Nonunion After Clavicle Osteosynthesis: High Incidence of *Propionibacterium acnes*

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Objective: The objective of this study was to review the etiology of clavicle nonunions after osteosynthesis and investigate the outcomes of a treatment with a single-stage revision.

Design: Retrospective case series.

Setting: Orthopaedic specialty hospital.

Patients: Twenty cases of nonunion after osteosynthesis of the clavicle were identified. The average age was 44 years (±13 years). In 9 cases, there was catastrophic implant failure that prompted the revision surgery. In the 18 cases in which cultures were taken, 15 of the 18 (83%) were treated as infections with a course of antibiotics. In 14 cases, the cultures were positive for *Propionibacterium acnes*.

Results: Fifteen patients were treated with a prolonged course of antibiotics. Eighteen patients had follow-up, and the average time to radiographic union was 22 weeks. There were no cases of nonunion after revision surgery.

Conclusions: There is a high rate of positive cultures in cases of nonunion after osteosynthesis of the clavicle. This suggests the etiology of midshaft clavicle nonunions may result from a combination of suboptimal mechanical fixation and latent infection. Our treatment protocol of superior and anterior plating, interfragmentary fixation, bone grafting, and appropriate antimicrobial treatment of latent infections has resulted in 100% union rate.

Key Words: clavicle nonunion, clavicle infection, implant failure, *Propionibacterium acnes*, clavicle osteosynthesis, clavicle fracture

Level of Evidence: Prognostic Level IV. See Instructions for Authors for a complete description of levels of evidence.

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INTRODUCTION

The incidence rate of clavicle fractures is 5.8 cases per 10,000 person-years.[1] In 1960, Neer[2] reported a higher nonunion rate in clavicle fractures after operative treatment compared with clavicle fractures treated nonoperatively. For the next 3 decades, there was a tendency to treat midshaft clavicle fractures nonoperatively. After 2005, this approach shifted, as a series of reports from Robinson et al[3] and Hillen et al[4] reported unacceptably high rates of nonunion in midshaft clavicle fractures treated nonoperatively. Since 2005, there has been a change in practice toward treating these fractures with osteosynthesis.[5,6]

The complications of clavicle osteosynthesis frequently discussed in the literature include cosmetic dissatisfaction, numbness, and symptomatic implants.[7,8] The rate of nonunion after osteosynthesis of the clavicle has been reported between 1.4% and 4.6%.[8–12] Although studies have examined risk factors for malunion or nonunion in patients undergoing nonoperative management of clavicle fractures,[13,14] there is limited literature pertaining to risk factors for patients after operative management. Female sex, increased age, comorbidities, and treatment at a community-based practice increase the odds of nonunion after operative treatment[10,15]; fracture comminution and alcohol intoxication at the time of injury are associated with increased rates of complications.[16,17]

The literature pertaining to infection after osteosynthesis of clavicle fractures is also scant. The infection rate after open reduction and internal fixation of clavicle fractures is reported between 1.8% and 7.8%.[16,18] In one series of cases of infection after plate fixation of clavicle fractures, the authors reported that 4 of 6 infected patients went on to chronic nonunion.[19] To date, a single case report and 2 small case series have identified *Propionibacterium acnes* after clavicle osteosynthesis.[19–21]

With the documented increase in operative fixation of clavicle fractures in recent years,[5,6] it is important for orthopaedic surgeons to be familiar with complications related to osteosynthesis. The purpose of this study was to better understand potential causes of clavicle nonunion after osteosynthesis and to determine the outcome of a single-stage protocol. We hypothesized that the indolent infection rate among patients who develop nonunion after clavicle osteosynthesis is high and that a single-stage revision surgery followed by targeted antibiotic therapy would produce successful outcomes.

PATIENTS AND METHODS

After approval from the institutional review board, a search was conducted using the orthopaedic trauma service database using operative case logs at a single institution to identify all patients treated for a nonunion of the clavicle between 1995 and 2014. A secondary search for cases was performed using the *International Classification of Diseases, Ninth Revision* codes of 733.82 (nonunion) and 810.00 (clavicle fracture) in combination. Inclusion criteria were previous treatment of a midshaft clavicle fracture with osteosynthesis, presence of a nonunion at least 6 months after the index surgery based on clinical and radiographical examination, and age older than 18 years. In addition, refracture within 2 months after removal of the clavicle plate in the absence of significant trauma to the clavicle was also considered a nonunion and those patients were included in the study. Cases were also included as nonunions if there was implant failure and no evidence of healing by 4 months after the index surgery. One patient with no postoperative imaging was excluded.

The data were collected to define patient characteristics, comorbidities, and concomitant injuries. Radiographs were reviewed and, when available, the original fractures were classified according to the OTA/AO classification.[22]

Surgical Technique

The patient is positioned supine on a radiolucent table. Antibiotics are held to obtain cultures. The operative extremity is prepped and draped free, and the clavicle is prepped widely. In cases where iliac crest bone graft (ICBG) was used, the iliac crest was prepped and draped simultaneously. In all cases, the skin incision from the index procedure was used and in certain cases extended. The skin is prepped according to individual surgeon preference, with either betadine or chlorhexidine. Antibiotics are held before skin incision. The supraclavicular nerves are identified and protected. The fracture site is identified and previous plate and screws, or intramedullary rods are removed. Then, the nonunion site is debrided thoroughly with rongeurs and curettes as described previously.[23] Soft tissues and fibrous nonunion tissue are debrided, and this tissue is immediately transferred into sterile containers, avoiding touching the tissues with surgical gloves.

According to our institutional protocol, 5 specimens are sent for anaerobic and aerobic cultures. Five different instruments are used to take the 5 cultures, and they are each harvested from a unique area of the wound after all previously placed hardware has been removed. Intravenous antibiotics are then dosed. The specimens are inoculated to standard aerobic and anaerobic media; thioglycolate broth cultures are incubated anaerobically for 14 days, as previously described.[24]

Tricortical ICBG is used when a large defect or shortening is present as deemed necessary by the primary surgeon; otherwise demineralized bone graft is used. The nonunion site is then reduced, paying close attention to length and rotation. Choice of plate varies based on the fracture pattern, quality of bone, and the size of the patient and their covering soft tissues. In general, our preferred fixation is a 2.7-mm reconstruction (recon) plate superiorly and a 2.4-mm locking compression plate (LCP) anteriorly. Care is taken to prebend the plates to match the contour of the clavicle. If the fracture is purely transverse and no interfragmentary fixation is possible, the fracture is compressed through a pull screw outside the plate and eccentric placement of screws within the plate. In all cases where the fracture pattern permits, interfragmentary fixation is attempted, ideally through one of the plates.

All patients are placed in a simple sling after surgery and instructed to not bear weight through the operative extremity. Range of motion exercises initiated immediately postoperatively. Once evidence of radiographic healing is present, weight bearing is initiated.

Statistical Analysis

Statistical analyses were performed using STATA software version 14.0 (StataCorp LP, College Station, TX). Descriptive statistics were used to analyze continuous data.

The Wilcoxon signed-rank test was used to test whether the time to union differed between patients with cultures positive for *P. acnes* compared with those without. All analyses that generated *P*-values were 2-tailed.

RESULTS

Twenty consecutive cases of nonunion after primary osteosynthesis of clavicle fractures met the inclusion criteria at our institution in the past 20 years (Table 1). The average age was 44 years (±13 years), and there were 9 males and 11 females in the cohort. Three patients endorsed tobacco use (15%). Twelve of the 20 patients were initially treated at outside hospitals and presented to our institution after their index procedure; the remaining 8 patients had their index procedures at our institution. Of the patients referred within our institution, 1 of the 8 had their index procedures by a fellowship-trained trauma surgeon within our department, and the remaining 7 patients had their index surgeries at our institution performed by nontrauma fellowship-trained surgeons. The query of the trauma department database identified a total of 183 cases of primary clavicle osteosynthesis during the study period, indicating a 0.55% rate of nonunion. Eighteen patients were initially treated with plate fixation and 2 patients were initially treated with intramedullary nails. Interfragmentary screw fixation was applied in 7 of the 20 index surgeries. All the nonunions in this series were atrophic. All original clavicle fractures were closed injuries. In 4 cases, the nonunions were diagnosed radiographically after the implant was removed from the primary osteosynthesis (20%) (Fig. 1). One patient presented with drainage from the incision; that patient ultimately had 4/5 cultures positive for *P. acnes* and was treated with an extended course of antibiotics. The remaining patients presented with pain, gross motion, and/or failure of implant (Fig. 2). The average time elapsed between index osteosynthesis and presentation for nonunion was 14.6 months (range 4–37 months).

In all but 2 cases, cultures were taken at the time of revision fixation, and 17 of the 18 patients (94.4%) had

TABLE 1. Summary of Cases Presenting as Clavicle Nonunions After Primary Osteosynthesis

Case	Months From Index Surgery to Revision Surgery	No. of Cultures Taken	Positive Culture?	No. of Positive Cultures	Organism(s)	Treated as Infection?
1	11	4	Yes	2	*Enterococcus faecalis, P acnes*	No
2	37	5	Yes	4	*P. acnes*	Yes
3	9	3	Yes	3	*Staphylococcus epidermidis*	Yes
4	4	0	N/A	0	N/A	No
5	30	5	No	0	N/A	No
6	21	2	Yes	1	*P acnes*	Yes
7	5	5	Yes	5	*P. acnes*	Yes
8	6	5	Yes	4	*P. acnes*	Yes
9	4	5	Yes	4	*P. acnes*	Yes
10	7	5	Yes	3	*Staphylococcus epidermidis*	Yes
11	17	1	Yes	1	*P. acnes*	Yes
12	26	2	Yes	1	*P. acnes*	Yes
13	11	5	Yes	1	*P. acnes*	Yes
14	19	5	Yes	5	*P. acnes*	Yes
15	12	5	Yes	5	*P. acnes*	Yes
16	20	6	Yes	5	*P. acnes, Staphylococcus auricularis*	Yes
17	30	5	Yes	3	*P. acnes*	Yes
18	12	5	Yes	1	Alpha-*Streptococcus*	No
19	4	0	N/A	N/A	N/A	No
20	7	5	Yes	1	*P. acnes*	Yes
Total/Avg	15		17/18			15/18

Case	No. of Cultures Taken	Revision Surgery Superior Plate	Revision Surgery Anterior–Inferior Plate	Initial IF Screw (s)	Revision IF Screw (s)
1	4	2.7 recon	2.4 LCP	N	Y
2	5	2.7 recon	2.4 LCP	Y	Y
3	3	2.7 recon	2.4 LCP	N	N
4	0	2.7 recon	2.4 LCP	N	Y
5	5	2.7 recon	2.4 LCP	N	Y
6	2	2.7 recon	2.4 LCP	N	Y
7	5	2.7 recon	2.4 LCP	N	Y
8	5	2.7 recon	2.4 LCP	N	Y
9	5	None	3.5 recon	N	Y
10	5	2.4 LCP	2.7 recon	Y	Y
11	1	None	3.5 recon	Y	Y
12	2	None	3.5 recon	Y	Y
13	5	2.7 recon	2.4 LCP	Y (2)	Y
14	5	2.7 recon	2.4 LCP	N	Y (2)
15	5	2.7 recon	2.4 LCP	N	Y (2)
16	6	2.7 LCP	2.4 LCP	N	N
17	5	2.7 recon	2.4 LCP	Y	Y
18	5	2.7 recon	2.4 LCP	N	N
19	0	None	3.5 recon	N	Y
20	5	3.5 locking	2.4 recon	Y	Y
Total/Avg				7/20	17/20

Avg, average; IF, interfragmentary; LCP, locking compression plate; recon, reconstruction plate; N/A, not applicable.

positive cultures. Of the 17 patients with positive cultures, 15 were treated for infection with an extended course of antibiotics (Table 2). The culture results of the remaining 2 were considered to be contaminants and were not treated (Table 1). Of the 15 patients treated for infection, 13 had cultures positive for P. acnes (1 of which was a dual infection with *Staphylococcus auricularis* in addition to *P. acnes*), and the remaining 2 patients treated for infection

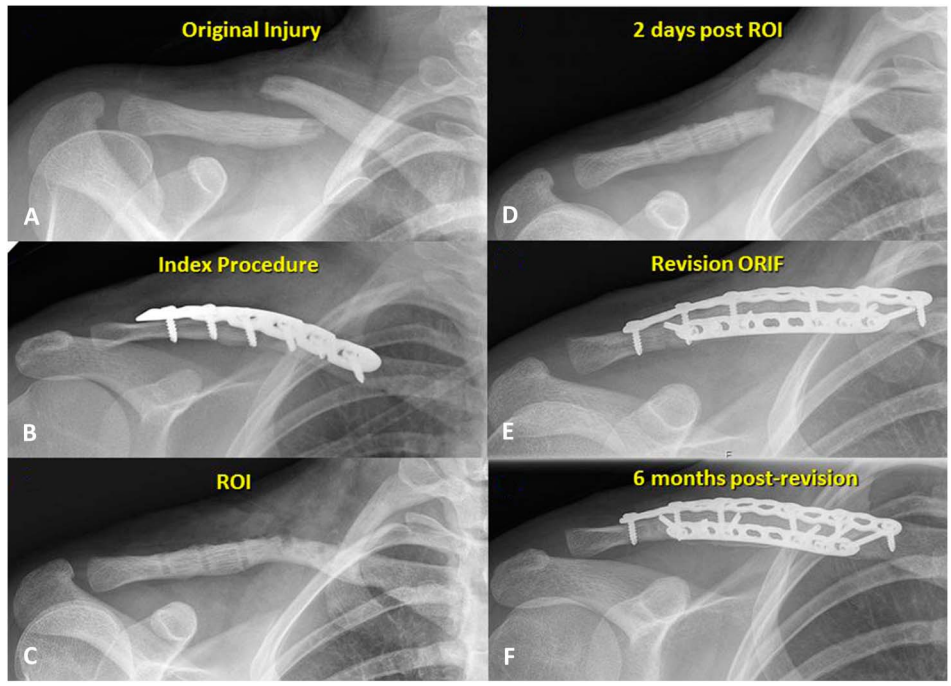

FIGURE 1. An 18-year-old female sustained a right clavicle fracture (A) and underwent right clavicle open reduction internal fixation (ORIF) (B). She had the clavicular plate removed over 18 months after the index procedure (C). Two days after implant removal, she felt persistent pain in the shoulder and presented with "re-fracture" (D). The patient underwent revision osteosynthesis with a 2.4 locking compression plate anteriorly and a 2.7 reconstruction plate superiorly (E). Radiographs taken at 6 months postoperatively demonstrate healing and maintained alignment (F). ROI, removal of implant. **Editor's Note:** A color image accompanies the online version of this article.

had cultures positive for *Staphylococcus epidermidis*. Of the 2 patients with positive cultures that were regarded as contaminants and not treated with antibiotics, 1 had 1 of 5 cultures positive for an alpha-hemolytic *Streptococcus* species, and the other had 1 of 4 cultures positive for *P. acnes* and 1 of 4 cultures positive for *Enterococcus faecalis*. Of the 18 patients who were cultured intraoperatively, only 1 patient had no positive cultures; all 5 cultures sent from this patient were negative.

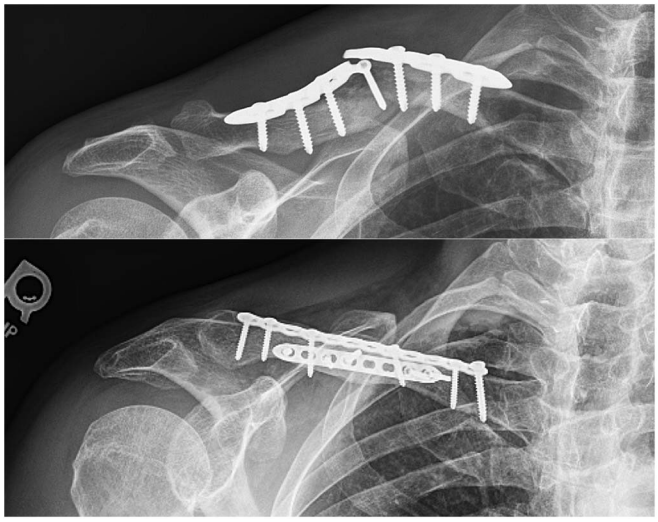

FIGURE 2. Case #15, a 65-year-old male who underwent ORIF of the right clavicle at an outside hospital. He presented 1 year later complaining of fatigue and weakness of his right shoulder. Radiograph at the time demonstrated the broken superior plate and nonunion (above). He underwent removal of the implants, takedown of the nonunion, and revision osteosynthesis with an anterior 2.4-mm locking compression plate and a superior 2.7-mm reconstruction plate (below). Cultures at the time of revision were positive for *P. acnes*.

In cases of positive cultures, an infectious disease specialist was consulted who gave recommendations for type and duration of antibiotics. Eight patients were treated with a course of intravenous antibiotics on discharge through a peripherally inserted central catheter, and 7 patients were treated with oral antibiotics (Table 2).

For the first 4 cases of the series, a single anterior inferior reconstruction plate was used in the revision surgery. However, midway throughout the study, a new protocol of an anterior locking compression plate in combination with a superior reconstruction plate was adopted. In 17 of the 20 cases, an interfragmentary screw was used. In 18 of 20 cases, bone graft was used; ICBG was used in 8 cases. Demineralized bone matrix was used in 7 cases. In 1 case, bone morphogenetic protein (BMP) (Infuse)© was used, and in 2 cases, bone marrow aspirate concentrate was used.

One patient (case #5 with no positive cultures) was lost to follow-up after 5 weeks, and another patient did not initially return for postoperative follow-up but returned for another injury 5 years after the revision surgery and was reassessed. The remaining 18 patients with timely postoperative follow-up achieved union at an average 20.9 weeks (range 5–63 weeks) after revision surgery (Fig. 3). There was no significant difference in time to radiographic union between patients with P. acnes compared with patients without P. acnes cultures ($P = 0.8825$). Average clinical follow-up was 30 months (range 2–145 months), and the average radiographic follow-up was 33 months (range 2–145 months). No patients required a revision procedure after the nonunion surgery.

TABLE 2. Cases of Clavicle Nonunions Treated With Antibiotics for Infection

Case	Positive Cultures	Organism	Antibiotic Regimen	Antibiotic Duration, wk
2	4/5	*P acnes*	Rocephin IV × 6 wk followed by penicillin PO × 3 mo	16
3	3/3	*Staphylococcus epidermis*	Rocephin IV and rifampin PO × 6 wk followed by rifampin PO and cephalexin PO × 6 wk	12
6	1/2	*P acnes*	Clindamycin PO	4
7	5/5	*P acnes*	Amoxicillin PO	16
8	4/5	*P acnes*	Ciprofloxacin PO and rifampin PO	6
9	4/5	*P acnes*	Penicillin PO	12
10	3/5	*Staphylococcus epidermidis*	Linezolid PO	10
11	1/1	*P acnes*	Clindamycin PO	4
12	1/2	*P acnes*	Penicillin PO	8
13*	1/5	*P acnes*	Ceftriaxone IV × 3 wk followed by daptomycin IV × 3 wk followed by 4.5 mo suppression with doxycycline PO	24
14	5/5	*P acnes*	Ceftriaxone IV × 6 wk followed by amoxicillin PO × 30 wk	36
15	5/5	*P acnes*	Ceftriaxone IV × 6 wk followed by suppression with amoxicillin PO × 28 wk	34
16	5/6	*P acnes, Staphylococcus auricularis*	Daptomycin IV	6
17	3/5	*P acnes*	Ceftriaxone IV × 6 wk followed by amoxicillin PO × 24 wk	30
20†	1/5	*P acnes*	Piperacillin/tazobactam IV × 5 wk followed by vancomycin IV × 1 wk followed by rifampin PO and minocycline PO × 30 wk	36

*This patient was switched to daptomycin after developing neutropenia on ceftriaxone.
†This patient was switched from piperacillin/tazobactam to vancomycin after developing fevers.
IV, intravenous; PO, per os (orally administered).

DISCUSSION

A review of a tertiary center's orthopaedic trauma service database identified 20 cases of nonunion after primary osteosynthesis of closed midshaft clavicle fractures. The purpose of the study was to establish potential causes for nonunion and determine the outcome of a single-stage revision. We noted a surprisingly high rate of infection as 15 of the 18 (83%) cases in which cultures were taken were considered infected and treated with antibiotics. Using treatment principles previously described, all cases with greater than 6-month follow-up achieved radiographic and clinical union after single-stage nonunion takedown and revision open reduction, internal fixation. Targeted antibiotic treatment was added when an infection was diagnosed.

Nonunion as a complication after nonoperative management of clavicle fractures is frequently reported in the literature,[3,13,25] but nonunion as a complication after primary osteosynthesis is not well described. In this series, 94% (17 of 18) of the nonunions had positive cultures, of which 15 were considered to represent the presence of infection. Fourteen of 18 had cultures positive for *P. acnes*. Although *P. acnes* has been reported frequently in open shoulder surgery,[26,27] only several case studies have documented its association with clavicle fractures.[19–21] The incidence of infection in this study is higher than the incidence reported in cases of nonunion after osteosynthesis of humerus fractures (28%).[28] The incidence of positive culture in this study is also higher than that reported in primary or revision arthroplasty surgery of the shoulder (29%–42%).[29,30]

As positive cultures are often identified incidentally, the clinical significance of *P. acnes* presents a quandary for orthopaedic surgeons. A recent diagnostic study found a 20.5% (24 of 117) rate of positive culture for all patients undergoing shoulder surgery using the deltopectoral approach, and 83% of those cultures grew *P. acnes*.[26] In patients undergoing arthroscopic shoulder surgery, the rate of positive culture for *P. acnes* was reported as high as 56%.[31] Patel et al[32] reported a higher burden of *P. acnes* near the anterior and posterior acromion compared with the axilla. Hudek et al[27] reported twice as high of an infection rate when using the anterolateral approach compared with the deltopectoral approach for proximal humerus fractures, which may be secondary to higher bacterial burden in this area. Males have a higher *P. acnes* burden compared with females,[27] and lack of hair may be protective against *P. acnes* colonization.[33]

Despite the controversy surrounding its clinical importance, the remarkably high incidence of cultures positive for *P. acnes* (72%) in this series suggests a role of *P. acnes* in the pathogenesis of clavicle nonunion after primary osteosynthesis. Additional factors that may contribute to the higher rate of infection found in clavicle nonunions in this study compared with nonunions of other long bones after osteosynthesis are the more superficial anatomy of the clavicle, its lack of soft tissue coverage, or the tendency toward stripping the periosteum and blood supply during the dissection to expose the fracture.

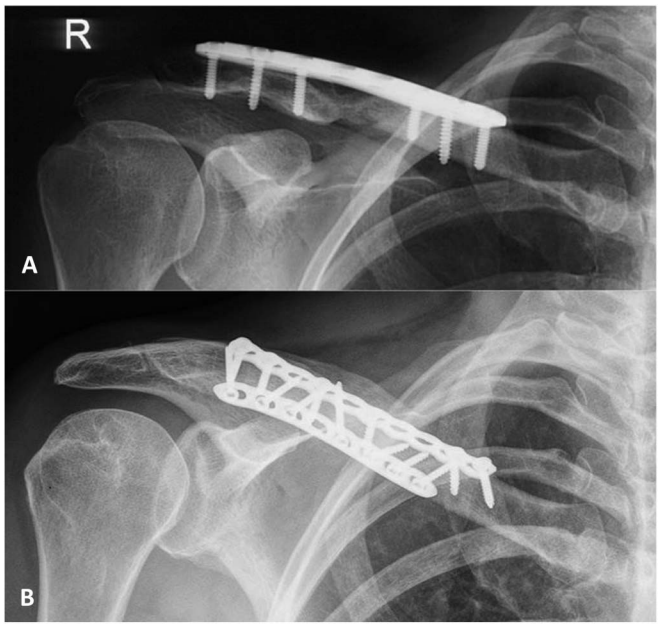

FIGURE 3. Forty-nine-year-old female presented with an atrophic nonunion after primary osteosynthesis of the clavicle (A). The fracture was debrided and a 2.4-mm locking compression plate was applied anteriorly and a 2.7-mm reconstruction plate applied superiorly. At 2 months postoperatively, there was evidence of healing (B).

The current protocol at our institution has evolved to treating *P. acnes* infections with a 6-week course of intravenous antibiotics followed by oral antibiotic suppression, usually until the nonunion heals and/or the implants are removed. Conducting a prospective study to determine the necessity of this antibiotic regimen would be challenging, given the rarity of clavicle nonunions, and the tendency of clinician preference toward treatment. However, we can infer from this series that our treatment protocol of single-stage revision with antibiotic treatment in case of positive cultures and suspicion of infection has resulted in 100% union rate. Although in this series, the preferred method of fixation for clavicle nonunions was with dual plating, others have reported success in treating clavicle nonunions with an anterior plate.[34]

Technical errors and poor fixation, notably short plate fixation and unicortical screws, have been associated with increased risk of clavicle nonunion in the literature.[18] In this study, interfragmentary fixation was applied during the primary surgery in only 7 of the 20 cases, potentially leading to increased motion at the fracture site and contributing to the development of nonunion in the 13 cases without interfragmentary fixation. In addition to treating the infection, achieving compression through the nonunion site is essential to the procedure's success. Wherever possible, compression was achieved in this series through interfragmentary screw placement. In cases of transverse fractures of the clavicle, compression was achieved either using compression plates and through a pull screw outside the plate. Furthermore, the biomechanical importance of interfragmentary fixation in treating nonunions has previously been described.[23,28]

As most patients in this series were initially treated at outside institutions and presented to our service for management of their nonunion, there is a possibility of selection bias inherent in this series. In addition, there is a possibility that cases of clavicle osteosynthesis performed at our institution were ultimately treated for nonunions at outside institutions and not included here. Therefore, the 0.55% rate of clavicle nonunion after primary osteosynthesis that we identified may not accurately estimate the rate of nonunion after primary osteosynthesis. Furthermore, throughout the study period, the suspicion for infection was not uniformly high among patients with clavicle nonunions after osteosynthesis. As a result, there is a lack of consistency across the cohort in the number of cultures taken during each case and the antibiotic regimen chosen (Tables 1 and 2). Likewise, histology was not routinely obtained, although histology for indolent orthopaedic *P. acnes* is often not found to be consistent with infection in our experience. Although histology has proven value for confirming diagnosis of infected total hip and knee arthroplasty, the literature regarding histology in *P. acnes* shoulder infection is scant and suggests that an altered histologic guideline be considered for diagnosing such infections.[35]

An additional inherent limitation to this study is the heterogeneity of the 20 patients in this series, with several cases of nonunion identified immediately after implant removal and potentially representing refracture. Given the low-energy nature and proximity of the "re-fracture" to the implant removal, those cases were classified as fibrous nonunions in this series, but they potentially reflect a refracture through a previous screw hole. There was also additional heterogeneity in the choice of antibiotic and duration of antibiotic treatment.

Notably, cases 6, 11, and 12 had only 1 or 2 cultures available for our review, making the positive results difficult to interpret and raising the potential for a laboratory contaminant in these cases (Table 1). In addition, cases 13 and 20 had 1 of 5 positive for bacteria and were treated with antibiotics—these 2 cases could have been interpreted as a contaminant according to many surgeons' protocols. Even if these 2 cases are considered noninfected, this still gives a 13 of 18 (72%) infection rate to the series, which remains clinically important. Recent literature has reported the rate of "surprise" infection in nonunions of long bone fractures as high as 20%.[36] The authors recommend obtaining cultures in all cases of nonunions, regarding all positive cultures as infections and treating such patients with antibiotics. Further research is warranted to investigate the cost-effectiveness of this approach.

The main strength of the study is the number of consecutive clavicle nonunions reported and followed for an average 30 months. This is the largest series of clavicle nonunions after primary osteosynthesis and reinforces the need to consider infection when clavicle fractures fail to heal after fixation.

CONCLUSIONS

In our cohort of clavicle nonunions after operative fixation over a 20-year period, we found a high incidence of

indolent infection and a low rate of interfragmentary fixation. Revision surgery for clavicle nonunions should focus of the diagnosis and treatment of potential infection and emphasize compression across the nonunion site with interfragmentary fixation or compression plating. If these issues are addressed, the success rate of single-stage revision surgery is very favorable.

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