative death	1 (0.2%)
Total	64 (9.9%)

No significant difference ($p = 0.56$) was found in the overall rate of complications between patients who were treated with a short Gamma nail (9.7%) and those treated with a long Gamma nail (11.6%). On average, use of short Gamma nails required significantly less operative ($p < 0.001$) and fluoroscopy ($p < 0.001$) time and was associated with significantly less blood loss ($p < 0.001$) in comparison with long Gamma nails (Table III). There was no significant difference in the length of the hospital stay between patients treated with a short Gamma nail and those treated with a long Gamma nail ($p = 0.21$).

There was no significant difference in the complication rate between short Gamma nails with (9.1%) and those without (10.7%) a distal locking screw ($p = 0.57$) or between long Gamma nails with (9.7%) and those without (14.3%) a distal locking screw ($p = 0.64$). There was also no significant difference in the complication rate between 2-part intertrochanteric fractures and multifragment intertrochanteric fractures ($p = 0.16$) or subtrochanteric fractures ($p = 0.20$).

Twenty-seven patients (4.2%) had a peri-implant femoral fracture postoperatively. Three of these fractures (0.5% of all cases) were subtrochanteric, 12 (1.9%) were in the femoral shaft, and 12 (1.9%) were in the distal part of the femur. The median time from the operation to the refracture was 2.4 years (range, 0.1 to 15.6 years). Ten peri-implant fractures (1.6%) occurred within 3 months of the Gamma nail surgery. Only 3 peri-implant fractures were related to a long Gamma nail, and those fractures all occurred in the supracondylar area close to the distal part of the nail. There was no significant difference ($p = 0.77$) in the rate of peri-implant fractures between short Gamma nails (4.1%) and long Gamma nails (4.6%). Figure 2 demonstrates that the rate of peri-implant fracture was highest in the first year after the operation. However, more than half (56%) of the 27 peri-implant fractures occurred >1.5 years after the index operation.

Of the 644 patients in this study, 63 (9.8%) required additional surgery on the ipsilateral femur (Table IV), most commonly conversion of the Gamma nail to a long Gamma nail, hemiarthroplasty, or extraction of the Gamma nail. The median time from the primary operation to the reoperation was 0.8 year (0.0 to 15.6 years).

Discussion

The key findings in this study were that patients treated with a short or long Gamma nail had an overall rate of major implant-related complications of 9.9% and a 30-day mortality rate of 9.5%. A higher preoperative ASA class was found to be a significant predictor of mortality.

This study demonstrated a 4.2% rate of peri-implant fractures. Interestingly, the authors of a similar study reported only a 0.6% rate of postoperative femoral shaft fractures after treatment with a Gamma nail[13]. We observed a low rate of lag-screw cutout (1.1%) in this study, which is consistent with the 1.85% rate reported in the similar study of complication rates after use of Gamma nails[13]. Our rate of surgical site infection (0.6%) was quite low as well. These findings are relevant given the high morbidity and mortality rates associated with refractures and revision surgery in these elderly patients.

The reason for the high 30-day and 1-year mortality rates found in this study is likely multifactorial. As reported in a study of the Norwegian Hip Fracture Register[14], hip fractures are associated with a high likelihood of mortality not necessarily linked to Gamma nail surgery. Roche et al. found that 9% of patients with a hip fracture developed a postoperative chest

TABLE III Comparison of Values Between Short and Long Gamma Nail Groups

	Short Gamma Nail	Long Gamma Nail	P Value
Overall complication rate *(%)*	9.7	11.6	0.56
Estimated blood loss* *(mL)*	277.8 ± 200.8	558.7 ± 538.2	<0.001
Operative time* *(min)*	62.5 ± 25.5	144.3 ± 42.9	<0.001
Fluoroscopy time* *(min)*	3.3 ± 2.2	6.4 ± 5.0	<0.001
Length of hospital stay* *(days)*	4.2 ± 3.7	4.8 ± 4.3	0.21

*The values are given as the mean and standard deviation.

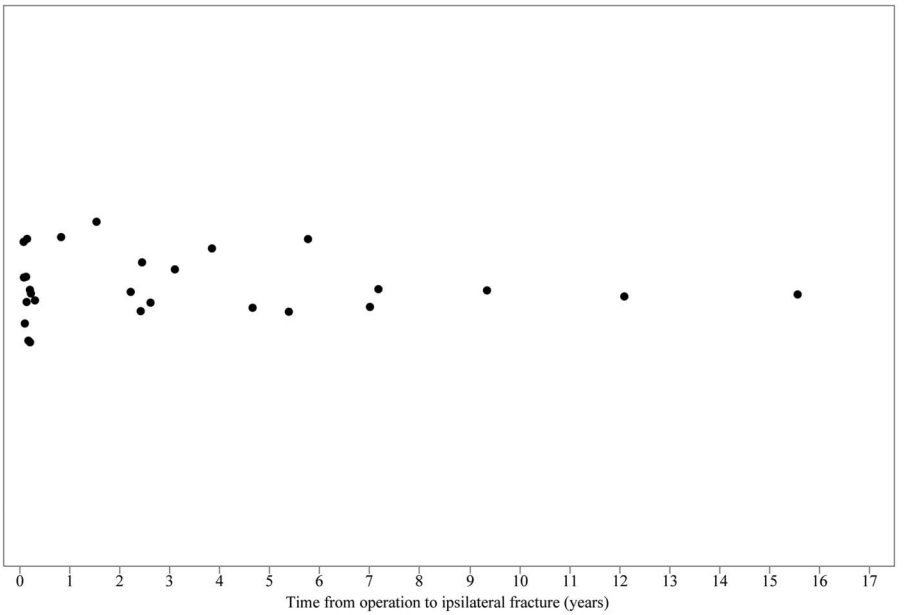

Fig. 2
Jitter plot displaying when ipsilateral fractures of the femur occurred after treatment with a Gamma nail.

infection and 5% developed heart failure, which were associated with 43% and 65% 30-day mortality rates, respectively[15]. Bjorgul et al. determined that ASA class could be used as a comorbidity index in hip fracture surgery and that the preoperative ASA class predicted long-term mortality after hip fracture[3]. This finding is consistent with the results in our study, which also showed a higher ASA class to increase the risk of mortality after treatment with a Gamma nail. Although one of the major goals of operative treatment of hip fractures is to allow early mobilization, other medical factors may prevent early mobilization despite successful fracture fixation. It has been established that decreased mobility after a hip fracture is strongly correlated with mortality rates[15]. The preliminary results of a randomized controlled trial that is currently in progress suggest that accelerating surgery (i.e., performing it <6 hours from the diagnosis) may improve the outcomes of hip fracture treatment[16].

TABLE IV Additional Operations Performed on Femur Previously Treated with Long or Short Gamma Nail

Additional Operation	No. (%) of Patients
Conversion to long Gamma nail	13 (2.0%)
Hemiarthroplasty	13 (2.0%)
Extraction of entire Gamma nail	12 (1.9%)
Locking compression plate	7 (1.1%)
Dynamic hip screw	4 (0.6%)
Operation due to surgical site infection	4 (0.6%)
Retrograde nail	3 (0.5%)
Total hip arthroplasty	2 (0.3%)
Extraction of part of Gamma nail	2 (0.3%)
Revision of distal locking screw	1 (0.2%)
AO angular blade plate	1 (0.2%)
Cerclage wiring	1 (0.2%)
Total	63 (9.8%)

As mentioned earlier, only 10 (37%) of the 27 peri-implant fractures in our study occurred within the first 3 months after the surgery. Thus, a higher percentage of peri-implant fractures occurred after the primary fracture had healed and the implant was still in place. Peri-implant fractures continued to occur more than a decade after the initial operation, highlighting the probability that, in most studies, the follow-up time is not adequate to obtain a true appreciation of the lifetime risk of peri-implant fractures after Gamma nailing. This is likely true for other implant types as well.

Interestingly, we observed no significant difference in the rates of major implant-related complications or of peri-implant fractures between patients treated with a short Gamma nail and those treated with a long nail. This observation is consistent with previous findings in the literature[17]. However, long Gamma nails were associated with significantly higher blood loss and operative time compared with short nails. It should be noted that a long Gamma nail is recommended when there is subtrochanteric extension of the fracture line or an unstable intertrochanteric fracture. Either a short or long Gamma nail can be used for stable intertrochanteric fractures, with comparable outcomes, but short Gamma nails may be more cost-effective in those situations[18].

There is some debate in the literature regarding the need for distal locking screws in cephalomedullary nails. Earlier biomechanical studies have suggested that distal locking of

the Gamma nail is most likely unnecessary for stable intertrochanteric fractures[19,20]. Our results support this as we observed no significant difference in the rate of implant-related complications between Gamma nails with and those without distal locking. A clinical study of cephalomedullary nails used to treat stable intertrochanteric fractures also demonstrated no difference between the rates of complications based on whether a distal locking screw had been used[17]. These results probably do not hold true for unstable fracture patterns. Biomechanical and cadaveric studies suggest that the additional rotational stability provided through distal locking screws is necessary for such patterns[21].

Although we found a 9.9% rate of major complications associated with the Gamma implant, there are several factors that may cause an individual institution's or surgeon's complication rate to vary. These include technical factors, such as proper positioning of the lag screw in the femoral head to reduce the risk of cutout[22], and the learning curve of the surgeon and/or surgical staff. Furthermore, it known that infection rates may vary significantly between institutions[23].

The strengths of this study include the large sample size; long follow-up time (minimum, 13 years); and the fact that, despite this long follow-up time, only 1 patient was lost to follow-up. However, the study is not without limitations. Care must be taken in interpreting the comparative results given incomplete control of confounding factors. For instance, the long Gamma nails were more likely than the short nails to be used to treat more unstable fracture patterns and subtrochanteric fractures, which could have influenced the outcomes. A patient's condition prior to surgery may also affect the surgeon's decision to use a long or short Gamma nail. In addition, we grouped the injuries into 2-part intertrochanteric fractures, multifragment intertrochanteric fractures, or subtrochanteric fractures. However, ideally, these groups would have been subdivided according to the specific fracture patterns (i.e., the AO classifications). Finally, despite the large sample size in this study, only bivariate analysis was performed because of the low event rate.

When considering the generalizability of these results, it should be remembered that different models or designs of cephalomedullary nails are associated with different rates of complications and reoperations[24]. In addition, the patients included in this study were disproportionately female (71.7%), and most patients (86.6%) were treated with a short Gamma nail.

Future studies should focus on continuing to develop strategies to reduce the rates of postoperative complications after treatment of hip fractures with a Gamma nail. Our findings suggest that intramedullary nails may do something fundamental to the strength of long bones to increase rates of femoral shaft fractures even after the original injury is well healed. It is unclear if other implants such as sliding hip screws or femoral stems used in hip arthroplasty have similar long-term effects. Further understanding of why intramedullary nails lead to increased fracture rates may be the first step in developing strategies to reduce the rate of this serious complication.

In conclusion, Gamma nails are effective in the treatment of intertrochanteric and subtrochanteric fractures. However, 9.8% of patients have complications that require additional surgery. The most common complications include peri-implant fracture, lateral thigh pain, and lag-screw cutout. Several peri-implant fractures occurred long after the index procedure. This highlights the need for long follow-up times in similar studies; otherwise, rates of peri-implant fractures are likely to be underreported. The mortality rate was high (27%) at 1 year, and a higher preoperative ASA class was found to be a predictor of an increased risk of mortality. Therefore, clinicians must carefully consider preoperative comorbidities when counselling patients on the risks of surgery. ■

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