Treatment of unstable trochanteric fractures

The balance between man and material

Behandeling van instabiele pertrochantere fracturen

De balans tussen mens en materiaal

Proefschrift

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CHAPTER 1

Introduction to the topic and outline of this thesis

INTRODUCTION

Treatment of unstable trochanteric fractures poses a challenge to surgeons in many ways. Accepting this challenge requires understanding of those parameters that determine the outcome. In operative fracture care at least four elements influence the outcome of treatment: the patient, the fracture, the fixation device, and the surgeon. The degree of impact varies per specific element, as does the mutual relationship.

The general physical state of the patient with a hip fracture is a parameter that is strongly related to fracture type and outcome, but cannot or only minimally be influenced by the surgeon; it is a relatively static parameter. The type of fracture that is sustained has similar static characteristics: it presents as a fixed value parameter that both directly and indirectly influences outcome, through its intrinsic stability and its tendency to redislocation. The fixation device that will be used for osteosynthesis depends on the patient, the fracture characteristics, the way the fracture is classified, hospital logistics and the skills, experience and preference of the operating surgeon. Figure 1 shows a schematic overview this mixture of these factors with their complex and interactive connections. All these factors, separate and combined, apply their influences upon outcome.

The ongoing quest for the optimal operative treatment of unstable trochanteric fractures, especially in the elderly, focuses mainly on optimalisation of the fixation device; but the influence of human factors should not be underestimated. Exact weights of each of these separate parameters are difficult to obtain, leaving clinical consequences of a mathematical equation limited. It does however, reflect the balance between man (the patient, the surgeon) and material (the fracture, the fixation device) that mainly determines clinical outcome.

The problems encountered in treatment of unstable trochanteric fractures in the elderly, a population with a poor bone stock, force us to determine, investigate and if possible quantify the most important factors, as well as their mutual relations. Many investigations have been performed to quantify patient related parameters. This thesis on unstable trochanteric fractures, focuses primarily on the reliability of fracture determination and classification, the (biomechanical) influence of the fracture on the fixation device, and the effect of a given fixation device on the fracture (healing and outcome). As surgeons often tend to forget their own contribution to and influence on (un)successful treatment outcome, we aimed to analyse

the quality of fracture handling (classification and reduction) and stabilisation by the surgeon, and the subsequent impact on treatment outcome.

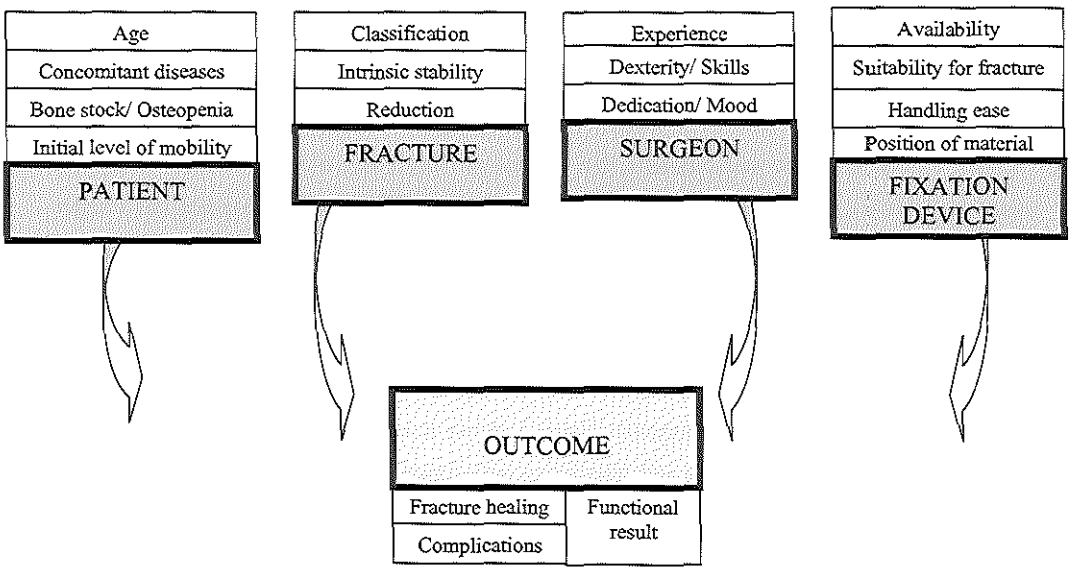

Figure 1. *The influences of man (patient and surgeon) and material (fracture and fixation device) in determining outcome.*

OUTLINE OF THIS THESIS

The best strategy for the operative treatment of unstable trochanteric femoral fractures, and more specifically the differentiation between an intramedullary or extramedullary fixation preference, remains topic of debate. In **Chapter 2** we reviewed the published prospective randomised clinical trials that compared two basic methods of treatment for unstable trochanteric femoral fractures in order to find answers to the following questions:

- *What evidence-based support can be found for a consensus of best treatment for trochanteric femoral fractures?*
- *What is the current state of the art in treatment of unstable trochanteric fractures?*

Systematic classification of fractures may limit problems related to interpretation of the fracture pattern and may facilitate the choice of the appropriate method of treatment. For a reliable assessment and comparison of clinical studies on different types of trochanteric hip fractures, a reproducible classification is mandatory. Nowadays, the most commonly used system for trochanteric fractures is the 31A fracture group classification of the AO (Müller et al. 1990). Despite its common use and wide acceptance, reliability and reproducibility have not been established. **Chapter 3** provides an answer to the question to what extent the 31A trochanteric fracture group meets the criteria of an ideal classification:

- *Is it consistent and reproducible in terms of interobserver and intra-observer reliability?*
- *Does it provide a guideline for treatment?*
- *Is it a classification by which we can report, assess, and compare results?*
- *Does it facilitate communication about fracture treatment and outcome?*

Unstable trochanteric fractures (AO type 31A) can be divided into two specific groups, - A2 and A3 fractures -, each with their distinctive fracture patterns. The anatomical differences between these two groups probably result in unique biomechanical needs for stable and reliable fixation. In **Chapter 4** we studied the differences between patients with 31A2 and A3 fractures, during and after intramedullary treatment, in an attempt to answer the questions:

- *Do the distinct patterns of A2 and A3 fractures require separate operative treatment methods?*
- *Do A2 and A3 fractures render different complications and outcome?*

Several implants have been developed to overcome the difficulties encountered in treatment of unstable trochanteric femoral fractures. The Proximal Femoral Nail®, combining the advantages of an unreamed intramedullary nail, a load bearing femoral neck screw and an extra hip pin which provides rotational stability, finds itself among a group of recently introduced intramedullary implant systems. The incidence and clinical relevance of the assumed advantages and possible complications were still to be established and compared with a generally accepted method of treatment. In **Chapter 5** the results of a multicentre prospective randomised clinical trial, comparing the Gamma Nail® and the Proximal Femoral Nail® in treatment of unstable trochanteric fractures, are presented, aiming to answer the questions:

- *Is there a difference of type and number of complications and reoperations between the two intramedullary fixation devices?*
- *Do fracture reduction and positioning of the fixation device relate to complication rate and/ or give rise to specific complications?*
- *Can any of the complications be accounted for by the implant?*

Considerable load on the hip pin of the Proximal Femoral Nail® is thought to provoke its medial migration and cutout. In **Chapter 6** the biomechanical behaviour of the hip pin and the femoral neck screw as part of the standard Proximal Femoral Nail® on the one hand, and of an experimentally-modified Proximal Femoral Nail® (in which the hole through the nail for the hip pin was modified to a slot) on the other hand, were studied. The amount of load carried by the hip pin was determined for both implants, as was the amount of migration, during intermittent loading, aiming to answer the questions:

- *Does the non-constrained lateral end of the hip pin reduce the bending load applied to the implant?*
- *Will the non-constrained hip pin mechanism, prevent or reduce the risk of cutout and medial migration of the hip pin and/or femoral neck screw?*

In **Chapter 7** the results of a European pilot study, investigating the clinical results of operative treatment of unstable trochanteric fractures with use of a modified Proximal Femoral Nail®, in which the hip pin passes through a non-constraining (oval) hole, are presented. This

prospective descriptive observational investigation was initiated in an attempt to formulate answers to the questions:

- *Are there any technical (handling) problems concerning the modified PFN®?*
- *Are any complications, related to this specific implant (breakage, cut-out, migration), observed?*
- *Is the oval hole concept correct?*

Chapter 8 presents a general discussion and reflections on the factors that influence the balance between man and material in determining outcome.

Chapter 9 summarises the findings and the answers presented in this thesis, and **Chapter 10** presents a Dutch summary of the contents.

CHAPTER 2

Unstable trochanteric femoral fractures:

Extramedullary or intramedullary fixation

Review of literature

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Introduction

Trochanteric fractures pose a challenge to the trauma surgeon in many ways: the nomenclature is often confusing, uniform classification is difficult because of the use of different classification systems, and the various treatment options are diverse, not evidence based and without consensus. An unstable trochanteric fracture adds to this, the challenge of a biomechanically very unfavourable fracture. A good treatment plan therefore starts with proper fracture classification.

Several trochanteric fracture classifications exist[21,27,33,39,40]: the most basic and rational is to divide trochanteric fractures into stable or unstable fracture patterns[21,27,45,55]. In general, instability is determined by the presence of a zone of comminution of the medial cortex[30,34,38,39,47,50] and posterolateral instability[53]. Nowadays, the most commonly used classification is that of the AO/ASIF group[40] (figure 1). This classification has a good reproducibility[48] as it basically divides the trochanteric fractures (type 31A) into three groups: A1 fractures (stable pertrochanteric fractures), A2 fractures (unstable **per**trochanteric fractures with medial comminution including a fractured lesser trochanter) and A3 fractures (unstable **inter**trochanteric fractures with or without medial comminution). The instability of A2 and A3 fractures is created when one, or both, of the cortices is comminuted in a way that progressive (varus) displacement will follow unless intrinsic

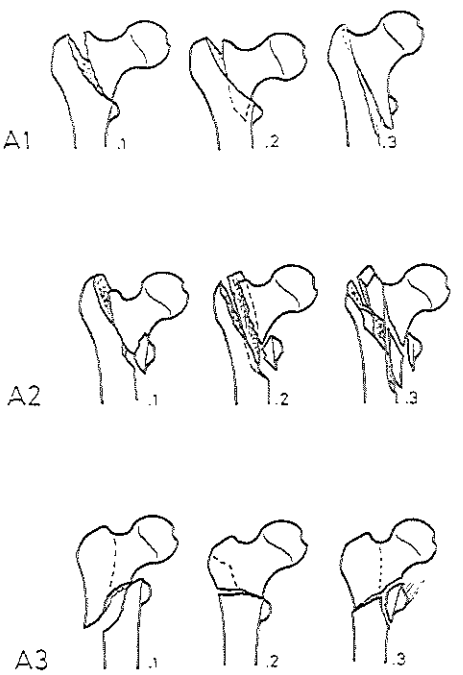

Figure 1. *The AO/ASIF classification[40] for trochanteric femoral fractures (= type 31A) is divided into 3 main groups: A1 fractures are stable pertrochanteric fractures and A2 fractures are unstable pertrochanteric fractures with medial comminution including a fractured minor trochanter. A3 fractures are unstable intertrochanteric fractures with or without medial comminution, including the reversed intertrochanteric fractures and transverse intertrochanteric fractures, with possible dorsolateral comminution.*

stability is provided by means of a stabilising implant. The forces that tend to displace the fracture must be neutralised by the implant. Theoretically these forces are best transmitted through an implant close to the centre of axial loading, resulting in a shorter lever arm and a lower bending moment. The implant should, together with the fracture fragments, be able to bear full load. It should allow controlled fracture impaction (a gliding mechanism) in order to facilitate impaction and compression, therewith increasing stability.

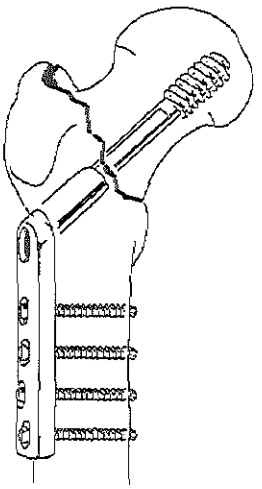

Figure 2. *Example of a sliding hip screw device, the Dynamic Hip Screw®*

The risk of the implant cutting out in osteoporotic bone should be as small as possible and the periostal blood supply should be disturbed as little as possible[57]. Together, these demands stress the importance of an adequate interpretation of what may be expected (biomechanically) from a fracture-implant construct. The choice of implant depends on the degree of instability: the more unstable the fracture, the more stability is required of the method of fixation.

In general, for treatment of unstable trochanteric fractures two options exist: extramedullary or intramedullary stabilisation. The extramedullary option (figure 2) comprises any kind of sliding hip screw (SHS) connected to a plate at the lateral cortex: for instance the Dynamic Hip Screw® (DHS, Mathys Medical) or the Compression Hip Screw® (CHS, Smith and Nephew). The indicated advantages consist of the possibility of direct open fracture reduction and a relatively simple surgical technique, which is safe and very forgiving. The intramedullary method basically exists of a percutaneously inserted nail connected to one or more neck screws sliding through the nail. Examples of the intramedullary devices are the Gamma Nail® (Stryker Howmedica), the Intramedullary Hip Screw® (IMHS, Smith and Nephew) and the Proximal Femoral Nail® (PFN, Synthes), as shown in figure 3. This minimally invasive intramedullary technique is said to be associated with less blood loss and a lower infection rate, and the implant construction should allow direct full weight bearing because of its

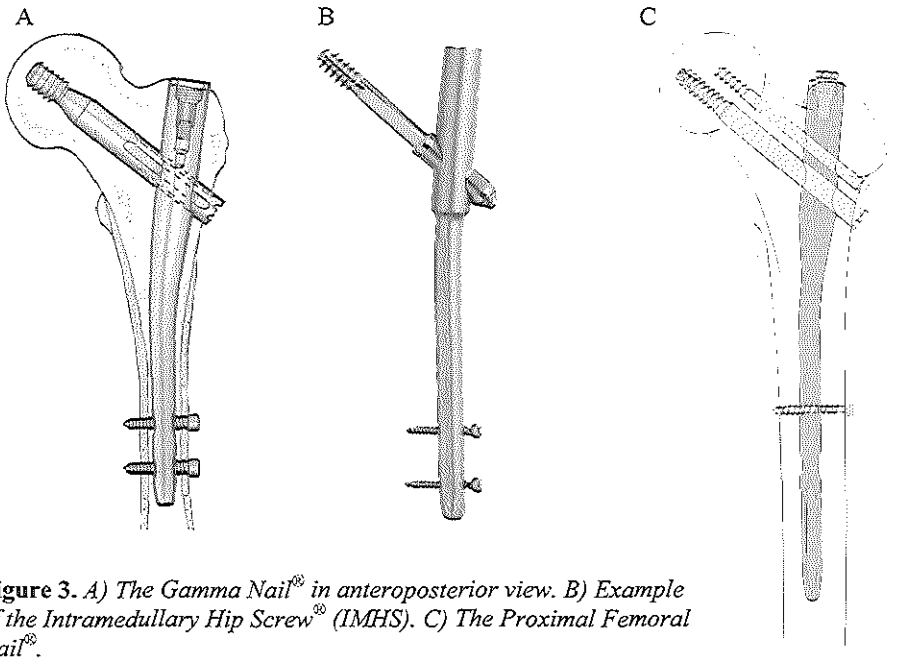

Figure 3. *A) The Gamma Nail® in anteroposterior view. B) Example of the Intramedullary Hip Screw® (IMHS). C) The Proximal Femoral Nail®.*

favourable biomechanical properties. Results of randomised clinical studies comparing the results of intramedullary and extramedullary fixation techniques for unstable trochanteric fractures are inconsistent and rare. Most comparative studies focus on treatment of stable trochanteric fracture types[3,8,31,32,41,42,44]. We performed a literature review in an attempt to find consensus about the best treatment strategy for unstable trochanteric femoral fractures.

Methods

A Medline literature search was performed for prospective randomised clinical trials - comparing two basic methods of treatment for trochanteric femoral fractures - published since 1990. Studies comparing more than two treatment options in one randomised trial[36,37] were omitted, for reasons of statistical conflict using too small groups. There was no language restriction. The search term used was " ~trochanteric femoral fracture", limited to randomised trials. We reviewed these articles for relevant parameters like complication and re-operation rates, mortality and functional results as published. We were exclusively interested in the treatment results of unstable trochanteric fractures.

Additionally we performed a search for recent clinical cohort and comparative studies concerning intramedullary treatment of unstable trochanteric fractures.

Randomised clinical trials since 1990

The literature search revealed 20 prospective randomised clinical trials comparing two methods of treatment for unstable trochanteric femoral fractures, published since 1990. Two publications[9,10] reported only preliminary results or results of a trial that had been published before, and were therefore combined with the companion paper[11,52].

Ten of the 18 remaining randomised trials did not analyse the results for unstable fractures separately from stable fractures. Results of these ten studies are summarized in table 1. The other 8 trials (table 2), of which 5 studies did compare extramedullary with intramedullary treatment options, are discussed in more detail.

Intramedullary versus extramedullary treatment

IMHS versus sliding hip screw

Two randomised trials[5,29] compared the results of fracture fixation using the Intra Medullary Hip Screw (IMHS®) with an (extramedullary) sliding hip screw. When stable and unstable fractures were examined separately, several differences became apparent in unstable fractures. The intramedullary device was associated with up to 23% less surgical time and up to 44% less blood loss compared to the SHS[5,29]. The IMHS® was also associated with less impaction of the fracture and consequently, with less shortening of the limb, which resulted in a higher mobility score at each follow-up[29]. In patients treated with the IMHS® weight bearing was significantly better tolerated (as measured by the mobility score) direct postoperatively and at discharge from the hospital, compared with the sliding hip screw. There were 4% post-operative femoral shaft fractures in one trial[5]. Cutout numbers were equally distributed over both treatment groups, and were concluded to be mainly caused by malpositioning of the screw in the femoral neck. Both papers, although having limited numbers of patients for analyses of stable and unstable fractures separately, concluded that the SHS device is to be preferred for treatment of stable trochanteric fractures. The intramedullary nail was said to be a promising alternative for treatment of comminuted, unstable fractures[5,29].

Table 1. *Randomised trials comparing treatment results of trochanteric fractures, not specified for unstable fractures.*
GN = Gamma Nail, CHS = Compression Hip Screw, DHS = Dynamic Hip Screw, IMHS = Intramedullary Hip Screw, SHS = Sliding Hip Screw

Author	Year	Method	Number of patients	Average age (years)	Unstable TF (%)	Fixation failure (%)	Cutout/ varus (%)	Femoral fracture (%)	Wound problems/ infections (%)	Reoperation (%)
Bridle	1991	GN	49	82	63	?	4	8	2	12
		DHS	51		56	?	6	0	8	6
Stark	1992	SHS	56	75	57	0	?	?	5	2
		Ender Nail	36		50	0	?	?	0	11
Radford	1993	GN	100	81	?	2	2	11	3	3
		DHS	100		?	3	3	1	12*	6
Aune	1994	GN	177	77	51	0	2	6	?	7
		CHS	201		57	0	1	0	?	3*
Butt	1995	GN	47	79	51	7	4	17	4	?
		DHS	48		38	7	6	0	4	?
O'Brien	1995	GN	53	?	43	2	6	6	2	9
		DHS	49		43	2	2	0	2	4
Hoffman	1996	GN	31	81	33	?	0	10	?	1
		Ambi Hip Screw	36		33	?	10	0	?	1
Park	1998	GN-Asia Pacific	30	73	53	0	4	0	1	?
		CHS	30		63	0	6	0	1	?
Hoffmann	1999	DHS	54	82	63	0	4	0	13	4
		IMHS	56		64	4	0	4	5	4
Dujardin	2001	DHS	30	84	53	0	?	?	?	?
		Static Nail	30		73	0	?	?	?	?

* = significant difference, $p \leq 0,05$.

Table 2. *Randomised trials comparing treatment results of unstable trochanteric fractures. GN = Gamma Nail®, DCS = Dynamic Condylar Screw®, DHS = Dynamic Hip Screw, PFN = Proximal Femoral Nail®, SHS = Sliding Hip Screw, (R)AB-plate = (right) angle blade plate, CHS = Compression Hip Screw, IMHS = Intramedullary Hip Screw®*

Author	Year	Method	Number of patients	Average age (years)	Unstable TF (%)	Operation time (min)	Blood loss (ml)	Fixation failure (%)	Cutout/ varus (%)	Femoral fracture (%)	Wound problems/ Infections (%)	Reoperation (%)
Desjardin	1993	Anatom. reduction	57	81	100	83	340	0	9	0	23	2
		Medial displ. osteotomy	52		100	103*	460*	0	10	0	21	4
Bucioto	1998	CHS	122	81	100	63	400	2	15	?	?	11
		RAB-plate	111		100	64	400	2	7*	?	?	5
Baumgaertner	1998	DHS	68	79	49	80	340	0	3	0	?	7
		IMHS	67		46	72	245*	0	3	4	?	9
Hardy	1998	DHS	50	80	68	57	144	0	2	0	0	?
		IMHS	50		74	71*	198*	0	0	2	0	?
Fritz	1999	GN	40	79	100	62	296	0	8	0	5	10
		Gliding Nail	40		100	63	338	0	0	3	8	8
Adams	2001	GN	203	81	53	55	244	6	4	2	1	6
		SHS	197		55	61	260	4	3	0	1	4
Pelet	2001	GN	13	70	100	86	550	0	6	0	0	0
		AB-plate	13		100	169*	1150*	6	22	0	0	22*
Sadowski	2002	PFN	20	?	100	82	?	0	5	0	0	0
		DCS	19		100	166*	?	5	30*	0	5	30*

* = significant difference, $p \leq 0,05$

Gamma Nail® versus sliding hip screw

Adams et al [1] randomised patients for treatment with the Gamma Nail® or sliding hip screw. Some of the outcome parameters were analysed for unstable fractures and stable fractures separately. Specific figures for revision surgery and functional outcome were not given, however 83% of the fixation failures in the Gamma Nail® group and 85 % in the SHS group (as shown in table 2) occurred in unstable fractures. Other complications were distributed equally over both implant groups, and functional results were similar. The overall conclusion of this study is that the Gamma Nail® should not routinely be adopted for all trochanteric fractures. Although this study analysed a considerable number of patients with unstable trochanteric fractures, the fact that exact figures for complications, functional outcome and mortality in patients with unstable fracture types were not given separately (but were said to be similar as in stable fractures), reduces the reliability of their conclusion.

Gamma Nail® versus angled blade-plate

Pelet et al[43] compared the 90°-fixed angle blade plate to the Gamma Nail® in a randomised trial, in a small group of 26 patients with unstable trochanteric fractures. After 13 angled blade plate insertions, 3 femoral head necroses, 2 non-unions, 2 mal-unions and one blade breakage were found. All intramedullary treated fractures showed uneventful consolidation within 5 months. Because both treatment groups are too small, figures are far from conclusive.

PFN® versus DCS®

Recently, Sadowski et al.[46] published their results of a randomised trail comparing the treatment results of the Dynamic Condylar Screw® (DCS, Synthes) and the Proximal Femoral Nail® (PFN) in unstable trochanteric (AO/ASIF A.3) fractures. The main difference between the PFN® (figure 3c) and the other intramedullary devices, is that in the PFN® an additional antirotational hip pin is placed through the proximal part of the nail into the upper part of the femoral neck to prevent rotation of the head-neck fragment[51]. The background for this study was the idea that the SHS was generally favoured for stabilisation of A1 and A2 fractures, but not for A3 fractures with their distinct and different fracture patterns. Of the 39 patients analysed, 19 were randomised for the DCS®, and 20 for treatment with the PFN®. Extramedullary fixation was associated with a mean operative time twice as long (table 2) as

PFN®-fixation. Open fracture reduction was part of the approach in the extramedullary treatment, and was reported to be difficult in almost half of the cases, whereas only a quarter of the intramedullary treated fractures required open reduction, and overall reduction was judged to be difficult in 30% ($p < 0.05$). Postoperatively, (full) weightbearing was encouraged in both groups. Patients with a DCS® stayed significantly ($p < 0.05$) longer (18± 7 days) in hospital, compared with patients with a PFN® (13 ± 4 days). At one-year follow-up, in seven patients with a DCS® consolidation had failed: five sustained screw cutout of the femoral head, one plate fatigue, and there was one non-union with an intact implant. Six of these patients had further surgery, compared with none in the PFN® group. For analysis of functional results all patients with treatment failure, as described above, were excluded. In 30 remaining patients available for follow-up, no differences in functional outcome were found. The authors stated that the intramedullary implant provides excellent fixation in unstable fractures, with the advantages of shorter operating time, less blood loss, shorter hospital stay and less revision surgery, compared with the extramedullary DCS® fixation. The relevance of their conclusions is limited by the low number of patients included and the fact that the DCS® is not generally accepted for treatment of unstable trochanteric fractures.

Extramedullary treatment

Medial displacement osteotomy versus sliding hip screw

Focussing on extramedullary treatment options, Desjardin et al[17] reported on 109 unstable trochanteric fractures randomised for anatomical reduction (n = 57) or valgus- and medial displacement osteotomy (n = 52), with sliding compression screw fixation in both groups. Although osteotomy is no longer used as standard treatment for unstable trochanteric fractures, it provides us with the basic insight in changing the biomechanical features in such a way that bending forces are converted into compression forces, using extramedullary fixation[6]. The principle of this type of fixation is based on resection of the comminuted area, creating medial support and stable fixation with intraoperative impaction of the spike

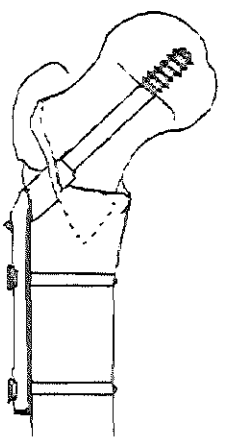

Figure 4. *Schematically drawn valgisating medial displacement osteotomy.*

of the medial cortex into the femoral shaft[18] (Figure 4). Significantly longer operation time and more blood loss (table 2) were found in the medial displacement osteotomy group, whereas the incidence of implant related complications (9% - 10%), overall mortality (16% - 22%) and level of mobility at follow up were similar in both groups. In both groups no mechanical implant failures were reported. Generally, and compared with the results of the other studies on unstable trochanteric fractures, both methods showed a very high number (21%-23%) of wound problems (table 2). Overall treatment results after anatomical reduction combined with compression hip screw fixation were favourable. Based on these data, the medial displacement osteotomy was not recommended as a standard treatment for unstable trochanteric fractures.

Compression hip screw versus angled blade-plate

Another study[11] covered only unstable trochanteric fractures, and also randomised between two extramedullary fixation methods: the compression hip screw and a 120°-fixed angle blade-plate with a buttress rod. Two hundred thirty three patients were included. All patients were encouraged to bear full weight immediately postoperatively. Results (table 2) revealed more cutout (5%), varus displacement (6%) and malunion (15%) in patients treated with the compression hip screw. The functional outcome was not analysed, which is a major limitation of this study. The investigators conclude that the blade-plate is a safe implant for fixation of unstable trochanteric fractures and that it can be regarded as a good alternative to the compression hip screw. This study proved that, in skilled hands, the angled blade-plate gives excellent results, however this technique is no longer widely used or taught as a standard treatment for trochanteric fractures, due to the demanding and relatively unforgiving operation technique[43].

Intramedullary treatment

Gamma Nail® versus Gliding Nail®

Fritz et al[24] performed a randomised clinical trial comparing two intramedullary devices: the Gliding Nail and the Gamma Nail®, in 80 unstable trochanteric fractures. The Gliding Nail consists of an intramedullary nail with a dynamic femoral neck blade. Operation time, blood loss (table 2), weight bearing capacity and functional results were similar in both treatment groups. Mortality at one year (15%), hospital stay (10 days) and functional outcome were

comparable for both treatment groups and did not differ from stable fractures that had been treated with a DHS®. In three patients with Gamma Nails, a cutout of the femoral neck screw was observed. No shaft fractures were reported in patients treated with the Gamma Nail®. It was attributed to the special design of the blade of the Gliding Nail, that it showed a minor tendency to cut out. The results of this study suggest that unstable fractures are so well stabilised by the intramedullary implants that after 6 months results were similar to those of stable fractures.

Other (non-randomised) studies on unstable trochanteric fractures

Screw-plate systems

In a multicentre clinical trial Lunsjö et al[36] compared the efficacy of four extramedullary fixation systems, the Medoff sliding plate, the DHS®, DHS with trochanter side plate® (TSP, Synthes), and the DCS®, in unstable trochanteric fractures. In 569 included patients, fixation failure rates varied from 4.6% to 8.2%, which is relatively low compared with the earlier published average fixation failure rates of the SHS systems in unstable fractures of about 10%[4,8,11,17,35,56]. The study did not reveal superiority of any of the tested screw-plate systems.

Gamma Nail®

Many studies reported on the treatment results of the Gamma Nail® [3,7,8,13,16,23,28,35,37,54]. Most of these were clinical cohort studies that retrospectively or prospectively analysed considerable numbers of patients. Overall, the Gamma Nail® proved to provide adequate stability for unstable trochanteric fractures[14,22] and to be strong enough to overcome the massive tensile forces laterally and compressive forces medially. However, within this concept, there is a need for implant improvement concerning fixation failure[25], implant properties and shaft fractures[2], and implantation technique[44], based on problems en complications encountered in using the Gamma Nail®.

Proximal Femoral Nail®

Recently the results of three prospective clinical studies on the use of the Proximal Femoral Nail® (PFN) were published[19,49,51]. All studies concerned the treatment of unstable trochanteric fractures in cohorts of over one hundred patients each. They showed cutout rates of 0.6% to 1.4%, whereas the tendency to varus displacement was low in comparison with other

implants. In all studies no shaft fractures at the tip of the implant, or mechanical failure of the implant, were found. These remarkable clinical findings are supported by biomechanical studies and by comparable in-vitro investigations[22,26].

Biomechanical studies

Weight bearing capacity and implant stability of the DHS®, Gamma Nail® and the PFN®, were tested in-vitro in unstable trochanteric fractures, using static and dynamic loading[14,22,26]. The intramedullary devices were found to be several times stronger than the DHS®, with less or no deformity at maximum loads[26]. These biomechanical studies conclude that, when perfectly inserted, the intramedullary implants enable immediate postoperative and uncompromised mobilisation under full weight bearing conditions[22,26].

Discussion

This review was performed in an attempt to find evidence-based support for consensus of best treatment of unstable trochanteric femoral fractures and to discuss the current state of the art of treatment. There are some limitations to this review: Literature since 1990 revealed a limited number of publications assessing too many different treatment methods to perform a systematic review. Moreover, methodology of the studies was found to be too defective for meta-analysis, as for instance, method of randomisation was not known in nearly half of the studies, and most did not include enough patients (power-analysis was rarely presented). Many trials included both stable and unstable fractures, but failed to analyse results according to fracture type. Because of this, only 8[1,5,11,17,24,29,43,46] of the 18 [3,8,12,20,31,32,41,42,44,52] published studies could be used for specific analysis of results in unstable fractures.

Randomised trials were selected starting from publication year 1990, as earlier study results may have been biased in favour of the sliding hip screw, because of limited experience with intramedullary devices. When we consider the results of the 8 retrieved trials[1,5,11,17,24,29,43,46] in general, treatment of unstable trochanteric fractures with extramedullary devices showed high cutout and varus displacement rates, and a very high incidence of wound problems and infections[11,17]. Treatment of unstable trochanteric fractures with intramedullary[1,5,24,29,43,46] devices showed less complications and reoperations. Although Adams et al[1] could not confirm the theoretical advantages of the Gamma Nail®, Baumgartner et al and Hardy et al, who

also studied unstable fractures as a separate group, concluded differently: in their studies the intramedullary fixation showed a lower risk of implant related complications, earlier and better mobilisation capacity, less impaction of the fracture area and therewith less limb shortening. Finally, Pelet et al focussed on patients with unstable fractures only, and found significant fracture related complications and implant failures after extramedullary treatment, whereas hardly any of these problems were seen after intramedullary stabilisation.

Unfortunately, none of the reviewed trials comparing intramedullary and extramedullary treatment, analysed groups with high numbers of unstable trochanteric fractures. Based on the above-mentioned limitations, attempts to find an evidence-based clinical consensus for the treatment of unstable trochanteric fractures remain unsuccessful.

As the experience of surgeons with the various intramedullary fixation systems increases, treatment results tend to improve, with less intraoperative and postoperative complications. Modifications like adapted distal interlocking options have reduced the risk of postoperative adverse events, and emphasise the correct positioning of the fixation device in the femoral head after optimal reduction of the fracture, since the combination will help further decrease the risk of cut-out.

Conclusions

The diversity of fixation devices available for treatment of unstable trochanteric femoral fractures illustrates the difficulties encountered in the actual treatment. Reduction of cutout numbers is unlikely to be accomplished by other and newer intramedullary implants, since optimal implants cannot make up for suboptimal fracture reduction or poor implant position. In view of the overall results of this literature review, routine use of intramedullary fixation devices is not to be recommended for stable trochanteric fractures[5,24,29]. For these fractures, one of the sliding hip screw systems provides a safe and simple alternative[15]. For unstable fractures the intramedullary implant is biomechanically[14,44] superior. Clinical advantages are suggested and advocated, but still remain to be demonstrated on evidence base.

References

1. Adams CI, Robinson CM, Court-Brown CM, McQueen MM. Prospective randomized controlled trial of an intramedullary nail versus dynamic screw and plate for intertrochanteric fractures of the femur. J Orthop Trauma 2001; 15: 394-400.

2. Albareda J, Laderiga A, Palanca D, et al. Complications and technical problems with the gamma nail. Int Orthop 1996; 20: 47-50.

3. Aune AK, Ekeland A, Odegaard B, et al. Gamma nail vs compression screw for trochanteric femoral fractures. 15 reoperations in a prospective, randomized study of 378 patients. Acta Orthop Scand 1994; 65: 127-130.

4. Bannister GC, Gibson AG, Ackroyd CE, Newman JH. The fixation and prognosis of trochanteric fractures. A randomized prospective controlled trial. Clin Orthop 1990; 242-246.

5. Baumgaertner MR, Curtin SL, Lindskog DM. Intramedullary versus extramedullary fixation for the treatment of intertrochanteric hip fractures. Clin Orthop 1998; 87-94.

6. Besselaar PP, Marti RK. Valgisation osteosynthesis for the unstable pertrochanteric fracture in the elderly patient. In: Marti RK, Dunki Jacobs PB, eds. Proximal femoral fractures; operative techniques and complications. Medical press Ltd, London; 1993. pp 299-310.

7. Boriani S, Bettelli G, Zmerly H, et al . Results of the multicentric Italian experience on the Gamma nail: a report on 648 cases. Orthopedics 1991; 14: 1307-1314.

8. Bridle SH, Patel AD, Bircher M, Calvert PT. Fixation of intertrochanteric fractures of the femur. A randomised prospective comparison of the gamma nail and the dynamic hip screw. J Bone Joint Surg Br 1991; 73: 330-334.

9. Brostrom LA, Barrios C, Kronberg M, et al. Clinical features and walking ability in the early postoperative period after treatment of trochanteric hip fractures. Results with special reference to fracture type and surgical treatment. Ann Chir Gynaecol 1992; 81: 66-71.

10. Buciuto R, Hammer R. RAB-plate versus sliding hip screw for unstable trochanteric hip fractures: stability of the fixation and modes of failure--radiographic analysis of 218 fractures. J Trauma 2001; 50: 545-550.

11. Buciuto R, Uhlin B, Hammerby S, Hammer R. RAB-plate vs Richards CHS plate for unstable trochanteric hip fractures. A randomized study of 233 patients with 1-year follow-up. Acta Orthop Scand 1998; 69: 25-28.

12. Butt MS, Krikler SJ, Nafie S, Ali MS. Comparison of dynamic hip screw and gamma nail: a prospective, randomized, controlled trial. Injury 1995; 26: 615-618.

13. Chevalley F, Gamba D. Gamma nailing of pertrochanteric and subtrochanteric fractures: clinical results of a series of 63 consecutive cases. J Orthop Trauma 1997; 11: 412-415.

14. Curtis MJ, Jinnah RH, Wilson V, Cunningham BW. Proximal femoral fractures: a biomechanical study to compare intramedullary and extramedullary fixation. Injury 1994; 25: 99-104.

15. David A, von der HD, Pommer A. [Therapeutic possibilities in trochanteric fractures. Safe--fast--stable]. Orthopade 2000; 29: 294-301.

16. Davis J, Harris MB, Duval M, D'Ambrosia R. Pertrochanteric fractures treated with the Gamma nail: technique and report of early results. Orthopedics 1991; 14: 939-942.

17. Desjardins AL, Roy A, Paiement G, et al. Unstable intertrochanteric fracture of the femur. A prospective randomised study comparing anatomical reduction and medial displacement osteotomy. J Bone Joint Surg Br 1993; 75: 445-447.

18. Dimon JH, Hughston JC. Unstable intertrochanteric fractures of the hip. J Bone Joint Surg Am 1967; 49: 440-450.

19. Domingo LJ, Cecilia D, Herrera A, Resines C. Trochanteric fractures treated with a proximal femoral nail. Int Orthop 2001; 25: 298-301.

20. Dujardin FH, Benez C, Polle G, et al. Prospective randomized comparison between a dynamic hip screw and a mini-invasive static nail in fractures of the trochanteric area: preliminary results. J Orthop Trauma 2001; 15: 401-406.

21. Evans EM. The treatment of trochanteric fractures of the femur. J Bone Joint Surg 1949; 31-B, 190-203.

22. Friedl W, Clausen J. [Experimental examination for optimized stabilisation of trochanteric femur fractures, intra- or extramedullary implant localisation and influence of femur neck component profile on cut-out risk]. Chirurg 2001; 72: 1344-1352.

23. Friedl W, Colombo-Benkmann M, Dockter S, et al. [Gamma nail osteosynthesis of per- and subtrochanteric femoral fractures. 4 years experiences and their consequences for further implant development]. Chirurg 1994; 65: 953-963.

24. Fritz T, Hiersemann K, Krieglstein C, Friedl W. Prospective randomized comparison of gliding nail and gamma nail in the therapy of trochanteric fractures. Arch Orthop Trauma Surg 1999; 119: 1-6.

25. Gaebler C, Stanzl-Tschegg S, Tschegg EK, et al. Implant failure of the gamma nail. Injury 1999; 30: 91-99.

26. Götze B, Bonnaire F, Weise K, Friedl HP. Belastbahrkeit von Osteosynthesen bei instabilen per- und subtrochanteren Femurfrakturen. Akt Traumatol 1998 1998; 28: 197-204.

27. Hafner RHV. Trochanteric fractures of the femur. J Bone Joint Surg 1951; 33-B: 516.

28. Halder SC. The Gamma nail for peritrochanteric fractures. J Bone Joint Surg Br 1992; 74: 340-344.

29. Hardy DC, Descamps PY, Krallis P, et al. Use of an intramedullary hip-screw compared with a compression hip- screw with a plate for intertrochanteric femoral fractures. A prospective, randomized study of one hundred patients. J Bone Joint Surg Am 1998; 80: 618-630.

30. Harrington KD. The use of methylmethacrylate as an adjunct in the internal fixation of unstable comminuted intertrochanteric fractures in osteoporotic patients. J Bone Joint Surg Am 1975; 57: 744-750.

31. Hoffman CW, Lynskey TG. Intertrochanteric fractures of the femur: a randomized prospective comparison of the Gamma nail and the Ambi hip screw. Aust N Z J Surg 1996; 66: 151-155.

32. Hoffmann R, Schmidmaier G, Schulz R, et al. [Classic nail versus DHS. A prospective randomised study of fixation of trochanteric femur fractures]. Unfallchirurg 1999; 102: 182-190.

33. Jensen JS. A photoelastic study of the hip nail-plate in unstable trochanteric fractures. A biomechanical study of unstable trochanteric fractures II. Acta Orthop Scand 1978; 49: 60-64.

34. Johnson LL, Lottes JO, Arnot JP. The utilization of the Holt nail for proximal femoral fractures. A study of one hundred and forty-six patients. J Bone Joint Surg Am 1968; 50: 67-78.

35. Leung KS, So WS, Shen WY, Hui PW. Gamma nails and dynamic hip screws for peritrochanteric fractures. A randomised prospective study in elderly patients. J Bone Joint Surg Br 1992; 74: 345-351.

36. Lunsjo K, Ceder L, Thorngren KG, et al. Extramedullary fixation of 569 unstable intertrochanteric fractures: a randomized multicenter trial of the Medoff sliding plate versus three other screw-plate systems. Acta Orthop Scand 2001; 72: 133-140.

37. Madsen JE, Naess L, Aune AK, et al. Dynamic hip screw with trochanteric stabilizing plate in the treatment of unstable proximal femoral fractures: a comparative study with the Gamma nail and compression hip screw. J Orthop Trauma 1998; 12: 241-248.

38. Massie WK. Extracapsular fractures of the hip treated by impaction using a sliding nail-plate fixation. Clin Orthop 1962; 22: 180-201.

39. Murray RC, Frew JFM. Trochanteric fractures of the femur- A plea for conservative treatment. J Bone Joint Surg 1949; 31-B: 204-219.

40. Müller ME, Nazarian S, Koch P, Schatzker J. The comprehensive classification of fractures of the long bones. Berlin/Heidelberg: Springer-verlag; 1990.

41. O'Brien PJ, Meek RN, Blachut PA, et al. Fixation of intertrochanteric hip fractures: gamma nail versus dynamic hip screw. A randomized, prospective study. Can J Surg 1995; 38: 516-520.

42. Park SR, Kang JS, Kim HS, et al. Treatment of intertrochanteric fracture with the Gamma AP locking nail or by a compression hip screw--a randomised prospective trial. Int Orthop 1998; 22: 157-160.

43. Pelet S, Arlettaz Y, Chevalley F. [Osteosynthesis of per- and subtrochanteric fractures by blade plate versus gamma nail. A randomized prospective study]. Swiss Surg 2001; 7: 126-133.

44. Radford PJ, Needoff M, Webb JK. A prospective randomised comparison of the dynamic hip screw and the gamma locking nail. J Bone Joint Surg Br 1993; 75: 789-793.

45. Rasmussen KB. McLaughlin osteosynthesis in trochanteric fractures. Acta Chir Scand 1953; 105: 246-251.

46. Sadowski C, Lubbeke A, Saudan M, et al. Treatment of reverse oblique and transverse intertrochanteric fractures with use of an intramedullary nail or a 95 degrees screw-plate: a prospective, randomized study. J Bone Joint Surg Am 2002; 84-A: 372-381.

47. Sarmiento A, Williams EM. The unstable intertrochanteric fracture: treatment with a valgus osteotomy and I-beam nail-plate. A preliminary report of one hundred cases. J Bone Joint Surg Am 1970; 52: 1309-1318.

48. Schipper IB, Steyerberg EW, Castelein RM, van Vugt AB. Reliability of the AO/ASIF classification for pertrochanteric femoral fractures. Acta Orthop Scand 2001; 72: 36-41.

49. Schwab E, Höntzsch K, Weise K. Die Versorgung instabiler per- und subtrochantärer Femurfrakturen mit dem Proximalen Femurnagel (PFN®). Akt Traumatol 1999; 28: 56-60.

50. Scott JC. . Treatment of trochanteric fractures. J Bone Joint Surg 1951; 33-B: 508-512.

51. Simmermacher RK, Bosch AM, Van der Werken Chr. The AO/ASIF-proximal femoral nail (PFN): a new device for the treatment of unstable proximal femoral fractures. Injury 1999; 30: 327-332.

52. Stark A, Brostrom LA, Barrios C, et al. A prospective randomized study of the use of sliding hip screws and Ender nails for trochanteric fractures of the femur. Int Orthop 1992; 16: 359-362.

53. Tronzo RG. Surgery of the hip joint. Philadephia: Lea and Febiger; 1973.

54. Valverde JA, Alonso MG, Porro JG, Rueda D, Larrauri PM, Soler JJ. Use of the Gamma nail in the treatment of fractures of the proximal femur. Clin Orthop 1998; 56-61.

55. Wade PA, Campbell RD, Kerin RJ. Management of intertrochanteric fractures of the femur. Am J Surg 1959; 97: 634-643.

56. Watson JT, Moed BR, Cramer KE, Karges DE. Comparison of the compression hip screw with the Medoff sliding plate for intertrochanteric fractures. Clin Orthop 1998; 79-86.

57. Weise K, Schwab E. [Stabilization in treatment of per- and subtrochanteric fractures of the proximal femur]. Chirurg 2001; 72: 1277-1282.

CHAPTER 3

Reliability of the AO/ASIF classification for trochanteric femoral fractures

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Introduction

Systematic classification of a trochanteric femoral fracture may minimise problems related to interpretation of the fracture and may facilitate the choice of the appropriate method of treatment. To allow assessment of clinical studies on different types of trochanteric hip fractures, a reproducible classification is mandatory. Several fracture classifications exist[1-8]. The most basic classification is to divide the trochanteric fractures into stable or unstable fractures[4,9,10]. Stability of the fracture remains an important denominator in more recent and complex fracture classification systems. Ender (1970)[11] developed a classification based on the fracture mechanism in combination with his own method of internal fixation. Analysis of this classification[5] showed an unreliable prediction of instability of the fracture and in-sufficient discrimination between fracture types. Several other classification schemes have been developed based on comminution of the proximal medial cortex[8,12-16] and were found to be unreliable as they do not consider the postero-lateral instability[5]. The Tronzo classification takes both the medial and the postero-lateral instability into account[17]. This classification was shown to be rather complex with moderate results on predictive value for fracture stability[5]. Evans' (1949)[18] classification also aims to classify the instability of the fracture, comminution and primary dislocation. Prediction of the possibility of anatomical reduction and the risk of secondary displacement appeared sufficient[5] for the Evans' classification. The classification has proven to be very valuable and widely adopted. However, inter and intra-observer agreement were shown to be moderate[1].

Nowadays, the most commonly used classification scheme is *The Classification of Fractures of the Long Bones* introduced by the AO/ASIF group[7]. This classification is organized into hierarchical triads. For every bone segment (e.g. femur, tibia or humerus), three "types" of possible fractures exist (A, B, C), each of which can be divided into three fracture "groups" (e.g. for trochanteric fracture groups A1, A2, A3). The three fracture groups are each divided into three "subgroups" according to increasing fracture severity, indicating a greater difficulty in operative treatment, a higher likelihood of complications, and a poorer prognosis. Despite its common use and wide acceptance, its reliability and reproducibility have been questioned for a small number of specific fracture types[6,19-22].

The purpose of the present study was to assess the interobserver and intra-observer reliability of the AO/ASIF classification system for trochanteric femoral fractures. Interobserver reliability was assessed for fracture "group" classification and for "subgroup" classification

during two radiograph sessions. We also evaluated interobserver reliability between three specific groups of observers (surgeons, surgical residents and radiologists).

Material and Methods

The preoperative radiographs of 20 patients who had been submitted to our hospital in 1998 with trochanteric femoral fractures were selected from a trauma database. These radiographs were used for classification purposes in the present study. No special criteria were set as to the quality of the radiographs, other than that they had been accepted to form the basis of treatment. Prior to the study the radiographs were assessed in an expert panel consisting of the senior authors and two consultant radiologists from our clinics, to ensure representation of the full spectrum of trochanteric hip fractures, classified according to the segment 31 type A of the AO/ASIF classification. Each fracture was then classified by consensus of the panel. Fractures were defined as trochanteric when the fracture lines went through the major or minor trochanter. A fracture was considered to have subtrochanteric extension (A3) when the fracture lines extended distally from either the major or minor trochanter, to a maximum of 3 cm. below the minor trochanter.

The radiographs were reviewed by 15 observers: five surgeons involved in trauma-care, five surgical residents with special interest in orthopaedic trauma and five radiologists. None of the observers had previous experience with the AO/ASIF classification. Fracture classification sessions were conducted by one of the authors (I.B.S) in a standardised fashion. An explanation of the AO/ASIF classification segment 31 type A, its division into groups and subgroups and a copy of the original AO/ASIF classification were given as reference to each observer separately. Each observer was presented with 20 sets of (anterior-posterior and lateral) radiographs in random order and asked to classify each fracture as to group and subgroup (nine possible fracture classifications). The lateral views could be used for closer determination of involvement of the minor trochanter. Observers were not provided any feedback after the first session, nor were radiographs available to observers between the first and second classification session.

Three months later the same observers under the same conditions classified the same radiographs in a different order.

Statistics

We determined the interobserver reliability by comparing the classification results assigned by the 15 observers. Kappa values were calculated for interobserver reliability with and without subgroup classification of the fracture in the first and second session. Intra-observer reproducibility was assessed by comparing the classifications with subgroup and without subgroup of each observer on the two classification sessions.

The kappa coefficient of reliability provides a pair wise proportion of agreement between or among observers, corrected for chance. Kappa values can vary from $-p_e/1-p_e$ (complete disagreement) through 0 (chance agreement) to +1 (complete agreement).

Interobserver kappa values were calculated for each possible pair of the 15 observers for both classification sessions. Intra-observer kappa values were calculated comparing classification scores of each observer on the two different classification sessions.

An average kappa value was calculated to reflect the overall agreement between the observers. The uncertainty associated with this estimate could not be estimated with standard statistical approaches, since the dependency between kappas from the same observed should be taken into account. We therefore used a bootstrap resampling procedure[23]. Observers were drawn with replacement from the set of observers considered in the analysis. Note that if kappa values (rather than observers) were drawn with replacement, the dependency between kappas would have been ignored. The bootstrapping process replicated the situation that other observers had performed the classification, and hence provided insight in the variability of the estimated average kappa. We took 500 bootstrap samples and calculated the standard error of the estimated kappas over these samples. Based on the suggestion of a reviewer, we also used a SAS macro [24]. This resulted in identical estimates of the overall kappa value and somewhat smaller estimates of the standard error (results available from the authors).

We further aimed to compare the agreement of separate consultant groups (surgeons, surgical residents, radiologists). Average kappas were calculated per consultant group, with its standard error indicated by the bootstrapping procedure (500 replications).

Finally, a consensus classification was made by the senior authors and two consultant radiologists. The correspondence of classification from observers with this consensus classification was calculated for each radiograph.

Results

Twenty radiographs were reviewed twice by 15 observers. Classification scores are shown in table 1. Of the 600 (15 x 20 x 2) classification results obtained, correspondence with the final consensus varied from 0% to 100%. Mean correspondence was 52.5%. A substantial improvement in agreement was found when fractures were classified only according to main groups, rather than according to subgroups as well. Classification without subgroups resulted in an increase of mean agreement with the final consensus to 80.5%, as shown in figure 1 for the data of the second session.

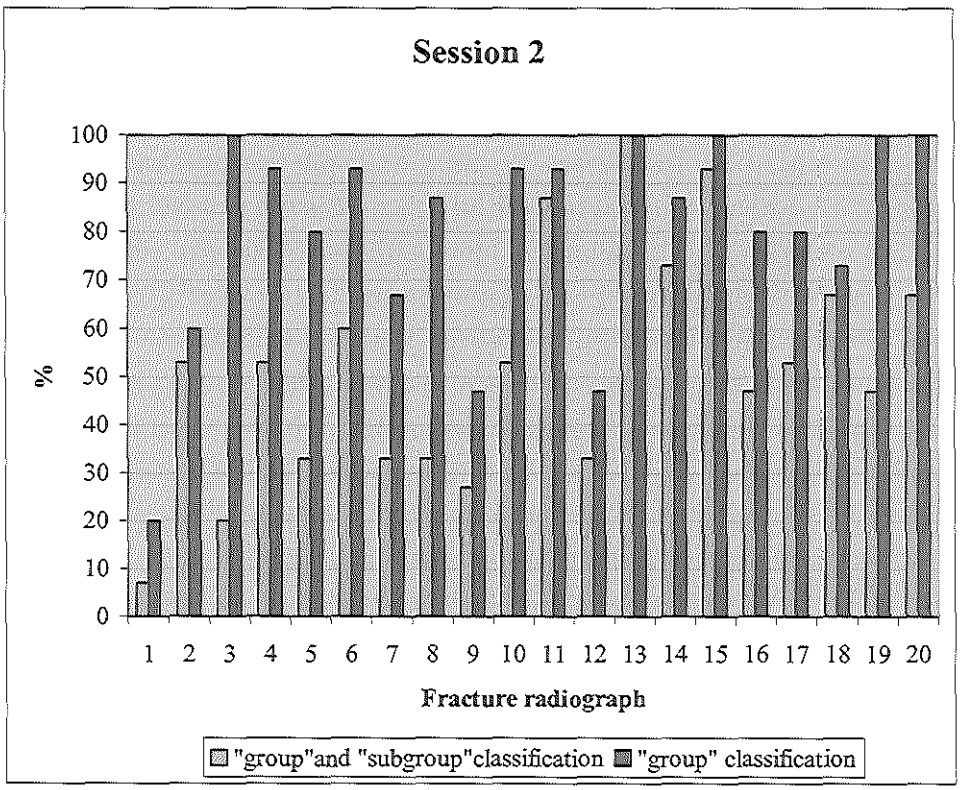

Figure 1. *Percentages agreement with the final consensus classification (table 1) for each fracture radiograph, assessed for group classification and for subgroup classification ($p < 0.001$) in the second viewing session. Session 1 showed similar results.*

Interobserver reliability

The interobserver reliability for classification of groups with their subgroups is shown in table 2. The mean kappa coefficient was 0.33 for the first classification session, for the second session the kappa value was similar (0.34). Interobserver agreement improved significantly if subgroup classifications were left out: the mean kappa coefficient was 0.67 in the first session, and 0.63 in the second session.

The mean kappa values for the different observer groups did not differ ($p = 0.35$) for the first classification session. Residents showed significantly worse interobserver reliability ($p=0.04$) compared to the surgeons and the radiologists during the second reading.

Intra-observer reliability

The mean kappa coefficient for intra-observer reliability for classification of fracture groups with their subgroups could not be calculated for 11 observers, since not all classifications used in the first reading were used in the second. For example, observer 1 classified images number 7 and 19 as 2.1 in the first reading and no images as such in the second reading (table 1). The mean kappa coefficient was 0.48 for 4 observers for whom an intraobserver kappa could be calculated. Mean intra-observer reliability for groups was substantially better, with a kappa coefficient 0.72 (table 2). Intra-observer agreement values for observer groups did not differ ($p=0.09$) for the surgeons, the surgical residents and the radiologists.

Discussion.

A valid fracture classification should meet four goals[25,26]. It should provide guidelines for treatment, it should be a method by which we can report, compare and assess results of treatment of similar fractures, it should provide a reliable language of communication, and it must be reasonably reliable and reproducible. Many authors have investigated different fractures and fracture classification systems regarding their reliability and reproducibility (table 3). Some classifications are based strictly on a specific fracture localisation, e.g. the Lauge-Hansen classification[27], Danis-Weber classification[25], Garden classification[2,3], Ruedi-Allgower classification[21,28], and the Neer classification[29,30], whereas the AO/ASIF classification provides systematic guidelines for classification of all fracture localisations of

Table 1. *Radiograph classification results for each fracture in both readings by 15 observers. Consensus classification is given separately.*

Nr.	Position	Session	Fracture 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
1	surgeon	1	2.2	2.3	3.3	1.1	2.2	1.1	2.1	1.2	2.3	3.1	2.3	2.3	3.3	2.2	3.1	1.1	1.2	1.2	2.1	1.2
2	surgeon	1	2.1	3.3	3.1	1.1	2.2	1.2	2.2	1.2	3.3	3.3	3.1	3.3	3.3	2.3	3.1	3.1	1.2	1.2	2.1	1.2
3	surgeon	1	3.3	3.3	3.3	1.2	1.3	1.1	2.2	3.3	1.3	3.1	3.3	3.3	3.3	2.2	3.1	3.1	1.2	1.2	2.2	1.2
4	surgeon	1	2.3	3.3	3.1	1.2	2.2	1.1	2.1	3.2	3.2	3.1	3.1	2.3	3.3	2.2	3.1	1.2	1.1	1.2	2.1	1.3
5	surgeon	1	2.2	3.3	3.3	2.1	2.1	1.1	2.1	1.2	3.2	3.1	3.3	3.3	3.3	2.3	3.1	1.2	1.2	1.2	2.2	1.2
6	resident	1	2.2	2.3	3.1	1.2	2.1	1.2	2.1	1.2	3.3	3.3	3.3	2.3	3.3	2.3	3.1	3.2	1.2	2.1	2.3	1.2
7	resident	1	2.1	2.3	3.1	2.1	2.1	1.2	2.1	1.2	2.3	3.3	3.3	2.2	3.3	2.3	3.3	3.1	2.1	1.2	2.1	1.2
8	resident	1	2.3	3.3	3.3	1.1	2.2	1.1	2.2	1.1	3.3	3.2	3.3	1.3	3.3	2.3	3.1	3.2	1.1	1.1	2.1	1.2
9	resident	1	2.3	3.3	3.1	1.2	2.1	1.1	2.2	1.2	3.3	3.3	3.3	3.2	3.3	2.3	3.1	1.2	1.2	1.2	2.2	1.2
10	resident	1	2.1	3.3	3.1	1.2	2.1	1.1	1.1	1.2	3.3	3.1	3.3	2.3	3.1	2.2	3.3	3.2	3.2	1.2	2.1	1.2
11	radiologist	1	2.3	3.3	3.1	1.1	2.1	1.1	2.1	2.1	2.1	3.1	3.3	3.3	3.3	2.3	3.1	1.3	1.1	1.1	2.2	1.1
12	radiologist	1	2.1	2.3	3.1	3.2	2.1	1.1	2.1	1.1	3.3	3.2	3.3	2.3	3.3	2.3	3.1	3.2	1.2	1.1	2.1	2.2
13	radiologist	1	2.2	2.3	3.1	1.1	2.1	1.1	2.2	2.3	2.1	3.1	3.3	2.3	3.3	2.2	3.1	2.2	1.1	1.2	2.2	1.2
14	radiologist	1	2.2	3.3	3.1	1.3	1.2	1.3	2.1	1.3	3.3	3.1	3.3	1.3	3.3	2.3	3.1	3.1	1.2	2.1	2.3	1.1
15	radiologist	1	2.2	2.3	3.3	2.2	2.2	1.1	2.3	2.2	3.2	3.3	3.3	3.3	3.3	2.3	3.3	3.3	1.2	1.2	2.3	1.2
1	surgeon	2	2.2	3.3	3.3	1.1	2.2	1.1	2.2	1.1	3.3	3.3	3.3	2.3	3.3	2.3	3.1	3.1	1.2	1.2	2.2	1.2
2	surgeon	2	3.1	3.3	3.3	1.1	1.2	1.2	1.2	1.1	2.3	3.1	3.3	3.1	3.3	2.3	3.1	1.2	2.1	1.2	2.2	1.2
3	surgeon	2	3.3	3.3	3.3	1.2	2.2	1.2	2.2	1.2	3.3	3.3	3.3	3.3	3.3	1.3	3.1	3.1	1.2	1.2	2.2	1.2
4	surgeon	2	2.3	2.3	3.1	1.2	2.1	1.1	2.1	1.1	1.3	3.1	1.3	2.3	3.3	2.3	3.1	3.1	1.2	1.1	2.2	1.2
5	surgeon	2	3.1	3.3	3.3	1.2	2.2	1.1	2.1	1.2	3.2	3.1	3.3	3.3	3.3	2.3	3.1	1.2	2.1	1.2	2.3	1.1
6	resident	2	2.1	3.3	3.1	1.1	2.1	1.2	1.1	1.2	1.3	3.1	3.3	2.3	3.3	2.3	3.1	3.2	1.2	1.2	2.3	1.2
7	resident	2	2.1	2.3	3.3	1.2	2.1	1.1	1.2	1.2	3.3	3.1	3.3	2.1	3.3	2.1	3.3	3.1	1.2	1.2	2.1	1.2
8	resident	2	2.3	3.3	3.3	1.2	2.1	1.2	2.3	1.3	3.3	3.3	3.3	3.1	3.3	2.2	3.1	3.2	1.1	1.1	2.1	1.2
9	resident	2	2.2	3.3	3.1	1.2	2.2	1.1	2.2	1.2	2.2	3.3	3.3	3.3	3.3	2.3	3.1	1.2	1.2	2.1	2.1	1.2
10	resident	2	2.1	2.3	3.3	1.1	2.1	1.1	2.1	1.1	2.1	3.1	3.3	2.2	3.3	2.3	3.1	3.1	1.1	1.2	2.1	1.2
11	radiologist	2	2.3	3.3	3.3	1.2	3.2	1.1	1.2	1.1	2.2	3.3	3.3	3.3	3.3	3.3	3.1	3.2	1.1	1.2	2.2	1.2
12	radiologist	2	2.2	2.3	3.3	1.1	2.2	1.1	2.2	1.1	2.1	3.3	3.3	2.3	3.3	2.3	3.1	3.2	2.1	1.1	2.1	1.2
13	radiologist	2	2.3	2.3	3.3	1.2	2.3	1.1	2.3	1.3	3.2	3.1	3.3	2.3	3.3	2.3	3.1	3.1	1.2	2.1	2.2	1.1
14	radiologist	2	2.3	3.1	3.3	1.3	1.3	1.2	1.1	2.1	2.1	3.1	3.3	3.1	3.3	2.3	3.1	3.1	1.2	2.1	2.2	1.2
15	radiologist	2	2.2	2.3	3.3	2.2	2.3	2.3	2.2	2.2	3.2	3.1	3.1	2.3	3.3	2.3	3.1	3.1	1.3	2.2	2.3	1.2
Consensus (expert panel)			**3.3**	**3.3**	**3.1**	**1.2**	**2.2**	**1.1**	**2.2**	**1.2**	**3.3**	**3.1**	**3.3**	**3.3**	**3.3**	**2.3**	**3.1**	**3.1**	**1.2**	**1.2**	**2.2**	**1.2**

Table 2. *Kappa-values for interobserver and intra-observer reliability (±SE)*

Kappa-values				
Interobserver	**First session**		**Second session**	
With subgroup classification	0.33	± 0.01	0.34	± 0.01
Without subgroup classification	0.67	± 0.01	0.63	± 0.01
residents	0.69	± 0.04	0.51	± 0.05
surgeons	0.62	± 0.03	0.64	± 0.05
radiologists	0.65	± 0.03	0.69	± 0.03
Intra-observer				
With subgroup classification	0.48*			
Without subgroup classification	0.72	± 0.02		
residents	0.70	± 0.05		
surgeons	0.73	± 0.02		
radiologists	0.72	± 0.05		

* intra-observer reproducibility of subgroup classification was only calculated for 4 observers (kappa-values 0.26, 0.48, 0.54, 0.64).

the long bones. Literature review shows that both the AO classification system and the non-AO classifications have broad ranges of kappa values (table 3). The AO classification system requires 3 sequential decisions of fracture classification. Each step of categorising fracture type, group and subgroup adds a risk of error to the previous classification step. Due to this cumulative error risk, interobserver and intra-observer disagreement increases. In our study, interobserver reliability was found to be poor for fracture subgroup classification (kappa-value 0.33) according to the scales of strength of agreement as proposed by Fleiss[31]. These results are consistent with those of previous AO/ASIF classification investigations as listed in table 3. Fracture group classification however was good, and with a kappa value of 0.67 even better then other reports[20-22,26]. The relatively low interobserver agreement among the residents confirms the idea that experience with classification of fractures and their treatment improves the reliability of using a classification system[6,20,26,28]. Intra-observer reliability for

Table 3. *Mean interobserver kappa values for 5 different fracture classification systems. The kappa values of AO/ASIF classifications are given separately for classification of fracture type, fracture group and subgroup.*

Author	Fracture Classification	Mean Interobserver Kappa value	
Horn et al. 1993	Gustilio-Andersen (open fractures)	0.53	
Siebenrock et al. 1993	Neer (shoulder)	0.30	
Kristiansen et al. 1988	Neer (shoulder)	0.30	
Dirsch et al.1997	Ruedi-Algower (ankle, distal tibia)	0.48	
Martin et al. 1997	Ruedi-Algower (ankle, distal tibia)	0.46	
Thomsen et al. 1991	Lauge-Hansen (ankle)	0.55	
	Weber (ankle)	0.57	
Siebenrock et al. 1993	proximal humerus; AO/ASIF segment 20	0.53	type
		0.42	group
Kreder et al. 1996	distal radius; AO/ASIF segment 23	0.68	type
		0.48	group
Martin et al. 1997	distal tibia; AO/ASIF segment 43	0.60	type
		0.38	group
Craig et al. 1998	ankle; AO/ASIF segment 44	0.77	type
		0.61	group

groups showed a kappa value of 0.72 and was also better than most results reported in the literature.

The main difficulty of a classification for trochanteric femoral fractures lies in the variety of fracture patterns, the possible involvement of the greater and lesser trochanter and the differentiation from lateral collum fractures and subtrochanteric fractures. Trochanteric fractures extending to the subtrochanteric region are difficult to categorise by the AO classification, as the AO/ASIF classification guidelines do not foresee in a specific classification of subtrochanteric fractures. The complexity of trochanteric and especially subtrochanteric fractures may prohibit further improvement of reliability of their classification. Applying a classification system for a complex fracture in a standardised

manner does not necessarily mean improvement of reliability. It is therefore recommended that classification of each fracture should be performed by means of consensus, in order to teach and encourage colleagues to discuss and determine specific characteristics of each fracture. Guidelines for treatment may be based upon the same systematic classification of fracture groups and, if classified by consensus of an expert team, of fracture subgroups. Using this classification, all fractures classified as 31.A.1 are treated with a Dynamic Hip Screw (Synthes, Mathys Medical, Netherlands) in our clinics. Patients with fractures classified as 31.A.2 and 31.A.3 are, because of their unstable fracture characteristics, treated by implantation of a Gamma-Nail (Stryker Howmedica, Netherlands) or a Proximal Femoral Nail (Synthes, Mathys Medical, Netherlands). However, the optimal treatment of trochanteric femoral fractures, particularly of types A.1.3, A.2.1 and A.3.3 often remains under debate, despite a valid fracture group classification system. These examples emphasise the need for a reliable subgroup classification and the clinical importance of valid further subdivision of stable and unstable pertrochanteric femoral fractures. Other, simpler subgroup classifications may be used for this purpose. Classification by consensus may again help to find uniform guidelines for treatment of all fracture subgroups. These classification related treatment guidelines should be further developed and investigated as reliability of subgroup classification increases with consensus classification and experience.

In our opinion the AO/ASIF classification for trochanteric femoral fractures (AO/ASIF 31A) meets the above-mentioned criteria for a valid fracture classification[25,26]:

- in our clinics it provides a guideline for treatment;
- it facilitates communication and diminishes confusion about fracture type and treatment;
- it is used to compare and asses results (currently comparing the Gamma-Nail with the Proximal Femoral Nail for similar trochanteric fracture groups in our clinics);
- interobserver and intra-observer reliability for fracture groups are fair to good with kappa statistics of 0.67 and 0.72 respectively, which provides a reasonable reliable and reproducible classification.

The results of our study also show that fracture classification systems do have their limitations. Poor interobserver reliability regarding subgroup classification poses the question whether subdivision into fracture subgroups should be encouraged.

In summary, both interobserver and intra-observer reliability were found to be good when classifying trochanteric fractures into AO groups. They were poor when further classifying them into AO subgroups. Although these results seem to be consistent with those of other research groups investigating the AO/ASIF fracture classification for different segments, more and larger studies should be performed to determine the characteristics of fractures that influence the reliability of a classification and fracture treatment.

References

1. Andersen E, Jorgensen LG, Hededam LT. Evans' classification of trochanteric fractures: an assessment of the interobserver and intraobserver reliability. Injury 1990;21(6):377-8.

2. Frandsen PA, Andersen E, Madsen F, Skjodt T. Garden's classification of femoral neck fractures. An assessment of inter-observer variation. J.Bone Joint Surg Br 1988;70(4):588-90.

3. Garden RS. Low-angle fixation in fractures of the femoral neck. J Bone Joint Surg 1961;43-B:647-63.

4. Hafner RHV. Trochanteric fractures of the femur. J Bone Joint Surg 1951;33-B(513):516.

5. Jensen JS. Classification of trochanteric fractures. Acta Orthop Scand 1980;51(5):803-10.

6. Johnstone J, Radford WJP, Parnell EJ. Interobserver variation using the AO/ASIF, classification of long bones fractures. Injury 1993;24:163-5.

7. Müller ME, Nazarian S, Koch P, Schatzker J. The comprehensive classification of fractures of the long bones. Berlin/Heidelberg: Springer-verlag; 1990.

8. Murray RC, Frew JFM. Trochanteric fractures of the femur- A plea for conservative treatment. J Bone Joint Surg 1949;31-B:204-19.

9. Rasmussen KB. McLaughlin osteosynthesis in trochanteric fractures. Acta Chir Scand 1953;105:246-51.

10. Wade PA, Campbell RD, Kerin RJ. Management of intertrochanteric fractures of the femur. Am J Surg 1959;97:634-43.

11. Ender J. Probleme beim frische per- und subtrochanter Oberschenkelbruch. Hefte Unfallheilk 1970; 106:2-11.

12. Harrington KD. The use of methylmethacrylate as an adjunct in the internal fixation of unstable comminuted intertrochanteric fractures in osteoporotic patients. J Bone Joint Surg Am 1975;57(6):744-50.

13. Johnson LL, Lottes JO, Arnot JP. The utilization of the Holt nail for proximal femoral fractures. A study of one hundred and forty-six patients. J Bone Joint Surg Am 1968;50(1):67-78.

14. Massie WK. Extracapsular fractures of the hip treated by impaction using a sliding nail-plate fixation. Clin Orthop 1962;22(180):180-201.

15. Sarmiento A, Williams EM. The unstable intertrochanteric fracture: treatment with a valgus osteotomy and I-beam nail-plate. A preliminary report of one hundred cases. J Bone Joint Surg Am 1970;52(7):1309-18.

16. Scott JC. . Treatment of trochanteric fractures. J Bone Joint Surg 1951;33-B:508-12.

17. Tronzo RG. Surgery of the hip joint. Philadelphia: Lea and Febiger; 1973.

18. Evans EM. The treatment of trochanteric fractures of the femur. J Bone Joint Surg 1949;31-B:190-203.

19. Craig WL, III, Dirschl DR. Effects of binary decision making on the classification of fractures of the ankle. J Orthop Trauma 1998;12(4):280-3.

20. Kreder HJ, Hanel DP, McKee M, Jupiter J, McGillivary G, Swiontkowski MF. Consistency of AO fracture classification for the distal radius. J Bone Joint Surg Br 1996;78(5):726-31.

21. Martin JS, Marsh JL, Bonar SK, DeCoster TA, Found EM, Brandser EA. Assessment of the AO/ASIF fracture classification for the distal tibia. J Orthop Trauma 1997;11(7):477-83.

22. Siebenrock KA, Gerber C. The reproducibility of classification of fractures of the proximal end of the humerus. J Bone Joint Surg Am 1993;75(12):1751-5.

23. Efron B, Tibshirani R. An introduction to the bootstrap. Monographs on statistics and applied probability. New York: Chapman and Hall; 1993.

24. Fleiss JL. Statistical methods for rates and proportions, second edition. In: John Wiley & Sons Inc., editor. New York: 1981.

25. Burstein AH. Fracture classification systems: do they work and are they useful? J Bone Joint Surg Am 1993;75(12):1743-4.

26. Martin JS, Marsh JL. Current classification of fractures. Rationale and utility. Radiol Clin North Am 1997;35(3):491-506.

27. Thomsen NO, Overgaard S, Olsen LH, Hansen H, Nielsen ST. Observer variation in the radiographic classification of ankle fractures. J Bone Joint Surg Br 1991;73(4):676-8.

28. Dirschl DR, Adams GL. A critical assessment of factors influencing reliability in the classification of fractures, using fractures of the tibial plafond as a model. J Orthop Trauma 1997;11(7):471-6.

29. Kristiansen B, Andersen UL, Olsen CA, Varmarken JE. The Neer classification of fractures of the proximal humerus. An assessment of interobserver variation. Skeletal Radiol. 1988;17(6):420-2.

30. Siebenrock KA, Gerber C. [Classification of fractures and problems in proximal humeral fractures]. Orthopade 1992;21(2):98-105.

31. Seigel DG, Podgor MJ, Remaley NA. Acceptable values of kappa for comparison of two groups. Am J Epidemiol 1992;135(5):571-8.

CHAPTER 4

Unstable trochanteric fractures and intramedullary treatment; The influence of fracture patterns on complications and outcome

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Introduction

Unstable trochanteric fractures can be divided into two main groups, according to the AO/ASIF Classification of the Long Bones 31A[1] (Figure 1). The A2 fractures are characterised by multi-fragment pertrochanteric patterns, lacking the abutment of the medial cortex as result of a fractured lesser trochanter. The A3 group represents the intertrochanteric fractures (between, not necessarily through, the greater and lesser trochanter), in which instability is caused by the reversed, transverse, or comminuted (subtrochantericly extending) fracture lines. These biomechanically very different fracture patterns may need a different therapeutical approach, since their distinct anatomical and mechanical characteristics may result in different dislocation patterns with subsequent intraoperative challenges and postoperative problems.

Generally, stabilisation of these unstable fractures with intramedullary devices has biomechanical[2] and biological[3] advantages, and is therefore considered the treatment of choice[4-7]. Two implants, the Gamma Nail® (Stryker Howmedica) and the Proximal Femoral Nail® (Synthes), have shown to provide a biomechanically stable construct[2,8,9] allowing early weight bearing, with low complication rates.

Since we do not know to what extent different fracture biomechanics may require tailored approaches for treatment, the purpose of this study was to determine and analyse the differences in intraoperative parameters and postoperative treatment outcome between A2 and A3 trochanteric fractures, using intramedullary fixation.

Materials and Methods

Patients and endpoints

All consecutive patients with unstable trochanteric fractures were documented in nine participating hospitals, i.e. eight teaching hospitals and one university hospital. Inclusion criteria were the radiological diagnosis of an unstable trochanteric fracture (figure 1), classified as 31A2 and 31A3 according to the AO/ASIF Classification for the long bones[1], and age over 60 years. Patients with (imminent) pathological fractures, fractures associated with polytrauma, and patients who were unable to walk prior to the fracture inflicting accident were excluded. The primary endpoint was defined as complete and uneventful radiological and clinical fracture healing. Secondary endpoints were local complications, reoperations (related to the failure of the primary treatment), and mortality.

Treatment protocol

All patients were operated according to the protocols for surgical procedure of either the Gamma Nail® (GN, Stryker Howmedica) or the Proximal Femoral Nail® (PFN, Synthes), which were summarised in the study protocol. The PFN® used for this study, was a 10 or 11 mm diameter solid titanium nail of 240 mm length, which was inserted without reaming of the medullary canal. The GN is a 200 mm cannulated steel nail, of 11 mm diameter. Reaming of the medullary canal was generally performed before insertion of the GN. In this study, both implants had a CCD angle of 130 degrees. Routine thrombosis prophylaxis were given pre-operatively and during the postoperative hospital stay according to local hospital protocols. All patients received prophylactic antibiotic coverage before starting the operation. Patients were operated on a fracture table, and if possible, closed reduction was performed with image intensifier control. Postoperatively, all patients were encouraged to mobilise fully weight bearing, assisted by a physiotherapist, as soon as possible.

Data-collection and follow-up protocol

Prospective data documentation and collection were facilitated by standardised case record-forms for the peri-operative period and follow-up. Baseline characteristics were documented as preoperative data. Operation time was recorded from incision to last stitch; time needed for closed fracture reduction was documented separately. Also documented were the estimated level of complexity of the actual procedure, the result of the fracture reduction, the position of the hip screw(s), and intraoperative complications. On the first day and after weightbearing, postoperative radiographs were obtained.

Follow-up was performed at 4 weeks, 4 months and 1 year postoperatively. If necessary, patients were examined more frequently. At each visit, besides clinical examination, standard investigations were performed (standard questionnaire, anteroposterior and lateral X-rays, Harris' hip score[10], Mini Mental State examination[11], Quality of Life score[12]). Study follow-up was discontinued after fracture healing, at re-osteosynthesis, or after one year at maximum.

Statistical methods

Statistical calculations were performed in SPSS 10.0. Method and result of reduction, complications, weightbearing ability, position of hip screw(s), intra-operative events, consolidation, reinterventions and complaints were compared using the chi-square test. Reduction time, operation time, complexity of surgery, and Harris' Hip score were compared between the two fracture types using Mann-Whitney tests. Exploratory subgroup analyses were performed to detect any influence of the type of fixation device. Differences in mortality, consolidation, overall numbers of local complications and reinterventions were calculated and tested using actuarial analysis with Wilcoxon statistics. Time periods were defined from inclusion to 4 weeks, from 4 weeks to 4 months, and from 4 months to 1 year. The level of statistical significance was set at a two-sided p-value of 0.05, but all p-values below 0.20 were reported.

Table 1. *Preoperative data, patients' baseline characteristics. ASA = American Society of Anaesthesiologists[17], MMSE = Mini Mental State Examination[11], SD = standard deviation, HHS = Harris' Hip Score[10].*

Fracture group		31.A2 (n=313)	31.A3 (n=100)
Female		258 (82 %)	82 (82 %)
Average age (years)		82.8 (SD 7.9)	80.8 (SD 8.9)
MMSE < 24		91 (37%)	28 (33%)
ASA classification	1	98 (32%)	33 (33 %)
	2	79 (26%)	22 (22%)
	3	131 (42%)	44 (44%)
	4	1 (0.3%)	
Mobility (HHS)		70 (SD 20)	69 (SD 21)
Fixation device: GN/ PFN		51%/ 49%	47%/ 53%

Results

Four hundred thirteen patients were included. All patients had sustained a low-energy injury, most often a fall. Three hundred thirteen fractures were classified A2 and 100 as A3. Patient

baseline characteristics were similar for both groups, as shown in table 1. Distribution of implants (GN or PFN®) was similar for both fracture groups.

Intraoperative data

Open reduction was performed in 25 cases, and significantly more frequent in A3 fractures (13% versus 4%, p = 0.001). Overall, open fracture reduction was significantly related to poor reduction results (p < 0.001), more intraoperative conversions to an alternative fixation method (p = 0.01), and fewer patients allowed weight bearing postoperatively (p < 0.001). Anatomical reduction was obtained more often in A2 fractures (p = 0.01). Time needed for reduction, actual surgery and fluoroscopy did not differ between the fracture groups, nor did the intraoperative complication rate.

The level of experience of surgeons who performed the operation seemed higher for the A3 than for the A2 group (66% versus 74% of the operations were done by residents), but no significance was found (p = 0.07).

Table 2. *Intraoperative data for both fracture groups.*

		31.A2 n = 313	31.A3 n = 100	p-value
Open reduction		12 (4%)	13 (13.0%)	0.007
Result of reduction	anatomical	178 (57%)	45 (45%)	0.01
Position of hip screw(s)	optimal	263 (86%)	85 (85%)	
Closed reduction time (min)		8.6 (SE 0.5)	9.7 (SE 0.9)	
Operation time (min)		59.5 (SE 1.3)	63.2 (SE 2.7)	
Intraoperative complications		28 (9%)	10 (10%)	
Complexity of surgery	easy	115 (36.7%)	23 (23.0%)	0.04
	moderate	157 (50.2%)	58 (58.0%)	
	difficult	39 (12.5%)	19 (19.0%)	

Various intraoperative complications were documented. Examples were problems concerning placement of the hip screw(s) or distal interlocking, breakage of K-wires, malrotation of the femur, and iatrogenic subtrochanteric fractures during nail insertion. Surgical procedures were

rated difficult more frequently in A3 fractures ($p = 0.04$), as were procedures with open reduction ($p < 0.001$). Data are shown in table 2. No relevant implant related differences were found.

Postoperative data

Full weight bearing was allowed more often ($p = 0.03$) in patients with A2 fractures (91%), compared to A3 fractures (84%). Mean duration of hospital stay was similar: 18.2 (A2) and 20.7 days (A3). Overall numbers of local and general complications did not differ between fracture groups. The number of reinterventions during primary admission was higher ($p = 0.003$) for the A3 fractures (8%), compared to the A2 fracture group (2%). This difference was predominantly caused by early cutout (3 patients), early lateral migration of the hip screw(s) (2 patients) and wound haematoma's (3). Only one of the five fractures that had to be reoperated due to dislocation of the hip screw(s), had originally been reduced anatomically; in none of these five fractures the hip screw(s) was (were) in the optimal position. Reoperations for haematoma's were not related to open reduction. Implants were equally distributed over both fracture groups. Exploratory subgroup analysis did not reveal any significant influence on overall primary and secondary endpoints.

Intramural mortality (20 days mean) did not differ between groups: 7% for patients with an A2 fracture and 6% for patients with an A3 fracture.

Follow-up until fracture healing or for one year maximum revealed similar mortality for A2 and A3 fractures, 25%($n = 65$) and 22% ($n = 18$) respectively ($p = 0.17$) according to actuarial analysis. During follow-up another 20 (16 A2, 4 A3) patients were lost for reasons of refusal of further participation or move abroad. Further reduction of numbers of patients during follow-up was due to complications and reoperations related to failure of the primary treatment, or to consolidation (table 3).

An overview of postoperative events and secondary endpoints is shown in table 3. Of the 71 patients with A2 fractures that had a local complication and 29 reoperations (table 4), 34 were related to failure of the primary treatment. For the 27 patients with A3 fractures that had a local complication and 18 reoperations (table 4), 14 were treatment related (secondary endpoint). Patients with A2 fractures showed a higher radiological consolidation rate at 4 months ($p = 0.05$), but at one year this difference was no longer found. Overall, uneventful

consolidation (primary endpoint) was documented in 197 of the 313 patients (63%) with A2 fractures and in 64 of the 100 patients (64%) with A3 fractures.

Table 3. *Data during postoperative follow-up at 4 weeks, 4 months and one year, calculated according to actuarial analysis.*

	Follow-up	31.A2	31.A3	p-value < 0.2
Local complications	4 weeks	39/239 (17%)	21/89 (23%)	0.09
	4 months	23/223 (10%)	4/67 (7%)	
	1 year	9/116 (9%)	2/47(4%)	
Reinterventions	4 weeks	7/277 (2 %)	6/96 (6%)	0.07
	4 months	15/251 (6%)	8/83 (9%)	
	1 year	7/122 (5%)	4/54 (7%)	#
Fracture consolidation	4 months	133/215 (62%)	36/71 (51%)	0.05*
	1 year	108/112 (96%)	44/47 (94%)	
General complications	4 weeks	46/239 (19%)	19/88 (21%)	
	4 months	32/222 (14 %)	12/72 (17%)	
	1 year	14/117 (12%)	2/47 (5%)	0.08
Mortality	4 weeks	36/277 (13%)	4/96 (4%)	
	4 months	18/251 (7%)	7/83 (8%)	
	1 year	11/122 (9%)	7/54 (13%)	

* significance at $p \leq 0.05$.

$p = 0.004$ for differences in overall numbers of interventions during follow-up.

Complications and reoperations

Although complication rates (table 4) tended to be higher in the A3 fracture group, no significance was found. Intraoperative complications were not related to method (open - closed) or result of reduction. Distribution of type of local complications was similar for both fracture groups. However, patients in whom fracture reduction had been obtained in an open manner suffered 40% local complications, whereas indirectly reduced fractures revealed a complication rate of 23% ($p = 0.05$). In A2 fractures the suboptimal positioning of the hip screw(s) was significantly related to more wound related and mechanical complications ($p = 0.05$).

The total reintervention rate (9% versus 18%) was higher for A3 fractures (p = 0.004). Main complications requiring reoperation in the A2 group were cutout and lateral migration of the hip screw(s) (table 4). This lateral migration and subsequent protrusion of the hip screw(s) was predominantly caused by inclavation of the fracture in both fracture groups. Numbers of cutout did not differ (p=0.4) between fracture groups. Other reoperations concerned wound debridements for infection or haematoma's.

Distribution and numbers of general complications did not differ between fracture groups (table 3).

Table 4. *Postoperative complications and reinterventions, 1-year cumulative percentages.*

	Complications		Reinterventions	
	31.A2 n =313	31.A3 n =100	31.A2 n =313	31.A3 n =100
Local complications				
Superficial wound infection	15 (5%)	8 (8%)	2 (1%)	2 (2%)
Deep infection	8 (3%)	3 (3%)	2 (1%)	3 (3%)
Haematoma	14 (5%)	3 (3%)	1 (1%)	3 (3%)
Cut-out	19 (6%)	4 (4%)	13 (4%)	4 (4%)
Lateral migration hip screw(s)	6 (2%)	2 (2%)	5 (2%)	2 (2%)
Medial protrusion hip screw(s)	0	1 (1%)	0	1 (1%)
Distal interlocking problem	1 (1%)	1 (1%)	0	0
Malrotation	3 (1%)	2 (2%)	1 (1%)	2 (2%)
Shaft fracture	4 (1%)	1 (1%)	4 (1%)	0
Nail fatigue	0	1 (1%)	0	1 (1%)
Pseudarthrosis	1 (1%)	1 (1%)	1(1%)	0
Overall	71 (22%)	27 (27%)	29 (9%)	18 (18%)*

* p = 0.004 for differences in overall numbers of interventions.

Functional outcome and Quality of life

The Harris' Hip Score (HHS)[10], scaled from 1 to 100, showed no differences (table 5) in functional state between fracture groups at 4 months and one year (mean 68). At 4 weeks, mean HHS was higher in patients with an A2 fracture (55 versus 48, p = 0.005). The MMSE

revealed no differences between fracture groups, nor did the mean score change over time for either of the groups (25 ± 1). Quality of life was measured in patients with an MMSE-score of 25 or higher, and did not reveal differences between groups, nor changes over time (table 5).

Table 5. *Functional state measured with the Harris' Hip score and Quality of Life.*

	31.A2	n =	31.A3	n =
Harris' Hip Score				
4 weeks	55.3 (SE 1.2)	199	48.5 (SE 2.1)*	77
4 months	62.0 (SE 1.4)	193	61.1 (SE 2.4)	66
1 year	66.3 (SE 1.8)	89	70.1 SE 2.7)	44
Quality of Life				
4 weeks	85.7 (SE 1.1)	121	87.0 (SE 1.9)	55
4 months	87.8 (SE 1.2)	111	88.2 (SE 1.8)	46
1 year	87.1 (SE 2.0)	52	91.7 (SE 1.7)	42

* $p = 0.005$

Discussion

This study reveals several differences between intramedullary treated A2 and A3 trochanteric fractures. First, reduction of A3 fractures was more problematic with more open reductions. The difficulty obtaining closed anatomical reduction in A3 fractures is well known[13]. In these fractures, the iliopsoas tendon remains attached to the lesser trochanter and thus, even with strong traction, the distal fragment tends to remain displaced in cranial and medial direction[14]. Our data also show that despite the higher tendency to an open approach, the result of reduction in A3 fractures was less satisfying compared to that of A2 fractures. Open reduction was associated with a higher number of local complications such as wound infection and early cutout. These cutouts were related to the earlier mentioned suboptimal reduction and subsequent suboptimal positioning of the hip screw(s). Another major difference between the fracture groups is the higher reinterventions rate for A3 fractures.

The results of this study once again emphasise the clear biomechanical differences between A2 and A3 fractures, and the importance of proper fracture reduction. Both open reduction

and malpositioning of implants, are closely related to higher complication rates. Therefore, a careful balance should be made between the possible unfavourable effects of open reduction and the documented disadvantages of closed reduction with suboptimally restored anatomy and subsequent poor positioning of the implant.

Although the overall reinterventions rate was higher in the A3 group, the (number of) complications and the final functional outcome were similar for both fracture groups. These results do therefore not confirm the suggestion that A3 fractures should be treated with a different device than A2 trochanteric fractures[15].

This study reveals, opposite to what has been suggested[16], that the AO classification[1] of 31 A fractures is very useful and relevant for the work of both clinicians and investigators, since its division into A2 and A3 fractures reflects important differences in fracture biomechanics, complexity of surgery and reintervention rate.

In conclusion, treatment of A3 trochanteric fractures is more demanding than that of A2 fractures. This is clearly confirmed by the results of our study, which show higher open reduction rates, worse results of reduction, less allowance of full weight bearing, and more early reinventions, in patients with A3 fractures. Fortunately, after intramedullary fixation long-term overall consolidation rates and final functional outcome are similar for both groups.

References

1. Müller ME, Nazarian S, Koch P, Schatzker J. The comprehensive classification of fractures of the long bones. Berlin/Heidelberg: Springer-verlag; 1990.

2. Götze B. Belastbahrkeit von Osteosynthesen bei instabilen per- und subtrochanteren Femurfrakturen. Akt Traumatol 1998; 28: 197-204.

3. Curtis MJ. Proximal femoral fractures: a biomechanical study to compare intramedullary and extramedullary fixation. Injury 1994 2000; 25: 99-104.

4. Radford PJ, Needoff M, Webb JK. A prospective randomised comparison of the dynamic hip screw and the gamma locking nail. J Bone Joint Surg Br 1993; 75: 789-793.

5. Friedl W, Clausen J. [Experimental examination for optimized stabilisation of trochanteric femur fractures, intra- or extramedullary implant localisation and influence of femur neck component profile on cut-out risk]. Chirurg 2001; 72: 1344-1352.

6. Sadowski C, Lubbeke A, Saudan M, Riand N, Stern R, Hoffmeyer P. Treatment of reverse oblique and transverse intertrochanteric fractures with use of an intramedullary nail or a 95 degrees screw-plate: a prospective, randomized study. J Bone Joint Surg Am 2002; 84-A: 372-381.

7. Ahrengart L, Tornkvist H, Fornander P, Thorngren KG, Pasanen L, Wahlstrom P, Honkonen S, Lindgren U. A randomized study of the compression hip screw and Gamma nail in 426 fractures. Clin Orthop 2002; 209-222.

8. Al yassari G, Langstaff RJ, Jones JW, Al Lami M. The AO/ASIF proximal femoral nail (PFN®) for the treatment of unstable trochanteric femoral fracture. Injury 2002; 33: 395-399.

9. David A, von der HD, Pommer A. [Therapeutic possibilities in trochanteric fractures. Safe--fast-- stable]. Orthopade 2000; 29: 294-301.

10. Harris WH. Traumatic arthritis of the hip after dislocation and acetabular fractures: treatment by mold arthroplasty. An end-result study using a new method of result evaluation. J Bone Joint Surg Am 1969; 51: 737-755.

11. Cockrell JR, Folstein MF. Mini mental state examination (MMSE). Psychophar Bull 1988; 24: 689-692.

12. Ware JE, Jr., Sherbourne CD. The MOS 36-item short-form health survey (SF-36). I. Conceptual framework and item selection. Med Care 1992; 30: 473-483.

13. Tronzo RG. Symposium on fractures of the hip. Special considerations in management. Orthop Clin North Am 1974; 5: 571-583.

14. DeLee JS. Fractures and dislocations of the hip. In: Rockwood CA, Green DP, Eds. Orthopaedic Surgery. Lippincott-Raven; 1996.

15. Haidukewych GJ, Israel TA, Berry DJ. Reverse obliquity fractures of the intertrochanteric region of the femur. J Bone Joint Surg Am 2001; 83-A: 643-650.

16. Pervez H, Parker MJ, Pryor GA, Lutchman L, Chirodian N. Classification of trochanteric fracture of the proximal femur: a study of the reliability of current systems. Injury 2002; 33: 713-715.

17. American Society of Anesthesiologists. New classification of Physical status. Anesthesiology 1963; 24: 111-114.

CHAPTER 5

Treatment of unstable trochanteric fractures:

Randomised comparison of the Gamma Nail and the Proximal Femoral Nail

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Introduction

Several fixation devices have been developed to overcome the difficulties encountered in treatment of unstable trochanteric femoral fractures. Until recently most trochanteric fractures were treated with a sliding hip screw system. Since this device performed less well in unstable trochanteric fractures, with high failure rates[1-5], intramedullary fixation devices are increasingly accepted as treatment for unstable trochanteric fractures[6-8]. The main principle of this intramedullary type of fixation is based on a sliding screw in the femoral neck-head fragment, attached to an intramedullary nail. From a biomechanical point of view, the intramedullary nail is favoured for treatment of unstable trochanteric fractures[7,9,10]. The Gamma Nail® (GN) (Stryker Howmedica), available since 1988, was designed specifically for the treatment of these fractures (figure 1), in order to combine the advantages of semi-closed intra-medullary nailing, a dynamic femoral neck screw, and early postoperative weight bearing[11-14]. Advantages of the GN over the DHS in these unstable fractures, were both suggested and advocated, but still remain to be clinically demonstrated on evidence base. Moreover, serious implant-related complications were described, such as femoral shaft fractures in up to 17%[5,11,13,15-19], fixation failure up to 7%[16-18,20,21] and distal

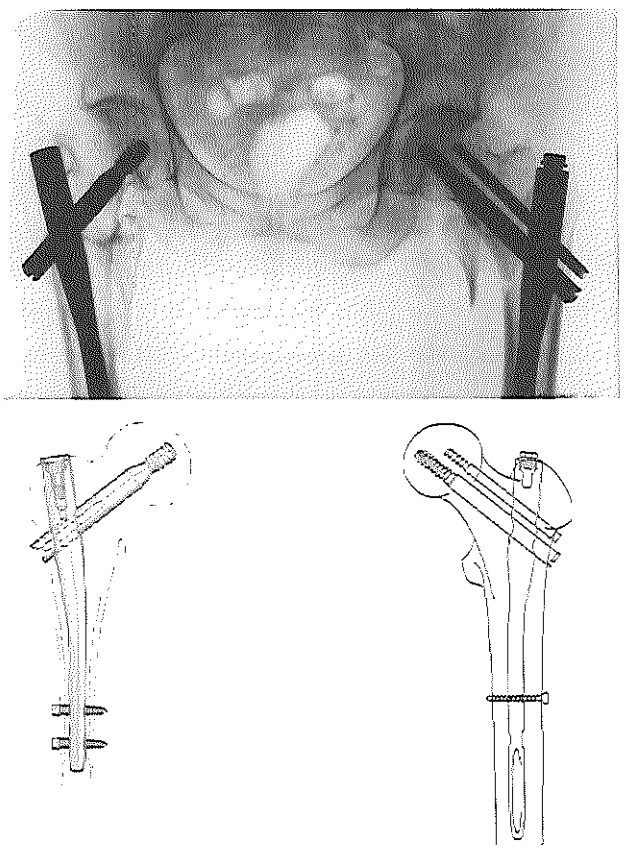

Figure 1.
Radiographic example and schematic drawings of the Gamma Nail® (left) and the Proximal Femoral Nail® (right), showing the increased length and the 2 neck screws of the PFN. The curvation of the nail is reduced in the PFN®; its diameter is smaller, allowing unreamed insertion into the shaft.

locking complications in up to 10%[13,15,22,23], requiring re-operation with subsequent morbidity and even mortality. Despite these complications, the GN is still widely used for treatment of unstable trochanteric fractures. Because of the apparent and persistent problems in treatment of unstable trochanteric fractures and subsequent complications, other intramedullary fixation devices were introduced. The Proximal Femoral Nail® (PFN) was developed to improve the rotational stability of the proximal fracture fragment, combining the features of an unreamed intramedullary femoral nail with a sliding load bearing femoral neck screw (figure 1). Furthermore, the nail tip was redesigned to decrease the risk of intra- and postoperative femoral shaft fractures by a significant reduction in bone stress[24]. Since the introduction of the PFN® in 1997 (Synthes), several clinical cohort studies[6,25] showed good results with few intraoperative problems and a low complication rate[26].

The clinical relevance of the presumed advantages and lower complication rates are still to be established and compared with a standard method of treatment. We therefore initiated a prospective randomised multicentre clinical trial comparing the GN and the PFN® for differences in intraoperative use, complications and outcome.

Methods

Participants

All consecutive patients with unstable trochanteric fractures were documented in nine participating hospitals, i.e. eight teaching hospitals and one university hospital. In each hospital a local trial coordinator was responsible for daily affairs and data-acquisition. Inclusion criteria were the radiological diagnosis of an unstable trochanteric femoral fracture (figure 2), classified as 31A2.1-3 and 31A3.1-3 according to the AO/ASIF Classification for the long bones[27], age above 60 years, and a signed informed consent by the patient (or relatives in case of demential syndrome). Exclusion criteria were determined as inability to walk prior to the fracture inflicting accident, other fractures interfering with rehabilitation or (suspicion of) pathological fracture.

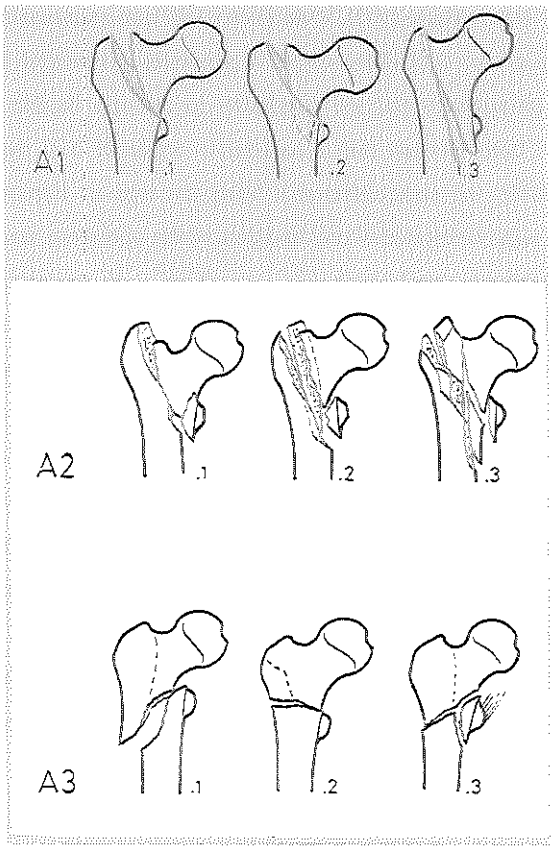

Figure 2. *Schematic illustration of the unstable trochanteric fracture types (AO/ASIF classification 31A2 and A3[27]) included in this study (high-lighted).*

Objective and outcome

The objective of this study was to compare the overall efficacy of the GN to the PFN® in management of unstable trochanteric femoral fractures. The hypothesis was that the PFN® would reveal fewer complications than the GN. The primary endpoint was defined as complete and uneventful radiological and clinical fracture healing (at 4 months and 1 year). Secondary endpoints were intraoperative complications, re-operations (related to the failure of primary treatment), and mortality. Baseline characteristics were documented preoperatively; outcome measures were subdivided into intraoperative, postoperative, and follow up data at 4 weeks, 4 months and one year.

Interventions

After randomisation, surgery was performed according to the protocols for surgical procedure of either the GN or the PFN®, which were summarised in the study protocol. The PFN® used in this study, was a 10 or 11 mm diameter solid titanium nail of 240 mm length, which is inserted without reaming of the medullary canal. A second hip pin is inserted in the femoral head-neck fragment. This hip pin is to provide rotational stability that a hip screw alone is assumed to lack[28]. The PFN® has a possibility of dynamic and static distal interlocking.

The other implant used in this study was a Mark-3 GN, which has a 200 mm cannulated steel nail of 11 mm diameter. Reaming of the medullary canal is generally performed before insertion. There is one hip screw proximally, and the possibility to perform double static interlocking distally. In this study, both devices had a nail-screw angle of 130 degrees. Operating procedures were comparable, the main difference being the type of implant. To ensure quality control, surgery was only performed if one member of the operating team had experience with at least five procedures (with both GN and PFN®). If necessary, an experienced surgeon was asked to attend in order to ensure proper procedures to be performed. As long as the trial was open for inclusion, no modifications were introduced concerning surgical technique and implant design. Routine thrombosis prophylaxis was given pre-operatively and during the postoperative hospital stay. Patients received prophylactic antibiotic coverage before starting the operation. Choice of prophylaxis depended on the local hospital protocols. General anaesthesia and spinal anaesthesia were applied for both treatment arms. Patients were operated on a fracture table, and if possible, closed reduction was performed with image intensifier control.

Postoperatively, analgesic care and diet restoration were according to local standards, and equal for both treatment arms. All patients were encouraged to mobilise full weight bearing, starting as soon as possible after operation, assisted by a physiotherapist.

Randomisation and data-acquisition

This trial was approved by the appropriate ethics committee of each participating institution. Patients received written information about the trial. Prior to randomisation, informed consent was obtained from each patient. Each participating hospital received 50 numbered and blinded randomisation envelopes. If necessary more randomisation envelopes were distributed. The randomisation order was computer-generated, based on randomly permuted balanced blocks of 4 and 6 patients, and was stratified for each participating centre. The randomisation order was well-documented and only known by the central trial co-ordinator.

Data collection was facilitated by standardised case record-forms for the peri-operative period and long-term follow-up. All data forms were collected by the central trial co-ordinating centre. For privacy reasons all patients were coded and identified by means of the randomisation number. All patients admitted for operative treatment of an unstable trochanteric fracture were registered, including those who refused randomisation and those who did

not meet inclusion criteria. Brief details of the reasons why the patients were not randomised were given. Preoperatively, physical state according to the ASA classification[29], mental status, and mobility prior to the accident were determined. Intra-operatively, blood loss was measured from the gauzes and the suction unit. Operation time was recorded from incision to last stitch, time needed for closed fracture reduction was documented separately, as was fluoroscopy time. The surgeon also documented the (subjective) overall ease or difficulty of the actual procedure, and the result of the fracture reduction: anatomical, acceptable (5- 10° varus/valgus and/or ante/recurvation,), or poor (> 10° varus/valgus and/or ante/recurvation). The position of the fixation devices if not optimal (position of screw(s) too cranial, caudal, dorsal or ventral, screw length too short or too long, malrotation, wrong insertion point of the nail, misplacement of distal locking bolt) was registered, as were intraoperative problems or complications. On the first day (or immediately after surgery) and on the seventh day (after weightbearing) postoperative radiographs were obtained. Follow-up at the outpatient clinic was at least at 4 weeks, 4 months and 1 year postoperatively. At each visit clinical examination and a standard scheme of investigations was performed (standard questionnaire, anteroposterior and lateral X-rays, functional state and mobilisation measured by the Harris' hip score[30] scaled from 1 to 100 (1 to 92 in the preoperative questionnaire on the situation before the fracture, since functional tests could not be measured), Quality of Life score[31], Mini Mental State examination[32]). Outcome assessments were performed by the treating surgeons and the research assistant, radiographs were also analysed by the radiologists and the research coordinator.

Sample size and Statistical analysis

Sample size calculations were based on intra- and postoperative complication rates with their related differences in recovery of mobility as presented in literature[5,6,11,13,15-19,25]. A difference of 10% (PFN®) versus 20% (GN) complication rate was to be detected with 80% power at the 5% significance level. This required a total of 420 patients for a chi-square test (210 in each group).

Data were analysed on an intention to treat basis. Statistical calculations were performed in SPSS 10.0. Method of reduction, intraoperative complications, conversion of method, weightbearing, position of fixation, intra-operative events, and complaints were compared using the chi-square test. Blood loss, operation time and were compared between the two pro-

cedures using Mann-Whitney tests. The preoperative Harris' Hip scores were corrected with a factor 1.089, since these scores were maximised at 92, whereas postoperative 100 points could be given. Exploratory subgroup analyses were performed to detect any influence of fracture types (A2 and A3). Differences in local complications, reoperations and general complications between implants and over time, were tested using actuarial analysis with Wilcoxon statistics. Time periods were defined from randomisation to 4 weeks, from 4 weeks to 4 months, and from 4 months to 1 year. The level of statistical significance was set at a two-sided p-value of 0.05, but all p-values below 0.20 were reported.

Trial results were not presented as long as the trial was open for intake or follow up.

Table 1. *Preoperative data, patients' baseline characteristics. Fracture characteristics according to the AO/ASIF classification of the long bones, type 31A*[27]*. Percentages are given for fracture groups per implant.*

Variables		PFN (n=211)	Gamma Nail (n=213)
Female		173 (82%)	176 (82.6%)
Average age (years)		82.2 (SD 8.4)	82.6 (SD 8.0)
MMSE < 24		76 (35.9%)	76 (35.7%)
ASA classification	1	66 (31.3%)	68 (31.9%)
	2	53 (25.1%)	50 (23.5%)
	3	88 (41.6%)	93 (43.7%)
	4		1 (0.5%)
Mobility (HHS)		68.9 (SD 20.9)	70.2 (SD 19.1)
Fracture	A2	156 (74.1%)	165 (77.4%)
	A3	55 (25.9%)	48 (22.6%)

ASA= American Society of Anaesthesiologists[29], MMSE = Mini Mental State Examination[32], SD = standard deviation, HHS = Harris' Hip Score[30].

Results

From 1 September 1998 until 1 January 2002, 424 patients were included in this study. Two hundred thirteen patients were randomised to a GN and 211 to a PFN® (figure 3). Both treatment groups were comparable at baseline (table 1). Fracture characteristics and distribution

were similar for both patient groups. All fractures resulted from a low-energy injury, most often a fall.

Peri-operative data

The method of anaesthesia (general or regional) did not differ between treatment groups, nor did the level of experience of surgeons who performed the operation; 72.4 % were operated by residents. Peri-operative data are shown in table 2. Mean intraoperative blood loss differed significantly: 220 ml in the PFN® group, compared to 287 ml in the GN group ($p = 0.001$). The mean operative time and fluoroscopy time did not differ between groups. Fracture reduction was judged anatomical in 51-57% (table 2). Relating quality of reduction to both type of implant and type of fracture (A2 or A3) revealed no significant differences regarding the implant ($p = 0.11$) nor the fracture type ($p > 0.2$). Open reduction was performed in 25 cases, 17 in the PFN® group and 8 times in the Gamma Nail group ($p = 0.06$). Surgical procedures were judged easy, moderately difficult and difficult in similar numbers for both implants (table 2).

Table 2. *Peri-operative data.*

		PFN n = 211	Gamma Nail n = 213
Operation time (min)		60 (SE 2)	60 (SE 2)
Open reduction (n)		17 (8.1%)	8 (3.8%)
Result of reduction (n)	anatomical	106 (50.7%)	121 (57.1%)
	acceptable	97 (46.4%)	89 (42.0%)
	poor	6 (2.9%)	2 (0.9%)
Perception of surgery (n)	easy	71 (34.1%)	73 (34.3%)
	moderate	103 (49.5%)	116 (54.5%)
	difficult	34 (16.3%)	24 (11.3%)
Blood loss (ml)		220 (SE 13)	287 (SE 18) *
Full weightbearing allowed (n)		185 (88.5%)	187 (91.2%)

* $p = 0.001$

Intraoperative complications

Local problems occurred 16 times intraoperatively, 9 times GN-related and 7 PFN® -related (table 3). Problems with insertion of the hip screw(s) were breakage of the K-wire (GN), perforation of the femoral head (PFN®), and converging of the K-wires (PFN®).

Intraoperative conversion to another method of treatment was documented 7 times. The main reason was subtrochanteric extension of the fracture, 5 times pre-existent on the radiograph but not diagnosed preoperatively, and twice caused by insertion of the GN. In one patient a PFN® was used instead of a GN, twice a long GN instead of a short one, once a long GN instead of a PFN® and once a DHS instead of a PFN®. Other reasons for using an alternative fixation device were unfamiliarity with intramedullary nailing (DHS instead of GN), and unavailability of the determined implant (GN instead of PFN®). Distal interlocking was troublesome in 9 cases: in 4 GNs the drill bit and/or screw missed the nail, in two other GNs the distal interlocking was technically impossible. In three PFNs the desired static interlocking failed, after which dynamic interlocking was performed. Intraoperative assessment of the position of the fixation device revealed no differences (p = 0,1): 4 GNs and 2 PFNs had wrong a screw length, 14 GNs and 25 PFNs had malposition of the hip screw(s), and 7 GNs and 2 PFNs were inserted at a suboptimal entry point. In three GNs and 1 PFN® locking bolts had missed the nail, malrotation of the femoral shaft was seen with 1 GN and 3 PFNs.

Table 3. *Intra-operative complications.*

	PFN (n = 211)	Gamma Nail (n = 213)
Local problems		
Problems proximal screw(s)	4	1
Problems distal interlocking	3	6
Fracture at the tip of the nail		2
Total	7 (3.3%)	9 (4.2%)
Suboptimal position of fixation device(s)	34 (16.3%)	28 (13.2%)
Other adverse events		
Organisational/ logistic problems	6	3
Cardiac complications		1
Conversion of method of fixation	3 (1.4%)	4 (1.9%)

Table 4. *Numbers of patients related to endpoints during postoperative follow-up, at 4 weeks, 4 months and one year, according to actuarial analysis. No significant differences were found.*

Follow-up	Endpoint	PFN	Gamma Nail
4 weeks	Mortality	24 (11.4%)	20 (9.4%)
	Reoperation	7 (3.4%)	10 (4.9%)
	Local complication	33 (14.9%)	43 (19.8%)
4 months	Mortality	15 (7.3%)	11 (5.4%)
	Fracture consolidation	81 (46.5%)	93 (52.5%)
	Local complication	12 (5.3%)	4 (1.7%)
	Reoperation	15 (8.1%)	7 (3.6%)
1 year	Mortality	7 (5.8%)	11 (9.4%)
	Fracture consolidation	63 (45.5%)	52 (38.5%)
	Local complication	6 (4.0%)	3 (2.0%)
	Reoperation	7 (6.9%)	4 (3.7%)
Overall	Mortality	46 (24.5%)	42 (24.2%)
	Fracture consolidation	144 (92.0%)	145 (91.0%)
	Local complication	51 (24.2%)	50 (23.5%)
	Reoperation	29 (18.4%)	21 (12.2%)
	Uneventful consolidation	129 (61.1%)	138 (64.8%)

Early postoperative outcome

In the early postoperative period (1-30 days), mean level of mobilisation was similar for both implant groups. Mean duration of hospital stay was 19.0 (SE 1.2) days for patients treated with a GN and 21.7 (SE 1.4) days for patients with a PFN® ($p = 0.14$).

At 4 weeks 44 patients had died and 374 were available for follow-up (190 in the GN-group and 184 in the PFN® -group, figure 3). Causes of death throughout the study were attributable to concomitant medical problems and were not related to the method of fixation. Both implant groups showed similar numbers and distribution of in-hospital and early postoperative general complications. Within 4 weeks local complications requiring reoperation were seen in 7 PFN®

-treated patients and in 10 patients with a GN (table 4). Six of these operations concerned the hip screw cutout of a GN, three were related to cutout of the PFN® (table 5); in 7 of these cases the position of the hip screw(s) had been suboptimal (4 GNs, 3 PFNs) or reduction (1 GN) had been poor (table 6). One PFN® showed excessive gliding of one of the hip screw with subsequent varus dislocation of the fracture, necessitating reoperation. Two PFNs showed medial protrusion of the hip screw or anti-rotational screw into the joint (table 5). These patients underwent a reoperation. Other reoperations concerned debridements of wounds, and correction of an intraoperatively introduced 20-degree endorotation.

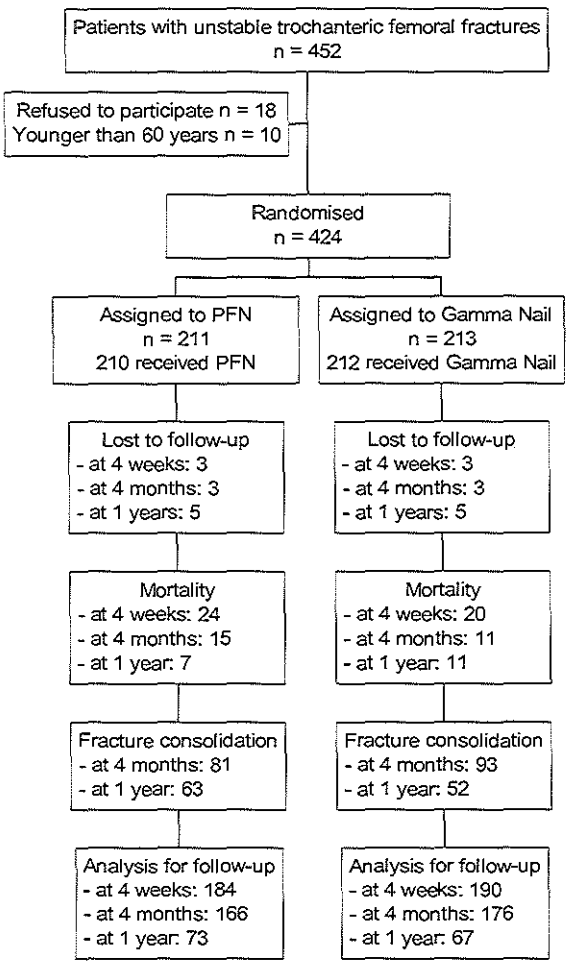

Figure 3. *Flow of participants through the phases of enrolment, allocation, follow-up and analysis.*

Four months follow-up.

From 4 weeks to 4 months 374 patients were followed. Analysis at 4 months learned that another 26 patients had died and 6 more patients were lost to follow-up, leaving 342 patients (GN 176, PFN® 166) available for follow-up analysis (figure 3). Reasons for patients being lost to follow-up (figure 3) were move to an unknown location or abroad, and refusal of further participation. Of the 342 patients, 174 (GN 93, PFN® 81) showed complete radiological consolidation (primary endpoint) at 4 months, and their study follow-up was therefore discontinued. Four local complications (resulting from cutout, intra-operative malrotation, fatigue of the GN, and infection) had been diagnosed in the GN-group and 12 (cutout, not previously diagnosed malrotation, shaft fracture, and infection)

Table 5. *Postoperative complications, 1-year cumulative percentages calculated with actuarial analysis.*

	PFN	Gamma Nail	P – value < 0.20
Local complications			
Superficial wound infection	8 (4.1%)	15 (7.4%)	0.13
Deep infection	5 (2.5%)	6 (3.0%)	
Haematoma	7 (4.5%)	10 (5.0%)	
Cut-out	11 (6.9%)	13 (6.6%)	
Lateral migration hip screw(s)	10 (7.6%)	2 (1.6%)	0.02
Medial protrusion hip screw(s)	2 (1.0%)	0	0.15
Distal interlocking problem	1 (0.5%)	2 (1.0%)	
Malrotation	3 (1.5%)	2 (1.0%)	
Shaft fracture	4 (2.0%)	1 (0.5%)	0.09
Nail fatigue	0	1 (0.5%)	
Pseudo-arthrosis	0	2 (2.2%)	0.15
Overall local complications	51 (24.2%)	50 (23.5%)	
Reoperations	29 (18.4%)	21 (12.2%)	
General complications			
Cardiovascular	30 (14.8%)	27 (15.5%)	
Pulmonal	11 (6.3%)	11 (5.5%)	
Urogenital	27 (13.8%)	27 (13.3%)	
Neurological	8 (4.3%)	11 (6.7%)	
Gastro-intestinal	1 (0.5%)	6 (3.6%)	0.08
Thrombo-embolic	4 (2.7%)	1 (0.5%)	
Psychiatric	14 (8.3%)	12 (6.0%)	
Pressure sores	14 (8.5%)	11 (5.6%)	

in the PFN® -group (table 5). These 4 GN treated patients were reoperated. Three more GN-treated patients underwent reoperation because of an earlier (intra-operative) and progressive varus dislocation (table 4). From 4 months postoperatively to one year post-operatively 168

patients were followed. During this period 10 patients were lost to follow-up, and 18 patients died.

Table 6. *Cutout, lateral and medial protrusion of the hip screw(s) in relation to result of reduction and position of the implant, for the GN and the PFN.*

	Cutout		Lateral migration		Medial migration	
	PFN	GN	PFN	GN	PFN	GN
Suboptimal reduction	2	6	4	1	2	
Poor (position of) fixation	1	3	1	1		
Both	6	3	2			
Neither	2	1	3			
Total	11	13	10	2	2	

One year follow-up

From 4 months postoperatively to one year postoperatively 168 patients were followed (figure 3). During this period 10 patients were lost to follow-up, and 18 patients died. Of the remaining 150 (GN 67, PFN® 73) both functional tests and radiographs were obtained, which showed radiological consolidation at one year in 115 patients (table 4). The complications that had occurred between four months and one year postoperatively, were infection (GN), cutout (GN and PFN®), pseudo-arthrosis (GN), and shaft fractures (GN and PFN®). All patients with these complications were reoperated. Inclavation of the fracture led to symptomatic lateral protrusion of the hip screw(s) in 8 patients treated with the PFN®. In two more patients, lateral migration of the hip screw(s) caused similar morbidity. The screw(s) were removed in all 10 patients.

Complications specifically seen in patients treated with a GN were pseudarthrosis and subsequent nail fatigue. After treatment with the PFN®, significantly more patients showed lateral protrusion of the proximal screw(s); in this study medial migration of the hip screw(s) was uniquely documented with the PFN®. Only three of the above mentioned patients had good fracture reduction and optimal implant positioning. Similar results concerning fracture reduction and implant positioning were found regarding cutout of the PFN® and GN (table 6).

General complications and functional outcome

General complications were comparable for both treatment modalities (table 5). The Harris' Hip Score (HHS)[30] showed no differences in functional state between the two implants at follow-up (table 7). There was a significantly decreased mean HHS, 4 weeks after operation ($p < 0.001$), with progressive recovery after 4 months and one year ($p < 0.001$). The majority (68%) of complaints related to the operation or fracture, concerned pain in the hip region. Other complaints concerned muscle weakness, lower endurance, or referred pain in the ipsi-lateral knee area. Numbers of patients without complaints were comparable for both implants and increased with time (table 7).

Table 7. *Mobility measured with the Harris' Hip score[30] preoperative, at 4 weeks, 4 months and 1 year. Complaints related to the fracture, implant or operation site were documented at 4 weeks, 4 months and 1 year postoperatively.*

	PFN	n =	Gamma Nail	n =
Harris' Hip Score				
Pre-operative	68.9 (SE 1.6)	181	70.3 (SE 1.4)	187
4 weeks	52.6 (SE 1.5)	140	53.9 (SE 1.5)	139
4 months	61.9 (SE 1.6)	133	62.0 (SE 1.7)	130
1 year	66.8 (SE 2.1)	73	69.5 (SE 2.0)	64
No complaints and/or restrictions				
4 weeks	65.0%	104/160	60.4%	102/169
4 months	66.0%	97/147	59.5%	91/153
1 year	77.6%	57/73	76.5%	51/67

Discussion

This trial was initiated in order to compare the GN and the PFN® for differences in treatment outcome, based on the hypothesis that the PFN® would reveal fewer complications than the GN. Pilot studies in relatively small patient groups[6,25,33,34] showed good outcome with few complications, after treatment with the PFN®. Two randomised trials of respectively 39[26] and 206 patients[35], compared extra- medullary fixation devices with the PFN® in stable and unstable trochanteric fractures: For unstable fractures the PFN® revealed better treatment

results. In these studies, no comparison was made with the most frequently used intramedullary fixation: the GN.

The present study revealed no important differences between the results of treatment with either the GN or the PFN®, in comparable patients groups. Intra-operative problems were encountered in 12 of the 211 PFN® and 15 of the 213 GN procedures. Two patients sustained an iatrogenic subtrochanteric fracture at insertion of a GN. This intraoperative complication has been described by before[11,13,16,36] and may be due to insufficient reaming, or by the wedge effect of the GN when introduced with a hammer. Mean blood loss during operation was higher in the GN group. This phenomenon was not described before, and most likely reflects the difference of respectively a reamed and undreamed insertion technique. Clinical relevance, however, is limited.

The most frequent postoperative complication was cutout of the femoral neck screw(s): in both the GN and the PFN® rates were 7 %. Based on these results, earlier theories about the so called 'knife-effect' of the PFN[37] (the composition of a large femoral neck screw and a smaller, more proximal anti-rotational screw in the cancellous femoral head, was proposed to function as a wedged knife and was therefore assumed to facilitate cutting out) could not be confirmed clinically. With regard to the numbers of cutout, we found no beneficial effect of the anti-rotation screw of the PFN®. However, we do not know to what extent the so-called knife-effect (cutout inducing) and the anti-rotational influence (cutout reducing), level each other out. In both the GNs and the PFNs cutting out generally resulted from poor positioning of the proximal screw(s) in the femoral head, rather than to be implant-related. About 80% of the operations in patients in whom cutout of the implant occurred, were reported as moderately or very difficult, the reduction was judged non-anatomical but acceptable and/or the position of the femoral neck screw(s) suboptimal. The importance of the proper positioning of the femoral neck screw has been emphasised before[4,5,38,39].

A relevant complication is the lateral protrusion of the proximal screws, due to impaction of the fracture. The question remains, why this complication occurred more often with the PFN®. Assuming that the anchorage of the lag screws in the femoral head of both implants is similar, the difference must be caused by collapse or impaction of the fracture rather than migration of the screws. A different gliding mechanism of the hip screw through the nail[4,40,41]may play a role. One of the factors that influence the sliding mechanism is the kind of metal used: titanium (PFN®) has a lower friction coefficient than stainless steel (GN). Overall, impaction

of the fracture is beneficial to the fracture consolidation. Restriction of the sliding mechanism may therefore prove to work contra-productive, and may even initiate the mechanism of cutting out or joint penetration. Suboptimal reduction, malpositioning of the implant, or the combination of both (table 6) may attribute to collapse of the fracture, irrespective of the implant used, and may facilitate the dynamisation and lateral protrusion of the hip screw(s).
Fatigue of a GN was seen in one patient with a delayed union. Similar cases have been reported[42].
Four patients treated with a PFN® sustained, after renewed substantial trauma, a femoral shaft fracture, distally of the implant. One patient, treated with a GN, did not reveal any external impact that might have caused his femoral shaft fracture. Results from other studies [5,11,13,15-19,43] show higher numbers of femoral shaft fractures, up to 17%. An explanation for our low number of implant-related shaft fractures may be the fact the general acceptance and use of intramedullary implants have resulted in a proper mastering of the surgical technique for insertion and fixation of these implants, with sufficient reaming of the medullary canal if necessary and without hammering on nail or screws.
Although not significantly different, patients treated with a PFN® tended to a higher re-interventions rate. In part, this may be explained by the more frequent occurrence of lateral migration of the proximal screws of the PFN®. Although this migration was often subtle and not clinically relevant, seven patients were reoperated for removal of the hip pin. Overall, reinterventions rates for both implants are high, and higher than reinterventions rates presented in other studies[11,16,18,19]. It should however be taken to in account that the present investigation exclusively concerned unstable trochanteric fractures, notorious for their lack of intrinsic stability, tendency to varus dislocation and distraction. Therefore, many of the formerly mentioned studies will have positively influenced re-operation rates compared to this study, since they predominantly considered stable trochanteric fractures with subsequent lower complication rates.
General complications and mortality rates did not reveal any surprising results and are in range with results of other studies[18,44]. Functional outcome and consolidation over time were similar for both treatment arms.

For many decades attempts have been made to overcome the difficulties that surgeons encounter in the treatment of unstable trochanteric fractures. Many questions have been asked

about what the perfect fixation device should look like. The results of our study show that the newly developed PFN® is as good as the Gamma nail, with similar pitfalls and comparable complications. Optimal fracture reduction and positioning of the nail and screws remain of crucial importance and should be obtained at all times. A skilled surgeon may treat the demanding unstable trochanteric fractures with any kind of fixation device, as long as he or she remembers that the fixation device will never make up for surgical failures. Therefore, improvement of treatment of the unstable trochanteric fractures will predominantly be in the hands of the surgeons, rather than in those of the industry.

References

1. Davis TR, Sher JL, Horsman A, Simpson M, Porter BB, Checketts RG. Intertrochanteric femoral fractures. Mechanical failure after internal fixation. J Bone Joint Surg Br 1990;72(1):26-31.

2. Jensen JS. A photoelastic study of the hip nail-plate in unstable trochanteric fractures. A biomechanical study of unstable trochanteric fractures II. Acta Orthop Scand 1978;49(1):60-4.

3. Kyle RF, Gustilo RB, Premer RF. Analysis of six hundred and twenty-two intertrochanteric hip fractures. J Bone Joint Surg Am 1979;61(2):216-21.

4. Simpson AH, Varty K, Dodd CA. Sliding hip screws: modes of failure. Injury 1989;20(4):227-31.

5. Bridle SH, Patel AD, Bircher M, Calvert PT. Fixation of intertrochanteric fractures of the femur. A randomised prospective comparison of the gamma nail and the dynamic hip screw. J Bone Joint Surg Br 1991;73(2):330-4.

6. Schwab E, Höntzsch K, Weise K. Die Versorgung instabiler per- und subtrochantärer Femurfrakturen mit dem Proximalen Femurnagel (PFN). Akt Traumatol 1999;28:56-60.

7. David A, von der HD, Pommer A. [Therapeutic possibilities in trochanteric fractures. Safe--fast-- stable]. Orthopade 2000;29(4):294-301.

8. Ostermann PA, Haase N, Ekkernkamp N. [Techniques of extramedullary osteosynthesis in proximal femoral fractures]. Chirurg 2001;72(11):1271-6.

9. Götze B. Belastbahrkeit von Osteosynthesen bei instabilen per- und subtrochanteren Femurfrakturen. Akt Traumatol 1998;28:197-204.

10. Friedl W, Clausen J. [Experimental examination for optimized stabilisation of trochanteric femur fractures, intra- or extramedullary implant localisation and influence of femur neck component profile on cut-out risk]. Chirurg 2001;72(11):1344-52.

11. Halder SC. The Gamma nail for peritrochanteric fractures. J Bone Joint Surg Br 1992;74(3):340-4.

12. Kempf I, Grosse A, Taglang G, Favreul E. [Gamma nail in the treatment of closed trochanteric fractures. Results and indications apropos of 121 cases]. Rev Chir Orthop Reparatrice Appar Mot 1993;79(1):29-40.

13. Leung KS, So WS, Shen WY, Hui PW. Gamma nails and dynamic hip screws for peritrochanteric fractures. A randomised prospective study in elderly patients. J Bone Joint Surg Br 1992;74(3):345-51.

14. Rosenblum SF, Zuckerman JD, Kummer FJ, Tam BS. A biomechanical evaluation of the Gamma nail. J Bone Joint Surg Br 1992;74(3):352-7.

15. Albareda J, Laderiga A, Palanca D, Paniagua L, Seral F. Complications and technical problems with the gamma nail. Int Orthop 1996;20(1):47-50.

16. Boriani S, Bettelli G, Zmerly H, Specchia L, Bungaro P, Montanari G et al. Results of the multicentric Italian experience on the Gamma nail: a report on 648 cases. Orthopedics 1991;14(12):1307-14.

17. Butt MS, Krikler SJ, Nafie S, Ali MS. Comparison of dynamic hip screw and gamma nail: a prospective, randomized, controlled trial. Injury 1995;26(9):615-8.

18. Parker MJ, Handoll HH. Extramedullary fixation implants and external fixators for extracapsular hip fractures. Cochrane Database Syst Rev 2002(4):CD000339.

19. Radford PJ, Needoff M, Webb JK. A prospective randomised comparison of the dynamic hip screw and the gamma locking nail. J Bone Joint Surg Br 1993;75(5):789-93.

20. Heinz T, Vecsei V. [Complications and errors in use of the gamma nail. Causes and prevention]. Chirurg 1994;65(11):943-52.

21. Valverde JA, Alonso MG, Porro JG, Rueda D, Larrauri PM, Soler JJ. Use of the Gamma nail in the treatment of fractures of the proximal femur. Clin Orthop. 1998(350):56-61.

22. Friedl W, Colombo-Benkmann M, Dockter S, Machens HG, Mieck U. [Gamma nail osteosynthesis of per- and subtrochanteric femoral fractures. 4 years experiences and their consequences for further implant development]. Chirurg 1994;65(11):953-63.

23. Sturmer KM, Dresing K. [Pertrochanteric fractures]. Zentralbl Chir 1995;120(11):862-72.

24. Huber SM, Heining SM, Euler E. Photoelastic stress measurement of the proximal femur. J Bone Joint Surg 1997 2000;79-B(Supp II):166.

25. Simmermacher RK, Bosch AM, Werken Ch van der. The AO/ASIF-proximal femoral nail (PFN): a new device for the treatment of unstable proximal femoral fractures. Injury 1999;30(5):327-32.

26. Sadowski C, Lubbeke A, Saudan M, Riand N, Stern R, Hoffmeyer P. Treatment of reverse oblique and transverse intertrochanteric fractures with use of an intramedullary nail or a 95 degrees screw-plate: a prospective, randomized study. J Bone Joint Surg Am 2002;84-A(3):372-81.

27. Müller ME, Nazarian S, Koch P, Schatzker J. The comprehensive classification of fractures of the long bones. Berlin/Heidelberg: Springer-verlag; 1990.

28. Lustenberger A, Bekic J, Ganz R. [Rotational instability of trochanteric femoral fractures secured with the dynamic hip screw. A radiologic analysis]. Unfallchirurg 1995;98(10):514-7.

29. American Society of Anesthesiologists. New classification of Physical status. Anesthesiology 1963;24:111-4.

30. Harris WH. Traumatic arthritis of the hip after dislocation and acetabular fractures: treatment by mold arthroplasty. An end-result study using a new method of result evaluation. J Bone Joint Surg Am 1969;51(4):737-55.

31. Ware JE, Jr., Sherbourne CD. The MOS 36-item short-form health survey (SF-36). I. Conceptual framework and item selection. Med Care 1992;30(6):473-83.

32. Cockrell JR, Folstein MF. Mini mental state examination (MMSE). Psychophar Bull 1988;24(4):689-92.

33. Bartonicek I, Dousa P. Prospective randomized controlled trial of an intramedullary nail versus dynamic screw and plate of intertrochanteric fractures of the femur. J Orthop Trauma 2002;16(5):363-4.

34. Al yassari G, Langstaff RJ, Jones JW, Al Lami M. The AO/ASIF proximal femoral nail (PFN) for the treatment of unstable trochanteric femoral fracture. Injury 2002;33(5):395-9.

35. Saudan M, Lubbeke A, Sadowski C, Riand N, Stern R, Hoffmeyer P. Pertrochanteric fractures: is there an advantage to an intramedullary nail? a randomized, prospective study of 206 patients comparing the dynamic hip screw and proximal femoral nail. J Orthop Trauma 2002;16(6):386-93.

36. Aune AK, Ekeland A, Odegaard B, Grogaard B, Alho A. Gamma nail vs compression screw for trochanteric femoral fractures. 15 reoperations in a prospective, randomized study of 378 patients. Acta Orthop Scand 1994;65(2):127-30.

37. Schipper IB, Bresina S, Wahl D, Linke B, van Vugt AB, Schneider E. Biomechanical evaluation of the proximal femoral nail. Clin Orthop 2002;405:277-86.

38. Wu CC. Biomechanical analysis of location of lag screw of a dynamic hip screw in treatment of unstable intertrochanteric fracture. J Trauma 1996;41(4):699-702.

39. Lyddon DW, Jr. The prevention of complications with the Gamma Locking Nail. Am J Orthop 1996;25(5):357-63.

40. Sim E, Schmiedmayer HB, Lugner P. Mechanical factors responsible for the obstruction of the gliding mechanism of a dynamic hip screw for stabilizing pertrochanteric femoral fractures. J Trauma 2000;49(6):995-1001.

41. Loch DA, Kyle RF, Bechtold JE, Kane M, Anderson K, Sherman RE. Forces required to initiate sliding in second-generation intramedullary nails. J Bone Joint Surg Am 1998;80(11):1626-31.

42. Gaebler C, Stanzl-Tschegg S, Tschegg EK, Kukla C, Menth-Chiari WA, Wozasek GE et al. Implant failure of the gamma nail. Injury 1999;30(2):91-9.

43. Osnes EK, Lofthus CM, Falch JA, Meyer HE, Stensvold I, Kristiansen IS et al. More postoperative femoral fractures with the Gamma nail than the sliding screw plate in the treatment of trochanteric fractures. Acta Orthop Scand 2001;72(3):252-6.

44. Bannister GC, Gibson AG, Ackroyd CE, Newman JH. The fixation and prognosis of trochanteric fractures. A randomized prospective controlled trial. Clin Orthop 1990;(254):242-6.

CHAPTER 6

Biomechanical evaluation of The Proximal Femoral Nail

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Introduction

In 1997, the proximal femoral nail (PFN®, Mathys Medical, Bettlach, Switzerland) was introduced for treatment of peritrochanteric femoral fractures. It was designed to overcome implant-related complications and facilitate the operative treatment of unstable peri-trochanteric fractures.[1, 8] The proximal femoral nail uses two implant screws for fixation into the femoral head and neck. The larger screw, the femoral neck screw, is intended to carry the majority of the load. The smaller screw, the hip pin, is inserted to provide rotational stability. Biomechanical analyses[1, 3] of the proximal femoral nail show a significant reduction of distal stress and an increase of overall stability compared with the Gamma nail. Evaluation of treatment results of the proximal femoral nail shows a relatively low percent of complications and a low incidence of implant failure[7,8]. Although complication rates remain low, cutout of the hip pin and the femoral neck screw (figure 1) is a serious complication that leads to revision surgery and related morbidity. The risk of cutout must be reduced as much as possible.

The adverse effects seem to originate from the biomechanical properties of the hip pin and the

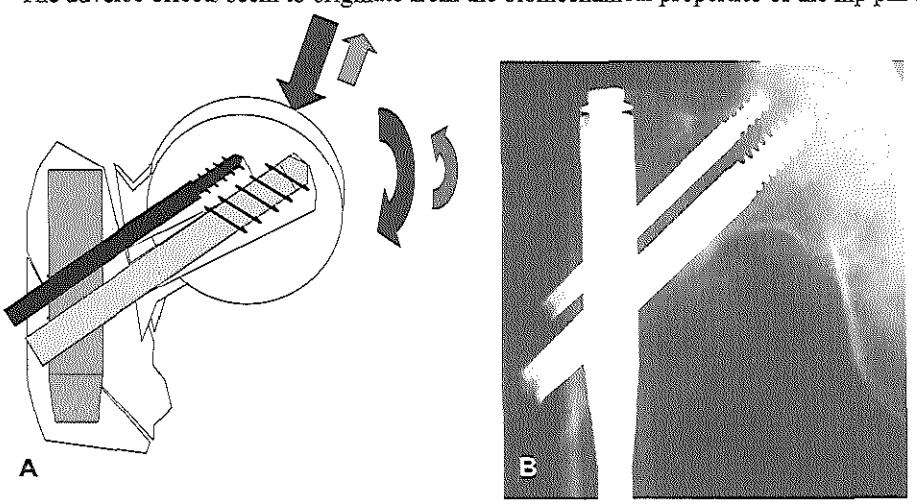


Figure 1. *(A) A schematic drawing of the knife effect is shown. Load bearing causes deflection of the hip pin (more than the femoral neck screw, because the femoral neck screw is thicker and, in the standard proximal femoral nail, bears less load). The deflection of the hip pin causes friction in the nail, which prevents sliding of the hip pin. The resulting vertical forces (arrows) on the hip pin create an oval hole in the cancellous bone around the tip of the hip pin, just cranially of the femoral neck screw, thus facilitating cutout.*
(B) A radiograph shows progressive varus dislocation of the femoral head and cutout of the (standard) proximal femoral nail in a 72-year-old female patient.

femoral neck screw: it is hypothesised that during load bearing the hip pin, which is intended to provide only rotational stability, becomes weightbearing. The current study concerns the biomechanical behavior of the hip pin and the femoral neck screw as a part of the standard proximal femoral nail and of an experimentally-modified proximal femoral nail in which the hole through the nail for the hip pin is modified to a slot (figure 2). Through this oval hole the hip pin can angulate toward the femoral neck screw if it becomes load bearing, thereby reducing its overload.

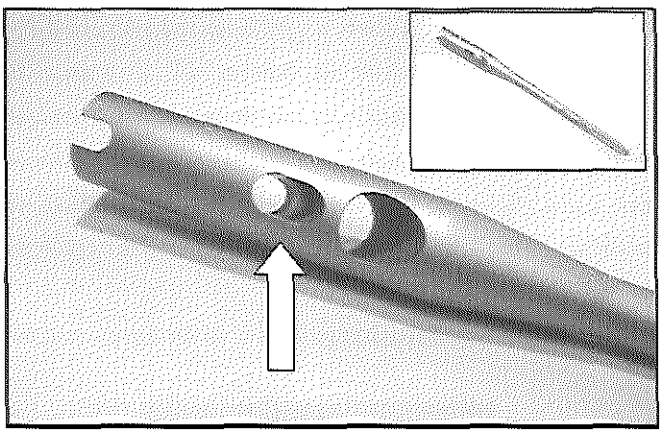


Figure 2. *The proximal side of the proximal femoral nail shows the experimentally modified oval hole (arrow) for the hip pin and an unchanged hole (the more distal one) for the femoral neck screw.*

The primary focus of the current study was on the distribution of load carried by the hip pin and the femoral neck screw. The testing was done to determine the amount of load carried by the hip pin and the femoral neck screw in a standard proximal femoral nail, and to investigate load distribution changes if the hole through the nail of the hip pin is modified to a slot. It was hypothesised that if load were removed from the hip pin there would be a reduction in implant cutout.

Materials and Methods

The implants used in these tests were the standard proximal femoral nail and the experimentally-modified proximal femoral nail. The standard proximal femoral nail and the modified proximal femoral nail had distal diameters of 11 mm and caput-collum-diaphyseal angles of 130°. In both proximal femoral nails the diameters of the femoral neck screw and the hip pin were 11 and 6.5 mm, respectively. The one difference between the standard proximal femoral nail and the modified proximal femoral nail was the changed shape of the

proximal hole in the intramedullary nail for the hip pin. In the standard proximal femoral nail this is a round hole (diameter 6.5 mm), whereas in the modified proximal femoral nail this hole is oval (6.5 x 10 mm) (figure 2).

Five matched pairs of fresh-frozen femurs from cadavers were collected and stored in a clean condition in frozen storage. Donor data are shown in Table 1. Before testing, the bones were defrosted at room temperature for 6 to 8 hours. Bone mineral density measurements of the femoral heads were done using the peripheral quantitative computed tomography technique using a Densiscan 100 (Scanco Medical AG, Bassersdorf, Switzerland).

The distal 115 mm of the femurs was removed, after which the end of the femoral shafts were embedded in beracryl. The embedded ends were fitted into aluminum boxes allowing positioning of the femurs in a physiologic 15° valgus and 5° angle in the sagittal plane. Standardized unstable peritrochanteric fractures (Type 31.A.2.2 fracture, according to the AO/ASIF classification for fractures of the long bones[5]) then were created. Each left and right femur of a matched pair was assigned randomly to a standard proximal femoral nail or a modified proximal femoral nail. The implants were inserted into the femurs by one of the authors (IBS) using a standard operating technique. The entrance of the intramedullary nail was determined 5 mm dorsally of the tip of the greater trochanter. The hip pin was chosen 10 mm shorter than the femoral neck screw in all implants. Strain gauges, type NRA-06-T001N-350 (Micro-Measurement Group Inc, Raleigh, NC), were fixed on the hip pin and the femoral neck screw 40 mm from the tip, and connected to the rod with Bond glue 610 (Micro-Measurement Group Inc). The wires were connected to a half-bridge for measuring bending strain using an Esam 2000 A-D strain-gauge amplification and data acquisition system (ESA Messtechnik GmbH, München, Germany).

Standard anteroposterior radiographs of each femur that was operated on were taken before and after testing. Determination of implant position in three directions was done with standardized measurements of the radiographs.

Cyclic loading of the femur, in a one-leg stance position, was done on a Bionix 858 servo-hydraulic testing machine (MTS® Systems, Minneapolis, MN), at a frequency of 1 Hz for 10,000 cycles. The cyclic loading varied between 100 N and 750 N. Measurements of load and strain were recorded on a computer-based Testar II data acquisition system running Testware SX software (MTS® Systems, Minneapolis, MN). Samples of strain were captured

for 100 cycles. Data were stored and analyzed at Cycles 50, 250, 500, 1000, 2000, 4000, 7500, and 9900.

Data Analysis

Loads were calculated from the recorded strain cycles using the implant geometry and material properties, represented by the following formulas:

$$LoadFNS = \frac{1}{2} \cdot E \cdot \varepsilon_{FNS} \cdot \left(\frac{I_{FNS} \cdot R_{FNS} \cdot \cos\alpha}{I_{FNS}} \right)^{-1}$$

$$LoadHP = \frac{1}{2} \cdot E \cdot \varepsilon_{HP} \cdot \left(\frac{I_{HP} \cdot R_{HP} \cdot \cos\alpha}{I_{HP}} \right)^{-1}$$

in which α is the angle between the direction of applied load and the direction of the femoral neck screw and hip pin, E is the elasticity modulus, ε is the measured strain, I is the distance on the hip pin or femoral neck screw from the strain gauges to the point of load application, R is the outer diameter of the hip pin or femoral neck screw, and I is the area moment of inertia. For every tested proximal femoral nail, load cycles on the hip pin and femoral neck screw were calculated from the sampled strain data. To minimise the influence of registration biases and outliers, all recorded values of strain and load during every cycle of axial loading were calculated and the middle 90% interval of the range of these values was interpreted as the amplitude of the signal. The relative values within this 90% interval were used for additional comparison between the hip pin and femoral neck screw.

Because the point of load application on the hip pin and femoral neck screw (related to I in the formulas) had to be estimated, all data were calculated for two assumptions: the load being concentrated on the tip of both pins, and the point of load application situated in the middle of the threaded section of the hip pin and femoral neck screw. Results showed a group of lower calculated load values (load assumed on the tip) and a group of higher values (load assumed in the center). Figure 3 shows the range of load between these virtual application points. For both assumptions load tendencies and percentages of load distribution in additional calculations were similar. Data analysis and interpretation of results were continued using the assumption that the point of load application was situated in the middle of the threaded

sections, bearing in mind that absolute load values become lower when this point moves toward the tip of the hip pin and femoral neck screw.

Statistical analysis of the obtained data was done using the paired Student's t test for mean values, significance was set at p less than 0.05.

Results

Bone density measurement values of the femur, age, and gender of the cadavers are shown in Table 1. The values represent the broad spectrum of bone mineral density in which the implants could be tested.

All collected data samples of the tested bones were converted to plotted diagrams to show strain and load tendencies during testing. The summarised load on the femoral neck screw and the hip pin together for each proximal femoral nail is shown in figure 3. For every proximal femoral nail the percentage of load carried by the hip pin and femoral neck screw separately was calculated using the obtained 90% load-intervals.

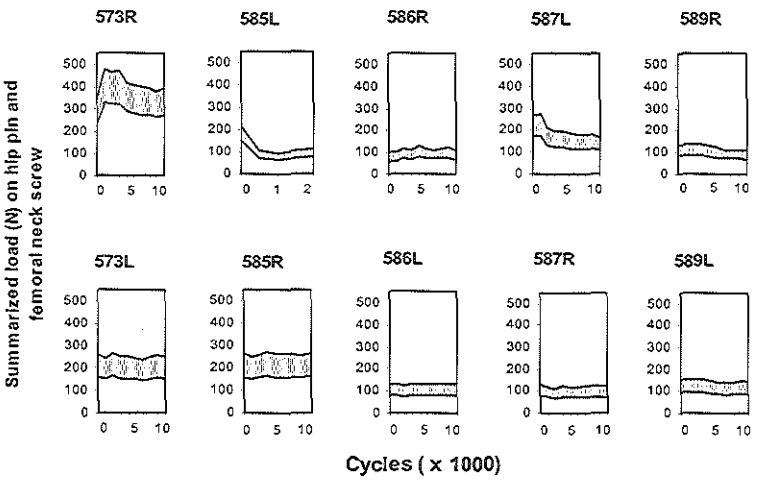
Figure 4 shows the percentages of total load in every proximal femoral nail carried by the

Table 1. *Bone density measurement values of the femurs and descriptive characteristics of the donors.*

Femur Number	Side	Implant	Gender	Age (years)	Bone Mineral Density (g/cm^3)
573	L	mPFN	F	83	.416
573	R	sPFN	F	83	.373
585	L	sPFN	M	73	.516
585	R	mPFN	M	73	.559
586	L	mPFN	M	60	.366
586	R	sPFN	M	60	.384
587	L	sPFN	M	80	.568
587	R	mPFN	M	80	.512
589	L	mPFN	?	?	.384
589	R	sPFN	?	?	.381

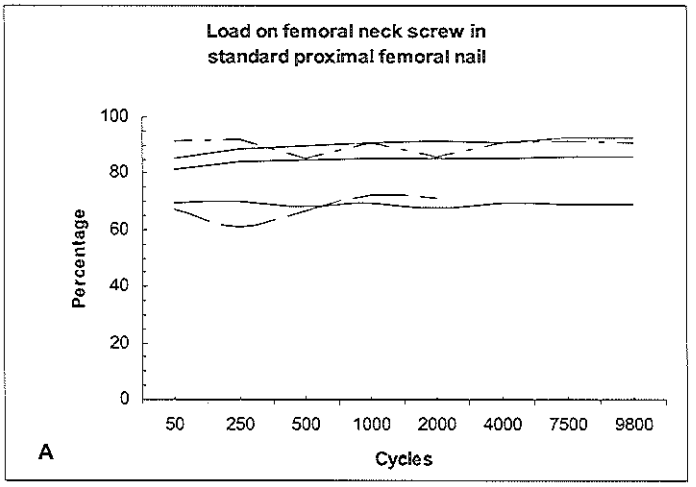
? = data not available; mPFN = modified proximal femoral nail; L = left femur; sPFN = standard proximal femoral nail; R = right femur; F = female; M = male

Figure 3. *The plotted diagrams show the calculated loads on hip pin and femoral neck screw together, in Newtons, during the test cycles. The upper line represents the calculated total load on the hip pin and the femoral neck screw when the point of load application is assumed in the middle of the threaded sections of the hip pin and femoral neck screw. The lower line represents the calculated summarised load when the virtual point of load application situated on the tip of both pins. R = right femur, L = left femur.*



femoral neck screw. In standard proximal femoral nails and modified proximal femoral nails, the majority of the load is on the femoral neck screw. Calculated load on the femoral neck screw in the standard proximal femoral nail ranged from 60.9% to 92.5% maximum of total load, which means a 7.5% to 39.1% load on the hip pin. Overall, the mean load on the femoral neck screw of the standard proximal femoral nail group was 80.3%. For the modified proximal femoral nail, load on the femoral neck screw varied from 92% to 98.1%, thereby reducing hip pin load to 2% to 8%. The overall mean load on the femoral neck screw of the modified proximal femoral nail group was 95.3%.

The mean load distribution between hip pin and femoral neck screw with their standard deviation for every proximal femoral nail is shown in figure 5. Comparison of these results with a paired t test showed a significantly higher load ($p = 0.0003$) on the hip pin of the standard proximal femoral nail compared with the hip pin of the modified proximal femoral nail. Additional interpretation of these data clearly showed a broader range of load in the standard proximal femoral nail group compared with the modified proximal femoral nail group. Except for one of the standard proximal femoral nails (585L, dotted black line in figure



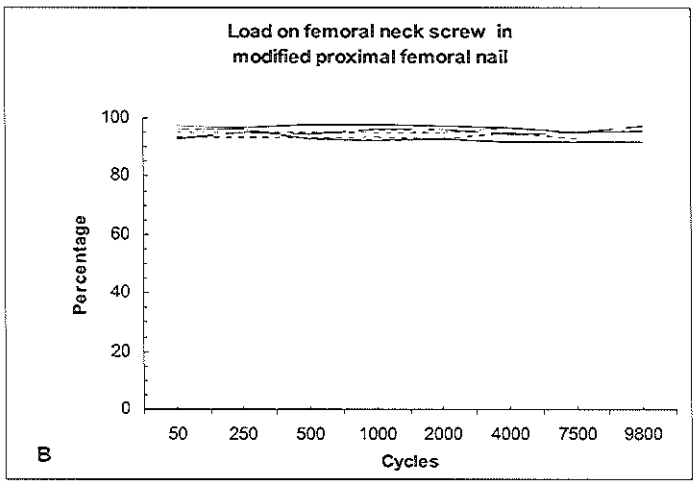


Figure 4. *(A) The percentages of total load carried by the femoral neck screws of the standard proximal femoral nails during testing are shown. Each line represents one implant. (B) The percentages of total load carried by the femoral neck screws of the modified proximal femoral nails during testing are shown. Each line represents one implant.*

4), in which a wire-breakage of the strain-gauge connectors occurred, distribution of load between hip pin and femoral neck screw was relatively constant with time for standard proximal femoral nails and modified proximal femoral nails. An overall increase of load on the femoral neck screw during testing was seen in the standard proximal femoral nail: the first sampled data for all standard proximal femoral nails show a mean femoral neck screw load of 78.9%, whereas the last samples during testing show a mean load of 84.5% ($p = 0.04$). This increase in load is not seen in the modified proximal femoral nail (respectively 95.0% and 95.6%; $p = 0.6$).

The measurements done on the radiographs showed one femur (573L-modified proximal femoral nail) in which the hip pin angulated toward the femoral neck screw, with the femoral neck screw lateralising 3.5 mm. Two fractures became impacted 3 and 1.5 mm (573R-standard proximal femoral nail and 587R-modified proximal femoral nail, respectively),

without additional displacement of the hip pin and femoral neck screw. In one case (586L-modified proximal femoral nail) the femoral neck screw migrated 4.5 mm medially. In femur 587L-standard proximal femoral nail the hip pin and the femoral neck screw lateralised 1.5 mm out of the femoral head. In the other five bones no changes of implant position were measured.

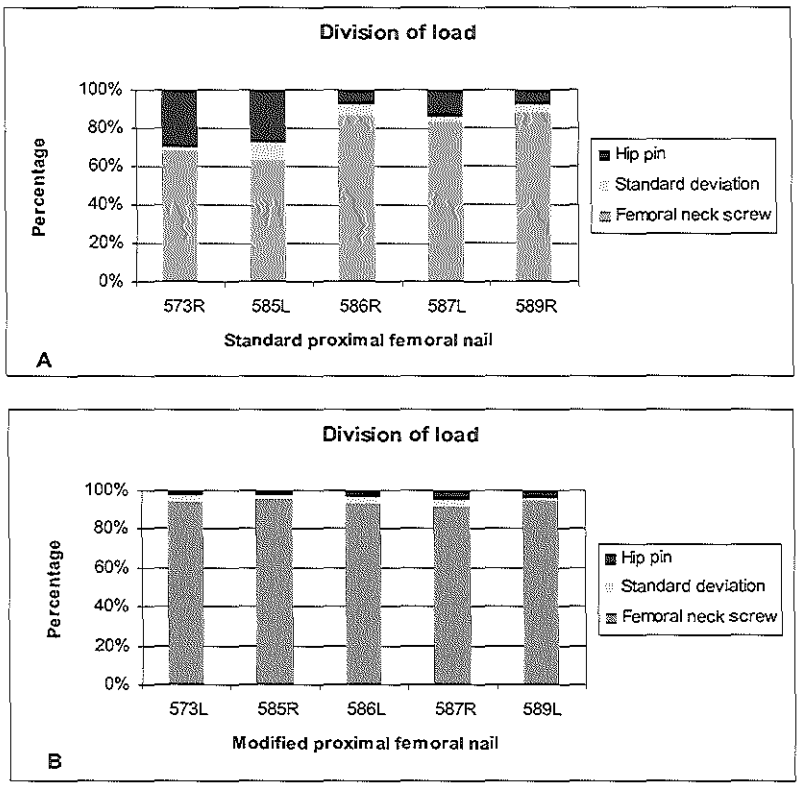


Figure 5. *(A) The mean distribution of load between hip pin and femoral neck screw with their standard deviations per standard proximal femoral nail are shown. R = right, L = left. (B) The mean distribution of load between hip pin and femoral neck screw with their standard deviations per modified proximal femoral nail are shown. R = right, L = left.*

Discussion

The primary focus of the current study was to determine the amount of load carried by the hip pin and the femoral neck screw in a standard proximal femoral nail, and to investigate load distribution changes if the hole through the nail of the hip pin is modified to a slot. The reduction of load on the hip pin was hypothesised to give a reduction in risk of implant cutout.

The low prevalence of cutout of the proximal femoral nail in clinical setting may be additionally reduced by introduction of this mechanism.

The results show that in all cases the majority of load is carried by the femoral neck screw in both types of nails. The standard proximal femoral nails in general, however, have signify-cantly more load applied to the hip pin compared with the modified proximal femoral nails (figure 5). This may facilitate cutout of the implant, because the load causes more deflection of the hip pin compared with the femoral neck screw, and sliding of the hip pin becomes restricted. If the intramedullary nail contains a slot through which the hip pin passes (figure 2) as in the modified proximal femoral nail, the femoral neck screw will carry as much as 98% of the load (figure 4). In the modified proximal femoral nail the hip pin carried significantly less load than in the standard proximal femoral nail, and approximately 1/20 to 1/50 of the load carried by the femoral neck screw (figure 5). This is caused by the removal of the constraint on the lateral end of the hip pin by the slotted hole.

Noncontrollable parameters such as individual differences between bone structure, fractures, and fracture reduction, influence similar and precise positioning of the hip pin and the femoral neck screw in the femoral head and may result in different and unpredictable load and strain distributions. However, the distribution of load in the currently used femurs seems to be far less predictable using the standard proximal femoral nail compared with the modified proximal femoral nail. The broad range of load distribution of all standard proximal femoral nails in Figure 4 shows this unpredictability of the load applied on the hip pin. An explanation for this phenomenon may be the increasing importance of the aforementioned uncontrollable factors when load is increased on the hip pin. Bone density hardly will be of any influence when a hip pin is not load bearing (as in the modified proximal femoral nail), but its properties (such as resistance to the hip pin) will become important if the hip pin becomes load bearing. Fracture impaction, fracture reduction, and position of the implant also may influence the range of load distribution per implant in a similar way. This may end up in a circle of factors increasingly influencing each other with varying load applied to the proximal femoral nail, finally resulting in an unpredictable load distribution between the hip pin and femoral neck screw.

In the current study, however, bone mineral density did not seem to influence the amount of displacement of the fracture and hip pin or femoral neck screw, because lateralization of the femoral neck screw occurred in femoral heads with high and low bone mineral density. Also,

fractures of high and low bone mineral density became impacted during testing. The migration of the femoral neck screw in standard proximal femoral nail 586R to medial may be influenced by the relatively low bone mineral density of this donor bone. The medialisation probably is initiated by the combination of cyclic loading on the femoral head and friction of the sliding mechanism in the lateral direction. Medialisation of more than 5 mm cannot occur with the femoral neck screw, because its lateral tip contains a shoulder, which prevents the femoral neck screw from sliding medially through the nail. Recently, the hip pin has been adjusted in a similar way.

If migration of the femoral neck screw or hip pin laterally or medially was less than 5 mm it was found to be within an acceptable ranges. No actual cutout of the femoral head occurred and no unacceptable implant dislocation or fracture displacement was measured during the tests. These results confirm the published data of clinical studies[6-8] in which implantation of the proximal femoral nail for unstable pertrochanteric femoral fractures leads to good post-operative results without considerate complication rates during early postoperative weight-bearing. Cadaver analysis[2] showed that the mechanism of impaired sliding is the main contributor to cutout of the femoral neck screw of the Dynamic hip screw and Gamma nail[2] and it seems to be a general problem of intramedullary and extramedullary osteosynthesis for peritrochanteric femoral fractures.

With the introduction of the antirotational screw of the proximal femoral nail several new components were introduced. As in former implants for peritrochanteric femoral fractures, the femoral neck screw carries the majority of the load and the hip pin provides rotational stability. When the femoral head becomes load bearing, this load is transduced partly to the femoral neck screw and hip pin, depending on their separate diameters and position. The forces produced by weightbearing cause minimal deflection of both hip screws (figure 1). If the screw has a small diameter (hip pin), a larger amount of deflection will occur compared to the screw with a big diameter (femoral neck screw). The larger the load, the more deflection will occur. Optimally, the (axial) loading forces may lead to sliding of the femur and nail medially and impaction of the fracture, inducing bone healing. The problem arises if the parallelism of the two screws is compromised. If the tips of the screws should converge or diverge, from improper insertion or from the load creating a higher deflection of the tip of the hip pin than the femoral neck screw, then the sliding of the two screws is restricted. When the sliding becomes impossible, the working forces will be restricted to almost completely

vertical forces and start to induce cutout. Through its small diameter the weightbearing hip pin may acquire the properties of a knife, cutting through the cancellous bone, leaving a hole for the larger femoral neck screw to fall into, facilitating additional varus dislocation of the femoral head and cutout (figure 1). The current authors called this theoretical effect the knife effect of the femoral head. Other influencing factors may be the bone mineral density, the position of the screw(s) in the femoral head, the diameter of the femoral head screw(s),[2] and rotational instability of the femoral head.[4]

The length of the hip pin also is an important parameter. During testing, the hip pin was chosen 10 mm shorter than the femoral neck screw in all implants, which is approximately 10 mm longer than used in clinical fracture treatment. This was done to allow the maximal effect of load bearing of the hip pin to occur. Between clinicians the discussion of the length of the hip pin continues. Shorter (20 mm shorter than the femoral neck screw) and longer hip pins (up to the length of the femoral neck screw) are favored. Additional studies, investigating the influence of various hip pin lengths on strain and load, should answer the question of what the optimal length of the hip pin is. The results of the current study suggest that a long hip pin in patients treated with a standard proximal femoral nail is not advisable, because it will increase the cutout risk. Even in the modified proximal femoral nail the length of the hip pin is an important parameter, considering nonaxial loading.

Other clinical factors of influence that have been eliminated during the biomechanical testing are the biologic variety of fractures, the anatomic fracture reduction, and the position of implants. For the current study, A.2.2 type femoral fractures[5] were created using a standard oscillating bone saw. Before implanting the proximal femoral nail, the fractures were reduced anatomically. Fracture reduction and positioning of the osteosynthesis were optimal because of direct visual control. In clinical settings this visual control is more indirect (fluoroscopy) and therefore less precise, which may lead to less anatomic reduction and less accurate positioning of the implants. These two (surgeon-related) parameters also are of major importance in determining the risk of cutout of a proximal femoral nail, because malpositioning of fracture, malpositioning of the implant material, or both, may lead to progressive load bearing of the hip pin and displacement of the fracture, resulting in cutout of the implant. Nonanatomic reduction of fracture and malpositioning of the implant also induce torsional forces that may compromise the parallelism of the two femoral screws other than in the axial direction. These forces cannot be reduced by the adjustments that were made in the modified

proximal femoral nail, because the oval hole for the hip pin only equalises the deflection of the hip pin induced by axial loading. Therefore, exact anatomic reduction should be achieved (this may implicate open reduction) before inserting the proximal femoral nail in the right position.

No actual cutout was found in both groups of tested proximal femoral nails. If cutout had occurred in the current tests, it was expected to be found in the standard proximal femoral nail group. The nonoccurrence of cutout may resemble some of the limitations of the current study: because the fractures were induced with a bone saw on cadaver femurs, none of the aforementioned fracture-related problems (fracture reduction, interposition) and surgeon-related problems (fracture reduction, implant positioning) were encountered. Also, the loads applied may have been too low to induce cutout in the current conditions. Higher loads combined with larger numbers of tested bones and implants might have resulted in the occurrence of cutout. Although a significant reduction of load on the hip pin of the modified proximal femoral nail was proven, the question whether reduction of load leads to prevention of implant cutout, is unanswered in the current study. To investigate the actual reduction in cutout incidence and to study other factors that may facilitate cutout (reduction of the fracture, position of the implant), an additional clinical trial was started to evaluate this modified, second generation proximal femoral nail in different fracture types and in weightbearing in the clinical situation.

From the results of the current biomechanical tests the authors conclude that modification of the standard proximal femoral nail has led to significant reduction of axial loads on the hip pin. In the modified proximal femoral nail, the hip pin carries less than 5% of the load, thereby theoretically reducing cutout risk, while maintaining rotational stability.

References.

1. Götze B, Bonnaire F, Weise K, Friedl HP: Belastbahrkeit von Osteosynthesen bei instabilen per- und subtrochanteren Femurfrakturen. Aktuelle Traumatol 28:197-204, 1998.

2. Haynes RC, Pölll RG, Miles AW, Weston RB: Failure of femoral head fixation: A cadaveric analysis of lag screw cut-out with the gamma locking nail and AO dynamic hip screw. Injury 28:337-341, 1997.

3. Huber SM, Heining SM, Euler E: Photoelastic stress measurement of the proximal femur. J Bone Joint Surg 79B:166, 1997.

4. Lustenberger A, Bekic J, Ganz R: [Rotational instability of trochanteric femoral fractures secured with the dynamic hip screw: A radiological analysis]. Unfallchirurg 98:514-517, 1995.

5. Müller ME, Nazarian S, Koch P, Schatzker: The Comprehensive Classification of Fractures of Long Bones. Berlin, Springer-Verlag 116-121, 1990.

6. Saudan M, Lubecke-Wolff A, Sadowski C, Riand N, Hoffmeyer P: PFN versus DHS/DCS pour les fractures de la région trochantérienne : Etude comparative prospective randomisée. Schweiz Med Wochenschr 129(Suppl):3, 1999.

7. Schwab E, Höntzsch K, Weise K: Die Versorgung instabiler per- und subtrochantärer Femurfrakturen mit dem Proximalen Femurnagel (PFN). Aktuelle Traumatol 28:56-60, 1999.

8. Simmermacher RK, Bosch AM, Van der Werken Ch: The AO/ASIF-proximal femoral nail (PFN): A new device for the treatment of unstable proximal femoral fractures. Injury 30:327-332, 1999.

CHAPTER 7

Can the Proximal Femoral Nail be improved?

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Submitted

Introduction

The current design of the Proximal Femoral Nail® (PFN), with its load bearing femoral neck screw and an extra anti-rotational hip pin, was developed to provide an improvement over existing cephalomedullary nail systems. The hip-pin seemed to be the solution for the problem of rotation of the head-neck fragment and its subsequent complications[7]. Recent clinical series[1-4,9,13] showed promising results after treatment of unstable trochanteric fractures with the PFN®, revealing low implant-related complication rates. The hip pin however, brought along two unexpected complications: First, the medial migration of the hip pin with possible penetration of the joint, which is presumed to be the result of unwanted intermittent loading of the hip pin as part of the bone-implant construct. To reduce the possibility of medial migration, a shoulder was mounted onto the lateral end of the hip pin. Medial migration was thus mechanically limited to about one cm, to where the shoulder of the hip pin is be stopped by the nail. The second specific problem is caused by the so-called knife-effect: Through its smaller diameter the weightbearing hip pin may easily cut through the cancellous bone, therewith creating a weak zone or even a hole for the larger femoral neck screw to fall into, facilitating varus dislocation of the head-neck fragment and cutout[10].

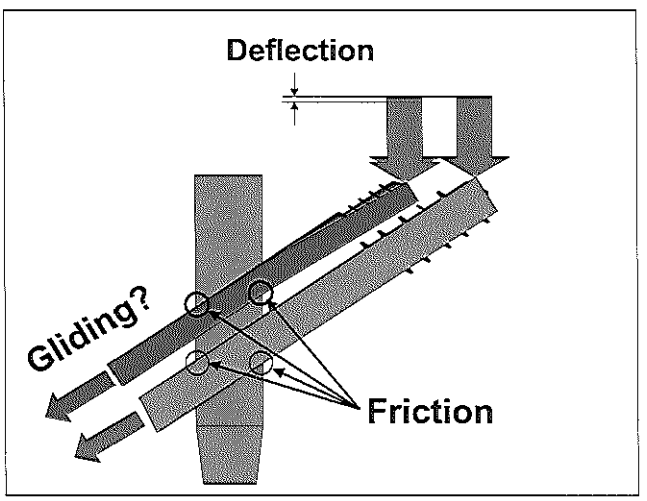

Figure 1. *In the hip pin, with its smaller diameter, more deformation will occur under load compared to the thicker femoral neck screw, so that the parallelism of the pin and screw will become compromised. If the tips of the screws should converge or diverge, from improper insertion or from the load applied, the hip pin and/or femoral neck screw will be intermittently jammed in the nail, so that sliding becomes restricted.*

Analysis of the problems

Both (rare) complications, the medial hip pin migration and the cutout risk, seem to result from similar bio-mechanical influences[6,12]: The forces produced by intermittent weightbearing cause minimal deflection of the hip pin and femoral neck screw. In the hip pin, with its smaller diameter, more flexion-deformation under load will occur compared to the thicker femoral neck screw. With increasing load, more deformation will occur, so that the parallelism of the pin and screw will become compromised. If the medial ends of hip pin or neck screw converge or diverge, due to improper insertion or by the load applied, one or both will be intermittently jammed in the nail, so that sliding becomes restricted (figure 1). The intermittent load and release may then 'draw' the hip pin medially, resulting in medial migration. When (lateral or medial) migration is no longer possible, the working forces will be restricted to almost completely vertical forces and start to induce cutout, facilitated by the described knife effect of the hip pin.

Both effects seem typical for the PFN® and result from the 'extra' hip pin, which was only meant to prevent rotation, but unfortunately appeared to become weight bearing under load[10]. For this reason a modified PFN® (mPFN) prototype was developed (figure 2a), with an oval instead of a round hole in the nail through which the hip pin passes. In this way, the hip pin kept its anti-rotational role while, at the same time, it could angulate under load (figure 2b). In turn, all load was exclusively taken by the neck screw. With this non-constraint lateral end of the hip pin, the bending load was neutralised, as was demonstrated in biomechanical studies that showed the hip pin of the mPFN to carry four times less load compared to the hip pin of the regular PFN® [10]. It is however, not clear to what extent the load reduction influences both types of migration of hip pin and neck screw in clinical setting. Therefore, a multi-center observational study was initiated, to investigate the handling of the modified PFN® design (mPFN), the stability and strength of the construct, the incidence and type of related complications, and whether the angulating hip pin concept functioned in clinical practice.

Since the incidence of medial migration and cutout is very low[13], it would not be possible to prove that these complications no longer occurred.

However, should they occur in the present limited study population, it would suggest that the modified PFN® concept offered insufficient solutions for the prevention of documented complications.

Material and Methods

Objectives and patients

The primary objective of this prospective multi-center* observational handling study was to examine -in clinical practice- the effects of the modification in the mPFN, in unstable trochanteric fractures. Focus was mainly on instrument handling, mechanical failure of the construct, implant related complications, and eventual secondary angulation of the hip pin. Data were analysed in relation to the age and functional state of the patient, associated injuries or illnesses, fracture pattern, result of reduction and position of the hip screw and pin. The endpoints were defined as fracture consolidation, re-osteosynthesis with exchange of implants, death, and maximal follow-up period (3 months) reached.

Consecutive patients over 18 years with unstable trochanteric fractures, defined as fractures of type 31.A2 and 31.A3 according to the AO/ASIF classification[8], suitable for treatment with an intramedullary implant, were entered in this documentation series. A signed informed consent form had to be obtained before inclusion.

Treatment protocol.

All patients received prophylactic antibiotic coverage before starting the operation. Patients were operated on a fracture table, and if possible, closed reduction was performed with image intensifier control. The operation was performed according to the protocol for surgical procedure of the Proximal Femoral Nail® (PFN), which was summarised in the study protocol. The PFN® with an oval hole used for this study, was a 10 or 11 mm diameter solid titanium nail of 240 mm length. The hip pin and neck screw, with CCD-angles of 130 degrees, were inserted percutaneously. Insertion technique of the screws prescribed central positioning of the hip pin and screw in the AP position, and slightly dorsal on the axial view. During the investigation, 'rules' for screw insertion were further specified, in order to create similar settings as the ones in which the hip pin (as a part of the standard PFN®) had been observed to migrate. Using maximal length screws (MLS) resulted in maximal loading,

* Participating centers: Universitätsspital Zürich, Klinik für Unfallchirurgie, Zürich, Switzerland; Universitätsklinikum Carl Gustav Carus, Klinik und Poliklinik für Unfall- und Wiederherstellungschirurgie, Dresden, Germany; Universitätsklinikum Charité, Klinik für Unfall- und Wiederherstellungschirurgie, Berlin, Germany; Kantonsspital Basel, Basel, Switzerland; Krankenhauszweckverband, Chirurgische Klinik III, Augsburg, Germany; University Medical Center Utrecht, Netherlands

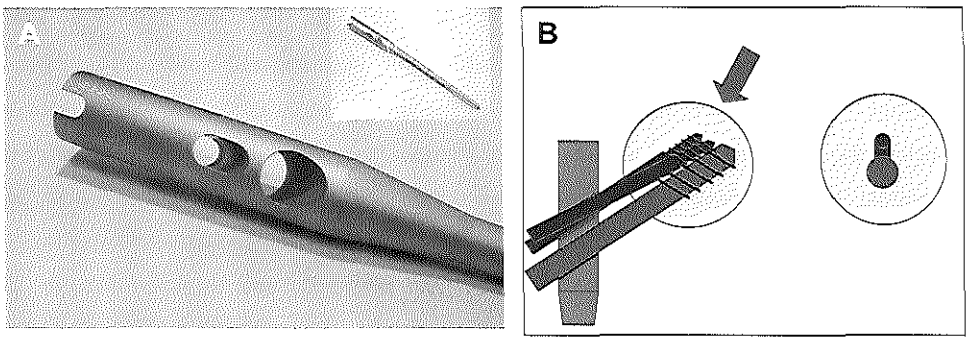

Figure 2. *A) Detail of the proximal side of the mPFN. B) Schematic drawing of the Proximal Femoral Nail® with an oval hole (mPFN) and the concept of angulation of the hip pin.*

thereby testing safety to the limit. In this way, forces and moments on both screws were calculated to be maximal, providing a challenge for migration and the occurrence of the knife-effect. For this purpose participating centres were encouraged to insert hip pins and neck screws of maximum length, which ideally resulted in both tips positioned at 5 mm or less from the articular surface of the femoral head (figure 3a).

Type of distal interlocking was not specified. Postoperatively, all patients were encouraged to mobilise full weight bearing, assisted by a physiotherapist, as soon as possible.

The treatment protocol was approved by the local ethics committee of the participating hospitals.

Data-collection and follow-up

Prospective documentation and data collection during clinical assessment and follow-up until at least 3 months was facilitated by standard registration forms. Specifications about patient, implant, actual surgery, postoperative complications, recovery and radiographs were documented peri-operatively. Study related follow-up visits were continued until 3 months postoperatively. During these 3 months, patients were (depending on day of dismissal) seen once or twice for study follow-up, preferably at 6 weeks and 3 months postoperatively. At each visit, besides clinical examination, AP and lateral radiographs of the fractured hip were made, and standard data forms were completed. The radiographs were evaluated concerning fracture reduction, femoral neck screw and hip pin position, consolidation, tendency to

telescoping or collapse, loss of parallelism, migration and cutout. Whenever an adverse event occurred this was reported at the central study coordinator. Study follow-up was discontinued after replacement of the mPFN by another fixation device or after three months postoperatively at maximum.

Analysis

We aimed to analyse 100 completely documented patients with maximum length screws (MLS). Only those patients with both tips positioned at 5 mm or less from the articular surface of the femoral head were included in this MLS- group.

To collect at least 100 patients with MLS, 250 patients were documented and operated with the mPFN prototype, of whom the initial radiographs were scored by the central trial monitor. Data of the remaining patients with "standard" length screws (SLS) were analysed separately.

Table 1. *Baseline characteristics of the included patients (n = 245). Age is given in years, bodyweight in kilograms. SLS = standard length screws, MLS = maximum length screws, SD = standard deviation.*

		SLS (n = 139)	MLS (n = 106)
Age (mean ± SD)		75.9 ± 13.7	76.5 ± 14.1
Body weight (mean ± SD)		69.7 ± 11.9	63.3 ± 13.1
Gender distribution	female	91 (66%)	79 (74%)
	male	48 (34%)	27 (26%)
Pre operative walking aids	none	95 (68%)	68 (64%)
	one cane	18 (13%)	14 (13%)
	two canes or frame	21 (15%)	21 (20%)
	wheelchair or bedridden	5 (4%)	3 (3%)
Pathologic fracture (%)		8 (6%)	1 (1%)
Fracture type	31 A2	120 (86%)	88 (83%)
	31 A3	19 (14%)	18 (17%)

Results

From 1 December 2000 to 1 December 2002, 250 patients with unstable trochanteric fractures were included and treated with the mPFN prototype in the six participating European teaching hospitals. Baseline characteristics of the included patients are summarised in table 1. After

initial inclusion 5 patients were excluded from data analysis since no postoperative radiographs were available.

Table 2. *Details concerning operation technique. SLS = standard length screws, MLS = maximum length screws, FNS = femoral neck screw, AP = anteroposterior.*

			SLS (n=139)	MLS (n=106)	Total (n=245)
Reduction	AP	anatomical/ acceptable	132 (95%)	99 (94%)	231 (94%)
		valgus ≥ 10°	4 (3%)	6 (5%)	10 (4%)
		varus ≥ 10°	3 (2%)	1 (1%)	4 (2%)
	lateral	anatomical/ acceptable	135 (97%)	104 (98%)	239 (97%)
		antecurvation ≥ 10°	1 (1%)	1 (1%)	2 (1%)
		recurvation ≥ 10°	3 (2%)	1 (1%)	4 (2%)
	AP and lateral anatomical/ acceptable		110 (79%)	88 (83%)	198 (81%)
Insertion	unreamed		112 (81%)	95 (90%)	207 (84%)
	reamed		27 (19%)	11 (10%)	38 (16%)
Diameter PFN	10 mm		64 (46%)	53 (50%)	117 (48%)
	11 mm		75 (54%)	53 (50%)	128 (52%)
Position FNS	AP	cranial	5 (4%)	4 (4%)	9 (4%)
		middle	44 (32%)	38 (36%)	82 (33%)
		caudal	90 (64%)	64 (60%)	154 (63%)
	lateral	anterior	23 (17%)	11 (10%)	34 (14%)
		middle	107 (77%)	77(73%)	184 (75%)
		posterior	9 (6%)	18 (17%)	27 (12%)

Intraoperative data

Surgery was performed by surgical residents in 55% of the procedures. Specifications concerning the result of reduction, the position of the fixation device, and operative technique are given in table 2. Several technical problems were encountered during operation: 5 times aiming device related problems (proximal or distal), 3 times difficulties with wire positioning, twice soft tissue bruising by the insertion device, and once the end-cap positioning was

problematic. The incidence and type of these handling problems did not differ from those found using the regular PFN®. Of the 245 patients available for analysis, 106 had had both hip pin and screw positioned with their tip less than 5 mm to the medial cortex of the femoral head (MLS), therewith being at maximum risk for migration, whereas 139 had "standard" length hip pins and neck screws (SLS).

Table 3. *Overall numbers of patients and types of postoperative events during 3 months follow-up.*

	SLS n = 139	MSL n = 106	Total n = 245
Postoperative wound problems			
wound infection superficial	7 (5%)	7 (7%)	14 (6%)
wound infection deep	1 (1%)	0	1 (1%)
haematoma	4 (3%)	1 (1%)	5 (2%)
Dislocation of proximal screws			
varisation > 10' / tendency to cutout	1 (1%)	2 (2%)	3 (1%)
medial migration > 5mm	0	0	0
lateral migration > 5mm	8 (6%)	1 (1%)	9 (4%)
Pseudarthrosis	1 (1%)	0	1 (1%)
Reintervention	13 (9%)	2 (2%)	15 (6%)
wound problem related	2 (1%)	0	2 (1%)
removal/ exchange of hip pin	6 (4%)	1 (1%)	7 (3%)
replacement of implant	5 (4%)	1 (1%)	6 (2%)
General complications	8 (6%)	5 (5%)	13 (5%)
Mortality	9 (6%)	8 (8%)	17 (7%)

Postoperative course

Full weight bearing immediately postoperative was actually practiced by 199/ 245 patients (106 SLS, 93 MLS). Superficial wound infections occurred in 14 patients (3 %), 7 from both groups; one patient died due to operation site induced sepsis. Haematoma's were documented in 5 patients. Median hospital stay was 17 days (range 1-202 days). A summary of the overall problems is given in table 3. These data did not differ between the SLS and MLS group.

Patient flow

After 6 weeks, 87 patients in the SLS group and 70 patients of the MLS group of the initial 245 patients were seen for study follow-up. Overall, 59 patients (32 SLS, 27 MLS) were lost to follow-up for reasons of move to an unknown location or abroad (4), refusal of further participation (20), inability to be transported to the hospital (12), or for unknown reasons (23). Seventeen patients had died (9 SLS, 8MLS). Six patients (5 SLS, 1 MLS) underwent replacement of the PFN® by another implant (causes discussed below) and were thereafter excluded from further follow-up.

At 3 months, 93 and 70 patients of the SLS and MLS group respectively, visited the outward clinics for study follow-up.

Six weeks' follow-up.

Events during follow-up were divided into medial migration, lateral migration, progressive angulation, and cutout of the hip pin and neck screw. Data are given in table 4. No actual cutout was documented, but 2 patients (1 SLS, 1MLS) showed imminent cranial migration, with slight angulation of the hip pin. Analysis of their direct postoperative x-rays showed imperfect reduction with pre-existent varisation and/ or suboptimal positioning of the hip pin and neck screw. In these two patients the PFN® was removed and replaced by respectively a hip prosthesis and a 95° angle blade plate. No medial migration was noticed in the first 6 weeks postoperatively, and minor lateral migration (not to be confused with telescoping or collapse of the fracture area) was documented in 4 patients, which remained without clinical consequences. One patient (MLS) had his hip pin replaced, since the post operative X-ray revealed that it was inserted too deeply and thus protruded into the hip joint.

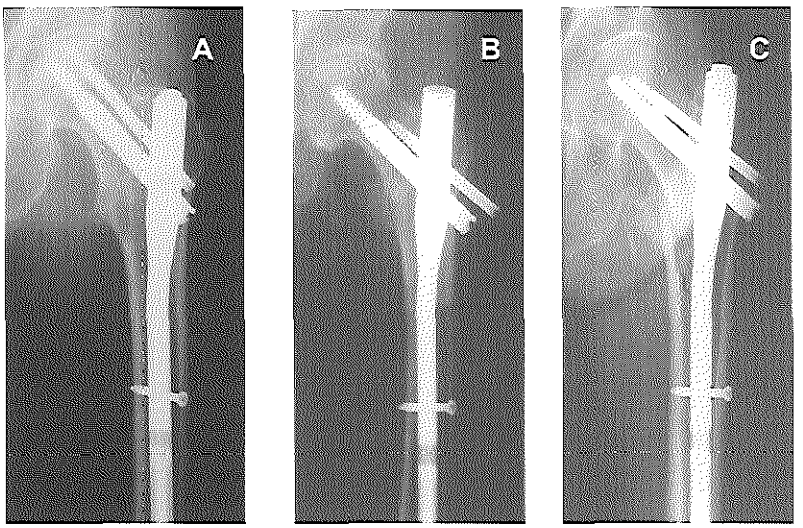

Figure 3. *A) To challenge the construct to the limit, participating centres were encouraged to insert hip pins and neck screws of maximum length (MLS), resulting in both tips positioned at 5 mm or less from the articular surface of the femoral head. B) Lateral migration (not to be confused with telescoping or collapse of the fracture area) varied from 5 to 75 mm and was documented predominantly in patients with standard length screws (SLS). C) The amount of angulation of the hip pin was documented during the first 3 months. The observation of angulation proved that the concept was correct.*

Three months' follow-up

At 3 months 62/93 (67%) patients with SLS and 45/70 (64%) patients with MLS showed radiological consolidation of their fracture. Except for one patient, all others had ongoing consolidation visible at the 3 months' x-rays. Limited cranial migration of one or both proximal screws with slight varus dislocation of the head-neck fragment was seen in 3 cases (table 4). Imminent cutout resulting in removal of the PFN[00] and a Girdlestone situation was documented in one patient. Apart from one patient with minimal (3mm) and clinically irrelevant medial migration of the hip pin, this phenomenon was not documented in the present study. Lateral migration, varying from 6 to 75 mm sliding out of the head-neck fragment, was seen more often with an incidence of 4% (n = 9), and mainly in the patient group with SLS (table 4). In this group 4 patients showed a lateral migration of the hip pin of respectively 20, 20, 40, and 75 mm (figure 3b) without fracture collapse. The complaints caused by this lateral migration and subsequent protrusion into the soft tissue, led in 6 (SLS) patients to hip pin removal. One patient showed substantial lateral migration of the hip pin

Table 4. *Numbers of patients with tendency to cut-out, migration, and loss of parallelism of the hip pin and the femoral neck screw, specified for standard length screws (SLS) and maximal length screws (MSL) at 6 weeks and 3 months postoperative follow-up.*

Follow-up		SLS		MLS	
	Distance mm	6 weeks (n = 87)	3 months (n = 93)	6 weeks (n = 70)	3 months (n = 70)
Tendency to cutout	1-5	2	3		
	6-10	1		1	1
Medial migration	1-5				1
Lateral migration	1-5	1	3	3	3
	6-10		4		1
	> 10		4		
Angulation hip pin	converging	12	16	11	13
	diverging	6	12	4	4

and neck screw, resulting in varus dislocation after 8 weeks. She underwent a reoperation with replacement of the PFN® by an angled blade plate.

Overall, 13 implant related reoperations were documented, of which 11 concerned patients with SLS (table 3). Seven patients underwent removal or replacement of the (protruding) hip pin. The other six reoperations concerned (total) implant removal or replacement: One patient got a hip replacement after confirmed pseudarthrosis, in another patient the PFN® was

exchanged for a dynamic hip screw due to persistent fracture distraction, three patients were reoperated due to imminent cutout with varus dislocation, and one patient showed loss of fracture reduction caused by lateral migration of the hip pin and neck screw.

No mechanical implant failure (nail fatigue or pin/ screw breakage) was found.

In order to see if the oval hole concept functioned adequately, the amount of angulation of the hip pin and neck screw, or loss of parallelism, was documented. Surprisingly, after 6 weeks and 3 months we did not only find patients with converging screws (figure 3c) but also a considerable number of diverging screws (table 4).

Discussion

The oval hole for the hip pin in the mPFN seemed a simple yet elegant solution for some specific implant related problems, as documented in earlier trials with the PFN® [1-3,9]. This study intended to find the answers to 4 questions concerning the treatment of unstable trochanteric fractures with a modified PFN® prototype:

Does the oval hole concept introduce new handling or technical problems?

Compared to the regular PFN® no specific handling problems were encountered, nor were any technical problems on pre-drilling and insertion of the hip pin and neck screw documen-ted. Loosening of the aiming device caused problems with the distal interlocking. This problem is also known from the regular PFN® and other intramedullary implants, and is not related to the modifications on the v. Based on the intraoperative findings of the surgeons, we consider handling of mPFN equal to using the regular PFN®.

Is the implant strong enough to withstand the forces at the side of the oval hole?

The regular PFN® has been tested extensively and was shown to easily withstand loading forces up to 7000 Newton[5]. Finite element analysis has shown, that the oval hole of the mPFN has no influence on the overall mechanical property of the device. Clinical practice and the results of this study do not suggest different load bearing capacities and biomechanical properties for the mPFN, since no fatigue of the nail at the site of the oval hole was documented, though most patients started full weightbearing immediately after the operation.

Does the angulation concept work?

Measuring the initial angulation of the hip pin and screw immediately after insertion, and the angulation on the 6 weeks' and 3 months' X-ray, led to surprising results. Not only was converging angulation documented in 29 patients, after 3 months diverging loss of parallelism

was found in 16 patients. We do not have a solid explanation for this latter finding. We feel that the overall 12% converging reflects part of the reduction in cutouts that might have been initiated when treatment had been performed with a regular PFN®.

Does the oval hole concept really prevent cutout and migration of the hip pin and neck screw?

No actual cases of cut-out were seen during this study, compared to 0.5 to 6% in earlier trials on the regular PFN® [2-4,11,13]. There were however, three reinterventions (1 SLS, 2 MLS) due to imminent anterior or cranial cutout and subsequent varus dislocation of the femoral head. Further analysis revealed an unsatisfactory reduction and/or suboptimal position of the hip pin and neck screw in all three patients. It is obvious that whatever adjustments are made, the fixation device can never make up for insufficient fracture reduction and implant positioning. Minimal cranial migration (less than 5 mm) of the hip pin and screw was documented in five patients with SLS; this phenomenon remained without clinical consequences.

Since the introduction of a shoulder on the lateral end of the hip pin and screw, medial migration was possible for only a very limited distance. Before this adaptation uncontrolled medial migration was seen in up to 3% of the patients with unstable trochanteric fractures treated with a PFN® [4,9]; in this study no clinically significant medial migration was documented.

Lateral migration of the hip pin and screw is a well-known problem of the PFN® that has been documented in up to 8% [4,9], resulting in patients with complaints of pain at the side of insertion, and relatively high numbers of screw removals. Although distinction between fracture collapse with subsequent protrusion of the screws at the lateral side, and true lateral migration of the hip pin and/or screw out of the head-neck fragment may be difficult, the current study attempted to differentiate between both events. This resulted in an incidence of pure lateral migration of 4%, the majority in patients with SLS. This was to be expected, since the longer screws must have had better grip in the firm subchondrall bone.

In conclusion, the angulation concept with the oval hole in the intramedullary nail has shown its effect on reduction of the knife effect by practically, but not completely, eliminating the cutout risk, when fracture reduction and implant positioning were adequate. Relevant medial migration of the hip pin and neck screw were no longer documented, whereas lateral

migration persisted, be it to a lesser extent than in the regular PFN®. Overall, the hip pin angulation concept of the mPFN seemed to reduce the risk of implant related complications. The results of this study will be used for the development of the next generation proximal femoral nails.

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References

1. Al yassari G, Langstaff RJ, Jones JW, Al Lami M. The AO/ASIF proximal femoral nail (PFN) for the treatment of unstable trochanteric femoral fracture. Injury 2002; 33: 395-399.

2. Banan H, Al Sabti A, Jimulia T, Hart AJ. The treatment of unstable, extracapsular hip fractures with the AO/ASIF proximal femoral nail (PFN)--our first 60 cases. Injury 2002; 33: 401-405.

3. Boldin C, Seibert FJ, Fankhauser F, Peicha G, Grechenig W, Szyszkowitz R. The proximal femoral nail (PFN)--a minimal invasive treatment of unstable proximal femoral fractures: a prospective study of 55 patients with a follow-up of 15 months. Acta Orthop Scand 2003; 74: 53-58.

4. Domingo LJ, Cecilia D, Herrera A, Resines C. Trochanteric fractures treated with a proximal femoral nail. Int Orthop 2001; 25: 298-301.

5. Götze B, Bonnaire F, Weise K, Friedl HP. Belastbahrkeit von Osteosynthesen bei instabilen per- und subtrochanteren Femurfrakturen. Akt Traumatol 1998; 28: 197-204.

6. Loch DA, Kyle RF, Bechtold JE, Kane M, Anderson K, Sherman RE. Forces required to initiate sliding in second-generation intramedullary nails. J Bone Joint Surg Am 1998; 80: 1626-1631.

7. Lustenberger A, Bekic J, Ganz R. [Rotational instability of trochanteric femoral fractures secured with the dynamic hip screw. A radiologic analysis]. Unfallchirurg 1995; 98: 514-517.

8. Müller ME, Nazarian S, Koch P, Schatzker J. The comprehensive classification of fractures of the long bones. Berlin/Heidelberg: Springer-verlag; 1990.

9. Nuber S, Schonweiss T, Ruter A. [Stabilisation of unstable trochanteric femoral fractures. Dynamic hip screw (DHS) with trochanteric stabilisation plate vs. proximal femur nail (PFN)]. Unfallchirurg 2003; 106: 39-47.

10. Schipper IB, Bresina S, Wahl D, Linke B, van Vugt AB, Schneider E. Biomechanical evaluation of the proximal femoral nail. Clin Orthop 2002; 405: 277-286.

11. Schwab E, Höntzsch K, Weise K. Die Versorgung instabiler per- und subtrochantärer Femurfrakturen mit dem Proximalen Femurnagel (PFN). Akt Traumatol 1999; 28: 56-60.

12. Sim E, Schmiedmayer HB, Lugner P. Mechanical factors responsible for the obstruction of the gliding mechanism of a dynamic hip screw for stabilizing pertrochanteric femoral fractures. J Trauma 2000; 49: 995-1001.

13. Simmermacher RK, Bosch AM, Van der Werken Chr. The AO/ASIF-proximal femoral nail (PFN): a new device for the treatment of unstable proximal femoral fractures. Injury 1999; 30: 327-332.

CHAPTER 8

The balance between man and material

General discussion

The various factors that influence clinical outcome of operative treatment of unstable trochanteric fractures are the central theme (figure 1) of this thesis. Many of these factors remained undiscussed, not because they are irrelevant, but simply because it is impossible to cover all possible factors of influence.

Although not the main subject of every chapter, one or more of the four main denominators of outcome - the patient, the fracture, the fixation device, and the surgeon - can be found as matter of importance in both clinical and non-clinical studies in this thesis. Therefore, the final discussion focuses on each element separately, but even more so on their mutual interactions.

The patient

Patient related factors, such as age, concomitant diseases, bone quality, initial level of mobility, requirements and expectations, have been addressed in many studies. Age under 85 years, ability to walk independently prior to the fracture inflicting accident and at discharge from the hospital, ASA grade I or II, and mental stability are reported to be factors that are strongly predictive for a return to independence after operative treatment of a hip fracture. They can however hardly be influenced at the acute moment of the fracture, despite the nowadays high-standard of medical treatment and care. Because of the relative static character of this 'patient factor', the primary influence of this parameter on outcome was only discussed indirectly, and did not become part of the parameters to be investigated. The interactions with the other three factors, - in terms of (patient) outcome -, should however not be neglected.

In our studies, outcome was defined as fracture consolidation and restoration of function rather than return to independence. Fracture consolidation is essential for recovery of function and return to independence, but a similar relation can be found for age, concomitant diseases, initial level of mobility and mental state.

The fracture

The fracture (type) is a major denominator of clinical outcome. Since we know that the type of fracture has consequences for the choice of operative treatment, classification has become the cornerstone of the treatment plan. The AO-classification for trochanteric fractures (31A) provides a classification with good interobserver and intra-observer reliability for the determination of fracture groups. A problem arises however when classification continues

into subgroups, which causes a dramatically decrease in reliability. For 31A1 and 31A2 no major harm is done when the fracture is not further classified into subgroups, since these subgroups result from similar mechanisms of injury and thus request similar approaches for fixation. The difference between A1 and A2 fracture groups is crucial, as it represents the difference between a stable and an unstable trochanteric fracture.

For A3 fractures, not being able to make a reliably subdivision is a shortcoming, because the three A3 (inter)trochanteric subgroups (reversed, oblique, and comminuted) are characterised by 3 different mechanisms of dislocation, caused by their distinct fracture patterns and different muscular insertion on fracture fragments. For this reason it may be necessary to develop a new, simple, but more reliable classification in subgroups that takes into account the above-mentioned concerns.

After classification, the subsequent biomechanical and clinical differences between fractures become obvious during and after surgery. Reduction of A3 fractures is more problematic and leads to more open reductions. Both a suboptimal result of closed reduction and open reduction are associated with higher numbers of local complications. This poses the dilemma whether to accept suboptimally restored anatomy in a closed way or to accept some extra risk of open reduction related complications.

The direct influence of the fracture on the overall clinical outcome is evident, but limited. None of the complications occurred significantly more often in the A3 fracture group. Based on the theory that axial load leads to impaction in A2 fracture, but that in A3 fractures such impaction does not occur, differences in cutout and migration rates were expected, but not found. Also, on the basis of biomechanical arguments, it has been advocated that A3 fractures, and especially A3.1 (reversed) fractures, should not be treated with devices that contain a sliding hip screw. Although the overall number of reinterventions is higher in the A3 fracture group, the number of complications and the long-term functional outcome are similar for both fracture groups. This does not confirm the previous suggestion that A3 fractures should be treated with a different device than A2 trochanteric fractures.

The fixation device

The quest for optimal treatment of unstable trochanteric fractures easily focuses on fixation devices. This is understandable, since the pliant aspects of the fixation devices (availability,

suitability for the fracture, handling ease, forgivingness, position of the material, biomechanical properties) seem to vary widely.

But are they really this various? The main question 'what is the best (intra- or extramedullary) device for the operative fixation of unstable trochanteric fractures' still remains open. The basis of treatment is provided by a stable 'fracture-fixation construct'. Biomechanically, the intramedullary implant is superior: it is stronger, shows less deformity, and it enables immediate full weight bearing with low risk of mechanical failure... when perfectly inserted. And this is probably what pleads in favour of an extramedullary type of fixation. Why is it that we have a biomechanically favourable fixation device, but we cannot provide any clinical, evidence-based advantages? Maybe it is the complexity of adequate positioning of the implant? We do know that the sliding hip screw systems (like the DHS) with their open reduction and 'more invasive' surgical fixation, facilitate reduction and positioning of the fixation device, and are therefore still advocated by many surgeons as the treatment of choice for both stable and unstable fractures. This, however, seems a way to compensate for the imperfection of the surgeon rather than for the (imperfection of the) implant. The intramedullary implant was indeed evidence based biomechanically favourable, its surgical use was, however, not.

Comparison of two of the many currently available intramedullary implants, supported the above-mentioned hypothesis. One of the implants, the Proximal Femoral Nail®, had been designed to overcome some of the complications seen with existing and well accepted intramedullary implants. The Gamma Nail and the PFN® did equally well in unstable fractures, with similar pitfalls and comparable complications. The most frequently documented adverse event was cutout with a rate of 7% for both implants. The phenomenon of cutout has been and still is topic of many investigations. The migration of the hip pin and screw remains in part a mystery that has not been solved completely. In our studies, almost all cases in which cutout or migration occurred, fracture reduction was documented suboptimal, position of fixation was judged poor, or both. This again emphasises the importance to aim for a (nearly) anatomical reduction and a perfect positioning and insertion of the implant. Even modifications as demonstrated in the prototype PFN®, reveal only a very modest effect on the complication rates. This observation proves that the overall influence of the implant on outcome is limited. A skilled surgeon may successfully treat complex unstable trochanteric fractures with any suitable fixation device (sliding hip screw, intramedullary system, angled

blade plate) and outcome will hardly be different, as long a the 'fracture-fixation complex' has gained combined stability by adequate reduction and good positioning of the fixation device.

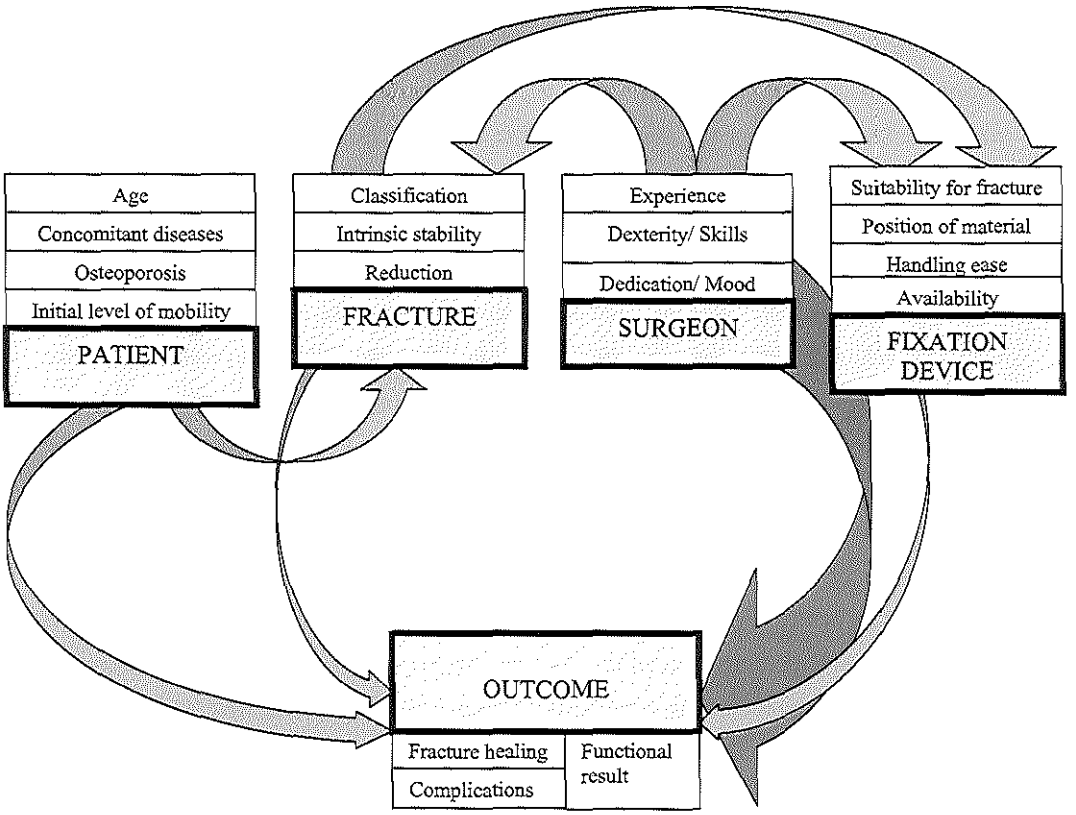

Figure 1. *The balance of man (the patient, the surgeon) and material (the fracture, the fixation device) in determining outcome is predominantly determined by the actions of the surgeon. The arrows indicate directions and quantity of influence between separate elements, and on outcome.*

The surgeon

More and more arrows are drawn into the direction of the surgeon. His or her experience with certain fractures and methods of fixation, will, in combination with the classification of the fracture and the availability of implants, determine what type of osteosynthesis will be

performed. The combination of the surgeons' dedication, experience, skills and self-criticism, will largely determine the result of the reduction, which we know is an important denominator of the course of the surgical procedure. Proper positioning of an implant is only possible if reduction is sufficient. The positioning of the implant and the result of the reduction are crucial for the outcome, and both factors can directly be influenced by the surgeon. This makes the surgeon the major determining factor for the outcome of treatment!

Looking at the many questions asked at the introduction of this thesis, it is inevitable that the strong influence of the human factor returns in every answer. Therefore, the balance between man and material in treatment of the unstable trochanteric fracture is and will be predominantly influenced by (wo)man, rather than by material. Future development should not (only) focus on optimising implants, further improvement of outcome will primarily be obtained by perfection of the surgical efforts. After all, a basic prerequisite of a good result is a perfect mastering of the surgical technique…

CHAPTER 9

Summary and answers to the questions

SUMMARY AND ANSWERS TO THE QUESTIONS

Chapter 1 provides a general introduction to the topic of treatment of unstable trochanteric fractures and poses the questions to be answered in this thesis.

In general, for operative treatment of unstable trochanteric fractures two options exist: extramedullary or intramedullary stabilisation. To answer the question "*What evidence-based support can be found for a consensus of best treatment for trochanteric femoral fractures?*" **Chapter 2** presents a review of 18 international articles that compared two different treatment methods for trochanteric fractures, in prospective randomised clinical trials. The review shows that clinical advantages of both treatment methods are suggested and advocated, but still remain to be demonstrated on evidence base. In view of the overall results, the answer to the second question, "*What is the current state of the art in treatment of unstable trochanteric fractures?*" is that there is no evidence to support the routine use of intramedullary fixation devices for stable trochanteric fractures. For these fractures one of the sliding hip screw systems provides a safe and simple alternative. For unstable fractures, the preference for intramedullary implants -though (biomechanically) superior-, is not based on better clinical outcome.

Systematic classification of trochanteric fractures may reduce problems related to inter-pretation of the fracture pattern and may facilitate the choice of the appropriate method of treatment. To allow reliable assessment and comparison of clinical studies on different types of trochanteric hip fractures, a reproducible classification is mandatory. **Chapter 3** describes a study in which 20 radiographs of trochanteric femoral fractures were classified for fracture "group" and "subgroup" according to the AO/ASIF Fracture Classification (type 31A) by 15 observers. Three months later the same radiographs were reviewed by the same observers. Mean correspondence of the observers with the final consensus varied from 52.5% (with subgroup classification) to 80.5% (without subgroups). The mean kappa value for interobserver reliability was 0.33 and 0.34 for classification with subgroup in both observer sessions respectively. Leaving the subgroup classification out resulted in better mean kappa values (0.67 and 0.63 respectively). Mean intra-observer reliability was 0.48 for fracture "subgroup" and 0.78 for "group" classification.

These results show that the AO/ASIF classification for trochanteric fractures is reliable for fracture groups (31A1, A2 or A3), which answers the question "*Is the AO-ASIF 31A classification consistent and reproducible in terms of interobserver and intra-observer reliability?*". Further classification of fracture subgroups leads to poor reproducibility. And therefore, the remaining questions

- *"Does it provide a guideline for treatment?"*
- *"Is it a classification by which we can report, assess, and compare results?"*
- *"Does it facilitate communication about fracture treatment and outcome?"*

can be answered affirmative for fracture group classification. Concerning fracture subgroups, the insufficient reproducibility discourages its use for comparison of scientific data and determination of treatment strategies.

Unstable trochanteric fractures can be divided into A2 and A3 fractures, each with their distinctive fracture patterns. The anatomical differences between these two groups, result in unique biomechanical needs for a stable fixation. **Chapter** 4 describes the results of a prospective study that attempted to determine and analyse the possible differences in intraoperative parameters and postoperative outcome between A2 and A3 trochanteric fractures, treated by intramedullary fixation. All consecutive patients with unstable trochanteric femoral fractures admitted in nine Dutch hospitals were included and treated with intramedullary fixation (PFN® or Gamma Nail®). Primary outcome was defined as complete and uneventful fracture healing. Secondary outcomes included local and general complications, re-operations and mortality. Results were documented at 4 weeks, 4 months and one year postoperatively. Data were analysed according to fracture pattern, revealing 313 patients with A2 fractures and 100 patients who were treated for A3 fractures. The question "*Do the distinct patterns of A2 and A3 fractures require separate operative treatment methods?*" was answered by the findings that in A3 fractures closed and anatomical reduction was obtained less frequently ($p = 0.007$), and surgical procedures for A3 fractures were generally judged to be more demanding. No differences in outcome were found when subgroup analysis for the different implants was performed. A2 fractures allowed immediate weight bearing in a higher percentage of the patients ($p = 0.03$). Reintervention rate was higher in patients with A3 fractures ($p = 0.004$), with a lower consolidation rate at 4 months ($p = 0.05$). After one year, complication rates and fracture healing were equal in both groups,

which answers the questions "*Do A2 and A3 fractures render different complications and outcome?*"

In conclusion, A2 and A3 fractures are indeed different; treatment of A3 trochanteric fractures is more demanding compared to A2 fractures, but overall outcome one year after intramedullary treatment is similar. Although fracture classification helps to predict what difficulties may be encountered, the main denominators of intraoperative parameters and postoperative outcome originate from the result of reduction and quality of fixation.

Management of unstable trochanteric femoral fractures is challenging, because of unfavourable biomechanical fracture properties and subsequent failure rates. The Proximal Femoral Nail® (PFN) is an intramedullary implant system, designed to improve results of treatment of these specific hip fractures. **Chapter 5** describes a multi-centre prospective clinical study, in which intra-operative use, complications, and treatment outcome of the PFN® were compared with those of the currently standard intramedullary fixation device, the Gamma Nail® (GN).

In nine hospitals 424 patients with unstable trochanteric femoral fractures were randomised either to stabilization with PFN® (n = 211) or with GN (n = 213). Primary outcome was defined as complete and uneventful fracture healing. Secondary outcomes included local and general complications, re-operations and mortality. Outcomes were assessed at 4 weeks, 4 months and one year postoperatively. The questions "*Is there a difference in type and number of complications and reoperations between the two intramedullary fixation devices?*" is answered by the following results. Intra-operative data did not differ significantly, except for blood loss, which was lower using the PFN® (220 ml versus 287 ml, p= 0.001). Postoperative complications revealed more lateral protrusion of the hip pin and screw of the PFN® (7.6%) compared to the GN (1.6%, p= 0.02). Other early- and late postoperative complications showed similar incidences for both treatment modalities, as did general complications and mortality rates. The finding that the majority of local complications were related to suboptimal fracture reduction and/ or malpositioning of the implant, answers the question "*Do fracture reduction and positioning of the fixation device relate to complication rate and/ or give rise to specific complications?*". Although lateral protrusion of the hip pin and/ or screw was seen more often with the PFN, this does not provide an answer to the question "*Can any of the complications be accounted for by the implant?*", since most of the fractures in which

this phenomenon occurred were inadequately reduced or had suboptimal implant positioning. Other possible implant induced complications were not documented. Functional outcome and consolidation were equal for GN and PFN®.
Overall, results of treatment of unstable trochanteric fractures were similar for PFN® and GN. Pitfalls and complications were comparable, and mainly surgeon- or fracture-related, rather than implant-related.

Treatment results of the PFN® for trochanteric fractures generally show a low complication rate. One of the most serious complications described in relation to the PFN® is the cutout of the hip pin and femoral neck screw. Considerable load on the hip pin is thought to provoke cutout. The biomechanical behaviour of the hip pin and the femoral neck screw as part of the standard Proximal Femoral Nail®, and of an experimentally modified Proximal Femoral Nail® (in which the hole through the nail for the hip pin was modified to a slot) was described in **Chapter 6**. It provides an answer to the question "*Does the non-constrained lateral end of the hip pin reduce the bending load applied to the implant?*". In the standard Proximal Femoral Nail®, the amount of the total load carried by the hip pin varies between 8% and 39% (mean 21%). If the hip pin passes through a slot in the nail, it carries only 2% to 8% (mean 5%) of the load. This proves that the nonconstrained lateral end of the hip pin reduces the bending load applied to the implant.
Although the answer to the question "*Will the non-constrained hip pin mechanism, prevent or reduce the risk of cutout and medial migration of the hip pin and femoral neck screw?*" can only be answered in a clinical setting, we do know that the slotted hole for the hip pin also allows the femur and the nail to medialise (fracture collapse), even if some varus dislocation of the head-neck fragment occurs with subsequent angulation of the hip pin. At the same time the bending load on the hip pin is limited. The combination of both findings provides theoretical support for a potential reduction of cutout of the Proximal Femoral Nail® by the introduction of the oval hole concept.

In **Chapter 7** the application and implications of the modified PFN® (mPFN) as described in chapter 6 were investigated in clinical practice. A multi-center observational study was performed, to investigate the handling of the modified PFN® design, the stability and strength

of the construct, the incidence and type of implant related complications, and whether the angulating hip pin concept functioned in clinical practice.

In six European teaching hospitals 250 patients with unstable trochanteric fractures were included and treated with the mPFN prototype.

Handling was found to be equal to the use of the regular PFN® and no specific problems occurred, which is the answer to the question "*Are there any technical (handling) problems concerning the modified PFN®?*". "*Do any complications, related to this implant (breakage, cut-out, migration), occur?*" was also answered by the results of this clinical trial. No breakage of the nail at the side of the oval hole was documented. The cutout risk was practically, but not completely, eliminated in the situation that reduction of the fracture and position of fixation devices were adequate. Medial migration was not documented, but this may be due to its rare occurrence and the limited number of included patients. Lateral migration persisted, be it to a lesser extent. In conclusion, the question "*Is the oval hole concept correct?* ", can be answered affirmative: The angulation concept with the oval hole in the intramedullary nail of the modified PFN® functioned properly, since loss of parallelism of the hip pin and neck screw was observed in patients with limited varus dislocation of the head- neck fracture fragment. This seemed to reduce the number of specific implant related complications, but does not completely eliminate them.

In **Chapter 8** the various factors influencing clinical outcome of treatment of unstable trochanteric fractures that form the central theme in this thesis, are discussed. Focus was on the fracture, the fixation device and the surgeon. Classification of the fracture reveals the different biomechanical and clinical features with subsequent clinical and surgical consequences. Reduction of A3 fractures is more problematic and leads to more open procedures. Both suboptimal (closed) reduction and open reduction are associated with higher risk of local complications. Although the overall reintervention rate is higher in A3 fractures, and their surgery is more demanding, the number of complications and the final functional outcome are similar for both A2 and A3 fractures. The influence of the fracture characteristics on the overall clinical outcome is therewith evident, but limited.

The influence of the type of implant used for internal fixation on the long-term clinical outcome appeared to be less than expected. The biomechanically favourable intramedullary treatment of unstable trochanteric fractures is apparently more demanding and less forgiving:

Suboptimal reduction and imperfect positioning of the implant are hardly tolerated and evidently increase risks on complication and reinterventions. Both the Gamma Nail® and PFN® show similar pitfalls and complication rates, which seem to be rather surgeon related than implant related.

Overall, most parameters that influence outcome of operative treatment of unstable trochanteric fractures are mainly determined by the quality of surgery. Therefore, future development should not (only) focus on optimising fixation devices; further improvement of outcome will primarily be obtained by perfection of the surgical effort. After all, a basic prerequisite of a good result is a perfect mastering of the surgical technique...

CHAPTER 10

Nederlandse samenvatting

SAMENVATTING

Hoofdstuk 1 geeft een algemene introductie van het onderwerp van dit proefschrift. Het benoemt de factoren die van invloed zijn op het resultaat van de behandeling van instabiele trochantere femurfracturen: de patiënt, de fractuur, het implantaat en de chirurg. De wederzijdse interactie en de balans tussen deze factoren worden besproken.

In het algemeen bestaan er twee soorten operatieve behandeling voor instabiele trochantere fracturen: extramedullaire of intramedullaire stabilisatie. **Hoofdstuk 2** presenteert een overzicht van 18 artikelen, waarin telkens twee methoden van behandeling van instabiele trochantere fracturen worden vergeleken middels prospectieve, gerandomiseerde klinische trials. Dit overzicht is opgesteld in een poging een wetenschappelijke consensus te vinden voor de behandeling van instabiele pertrochantere fracturen, en om de huidige keuzen van behandeling te bespreken. Wanneer we de resultaten van dit overzicht interpreteren, kan het routine gebruik van intramedullaire fixatie voor stabiele fracturen niet worden geadviseerd. Voor deze fracturen biedt het dynamische heup schroef (DHS) principe een veilig en simpel alternatief. Voor instabiele fracturen heeft intramedullaire fixatie echter (op biomechanische gronden) de voorkeur. Klinische voordelen worden gepropageerd en gesuggereerd, maar moeten nog op grond van wetenschappelijk bewijs worden aangetoond.

Systematisch classificeren van fracturen kan bijdragen aan een verbeterde interpretatie van het factuurverloop, en daarmee de keuze van de juiste methode van behandeling -intramedullair of extramedullair- vergemakkelijken. Om diverse redenen moet de gebruikte classificatie reproduceerbaar zijn. **Hoofdstuk 3** beschrijft een onderzoek waarbij de reproduceerbaarheid van de AO/ASIF classificatie werd getest. Vijftien proefpersonen classificeerden de fracturen op 20 röntgenfoto's in fractuurgroep en -subgroep. Na 3 maanden beoordeelden dezelfde 15 personen dezelfde 20 foto's opnieuw. Op deze wijze kon een interobserver betrouwbaarheid 0.33 voor subgroepclassificatie, en 0.65 voor fractuurgroepclassificatie worden bepaald. Intraobserver betrouwbaarheid was 0.48 voor subgroepclassificatie en 0.78 voor fractuurgroepclassificatie. Wij concluderen daaruit dat de AO/ASIF classificatie voor pertrochantere fracturen een betrouwbare classificatie is voor fractuurgroepen (31A1, A2, A3). Deze methode van classificatie is goed bruikbaar voor vergelijking van onderzoeksresultaten en het

bepalen van behandelingsstrategieën. Verder subclassificeren leidt tot een slechte reproduceerbaarheid en wordt daarom niet aangeraden.

Instabiele trochantere fracturen kunnen onderverdeeld worden in A2 en A3 fracturen, ieder met hun eigen specifieke fractuurverloop. De anatomische verschillen tussen deze twee fractuurgroepen resulteren in afzonderlijke biomechanische vereisten voor stabiele fixatie. **Hoofdstuk 4** beschrijft een prospectieve studie die de verschillen tussen A2 en A3 fracturen in per- en postoperatieve uitkomst analyseert, bij een gelijke (intramedullaire) behandeling. Alle opeenvolgende patiënten met instabiele trochantere femurfracturen werden in 9 Nederlandse ziekenhuizen geïncludeerd en behandeld met intramedullaire fixatie (een PFN® of Gamma Nail®). Primair werd volledige en ongecompliceerde fractuurconsolidatie bepaald. Daarnaast werd gekeken naar lokale en algemene complicaties, re-operaties en sterfte. De gegevens werden geanalyseerd per fractuurgroep. De resultaten toonden 313 patiënten met A2 en 100 patiënten met A3 fracturen. Bij A3 fracturen werd minder frequent een gesloten en anatomische repositie verricht (p=0.007), en de operaties werden in het algemeen als moeilijker beoordeeld dan bij A2 fracturen. Bij patiënten met A2 fracturen mochten een hoger percentage patiënten direct met volledig gewicht belasten (p=0.03). Het aantal reïnterventies was hoger bij patiënten met A3 fracturen (p=0.004), terwijl het aantal geconsolideerde fracturen na 4 maanden lager was (p=0.05). Eén jaar postoperatief was het aantal complicaties en geconsolideerde fracturen gelijk voor beide groepen. Concluderend stellen wij dat de behandeling van A3 fracturen veeleisender is dan die van A2 fracturen, maar dat de resultaten van behandeling na 1 jaar geen verschil meer tonen. De belangrijkste peroperative parameters met betrekking tot het behandelingsresultaat, zijn af te leiden van het resultaat van de repositie en de kwaliteit van de fixatie.

Behandeling van instabiele trochantere fracturen is in vele opzichten een uitdaging, onder andere door de biomechanisch ongunstige fractuureigenschappen en de vaak hoge complicatiefrequentie. De Proximal Femoral Nail® (PFN) is een intramedullair systeem dat ontworpen is om de resultaten van de behandeling van deze heupfracturen te verbeteren. **Hoofdstuk 5** beschrijft een multi-center gerandomiseerde klinische studie, waarin de behandelingsresultaten en complicaties van de PFN® zijn vergeleken met die van de huidige 'gouden standaard', de Gamma Nail® (GN).

In 9 ziekenhuizen werden 424 patiënten met een instabiele trochantere femurfractuur gerandomiseerd voor behandeling met de PFN (n = 211) of met de GN (n = 213). Primair werd gekeken naar volledige en ongecompliceerde consolidatie; secundaire eindpunten waren lokale en algemene complicaties, reoperaties en sterfte. De peroperatieve gegevens verschilden niet significant, met uitzondering van het peroperatief bloedverlies dat lager was bij de PFN® (220 ml versus 287 ml, p = 0.001). Postoperatief trad bij de PFN® (7.6%) frequenter laterale protrusie van de heupschroeven op vergeleken met de GN (1.6%, p = 0.02). Overige vroege- en laat postoperatieve complicaties, algemene complicaties en sterfte toonden een vergelijkbare incidentie voor beide implantaten. De meerderheid van de lokale complicaties was gerelateerd aan suboptimale fractuurreppositie en/ of slechte positionering van de heupschroeven. Functioneel herstel en fractuurconsolidatie waren gelijk na behandeling met de PFN en de GN. In het algemeen kan gesteld worden dat de behandelingsresultaten van de PFN en de GN bij instabiele trochantere femurfracturen gelijk zijn. De pitfalls en complicaties zijn vergelijkbaar, en lijken vaker chirurg-gerelateerd dan implantaat-gerelateerd.

De behandeling van trochantere fracturen met de PFN laat in het algemeen een lage complicatiefrequentie zien. Het uitbreken van de twee heupschroeven (de anti-rotatieschroef en heupschroef) wordt wel gezien als de meest ernstige complicatie. Het onevenredig belasten van de anti-rotatieschroef kan aanleiding geven tot het uitbreken van deze schroef. Het biomechanisch profiel van de anti-rotatieschroef en de heupschroef wordt, als onderdeel van de standaard PFN® en een experimenteel gemodificeerde PFN®, in **Hoofdstuk 6** bestudeerd. De gemodificeerde PFN® heeft een ovaal gat voor de anti-rotatieschroef in plaats van rond, zodat de schroef kan kantelen zodra er gewicht op komt. In de standaard PFN® draagt de anti-rotatieschroef tussen 8 en 39% (gemiddeld 21%) van de belasting, in de gemodificeerde PFN® is dit tussen de 2 en 8 % (gemiddeld 5%). Het laterale uiteinde van de anti-rotatieschroef kan vrij bewegen in verticale richting wanneer de schroef kantelt, waardoor ook de buigkrachten op het implantaat gereduceerd worden. Daarnaast blijft de mogelijkheid tot medialiseren van het femur en de pen (en dus inclaveren van de fractuur) bestaan, zelfs als de anti-rotatieschroef en de heupschroef niet meer parallel in de femurkop lopen.
Mogelijk kan de prevalentie van uitbreken van de PFN® verder gereduceerd worden door introductie van dit mechanisme in de praktijk.

In **Hoofdstuk** 7 wordt de klinische toepassing van de gemodificeerde PFN® (mPFN), zoals besproken in hoofdstuk 6, onderzocht. Om het gebruik van het prototype mPFN, de sterkte van de constructie, de incidentie van implantaat gerelateerde complicaties zoals uitbreken en migratie, en het functioneren van een angulerende anti-rotatieschroef te onderzoeken, werd een descriptieve, observationele studie in meerde klinieken opgezet. In 6 Europese opleidingsziekenhuizen werden 250 patiënten met instabiele trochantere fracturen behandeld met de mPFN. Het gebruik bleek gelijk aan dat van de standaard PFN®, en er trad geen penbreuk op ter plaatse van het (grotere) ovale gat. De kans op uitbreken was vrijwel nihil, vooropgesteld dat er een adequate repositie en plaatsing van fixatie was verricht. Mediale migratie van de antirotatie schroef en de heup schroef werd niet langer gezien, laterale migratie kwam nog steeds voor, zij het in geringere mate dan bij de standaard PFN®. Vijf patiënten werden gereopereerd waarbij de mPFN werd vervangen door een ander implantaat. Concluderend helpt het mPFN concept het aantal implantaat gerelateerde complicaties verder te reduceren, maar nog niet volledig te elimineren.

In **Hoofdstuk 8** worden de diverse factoren, die het resultaat van de behandeling van instabiele pertrochantere fracturen beïnvloeden, en als rode draad door dit proefschrift lopen, nader beschouwd. Hierbij ligt de nadruk op de fractuur, de fixatie methode, en de operateur. Uit de diverse onderzoeken blijkt dat de directe invloed van de fractuur/ het fractuurtype op het behandelingsresultaat gering is; indirect (via fractuur repositie en de chirurg) bestaat er wel een duidelijke invloed. Hetzelfde geldt voor de fixatie methoden. Complicaties, valkuilen, en behandelingsresultaten zijn grotendeels gelijk, ongeacht het implantaat. Wel maakt uit hoe de fractuur gereponeerd is en waar en hoe het materiaal geplaatst is. Veranderingen aan implantaten hebben slecht een zeer beperkt effect op voorkomen van complicaties.
De meeste parameters die van effect hebben op het behandelingsresultaat, worden direct of indirect beïnvloed door de operateur. Daarom zal de toekomst zich niet (alleen) moeten richten op het verder optimaliseren van implantaten, maar met name op het perfectioneren van de chirurgische inspanning. Immers, een basale vereiste voor een goed resultaat is een perfecte techniek...

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