J Shoulder Elbow Surg (2015) 24, e1-e6

ELSEVIER

Journal of Shoulder and Elbow Surgery

www.elsevier.com/locate/ymse

The treatment of clavicular shaft fractures with an innovative locked intramedullary device

Paul R. King, MBChB, Ajmal Ikram, FC Orth, Robert P. Lamberts, PhD, FECSS*

Division of Orthopaedic Surgery, Department of Surgical Sciences, Faculty of Medicine and Health Sciences, Stellenbosch University, Tygerberg, South Africa

Background: Displaced and shortened clavicular shaft fractures can be treated by intramedullary fixation; however, hardware migration and soft tissue irritation at the insertion site have complicated its use. The aim of this study was to determine whether the new Sonoma CRx intramedullary device (Sonoma Orthopedic Products Inc, Santa Rosa, CA, USA) could be used successfully to treat displaced and shortened clavicular shaft fractures and restore the functional capacity of shoulder without the development of secondary complications.

Methods: Displaced and shortened clavicular shaft fractures in 47 consecutive patients were treated with the CRx device. Incision size was captured during the surgical procedure. The union rate was evaluated postoperatively. Shoulder function was assessed by Disabilities of the Arm, Shoulder and Hand (DASH) score, the Constant Shoulder Score, and a range of motion score. Patients were assessed after 3 to 6 months (group I), 6 to 9 months (group II), or 9 to 12 months (group III) postoperatively.

Results: Union was achieved in all patients at the time of review, without any incidence of hardware migration. Postoperative complications developed in 3 patients, comprising infection in 1 and hardware failure in 2. No differences among the groups were found for the DASH score ($P = .33$), Constant Shoulder Score ($P = .38$), and range of motion score ($P = .96$). The DASH, Constant Shoulder, and range of motion scores were similar to other successful treatment options, such as plating.

Conclusion: The Sonoma CRx is a good alternative device to treat displaced and shortened clavicular shaft fractures and restore the functional capacity of the shoulder. Future research should focus on when nailing and plating should be used to treat clavicular shaft fractures most optimally.

Level of evidence: Level IV, Case Series, Treatment Study.

Keywords: Clavicle; collarbone; fracture; intramedullary nail; fixation; CRx

Fracture of the clavicle is a relatively common injury, thought to account for 35% of all shoulder girdle injuries in adults.[13] Shaft fractures comprise 69% of fractures, with 48% of these fractures being displaced and 19% comminuted.[18] Treatment options for clavicular fractures include nonoperative and operative approaches, depending on the severity of the injury.[13,19] In displaced fractures, for example, nonoperative treatment in a simple sling has been shown to give excellent results with low complication rates.

The study was approved by the Stellenbosch University Health and Research Ethics Committee (IRB0005239, N11/02/032) and performed in accordance with the principles outlined in the Declaration of Helsinki.

*Reprint requests: Robert P. Lamberts, PhD, FECSS, Division of Orthopaedic Surgery, Department of Surgical Sciences, Stellenbosch University, Tygerberg Campus, PO Box 19063, Tygerberg 7505, South Africa.

E-mail address: rplam@hotmail.com (R.P. Lamberts).

1058-2746/$ - see front matter © 2015 Journal of Shoulder and Elbow Surgery Board of Trustees.
http://dx.doi.org/10.1016/j.jse.2014.04.018

However, in the case of displaced and shortened fractures, operative treatment results in higher union rates, higher functional outcome scores, and fewer complications compared with nonoperative treatment.[2,8,23]

Surgical options for these more complicated fractures include extramedullary and intramedullary fixation devices. Extramedullary fixation typically involves a plate and screw construct and may take the form of a fixed-angle or a nonfixed-angle device. Intramedullary fixation may involve rigid or flexible devices in the form of rigid screw designs or flexible titanium nails, respectively.[13] Extramedullary and intramedullary fixation methods are both effective,[5,9] but each treatment modality is associated with certain concerns. For example, extramedullary fixation can be prominent subcutaneously, which might interfere with certain tasks (eg, carrying a backpack).[19,22] Conversely, intramedullary devices have been associated with fixation problems, which can lead to migration of the device and soft-tissue irritation due to protruding hardware at the insertion site.[21,22] Hardware failure has been reported in both devices.[17,22] Extramedullary and intramedullary devices are both associated with a relatively high rate of secondary surgical interventions to remove the hardware.[20]

In response to the concerns associated with existing fixation devices, a new intramedullary device for the treatment of displaced and shortened clavicular shaft fractures has recently been introduced.[14] The novelty of this device is that it has a flexible medial end, which allows it to follow the curvature of the clavicle at its medial end. The device is then activated to become rigid once the desired fracture position is achieved and to deploy grippers at its medial end to lock the device. Laterally, the device is locked with a screw placed through a jig. These design features are intended to prevent the device from migrating and to stabilize device length and rotation, thereby reducing the risk of subsequent complications.

These claims have not yet been confirmed in a controlled research setting. The main aim of this study was therefore to determine whether this new intramedullary device could be used successfully to treat displaced and shortened clavicular shaft fractures, while showing no evidence of migration in the months after surgery. To achieve this research aim, consecutive patients treated with this device in a 12-month period were monitored and assessed postoperatively for 3 months to 12 months.

Methods

Recruitment

The study recruited 47 consecutive patients with displaced and shortened clavicular shaft fractures, who were treated with the Sonoma CRx intramedullary device (Sonoma Orthopedic Products Inc, Santa Rosa, CA, USA). All patients were treated by the same surgeon at Tygerberg Academic Hospital, Cape Town, South Africa. Before participation in the study, all patients were thoroughly informed about the study and the associated risks, and an informed consent was signed before the device was implanted.

Study design

All patients who participated in the study were diagnosed with a displaced and shortened clavicular shaft fracture and were treated surgically using the innovative Sonoma CRx intramedullary device over a 12-month period. Patients were treated within 7 days of the injury, after which the shoulder was immobilized for 6 weeks in a shoulder immobilizer. During this period, patients were asked to remove the immobilizer 6 times a day and perform antigravity pendular exercises of the shoulder and range of motion exercises of the ipsilateral elbow. At 6 weeks, patients were allowed to remove the immobilizer and return to normal activities of the shoulder. No physiotherapy-guided exercise program for the shoulder was provided.

The study protocol called for the study patients to return to the hospital on one occasion, which was planned between 3 and 12 months after the surgery. On the basis of the interval between the surgery and the follow-up assessment, patients were retrospectively categorized as 3 to 6 months postoperative (group I), 6 to 9 months postoperative (group II), or 9 to 12 months postoperative (group III).

The range of follow-up times was used to provide insight into the healing capacity (union rate) with the use of the new device and, when possible, when complications with the device might tend to occur. In addition, the range of follow-up periods was intended to provide insight into how quickly functional shoulder capacity tends to be restored. During the assessment visit, standard anterior-posterior and 15° cephalad tilt radiographs were obtained. An independent radiologist reviewed these for union, loss of fixation, and hardware migration. A physical examination was used to determine whether migrated or protruding hardware was causing soft-tissue irritation.

The functional capacity of the shoulder was assessed using the Disabilities of the Arm, Shoulder and Hand (DASH) score and the Constant Shoulder Score.[3,10] Range of motion of the affected shoulder was determined and scored using the range of motion section of the Constant Shoulder Score, ranging from 0 to 40.[3] Flexion, abduction, and internal and external rotation were each graded out of 10 and scored accordingly. The Constant Shoulder Score and range of motion were determined by an independent physical therapist, whereas the DASH score questionnaire was completed during a visit to an independent occupational therapist.

Device description

The Sonoma CRx is an innovative clavicular fracture repair system that transforms from a flexible intramedullary device at insertion into a rigid fixation system after placement inside the clavicular bone. The stainless steel device consists of a solid straight hub, a flexible tubular medial section, and an internal fixation system (Fig. 1). The device is inserted into the medullary canal after reduction of the fracture. The medial flexible portion of the device follows the axial and coronal curvature of the clavicle. Once the device has been properly seated in the medullary canal and accurate fracture reduction has been achieved, the internal WaviBody (Sonoma) assembly is activated. Upon activation, the