

# Early Weightbearing and Range of Motion Versus Non-Weightbearing and Immobilization After Open Reduction and Internal Fixation of Unstable Ankle Fractures: A Randomized Controlled Trial

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**Objectives:** The aim of this study was to compare early weightbearing and range of motion (ROM) to nonweightbearing and immobilization in a cast after surgical fixation of unstable ankle fractures.

**Design:** Multicentre randomized controlled trial.

**Setting:** Two-level one trauma centers.

**Patients:** One hundred ten patients who underwent open reduction and internal fixation of an unstable ankle fracture were recruited and randomized.

**Intervention:** One of 2 rehabilitation protocols: (1) Early weightbearing (weightbearing and ROM at 2 weeks, Early WB) or (2) Late weightbearing (nonweightbearing and cast immobilization for 6 weeks, Late WB).

**Main Outcome Measurements:** The primary outcome measure was time to return to work (RTW). Secondary outcome measures

included: ankle ROM, SF-36 health outcome scores, Olerud/Molander ankle function score, and rates of complications.

**Results:** There was no difference in RTW. At 6 weeks post-operatively, patients in the Early WB group had significantly improved ankle ROM (41 vs. 29,  $P < 0.0001$ ); Olerud/Molander ankle function scores (45 vs. 32,  $P = 0.0007$ ), and SF-36 scores on both the physical (51 vs. 42,  $P = 0.008$ ) and mental (66 vs. 54,  $P = 0.0008$ ) components. There were no differences with regard to wound complications or infections and no cases of fixation failure or loss of reduction. Patients in the Late WB group had higher rates of planned/performed hardware removal due to plate irritation (19% vs. 2%,  $P = 0.005$ ).

**Conclusions:** Given the convenience for the patient, early improved functional outcome, and the lack of an increased complication rate, we recommend early postoperative weightbearing and ROM in patients with surgically treated ankle fractures.

**Key Words:** ankle fracture, weightbearing, weight bearing, weight-bearing, ROM, mobilization, RCT, randomized controlled trial

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**Level of Evidence:** Therapeutic Level I. See Instructions for Authors for a complete description of levels of evidence.

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## INTRODUCTION

Ankle fractures are the third most common fracture in North America, accounting for 13%, or 2.1 million, fractures per year.<sup>1</sup> Unstable ankle fractures include fracture dislocations, isolated malleolar fractures with talar shift, and bimalleolar and trimalleolar ankle fractures.<sup>2</sup> Although indications for surgical intervention for acute ankle fracture are relatively well-defined, the postoperative protocol with respect to time to full weightbearing and initiation of ankle range of motion remains controversial.<sup>2–4</sup> The standard of care has generally been non-weightbearing and cast immobilization for 6 weeks after the surgical repair of unstable ankle fractures. However, a more contemporary approach utilizes functional bracing and allows for early weightbearing and range of motion. Early weightbearing and mobilization is thought to expedite rehabilitation, result in earlier return to function,<sup>5</sup> and prevent complications of joint immobilization such as stiffness and muscle atrophy.<sup>6</sup> However, a potential risk of this accelerated protocol is that early weightbearing and/or range of motion may increase the risk of fracture displacement, fixation failure, and/or wound complications.<sup>7</sup>

Prior randomized controlled trials (RCTs) have compared early postoperative weightbearing and/or mobilization to non-weightbearing and/or immobilization.<sup>5–16</sup> The results of these studies have been contradictory, with some demonstrating improved outcomes,<sup>8–11,14,15</sup> some no difference in outcomes,<sup>7,13</sup> whereas others demonstrate an increase in complications.<sup>7</sup> Weaknesses of these prior studies include small sample sizes, poorly-defined inclusion and exclusion criteria with heterogeneity of fracture patterns, and usage of outdated surgical techniques. Many studies have included a combination of unimalleolar, bimalleolar, and trimalleolar fractures with or without syndesmotic injury in the same analysis.<sup>5,7–13,15,17</sup> This is problematic as the standard of postoperative care for an isolated displaced lateral malleolar fracture is quite different than that of a trimalleolar fracture with a syndesmotic disruption. Heterogeneity in fracture fixation technique also exists among studies. Some studies utilized unstable osteosynthesis techniques (cerclage wire, staples, pins)<sup>10,11,14</sup> rather than stable osteosynthesis techniques (lag screws and plates), which is the current standard of care in North America.

The implications of a modern, comprehensive randomized controlled trial are far-reaching. Safe, early weightbearing could not only facilitate rehabilitation, but also hasten return to work, minimize “downtime,” and thus significantly decrease the cost of this common injury to the healthcare system and society. To our knowledge, no large multicentered randomized controlled trial has prospectively compared traditional postoperative nonweightbearing and cast immobilization with early full weightbearing and mobilization for unstable ankle fractures treated with modern standard surgical techniques. The aim of this study was to compare early weightbearing and mobilization to nonweightbearing and immobilization in a cast. Our hypothesis was that early

weightbearing and mobilization would allow earlier return to work and improve early functional outcomes without increasing the risk of complications. The null hypothesis was that there were no differences regarding return to work, functional outcome, or adverse events between the 2 groups.

## PATIENTS AND METHODS

This study is a pragmatic multicentered randomized control trial, which took place at 2 Level One Trauma Centers (Sunnybrook Health Sciences Centre and St. Michael’s Hospital) in Toronto, Canada, from 2010 to 2014. Research ethics board approval was acquired at both sites. Funding was obtained via research grants from several sources: the Canadian Orthopaedic Association (COA); the Orthopaedic Trauma Association’s (OTA) Resident Research Grant; the Canadian Orthopaedic Trauma Association’s (COTS) Young Investigator Award; and a Physician Services Incorporation (PSI) Resident Research Grant. There are no conflict of interests for any of the authors with regard to this study. This manuscript was prepared by use of the CONSORT statement.<sup>18</sup>

### Sample Size Calculation

The primary outcome measure was the time to return to work. Using an effect size of approximately 11 days and a variance of 20 days (similar to previous studies<sup>5,17</sup>), it was calculated that 53 patients per group would be needed to obtain 80% power with an alpha level of 0.05. Accounting for a 4% drop out rate, we planned to recruit 55 patients per group, for a total of 110 patients in the study.

### Inclusion Criteria

Acute unstable unilateral ankle fracture that was considered by the attending staff surgeon to require surgical fixation, including:

1. Isolated lateral malleolus fracture with talar shift
2. Vertical shear medial malleolus fractures
3. Bimalleolar fractures
4. Trimalleolar fractures that did not require posterior fragment fixation (typically <25% of articular surface).

Closed, grade I, or grade II open fractures were included.

### Exclusion Criteria

Exclusion criteria included patient and fracture specific factors. Patient-related exclusion factors included: skeletal immaturity, previous ipsilateral ankle surgery, nonambulatory status before injury, inability to comply with postoperative protocol (ie, advanced dementia), medical comorbidity precluding operative intervention, and workers compensation patients. Polytrauma patients were specifically excluded due to the confounding effect their other injuries would have on both our primary and secondary outcome measures.

Fracture-related exclusion factors included:

1. Surgical fixation greater than 14 days from time of injury
2. Grade III open fractures
3. Tibial plafond fractures
4. Syndesmotic injuries/fixation
5. Posterior malleolar fractures requiring fixation (typically >25% articular surface involved).

There were no exclusion criteria with regard to patient age, presence of osteoporosis/osteopenia, or body mass index (BMI).

## Randomization

Randomization was performed by the research coordinators at the 2-week postoperative visit by use of concealed sequentially numbered, opaque, sealed envelopes, in 1:1 ratio. Patients were randomized to 1 of 2 postoperative protocol groups: (1) “Non-weightbearing, immobilization” (Late WB group), or (2) “Early weightbearing, ROM” (Early WB group). Allocation was concealed from patients and investigators until the randomization was completed. Although it would have been desirable, it was not practical to blind patients or investigators to their treatment group.

## Intervention

All participants underwent open reduction internal fixation of an unstable ankle fracture by use of rigid osteosynthesis techniques using a standard surgical protocol. All procedures were performed by, or under the direct supervision, of an attending staff surgeon. The lateral malleolar fracture was fixed by use of a lag screw if possible, followed by the addition of a plate and screws (minimum 3 screws proximal, 2 screws distal). The medial malleolus was secured by use of 1 or 2 lag screws depending on the size of the fragment. Medial malleolar comminution or a vertical fracture pattern (as seen with a supination/adduction type injury) was addressed with a small fragment one-third tubular plate in a buttress fashion. In all cases, the syndesmosis was assessed intraoperatively using a previously described, standard method for syndesmosis injury, and surgical fixation was performed if needed.<sup>19</sup> Patients with syndesmosis injuries requiring fixation were excluded from participation in the study. Postoperatively all patients were placed in a below knee posterior plaster slab and instructed not to bear weight on the affected extremity.

At the first postoperative visit (2 weeks postoperatively), the posterior slab and sutures/staples were removed. Patients who met the inclusion criteria were then approached by the site research coordinator to participate in the study. Written informed consent was obtained in all cases, and patients were then randomized as described above to 1 of the 2 treatment groups.

Patients in the Late WB group were placed in a below knee fiberglass cast at 2 weeks postoperatively and instructed to remain nonweightbearing for a further 4 weeks (6 weeks total). At the 6-week postoperative visit, the cast was removed, and patients were allowed to perform ankle range of motion exercises and begin full weightbearing with use of a boot orthosis. Patients were seen by a physiotherapist, who discussed instructions regarding weightbearing and range of motion exercises. They were also instructed to wean from the orthosis over the next 2 to 4 weeks.

Patients in the Early WB group were placed a boot orthosis at the 2-week postoperative visit and instructed to start full weightbearing as tolerated. They were also instructed to remove the orthosis 4 times a day and perform ankle dorsi flexion, plantar flexion, inversion, and eversion exercises.

Patients were seen by a physiotherapist, who gave them instructions regarding weightbearing and range of motion exercises. At the 6-week postoperative visit, patients were instructed to wean from the boot orthosis over the next 2 to 4 weeks (Fig. 1).

In both groups, the boot orthosis utilized was the Künzli Ortho Rehab 3 boot (Künzli Swiss Schuh; Narimay Pharmaceuticals Inc, Windisch, Switzerland—see **Figure, Supplemental Digital Content 1**, <http://links.lww.com/BOT/A671>). Patients were also provided with a night splint, the “Ortho Nacht” to be worn in bed when the boot was removed.

## Follow-up Schedule

Patients were seen for follow-up at 2 weeks, 6 weeks, 3 months, 6 months, and 12 months postoperatively in outpatient fracture clinics. At each visit, they underwent a comprehensive examination that included an objective assessment of their wound (signs of wound healing problems, dehiscence, and infection); assessment of ankle dorsi flexion/plantar flexion by trained research staff with use of a goniometer; and a standard radiographic assessment. Patients were asked a standard set of questions by the research staff regarding their return to work and activity and adverse events. They also completed the SF-36 Health Survey and the Olerud and Molander Ankle Score.<sup>20,21</sup>

## Outcome Measures

The primary outcome in this study was time to return to work. Secondary outcome measures included ankle range of motion (ROM), ankle functional outcome scores (Olerud/Molander), health outcome scores (SF-36 Health Survey), wound complications (dehiscence, delayed healing, infection), and fracture fixation complications (fixation failure, loss of reduction, reoperation). Loss of reduction was defined as any shift in fracture position greater than 2 mm.

## Data Analysis

Means and standard deviations were calculated for continuous variables, and absolute and relative frequencies were measured for discrete variables. SAS System for Windows, Version 9.3 (SAS Institute Inc, Cary, NC) was employed for statistical analysis. Student *t* test and Mann–Whitney tests were used to compare differences between groups for continuous variables, and the  $\chi^2$  test for nominal variables. A *P* value of less than 0.05 was considered statistically significant. Patients were analyzed based on intention to treat principles.

## RESULTS

In total 110 patients were recruited, 54 randomized to the Late WB group and 56 to the Early WB group. There were 47% females and 53% men, with a mean age of 42 years. The mean time from injury to surgical fixation was 6.5 days (range, 0–19 days). There were 14 fractures that involved the posterior malleolus; however, the majority of these were small fragments (<25%) and treated nonoperatively. There were no statistical differences between the 2 groups with regard to demographics, fracture type, time to

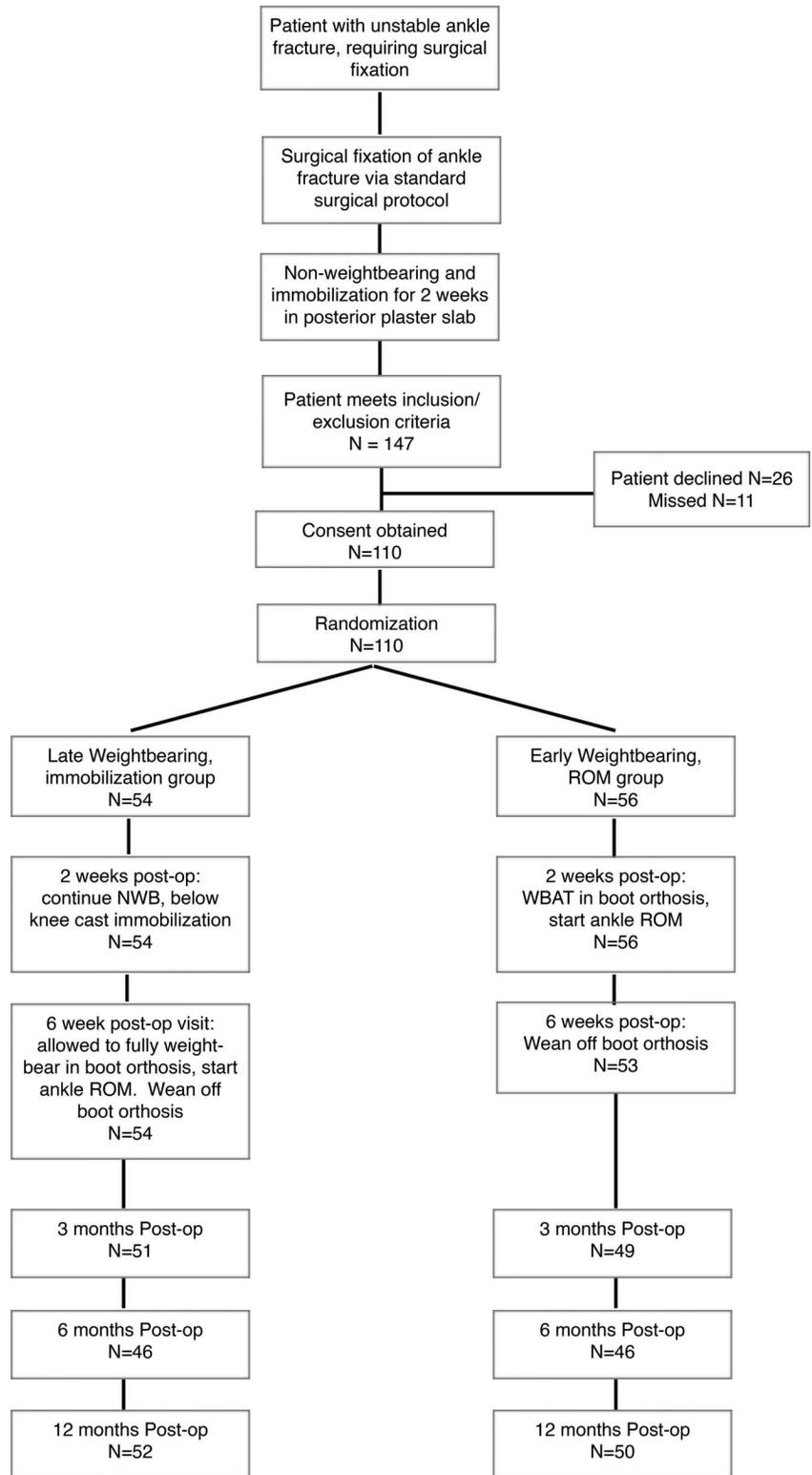


FIGURE 1. Flow diagram demonstrating study design.

surgery, preinjury occupation, or baseline health outcome scores and range of motion (Table 1). There was however a difference between return to work at baseline between the 2 groups (see “Return to work,” below).

### Return to Work

Return to work was assessed in patients who were employed at the time of injury (N = 97), whereas patients who were retired or unemployed were excluded from these calculations (N = 13). One patient was lost to follow-up before returning to work, and 4 patients did not have the exact date of return to work recorded. One patient from each group did not return to work by 12 months postoperatively and were excluded from the return to work analysis. Therefore, 90 patients with complete results were available for calculation of time to return to work.

At the time of randomization (2 weeks postoperatively), more patients in the Late WB group had already returned to work (33%) compared to the Early WB group (16%), which

was statistically significant ( $P = 0.05$ ). Beyond this point (2 weeks postoperatively, or “baseline”), there were no differences in the rate of return to work at any other time point. Overall, 48% of patients had returned to work by 6 weeks, 80% by 3 months, 94% by 6 months, and nearly all (98%) by 12 months postoperatively. There was no difference between the 2 groups with regard to total days off work (Early WB 51.2 days, Late WB 47.8,  $P = 0.72$ ) (see **Table, Supplemental Digital Content 2**, <http://links.lww.com/BOT/A672>).

### Ankle Range of Motion

There was a statistically significant improvement in the total dorsiflexion/plantar flexion arc of motion in the Early WB group compared with Late WB group early in the postoperative period. At 6 weeks postoperatively, the total arc of motion was 41 degrees in the Early WB group compared with 29 degrees in the Late WB group ( $P < 0.0001$ ). There was no difference between the 2 groups at subsequent visits (Fig. 2).

### Ankle Functional Outcome Scores

With regard to Olerud/Molander ankle function scores, there was a statistically significant improvement at 6 weeks postoperatively in the Early WB group compared with the Late WB group (45 vs. 32,  $P = 0.0007$ ). There were no statistically significant differences noted at subsequent visits. At 1-year postoperatively, patients in both groups had achieved similar mean outcomes scores (Fig. 3).

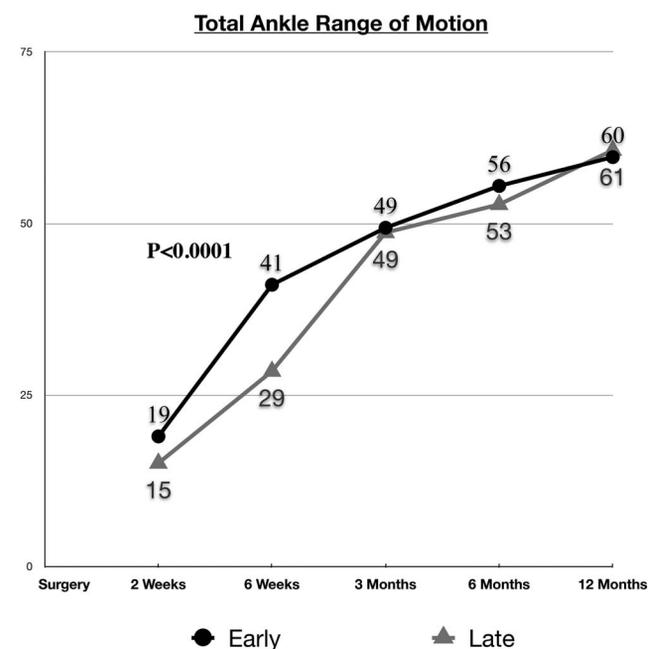
### Health Outcome Scores

With regard to the SF-36 Health Outcome scores, there was a statistically significant improvement in outcomes at

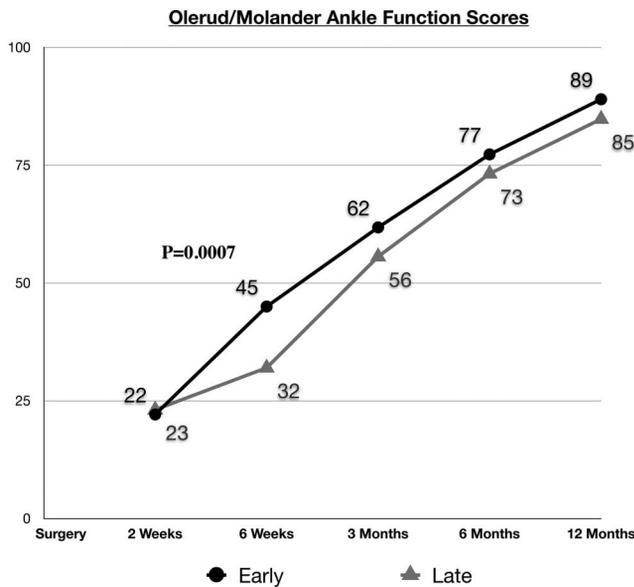
**TABLE 1.** Patient Baseline Information (at 2 Weeks Postoperatively, Before Randomization)

Baseline Characteristics	Overall	Early WB	Late WB	P
	Mean ± SD	Mean ± SD	Mean ± SD	
Age, y	41.9 ± 15.1	41.7 ± 15.1	42.1 ± 15.4	0.9
Time to OR, d	6.5 ± 4.2	7.0 ± 4.1	6.2 ± 4.3	0.32
Range of motion	17 ± 14	19 ± 15	15 ± 13	0.23
SF-36 health outcome scores				
Mental component	54 ± 19	52 ± 20	56 ± 19	0.35
Physical component	36 ± 13	35 ± 12	37 ± 14	0.5
Olerud molander scores	23 ± 18	22 ± 18	23 ± 18	0.78

Baseline Characteristics	Overall	Early WB	Late WB	P
	N/110 (%)	N/56 (%)	N/54 (%)	
Male	59 (54)	32 (57)	27 (50)	0.45
Female	51 (46)	24 (43)	27 (50)	
Occupation				0.55
Labor	11 (10)	7 (12)	4 (7)	
Intermediate	28 (25)	16 (29)	12 (22)	
Sedentary	58 (53)	28 (50)	30 (56)	
Unemployed/retired	13 (12)	5 (9)	8 (15)	
Fracture side				0.44
Left	51 (46)	28 (50)	23 (43)	
Right	59 (54)	28 (50)	31 (57)	
Fracture type				0.27
Unimalleolar	44 (40)	26 (46)	18 (33)	
Bimalleolar	52 (47)	25 (45)	27 (50)	
Trimalleolar	14 (13)	5 (9)	9 (17)	
OTA fracture type				0.72
44A1	2 (2)	1 (2)	1 (2)	
44A2	2 (2)	2 (4)	0 (0)	
44B1	31 (28)	17 (30)	14 (26)	
44B2	47 (43)	20 (36)	27 (50)	
44B3	20 (18)	11 (20)	9 (17)	
44C1	6 (5)	4 (7)	2 (4)	
44C2	2 (2)	1 (2)	1 (2)	



**FIGURE 2.** Total arc of motion in early weightbearing, ROM vs. late weightbearing, immobilization groups.



**FIGURE 3.** Olerud/Molander ankle function scores in early weightbearing, ROM vs. late weightbearing, immobilization groups.

6-weeks postoperatively in the Early WB group compared with the Late WB group. This difference was noticeable in the physical component (51 vs. 42,  $P = 0.008$ ) and the mental component (66 vs. 54,  $P = 0.0008$ ). There were no differences between the 2 groups at 3 months postoperatively. However, at 6 months, the Early WB group had a trend toward improved outcomes for both physical (79 vs. 72,  $P = 0.07$ ) and mental components (84 vs. 79,  $P = 0.08$ ). At 12 months, the early WB group had statistically superior physical component scores (85 vs. 79,  $P = 0.04$ ) and a trend toward improved outcomes in the mental component (87 vs. 83,  $P = 0.09$ ) compared with the Late WB group (Fig. 4).

### Protocol Violations

Due primarily to the limited operating room time available in our publicly funded system, 7 patients had their surgery greater than 14 days after their injury: (Early WB group 3 patients: on day 16, 15, 17; and Late WB group 4 patients: on day 15, 15, 16, 19). One patient in the Early WB group had percutaneous screw fixation of a posterior malleolar fracture.

### Complications

There were no differences between the 2 groups with regard to surgical site infections, wound complications, loss of fixation, loss of reduction, or reoperations.

There were 7 cases of superficial infections [4 in the Early WB group and 3 in the Late WB group, ( $P = 0.72$ )], all treated successfully with oral antibiotics. The majority of infections were diagnosed at the 6-week postoperative visit. There was no wound dehiscence or deep infections requiring surgical treatment in either group. There were 4 cases with wound healing complications (1 in the late WB group and 3

in the Early WB group,  $P = 0.61$ ). All patients were treated uneventfully with local wound care and dressing changes.

There were no cases of loss of fixation or loss of reduction in either group at any time point. With regard to reoperations, 11 patients had scheduled or had elective hardware removal performed due to hardware irritation. The rate of hardware removal in the Late WB group was 19% (10/52) compared with 2% in the Early WB group (1/50), and this was statistically significant ( $P = 0.005$ ).

## DISCUSSION

The results of this randomized controlled trial demonstrate that there was no difference in time to return to work between the early and late weightbearing groups. However, at 6 weeks postoperatively, the Early WB group had both statistically and clinically superior outcomes in a number of areas including ankle range of motion, improved ankle functional scores, and improved mental and physical health outcome scores. This is consistent with the previous literature that early weightbearing and/or mobilization leads to improved early functional outcomes.<sup>5,8,9,14-16</sup>

It is unclear why these early improvements in range of motion, ankle functional outcomes scores, and SF-36 scores did not translate into earlier return to work in the Early WB group. It may be that return to work is a multifactorial process with substantial intrinsic variability, such that it is difficult for 1 factor to be determinative. Additionally, the fact that at the time of randomization (two-week/baseline visit), significantly more patients in the Late WB group had returned to work (15/46, 33%), compared with the Early WB group (8/51, 16%), may have biased the results. Because the treatment of all patients was identical up to this point (surgery, posterior splint, nonweightbearing), this difference appears to be due to chance alone. However, this puts the Early WB group at an intrinsic disadvantage in the subsequent analysis of return to work. After randomization (from 2 weeks to 6 weeks postoperatively), more patients in the Early WB group returned to work (15/49, 31%) compared with the Late WB group (7/46, 15%), which was significant ( $P = 0.047$ ). However, as more patients in the Late WB had already returned to work at the 2-week baseline visit, there was no overall difference at this time point (47% in Early WB, 48% in Late WB).

Although there were no long-term differences between the 2 groups regarding ROM and Olerud/Molander ankle functional outcome scores, there was a trend toward long-term differences between the 2 groups with regard to the SF-36 Health Outcome scores. At 3 months postoperatively, the Late WB group appears to improve the level of the Early WB group in the physical and mental component scores of the SF-36. This finding could be due to the late rehabilitation start time of the Late WB group, and the potential for large improvements in the mental and physical component scores from 6 weeks to 3 months time. However, in the long term, the Early WB group appears to have slight improvements in these scores. At 6 months postoperatively, the Early WB group had slight improvement on the physical (7 points,  $P = 0.07$ ) and mental (5 points,  $P = 0.08$ ) components, which trended toward significance. At 12 months postoperatively,

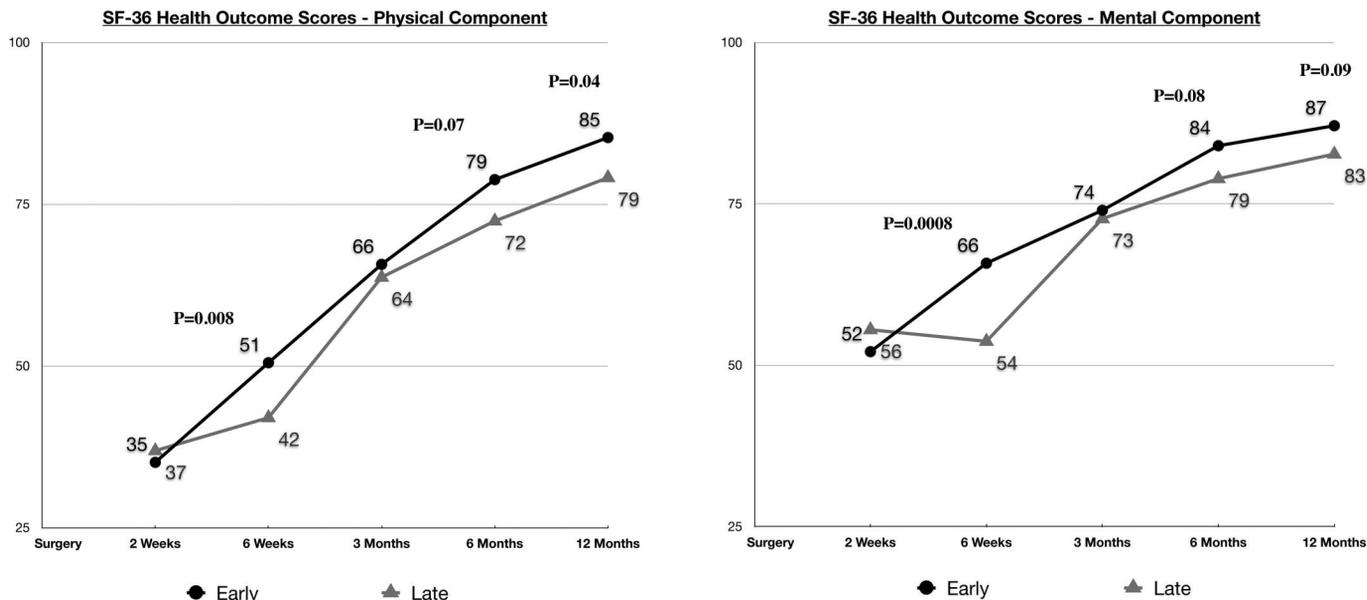


FIGURE 4. SF-36 health outcome scores in early weightbearing, ROM vs. late weightbearing, immobilization groups.

the Early WB group has significantly improved scores in the physical component (6 points,  $P = 0.04$ ) and trend toward significance in the mental component scores (4 points,  $P = 0.09$ ). The reason for, and clinical significance of, these higher scores for the Early WB group is unknown.

An unexpected outcome of this study was the significantly lower proportion of patients with hardware irritation and planned or performed hardware removal in the Early WB group compared with the Late WB group (1/50 vs. 10/52,  $P = 0.005$ ). It is unclear why a higher proportion of patients treated with late weightbearing and immobilization would suffer from hardware irritation sufficient to warrant removal. It is possible that immobilization may lead to increased scarring of the tissues and tendons around the fibular (or medial malleolar) hardware. It is possible that early mobilization decreases local scarring and decreases tendon and/or skin irritation around the plates/screws. This is a concept supported by the clinical experience of the authors and by personal communications following the presentation of this study in various venues. Further studies on this topic are warranted to better delineate the exact cause of this phenomenon.

A major clinical concern with early weightbearing is that it would result in an increase in wound complications or fixation failure. There have been multiple previous randomized controlled studies investigating the effects of early weightbearing, or early mobilization, or both, after surgical fixation of ankle fractures. Despite the conflicting results with regard to functional outcomes and return to work, none of the studies published on this topic have reported a clinically relevant increase in loss of reduction or fixation failure. Ahl et al surgically treated ankle fractures with staples, cerclage wires and pins, and compared early weightbearing to late weightbearing. The early weightbearing group had improved ankle function scores at 3 months postoperatively. Using

Roentgen stereophotogrammetric analysis (RSA), they found no difference in postoperative fracture displacement between the early and late weightbearing groups.<sup>11</sup> In a follow-up study, the same group<sup>10</sup> reported increased fracture mobility and mortise widening with early mobilization with RSA (perhaps due to the surgical technique). However, the authors stated that these changes in position were small and not clinically significant, and they recommended early weightbearing following the surgical fixation of ankle fractures. Van Laarhoven et al compared immediate weightbearing in a cast to nonweightbearing and demonstrated improved linear analogue scores and higher subjective ankle scores at 6 weeks, and a trend to earlier return to work, in the early weightbearing group. Complications in both groups were similar.<sup>9</sup> Honigsmann et al<sup>8</sup> compared full weightbearing in a boot orthosis at 2 weeks postoperatively to partial (15 lb) weightbearing. Both groups were also permitted to perform range of motion exercises. There were no differences in Olerud/Molander scores or complications. However, the early weightbearing group demonstrated significantly less swelling and shorter time to walk on stairs confidently. A large prospective nonrandomized cohort study of 650 patients with ankle fractures was recently presented at the OTA annual meeting.<sup>22</sup> Patients were treated surgically (35%) or nonoperatively (65%) and were allowed to weight-bear fully immediately postinjury. There was no loss of fracture reduction in any patient.

Prior RCT's focusing on early mobilization after ankle fracture fixation has also revealed mixed results. Lehtonen et al<sup>7</sup> conducted an RCT comparing early mobilization with functional bracing to cast immobilization, with full weightbearing allowed at 4 weeks postoperatively for all patients. They reported a significant increase in wound complications in the early mobilization group (66% vs. 16%,  $P = 0.0005$ ). Complications included superficial infections, deep infections,

wound dehiscence, and other wound irritations. There were no differences with regard to loss of fixation, functional outcome scores, or time to return to work. Multiple other RCTs have failed to demonstrate such an increase in complications. Cimino et al<sup>13</sup> and Hedstrom et al<sup>14</sup> compared early mobilization to cast immobilization with full weightbearing permitted in both groups. There were no differences in complications or ROM although Hedstrom reported better visual analogue scores for pain at 3 weeks in the early mobilization group. Egol et al<sup>15</sup> compared early mobilization to cast immobilization, whereas all patients were kept nonweightbearing for 6 weeks. They reported no difference in complications. However, the early mobilization group had improved early functional scores and SF-36 scores, and an earlier return to work (53 vs. 107 days). Another similar RCT by Sondenna et al<sup>16</sup> reported improvement in ROM at 6 weeks postoperatively.

The strengths of this study include a large sample size, use of 2 separate centers with multiple surgeons, utilization of standardized modern surgical techniques, and its prospective randomized trial design. Although previous studies have focused on either early weightbearing or early mobilization, this study investigated a more aggressive rehabilitation protocol, which combined both early weightbearing and early mobilization. This approach was selected to maximize the potential for rapid return to preinjury function.

Weaknesses of this study include the unequal distribution of patients who had returned to work at baseline between the 2 groups, which may have substantially impacted our primary outcome measure. Another potential criticism is that we did not have any method of confirming if patients were compliant with their respective rehabilitation protocols. Although we were unable to confirm patient compliance, this likely improves the external validity and applicability of the results of this pragmatic study to the general population, who may not be fully compliant with postoperative instructions. On a practical level, this reinforces our belief that patients can weight bear to whatever level they feel comfortable with postoperatively, without negative clinical or radiographic repercussions in the specific setting of surgically treated ankle fractures. Lastly, there were multiple surgeons and physiotherapists involved in this study, which has the potential to introduce significant variability (decreased internal validity). However, this again improves the external validity and applicability to the general orthopaedic patient population.

Rapid return to function, minimizing disability, and enhanced patient convenience and autonomy are priorities of modern fracture care. This pragmatic study demonstrates that early weightbearing and mobilization after surgical repair of displaced ankle fractures significantly improved early (6 week) functional outcomes with no increase in adverse events. In addition, it minimizes patient inconvenience and simplifies postoperative care and may decrease irritation from implanted hardware and the subsequent need for removal. Combined with available information from the previous literature and the lack of evidence of any increased risk of

complications, our study clearly supports early weightbearing and mobilization after surgical fixation of unstable ankle fractures.

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