Incidence of Hardware-Related Pain and Its Effect on Functional Outcomes After Open Reduction and Internal Fixation of Ankle Fractures

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Objectives: To document the incidence of late pain and hardware removal after open reduction and internal fixation (ORIF) of ankle fractures. To test the hypothesis that late pain overlying the distal tibial and fibular hardware is associated with poorer functional outcomes.

Design: Retrospective review.

Setting: Level II trauma center.

Patients: One hundred twenty-six skeletally mature patients undergoing ORIF of unstable malleolar fractures who were followed up for at least six months from injury were included.

Main Outcome Measurements: Analog pain score, Short Form-36 Health Survey (SF-36), and Short Form Musculoskeletal Functional Assessment (SMFA).

Results: Thirty-nine (31 percent) of the 126 patients had lateral pain overlying their fracture hardware. Twenty-nine patients (23 percent) had had their hardware removed or desired to have it removed. Of the twenty-two patients with hardware-related pain who had undergone hardware removal, only eleven had improvement in their lateral ankle pain; the mean analog pain score decreased from 6 ± 3.16 (mean ± standard deviation) before hardware removal to 3 ± 2.9 after hardware removal (p = 0.008). In general, SF-36 and SMFA scores at final follow-up were significantly lower for patients who had pain overlying their lateral hardware than for those who had no pain. For the group of patients who had lateral ankle pain, no significant difference was noted in SMFA or SF-36 scores for patients who had and who had not had their lateral hardware removed (p > 0.5).

Conclusion: The incidence of late pain overlying the distal tibial and fibular plate or screws is not insignificant. Although pain is generally decreased after hardware removal, nearly half of patients continue to have pain even after hardware removal. Functional outcome scores are poorer for patients with pain overlying lateral ankle hardware than in those with no pain at this location; this poorer outcome seems to be independent of whether the hardware was removed. Although the results of this study do not support or condemn the routine removal of fracture hardware after healing of unstable ankle fractures, they give orthopaedic surgeons some information that may assist them in counseling patients as to the expected functional outcome after ORIF of ankle fractures and the likelihood of relief of pain after removal of fracture hardware from the distal tibia and fibula.

Key Words: Ankle fracture, Hardware removal, Open reduction and internal fixation, Pain, Painful hardware.

Open reduction and internal fixation (ORIF) of fractures of the ankle is one of the most common fracture surgeries performed in general orthopaedic practice. Whereas the surgical treatment of this injury has clearly resulted in outcomes superior to those of closed reduction and cast immobilization (3,4,6,8,9,12,15), the presence of a plate or screws in a subcutaneous location on the distal tibia or fibula can result in long-term tenderness and pain. This causes some patients to have elective removal of the plate or screws after fracture healing has occurred (5). The incidence of late pain at the site of fracture hardware in malleolar fractures has not been clearly documented in the orthopaedic literature, nor has the incidence of hardware removal for late pain (1,3,4,7,8,9,10,14). The purpose of this investigation was to document the incidence of late pain related to the presence of distal tibial and fibular plates or screws and to document the incidence of hardware removal after ORIF of ankle fractures.

MATERIALS AND METHODS

A retrospective review was conducted of 126 patients who had undergone ORIF for displaced ankle fractures during a five-year period from May 1994 to December 1998. Patients were included in the study if they had an unstable ankle fracture treated by ORIF of the
distal fibula with plates and screws (with or without stabilization of the medial malleus), were skeletally mature at the time of injury, and had been followed up for at least six months after injury. The mean age of patients at the time of surgery was 49 ± 18 years (mean ± standard deviation) (range 17 to 85 years). The mean interval to follow-up was 27 ± 17 months (range 6 to 64 months). According to the Orthopaedic Trauma Association classification system (11), there were seven 44A fractures, eighty-nine 44B fractures, and thirty 44C fractures.

Information was obtained from the patient (interview, pain score, Short Form-36 Health Survey [SF-36], and Short Form Musculoskeletal Functional Assessment [SMFA]), from the hospital chart (injury and treatment information), and from the postoperative radiographs (healing of the fracture, type of plate and screws, and prominence of the hardware). Each patient was interviewed by one of the investigators to determine the presence and severity of pain overlying the ankle hardware, whether the hardware had been removed, and whether the patient desired to have the hardware removed. An analog pain scale was used to rate pain: patients were asked to rate their distal fibular pain on a scale from one (no pain) to ten (the most pain imaginable). An analog pain score of five or more was considered to represent pain, and a score less than five was considered to represent no pain. Patients who had undergone hardware removal were asked to give two analog pain scores, one each corresponding to pain before and after hardware removal.

Pain scores were correlated with functional outcome scores in all patients, which were assessed using the SF-36 (13,16) and the SMFA. Statistical analysis of functional outcome and pain scores was performed using the Student t test for two samples assuming unequal variances. All other means were tested by the Student t test for paired samples. The results were considered significant if p was less than 0.05 in a two-tailed study.

RESULTS

Thirty-nine (31 percent) of the 126 patients reported pain overlying their tibial and fibular hardware. Twenty-two of the thirty-nine patients with painful hardware (17 percent of total) had had their hardware removed and seventeen had not. Of the seventeen patients with painful hardware who had not had their hardware removed, seven desired their hardware to be removed. Thus, the total number of patients with hardware-related pain who had had their hardware removed or desired it to be removed was twenty-nine (23 percent of total). Of the eighty-seven patients who did not have pain overlying their hardware, eight (6 percent of total) had had their hardware removed for reasons other than pain (one for infection and seven because of patient preference for removal of painless hardware). Thus, a total of thirty patients had undergone hardware removal (twenty-two for pain and eight for reasons other than pain), for an overall rate of hardware removal of 24 percent (Fig. 1).

After elective removal of painful ankle hardware, eleven (50 percent) of twenty-two patients reported a decrease in their analog pain score (Fig. 1). In this group of patients, analog pain scores decreased from a mean of 6 ± 3.16 before hardware removal to 3 ± 2.9 after hardware removal (p = 0.008). Of the eight patients without ankle pain who had their hardware removed, four had no change in analog pain score; one had a modest decrease in the pain score; and three had an increase in pain score. There was, however, no statistically significant change in mean analog pain score in these patients before and after hardware removal (p > 0.5). The average time from injury to removal of hardware was thirty-seven weeks (range 7 to 172 weeks).

Scores for the SF-36 are shown in Figure 2. Higher scores indicate a higher functional level. The mean SF-36 scores for patients with hardware-related pain (n = 39) were significantly lower in all subscore areas except emotional problems (p = 0.18) than for patients without pain (n = 87) (p < 0.004 for all). The greatest
difference was observed in the area of bodily pain, in which patients with hardware-related pain had a mean score of 49.9 ± 24.8, whereas patients without pain had a mean score of 72.5 ± 24.8 (p = 0.00007).

Scores for the SMFA are shown in Figure 3. Lower scores indicate a higher functional level. The mean SMFA scores for patients with hardware-related pain (n = 39) were significantly higher in all subscore areas except arm and hand function (p = 0.6) than for patients without pain (n = 87) (p < 0.006 for all). The most significant subscores for the SMFA were average bother index score and average emotional score. The average bother index score was 29.72 ± 21.1 for patients with pain and 13.84 ± 15.9 for patients without pain (p = 0.00004). The average emotional status was 36.79 ± 22.0 for patients with pain and 21.76 ± 15.9 for patients without pain (p = 0.001).

**DISCUSSION**

Retrospective analysis of the 126 patients in this study showed that 31 percent of patients had significant pain with hardware and 17 percent had had their hardware removed at a mean follow-up of twenty-seven months. These results indicate that painful hardware is a significant issue after ORIF of unstable ankle fractures and that the incidence of hardware removal is higher than previously reported (1,2,7). Although some pain relief after removal of painful hardware was observed, a decrease in pain occurred in only approximately one half of patients. That there was a wide range in the interval from injury to hardware removal suggests that the time to removal may not be a significant factor in regards to pain or function.

The results of this study also support the contention that patients without ankle pain after ORIF of unstable ankle fractures have better functional outcomes than do patients experiencing significant hardware-related pain. All subscores in SF-36 and SMFA show higher functional levels for patients who did not experience pain (Fig. 2 and 3). The performance of patients with and without pain was inconsistent in the area of emotional functioning between the two outcome measures; these inconsistent results indicate that emotional problems may or may not be a major determinant of function after operative treatment of an unstable ankle fracture. All other SF-36 subscores, however, showed statistically significant differences between patients with pain and those without pain. In addition, all the SMFA subscores, with the exception of hand and arm function, showed significantly better functioning in the group of patients without ankle pain. The lack of correlation of ankle pain with hand and arm function is to be expected in patients being examined after an ankle fracture.

In one recent study, 75 percent of patients with complaints after ORIF of an ankle fracture reported improvement after hardware removal (5). These results contrast with those of this study, in which only 50 percent of patients had improvement in pain scores after hardware removal. Another recent report concluded 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 (7), a statement that our results confirm. Although our study attempted to define precisely hardware-related pain, there is no way of knowing that the patients in the study did not also report pain caused by other factors. Similarly, the poor performance on the functional outcome measures may have been related to factors other than the previous ankle fracture; it was our assumption, however, that the incidence of these confounding conditions was nearly equal in the groups with and without pain.

The results of this study indicate that the incidence of late ankle pain overlying the fracture hardware is not insignificant. Also, whereas pain is often decreased after hardware removal, some patients, particularly those undergoing hardware removal in the absence of lateral pain, may have increased pain after hardware removal. Functional outcome scores are poorer for patients with pain overlying ankle hardware than in those with no pain at

**FIG. 2.** Selected SF-36 subscores for patients with and without hardware-related ankle pain. Higher scores mean better function. Statistical significance was reached for each subscore presented (p < 0.004 for all). The difference in role limitations attributable to emotional problems between the two patient groups (data not shown) was not statistically significant (p = 0.6).

**FIG. 3.** Selected SMFA subscores for patients with and without hardware-related ankle pain. Lower scores mean better function. Statistical significance was reached for each subscore presented (p < 0.006 for all). The difference in arm and hand function between the two patient groups (data not shown) was not statistically significant (p = 0.6).
this location. This poorer outcome seems to be independent of whether the hardware was removed. Although the results of this study do not support or condemn the routine removal of fracture hardware after healing of unstable ankle fractures, they give orthopaedic surgeons some information that may assist them in counseling patients as to the expected functional outcome after ORIF of ankle fractures and the likelihood of relief of pain after removal of fracture hardware from the ankle.

REFERENCES