Do large pragmatic randomised trials change clinical practice?

ASSESSING THE IMPACT OF THE DISTAL RADIUS ACUTE FRACTURE FIXATION TRIAL (DRAFFT)

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Aims
Our aim, using English Hospital Episode Statistics data before during and after the Distal Radius Acute Fracture Fixation Trial (DRAFFT), was to assess whether the results of the trial affected clinical practice.

Patients and Methods
Data were grouped into six month intervals from July 2005 to December 2014. All patient episodes in the National Health Service involving emergency surgery for an isolated distal radial fracture were included.

Results
Clinical practice in England had not changed in the five years before DRAFFT: 75% of patients were treated with plate fixation versus 12% with Kirschner (K)-wires. After the publication of the trial, the proportion of patients having K-wire fixation rose to 42% with a concurrent fall in the proportion having fixation with a plate to 48%. The proportion of ‘other’ procedures stayed the same.

Take home message. It appears that surgeons in the United Kingdom do change their practice in response to large, pragmatic, multicentre clinical trials in musculoskeletal trauma.

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The purpose of these large trials is to reflect practice across the entirety of a healthcare system, thereby producing results that are externally valid or ‘generalisable’ and which, therefore, can be applied throughout that health system. The explicit intention is to change practice and policy on a large scale. But do surgeons take any notice of these results? Does practice actually change after the publication of large multicentre trials?

We used Hospital Episode Statistics (HES) data from England to track the change in clinical practice before, during and after the delivery of one such trial: the United Kingdom DRAFFT.

Patients and Methods
The DRAFFT compared percutaneous Kirschner (K)-wire) fixation with volar locking-plate fixation for the treatment of adult patients with a dorsally displaced fracture of the distal radius. Patients with intra-articular fractures in which the joint surface could not be reduced by closed means were excluded. The trial recruited 461 patients operated on by > 200 surgeons at 18 trauma centres in the United Kingdom. Contrary to the existing literature, and against the dominant use of locking-plate fixation, the trial showed no difference in functional outcome between K-wires and locking-plates.

An embedded health economic evaluation, involving both an NHS and personal societal perspective, showed that the difference in costs was almost entirely driven by the choice of implant. Since volar plate fixation is considerably more expensive for no benefit in health-related quality of life, K-wire fixation must be recommended on cost-effectiveness grounds.
We reviewed English HES data (collected on all NHS patients) between July 2005 and January 2015. Data were grouped into six-monthly intervals. All episodes involving emergency surgery for an isolated fracture of the wrist were included (International Classification of Diseases: ICD-10 codes S525 - fracture of lower end of radius - and S526 - fracture of both lower end of radius and ulna). Percutaneous K-wire fixation was coded as: ‘W242 Closed reduction of fracture of long bone & rigid internal fixation and Z705 Lower end of radius’. Internal fixation with a plate was coded as: ‘W201 Primary open reduction of fracture of long bone and extramedullary fixation using plate, and Z705 Lower end radius’. We grouped any other surgical interventions (including manipulation under anaesthesia and cast, or external fixation) under the heading: ‘other’.

Since it was possible that any change in clinical practice was confined to the centres which took part in the trial, we performed a secondary analysis to compare the type of fixation over time in the DRAFFT centres versus all other centres in England. We also looked at the variation in the type of fixation by individual hospital.

An issue, which was raised both during and after DRAFFT was the equipoise, or lack thereof, concerning specialist hand trauma surgeons. In order to determine if any change in clinical practice was confined to ‘general’ trauma units, we undertook a further analysis to compare the type of surgery over time in specialist hand surgery units compared with all centres in England. In the absence of a definitive list of hand surgery units, we used those centres which host United Kingdom Advanced Training Fellowships in Hand Surgery as a surrogate for ‘specialist hand units’.

Since the number of cases included in this ‘big data’ set is large, we chose to use descriptive statistics and graphical summaries alone, rather than inference statistics.

**Results**

In the period between 2005 and 2010, before the start of DRAFFT, the proportion of distal radial fractures treated by K-wire fixation *versus* internal fixation with plates did not change across all centres in England (Fig. 1). Internal fixation with plates was the most popular form of fixation accounting for about 75% of the total. In contrast, K-wire fixation was performed in only 12% of cases. Other procedures were performed in the remaining 13%.

This trend changed dramatically during the course of the trial and continued to change after first the presentation of the results of DRAFFT, and then the publication in peer-review journals. In the second half of 2014 the proportion of patients having K-wire fixation had risen to 42% with a concurrent fall in the proportion having fixation with a plate to 48%. The proportion of ‘other’ procedures stayed the same. Figure 2 shows the actual number of procedures performed during this period.

Figure 3 shows the trend in fixation over time in the DRAFFT centres *versus* all centres in the United Kingdom. The change in practice was of the same magnitude in all centres, and occurred at the same time-points.

Figure 4 shows the trend in fixation in ‘specialist hand units’ *versus* all centres in the United Kingdom. In the hand units, there was no change in clinical practice during the period when the trial was taking place. However, there was a change in practice after the initial results were presented and this continued after the publication of the full results. The proportion of patients treated with fixation using a
plate versus K-wire fixation was still lower in the ‘specialist hand units’, at least until 2015.

There is marked variation in both the number of operations and the type of fixation used, with some units avoiding the use of K-wires during the entire period. The shift in type of fixation has certainly not been universal.

**Discussion**

There has been a clear change in the surgical treatment of fractures of the distal radius in England between 2005 and 2015.

Before the DRAFFT, the great majority of patients were treated by internal fixation using a plate. This practice has also been shown in other countries. After the DRAFFT, and in keeping with the results of the trial, there was a large shift in practice towards K-wire fixation.

This change occurred over the same period and to the same extent in those centres which took part in the trial compared with all centres in England. This suggests that large, multicentre pragmatic clinical trials can indeed change practice throughout the healthcare system which they are designed to reflect.

Interestingly, the trend towards increased use of K-wire fixation appears to have begun even before the results of the trial were known. This could easily be explained in the DRAFFT centres by the fact that in those units half of the patients with a dorsally displaced fracture of the distal radius were randomised to volar locking-plates and half to K-wire fixation. However, this does not explain the same trend, over the same period, in the other centres. One possible explanation is that DRAFFT, which was funded by the NHS via the National Institute for Health Research, raised the profile of this question and confirmed the clinical acceptability of both treatments. It seems that simply raising the research question at a national level may provide surgeons with the impetus to re-consider their practice.

Given that the proportion of patients having plate versus K-wire fixation was entirely consistent for the five years before the trial, it seems unlikely that this change occurred by chance.

‘Specialist hand surgery centres’ appeared to wait until the results of the trial were presented and were then slower to change practice compared with all centres in England. However, even in specialist units, there has been a substantial change in practice towards K-wire fixation since the results of the trial were known.

Although the overall change in clinical practice across all NHS centres is considerable, the data for individual hospitals show that not all centres have adopted the results of the trial. Some centres do not appear to have changed practice. This may change over the coming years as the results are disseminated further or as a result of changes in commissioning guidelines.

Not all of the change in the choice of fixation for distal radial fractures can be attributed to the DRAFFT. In this time of austerity, there is an increasing focus upon cost-saving and
efficiency measures in the English NHS. Since K-wire fixation is both cheaper and takes less time to perform, surgeons may have already started to look at a change in practice. Also, other evidence which threw into doubt the efficacy of volar locking plate fixation was published in the same time-frame. Most notably, Karantana et al. reported a similar result in a study performed in a single specialist hand surgery unit recording no difference in functional outcome after three months. This may have had a particular influence upon surgeons in the ‘specialist hand surgery’ centres.

Our study has limitations related to the use of HES. First, the HES data does not separate out volar-locking plates from all other forms of plate fixation. Therefore, the ‘internal fixation with plate’ code also included non-locking and dorsal plate fixation. Similarly, the code ‘lower end of radius’, is not specific for ‘dorsally displaced’ fractures. However, dorsally displaced fractures are by far the most common form of fracture. Furthermore, the inclusion of other forms of plate fixation does not affect the overall picture which shows a clear shift towards K-wire fixation. In fact the inclusion of other forms of plate fixation, for other indications, would dilute the size of the change specific to the management of dorsally displaced fractures, making the scale of the change in practice even more remarkable. Finally, the change in practice noted here, applies only to England. Although the effects of locking-plate versus K-wire fixation are unlikely to be inherently different in other healthcare systems, the response to clinical trials in other countries may well be different.

In conclusion, it appears that surgeons in England are willing to change clinical practice in response to large, multi-centre clinical trials in musculoskeletal trauma. Further studies should examine the influence of other trials in trauma and other areas of orthopaedic surgery. The DRAFFT cost the taxpayer about £1.5 million. However, given the increasing number of operations being performed in England each year for fractures of the distal radius, the 25% shift in clinical practice from locking-plates to K-wire fixation has already saved the health service about £1.6 million in implant costs alone. This saving is likely to continue year on year. Of course, it is important that we continue to monitor both the trends in clinical practice and, most importantly, the associated outcome of patients with a fracture of the distal radius in the long term.

Supplementary material

A graph showing distribution of operations undertaken for fractures of the distal radius performed in England between July 2014 and January 2015, by Trust, is available alongside the online version of this article at www.bjj.boneandjoint.org.uk

References


