SURGICAL TECHNIQUES

A NOVEL INTRAMEDULLARY LOCKED FIXATION
DEVICE FOR TREATMENT OF CLAVICLE
SHAFT FRACTURES

Paul R. King, MD, MMed(Orth), FC Orth, Carl J. Basamania, MD, Robert P. Lamberts, PhD, FECSS

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Introduction

An intramedullary nail (the Sonoma CRx) with a unique flexible anatomical design and locking system is a viable alternative for treatment of displaced and shortened clavicle shaft fractures. Displaced and shortened clavicle shaft fractures may be considered for surgical fixation to restore the anatomy and functional capacity of the shoulder. This can be achieved by using an anatomically contoured plate (extramedullary fixation) or an intramedullary nail. Recently, an innovative intramedullary nail, with a novel flexible anatomical design and unique locking system, was developed to treat clavicle shaft fractures.

Clavicle fractures are relatively common¹⁻³ in young, physically active individuals⁴. Minimally displaced fractures are generally treated conservatively, with excellent results. In contrast, conservative treatment of displaced and shortened fractures has been followed by nonunion and malunion rates as high as 15%, with their associated morbidity^{5,6}. On the basis of these findings, the management of displaced and shortened clavicle shaft fractures has evolved over the past two decades from purely supportive to a more invasive surgical approach^{7,8}. The different treatment options for displaced and shortened clavicle shaft fractures can be categorized as extramedullary and intramedullary. Although both modalities are effective, each is associated with different complications and limitations. Patients treated with the extramedullary technique can have a prominent painful subcutaneous plate and screws^{9,10}, whereas intramedullary devices can migrate and there can be soft-tissue irritation at their insertion site¹¹⁻¹³; device failure has been reported with both techniques^{10,14}. Potential advantages of intramedullary nailing are smaller surgical scars and thus potentially better cosmetic results as well as the possibility of preserving the vascularity to the bone.

Recently Sonoma Orthopedic Products, Inc., developed an innovative intramedullary device called the Sonoma CRx. This intramedullary nail is unique because of its flexible anatomical design (of the medial part of the nail)

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and locking system. The aim is to restore the anatomy of the clavicle bone through a minimally invasive technique, with the goal of preserving the blood supply to the clavicle bone and minimizing scarring. While a study comparing the Sonoma CRx nail with a traditional anatomically contoured plate has yet to be completed¹⁵, a preliminary study showed the Sonoma CRx to be a viable alternative for the treatment of displaced and shortened clavicle shaft fractures and restoration of the functional capacity of the shoulder¹⁶.

A patient who is to be treated with the Sonoma CRx intramedullary nail is positioned in the beach-chair position after administration of a general anesthetic. After the fracture site is opened, the medial and lateral fragments of the clavicle bone are prepared for the insertion of the intramedullary nail. An introduction point in the lateral fragment is created before the nail is inserted from the lateral side and passed as far as possible into the medial side of the clavicle; this is possible because of the flexible design of the device. Although the Sonoma CRx intramedullary nail is currently available in only one diameter (4.2 mm), a previous anatomical study by one of us and colleagues¹⁷ showed that the nail can be implanted in the vast majority of patients. After the nail is positioned, the locking system is activated, transforming the flexible part of the device into a rigid one. In addition, a locking screw is placed on the lateral side of the clavicle; this provides length and rotational stability as well as prevents the device from migrating. A detailed description of the steps of the surgical technique is presented below.

Indications & Contraindications

Indications

- Displaced and shortened clavicle shaft fracture requiring surgical intervention to restore the anatomy of the clavicle bone.
- Open clavicle shaft fracture.
- Clavicle shaft fracture in a polytraumatized patient.

Contraindications

- Clavicle shaft fracture extending to within 50 mm of the medial end of the clavicle bone.
- Clavicle shaft fracture extending lateral to the coracoid process or conoid tubercle.
- A medullary canal that is too small to accommodate the 4.2-mm-diameter nail¹⁷.

Step 1: Positioning

Place the patient in the beach-chair position (Fig. 1) and drape the arm free so that you can obtain an exaggerated anteroposterior and an axial fluoroscopic view of the clavicle by manipulating the position of the arm.

- Place the patient in the beach-chair position with the upper body 45° to the horizontal and the head and neck secured in a neutral position.
- Drape the arm on the fractured side free, so that you can flex and extend the shoulder. This will allow you to position the clavicle in such a way that an exaggerated anteroposterior (almost caudal tilt) view and axial view of the clavicle can be captured with fluoroscopy.
- Place the fluoroscopy machine in line with the patient, with the C-arm over the patient's shoulder and fractured clavicle. Because you can flex and extend the patient's shoulder, the position of the C-arm does not have to be changed during the surgical intervention.
- Infiltrate the surgical incision site with a mixture of epinephrine and local anesthetic to reduce bleeding at the incision site. (We used 1 mL of a 0.1 mg/mL solution of epinephrine mixed with 5 mL 0.5% Marcaine [bupivacaine] solution.)
- Drape the arm and fractured clavicle sterilely in such a way that allows access to the surgical area as well as manipulation of the arm.

Fig. 1

Fig. 1 The patient is placed in the beach-chair position.

Step 2: Skin Incision

The surgical technique necessitates opening the fracture site in order to implant the device.

- Make an incision of about 2 to 3 cm from the tip of the medial fragment and extend it laterally. The length of the incision is dictated by the fracture configuration and amount of comminution at the fracture site, but keep the incision as short as possible.
- Alternatively, an oblique incision can be made along the Langer lines over the distal tip of the medial fragment. If the incision needs to be extended medially or laterally, the incision can be “z’ed” by extending the inferomedial aspect of the incision medially and the superolateral aspect laterally. The primary advantage of the oblique incision is that it tends to heal quite well cosmetically since it does not cross the Langer lines (Fig. 2).
- Identify and preserve the branches of the supraclavicular nerves.
- Try to avoid stripping off the periosteum from the medial and lateral clavicle fragments.
- The incision should allow you access to the less mobile lateral clavicle fragment, which is secured by the coracoclavicular ligaments, and the more mobile medial fragment.

Fig. 2

Fig. 2 Image of a left shoulder and clavicle after treatment with the intramedullary nail. The scar shows the location of the transverse incision over the fracture, while the dotted line indicates the location of an alternative longitudinal incision.

Step 3: Preparing the Medial Fragment (Video 1)

The preparation of the medial fragment is of utmost importance as the intramedullary Sonoma CRx nail should be placed as far as possible into the medial fragment of the clavicle, to provide the highest level of stability and the lowest risk of device failure.

- Locate the medial fragment of the clavicle bone and maneuver the fragment to enable easy access to the medullary canal. The lateral end of the medial fragment can be grasped with a towel clip to elevate it into the incision. Placement of a Key elevator under the medial fragment decreases the likelihood of the drill or awl skiving off and going deep to the medial fragment, potentially causing damage to the underlying neurovascular structures.
- Open the medial medullary canal with a 3-mm curved awl. If needed, use a 2-mm drill to open the initial 1 cm of the medial medullary canal (Video 1). Ensure that the awl penetrates only the medullary canal and does not pass behind the clavicle bone, as this could damage neurovascular structures.
- After opening the medullary canal with the awl, gently enlarge the entry point by sliding the sharp point of the awl against the superior roof of the medullary canal. It is very important that the awl be passed with a slight oscillating movement because turning the awl in too much will cause the path through the canal to be oblong rather than round.
- Ream the medullary canal with a 4.5-mm blunt reaming awl that is curved to follow the curvature of the clavicle bone in the axial plane (Video 1). Prepare the medial fragment canal as deeply as possible—at least 5 cm past the fracture site.
- Keep fluoroscopy times to the bare minimum during the surgical procedure. (Note that the fluoroscopy times used in Video 1 were for the purposes of demonstrating the technique and are longer than would be used normally.)

Video 1 Preparing the medial fragment of the clavicle.

Step 4: Preparing the Lateral Fragment (Video 2)

Preparation of the lateral fragment is more challenging than preparation of the medial fragment because of its relative immobility and shorter medullary canal.

- Locate the lateral fragment of the clavicle bone and maneuver the fragment to enable access to the medullary canal. Although good exposure is preferred, do not violate the coracoclavicular ligaments on the inferior border of the lateral third of the clavicle during this procedure. If it is too difficult to access the canal because of the patient's head and neck, externally rotate the involved arm to bring the fragment into more of an anterior-posterior orientation rather than a medial-lateral orientation.
- Open the medullary canal again with a straight, sharp 3-mm awl. Alternatively, a 2-mm drill-bit can be passed to check the orientation of the lateral canal (Fig. 3). By flexing and extending the shoulder you can obtain an "anteroposterior" and an "axillary" equivalent fluoroscopic image. The trajectory of the drill-bit on the axillary view should be to a midpoint on the posterolateral cortex of the clavicle halfway between the conoid tubercle and the acromioclavicular joint.
- On the anteroposterior view, the drill-bit should be at the "equator" of the clavicle. The combination of these two aiming points represents the ideal exit point on the lateral fragment. Exiting too high may result in the fragments being flexed superiorly in relation to each other, and exiting too low can result in an apex inferior angulation. Exiting too far medially can cause an apex posterior angulation of the clavicle, and exiting too far laterally can result in an apex anterior angulation.
- Enlarge the canal with a straight 4.5-mm blunt awl or drill-bit (Fig. 4). Note that, in most cases, the blunt awl can be passed only about 2 cm beyond the fracture site.
- Place an aiming awl in the medullary canal and drill a Kirschner wire through the cannulated aiming device from the medial side to the lateral side of the fragment. The Kirschner wire should exit on the posterior-lateral surface at the equator of the clavicle, halfway between the conoid tubercle and the acromioclavicular joint.
- Once the wire has penetrated the skin, make a 1-cm incision that can accommodate the passage of a cannulated drill over the Kirschner wire and, at a later stage, the Sonoma CRx intramedullary nail.
- With a 4.5-mm cannulated drill-bit, open the lateral entry point in the lateral fragment over the Kirschner wire.
- Remove the Kirschner wire and pass a "flutter" flexible guidewire into the cannulated drill with only the flattened tip of the guidewire protruding from the end of the cannulated drill.
- Then pass the cannulated 4.5-mm drill-bit in a retrograde fashion to ream the lateral canal (Fig. 5). Once the tip of the drill-bit is slightly medial to the medialmost aspect of the lateral fragment, use the drill-bit to obtain a provisional fracture reduction. This is done by lifting up the patient's elbow to counteract the downward displacement of the lateral fragment due to gravity while at the same time depressing the medial fragment downward. Then pass the 4.5-mm drill-bit and guidewire a short distance into the medial fragment. Compare the diameters of the two fragments to make sure that they are equal; a difference in their diameters can represent a rotational deformity and must be corrected. Loss of length caused by fracture comminution can also result in a discrepancy in fragment diameter.
- Use the 4.5-mm cannulated drill to place the flutter flexible guidewire into the medial fragment of the clavicle bone (Fig. 6 and Video 3). Generally, this can be achieved the most easily by asking an assistant to lift up the patient's elbow while the surgeon pushes the medial fragment of the clavicle bone down.
- Once you have entered the medullary canal of the medial fragment, pass the flexible guidewire into the most medial end of the medial fragment.

- Ream the entire canal with a 4.5-mm flexible reamer under power, from the lateral side of the lateral fragment to the most medial part of the medial fragment (Video 3). Once the most medial part of the medial fragment is reached, make sure that at least 50 mm of the medial fragment has been reamed; there is a band on the flexible reamer marking the 50-mm length (Fig. 7).
- Disconnect the drill and place the measuring device over the reamer. Read the required nail length of the measuring device.
- Remove the reamer and measuring device, but not the flexible guidewire.
- Pass the insertion device over the guidewire into the lateral fragment for about 1 cm. Remove the guidewire and the inner tube of the insertion device, leaving only the guide channel in the medullary canal.
- Keep fluoroscopy times to the bare minimum during the surgical procedure. (Note that the fluoroscopy screening times used in Video 2 were for the purposes of demonstrating the technique and longer than would be used normally.)

Fig. 3

Fig. 4

Fig. 5

Fig. 6

Fig. 7

Video 2 Preparing the lateral fragment of the clavicle.

Fig. 3 Opening the lateral entry point using a 2-mm drill-bit.

Fig. 4 Enlarging the entry point using a 4.5-mm drill-bit.

Fig. 5 Opening the medullary canal of the lateral fragment of the clavicle with a 4.5-mm cannulated drill-bit.

Fig. 6 Reduction of the fracture, and positioning of the flutter wire using the drill.

Video 3 Preparing the medullary canal and placement of the nail.

Fig. 7 The fracture is held reduced while the canal is reamed with the flexible reamer.

Step 5: Placement of the Intramedullary Nail (Video 3)

Use the longest possible intramedullary nail that the clavicle can accommodate and insert the nail as far medially as possible into the medullary canal of the clavicle bone.

- Connect the selected Sonoma CRx intramedullary nail to the lateral locking jig. Make sure to use the longest possible intramedullary nail that the clavicle can accommodate.
- Insert the Sonoma CRx intramedullary nail, which is 4.2 mm in diameter, along the guide channel into the medullary canal of the lateral fragment. Once the tip of the intramedullary nail is inside the lateral fragment, remove the guide channel.
- To ensure that the intramedullary nail enters the medial fragment, reduce the fracture site with the use of reduction clamps. While doing so, gently tap on the back of the jig with a light hammer to insert the device fully into the medial side of the clavicle bone. Inserting the nail as deeply as possible into the medial fragment of the clavicle provides the optimal stability for the fracture and minimizes the risk of device failure. Note that the notch of the lateral locking screw should be placed just past the superior cortex and be visible on fluoroscopy, to ensure that the lateral locking screw can be placed.
- Take care not to insert the device so deeply that the lateral end is buried under the cortex of the clavicle as this will make removal of the device considerably more difficult.
- Keep fluoroscopy times to the bare minimum during the surgical procedure. (Note that the fluoroscopy screening times used in Video 3 were for the purposes of demonstrating the technique and longer than would be used normally.)

Step 6: Activation of the Locking Device (Video 3)

Lock the device at its medial end with distally deployed grippers and laterally with a locking screw placed through a jig.

- Once the Sonoma CRx intramedullary nail is placed in the desired position, activate its innovative locking device with use of the torque-limiting actuation driver. This activation will cause the flexible part of the nail to become rigid in the desired anatomical shape, while a set of grippers at the medial end of the nail is deployed. Turn the driver approximately twenty times until the lines on the driver handle line up with the lines on the shaft of the driver.
- Confirm full deployment of the grippers with fluoroscopy.
- Once the device is locked medially, place a drilling sleeve through the locking guide on the lateral side of the nail. This drilling sleeve will indicate the position of the lateral locking hole.
- Make a 1-cm incision at the indicated location of the lateral locking hole.
- Drill a hole using the lateral locking jig to place the lateral locking screw. Do this carefully as the drill-bit is quite thin and can become misaligned. Ensure that the locking guide is flush with the bone with no intervening soft tissue. The locking screw should engage the superior and inferior cortices of the clavicle, as this provides the best rotational stability.
- Once the locking screw is placed, replace the actuation driver in the lateral end of the nail (Video 3). If the driver engages the nail, the locking hole has been missed and should be repositioned.
- Confirm the correct placement of the Sonoma CRx intramedullary nail with fluoroscopy.

Step 7: Management of Comminuted Fracture Fragments

Comminuted fractures are not a contraindication to the use of the intramedullary device as they can be reduced by the nail and secured by using cerclage sutures.

- Hold the comminuted fracture out to length before activating the intramedullary nail and passing the interlocking screw, to ensure that the anatomical length is being restored.
- Use absorbable cerclage sutures to secure all comminuted fracture fragments to the intramedullary nail, while trying to preserve their soft-tissue attachments. While taking care not to strip off soft tissue unnecessarily, pass the suture around the fracture fragment as either a single or a double strand under direct vision. A specially designed Crego elevator in the set facilitates this.
- Suture smaller comminuted fracture fragments back onto the strut provided by the nail, again ensuring that soft-tissue attachments are preserved. Suturing small fragments back onto the nail provides bone stock at the fracture site, enabling union of even comminuted fractures.

Step 8: Postoperative Management

Protect the affected shoulder in a shoulder immobilizer for six weeks.

- The patient wears a broad arm sling for six weeks, during which time he/she performs pendulum-type exercises of the shoulder and range-of-motion exercises of the elbow six times a day. Heavy lifting and strenuous overhead activities are avoided until bridging callus is seen on follow-up radiographs.
- If bridging callus is seen on six-week postoperative radiographs, the patient is allowed to return to activities as tolerated. Since an intramedullary nail is a load-sharing device, allowing full function will facilitate healing—unlike the case with a plate, which is load-bearing. An important distinction between bone healing after use of an intramedullary device and that after plate fixation is that callus can be seen and followed on radiographs after intramedullary fixation. Because of the direct, noncallus nature of bone healing following plate fixation, healing can only be inferred based on a lack of complications such as screw loosening or plate breakage.
- Most patients have achieved a full range of motion and normal shoulder function by three months.

Results

In our original study¹⁶, forty-seven consecutive patients with a displaced and shortened clavicle shaft fracture were treated with open reduction and internal fixation using the Sonoma CRx device.

The average duration (and standard deviation) of the operation to implant the Sonoma CRx intramedullary nail was 74 ± 16 minutes, and the mean incision length (the total for the three incisions needed to implant and lock the device) was 49 ± 17 mm. The patients were divided into three groups according to whether the postoperative assessment had been performed at three to six months, six to nine months, or nine to twelve months postoperatively. All forty-seven fractures had fully united at these assessments. Two patients (4%) were diagnosed with device failure, but retrospective analysis suggested that these failures were most likely caused by a second traumatic incident (one patient) and nonadherence to the immobilization protocol (one patient). Although the device failed, both fractures united without additional intervention.

The functional capacity of the shoulder was assessed on the basis of the range of motion; the Disabilities of the Arm, Shoulder and Hand (DASH) score¹⁸; and the Constant Shoulder (CS) score¹⁹. The range of motion and DASH and CS scores were good in all three groups and did not differ among the groups. These findings suggest that displaced and shortened clavicle fractures can be treated with the Sonoma CRx intramedullary nail and that full function of the shoulder can be regained as early as three to six months postoperatively¹⁶. However, as this study was cross-sectional, no conclusions regarding changes over time could be drawn. In addition, because no patients were

treated with an anatomically contoured plate, it was also not possible to draw conclusions regarding the effectiveness of the Sonoma CRx intramedullary nail compared with traditional anatomical plate fixation.

Two of us and a colleague are currently conducting a randomized controlled trial comparing anatomically contoured plate fixation with intramedullary nailing for displaced and shortened clavicle fractures¹⁵. We randomly assigned patients to treatment with either a traditional anatomically contoured plate or a Sonoma CRx intramedullary nail. Patients were followed at twelve months postsurgery. At the time of writing, forty-seven patients (twenty-five in the anatomical plate group and twenty-two patients in the intramedullary nail group) had completed the study. Preliminary data from this cohort revealed that, on average, the nailing group had a shorter operating time (43 ± 8 minutes versus 60 ± 19 minutes, $p = 0.0029$) and a shorter incision (38 ± 9 mm versus 118 ± 19 mm, $p < 0.0001$). No failure of either the anatomical plate or the intramedullary nail was observed. The intramedullary nail group also had a lower mean DASH score (2 ± 5 versus 16 ± 18 , $p = 0.0071$) and a higher mean CS score (96 ± 6 versus 90 ± 18 , $p = 0.0122$) twelve months postoperatively. Although the trial has not yet been completed and has not reached sufficient power, the initial findings suggest that the Sonoma CRx intramedullary nail may be an effective alternative for the treatment of displaced and shortened clavicle fractures. However, there will always be a place for both plate fixation and nailing in the treatment of clavicle fractures, and that treatment choice should be based on the patient's personal profile and goals.

Pitfalls & Challenges

- Place and secure the patient in the beach-chair position so that adequate fluoroscopic images of the clavicle bone can be obtained. Before starting the surgery, make sure that you can see the medial and most lateral aspects of the clavicle using the fluoroscopy machine.
- Avoid periosteal stripping of the medial and lateral fragments, and preserve the soft-tissue attachments and blood supply of comminuted fracture fragments.
- Prepare the medial fragment canal as deeply as possible—at least 5 cm past the fracture site.
- Use the longest possible intramedullary nail to achieve the highest level of stability and lowest chance of device failure.
- Reduce comminuted fracture fragments back onto the implant and secure them with absorbable cerclage sutures.
- A special device is available for removal of the nail, which can be done with relative ease. The lateral locking screw needs to be removed, a small incision over the entry point laterally is made, and the device is deactivated. This allows the medial grippers to retract to allow extraction of the nail.

Clinical Comments

- Initial findings suggest that the Sonoma CRx intramedullary nail is a good alternative for the treatment of displaced and shortened clavicle shaft fractures.
- Preliminary data have shown that the Sonoma CRx intramedullary nail yields a good union rate with a very low rate of device migration.
- The aim of future research should be to determine the advantages of plate fixation and nailing of clavicle shaft fractures in different populations.

Paul R. King, MD, MMed(Orth), FC Orth

Carl J. Basamania, MD

Robert P. Lamberts, PhD, FECSS

Division of Orthopaedic Surgery, Department of Surgical Sciences, Stellenbosch University, Tygerberg Campus, Tygerberg, South Africa

The Polyclinic and Swedish Orthopaedic Institute, Seattle, Washington

E-mail address for R.P. Lamberts: RPLam@hotmail.com

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