



Intramedullary nailing of dislocated midshaft clavicle fractures with the Rockwood Clavicle Pin, a retrospective study

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This retrospective study evaluated the outcome after intramedullary nailing with the Rockwood Clavicle Pin (RCP) for acute displaced middle third clavicle fractures in adults.

Of 84 included patients treated for this fracture 2003-2009, 66 (79%) were evaluated. Of these, 52 (79%) were re-examined, including fluoroscopy, while 14 patients (21%) were evaluated by mailed questionnaire. Primary outcome was Constant score (CS), secondary outcomes included: Subjective Shoulder Value (SSV), healing rate at follow up, complications, and cosmetic appearance.

Patients were re-evaluated with a mean follow-up of 39 months (range 13-96). Mean CS at follow up was 90 (range 55-100) and mean shoulder function measured with the SSV was 93 (range 36-100). Three (6%) of the re-examined patients had a non-union at follow up. Twelve (18%) had wound problems, with exposure of the lateral part of the pin in five patients (8%). There were no deep infections but seven patients (11%) were treated for superficial wound infections. Breakage of the implant occurred in one case (2%).

Treatment of displaced midshaft clavicle fractures with the RCP results in good clinical outcome and a high patient satisfaction with a high healing rate. However, the technique is associated with postoperative complications.

Level of evidence: Level IV, Case series with no comparison group. Treatment study.

Keywords: Constant Score; Quick DASH; Subjective Shoulder Value; intramedullary fixation; outcome; adults

INTRODUCTION

Acute midshaft clavicle fracture is a common fracture with an annual incidence of 64 per 100,000 adults reported by Nordqvist et al. (24). Most clavicle fractures heal well with conservative treatment, but for displaced midshaft clavicle fractures, classified as type Robinson 2B, there is a risk for malunion with shortening of the clavicle which can result in mobility restrictions as well as weakness (Fig. 1) (26). Other complications are pain both at rest and during movement, non-union and cosmetic complaints (11,20,25).

Studies have indicated that operative treatment improves the short-term outcome for displaced middle third clavicle fractures (Fig 1) (17). However,

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Figure 1. — Radiograph shows a midshaft clavicle fracture with no bony contact and at least a clavicular bone width between the medial and lateral clavicle fragment and a transverse intermediary fragment.

there is no standard surgical treatment for this type of fracture and several different methods have been proposed for this type of fracture, including plates (5,27), and different types of intramedullary pins (4,8,14-16,28,32) even though both technique has its drawbacks regarding complications related to the hardware (12,31). Previous studies have favored intramedullary nailing over plate fixation (2,6,23,32), other have yielded similar outcome for the two treatment options (1,9,29). A meta-analysis of randomized control trials and observational studies comparing plate fixation with intramedullary fixation showed no difference in long-term outcome measured with Constant Score (12). Another recent meta-analysis of prospective randomized control trials demonstrated that these two methods were comparable regarding outcome and complications in the treatment of displaced midshaft clavicle fractures (31).

A recent multicenter randomized study (27) as well as a Cochrane report (18) concluded that there are limited evidence available from randomized controlled trials on the relative effectiveness of surgical versus conservative treatment for acute middle third clavicle fractures. Considering the increasing incidence of surgically treated clavicle fractures the last decades (13), there is a need to further evaluate surgical methods and so far, there are limited reports on the Rockwood Clavicle Pin (RCP) (Zimmer Biomet, Warsaw, Indiana, USA), which is a locked intramedullary nail (9,19,21,22). The advantage of a RCP compared to plates is that it provides compression and is less invasive with a smaller incision and less damage to the soft tissue.



Figure 2. — Radiograph shows a midshaft clavicle fracture treated with a Rockwood Clavicle Pin.

The purpose of this study was to retrospectively review the clinical and radiographical outcome after intramedullary nailing of displaced midshaft clavicle fractures.

METHOD

Intramedullary nailing of acute clavicle fractures with the RCP, has been used in our clinic since 2003. All charts of patients treated with intramedullary nailing for clavicle fractures at our clinic during 2003-2009 were retrospectively reviewed. A clavicle fracture was defined as acute when operated within 4 weeks. Indications for surgery were a displaced midshaft (middle 3/5th) clavicle fracture with displacement of at least one clavicular bone width between the medial and lateral clavicle fragment, classified as Robinson type 2B (Figures 1 and 2). The fractures were also divided into subgroups, simple or wedge comminuted fractures (type 2B1) and isolated segmental or segmentally comminuted fractures (type 2B2) (26). The exclusion criteria for the study population were: immature bone, open dislocation, pathological fracture, neurovascular injury, severe osteoporosis, follow-up less than 1 year, and other concomitant shoulder injuries or surgery of the shoulders. Among the 105 patients retrieved with surgically treated clavicle fractures, 21 were excluded; 6 had surgery due to non-union of conservative treated clavicle fractures, 5 patients had previous clavicle fractures, 4 patients had previous shoulder injuries, 2 were not treated with a RCP, 1 had a fracture classified as Robinson 2A2, 1 had a concomitant plexus injury caused by the trauma, 1 had a previous plexus injury and 1 had open clavicle physes, i.e. immature bone. Thus,

84 patients treated with intramedullary nailing of a displaced midshaft clavicle fracture were included in the study.

Clinical evaluation

All patients were offered to be evaluated in person by an orthopaedic surgeon and physiotherapist not involved in the previous surgery. If the patient declined to be re-examined, evaluation by a mailed questionnaire was performed.

The primary outcome was Constant score (CS) at follow up (7). A physiotherapist evaluated the shoulder and calculated the CS for the re-examined patients' both shoulders. This score is graded 0-100, where 100 is best possible score, and consists of four dimensions : pain (0-15 points), activity level (0-20 points), range of movement (0-40 points) and power (0-25 points) (7). At the follow-up examination, a regular calibrated IsoBex isometric dynamometer (Cursor, Bern, Switzerland) was used to measure isokinetic power. For the patients not willing to attend a follow-up visit the method to evaluate the CS by a mailed questionnaire described by Boehm et al was used, which has been shown to be reliable and valid (3). Patients were asked about pain, activity level, and range of motion. To assess power, patients were asked how many kilograms they could lift with the injured arm in 90 degrees.

All patients rated Subjective Shoulder Value for both shoulders (SSV ; 0-100%, 100% represents a completely normal shoulder), degree of satisfaction with the result after surgery (excellent, good, fair, poor, and unacceptable) and if they would redo the surgery (10). The aim of the study was also to evaluate the rate of non-union as well as other major and minor complications. All patients in the study were asked if they had had any complications and the charts of the patients in the study were reviewed to detect complications such as infection, re-fracture, nerve injury, skin erosion, or if they had undergone re-operation. The patients also rated the satisfaction with the scar (acceptable or unacceptable).

Radiological evaluation

All preoperative radiographs, consisted of an axillary view and antero-posterior view of the

injured shoulder, were reviewed. No radiographs of the uninjured shoulder were taken preoperatively. At follow up, the patients willing to participate in person were examined with fluoroscopy by an orthopaedic surgeon. The injured clavicle was evaluated to determine if the fracture was healed. Union was defined as bony callus bridging the fracture site.

Surgical technique

All patients were given a prophylactic single dose of 2 grams cloxacillin intravenously 30 minutes before surgery. Patients were placed in the beach chair position. Intraoperative fluoroscopy was not used. Under general anaesthesia, a 5 cm long incision parallel to the Langer lines, was made just lateral of the medial fragment of the fracture. Dividing the fibres of the platysma exposed the fracture and supraclavicular nerve branches were protected if encountered. The medial, lateral and, if suitable, intermediate fragments were identified. The medullary canal of the medial and lateral fragment was drilled and tapped to the largest size of RCP fitting the patient's medullary canal. The corresponding nail was introduced into the lateral fragment with the sharp end passing out through the posterolateral cortex of the clavicle. The skin was opened (incision about 1 cm) over the palpable tip of the pin to allow it to protrude through the skin dorsally of the acromion. The fracture was reduced by passing the pin into the medial fragment and the 2 nuts were placed on the lateral threaded end of the pin and cold welded together. The pin was then backed out of through the lateral incision and cut flush with the lateral edge of the nuts, and then advanced again into the medial fragment. The butterfly fragments were cerclaged around the pin with non-absorbable suture (Fibrewire No 2, Arthrex, USA) before closure of the operating wound with absorbable sutures (Vicryl and Monocryl, Ethicon, USA) was performed. The intramedullary nails used had a diameter of 2.5 to 4.5mm.

The extirpation of the RCP was performed with the patients in the beach chair position using general anesthesia or just local anesthesia. The pin was removed by using the medial nut wrench through the

small incision dorsally of the acromion, if possible. The incision was closed in layers with absorbable sutures (Vicryl and Monocryl, Ethicon, USA).

Rehabilitation

All patients had a collar n’cuff sling for two weeks and were allowed to use their arm for daily activities and movement below shoulder level until 6 weeks postoperatively. After approximately 6 weeks postoperatively, patients were routinely seen in the clinic and if there were signs that the fracture was healed clinically and radiographically, the patients were allowed free movement. Load was increased gradually and by three months patients were allowed full load. All patients were offered physiotherapy and given written instructions regarding rehabilitation. After extraction of the pin, after an average of 15 weeks (range 6-33), the patients were advised to avoid risk activities for 4 weeks.

The study received IRB approval from our institution.

Statistical methods

Descriptive statistics, such as counts, percentage, mean with range were used to analyze data on subjective and objective shoulder function and cosmesis. Fisher’s exact test was used to analyze

variables measured on a nominal scale between patient in the reexamined group and phone/letter interview group. The Mann Whitney U tests were used to compare continuous and ordinal variables between the two groups. Spearman rank correlation was used for investigation of correlation of continuous variables. P values of .05 or less were considered significant. Statistical analysis was performed with the statistical program SPSS for Mac 22.0 (SPSS Inc., Chicago, IL, www.spss.com).

RESULTS

Of the 84 patients included in the study, 17 patients were lost to follow-up and one declined to participate. Thus, 66 patients treated for a displaced midshaft clavicle fractures with the Rockwood Clavicle Pin were re-evaluated with the mean follow up of 39 months (range 13-96). Forty-nine patients, (74%) had a follow up time of more than 2 years. The mechanism of injury for a majority of patients was related to bicycling (30%), motorcycling accidents (20%), downhill skiing (20%). Fifty-two patients were re-examined by a doctor and a physiotherapist. Fourteen patients declined to participate in person, but completed the CS questionnaire by letter, but did not undergo fluoroscopy. The injured shoulder was compared to the uninjured shoulder. The flow of the patients through the study is illustrated in Figure 3. The demographics of the 66 patients included in the

Table I. — Baseline data for the patients included in the study

Variable *	Re-examined (n = 52)	Phone/Letter examined (n = 14)	Total (n = 66)	P-value **
Age at trauma, years	37 (15-67)	35 (17-55)	36 (15-67)	0.994
Female	13 (25%)	4 (29%)	17 (26%)	0.786
Injured dominant side	21 (40%)	7 (50%)	28 (42%)	0.555
Robinson Classification				0.375
2B1	19 (36%)	7 (50%)	26 (39%)	
2B2	33 (64%)	7 (50%)	40 (61%)	
Transverse fragment				0.462
yes	47 (90%)	12 (86%)	59 (89%)	
no	5 (10%)	2 (14%)	7 (11%)	
Time from trauma to surgery, days	9 (1-27)	8 (2-17)	9 (1-27)	0.334
Follow-up time from surgery, months	33 (13-86)	61 (36-96)	39 (13-96)	< 0.001

* Continuous data are presented as mean (range) ; categoric data as number. ** Rexamined vs. Phone/letter examined, Fisher’s exact test and Mann-Whitney U test for testing the homogeneity between the groups.

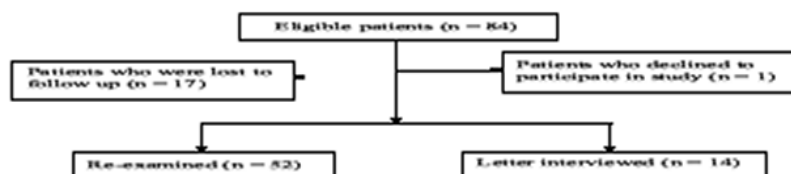


Figure 3. — Patient flow through the study.

study are presented in Table 1. The mean operating time was 75 minutes (range 25-155) and 14 minutes (range 1-40) for extirpation of the RCP.

Clinical outcome

Patients mean CS at follow up was 90 (range 55-100) and there was no statistical difference between re-examined patients and patients evaluated by questionnaire (Table 2). Four patients sent incomplete questionnaires, therefore results exist only from 62 patients. In their injured shoulder, the patients had an average of 97% (range 58-104%) of the CS of the uninjured side (CS 93 (range 74-100)). There was no significant correlation between the follow-up time and Constant score (r_s , .001, $P = 0.992$). Mean shoulder function of the injured side measured with the SSV was 93 (range 36-100). The SSV in the patients injured shoulder was in average 93% (range 36-101%) ($n = 66$) of the SSV of the uninjured side (SSV 99 (range 83-100)). Forty-five out of 52 patients (87%) were satisfied with the appearance of the scar at the time of follow-up.

Radiological evaluation

The fluoroscopy of the re-examined patients showed that 49 of 52 fractures (94%) had united. Thus, three patients (6%) had a non-union at follow up. One patient of these had pain and motion at the fracture site and chose to undergo secondary open reduction, bone graft and plate fixation. The fracture united after surgery. The other two patients declined surgery because they had minimal disability. These two patients had in their injured shoulder, 96% and 98% respectively of the Constant score of the uninjured side. The retrospective review of the charts did not reveal any cases of non-union among the patients evaluated by a mailed questionnaire, however, there may be non-symptomatic non-unions present.

Surgical complications

No intraoperative complications occurred during the fracture stabilization with the RCP. Of the 66 patients, there were 16 postoperative complications

Table II. — Clinical evaluation of subjective and objective shoulder function at follow-up

	Re-examined (n = 52)	Letter interviewed (n = 14)	Total (n = 66)	P-value *
Constant Score				
Pain ** (0-15)	14 (5-15)	15 (13-15)	14 (5-15)	0.239
Activity level ** (0-20)	18 (6-20)	19 (16-20)	18 (6-20)	0.358
Range of movement ** (0-40)	39 (18-40)	38 (34-40)	38 (18-40)	0.350
Power *** (0-25)	19 (6-25)	20 (9-25)	19 (6-25)	0.694
Constant Score *** (0-100)	90 (55-100)	92 (83-100)	90 (55-100)	0.625
SSV (0%-100%)	92 (36-100)	93 (76-100)	93 (36-100)	0.270
Number of patients who would redo the surgery ***	50 (96%)	13 (100%)	63 (97%)	1.00
Number of patients rated their result as excellent or good ***	43 (83%)	13 (100%)	56 (86%)	0.115

Values are mean (range). Constant Score : 100, best possible score ; 0, worst possible score SSV, Subjective Shoulder Value : 0%, completely dysfunctional shoulder ; 100%, completely normal shoulder. * Re-examined vs. Phone/letter examined, Mann-Whitney U test and Fisher's exact test for testing the homogeneity between the groups. ** Missing data for one letter interviewed patients. *** Missing data for four letter interviewed patients.

Table III. — Complications before and after removal of Rockwood Clavicle Pin

Number of patients *	Re-examined (n=52)	Letter interviewed (n=14)	Total (n=66)
Major			
Nonunion	3 (6%)	0	3
Deep infection	0	0	0
Refracture	0	0	0
Permanent nerve injury **	0	0	0
Minor			
Superficial infection	7	0	7 (11%)
Pin breakage	1	0	1 (2%)
Skin erosion with pin exposure	3	2	5 (8%)
Temporary brachial plexus palsy	0	0	0

* No patient experienced more than one complication. ** Not including cases of hyper- or hypoaesthesia.

(24%), including three patients (6%) with non-union, observed in 16 patients (Table 3). In five patients (8%) (4 fractures with a transverse intermediary fragment and 1 without, $P = 0.440$) the lateral part of the pin penetrated the skin during the healing period, but without signs of infection. None of these patients required revision surgery, but four patients were managed with oral antibiotics (flukloxacillin) as prevention of superficial wound infection until healing. There were no deep infections, but seven patients (11%) were also treated with oral antibiotics due to superficial wound infections without the pin penetrating the skin. Breakage of the implant occurred in one case (2%) and the medial part of the pin was left when the extirpation of the RCP was performed. In another case an unbroken clavicle pin could not be removed during surgery, only the nut was removed and the clavicle pin was left in the patient. However, the clinical outcome was satisfactory in these patients with parts of the implant left after fracture healing. The two patients had in their injured shoulder, 101% and 95% respectively, of the Constant score in their uninjured contralateral shoulder.

DISCUSSION

This study demonstrates that intramedullary nailing of patients with an acute displaced midshaft clavicle fracture with or without a transverse intermediary fragment, treated with a Rockwood pin resulted in good functional and radiographic outcome, high patient satisfaction but is associated

with several postoperative complications. This is in accordance with the literature but to our knowledge there are limited reports on the RCP and acute displaced midshaft clavicle fractures (9,19,21,22), and of these studies, we are only aware of one small study (9) with 17 patients reporting functional outcome using Constant score and two studies (19,21) with functional assessments 1 year or more, after surgery.

The clinical results from the present study are better than what has been reported by non-operative management in a large prospective, long-term follow-up study by Nowak et al. where almost half (46%) of the patients did not consider themselves fully recovered after conservative treatment (25). However, Judd and colleagues reported no differences in a prospective randomized study comparing 13 patients with acute stabilization of clavicle fractures with a Hagie pin, an intramedullary pin with a similar design to the RCP, to 14 conservatively treated patients with displacement or shortening of the clavicle more than 2 cm. Patients in their study who underwent operative treatment had statistically significant better functional scores evaluated with SSV at 3 months compared to patients in the non-operative group, but there were no significant differences between the two groups at the 6 months and one year follow up (14). Ferran et al conducted a randomized trial comparing RCP versus plating for displaced mid-shaft clavicle fractures (9). Even though the number of patients in both groups was small, 17 patients in the RCP group and 15 in the plating group, this is an important study

that concluded that both methods produced good functional results after an average of 12 months after the fracture. Mudd and colleagues reported in their retrospective case serie 14 complications in 10 out of 18 patients treated with RCP and three (17%) of these were nonunion (22). However, our results illustrate a low risk of major complications i.e. nonunion (6%), and the rate of nonunion in our study is lower than the 14% previously reported in the literature regarding non operative treatment for displaced clavicle fractures (17). There is also the possibility of non-symptomatic non-unions among the 14 patients (21%) who were evaluated by mailed questionnaire. In a retrospective study of 86 cases with clavicle fractures stabilized with RCP the rate of non-union was 3% (19) which is slightly higher than a recent randomized trial with 200 patients (27) who reported a nonunion rate of 1% for displaced fractures treated with locking plates compared to a non-union rate of 14% for patients treated conservatively in the same study. Other randomized trials report similar results evaluating the outcome of plate fixation (5,30).

A disadvantage of the RCP is that the lateral part of the tip may cause wound problems. Whether metal protruding through the skin is considered a major or minor complication can be discussed. In our study and in a previous published study, skin erosion with pin exposure was considered a minor complication because none of the infections were deep or required revision surgery and did probably not affect the clinical outcome (21). However, the rate of 8% is alarming and is in accordance with the 9% reported by Millet et al. (21) in a retrospective case serie of 58 patients treated with RCP but lower than the 50% reported by Mudd (22). To minimize the risk of this complication it is important to cut the lateral part of the pin even with the lateral edge of the nuts. In the present study there were no significant difference regarding the rate of pin exposure in fracture with or without intermediary fragment. However, there is a possibility that the RCP is more appropriate in fractures which have longitudinal stability when reduced as opposed to more complex fractures which would be more prone to shortening with an intramedullary device which may lead to skin erosion with metal with pin

exposure. In our study seven patients (11%) were also treated for superficial wound infections. Even though a benefit of the RCP compared to plate fixation is less soft tissue damage, studies on plate fixation have reported a much lower soft tissue complication rate (5,27).

Plate removal is usually only advocated when requested by the patient due to local symptoms of pain or limited range of shoulder motion related to the prominence of the plate (31). Several studies have indicated that there is a higher risk of re-fracture after plate removal compared to after intramedullary device removal (9,12,23). Even though the implant could not be removed in two patients in the present study, removing the pin was easy in most cases and was in some cases done under local anesthesia, and less traumatic compared to removing a plate after fracture healing. However, in one patient the pin broke during healing and the medial pin was left in place and in our clinic we do not routinely remove the RCP any more but due to the risk of such complication we do not recommend using the RCP with diameter of 2.5 mm. We are not aware of previous reported data regarding the cosmesis after treatment with RCP but in our study most patients rated the cosmetic result as acceptable.

We recognize several potential limitations in the study. First, it is a retrospective case serie without controls, ideally the study should also include both a plate fixation group and a conservative treated group. However, the study group is relatively large compared to previous similar studies. Second, even though patients were evaluated objectively and subjectively with validated and current questionnaires the outcome was based on patients who were re-examined and patients who declined to participate in person, and there was a difference in how the primary outcome was measured. However, when we compared the re-examined patients and those letter interviewed, the groups did not differ in results or in demographics except for follow up time. Third, there is also a possibility for attrition bias due to the rate of incomplete outcome data.

Operative treatment for acute clavicle fractures is still controversial. One reason is that studies on this type of surgical treatment cannot be directly compared with each other, not only because of

the different types of implants, but also because rigid anatomical plates are more common today compared to older reconstruction plates, as well as several different types of intramedullary pins. Not all previous studies have reported fracture classification and some studies includes both non-displaced and displaced clavicle fractures. However, if surgery is indicated, intramedullary nailing with RCP offers a technique with good clinical and radiographic outcome. Whilst the results are satisfactory we cannot from the results from this study conclude if this technique is equivalent let alone superior to other treatment options i.e. plate fixation.

CONCLUSIONS

Intramedullary nailing of acute clavicle fractures with the RCP results in good long-term functional results and high patient satisfaction but is associated with several postoperative complications. However further prospective studies are needed to determine which fractures that benefit from surgery, how to minimize postoperative complications, and when to nail and when to use other surgical methods.

Authors' Contributions

Authors 1, 2, 3, 4 and 5 participated in the design of the study. Authors 1, 3 and 4 collected the data and Author 2 and 3 analyzed it. All the authors participated in the writing of the manuscript and read and approved the final version.

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