

Titanium versus Stainless-Steel Plating in the Surgical Treatment of Distal Radius Fractures: A Randomized Trial

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Abstract

Our purpose was to compare postoperative complications and rate of plate removal in titanium and stainless-steel plating of distal radius fractures (DRF). Patients following DRF were randomly fixed with titanium or stainless-steel plates using the same plating system. Complications, second surgeries, and plate prominence were documented. A total of 41 patients were treated with stainless-steel and 22 with titanium plates. Average follow-up was 60 ± 5.6 months. There was no difference in demographics, fracture characteristics, or follow-up between the groups. Plate prominence was found in 50% of radiographs (mean distance: 1.4 mm). Four titanium plates and three stainless-steel plates were removed (11%). Mean time to plate removal was 18.4 ± 4.6 months. There was no difference in removal rates between the groups. Plate material and prominence, age, fracture comminution and smoking status were not associated with plate removal. Our results support using volar and dorsal plates regardless of the plate material.

Keywords

- distal radius
- fracture
- plate
- removal
- stainless steel
- titanium

Introduction

Intra-articular fractures of the distal radius have traditionally been treated with open reduction and internal fixation (ORIF). The last decade has seen a significant increase in the use of plate fixation for these fractures, most recently volar plates and plates used in fragment-specific fixation.^{1–3} With increased use of volar plating, certain complications are being described. Many of the complications are not unique to plating such as infection, malunion, and loss of fixation, but rupture of flexor tendons was rarely described before the advent of volar plating.⁴ Lately, multiple authors have described rupture of flexor tendons over plates used in the distal radius.^{1,5–8} Since the plates are relatively low profile with the pronator quadratus interposed between the plate and the

flexors, it is postulated that the reason for this complication may be a prominent plate edge.⁹

The use of titanium in extraosseous implants and specifically in distal radius plating systems has generated some concern. Clinically, the difficulty in removing the plates has been attributed to bony integration as well as mechanical binding between the titanium screw and plate.^{10,11} Furthermore, the interaction between the plates and the overlying tendons has been implicated in a greater number of inflammatory responses and attrition ruptures. These have been compared in vivo to stainless-steel plates and found to be more problematic.¹² As a result, titanium has been processed differently.¹³ The clinical significance and outcomes of these plating systems are still under study.

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The purpose of this study is to compare the complication rate—specifically the need for plate removal—with ORIF of distal radius fractures using titanium and stainless-steel plates with the same plating system.

Methods

All consecutive patients treated surgically for an intra-articular distal radius fracture in a level one trauma center were eligible for inclusion in the study. Patients were randomized into surgery with titanium or a stainless steel plating system (Synthes locking compression plate 2.4-mm distal radius system, DePuy Synthes, Raynham, MA). Randomization was performed using a list. Patients signed an informed consent before the surgery and the study was approved by the institutional review board before commencement. The surgeons were not blinded as to plate type for obvious reasons.

Patient information was accrued including age, gender, occupation, background disease, such as diabetes, hypothyroidism, rheumatoid arthritis, medications, previous surgery on the same hand/wrist, fracture characteristics; mechanism of injury, intra-/extra-articular, distal radioulnar joint involvement, number of intra-articular fragments, plate use, number of screws, use of bone graft, and type of bone graft used, external fixation, Kirschner wires (K-wires), and their location.

The surgery was performed using standard volar and dorsal approaches to the wrist. The decision whether to use volar and/or dorsal plates was based on the fracture pattern and degree of comminution as well as the quality of the bone. Following surgery, the patients were all immobilized in a wrist splint for 5 to 6 weeks but were encouraged to use their fingers. At 6 weeks the splint was removed and the patients commenced treatment for a range of motion and gradual strengthening. The patients were followed up on a biweekly basis until 3 months following surgery. Complications were documented as well as any second surgeries, especially plate removals and the reason for their removal. Patients were evaluated at an average of 48 months postsurgery and then reevaluated a year later.

Plate removal is the solution for most significant plate-related complications such as synovitis, stiffness, or tendon rupture. It was therefore used as an outcome measure. The decision to remove the plate was not based on radiographs or knowledge of plate material (though the treating surgeon was not blinded to this information and it could be found in the operative note). The decision was made clinically, usually a joint decision between the patient and the treating surgeon stemming from patient complaints such as swelling, discomfort, or limitation of motion despite adequate therapy and patient adherence.

Postoperative radiographs were examined for plate prominence. These were reviewed using a digital measurement tool (Stentor iSite picture archive and communications system, Philips Medical Systems, Cleveland, OH). On the posteroanterior views any lateral prominence was noted and measured and on the lateral view the greatest distance between the plate and the bone, either volar or dorsal, was measured. We then recorded the largest of these measurements.

Statistical Analysis

The Student and paired *t*-test were used to compare continuous variables between the two groups and the chi-square test was used for categorical variables. The Fishers exact test and the Mann–Whitney U test were used for nonparametric data.

Results

Totally, 41 patients were treated with the stainless-steel set and 22 with the titanium plating system. The average age was 54.5 (18.6), with 34 females and 29 males. There were 17 smokers (27%), 29 (46%) patients had a relevant medical history such as documented osteoporosis, diabetes or inflammatory disease. In 43% of the patients, the dominant hand was the operated hand. There were no significant demographic differences between the two groups (► **Table 1**).

A total of 46 patients (73%) were injured due to a high-energy mechanism such as a fall from a height or road traffic accident. All of the fractures had an intra-articular component. Overall, 68% of the fractures were classified as C3 fractures according to the Arbeitsgemeinschaft für Osteosynthesefragen (AO) classification system for distal radius fractures. The follow-up period for the group as a whole was 60 ± 5.6 months. There were no new cases of plate removal or other complications between the evaluation at 48 months and the final evaluation at 60 months. There was no significant difference in fracture characteristics and in length of follow-up between the two groups (► **Table 2**).

During surgery 52 volar, 1 lateral, and 2 dorsal plates were used. In eight cases combined dorsal and volar and/or lateral plates were applied. Bone graft was used in 16 (25%) of the surgeries. In 19 (30%) cases K-wires were used to supplement the plate fixation. These were all removed at 6 weeks following the surgery. In 50% of the postoperative radiographs, some degree of plate prominence was appreciated. The mean distance was 1.4 mm (1.6).

There were no malunions or nonunions. Four titanium plates and three stainless-steel plates were removed during the follow-up period (11%). Mean time to plate removal was 18.4 ± 4.6 months. Reasons for hardware removal included chronic regional pain syndrome, tenosynovitis, carpal tunnel

Table 1 Comparison between the titanium and stainless-steel cohorts

	Titanium (n = 22)	Stainless steel (n = 41)	p Value
Age in y (SD)	53.7 (20.1)	54.7 (18.2)	0.85
Gender, male (%)	25	45.5	0.14
Smokers (%)	22.7	29.3	0.57
Background disease (%)	37.5	35.3	0.63
Dominant hand = injured hand	90.9	80.5	0.47

Abbreviation: SD, standard deviation.

Table 2 Comparison of fracture and surgical characteristics between titanium and stainless-steel-plated distal radius fractures

	Titanium (n = 22)	Stainless steel (n = 41)	p Value
Mechanism of injury: high energy (%)	90	100	0.18
Fracture AO grade (C3)%	67.9	68.4	0.72
Plate prominence (SD) mm	1.6	1.3	0.2
Bone graft use	24.4	22.7	0.88

Abbreviations: AO, Arbeitsgemeinschaft für Osteosynthesefragen; SD, standard deviation.

Note: There were no differences in fracture characteristics between the two groups.

syndrome, decreased tendon excursion. In one patient there was frank tendinitis over the volar plate which was a stainless-steel plate. There was no difference in removal rates between the two groups ($p > 0.67$).

Neither plate material nor plate prominence had an effect on plate removal ($p = 0.34$). Despite this, 80% of the plates that were removed were prominent > 1.6 mm as opposed to an occurrence of plate prominence of 45.5% in the patients that did not necessitate plate removal. Age, fracture comminution, and smoking status were not related to the frequency of plate removal.

Discussion

Despite documentation of hardware-related complications (specifically tendon injury) and despite the plethora of different types of plating systems and different materials used for fractures of the distal radius, the literature on low-profile titanium plates and implants for the treatment of these intra-articular fractures remains limited.^{14,15} Van Nortwick et al discuss the difficulty in titanium plate removal due to titanium integration into the bone and mechanical binding between the titanium screw and plate.¹⁰ Other studies evaluated complications of volar plating including transient nerve injuries, loss of reduction, and tendon irritation. In all the incidence of these complications seems to be low.^{16,17}

In this study, we did not find any differences in hardware-related complications between titanium and stainless-steel plating systems. An advantage of the study is the use of the same plating system thus controlling for any effects of plate design and profile. Furthermore, we found no differences in plate prominence or other characteristics of the fracture and fixation between the titanium and stainless-steel groups. Our results are very similar to a recent study evaluating patients with distal radius fractures treated with titanium low-profile dorsal plates.¹¹ They reviewed 125 patients with displaced distal radius fractures treated with a low-profile titanium dorsal plating system. Though their follow-up period was only 1 year and

most of our plates were volar while theirs were all dorsal, the percentage of patients requiring plate removal was 8% while we removed 11%. Similarly, Wei et al in a meta-analysis found that the results of dorsal and volar plating for distal radius fractures were similar¹⁸ and Chou et al did not find differences between dorsal and volar titanium plates.¹⁹ A recent retrospective study found a plate removal rate of 9% regardless of dorsal or volar plating. This is again in tandem with our results.²⁰ It is possible that due to our relatively low rate of plate removal, we did not have enough power to detect a true effect of plate prominence. Since at the time of study design, plate removal statistics were unclear, a power calculation could not be performed before study commencement. Furthermore, despite similar values in the literature, since the decision to remove the plates remains clinical, it is likely that plate removal varies with surgeon preference and experience.

Previous studies found that plate prominence was related to plate removal.²¹ Asadollahi and Keith in a meta-analysis concluded that positioning of the plate proximal to the "watershed" line and early removal when the plates are prominent may reduce the risk of flexor tendon injuries.¹⁵

The main limitations of the study stem from the type of population being evaluated. The study was performed at a level-1 trauma center. In this patient population, follow-up may be limited since patients tend to follow-up in their communities, in general, may have poor adherence, and may completely fail to follow-up in the longer term. It is possible that further complications related to the plates occurred but were not documented in our system. Furthermore, our population was fairly homogenous consisting of a high percentage of high-energy fractures in a relatively young population with complex fractures (the vast majority grade C3 according to the AO classification system). The conclusions of this study may therefore not necessarily apply to all populations with intra-articular distal radius fractures specifically the older population with fragility fractures.

We did not identify any new plate removals between the evaluation at 48 months and the final evaluation. It may be possible to advise patients following this surgery that the majority of complications appear during the first 24 to 30 months following surgery.

The results of this study support the use of both volar and dorsal plating systems regardless of the plate material. It is possible that we are seeing these results as opposed to original studies describing tendon irritation and rupture on plates since there has been much advancement and change in the processing and design of these materials.¹³

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