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Complications of clavicle fractures treated with intramedullary fixation

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Hypothesis: Recent studies have demonstrated better outcomes with operative fixation of displaced midshaft clavicle fractures. We hypothesize that the risk of major complication with intramedullary fixation for clavicle fractures will be low.

Materials and methods: Clavicle fractures in 58 patients were treated with intramedullary fixation. Patients were excluded for concomitant pathologies and prior surgery status. Data collected included age, gender, treatment, fracture location, time of pin removal, type of complication, dates of further surgery, and American Shoulder and Elbow Surgeons (ASES) score. Complications were grouped into major (infection, nonunion, malunion) and minor (skin erosion, painful hardware, hardware breakage without consequence) categories. The mean age at surgery was 38 years (range, 18-67 years). All pins were removed at an average of 67 days (95% confidence interval, 54-85).

Results: Of the 58 patients, 15 (25.8%) complications occurred in 14 patients (24.1%). Five (8.6%) were classified as major (5 nonunions requiring revision surgery). Ten (17.2%) were classified as minor (1 delayed union, 2 superficial wound infections, 2 hardware failures after union, 5 skin erosions with pin exposure but without significant infection). Postoperative ASES scores average 89 at a mean follow-up of 7 years.

Discussion: Complete union and function were achieved in most patients, with an 8.6% risk of major complication. Intramedullary fixation has the potential for early but temporary hardware prominence, hardware exposure, and a slightly higher incidence of nonunion.

Conclusion: Patients with intramedullary fixation can expect smaller scars, no long-term hardware complications, and small potential for refracture or further hardware-related complications after hardware removal.

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

Keywords: Midshaft clavicle; intramedullary fixation; Rockwood clavicle intramedullary fixation

Clavicle fractures are relatively common injuries and have traditionally been treated with nonoperative care.[9] Studies have historically report a high rate of union and insignificant sequelae from malunited fractures.[10,13] More recent reports, however, have shown a higher nonunion rate and worse patient outcomes with displaced clavicle fractures treated nonoperatively than previously reported.[6]

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A recent study has also shown that patients with displaced midshaft clavicle fractures tend to have Constant shoulder scores and Disabilities of Arm, Shoulder and Hand (DASH) scores that indicate significant residual shoulder disability in addition to loss of significant shoulder strength and endurance.[7]

Operative fixation of displaced midshaft clavicle fractures has become more common in the last few years, possibly as a reaction to these more recent studies.[4,6,17] In fact, a recent multicenter, randomized, clinical trial comparing nonoperative treatment of displaced clavicle fractures with plate fixation demonstrated improved patient satisfaction, objective functional scores, time to union, and less symptomatic malunion in the group treated with open reduction and plate fixation.[4]

The most common surgical options for operative management of displaced midshaft clavicle fractures are plate fixation and intramedullary fixation. Plate fixation has been extensively studied and used with good results and few complications.[8,12,17] However, some patients complain of scar-related pain, prominent plate hardware, and cosmetic complaints due to the scar.[16]

Intramedullary fixation is an accepted method of treating displaced midshaft clavicle fractures and was originally described by Peroni in 1950.[11] The modern use of intramedullary fixation has advantages of smaller incisions, less extensive dissection, load-sharing fixation that encourages copious callous formation, and obligatory hardware removal that eliminates the concern for future hardware complications.[2,15] Despite these potential advantages, some significant complications have been recently reported:

- Strauss et al[14] reported complications in 8 of 16 patients (50%) after the use of smooth Hagie pins, including 3 cases of hardware prominence with 1 case of skin breakdown, 2 cases of pin breakage, 2 cases of decreased sensation at the incision, and 1 case of persistent pain at the fracture site after pin removal.
- Arrington and Johnson[1] document an intraoperative complication rate of 16% while using the Hagie pin. These problems included incidents of pin breakage, anterior cortical penetration, and drill bit breakage during placement of the implant. They also reported postoperative complications of 43% skin irritation, 22% loss of reduction greater than 5 mm, and 5% superficial wound infections.
- Grassi et al[5] evaluated the outcomes after the use of 2.5-mm threaded pins and reported complications of 20% infection, 7.5% refracture after pin removal, and 5% hardware failure.

Despite literature outlining significant complications using Steinman and Hagie pins, reports regarding the complication profile of the intramedullary clavicle pin (Rockwood Pin, Depuy, Warsaw, IN) appear more promising. Thyagarajan et al[16] reported a complete lack of complications after the use of the modern Hagie-type clavicle pin in 17 cases. To date, this small case series of 17 patients is the only reported series of this type of fixation device and its use for acute displaced midshaft clavicle fractures that compares results with plate and screw and nonoperative treatment.

The purpose of this study was to examine the complication profile of 58 consecutive patients with displaced clavicle fractures treated with the modern type intramedullary clavicle pin, a device specifically designed for operative treatment of clavicle fractures.

Materials and methods

Data collection for this study was approved by the Vail Valley Medical Center Institutional Review Board, which had a yearly renewal protocol.

This was a retrospective chart review of consecutive patients who underwent operative treatment with intramedullary clavicle fixation using the Rockwood Clavicle Pin from 2000 to 2007. We identified 66 patients with diaphyseal midshaft clavicle fractures that failed conservative management or elected for acute operative fixation. No patients with proximal or distal clavicle fractures were included. Eight patients were excluded, 2 with concomitant fractures that required surgical intervention, 1 patient had a prior surgery on the involved shoulder, and 3 patients were aged younger than 18. There were 58 patients (45 men, 13 women) in the final study population. The mean age at surgery was 38 years old (range, 18-67 years). All patients that presented to the senior authors (P.J.M., R.J.H.) were candidates for inclusion in this series. Patients typically had type 2 midshaft fractures. Patients with butterfly fragments were included.

A plate was chosen if there was a segmental component, the bone quality was poor, there were relevant comminution, or if the fracture extended beyond the middle third. Even with these preoperative selection criteria, 51 patients underwent intramedullary fixation, with plate fixation used in only 7 patients. Data collected included age, gender, injury site, surgery date, surgeon, treatment, fracture location, the time of pin removal, type of complication, dates of further surgery, and American Shoulder and Elbow Surgeons (ASES) score (scale 0-100, 100 = best) and daily pain (1-10, 1 = no pain and 10 = extreme pain).

Complications were classified as major and minor. Minor complications included skin irritation, skin breakdown with pin exposure but without infection, superficial wound infection, painful prominent hardware, delayed union, or hardware failure with union. Major complications included deep tissue infection, fracture nonunion or malunion, nerve injuries, and hardware failure without union. The postoperative course was reviewed in an effort to determine the incidence of postoperative complications. Univariate analysis was performed with the analysis of variance test for 2-group comparisons. Continuous data are reported with the 95% confidence intervals (CI).

Surgical technique

After administration of general anesthesia, the patient was placed in the beach chair position with the injured extremity prepared and

draped similar to open reduction of the clavicle using plate osteosynthesis. It was important to prepare the extremity past midline so that the sternoclavicular joint was in the operative field. This allowed for easier manipulation of the medial fracture fragment during the case. A large fluoroscopy C-arm unit was also prepared into the field for use during the case. It is helpful to place the intensifier behind the patient's shoulder and set the unit perpendicular to the clavicle. Once set to the optimal position to easily see the sternoclavicular joint and acromioclavicular joint with small movement of the C-arm, the unit can be canted or slid out of the way for exposure.

The skin incision was centered over the fracture parallel to the Langer lines. The skin incision was typically 5 to 6 cm long and was perpendicular to the platysma fibers, which was then split in-line with its fibers. Branches of the supraclavicular nerve were protected if encountered. Once the platysma was split, the fracture hematoma was expressed. The bone edges were debrided of any tissue that would prevent anatomic reduction, and large butterfly fragments were preserved with their soft-tissue attachments.

The intramedullary pin was placed according to the manufacturer's guidelines by first reaming the medial fragment with the appropriate drill bit using fluoroscopic guidance. Care was taken to avoid penetrating into the sternoclavicular joint and violating the anterior cortex of the clavicle. The lateral fragment was reamed in a similar fashion using the same drill bit. Both segments were tapped, and the appropriate matching pin size was selected. The pin was placed in an antegrade fashion through the lateral bone fragment and out through the posterolateral cortex of the clavicle. It was important to have the pin exit as low as possible on the posterolateral cortex to avoid prominence of the lateral locking nuts beneath the skin. Once the pin was tenting the skin, a small 1-cm incision was made to allow the pin to come out of the skin, posterolaterally.

The drill was then applied to the lateral pin tip, and the pin was advanced retrograde until the blunt medial end of the pin was within the fracture site. The fracture was reduced and the 2 hexagonal nuts were placed on the lateral pin threads and advanced together to cold weld them together. After this, the pin is advanced by hand in a retrograde fashion into the medial fragment using the lateral nut hexagonal wrench. Once the medial threads of the pin were advanced to the appropriate position within the medial fragment, the medial nut was advanced to the posterolateral cortex to provide fracture site compression. The lateral nut was then advanced down to the medial nut to "lock" the two nuts together and prevent any further migration of the pin.

Because conventional pin cutters leave the pin too proud beyond the edge of the nuts and put the skin at risk for breakdown, it is important to ensure that the pin is cut flush with the end of the nuts. This can be achieved by backing up the pin construct out of the wound using the medial wrench and cutting the pin flush with the nuts. Once the pin construct was advanced back down to bone, the butterfly fragments could be cerclaged around the pin with nonabsorbable suture before closure.

Final fluoroscopic pictures were taken and the wounds were closed. We approximated the platysma with absorbable sutures and closed the skin with a subcuticular absorbable stitch. The total surgical time depended on the nature of the fracture and the degree of comminution. However, a typical acute fracture could be fixed in 30 to 45 minutes once the surgeon was comfortable with the technique. We have fixed many in less than 20 minutes.

Patients were then placed in a simple sling and allowed gentle passive range of motion as tolerated immediately after surgery. If the fracture was judged as being stable, then active motion would be started immediately as well. If it was unstable, then active motion would be delayed for 2 to 4 weeks. Once the patients obtained full and painless shoulder range of motion, they were allowed to participate in noncontact athletics.

The pin was removed once there were clinical and radiographic signs of fracture healing—typically between 10 and 14 weeks after surgery. This was typically performed in an outpatient setting using local anesthesia and sedation with or without brief laryngeal mask anesthesia.

It is important to closely monitor the posterior wound during the postoperative course because a prominent pin can cause skin breakdown. In the case of early skin breakdown, the pin could be removed if there were signs of consolidation at the fracture site. However, if there were no signs of bony healing, the exposed pin was treated with local wound care until there was healing of the fracture.

Results

The results are summarized in Table I. Of the 58 patients, there were 15 complications (25.8%) in 14 patients (24.1%). Five (8.6%) were nonunions requiring revision surgery and were classified as major. Ten (17.2%) were classified as minor and included 1 delayed union, 2 superficial wound infections, 2 hardware failures after union, and 5 skin erosions with pin exposure but without significant infection.

Surgeon 1 (P.J.M.) performed 24 of the operations and the other (R.J.H.) performed 34. There were no nerve or vascular injuries in our series and no deep infections or osteomyelitis. There was no hardware failure or pin breakage in the setting of nonunion. The 2 patients who presented with hardware failure both experienced violent falls on the involved shoulder. One patient had complete union of the fracture but broke the distal end of the pin with the bolts after a fall; the other patient fell on the involved shoulder during the second postoperative week and fractured the pin through the inferolateral cortex of the lateral fragment, necessitating hardware removal. One patient insisted on early removal of the pin on postoperative day 14 because of hardware prominence, despite being counseled on the potential loss of reduction with early pin removal. The fracture ultimately went on to a symptomatic nonunion secondary to the subsequent displacement, and the patient elected for revision open reduction and internal fixation with bone grafting at 11 months after the initial pin placement.

All pins were removed and the average time from surgery to pin removal was 67 days (95% CI, 54-85). The patients with skin breakdown and pin exposure underwent pin removed an average of 71 days (95% CI, 46-96) from surgery, whereas the remaining patients without skin breakdown underwent pin removed at an average of 66 days (95% CI, 49-83) from surgery. There was no

Table I Patient complications after intramedullary fixation

Complication type	No.
Major	
Nonunion	5
Deep infection	0
Refracture	0
Permanent nerve injury	0
Minor	
Delayed union	1
Superficial infection	2
Pin failure with union	2
Skin erosion with pin exposure	5
Temporary brachial plexus palsy	0
Total	15

significant difference between the groups with or without skin breakdown ($P > .05$; 6.2% power). There was no significant difference in time from injury to fixation. There was no significant difference in complications rate between the 2 surgeons ($P > .05$: 12% power). Patients that achieved union had an average of 9 days (range, 0-100 days) between injury and surgery, and those with nonunion averaged 7 days (range, 3-11 days; $P > .05$: 6.0% power). For those patients that did not progress to a revision surgery, at an average of 7 years (range, 0 .17- 12 years) postoperative, the ASES score was 89 (range, 35-100), which significantly improved from 42 (range, 25-57) preoperatively ($P < .05$). The average daily pain score was decreased from 3 preoperatively to 1 postoperatively, and mean satisfaction with surgical outcomes was 8 of 10 points.

Discussion

In this series of patients treated with intramedullary clavicle pins, we found an 8.6% (5 of 58) major complications rate and a 17% (10 of 58) minor complication rate. The mean postoperative ASES score significantly improved 47 points from preoperative status ($P < .05$). With the numbers available, there was no statistically significant difference or clinically meaningful difference in the time to pin removal between the patients with and without skin breakdown.

Recent data suggest that some displaced midshaft cla vicular fractures will have better outcomes with operative reduction and internal fixation.[4] The use of intramedullary fixation rather than plate fixation is not a new concept, and the potential benefits of intramedullary fixation include smaller incisions, minimal periosteal stripping, load-sharing device properties, and obligatory hardware removal that eliminates the concern for long-term hardware complications. Another advantage is the relative stability that an intramedullary device provides with its load-sharing biomechanical profile and resulting callus formation. Limited literature is available on the outcomes of intramedullary fixation for the clavicle, but this is the gold standard for most other long-bone fractures. For the clavicle, case reports and case series have documented the potential complications of this surgical approach, but these studies have small patient numbers and often a mixed cohort of different types of intramedullary fixation devices. This study reports the perioperative complications of a large cohort of similar patients who underwent fixation with one type of clavicle pin, the Rockwood Pin.

In this series of patients treated with intramedullary clavicle pins, there were a similar number of total complications compared with other reports for plate fixation (24.1% complications in intramedullary fixation compared with 37% in plate fixation).[4] Despite the similar incidence of total complications, complication profiles were very different. No nerve injury occurred in our patients; however, there was an 8% incidence of transient brachial plexopathy in the large plate fixation series. In addition, Böstman et al[3] reported a 2% incidence of ''brachial plexus irritation'' in their series of 103 patients treated with plate fixation. Although nerve injury is a risk in any operative treatment of clavicle fractures, the different incidence of nerve injury between our intramedullary population and the previously reported plate population could be related to screw placement during plate fixation, drilling, or the extent of dissection necessary for plate fixation. Transient brachial plexus palsy after clavicle pinning was reported by Ring and Holovacs,[15] but this problem was not encountered in our cohort. Despite the valid hypothesis that the manipulation of the fracture ends required for intramedullary fixation puts the brachial plexus at risk, we, fortunately, did not encounter that complication in our cohort using a similar technique of fracture site manipulation.

Hardware prominence from the posterior locking mechanism is a well-known characteristic of this intramedullary implant, but it rarely causes significant pain or problems. Skin erosion from pin exposure is considered a minor complication because significant infections were rarely associated with skin breakdown. None of the five patients with pin exposure presented with symptoms of cellulitis or deep infection, and all were treated with local wound and pin care until the pin could be removed safely. Although the average time to pin removal for all patients was 67 days (95% CI, 54-85 days), those patients with skin breakdown and pin exposure had an average time to removal of 71 days (95% CI, 46-96 days). This difference was not statistically significant, but we believe that both hardware prominence and skin erosion with pin exposure is most likely related to modifiable factors such as improved surgical technique, improved implant design, patient education, patient activity, and appropriate timing for pin removal.

Hardware failure and pin breakage have been reported complications with intramedullary fixation.[5,14] Grassi et al[5] reported 5% pin breakage with the use of fully threaded 2.5-mm pins. Strauss et al[14] documented 2 cases of pin

failure in their cohort of 16 patients using a different variety of intramedullary Hagie pin (Smith & Nephew, Andover, MA). We report 2 types of pin failure, and both of these patients had significant postsurgical falls. One failure was pin breakage, but it occurred outside the clavicle at the junction of the bolts and posterolateral clavicle. The other patient sustained a blow-out of the pin through the posterolateral clavicle; after removal of the pin, the fracture displacement was minimal, revision fixation was not performed, and the patient healed uneventfully. None of our patients with nonunion presented with pin breakage. This could be due to slightly less activity in these patients or close clinical follow-up before the inevitable pin breakage in the setting of nonunion. Regardless of the reported differences between our reported incidence of pin breakage and those documented in the literature, it is clear that our implant is a different variety than those previously reported intramedullary implants, and this could be a significant factor in the varying reports on pin breakage.

Because of the prominence of the posterolateral bolts and risk of skin erosion, removal of the intramedullary clavicle pin is obligatory. Hardware removal can be seen as an unnecessary second surgery with additional anesthesia exposures and increased costs. However, removal of the intramedullary implant eliminates future concerns for hardware irritation, and the only defect that remains is a small hole on the posterolateral cortex. Pin removal is typically well tolerated and can be successfully performed under local anesthesia using brief supplemental sedation. Plate fixation has significant bulk that can cause irritation to the thin skin above the clavicle and a visible prominence that some thin patients may deem unsightly. The clinical trial of clavicle fixation from the Canadian Orthopaedic Trauma Society reported that 8% of the patients required hardware removal because of irritation.[4] With the remaining empty screw holes acting as stress risers, plate removal does pose a risk of refracture, especially in a highly active patient. Although the actual refracture risk after pin removal is unknown, we believe that the remaining 3.2-mm posterolateral hole after pin removal presents a minimal refracture risk compared with the multiple holes that remain after plate removal.

The nonunion rate in this series was 8.6% (5 of 58) and only slightly lower than the reported nonunion rates for nonoperative treatment.[4,6,7] There are multiple theoretic causes for this degree of nonunion with pin fixation, including limited rotational stiffness, fracture site violation, and operative technique. This nonunion rate is in contrast to that of plate fixation, where more modern plating constructs have reported nonunion rates of approximately 5%.[4] This difference in nonunion rate highlights the importance of only presenting this surgical option to patients who believe that the larger scar and permanence of hardware associated with plating outweighs the increase in nonunion associated with intramedullary fixation. One patient in our study requested to have the pin removed 14 days postoperatively, despite being counseled that diaphyseal fractures can take up to 4 months to heal. In addition, this difference in union rate emphasizes the unique complication profiles of intramedullary fixation and plate fixation. Although this difference suggests that some clavicle fractures are better suited for plate fixation whereas others could be better suited for intramedullary fixation, these criteria have yet to be defined but are most likely related to degree of fracture comminution.

This study has several limitations that are inherent in retrospective chart reviews. Although this is one of the largest cohorts of clavicle fractures treated with an intramedullary fixation device, some of the comparisons are underpowered. The study's subjective outcome results could also suffer from bias because we had less than 85% follow-up. Preoperative data were not routinely collected on fracture patients, and we had only 79% (46 of 58) postoperative follow-up in this study, so we limited our comments of the outcome measures. However, compared with reports of clavicle fixation with other means, it does seem clear that clavicle pinning presents with a unique complication profile.

Similar to another review of complications after clavicle plating, we did not notice any differences in complication incidence or type between surgeon or date of surgery.[3] Therefore, surgical technique did not seem to be a contributing factor in our cohort of patients. It is also possible that fracture pattern and degree of comminution had an effect on union rate. However, some of the earlier radiographs in this study were purged from our database during conversion of the clinic to digital imaging, which prevented an accurate analysis of the preoperative fracture pattern.

It seems clear that intramedullary and plate fixations have their own unique complication profiles and that and the patient should be educated about these differences when deciding on the surgical approach. With plate fixation, the patient should be warned of potentially long-term hardware irritation, larger anterior scars, and a slightly higher incidence of brachial plexus injury; however, union rates appear to be slightly higher than intramedullary fixation. With intramedullary fixation, the patient should be informed of the potential for early, but temporary hardware prominence, hardware exposure, and a higher incidence of nonunion; however, the patient can expect smaller scars, no long-term hardware complications, and small potential for refracture and further complications after hardware removal. Although neither fixation technique is a panacea for the treatment of all displaced midshaft clavicle fractures, each technique does have distinct benefits that make both plating and pinning valuable approaches to clavicle fracture treatment.

Conclusion

Operative fixation is becoming more commonly used in the treatment of midshaft clavicle fractures. The purpose

of this study was to review complication rates seen with intramedullary fixation using the Rockwood clavicle pin. Although complications are still seen with pinning, the complication profile is quite different from plate fixation. The benefits of this type of fixation include smaller scars, no long-term hardware complications, and a smaller chance of refracture. Patients should be educated about the advantages and disadvantages of each fixation technique.

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