Reviewer's report

Title: Randomised prospective comparative multi-center trial of children with angulated fractures of the forearm comparing intervention and conservative treatment (AFIC)

Version: 1 Date: 20 April 2015

Reviewer: Daniel Christopher Perry

Reviewer's report:

SUMMARY

This is a non-inferiority RCT, which broadly seeks to determine if fractures of the distal radius in children need reducing within defined limits. The premise therefore is to perform a trial to test the remodeling capacity of the wrist.

MAJOR REVISIONS

In my experience, perhaps the primary reason that a greater reliance is not made of remodeling, is the dissatisfaction of parents with this approach – this therefore needs to be measured and recorded closely. The need for a wire in the control group also seems to limit the generalisability of the approach – as the vast majority of cases (certainly within the UK and Canada where I have trained) would be managed without wires.

This trial will therefore be of interest to a wide readership to demonstrate the power of remodeling – although in its current form I am not terribly sure that the results of the trial would be seen as particularly applicable to practice (which ever way it reports).

My main concern is the Cooney Score – for which I can find little detail – either within the text, or more generally in the literature. Is this the same as the mayoc wrist score? Is there any evidence of the use of this in children? Is it validated in children? Is there evidence of the use of this in 7 year old children with distal radius fractures? What is the range expected within this population – and how were these arrived at? How were the values used to derive the sample size that has been arrived at? The Cooney score that I can access online refers to employment status….I’m not sure of the relevance to 7 year olds. Likewise, it includes grip strength – can 7-year olds comply with this reliably?

MORE MINOR COMMENTS:

HEADING: Treatment. Group 1 – The brackets need altering, as this currently does not read correctly.

Treatment. Group 2 – The intervention therefore MUST have wires – correct? I think that this will severely limit the application of the study in the longterm – simple MUA and plaster is surely the most common current intervention. If you are trying to test the premise of remodeling, your treatment group should, in my
opinion, been more pragmatic – i.e. whatever the surgeon wants to do vs. do nothing.

If the child is discharged on the same day as surgery, do they become ineligible for entry to the trial – as you allude to them requiring admission for one or two days post-op?

What is the parental satisfaction measure? In my practice, one of the primary reason to operate is that parents aren’t happy with the treatment if the arm appears angulated – and reassurance that all will be well in two years (probably) often fails to offer reassurance. This will be a major barrier to recruitment, and should be measured.

“After seven days a clinical control and an X-ray control is done to see if there is a secondary dislocation” – A secondary dislocation of what – nothing was dislocated in the first place?!?

**Level of interest:** An article of limited interest

**Quality of written English:** Acceptable

**Statistical review:** Yes, and I have assessed the statistics in my report.

**Declaration of competing interests:**

None