

Functional recovery after treatment of extra-articular distal radius fractures in the elderly using the IlluminOss® System (IO-Wrist); a multicenter prospective observational study.

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Abstract

BACKGROUND:

Approximately 17 % of all fractures involve the distal radius. Two-thirds require reduction due to displacement. High redislocation rates and functional disability remain a significant problem after non-operative treatment, with up to 30 % of patients suffering long-term functional restrictions. Whether operative correction is superior to non-operative treatment with respect to functional outcome has not unequivocally been confirmed. The IlluminOss® System was introduced in 2009 as a novel, patient-specific, and minimally invasive intramedullary fracture fixation. This minimally invasive technique has a much lower risk of iatrogenic soft tissue complications. Because IlluminOss® allows for early mobilization, it may theoretically lead to earlier functional recovery and ADL independence than non-operative immobilization. The main aim of this study is to examine outcome in elderly patients who sustained a unilateral, displaced, extra-articular distal radius fracture that was treated with IlluminOss®.

METHODS/DESIGN:

The design of the study will be a multicenter, prospective, observational study (case series). The study population comprises elderly (60 years or older; independent in activities of daily living) with a unilateral, displaced, extra-articular distal radius fracture (AO/OTA type 23-A2 and A3) that after successful closed reduction was fixed within 2 weeks after the injury with IlluminOss®. Critical elements of treatment will be registered, and outcome will be monitored until 1 year after surgery. The Disabilities of the Arm, Shoulder, and Hand score will serve as primary outcome measure. The Patient-Rated Wrist Evaluation score, level of pain, health-related quality of life (Short Form-36 and EuroQoL-5D), time to ADL independence, time to activities/work resumption, range of motion of the wrist, radiological outcome, and complications are secondary outcome measures. Health care consumption and lost productivity will be used for a cost analysis. The cost analysis will be performed from a societal perspective. Descriptive data will be reported.

DISCUSSION:

The results of this study will provide evidence on the effectiveness of operative treatment of patients who sustained an extra-articular distal radius fracture with the IlluminOss® System, using clinical, patient-reported, and societal outcomes.

TRIAL REGISTRATION:

The study is registered at the Netherlands Trial Register (NTR5457 ; 29-sep-2015).

KEYWORDS:

Costs; Distal radius fracture; Elderly; Extra-articular; Fracture; Intramedullary; Outcome

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