Removal of Painful Orthopaedic Implants After Fracture Union

By Reuven B. Minkowitz, MD, Siraj Bhadsavle, MD, Michael Walsh, PhD, and Kenneth A. Egol, MD

Investigation performed at the Department of Orthopaedic Surgery, New York University-Hospital for Joint Diseases, New York, and the Department of Orthopaedic Surgery, Albany Medical Center, Albany, New York

Background: Persistent pain in the region of implanted hardware following fracture fixation commonly leads to implant removal. This prospective study evaluated patient outcomes and pain reduction following removal of orthopaedic hardware implanted for fracture fixation.

Methods: Sixty patients who had been treated previously for a fracture and complained of pain in the region of the fracture fixation hardware constituted the study cohort. Patients were carefully examined by the treating physician to rule out other causes of pain such as infection and nonunion. Baseline data were recorded preoperatively. Data obtained postoperatively at three, six, and twelve months included a visual analog pain scale score and results on the Short Musculoskeletal Function Assessment Questionnaire and the Medical Outcomes Study Short Form-36. At the one-year interval, a patient satisfaction questionnaire was completed and outcomes were analyzed.

Results: There were no complications associated with implant removal surgery. Three patients did not have complete follow-up, leaving a total of fifty-seven patients with complete follow-up. At one year, all patients indicated that they were satisfied, that they would have the procedure done again, and that their overall function had improved. The scores for pain on the visual analog scale decreased from a mean (and standard deviation) of 5.5 ± 2.5 before hardware removal to 1.3 ± 1.8 after hardware removal, with an overall improvement at one year of 76% ($p = 0.00001$). At one year, thirty (53%) of the fifty-seven patients had complete resolution of pain. In addition, the results on the Short Musculoskeletal Function Assessment Questionnaire showed a 43% improvement from baseline ($p = 0.0001$), and the results on the physical component of the Short Form-36 showed a similar improvement of 40% ($p = 0.0001$).

Conclusions: Following fracture-healing, removal of hardware is safe with minimal risk. Improvement in pain relief and function can be expected.

Level of Evidence: Therapeutic Level IV. See Instructions to Authors for a complete description of levels of evidence.

Persistent pain in the region of implanted orthopaedic hardware after radiographic evidence of fracture union commonly leads to implant removal[1-3]. In addition, concerns about systemic and local effects of retained implants have led many patients to request elective hardware removal[3,4]. It is important to understand what appropriate patient expectations for pain relief and functional improvement should be.

When hardware is removed for pain relief alone, the results may be unpredictable and dependent on the type of implant and its anatomic location. Published studies on hardware removal for pain have all been retrospective[2,5-10]. Given the costs of the procedure as well as time off for postoperative recovery, the decision to remove hardware has substantial economic implications[1,5]. While these procedures are frequently viewed as simple, they can be challenging. Furthermore, hardware removal can lead to further complications, such as neurovascular injury, refracture, a retained implant, or recurrence of deformity[3,11-13]. This study was designed to determine prospectively whether removal of symptomatic fracture-fixation

Disclosure: The authors did not receive any outside funding or grants in support of their research for or preparation of this work. Neither they nor a member of their immediate families received payments or other benefits or a commitment or agreement to provide such benefits from a commercial entity. Commerical entities (Stryker, Synthes, Biomet, and Richards) paid or directed in any one year, or agreed to pay or direct, benefits in excess of $10,000 to a research fund, foundation, division, center, clinical practice, or other charitable or nonprofit organization with which one or more of the authors, or a member of his or her immediate family, is affiliated or associated.

hardware provides pain relief and functional improvement of the affected extremity.

Materials and Methods

Over a two-year period, from 2004 to 2006, sixty consecutive patients between seventeen and eighty-one years of age (mean, 46.9 years) were identified at our institutions as having symptomatic hardware following operative fracture care. All fractures were united radiographically, and the patients were seen long enough after their injuries to have reached maximal recovery. The study protocol had institutional review board approval, and all patients signed an informed-consent form.

All patients were carefully examined by the treating physician to rule out other causes of pain such as infection, neurogenic origin, and fracture nonunion. Patients in whom hardware was removed for a known infection or had been placed with planned later removal were excluded from the study.

All patients had generalized complaints of pain in the region of the implants. These complaints were suspected by point tenderness over superficial metal implants on physical examination. Radiographic confirmation was used for deeper implants. Intramedullary nail-related symptoms were confirmed if patients complained of pain at the site of the entry portal or pain in the region of the locking bolts and other causes of pain had been excluded. All fractures had united both clinically and radiographically at the time of hardware removal.

The baseline data were recorded preoperatively and included patient age, sex, medical comorbidities, and level of pain as rated on a visual analog scale from 0 (no pain) to 10 (the most pain imaginable). Smoking status, body mass index, insurance status, Workers' Compensation status, and length of time that the hardware had been in place were also recorded. The Short Musculoskeletal Function Assessment Questionnaire (SMFA) and the Medical Outcomes Study Short Form-36 (SF-36), two standardized surveys assessing functional outcome, were completed at baseline as well as at three, six, and twelve months postoperatively[2].

All surgeries were performed on an outpatient basis with the patient under regional or general anesthesia in the operating room. In patients in whom infection was suspected on the basis of conditions found at the time of surgery, deep cultures were obtained.

At one year, a patient satisfaction questionnaire was administered to all patients. It consisted of three questions: (1) Are you happy that the hardware was removed? (2) Would you have the surgery performed again? (3) Do you think your overall function has improved since you underwent this procedure?

Statistical Methods

Standard statistical methods were used. Pain scores (assessed on a visual analog pain scale) were correlated with the functional outcome scores (SMFA and SF-36) for all patients. Statistical analysis of functional outcome and pain scores was performed with use of paired t tests to compare baseline scores on the pain visual analog scale, SMFA, and SF-36 with those at each follow-up point. A linear regression model was used to assess whether body mass index, smoking, comorbidities, insurance status, Workers' Compensation status, and age had an effect on overall outcome. The level of significance was set at $p < 0.05$.

Our power analysis showed that sixty patients would provide >90% power to detect a difference of 1.5 points on the SMFA between baseline and the one-year follow-up evaluation. This difference was based a priori on our belief that a difference of <2 points on the SMFA would indicate a return to baseline function, while a difference of >2 points would indicate incomplete recovery. We used 1.5 points as a more conservative estimate.

Results

Between September 2004 and December 2005, sixty consecutive patients who had reported pain in the region of retained fracture-fixation implants were identified and recruited. Approximately 30% of the patients had had the hardware im-

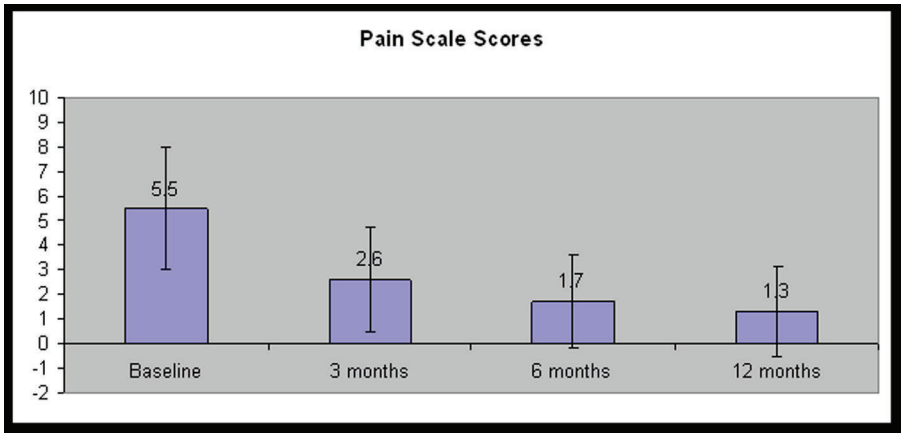

Fig. 1

The overall pain scores decreased from a mean (and standard deviation) of 5.5 ± 2.5 before hardware removal to 1.3 ± 1.8 after hardware removal ($p = 0.0001$).

TABLE I Demographic Data on the Sixty Patients and Hardware Type by Region of Hardware Removal

	Total No. of Patients	Male Patients	Mean Age *(yr)*	Mean Body Mass Index *(kg/m²)*	Mean Time in Situ *(mo)*
Upper extremity	8	4	35.7	27.4	24.9
Shoulder	1	1	38.1	32.0	108.0
Humerus	2	1	35.3	27.8	13.0
Elbow	1	1	45.5	25.6	47.0
Olecranon	3	0	31.3	27.3	6.0
Forearm	1	1	37.7	24.3	13
Lower extremity	52	23	48.6	26.2	40.7
Hip	4	1	53.0	28.8	32.3
Femur	5	2	52.1	23.2	56.8
Patella	1	0	67.4	27.0	10.0
Tibia and/or fibula	13	4	48.3	28.3	35.1
Distal part of the tibia	2	1	51.5	27.1	18.5
Ankle	22	12	48.3	28.3	46.0
Calcaneus	4	3	40.7	30.3	42.5
Foot	1	0	31.8	21.6	15.0
Total	60	27	46.9	26.3	38.6

*Including hypertension, stroke, and chronic obstructive pulmonary disease. Some patients had more than one comorbidity.

planted at an outside institution. Fifty-seven patients (95%) who completed follow-up at all time-points form the basis for this study. One patient was lost to follow-up after the three-month follow-up visit. One patient was involved in ongoing litigation and was advised by her lawyer not to complete the study three months postoperatively. One patient was excluded after final operative cultures were positive for infection.

The patients enrolled in this study included thirty-three women and twenty-seven men who were between the ages of seventeen and eighty-one years (mean, 46.9 years). Fourteen (23%) of the sixty patients had Medicaid insurance. Five of the sixty patients were involved in a Workers' Compensation claim. The average time that the metal implant had been in place was 38.6 months (range, six to 216 months; median, fifteen months). The average body mass index was 26.3 (median, 26.7). Nineteen patients had comorbidities, and eleven patients were smokers. The implants were in the upper extremity (shoulder, humerus, olecranon, or forearm) in eight patients and in the lower extremity (hip, femur, tibia, ankle, or calcaneus) in fifty-two patients. Demographic data, implant locations, and type of metal implant are listed in Table I. There were no intraoperative or postoperative complications associated with implant removal surgery.

The score for pain on the visual analog scale (Fig. 1) showed a mean reduction in pain of 76% from the baseline preoperative value at one year ($p = 0.0001$). The overall pain scores decreased from a mean (and standard deviation) of 5.5 ± 2.5 before hardware removal to a mean of 1.3 ± 1.8 after hardware removal. Thirty (53%) of the fifty-seven patients had complete resolution of pain at one year, with a response of 0 on the visual analog pain scale.

The SMFA results (Fig. 2) showed an overall improvement of 44% in function from baseline ($p = 0.0001$). With a lower SMFA score indicating a higher functioning level, the mean score was 99.2 ± 31.9 at baseline and improved to 56.0 ± 14.5 at the final evaluation ($p = 0.0001$).

The score on the physical component of the SF-36 (Fig. 3) showed a similar improvement of 39% ($p = 0.0001$) at one year compared with baseline. A higher SF-36 score indicates a higher functioning level. The actual mean score improved from 39.1 ± 10.8 at baseline to 54.2 ± 6.5 at one year.

The score on the mental component of the SF-36 showed the greatest improvement at three months, with a 10.5% gain compared with baseline ($p = 0.0063$). The mean score was 45.5 ± 12.9 before surgery and 50.4 ± 10.5 at three months. At one year, the mean score was 48.6 ± 8.04, an overall improvement of only 6.8% compared with baseline and the difference was not significant ($p = 0.108$).

We also analyzed the outcomes on the pain scale, SMFA, and SF-36 to determine whether there was a difference between patients with upper extremity hardware and those with lower extremity hardware. Fifty patients had hardware in the lower extremity, and seven patients had hardware in the upper extremity. For the seven patients in the upper extremity group, the average score on the visual analog pain scale was 4 ± 2.3 at baseline and 1.8 ± 3.1 at the one-year follow-up examination, which was an overall improvement of 55% ($p = 0.03$).

For the fifty patients with hardware in the lower extremity, the average score on the visual analog pain scale was 5.6 ± 2.5 at baseline and 1.3 ± 1.7 at the one-year follow-up exami-

TABLE I ***(continued)***

Patients with Comorbidities			Payer Type *(no. of patients)*		Hardware Location and Type *(no. of patients)*			
Smoking	Diabetes	Other*	Insured	Workers' Compensation	Small Fragment	Large Fragment	Intramedullary	Tension Band
0	0	0	6	2	6	0	0	2
0	0	0	1	0	1	0	0	0
0	0	0	2	1	2	0	0	0
0	0	0	1	0	1	0	0	0
0	0	0	2	0	1	0	0	2
0	0	0	0	1	1	0	0	0
11	5	5	40	3	29	10	12	1
0	2	1	2	0	0	4	0	0
1	0	0	3	0	0	1	4	0
0	0	0	1	0	0	0	0	1
3	1	0	10	1	0	5	8	0
0	0	0	2	0	2	0	0	0
4	2	4	18	1	22	0	0	0
3	0	0	3	1	4	0	0	0
0	0	0	1	0	1	0	0	0
11	5	5	46	5	35	10	12	3

nation, which was an overall improvement of 77% ($p = 0.001$) (see Appendix). The patients with hardware in the upper extremity were less symptomatic initially than the patients with hardware in the lower extremity, with a lower pain level at baseline (4.0 compared with 5.6) and therefore a smaller reduction in pain at one year (55% compared with 77%).

The mean SMFA score for the upper extremity group was 76.3 ± 24.1 at baseline and 49.5 ± 8.1 at the time of the final follow-up, an improvement of 35% ($p = 0.013$). For the lower extremity group, the mean score on the SMFA was 101.9 ± 31.8 at baseline and 57.0 ± 15.1 at one year, an overall improvement of 44% ($p = 0.001$) (see Appendix).

The SF-36 physical component score for the upper extremity group showed an overall improvement of 32% ($p = 0.003$) at one year. The actual mean score increased from 44.1 ± 6.3 at baseline to 58.2 ± 3.5 at one year. For the lower extremity patients, the SF-36 physical component demonstrated a 41% improvement ($p = 0.001$) at one year. The actual mean score increased from 38.2 ± 11.0 at baseline to 53.7 ± 6.6 at one year (see Appendix).

Fig. 2

A lower SMFA (Short Musculoskeletal Function Assessment Questionnaire) score indicates a higher functioning level. The mean score improved from 99.2 ± 31.9 at baseline to 71.8 ± 27.0 at three months, with further improvement to 63.2 ± 20.1 at six months. At one year, the final mean score was 56.0 ± 14.5 ($p = 0.0001$).

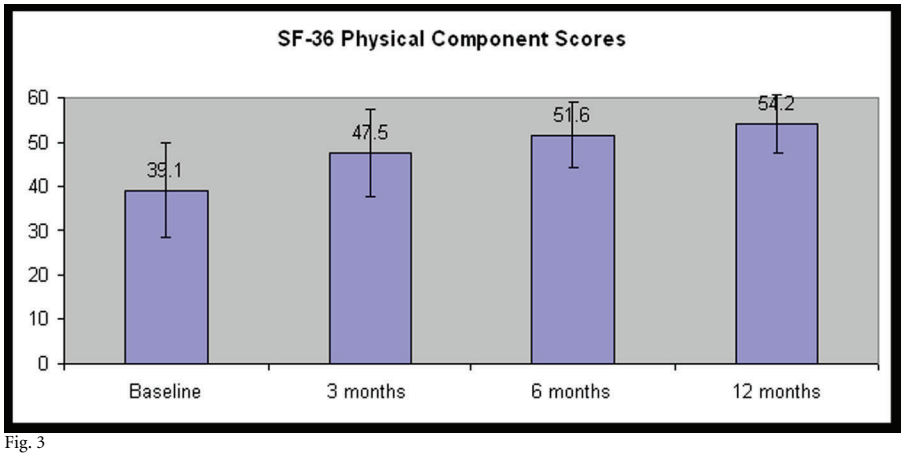

Fig. 3

Higher SF-36 (Short Form-36) scores indicate a higher functioning level. The mean SF-36 physical component score improved from 39.1 ± 10.8 at baseline to 47.5 ± 9.8 at three months. At six months, the mean score improved to 51.6 ± 7.4. The final overall mean score was 54.2 ± 6.5 at one year ($p = 0.0001$).

In summary, the patients who had an implant removed from a lower extremity had a slightly larger percentage of improvement in the SF-36 score (41%) compared with the patients who had an implant removed from an upper extremity (32%). They also had had a greater baseline disability, which may explain the degree of improvement. However, the upper extremity group still had slightly better SF-36 scores than the lower extremity group at one year (58.2 compared with 53.7).

We also evaluated the impact of body mass index, smoking, comorbidities, insurance status, Workers' Compensation status, and age on the overall outcome. With the numbers studied, these potential confounders did not appear to have an effect on the change in pain or SMFA functional scores between baseline and any time-point. The one exception was the effect of age on the SMFA scores. For each one-year increase in age, the difference between the total SMFA score at baseline and at one year increased by >0.5 point ($\beta = 0.66$, $p = 0.015$).

At one year, all fifty-seven patients (100%) responded on the satisfaction questionnaire that they were satisfied, that they would have the procedure done again, and that their overall function had improved.

Discussion

Removal of fracture fixation hardware is a common procedure, accounting for approximately 5% of all orthopaedic procedures done in the United States[14]. We found that all patients who underwent removal of fracture fixation implants that had been causing symptoms were ultimately very satisfied with the outcome and would undergo the procedure again. In addition, all patients had improvement in all aspects of the SMFA and SF-36 scores as early as three months postoperatively, and those trends continued to one year. All sixty procedures were performed on an outpatient basis without complications.

In one study, 5095 implants placed for fracture fixation were removed after fracture-healing[1]. In relation to the number of internal fracture fixations performed, the total removal percentage was 81%. Removal of the implant accounted for 29% of the elective procedures and 15% of total orthopaedic procedures performed at that institution during a seven-year period compared with a rate of 6% of orthopaedic procedures in all of Finland for the duration of that study.

Rates of implant removal have varied on the basis of the anatomic location and type of implant. In one study of fifty-five patients undergoing tension-band wire fixation of olecranon fractures, 61% required revision surgery for painful hardware[10]. In a retrospective review of surgically treated patellar fractures, nine of eighty-seven patients underwent removal of symptomatic hardware[5]. Neither study, however, noted pain relief outcomes.

Intuitively, one may assume that superficial implants present a greater problem with regard to symptoms; however, that does not seem to be borne out in the literature. Regarding deep implants such as intramedullary nails, a retrospective review of eighty patients by Dodenhoff et al. noted that eleven of seventeen patients who underwent implant removal following a healed femoral fracture experienced pain relief[7]. With tibial intramedullary nails, knee pain has been a common indicator for removal. Keating et al.[8] showed a 45% rate of complete relief of knee pain in 110 knees after tibial nail removal. In addition, 35% of the patients experienced partial relief, while 20% had no relief. In a retrospective review of the cases of 169 patients, Court-Brown et al.[9] noted that 27% had complete pain relief and 69% had marked relief after nail removal. However, 3.2% of the patients reported worsening pain after hardware removal. In another study involving 100 patients, 12% of previously asymptomatic patients had knee pain develop after tibial nail removal[15].

In a retrospective study published in 2004, Gosling et al.[16] found that after femoral nail removal in fifty-one patients

who had been asymptomatic preoperatively, ten (20%) had symptoms develop postoperatively. Furthermore, of the fifty-eight patients who had pain preoperatively, 78% reported improvement after nail removal, which was similar to the rate in the present study. Those authors concluded that only symptomatic patients should be considered for femoral nail removal. In the present prospective study, we had a very similar overall improvement rate (77%), yet none of the five patients who had removal of a femoral nail had a new onset of pain postoperatively.

In a recent study that used the same outcome measures as were used in the present study, Brown et al.[2] retrospectively examined functional outcomes after internal fixation of ankle fractures and found lower scores for pain, measured with a visual analog scale, and lower scores on the SMFA and SF-36 questionnaires for patients with pain overlying hardware on the lateral side of the ankle. Of the thirty-nine patients who reported pain, twenty-two underwent removal of hardware, but only eleven had improved pain relief. According to the authors, the results confirmed "that removal of hardware after operative treatment of a fracture was associated with neither an optimal functional result nor a reduction in long-term complications." This is in contrast to our prospective results, which showed a 77% reduction of pain.

Richards et al., in 1992[4], prospectively observed the removal of metal internal fixation devices in eighty-six patients. Of those patients, only twenty-seven requested surgery because of pain. The others were admitted for routine surgery on medical advice. The authors reported that there was no correlation among symptoms, the length of time the implant had been in situ, or the location of the implant. Good results were achieved in 91% of the symptomatic patients on the basis of patient questionnaires. Overall, the complication rate was 3%, and the authors concluded that it might be appropriate to leave asymptomatic implants in situ. While our study group comprised only symptomatic patients, it confirmed the observations of Richards et al.

Although we did not intend to enroll patients who had an infection around the hardware, one patient in the study had positive cultures for infection and was subsequently excluded. This confounding variable may account for some pain at hardware sites postoperatively.

Age was the only factor that we could identify that was related to functional outcome scores. This finding may be interpreted to mean that, if the hardware is truly causing pain, other variables except for increasing age may have less impact on functional status. This is intuitive because the overall functional status of an eighteen-year-old patient is different from that of a seventy-year-old patient.

One limitation in our study is that we did not know the percentage of patients with a healed fracture who had removal of symptomatic hardware. Patients who underwent fracture fixation at our institution may have had follow-up care provided elsewhere, and some were lost to follow-up. We enrolled and followed only patients with a complaint of pain related to hardware.

In addition, one of the difficulties in evaluating patients for functional improvement on the basis of the SF-36 and SMFA questionnaires is the fact that they may have additional disabilities not related to orthopaedic hardware that compromise the overall functional and mental scores. Furthermore, posttraumatic arthritis related to the initial injury may have developed in some patients. This may explain why the improvement in function based on the SF-36 and SMFA scores in the present study was not as substantial as the overall pain reduction.

In our study, implants in all anatomic locations were considered when patients were enrolled, to evaluate the spectrum of orthopaedic hardware removal and the potential improvements. We did differentiate, however, between upper and lower extremity implants. It appears that the patients with an implant in the upper extremity were less symptomatic since they started from a lower pain level (4 compared with 5.6), with only a 55% reduction in pain compared with a 77% reduction for patients with an implant in a lower extremity. The functional outcomes (SMFA and SF-36) also showed more improvement in the patients with an implant in a lower extremity. A larger prospective study would be needed to clarify the outcomes at various anatomic locations.

In conclusion, it is important to be able to counsel patients about the expected level of success when planning the removal of fracture fixation implants that are presumed to be the cause of discomfort. The high level of patient satisfaction, the improvement in both pain relief and function, as well as the overall minimal risk for complications make this particular procedure an excellent choice for patients who have persistent pain following uneventful fracture-healing in the region of an orthopaedic implant.

Appendix

(eA) Graphic representations of the scores on the mental and physical components of the SF-36 and comparisons of scores for patients with hardware in an upper extremity and those with hardware in a lower extremity are available with the electronic versions of this article, on our web site at jbjs.org (go to the article citation and click on "Supplementary Material") and on our quarterly CD-ROM (call our subscription department, at 781-449-9780, to order the CD-ROM). ■

NOTE: The authors thank Uzoma Nwoso, MD, and Jaspal Singh, MD, for their help in the preparation of this manuscript.

Reuven B. Minkowitz, MD
Michael Walsh, PhD
Kenneth A. Egol, MD
New York University-Hospital for Joint Diseases, 301 East 17th Street, New York, NY 10003. E-mail address for R.B. Minkowitz: RubieMinkMD@yahoo.com

Siraj Bhadsavle, MD
Department of Orthopaedic Surgery, Albany Medical Center, 107 Wellington Avenue, Albany, NY 12203

References

1. Bostman O, Pihlajamaki H. Routine implant removal after fracture surgery: a potentially reducible consumer of hospital resources in trauma units. J Trauma. 1996;41:846-9.

2. Brown OL, Dirschl DR, Obremskey WT. Incidence of hardware-related pain and its effect on functional outcomes after open reduction and internal fixation of ankle fractures. J Orthop Trauma. 2001;15:271-4.

3. Busam ML, Esther RJ, Obremskey WT. Hardware removal: indications and expectations. J Am Acad Orthop Surg. 2006;14:113-20.

4. Richards RH, Palmer JD, Clarke NM. Observations on removal of metal implants. Injury. 1992;23:25-8.

5. Smith ST, Cramer KE, Karges DE, Watson JT, Moed BR. Early complications in the operative treatment of patella fractures. J Orthop Trauma. 1997;11:183-7.

6. Jacobsen S, Honnens de Lichtenberg M, Jensen CM, Torholm C. Removal of internal fixation—the effect on patients' complaints: a study of 66 cases of removal of internal fixation after malleolar fractures. Foot Ankle Int. 1994;15:170-1.

7. Dodenhoff RM, Dainton JN, Hutchins PM. Proximal thigh pain after femoral nailing. Causes and treatment. J Bone Joint Surg Br. 1997;79:738-41.

8. Keating JF, Orfaly R, O'Brien PJ. Knee pain after tibial nailing. J Orthop Trauma. 1997;11:10-3.

9. Court-Brown CM, Gustilo T, Shaw AD. Knee pain after intramedullary tibial nailing: its incidence, etiology, and outcome. J Orthop Trauma. 1997;11:103-5.

10. Romero JM, Miran A, Jensen CH. Complications and re-operation rate after tension-band wiring of olecranon fractures. J Orthop Sci. 2000;5:318-20.

11. Sanderson PL, Ryan W, Turner PG. Complications of metalwork removal. Injury. 1992;23:29-30.

12. Beaupre GS, Csongradi JJ. Refracture risk after plate removal in the forearm. J Orthop Trauma. 1996;10:87-92.

13. Langkamer VG, Ackroyd CE. Removal of forearm plates. A review of the complications. J Bone Joint Surg Br. 1990;72:601-4.

14. Rutkow IM. Orthopaedic operations in the United States, 1979 through 1983. J Bone Joint Surg Am. 1986;68:716-9.

15. Boerger TO, Patel G, Murphy JP. Is routine removal of intramedullary nails justified. Injury. 1999;30:79-81.

16. Gosling T, Hufner T, Hankemeier S, Zelle BA, Muller-Heine A, Krettek C. Femoral nail removal should be restricted in asymptomatic patients. Clin Orthop Relat Res. 2004;423:222-6.