Hardware removal after tibial fracture has healed

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Background: Tibial fractures are the most common long bone fracture. The standard of care for the treatment of diaphyseal tibial fractures is an intramedullary nail (IMN). Implant removal is one of the most common procedures in bone and joint surgery, and criteria for implant removal are typically left to the treating surgeon. Currently, no clear criteria exist to guide a surgeon's decision to remove implanted tibial IMNs after healing. **Methods:** We undertook a retrospective chart review of a single surgeon's practice from January 1996 to February 2005. We identified patients aged 16–70 years with a tibial fracture treated with an IMN. Patients were followed until fracture union and/or request for IMN removal. The following parameters were recorded: reason for implant removal, age, sex, mechanism of fracture, location of fracture, diameter of IMN, Workers' Compensation Board (WCB) status, activity level, litigation status, insurance involvement, height, weight and body mass index (BMI). **Results:** Factors influencing the likelihood of removal were sex and litigation. Factors not influencing the likelihood of removal were age, weight, height, BMI, diameter of IMN, patients' level of activity, insurance claim involvement and WCB involvement. Overall, 72.2% of patients had an improvement in their symptoms after IMN removal. **Conclusion:** Sex and litigation are positive predictive factors for patient requests to have tibial IMNs removed after healing.

Contexte : Les fractures du tibia sont les fractures des os longs les plus fréquentes. Le clou intramédullaire (CIM) constitue la norme de soin pour traiter la fracture de la diaphyse du tibia. L'enlèvement de l'implant est une des interventions les plus courantes en chirurgie des os et des articulations et les critères d'enlèvement de l'implant relèvent habituellement de la discrétion du chirurgien traitant. Il n'existe actuellement aucun critère clair pour guider la décision du chirurgien qui doit enlever, après la guérison, le CIM implanté dans le tibia. **Méthodes :** Nous avons effectué une étude rétrospective des dossiers de la pratique d'un seul chirurgien de janvier 1996 à février 2005. Nous avons repéré les patients âgés de 16 à 70 ans qui avaient subi une fracture du tibia traitée au moyen d'un CIM. Les patients ont été suivis jusqu'à la fusion de la fracture ou jusqu'à ce qu'ils demandent qu'on enlève le CIM. On a consigné les paramètres suivants : motif de l'enlèvement de l'implant, âge, sexe, mécanisme de la fracture, lieu de la fracture, diamètre du CIM, statut face à la commission des accidents du travail (CAT), niveau d'activité, statut de tout litige, intervention des assurances, taille, poids et indice de masse corporelle (IMC). **Résultats :** Le sexe et l'existence de litiges étaient les facteurs qui jouaient sur la probabilité d'enlèvement. Les facteurs sans effet sur cette probabilité étaient l'âge, le poids, la taille, l'IMC, le diamètre du CIM, les nouvelles activités des patients, l'existence de réclamations aux assurances et l'intervention de la CAT. Dans l'ensemble, 72,2 % des patients ont vu leurs symptômes s'améliorer après l'enlèvement du CIM. **Conclusion :** Le sexe et l'existence de litiges sont des facteurs prédicteurs positifs indiquant que le patient demandera qu'on enlève le CIM du tibia après la guérison.

Tibial fractures are the most common long bone fracture.[1] The method of fracture treatment depends on the characteristics of the fracture and on surgeon preference. Currently methods used include casting, plate fixation, external fixation and intramedullary nailing. For displaced diaphyseal tibial fractures, intramedullary nails (IMNs) have become the treatment of choice.[2] IMN treatment provides a high rate of union and a decreased incidence of malunion and joint stiffness, compared with other treatments. [2,3]

Implant removal represents one of the most common operations in bone and joint surgery.[4] Implant removal is a procedure with various known morbidities such as refracture, hematoma, lengthy operative

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times and implant breakage.[4,5]

Within the literature, previously listed criteria for implant removal include 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 owing to the potential for refracture or implant failure and the possibility that removal will improve functional outcome.[6–10]

Currently, there is little consensus among orthopedic surgeons regarding criteria for tibial IMN removal postunion.[9] Most orthopedic surgeons rely on patient symptoms, especially knee and/or leg pain, to determine whether or not the implant should be removed after healing.[11,12] Little evidence exists in the literature regarding the efficacy or characteristics of patients who request IMN removal. Some authors argue for an improvement in symptomatology after removal, whereas others have not found any significant improvement.[13,14] This study examined the rate of IMN removal in tibial diaphyseal fractures after healing, as well as the characteristics of patients requesting IMN removal.

Methods

We undertook a retrospective chart review of patients in the senior author's practice who sustained a traumatic tibial fracture treated with an IMN between January 1996 and February 2005. Ethics approval was obtained from the Calgary Health Region. Patients were those seen at a level I trauma centre who sustained a tibial fracture from a traumatic mechanism of injury. We excluded patients if the fracture was pathological. We also excluded patients under age 16 years or over age 70 years. Bilateral fractures were treated as separate fractures. Implantation was performed either by the senior author (R.E.B.) or under direct supervision of the senior author according to standard, previously described techniques. The IMN used was a titanium locked reamed tibial nail (either Synthes or DePuy ACE). The senior author followed each patient until fracture union. Fracture union was defined as patients being more than 9 months postinjury with evidence of healing of 4 cortices on 2 tangential radiographs. We subsequently excluded patients who needed to have their IMN removed because of nonunion or infection. We did not consider patients for implant removal until fracture union had occurred. Patients who requested that their IMN be removed had their symptoms documented. Symptomatology included anterior knee pain, tibial pain and pain over locking bolt sites and needed to be at a level that compromised work or leisure activities. Removal was considered to be the removal of any portion of the IMN — either locking bolt(s) alone or the entire IMN (nail and locking bolts). We analyzed the data for locking bolt removal and entire IMN removal separately.

We recorded the following parameters: reason for implant removal, patient age and sex, mechanism of fracture, location of fracture, union (v. nonunion), length and diameter of IMN, Workers' Compensation Board (WCB) status, activity level (as per WCB grading),[15] litigation status, insurance status, height, weight and body mass index (BMI). Patients who had their IMNs removed were contacted by phone and questioned regarding their current symptomatology and satisfaction with the implant removal. We asked 3 questions: Have your symptoms improved since IMN removal? How would you rate your pain (on a 0–10 scale)? and If you were in the same situation again, would you have the IMN removed? We analyzed statistics with Microsoft Excel after consultation with an independent statistician. Parametric data were analyzed with Student's *t* test, and nonparametric data were analyzed with the χ^2 test.

Results

Tibial fracture characteristics

We identified 130 patients with 134 tibial fractures who met both inclusion and exclusion criteria; 4 patients had bilateral tibial fractures. We analyzed each fracture as a separate fracture. The characteristics of both the patients and their fractures are outlined in Table 1. Our study demonstrates an overall union rate of 91.0% (122/134), which is consistent with previously quoted union rates for locked reamed nails.[2]

Overall IMN removal characteristics

Overall, 40 patients with 42 fractures (31.3% of all the fractures; 24 male and 18 female) had a second operative procedure for implant removal. Locking bolts were removed in 33.3% (14/42) of the fractures, and the entire IMN was removed in 66.6% (28/42). Among the locking bolts (14 fractures in 14 patients), 14.3% (2/14) were removed owing to dynamization of the IMN (delayed union or nonunion) and 85.7% (12/14) were removed because of implant pain due to the locking bolt. Among the removed IMNs (28 fractures in 26 patients), 60.7% (17/28) were removed owing to pain surrounding the implant, 28.6% (8/28) were removed to exchange a nail because of delayed or nonunion, 7.1% (2/28) were removed owing to infection, and 3.6% (1/28) removed because there was a periprosthetic fracture. There was no difference between implants used, but those with more than a few millimetres of prominence had a higher incidence of knee pain. We excluded patients who had their implant (or a portion thereof) removed for delayed union, nonunion, infection or fracture. This left 29 patients with 29 fractures who had their

IMN removed for symptomatology, giving an overall removal rate of 23.9% (29/121). In all patients, the indication listed for removal was a combination of either pain (anterior knee or leg pain) or prominence surrounding their implant (locking bolt prominence). The average time until removal was 25.19 months (range 5.29–77.62 mo). Removal data are presented in Table 2.

Patients were classified into 2 major groups according to their mechanism of injury. Patients involved in a motor vehicle or motorcycle collision, along with those who experienced pedestrian-versus-automobile incidents, were felt to have sustained high-energy fractures, whereas patients who sustained their tibial fracture as a result of a fall or from a sporting activity were felt to have sustained a low-energy fracture. We found no significant difference between these 2 groups ($p \leq 0.20$).

According to our data, age ($p = 0.37$), age groupings ($p \leq 1$), weight ($p = 0.07$), obesity ($p \leq 1$), height ($p = 0.15$), BMI ($p = 0.17$), fracture location ($p \leq 1$), WCB claim status ($p \leq 1$), insurance claim status ($p \leq 1$), level of activity ($p \leq 1$), diameter of IMN ($p \leq 1$), patient sex and removal of locking bolt only ($p \leq 1$) and mechanism of injury ($p \leq 0.20$) were not correlated to the rate of IMN removal postunion. Our data demonstrated that patient sex ($p \leq 0.05$) and litigation status ($p \leq 0.01$) were related to the rates of IMN removal postunion.

Follow-up telephone questionnaire data

We attempted to contact all 29 patients who had requested implant removal. In total, we were able to contact 20 patients (68.9%; 20/29). Nine patients were lost to follow-up, a known occurrence especially within the trauma population.[16] Of the 20 patients contacted, 45% (9/20) had their locking bolts removed and 55% (11/20) had their entire IMN

Table 1

Overall characteristics for all identified patients (130 patients; 134 fractures)

Characteristic	No. (and %)*
Sex	
Male	91 (67.9)
Female	43 (32.1)
Age at time of implantation, mean (and range) y	
Mean overall	37.0 (16.9–70.8)
Male patients	35.9 (16.9–69.5)
Female patients	39.2 (18.1–70.8)
Measurements, mean (and range)	
Weight, kg	76.1 (50–115)
Height, m	1.70 (1.46–1.91)
Body mass index	25.1 (16.98–40.75)
IMN characteristics, median (and range) mm	
Length	345 (270–400)
Diameter	10 (8–13)
Level of activity	
Sedentary/light	71 (53.0)
Medium	34 (25.4)
Heavy	29 (21.6)
Mechanism of injury	
Sports-related	34 (25.4)
Fall	32 (23.9)
Motor vehicle collision	31 (23.1)
Motorcycle collision	18 (13.4)
Pedestrian hit by car	12 (9.0)
Work-related injury	5 (3.7)
Assault	2 (1.5)
Claims identified	
Insurance	42 (31.3)
Litigation	36 (26.9)
Workers' Compensation Board status	9 (6.7)
Type of fracture	
Closed	86 (64.2)
Open	48 (35.8)
Grade I	13 (27.1)
Grade II	24 (50.0)
Grade IIIA	7 (14.6)
Grade IIIB	3 (6.2)
Grade IIIC	1 (2.1)
Location of fracture	
Proximal 1/3	7 (5.2)
Middle 1/3	66 (49.2)
Distal 1/3	61 (45.6)
Nonunions	
Total	12 (8.9)
Nonunion treatment	
Bone grafting of defects	2
Nail dynamization	2
Exchange nail	8

IMN = intramedullary nail.
*Unless otherwise indicated.

Table 2

Characteristics of patients with IMN removed because of symptomatology*

Characteristic	IMN status; no. (and %)†		
	Removed 29 fractures (29 pts)	Not removed 92 fractures (90 pts)	*p* value
Overall rate,% (ratio)	23.97 (29/121)		
Time, mean (range) mo	25.19 (5.29–77.62)		
Age, mean (range) y	33.8 (17.1–68.6)	37.2 (17.0–70.8)	$p = 0.37$
Sex			
Male	15 (51.7)	67 (72.8)	$p \leq 0.05$
Female	14 (48.3)	25 (27.2)	$\chi^2 = 4.50$
Weight, mean (range) kg	72 (52–91)	77 (50–115)	$p = 0.07$
Height, mean (range) m	1.71 (1.55–1.88)	1.74 (1.46–1.91)	$p = 0.15$
BMI, mean (range) kg/m^2	24.35 (19.31–32.47)	24.4 (16.98–40.75)	$p = 0.17$
Age groupings, y			
15–30	15 (11.26)	32 (35.74)	$p \leq 1$
31–49	11 (12.70)	42 (40.30)	$\chi^2 = 3.01$
50–70	3 (5.03)	18 (15.97)	
Locking bolt only and sex			
Male	7 (8.53)	67 (65.46)	$p \leq 1$
Female	5 (3.46)	25 (26.54)	$\chi^2 = 1.09$
Entire IMN and sex			
Male	8 (11.70)	67 (63.30)	$p \leq 0.05$
Female	9 (5.30)	25 (28.70)	$\chi^2 = 4.44$
Fracture location			
Proximal 1/3	2 (1.44)	4 (4.56)	$p \leq 1$
Middle 1/3	12 (14.14)	47 (44.86)	$\chi^2 = 0.96$
Distal 1/3	15 (13.42)	41 (42.58)	
WCB			
Claim involved	3 (2.16)	6 (6.84)	$p \leq 1$
Claim not involved	26 (26.84)	86 (85.16)	$\chi^2 = 0.47$
Insurance			
Claim involved	8 (8.39)	27 (26.61)	$p \leq 1$
Claim not involved	21 (20.61)	65 (65.39)	$\chi^2 = 0.03$
Litigation			
Litigation involved	13 (7.19)	17 (22.81)	$p \leq 0.01$
Litigation not involved	16 (21.81)	75 (69.19)	$\chi^2 = 8.21$
Level of activity/employment			
Sedentary/light	17 (15.10)	46 (47.90)	$p \leq 1$
Moderate	6 (7.19)	24 (22.81)	$\chi^2 = 0.67$
Heavy	6 (6.71)	22 (21.29)	
Diameter of IMN, mm			
Average	9.97	10.283	$p = 0.23$
8–9	10 (7.43)	21 (23.57)	$p \leq 1$
10	8 (8.14)	26 (25.85)	$\chi^2 = 1.75$
11–13	11 (13.42)	45 (40.30)	
Obese v. nonobese			
Obese (BMI > 25)	12 (12.46)	40 (39.54)	$p \leq 1$
Nonobese (BMI < 25)	17 (16.54)	52 (52.46)	$\chi^2 = 0.03$
Mechanism of injury			
High energy	9 (12.22)	42 (38.78)	$p \leq 0.20$
Low energy	20 (16.76)	50 (53.22)	$\chi^2 = 1.93$

BMI = body mass index; pts = patients; IMN = intramedullary nail; WCB = Workers' Compensation Board.
*121 fractures; 119 patients.
†Unless otherwise indicated.

removed. Of the 9 patients with locking bolts removed, 2 did not recall having any portion of their implant removed and were excluded from the analysis. This left 18 patients for our follow-up questionnaire data. These patients described pain surrounding their implants (at the knee or up and down the leg) as the principal reason for having their IMN removed. Patient information obtained after hardware removal is presented in Table 3.

Overall, 77.8% (14/18) of patients were satisfied with their IMN removal and would undergo the procedure again if given the opportunity. The average pain score after removal was 4 out of 10. We had no preremoval pain score with which to compare these values. Overall, 72.2% (13/18) of the patients felt that their symptoms had improved since the removal. Patients who had their entire IMN removed had increased symptom resolution as compared with patients who had only a portion of their IMN removed (88.0% v. 71.4%)

Discussion

The literature is unclear regarding the criteria for and incidence of tibial IMN removal.[9] Most of the literature focuses on techniques or unique complications associated with implant removal. Previously "established" criteria such as infection, metal toxicity, metal hypersensitivity, corrosion and neoplasia have rarely been shown to be important.[11,17] Localized osteopenia from stress shielding has been demonstrated to be more relevant for plate osteosynthesis and has not been found to be significant after fixation with an IMN.[18,19] A known complaint regarding tibial IMNs is that of anterior knee pain. The literature records mixed results regarding the resolution of symptoms after IMN removal. Whereas Court-Brown and colleagues[13] demonstrated a "complete or marked improvement" in

anterior knee pain symptoms in 97% of patients, Boerger and colleagues[14] found a more modest 56% improvement in symptomatic patients after removal, along with a 12% incidence of new anterior knee pain in previously asymptomatic patients. The concept that implant removal may improve long-term functional outcome can be questioned because it has been demonstrated that high-level athletes with retained IMNs return to active contact sports with minimal symptomatology.[20]

There is no consensus regarding the criteria and indications for removal of tibial IMNs after healing. The only consensus within the literature is that removal of implants is an operative procedure with a set of risks and complications that need to be considered on a case-by-case basis. Our study examined the incidence of tibial IMN removal after healing along with the characteristics of those patients requesting IMN removal. To our knowledge, this is the only paper within the orthopedic trauma literature that examines the characteristics of patients requesting tibial IMN removal after healing.

There was no significant difference found when age was considered as a parameter ($p \leq 1$). This was an unexpected result because we had thought that younger patients (who we considered to be more active) would ask to have their IMN removed more frequently than older and less active patients. Despite the lack of statistical significance, a trend did exist for younger patients to have their IMN removed more frequently than older patients. Among patients aged 15–30 years, 31.9% (15/47) had their IMN removed, compared with 20.8% (11/53) of patients aged 31–49 years and 14.3% (3/21) of patients aged 50–70 years.

Sex was found to be related to the likelihood of having the entire IMN removed ($p \leq 0.05$). We had not anticipated this difference. We believe that this may be related to other confounding variables such as litigation. Our data indicated that 33% (5/15) of male patients requesting IMN removal were litigants, compared with 57% (8/14) of female patients. This possibly contributed to the statistically significant difference between male and female patients because we found that, at 43.3% (13/30), litigants had a very high rate of IMN removal in comparison with nonlitigants' rate of 17.6% (16/91). When we examined sex and rates of locking bolt removal, we did not find any significant difference ($p \leq 1$), which was an expected result.

With regard to litigation, our results are similar to those of Hui and colleagues,[21] who also found a correlation between litigation and the overall rate of femoral IMN removal. When we consider why litigants request that their IMN be removed more frequently than nonlitigants, there are several possibilities to explore. Evidence from patient-based studies suggests that involvement in litigation is associated with poorer outcomes.[22] In their meta-analysis of 7651 subjects, Rohling and colleagues[23] demonstrated that receiving financial compensation from an injury was associated with poorer outcomes and reduced treatment efficacy; this may indicate ongoing pain surrounding a tibial IMN, which would lead to a higher incidence of IMN removal. Finally, it is possible that litigants obtain increased compensation as a result of prolonged symptoms and additional operative procedures.

We had felt that there might be a trend toward patients with lower BMI having more frequent IMN removal because, with less soft-tissue coverage over prominent implants, they might experience increased symptomatology. The data did demonstrate a nearly significant difference ($p = 0.07$) in regard to weight (72 kg for the removal group v. 77 kg for the nonremoval group) but no significant difference in BMIs. We are not sure whether this is owing to a true lack of correlation between soft-tissue coverage and implant removal or whether our measure of BMI inaccurately measured soft-tissue coverage in the lower leg. Perhaps future studies with more patients may demonstrate a correlation in this regard. A more accurate method for measuring ankle and leg soft-tissue coverage, such as skin-fold measurements, needs to be studied.

When patients were divided into 2 groups according to the energy imparted at the time of fracture, we did not find any significant between-group difference ($p \leq 0.20$). This was an expected result. We did not feel that the energy imparted at the time of fracture would have any correlation with the rates of IMN removal.

Overall, the literature lacks data with which to compare our results. With regard to symptomatology relief after implant removal, our data demonstrated that 77.8% (14/18) of the patients were satisfied with their IMN removal and would undergo the procedure again; this is similar to the results obtained by Keating and

Table 3

Information obtained from patients after hardware removed

Hardware removed	Postremoval pain score 0–10	% positive response	
		Symptoms improved	Would have IMN removed again
Locking bolt	4.1	71.4 (5/7)	85.7 (6/7)
Entire IMN	3.9	88.0 (8/11)	88.0 (8/11)
Overall	4.0	72.2 (13/18)	77.8 (14/18)

IMN = intramedullary nail.

colleagues,[16] who found that 80% of patients had partial or complete relief of anterior knee pain after IMN removal.

This study has several strengths. First, to our knowledge, it is the first study in the literature to specifically examine the relation between patient factors and the rate of tibial IMN removal. Second, the population we examined was quite uniform: we included only patients between the ages of 16 and 70 years admitted to a tertiary trauma centre with a traumatic mechanism of injury. Third, because a single surgeon oversaw patients from the time of implantation until union, the criteria for removal were rigid and uniform. We considered only patients who insisted, because of pain, that their implant or a portion thereof be removed as a result of ongoing symptomatology after healing. Symptomatology was considered significant when it was felt that their pain level significantly impaired their ability to work or pursue leisure activities.

The weaknesses of this study include its retrospective nature, a patient sample recruited from a single surgeon's practice and that some patients were lost to follow-up (a known occurrence within the trauma population[24]). Additionally, there were some patients in the study who will in the future likely experience ongoing pain related to their IMN and will request IMN removal. These patients were analyzed in the group that did not have their IMN removed.

Conclusion

Our study demonstrated an overall tibial IMN removal rate of 23.9%. The average time from implantation until removal was 25.19 months. The factors influencing the rate of IMN removal were sex and litigation status. Factors not related to the incidence of removal included age, level of activity, location of fracture, BMI, WCB status, insurance and mechanism of injury. Overall, 72.2% of patients experienced an improvement in their symptoms after IMN removal. Further prospective evaluation and trauma registry information will assist surgeons to predict whether a trauma patient will require tibial IMN removal.

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Contributors: Both authors contributed equally to the design of this study, the acquisition and analysis of data and writing and reviewing the article, and both authors provided final approval for publication.

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