Tibial Nail Removal in Younger and Active Patients with Discomfort: A Cohort Study of 40 Patients

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Abstract

Introduction: The benefit of subsequent removal of an intramedullary tibial nail after osteosynthesis of a tibial fracture is uncertain. Studies on removal outcome are both few and negative. The aim of this study was to evaluate the change in pain, physical activity and employment status after implant removal in patients with a tibial fracture primarily treated with an intramedullary nail. Furthermore, possible predictors for implant removal were identified.

Methods: The study was a retrospective cohort study with written follow-up. We collected data on all patients with a tibia fracture treated with insertion of a tibial nail at the orthopedic department in Slagelse, Denmark from 2009-2011. Medical journals for each patient were reviewed and a questionnaire was mailed to all patients to evaluate change in pain, physical activity and employment status.

Results: Forty patients were included and 21 had implant removal. Implant removal reduced pain scores at rest (3.5 ± 0.6 to 1.2 ± 0.4; p < 0.001) and stress (6.6 ± 0.5 to 3.7±0.6; p < 0.001). There was no significant increase in physical activity although a trend was seen towards regaining pre-fracture level. Young age was slightly associated with implant removal but not statistically significant.

Conclusion: In our study, younger patients with persistent pain after primary treatment of a tibial fracture with an intramedullary tibial nail showed reduced pain and improved physical activity after removal of the tibial nail or locking screws only.

Key words: Tibia shaft fracture is commonly treated with intramedullary nailing, but the effect of removal of nail and screws are uncertain and have many cofactors. This study provides a part of the answer, by dealing with pain and activity level.

Introduction

Tibia shaft fracture is one of the most common fractures in adults¹ and often treated with a tibial intramedullary nail which is an effective and stable osteosynthesis [1-6]. Other types of treatments are plate osteosynthesis, external fixation or conservative treatment with at a splinting cast [7].

Subsequent routine removal of the tibial nail or locking screws is not recommended [1,4,6,8]. Asymptomatic patients may experience pain after nail removal, and in symptomatic patients, only partial or no effect on pain has been shown after the procedure [4,6,9]. In addition, routine implant removal is a resource-intensive procedure [8].

No consensus exists on when or if the tibial nail should be removed [1-6]. Implant removal may be decided based upon the experience of the individual surgeon, the tradition at each orthopedic department [3] or an individual assessment of each patient's pain and discomfort levels. Therefore we performed a cohort study on patients treated at our clinic.

The aim of the present study was to evaluate the change in pain, physical activity and employment status after implant removal in patients with a tibia fracture primarily treated with an intramedullary tibial nail. Furthermore, possible predictors for implant removal were identified.

Methods

The study was a retrospective cohort study with written follow-up. We collected data on all patients with a tibia fracture treated with insertion of a tibial nail at the orthopedic department in Slagelse, Denmark from 2009 - 2011. All tibial nails used in the study period were manufactured by Smith and Nephew, London, United Kingdom. All insertions of tibial nails were performed by a specialist in orthopedic surgery or by a resident under the direct supervision of a specialist. Medical journals for each patient were reviewed from time of fracture until March 2013. Furthermore, a questionnaire was mailed to all patients to evaluate outcome after removal of the tibial nail on pain, physical activity and employment status. Patients who did not reply by mail were contacted by phone and were asked to answer the questionnaires by phone. All patients who responded to the questionnaire were included.

Assessment

The questionnaire administrated included questions on each patient's pain, physical activity and employment status from before the fracture, before implant removal and at the time of...
follow-up. Patient that did not undergo implant removal were only asked on status before fracture and at the time of follow-up. To measure pain, we used a Numeric Rating Scale (NRS), on which the patients were asked to rank their pain from 0 (no pain at all), to 10 (worst imaginable pain) [10]. Patients were asked about pain at rest, under stress, pain at fracture location, knee pain and pain at screw position. Physical activity was measured in hours of physical exercise per week. Employment status was divided into sedentary, lightly active or hard labor. In addition, patients with implant removal were asked about their subjective opinion regarding their own satisfaction with implant removal and activity level.

From the medical journal, we obtained data on age, gender, side of fracture, closed or open fracture, coexisting fibula fracture, level of fracture on the tibia, comminuted fractures, surgeon level and point of access with regard to the patellar ligament. We also examined if any indication for implant removal was stated in the medical journal.

**Statistical analysis**

The results are presented as the means ± Standard Errors of Means (SEM) and background parameters are presented as the means ± standard deviations (s.d.) unless otherwise stated. Paired t-tests were used to compare longitudinal data, and two-sample t-tests were used to compare cross-sectional data. Fisher’s exact test was used to compare categorical variables. *P*-values less than 0.05 were considered significant. Analyses were performed using SPSS software, version 21 (IBM Corporation, Armonk, NY, USA).

**Results**

Fifty-two patients underwent primary insertion of a tibial nail between January 2009 and December 2011. Forty patients (77%) answered the questionnaire and were included in the study. Four patients had died, three patients did not reply and five patients had missing contact data. Twenty-one (53%) of the 40 patients included underwent implant removal (Flowchart 1). There were 11 women (28%) and mean age was 51 years at the time of fracture (Table 1). Median follow-up time was 4.2 (range 2-6) years for the questionnaires.

Twenty-one patients underwent implant removal. Ten patients underwent total implant removal (tibial nail and locking screws) however in three patients locking screws were removed first and then subsequently the tibial nail was removed. In the remaining 11 patients only locking screws were removed. Mean time from primary insertion of the tibial nail to decision for implant removal was 18 months (95% CI = 14.28 - 21.72). In patients for whom only locking screw removal was indicated the time was 13 months (95% CI = 9.86 - 16.14). Two patients who underwent total implant removal proved to have infections. In three patients the locking screws were removed due to delayed healing after 3.5 months.

Patients who underwent implant removal reported decreased pain at rest (3.5 ± 0.6 vs. 1.2 ± 0.4; *p* < 0.001), as well as decreased stress pain (6.6 ± 0.5 to 3.7 ± 0.6; *p* < 0.001) after implant removal (Figure 1). At the time of follow-up all patients had equal pain scores except for higher knee pain in patients who underwent implant removal (Table 2).

In patients who underwent implant removal we found no significant change in physical activity levels before and after implant removal, but there was a trend towards regaining physical activity level from before fracture (Figure 2). Fifteen of 21 patients who underwent implant removal reported being more physically active after the procedure. No change was seen in the patient’s employment status. Of the patients who underwent implant removal 95% (no 19) reported a lowering in the experience of pain and 98.5% (no 20) would recommend the procedure to other patients. All patients claimed it was worth undergoing implant removal compared to the effort included (taking time off, being admitted at the hospital and the risk of anesthesia).

We found no variables (gender, side of fracture, closed or open fracture, coexisting fibula fracture, level of fracture on the tibia, comminuted fractures, surgeon level and point of access with regard to the patellar ligament) to be associated with removal of the implant for either tibial nail or locking screw only removal. Young age tended to be associated with tibial nail removal (Table 1).

Indications for implant removal were anterior knee pain, pain at rest, pain under stress, ankle pain or at the patient’s request. Removal of the locking screws only was chosen when the pain was limited to the area overlying the screws.

**Discussion**

**Key results**

Implant removal after primary treatment of a tibial fracture with an intramedullary nail reduced pain. There was no significant increase in physical activity although a trend was seen towards regaining pre-fracture activity level. Young age was slightly associated with implant removal but not statistical significant.

**Flowchart 1:**

![Flowchart 1](image-url)
Limitations and strengths

There were several limitations to the study. Only a small number of patients were included and there was a risk of recall bias. Patients were asked to recall their pain and physical activity levels from before their fracture and implant removal, which were as much as 6 years prior. Other limitations are the placebo effect of surgery, no control group and no existing premanufactured and validated questionnaires. Two patients proved to have infections and in three cases the locking screws were removed due to delayed healing which might have affected the results. However, we endeavored to determine how implant removal affected pain and physical activity, and included all patients who underwent implant removal. Moreover, we had no data on patient BMI or comorbidity at time of fracture or implant removal which could also influence outcome after tibial nailing and subsequent implant removal. In spite of these limitations the strength of our study was that it evaluated not only anterior knee pain but pain in the affected leg in a broader perspective (pain at rest or under stress, pain at fracture location, knee pain and pain at screw position) and we included patient physical activity levels and patient satisfaction.

Interpretation

Impact on Pain and Physical Activity: This study showed a significant decrease in pain both at rest (3.5 ± 0.6 to 1.2 ± 0.4; \( p < 0.001 \); Figure 1) and with stress (6.6 ± 0.5 to 3.7 ± 0.6; \( p < 0.001 \); Figure 1) in patients that underwent implant removal. It is however possible that a decrease in pain might have occurred even without implant removal, as a natural course of pain after a tibial fracture.

Pain localized at the position of the locking screws was significantly more common in the patients who had both tibial nail and locking screws removed at the time of follow-up than other patients (Table 2). The reason for this is unknown.

In our study, patients who underwent implant removal (screws only as well both screws and nail) reported significantly more knee pain for unknown reasons, than patients who had not undergone implant removal at the time of follow-up. Knee pain is multifactorial [1,2] and can be caused by the point of incision, the protrusion of the nail or repeated trauma to the gliding tissue (Hoffa’s corpus). Keating et al. [2] recommended nail removal on the basis of knee pain, although only 55% of their patients experienced either a great or a partial effect on knee pain after the procedure. Court-Brown, et al. [1] found that younger patients developed knee pain more often than older
patients. The authors stated that the younger patients’ increased activity levels, compared with older patients, explained why the younger patients more frequently developed anterior knee pain. After nail removal, only 17% of this study’s patients experienced a substantial effect, 69% reported some effects and 3.2%, had worse pain following removal. The authors stated that it was the nail itself that created the anterior knee pain and not damage to the corpus Hoffa’s corpus. There is contradictory studies on the association between point of incision and anterior knee pain [1,2], which emphasizes that anterior knee is multifactorial.

Patients who underwent implant removal exercised less before implant removal than before the fracture. This finding could either be because the patients still experienced pain from the fracture or because of mechanical discomfort or pain from the implant. At the time of follow-up, exercise levels resembled the levels prior to fractures. Sixteen of our 21 patients reported they were more active at the time of follow-up than they had been prior to implant removal, however no statistical improvement was determined and 19 of the 21 reported that the removal had helped. Patients who did not undergo implant removal had unchanged exercise levels.

**Predictors of Implant Removal:** The only variable that influenced the rate of implant removal was age, which was borderline significant (46 ± 18 vs. 56 ± 15 years; \( p = 0.074 \); Table 1). Other studies also report of younger age being a reason itself for removing implants [3,9]. No studies exist on why younger patients benefit more from implant removal than older patients. It may be because increasing age results in lower physical activity and thereby less physical demand of the injured leg.

We found no association between an incision through the patellar tendon or medial to the tendon with the rate of tibial nail removal (Table 1). We also found no association between the point of incision and knee pain, but 33 (82,5%) of our patients had a medial incision and the study was not powered to determine if any true association existed.

**Implant Removal or Not?**

Implant removal is not recommended on a routine basis but only when indicated [1,2,4,6,9,11]. This was investigated in a study by Karladani, et al. [4]. The indications for tibial nail removal were mostly pain and mechanical discomfort, but in 26 patients (37%) there were no clinical indication for implant removal which might have influenced the outcome of implant removal. The study by Karladani, et al. [4] strongly indicated that routine nail removal should not be recommended and tibial nail removal should not be performed to alleviate pain. In contrast,
our study showed that in younger patients with pain at rest and under stress tibial nail removal is a beneficial procedure.

In our study, no standard indications existed to decide implant removal, and it was left to each surgeon to decide if the patient should undergo implant removal, total or locking screws only. In general, locking screw only removal was chosen when patients had isolated complaints of pain localized in the area overlying the locking screws. Complete tibial nail removal was chosen when patients had complaints other than local pain at the screw position such as anterior knee pain, pain at rest or under stress, ankle pain and at patient request. Previous studies have identified pain in the leg or ankle, knee pain, prominent screws, young age, active patient and infection as indications for implant removal [3,4,6]. There is no known pain threshold or location of pain that may predict a beneficial outcome after implant removal. In our study, younger patients who underwent implant removal had a mean pain score of 3.5 for pain at rest and 6.6 for stress pain before removal. In a larger-scale prospective study, potential predictors or pain threshold could be identified to determine which patients would benefit from implant removal.

Conclusion

In our study, younger patients with persistent pain after primary treatment of a tibial fracture with an intramedullary tibial nail reported reduced pain and improved physical activity after removal of the tibial nail or locking screws only. This contrast existing knowledge but well-designed studies are still needed to determine the true outcome after implant removal.

Declarations

Ethical Approval and clinical trial registration

The study was approved by the Danish Data Protection Agency (Study ID: REG-19-2013), and written consent was obtained from all included patients. As the present study only consisted of a questionnaire and no intervention was performed it could be conducted without approval from the Ethics Committee according to Danish legislation on research (Committee Act § 1).

Conflict of interest

None of the authors have received any grant support of research funding or proprietary interest in the material described in the article.

References