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A review of outcomes after operative fixation of clavicular fractures over a 10-year period—a single tertiary trauma unit experience



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Background: Early definitive fixation of clavicular fractures is rising in popularity when compared with conservative management. Despite this, the relative risk of subsequent hardware removal or revision surgery is relatively undocumented in the literature. The aim of this study was to review all clavicle fractures treated operatively in a single tertiary referral trauma unit and determine the true incidence of hardware removal and revision rates among this cohort.

Methods: A retrospective electronic review was performed in a single tertiary trauma unit for all open reduction internal fixation of clavicle fractures over 10 years (2010–2019 inclusive). All patients were cross referenced for hardware removal during the same period. Patients identified as having undergone ORIF clavicle were reviewed via the National Integrated Medical Imaging System to identify the fracture pattern, fixation method, radiographic nonunion, or radiographic malunion. Age, gender, time from injury to fixation, and time from insertion to removal of hardware where relevant were also collected.

Results: Over the 10-year period from 2010 to 2019, 352 patients underwent ORIF of clavicular fractures. After application of inclusion and exclusion criteria, 346 patients (76% male and 24% female) were analyzed with a mean age of 34.46 years old (95% confidence interval [33.02–35.91]). In total, 54 (15.6%) patients underwent removal of hardware. When fracture type and fixation method were accounted for, only 11% of plate fixations for mid-shaft fractures ($n = 29$) were removed, whereas 76% of clavicular hook plates for distal fractures ($n = 25$) underwent removal ($P < .001$). No distal clavicle fractures treated with locking plates underwent removal ($n = 23$). Women were almost 3 times more likely to undergo removal of hardware than men (28.6% vs. 11.5%, $P < .001$). Seven patients (2%) underwent revision ORIF in the 10-year period for nonunion ($n = 3$), malunion ($n = 2$), and failure of fixation ($n = 2$). The mean follow-up time was 1 year (366 days) for those who underwent subsequent surgery and 5.7 years (2087 days) for those who did not.

Conclusion: Clavicular fracture fixation using either locking or hook plates is a safe method of treatment with a very low reoperation rate for either hardware removal or revision. Women are more likely to request plate removal. Distal locking plates are a safe alternative to hook plates for distal one-third clavicle fractures with lower reoperation rates. Newer techniques are emerging for the management of distal fractures such as tight rope fixation and locking plates which also appear to be successful.

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Clavicle fractures are a very common entity^{16,19} with management evolving over the last 20 years. An increasing proportion of

Tallaght University Hospital Clinical Research Ethics committee advised that our study was classified as being in the category of “clinical research, retrospective chart review” and as such was deemed exempt from formal ethical approval by the committee.

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surgeons are advocating for early definitive fixation for appropriate fracture configurations compared with the more traditional conservative approach which has previously been proven successful.^{15,20,22} This more recent shift toward operative management is largely due to increasing reports of unacceptably high rates of nonunion, symptomatic malunion, and dis-satisfied patient cohorts who were treated conservatively.^{3,8,11}

Furthermore, more novel techniques have emerged in recent years especially in the treatment of distal clavicle fractures. Hook plates were previously the mainstay of treatment for such fractures,

but reoperation for hardware removal is routinely recommended and undertaken;^{5–7,12} hence, they are slowly being replaced with specific distal clavicle locking plates or tight rope fixation techniques. Locking plates have been shown to have equivalent union rates compared with hook plates but offer the advantage of not routinely requiring removal.^{5,23,25,26} Previous studies have demonstrated no difference in reoperation rates between plate types or location,¹ as well as any difference in union or plate removal rates; however, these were relatively small sample sizes.²

Although in many cases it is necessary, avoiding implant removal is desirable to prevent the morbidity associated with a second surgery along with the associated cost to the health care service¹⁸ and the patient. Reoperation is one of the most common complications discussed in the literature, but there is a scarcity of large cohort studies available for review.^{1,14}

The aim of this study was to review all clavicle fractures treated operatively in our unit and determine the true incidence of fracture types and the operative techniques used to treat these fractures and assess if this changed over the years. In addition, the study sought to evaluate our reoperation rate for both hardware removal and revision among this cohort. It also wished to identify any risk factors which impacted on the rate of second surgery among these patients so as to provide tailored, patient-centered, evidence-based decisions when managing these injuries.

Materials and methods

A retrospective cohort study was conducted via the hospital's various electronic databases. Patients were identified using the unique theater code used only for open reduction internal fixation of clavicle fractures. A further review of all procedures involving removal of hardware over the same period from January 2010 to December 2020 was performed. These cohorts were then cross-referenced to identify patients who underwent open reduction internal fixation clavicle and subsequent removal of that fixation metalwork. All patients identified as having undergone open reduction internal fixation clavicle were also individually reviewed via the National Integrated Medical Imaging System (NIMIS), which is a national information technology system of radiological data. This allowed the fracture pattern and fixation method to be identified as well as any radiographic nonunion or malunions. Patient demographics, such as age, sex, date of injury, date of surgery, date of hardware removal or reintervention if applicable, were extracted from medical records and imaging systems.

Inclusion criteria were all surgically treated fractures of the middle and distal thirds of the clavicle between January 2010 and December 2020 at an urban tertiary referral university hospital. This included the use of conventional hook plates, low-contact dynamic compression plates, and precontoured locking plates. It also included distal clavicular precontoured locking plates, tight rope techniques, and intramedullary devices. Exclusion criteria were the absence of an internal fixation construction (eg examination under anaesthesia or manipulation under anaesthesia only) and fixation of an anatomical region other than the clavicle (eg acromioclavicular joint). Cases which underwent revision were identified and analyzed separately.

The primary outcomes were the need for removal of hardware for any reason and the need for revision surgery due to nonunion or loss of fracture fixation. Differences in patient demographics and clinical characteristics by the fixation method were examined, and a univariate analysis was performed to examine associations between predictor variables and the primary outcomes. The unadjusted odds ratios were reported with 95% confidence intervals (CIs) for each outcome. Statistical significance was determined using a type 1 error probability threshold of <5% ($P < .05$). The end

point was defined as the date of subsequent surgery. For those who did not undergo surgery, the end point was the date of the final data collection (01/04/2021). The mean follow-up time for patients was 5.7 years (2087 days) for those who did not undergo repeat surgeries and 1 year (366 days) for those requiring a subsequent surgery.

This study was classified as being in the category of “clinical research, retrospective chart review” by Tallaght University Hospital Institutional Review Board. As such, it was deemed exempt from formal ethical approval by the Research Ethics Committee of Tallaght University Hospital.

Results

Over the 10-year period from 2010 to 2019 inclusive, 352 patients were identified using our electronic database as having undergone open reduction internal fixation of clavicular fractures in a single tertiary trauma unit. After application of inclusion and exclusion criteria and radiological review of patient data, 346 patients (76% male and 24% female) were correctly identified as having undergone open reduction internal fixation clavicle during the timeframe (Fig. 1) with a mean age of 34.46 years old (95% CI [33.02–35.91]). Eighty-one percent of fractures involved the middle one-third of the clavicle, whereas 19% involved the distal, or lateral, one-third of the clavicle. Eighty-seven percent ($n = 301$) clavicle fractures were treated with a locking plate construct, 10% with hook plates, 0.3% with intramedullary fixation, and 2.6% with the tight rope fixation method with a mean time of 52.82 days from injury to operative fixation ($n = 299$, range 0.5–1738 days). When treatment was subdivided into primary acute fixation within 4 weeks vs. fixation for delayed/nonunion (>4/52 after injury), the mean time to fixation was 8 days ($n = 226$, range 0.5–28 days) for primary fixation and 194 days until secondary fixation ($n = 73$, range 28–1738 days).

In total, 54 (15.6%) patients underwent removal of hardware, but when fracture and the fixation method were accounted for, only 11% of plate fixations for mid-shaft fractures ($n = 29$) were removed, whereas 76% of clavicular hook plates for distal fractures ($n = 25$) underwent removal. No distal clavicle fractures treated with locking plates underwent removal ($n = 23$). Twenty-three percent ($n = 17$) of secondary fixations (for malunion/delayed union or nonunion) underwent removal, whereas only 17% ($n = 39$) of acute primary fixations underwent removal. The mean timeframe from the initial surgery to secondary surgery, for any reason, was 366.34 days (95% CI [248.25–484.44]). Women were almost 3 times more likely to undergo removal of hardware than men (28.6% vs. 11.5%, $P < .001$). Seven patients (2%) underwent revision open reduction internal fixation in the 10-year period for nonunion ($n = 3$), malunion ($n = 2$), and failure of fixation ($n = 2$).

Discussion

Clavicle fractures are a common injury dealt with by the orthopedic trauma surgeon. Although many of these fractures can be safely treated conservatively, there has recently been an increased interest in the use of surgical interventions for certain subsets to decrease nonunion rates and improve short-term outcomes.²⁷ Indications for surgery include open fractures, neurovascular complications, significant comminution, severe displacement (>100%), clavicular shortening (>1.5–2 cm), or floating shoulder.^{23,27} Furthermore, the decision to operate may be influenced by the individual functional demands of the patient, such as occupation or sports involvement.³

Clavicle fractures are usually fixed with either a hook or a locking plate.²¹ Other surgical procedures have also been described,

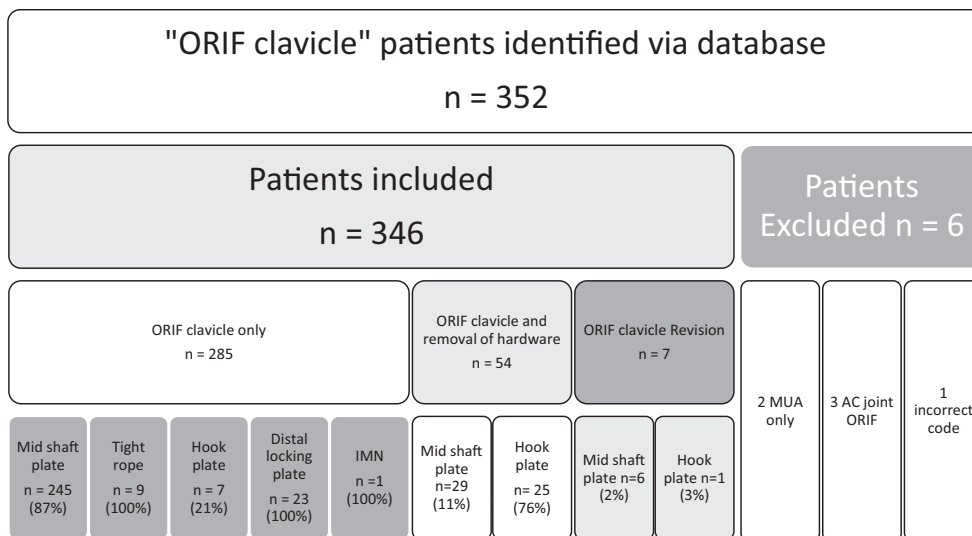


Figure 1 Inclusion/exclusion criteria selection process. ORIF, open reduction internal fixation.

such as tension band wiring, intramedullary pinning, transacromial K-wires, subcoracoid lasso, and tight rope fixation.⁹ Given the vast number of treatment options, it is no surprise that there lacks a consensus²⁷ as to what the optimal method of fixation is.

Although hook plates are effective in maintaining reduction in distal clavicle fractures, reoperation for hardware removal is routinely recommended and undertaken^{4,8,11} because of complications such as acromial erosion, subacromial impingement, and rotator cuff tear.^{4,6-8,11,12} Distal clavicle fractures are relatively uncommon, accounting for less than a third of clavicle fractures resulting in small cohorts of patients in the available literature.^{24,25} Locking plates more recently have been modified to provide another option to the management of distal clavicle fractures.¹⁷ Such precontoured distal locking plates have been shown to have equivalent union rates compared with hook plates but offer the advantage of not routinely requiring removal.^{4,5,9,12} The use of a tight-rope technique has also been described as an alternative for the management of distal clavicle fractures and also avoids the need for scheduled reoperation for removal of hardware. Although in many cases it is necessary, avoiding implant removal is desirable to prevent the morbidity associated with a second surgery along with the associated cost to both the health care service²⁶ and the patient. The heterogeneity of study designs and patient populations has made it difficult to extrapolate the optimal treatment method from the findings of meta-analyses with most studies comprising retrospective reports of a single fixation type.^{23,27}

These results show that the use of hook plates in the management of distal clavicle fractures places a significant burden on the patient, the surgeon, and the health care system in relation to the need for a scheduled reoperation. When newer techniques such as tight rope fixation, transosseous fixation, or tailored distal clavicle locking plates were used for this fracture subtype, the results of this study showed neither of these techniques required reoperation for hardware removal or revision fixation.

Mid-shaft clavicles by far account for most of the cohort. They had a much lower removal rate at approximately 11%, which was unsurprising given the known complications of hook plates when retained. However, this data set does show slightly lower rates of reoperation than other international articles which quote anywhere from 12% to 20%.^{1,10,13}

This study is the first article, to the authors' knowledge, to review 10 years of data from a single teaching unit. However, there

are limitations to the trial, the biggest of which is the possibility of patients undergoing removal of hardware or revision surgery at another institution. Using the NIMIS system, the study was able to review each case on the national database to ascertain if any procedures were performed elsewhere, but this method relies on radiological data which may not have been performed at time of removal, for example. NIMIS also does not include every hospital in Ireland and again allows for a possibility of error. Furthermore, the data set does not elaborate on the indications for hardware removal, and other than female gender, we were not able to identify any further risk factors of significance. We hypothesize that female gender was a predictive factor due to the cosmetic effect of clavicular open reduction internal fixation as we found no difference in any other variables between the sexes in relation to fracture type or intervention received.

Conclusion

Clavicular fracture fixation with locking plates or hook plates is a safe method of treatment with a very low reoperation rate for either hardware removal or revision. Women are more likely to request plate removal. Distal locking plates are a safe alternative to hook plates for distal clavicle fractures and confer an added benefit that they do not warrant hardware removal in the future, which hook plates do. Newer techniques are emerging for the management of distal fractures such as tight rope fixation and locking plates, and these appear to have a high success rate.

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