

Splinting after contracture release for Dupuytren's disease (SCoRD) – a pragmatic, multi-centre, randomized controlled trial

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### Hypothesis

The use of a static night splint in addition to post-operative hand therapy after fasciectomy or dermofasciectomy will result in better self-reported hand function, improved finger range of motion and higher patient satisfaction at one year after surgery.

### Methods

The evidence for post-operative splinting is equivocal and of poor quality reporting both positive and negative findings. A large, multi-centre, pragmatic, randomised controlled trial was designed with Research and Ethics committee approval. Patients presenting to a surgeon with a Dupuytren's contracture affecting one or more digits of the hand and requiring fasciectomy or dermofasciectomy were eligible and invited to take part in the study.

Patients were randomised to one of 2 groups after undergoing surgery: i) splint group receiving a static night splint at approximately 10 days after surgery to be worn for 6 months as well as hand therapy; or ii). non-splint group receiving hand therapy only. Patients in the splint group were asked to complete weekly splint diaries to monitor adherence. The primary outcome was self-reported hand function and disability assessed through DASH (Disabilities of Arm, Shoulder and Hand) questionnaire. Secondary outcome measures were total range of finger movement and patient satisfaction. Data was collected prior to surgery, at 3 months, 6 months and 1 year after release. In order to detect a minimally clinically important difference of 15 points on the DASH with a power of 90% a minimum of 51 patients were required in each group. The main analysis will use an intention-to-treat approach

### Results

218 patients were invited to join the study of whom 172 (79%) consented. 18 patients were subsequently excluded due to a variety of reasons e.g. death/delayed or cancelled surgery. A total of 154 patients with a mean age of 67 years (range 36 to 89) were randomised to a splint (77 patients) or non splint (77 patients) group. 78% were male and the most common contracture involved the little then ring finger. 76% of operations were for single digit disease. Five patients have been lost to follow up and final data collection will be completed in January 2010 with the full results available in April 2010.

### Summary

This definitive pragmatic randomised controlled trial will provide much needed high quality evidence regarding the clinical effectiveness of night-time splinting for patients undergoing fasciectomy/ dermofasciectomy