



Recommendation of use of checklists in tibial intramedullary nail removal: Retrospective study of mechanical complications related to nail removal

Antti Stenroos*, Tuomas Brinck, Lauri Handolin

Department of Orthopedics and Traumatology, University of Helsinki and Helsinki, University Hospital, PO Box 266, FI-00026 HUS Finland

ARTICLE INFO

Article history:
Accepted 9 May 2018

Keywords:
Tibia fracture
Iatrogenic fracture
Intramedullary nail removal
Complication

ABSTRACT

Background: The removal of implants such as intramedullary nails is one of the most common operations in orthopedic surgery. The indications for orthopedic implants removal will always remain a subject of conversation and hardly supported by literature. The aim of this study to report injuries of treatment in tibial nail removal and to determine if there are fracture characteristics, patient demographics, or surgical details that may predict a complication.

Methods: This is a retrospective seven-year (2010–2016) study including a total of 389 tibial intramedullary nail removals at the Helsinki University Hospital's orthopedic unit. Patients with tibial fracture and removal of intramedullary nail were identified from the hospital discharge register and analyzed.

Results: A total of 21 (5,4%) nail removal related mechanical complications (iatrogenic fractures, nerve injuries, failures to remove the nail) were noted. The most common complication was iatrogenic fracture (n = 15, 3,8%). In 6/15 cases the fracture was caused by broken interlocking screws, In 5/15 cases the iatrogenic fracture was caused accidentally by extracting the nail without prior removal of all distal interlocking screws. In one case, new condensed bone had formed around the nail's distal end and case the forced nail extraction caused a re-fracture in both tibia and fibula.

Conclusion: Nail removal can be a challenging operation which does not always receive the necessary preoperative planning or operative expertise. Iatrogenic fractures were most often caused by inadequate preoperative planning or assuming that a broken interlocking screw tilts during the extraction. We suggest the use of checklists in preoperative planning to avoid fractures caused by broken or undetected interlocking screws.

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Background

Tibial fracture is the most common long bone fracture, seen by trauma units on almost a daily basis [1], and intramedullary nails have become widely accepted as the treatment of choice [2–5].

The removal of implants such as intramedullary nails is one of the most common operations in orthopedic surgery [6]. However, despite the prevalence of the procedure, there is currently no consensus among orthopedic surgeons regarding the criteria for tibial intramedullary nail removal. The decision to remove a tibial intramedullary nail has largely been considered routine – or elected by the patient. Removal of an intramedullary nail is generally regarded as a minor, low-risk procedure with little

morbidity [7], even though implant removal is associated with various known complications such as re-fracture, hematoma, lengthy operating times and implant breakage [7–13].

Within the literature, previously listed criteria for implant removal included: symptomatic hardware, skeletally immature patients, broken hardware, compromised skin, nonunion, malunion, infection, fear of carcinogenesis, peri-implant failure, prevention of postunion stress-shielding, prevention of future bacterial colonization, avoidance of difficult surgery in case of re-fracture or implant failure, avoidance of problems with a future joint replacement, and the possibility that removal will improve functional outcome [10,11,14–16].

The aim of this study is two-fold: 1) to report the unplanned events and injuries of treatment of a large retrospective series of patients who underwent a tibial nail removal operation at a single academic institution (Helsinki University Hospital's orthopedic trauma unit); and 2) to determine if there are fracture

* Corresponding author.

E-mail address: antti.stenroos@helsinki.fi (A. Stenroos).

characteristics, patient demographics, or surgical details that may predict a complication.

Materials and methods

This is a retrospective seven-year (2010–2016) study including a total of 389 tibial intramedullary nail removals at the Helsinki University Hospital's orthopedic unit. Patients with tibial diaphyseal fracture or distal tibial fracture (ICD-10 diagnosis codes S82.2 and S82.3) and removal of intramedullary nail from lower leg (code NGU20 in NOMESCO Classification of Surgical Procedures) were identified from the hospital discharge register. Stress or pathological fractures were excluded from the study, however osteoporotic fractures were included. Also, patients who experienced nail removal during re-do nailing due to malalignment after the primary operation during the same hospital period were excluded from the study. Bilateral fractures were recorded as separate fractures. Intramedullary nails (IMN) used in our institution are titanium locked reamed tibia nails (either DePuy Synthes ETN[®] or Stryker T2[®] nails).

Hospital records were retrospectively reviewed to collect the following data: age, gender, comorbidities, patient's body mass index (BMI), documented reason for implant removal, length and diameter of the intramedullary nail, time of removal, experience of the surgeon (consultant, senior orthopedic registrar or surgical registrar). Tibia fractures were classified according to the Müller's Arbeitsgemeinschaft für Osteosynthesefragen (AO) classification with the aim of finding the fracture patterns that might be associated with complications.

Results are presented as medians and means \pm standard deviation (SD) for continuous non-skewed variables. The frequency distribution of the categorical variables is compared between the groups with the Chi-square test. The statistically significant level is set as $p < 0.05$. Binary regression analysis was performed to determine which parameter (age, BMI, fracture type, nail size, operator's experience) was independently of the significance for prediction of complication. Statistical program SPSS 22 (IBM Corp. released 2009. IBM SPSS Statistics for Windows, version 13.0. Armonk, NY: IBM Corp.) was used for analyzes.

Results

Overall, 389 tibial intramedullary nails (ETN[®] = 357, Stryker T2[®] = 32) were removed from 385 patients at our institution over a 7-year period from January 2010 to December 2016. Of the 389 removed tibial intramedullary nails, 28 were inserted in other hospitals. During the same time period 950 patients were treated with intramedullary nails at our institution, resulting in an average 38% computational nail removal rate.

The mean IMN length was 360 mm (range 300–395) and mean IMN diameter was 10 mm (range 8–11 mm). Prior the nail removal all patients received prophylactic intravenous antibiotics in operating room. Mean age of the patients was 40 years (range 23–58 years), and there was a male dominance in the study population ($n = 212$, 55%). The mean time from IMN insertion to removal was 21 months (range 12–132 months). The mean body mass index of the patients was 26 (range 20–34). The most

Table 1

Reason for intramedullary nail removal.

	Removals	Percentage
Routine removal	216	55,5 %
Anterior knee pain	75	19,2 %
Pain at locking screw site	61	15,6 %
Patient request	28	7,2 %
Not stated	5	1,2 %
Delayed union	1	0,3 %
Deep infection	1	0,3 %
Broken implant	1	0,3 %
Nail migration	1	0,3 %
Total	389	100%

common reason for nail removal was routine removal ($n = 216$, 55%) followed by anterior knee pain ($n = 75$, 19%) and pain at locking screw site ($n = 61$, 16%) (Table 1).

Seventy-five procedures (19%) were performed by surgical registrars, 127 (33%) by senior orthopedic registrars and 187 (48%) by orthopedic consultants.

A total of 21 (5,4%) nail removal related mechanical complications (iatrogenic fractures, nerve injuries, failures to remove the nail) were noted in 19 patients (4,8%). The most common complication was iatrogenic fracture ($n = 15$, 3,8%) More detailed information on all complications is presented on Table 2.

There were 31 (8,0%) cases with broken distal interlocking screw(s). In 25/31 cases the broken screws were identified on preoperative x-rays and 4/31 were identified while removing the interlocking screws. There were two cases where surgeon didn't notice broken interlocking screws, but intraoperative fluoroscopy, applied after the nail failed to come out, revealed the case. In 22 cases, all parts of broken screws were removed prior the nail retraction, resulting in 9 cases where the distal part of broken screw was left in place assuming it tilts and gives away during nail extraction. In 3/9 cases the broken distal interlocking screw part tilted and caused no further harm. On the other hand, in 6/9 cases the broken left behind interlocking screw part did not tilt and caused iatrogenic fracture.

In 5 cases the iatrogenic fracture was caused accidentally by extracting the nail without prior removal of all distal interlocking screws due to misjudgment in preoperative planning. In 3/5 cases the undetected interlocking screw was accidentally left in the nail's distal oblique locking hole (Fig. 1.). In one case, a distal AP interlocking screw was partially removed and left to prevent nail rotation while attaching the nail removal instrument, but then forgotten and not removed completely prior to nail extraction. This resulted in a longitudinal anterior cortex fracture (Fig. 2). In one case, the surgeon was not able to find the distal AP interlocking screw and moved to proximal screws, forgetting then to remove the remaining distal interlocking screw and causing a complex fracture (Fig. 2.). In all 5/5 cases there were additional metal implants in distal fibula or distal tibia.

There were four iatrogenic fractures in cases where all the locking screws were removed prior the nail extraction. In one case, new condensed bone had formed around the nail's distal end (Fig. 3.) resulting in a firm consolidation. In this case the forced nail extraction caused a re-fracture in both tibia and fibula. In one case

Table 2

Detailed information on nail removal related mechanical complications in 389 operations.

Surgeons experience	Number of removals	Iatrogenic fracture	Failure to remove	Nerve injury
Registrar	75 (19,3%)	4 (5,3%)	1 (1,3%)	0
Senior registrar	127 (32,6%)	5 (3,9%)	0	2 (1,6%)
Consultant	187 (48,1%)	6 (3,2%)	2 (1,1%)	1 (0,5%)
Total	389	15 (3,8%)	3 (0,7%)	3 (0,8%)



Fig. 1. X-ray of a patient with oblique distal lockin screw giving an instant idea of three screws. More careful assesment reveals the actual number of four locking screws.

posterior tibial plateau fissure was noted perioperatively after the nail was removed and in one case a bone block broke from anterior tibial plateau. One tibial medial condyle fracture was observed four weeks after nail removal (Fig. 2). More detailed information on iatrogenic fractures is presented in Table 3.

Two patients had neuralgic pain at incision site after nail extraction (one had also an iatrogenic fracture). One patient with a complex tibia fracture (Fig. 2) suffered both sensory and motoric peroneal nerve injuries.

There were three failed attempts to remove a nail. In one case, the appropriate instrumentation (Targon® T universal interlocking nail) was not available for the nail that had been implanted in another hospital. In two cases the nail was buried so deep that removal would have caused unacceptable destruction of the tibia plateau and the surgeon decided to abandon the operation.

None of the surgeons caused more than one iatrogenic fracture. There were no statistically significant differences in iatrogenic fracture rate between surgical registrars, senior orthopedic registrars or consultants (5% vs. 4% vs. 3%, $p = 0.72$). Our attempt to establish a pattern of injury and fracture type among the patients who suffered a mechanical complication failed. All complications were associated with ETN®, however, due to the small sample size of T2® we could not find any statistical significant differences between ETN® and T2®. Age, sex, BMI, AO fracture type, time to nail removal, operator's experience, nail size, presence of infection or other illnesses showed no statistically significant correlation with complications.

Discussion

The iatrogenic fracture rate is high in our institution. Iatrogenic fractures were most often caused by inadequate preoperative planning or assuming that a broken interlocking screw tilts during the extraction.

In earlier studies on IMN removal, re-fracture and iatrogenic fracture rate has been generally low (0–3%) [8,10–13,17–22]. Most of the fractures caused by nail extraction are limited to case reports [21,23–26], Sanderson [27], Boerger [7] and Hora [12] each reported one fracture and White [13] reported 2 cases. We believe that fractures caused by nail extraction are an unfortunate and serious complication that is an under-reported in literature even though the only available prospective data (Vos et al. [17]) found no re-fractures or iatrogenic fractures. Though, most INM removal studies investigate the indications and relief of symptoms after removal instead of focusing on the complications. Folwaczny et al. [9] reported 6/103 iatrogenic fracture rate, which is relative similar to our results. Though, in their study all patients had ACE®-tibia nail with a distal 5° bend towards the ventral, which has been associated with iatrogenic fractures in several case reports [24–26].

Retrospectively, more than half of these iatrogenic fractures in our study could have been avoided by adequate preoperative planning and by continuous internal institutional assessment of treatment quality, which should be a part of modern fracture treatment. Causing an iatrogenic fracture is a lesson a surgeon can



Fig. 2. X-rays of patients with iatrogenic fractures. 1) Complex fracture, 2) Posterior fissure, 3) Posterior fracture, 4) Short distal fracture 5) Fracture of the medial condyle 6) Anterior fracture.



Fig. 3. New condensed bone formation through the intramedullary empty screw hole.

Table 3

Types and treatment of 15 nail removal related iatrogenic fractures in 389 operations.

Cause of fracture	Surgeons experience	Type of fracture	Treatment
Broken screw not tilting	Registrar	Longitudinal fissure	Long leg cast 4 weeks
Broken screw not tilting	Registrar	Longitudinal fracture	Long leg cast 6 weeks
Broken screw not tilting	Senior registrar	Complex mid diaphysis	Re-nailing
Broken screw not tilting	Consultant	Short distal fissure	NWB* 6 weeks
Broken screw not tilting	Registrar	Short distal fissure	NWB 6 weeks
Broken screw not tilting	Senior registrar	Longitudinal fissure	Long leg cast 4 weeks
Undetected oblique screw	Registrar	10 cm distal groove	Long leg cast 6 weeks
Undetected oblique screw	Consultant	Longitudinal fracture	Long leg cast 12 weeks
Undetected oblique screw	Consultant	Longitudinal fracture	Long leg cast 12 weeks
Forgotten screw	Senior registrar	Complex fracture	Long leg cast 12 weeks
Forgotten screw	Consultant	Anterior longitudinal fracture	Long leg cast 6 weeks
Difficult removal	Consultant	Proximal posterior fissure	NWB 4 weeks
Difficult removal	Senior registrar	Broken bone block	NWB 4 weeks
Difficult removal	Senior registrar	Anteromedial fissure	NWB 8 weeks
Undetected new bone formation in distal nail	Consultant	Oblique fracture at primary fracture site	Long leg cast 12 weeks

*NWB, non-weight bearing.

hardly forget. When reporting and analyzing all complications objectively, there is a possibility to learn from other surgeon's errors. As this knowledge and experience becomes more common, it will increase the quality of trauma care.

It seems that assuming the broken interlocking screw to tilt is an unnecessary risk. Brumback [28] stated that: "Removal of an interlocking nail with a portion of an interlocking screw visibly protruding from an interlocking screw hole should never be attempted." Considering the results of our study, we agree and recommend the removal of all broken screw parts prior to the extraction of the nail.

The possibility of nail rotation while attaching the extraction instrument is unlikely due to IMN's anatomic anterior bend. We suggest removing all distal locking screws at the same time instead of leaving one as anti-rotational screw for later removal and thus,

increasing the risk of human error/distraction resulting in interlocking screws accidentally being left in place. In case of a difficult removal, we strongly recommend the use of fluoroscopy instead of forcing the IMN. If the fluoroscopy does not reveal forgotten or broken screws, one should look for new condensed bone around the IMN's distal interlocking screw holes. The new bone formation around an IMN is a mechanical barrier, which effectively forces the distal part of the nail to jam against the cortex and can cause a fracture. Stedtfeld et al [29] and Seebauer [30] reported similar problems. Unlike Stryker's T2[®] nail, which has three distal interlocking screw holes, the Expert Tibia Nail[®] has four holes. When less than all four holes at the distal end are not used, there is a possibility of increased ingrowth of bone fragments into the screw holes that have been left open [30,31]. When ingrowth at left-open screw holes is suspected we agree with Dr. Krettek's [31]

Table 4
Checklist for removal of tibial intramedullary nails.

Preoperatively
Obtain recent x-rays with AP and lateral view
Identify the implant
Make sure that right instrumentation is available
Count the screws from X-rays and patient records
Measure the distance between screws from AP and lateral views
Look for new condensed bone around screw holes
Make sure that fluoroscopy is available
Plan the removal of possible broken screws/implants
Intraoperatively
Remove all screws and count the screws
Inspect the removed screws
Remove broken screws parts
When ingrowth in an exposed screw hole is suspected, empty the exposed hole

recommendation on emptying the nail using a long Kirschner wire and/or emptying left-open holes with a drill.

There were three failed attempts nail removal. In one case, appropriate instrumentation was not available for a nail that had been implanted in another hospital. This should have been taken in consideration in preoperative planning. In two cases the position of the nail was such that removal would have needed excessive chiseling and destruction of bone. In both cases the preoperative X-rays showed the nail was buried deep in the tibia. In cases where the IMN is buried deeply, the surgeon should pre-operatively consider the tradeoff between the risks and benefits of the IMN's removal.

Finally, the ability of the surgeon to be able to identify possibly broken or oblique interlocking screws and bone ingrowth is of major importance to preventing complications. We must emphasize the preoperative planning. Firstly, there needs to be a protocol in place where the number of screws is counted from both AP- and lateral views and patient records. Second, attention needs to be placed on the distance between distal interlocking screws in AP- and lateral X-ray views, because the oblique interlocking screw can go unnoticed on plain X-ray views, especially when using only one view, as presented on Fig. 1. The presence of fibular or other hardware can make identification of all distal interlocking screws difficult especially when oblique distal interlocking screw is present. Therefore, we suggest the use of checklists (Table 4.) in preoperative planning which account for the number of interlocking screws in all x-ray views and from patient records. Another essential element of the checklist would be the careful inspection of interlocking screws after removal in order to reveal broken screws. This would assist in avoiding fractures caused by interlocking screw parts accidentally left behind.

In our study two patients who had previously been asymptomatic developed anterior knee pain at the incision site following the IMN removal. Infrapatellar nerve damage was found in both patients. There are reports of injury to the infrapatellar branch of the saphenous nerve after tibial intramedullary nailing [10]. The course of the infrapatellar nerve makes it susceptible to iatrogenic injury during extraction and insertion, when medial and midline incisions are being used [32,33]. This complication can hardly be avoided by using checklists and several authors have reported knee pain with horizontal incisions as well [32].

This study has several limitations. Its retrospective nature is the most prominent one. Due to poor documentation, we could not count the number of times when fluoroscopy was used, and for the same reason we were not able to determine the exact length of surgery. At our institute, X-rays are not routinely taken after IMN removals, so there is a possibility that some small fissures have gone unnoticed. In many cases the records just stated that it was a difficult removal but no explanation of details or reasons behind difficulties was reported. But a relatively large study population of a single tertiary care trauma unit made it possible to analyze

iatrogenic fractures that had clinical significance and thus give reliable incidence of mechanical complications associated with IMN removal surgery.

Conclusion

Nail removal can be a challenging operation which does not always receive the necessary preoperative planning or operative expertise. The majority of the iatrogenic fractures in this study were avoidable. We suggest the use of checklists in preoperative planning to avoid fractures caused by broken or undetected screws.

Conflicts of interest

None. This research received no funding from Helsinki University and no grants from any funding agencies in the commercial or not-for-profit sectors.

Acknowledgments

AS: planning of the study design, data collection, statistical analysis, and preparation of manuscript. TB: planning of the study design, data collection, and preparation of manuscript. LH: planning of the study design and preparation of manuscript.

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