

Functional Bracing Leading to Secondary Surgery in Closed Humeral Shaft Fractures – A Comparison of Randomized and Nonrandomized Patients of the FISH Trial

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INTRODUCTION: Previous evidence from randomized controlled trials (RCT) suggests that up to one third of nonsurgically treated humeral shaft fracture patients may need delayed surgery due to healing problems and the results of those patients remain inferior up to 2 years after injury. Here, we compare the data from our RCT with an eligible cohort of patients who declined randomization (non-RCT) to validate the findings of the RCT and investigate if patient's treatment preference affects the outcomes.

METHODS:

The Finnish Shaft of the Humerus (FISH) trial compared open reduction and internal plate fixation (ORIF) with functional bracing in adult patients with displaced, closed humeral shaft fractures. A total of 321 patients with this injury were evaluated at 2 university hospital trauma centers in Finland between November 2012 and January 2018. We excluded 181 patients due to the fracture extending outside the predefined fracture zone (n=91), cognitive disabilities or multimorbidity (n=60), open fracture or polytrauma (n=16), and other reasons (n=24). Of the remaining 140 patients, 82 patients were randomized to either ORIF or functional bracing. Of the 58 patients declining randomization, 42 consented to participate a non-RCT cohort where the patient was able to choose the treatment method between ORIF and functional bracing.

In this study, we compared the previously reported outcomes of the RCT with the results of the non-RCT cohort. The primary outcome of this exploratory analysis was the Disabilities of Arm, Shoulder, and Hand (DASH) score. The secondary outcomes included Constant-Murley score and proportion of patients who were satisfied with the upper extremity (7-item Likert scale, those scoring 1 or 2 were considered satisfied). The outcomes were recorded at baseline, 6 weeks, 3, 6, 12 months, and 2 years. Patients of the RCT and non-RCT were analyzed separately in 3 groups: 1) initial surgery, 2) successful functional bracing, and 3) late surgery due to fracture healing problem with functional bracing. We used multilevel mixed effects linear regression to compare the treatment effect between 3 groups.

RESULTS:

In the RCT, 38 patients had initial surgery and of the 44 patients randomized to functional bracing, 30 (68%) healed successfully and 14 (32%) underwent late surgery (within 14 months) due to healing problem. In the non-RCT cohort, 9 patients preferred initial surgery (2 had to undergo secondary surgery due to nonunion). Of the 33 patients preferring functional bracing, 26 (79%) healed successfully and 7 (21%) underwent late surgery (within 12 months after the injury). The DASH scores of the RCT and non-RCT are presented in Tables 1 and 2 and in Figure 1. The secondary outcomes are given in Figures 2 and 3.

DISCUSSION AND CONCLUSION:

The results of the non-RCT are in line with our previous RCT findings. The patients of the non-RCT cohort with late surgery due to healing problems after functional bracing had inferior outcomes up to 2 years after injury. The patients' treatment preference at the time of injury did not protect from the inferior results of the late surgery we found in the RCT earlier. These prospects should be included in the shared decision-making process when contemplating the best treatment method for adult patients with closed humeral shaft fractures.

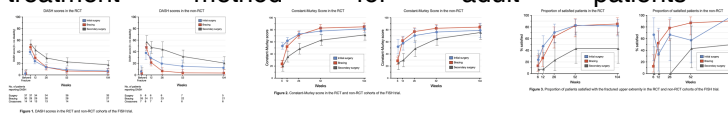


Table 1. DASH scores of the RCT.

Time	Initial surgery	Successful functional bracing	Late surgery
Baseline	32.5	32.5	32.5
6 weeks	28.5	28.5	28.5
3 months	24.5	24.5	24.5
6 months	21.5	21.5	21.5
12 months	18.5	18.5	18.5
2 years	15.5	15.5	15.5

Table 2. DASH scores of the non-RCT.

Time	Initial surgery	Successful functional bracing	Late surgery
Baseline	32.5	32.5	32.5
6 weeks	28.5	28.5	28.5
3 months	24.5	24.5	24.5
6 months	21.5	21.5	21.5
12 months	18.5	18.5	18.5
2 years	15.5	15.5	15.5