

# Assessing the Change in Operative Treatment Rates for Acute Midshaft Clavicle Fractures

## Incorporation of Evidence-Based Surgery Results in Orthopaedic Practice

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**Background:** In 2007, a randomized controlled trial (RCT) by the Canadian Orthopaedic Trauma Society (COTS) demonstrated better functional outcomes and a lower proportion of patients who developed malunion or nonunion following operative, compared with nonoperative, treatment of midshaft clavicle fractures. The primary aim of the present study was to compare the proportion of midshaft clavicle fractures treated operatively prior to and following the publication of the COTS RCT. An additional exploratory aim was to assess whether the proportion of midshaft clavicle fractures that were treated with surgery for malunion or nonunion decreased.

**Methods:** This retrospective cohort analysis used population-level administrative health data on the residents of British Columbia, Canada. Cases were identified by International Classification of Diseases, Ninth Revision (ICD-9) diagnostic codes and procedure fee codes. Adult patients ( $\geq 18$  years) with closed middle-third clavicle fractures between 1997 and 2018 were included. Multivariable logistic regression modeling compared the proportion of clavicle fractures treated operatively before and after January 1, 2007, controlling for patient factors. The Pearson chi-square test compared the proportion of fractures treated operatively for malunion or nonunion in the cohorts.

**Results:** A total of 52,916 patients were included (mean age, 47.5 years; 65.6% male). More clavicle fractures were treated operatively from 2007 onward: 6.9% compared with 2.2% prior to 2007 (odds ratio [OR] = 3.35, 95% confidence interval [CI] = 3.03 to 3.70,  $p < 0.001$ ). Male sex, moderate-to-high income, and younger age were associated with a greater proportion of operative fixation. The rate of surgery for clavicle malunion or nonunion also increased over this time period (to 4.1% from 3.4%, OR = 1.26, 95% CI = 1.15 to 1.38,  $p < 0.001$ ).

**Conclusions:** We found a significant change in surgeon practice regarding operative management of clavicle fractures following the publication of a Level-I RCT. With limited high-quality trials comparing operative and nonoperative management, it is important that clinicians, health-care institutions, and health-authority administrations determine what steps can be taken to increase responsiveness to new clinical studies and evidence-based guidelines.

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

Evidence-based medicine is “the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients.”<sup>1</sup> In medicine and surgery, technological and pharmacological advancements continually offer new treatment methods and modalities for diseases and injuries<sup>2</sup>. Accordingly, it is imperative that clinicians remain critical in analyzing new research and recommendations for validity and relevance to their patients.

Clavicle fractures are common injuries that have traditionally been treated nonoperatively<sup>3,4</sup>. Despite earlier general

acceptance that functional outcomes after closed treatment options were reasonable, information from the 2000s produced a counter narrative—one of high incidence rates of nonunion and long-term impacts on shoulder function due to deformity<sup>5-7</sup>.

A multicenter randomized controlled trial (RCT) by the Canadian Orthopaedic Trauma Society (COTS) assessed outcomes in 132 patients with acute displaced midshaft clavicle fractures, comparing those treated nonoperatively with those treated with plate fixation<sup>8</sup>. The study, published in January 2007, concluded that operative fixation results in better

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functional outcomes and lower incidence rates of malunion and nonunion compared with nonoperative treatment, and supported primary fixation. In recognition of its impact, the study won the 2005 Edwin G. Bovill, Jr. MD Award for the most outstanding Orthopaedic Trauma Association Annual Meeting scientific paper<sup>9</sup>, and it was determined to have had the largest influence on surgeon practice according to a 2013 survey of Canadian orthopaedic surgeons<sup>10</sup>.

Despite the interest in RCTs in orthopaedics, discussions regarding their impact on clinical practice are infrequent. Given the impact of the COTS RCT<sup>8-10</sup>, any change in the proportion of clavicle fractures treated operatively may act as a surrogate for surgeons' use of evidence-based medicine. The primary aim of the present study was to compare the rate of operative fixation for midshaft clavicle fractures prior to and following the publication of the COTS RCT in January 2007. Our hypothesis was that the rate of operative clavicle fracture fixation increased after January 2007. An additional exploratory aim of the study was to assess whether the proportion of clavicle fractures that were treated with surgery for malunion or nonunion decreased.

## Materials and Methods

### Patient Population

A retrospective cohort analysis was performed using Population Data BC (PopDataBC), a multi-university data and education resource containing longitudinal, person-specific health records for the residents of British Columbia, Canada, from 1985 onward<sup>11</sup>. De-identified patient data are compiled from >30 data sets from federal and provincial sources, including provincial health authorities, into linked databases. These include the Discharge Abstracts Database (Hospital Separations) data set, which contains administrative and clinical data on patients discharged from hospitals<sup>12</sup>; the Medical Services Plan (MSP) Payment Information File, which contains data on medically necessary services provided by practitioners in the province<sup>13</sup>; and the Consolidation File (MSP registration and premium billing) data set, which collects patient demographics, including their income quintile<sup>14</sup>.

Adult patients ( $\geq 18$  years) with an acute midshaft clavicle fracture between January 1, 1997, and December 31, 2018, were identified by the ICD-9 (International Classification of Diseases, Ninth Revision) diagnosis code 810.0. Patients were excluded if they were listed as "living out of province," had an open injury (ICD-9 code 810.1 or MSP code 52708, irrigation and debridement open clavicle fracture), or had sustained a medial- or lateral-third clavicle fracture (ICD-9 code 810.01 and 810.03, respectively). Two cohorts were defined on the basis of whether the clavicle fracture management occurred prior to publication ("pre-publication cohort": January 1, 1997, to December 31, 2006) or following publication ("post-publication cohort": January 1, 2007, to December 31, 2018) of the COTS RCT.

### Outcomes

The primary outcome was the proportion of acute midshaft clavicle fractures that underwent operative treatment, as assessed by the MSP billing code 52705 ("open reduction internal fixation clavicle"). Patients who underwent concurrent bone

grafting or osteotomy to treat a malunion or nonunion of the clavicle were excluded from this analysis.

The secondary outcome was the proportion of clavicle fractures that were treated with surgery for malunion or nonunion. Such cases were identified by the MSP billing code for bone grafting of the clavicle (52652) or clavicle fixation for malunion/nonunion (52602).

### Statistical Analysis

Patient variables were assessed for associations with the proportion of operative clavicle fixation and any potential confounders. Patient variables included age, sex, and income quintile. Patient age was presented as a categorical variable (18 to 30, 31 to 50, and  $\geq 51$  years). Patient income was divided into low (quintiles 1 and 2) and moderate-to-high categories (quintiles 3, 4, and 5).

Descriptive data on patients with clavicle fractures were reported by year, using counts with proportions for categorical data or the mean and standard deviation for continuous variables. The proportion of operative clavicle fixation was initially compared between the cohorts using the unadjusted Pearson chi-square test. Thereafter, subgroup analyses assessing the association of covariates with the cohorts was performed using the independent-sample t test or chi-square test. Finally, multivariable logistic regression modeling that controlled for potential confounders was performed. A p value of  $< 0.05$  was considered significant. All data analysis was performed using IBM SPSS Statistics (version 27.0).

### Source of Funding

No external funding was received for this study.

## Results

Data on 52,916 patients (34,721 [65.6%] male; mean age, 47.5 years) were included. The pre-publication cohort included 22,744 patients (15,181 [66.7%] male; mean age, 45.3 years). The post-publication cohort included 30,172 patients

TABLE 1 Patient Demographics

	Pre-Publication Cohort (1997-2006, N = 22,744)	Post-Publication Cohort (2007-2018, N = 30,172)	P Value
Age			<0.001
18-30 yr	6,696 (29.4%)	7,212 (23.9%)	
31-50 yr	8,076 (35.5%)	9,152 (30.3%)	
$\geq 51$ yr	7,972 (35.1%)	13,808 (45.8%)	
Sex			<0.001
Male	15,181 (66.7%)	19,540 (64.8%)	
Female	7,563 (33.3%)	10,632 (35.2%)	
Income level			0.544
Low, quintiles 1-2	9,150 (40.2%)	11,871 (39.3%)	
Moderate-high, quintiles 3-5	13,594 (59.8%)	18,301 (60.7%)	

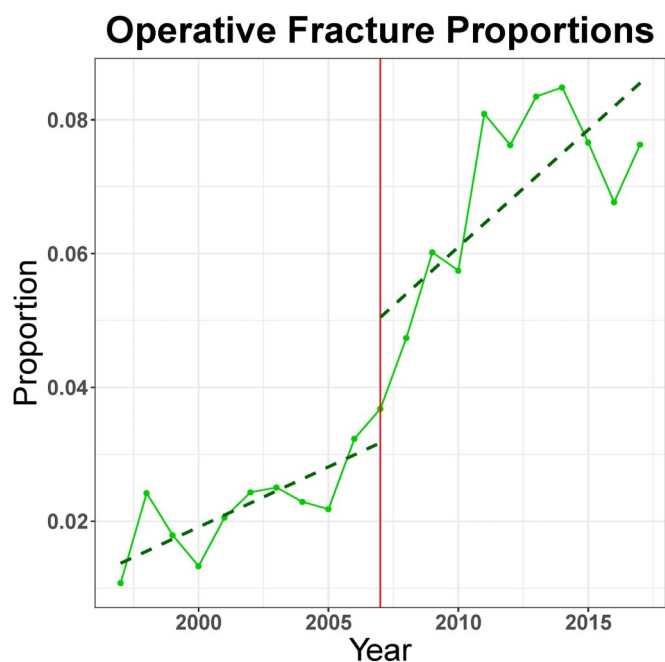


Fig. 1 Proportion of clavicle fractures treated with operative fixation over time. The January 2007 publication of the COTS RCT is represented by the vertical red line. The green dashed lines represent the slope trend lines for the pre- and post-publication cohorts.

(19,540 [64.8%] male; mean age, 49.2 years). There were significant differences in age and sex ( $p < 0.001$ ), but no difference in income levels ( $p = 0.544$ ), between the 2 cohorts (Table I).

Figure 1 displays the proportion of operative fixation of clavicle fractures by year. There was a significant increase in the incidence proportion of operative treatment from 2.2% in the pre-publication cohort to 6.9% in the post-publication cohort (unadjusted odds ratio [OR] = 3.35, 95% confidence interval [CI] = 3.03 to 3.70,  $p < 0.001$ ) (Table II).

After adjusting for age, sex, and income level, the difference in operative treatment between the cohorts remained significant (adjusted OR = 3.66, 95% CI = 3.31 to 4.05,  $p < 0.001$ ) (Table III). There was a higher proportion of operative treatment in the post-publication cohort in all age groups. The proportion in the patients who were  $\geq 51$  years old was significantly lower than the proportions of all patients  $< 51$  years old (adjusted OR = 0.48, 95% CI = 0.43 to 0.53,  $p < 0.001$ ) (Fig. 2). Male sex was associated with a higher pro-

portion of operative treatment (adjusted OR = 1.50, 95% CI = 1.36 to 1.65,  $p < 0.001$ ) (Fig. 3; see also Appendix 1).

The proportion of clavicle fractures that were treated with surgery for malunion or nonunion also increased significantly ( $p < 0.001$ ), from 3.4% (770) pre-publication to 4.1% (1,244) post-publication (Table II). After adjusting for age and sex, the difference in the incidence proportion of surgery for clavicle malunion or nonunion remained significantly different between the cohorts (adjusted OR = 1.26, 95% CI = 1.15 to 1.38,  $p < 0.001$ ) (Table IV; see also Appendix 2).

### Discussion

We used population-level administrative health data to assess the utilization of evidence-based medicine in orthopaedic surgery by evaluating the change in practice regarding operative versus nonoperative management of clavicle fractures following the January 2007 publication of the influential COTS RCT<sup>8</sup>. There was a significant increase in the proportion of clavicle fractures treated with operative fixation from the period before January 2007 to the period after that date, even when controlling for available patient factors. Although the change in the rate of operative clavicle fixation cannot be completely attributed to the COTS RCT, a 2013 survey of 178 Canadian orthopaedic surgeons identified the findings of that RCT as having had the greatest influence on “advancing overall knowledge in the field” and on “changing practice.”<sup>10</sup> Given the survey results, the timing of the change in practice, and the study population (i.e., patients treated by surgeons in a Canadian province), the COTS RCT likely had an influence on the change in clavicle fracture management.

Our findings agree with previous studies evaluating clavicle fixation rates over time. Congiusta et al.<sup>15</sup> conducted a retrospective study of the U.S. Nationwide Inpatient Sample database from 2001 to 2013 to assess operative clavicle fracture fixation. Their reported operative fixation rate increased from 5% in patients treated before the COTS RCT publication to 11% in patients treated afterward. Similar to our findings, both age and sex were significantly associated with clavicle fracture fixation. They also found race and insurance status to be associated with clavicle fracture management. These results were reproduced by Schairer et al.<sup>16</sup> using multicenter data from patients with clavicle fractures in the U.S. states of California and Florida, which showed an increase in the operative fixation rate from 3.7% to 11.1% between 2005 and 2010. Similarly, Huttunen et al.<sup>17</sup> assessed the operative fixation rate for clavicle fractures using a Swedish database and found an increase from 2.5% to 12.1% between 2001 and 2012.

TABLE II Incidence of Operative Management

	Pre-Publication Cohort (1997-2006, N = 22,744)	Post-Publication Cohort (2007-2018, N = 30,172)	Odds Ratio (95% CI)	P Value
Operative treatment of clavicle fractures	489 (2.2%)	2,068 (6.9%)	3.35 (3.03-3.70)	<0.001
Operative treatment of clavicle fracture malunion or nonunion	770 (3.4%)	1,244 (4.1%)	1.23 (1.12-1.34)	<0.001

TABLE III Variables Associated with Operative Management of Clavicle Fractures*			
	Adjusted OR	95% CI	P Value
<b>Cohort</b>			
Pre-publication	Ref.		
Post-publication	3.66	3.31-4.05	<0.001
<b>Age</b>			
18-30 yr	Ref.		
31-50 yr	1.07	0.97-1.18	0.160
≥51 yr	0.48	0.43-0.53	<0.001
<b>Sex</b>			
Female	Ref.		
Male	1.50	1.36-1.65	<0.001
<b>Income level</b>			
Low, quintiles 1-2	Ref.		
Moderate-high, quintiles 3-5	1.18	1.08-1.28	<0.001

\*Multivariable logistic regression.

One other study has assessed clavicle fixation rates before and after publication of the COTS RCT in January 2007. Schneider et al.<sup>18</sup> compared the pre- and post-publication proportions of displaced midshaft clavicle fractures in patients aged 16 to 60 years that were treated with surgery in 2 North American Level-I trauma centers, and found an increase from 3.7% to 34.1%. The disparities in fixation magnitude compared with our findings can be explained by differences in the patient populations, as Schneider et al. only included younger patients with displaced midshaft fractures

and such patients are more likely to have multiple orthopaedic injuries, which are a relative indication for operative clavicle fixation.

Surprisingly, our study found that the proportion of clavicle fractures that were treated with surgery for malunion or nonunion also increased, from 3.4% pre-publication to 4.1% post-publication. The COTS RCT found a lower rate of malunion or nonunion following operative treatment than after nonoperative treatment<sup>8</sup>. We had hypothesized that an increase in the proportion of operative treatment following the January 2007 publication would result in a decrease in the proportion of fractures treated operatively for malunion or nonunion. This observed increase in the operative fixation rate may not reflect an increase in the incidence rates of clavicle malunion and nonunion, but rather improved recognition of these pathologies by surgeons and their comfort with operative treatment. Historically, Neer<sup>19</sup> found that only 0.1% (<sup>3</sup>) of 2,235 patients treated nonoperatively for a clavicle fracture developed a nonunion. However, the dogma that clavicle fractures do not develop symptomatic nonunions has been challenged. Zlowodzki et al.<sup>20</sup> performed a systematic review and found that the incidence rate of nonunion following nonoperative treatment of clavicle fractures was 5.9%, with displaced fractures having an incidence rate of 15.1%. Recent systematic reviews of RCTs have indicated similar findings<sup>21-23</sup>. Also, McKee et al.<sup>5</sup> demonstrated a significant improvement in Disabilities of the Arm, Shoulder and Hand (DASH) scores in a case series of 15 patients who were operatively treated for clavicle malunion. Thus, the increase in malunion and nonunion surgery is likely due to changes in practice in response to newly available evidence, and again reflects the utilization of

**Proportions of Operative Fractures for Each Age Group**

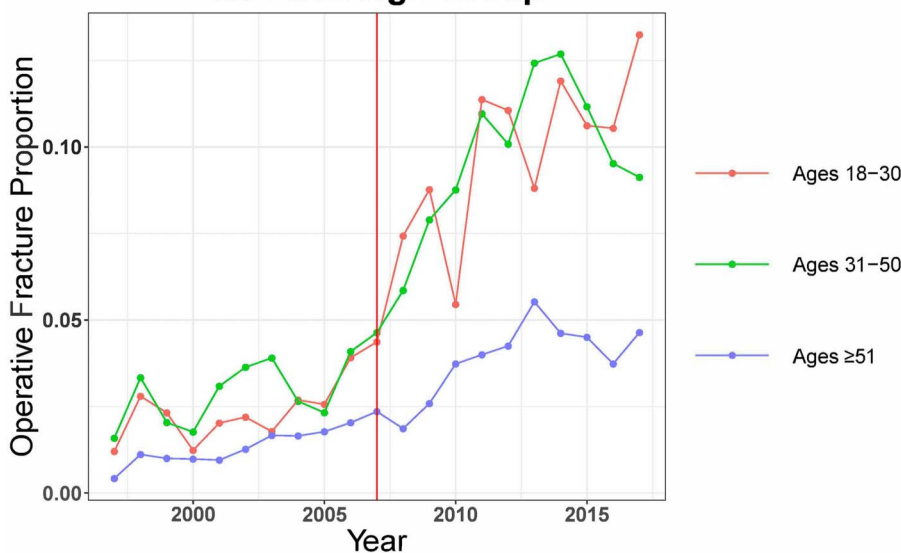


Fig. 2 Proportion of clavicle fractures treated with operative fixation, stratified by age, over time. The January 2007 publication of the COTS RCT is represented by the vertical red line.

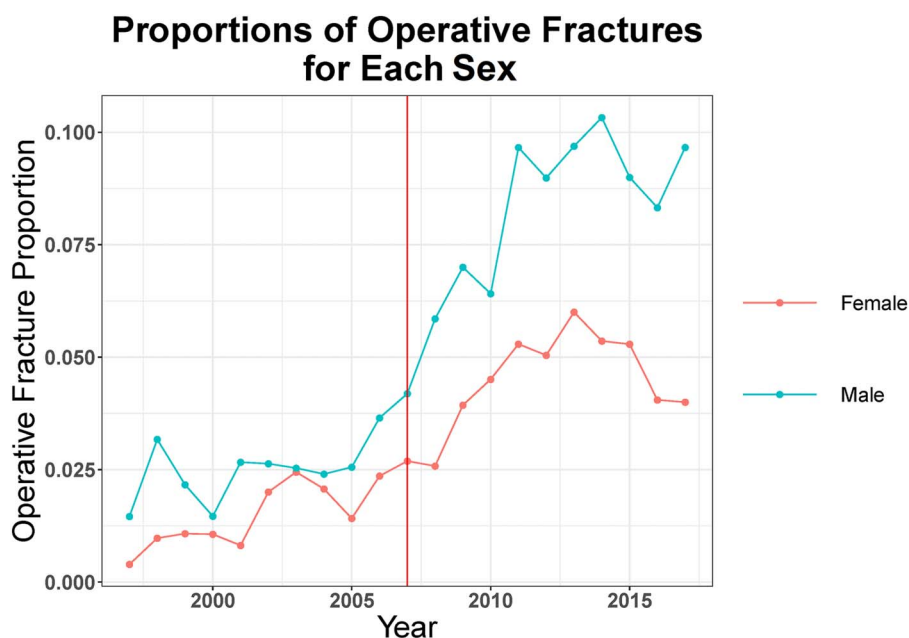


Fig. 3 Proportion of clavicle fractures treated with operative fixation, stratified by sex, over time. The January 2007 publication of the COTS RCT is represented by the vertical red line.

evidence-based practice in orthopaedics. However, given the limited sample population and data on potentially confounding variables, no firm conclusions can be made regarding the results from this exploratory aim.

Surgery as a discipline can be slow to implement evidence-based principles<sup>24-26</sup>. Nonetheless, our study demonstrates rapid changes in clinical practice associated with the COTS RCT publication. The increase in the incidence proportion of operative management of clavicle fractures that can be seen in Figure 1 appears to have started prior to January 2007. The dissemination of study results from the COTS RCT prior to publication, via meeting and symposium abstracts and proceedings in October 2005 and March 2006<sup>27,28</sup>, may explain this change in practice. The fact that McKee et al.<sup>6</sup> published a study in January 2006 showing deficits in 30 patients following nonoperative treatment of displaced midshaft clavicle fractures likely also played a role. In addition, many hospitals in Canada with large trauma case volumes<sup>29</sup>, including those in British Columbia, were involved in actively recruiting patients for the COTS RCT, so it is possible that a “culture shift” had already begun prior to January 2007.

The widespread response to the COTS RCT can be attributed to numerous factors, but particularly to the study design. In a survey distributed to Canadian orthopaedic surgeons, 98% of responders stated that the study design was “important” or “very important” in the ability of a research study to affect clinical practice<sup>30</sup>. Furthermore, 99% of responders stated that the results of an “RCT” have the potential to influence clinical practice, which was larger than the proportion who stated this about a “meta-analysis” (87%) or a “systematic review” (85%). The influence of RCTs in evidence-based medicine is understandable, as observational studies are prone to selection

bias and can overestimate treatment effects. Unfortunately, RCTs only represent 3% of published orthopaedic literature<sup>31</sup>. Conducting RCTs can be prohibitive because of cost and/or feasibility, and a lack of clinical equipoise may ethically prohibit conducting trials comparing operative and nonoperative management. The lack of Level-I evidence in orthopaedic surgery may contribute to the perceived lack of evidence-based surgical decision-making<sup>32</sup>.

Given the above, our findings indicate that caution should be used with regard to adopting new surgical practices after the publication of a single RCT. Although the COTS RCT demonstrated better patient outcome measures and lower nonunion

TABLE IV Variables Associated with Surgery for Clavicle Fracture Malunion or Nonunion*			
	Adjusted OR	95% CI	P Value
Cohort			
Pre-publication	Ref.		
Post-publication	1.26	1.15-1.38	<0.001
Age			
18-30 yr	Ref.		
31-50 yr	1.77	1.57-1.99	<0.001
≥51 yr	1.08	0.95-1.23	0.232
Sex			
Female	Ref.		
Male	1.02	0.93-1.13	0.656

\*Multivariable logistic regression.

and malunion incidence rates with operative fixation, subsequent studies had less impressive results. Robinson et al.<sup>33</sup> demonstrated no differences in functional outcome scores between operatively and nonoperatively treated patients who achieved union. McKee et al.<sup>34</sup> performed a meta-analysis of RCTs that found no clinically important long-term difference in Constant scores between groups despite a significantly lower incidence rate of symptomatic malunion or nonunion in the operatively treated group. Furthermore, concerns have been raised regarding overtreatment of clavicle fractures, as shown in hospital surveys in Sweden, Denmark, and Finland<sup>35</sup>. With ongoing studies on clavicle fractures and increasing patient data, efforts should be made to define the patients most at risk for malunion and nonunion<sup>36</sup>, so that operative management of clavicle fractures can target this population.

As Canada has a single public health-care system administered by provincial governments, all outpatient and hospital encounters in British Columbia are collected. Thus, the risk of missing patients with a clavicle fracture is low. Operatively treated clavicle fractures were collected from surgeon billing codes and hospital discharge data. Nonetheless, there are several limitations inherent to all administrative database studies. Clavicle fracture location was not always specified in the ICD codes, given that coding was only required to 1 decimal place. Thus, lateral and medial clavicle fractures that were not specified as such were not excluded from the data analysis. However, misclassification of injury location is unlikely to have varied between the cohorts and is therefore unlikely to present significant selection bias. Similarly, the severity of fracture displacement is not specified. However, as with fracture location, it is unlikely that the degree of displacement changed so considerably over time that it explains the magnitude of change observed in operative fixation rates. Furthermore, given that the majority of operative fixation involves displaced fractures, inclusion of less displaced fractures would decrease the treatment effect size, biasing results toward the null; however, our study still found a significant difference between cohorts despite this potential bias. The variables that were analyzed were limited to those collected in the PopDataBC databases. Notable missing variables that may influence surgical decision-making include patient comorbidities, the presence of other orthopaedic injuries, hospital variables, and surgeon variables.


Other limitations unrelated to the PopDataBC databases include the limited external validity of the study. Results are based on a single Canadian province, and hence may not be representative of the practices of all Canadian surgeons. However, similar trends during the same time period have been reported using patients across Canada, the U.S., and Europe<sup>15-18</sup>. Because data were collected immediately before and after the publication of the COTS RCT without a washout period, there is a risk of information bias (i.e., clavicle fractures treated 1 day

before or 1 day after publication are unlikely to be influenced differently but are classified in separate cohorts for analysis). The misclassification of exposure would bias the results toward the null hypothesis, yet our results reached significance, so this bias would not change the outcomes. Given that the COTS RCT was performed on acute displaced midshaft clavicle fractures, it is not possible to determine the effects on decision-making for clavicle malunion or nonunion, but rather only in the studied subset of displaced fractures. There were no data on the actual incidence rate of malunion or nonunion, only on those treated with surgery, so there may have been asymptomatic non-unions that were not treated with surgery, both before and after publication of the COTS RCT. Lastly, the PopDataBC data set did not include radiographic data on displacement or comminution, nor did it permit an assessment of the impact of the introduction of precurved, low-profile, titanium clavicle plates.

### Conclusions

We found a significant change in surgeon practice regarding operative management of clavicle fractures following the COTS RCT publication. These findings are in keeping with orthopaedic surgeons practicing evidence-based medicine. With limited high-quality trials comparing operative and nonoperative management, it is important to determine what steps can be taken to increase responsiveness to new clinical studies and guidelines.

### Appendix

 Supporting material provided by the authors is posted with the online version of this article as a data supplement at <http://links.lww.com/JBJSOA/A507>. ■

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