When is early return too early? Clavicle plate fixation in Australian Rules football athletes: A retrospective review of cases [version 1; peer review: 2 approved with reservations]

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Abstract
Background: We retrospectively reviewed return to sport times and results for a series of professional Australian Rules football (AFL) players after clavicle fracture management using a precurved Titanium (Acumed) plate and screws. We allowed very early use and aimed to assess if this construct is strong enough to withstand collision sport activities before radiological union is confirmed.

Methods: We reviewed 14 consecutive senior listed AFL players who underwent plate fixation by the senior author over a 10 year period. Outcome measures were taken between 12 and 36 months post operatively and included time to return to play, Nottingham Clavicle Score (NCS) and the Oxford Shoulder Score.

Results: The median time for return to training was 3.5 weeks and 6 weeks for return to full competition. All fractures eventually united. Three of the players that returned before 6 weeks post-operatively suffered significant impacts that caused a bend in the titanium plates. One of these required revision fixation surgically due to perceived weakness in the bent plate construct and cosmetic deformity. The mean Nottingham Clavicle Score and Oxford Shoulder Score were 87.9 and 45.1 points respectively. Survival analysis showed that more than half of the players returned to training at 4 weeks and over 80% at 12 weeks.

Discussion: The decision to operate early on AFL players who suffered a clavicle fracture in competition play resulted in excellent longterm results. However, the decision to return some players earlier than accepted times for bony union resulted in bending of plates in a significant number, and the risk of further injury must be weighed up in a collision sport. The early return to play time had no adverse effects on performance and participant satisfaction was high, as reflected by the Nottingham Clavicle score and the Oxford shoulder score.

Keywords
Clavicle, fracture, fixation, professional, sport, return
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Author roles: Ricks M: Formal Analysis, Project Administration, Writing – Original Draft Preparation, Writing – Review & Editing; Borbas P: Data Curation, Writing – Review & Editing; Perret M: Formal Analysis, Project Administration, Writing – Review & Editing; Warby S: Data Curation, Formal Analysis, Software; Hoy G: Conceptualization, Data Curation, Project Administration, Resources, Supervision, Writing – Review & Editing

Competing interests: No competing interests were disclosed.

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Introduction
Clavicle fractures are common making up 10% of all fractures and 30% of fractures sustained during sport\(^1\). Of all sport related fractures, clavicle fractures have the third longest return time to sport\(^1\). Clavicle fractures are commonly divided into the anatomical location of fracture (medial, midshaft and lateral) and whether the fracture is undisplaced or displaced. The commonest location of a clavicle fracture is the midshaft in sporting populations\(^4\). In a general population, clavicle fractures are managed conservatively or surgically depending on the location, fracture morphology and patient factors\(^5\). In athletic individuals, operative intervention is commonly performed for lateral clavicle fractures; however, the management of midshaft fractures is still divided\(^6\). Some studies recommend fixation in fractures that are completely displaced, shortened by greater than 2 centimetres or comminution; however, these are based on the non sporting populations and do not transfer across to high level athletes\(^7\).

Clavicle fracture fixation carries with it a major complication profile that includes neurovascular injury and infection that can have significant morbidity to the patient. An operative fixation in a displaced fracture of the clavicle has shown improved functional outcomes and a lower malunion and non-union rate compared with nonoperative\(^8\)\(^-\)\(^10\). Plate fixation has been shown to have a high removal rate electively due to plate irritation\(^7\). Studies propose that there is an acceptable margin of safety with fracture fixation when clinically indicated and when performed by a specialist orthopaedic surgeon\(^11\)\(^-\)\(^13\).

Australian rules football when played professionally in either the Australian Football League (AFL) or the Victorian Football League (VFL) is a physically demanding contact team sport\(^1\). Clavicle fractures of the midshaft in an athletic patient are commonly managed surgically, as conservative management causes a reduced ability to return to sport, an increased reinjury rate, scapula dysfunction and poor function secondary to non-union or mal union\(^9\). The surgical management of clavicle fractures in contact sports players has been shown to allow safe and early return to sport\(^13\).

There is limited evidence on return to sport time frames post surgically managed clavicle fractures, and no evidence of return to play time frames in AFL and VFL populations. The current return to sport times in surgically managed clavicle fracture in the AFL and VFL are based on expert opinion only. There is a need to provide surgeons, sports physicians, coaches, physiotherapists and players with evidence-based guidelines on safe return to play for AFL and VFL players who have post surgically managed clavicle fractures. A timely and safe return to play post injury is of a high interest to players, clubs and medical practitioners involved in AFL and VFL player care, as a team player lost to injury can affect team dynamics, on field performance and participation satisfaction of the individual\(^1\). It is unknown whether a return to a contact sport like AFL with a surgically managed clavicle fracture that has not united results in complications.

The primary aim of the present study is to retrospectively review the time frames for return to sport, patient reported outcomes measures (PROMS) and complications in a group of professional Australian Rules Football players who were surgically managed for a midshaft clavicle fracture. The secondary aim is to investigate any complications with surgically managed clavicle fractures with an early return to sport before radiographic confirmation of union.

Methods
Participant inclusion
Following ethical approval from the institutional review board at Ramsay Health Care (approval: Project 165), a retrospective analysis of all consecutive AFL players who underwent open reduction and internal fixation of a midshaft clavicle fracture was performed. All patients gave written consent for inclusion in the study. The patient data was collected from the Melbourne Orthopaedic Group (Melbourne, Australia) medical database; Ramsay Health Care runs the hospitals that the Lead Surgeon/ Author (GH) operates from. We included Australian Rules Football players that played in the professional leagues of the AFL and the VFL who were over the age of 18. Patients who sustained concurrent upper limb injuries (e.g. shoulder dislocation) or who had associated pathology to the clavicle fracture (e.g. ACJ dislocation) were excluded from the study.

Surgical technique
All operations were carried out by the Lead Author (GH) under a general anaesthetic. The surgery is performed in a beach chair position with fluoroscopic assistance. A horizontal skin incision over the midshaft of the clavicle is used and fixation was performed using a precurved Titanium (Acumed) plate. The aim of the surgery is to achieve a rigid fixation construct that would promote union and allow an early return to contact sports. If appropriate a lag screw technique was used and at least 6 cortices engagement with the screws either side of the fracture site.

Post op protocol
The patient left the hospital with a sling and was advised when comfortable to discard and perform early mobilisation of the shoulder. Physiotherapy and exercises were started within a week of discharge with phone consultations and face to face appointments used to promote compliance. The wound had absorbable subcuticular closure with glue sealing the wound. A waterproof dressing was placed over the wound and advised to keep covered till 14 days post-surgery. The patient was advised they were allowed unrestricted movement immediately post op but to refrain from contact sports or weight training till 3 weeks post op.

Return to play functional assessment
Each of the patients were followed up and the time taken for each patient to return to sport, any post op complications, or concurrent injuries sustained following the operation were documented. The level the player returned to and whether this was the same league or below was also recorded. The time
for return to training and to play along with on field performance scores were collected from the National player database, which is maintained by AFL Australia. A telephone consultation and clinical review was carried out by the Lead Author (GH) collecting the Nottingham clavicle score, Oxford shoulder score and any reported complications from the surgical procedure at six months and one year follow-up.

Statistical analysis
Statistical analyses were performed using SPSS (v22; IBM). Within-group analyses for the probability of return to training and the probability of return to full competitive play were estimated as a function of time using Kaplan-Meier survival analyses. Survival analysis is used to estimate the time for a particular event to occur within a specified observation time period. In this study, the “event” was return to training and then return to full competitive play. Participants who did not have an “event” (did not return to training or competitive play) within the pre-determined observation time period were censored and still accounted for in the analysis to allow for valid inferences. Censorship means that these participants did not reach their “event” (return to training or return to competitive play) at all or reached their “event” outside the observed time period.

The observation time period was set to 12 weeks post operation date for return to training and 18 weeks post operation date for return to full competitive play, as we would expect professional AFL players to have returned to training and play within these time periods, even if their operation was performed near or at the end of the season. For return to training, survival tables at 2, 4, 8 and 12 weeks were collated. For return to full competitive play, survival tables at 2, 4, 6 and 18 weeks were collated. Mean and median values with 95% confidence intervals were expressed for time to return to training and time to return to full competition.

Results
Of the 98 clavicle fractures that were available on the Melbourne Orthopaedic Group medical database, 15 were of professional AFL players. One was lost to follow up and was excluded from the study leaving 14 patients. In total, 10 of the players injured their left shoulder and 4 injured the right shoulder with 2 of the players injuring their dominant arm. The median age of the players was 28.5 years with a range from 22 to 37 years old (Table 1). The players were operated on between the dates of 2003 to 2017. There were 12 men and 2 women in the study population. A total of 12 of the players were playing in the AFL and 2 were in the VFL and all AFL players returned to their pre injury league of play. The 2 female VFL players did not return to their league level. The mean time to return to training was 4.4 weeks (SD 3.2) with a range of 1.8 to 12. The mean time to return to play was 12.8 weeks (SD 12.8) with a range of 2.5 to 37.5 (Table 2). The median time for return to training was 3.5 weeks and 6 weeks for return to full competition. Figure 1 shows a Kaplan-Meier graph for the return to training and Figure 2 shows the return to same level of play.

Clinical results
The mean Nottingham clavicle score was 87.9 (SD 10.5) with a range of 68 to 100. The mean Oxford shoulder score was 45.1 (SD 4.1) with a range of 35 to 48.

Complications
Three patients (21%) sustained a bending of the plate. One of these was on the first game back following the operation and was re-operated on. The other patients had a clinical bending

<table>
<thead>
<tr>
<th>Player</th>
<th>Age</th>
<th>Gender</th>
<th>Type of fracture</th>
<th>Mechanism of injury</th>
<th>Side of injury (Dominance)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>35</td>
<td>Male</td>
<td>Midshaft</td>
<td>Tackled</td>
<td>Left (Right)</td>
</tr>
<tr>
<td>2</td>
<td>31</td>
<td>Male</td>
<td>Midshaft</td>
<td>Landed on shoulder</td>
<td>Left (Right)</td>
</tr>
<tr>
<td>3</td>
<td>30</td>
<td>Male</td>
<td>Midshaft</td>
<td>Tackled</td>
<td>Left (Right)</td>
</tr>
<tr>
<td>4</td>
<td>32</td>
<td>Male</td>
<td>Midshaft</td>
<td>Landed on shoulder</td>
<td>Right (Left)</td>
</tr>
<tr>
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<td>26</td>
<td>Male</td>
<td>Midshaft</td>
<td>Tackled</td>
<td>Right (Right)</td>
</tr>
<tr>
<td>6</td>
<td>27</td>
<td>Male</td>
<td>Midshaft</td>
<td>Collision</td>
<td>Left (Right)</td>
</tr>
<tr>
<td>7</td>
<td>33</td>
<td>Male</td>
<td>Midshaft</td>
<td>Collision</td>
<td>Left (Right)</td>
</tr>
<tr>
<td>8</td>
<td>25</td>
<td>Male</td>
<td>Midshaft</td>
<td>Tackled</td>
<td>Right (Right)</td>
</tr>
<tr>
<td>9</td>
<td>24</td>
<td>Female</td>
<td>Midshaft</td>
<td>Tackled</td>
<td>Left (Right)</td>
</tr>
<tr>
<td>10</td>
<td>22</td>
<td>Female</td>
<td>Midshaft</td>
<td>Collision</td>
<td>Left (Right)</td>
</tr>
<tr>
<td>11</td>
<td>22</td>
<td>Male</td>
<td>Midshaft</td>
<td>Direct blow</td>
<td>Right (Left)</td>
</tr>
<tr>
<td>12</td>
<td>25</td>
<td>Male</td>
<td>Midshaft</td>
<td>Tackled</td>
<td>Right (Right)</td>
</tr>
<tr>
<td>13</td>
<td>34</td>
<td>Male</td>
<td>Midshaft</td>
<td>Tackled</td>
<td>Left (Right)</td>
</tr>
<tr>
<td>14</td>
<td>37</td>
<td>Male</td>
<td>Midshaft</td>
<td>Collision</td>
<td>Left (Right)</td>
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</table>
Table 2. Results of patient reported outcomes measures and return to play.

<table>
<thead>
<tr>
<th>Player</th>
<th>NCS final score</th>
<th>OSS final score</th>
<th>Level at injury</th>
<th>Level after return to play</th>
<th>Time to return to training (weeks)</th>
<th>Time to Return to play (weeks)</th>
<th>Comments/ Re-injuries</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>100</td>
<td>48</td>
<td>AFL</td>
<td>AFL</td>
<td>6.5</td>
<td>37.5*</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>78</td>
<td>40</td>
<td>AFL</td>
<td>AFL</td>
<td>2</td>
<td>4.5</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>98</td>
<td>48</td>
<td>AFL</td>
<td>AFL</td>
<td>4</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>76</td>
<td>43</td>
<td>AFL</td>
<td>AFL</td>
<td>2</td>
<td>3.5</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>84</td>
<td>45</td>
<td>AFL</td>
<td>AFL</td>
<td>9</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>98</td>
<td>48</td>
<td>AFL</td>
<td>AFL</td>
<td>3.5</td>
<td>20*</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>68</td>
<td>40</td>
<td>AFL</td>
<td>AFL</td>
<td>3</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>96</td>
<td>48</td>
<td>AFL</td>
<td>AFL</td>
<td>4</td>
<td>6</td>
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</tr>
<tr>
<td>9</td>
<td>96</td>
<td>48</td>
<td>AFL</td>
<td>AFL</td>
<td>2</td>
<td>2.5</td>
<td></td>
</tr>
<tr>
<td>10</td>
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<td>48</td>
<td>AFL</td>
<td>AFL</td>
<td>3</td>
<td>4.5</td>
<td></td>
</tr>
<tr>
<td>11</td>
<td>92</td>
<td>47</td>
<td>AFL</td>
<td>AFL</td>
<td>12</td>
<td>31.5*</td>
<td></td>
</tr>
<tr>
<td>12</td>
<td>96</td>
<td>48</td>
<td>AFL</td>
<td>AFL</td>
<td>1.8</td>
<td>28*</td>
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</tr>
<tr>
<td>13</td>
<td>80</td>
<td>35</td>
<td>VFL</td>
<td>**</td>
<td>NYR</td>
<td>NYR</td>
<td></td>
</tr>
<tr>
<td>14</td>
<td>76</td>
<td>45</td>
<td>VFL</td>
<td>**</td>
<td>NYR</td>
<td>NYR</td>
<td></td>
</tr>
</tbody>
</table>

Mean (SD) 87.9 (10.5) 45.1 (4.1) 4.4 (3.2) 12.8 (12.8)

Range 68 to 100 35 to 48 1.8 to 12 2.5 to 37.5

Note: * Refers to players who were injured near the end of season and did not return to play until the following season. ** Players who have not yet returned to play.

Figure 1. A Kaplan-Meier graph showing the return to training of the professional contact sport athletes.
of the plate following a contact but in discussion with the patient they were conservatively managed and went on to unite. One of these patients underwent removal of the plate electively at one year and full fracture union was noted. One patient had a refracture one year post fixation a long time after radiographic union was confirmed. There were no cases of neurovascular injury or infection in this patient group. All of the players returned to training and contact play following the fixation. The complications are displayed in Table 3.

Discussion
This is the largest series of professional AFL players in the literature showing the return to contact sports following an open reduction and internal fixation of a midshaft clavicle fracture. This patient population is different to the general population due to their high demand and contact nature of their sport. Survival analysis showed that more than half of the players returned to training at 4 weeks and over 80% at 12 weeks. For return to full competitive play, just over half had returned at 6 weeks and this value did not change within the observed time period (18 weeks). One female patient decided to take a season off playing following the injury despite being able to play prior to this and would impact upon the data set. We show in our series that all of the professional AFL players returned to the same level of play post operatively with a mean Oxford shoulder score of 45.1 and a mean Nottingham clavicle score of 87.9. This shows an excellent range of movement and function post operatively.

A study by Verborgt et al. (2005) demonstrated within their semi-professional population (mountain bikers, cyclists, soccer players and swimmers) a 75% patient satisfaction rate who were managed with a fixation of their displaced midshaft clavicle fracture. They showed an infection rate of 18% and a refracture rate of 8% in their professional athletes with 5% nonunion rate. The authors proposed that they showed good results in semi-professional athletes; however, an early return to contact or heavy activities at the expense of significant risk profile would not be considered acceptable in patients with a lower functional demand. We demonstrated no infections within our study but there were three bent plates (21%) from contacts during play, with one of them requiring a reoperation. This may not have occurred if the population were protected from contact; however, the remaining 11 players (79%) returned to contact before radiographic union and all of the AFL players played at the same level without any structural compromise to the fixation. Despite the three bent plates the players had a very high Oxford shoulder score and Nottingham clavicle score. This study shows that the fixation of the fracture leads to high patient reported outcomes following the surgery but carry the risk of bending of the plates.

A study by Jack et al. (Aug, 2017) showed that surgical fixation of clavicle fractures in professional football players (NFL, USA) lead to decreased union rates, improved shoulder strength and
a decreased residual functional impairment. In that series, the mean return to play was 211 days post surgery with 7 (44%) returning in the same season as their injury and subsequent fixation\textsuperscript{16}. Our series of clavicle fixations in collision athletes shows a quicker return to training (4.4 weeks) and playing sport (12.8 weeks). Jack \textit{et al.} also showed 88.2\% of the players remained in the NFL one year after surgery with no difference in post op performance scores or games per season\textsuperscript{16}. In our series, all of the AFL players returned to the same level of play within a year of playing. Another contrasting study by Jack \textit{et al} (Sep, 2017) showed a return to sport of 96.9\% at a mean length of time of 244 days following conservative management of midshaft clavicle fractures in 30 professional NFL players\textsuperscript{17}. That series shows that conservative remains an option in this population; however, it is a slower return when compared with their previous surgical series\textsuperscript{16} and our study. Robertson and Wood (2016) showed a return rate to sport of 97\% with a mean return time of 12 weeks of a midshaft clavicle fracture fixation\textsuperscript{13}, which is a similar length of time to our return to play, but these were noncontact athletes and therefore a different population. Robertson \textit{et al.} (2018) advocated that surgery in the sports population in a displaced mid shaft clavicle fracture provided an improved return to sport over conservative management. That study did highlight that it was based on low level evidence and that further randomised controlled trials were required to draw more accurate conclusions\textsuperscript{18}. A recent systematic review on the return to sports following clavicle fractures highlighted the difficulty in reporting the return to sports post clavicle fracture due to the lack of detailed studies. The authors of the systematic review advised further studies with a detailed return to sports including time frames, number of weeks missed and if the players returned to their previous level allowing an evidence based recommendation to be\textsuperscript{13}. We have been able to present this data for Australian Football and would encourage other sports to collect the data to allow further evidence and conclusions to be made.

**Conclusion**

The decision to operate early on AFL players who suffered a clavicle fracture in competition play resulted in excellent long term results. However, the decision to return some players earlier than accepted times for bony union resulted in the bending of plates in a significant number of players, and the risk of further injury must be weighed up in a collision sport. The early return to play led to a high Oxford shoulder score and Nottingham clavicle score, resulting in a high level of patient satisfaction. We advocate that plate fixation of mid shaft clavicle fractures is a safe option allowing a very good function and early return to sport, but with the risk of bending of the plate.

**Data availability**

All data underlying the results are available as part of the article and no additional source data are required.

**Grant information**

The author(s) declared that no grants were involved in supporting this work.

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<tr>
<th>Player</th>
<th>Post operative infections</th>
<th>Neurovascular injury</th>
<th>Metal work compromise</th>
<th>Reoperation or intervention</th>
</tr>
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<td>Nil</td>
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<tr>
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<tr>
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<td>Bent Plate during contact</td>
<td>Conservative management</td>
</tr>
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<td>Nil</td>
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<td>10</td>
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</tr>
<tr>
<td>11</td>
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<td>Nil</td>
<td>Nil</td>
</tr>
<tr>
<td>12</td>
<td>Nil</td>
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<td>Bent plate during contact</td>
<td>Removal of metalwork, replating and bone grafting</td>
</tr>
<tr>
<td>13</td>
<td>Nil</td>
<td>Nil</td>
<td>Nil</td>
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<td>Nil</td>
<td>Nil</td>
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<td>Conservative management</td>
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References


Open Peer Review

Current Peer Review Status: ?

Reviewer Report 03 October 2019

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Benjamin Dean
Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences (NDORMS), University of Oxford, Oxford, UK

Overall:

This is a useful piece of work which challenges the way in which clavicle fractures may be rehabilitated following surgery in athletes.

Specifics:

Abstract:
- I would re-write the background as some of this relates to methods and not background. Just frame the rationale for this study.
- Do you know what the time to union was? (May be useful to put this in the abstract).

Main paper:

Introduction:
- May be worth stating what is roughly standard practice in athletes? If there is evidence here quote it, if not then state what is generally done – I suspect the standard practice is to wait for evidence of some bony union before allowing contact, hence why this study is interesting as it questions current practice.

Aims:
- You mention complications in both primary and secondary aims, can you refine this?

Results:
- Would be worth adding in time to union if you have this?
- Table 1 – would be worth adding another row with the median/average values of age etc
Discussion:
- I would re-do the first paragraph to concisely summarise your key results and why this is important, i.e. that early return to full contact is possible and there is a risk/benefit to this approach as shown by your results.

Conclusion:
- I would make this a bit more concise to summarise that early return to full contact is feasible and results in excellent outcomes but there is the risk of…….

Is the work clearly and accurately presented and does it cite the current literature?
Yes

Is the study design appropriate and is the work technically sound?
Yes

Are sufficient details of methods and analysis provided to allow replication by others?
Yes

If applicable, is the statistical analysis and its interpretation appropriate?
Yes

Are all the source data underlying the results available to ensure full reproducibility?
No

Are the conclusions drawn adequately supported by the results?
Yes

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Upper limb surgery and pain

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.
This is a retrospective cohort review of professional AFL collision athletes undergoing clavicle fracture internal fixation.

The authors report very early return to play before the progression to osseous union.

The authors include 14 patients. However 2 patients (13 & 14) have not yet returned to play. If these patients are to be included in the series and explanation of the lack of return to either training or play must be included. If this information is not available they should be excluded from analysis.

The authors identify that the majority (80%) were able to return to training at 4-6 weeks without complications. However 20% suffered plate damage. This is an avoidable complication such that 1 patient in the series required reoperation. This patient (12) did not return to play for 28 weeks, far longer than would have been necessary. Little detail is provided as to what happened after return to training/play in the groups. I doubt that this information is available but it is highly likely that those patients who had plate failure did so because of greater impacts that those who did not. Returning to training in the early phase is likely to be safe if you can avoid heavy impact on the shoulder until union has occurred. This is likely to be influenced by the position of the player (known) and the frequency of collisions (unknown).

The authors have documented that the bent plates were managed conservatively in patients 8 and 14. How long were they kept out of play for after the bending occurred? This is important as it would highlight the implications of the reinjury on end return to play time. From the data patient 14 has not yet returned to play, 12 took 28.5 weeks. Patient 8 returned to play at 6 weeks but we do not know when the plate bent and whether he required a further period of rest after the initial return to play.

Whilst the authors conclude that this study shows that early return to play is possible, it shows the high rate of significant avoidable harm that this approach entails. These risks may be taken on by the patient after appropriate education but the authors cannot conclude (as in the discussion) that early return to play had no adverse effects on performance. It should be stated clearly that if plate failure does occur then overall return to play is significantly longer.

Is the work clearly and accurately presented and does it cite the current literature?  
Yes

Is the study design appropriate and is the work technically sound?  
Yes

Are sufficient details of methods and analysis provided to allow replication by others?  
Yes

If applicable, is the statistical analysis and its interpretation appropriate?  
Yes

Are the conclusions drawn adequately supported by the results?  
Partly

Competing Interests: I am the current fellowship clinical supervisor of the lead author
Reviewer Expertise: Shoulder surgery

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.

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