

■ ANNOTATION

Dorsally displaced fractures of the distal radius

A CRITICAL APPRAISAL OF THE DRAFFT (DISTAL RADIUS ACUTE FRACTURE FIXATION TRIAL) STUDY

S. Fullilove,
C. Gozzard

From Plymouth
Hospitals NHS Trust,
Plymouth, United
Kingdom

The results of the DRAFFT (distal radius acute fracture fixation trial) study, which compared volar plating with Kirschner (K-) wire fixation for dorsally displaced fractures of the distal radius, were published in August 2014. The use of K-wires to treat these fractures is now increasing, with a concomitant decline in the use of volar locking plates.

We provide a critical appraisal of the DRAFFT study and question whether surgeons have been unduly influenced by its headline conclusions.

Cite this article: *Bone Joint J* 2016;98-B:298–300.

Surgeons are influenced by many factors when deciding how to manage fractures of the distal radius: these include their own personal experience, evidence from the literature and trends in surgical implants and techniques. Despite many publications on the subject, it remains unclear which fractures of the distal radius need to be treated operatively, and the best surgical procedure to use. Three separate Cochrane reviews have reported on the management of this injury, but have been unable to resolve these issues.¹⁻³ Most studies conclude that larger, high quality trials are needed.

The DRAFFT study is a pragmatic, multi-centre, two-armed, parallel group, assessor-blind, randomised controlled trial which was undertaken in 18 United Kingdom trauma centres in 2011 and 2012: it aimed to provide answers to many of the questions surrounding the management of fractures of the distal radius.⁴ It compared the functional outcome of 461 adults with a dorsally displaced fracture of the distal radius, randomised to treatment either by closed reduction and Kirschner (K-) wire fixation, or open reduction and fixation with a volar locking plate. The primary outcome measure was the Patient-Rated Wrist Evaluation⁵ (PRWE), a patient-reported outcome measure (PROM) designed to assess the degree of wrist pain and disability. Secondary outcome measures included the incidence of complications, a measure of health-related quality of life (the EuroQol 5 Domain questionnaire,⁶ EQ5D), and a second PROM, the Disability of the Arm, Shoulder and Hand⁷ (DASH) score. The authors reported no clinically relevant or statistically significant difference in the PRWE or DASH scores, the EQ5D

score, or the rate of complications at three, six or 12 months.

The results of the DRAFFT study were published in the BMJ in August 2014, with the conclusion that ‘this trial found no difference in functional outcome in patients with dorsally displaced fractures of the distal radius treated with K-wires or volar locking plates. K-wire fixation, however, is cheaper and quicker to perform.’

A subsequent publication⁸ provided an economic evaluation which compared the cost-effectiveness of the two treatment arms of the study using the criteria of the United Kingdom National Institute for Health and Care Excellence. This study concluded that, when compared with K-wire fixation, volar locking plate fixation of a dorsally displaced distal radial fracture is not a cost-effective intervention, and suggested that current practice should change back to using wires to treat such fractures.

The results of the DRAFFT study have been widely publicised in the literature,^{4,8,9} on surgical society podcasts,¹⁰ and at national and international scientific meetings. As a result, there has already been a substantial move away from volar plate fixation of fractures of the distal radius.¹¹ Our own experience would suggest that since the publication of the DRAFFT study, even fractures which were not covered by the study (volar displaced fractures and fractures of both distal radius and distal ulna) are more likely to be treated with wires than they were previously.

While the authors of the DRAFFT study are to be congratulated for running such an impressive, multicentre, randomised trial, it is important that the results are interpreted in a

■ S. Fullilove, MBBS, MA (Oxon), FRCS (Orth), Consultant Orthopaedic Hand Surgeon, Orthopaedic Department

■ C. Gozzard, BSc MD FRCS (Orth), Consultant Orthopaedic Hand Surgeon, Orthopaedic Department Plymouth Hospitals NHS Trust, Derriford Road, Plymouth PL6 8DH, UK.

Correspondence should be sent to Miss S. M. Fullilove; e-mail: suefullilove@doctors.org.uk

©2016 The British Editorial Society of Bone & Joint Surgery
doi:10.1302/0301-620X.98B3.36771 \$2.00

Bone Joint J
2016;98-B:298–300.

balanced and objective way. Without a full examination of the details of the study and its limitations, there is a risk that both surgeons and healthcare commissioners may be unduly influenced to change their practice.

The DRAFFT study assessed 12 162 patients for eligibility. Many of the exclusion criteria were well-defined and objective. These included the exclusion of children; patients not requiring, or not fit for, surgery; patients unable to consent to, or comply with, the requirements of the study; patients with open fractures, and patients with fractures more than two weeks old. Removing these left 4760 patients.

The remaining exclusion criteria were more subjective and open to interpretation by the treating surgeon. They included an assessment of the fracture configuration and whether the fracture required an open surgical approach to achieve reduction. After application of these more subjective exclusion criteria, 4121 patients (87% of the total) were deemed unsuitable for inclusion in the trial, leaving only 639, of whom 178 declined to participate. Ultimately, only 461 patients were entered into the study, less than 4% of those screened.

The authors do not report how those excluded from the trial were treated. The main reasons given for exclusion were that the surgeon considered closed reduction of the fracture to be impossible (430 patients) or that the fracture configuration was of a more unstable type (with the fracture or fracture lines extending more than 3 cm proximal to the radiocarpal joint; this was reported for 3100 patients). Based on current surgical practice in the United Kingdom, it is our belief that the vast majority of these more unstable, difficult fractures, would have been plated.

The risk of selection bias in determining the final study group therefore represents a significant limitation when it comes to applying the findings of the DRAFFT study to the larger population of patients with a fracture of the distal radius. Evidence for the presence of selection bias is that a disproportionate number of patients in the study were over 50 years of age and female, compared with Western averages.¹² The screening process for eligibility removed proportionally more younger patients than older patients, and more men than women than could be accounted for on the basis of the objective exclusion criteria. Figures are not given but, almost certainly, most patients with multifragmentary intraarticular injuries would have been excluded, it being felt that they were more suited to open reduction and plate fixation. There was also a preponderance of low-energy injuries (82%), less than 2% of cases being the result of high-energy road traffic accidents.

Over two-thirds of the operations were carried out by surgeons who were not consultants. Of the operating surgeons, 13% had used a volar plate fewer than ten times, and another 13% had undertaken fewer than 20. The median number of operations per surgeon in the study was one (interquartile range one to two).

While the DRAFFT study concluded that there was no difference between wire fixation and volar plating in functional outcome at 12 months, all of the primary and secondary outcome measures were better for volar plating than for wire fixation at six and 12 months, albeit that none reached statistical significance. Several other prospective, randomised studies which have compared volar plating with K-wiring report some benefits associated with the use of volar plating. Karantana et al¹³ randomised 130 patients to each type of treatment and found that the volar plate group had a better anatomical reduction and better grip strength throughout the study (final follow-up one year), as well as better early functional recovery and return to driving. McFadyen et al¹⁴ randomised 56 patients with an extra-articular distal radial fracture and found better restoration of anatomy and better functional outcomes throughout follow-up, to six months. Marcheix et al¹⁵ randomised 103 patients over the age of 50 with dorsally displaced fractures and found better functional outcomes in the plated group up to final follow-up at 26 weeks.

In agreement with many other reports^{13,14} the DRAFFT study showed conclusively that restoration of anatomy as assessed by radiological outcome was significantly better after volar plating than after wiring.⁹ Patients were only followed-up for 12 months, so the potential long-term advantage of a better restoration of anatomy with volar plate fixation, such as a lower risk of post-traumatic arthritis, would not be captured by this study.

The economic analysis in the DRAFFT study showed that the locking plate was the more expensive implant and required a longer operation. However, wiring is associated with the additional costs of more follow-up outpatient visits for plaster changes and removal of wires: these costs are not accounted for, even in the subsequent detailed economic analysis of the DRAFFT trial.⁸ The economic analysis also found that the cost of lost productivity (days off work) is higher for patients treated with wires than for patients treated with plates (£394 *vs* £249) but that this difference is not statistically significant.

Beyond the comparison of lost working days, there is little in the analysis to reflect the additional costs of a delayed return to full function. Other authors have studied this in more detail. Goehre et al¹⁶ reported that, in 65-year-olds, patients treated with a volar locking plate returned to their normal activities of daily living by four weeks, whereas patients treated with wires took eight weeks to recover to this level of function. Espinosa Gutiérrez and Moreno Velázquez¹⁷ showed that for patients with a wrist fracture treated by volar plating, the medical costs were more than offset by the savings in societal costs resulting from a more rapid return to function. Shauver et al¹⁸ compared the costs and utilities for casting, wire fixation, external fixation, and plating of distal radial fractures in North America. They did not compare costs and utilities of plating to wiring but they found that the incremental cost-utility ratio for plating compared with casting was \$15 330 per quality-adjusted life

year (QALY) and that using the traditional benchmark of \$50 000/QALY for societal acceptability, plating would be considered worthwhile.

Complications in the two groups in the DRAFFT study were similar but no cases of complex regional pain syndrome were recorded. This is surprising in 461 adults with an acutely injured and operated forearm.

In summary, the DRAFFT study examined a very selective group of adult dorsally-displaced fractures of the distal radius: these represented less than 10% of the cohort treated surgically in the United Kingdom. The procedures were largely performed by surgeons who were not consultants, often in the early phases of their learning curve. Despite this suboptimal treatment, there was better restoration of the anatomy suggesting that the outcome may well have been better for volar plates had the follow-up been longer.

One of the acclaimed strengths of the DRAFFT study is that it was pragmatic; that is, it reflected current practice in the management of fractures of the distal radius across the United Kingdom. Such pragmatism in research may give a realistic view of the current situation, but allows no ambition for improvement. With other studies showing potential to improve our patients' outcomes, should we not be striving to refine our surgical training and skills in volar plating, treating it with the regulation and respect we now afford large joint arthroplasty, rather than relegating it to the most junior member of the surgical team or simply abandoning the procedure? The true merit of this technique can only be assessed if it is used by fully-trained surgeons in studies with sufficient follow-up. Only if these criteria are met, and there remain no demonstrable benefits to volar plating, will we be justified in moving on.

The correct conclusion to draw from the DRAFFT study is that for adults with a dorsally displaced fracture of the distal radius which needs surgical intervention, after excluding more than 85% of fractures which were not considered suitable for randomisation, and most of which will undergo plating, there are only marginal, if any, functional benefits of volar plating over wiring at one year. The authors encourage us to abandon plating in favour of wiring in this small group of patients for reasons of the health-care economy. Since this small cohort is weighted towards older females, whom we know generally tolerate malunion well¹⁹ the reality may actually be that neither of the treatment interventions has significant benefits, other than in terms of societal costs, over treating the patient in plaster.

We do not suggest that there is unequivocal evidence in favour of volar plating, but we do maintain that the DRAFFT study does not provide any good evidence against it.

Author contributions:

S. Fullilove: Literature review, data analysis, writing the annotation.
C. Gozzard: Literature review, data analysis, writing the annotation.

No benefits in any form have been received or will be received from a commercial party related directly or indirectly to the subject of this article.

This article was primary edited by A. D. Little and first proof edited by A. C. Ross

References

1. Handoll HH, Huntley JS, Madhok R. External fixation versus conservative treatment for distal radial fractures in adults. *Cochrane Database Syst Rev* 2007;18:CD006194.
2. Handoll HH, Vaghela MV, Madhok R. Percutaneous pinning for treating distal radial fractures in adults. *Cochrane Database Syst Rev* 2007;18:CD006080.
3. Handoll HH, Madhok R. Surgical interventions for treating distal radial fractures in adults. *Cochrane Database Syst Rev* 2009;8:CD003209. 2009.
4. Costa M, Achten J, Parsons NR, et al. Percutaneous fixation with Kirschner wires versus volar locking plate fixation in adults with dorsally displaced fracture of distal radius: randomised controlled trial. *BMJ* 2014;349:4807.
5. MacDermid JC, Turgeon T, Richards RS, Beadle M, Roth JH. Patient rating of wrist pain and disability: a reliable and valid measurement tool. *J Orthop Trauma* 1998;12:577–586.
6. Dolan P. Modeling valuations for EuroQol health states. *Med Care* 1997;35:1095–1108.
7. Hudak PL, Amadio PC, Bombardier C. Development of an upper extremity outcome measure: the DASH (disabilities of the arm, shoulder and hand) [corrected]. The Upper Extremity Collaborative Group (UECG). *Am J Ind Med* 1996;29:602–608.
8. Tubeuf S, Yu G, Achten J, et al. Cost effectiveness of treatment with percutaneous Kirschner wires versus volar locking plate for adult patients with a displaced fracture of the distal radius. *Bone Joint J* 2015;97-B:1082–1089.
9. Costa ML, Achten J2, Plant C, et al. UK DRAFFT: a randomised controlled trial of percutaneous fixation with Kirschner wires versus volar locking-plate fixation in the treatment of adult patients with a dorsally displaced fracture of the distal radius. *Health Technol Assess* 2015;19:1–124, v-vi.
10. No authors listed. British Orthopaedic Association. <http://www.boa.ac.uk/orthopodcast/episode-4-drafft-trial/> (date last accessed 26 November 2015).
11. No authors listed. Health & Social Care Information Centre, HES data. <http://www.hscic.gov.uk> (date last accessed 26 November 2015).
12. Nellans KW, Kowalski E, Chung KC. The epidemiology of distal radius fractures. *Hand Clin* 2012;28:113–125.
13. Karantana A, Downing ND, Forward DP, et al. Surgical treatment of distal radial fractures with a volar locking plate versus conventional percutaneous methods: a randomized controlled trial. *J Bone Joint Surg [Am]* 2013;95-A:1737–1744.
14. McFadyen I, Field J, McCann P, et al. Should unstable extra-articular distal radial fractures be treated with fixed-angle volar-locked plates or percutaneous Kirschner wires? A prospective randomised controlled trial. *Injury* 2011;42:162–166.
15. Marcheix PS, Dotzis A, Benkő PE, et al. Extension fractures of the distal radius in patients older than 50: a prospective randomized study comparing fixation using mixed pins or a palmar fixed-angle plate. *J Hand Surg Eur Vol* 2010;35:646–651.
16. Goehre F, Otto W, Schwan S, et al. Comparison of palmar fixed-angle plate fixation with K-wire fixation of distal radius fractures (AO A2, A3, C1) in elderly patients. *J Hand Surg Eur Vol* 2014;39:249–257.
17. Espinosa Gutiérrez A, Moreno Velázquez A. Costo-beneficio de diferentes tratamientos en pacientes con fractura distal de radio. *Acta Ortop Mex* 2010;24:61–65. (Article in Spanish).
18. Shauver MJ, Clapham PJ, Chung KC. An economic analysis of outcomes and complications of treating distal radius fractures in the elderly. *J Hand Surg Am* 2011;36:1912–8.e1, 3.
19. Gehrmann SV, Windolf J, Kaufmann RA. Distal radius fracture management in elderly patients: a literature review. *J Hand Surg Am* 2008;33:421–429.