The burden of hardware removal in ankle fractures: How common is it, why do we do it and what is the cost? A ten-year review

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ABSTRACT

Background: Ankle fractures account for 9% of all fractures and 40% require surgical management. The ankle is the most common site of hardware removal. The purpose of our study was to investigate the incidence, indication and economic cost associated with removal of hardware from the ankle.
Methods: We conducted a ten-year retrospective review of 1482 patients treated by open reduction internal fixation for an unstable ankle fracture. Skeletally immature patients were excluded. Data collected was cross referenced from patient medical records, the radiological and electronic patient database. The casemix and hospital inpatient enquiry system (HIPE) were used to calculate costs.
Results: The mean age was 39.9 years with 53.6% male. 185 patients (12.5%) underwent hardware removal with unplanned removal performed in 6% of cases. The average cost of removal was €1113.
Conclusion: Removal of hardware continues to be a common operation with significant costs to all involved. More than one in 10 patients underwent future removal of hardware.
Level of evidence: Level 3.

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1. Introduction

Ankle fractures are the second most common fracture of the lower limb and account for 9% of all fractures [1,2]. They comprise approximately 17% of all hospitalised fractures and are the most frequent fracture requiring operative treatment in those under the age of 60 [3]. Recent studies have shown the incidence of them is rising in the elderly with the numbers over the age of 65 expected to triple by 2030 [4]. Approximately 40% require surgical management most commonly in the form of open reduction internal fixation (ORIF) [2,5].

Metalwork is removed in both asymptomatic and symptomatic patients for a variety of reasons with considerable variation in rates of hardware removal amongst studies, ranging from 10 to 81% [6]. No specific guidelines or consensus exists around whether hardware should be removed or not, with practices differing from surgeon to surgeon and even country to country. Hardware removal from the ankle is the most common site of removal often due to the small amount of overlying subcutaneous tissue resulting in palpable or prominent hardware that can be symptomatic with foot wear and activity [7].

While removal of hardware is often viewed as a straightforward procedure it can be more challenging and does not come without both its complications and costs to patients, institutions and society. Complication rates in some studies are as high as 20% following routine removal of hardware [8,9]. Patient satisfaction and symptomatic relief following this procedure also vary [7,10].

The purpose of this study was to examine the incidence over a ten-year period of hardware removal following ORIF, the reasons behind removal and quantify the cost of removal.

2. Materials & methods

A retrospective observational study was conducted of all patients that underwent ORIF for an unstable ankle fracture between January 1st 2007 and December 31st 2016 in Galway University Hospital (GUH). GUH is a public tertiary referral hospital for the province of Connacht serving the west and northwest of Ireland. Connacht has a population catchment area of 709,000 and makes up a large geographical area, 32% of the geographical area of the Republic of Ireland [11]. The Department of Orthopaedics consists of one specialist fellowship trained foot and ankle surgeon and nine experienced orthopaedic surgeons which treat both paediatric and adult patients. The study was conducted according the to the clinical governance guidelines of our institution and ethical approval was granted by the clinical research ethics committee.

Patients were identified from theatre logbooks and cross referenced with the radiological database. All patients who had

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undergone ORIF of an ankle fracture were initially identified (n = 1529). Those patients who had suffered ankle injuries effecting the physeal growth plate were then excluded (n = 47). All radiographs were reviewed by CF and JGG to ensure patients had undergone ORIF as had been recorded in the theatre logbooks. Fractures of the proximal, mid and distal tibia were excluded (AO classification 41, 42 and 43) as were patients treated with external fixation as the definitive treatment mechanism. Patient medical records and the electronic patient database were reviewed to identify any future admissions related to the primary operation and the reason for removal.

Prior to primary surgery, patients without a penicillin allergy routinely received one dose of intravenous cefuroxime prior to incision and two doses post operatively. For those who underwent removal of hardware a single dose of intravenous cefuroxime was given preoperatively. The decision to remove a syndesmosis screw was combined decision made between the patient and orthopaedic surgeon taking into a number of factors such as age, level of activity, comorbidities etc. Routine syndesmosis removal was not done in our institution. Syndesmosis screws, if removed, were routinely removed between 8 to 12 weeks after initial surgery.

Syndesmosis screws were not routinely removed in our institution however in some cases scheduled removal was performed. In such cases this was a decision made between the patient and doctor in the outpatient's department after their surgery. A number of factors were taken into consideration such as age, level of activity, comorbidities and potential complications. If a decision was made to remove a syndesmosis screw this was done between 8 to 12 weeks after initial surgery. Patients who underwent scheduled removal of hardware (K-wire or screw removal) have been defined as planned removal in our study.

Basic demographic and descriptive data were collected including age, gender, Danis–Weber fracture classification, time from injury to surgery, indication for hardware removal and time from primary surgery to removal of hardware. Time to surgery (TTS) was defined as the time from presentation to time of definitive surgery. Length of follow up was calculated from the date of surgery to the date of last radiograph. The follow up period ended on July 1st 2017. The indications for hardware removal were classified into three categories, (1) planned removal, (2) infection and (3) symptomatic hardware (pain, prominence, stiffness). The scheduled removal of hardware was determined by the consultant.

The Hospital Inpatient Enquiry System (HIPE) is the national Irish data collection source for all acute public hospitals. It collects demographic, clinical and administrative data creating an electronic record of each patient admission (diagnosis, investigations, procedures, consultations etc.). Using this record, a casemix points score is calculated based on the complexity of the case and a cost orbill is created. Casemix is a system initially developed in the United States in the 1970s but now used internationally to categorise and quantify the 'mix' of patients into groups or Diagnoses Related groups (DRGs). In Ireland the "National Casemix Programme" was introduced in 1993 with coding and treatment costs using DRGs set at a national level. In our study we used the HIPE and casemix system to calculate the cost of hardware removal in the ankle. This system calculates a cost based on patient and procedure complexity using parameters such as patients age, gender, comorbidities, length of stay, diagnoses and complications. In our study the average cost of removal of hardware procedures performed in 2016 was used. There were no cases of removal for infected hardware in 2016. The year 2016 was chosen so to provide an up to date minimum cost reference. Simple descriptive statistics were calculated for patient demographics using Stata® version 14.0 (StataCorp LLC, TX, USA). For continuous variables the mean and standard deviation (SD) were used while categorical variables were described according to their frequency distribution. A Chi Square test was used to compare the two groups in terms of age and gender.

3. Results

In the ten-year period 1482 patients underwent operative repair of an unstable fracture of the ankle. At the time of presentation, the mean age of patients was 42.7 years (SD 17.9 years) and 751 patients (50.6%) were male. The majority of fractures, 67.4%, were Weber B trans-syndesmotic fractures, while Weber C supra-syndesmotic fractures accounted for 21.6% and Weber Type A infra-syndesmotic fractures 4.2%. Fractures that could not be classified by the Danis Weber classification accounted for 6.8% of fractures such as isolated medial malleolus or isolated posterior malleolus injuries. A syndesmosis screw was inserted in 24.9% of patients (369 patients) predominantly in supra-syndesmotic (Danis Weber C) fractures. Radiographic follow up was available for 90.8% of patients (1346 patients) with a mean length of radiographic follow up of 8.0 months

One hundred and eighty-five patients (12.5%) underwent removal of metal during the study period. For this cohort the mean age was 39.9 years, with 53.6% of patients male. Just under half of all procedures, 49.2% (91 patients), were for planned removal of hardware. The other reasons for removal included 85 patients (46%) due to symptomatic hardware and 7 patients (3.8%) due to infection. A Chi square test was undertaken and there was no significant difference between the two groups with respect to age and gender (p = 0.81). In two patients unplanned removal was performed but the exact reason for removal was unclear. The median time to removal was 4 months (range 2–123 months), with 71.9% of procedures performed within 12 months of the primary surgery (Table 1).

Table 1
Descriptive data of ankle fractures from 2007 to 2016.

	Number (N)	Percentage (%)
Number of patients	185	12.5
Mean age, years (standard deviation, SD)	39.9 (16)	
Gender, male	99	53.6
Weber Fracture classification		
-Weber A	7	3.8
-Weber B	71	38.4
-Weber C	93	50.3
-Other[a]	14	7.5
Median time to Hardware removal, months (range)	4 (2–123)	
Indication for removal		
-Planned	91	6.1
-Symptomatic	85	5.7
-Infection	7	0.5
-Other	2	0.1

[a] Other = isolated medial or posterior malleolus fractures, syndesmosis injuries.

Table 2
Subgroup descriptive data for hardware removal.

	Planned removal	Unplanned removal
Number of patients	91	92
Age, years (SD)	37.6 (15)	42.2 (16.7)
Gender, male (%)	63.7	42.4
Time to removal, months (SD)	3 (2–9)	13 (2–123)

3.1. Planned/asymptomatic removal

Ninety-one patients underwent planned removal in the form of K-wires, screws and syndesmotic screws, accounting for 6.1% of all patients. 63.7% of patients were male with a mean age of 37.6 years (SD 15). The median time to removal of hardware for this group was 3 months (range 2–9 months) (Table 2). The majority of planned removal of hardware was for the removal of a syndesmosis screw (87 patients, 95%) which represented 23.6% of all patients (369 patients) who had a syndesmosis screw inserted. Planned removal was also performed for Kirschner wire removal (4 patients)

3.2. Unplanned/symptomatic removal

92 patients underwent unplanned removal of hardware. 42.4% of patients were male with mean age of 42.2 years (SD 16.7). For unplanned removal of hardware, the median time to removal was 13 months (range 2–123 months) with 85% of procedures being done within two years of the primary operation (Table 2). 85 patients underwent removal due to symptomatic hardware. Of these, 71 patients (83.5%) underwent removal of symptomatic hardware from the lateral malleolus, representing 5.4% of all patients who underwent fixation of the lateral malleolus (n = 1310). Fourteen patients underwent removal of medial malleolus screws, 2.4% of all patients who underwent medial malleolus fixation. Seven patients required removal of hardware due to infection, accounting for 3.8% of hardware removal and 0.5% of all patients over the ten-year period. Six of the seven patients were male with a mean age of 61.7 years (SD 25.9). All seven patient required admission for removal of hardware and treatment with intravenous antibiotics. One patient required a future skin graft.

3.3. Cost of procedure

The average cost of hardware removal from the ankle in 2016 was €1113. This cost was calculated using the HIPE and casemix system from 15 patients who all underwent removal of hardware under general anaesthetic as a day case procedure. There no cases of removal of hardware for infection in 2016.

4. Discussion

Hardware or implant removal makes approximately 5% of all orthopaedic operations however this figure is now over 30 years old [12]. The incidence of hardware removal has shown considerable variation between studies with rates as high as 81% [6]. In our study over the ten-year period 12.5% of all patients underwent removal of hardware, with the most common reasons for removal being planned removal (6.1%) followed by symptomatic hardware (5.7%) and infection (0.5%). Practices around hardware removal differ amongst surgeons with the majority performed for what are often termed relative indications including pain, irritation, prominence or stiffness. Most surgeons would remove symptomatic hardware but this is often with caveat that it may not relive the pain and comes with other increased risks.

Just over one in twenty patients (6.3%) underwent unplanned removal of hardware most commonly for complaints including pain, irritation and stiffness. In our study those who underwent unplanned removal were predominantly female (57.6%) with a similar age (42.2 years) to our population mean (42.7 years). This similar retrospective study by Naumann et al. of looking at 997 patients which found the unplanned removal to occur predominantly in females however age was not given in this paper [13]. Infection accounted for a small percentage (3.8%) of unplanned hardware removal and affected a very small number of patients overall (0.5%). However, it must be noted that this does not include patients who may have been treated for infection in the outpatient setting or required inpatient admission. Naumann et al. found in their study that 16% of hardware removal or 2.6% of all procedures required removal due to infection.

The rate of syndesmosis screw fixation (24.9%) in our study was similar to other studies with that have reported rates of 20% [14]. Removal of a syndesmosis screw accounted for nearly all (95%) of planned removal of hardware however less than one quarter of syndesmosis screws were removed (23.3%). Debate continues to surround whether syndesmosis screws should be removed. Proponents of removal believe preservation of it leads to restricted movement [14]. While opponents point to recent studies showing no significant functional, clinical or radiological benefit at one year between those with syndesmosis screws removed and not [15]. Dingemans et al. recent systematic review concluded that the current literature does not support routine removal [16]. However, they did note that the evidence is of insufficient quality to draw any definitive conclusions.

The removal of hardware is not without its risks. Recognised complications include anaesthetic issues, infection, neurovascular injury, pain, refracture or displacement. Studies looking at ankle hardware removal for pain report varying degrees of improvement in pain from 50 to 96% depending on the indication [7,10,17]. However, some also report increased levels of pain following the procedure [7]. Infection is another area of concern with a study by Schepers et al., that examined the routine removal of a syndesmosis screw, reporting a rate of infection of 9.2% of which 2.6% suffered deep infections requiring reoperation [8]. These rates of infection are similar to other studies such as that by Backes et al. which reported 10% superficial infections and 1.6% deep infections [18].

Hardware removal also comes at both a cost to patients, hospitals and society through utilisation of healthcare resources and absence from work. The economic cost of removal is often cited but it is difficult to accurately cost due to the multifactorial nature of healthcare. "The Productive Operating Theatre" (TPOT) project launched by the NHS estimated the running cost of theatre are approximately 1200 per hour or €1500 [19,20]. A study by Lalli et al. from the United States found the average cost of syndesmosis screw removal was $3579, with a range of $2871–$9981 [21]. They included anaesthesia, operating room, recovery room fees as well as pharmacy, labs and supplies cost. In our study the cost of hardware removal was found to be €1113. This figure represents the minimum cost of removal and does not include factors such as increased length of stay, comorbidities or additional consultations that may increase the cost. It also does not include the economic impact to the patient and society through work missed and loss of income.

Our study is not without limitations. Firstly, the study is retrospective in nature and therefore reliant on the quality and completeness of records that exist. Also patients who were initially treated in our institution may have undergone follow-up care elsewhere thus our figure of hardware removal (12.5%) is likely an underrepresentation as is the number of patients who may have experienced infection. While we have identified the reason for

removal we did not investigate associated risk factors for removal or clinical outcome information.

5. Conclusion

Over the ten-year study period, 12.5% of patients underwent removal of hardware with similar numbers undergoing planned (6.1%) and unplanned (6.2%) removal. Planned removal nearly always for removal of syndesmosis screw was done in younger male patients. It is important to counsel patients around the time of the initial injury about the possibility of future removal. While the absolute need for plate removal is low the relative need is higher. Patient expectations must be managed when addressing the issue of implant removal and patients must be informed of the potential complications. Removal of hardware continues to be associated with significant costs to all involved.

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Conflicts of interest

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