

**STATEMENT OF PURPOSE**

The purpose of the current study is to evaluate demographic trends, and identify causative reasons in all removal of hardware cases in foot and ankle surgery by one surgeon, over an 11 year period.

**INTRODUCTION**

Removal of implanted hardware within the foot and ankle is a common procedure within the orthopedic and podiatric communities. Hardware is removed for a variety of reasons including pain, prominence, infection, non-union, and failure with removal rates ranging from 10 to 81%<sup>1</sup>. A combination of sex, older age, elevated BMI, diabetes, and tobacco have all been reported to contribute to complications necessitating removal of hardware<sup>2</sup>. While hardware removal is a common procedure, there are still risks, costs, and a complication rate reports up to 20%<sup>3,5,7</sup>.

As part of preoperative discussions, the possibility of removing hardware is discussed with the removal rates which are widely published for specific procedures. Less frequently reported on are patient demographics, risk factors and specific reasons for having to remove hardware. This retrospective review was conducted with the purpose of reporting on a large group of patients undergoing hardware removal to evaluate possible risk factors and trends in the population.

**METHODS**

An IRB was obtained and a comprehensive search of the surgical database of the senior author (PRB) was performed to find patients who had undergone removal of hardware surgical procedures in the operating room from 2006 – 2017.

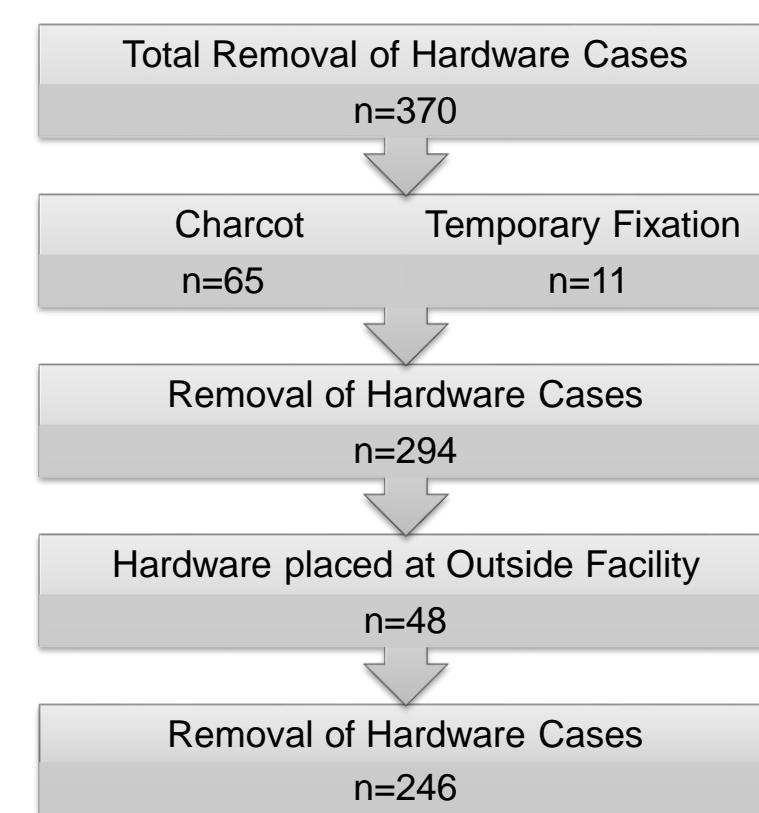


Figure 1: Exclusion Criteria

**RESULTS**

294 patients underwent hardware removal by the senior author (PRB) with demographics shown in table 1. Of the 294 patients, 48 were referred with hardware placed at an outside institution and were placed in a separate category as they had limited information available regarding the original surgery.

The hardware was in place for an average of 71.17 weeks prior to removal. 11.7% of our patient population has diabetes with neuropathy, with an average BMI of 30.4. Nicotine use in the past 5 years was reported in a high percentage of the population at 43.6%. The majority of cases included hardware at the level of the ankle, at 35.4%, followed by rearfoot at 27%, forefoot at 25.3% and midfoot at 16.1% (Table 2).

The large majority of cases were various types of arthrodesis procedures, followed in incidence by open reduction internal fixation fracture management (Table 3). Reported reasons for hardware removal (Table 4) were obtained from chart review based on patient subjective patient complaints, objective findings and review of obtained imaging.



Figure 2: Removal of painful 1st MPJ arthrodesis hardware 3 years after placement

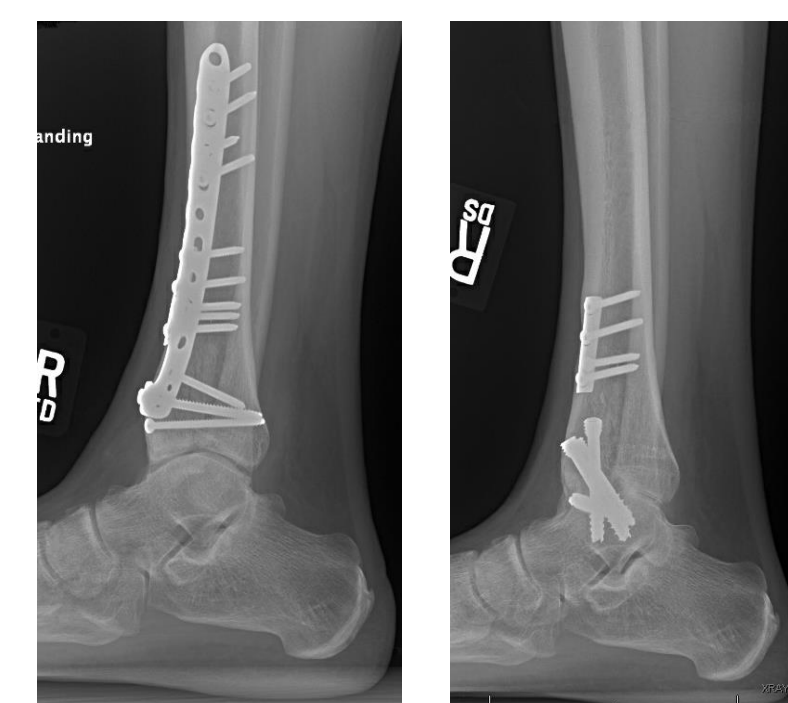


Figure 3: Pilon ORIF hardware removal for conversion to ankle arthrodesis

Patient Demographics		
	Including patients from OSH (n=294)	Excluding patients from OSH (n=246)
Mean time hardware was implanted	80.7 weeks*	71.17 weeks
Mean BMI	30.4	30.4
Diabetic with neuropathy	11.7%	11.8%
Nicotine use in past 5 years	43.6%	43.9%

Table 1: Patient demographics

Anatomic Location of Implanted Hardware		
	Including patients from OSH (n=294)	Excluding patients from OSH (n=246)
Forefoot (Distal to tarsometatarsal joints)	25.3%	26.8%
Midfoot (Tarsometatarsal joints)	16.1%	19.9%
Rearfoot (Calcaneus, talus, navicular, cuboid)	27.0%	26.4%
Ankle (Tibiotalar joint)	35.4%	30.5%

Table 2: Anatomic Location

**RESULTS (CONT)**

The presence of a wound was documented as per physical exam findings and infection diagnosis was dependent on positive intraoperative wound cultures. Most patients (93.7%) reported painful hardware during the decision to undergo removal. Pain was reported in relation to hardware failure, nonunion, or occasional prominent hardware in the appropriately placed after resolution of the postoperative edema. In the cases of nonunion, hardware was removed as part of the revision procedure. In 12.8% of hardware removal cases, the surgeon was performing a procedure in an anatomically adjacent area and required removal, or partial removal, for execution of a separate procedure.

Original Procedure		
	Including patients from OSH (n=294)	Excluding patients from OSH (n=246)
Arthrodesis	58.0%	69.5%
Osteotomy	4.1%	3.3%
Bunionectomy	5.7%	5.3%
ORIF	29.4%	21.1%
Arthroeresis	1.9%	0.8%

Table 3: Implanted hardware categorized by procedure type

Reasons for Removal of Hardware		
	Including patients from OSH (n=294)	Excluding patients from OSH (n=246)
Presence of wound	9.5%	9.3%
Infection with positive cultures	9.8%	10.2%
Painful hardware	93.7%	92.7%
HW failure (Prominent/broken)	27.8%	31.3%
Non-union	24%	27%
Removed to make room for other procedures	12.8%	8.5%

Table 4: Reasons for removal of hardware

**DISCUSSION**

Hardware removal remains a common practice among podiatric and orthopedic surgeons with underreported demographic trends and causative reasons.

The trend to maintain hardware for at least 1 year prior to removal was demonstrated with an average retained hardware time of 71 weeks, despite including infection and non-elective removals in this study. Painful hardware was the most common reason for removal at 93.7% with infection management constituting the remaining 9.8%. Considering the reported rate of diabetes with neuropathy is 11.7%, this suggests that pain was an involved factor in essentially all patients with intact protective sensation. An interesting findings was that 12.8% of cases were not related to issues with the hardware or the original surgery, but to an anatomically close separate procedure.

**DISCUSSION (CONT)**

The trends seen in patients whose hardware was placed at our own institution were seen similarly demonstrated when including the 48 patients who had hardware placed by an outside surgeon. While the 48 people were not analyzed in their own category, this does provide some confidence that our findings would translate to a larger population. There is a well reported relation between surgical complications and nicotine use which is consistent with our surprisingly high reported rate of nicotine use at 43.6%. VanPelt et al. found that patients with a BMI greater than 30, without diabetes, greater than 37 years of age, and tobacco use had complications associated with retained hardware at a higher rate<sup>2</sup>. This finding is consistent with our study which had a patient demographic of a mean age of 44 years, mean BMI of 30.4, and reported tobacco use in 43.6%.

This study will be used as a pilot and guide further research to help better understand the reasons behind hardware removal.

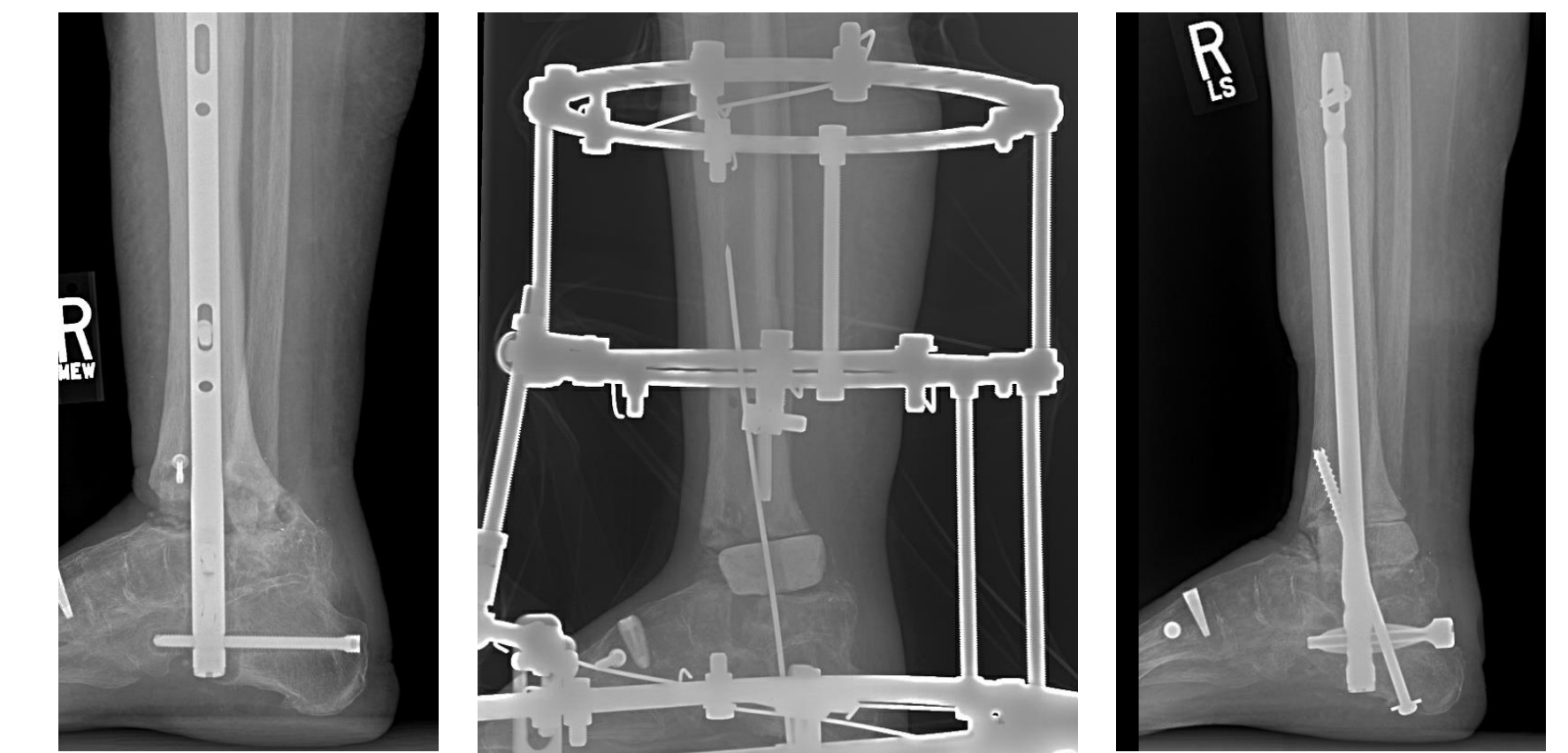


Figure 4. Case of infected intramedullary nail with staged management

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