Author's response to reviews

Title:"Angulated fractures of the distal forearm in children, comparing intervention and conservative treatment: study protocol for a randomized controlled trial".

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Author's response to reviews: see over
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.

Comment: To measure the satisfaction and acceptance of parents we have raised a standard questionnaire (ZUF-8) with questions about satisfaction of treatment, the procedures and the information given by a doctor. You can find this information in the manuscript on page

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.

Unfortunately the vast majority of children in Germany, Austria and Switzerland is treated by non pediatric surgeons and therefore a wire or even a plate is used in a lot of cases. To demonstrate the power of remodeling this trial is urgently needed, that includes conservative and operative treatment, so not only the easy cases are treated conservatively.

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).

The authors included the German Society of Pediatric surgery and the German Society for Trauma Surgery in planning and conduct of this trial. This trial was selected from both societies because of its high priority. These societies, the surgical trial network and the German Surgical Society are continuously informed about the trial and its development. These efforts should ensure that the results of this trial will have broad acceptance under German surgeons.

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 mayo 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?
Comment: The Cooney Score is valid for children and adults and has nothing to do with the Mayo wrist score. The range expected is the same as in adults and it is always a comparison to the other wrist. And sure a 7 year old can show grip strength as every other person.

This trial with its protocol was reviewed by an international committee, revised in some details and finally accepted. It is funded by the DFG with 1.9 million Euros. The Cooney score was successfully used in the pilot study conducted at 5 German institutions in Schleswig-Holstein (SH-trial) including 380 patients with pediatric distal forearm fractures.

The Cooney score includes pain (25 points), function (25 points), range of motion (25 points) and strength of grip (25 points). Results: Excellent: 90-100 points, Good: 80-90 points, Satisfactory: 70-80 points, Fair: more than 65 points, Poor: less than 65 points.

Power calculation
The rates of patients reaching a Cooney score of $\geq 90$ are expected to be 95% in both treatment groups. A non-inferiority bound of -5% referring to the absolute difference of success rates (Cooney score $\geq 90$) was chosen.

We included the following parts in the publication:

Primary endpoint is the validated Cooney-Score. This score considers subjective (pain, strength, activity before and after trauma) as well as objective (range of motion) parameters and is validated in several trials, also including children and adolescents. As it is assumed that differences between the treatment groups with respect to the Cooney Scores fully disappear until (and not clearly before) two years after surgery/immobilization, an earlier time was not chosen for primary analysis.

Cooney Scores will be calculated according to the standard approach of aggregating the single items (Cooney et al 1979, Stoffelen et Broos 1998, Toh et al 2003, Huckstadt et al 2007).

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.

Comment:The trial is funded by the DFG, the international reviewer accepted just the two arms: Doing nothing and K-Wire. Reduction without K-Wire was not accepted.

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?

Comment: The child becomes not ineligible for entry to the trial but it is common in Germany that children stay one or two nights in hospital after this surgery. Still it is not a must.

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.
Comment: As we mentioned above the satisfaction is measured by a questionnaire. We are aware of this fact and try to lower this barrier with any possible efforts. “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?!
Comment: With secondary dislocation we refer to a dislocation at all. Maybe this is a translation issue, as we call it secondary dislocation if there was none in the first place but there is one in the x-ray-control.
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