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Original article

Complications following implant removal in patients with proximal femur fractures – an observational study over 16 years

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ABSTRACT

Background: Fractures of the proximal femur commonly occur but the majority of orthopaedic surgeons do not consider general hardware removal as a routine necessity. Indications and time interval for hardware removal in this special selected patient group is still controversial. Therefore we performed a retrospective study to address the following questions: 1) Is there a difference between the medically- (infection, mechanical problems, implant failure) and non-medically indicated group (patients demand, meteoro-sensitivity, foreign body sensation) in relation to complications? 2) Is there a correlation regarding time interval between implantation and removal comparing these two groups? 3) Is there a context related refracture rate? 4) Should non-medically indicated implant removal (IR) be performed due to persistent pressure from the patient?
Hypothesis: We hypothesized that non-medically indicated implant removals should be avoided due to a significantly higher number of associated complications.
Patients and methods: A total of 371 consecutive patients with 424 hardware removal procedures following a proximal femur fracture, between 08/1992 and 11/2008, have been included. Study population was divided into two groups according to their indication for implant removal: medically indicated group (MIR) consisted of 299 patients (80.59%) and 72 patients (19.41%) were assigned to the non-medically indicated (NMIR) group.
Results: In the NMIR subgroup a total of ($n = 21$) 28% complications occurred compared to 11.46% in the MIR subgroup; ($P < 0.005$), 86.51% of IR in the MIR group were performed within 1.5 years, compared to 79.17% in the NMIR group after 2 to 3.5 years (NS). In the MIR group 1 refracture occurred, compared to 4 in the NMIR group (NS).
Conclusion: Non-medically indicated implant removal should be avoided due to the higher complication rate of 28%. Surgeons and patients should be aware of the imminent complications and therefore implant removal should only be performed for good medical reasons.
Level of evidence: Level IV. Historical case study.

1. Introduction

Fractures of the proximal femur represent some of the most challenging situations for treatment [1]. They commonly occur as low-energy fractures in an elderly population or as high-energy fractures in a young population [1]. The annual cost in the United States for treating hip fractures alone is estimated to be nearly $ 10 billion [1]. Although 58% of orthopaedic surgeons do not consider implant removal (IR) as a necessary routine, it is accounting for approximately 5% of all orthopaedic procedures, performed in the United States [2]. The majority of published papers on complications associated with proximal femoral fractures have focused on the different devices and procedures used for fixation [3–9]. Information of complications associated with implant removal in those studies can be seen as limited [1,2,10–14].

Hardware removal from a healed intertrochanteric fracture is not a routine procedure; however, it may be necessary to remove a metal implant in pediatric or young patients or in the presence of loose or painful hardware, metal allergy, or infection [10,15]. Indications and time interval for hardware removal in this special selected patient group is controversial in the literature [2,10,11,13–18]. Although several authors have reported a femoral

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neck fracture in the presence of fixation for intertrochanteric fractures, reports of ipsilateral femoral neck fractures after hardware removal from healed fractures are rare in the previous literature [9–13,18,19]. Secondary fractures after implant removal have a range from 27 to 44% in proximal femoral fractures [2,19], while other complications associated with IR are mechanical failure, pain and infection [12,14].

The purpose of our study was to assess the following questions:

- is there a difference between the medical- and non-medical indicated group related to complications?
- is there a correlation in time interval between implantation and removal between the two groups?
- is there a context related to refracture rate?
- and as consequence, should non-medical indicated IR be performed due to persistent pressure from the patient?

2. Patients and methods

2.1. Patients

A total of 371 consecutive patients with hardware removal after a proximal femur fracture, admitted to our department, from 08/1992 to 11/2008 have been included retrospectively, approved by IRB (EK 814/2010, Wien). Study population showed the following fracture types according to OTA classification [20] described in detail in Table 1. A total of 424 hardware removals were performed in these 371 patients. Study population was subdivided into the following groups: medical indication for implants removal (MIR) and non-medical indications for implant removal (NMIR). After discharge from hospital, patients were followed-up in our clinic at least 12 months after the last IR procedure. We were able to trace the outcomes of all patients by a data adjustment with the Austrian Death Register.

Inclusion criteria was a proximal femoral fracture, treated with implants as described in detail in Table 1, followed by at least one hardware removal procedure. MIR was defined as: infection, mechanical problems, implant failure (e.g. break, loosening, cut-out), periprosthetic fracture, aseptic necrosis, non-union, pain with a traceable source (overlapped, loose or broken screws or loose implant). NMIR was defined as: patients demand without reasonable intention, meteoro-sensitivity, foreign body sensation, elective implant removal depending on physicians' choice, and pain without any traceable source. Exclusion criteria: all patients younger than 18 years at time of initial surgery for fracture consolidation and all fractures with an already implanted device for fracture stabilization.

Table 1
General patients characteristics.

	n	%
Total patients	371	100
Gender		
Male	126	34.1
Female	241	65.9
Age	66.8	18–100[a]
Type of fracture		
Pertrochanteric	161	43.4
Subtrochanteric	37	9.97
Per- and subtrochanteric	9	2.56
Media femoral neck	158	42.59
Lateral femoral neck	6	1.62
Time interval Fx to PS (days)	2 ± 11.6, (1–209)	
PS < 24 hours of accident	316	85.18
PS > 24 hours of accident	55	14.82
Implants		
Gamma nail	158	42.59
Dynamic hip screw	154	41.51
Screw fixation	27	7.3
PFN	3	0.81
PFNA	4	1.08
Other[b]	25	6.78

Fx: fracture; PS: primary surgery; PFN: proximal femur nail; PFNA: proximal femur nail antirotation.

[a] Results are range in years.

[b] Other: 11 hemi-arthroplasties because of periprosthetic fractures, 6 external fixator, 2 Ender nails, 2 gliding nails, 2 total arthroplasties, 1 dynamic condylar screw, and 1 blade plate.

2.2. Methods of assessment

Complications associated with IR were defined as: refracture, delayed wound healing, vascular and nerve lesion, new incident pain, new limb length discrepancy > 1 cm after IR, further bleeding resulting in revision, avascular hip necrosis, sensibility disruption, broken implant, persistent pain, limitation in range of motion, defective position, wound infection leading to revision, and haematoma leading to revision.

2.3. Statistical methods

For statistical analyses, we used the SPSS 16.0 software package (SPSS, Chicago, Ill., USA). Mean values and standard error of the mean were given unless otherwise indicated for continuous variables. Discrete data are presented as counts and percentages. A two-tailed values $P < 0.05$ was considered statistically significant.

3. Results

We enrolled 371 patients with a mean age of 66.8 (range 18 to 100); ($n = 241$) 65.9% of those representing females, and ($n = 126$) 34.1% were male. Mean time interval for primary treatment for fracture was 2 days (SD: 11.6 days). In ($n = 316$) 85.18% of patients, primary surgery was performed within 24 hours. Implants used for those procedures were: gamma nail ($n = 158$, 42.59%), dynamic hip screw (DHS) ($n = 154$, 41.51%) and 15.9% for other implants as described in Table 1. The MIR subgroup consisted of 299 patients (80.59%) and 72 patients (19.41%) were assigned in the NMIR subgroup as seen in Table 2.

Our hypothesis was approved by statistical significant results ($P < 0.005$), showing 21 complications (28%) for the NMIR group, compared to 40 (11.46%) in the NMIR group.

Mean time interval from hardware implantation until removal was 64 ± 99 weeks, with a range from 1 day to 17 years; 86.51% of IR in the MIR subgroup were performed within 1.5 years after implantation compared to 79.17% in the NMIR group after 2 to 3.5 years (NS).

Refracture rates differ between the two groups: 1 case in MIR group versus 4 cases in the NMIR group (NS).

The total number of implant removal procedures ($n = 424$) needs further clarification (Table 3). IR procedures were subdivided in IR 1 to 4, representing separate sequential procedures in one patient each. In 371 patients, one implant removal (IR) was performed resulting in a total of 53 complications (14.29%). IR 2 subgroup, where a second IR was performed consisted of 45 patients with 8 complications (17.78%) ($P < 0.05$). IR 3 and IR 4 consisted of 6 and 2 patients with no complications. To simplify those numbers for further calculations a total number of 424 IR with a complication rate of ($n = 61$, 14.39%) in 60 patients were set. In 32 cases (80%) of IR, a new device was implanted. Pain in the NMIR subgroup did not vanish after IR in 19%, and in one asymptomatic case, pain occurred after IR.

Complications correlated with duration of implant showed a peak after 3 years, with a range of 1 to 4 years. This finding was

Table 2
Implant removal (IR) in detail.

	n	%	*P* value
Total patients	371	100	
MIR	299	80.59	
NMIR	72	19.41	
Total IR procedures	424	100	
MIR	349	82.31	
NMIR	75	17.69	
Time interval PS to IR[a]	9.1	SD: 14.1, (1 day–17 days)	<0.05
MIR	49	SD: 98.63, (1 day–17 years)	
NMIR	127	SD: 58.99, (36–468)	
Age	62	SD: 24, (23–97)	<0.05
MIR	74	SD: 16.2, (24–100)	
NMIR	44	SD: 18.7, (22–89)	
Gender distribution[b]	1: 1.1		<0.05
MIR	2.6: 1		
NMIR	1: 1.8		
Indications			
MIR			
Mechanical problems	248	82.94	
Infection	40	13.38	
Pain	11	3.68	
NMIR			
Patients demand	35	48.61	
Elective surgery	19	26.39	
Pain[c]	18	25	
Complications after IR	61	14.39	<0.005
MIR	40	11.46	
NMIR	21	28	

MIR: medical indicated implant removal; NMIR: non-medical indicated implant removal; PS: primary surgery.
[a] In weeks.
[b] Female: male.
[c] Without any traceable source.

almost similar in both subgroups and therefore no impact can be suggested (Table 4).

4. Discussion

Information about indication and complications for IR in healed proximal femur fractures can be seen as sparse in the current literature [1,2,11–14]. When comparing the MIR with the NMIR subgroup, a statistical significant finding according to complications with 11.46% versus 28% was observed. This means a 2.4 increase of complications in a relatively unnecessary surgery.

Table 3
Implant removal and complications.

	n	Complications	%
IR1	371	53	14.29
IR2	45	8	17.78
IR3	6	0	0
IR4	2	0	0
Total	424	61	14.39

IR: implant removal; 1: one procedure; 2: two procedures; 3: three procedures; 4: four procedures.

Table 4
Complications in MIR and NMIR subgroups.

	MIR		NMIR		
	IR 1	IR 2	Patient demand	Elective	Pain[a]
Complication					
Refracture		1	4		
Delayed wound healing	2	2	2	1	
Nerve damage	3		1		
New pain				1	
LLD > 1 cm	2		1	1	
Further bleeding with revision	1				
AVN	1		1		1
Sensibility problems	1		1		
Broken implant in situ		1		1	1
Persitent pain	3				3
Limitation in ROM					1
Defective position					1
Wound infect with revision	9				
Haematoma with revision	6				
Other	2				
Total	32	8	9	4	8

MIR: medical indicated implant removal; NMIR: non-medical indicated implant removal; IR: implant removal; LLD: limb length discrepancy; AVN: avascular necrosis of the femoral head; ROM: range of motion.
[a] Without any traceable source.

The current study has several limitations:

- it was a retrospective data evaluation study, performed at only one level I Trauma Centre. Also the group splitting in MIR and NMIR can be seen critical by some readers;
- we only evaluated predominantly Caucasian, Austrian patients, a study population that might not be comparable to other regions in the world.

Most hip fractures are treated surgically, with use of either internal fixation or prosthetic replacement of the femoral head [9]. However there is little discussion on the routine hardware removal in the setting of healed intertrochanteric fractures [6,10,12]. Those indications are also seen as hard proven to perform an IR in the literature [2,10,14,21–26]. Due to the fact that only Hora et al. [27] investigated complications after IR in correlation with indication, a comparison to the existing literature might be tricky. In the MIR subgroup mechanical problems, infection and pain were seen as indications for IR. The NMIR subgroup is difficult to interpret because patients demand, elective surgery and non-manifest pain are not clearly or separately outlined in the existing literature. Complication rates after IR, independent from implant device and localization is reported between 3 and 20%, a finding that is in accordance with our result of 14.39% [22,23,26,27].

In the MIR subgroup, wound infection with or without revision surgery represented the most common cause for IR. One has to have in mind that in 32 cases (80%) of IR, a new device was implanted. In the NMIR subgroup, 4 patients experienced a refracture after a mean time of one month, following IR. Refracture therefore represents the most common complication in the NMIR subgroup [11,14,18].

Femoral neck fracture after IR from a healed intertrochanteric fracture has been reported incidentally by Mendez et al. [18]. Finsen and Benum [28] supported the safety of hardware removal reporting that there were no femoral neck fractures after removal of fixation devices from healed intertrochanteric fractures. In contrast to that observation, current publications showed a refracture rate after implant removal of 9.0% [10,11,16,17].

Pain in the NMIR subgroup did not vanish after IR in 19%, and in one asymptomatic case, pain occurred after IR, a finding that is also confirmed by others [22,29,30]. This should clearly question the indication for IR in patients with diffuse pain without any source.

We also observed a strong correlation between indication for IR and duration of implant in the human body: 86.51% of IR in the MIR subgroup were performed within 1.5 years after implantation compared to 79.17% in the NMIR group after 2 to 3.5 years. A time point in the NMIR subgroup associated with a lower complication rate could not be detected.

Recommendations regarding timing of IR vary, but 12 to 18 months of intramedullary nail fixation of femoral shaft fractures is generally accepted [31,32]. Findings in the paediatric literature have shown that the stiffer the hardware, the higher the likelihood of refracture after removal [33–35].

5. Conclusion

Non-medical indicated implant removal should be avoided due to a high complication rate of 28%. Careful considerations must be undertaken in this special subgroup when considering a hardware removal procedure. Surgeons and patients should be aware of the imminent complications associated with implant removal in non-medical indicated patients after a proximal femoral fracture. This procedure should only be performed for good reasons.

Disclosure of interest

The authors declare that they have no competing interest.

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