

A single centre experience of pre-contoured clavicle plates by an anterior approach[☆]



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ABSTRACT

Aim: In recent years there has been increasing evidence that comminuted and shortened clavicle fractures should be treated surgically. The aim of this study was to assess the outcome of patients who had their clavicle fracture fixed using a pre-contoured, clavicle specific plate from an anterior approach.

Method: A retrospective analysis was carried out of all patients treated with pre-contoured clavicle plates from an anterior approach between May 2014 and June 2016.

Medical records were analysed, and a phone survey was carried out to assess patient function and note any complications.

Results: Thirty-five eligible patients were identified. Post-operative complications included: 3 patients experienced altered sensation of the anterior chest wall, 2 suture granulomas, 1 incidence of prominent metalwork. In addition, 2 patients suffered peri-implant fractures due to secondary trauma after union. Patients who had Open Reduction and Internal Fixation (ORIF) for acute fractures had a mean qDASH of 8.93 and those who had a ORIF and bone grafting for non-union had an mean qDASH of 34.38.

Conclusion: Although there are 6 complications listed for 33 procedures, these would be considered minor. Patients appear to do better if treated for an acute fracture. Anterior approach for clavicle ORIF using an anatomically shaped pre-contoured plate appears to be a safe and effective procedure.

1. Introduction

Clavicle fractures are extremely common, accounting for approximately 2.6% of all fracture. These fractures tend to occur in young, active patients, who have high functional demands.¹ There has been much debate in recent years about the optimal treatment strategy for clavicle fractures. Traditionally these fractures had been managed conservatively. This had been the long established practice for hundreds of years and papers published in the 1960's, which were widely quoted, suggested the non-union rate was as low as 0.1%.² In 2007 an influential paper was published which caused widespread changes in orthopaedic practices. The Canadian Orthopaedic Trauma Society ran a multi-centre prospective trial and concluded that they supported primary plate fixation in totally displaced clavicle fractures in active adults.³ A number of other trials and meta-analysis studies followed this publication and suggest a better outcome and earlier functional recovery for comminuted and displaced clavicle fractures, if treated surgically.^{4–6}

Where plates are used as the method of fixation one of the most

frequent problems that arise after clavicle plating is prominent metalwork requiring removal. This is understandable given the fact that the clavicle is quite a superficial bone, with little soft tissue cover. In the meta-analysis by Houwert et al. they found that plate fixation was significantly less likely than intra-medullary fixation to require implant removal, however the rate of plate removal was still relatively high at 38%.⁷ In a time of increasingly strained hospital budgets and pressures on bed availability this high rate of re-operation poses both an inconvenience and risk to patients and a problem for healthcare budgets. Several studies have been done looking at different methods to try and reduce the incidence of re-operation. One area of interest is whether the surgical approach to the clavicle influences the rate of irritation and implant removal. Formaini et al. carried out a retrospective study comparing the anterior-inferior approach to the superior approach. They found that the anterior-inferior approach had a lower incidence of implant related irritation (29% vs 54%) and a lower rate of implant removal (9% vs 19%).⁸ Other purported benefits of anterior-inferior plating include that it induces deformation modes similar to intact clavicle on biomechanical studies and so is less likely to fail during

[☆] The above named research project was undertaken in the Department of Orthopaedics and Trauma in University Hospital Galway, Ireland. I, Eoin Fahey, as the main corresponding author for this project collected the data on patients, analysed the radiographic images, conducted phone studies with patients and wrote up the paper. Mr. John Galbraith gave advice and assistance throughout this process, as well as being involved in the statistical analysis and proof reading of the paper. Mr. Ken Kaar was the consultant in charge of this project, who performed all the operations and supervised the project throughout.

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normal physiological loading, sharp instrumentation is directed away from the infraclavicular neurovascular bundle and there is less disturbance to the periosteal derived blood supply for the middle third of the clavicle.^{9–11}

Most of the studies done comparing plate positions were done using Limited Contact Dynamic Compression Plates (LC DCP). Given the unusual s-shaped anatomy of the clavicle it is not ideally suited to the use of these straight plates. Recent studies have suggested that pre-contoured plates lead to lower levels of symptomatic prominent metalwork and require fewer removal procedures.^{12–14} The rate of hardware removal in these cases ranged from 10.7 to 14.7%. These studies were based on pre-contoured clavicle plates from a superior approach. A review of the literature found only two studies looking at the clinical outcomes of pre-contoured anterior clavicle plates.^{9–15} These studies reported a rate of implant removal as 3.4% and 9.5% respectively.^{9–15} The aim of our study was to retrospectively analyse all patients who had an anatomically shaped, pre-contoured plate inserted by an anterior approach for clavicle fixation in our centre in order to assess the efficacy and rate of complications. Primary outcomes were time to clinical union and occurrence of complications post-operatively, with implant related irritation and removal of implant being a sub-group of particular interest.

2. Method

This was a retrospective study of all patients who were treated with anatomically shaped pre-contoured plates (Variax, Stryker), in a single centre, using an anterior approach between May 2014, when these pre-contoured plates were first used in University Hospital Galway (UHG), and June 2016. These pre-contoured plates have been designed with three dimensional contours to fit the clavicle, based on a database of CT scans of clavicles in patients of different size, gender and ethnicity. Patients were identified by analysis of operating theatre records. All patients had a general anaesthetic and anterior approach to the clavicle as described in the AO Foundation literature by Andermahr et al.¹⁶ After fracture reduction the pre-contoured plate was placed on the anterior side of the clavicle and fixed in place with three non-locking, bicortical screws at each side of the fracture site. The wounds were then closed in a layered manner and subcuticular closure with dissolvable sutures. Patients being treated for clavicle non-union had plating with iliac crest bone autograft. Patients being treated for acute fractures underwent plating alone.

The patient notes, operative records and radiographs were then reviewed. Patients' demographic information, cause of fracture, fracture pattern and any noted complications were recorded. In patients who completed all their planned clinic appointments time to union was calculated. Phone interviews were conducted with patients in March 2017, this included a quick Disability of the Arm, Shoulder and Hand score (qDASH). The qDASH is a questionnaire designed to be completed by patients as a self-assessment of the symptoms and function of the entire upper limb.¹⁷ The qDASH has 11 items, 3 for symptoms and 8 for function. It gives a score between 0 and 100, with 0 being best and 100 being worst. The generally accepted cut-off marks are: < 15 = "no problem," 16–40 = "problem, but working," and > 40 = "unable to work".¹⁷ The mean and standard deviation (SD) of the scores for the acute and non-union cohorts were then calculated.

The degree of shortening on initial presentation to UHG was measured using the methods described by Silva et al.¹⁸ A line was drawn through the middle of each fracture fragment. From these lines perpendicular lines were drawn. Bone shortening was defined as the distance between the perpendicular lines on an anterior-posterior radiograph (See Fig. 1). A difficulty we encountered during the study was that the fracture sites were difficult to visualise post-operatively with plain radiographs due to anterior plate placement. For this reason, union time was based on clinical assessment and absence of tenderness. All patients who had a procedure using the pre-contoured clavicle plate

by anterior approach, both acute fractures and non-unions, were included to identify any safety issues with the approach or post-op complications.

3. Results

Three patients were excluded as they were followed up in a different centre. Thirty-five consecutively treated patients eligible for the study were identified. The mean age of these patients was 37.7 years old (SD 15.2). Eight of the patients operated on were female (22.85%). 26 procedures were carried out for acute fractures (74.2%), 9 were carried out for non-union (25.7%). The cases of non-union had all been managed conservatively initially. They all had surgery at least 6 months post-injury, but this varied widely, with some having initially fractured their clavicles > 10years previously. In the majority of cases the mechanism of injury for fracture was either fall off a bicycle or contact sport (Table 1).

On pre-op radiograph 18 of the fractures were comminuted (51%), mean displacement was 1.69 cm (SD 0.62 cm), mean shortening was 1.38 cm (SD 1.1 cm). Twenty-six patients returned to all their scheduled clinics appointments and were discharged after reaching clinical union. The mean time to union was 15.6 weeks (SD 6.8). Mean time for union of acute fractures was 14.27 weeks (SD 7.19). Mean time for union of previous non-unions treated with ORIF and bone graft was 19.36 weeks (SD 6.65).

Post-operative complications included: 3 patients experienced altered sensation/numbness on the anterior chest wall, 2 patients had suture granulomas, 1 patient with postoperative urinary retention and 1 patient required removal of prominent metalwork. While it is not a complication of surgery it is notable that two of the patients went on to have peri-implant fractures due to secondary trauma. Both patients are young men in their twenties. In both cases the primary injury and the peri-implant fractures occurred while engaged in contact sport.

Twenty-eight out of thirty-five patients responded to a phone survey and this was used to calculate a qDASH score. No patients refused to take part: 4 patients didn't answer the phone after multiple attempts to call, 1 number was disconnected, 1 patient had emigrated and 1 patient was not contacted as he was < 18years old. Results of the phone survey are summarised in Table 2.

4. Discussion

The aim of this study was to retrospectively analyse all patients who had an anatomically shaped, pre-contoured plate inserted by an anterior approach for clavicle fixation to assess the safety and efficacy of this procedure.

This study demonstrated excellent union rates 100% of patients that completed their clinic follow-up went on to clinical union, an issue identified with these plates is that they often obscure the fracture and can make assessment of radiographic union difficult. The results of the qDASH scores in the acute fracture cohort are also very encouraging, especially in the acute fracture group where a mean qDASH of 8.93 (\pm 8.2) indicates excellent function of the affected upper limb after surgery.

The difference in qDASH scores between the acute fractures (8.93) and those done for non-union (34.4) is an interesting finding. Unfortunately, it is impossible to determine the significance of this difference due to the relatively small cohort of patients involved. Only 6 of the patients that underwent ORIF and bone grafting answered the phone survey. Of these 6 patients 2 had been involved in high speed road traffic accidents (RTA's) and had multiple injuries. Their more life-threatening injuries were managed in the acute phase and they had ORIF and bone grafting of their clavicles as a delayed procedure after going on to symptomatic non-union. Their qDASH scores were 77.3 and 66.7 respectively. As the qDASH is a measure of everyday functioning and patients' satisfaction with doing certain tasks the results may have

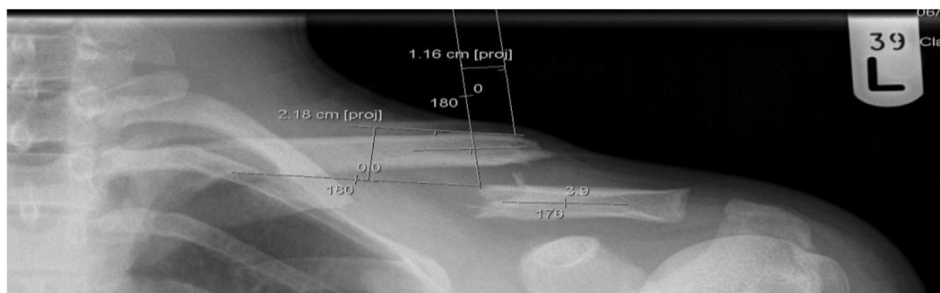


Fig. 1. Example of Pre-op x-ray of patient in this study with lines drawn to measure shortening, displacement and angulation.

Table 1
Mechanism of injury in this cohort of patients.

Mechanism of Injury	Numbers
Bicycle	11 (31.4%)
Contact Sport	10 (28.5%)
RTA	5 (14.2%)
Fall	5 (14.2%)
Workplace accident	2 (5.7%)
Skiing	1 (2.8%)
Not recorded	1 (2.8%)

been confounded by the morbidity associated with their other injuries. In this small subset of patients these poor qDASH figures for two of the six patients caused a large rise in the mean qDASH.

Seven of the thirty-five patients (20%) in the cohort experienced a complication. At first glance this appears to be quite a high complication rate. Closer analysis of these complications shows that these would all be classed as minor complications, or Class 1 as per the Clavien and Dindo Classification of post-operative complications. One patient developed post-operative urinary retention, this is a complication that may be seen in any surgery and is probably related to the use of general anaesthesia and opioid analgesia. This was a minor complication and did not delay discharge. Two patients had minor wound issues with suture granulomas that were plucked in the out-patient clinic on review. Three patients complained of a small area of anterior chest wall numbness/altered sensation. This is an accepted side effect of open reduction and all patients were counselled of the possibility of this occurring. The quoted incidence of this chest wall numbness is as high as 83% at two weeks post-operatively and 54% at one year post-operatively. It is not found to affect shoulder function.¹⁹ The real highlight of this study was the low rate of prominent metalwork, with only one patient bothered by it and requesting a removal of metalwork procedure. This is a rate of 2.8%. This compares very favourably with the rates of removal of metal quoted in other papers, with a meta-analysis by Houwert et al. in which 38% of patients required removal of implant procedures due to implant related irritation. It adds to the body of evidence that pre-contoured clavicle plates from an anterior-inferior approach have a lower incidence of prominent metalwork than other methods of operative fixation.^{9–15}

This study has a number of limitations. It is a retrospective analysis and involves relatively small numbers of patients. The retrospective nature of the study meant that follow-up intervals were not standardised and outcome measurements like the qDASH were done at varying

intervals after the surgery. The retrospective nature of the study also probably contributed to the poor response rate to the phone survey (28/35) with a number of subjects having either changed their contact details or emigrated in the interim. The small numbers involved made meaningful statistical analysis impossible.

In conclusion although this study has a number of limitations it demonstrates that use of a pre-contoured clavicle plate from an anterior approach can be an effective and safe treatment of clavicle fractures. It has the added benefit of having a low incidence of prominent metalwork and in this cohort the incidence of removal of metal procedures was far below the quoted rate for other plate designs and approaches to the clavicle.

5. Conclusions

In conclusion there is a changing trend in the management of displaced clavicle fractures. The trend now is towards more invasive treatment and operative fixation, as studies have shown that there is a benefit in terms of shoulder function at both short and long term follow up. There is an ongoing debate as to which method of fixation is the safest and most effective treatment of displaced clavicle fractures. Options include intra-medullary fixation and plate fixation. Neither method has been proven to be safer or more effective than the other. A major issue with all clavicle fixation methods, due to the superficial position of the clavicle is the problem of implant prominence and implant related irritation. This means that there is quite a high incidence of re-operation for these patients to have implants removed. In an era when health budgets are under increasing strain, and hospitals are constantly striving for more effective practices, the relatively high incidence of re-operation is obviously a cause for concern. Hospital bed spaces and theatre time are finite and valuable commodities and so any method of fixation that can limit the use of these valuable resources is obviously of interest. It also goes without mentioning that having a second operation puts the patient at increased risk. They require another general anaesthetic, will have a new surgical wound that will take time to heal, they are likely to miss work for the surgery and recovery and having to be readmitted to hospital is sure to cause patients an increased amount of stress and anxiety.

There have been a number of studies that suggest that plating has a reduced rate of re-operation compared to intra-medullary fixation. Similarly there was a trend in other studies that 1) pre-contoured plates had a lower rate of prominent metal work than standard plates when placed superiorly on the clavicle and 2) standard plates placed anteriorly have a lower rate of prominent metal work than superiorly placed

Table 2
Results of phone survey.

Cohort	No. of responders	Mean age	Gender M:F	Mean time from surgery to survey (months)	Mean qDASH
Acute	22	37.5 (± 16.3)	19:3	18.4 (± 8.9)	8.93 (± 8.2)
Non-union	6	48.3 (± 10.9)	2:4	18.8 (± 8.9)	34.4 (± 32.2)

plates. Extrapolating from these two trends the hypothesis is that pre-contoured plates placed from an anterior approach would have lower rate of metal prominence than other constructs. This hypothesis has been poorly tested in the literature with only two studies relating to the subject on Pubmed. Neither of these was a randomised controlled trial. The figure of 2.8% of patients complaining of prominent metalwork in our study is encouraging and provides some weak evidence that the hypothesis may have some truth behind it. As this is a retrospective study with no control arm the strength of this evidence is weak and further studies, ideally with a randomised control trial, are necessary to try and prove this hypothesis.

It must be acknowledged that there are inherent flaws to retrospective chart reviews and phone surveys. An 80% response rate for the phone survey is quite a good response rate in a predominantly young male trauma patient cohort. At the same time the possibility of underestimating the true re-operation rate due to patients being lost to follow up cannot be ruled out. The nature of a retrospective chart review lead to inherent inconsistency in the follow up times of patients. The time from surgery to the phone survey ranged from 8 months to 33 months. It is possible that some of these patients with briefer follow-up may go on to develop problems with implant related irritation in the medium to long term.

Another interesting finding during the phone surveys was that two of the patients had refractured their clavicles with the plates in situ. Both of these patients were young men in their mid-twenties. Their initial clavicle fractures were playing rugby and football respectively. Their refractures occurred more than six months post-operatively, after they had been discharged from the follow-up clinics with clinical and radiographic evidence of bony union. Both refractures occurred during games after return to competitive full contact sport. It is possible that these two men were simply unfortunate and suffered another high energy injury to their shoulders and there are possibly some patient related issues such as tackling technique etc that predisposed these men to clavicle injuries. A broader survey of young field athletes that have had clavicle plating might be useful to see if this is a more widespread phenomenon. Biomechanical studies of plated, intact clavicles might also be a useful additional study to investigate the possibility that screws or screw holes are acting as stress risers in clavicles that have undergone plate fixation.

In conclusion this study provides some preliminary evidence that clavicle plating using an anatomically pre-contoured plate from an anterior approach is a safe and effective procedure. There were no serious complications during the application of the plates and the re-operation rate for prominent metal work was well below the rates reported in the literature for other methods of fixation. Our study suggests that more detailed clinical and biomechanical studies would be of benefit to provide a stronger evidence base for clavicle plating from this approach.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.jor.2019.02.001>.

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