Use of an Absorbable Plate in the Management of a Clavicle Fracture in an Adolescent

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Abstract

Management of clavicle fractures continues to evolve. Indications for operative management seem to be expanding, particularly in athletic youth. Surgical intervention has potential complications, many associated with use of metal implants. To my knowledge, this case report is the first to describe use of a biodegradable implant. The subcutaneous position of the clavicle makes it ideal for fixation with a biodegradable implant in which no second surgery is required for implant removal.

The shoulder, the most mobile joint in the body, is prone to instability and injury. Due to the subcutaneous and relatively anterior location, and because its thin midshaft lacks muscular and ligamentous support, the clavicle is a common injury site. Clavicle fractures constitute 5% to 10% of all fractures[1] and traditionally are managed nonoperatively.[2,3] However, recent studies have found that displaced or comminuted fractures have a nonunion rate higher than 15%.[4,5] Furthermore, compared with nonoperative management, surgery may have a lower nonunion rate and improved patient-oriented outcomes.[5-7] Therefore, many surgeons elect operative repair, particularly when patients present with risk factors for nonunion, such as significant fracture displacement or shortening.[4,7-10]

Multiple operative fixation methods have been developed to control clavicle fractures while minimizing the implant prominence and irritation that ultimately lead to second surgeries for implant removal. Biodegradable implants have been used in subcutaneous fractures, including fractures of the mandible and the fibula. In the case reported here, a biodegradable plating system was successfully used to manage delayed union of a displaced and shortened clavicle fracture. The patient provided written informed consent for print and electronic publication of this case report.

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Case Report

A right-handed, 17-year-old girl injured her left shoulder and right wrist in a fall from a mountain bike. Initial management at an outside emergency department consisted of a simple sling for a left midshaft clavicle fracture (Figure 1) and a volar wrist splint for a right comminuted intra-articular distal radius fracture. One day later, the patient received a univalved short arm cast with appropriate molding and underwent computed tomography for the intra-articular fracture. No tenting of the skin over the clavicle was noted during this visit to our facility.

Sixteen days after injury, the distal radius fracture was managed with open reduction and internal fixation (ORIF), and the patient elected to convert to a figure-of-8 brace for the clavicle. Over the next 2 weeks, she discontinued use of the figure-of-8 brace (this according to her mother at the 6-week postoperative visit for the wrist). Examination 8 weeks after injury revealed no focal tenderness at the clavicle fracture and full range of motion (ROM) of the shoulder. No deficits in neurologic function or vascular status were noted.

Three months after injury, the patient returned to our clinic reporting pain at the clavicle fracture site and

Figure 1. At initial presentation, anteroposterior radiograph of left shoulder shows displaced and shortened clavicle fracture.

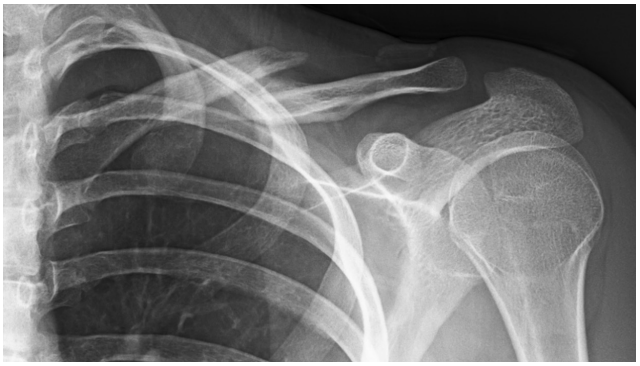

Figure 2. Three months after injury, anteroposterior radiograph of left shoulder shows some callus formation but continued radiographic lucency.

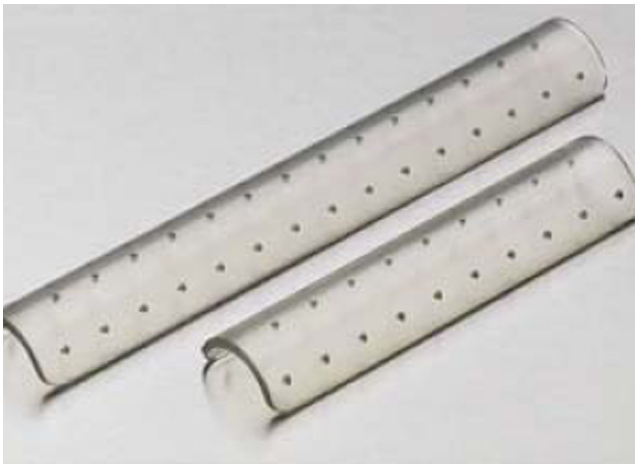

Figure 3. Concave FreedomPlate (Inion, Weston, Florida).

obvious deformity and prominence. ROM was nearly symmetric, lacking only 5° in forward elevation and external rotation, as compared with the contralateral shoulder. At this time, the wrist was doing well, and the only deficit was 5° less extension in comparison. The patient reported that, as wrist symptoms decreased, she was becoming more aware of increasing pain in the clavicle. An anteroposterior radiograph of the clavicle showed some callus formation but continued lucency at the fracture site (Figure 2).

The patient elected to undergo ORIF of the clavicle secondary to painful delayed union (this procedure was performed 14 weeks after injury). She requested an implant that would not have to be removed, and was therefore fixated with the biodegradable OTPS FreedomPlate (Inion, Weston, Florida) (Figure 3) and six 2.8-mm compatible screws. The surgery involved a standard anterior approach. The fracture was found to have abundant callus but no union. Excess bone was removed and saved for use as bone graft. The fracture was reduced and held in transient fixation with a 0.062-in Kirschner wire. The 100-mm concave implant was chosen and cut to a length of 75 mm to match the need of the patient. The implant was placed in a warm saline bath, per manufacturer instructions, and then was

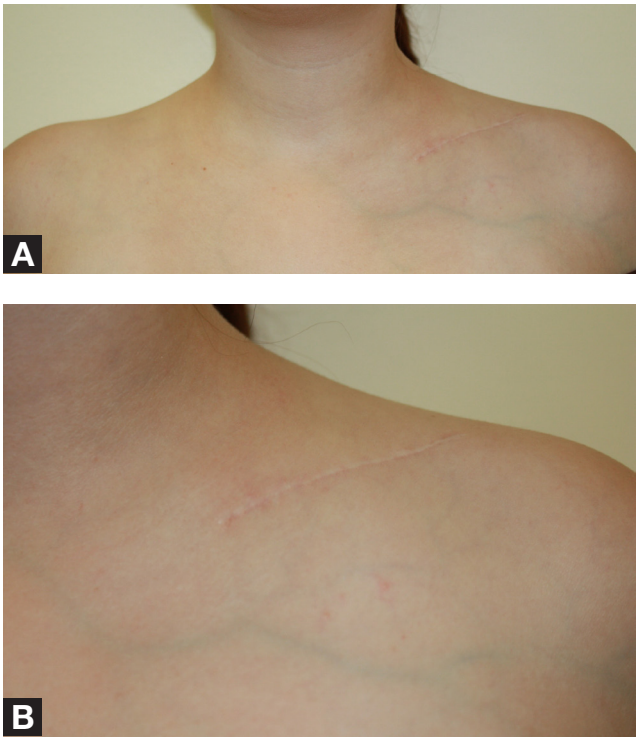

Figure 4. Clinical photographs. (A) Bilateral shoulders symmetrical in contour. (B) Left shoulder with well-healed incision and no evidence of cutaneous irritation.

quickly molded over the clavicle and fracture site. With the new well-molded shape obtained, the plate was then held in place using reduction clamps. Three bicortical 2.8-mm screws were then placed on either side of the fracture. A drill one size smaller than recommended was used to allow for plate tapping and screw locking. Once inserted, the screw heads were cut to make the entire fixation low-profile (the plate is only 1.4 mm thick).

The patient's visit 1 week after surgery was uneventful, but at 5 weeks, the patient returned, early, for a nurse visit, reporting a raised red nodule on the medial aspect of the incision that had drained a small amount of "yellow" fluid at 4 weeks. At this visit, however, the incision was dry and nontender, and there were no constitutional symptoms. A week later, but before the scheduled 6-week postoperative visit, the nodule had defervesced, exposing a small fragment of absorbable subcutaneous suture. The patient had removed the fragment and begun use of an over-the-counter antibiotic ointment. At the clinic evaluation, she was prescribed cephalexin (Keflex) 500 mg twice a day for 7 days as a prophylactic measure. Physical therapy for upper extremity strength was initiated.

Six months after injury (3 months after surgery), the patient discontinued physical therapy and was having no pain or issues regarding the clavicle. Given the unique nature of the implant used, she was asked to return after 1 year for repeat clinical and radiographic evaluation of the clavicle. Eighteen months after injury, she returned for final evaluation. She reported no limitation

with the left shoulder but some limitation with the right wrist. Physical examination revealed full active shoulder ROM and a well-healed incision with no evidence of erythema or underlying reaction to the implant (Figure 4). The area over the former fracture site was nontender to palpation. The plate edges were not discernible, but remnant plate was palpable under the skin. In addition, the right wrist was nontender, and the incision was well healed. The patient's overall DASH (Disabilities of the Arm, Shoulder, and Hand) Outcomes Measure score was 9.5, and her optional Work module score was 0 (she indicated she worked in "food service, housekeeping, basic construction remodeling"). Explaining she did not do sports or play musical instruments, she did not complete the optional Sport module. Final radiographs showed a well-healed fracture with continued radiographic evidence of the biodegradable screws (Figure 5).

Discussion

To my knowledge, this was the first reported case of successful use of a biodegradable plating system in the fixation of a clavicle fracture. Although management was complicated by a stitch abscess (successfully treated with oral antibiotics), after 18 months of follow-up, there were no apparent complications specific to the implant. However, many issues need to be addressed before this plate can be used en masse in the management of clavicle fractures.

It is important to understand the fixation system used. The OTPS FreedomPlate is made of 3 polymers: trimethylene carbonate, L-lactide, and D,L-lactide. The materials are amorphous and degrade by hydrolysis, gradually losing their strength 4 months to 9 months after implantation. They are metabolized into carbon dioxide and water, achieving complete resorption within 2 years to 4 years. The stiff plate, after being heated in the warm saline bath, becomes malleable, which allows for bone-specific contouring. This process can be repeated without fatiguing the plate. The biodegradable screws can be placed anywhere on the plate, as there are no preplaced holes, and the implant allows for off-axial placement. If the drill holes are tapped, then the screws will interlock with the plate. Once interlocked, the screw heads can be cut off flush with the plate to minimize the profile of the construct.

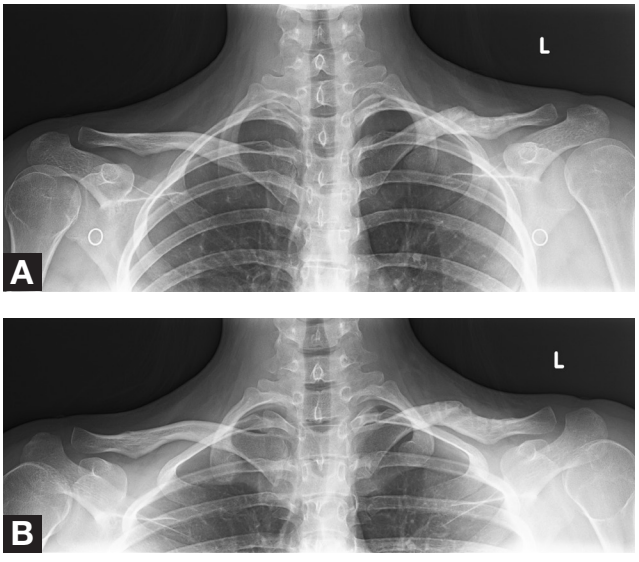

Figure 5. Eighteen months after injury. (A) Final bilateral anteroposterior radiograph. (B) Final bilateral serendipity radiograph. Radiolucent implants are still visible within left clavicle.

There are many advantages to using a biodegradable implant of this kind. It can be easily contoured to the relatively irregularly S-shaped clavicle. Excision of screw heads makes the implant very low-profile but without compromising its strength. No second surgery is required for implant removal. The superior plating position can be readily used to maximize biomechanical stability.[11,12] In addition, amount of subcutaneous irritation seems to be insignificant. In comparison, metal implants are stiffer, and such rigid fixation prevents periosteal callus proliferation and alters the natural bone stress distribution.[13] Other disadvantages of metal are metal allergy, hypersensitivity, and neoplasm. Biodegradable materials provide stability during bone healing, may compensate for the shortcomings of metal fixation, and present a biologically inert solution.

However, there are potential disadvantages to biodegradable implants. The complex 3-dimensional shape of the clavicle and its function as a strut require that specific mechanical properties be met by the fixation construct in order to secure the fracture and to reduce the risk for complications.[14,15] Proper biomechanical strength is required of the biodegradable implant to resist the natural stresses within bone and should not be compromised when new materials are introduced. Studies have not been conducted to evaluate the biomechanics of these plates when used in the management of clavicle fractures—particularly in comparison with metal implants. The only implant comparison was made in zygomaticomaxillary complex fractures. Hanemann and colleagues[16] evaluated various combinations of titanium implants and resorbable implants. Titanium implants provided stronger fixation. Mode of failure seemed to depend more on fracture location. Direct comparisons of pullout strength have yet to be performed. A period of prospective evaluation is needed to fully evaluate use of this plating technology as it relates to clavicle fractures. Furthermore, depending on the product used, the cost of biodegradable implants can be much higher than that of metal implants.

Conclusion

Use of biodegradable implants is not unprecedented, but their use in the management of clavicle fractures is unique. Although biomechanical testing is needed to safeguard these fractures from higher nonunion rates

and construct failures, the concept is encouraging. If test results can ensure the efficacy of this plating technology, then its implementation in managing clavicle fractures will overcome many of the drawbacks inherent in metal implants and should limit potential complications associated with surgical management of clavicle fractures, including potential need for a second surgery for removal of a prominent implant.

Author's Disclosure Statement

The author reports no actual or potential conflict of interest in relation to this article.

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