

## **Weight Bearing or Non-Weight Bearing After Surgical Treatment of Ankle Fractures: The WOW! Study. A Multicenter Randomized Controlled Trial**

*Diederik Pieter Johan Smeeing, MD<sup>1</sup>; Roderick Marijn Houwert<sup>2</sup>; Jan P. Briet<sup>3</sup>; Koen Lansink, MD, PhD<sup>4</sup>; Loek Leenen, MD, PhD<sup>2</sup>; Peer Van der Zwaal<sup>5</sup>; Stephan W.A.M. Van Zuthpen<sup>6</sup>; Bas Twigt<sup>7</sup>; Jochem M. Hoogendoorn<sup>5</sup>; Egbert Verleisdonk<sup>3</sup>; Michiel J.M. Segers; Falco Hietbrink<sup>2</sup>*

<sup>1</sup>St. Antoniusziekenhuis, Utrecht, Utrecht, NETHERLANDS

<sup>2</sup>UMC, Utrecht, NETHERLANDS

<sup>3</sup>Diakonessenhuis, Utrecht, NETHERLANDS

<sup>4</sup>Elisabeth-Tweesteden Hospital, Tilburg, Noord Brabant, NETHERLANDS

<sup>5</sup>MCH, The Hague, NETHERLANDS

<sup>6</sup>ETZ, Tilburg, NETHERLANDS

<sup>7</sup>BovenIJ, Amsterdam, NETHERLANDS

**Purpose:** The aim of this trial was to provide evidence for the optimal postoperative care regimen after surgical repair, solely for Lauge Hansen supination exorotation stage 2, 3, and 4 ankle fractures. The null hypothesis was that ankle-specific disability assessed with the Olerud Molander Ankle Score (OMAS) is less for unprotected weight bearing when compared to protected weight bearing and unprotected non-weight bearing.

**Methods:** A multicenter, randomized controlled trial was performed in 4 different level hospitals in the Netherlands. Patients, ranging from 18 to 65 years of age, with a supination exorotation type 2, 3, or 4 ankle fracture were included. All fractures had an articular incongruity of >2 mm on the radiograph. Before inclusion of a patient the following criteria had to be met in the following order: (1) the patient's informed consent had to be obtained, (2) the fracture was classified by at least 3 out of 6 trauma surgeons in the expert panel as a supination exorotation ankle fracture, and (3) the operating surgeon had to agree with the inclusion of the patient after testing the syndesmosis during the operation followed by a successful operative treatment. Patients were randomized using a computerized random number generator. The 3 postoperative care regimens were: (1) unprotected non-weight bearing, (2) protected weight bearing, or (3) unprotected weight bearing. The primary end point of the study was the OMAS, which was filled out at 6 weeks, 12 weeks, 6 months, and 1 year after randomization.

**Results:** A total of 115 consecutive patients with a mean age of 39 ( $\pm 14$ ) years were included. Randomization took care of an even distribution of baseline characteristics between the 3 groups. The OMAS showed significant better results in the unprotected weight-bearing group after 6 weeks. All other follow-up moments did not show significant different between the groups. There were no significant differences in the rate of complications between groups.

**Conclusion:** Unprotected weight bearing and mobilization as tolerated is a safe postoperative care regimen in adult patients without comorbidities with a supination exorotation type 2, 3, or 4 ankle fracture. Unprotected weight bearing and mobilization as tolerated shows a better functional outcome in the short term.

The FDA has stated that it is the responsibility of the physician to determine the FDA clearance status of each drug or medical device he or she wishes to use in clinical practice.