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Increased risk for complications following removal of hardware in patients with liver disease, pilon or pelvic fractures: A regression analysis

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ABSTRACT

Purpose: Indications for removing orthopedic hardware on an elective basis varies widely. Although viewed as a relatively benign procedure, there is a lack of data regarding overall complication rates after fracture fixation. The purpose of this study is to determine the overall short-term complication rate for elective removal of orthopedic hardware after fracture fixation and to identify associated risk factors.
Materials and methods: Adult patients indicated for elective hardware removal after fracture fixation between July 2012 and July 2016 were screened for inclusion. Inclusion criteria included patients with hardware related pain and/or impaired cosmesis with complete medical and radiographic records and at least 3-month follow-up. Exclusion criteria were those patients indicated for hardware removal for a diagnosis of malunion, non-union, and/or infection. Data collected included patient age, gender, anatomic location of hardware removed, body mass index, ASA score, and comorbidities. Overall complications, as well as complications requiring revision surgery were recorded. Statistical analysis was performed with SPSS 20.0, and included univariate and multivariate regression analysis.
Results: 391 patients (418 procedures) were included for analysis. Overall complication rates were 8.4%, with a 3.6% revision surgery rate. Univariate regression analysis revealed that patients who had liver disease were at significant risk for complication ($p = 0.001$) and revision surgery ($p = 0.036$). Multivariate regression analysis showed that: 1) patients who had liver disease were at significant risk of overall complication ($p = 0.001$) and revision surgery ($p = 0.039$); 2) Removal of hardware following fixation for a pilon had significantly increased risk for complication ($p = 0.012$), but not revision surgery ($p = 0.43$); and 3) Removal of hardware for pelvic fixation had a significantly increased risk for revision surgery ($p = 0.017$).
Conclusions: Removal of hardware following fracture fixation is not a risk-free procedure. Patients with liver disease are at increased risk for complications, including increased risk for needing revision surgery following hardware removal. Patients having hardware removed following fixation for pilon fractures also are at increased risk for complication, although they may not require a return trip to the operating room. Finally, removal of pelvic hardware is associated with a higher return to the operating room.

Introduction

The number of procedures involving orthopedic internal fixation has significantly increased over the past decades, and subsequently so has the number of surgeries for removal of these fixation implants. Removal of deep implant (CPT code 20680) is one of the most common elective orthopedic procedures, representing up to 15% of elective orthopedic surgeries [1]. Hardware is surgically removed for numerous reasons including failure of hardware, fracture non-union, or infection. However, the most common reason for removing orthopedic hardware is on an elective basis based on patient's preferences for pain or cosmetic related issues after the purpose of the hardware has been fulfilled [2,3]. Although these procedures can be viewed as relatively benign, there is controversy with regards to whether or not hardware should be removed due to the potential risks involved [3,4]. There have been numerous studies researching indications

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for removing hardware, but in the current literature, few have attempted to assess the complications surrounding elective removal of orthopedic hardware following fracture fixation. Elective removal is being defined as removal due to patient preference secondary to pain or impaired cosmesis directly related to the orthopedic hardware and not related to hardware failure or infection. Complications such as deep infections, wound dehiscence, and re-fracture after surgical hardware removal can have a profound negative impact on the quality of patients' lives. The purpose of this study was to evaluate the types of complications associated with elective hardware removal after fracture fixation, the rates at which they occur and associated risk factors.

Materials & methods

After institutional review board (IRB) approval, a retrospective study was performed on skeletally mature patients who had elective hardware removal between July 2012 and July 2016 at a single Level 1 trauma center. Inclusion criteria included patients with hardware related pain and/or impaired cosmesis with complete medical and radiographic records, and at least 3-month follow-up after hardware removal. Exclusion criteria included patients indicated for hardware removal for a diagnosis of malunion, non-union, and/or infection. Data collected included patient age, gender, anatomic location of hardware removed, body mass index (BMI), ASA score, and type of associated comorbidities (diabetes, smoking history, immunosuppressive disease, heart disease, liver disease, renal disease, inflammatory disease, pulmonary disease, chronic steroid use, dementia, thyroid disease, neuromuscular disease, peripheral vascular disease, chronic anticoagulation, stroke, and cancer history). All patients received a standard dose of intravenous antibiotics within one hour of surgical incision. The specific hardware that was removed was confirmed either through operative dictations and/or direct radiographic evaluation of *peri*-operative films. Overall complications (including superficial infections requiring oral antibiotics), as well as complications requiring a revision surgery were recorded. Statistical analysis was performed with SPSS 20.0, and included univariate and multivariate regression analysis; significance was set at $p < 0.05$.

Table 1
Cohort characteristics (n = 418).

Mean age (SD)	44.1 (15.6)
M:F, %	51.4 : 48.6
Location, n (%)	
Tibia locking screws	58 (13.9)
Lateral malleolus/syndesmosis	58 (13.9)
Bilateral malleolus	52 (12.4)
Femur locking screws	38 (9.1)
Tibial plateau	30 (7.2)
Clavicle	24 (5.7)
Pelvis	23 (5.5)
Foot	20 (4.8)
Forearm/wrist	19 (4.5)
Pilon	16 (3.8)
Femur nail	15 (3.6)
Tibial nail	15 (3.6)
Humerus	14 (3.3)
Elbow	12 (2.9)
Patella	10 (2.4)
Distal femoral plate	8 (1.9)
Medial malleolus	6 (1.4)
ASA	
ASA	63 (15.1)
ASA 2	243 (58.1)
ASA 3	104 (24.9)
ASA 4	8 (1.9)
Comorbidities, n (%)	
Diabetes	49(11.7)
Smoker	160 (38.3)
Immunosuppressive disease	17 (4.1)
Cardiac disease	26 (6.2)
Renal disease	15 (3.6)
Liver disease	5 (1.2)
Dementia	1 (0.2)
Neuromuscular disorder	9 (2.2)
Pulmonary disease	39 (9.3)
Thyroid disease	37 (8.9)
Rheumatologic condition	10 (2.4)
Chronic steroid	7 (1.7)
Peripheral vascular disease	5 (1.2)
Stroke history	12 (2.9)
Anticoagulation	14 (3.3)
Oncologic history	39 (9.3)

Results

Three hundred and ninety-one patients (418 procedures) were included for analysis. Mean patient age was 44.1 ± 15.6 years and mean BMI was 29.6 ± 13.7. Gender distribution was relatively equal (M: 51.4%; F: 48.6%) and the most common sites of hardware removal were the tibia (intramedullary nail locking screws, 13.9%), the syndesmosis (13.9%), and both medial and lateral malleoli (12.4%) (Table 1).

Overall complication rates were 8.4%, with a 3.6% need for revision surgery. Specific complications requiring return to the operation room included deep infection/wound dehiscence (1.9%), hematoma (0.5%), bladder tear (0.2%), dural tear with cerebrospinal fluid leak (0.2%), external iliac vein thrombosis (0.2%), pelvic instability requiring arthrodesis (0.2%), and repeat fracture (0.2%) (Table 2). Non-operative complications (4.8%) included superficial infection requiring antibiotics (3.1%) and superficial wound dehiscence (1.7%) (Table 2).

Univariate regression analysis revealed significant risk for complication ($p = 0.001$) and need for revision surgery ($p = 0.036$) in those patients who had liver disease (Table 3). Similarly, multivariate regression analysis showed that patients with liver disease were at significant risk of overall complications ($p = 0.001$) and need for revision surgery ($p = 0.039$) (Table 4). Multivariate regression analysis also revealed that patients who had removal of hardware following fixation of a pilon fracture were at significant risk for complications ($p = 0.012$), but not revision surgery ($p = 0.43$)(Table 5). Additionally, multivariate regression analysis revealed that patients who had removal of hardware after pelvic fixation had a significantly increased risk for return to the operating room ($p = 0.017$, Table 5). All other variables did not reach significance.

Table 2
Complication types.

Complication type	n (%)
Overall rate	35 (8.4)
Return to operating room	15 (3.6)
- Deep infection/wound dehiscence	8 (1.9)
- Hematoma	2 (0.5)
- Bladder Tear	1 (0.2)
- Dural Tear/CSF Leak	1 (0.2)
- External iliac vein thromobosis	1 (0.2)
- Pelvic instability	1 (0.2)
- Re-fracture	1 (0.2)
Non-operative Complication	20 (4.8)
- Superficial infection	13 (3.1)
- Superficial wound dehiscence	7 (1.7)

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