

EARLY WEIGHT-BEARING AFTER ANKLE FRACTURE FIXATION: A PROSPECTIVE, RANDOMIZED AND NON-BLINDED, OUTCOME STUDY

J.M. Muthuuri, MBChB, MMed (Surg.), H.Dip.Orth (SA), FCS (ECSA), Consultant Orthopaedic Surgeon, The Mombasa Hospital Private Clinics, P.O. Box 84074, Mombasa, Kenya. E-mail: michenimuthuuri@yahoo.com

ABSTRACT

Background: In early 2006 during AO-scholarship training at Hadassah Hospital in Jerusalem, I witnessed patients being walked on the same day after fixation of ankle fractures. This was contrary to my original teaching of protected non-weight bearing for six weeks. Literature review in this subject was inconclusive. I then determined to study and compare the functional benefit of early weight-bearing as compared to non-weight-bearing in these patients.

Design: Prospective, randomized non-blinded, outcome study.

Objective: To compare the functional outcome of early weight-bearing in patients with ankle fracture after open reduction and internal fixation.

Methods: Between June 2006 and June 2012 we randomized prospectively 70 consecutive patients who had open reduction and internal fixation for similar fractures of the ankle into two groups. All patients had below-knee cast applied post-operatively. Group 1 (study group) were allowed immediate partial weight-bearing with crutches while group 2 (control group) were mobilised non-weight-bearing with crutches for six weeks. All the patients were seen at 2, 6, 12 and 25 weeks. After six months (around the 25th week) we used a modified form of the American Academy of Orthopaedic Surgeons (AAOS) foot and ankle scale to evaluate the patients.

Results: We had a total of 62 patients by the end of the study, 30 in group 1 (mean age 41 years) and 32 in group 2 (mean age 41 years). Those in group 1 had higher functional scores at the last follow-up (75.1% vs. 55%, $P < 0.001$) which is highly significant. There was no sepsis in the study or control group. There was no loss of fixation in either group.

Conclusion: Our findings support the use of early protected weight-bearing after surgery for fractures of the ankle.

INTRODUCTION

The aim of operative treatment for any fracture is to achieve reduction and stabilization. In a weight bearing bone, stable fixation is desirable to allow early movement. However, rehabilitation of ankle injuries emphasizes maintenance of a neutral functional position, protection of the injured area from excessive forces, restoration of motion, and progressive resumption of weight bearing as soon as safe (1). Ankle fractures are unique in that adequate immobilisation is possible by casts and other forms of external splintage. Traditionally, patients were not allowed to weight-bear until the fractures showed signs of healing by developing callus. A lot of surgeons would allow guarded weight-bearing after six weeks whether there is callus or not. Various studies have examined combinations of management strategies after surgical treatment which have included either full weight-bearing, partial weight-bearing or complete immobilisation. The results from these studies have been inconclusive for any benefit at short term. However, some of the studies have shown no difference in outcome at one year (2). In this study we have used functional scores to assess the outcome

of early weight-bearing at six months after operative treatment of unstable ankle fractures. We randomised to create a control group of patients who were not allowed to weight-bear.

MATERIALS AND METHODS

There were seventy eight patients admitted for operative treatment of ankle fractures over a period of 36 months between August 2009 and August 2012. This was an average of about two patients per month. Patients with Gustilo type I open fractures were included in the study. Exclusions included patients with severely contaminated open fractures (2 cases), open fractures (Gustilo type III, and IIIB (2 cases), short period stay visitors (4 cases), patients with neuropathic ankle joints or Charcot's joints (2 cases) and severe osteoporosis (1 case). Seventy patients were eligible for the study. All the patients were above the age of 18 years. The fractures were classified according to the system of Lauge-Hansen (3). The lateral malleolus was fixed with a well contoured 6-8 hole 35mm DCP and the medial malleolus with two lag screws (35-45 mm malleolar screws). All implants were metallic and non-biodegradable. After the operation, all the operated

limbs were put in a below-the-knee plaster cast. They were then randomly assigned to one of the two modes of treatment. Permuted block randomization method was used for randomization in this study. Being a two group design, 100 card blocks having equal numbers of A's and B's (A = Early weight-bearing and B = non-weight-bearing (control) were used. The order of treatments within the block was randomly permuted.

Both groups were mobilized with crutches and were instructed on active and passive exercises of the lower extremity by a physiotherapist. The study group was allowed to partially weight bear while the control group were instructed not to weight bear. The casts were changed in both groups after two weeks when the wounds were inspected and stitches removed as required. Group 1 was allowed to continue to weight bear while group 2 remained non weight-bearing for another 4 weeks. After six weeks both groups were around full weight-bearing. Those with a screw across the syndesmosis had it removed under local anaesthetic around the 8th week, irrespective of the group.

The patients were reviewed at 2, 6, 12 and 25 weeks (6 months). Radiographs were taken at 6 weeks and rarely at 12 weeks and 6 months and only if necessary. After 6 months the patients were individually assessed using a Modified American Academy of Orthopaedic Surgeons Foot and Ankle Scale (MAAOSFS). This modification was made from the American Academy of Orthopaedic Surgeons (AAOS scale, 2004) which has 4 subscales (20 items) totalling 100 points with 45 given to pain, 30 function, 10 to stiffness and swelling and 15 to giving way (4). The modified scale retains the 4 subscales with 10 questions each scoring a maximum of 10 in an objective scale, 40 given to pain, 20 to function, 20 to stiffness and swelling and 20 to giving way (Table 1). The items were scored on a variable scale ranging from 0 to maximum 10 points. The scores are summed and then subtracted from 100 to portray functionality so that the lower the score, the greater the patients disability (a maximum score of 100 points and a minimum score of 0 points could be obtained). The highest activity in the AAOS scale is jogging. We found this difficult to assess as most of our patients don't jog. We therefore, substituted jogging with climbing the stairs.

Statistical analysis: Our null hypothesis was that early weight bearing in protected casts has no clinical or functional effect. To test this we desired

a confidence level of 95%. To calculate minimum sample size required to give us a reasonable chance (.80) of detecting an effect we used a power table. A sample size of 60 was found reasonable.

Table 1
Modified AAOS foot and ankle scale

Scale	Activity	Maximum Points
Pain (40)	Do you have pain when you?	
	Walk the Stairs	10
	Walk normal terrain	10
	Are at rest	10
Function (20)	Are you able to?	
	Walk the stairs	10
	Walk normally	10
	Are you able to?	
Giving way (20)	Does the ankle give way when you?	
	Walk the stairs	10
	Walk normally	10
	Does the ankle give way when you?	
Swelling/Stiffness (20)	Do you experience swelling at the ankle/foot?	10
	Stiffness	
	Do you experience stiffness of the ankle/foot?	10
	Total	100

The sample size calculation was done post hoc. IBM SPSS 19 and computer based statistics to calculate the chi-squared or Students T test and was used to determine if there were differences in age, gender, aetiology and injury between the two groups.

The confidence interval and the p values were obtained for the mean of scores between the groups. A p-value of less than 0.05 was considered statistically significant.

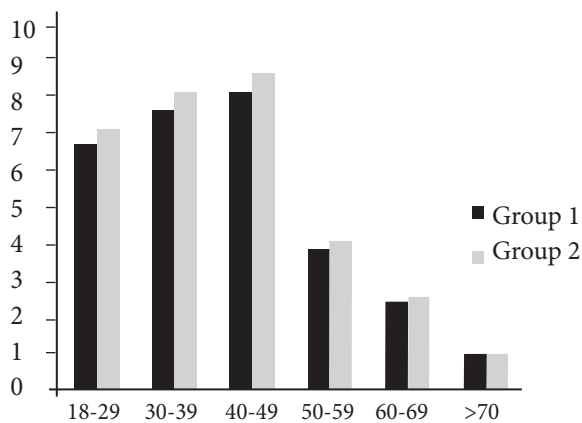
RESULTS

Of the 70 patients entered into the study, three developed wound complications (one deep sepsis and two superficial) and five were lost to follow-up. We were left with 62 patients who completed the 6th month follow up questionnaire. In all the 62 patients the fractures were fully united by 12 weeks. There was no loss of fixation or malalignment.

Table 2
Age group distribution

Age Group	Group 1	Group 2	Total	P value
18-29	10	4	14	
30-39	3	13	16	
40-49	8	9	17	
50-59	6	2	8	
60-69	2	3	5	
>70	1	1	2	
Total	30	32	62	0.504

Figure 1
Age group distribution



Tables 2 and Figure 1 show the patient distribution according to the age group. It is worth noting that the distribution is positively skewed. There were no significant differences in the two groups across the age groups ($P = 0.504$).

In group 1 there were 30 patients (17 men, 13 women), mean age 41 years (18 to 72 years) and in group 2 there were 32 patients (18 men, 14 women), mean age 41 years (18 to 73 years). There was no gender disparity ($P = 0.5793$) as shown on Table 3.

Table 3
Gender distribution

	Group 1	Group 2	Total	P value
Male	17	18	35	
Female	13	14	27	
Total	30	32	62	0.5793

The commonest cause of injury was a fall (45%). These are falls while people are walking in wet areas and beaches, falling into ditches or manholes and falls from heights. Road accidents involving a motor vehicle or a motor cycle are the next culprit (44%). Industrial accidents and sporting activities constitute a negligible percentage (Table 4).

Table 4
Aetiology

Aetiology	Group 1	Group 2	Total	(%)
Fall	11	17	28	45
Motorcycle	11	8	19	31
MVA	5	3	8	13
Industrial accidents	2	2	4	6
Sports	1	2	3	5
Total	30	32	62	100

The fractures were classified according to the classification of Lague-Hansen (Table 5). According to this classification, Supination-External Rotation (SER) injuries predominated and accounted for 39 (63%) of the fractures. There were 11(18%) Pronation-Abduction (PA) injuries and 7 (11%) Supination-Adduction (SA) fractures. The rarest fracture was Pronation-External Rotation (PER) where only 5 (8%) were encountered.

Table 5
Lague-Hansen Classification

Classification	Group 1	Group 2	Total	(%)
SER	19	20	39	63
PA	3	8	11	18
SA	4	3	7	11
PER	4	1	5	8
Total	30	32	62	100

Table 6
Ankle scores

Statistics		Group 1	Group 2
Ankle Score			
n		30.0	32.0
Mean		75.1	55.0
Median		79.0	56.0
Std. Deviation		15.6	12.0

Group	Description	number n	m mean ankle score	Sd	sed	Zscore	P-value
Group 1	W Bearing	30	75	16	0.90	22.312775	0.0001
Group 2	NW Bearing	32	55	12			

After six months, functional assessment was done using the MAAOS criteria as earlier outlined. Table 6 shows a summary of the results of the ankle scores for both groups. The mean score for group 1 was 75.1 and 55.0 for group 2. The difference was highly significant ($p < 0.01$).

DISCUSSION

One of the chief aims for open reduction and internal fixation of the ankle fractures is to obtain reduction and maintain alignment until healing. The other aim is to allow early movement especially after a stable fixation. This movement may be passive without weight-bearing or with early weight-bearing and mobilisation. Passive movements are encouraged where weight-bearing may be unsafe (elderly, debilitated, osteoporotic, and those grossly obese patients). The biology of fracture may dictate against early weight bearing (intra-articular fractures, defects of articular cartilage and in severe soft tissue injury). At six months we found a higher functional outcome scores for the patients who were allowed to immediately weight-bear (group 1) than for those who had a six week delay before weight-bearing. This difference was highly significant ($p < 0.01$).

Other studies have shown different results from ours. van Laarhoven *et al* (5) in a prospective, randomised trial of 81 patients with fractures of the ankle compared two similar groups. The patients were mobilised either non-weight-bearing with crutches or weight-bearing in a below-knee walking plaster. There were no significant differences between the groups in the loaded dorsal range of movement (25° v 23° , Mann-Whitney test, cft, $p = 0.16$) or in the overall clinical results. Both treatments were considered to be satisfactory. Finsen *et al* (6) randomly assigned 56 patients into one of the three treatment groups: plaster cast and non-weight-bearing, no cast and non-weight-bearing and short-leg cast with weight-bearing as tolerated. No differences were found among them, although it is worth noting that each of the 3 groups had

more than 20 patients. They concluded that there was no advantage of one form of treatment over another. Sondenaa *et al* (7) randomised 43 patients; the first group had a plaster and early weight-bearing and the other group had no plaster, no weight-bearing but were allowed passive movements. At six weeks the range of movement was poorer in the plaster group but had less pain than the non-weight-bearing group. They offered no recommendations as to treatment.

Other authors have come out strongly for early weight-bearing. Egol *et al* (8) randomised prospectively 60 consecutive patients after internal fixation for ankle fractures into two groups; one was treated by immobilisation in a below-knee cast and the other by a functional brace with early movement. Their findings supported the use of early movement after surgery for fractures of the ankle. Lindsjö (9) in a prospective study of 321 consecutive cases of dislocation ankle fractures operatively treated, 306 cases (95%) were followed up for two to six years after surgery. He found that subsequent full weight-bearing in a below-the-knee walking plaster is essential for a good end result of fracture-dislocations of the ankle joint. It is noted that this study had a large sample size. Papachristou *et al* (10) studied the distribution of axial load to the lip of the tibia in 15 patients with fracture of the posterior malleolus that comprised 0% to 33% of the articular surface. All patients had open reduction and internal fixation and were allowed full weight bearing in a cast within 7 days of surgery. All patients had an uneventful recovery. Their conclusion was that early weight bearing after open reduction internal fixation of posterior malleolar fracture of the ankle joint, facilitates recovery, promotes fracture union, and allows the patient to assume normal activity by the third month after surgery.

In 2008, a Cochrane database systematic review of 31 studies by Lin *et al* (11) while looking at various rehabilitating aspects concluded that there was limited evidence supporting the use of a removable type of immobilisation and exercise during the immobilisation

period, early commencement of weight-bearing during the immobilisation period against no immobilisation after surgical fixation of ankle fracture. The authors confirm heterogeneity in their review. There was no uniformity on the procedure and implants used. In 1993 Ahl *et al* (12) in a controlled study of 40 patients with bimalleolar ankle fractures reported a lack of lasting superior clinical results achieved by early ankle movement. All their ankles were operated on using cerclage, staples and pins.

Our study used assessment of functional outcome to compare the two modalities of treatment at six months post injury. A longer follow up was not possible as most patients were lost to follow up, less than half responding after one year. Some studies show no difference after one year (8,9). However, the short term benefit of early weight-bearing which include reducing the risk of thromboembolic disease. Active movement reduces joint stiffness while maintaining the muscle bulk.

The study recorded no reoperations for fixation failure, implant failure or non-unions. Different authors have confirmed safety of early weight bearing after stable fixation as long as the cast is well padded and the ankle is held in a neutral position (13-15).

The limitations of the study include the fact that the operating surgeon also performed the follow-up functional assessment. This may have caused unintended bias. The patient's occupation, compensation expectations or concurrent medical comorbidity were not taken into account. These confounders may have contributed to continued symptomatology in some patients.

We recommend early-weight-bearing in a below-knee total contact cast after surgical stabilisation of ankle fractures as long as the exclusion criteria is satisfied.

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