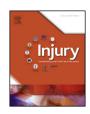
## **ARTICLE IN PRESS**

Injury, Int. J. Care Injured xxx (2018) xxx-xxx



Contents lists available at ScienceDirect

### Injury



journal homepage: www.elsevier.com/locate/injury

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

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ARTICLE INFO	ABSTRACT			

Article history: Accepted 9 May 2018

Keywords: Tibia fracture latrogenic fracture Intramedullary nail removal Complication *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

\* Corresponding author. *E-mail address:* antti.stenroos@helsinki.fi (A. Stenroos). 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 refracture 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

https://doi.org/10.1016/j.injury.2018.05.005 0020-1383/© 2018 Elsevier Ltd. All rights reserved.

Please cite this article in press as: A. Stenroos, et al., Recommendation of use of checklists in tibial intramedullary nail removal: Retrospective study of mechanical complications related to nail removal, Injury (2018), https://doi.org/10.1016/j.injury.2018.05.005

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

#### Table 1

Reason for intramedullary nail removal.

#### 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<sup>®</sup> or Stryker T2<sup>®</sup> 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<sup>®</sup> = 357, Stryker T2<sup>®</sup> = 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

	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	latrogenic 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%)

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