Early Postoperative Failure of a New Intramedullary Fixation Device for Midshaft Clavicle Fractures

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abstract

The Sonoma CRx device (Sonoma Orthopedic Products, Santa Rosa, California) is a recently introduced intramedullary device with a flexible shaft that becomes rigid once actuated to allow deployment within the sigmoidal contour of the clavicular shaft. Medial intramedullary cortical purchase is obtained by grippers and lateral purchase through a locking bicortical buttressing screw. This article describes 2 cases of early hardware failure using this device. In both cases, early postoperative radiographs demonstrate adequate initial fracture reduction and implant position. Both patients sustained repeat injuries, one under low physiologic load and the other after returning to mixed martial arts 4 months postoperatively. Implant failure was noted after reinjury in both cases. Complete healing and full return to function was documented for both patients at 2 years. Proper patient selection and counseling regarding the limitations of this intramedullary fixation device are important. Biomechanical comparison of this implant to plate fixation under physiologic loads of combined axial compression and torsion may shed light on differences in fixation stability.

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Figure: Anteroposterior radiographs of the left clavicle showing injury (A) and immediate postoperative reduction and intact implant (B).
The treatment paradigm for displaced midshaft clavicle fractures is shifting from traditional nonoperative management to operative fixation for specific fracture patterns. An 86% reduction in the rate of nonunion has been reported with operative fixation of displaced middle one-third clavicle fractures. Plating has been associated with more symptomatic hardware events than intramedullary fixation. Multiple intramedullary devices have been developed and used for treatment of middle one-third clavicle fractures, offering an effective, low-profile solution to fracture fixation.

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Case Reports

Patient 1
An otherwise healthy 27-year-old man sustained a displaced middle one-third clavicle fracture during a low-speed motorcycle collision. On physical examination, a prominent deformity was noted without evidence of an open fracture or skin tenting. Radiographs demonstrated a displaced, transverse middle one-third clavicle fracture with 28 mm of shortening (Figure 1A). The patient underwent an uncomplicated open reduction and intramedullary fixation with the Sonoma CRx device 28 days after injury. Postoperative radiographs demonstrated near anatomic reduction and adequate compression at the fracture site (Figure 1B). The patient was immobilized in a sling and swath in the immediate postoperative period. Physical therapy was initiated for early range of motion at his initial postoperative visit.

Fourteen days postoperatively he reported immediate-onset pain at the previous fracture site after rolling over in bed. Repeat radiographs demonstrated diastasis at his fracture site, 30% cortical displacement with 15° of apex anterior deformity (Figure 1C), and hardware failure just medial to the fracture site. The patient was treated nonoperatively with a sling. The hardware was left in place, and repeat radiographs at 3, 4, 6, and 12 months postoperatively demonstrated a stable fracture site and progressive healing at the fracture site with continued mild deformity (Figure 1D). At more than 2 years after reinjury, he had full painless range of motion and returned to full activity without limitation.

Patient 2
An otherwise healthy 23-year-old man sustained an isolated clavicle fracture during mixed martial arts training. On physical examination, no evidence existed of an open fracture or skin tenting. Radiographs demonstrated a displaced, comminuted middle one-third clavicle fracture with 25 mm of shortening (Figure 2A). The patient underwent open reduction and intramedullary fixation with the Sonoma CRx device 4 days after injury. Postoperative radiographs demonstrated near anatomic reduction and compression at the fracture site (Figure 2B). The patient’s early postoperative course was uncomplicated, and he advanced through physical therapy, gaining full painless range of motion, strength, and return to full activity by 12 weeks postoperatively. He restarted his martial arts regimen and participated in competition events at 4 months postoperatively (Figure 2C).

Six months after injury, he presented reporting pain with shoulder range of motion. He reported no repeat injury. Repeat radiographs demonstrated hardware fail-
ure 40 mm medial to the buttressing screw without significant fracture displacement and hypertrophic callous formation was noted (Figure 2D). A nonunion workup was negative for infection. Computed tomography demonstrated hypertrophic callous formation at the fracture site. The patient was treated with a bone stimulator and was relieved of his pain symptoms at 10 months after injury. At more than 2 years after reinjury, the patient had full painless range of motion and returned to mixed martial arts competition.

**DISCUSSION**

More than 80% of clavicle fractures involve the middle-third. Common mechanisms of injury include axial compression through shoulder impact and direct anterior compression. Historically, these fractures have been treated with short-term sling immobilization or figure-of-eight bracing, followed by early range of motion. Common complications with nonoperative treatment include pain, cosmetic deformity, nonunion, and symptomatic malunion. Robinson et al reported 868 patients with midshaft clavicle fractures treated nonoperatively and found an average nonunion rate of 4.5%. Their study found that independent risk factors for nonunion include advanced age, female sex, complete displacement, and comminuted fractures. In an evaluation of 30 patients, McKee et al found that those with completely displaced fractures went on to develop significant residual shoulder disability and loss of shoulder strength and endurance. Hill et al reported 52 patients with displaced midshaft clavicle fractures treated nonoperatively and found unsatisfactory results in 31% of the patients.

Plate fixation of midshaft clavicle fractures has been shown to reduce the risk of nonunion and neurologic complications and increase patient satisfaction with cosmesis. In a recent meta-analysis comparing operative fixation for clavicle fractures with operative fixation for displaced midshaft clavicle fractures, no significant difference was found in outcome; however, plate fixation was associated with a higher rate of symptomatic hardware events than intramedullary fixation.

Intramedullary fixation relies on indirect (secondary) bone healing with micromotion present at the fracture site, and, as a result, generous callous formation is seen throughout the healing process to intramedullary fixation. Several studies have demonstrated the biomechanical superiority of superior locking plate fixation compared with intramedullary devices under 3-point bending, torsional, and axial loading stresses. However, equivalent clinical outcomes and rates of union have been shown using both intramedullary devices and plate fixation when compared with nonoperative treatment, implying that intramedullary hardware rigidity and stability may not be relevant to clinical outcomes, except the intramedullary device must withstand normal physiologic stresses until the clavicle is healed.

Iannolo described axial loading and torsional stress as the primary force across the mid-shaft clavicle during shoulder abduction and humeral rotation. Taylor et al further defined the normal physiologic forces at the midshaft of a clavicle during the normal process of bringing the hand to the mouth (50° internal rotation of the humerus, 15° glenohumeral abduction, and 45° of forward flexion) using a computational model. The study found axial compression and torsional forces produced a rotational bending moment at the fracture site, resulting in downward and posterior displacement of the lateral fragment. This pattern of lateral fragment displacement is seen in both device failure cases presented in the current report.

Intramedullary hardware must be rigid enough to withstand the normal physiologic stresses of early healing and rehabilitation. Millet et al described 2 early hardware failures in a series of 58 patients treated with intramedullary fixation (Rockwood Pin; DePuy, Warsaw, Indiana). In this series, the overall complication rate was 25.8%. Both cases of early hardware failure resulted from “violent falls” in the early postoperative period. Earlier reports on intramedullary devices describe a 5% to 12% incidence of pin breakage, with 16% to 50% overall complication rates reported.

Both of the current cases failed within the first 5 months postoperatively. In the first case presented, early hardware failure occurred after reportedly low-mechanism, indirect trauma. The device appears to
have failed 60 mm medial to the lateral buttressing screw, at the interface between the flexible segment and the rigid lateral segment. This may represent failure of the actuating device without complete hardware failure. The patient went on to heal without complication and had pain-free range of motion and full return to function. Failure in the second case was likely associated with a hypertrophic non-union. Insufficient fracture stability resulted in hypertrophic nonunion, and early return to full activity, as demonstrated by this patient’s performance in competitive mixed martial arts, may have predisposed to early implant failure.

**Conclusion**

Early device failures may be indicative of insufficient hardware rigidity. Proper patient selection and counseling regarding the limitations of this intramedullary fixation device are important. Biomechanical comparison of this implant to plate fixation under physiologic loads of combined axial compression and torsion may shed light on differences in fixation stability.

**References**