Incidence of intramedullary nail removal after femoral shaft fracture healing

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Introduction: There are limited data on hardware removal after femoral fracture healing. We determined the incidence of intramedullary nail (IMN) removal after midshaft femoral fractures. We also studied demographic factors influencing IMN removal. **Methods:** The senior author reviewed all adult femoral fractures with IMN placement in the trauma practice between July 1990 and November 2003. There were a total of 74 IMNs in 68 subjects with midshaft fractures. The incidence of hardware removal was the primary outcome measure. We also analyzed age, sex, body mass index (BMI), mechanism of injury, IMN dimensions, occupation, and Workers' Compensation Board (WCB) insurance and litigation involvement. **Results:** Overall incidence of IMN removal was 20% (15 of 74 fractures). No significant difference was found with age *($p = 0.965$)*, sex *($p = 0.086$)*, BMI *($p = 0.423$)*, occupation *($p = 0.341$)*, insurance involvement *($p = 0.229$)*, WCB involvement *($p = 0.663$)* or IMN dimensions *(*width, *$p = 0.752$;* length, *$p = 0.312$)*. Litigants had the highest incidence of IMN removal *($p = 0.004$)*. **Discussion:** All hardware was removed for pain or irritation. These results suggest that litigants require hardware removal more often than nonlitigants. A larger study is needed to identify specific criteria for hardware removal and to determine whether secondary gains affect the incidence of femoral removal.

Introduction : Les données sur l'enlèvement du matériel de fixation après la guérison d'une fracture du fémur sont limitées. Nous avons déterminé l'incidence de l'enlèvement du clou centromédullaire (CCM) après une fracture au milieu du corps du fémur. Nous avons étudié aussi des facteurs démographiques jouant sur l'enlèvement du CCM. **Méthodes :** L'auteur principal a examiné toutes les fractures du fémur subies par des adultes chez lesquels on a mis en place un CCM en traumatologie, entre juillet 1990 et novembre 2003. On a implanté au total 74 CCM à 68 sujets qui ont subi une fracture au milieu du corps du fémur. La principale mesure de résultat a été l'incidence de l'enlèvement du matériel de fixation. Nous avons aussi analysé les facteurs suivants : âge, sexe, indice de masse corporelle (IMC), mécanisme du traumatisme, dimensions du CCM, profession, interventions de la Commission des accidents du travail (CAT) ou d'assurances, et litiges. **Résultats :** L'incidence globale d'enlèvement du CCM s'est établie à 20 % (15 fractures sur 74). On n'a constaté aucune différence significative sur les plans de l'âge ($p = 0{,}965$), du sexe ($p = 0{,}086$), de l'IMC ($p = 0{,}423$), de la profession ($p = 0{,}341$), de l'intervention d'une assurance ($p = 0{,}229$), de l'intervention de la CAT ($p = 0{,}663$) ou des dimensions du CCM (largeur, $p = 0{,}752$; longueur, $p = 0{,}312$). Les parties à un litige présentaient l'incidence la plus élevée d'enlèvement du CCM ($p = 0{,}004$). **Discussion :** Dans tous les cas, on a enlevé le matériel de fixation à cause de la douleur ou de l'irritation. Ces résultats indiquent que les parties à un litige exigent l'enlèvement du matériel de fixation plus souvent que les autres patients. Une étude de plus grande envergure s'impose pour déterminer des critères particuliers d'enlèvement du matériel et si les gains secondaires ont un effet sur l'incidence de l'enlèvement de clous fémoraux.

Intramedullary nailing is the standard of practice for treatment of femoral shaft fractures.[1–6] Advantages of intramedullary nailing are well known and include early mobilization and rehabilitation of the injured extremity.[5–7] For patients with multiple injuries, intramedullary nailing provides rapid stabilization and reduces early mortality.[6] However, there is little direction in the literature regarding the necessity or incidence of intramedullary nail (IMN) removal after the healing of femoral fractures. Reasons for nail removal

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have traditionally been prominent or symptomatic hardware, skeletally immature patients, broken hardware, revision fracture surgery for nonunion, malunion, infection and peri-implant failure.[8–11] Reported rates of refracture after hardware removal are low.[9,12] There have also been reports of less-than-successful cases of asymptomatic hardware removal owing to intraoperative and postoperative complications.[9,13–15] The current study aims to illustrate, through one trauma surgeon's practice, the incidence of IMN removal in healed midshaft femoral fractures. It is a descriptive study that also looks at certain demographic factors that may influence the incidence of IMN removal. The intention of this study is to aid in the future development of clinical criteria for femoral nail removal.

Methods

We performed a chart review from the practice of the senior author on all adult patients who underwent IMN implantation for acute midshaft femoral fractures between July 1990 and November 2003. The senior author is a trauma surgeon at a level-1 trauma centre and teaching hospital in Canada, with a varied patient population. Each IMN had been implanted for the purpose of fracture fixation. We included patients between the ages of 15 and 65 years with traumatic femoral shaft fractures treated with an IMN. We did not include patients with plated femurs or with pathological fractures in this study. We also excluded femoral fractures treated without hardware implantation. Subtrochanteric and distal femoral fractures were excluded, leaving only midshaft fractures to be studied.

Three patients died and were removed from the analysis because they were not subjected to the risk of removal. Six patients with bilateral femur fractures were eligible for the study. For the purpose of this study, each femoral fracture was treated as a separate IMN implantation and removal. Therefore, we included 68 patients, for a total of 74 fractures, in the analysis.

The senior author performed both the implantation and removal, using standard techniques. An approximate 2-inch long incision was made on the lateral aspect of the thigh. All nails were implanted in an anterograde fashion; retrograde nails were excluded. The IMN used for femoral shaft fractures during this time was the Synthes titanium locked femoral nail. All nails were inserted using the piriformis entry site with intraoperative x-ray confirmation of the site of location in the piriformis fossa. The nails were inserted with both reamed and unreamed techniques, depending on the clinical situation.

In the analysis, we did not include hardware removal of proximal and/or distal locking screws and considered only those patients with the entire IMN removed. Nail removal for nonunion was not included, and no nails were removed without patient symptomatology. Patient symptomatology was defined as pain or irritation directly related to the hardware and affecting activities of daily living.

The IMN was only removed when the surgeon judged that the fracture had united radiographically and clinically (minimum 6 months). Removal of the IMN was done as a day procedure. Patients were instructed to weightbear fully and return to their usual activities. Patient follow-up took place 2 weeks after the removal of the IMN for wound check and for patient education.

We administered a telephone questionnaire (Appendix A) to the 15 patients who had hardware removed to determine the effectiveness of hardware removal.

The primary outcome measure was the overall incidence of IMN removal after midshaft femoral fractures. We collected demographic data on patient age, sex, nail dimensions, mechanism of injury, fracture type, complications, occupation and body mass index (BMI). We also gathered any data regarding insurance claims, Workers' Compensation Board (WCB) claims and litigation.

Occupation was defined as sedentary, light, medium and heavy according to the classification of the WCB.[16] For BMI analysis, patients with a BMI of ≥ 25 were considered overweight, according to the World Health Organization expert committee definition.[17]

An independent PhD statistician analyzed the results, and univariate statistical analysis (student's *t*-test, chi-square analysis) was calculated with a commercially available statistical software package (Intercooled STATA V8.0; STATA, College Station, Tex.). Data were also analyzed with Kaplan–Meier (K-M) survival curves regarding age, sex, occupation, litigation, BMI and nail width.

Results

Patient profile

Between July 1990 and November 2003, 68 patients had a total of 74 locked IMNs inserted in anterograde fashion for acute midshaft femoral fractures in this trauma practice. The case notes were available for review of all 74 fractures, with 5 patients (7%) lost to follow-up for the telephone questionnaire.

Of these patients, 48 were male and 20 female with an average age of 29 years (Table 1). The mean follow-up time was 665 days (range 169–3185 d). Of these, 32 injuries resulted from polytrauma, with 11 (15%) open fractures. Motor vehicle collisions accounted for 48 (71%), and 13 (19%) resulted from a fall. Other mechanisms, such as sports, accounted for the remaining patients.

The overall complication rate was 19% (13 of 68 patients). Two patients required exchange nailing for delayed union. For the purpose of this study, delayed union was defined

as the failure to unite at 6 months from the initial intramedullary nailing. Screw breakage was identified in 4 patients, and 2 patients had nonfatal fat embolism syndrome. One patient had osteopetrosis and developed osteomyelitis, requiring several exchange nailings. There were 2 patients with neurapraxia injuries who subsequently improved over the course of the follow-up. Minor heterotopic ossification was seen in 1 patient, and a postoperative seroma was seen in another. These were successfully managed conservatively.

Hardware removal

The overall incidence of femoral nail removal after midshaft femoral fracture healing was 20% (15 of 74 fractures). Fourteen patients with 15 femoral shaft fractures underwent IMN removal (Table 1, Table 2). The most common reason for removal was persistent femoral pain or irritation. Screw breakage was identified in 3 patients who had IMN removal, compared with only 1 patient in the group without nail removal. This was found to be statistically significant ($p = 0.002$). Two patients had the distal locking screws removed secondary to hardware pain but kept the rod in place. These patients were not included in the IMN removal group. The need for revision surgery did not influence the removal rate. Revision surgery was required in 13% of fractures in each group. The mean number of follow-up days was 1141 (range 478–3185 d) in patients with hardware removed, compared with 536 (range 169–2638 d) in those without removal. This is not surprising, because the hardware removal group would have had more visits secondary to hardware symptoms as well as visits related to planning, surgery and postoperative follow-up.

Litigation was involved in 26% (18/68) of patients. Of those patients with IMN removal, 57% were litigants, compared with 19% in the nonremoval group. This was statistically significant *($p = 0.005$)*. Analysis using K-M survival curves is also consistent, showing litigants having their nails removed more frequently. However, it did not show nails becoming more symptomatic with time.

There were no statistically significant differences between the IMN removal and nonremoval groups in terms of age, sex, BMI, occupation, insurance involvement, WCB involvement or nail dimensions (Table 1,2).

Of the 14 patients who underwent hardware removal, we were able to contact 9 (64%). All 9 completed our questionnaire regarding pain relief and the effectiveness of

Table 1

Patient demographics

	Patient group; average (range) (median)*		
Demographic characteristics	IMN removed ($n = 14$)	IMN not removed ($n = 54$)	p value ($p < 0.05$)
Age (years)	29 (15–63) (23)	29(15–65) (27)	0.965
Sex, no. (%)			0.086
Male	7 (50.0)	41 (75.9)	
Female	7 (50.0)	13 (24.1)	
Weight (kg)	72 (50–110) (70)	78 (49–107) (82)	0.418
Height (m)	1.72 (1.63–1.83) (1.73)	1.77 (1.60–1.93) (1.78)	0.095
BMI (kg/m^2)	23.0 (17.8–27.4) (22.0)	24.4 (13.9–31.9) (24.6)	0.423
Polytrauma, no. (%)	4 (28.6)	31 (57.4)	0.065
Mechanism of injury			0.631
Motor vehicle collision, no. (%)	9 (64.3)	39 (72.2)	
Fall, no. (%)	4 (28.6)	9 (16.7)	
Other, no. (%)	1 (7.0)	6 (10.5)	
Occupation			0.341
Sedentary, no. (%)	5 (35.7)	23 (42.6)	
Light, no. (%)	1 (7.1)	10 (18.5)	
Medium, no. (%)	5 (35.7)	9 (16.7)	
Heavy, no. (%)	3 (21.4)	12 (22.2)	
Insurance, no. (%)	4 (28.6)	8 (14.8)	0.229
WCB, no. (%)	1 (7.1)	6 (11.1)	0.663
Litigation, no. (%)	8 (57.1)	10 (18.5)	0.004

BMI = body mass index, IMN = intramedullary nail, WCB = Workers' Compensation Board, *unless otherwise indicated.

Table 2

Fracture characteristics

	Patient group; median (range)*		
Characteristics	IMN removed ($n = 15$)	IMN not removed ($n = 59$)	p value ($p < 0.05$)
Nail width (mm)	11 (9–12)	11 (8–14)	0.752
Nail length (mm)	40 (36–42)	40 (26–46)	0.312
Type			0.789
Open, no. (%)	2 (13.3)	9 (15.3)	
Closed, no. (%)	13 (86.7)	50 (84.7)	
Screw breakage, no. (%)	3 (20.0)	1 (1.7)	0.005
Complications, no. (%)	4 (26.7)	9 (15.3)	0.531

IMN = intramedullary nail.

hardware removal. Of these, 8 (89%) had hardware removed for hardware-related pain and 1 had the nail removed owing to mechanical symptoms (clicking) from broken hardware. All responders (9 of 9 patients) stated that they had an improvement in their pain and, although 5 of 9 responders still currently experience pain, this pain is unrelated to the hardware (i.e., mechanical low back pain and osteoarthritis). Eight of the 9 responders (89%) stated they would have the hardware removed again if they were in a similar situation. The remaining patient had symptoms related to broken hardware and would not have the removal operation again if the nail did not break or cause any hardware-related pain.

Discussion

The indications and timing of IMN removal in femoral fractures remains controversial. In our patient population, 21% (14 of 68 patients) undergoing IMN placement for femoral shaft fractures will require a second surgery for hardware removal. This incidence rate shows the importance of identifying what demographic factors influence hardware removal, as well as the reasons for IMN removal.

Routine removal of intramedullary rods in asymptomatic patients is not recommended.[5,14,15] Further, Bostman and colleagues[18] have done several studies in Scandinavia looking at the removal of all implants after fracture healing. It is not cost-effective.[18] We have studied the incidence of IMN removal after midshaft femoral fracture healing in one trauma surgeon's practice and have also looked at the effect of age, sex, nail dimensions, complications, occupation, BMI, insurance, WCB and litigation as factors that may influence IMN removal. The goal of the current study was to determine the incidence of IMN removal and the potential factors influencing hardware removal in this specific group of trauma patients.

There were no asymptomatic IMN removals in this study. Patients had to present with a complaint of pain or irritation to be considered for IMN removal. Toms and colleagues[5] studied hardware-related pain, using the well-validated Short Form 36 (SF 36) health questionnaire. The incidence of IMN removal at their institution was 37%, with the most common reason being persistent femoral pain.[5] They found that, after IMN removal, both the physical and mental components of the SF 36 improved, compared with patients in whom the nails were left in situ.[5]

Acording to the results of our telephone questionnaire, IMN removal for hardware-related pain was effective for pain relief (100% of responders), and most patients would want the second operation to remove the hardware if they were in a similar situation again.

Insurance, WCB and litigation

We found that insurance and WCB involvement did not change the incidence of hardware removal in our study patients *($p = 0.663$)*. However, when litigation was involved, the patients tended to have IMN removal more consistently *($p = 0.004$)*.

Pain is a very complex entity and in-depth discussion about levels of pain is beyond the scope of this paper. There is no specific literature regarding pain in litigants after femoral fractures or nailing. However, it is clear that different patients have different perceptions of pain. Suter found that litigation increases the individuals' perception of pain, depression and disability.[19] Swartzman and others suggested that litigants had a "compensation neurosis" and that perhaps litigants fear that pain will render them unable to work in the future; thus they look to the litigation system to ensure financial security.[20] Both studies showed that, once the case was settled, the pain seemed to improve.[19,20] It would be interesting to determine whether this finding is applicable to our specific study population of midshaft femoral fractures treated with intramedullary nailing.

Age and sex

We believed that younger patients with an increased level of activity would lead to more hardware irritation and potentially more hardware pain. This was not the case: patient age did not have any statistically significant impact on the incidence of hardware removal *($p = 0.965$)*. However, younger patients may receive IMN removal more often than older patients to eliminate the future risk of implants in situ.

There were no hypotheses with regard to sex before this study, and we found that sex was not statistically significant *($p = 0.086$)*. However, we did observe that, at a higher level of significance, sex would have made a difference. It is unclear whether this result can be attributed to the small sample size and even smaller sampling of female patients in our study. This area would benefit from further study.

Body Mass Index

We thought that thinner people, with a smaller body habitus, would potentially have more pain secondary to hardware prominence.[6] There was no difference in IMN removal between overweight and not overweight patients in our study *($p = 0.423$)*.

Occupation

We expected that people in occupations with a heavier physical requirement would desire hardware removal more often because of hardware irritation. This was not found. There was no significant change in the incidence of hardware removal based on occupation *($p = 0.341$)*.

Nail dimensions

Analysis of varying widths and lengths

of the IMN implants revealed no significant difference *(width, $p = 0.752$; length, $p = 0.312$)* on the incidence of hardware removal in the femur. We feel this is particularly important, because it means that the surgeon could predictably place any size of IMN to achieve optimal fit, without being concerned that larger IMN implants will result in an increased incidence of removal.

Screw breakage

Screw breakage was identified in 4 patients, 3 of whom were in the hardware removal group. This was statistically significant *($p = 0.002$)*. The most likely explanation for this result is that the screw breakage led to increased pain and, eventually, hardware removal.

Previous studies in this area have analyzed the economic value of hardware removal,[18] routine IMN removal,[14,15] other locations of hardware removal[10–12] and techniques for removing difficult or broken IMNs.[9] The biggest strength of this study is that it is based on the practice of only 1 trauma surgeon who performed all of the surgeries and observed all of the patients. There is only one level-1 trauma centre serving this area, and the population remains captured with very few patients lost to follow-up. We studied a specific patient population — adult midshaft femoral fractures treated with anterograde locked intramedullary nailing.

There is little in the current literature regarding the incidence and factors influencing hardware removal in femoral fractures. This study attempts to address the myths of hardware removal by exploring the various demographic factors potentially affecting IMN removal in femoral shaft fractures. It is not intended to provide conclusions as to which patients will require IMN removal after midshaft femoral fractures. Rather, it introduces demographic factors potentially affecting hardware removal in patients with femoral shaft fractures.

The main weakness of this study is its retrospective nature and relatively small sample size. Given the study design, there is always potential for selection bias. Another weakness, which is related to the retrospective nature of this study, is the administration of a telephone questionnaire to address the issue of pain relief after nail removal. Problems with this include changes in patients' contact information and recall bias in their responses to pain relief. We know from Murnaghan and Buckley's study that trauma populations are a separate epidemiological group that is at a higher risk for loss of follow-up.[21] We were able to contact most of our patients (64%; 9/14) who underwent hardware removal in this study. Unfortunately, unless a prospective study design is undertaken, these biases cannot be avoided.

We did not radiographically assess the amount of hardware prominence in this study, which would have allowed for an objective measure of whether hardware prominence is more than just a subjective experience. However, Dodenhoff and colleagues did examine radiographs for evidence of nail protrusion, heterotopic bone formation, and implant failure or fracture in their investigation of proximal thigh pain after femoral nailing.[6] In their study, prominence of the nail proximally was not associated with pain, but protuberance of laterally-based proximal locking screws caused problems, along with heterotopic bone formation.[6]

The current knowledge base on indications for hardware removal is still limited and would benefit from further exploration. The care of patients regarding hardware removal is still dependent on orthopaedic surgeons. The approach for removal will change based on experience and personal biases and, currently, the only indication seems to be hardware pain. Perhaps basic science and research into inflammatory mediators could help define the cause of hardware pain, and with this being more clearly defined, pharmacological therapy could play a role in the management of this pain.

The findings from this descriptive study tell us that few demographic factors influence hardware removal. A large prospective cohort study to determine prognostic features of patients that require hardware removal is needed. This would help to determine whether secondary gains affect the incidence of hardware removal in this specific trauma population. In addition, it would be useful to develop and validate a tool to study hardware pain.

Competing interests: None declared.

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Appendix A. Nail removal telephone questionnaire

1. Do you remember why you had the nail removed?

Yes ( ) or No ( )

If yes, why was it done?

2. Are your symptoms improved now that the nail is out?

Yes ( ) or No ( )

If yes, please describe the symptoms.

If you have pain, please rate it from 0–10 (0 = no pain, 10 = most pain).

3. Would you have the nail removed again if you had to do it all over again?

Yes ( ) or No ( )

Why/Why not?