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ORIGINAL STUDY

Surgical treatment of displaced clavicle fractures with a novel intramedullary device; comparison of less-invasive versus standard technique

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This study compared the standard technique with a less invasive technique for implantation of Sonoma Crx device in patients with displaced clavicle fractures.

Patients were randomly allocated into two treatment groups based on the planned surgical method; Group 1 patients (n = 36) received the standard method whereas group 2 patients (n = 35) received the less invasive method originally developed by our team. Follow-up information included radiographic data, quick-DASH scoring, range of motion measurement and Constant shoulder score.

The time of operation ($p < 0.001$) and mean time of fluoroscopy were significantly shorter ($p < 0.001$) in Group 1 vs. to Group 2. The mean time of hospital stay was significantly longer in Group 1 vs. Group 2 ($p = 0.01$). The time until bony union was slightly longer in Group 1 compared to Group 2 ($p = 0.01$).

Sonoma Crx device can safely be implanted through a medial single incision with closed reduction.

Keywords: Clavicle fractures ; intramedullary fixation ; less-invasive.

INTRODUCTION

Clavicle fractures are common with an estimated incidence of 24.4 fractures per 100,000 person-years. They may occur as a result of various mechanisms including sports related accidents, multiple traumatic vehicle accidents or bicycle fall injuries with the incidence being higher among males than females and in military personnel than in normal population *(14, 5)*. More than two-thirds of patients with clavicle fractures have midshaft fractures where displacement is also far most common. *(4)*. In recent years, surgical treatment has increasingly become preferred in treatment of displaced midshaft clavicle fractures. Presence of a displaced fracture was linked to malunion or nonunion, however it is still controversial whether all displaced clavicular fractured should surgically be treated to prevent malunion *(10)*.

Recent evidence supports the use of intramedullary devices particularly in patients expecting faster recovery to return professional occupations as use of these devices was found to be associated with superior functional outcomes compared to non-operative treatment *(3)*. Sonoma CrX (Sonoma Orthopedics, USA) intramedullary fixation nail is a novel device featuring a combination of flexible

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and rigid body ensuring its optimal positioning within the medullary canal. It has also been featured with distal actuating grippers to improve fracture stability. In this randomized preliminary study, we compared standard implantation method for the Sonoma Crx device (as described by the manufacturer) with a less invasive technique we developed.

MATERIALS AND METHODS

The study was approved by local ethics committee. A prospective randomized study was undertaken in a tertiary university hospital and study participants were enrolled among patients presented with clavicle fractures between November 2009 and September 2013. Patients were considered eligible for the study if they were >18 years of age, if they admitted before 2 weeks after injury and if they had Robinson Type 2B1 and 2B2 displaced midshaft fractures with > 2 cm clavicle shortening *(12)* (Figure 1). Patients with open comminuted fractures, rib fractures or multiple fractures, pneumothorax or neurovascular injuries and those having any previous history of surgery on shoulder, arm or chest were excluded. Patients were randomly allocated into two treatment groups based on the planned surgical method; in Group 1 (n = 36, mean age: 35.22 ± 8.80, male:female ratio: 23:13) patients received the standard method for Sonoma Crx that was described by the manufacturer whereas in group 2 (n = 35, mean age: 41.82 ± 13.65, male:female ratio: 21:14) patients received the less invasive method that was originally developed by our team. Patient randomization was performed using a computer based random number generator. Operations in the medial technique group were always performed by the same surgeon whereas operations in the lateral technique group were performed by one of several surgeons from our team.

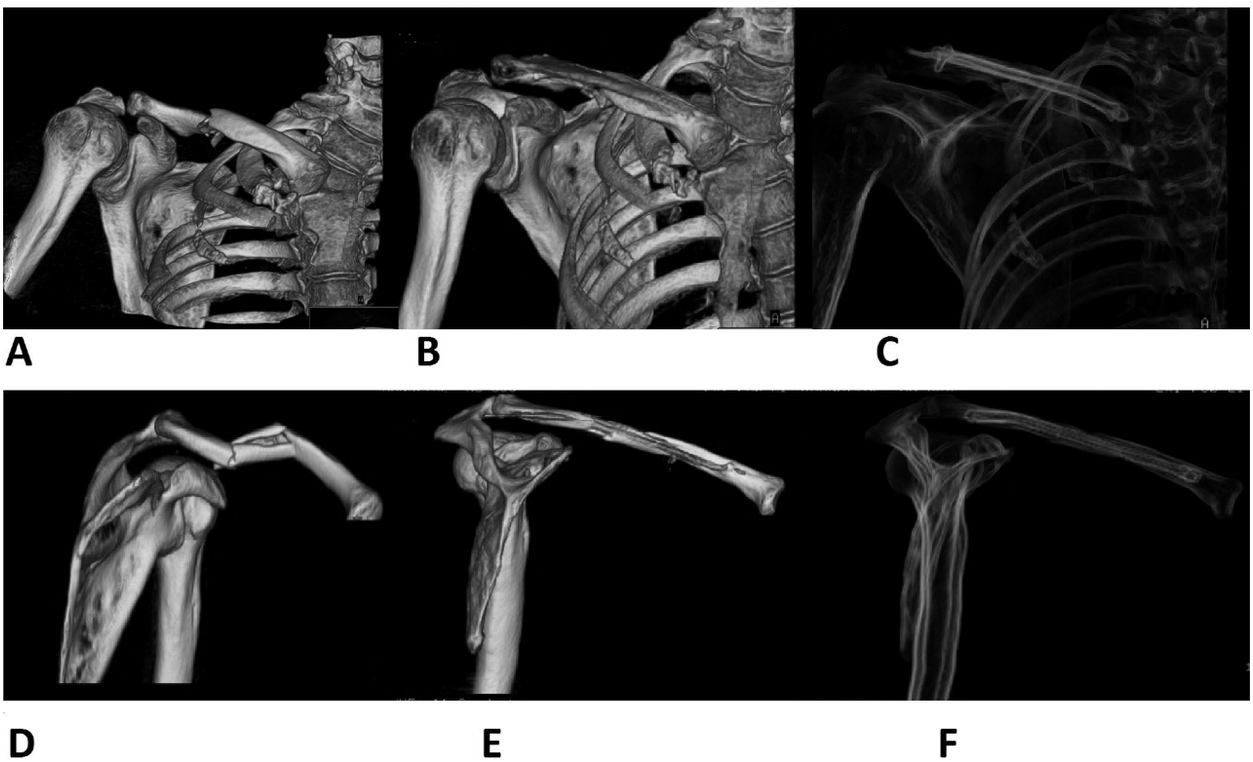

Fig. 1. — Upper three photographs show standard lateral approach in a patient with right clavicle fracture in Group 1 and lower three photographs show less-invasive medial approach in another patient in Group 2, before (left) and after (middle and right) the operation. Please note that perpendicular screw enters close to the head of the nail in both alignments

In both groups, all of the operations were performed under general anesthesia with the patient being placed in beach chair position. The patients were given 1 g of intravenous cefazolin 30 minutes before the skin incision was made.

In Group 1, Sonoma Crx was implanted as described by the manufacturer and standard surgical steps were similar to those reported in a recent study by King et al *(7)*. First, an oblique incision was made over the fracture site and the fractured ends were explored by stripping the periosteum and callus covering the fracture site. Entering from the fractured end, medial intramedullary canal was reamed towards the sternoclavicular joint (about 50 mm). An additional incision was then made just over the posterolateral aspect of the clavicle close to the claviculo-acromial joint to insert the aiming device. A flexible reamer was drilled to connect the medullary canals of two fragments. The fracture was reduced using open technique through the incision. The device was passed from lateral through medially fragments and distal actuating grippers were activated in its final position. An additional small incision was made to place a perpendicular fixation screw laterally.

In Group 2, C-arm was placed at the involved side and the surgeon stood at the contralateral side. C-arm angles were set before the operation and specific angles for optimal view at each step were recorded. A small incision (~ 1 cm) was made anteriorly and 1 cm laterally to the sternoclavicular joint. A curved cannulated awl was inserted in to the medullary canal and a ball tip guide wire was introduced (this guide avoids penetrating outside the cortex). Medullary canal of the medial fragment was reamed with a flexible reamer until the fracture site. The fracture was closely reduced and a spade tip guide was introduced into the medullary canal of the lateral fragment. Then, the lateral fragment was reamed with the burr tip flexible reamer from medial through lateral part of the fracture. (Reduction of the lateral fragment was achieved by doing shoulder maneuvers since the lateral fragment is more mobile as compared to the medial fragment. Elevating the shoulder and abducting the arm at 90 degrees allows staying away from the subclavian artery and vein). No additional incision was made over the fracture site. An appropriate sized intramedullary nail was inserted in reverse (mirror) configuration of that described in Group 1; the distal sharp tip including actuating grippers was close to the acromioclavicular joint and proximal tip to the sternoclavicular joint. Distal end of the implant was intended to be placed at least 50 mm far past the fracture site to avoid overlapping with the elastic segment. Distal grippers were then actuated and the implant was fixed with a single perpendicular screw which was inserted through the same incision made initially.

In both groups, arms at the involved sides were placed in arm slings for two weeks after the operation. Beginning on the day after surgery, all patients were encouraged to perform shoulder range of motion (ROM) exercises. Partial weight bearing was allowed 4 weeks after surgery and unlimited use of the upper limb was allowed after bony union occurred. Follow up visits were performed at 1st month and every 3 months thereafter. At least 12-month follow-up was complete in all patients and included radiographic data, quick-DASH scoring system *(6)*, ROM measurement and Constant shoulder score *(2)*.

Statistical analyses were performed with SPSS (SPSS version 16.0 Inc. Chicago, IL. USA) software. Visual and analytical methods (Shapiro-Wilk's test) were used to test normal distribution. Continuous variables were defined as mean ± standard deviations. Parameters with normal distribution were compared using t-test whereas those with non-normal distribution were compared using Mann Whitney test. Categorical data were compared using chi-square test or Fisher's exact test. A p-value of less than 0.05 was considered to be statistically significant.

An a priori sample size estimation was performed based on results reported in a recent study by King et al. *(8)* using Sonoma Crx device in midshaft clavicle fractures. The authors reported a mean Constant shoulder score of 89 (range 58-100) with a standard deviation of 13 at 3-6 month follow-up. Assuming a 10% increase in Constant scores from that reported by these authors (i.e 89 ± 13 vs. 98 ± 13), with a significance level of $\alpha = 0.05$, and $1-\beta = 0.80$, we found that 34 subjects were required in each group.

Table I. — Comparison of baseline characteristics between two groups

Variable	Group 1 (Standard approach) n=36	Group 2 (Less invasive approach) n=35	P value
Age	35.22±8.80	41.82±13.65	0.03
Male gender	23 (63.9%)	21 (60.0%)	0.73
Mechanism of injury			
Falling	26 (74.3%)	23 (63.9%)	0.34
Traffic accident	7 (20.0%)	8 (22.2%)	0.81
Sports injury	2 (5.7%)	5 (13.9%)	0.42
Right-sided involvement	17 (47.2%)	24 (68.6%)	0.06
Time to operation (days)	2.11±1.14	1.85±1.33	0.12

RESULTS

Comparison of baseline characteristics between two groups was shown in table I. Two groups were similar in terms of gender, mechanism of injury and side of involvement whereas patients in Group 2 were significantly older than those in Group 1. Time from injury to operation was 2.11 ± 1.14 days in Group 1 and 1.85 ± 1.33 in Group 2 (p = 0.12).

The study outcomes were given in Table 2. Mean time of operation (p < 0.001) and mean time of fluoroscopy were significantly shorter (p < 0.001) in Group 1 compared to Group 2. None of the patients had disability in motion and hematoma, bleeding or early implant migration did not occur. No revision operation was performed in any patient. Mean time of hospital stay was significantly longer in Group 1 compared to Group 2 (p < 0.01).

The time until radiographic bony union was slightly longer in Group 1 compared to Group 2 and the difference was at the limit of statistical significance (p = 0.01). At least 12 months of

Table II. — Comparison of study outcomes between two groups

Variable	Group 1 (Standard approach) n=36	Group 2 (Less invasive approach) n=35	P value
Mean time of operation (min)	38.05±6.20	51.20±10.56	<0.001
Mean time of fluoroscopy (sec)	12.11±1.28	27.31±4.99	<0.001
Mean days of hospital stay	3.33±1.77	2.34±0.76	0.01
Range of motion (degrees)	35.33±2.86	35.88±3.10	0.43
Quick DASH Score	8.24±2.29	3.82±1.67	<0.001
Constant Shoulder Score	94.38±5.23	92.85±4.20	0.10
Time to union (weeks)	13.55±2.65	11.97±1.91	0.01
Cosmetic dissatisfaction	12 (33.3%)	0 (0.0%)	<0.001
Skin irritation	1 (2.8%)	0 (0.0%)	1.00
Dysesthesia	2 (5.6%)	0 (0.0%)	0.49
Delayed union	1 (2.8%)	1 (2.9%)	1.00
Implant failure	2 (5.6%)	2 (5.7%)	1.00

follow-up was complete in all patients. Mean time to follow-up was 28.05±10.66 months in Group and 29.00 ± 10.24 months in Group 2 (p = 0.70).

During the course of follow-up, implant failure occurred in two patients from each group (p = 1.00). In group 1, the implant was broken due to falling down from height in one patient and due to falling to the ground after being exposed to domestic violence in the other. A shoulder sling was applied to these patients and bony union was achieved in 18 and 15 weeks respectively. In group 2, implant failure was due to premature weight bearing in one patient. The other patient with implant failure was a 67-year-old male with Alzheimer disease. Failure was due to inadequate stabilization of shoulder during recovery. Both these patients recovered without intervention.

At the latest follow-up, mean quick DASH scores were significantly higher in Group 1 compared to Group 2 (p < 0.001) whereas there was no significant difference between two groups in regard to mean ROM levels and Constant shoulder score. Cosmetic dissatisfaction was significantly more common in Group 1 than that in Group 2 (p < 0.001).

Our study was underpowered to reveal whether the technique we developed was better than the standard practice in terms of complication rates and early bony union. Based on results from the present study, a post-hoc analysis showed that a future study should at least include 95 patients in each group to achieve a 90% power or 117 patients in each group to achieve a 95% power to demonstrate the effect we found in time to bony union (13.55 ± 2.65 weeks vs. 12.40 ± 2.17 weeks, p = 0.05) at an alpha error level of 0.05.

DISCUSSION

We achieved satisfactory outcomes using a less-invasive technique for implantation of Sonoma Crx device in treatment of midshaft clavicular fractures. Patients who received this less invasive procedure stayed significantly shorter time in hospital. We think that a short incision might have caused less need to analgesics or made the patient feel more comfortable to gain freedom after the operation. Avoiding making an incision over an already being injured area; the technique never caused cosmetic dissatisfaction which occurred more than one-third of the patients who received the standard method for implantation.

Although there were no significant differences between two groups in regard to Constant Shoulder Scores and range of motion degrees, medial implantation technique provided significantly lower quick DASH scores at follow-up. Constant Shoulder score asks about objective clinical symptoms including pain, arm strength and range of motion whereas quicks DASH score is a subjective tool that mainly focuses patients' difficulty in several daily functions that need arm motions *(1)*. Thus, medial technique seems to offer better recovery of shoulder and arm functions as subjectively expressed by the patients however this superiority is not likely to be reflected by objective parameters.

The technique also seems applicable in selected patients since we never abandoned the procedure at the time of operation and thus procedural cross-over did not occur. However, our study was underpowered to detect any difference in rates of complications between the less-invasive technique and the standard technique. Nevertheless, given the low occurrence rate of complications the technique we developed does not seem to increase procedural risk to the patient.

There have been only a number of reports regarding the use of Sonoma Crx device for clavicle fractures. King et al *(8)* used the device in 47 patients with displaced clavicle fractures. The mean operation time they reported was 74 ± 16 minutes (range, 45-110 minutes) which is somewhat longer than that we achieved. In our study, it took significantly longer to implant the device using the less invasive technique compared to standard technique, which might be related with the upward slope of our learning curve although the operative team performed near-equal number of operations using each technique before undertaking this study. They *(8)* also reported a mean incision length of 49±17 mm required for implantation of Sonoma Crx over the fracture site. However, both these authors and us performed extensive stripping off the soft tissues from comminuted fragments

during standard technique. Two additional incisions were often required for implantation of Sonoma Crx which was unavoidable to achieve adequate stabilization within the bone. However, in less invasive technique, implanting the device was achievable through a single small incision (~ 1 cm) by which insertion of the final fixation screw could also be easily performed without the need for an additional incision.

There have been several other intramedullary nails and devices used for surgical treatment of displaced clavicular fractures. Among these, Herbert cannulated screw features double threads without any heads that is to be used to fix small bone fractures. In one study, Richardson et al *(11)* used Herbert cannulated screw in 114 patients and they reported satisfactory functional outcomes Wu et al *(15)* used Knowless pins in 337 patients with displaced fractures among which 19 had nonunion after the operation. The authors of the study reported that need for cerclage sutures was an independent predictor of nonunion which potentially limits its use especially in elderly. Hagie pin has also been used but not widely, possibly because of high mechanical complication rates it caused (up to 50%) in initial series *(13)*.

Titanium elastic nails are among the alternatives for intramedullary devices for surgical treatment of displaced clavicle fracture. They have begun to be used for such purposes after being established to be successful in treatment of long-bone fractures *(7)*. The procedural steps for implantation of this device are somewhat similar to that we used as the less invasive technique; medullary canal is being reamed by entering medially and fracture is being reduced without dissecting over the fracture site. Lu et al *(9)* reported a case series of 27 patients (mean age 45.8 years) having markedly displaced clavicle fractures who received titanium elastic nails. The authors reported that using the technique they encountered several complications including medial nail tip protrusion (5 patients), iatrogenic perforation of the posterolateral cortex (3 patients) and >1 cm clavicle lengthening that occurred due to distraction of the fracture site (1 patient). The authors also reported that about one-third of their patients had difficulty in medial entry point.

In our study, none of these procedural complications occurred in less-invasive group although procedural steps followed by us and by those authors were quite similar. We thus postulate that Sonoma Crx seems quite appropriate to be implanted through medial approach owing to its semi-flexible design which allows it to be passed easily beyond the fracture site.

Also, the less-invasive technique we used does not differ from the standard technique with procedural steps including drilling the medullary canal and placing the final screw being almost identical. However, entering the medullary canal medially and advancing the reamer beyond the site of fracture towards laterally require some gentle skill of the operator to avoid piercing out the bone.

The main purpose of developing a less invasive technique entailing medullary entry for implantation of Sonoma Crx was avoiding the need for fracture site dissection which might potentially improve fracture healing and thereby shorten the time required for union. We found that patients who received this technique tend to achieve union earlier but the difference was at the limit of significance. However, our results regarding "time to union" should cautiously be interpreted since second follow-up was performed at about 3-months after the operation (about 12 weeks). A six-week follow-up, which is the average union time for such type of fractures, might have produced different results. Hence, small sample size was one the major limitations of this preliminary study particularly in this regard. Second, although the investigator who assesses the radiographs was an independent observer, a flawless blinding is impossible because the nail lies in opposite configuration in radiographs. Single institution setting and short term follow-up were the other limitations of the present study.

CONCLUSION

Owing to its semi-flexible design, Sonoma Crx device can safely be implanted through a medial single incision without adding procedural risks of complications. Short-term functional outcomes are encouraging as the technique provided better subjective functional outcomes (i.e better DASH

scores) although objective functional outcomes (i.e Constant Shoulder Score) did not differ significantly.

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