



Complications of implant removal in ankle fractures

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ABSTRACT

Background: Although the complications of internal fixation in ankle fractures are well-known in a number of reports, there have been few reports revealing the complications of implant removal in ankle fractures. The aim of this study was to investigate the perioperative complications of implant removal in ankle fractures and analyze the associated factors of such complications.

Methods: Patients who underwent open reduction and internal fixation using metal implants for ankle fractures and had their implants removed between 2010 and 2015 were enrolled in the study. We investigated the rate and details of perioperative complications and collected information on the possible risk factors including the age, comorbidities, fracture type, number of skin incisions, operative time, and surgeon's grade from the medical charts.

Results: A total of 80 patients were included for analysis. Perioperative complications occurred in 11 patients (14%) including arterial injury in one patient, blistering in three, nerve injuries in three, skin necrosis in two, and infection in two. In patients with perioperative complications, the rate of patients with peripheral vascular disease and multiple skin incision was significantly higher (18% vs 3%, $p = 0.031$ and 64% vs 32%, $p = 0.042$, respectively) and the operative time was significantly longer (102 min vs 57 min, $p < 0.001$) than those without perioperative complications.

Conclusion: The indication of implant removal in ankle fractures should be considered carefully, especially in patients with possible risk factors and without implant-related symptoms, due to the high incidence of perioperative complications.

1. Introduction

Ankle fractures are one of the most common types of fracture, and internal fixation is often the surgical treatment of choice due to its generally positive outcomes.^{1,2} However, patients with a metal implant in the foot and ankle region would likely be symptomatic due to the limited amount of soft tissue cushioning, interference with the shoe wear, and demands of weight-bearing activities.³ Implant removal is usually performed for these symptomatic patients and sometimes done for asymptomatic patients according to the patient's request or surgeon's recommendation. Since there are complications in implant removal, including neurovascular injury, refracture, wound healing problem, infection, or retained implant, the appropriate indication for implant removal remains a controversy. While there have been many reports on the complications of internal fixations for ankle fractures, a limited number of reports have focused on the complications after the removal of these metal implants.^{3–8} Moreover, these reports were not referring to the risk factors of the complications of implant removal.

Therefore, the purpose of this study was to gather information on the prevalence of perioperative complications associated with implant removal in ankle fractures and investigate their risk factors.

2. Patients and methods

2.1. Study design

We conducted a retrospective study on patients who underwent open reduction and internal fixation for AO43 and AO44 ankle fractures with subsequent implant removal between 2010 and 2015 in a single teaching hospital. The physicians recommended proactive implant removal for symptomatic patients while implant removal was performed according to the patient's request or surgeon's recommendation for asymptomatic patients. Written informed consent was obtained from all subjects for the data use in research.

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2.2. Surgery

The same skin incision site as the initial surgery was used during the implant removal. A cast was not used postoperatively, and the patients were allowed to walk on the day of surgery with full weight-bearing as tolerated.

2.3. Data collection

The following information about the patients' demographic data and risk factors were collected from the medical charts: age, sex, body mass index (BMI), indication for implant removal, comorbidities (hypertension, diabetes, peripheral vascular disease, and obesity), period from the initial operation to implant removal, history of smoking and alcohol use, fracture type (AO43/AO44), number of skin incisions, operative time, and grades of surgeon who performed the implant removal. Obesity was defined as a BMI ≥ 25 kg/m². The surgeon's grades were divided into two categories according to the certification system of an orthopedic specialist in Japan: a non-specialist, less than six years of experience as an orthopedic surgeon, and specialist, six years or more of experience as an orthopedic surgeon. Complications which occurred within a month after implant removal were considered as perioperative complications, and their outcomes were observed.

2.4. Statistical analysis

Continuous variables were expressed as mean with range. The Student's *t*-test was used to determine significant differences in comparison of continuous variables between the two groups. Proportions were summarized using counts and percentages. Pearson's Chi-square test or Fisher's exact test was conducted for univariate comparisons of the proportions between the two groups. All statistical analyses were performed using JMP Pro version 13.2 (SAS Institute Inc., USA). The level of significance was set at $p < 0.05$.

3. Results

3.1. Patients' demographic data

A total of 80 patients were included in the study. The patients' demographic data were summarized in Table 1. The indications for implant removal were as follows: patient's request in 55 asymptomatic

Table 1
Demographic characteristics of patients with implant removal in ankle fractures (N = 80).

Age (years)	41 (16–78)
Sex	
Male	48 (60%)
Female	32 (40%)
Comorbidities	
Diabetes	4 (5%)
Hypertension	12 (15%)
Peripheral vascular disease	4 (5%)
Obesity	16 (20%)
Habit	
Alcohol	20 (25%)
Smoking	15 (19%)
Fracture type	
AO43 A - B - C	5 - 10–5 (25%)
AO44 A - B - C	5 - 45–10 (60%)
Number of skin incision	
1	51 (64%)
2	29 (36%)
Operative time (min)	63 (10–251)
Period from initial operation (months)	16 (2–236)
Grades of the surgeon	
Non-specialist	77 (96%)
Specialist	3 (4%)

patients, implant-related symptoms in 21 patients, and surgeon's recommendation in four patients with syndesmotic screws. All patients were relieved of their implant-related symptoms after the implant removal.

3.2. Complications

Complications occurred among 11 out of 80 patients (14%), including arterial injury in one patient, nerve injury in three, skin necrosis in two, blistering in three, and infection in two. Among the 55 patients who underwent surgery per patients' request, 7 of them developed complications. Complications were noted in 4 out of 21 patients who had surgery based on implant-related symptoms. There were no complications in four patients who underwent surgery according to the surgeon's recommendation. The injured artery was an anterior tibial artery and was successfully sutured intraoperatively without circulatory deficit afterwards. The injured nerve was a superficial peroneal nerve in all three cases. No cases of refracture were noted. Complete recovery was noted without further surgical interventions except for 2 out of 3 patients with nerve injuries where dysesthesia remained (Table 2).

3.3. Risk factors

No significant differences were noted in age, sex, diabetes, hypertension, obesity, alcohol, smoking, fracture type, period from internal fixation to implant removal, and surgeon's grades between patients with and without complications. The proportion of patients with multiple skin incisions and peripheral vascular disease was significantly higher and the operative time was significantly longer in patients with complications than in those without complications (64% vs 32%, $p = 0.042$; 18% vs 3%, $p = 0.031$; 102 min vs 57 min, $p < 0.001$, respectively) (Table 3).

4. Discussion

Because the soft tissue around the ankle is thin and the ankle is a highly mobile weight-bearing joint, implant-related pain after surgery for ankle fracture is common.⁹ Jacobsen et al. conducted a retrospective study of 66 cases of metal removal after malleolar fractures and reported that 75% of symptomatic patients improved after implant removal.¹⁰ Williams et al. reported in their prospective study of 69 cases of implant removal in the foot and ankle that 91% of the symptomatic patients reported satisfaction after implant removal.³ In a prospective study investigating the outcome of routine implant removal after 56 ankle and 24 distal tibia fractures, Jung et al. reported that routine implant removal relieved implant-related pain and improved the patient's activities of daily living and satisfaction.¹¹ These previous studies were consistent with the present study which showed that implant-related symptoms improved after the implant removal in all symptomatic patients. Although the implant removal is a recommended procedure for implant-related symptoms in ankle fractures backed by these reports, there is no consensus on the issue of implant removal in asymptomatic cases due to the lack of adequate information about its complications.¹²

There are a limited number of previous reports about the complications of implant removal in cases of ankle fractures^{3–8} (Table 4). The complication rate in the present study was 14%, and the complications included arterial injury, nerve injury, skin necrosis, blistering, and infection. The retrospective study on the complications of metalwork removal in 188 patients by Sanderson et al. reported that 11 out of 75 patients (15%) with ankle fractures had complications. All reported complications were infections. The operations were performed by surgeons with varying grades, and all the nerve injuries, though they were not the cases of ankle fracture, were reportedly caused by unsupervised junior surgeons.⁴ The observations on the routine removal of metal implants in 86 patients by Richards et al. reported no complications in

Table 2
Summary of 11 patients with complications of implant removal in ankle fractures.

No.	Age	Sex	Complication	Indication	Outcome	Comorbidity	Habit	Fracture type	No. of skin incision	Operative time (min)	Period from initial surgery to implant removal (months)	Surgeon
1	27	F	Arterial injury	Request	Improved	–	SM	43C	2	251	15	N-S
2	70	F	Nerve injury	Request	Improved	HT	–	43A	2	68	15	N-S
3	46	M	Nerve injury	Request	Residual dysesthesia	–	–	44B	2	66	16	N-S
4	43	M	Nerve injury	Request	Residual dysesthesia	–	–	44C	1	54	13	N-S
5	33	M	Skin necrosis	Request	Improved	–	–	43A	1	126	18	N-S
6	46	M	Skin necrosis	Symptom	Improved	HT PV OB	AL	44B	2	69	15	N-S
7	37	F	Blistering	Symptom	Improved	–	–	43C	2	185	11	N-S
8	38	F	Blistering	Request	Improved	–	SM	43B	2	137	13	S
9	78	F	Blistering	Symptom	Improved	HT PV DM	–	44B	2	65	21	N-S
10	49	M	Infection	Request	Improved	–	AL SM	44B	1	38	12	N-S
11	20	M	Infection	Symptom	Improved	–	–	44B	1	67	13	N-S

Request, Patient's request; Symptom, Implant-related symptom; HT, Hypertension; PV, Peripheral vascular disease; OB, Obesity; DM, Diabetes; AL, Alcohol; SM, Smoking; N-S, Non-specialist; S, Specialist.

Table 3
Univariate comparison of possible risk factors between groups with or without complications.

	Patients with complications (n = 11)	Patients without complications (n = 69)	p-value
Age (years)	44 (16–66)	41 (20–78)	0.436
Sex: Male (%)	6 (55%)	42 (61%)	0.691
Comorbidities (%)			
Diabetes	1 (9%)	3 (4%)	0.503
Hypertension	3 (27%)	9 (13%)	0.220
Peripheral vascular disease	2 (18%)	2 (3%)	0.031
Obesity	1 (9%)	15 (22%)	0.330
Social history			
Alcohol	2 (18%)	18 (26%)	0.574
Smoking	4 (36%)	11 (16%)	0.107
Fracture type			
AO43 A/B/C	2/1/2	3/9/3	
AO44 A/B/C	0/5/1	5/40/9	0.213
Multiple skin incision (%)	7 (64%)	22 (32%)	0.042
Operative time (min)	102 (38–251)	59 (10–185)	< 0.001
Non-specialist (%)	10 (91%)	67 (97%)	0.315

25 patients with ankle fractures. All operations were reportedly performed by consultant surgeons or their middle grade staff.⁵ The prospective study evaluating 60 patients who underwent implant removal caused by implanted-related pain in the upper and lower extremities demonstrated no complications overall, which involved 22 ankle fractures, and provided no information on the grade of the surgeons who performed the procedures.⁷ The prospective study by Williams et al. assessing the benefits of implant removal in the foot and ankle reported two cases of infection among 69 patients (2.2%) after the implant

removal. All patients were treated by a single orthopedic foot and ankle specialist.³ The retrospective study at a single trauma center by Reith et al. reported that 13 out of 70 patients (19%) had complications after implant removal in ankle fractures, including impaired wound healing in 11%, nerve injury in 4%, and infection in 4%. They did not provide any information about the surgeon's grades.⁶ The multicenter, randomized clinical trial investigating the effect of antibiotic prophylaxis on surgical site infections after implant removal in foot, ankle, and lower leg fractures reported the overall high infection rate of 14% among 477 patients without a significant prophylactic effect of a single pre-operative dose of intravenous antibiotic. In this study, complications other than infection were not investigated, and the information about the grades of the surgeon was not provided.⁸

There are no previous reports analyzing the risk factors for complications after implant removal in ankle fractures. In the present study, multiple skin incisions, longer operative time, and peripheral vascular disease were found to be associated with the complications. Multiple previous incisions and peripheral vascular disease have been well-reported as risk factors of wound complications in general orthopedic surgeries, which are assumed to cause circulatory deficit around skin incisions.^{13–15} Longer operative time is also a well-known risk factor in a variety of orthopedic surgical procedures including internal fixation for ankle fractures.^{16–19}

Some related literature have demonstrated the association of the surgeon's grades with perioperative complications during internal fixation of ankle fractures^{16,20}; however, complications after implant removal in ankle fractures have not been elucidated due to the lack of information about the surgeon's grades, limited number of cases, and no direct comparison in literature^{3–8} (Table 4). Although there was no significant difference in the occurrence of complications between the non-specialist and specialist in the present study, it may be unsuitable to negate a significant effect of the surgeon's grades from this result

Table 4
Literature on the complications of implant removal in ankle fractures.

Study (year) [reference number]	Region	Complication rate	Details of complication	Surgeon
Sanderson (1992) ⁴	Ankle	15% (11/75)	Infection	Various
Richards (1992) ⁵	Ankle	0% (0/25)		Above middle-grade
Minkowitz (2007) ⁷	Ankle	0% (0/22)		N.I.
Williams (2012) ³	Foot & Ankle	3% (2/69)	Infection	Single specialist
Reith (2015) ⁶	Ankle	19% (13/70)	Impaired wound healing, Nerve injury, Infection	N.I.
Backes (2017) ⁸	Below the knee	14% (66/470)	Infection	N.I.
The present study	Ankle	14% (11/80)	Arterial injury, Nerve injury, Skin necrosis, Blistering, Infection	Non-specialist: 96% Specialist: 4%

N.I., no information.

because most cases were performed by non-specialists.

Following the results of the present study, we have several recommendations for the implant removal in ankle fractures. First, it is necessary above all to avoid the occurrence of implant-related symptoms in the initial surgery by being careful not to irritate or make an impingement between soft tissues and metal implant, adhesion, and unnecessary skin incision. Second, if asymptomatic patients request for implant removal, the surgeons should let them decide after possible postoperative complications are well-understood. Third, although implant removal is predisposed to be performed by young residents, an experienced surgeon should perform the procedure in cases with known risk factors or anticipated difficulties. Finally, appropriate postoperative treatment tailored to each patient's individual conditions, including adequate postoperative rest, elevation, and external fixation, is recommended in order to decrease wound healing problem.

This study has several limitations. First, this is a retrospective study that may have resulted in an underestimation of complications. Second, the surgeries were performed by multiple surgeons. Third, this study did not distinguish the types of implant removed. Fourth, the sample size was not large enough to conduct multivariate analysis in order to control the confounding variables and elucidate the direct attributable proportion of each extracted risk factors.

Despite these limitations, we believe that the findings of this study will be of interest and use in the accumulation of evidence on the complications of implant removal in ankle fractures. A large, prospective, randomized control study would be needed for further clarification on the risks and benefits of implant removal depending on individual cases.

5. Conclusion

The complication rate associated with implant removal in ankle fractures was as high as 14%. Patients with multiple skin incisions, longer operative time, and peripheral vascular disease are more likely to develop complications. The surgeons should not assume that implant removal in ankle fractures is merely a simple task but pay attention to the indication and surgical plan, especially in cases with possible risk factors.

Author contribution

Study conception and design: Kasai, Iga; *Acquisition of data:* Kasai; *Analysis and interpretation of data:* Kasai, Matsumoto, Tanaka; *Drafting of manuscript:* Kasai, Matsumoto.

Declaration of interest

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