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RESEARCH ARTICLE

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Fixation of Fractures of the Shaft of the Humerus with Dynamic Compression Plating or Intramedullary Fixation. A Review of the Effect of Treatment on Post-Operative Function and Complications

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ABSTRACT

The majority of humeral shaft fractures can successfully be treated non-surgically by various methods of reduction and immobilisation (including U-shaped splints or types of functional bracing) with high union rates of approximately 90%. These methods have been found to give better results in most common humeral shaft fractures and with fewer complications than the use of open reduction and internal fixation. However one may appreciate that no modern studies have replicated these results recently. Operative treatment has usually been reserved for the treatment of non-union, multiply injured patients, neurovascular injuries, open fractures, "floating elbows" and in cases where non-operative treatments cannot adequately maintain a satisfactory reduction.

We report the results of a review of the literature comparing humeral dynamic compression plating to humeral intramedullary nailing. Our review concludes that the current evidence base shows similar levels of humeral function and complications with either technique. Intramedullary nailing is associated with poorer shoulder function and dynamic compression plating is associated with infection. The current evidence base supports using either technique depending on which surgical complications are more palatable and on the familiarity and proficiency of the surgeons with an individual technique.

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Introduction

The majority of humeral shaft fractures can successfully be treated non-surgically by various methods of reduction and immobilisation (including U-shaped splints or types of functional bracing) with high union rates of approximately 90%. These methods have been found to give better results in most common humeral shaft fractures and with fewer complications than the use of open reduction and internal fixation. However, one may appreciate that no modern studies have replicated these results recently. Operative treatment has usually been reserved for the treatment of non-union, multiply injured patients, neurovascular injuries, open fractures, "floating elbows" and in cases \

here non-operative treatments cannot adequately maintain a satisfactory reduction [1-5].

Historically open reduction and internal fixation of the humeral shaft has been the most common procedure to operatively treat humeral shaft fractures. There are a variety of techniques and implants that can be used to reduce and hold the fracture in a reduced position. There are two commonly used approaches the anterior and the posterior approach [6]. The anterior approach provides access to the mid-shaft and proximal humerus. During this surgical exposure there is a risk of damage to a number of vital structures including the radial nerve. Another commonly used approach is the posterior approach which provides good access for mid-shaft and more distal fractures. The key structures that can be damaged in this approach also include the radial nerve, the profunda brachii artery and if the long head of the triceps muscle is retracted medially there is the possibility of injury to the ulnar nerve also. Other approaches have been described including the lateral approach but these are used less commonly than the previous two methods [7]. Once the fracture has been exposed the most commonly used fracture fixation technique involves dynamic compression plating. It has been noted that "open reduction and internal fixation often necessitates extensive dissection and tissue devitalisation, creating an environment less favourable for fracture union and more prone to bone infection" [8].

In contrast most intramedullary fixation techniques rely on a closed reduction and relative stability [9]. Antegrade nailing involves a deltoid splitting approach to achieve access to the intramedullary canal. The deltoid muscle and rotator cuff can be damaged during this procedure and there is risk of injury to the axillary nerve. Retrograde nailing systems enter the medullary canal through the olecranon fossa where there is a risk of impingement on elbow extension if the implant is too long or too bulky. Distal locking screws have the potential to cause damage to the radial nerve, ulnar nerve, median nerve

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and brachial artery depending up on the orientation of the nail. The theoretical advantage of intramedullary fixation is that the local tissues around the fracture site are disturbed minimally and that the relative stability achieved encourages healing by callous formation which is thought to be quicker and more reliable than direct bone healing [8]. Other theoretical advantages include less invasive surgery, decreased stress shielding, autografting of the fracture site whilst reaming and "improved biomechanics with higher moments of inertia and load sharing capabilities" [10].

It is difficult to find an objective, reproducible and validated assessment of humeral function post mid shaft fracture. There is no specific scoring system for this type of injury necessitating the use of a more general outcome measure. One of the most commonly used outcome measures in the literature is the American Shoulder and Elbow Surgeon's score (ASES). The ASES score is a relatively well validated patient self reporting assessment tool and will be used as the primary outcome measure [11].

Secondary outcome measures include post-operative complications, specifically radial nerve injury, re-operation for non-union and surgical site infections.

Methods

Studies were identified on the 25th May 2021 using the search strategy identified below.

Due to the multifactorial and complex nature of the rehabilitation of patients after operative intervention for fracture of the humerus an attempt to reduce the influence of confounding factors was made by searching only for randomised controlled trials.

1. The Cochrane Database of Systematic Reviews: Bone, Joint and Muscle Trauma Group "humerus"
2. PubMed Search ("Bone Plates"[Mesh] and "Fracture Fixation, Intramedullary"[Mesh] and "Humeral Fractures"[Mesh]). Results were limited to only include randomised controlled trials.
3. Review of references cited in articles identified by the above search strategy for further eligible studies

A meta-analysis was deemed to be inappropriate due to lack of homogeneity between the different populations, different criteria used to include patients, different implants used, differing descriptions of what constitutes union and infection, a lack of consistency between studies on outcome measures and poor internal validity in the case of some of the studies. All studies have been critically appraised using the consort criteria [12,13].

Results

Six randomised controlled trials were identified using our search strategy. In 2007 Changulani et al reported results of a prospective randomised controlled trial comparing the dynamic compression plate versus the intramedullary nail for humeral fractures. This single centre study enrolled 47 consecutive patients into a randomised study. There is no mention of having received ethical approval for this trial and the method of randomisation has not been explained. There was no blinding and no clearly indicated primary outcome measure or power analysis based on any of the outcome measures measured. Bone grafting was used at the surgeon's preference and one type of each prosthesis was used with the same surgical technique for each patient. Only two patients were lost to follow-up which was encouraging. However, there was a gross lack of homogeneity in the two tested groups. The inclusion criteria were vague and included "unstable fractures" with no definition of what this actually means or who was deciding this and a mixture of open and closed fractures. There were no time constraints on eligibility with some fractures being treated acutely and some at three months. Thus, the standard deviation of the time from injury to operation was very large. The paper is inconsistent in its description of the length of follow up achieved. In the methods section it is stated that all patients were followed up for 12 months however in the results the follow up interval varies from 6 to 33 months. There was no significant difference in the ASES scores at 6 months between both groups. Time to union was also discussed in detail without at any point defining what the assessors regarded as a united fracture. With regard to complications there was an infection rate with plate fixation of over 20% which appears to be alarmingly high [5,10]. One wonders if any systems were in place to halt the trial in case of adverse events. There were three non-unions in each group and two nerve injuries. These comprised of one axillary nerve injury in the intramedullary nail group and one radial verve injury in the plating group. Four patients required nail removal due to impingement at the shoulder [14].

In 2000 McCormack et al reported results from a prospective randomised controlled trial comparing dynamic compression plating to locked intramedullary nail fixation. Forty four patients were randomised prospectively. Patients randomised to the plating group received their treatment via the anterior or posterior approach. There was no further information given on this potential confounder. There is no evidence that efforts were made to improve the quality of data collection by for example having multiple assessors. The length of plate and use of autogenous bone grafting was not restricted by the trial and no attempt made in the results to reflect the possible effect of this confounder. No power calculation was made. A mixture of antegrade and retrograde techniques were used without more explanation into the decision making process behind these decisions. Reaming was also used on a fairly ad-hoc basis. The importance of these failings of the study are alluded to in the discussion "we are aware that by inserting intramedullary nails both antegrade and retrograde, and using variable degrees of reaming, we introduced variables which weakened direct comparison with dynamic compression plating" [10]. Follow-up varied from between 6 and 33 months, it is not mentioned whether the ASES scores were representative of the patients at the 6 months stage or later. Three patients were lost to follow up. The paper acknowledges that further improvements in function can occur following the initial 6 month period but claim that "we calculated that ... with our design that any difference would be the same in both groups". This unsubstantiated claim raises further doubt on the external validity of these results. No explicit primary outcome was mentioned though it appears that the ASES score, visual analogue pain scores, operative time, blood loss, post operative blood loss and development of deformity were all measured. The randomisation process has not been described in any detail and no information was provided who was collecting the outcome data. This methodological flaw gives an opportunity for bias to affect the data set and increases the chances of generating a type

1 error. The results show no statistically significant difference in ASES scores between the intramedullary nailing group and the dynamic compression plating group. Similarly all other outcome measures showed no difference in the population groups other than post operative complications. These adverse events were frankly discussed. In the intramedullary nailing group there were 13 complications requiring 7 reoperations. In the plating group there were 3 complications requiring 1 reoperation. There were 3 radial nerve injuries in the nailing group. Two of these were neuropraxias which recovered completely and one patient required reoperation and radial nerve exploration but this found an intact nerve. There were no radial nerve problems in the plating group.

In 2000 Chapman et al reported on results of a randomised prospective study comparing plate fixation to intramedullary nail fixation. Over a four year period 89 adult patients with diaphyseal fractures requiring operative fixation in a single centre with multiple surgeons were prospectively randomised to receive either a locked antegrade humeral nail or open reduction and internal fixation with a dynamic compression plate. Randomisation was performed using a "sealed envelope technique" [5]. No blinding was performed which is understandably quite difficult to achieve with surgical randomised controlled trials [15].

Again multiple different surgical techniques were permitted at the surgeon's discretion including bone grafting, use of dynamic or static locking and choice of anterolateral, posterior or direct lateral approach for open reduction and internal fixation. Inclusion and exclusion criteria were well defined. Patients who had a pre-operative radial nerve deficit had their radial nerve explored intra-operatively. The primary outcome measure is not stated explicitly but time to union, complications and pain/functional assessment appear to be the main topics of interest to the author. The definition of union has not been made. Within the context of orthopaedic research the diagnosis of union is difficult to determine and radiographs in particular are known to be unreliable in diagnosis of union. An unvalidated functional assessment showed a statistically significant association between antegrade nailing and shoulder pain (and decreased range of movement) and between plating and elbow pain (and decreased range of movement). Thirty percent of the trial population had a pre-operative radial nerve injury. There was one radial nerve injury in the plating group and two posterior inter-osseous nerve injuries in the nailing group and all iatrogenic neurological injuries recovered with time. Three infections presented in the plating group though these were associated with open injuries, whilst there were no infections in the nailing group (even though 24% of the nailing group were open injuries) [16].

In 1995 Rodriguez-Merchan published results of compression plating versus Hackethal nailing in closed humeral fractures that had failed non-operative reduction [17]. Hackethal flexible nailing is a different intramedullary technique as compared to locked intramedullary fixation with the aim being to pass multiple thin flexible nails down the canal until the canal is filled. There are no locking screws and thus no resistance to rotational, distraction or compression forces. By passing larger numbers of nails into the humeral canal increased stability can be achieved [18]. Over a ten year period 92 closed mid-shaft humeral fractures were seen by a single surgeon, 52 of which were treated non-operatively. This appears to a be fairly low volume trauma unit seeing one humeral fracture every one to two months. The other 40 patients were entered into a "prospective randomised study" [17]. Though this assertion is refuted later on in the paper "although it is claimed that the two groups were prospectively randomised, this is not completely so because it was based on surgeon preference". This study is clearly not randomised in any meaningful way. It also seems odd that 43% of all patients with closed humeral mid-shaft fractures ending up being recruited into an operative trial given that even the reporting author realises that "the primary treatment for diaphyseal humeral fractures is clearly nonoperative". Unsurprisingly no ethics committee has approved this study. Radial nerve function appears not to have been assessed in either the pre or post operative stage. There was one "superficial" wound infection in the plating group. However the fact that this "superficial" infection required two further general anaesthetics to wash the wound out suggests that it may not have been as superficial as the author suggests. There was one delayed union in the plating group (5 months) and one non-union in the intramedullary nailing group. The author goes on to fabricate a functional scoring system with no validation or explanation that apparently shows no differences between the two groups. These points and the long period of recruitment imply that this study is most likely a case series where the surgeon was fairly random in his decision making rather than a prospective randomised controlled trial. This study in particular has systematically failed to exclude type 1 and type 2 error, is flawed from start to finish and has little to no external validity in determining a difference between compression plating and intramedullary nailing of the humerus.

In 2020 Akalin et al reported results of a randomised controlled trial including 63 patients comparing compression plating to locked intramedullary nailing. The study has no predefined primary outcome measure that it was powered for and randomisation was poorly described. The key findings included possible superiority in the UCLA for plating over nailing with improved visual analogue pain scores for nailing over plating. Given the large number of outcome measures, conflicting results and small sample size this study likely to be susceptible to systematic type 2 error. The study suggest no significant differences in terms of non union, nerve injury, deep infection, ASES score and DASH scores [19].

In 2009 Putti et al reported results of a randomised study comparing nailing to plating with a trial population of 34 patients. There is no power calculation, primary outcome measure or any description of the randomisation process. In the study's favour there was a long follow up period of 2 years for the ASES score. The study demonstrated no significant results in terms of ASES score, nerve injury or non union and again is likely to be systematically underpowered [20].

Discussion

There are known hurdles to overcome when creating a surgical randomised controlled trial. There are inherent problems in for example, ethical considerations, blinding, randomisation and logistics [15]. All studies examined in this review are to a lesser or greater extent flawed. No study had thorough well documented and explained randomisation and one was not randomised at all. Primary outcome measures and sample size calculations based on these measures have not been stated or performed in any study. Finally in many instances the conclusions drawn were not corroborated by the results at all.

Meta-Analysis is a proven technique that can extract meaningful information from an unclear evidence base [21]. Previous studies have tried to apply these techniques to the topic of diaphyseal humeral fractures [22-24]. Even the most rigorous application of validated tools such as the Oxnam and Guyatt instrument or the QUORUM statement can fail to identify serious flaws in the originating evidence base. Previous meta analyses on this topic score highly via both assessment systems. However one of the randomised controlled trials reviewed in this article and in other meta-analyses is not actually randomised. Also in using this article's data in a meta analysis one assumes that hackethal nailing is equivalent to a modern locked intramedullary device. These are two completely different techniques and it fails the test of face validity to suggest that the results from one procedure can be generalised to the other. Changulani's trial reported a deep infection rate of 20%. Attempting to generalise the results from this group of patients with a clearly anomalous rate of deep infection also fails the test of face validity. Given that half the evidence base on diaphyseal humeral fractures is flawed by a severe lack of homogeneity it follows that statistics performed on these studies will produce similarly limited results.

There are few points that can be determined from these studies. Both techniques of fixation appear to have similar outcome according to the ASES score. The study by McCormack et al performs a limited sample size calculation in the conclusion section and this suggests that a prohibitively large trial would be required to elucidate a difference in ASES score between the two methods. Or in other words that the difference in ASES scores may be so small that it is not worth investigating further. A number of patients in all studies had nail removal due to impingement in the shoulder and in study there appears to be an association with antegrade humeral nailing and decreased shoulder function post-operatively. This same study also suggests worse elbow function in the plating group.

With regard to post-operative complications, infection appears to more closely associated with dynamic compression plating with three out of four studies showing significantly more infections in the plating groups (the fourth study had no plate infections and one nail associated infection). Of 102 patients who received intramedullary fixation across all studies only two (1.9%) infections were recorded. However, nine (7.9%) of the 113 patients who received dynamic compression plating across all studies had post-operative deep infection. Iatrogenic radial (or posterior inter-osseous) nerve injury occurred more often in the plating group in two studies and more often in the nailing group in one. Overall, the numbers of iatrogenic nerve injuries were small and no study was adequately powered to explore this issue.

Non-union and delayed union which result in revision surgery are difficult topics to measure in randomised controlled trials. The most common methods of assessment involve radiographs and clinical assessment both of which are known to be unreliable making it difficult to compare between studies and to extend these comparisons to one's own practise. There were small numbers of non-unions requiring revision surgery in all groups.

Conclusion

At present the current evidence does not show a difference in post operative function between dynamic compression plating and intramedullary nailing of the humerus. Nerve injury is a hazard with both humeral plating and intramedullary nailing. With regard to the secondary outcomes it appears that by choosing one intervention over another there is some evidence that a surgeon is essentially choosing which type of complication the patient suffers. Antegrade humeral nailing appears to be associated with poorer shoulder function while dynamic compression plating may be associated with higher rates of deep infection. The current evidence base supports using either technique depending on which surgical complications are more palatable and on the familiarity and proficiency of the surgeons with an individual technique.

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