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Dr. M Meenakshi Rakesh
Department of Orthopaedics, Saveetha Medical College and Hospital, Thandalam, Chennai, Tamil Nadu, India

Dr. G Arjun Krishnan
Department of Orthopaedics, Saveetha Medical College and Hospital, Thandalam, Chennai, Tamil Nadu, India

Dr. S Nitheesh
Department of Orthopaedics, Saveetha Medical College and Hospital, Thandalam, Chennai, Tamil Nadu, India

Dr. D Raja Sujith Kumar
Department of Orthopaedics, Saveetha Medical College and Hospital, Thandalam, Chennai, Tamil Nadu, India

Dr. Yeshwanth Subash
Department of Orthopaedics, Saveetha Medical College and Hospital, Thandalam, Chennai, Tamil Nadu, India

Corresponding author:
Dr. Yeshwanth Subash
Department of Orthopaedics, Saveetha Medical College and Hospital, Thandalam, Chennai, Tamil Nadu, India

Factors predicting enhanced early clinical outcomes following elective implant removal

Dr. M Meenakshi Rakesh, Dr. G Arjun Krishnan, Dr. S Nitheesh, Dr. D Raja Sujith Kumar and Dr. Yeshwanth Subash

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Abstract
Objective: Patient-related pain is commonly observed after surgically treated fractures. Studies have examined pain and function improvements as well as complications after elective implant removal. Outcomes vary based on factors like implant location and patient characteristics. However, most patients with initial pain and dysfunction show improvements in standardized scoring systems. Previous studies relied on subjective pain scores and patient satisfaction, but newer tools like PROMIS offer better assessment. Certain questions remain unanswered, such as outcomes in terms of MCID. The study aims to predict patient-reported outcomes after elective implant removal by analyzing preoperative factors. To determine preoperative factors predictive of improvement in pain and function after elective implant removal. We hypothesized that patients undergoing orthopaedic implant removal to relieve pain would have significant improvements in both pain and function.
Methods: Retrospective cohort study. Level I Trauma Center. 36 were enrolled after consenting for orthopaedic implant removal to address residual pain. 30 were available for 3-month follow-up.
Results: Preoperative and postoperative outcome measures including Patient Reported Outcomes Measurement Information System (PROMIS) scores were compared. Preoperative scores, surgeon prediction of pain improvement were analyzed as predictors of outcomes. Median PROMIS physical function and pain interference scores and visual analogue scale significantly improved by 6, 8, and 2 points, respectively. Worse preinjury scores predicted improvement in respective postoperative outcomes. Surgeon prediction of improvement was associated with improved PROMIS pain interference, patient subjective assessment of pain improvement, and subjective percent of pain remaining at 3 months.
Conclusions: Although the primary indication for implant removal in this population was pain relief, many patients also had a clinically relevant improvement in physical function. In addition, patients who start with worse global indices of pain and function are more likely to improve after implant removal. This suggests that implant-related pain directly contributes to global dysfunction.

Keywords: elective implant removal, patient reported outcomes measurement information system

Introduction
Post-surgical fractures often lead to implant-related pain, even during routine healing. Many studies have investigated the effects of removing elective implants on pain, function, and complications. The outcomes vary depending on the reason for removal, patient characteristics, and implant location [1-3]. However, most patients experiencing pain and dysfunction tend to show measurable improvements in standardized scoring systems, such as the visual analogue scale (VAS) pain scale, short musculoskeletal functional assessment, and SF-36 [4-6]. In the past, reported data were limited to subjective pain scores and patient satisfaction, which have notable limitations. Recently, the Patient Reported Outcome Measurement Information System (PROMIS) physical function (PF) and pain interference (PI) computer adaptive tests have been developed and used in orthopedic patients to provide more informative outcomes [7-9]. The PROMIS PI domain links pain to the ability to perform daily activities and has established societal mean and standard deviation values, enhancing score interpretation. Despite these advancements, previous studies left unanswered questions for surgeons, particularly in terms of counselling patients about postoperative expectations.

The outcomes after elective implant removal were not reported based on the minimal clinically important difference (MCID), making it difficult to gauge whether the patients' improvements were noticeable and meaningful [10-13]. This study aimed to explore preoperative factors that could predict patient-reported outcomes after elective implant removal. The hypotheses were that appropriately selected patients with residual pain would experience improved subjective and objective short-term outcomes after implant removal, with quantifiable enhancements in function and pain surpassing the MCID [14-15].

Materials and Methods

We conducted a prospective cohort study involving patients who chose to undergo implant removal, with the approval of our institutional review board. The study had specific inclusion and exclusion criteria. Inclusion criteria consisted of patients above 18 years of age, who experienced pain as the primary reason for implant removal. Additionally, patients needed to have achieved clinical and radiographic healing of all fractures or reconstructive procedures associated with the implants. They were included only if they failed to experience pain relief despite trying nonsurgical treatments such as symptomatic treatment, anti-inflammatories, and physical therapy. Notably, asymptomatic patients seeking implant removal for reasons other than pain and those with planned staged implant removal were not eligible for the study. Exclusion criteria included ongoing pain at locations unrelated to the implant site, a history of implant-related infection, and current nonunion.

Patient identification and enrolment took place at the orthopaedic clinic during the appointment when informed consent for implant removal was obtained. Preoperative data collection involved various measurements and assessments, such as PROMIS PF and PI scores, VAS pain scores, and the presence of local physical examination findings like tenderness, prominence, and crepitus. Additionally, the surgeon provided their opinion on whether the patient would experience postoperative pain improvement. Follow-up data were collected three months after the implant removal surgery. This included gathering PROMIS PF and PI scores, VAS pain scores, and recording any complications that occurred. Patients were also asked to complete a questionnaire, reporting their subjective assessment of pain (whether it improved, remained unchanged, or worsened) and indicating the percentage of pain that persisted after the procedure. Statistical analysis was done with SPSS software. Mann-Whitney test was used to assess continuous variables and Chi square test was used in the comparison of categorical variables. A P value <0.05 was taken to be statistically significant.

Results

In a study involving 36 patients, 6 patients were excluded from the analysis due to insufficient follow-up, resulting in 30 patients available for data analysis. The mean age of the participants was 43 years, ranging from 18 to 79. Out of the 30 patients, there were 18 males and 12 females [figure 1]. The implants that were removed included plates, screws, intra-medullary nails, cables, and wires, which were initially placed for fracture fixation or reconstructive osteotomies. Among the implants removed, 20 were from the lower extremities and 10 were from the upper extremities. The breakdown of implant types removed is as follows: (a) screws - 13 patients, (b) plates - 8 patients, (c) intramedullary nail – 5 patients, (d) wire - 1, and (e) others - 3 patients [Table 1]. One patient had both an intramedullary nail and plates with screws. At the 3-month follow-up, 5 patients (18%) experienced complete resolution of pain, while 12 patients (42%) estimated at least 90% pain resolution. Most patients demonstrated improvement in outcome measures, but approximately one-fifth of patients experienced worsening for each outcome. The analysis showed that worse preoperative PROMIS PF, PROMIS PI, and VAS pain scores were significant positive predictors for improvement in each respective score at the 3-month follow-up.

The surgeon's prediction of pain improvement was correct 82% of the time overall. When predicting improvement, the prediction accuracy was 84% (24 out of 30 patients), while for predicting no improvement, it was 50% (3 out of 6). Preoperative prediction of improvement was significantly associated with improvements in PROMIS PI, patient subjective assessment of pain improvement, and patient percent estimate of pain remaining at 3 months. However, it was not predictive for improvement in VAS pain scores. Palpable implants associated with tenderness and/or crepitus were present in 21 patients (70%), but this factor was not predictive for changes in PROMIS PF, PROMIS PI, VAS pain, patient assessment of pain improvement, or percent of pain remaining at 3 months [Figure 2]. Only one patient (3%) experienced complications associated with the implant removal procedure, including postoperative infection treated with surgical debridement and postoperative neuropathic pain that persisted at the 3-month follow-up

Discussion

The topic of removing orthopaedic implants after a fracture has healed has always been a matter of discussion. This is primarily due to the ever-evolving field of biomechanics in internal fixation, with the continuous development of newer and improved fixation devices. Additionally, the criteria for implant removal have never been clearly documented. However, it is widely accepted that the removal of implants in situ is necessary when complications arise after the fracture has healed. These complications may include pain in the area surrounding the implants, postoperative infection, fractured implants, or when adjacent vital structures are affected. Nevertheless, the removal of implants is not without its own set of challenges, such as potential neurovascular injuries, particularly when performed by less experienced team members, as well as the risks of re-fracture and wound sepsis.

A significant majority of patients requiring implant removal were men, comprising 85.5% of the cases. Shrestha *et al* also observed a predominance of males in their retrospective series, with 189 out of 275 patients (72%) being male [8]. However, their study included children as well. Abidi *et al*. examined 40 patients with implant-related pain necessitating removal, of which 30 (75%) were males [7]. These findings strongly suggest a notable male bias in the need for implant removal surgeries. The most common reason for implant removal in our study was pain or discomfort associated with the implant, accounting for 39.75% of cases. Brown *et al* discovered that 31% of patients undergoing open reduction and internal fixation of ankle fractures experienced persistent lateral pain. Additionally, only 11 out of 22 patients who had their hardware removed reported pain improvement [4]. In a prospective study by Minkowitz *et al*. all 60 patients who underwent implant removal for hardware pain reported satisfaction at the one-year follow- up [1]. While our primary focus was not to evaluate the outcomes after removal, all our

patients experienced some relief in hardware pain at the four-month follow-up, with complete relief observed in approximately 44% of cases. There was a statistically significant improvement in the average pain Visual Analog Scale (VAS) scores following implant removal. The indications for removing orthopaedic implants will always remain a topic of debate. In our study, patients with peri-implant pain experienced relief from severe pain after their operations. No intraoperative factors could explain their symptoms. Objectively, the visual analog pain score improved from 6.3 before the operation to 1.0 at one-month post-operation, and the patients remained pain-free since then. This finding is consistent with the results of Minkowitz *et al*., who reported a significant decrease in pain scores from an average of 5.5 to 1.3 in their study, along with an overall improvement of 76% at one year of follow-up. However, a separate report by Busam *et al*. cautioned that the effectiveness of implant removal for pain is unpredictable and depends more on the type and location of the implant rather than the removal procedure itself, which contradicts the optimistic findings observed in our study and the study by Minkowitz *et al*. [11].

Our series demonstrates that elective removal of implants in appropriately selected patients experiencing residual pain can result in significant improvements in function and pain, with a low likelihood of complications. On average, there were significant improvements in PROMIS PF, PROMIS Pl, and VAS pain scores from before the surgery to the 3-month follow-up. Approximately 75% of patients reported improvement in both PROMIS PF and PI scores, while around 20% experienced worsening. When considering the clinical relevance for individual patients, more than half of them showed scores that improved beyond the minimum clinically important difference (MCID), about one-third remained within the MCID range, and approximately one-tenth experienced a worsening greater than the MCID (which may not be directly linked to the implant removal itself). These results can be taken into account when counselling patients prior to the surgery regarding the expected outcomes of implant removal. It is worth noting the incidence of patients who worsened from before the surgery to 3 months after the surgery when discussing the risks of implant removal during the Informed consent process. Contrary to expectations, worse preoperative function and pain scores were associated with greater improvement in both function and pain at the 3- month follow-up. This suggests that painful implants can significantly impact overall function and pain levels. It is important to consider that longer follow-up periods could reveal symptom relapse, subjective differences in patient outcomes, or potentially improved pain and function in the 20% of patients who reported worsening of symptoms. We chase a 3-month follow-up duration as we believed it allowed sufficient time for patients to recover from the surgical procedure and enabled the quantification of changes directly related to the implant removal Extending the follow-up period might introduce additional confounding factors. Another limitation of the study is the heterogeneity of the patient group. There were no exclusion criteria based on demographic or medical factors, and implant removals from all locations were included. Therefore. It is challenging to use our data to counsel specific subsets of patients based on individual characteristics Furthermore, our study's conclusions must be considered within the context of our inclusion criteria. The findings cannot be generalized to patients undergoing implant removal for reasons other than pain alone, such as planned staged removal or infection, Additionally, patients were only enrolled after obtaining informed consent for implant removal, so there may have been patients in the orthopaedic clinic with residual pain and retained implants who either were not offered surgery or did not consent to it. Our study lacks information about those patients, preventing us from drawing conclusions about the factors that differentiate patients who undergo implant removal from those who do not. Thus, surgeons should not rely on our data to determine whether a patient should be offered implant removal but rather use it to counsel patients whom they already consider suitable candidates for the procedure. In conclusion, this study provides valuable information for surgeons to discuss the expected outcomes of elective implant removal with patients who still experience residual pain. Surgeons expectations generally appear to be reliable predictors of outcomes. While pain improvement is the primary motivation for these patients to undergo surgery, functional improvements are often achieved as well, and the risk of complications is minimal.

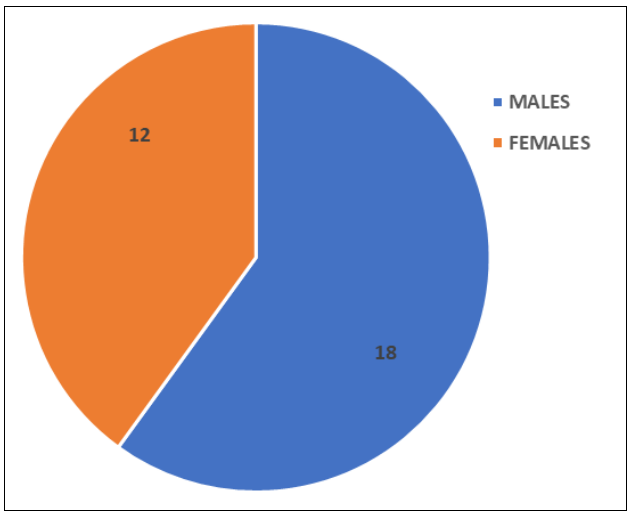

Fig 1: Distribution of gender of the study participants.

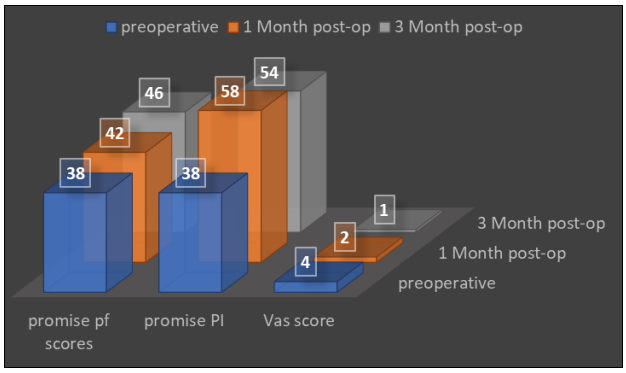

Fig 2: Analysis of Preoperative Versus 1-Month post op, 3-month post op Patient-Reported Outcomes.

Table 1: Types of Implants Removed

Type of Implant	No. of Patients
Screw	13
Plate	8
IMIL nail	5
Wire	1
Others	3

Table 2: Patient demographics and data

S. No	Age/sex	comorbidities	Location	Fracture	Implant type	Sno	Age/sex
1	44/M	DM type 2	Right tibia	Shaft fracture	IMIL Nailing	1	44/M
2	40/M	HTN	Left femur	IT fracture	PFNA-2	2	40/M
3	38/M	`NIL	Right humerus	Shaft fracture	ORIF WITH PO	3	38/M
4	37/M	NIL	Right clavicle	Shaft fracture	ORIF WITH PO	4	37/M
5	41/M	NIL	Right radius and ulna	Shaft fracture	ORIF WITH PO	5	41/M
6	47/F	NIL	Right tibia	Shaft fracture	IMIL Nailing	6	47/F
7	48/F	HTN	Left clavicle	Shaft fracture	ORIF WITH PO	7	48/F
8	48/F	NIL	Left femur	Shaft fracture	IMIL Nailing	8	48/F
9	35/F	HTN	Left clavicle	Distal 1/3rd fracture	ORIF WITH PO	9	35/F
10	35/F	NIL	Right femur	IT fracture	PFNA-2	10	35/F
11	38/F	NIL	Right clavicle	Mid shaft fracture	ORIF WITH PO	11	38/F
12	37/M	NIL	Left tibia	Shaft fracture	IMIL Nailing	12	37/M
13	39/M	NIL	Left femur	IT fracture	PFNA-2	13	39/M
14	32/M	NIL	Right femur	Shaft fracture	IMIL Nailing	14	32/M
15	32/M	DM type 2	Left femur	IT fracture	PFNA-2	15	32/M
16	34/M	NIL	Right femur	Shaft fracture	IMIL Nailing	16	34/M
17	33/M	NIL	Right femur	IT fracture	PFNA-2	17	33/M
18	44/M	NIL	Right tibia	Shaft fracture	ORIF WITH PO	18	44/M
19	45/F	HTN	Left clavicle	Shaft fracture	ORIF WITH PO	19	45/F
20	47/F	NIL	Left clavicle	Shaft fracture	ORIF WITH PO	20	47/F
21	47/F	NIL	Left tibia	Shaft fracture	ORIF WITH PO	21	47/F
22	50/F	NIL	Right femur	Shaft fracture	IMIL Nailing	22	50/F
23	49/M	NIL	Right tibia	Shaft fracture	ORIF WITH PO	23	49/M
24	48/M	DM type 2	Right femur	IT fracture	PFNA-2	24	48/M
25	48/M	NIL	Left femur	Shaft fracture	IMIL Nailing	25	48/M
26	47/M	NIL	Left tibia	Shaft fracture	IMIL Nailing	26	47/M
27	46/F	NIL	Left clavicle	Shaft fracture	ORIF WITH PO	27	46/F
28	45/F	NIL	Left tibia	Shaft fracture	ORIF WITH PO	28	45/F
29	49/M	DM type 2	Right clavicle	Shaft fracture	ORIF WITH PO	29	49/M
30	50/M	NIL	Right tibia	Shaft fracture	ORIF WITH PO	30	50/M

Conclusion

Although the primary indication for implant removal in this population was pain relief, many patients also had a clinically relevant improvement in physical function. In addition, patients who start with worse global indices of pain and function are more likely to improve after implant removal. This suggests that implant-related pain directly contributes to global dysfunction.

Declarations

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Conflict of interest: None declared
Ethical approval: Not required

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