

The Burden of Hardware Removal

1. Introduction

Historically, metal has been the most popular material for fracture fixation. Metal implants provide strong fixation during bone healing but remain in the patient's body permanently unless subsequently surgically removed. The reasons for hardware removal include pain and soft tissue irritation, deep late infection, metal allergy or toxicity, hardware migration, metal failure, and secondary fracture. The hardware removal rates reported by previous studies have varied between 12% and 80% (Partio et al. 2020). While the removal of hardware after fracture surgery is often a straightforward procedure, it can be more challenging and does not come without both its complications and costs to patients, institutions and society.

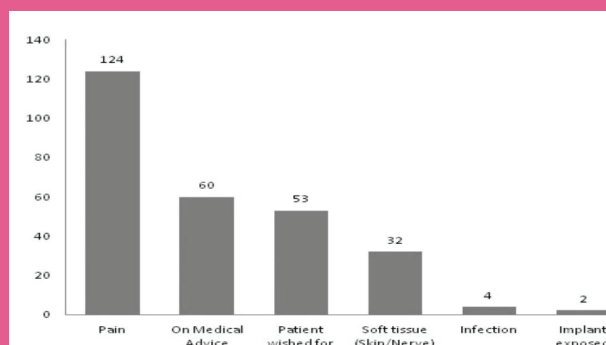
2. Reasons and complications related to metal hardware removals

When implants need to be removed, it is usually because they protrude out of the bone and cause discomfort. Plates can also interfere with tendons gliding over them, causing local inflammation, and such complications might necessitate implant removal. However, removal of fracture fixation implants after healing is a surgical operation not without risk (Aspenberg 2014). Complication rates in some studies are as high as 20% following routine removal of hardware (Fenelon et al. 2019, Partio et al. 2020). Recognized complications include anaesthetic issues, infection, neurovascular injury, pain, refracture or displacement (Fenelon et al. 2019). Postoperative complications include infections, impaired wound healing, refractures, tissue and nerve damage, postoperative bleeding, and incomplete removal (Partio et al. 2020).

On top of that patient satisfaction and symptomatic relief following removal of fracture fixation implants vary (Fenelon et al. 2019, Pot et al. 2011, Shrestha et al. 2013). According to a retrospective study by Pot et al., ankle fracture patients with hardware related pain had

significantly worse functional outcome scores than patients without hardware related pain, and after elective hardware removal, pain reduction was achieved only in 71% of the patients leaving a substantial number of patients with persistent complaints. Therefore the patient should be informed correctly about the risks and expectations of the second operation (Pot et al. 2011).

Figure 1: Indications of implants removal (Shrestha et al. 2013)



3. How common are metal hardware removals?

Implant removal is surprisingly common. As a matter of fact, implant removal procedures are one of the most commonly performed elective orthopedic surgeries (Shrestha et al. 2013).

According to Shrestha et al., orthopedic implant removal procedures accounted for 7.8% of all the orthopedic and trauma operations carried out in the Kathmandu University Hospital. In their study, the overall fracture fixation implant removal rate was 26.3%. The most common indication for implant removal was pain (45%), and the most common complication associated with the procedure was nerve injury.

Figure 2: Age wise distribution of implant removals
(Shrestha et al. 2013)

Age Distribution	Implant Removal	Age matched Total population of Fracture Fixation with orthopedic Implants	Percentage
Pediatric (≤16years)	111	321	34.5%
Young Adult (17 to 39 years)	114	407	28.0%
Middle aged (40 to 59 years)	42	215	19.5%
Elderly (≥60 years)	8	101	7.9%

In Sweden, 37,000 adult patients received metal fracture fixation implants in 2011, and 13,000 underwent implant removal. The number of adults undergoing fracture surgery in Sweden increased from 2005 to 2011 by 20 %, but removals increased by 35 %. The highest rate of removal (70%) was reported for the ankle and foot (Aspenberg 2014). Ankle fractures account for 9% of all fractures and 40% require surgical management. The ankle is the most common site of hardware removal due to the small amount of overlying subcutaneous tissue resulting in palpable or prominent hardware that can be symptomatic with foot wear and activity (Fenelon et al. 2019).

In their ten-year retrospective review of 1482 ankle fracture patients Fenelon et al. (2019) found that 13% of patients who had had ankle fracture surgery in Ireland underwent hardware removal. In the retrospective cohort study by Naumann et al. (2016), in total 17% of Norwegian ankle fracture patients had implant removal after open reduction and fixation, the majority (85%) because of subjective complaints and 15% due to infection.

4. Costs of metal hardware removals

Partio et al. (2020) recently carried out a nationwide register study covering all patients 18 years of age and older who had an ankle fracture treated with ORIF in Finland between the years 1997 and 2016. Patient data were obtained from the Finnish National Hospital Discharge Register. In total 68,865 patients had an ankle fracture treated with ORIF in Finland during the 20-year study. A hardware removal

procedure was performed on 27% of patients (n = 18,648). A notable number, 8% (n = 1,516), of hardware removal procedures were performed after 3 years. Therefore, the authors believe that previous studies have underestimated the hardware removal rate due to shorter follow-up. According to the Finnish DRG-based hospital payment pricing, the direct costs for one hardware removal are €797, and the total costs of removal procedures in Finland in 2016 were approximately €472,600. However, these numbers do not include the costs of drug prescriptions, missed work, or loss of income. Hardware removal causes significant costs to patients, hospitals, and societies through the consumption of healthcare resources and absence from work. The total economic cost of removal is difficult to evaluate due to the multifactorial nature and financing of the Finnish healthcare system.

Fenelon et al. (2019) reported the cost of hardware removal to be €1,113 per patient in Ireland. 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 (Fenelon et al. 2019).

According to the PearlDiver Patient Records Database, a database of 4.2 million orthopaedic patients and their records between 2004 and 2006 collected from a consortium of insurance companies in the United States, a secondary procedure for hardware removal after open treatment of lateral malleolar fracture is carried out in 16% of cases during the first postoperative year. A study by Lalli et al. (2015) from the United States found the average cost of syndesmosis screw removal to be \$3,579 (\$287 to \$9,981). In this figure, they included anesthesia, operating room and recovery room fees, as well as pharmacy, laboratory, and supplies costs.

5. Avoidance of hardware removals

It is clear that removal of hardware continues to be a common operation with significant costs to all involved (Fenelon et al. 2019). To reduce the costs the avoidance of secondary operations is crucial (Partio et al. 2020). Biodegradable fixation implants have been developed to

avoid secondary hardware removal. The main attraction of a biodegradable device, to both surgeons and patients, is that it provides the correct amount of strength when necessary and harmlessly degrades over time, until the load can be safely transferred to the healed bone. This means that there is no need for an additional, removal operation, reducing the total treatment and rehabilitation time of the patient. As well as the benefits to patients and surgeons, there are obvious economical advantages to avoiding an expensive removal operation.

It has taken more than 30 years to develop today's biodegradable materials and implants which are much safer and stronger than the first generation biodegradable implants. They are still not as strong as metal implants, and

therefore cannot be used in the treatment of all fractures. However, for example the Inion Freedom™ biodegradable fracture fixation implants could have a significant role in the reduction of costs related to the secondary hardware removal since the Inion implants have been shown to provide comparable fracture healing and functional results as metal implants in the treatment of ankle fractures (Noh et al. 2012, Kukk and Nurmi 2009), i.e., in the most common site of hardware removal. Although the use of biodegradable implants may not completely eliminate the need for secondary hardware removal, the frequency (2-8% according to Kukk and Nurmi) is clearly lower than the frequency after use of conventional metal implants (as discussed above).

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