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Is Surgery for Displaced, Midshaft Clavicle Fractures in Adults Cost-Effective? Results Based on a Multicenter Randomized Controlled Trial

Abstract

Objectives—To determine the cost-effectiveness of open reduction internal fixation (ORIF) of displaced, midshaft clavicle fractures in adults.

Design—Formal cost-effectiveness analysis based on a prospective, randomized controlled trial.

Setting—Eight hospitals in Canada (seven university affiliated and one community hospital)

Patients/Participants—132 adults with acute, completely displaced, midshaft clavicle fractures

Intervention—Clavicle ORIF versus nonoperative treatment

Main Outcome Measurements—Utilities derived from SF-6D

Results—The base-case cost per quality adjusted life year (QALY) gained for ORIF was \$65,000. Cost-effectiveness improved to \$28,150/QALY gained when the functional benefit from ORIF was assumed to be permanent, with cost per QALY gained falling below \$50,000 when the functional advantage persisted for 9.3 years or more. In other sensitivity analyses, the cost per QALY gained for ORIF fell below \$50,000 when ORIF cost less than \$10,465 (base case cost \$13,668) or the long-term utility difference between nonoperative treatment and ORIF was greater than 0.034 (base-case difference 0.014). Short-term disutility associated with fracture healing also affected cost-effectiveness, with the cost per QALY gained for ORIF falling below \$50,000 when the utility of a fracture treated nonoperatively prior to union was less than 0.617 (base-case utility 0.706) or when nonoperative treatment increased the time to union by 20 weeks (base-case difference 12 weeks).

Conclusions—The cost-effectiveness of ORIF after acute clavicle fracture depended on the durability of functional advantage for ORIF compared to nonoperative treatment. When functional benefits persisted for more than 9 years, ORIF had favorable value compared with many accepted health interventions.

INTRODUCTION

Fractures of the clavicle are common injuries, representing 4% of all fractures and occurring with an incidence of 64 per 100,000/year.^{1,2} Approximately 70% of clavicle fractures involve the midshaft, with males accounting for 70% of these fractures.³ Given that the average age of a patient sustaining a midshaft clavicle fracture is 33 years, any functional deficit associated with the injury has the potential for substantial economic impact.

Traditionally, midshaft clavicle fractures have been treated nonoperatively with either a sling or figure-of-eight harness. The classic literature suggested that the nonunion rate for clavicle fractures was under one percent and that very few patients had long term functional deficits related to the fracture.^{4,5} However, more recent studies of nonoperative treatment of displaced midshaft clavicle fractures have demonstrated nonunion rates of 13–15% and a 20–25% decrease in shoulder and arm strength at five year follow-up.^{6–9} These findings have prompted surgeons to reconsider operative treatment of these injuries.

Open reduction and internal fixation (ORIF) of the clavicle has typically been reserved for fractures that are open, threaten the overlying skin or go onto nonunion following nonoperative treatment. However, a recent randomized controlled trial (RCT) comparing initial ORIF to nonoperative treatment for displaced, midshaft clavicle fractures in adults demonstrated that ORIF resulted in significantly better outcomes as measured by the Constant shoulder score and the Disabilities of the Arm, Shoulder and Hand (DASH) scale out to one year.¹⁰ In addition, the complications associated with ORIF of the clavicle were uncommon and relatively benign (the majority related to hardware or superficial infection).^{9,10} Given these findings, orthopaedic surgeons must now decide if operative treatment of displaced, midshaft clavicle fractures should be offered to patients as initial treatment.

Operative treatment of all displaced, midshaft clavicle fractures would substantially increase the cost of treating this common injury. In addition, it is unclear if the functional benefits of surgery outweigh the surgical risks and justify the costs associated with operative treatment. As a result, this study was performed to determine the cost-effectiveness of ORIF compared to nonoperative treatment of displaced, midshaft clavicle fractures in adults. The next section offers a brief introduction to cost-effectiveness analysis for those unfamiliar with it.

Introduction to Cost-Effectiveness Analysis

Cost-effectiveness analysis (CEA) aims to determine the cost to society for the incremental health benefit derived from an intervention that is more costly than an alternative, less effective treatment. In order to compare the cost-effectiveness of a wide variety of treatments across many medical specialties, a universal scale of health must be used to measure preference for health outcomes. In cost-effectiveness analysis, the quality-adjusted life year (QALY), which combines both length and quality of life in a single number is the recommended measure of health benefit. To estimate QALYs, a *utility*, which is a numeric preference rating of health ranging from 0 (equivalent to death) to 1 (perfect health) is used to value each health state. Classically, utilities have been derived using techniques like the time trade-off, which essentially determines how much time in a state of suboptimal health people would be willing to trade for a lesser amount of time in perfect health.¹¹ More recently, techniques have been developed to determine utilities based on standard questionnaires like the SF-36.¹² The QALYs are determined by multiplying utility for each health state by the length of time in each health state and summing up over time. For example, 2 years spent in a poor health state with a utility of 0.5, followed by 10 years in a good health state with a utility of 0.8 would be equivalent to 9 QALYs. To compare the benefits of various interventions, cost-effectiveness analysis determines the gain in *quality adjusted life years* (QALYs) associated with an intervention. The advantage of QALYs is that they allow for the comparison of very different health states across medical disciplines.

The other half of the cost-effectiveness equation is the cost. While an intervention typically produces a health benefit, that benefit comes at a cost to society. Determining the cost of an intervention is challenging, so many cost-effectiveness analyses use gross costing based on average reimbursements for various procedures. After determining the costs and benefits associated with an intervention, these must be compared to another treatment. This is done by determining the *incremental cost effectiveness ratio* (ICER). The ICER is defined as the difference in cost between the two treatments divided by the difference in utility. Traditionally, an ICER of \$50,000/QALY has been used as a cost-effectiveness threshold as this was the ICER for hemodialysis, an intervention for which society has decided to pay.¹³ More recently, some authors have suggested that \$100,000/QALY is a more realistic cost-effectiveness threshold as many frequently used interventions fall in the \$50,000–\$100,000/QALY range.^{14–16} In theory, CEA should allow societies to maximize the value of their healthcare expenditures, and Great Britain has set ICER thresholds to determine which services should

be provided by their National Health Service.¹⁷ However, there is little evidence that healthcare systems, including those that currently ration care, have been consistently using CEA to guide rational treatment guidelines.¹⁸ As healthcare spending comes under greater scrutiny and decisions regarding which treatments to provide are made, evaluating the cost-effectiveness of an intervention will be essential.

PATIENTS AND METHODS

Randomized Controlled Trial

A recent multicenter RCT comparing ORIF to nonoperative treatment of displaced, midshaft clavicle fractures in adults was performed at eight centers in Canada.¹⁰ One hundred thirty-two patients were randomized to ORIF or nonoperative treatment, with 60 ORIF patients and 47 nonoperative patients completing one year follow-up. Study participants completed an SF-36 questionnaire at six weeks, three and six months, and one year following enrollment in the trial. Data from this study formed the basis for the event probabilities and utilities used in the current model. Further details about this study can be obtained from the original report.¹⁰

Decision Tree, Events, and Outcomes

A decision tree (Figure 1) modeling the possible events following the decision to pursue ORIF or nonoperative treatment after acute fracture was based on complications and outcomes reported in the RCT or other literature when unavailable from the RCT (Table 1, see *Event Probabilities*).^{9,10} Subsequent to undergoing ORIF, the following possible complications were modeled: deep infection requiring debridement, nonunion, and plate irritation requiring hardware removal. The model assumed that all fractures eventually united with surgery (repeat surgery for nonunion was included in the model), and that disutility related to complications was short-term, so that all surgically treated patients eventually reached the long-term post-ORIF health state (see *Health States and Utilities*, below). Following nonoperative treatment, the following complications were modeled: symptomatic nonunion requiring operative treatment, asymptomatic nonunion, and symptomatic malunion requiring operative treatment. If nonoperative treatment was initially selected but operative treatment was performed for nonunion or symptomatic malunion, the long-term post-ORIF health state was assigned. The model assigned the long-term post-nonoperative health state to those who did not require operative treatment for nonunion or malunion. The model took into account all possible combinations of events (i.e. multiple complications and operations could occur within a patient, although each patient was limited to one additional surgery for nonunion following the initial surgery), and it assumed that all patients eventually arrived at one of the two possible long-term health states (post-ORIF or post-nonoperative).

Event Probabilities

The probabilities of most events in the base case analysis were obtained from the RCT data (Table 1).¹⁰ These probabilities were very similar to those reported by the largest meta-analysis on the subject that reviewed twenty-two observational studies and a recent RCT comparing intramedullary nailing to non-operative treatment.^{9,19} The probability of events not reported in the RCT, including fracture healing following surgery for an established nonunion,²⁰ nonunion following corrective osteotomy for malunion,²¹ and symptomatic nonunion following nonoperative treatment,²² were obtained from other sources.

Health States and Utilities

Utilities for the two long-term health states (post-ORIF function and post-nonoperative function) and six short-term health states (ORIF prior to union, nonoperative treatment prior to union, nonunion [persisting beyond the average time to union], symptomatic malunion,

wound infection, and plate irritation) were estimated from the RCT SF-6D data (a subset of SF-36 responses) using the method reported by Brazier et al (Table 2).¹² In brief, this method converts SF-36 scores to utilities using equations derived from standard gamble results obtained in interviews with over 600 British citizens. This study performed the standard gamble on 249 health states, from which the utilities for all health states described by the SF-6D are estimated. The utilities for post-ORIF function and post-nonoperative function were estimated from the one year surveys of patients who did not sustain one of the modeled complications (nonunion, symptomatic malunion, wound infection or plate irritation). All patients who underwent surgery, either primarily or following nonunion or malunion, were assigned the same long-term utility since it has been shown that surgery for nonunion or malunion resulted in similar or only marginally inferior outcomes compared to those undergoing primary ORIF.²³ Given the absence of evidence that delayed surgery led to worse outcomes, we chose to assign the same long-term utility in order to avoid biasing the study against nonoperative treatment. The utility of living with a fracture prior to union following ORIF or nonoperative treatment was determined from the six-week and three-month surveys of patients who did not have a complication in order to estimate the average utility of living with a healing fracture over time. The utilities of the other short-term health states were estimated from the surveys of patients sustaining each complication at the following time points: nonunion and symptomatic malunion at six months (the earliest time at which these could be diagnosed), wound infection at six weeks, and plate irritation at one year (no plates were removed before one year).

The duration spent in each short-term health state was based on the typical clinical course of each state. Deep infection resulted in irrigation and debridement and was associated with a decreased utility modeled to persist for 6 weeks (taking into account the disutility of IV antibiotics, constitutional symptoms, wound care, etc). An unhealed fracture was modeled for 16 weeks following ORIF and 28 weeks following nonoperative treatment,¹⁰ symptomatic nonunion for 12 weeks beyond the typical time to union (then the model assigns the patient to surgery), symptomatic malunion 12 weeks following union (then the model assigns the patient to surgery), and plate irritation 36 weeks (based on plate removal at one year²⁴ following 16 weeks in the unhealed fracture state). The duration spent in the long-term health states (post-ORIF and post-nonoperative) was modeled as 55 months for the base case analysis. This was based on a cohort study of patients treated nonoperatively who had clinically significant decreases in DASH and Constant scores at an average of 55 months following injury.⁸ The duration of benefit of ORIF is unknown beyond one year (the duration reported in the RCT¹⁰). For sensitivity analysis, the duration of the long-term health states ranged from 1 year to 47 years (the average life expectancy of a 33 year old in the United States based on 2002 life tables;²⁵ 3% discounting was applied). The duration spent in the long-term health state reflects the duration of benefit of ORIF. Beyond that point, the outcomes are the same for the two treatment groups and no longer affect the analysis.

Utilities were multiplied by the expected duration spent in each state to yield QALYs, which were discounted 3% for the long-term health states that persisted longer than one year.¹¹

Estimated Costs

Direct costs for ORIF and treatment of associated complications were based on 2005 national average Medicare reimbursements for hospital, anesthesia, and physician services (Table 3).^{26,27} The cost of nonoperative treatment was based on the 2005 average Medicare reimbursement for physician services alone. The hospital reimbursements were based on the following diagnostic related groups (DRG): 443 “other OR procedure for injuries without CC” for ORIF and operative treatment of nonunion and malunion, 538 “local excision and removal of internal fixation devices except hip and femur without CC” for hardware removal, and 264

“skin graft and/or debridement for skin ulcer or cellulitis without CC” for wound infection debridement. The physician reimbursements were based on the following current procedural terminology (CPT) codes: 23515 (ORIF of clavicle fracture), 23500 (closed treatment of clavicle fracture), 23480 (operative treatment of nonunion or malunion), 20680 (removal of hardware), and 11080 (wound infection debridement). Anesthesia costs were also CPT based: 00450 (ORIF, wound infection debridement or removal of hardware) and 00452 (operative treatment of nonunion or malunion). The costs of emergency department visits and radiology were not considered since they were likely similar across the two groups.

Given that the vast majority of clavicle fractures are sustained in patients under 65 years old, Medicare reimbursements substantially underestimate the actual cost of treatment.²⁸ To account for this in the base case, average Medicare reimbursements were converted to Medicare charges based on the ratio of total 2005 Medicare charges to 2005 Medicare reimbursements for DRG 443, “Other OR procedure for injuries without CC” (a factor of 3.66).²⁹ Prior cost-effectiveness analyses have estimated that the typical private payer reimbursement is approximately 70% of total Medicare charges,¹⁶ so average Medicare reimbursements were multiplied by 2.56 (0.7×3.66) to yield an estimated average cost. The factor by which Medicare reimbursement was adjusted to yield cost is referred to as the Cost Multiplier and was varied from 1 (cost equal to average Medicare reimbursement) to 3.66 (cost equal to average Medicare charges) in sensitivity analyses. Since all costs were incurred over the short term, no discounting was performed. Costs are reported in 2005 US dollars.

Economic Analyses

In the base case analysis, average cost and expected quality adjusted life expectancy were calculated for nonoperative treatment and ORIF (using a time horizon of 25.8 years, the discounted life expectancy of a 33 year old). The incremental cost-effectiveness ratio (ICER) of ORIF compared to nonoperative treatment was expressed as cost per additional QALY gained. Analyses were completed using TreeAge Pro software (TreeAge Software Inc, Williamstown, MA)

Sensitivity Analyses

All variables including the probability of complications, utility of health states, time spent in health states, and costs of treatment were varied in one-way sensitivity analyses to identify threshold values that would yield an ICER of \$50,000 per QALY, a commonly accepted threshold for cost-effectiveness.¹¹ The ranges of probabilities on which sensitivity analyses were performed were based on the 95% confidence intervals from the largest meta-analysis on clavicle fractures⁹ and clinical judgment (Table 1). Utilities were varied over a range of the mean $\pm$ one standard deviation (Table 2). The costs were varied from average Medicare reimbursement to average Medicare charges.

RESULTS

Utility of Outcome Health States

The utilities for the long-term health states were 0.856 (range 0.43–1, standard deviation [SD] 0.123) for post-ORIF function and 0.842 (range 0.389–1, SD 0.164) for post-nonoperative function (Table 2). The utilities for the short-term health states were 0.761 (range 0.398–1, SD 0.140) for fracture treated with ORIF prior to union, 0.706 (range 0.364–1, SD 0.170) for fracture treated nonoperatively prior to union, 0.690 (range 0.457–0.948, SD 0.146) for nonunion (persisting beyond the average time to union), 0.637 (range 0.311–0.948, SD 0.196) for symptomatic malunion, 0.746 (range 0.559–0.869, SD 0.151) for plate irritation, and 0.607 (range 0.525–0.688, SD 0.115) for wound infection.

Cost-Effectiveness for the Base Case

The base case analysis assumed a discounted life expectancy of 25.8 years, a discounted duration of ORIF treatment benefit of 4.35 years, and a Cost Multiplier of 2.56. In this scenario, choosing initial nonoperative treatment yielded 24.830 QALYs at an average cost of \$5448, while choosing ORIF initially yielded 24.991 QALYs at an average cost of \$15,914. This yields an ICER of \$65,222/QALY for ORIF (0.160 additional QALYs for an additional \$10,466). In this scenario, one third of patients who initially had nonoperative treatment went on to have ORIF secondary to nonunion or symptomatic malunion.

Sensitivity Analyses

The duration of benefit of ORIF contributed the most uncertainty to the analysis, followed by the utilities of the long-term health states (post-nonoperative function and post-ORIF function) and the Cost Multiplier. The \$50K/QALY threshold was crossed in one way sensitivity analysis for each of these variables as well as for the utility of a fracture treated nonoperatively prior to union and the time to union with nonoperative treatment (Table 4).

The duration and magnitude of benefit of ORIF were the largest drivers of cost effectiveness in this model, with the ICER for ORIF varying from \$28,150/QALY if the duration of benefit was permanent to \$82,110/QALY if the benefit persisted for only one year. The ICER for ORIF fell below the \$50K/QALY threshold if the duration of benefit lasted for at least 9.3 years. The model was also sensitive to the magnitude of benefit associated with ORIF compared to nonoperative treatment. The ICER for ORIF varied from \$21,697/QALY if the long-term utility gain associated with ORIF was 0.14 to \$84,521/QALY if there was no long-term utility benefit associated with ORIF (assuming a long-term utility of 0.842 for nonoperative treatment). The ICER fell below the \$50K/QALY threshold when the long-term utility of ORIF was at least 0.03 greater than the long-term utility of nonoperative treatment. The relationship between duration and magnitude of benefit is demonstrated in the two-way sensitivity analysis (Figure 2).

In the short term, nonoperative treatment was associated with disutility prior to union and increased time to union, both of which contributed to substantial uncertainty in the model. The ICER for ORIF ranged from \$41,208/QALY if the utility associated with a nonoperatively treated fracture prior to union was 0.536 (compared to 0.761 for an unhealed fracture treated operatively) to \$80,376/QALY if there was no disutility associated with nonoperative treatment prior to union. The ICER fell below \$50,000/QALY when the utility associated with an unhealed fracture treated nonoperatively was less than 0.617 (base case 0.706). As the time to union with nonoperative treatment varied from 16 weeks (the average time to union for ORIF) to 32 weeks (28.4 weeks in the base case), the ICER ranged from \$111,626/QALY to \$56,982/QALY. The ICER fell below the \$50K/QALY threshold when the time to union with nonoperative treatment was greater than 37 weeks. The effect of the disutility and the increased time to union associated with nonoperative treatment prior to union is demonstrated in the two-way sensitivity analysis (Figure 3).

The cost of treatment was an important variable, as it is in all cost-effectiveness analyses. If Medicare reimbursement (i.e. Cost Multiplier=1) was an accurate representation of the costs associated with treating a clavicle fracture, initial ORIF would be cost effective, with an ICER of \$25,477/QALY. The ICER crossed the \$50K/QALY threshold when the cost multiplier was greater than 1.96, indicating ORIF is cost-effective when the costs are less than approximately twice the Medicare reimbursement rate. If Medicare charges accurately represent costs (Cost Multiplier=3.66), the ICER was \$93,247/QALY.

DISCUSSION

In the base case scenario, the incremental cost-effectiveness ratio for ORIF of displaced, midshaft clavicle in adults was \$65K/QALY, somewhat higher than the accepted cost-effectiveness threshold of \$50K/QALY but within the range of many widely used treatments.³⁰ However, this estimate was dependent on variables with a high level of uncertainty surrounding their actual values. Sensitivity analyses revealed that the duration and magnitude of functional benefit of ORIF, the disutility prior to union and increased time to union associated with nonoperative treatment, and the cost of treatment were the most substantial drivers of uncertainty in the current model.

The duration and magnitude of functional benefit of ORIF is largely unknown, and these variables were the most important factors driving cost-effectiveness. The only head to head comparison of ORIF to nonoperative treatment is a randomized controlled trial (RCT) that demonstrated a significant benefit of ORIF at one year follow-up.¹⁰ If the duration of functional benefit is assumed to persist for only one year, the ICER for ORIF was over \$80K/QALY, representing a relatively costly intervention. However, a case series of patients treated nonoperatively demonstrated DASH and Constant scores indicative of clinically meaningful deficits at a mean follow-up of 55 months, suggesting that the duration of benefit may be at least that long.⁸ Given that there is no biological mechanism to explain further improvement in function beyond five years in patients with healed clavicle fractures, the functional deficits associated with nonoperative treatment may be permanent. In this case, ORIF becomes a cost effective strategy (\$28K/QALY in a 33 year old patient). While the duration of functional benefit is obviously important, the magnitude of benefit of ORIF is also essential in evaluating the treatment decision. The RCT on which the current study was based revealed only a slight decrease in utility associated with nonoperative treatment at one year (0.842 nonoperative vs. 0.856 ORIF). However, this difference is likely clinically meaningful as the DASH and Constant scores were significantly lower at one year for patients treated nonoperatively.¹⁰ Given the wide range of utilities among those without complications in both treatment arms, the disutility associated with nonoperative treatment is likely to vary substantially between individuals based on their preferences.

The functional deficit prior to union and increased time to union associated with nonoperative treatment were the most influential short term factors driving cost-effectiveness. If the time to union following nonoperative treatment was equal to that of ORIF (16 weeks), the ICER for ORIF increased to \$111K/QALY, indicating that the benefit of faster union was a substantial driver of cost-effectiveness. The estimated times to union in the model were based on the reported times to radiographic union in the RCT,¹⁰ and clinical union may occur earlier. However, only the difference in time to union (12 weeks in the base case analysis) affects the incremental analysis. The model was also sensitive to the disutility of nonoperative treatment prior to union. In the base case, the utility for nonoperative treatment prior to union was 0.06 less than that for ORIF. This likely represents the clinical benefit of immediate stability following ORIF. Sensitivity analysis revealed that if the utility following nonoperative treatment prior to union was 0.14 less than the utility for ORIF, the ICER would fall below \$50K/QALY. Again, we observed a wide range of utilities prior to union in both treatment arms, suggesting that the disutility associated with nonoperative treatment is likely to vary substantially between individuals.

Cost is an important variable in most cost-effectiveness analyses (CEA), and the difficulty in determining the actual cost of medical treatment is well known.¹¹ Gross costing was used to determine the costs of treatment, while microcosting may have yielded more accurate cost estimates.¹¹ However, microcosting for surgical treatment is quite challenging, is rarely used for surgical CEAs,^{16,31} and does not easily take into account known regional variation in costs.

³² Our costs were based on national averages, lending credibility to the generalizability of our analysis. While selection of cost for the base case was somewhat arbitrary (i.e. 70% of the amount billed to Medicare), this approach has been used previously to approximate costs of treatment in the non-Medicare population.¹⁶ Estimating costs at the Medicare reimbursement level would have clearly underestimated the cost for the typical clavicle fracture patient. Costs can also be lower in other healthcare systems, which should be considered by those working outside the US. For example, the Canadian physician reimbursement is \$231.10 for clavicle ORIF, compared to the average Medicare reimbursement of \$576.80.³³ The ICER for ORIF varied from \$25K/QALY to \$93K/QALY over a wide range of costs, suggesting that the actual cost-effectiveness lies in a socially acceptable range and that clinical factors contributing to uncertainty may be more important to evaluate.^{14,34}

Comparison of our results to the literature is limited given that there are no prior CEAs of clavicle fracture treatment. In fact, the CEA literature surrounding fracture care in general is sparse.³⁵ The most comparable study compared operative fixation of non-displaced scaphoid fractures to nonoperative treatment and concluded that operative treatment is highly cost-effective (ICER of \$5438/QALY in a 25 year old patient).³¹ That study used Medicare reimbursements for costs, which likely resulted in a substantial underestimation of the actual costs of treating young patients (i.e. \$1747 for cost of operative treatment).²⁸ In addition, that model estimated that carpal arthritis occurred 50% more frequently in patients treated nonoperatively, persisted throughout life and was associated with a relatively low utility. While that study may have underestimated the ICER for operative treatment of scaphoid fractures, it does demonstrate that operative treatment of fractures traditionally treated conservatively can be cost-effective.

The current analysis shares the limitations of all CEAs and also has limitations specific to the clavicle fracture model. Uncertainty about the probabilities, utilities, durations, and costs in the model leads to substantial uncertainty in our base case analysis. While this was addressed with sensitivity analyses, the model was sensitive to many important clinical and cost variables, indicating that further research is needed to define these values more precisely. Also, to understand the impact of parameter uncertainty we employed a series of one-way sensitivity analyses—taking into account the uncertainty in each variable when considered alone. We acknowledge that a more complex probabilistic sensitivity analysis involving second-order Monte Carlo simulation could address the uncertainty associated with multiple variables simultaneously.³⁶ However, this technique requires additional assumptions regarding the probability distribution for each model parameter and was beyond the scope of our analysis. The current model only accounted for three complications associated with ORIF and two associated with nonoperative treatment, while many other complications are known to occur. In addition, patients were limited to one surgery for nonunion following the initial surgery since the rate of nonunion following surgery is low (around 3%), and one case series suggested that patients required no more than one revision surgery for nonunion.²⁰ Sensitivity analysis revealed that the model was relatively insensitive to variation in the probabilities and utilities of these complications, suggesting that adding less common or less disabling complications should not alter our conclusions. In addition, there were only two long-term health states in the current model. While there are clearly a spectrum of outcomes of both ORIF and nonoperative care, the data from the Canadian RCT provided an “average” outcome for patients who underwent the two treatments.

Utilities were derived from SF-6D surveys of patients in each health state, and the best method to determine utilities remains controversial.³⁷ The main limitation associated with our method is the low number of patients in the complication health states and the wide ranges of utilities associated with each health state. Given these constraints, statistical comparison of utilities was inappropriate. It is reassuring that the relationship between the utilities appear logical (i.e.

complication health states have lower utilities than healed fracture health states). In addition, the model was relatively insensitive to the complication health state utilities that were based on fewer patients.

The current analysis suggests that the cost-effectiveness of ORIF of displaced, midshaft clavicle fractures in adults is highly dependent on the duration and magnitude of functional benefit following ORIF, the disutility prior to union and increased time to union associated with nonoperative treatment, and the actual cost of treatment. In the base case analysis, the ICER for ORIF exceeded the conservative \$50K/QALY cost-effectiveness threshold though was below the \$100K/QALY level that some authors have suggested is a more appropriate benchmark.¹⁴ The large degree of uncertainty in this estimate should be taken into account, and future studies should specifically address the duration of functional benefit associated with clavicle ORIF. Open reduction and internal fixation is most cost-effective for patients who are sensitive to mild functional deficits and strongly value a more rapid return to normal function, particularly in low-cost environments.

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Figure 1.

Model indicating complications and outcomes following ORIF or nonoperative treatment. The broken lines indicate collapsed branches of the tree when a patient is assigned to surgery for a complication, and these branches have similar patterns to those shown for ORIF. p indicates the probability of an event, q indicates quality adjusted life years associated with a long-term outcome, and # indicates a probability of 1-probability of the alternative outcome.

Figure 2.

Two way sensitivity analysis for the long-term utility of ORIF (y-axis) and the duration of functional benefit following ORIF (x-axis). This plot allows one to evaluate the ICER for various combinations of these two variables. The blue shaded area indicates the combinations of these two variables that yield an ICER of below \$50,000/QALY, while the green area includes combinations with an ICER of above \$50,000/QALY. The black circle indicates the base case.

Figure 3.

Two way sensitivity analysis for the utility of nonoperative treatment prior to union (y-axis) and the time (years) to union with nonoperative treatment (x-axis). This plot allows one to evaluate the ICER for various combinations of these two variables. The blue shaded area indicates the combinations of these two variables that yield an ICER of below \$50,000/QALY, while the green area includes combinations with an ICER of above \$50,000/QALY. The black circle indicates the base case.

Table 1

Probabilities of complications used for the base case and range of probabilities used for sensitivity analyses.

Non-Operative Complications	Base Case Probability	Range for Sensitivity Analyses
Nonunion--nonoperative treatment	0.143 ¹⁰	0–0.2
Nonunion becoming symptomatic	0.97 ⁹	0.5–1
Symptomatic Malunion	0.184 ¹⁰	0–0.3
ORIF Complications		
Deep Wound Infection	0.048 ¹⁰	0–0.1
Nonunion--ORIF	0.032 ¹⁰	0–0.08
Nonunion following malunion surgery	0.067 ¹⁴	0–0.1
Plate Irritation	0.081 ¹⁰	0–0.2

Table 2

Utility and duration of health states for the base case and range for sensitivity analysis for duration. The range used for sensitivity analysis for the utilities was the mean $\pm$ 1 standard deviation.

Health State (model abbreviation)	Base Case Utility (SD)	n	Range	Base Case Duration in Health State (years)	Range for Sensitivity Analysis (years)
ORIF States					
Post-ORIF (no complications)	0.856 (0.123)	52	0.430–1.000	4.35	1–25.8
ORIF prior to union	0.761 (0.140)	47	0.398–1.000	0.32	0.12–0.64
Post-Operative Wound Infection	0.607 (0.115)	2	0.525–0.688	0.12	0.04–0.24
Plate Irritation	0.746 (0.151)	5	0.559–0.869	0.68	0.18–1
Nonoperative States					
Post-Nonoperative (no complications)	0.842 (0.164)	31	0.389–1.000	4.35	1–25.8
Nonoperative prior to union	0.706 (0.170)	32	0.364–1.000	0.55	0.32–1
Nonunion	0.690 (0.146)	8	0.457–0.948	0.24	0.12–0.68
Symptomatic Malunion	0.637 (0.196)	9	0.311–0.948	0.24	0.12–1

Table 3

Average national 2005 Medicare reimbursements and conversion to base case cost. Values shown in 2005 US dollars.*

Treatment	Physician reimbursement	DRG reimbursement	Anesthesia Reimbursement	Total Medicare Reimbursement	Base Case Cost
ORIF clavicle	576.80	4558.71	203.70	5339.21	13668.38
ORIF Nonunion- Malunion	828.06	4558.71	275.93	5662.7	14496.51
Wound Infection Debridement	175.47	4864.28	203.70	5243.45	13423.23
Removal of Hardware	288.02	4567.67	203.70	5059.39	12952.04
Nonoperative Treatment	185.32	n/a	n/a	185.32	474.42

* based on Cost Multiplier of 2.56

Table 4

Range of incremental cost effectiveness ratios (ICERs) for ORIF as determined by sensitivity analyses for different variables. The range over which the ICER for ORIF is less than \$50K is indicated.

Variable	Range for Sensitivity Analysis	ICER Range (\$K/QALY)	< \$50K/QALY Threshold
Post-nonoperative function (no complications)	0.678–0.856	19–83	<0.822
Duration of functional benefit following ORIF	1–25.8 yrs	82–28	>9.3 yrs
Utility of fracture treated nonoperatively prior to union	0.536–0.761	41–80	<0.617
Time to union for nonoperative treatment	0.32–1 yr	112–36	>0.72 yrs
Cost_Multiplier	1–3.66	25–93	<1.96