A Cost Analysis of Internal Fixation Versus Nonoperative Treatment in Adult Midshaft Clavicle Fractures Using Multiple Randomized Controlled Trials

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Background: To determine whether the cost of nonoperative treatment, including those who require delayed operative treatment, is less than those receiving initial operative management.

Methods: We identified 4 recent randomized controlled trials comparing operative and nonoperative treatment of displaced midshaft clavicle fractures in adults with a minimum of 1-year follow-up. A decision tree was then created from these data using reoperation for those treated with surgery or delayed operative treatment of those treated nonoperatively as end points. Actual costs estimated from 2013 Medicare reimbursement rates were applied and adjusted to better reflect private insurance rates. We then performed a 2-way sensitivity analysis to test the stability of our model.

Results: Based on our decision tree, the expected costs for operative and nonoperative treatment were $14,763.21 and $3112.65, respectively, producing a cost savings of $11,650.56 with nonoperative treatment. After application of a 2-way sensitivity analysis, our model remains valid until delayed operative treatment for nonoperative patients approaches 95% and reoperation after initial operative management falls below 15%.

Conclusions: From the perspective of a single payer, initial nonoperative treatment of midshaft clavicle fractures followed by delayed surgery as needed is less costly than initial operative fixation.

Key Words: cost analysis, economic analysis, decision tree, clavicle fractures, trauma

Level of Evidence: Economic Level III. See Instructions for Authors for a complete description of levels of evidence.

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INTRODUCTION

Clavicle fractures are common injuries accounting for 2.6%–4% of adult fractures, 80% of which are found in the middle third. They occur typically in a younger working population with a peak incidence in males younger than 30 years old.[1] Based on retrospective studies from the 1960s, nonoperative treatment has been advocated because of the low reported rates of nonunion (1%).[2,3] These results included adolescents and were based on radiographic healing and not patient-driven functional outcomes.

Acute surgical indications for clavicle fractures have been described in patients with open fractures, impending open fractures, multiple injuries, floating shoulder injuries, and symptomatic malunion or nonunion. The consequences of obligate clavicle malunion with nonoperative management for displaced midshaft fractures have been shown to affect not only the cosmetic appearance but also the strength and stamina of the shoulder.[4,5] With newer studies showing higher rates of nonunion (up to 15%) and decreased patient satisfaction,[6–8] a trend toward increased operative treatment has been seen.

Operative techniques have been described with plate osteosynthesis or intramedullary fixation.[9–12] Multiple randomized controlled trials (RCTs) have been published comparing operative with nonoperative treatment in terms of functional outcomes with Constant and DASH scores[13,14] and rates of complications, such as nonunion, symptomatic malunion, which favor initial operative stabilization in the short term.[9–11] Clinical and financial considerations from a patient's perspective show that a decreased recovery time with surgery leads to a more rapid return to work and less need for physical therapy, decreasing lost wages.[15] Because no clear consensus is available based on review of the large volume of literature available,[16] surgeons are faced with difficult decisions on how best to treat adults with displaced midshaft clavicle fractures.

At a time, when health care is under scrutiny, it is important for physicians to have all the information available to make treatment decisions that are both maximally beneficial to the patient and cost conscious. The goal of our study was to provide more data to the discussion of operative versus nonoperative treatment of displaced midshaft clavicle fractures in adults by performing an estimated cost analysis from the perspective of a single payer using multiple RCTs. Our hypothesis is that the cost of nonoperative treatment will remain the least costly even when accounting for nonunions and symptomatic malunions requiring delayed operative intervention.

Decision Tree Analysis

Decision tree analysis is a financial tool designed to produce the best economic decision possible given the

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information available. Specifically, in the field of orthopaedics, there have been many publications using this technique to evaluate the decisions made for a multitude of injuries.[17–22] For every choice that is made, a quantifiable financial cost is incurred in conjunction with an estimated probability. The ability to correctly identify and appropriately apply associated costs with each decision node is important. The variance in costs over time can be accounted for and tested through sensitivity analysis.

Sensitivity Analysis

Health care outcomes and costs will inevitably change over time, which will affect the decision tree model. Sensitivity analysis is an important component of any financial model prone to variations. As costs and/or probabilities change, each variable can be accounted for and the model changed to evaluate the impact of each variable on the overall outcome of the model. Daellenbach et al demonstrated the importance of sensitivity analysis in relation to decisions based on new orthopaedic technologies with their example of the effect of survivorship and cost implications in cemented versus cementless total hip arthroplasty. However, as their model did not have reliable outcome data on failure rates of cementless prostheses, they relied exclusively on clinical judgment and sensitivity analysis for the assumptions created.[23]

MATERIALS AND METHODS

We reviewed the literature for prospective RCTs and meta-analyses from peer-reviewed journals comparing operative and nonoperative treatment of displaced midshaft clavicle fractures in adults. Four RCTs and 1 meta-analysis reviewed were found to meet our criteria.[9–12,24] The 4 RCTs were reviewed in the meta-analysis and were found to have Detsky scores of 16/20 making them well-structured studies.[24] Two of the selected studies evaluated intramedullary fixation and 2 looked at plate fixation versus nonoperative management. Follow-up reported was 1 year for 3 studies and 2 years for 1 study. Functional outcomes were measured at interval during recovery and included Constant shoulder scores, DASH, SANE, and L'Insalata scores. A summary of each of the trials and their results and conclusions can be found in Table 1.

Complications reported in each study include incidences of nonunion, delayed union, symptomatic malunion, infection, and hardware irritation requiring removal. When deciding how best to structure our study, we considered only those complications that would be of most cost and consequence to the payer. We saw those patients in the operative and nonoperative groups who required any secondary surgical procedure after initial treatment as having a major cost-incurring event and looked at the probability of each of these occurring compared with the remainder of the patients in that group. This method of accounting for complications is unique in that it does not consider the patient's functional outcomes or potential cost to the patients in terms of quality-adjusted life-years (QALY). Nonunion and symptomatic malunion are concerning complications when dealing with clavicle fractures, however, not all patients who develop these will request operative treatment even in the face of reported functional deficits.[9] However, a planned hardware removal under general anesthesia may not be considered a complication, yet this is an additional surgery and incurs additional cost.

When constructing our decision tree, we looked at each group and determined the possible paths that each treatment could follow. When presented a patient with a displaced midshaft clavicle fracture and no absolute indications necessitating acute operative stabilization, the surgeon must decide between operative and nonoperative treatment. If operative management is selected, a cost is applied and the patient may then proceed down 1 of the 2 pathways: (1) no further operative intervention or (2) reoperation for any reason. In the selected trials, reoperation occurred in the operative cohort for the following reasons: hardware removal (planned or not), hardware removal with irrigation and debridement (for infection), revision ORIF because of hardware failure, and revision ORIF with bone grafting for nonunion.

In the nonoperative cohort, a similar path is followed. After the decision for nonoperative management is made, the cost is applied and the patient may follow 1 of the 2 pathways: (1) no operative interventions performed or (2) development of a condition requiring operative intervention. The delayed operative procedures performed in the nonoperative cohort included conversion to open reduction and internal fixation (ORIF) (for brachial plexus irritation and impending open fracture), osteotomy and ORIF (for symptomatic malunion), and ORIF with bone grafting for nonunion. Individual or multiple Current Procedural Terminology (CPT) codes were assigned to each of the end nodes of the tree and used to estimate cost. A summary of each CPT code and/or combination can be found in Table 2. The decision tree is shown in Figure 1.

Estimated Cost

Direct cost for each of the CPT codes associated with each of the end nodes in the decision tree was based on the 2013 national average Medicare reimbursement for physician, facility, and anesthesia fees.[25] Cost for nonoperative treatment (CPT 23500) was based on physician fee alone. A summary of the costs associated with each CPT code can be found in Table 2. For the anesthesia fees, the average Medicare reimbursement was found to be $14.88 per unit. Each anesthesia CPT code is associated with a set number of base units. The CPT codes used were 00450 (5 base units) for ORIF, hardware removal, and irrigation and debridement and 00452 (6 base units) for operative treatment of malunion or nonunion. Each 15 minutes of anesthesia time is 1 unit as well. For our estimations, we used 4 time units for ORIF, hardware removal (HWR), and HWR + irrigation and debridement (I & D) and 6 time units for revision ORIF and osteotomy with ORIF for malunion or nonunion to reflect the increased time expected in more complex cases. The 2013 Medicare facility fee reimbursement was based on outpatient surgical center rates for each of the CPT codes. Implants would be paid for through these facilities fees. For the physician and facility fees associated with multiple codes, the total cost was calculated as 100% reimbursement for the first code and 50% for the second.

The decision was made to use Medicare reimbursement data because it is readily available, uniform across the country,

TABLE 1. RCTs Comparing Operative Versus Nonoperative Treatment of Displaced Midshaft Clavicle Fracture

Author	Number of Patients	Operative Treatment	Reoperation for Any Reason—Operative Group	Nonoperative Treatment	Delayed Operative Treatment—Nonoperative Group	Operative Method
Virtanen et al[9]	60	28	0	32	1 (3.13%), ORIF for brachial plexus irritation	Plate
Canadian Orthopaedic Trauma Society[10]	111	62	10 (16.13%); 1 nonunion; 3 HWR and I & D; 5 HWR; 1 revision ORIF	49	19 (38.77%); 8 nonunion; 9 symptomatic malunion; 2 ORIF impending open fractures	Plate
Smekal et al[11]	60	30	18 (60%); 16 HWR; 2 revision ORIF	30	5 (16.67%); 3 nonunion; 2 symptomatic malunion	Pin
Judd et al[12]	57	29	7 (24.13%); 1 revision ORIF; 4 HWR; 2 HWR I & D	28	1 (3.57%); nonunion	Pin
Total	288	149	35 (23.48%)	139	26 (18.71%)	

Author	Number of Nonunions in Each	Average Age	Outcome Scores		Follow-up, y
			Operative	Nonoperative	
Virtanen et al[9]	Operative: 0/26; nonoperative: 6/25	37	CS = 86.5; DASH = 4.3	CS = 86.1; DASH = 7.1	1
Canadian Orthopaedic Trauma Society[10]	Operative: 2/62; nonoperative: 7/49	33.5	CS = 96.1; DASH = 5.2	CS = 90.8; DASH = 13.0	1
Smekal et al[11]	Operative: 0/30; nonoperative: 3/30	37.7	CS = 97.9; DASH scores significantly better in operative group for first 18 wk	CS = 93.7	2
Judd et al[12]	Operative: 1/29; nonoperative: 1/28	26.5	3-wk SANE = 49.8; 1-y SANE = 93.5	3-wk SANE = 36.4; 1-y SANE = 97	1
Total					

and have been used in previously published cost-effectiveness analyses.[17,26] We do acknowledge that the average age of patients in the studies are well below 65 years and that Medicare reimbursement substantially underestimates the actual cost to private payers. To more accurately reflect this cost, we used a cost multiplier derived in the cost analysis by Pearson et al.[26] Their method of conversion included taking Medicare reimbursement and converting them to charges. This factor was then multiplied by 70%, which has been presented as an estimate of private payer reimbursement based on Medicare charges. Using this previously accepted method, all estimated Medicare costs were multiplied by a factor of 2.56. As this multiplier is applied to both pathways, the effect on the model in terms of which is the optimal financial decision will not be affected. The only effect the multiplier can have is to increase or decrease the difference in costs between the pathways.

RESULTS

Data gathered from the 4 RCTs showed a reoperation rate of 23.48% in those initially treated with surgery, with the vast majority of those being for hardware removal. On the nonoperative side, 18.71% of patients went on to require operative intervention for nonunion, impending open fracture and symptomatic malunion.

Our decision tree analysis demonstrated that the expected cost for operative treatment of a displaced midshaft clavicle fracture to be $14,763.21. For nonoperative treatment, the expected cost was $3112.65, showing a projected cost savings of $11,650.56 in favor of this pathway. The incremental costs per patient treated by both operative and nonoperative means are $1653.60 and $2581.17, respectively. Incremental costs are those costs derived from the decision tree using a weighted average of subsequent procedures and their related costs after either initial nonoperative or operative management (Fig. 2).

Because this large discrepancy exists, the 2-way sensitivity analysis showed our model to be stable over a wide range of probabilities for secondary surgical procedures in the operative side and delayed surgical treatment in the nonoperative side. Only when the probability of an additional surgery in the operatively treated patients fall below 15% at the same time that the probability of delayed operative treatment in the nonoperative group approaches 95% or more does the model flip and initial operative management becomes less costly (Fig. 3).

A subanalysis was performed looking at the data from the 2 studies comparing plate osteosynthesis with nonoperative treatment. When the intramedullary nail patients were excluded, the rate of reoperation in the operative group fell from 23.48% to 11.11%. The rate of delayed operative treatment in the nonoperative group went from 18.71% to 24. 69%.

TABLE 2. Cost Estimation Based on CPT Codes and 2013 Medicare Reimbursement Rates

CPT Code	Description	Physician Fee Based on 2013 Medicare Reimbursement	Anesthesia Fee Based on 2013 Medicare	Outpatient Facility Fee Based on 2013 Medicare for CPT Codes	Medicare Fee Total	Adjusted Total Fee (Total × 2.56)
20680	Removal of implant; deep	$399.09	5 base units + 4 time units at $14.88/unit = $133.92	$1488.51	$2021.52	$5175.09
20680 + 10180	Removal of implant; deep + incision and drainage, complex, postoperative wound infection	$399.09 + (0.5 × $167.09) = $482.64	$133.92	$1488.51 + (0.5 × $1315.68) = $2146.35	$2762.91	$7073.05
23480	Osteotomy, clavicle, with or without internal fixation	$763.43	6 base units + 6 time units at $14.88/unit = $178.56	$3036.89	$3978.88	$10,185.93
23485	Osteotomy, clavicle, with or without internal fixation, with bone graft for nonunion or malunion	$893.31	$178.56	$5676.80	$6748.67	$17,276.60
23485 + 20680	Osteotomy, clavicle, with or without internal fixation, with bone graft for nonunion or malunion + removal of implant; deep	$893.31 + (0.5 × 399.09) = $1092.86	$178.56	$5676.80 + (0.5 × 1488.51) = $6421.10	$7692.52	$19,692.85
23500	Closed treatment of clavicle fracture without manipulation	$207.61	$0	$0	$207.61	$531.48
23515	Open treatment of clavicle fracture includes internal fixation when performed	$627.33	$133.92	$4359.69	$5120.94	$13,109.61
23515 + 20680	Open treatment of clavicle fracture includes internal fixation when performed + removal of implant; deep	$627.33 + (0.5 × 399.09) = $826.86	$133.92	$4359.69 + (0.5 × 1488.51) = $5103.95	$6064.73	$15,525.71

With creation of a new decision tree, the estimated cost of operative treatment went from $14,763.21 to $14,023.41 and the estimated cost of nonoperative management went from $3112.65 to $3854.94. This gives a decrease in the estimated cost saving, favoring nonoperative treatment from $11,650.56 to $10,168.46. The incremental cost decreased to $913.85 from $1653.60 for operative treatment and increased to $3323.46 from $2581.17 for nonoperative treatment.

The 2-way sensitivity analysis performed was unable to show any scenario where operative treatment was less costly over the entire range of probabilities for rates of reoperation and delayed operative treatment. The model remained stable in favor of nonoperative management as the least costly pathway.

DISCUSSION

Based on the results of our analysis, from the perspective of a single payer, it is much less costly to have all adult displaced midshaft clavicle fractures treated nonoperatively and pay for those who may go on to require delayed operative treatment. What is not accounted for in this analysis is the cost to the patients as performed by Althausen et al.[15] Are the improved functional scores and decreased time to union worth the additional cost to the payer to have them return to work and contribute as productive members of society? This is an important question given that the patients sustaining this injury are in the younger working population. The CEA by Pearson et al[26] of ORIF of clavicle fractures has demonstrated that the cost effectiveness depends greatly on the durability and magnitude of the functional advantage ORIF provides over nonoperative treatment. Unlike our analysis, this study was constructed using data from a single RCT. Their result was based on incremental cost-effectiveness ratio (ICER) and showed operative treatment to be favorable (<$50,000/QALY) when the benefits of surgery were assumed to last up to 9.3 years or more. The durability of

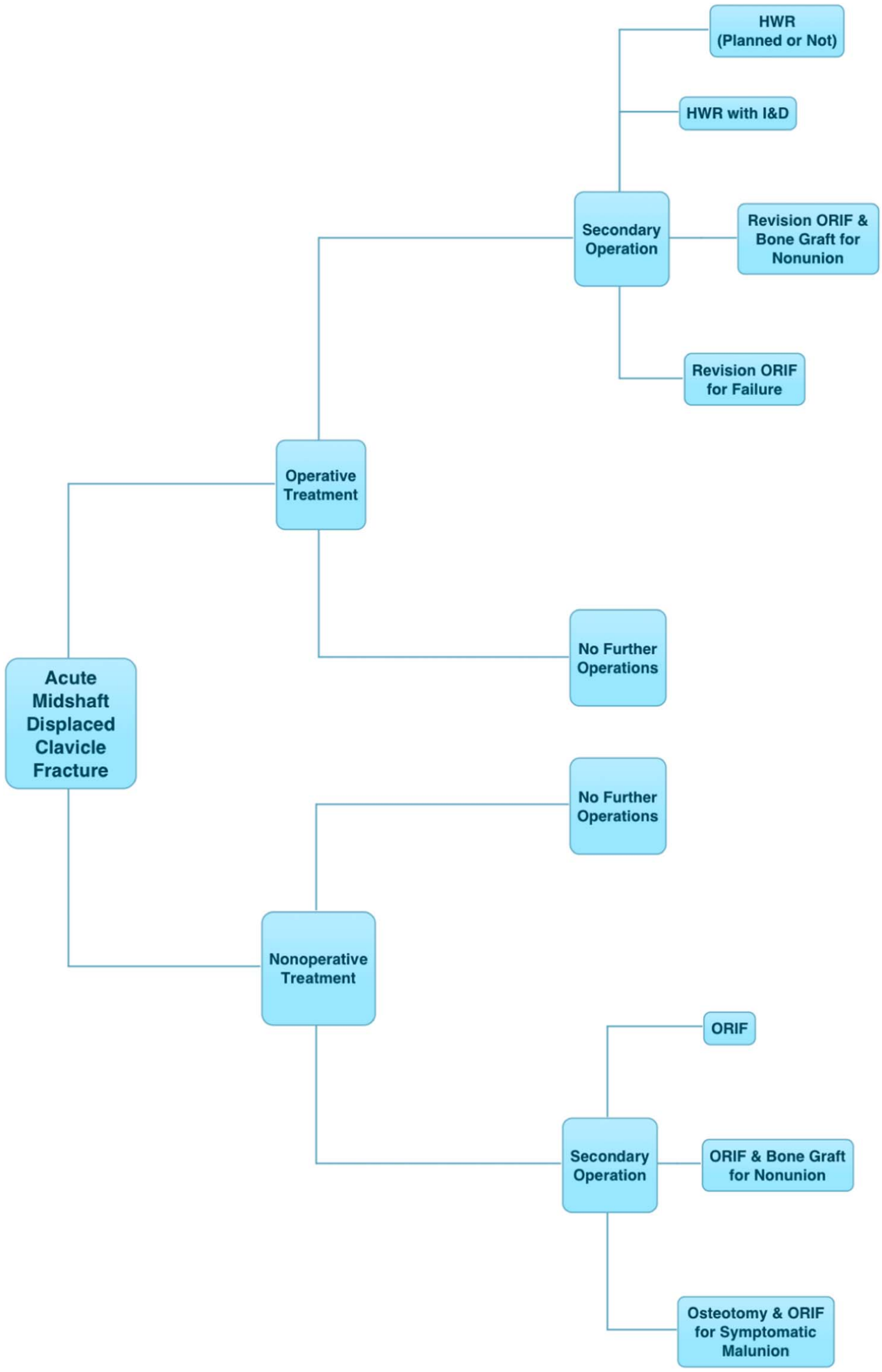

FIGURE 1. Decision tree without costs and probabilities. **Editor's note:** A color image accompanies the online version of this article.

the functional advantage of operative treatment is difficult to quantify because of the lack of long-term follow-up.

The subanalysis performed after exclusion of the studies using intramedullary fixation was done for several reasons. Although intramedullary fixation for clavicle fractures is a proven treatment option, our institution's preferred method of fixation is with a plate. The subanalysis evaluation therefore more closely matches our practice. There were, upon review, a higher number of patients treated with intramedullary fixation who required secondary operation as evident by the decrease from 23.48% to 11.11%. This is a function of the devices themselves and painful, and prominent hardware was seen as a disadvantage by Judd et al[12] with the use of the Hagie pin. Another reason the subanalysis

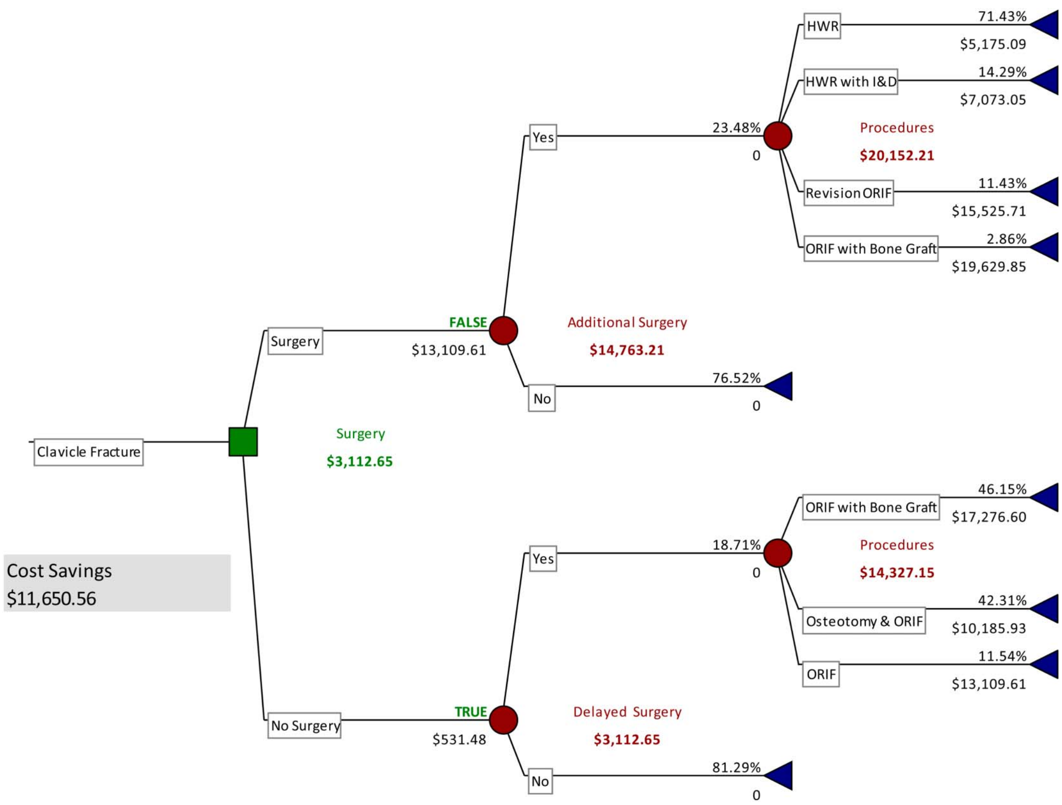

FIGURE 2. Decision tree with costs and probabilities. **Editor's note:** A color image accompanies the online version of this article.

was performed is that in this same study, the only function benefits were seen at 18 weeks with operative treatment. This is not consistent with the findings from the other trials reviewed. The use of the Hagie pin has been found to have high rates of complications in other studies. Strauss et al[27] concluded that the device should not be used for clavicle fixation.

The results of the subanalysis did not show any meaningful changes in the costs when compared with the original data. A decrease in cost savings of $1500.00 does not give a more compelling argument for the use of plate fixation over nonoperative treatment when such a large discrepancy still exists. The sensitivity analysis in this instance showed that no amount of variation in the percentages of reoperation or delayed operative treatment could change the model to favor initial operative stabilization as the optimal financial pathway.

The expected incremental costs represent the unaccounted costs one can assume, given the probabilities of secondary procedures after the initial treatment is rendered. This incremental cost is derived from a weighted average of the subsequent procedures after initial management. This value is lower in the operative group, given that the majority of reoperations in those initially treated with surgery are for removal of hardware (71%), which is much less costly than the delayed operative treatment in the nonoperative group such as repair of nonunion (46%) and symptomatic malunion (42%). It is important to understand this value to account for the true cost of a selected treatment from the perspective of the payer given the probability for further treatment. In the subanalysis, this difference was further exaggerated because of the exclusion of many of the reoperations due to hardware removal, thus bringing the expected cost of ORIF closer to the calculated cost.

The strengths of the study include the use of data from 4 high-quality RCTs.[9–12] These studies represent the best data available with direct comparison of operative and nonoperative treatment with multiple methods of fixation. Our analysis is unique in that it accounts for the major cost-incurring events for the payer alone over the short term. These costs do not strictly reflect the rates of complications associated with each form of treatment. This can be demonstrated in the study by Virtanen et al.[9] A number of patients in the nonoperative group developed symptomatic malunions and nonunions with a reported decrease in function, yet declined delayed operative treatment. As surgeons, we see this as a complication of nonoperative treatment; however, from the perspective of the payer, this outcome ultimately reflects the lowest cost treatment. Alternatively, patients who undergo elective planned hardware removal under general anesthesia after uneventful fracture union would not be considered by the surgeon to have had a complication of their original treatment. To the payer, however, this is another costly procedure and makes this option less financially favorable.

Some limitations of this study include to limited follow-up available from each of the randomized studies. There are many patients on both sides of the tree who may receive further surgical procedures directly related to their original

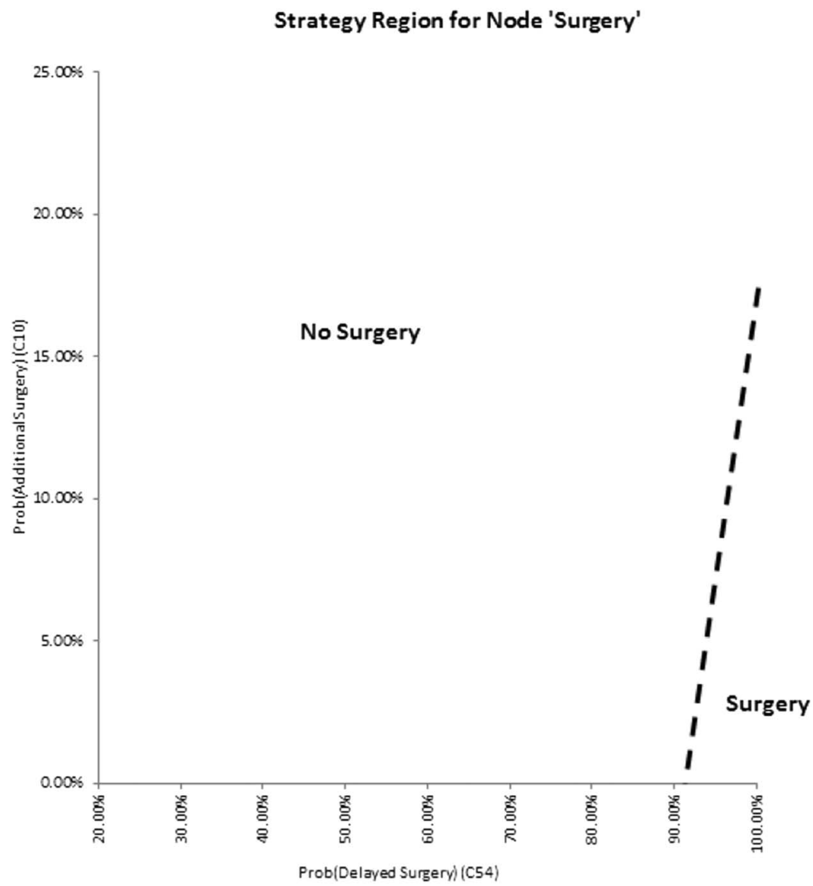

FIGURE 3. Two-way sensitivity analysis. The area to the left of the line represents the possible combinations of additional surgery and delayed surgery where initial nonoperative treatment will be the least costly. The area to the right of the line represents the possible combinations of additional surgery and delayed surgery where initial operative treatment will be the least costly.

treatment. In the studies by McKee et al and Potter et al looking at patients who presented for the treatment of symptomatic malunion, patients presented anywhere from 1 to 15 years out from injury.[28,29] This analysis is generated with data collected over the short term, thus long-term cost estimates cannot be made. Another limitation is the use of Medicare data to predict costs in a non-Medicare population. As described previously, the acquisition and uniformity of Medicare reimbursement makes it a favorable source and many previously published articles have performed so. Using the cost multiplier as previously performed,[26] we were able to more closely match expected private payer reimbursement. There are also unaccounted costs in our model such as radiographs and office visits. We believed as, although, these costs would be similar in each treatment group and would not significantly affect the model.

In summary, we as physicians need to take a lead role in managing the business of medicine. By looking at these data in these terms, it helps us to understand the impact of our decisions and guides our treatment with the goal of providing patients with the best functional outcomes while remaining financially responsible. Our study shows that nonoperative management of displaced midshaft clavicle fractures in adults is the optimal financial decision for the payer. The decision to perform initial operative stabilization must take into account the substantially higher cost and weigh that against the reported benefits of this treatment over nonoperative management.

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Invited Commentary

I applaud the authors for addressing a topic involving the economic impact of surgical decision making as financial considerations have become increasingly important in today's changing healthcare environment. However, I disagree with the authors' conclusions on multiple levels.

Some of the author's assumptions regarding cost to payers are incorrect. Each of these exaggerates the expense of surgical intervention to payers. In their cost assumption allocation, multiple procedures codes were entered for several endpoints. Although often market dependent, most payers do not reimburse for hardware removal during a nonunion surgery if the same incision is utilized as it is considered to be part of the nonunion procedure. In addition, irrigation and debridement is not reimbursed by most payers if a hardware removal is performed through the same approach. With the decreasing costs of implants due to generic alternatives, surgical costs may be inflated as well. At our institution, the average surgical time for operative fixation is under 30 minutes which would suggest that anesthesia estimated costs are also grossly overestimated as well. Finally, 71% of the secondary operations were performed for symptomatic hardware removal. Most surgeons would consider this to be an elective procedure and one dependent on the way the initial surgery was performed. Anterior plate placement, use of lower profile plates and careful attention to soft tissue coverage all decrease the need for repeat surgical intervention. With proper initial surgical intervention and patient education, many of these additional procedures could be avoided.

Unlike the studies of Althausen et al[1]and Pearson et al,[2] this study addresses only the cost to the payer, not the patient. As a result, only half of the total economic picture is visualized. Althausen et al demonstrated that in addition to better clinical outcomes, operative patients missed fewer days of work (8.4 days vs. 35.2 days) and required less assistance (3 days vs. 7 days) for care at home. Mean income lost was \$321.69 versus \$10,506.25. Operative patients required less physical therapy, and the mean physical therapy cost was \$971.76 versus \$1820. Non-operative patients required more pain medication (\$43.22 vs. \$45.98). Overall, the cost was \$12,976.94 for operative patients and \$18,068.27 for non-operative patients. Although the initial hospital bill for operative patients was higher because of surgical charges, it is balanced by less income loss, resulting in a cost savings of \$5091.33 in operative patients. At that time our hardware removal rate was and continues to be less than 3%. Pearson et al looked at 132 adults with displaced clavicle fractures and found that the base case cost per quality-adjusted life-year (QALY) gained for ORIF was \$65,000. In light of these