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Title

Surgery for type B Ankle fracture Treatment (CROSSBAT): Combined Randomised and Observational Study

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ABSTRACT

Objective

To determine if surgery is superior to non-surgical management for the treatment of type 44B1 ankle fractures with minimal talar shift

Setting/Participants/Interventions

Participants between 18 and 65 years with a type B ankle fracture and minimal talar shift were recruited from 22 hospitals in Australia and New Zealand. Participants willing to be randomised were randomly allocated to undergo surgical fixation followed by mobilisation in a walking boot for 6 weeks. Those treated non-surgically were managed in a walking boot for 6 weeks. Participants not willing to be randomised formed the observational cohort. Randomisation stratified by site and using permuted variable blocks was administered centrally. Outcome assessors were blinded for the primary outcomes.

Primary Outcomes

Patient-reported ankle function using the American Academy of Orthopaedic Surgeons Foot and Ankle Outcomes Questionnaire (FAOQ) and the physical component score (PCS) of the SF-12v2 General Health Survey at 12 months post-injury. Primary analysis was intention-to-treat; the randomised and observational cohorts were analysed separately.

Results

Between August 2010 to October 2013, 160 people were randomised (80 surgical and 80 non-surgical); 139 (71 surgical and 68 non-surgical) were analysed as intention-to-treat. 276 formed the observational cohort (19 surgical and 257 non-surgical); 220 (18 surgical and 202 non-surgical) were analysed. The randomised cohort demonstrated that surgery was not superior to non-surgery for the FAOQ (49·8 vs. 53·0; mean difference 3·2 [95% CI: 0·4 to 5·9], p=0·028), or the PCS (53·7 vs. 53·2; mean difference 0·6 [-2·9 to 1·8], p=0·63). 23 (32%) and 10 (14%) participants had an adverse event in the surgical and non-surgical groups, respectively. Similar results were found in the observational cohort.

Conclusions

Surgery is not superior to non-surgical management for 44-B1 ankle fractures in the short term,

and is associated with increased adverse events.

Funding

Australian Orthopaedic Association Research Foundation; National Health and Medical Research Council; Avant Mutual Group; the Royal Australasian College of Surgeons.

Trial Registration

The study was registered on www.clinicaltrials.gov (NCT01134094)

Article Summary

Strengths and limitations of this study

- The strengths of CROSSBAT include allocation concealment.
- In the randomised cohort, loss to follow-up and crossover rates were low, and the as-treated analysis supported the findings of the intention-to-treat analysis.
- Outcome tools were validated and relevant, and assessors were blinded.
- The addition of the observational arm added to generalisability of the findings and addressed selection bias.
- Limitations include the lack of blinding of the surgeons and participants which is unavoidable with this trial design.

WHAT THIS PAPER ADDS

Section 1: What is already known on this subject

OTA type 44-B1 ankle fractures (type B ankle fractures with minimal talar shift) are common and may be treated surgically or non-surgically. There was no clear consensus on the optimal management for this type of ankle fracture as there been a lack of evidence from randomised controlled trials for treating this type of ankle fracture.

Section 2: What this study adds

Our study shows that surgical management is not superior to non-surgical management for 44-B1 ankle fractures in the short term, and is associated with increased adverse events.

Ankle fractures are common, with one in 800 people fracturing their ankle every year (1-3). The most common pattern involves a fracture of the distal fibula (lateral malleolus) at the level of the tibiofibular syndesmosis, otherwise known as an AO (Association for the Study of Internal Fixation) or OTA (Orthopaedic Trauma Association) type B ankle fracture (4-7). If combined with displacement of the ankle mortise or a fracture of the medial malleolus, surgical fixation is the preferred treatment. However, the most common type of ankle fracture involves a type B lateral malleolus fracture without fracture of the medial malleolus or displacement of the talus (AO/OTA type 44-B1) (8).

Management options for these AO 44-B1 ankle fractures include surgical stabilisation by internal fixation using a plate and screws or non-surgical management using a cast or a walking boot (1). Advocates for surgical management emphasise the importance of achieving an anatomic reduction with internal fixation thereby limiting the potential for displacement and instability (9). Advocates for non-surgical management argue that functional outcomes are not superior with surgical stabilisation and surgery is associated with significant costs and possible adverse events (8,10-12). These include the general risks of anaesthesia and surgery, such as death, venous thromboembolism, infection, failure of fixation and the need for revision surgery (12). Slobogean *et al* showed that the average costs of non-surgical and surgical management of an unstable, isolated, lateral malleolar fracture were $1,892 and $6,404 (US dollars) respectively (13).

A national survey of 358 orthopaedic surgeons in Australia revealed that surgical management of this common fracture is preferred by approximately 40% of surgeons, despite a lack of evidence to support this approach (14). Recognising the costs and risks associated with surgery, the lack of evidence supporting the benefit of surgery and the considerable practice variation, we designed a randomised trial to determine the comparative effectiveness of surgical and non-surgical management.

In this study involving participants with a 44-B1 ankle fracture, we sought to determine whether surgical management provided superior ankle function and quality of life at 12 months post-injury when compared with non-surgical management. A concurrent observational cohort study was included to provide further evidence regarding the outcomes obtained in routine practice and to improve the generalisability of the results.

METHODS

Study Design

CROSSBAT (Combined Randomised and Observational Study of Surgery for type B Ankle fracture Treatment) was a pragmatic, multicentre, parallel-group, superiority, randomised controlled trial with an observational cohort that recruited participants from August 2010 to October 2013. It involved 22 hospitals in Australia and New Zealand that were a mix of rural, regional and metropolitan centres (a list of recruiting hospitals is provided in the supplementary appendix). The main study was the randomised group, and participants declining randomisation were invited to participate in the observational cohort. The protocol was approved by the ethics committees relevant for each site. The full protocol can be accessed as an online supplement on the BMJ website.

Participants

Consecutive adult patients presenting to a recruiting hospital during the study period with an isolated, closed AO type 44-B1 distal fibula fracture without significant talar shift presenting within ten days of injury were screened for eligibility. Significant talar shift was defined as medial clear space being at least 2mm wider than the superior clear space on mortise x-ray view of the ankle. Further inclusion criteria were patients aged between 18 and 65 years inclusive with no other concomitant fractures/dislocations; mobilising unaided/independently pre-injury; and willing to be followed up for 12 months. Exclusion criteria were participants that were medically unfit for anaesthesia/surgery; skeletally immature; previous trauma or surgery to the fractured ankle; inability to consent; pregnancy; the presence of or co-morbidities that impede mobilisation; and non-English speaking. Written, informed consent was obtained from all patients willing to participate.

Randomisation and blinding

Eligible participants willing to be randomised were randomly allocated in a 1:1 ratio to either the surgical or non-surgical intervention. The National Health and Medical Research Council Clinical Trials Centre (not otherwise involved in the study) generated the randomisation schedule using a permuted block approach with variable block size and stratified by site. Randomisation was administered using an automated telephone-based system that provided allocation concealment. Owing to the nature of the interventions, neither the investigators nor the participants were blinded. Outcome assessors were independent of the treating teams, and collected data using a

standardised telephone interview. As part of the opening conversation, patients were advised not to disclose their treatment so that the assessor could remain blind to treatment. After randomisation, the surgical group received surgery within ten days of injury. Eligible participants who declined randomisation were invited to enter the observational cohort. Treatment for the observational cohort was determined by participant and surgeon preference.

Procedures

During protocol development, members of the Australian Orthopaedic Trauma Society were consulted regarding the best practice for the surgical and non-surgical management of 44-B1 ankle fractures as well as the primary and secondary outcomes. Patient eligibility centred on the presence of the fracture of interest. An external rotation stress test to assess the stability of the ankle was not performed as it was not routine practice in Australia owing to uncertainty about its validity and clinical utility (15,16). The focus for the effectiveness of the interventions was patient-reported outcomes. Radiological measures beyond six weeks were not required as they were unlikely to demonstrate any osteoarthritic changes and because late mal-alignment was considered rare (with both methods of treatment) and unlikely to influence management without clinical symptoms. One recruiting site declined to randomise participants due to lack of equipoise within the orthopaedic department and contributed to the observational cohort only.

The technique for surgical management was surgical fixation using a plate and screws. Surgeries were performed by orthopaedic surgeons or by orthopaedic trainees under the supervision of consultant orthopaedic surgeons following the AO principles of fracture fixation. Plate placement and reduction techniques were left to the discretion of the surgeon. Adverse intra-operative or post-operative events were recorded. Post-operatively, all participants were non-weight bearing and placed in a below-knee plaster cast or walking boot. Discharge from hospital was determined by the participant's ability to walk 25 meters unaided with standby assistance as determined by a physiotherapist (usual discharge criteria). The treating surgeon reviewed the participant after 10-14 days for wound assessment and change of cast to a walking cast or a walking boot (cam walker). The participant was then allowed full weight bearing. The treating surgeon reviewed the participant six weeks post-injury with ankle radiographs and removed the cast or walking boot.

Participants who were treated non-surgically were managed with a walking boot and allowed full weight bearing. Discharge from hospital was determined as for the surgical group. All participants

were examined within 10-14 days post-injury by the treating surgeon who assessed the patient with new ankle radiographs. The treating surgeon reviewed the participant six weeks post-injury with repeat ankle radiographs and removed the cast or walking boot.

Referral to physiotherapy for all participants was at the discretion of the treating surgeon.

Outcomes

The primary outcome measures were patient-reported ankle function using the American Academy of Orthopaedic Surgeons Foot and Ankle Outcomes Questionnaire (FAOQ) and the health-related quality of life using the physical component score (PCS) of the SF-12v2 General Health Survey at 12 months post injury. The FAOQ is a validated, patient reported outcome measure that assesses ankle function with a higher value indicating better function (17,18). Normative FAOQ scores were used, with a score of 50 representing the mean in the general population, and a standard deviation of 10 (19). Similarly, the SF-12v2 is a validated patient reported outcome measure that has been used for the assessment of people with ankle fractures, with a higher value indicating better health (20-22). Both the SF-12v2 and the FAOQ have been used previously for patients with ankle fractures (22,23). Secondary endpoints included any adverse events in the 12 months post-injury; return to work at 6 weeks, and 3, 6 and 12 months post-injury; the PCS and FAOQ at 3 and 6 months post-injury; and the mental component score (MCS) of the SF-12v2 at 3, 6 and 12 months post-injury. Adverse events were classified as major (unplanned/repeat surgery; infection requiring admission to hospital; pulmonary embolus or death) or minor (neurological injury not requiring further intervention; infections not requiring hospital admission; deep vein thrombosis or other adverse events not requiring hospital admission or surgery) (24). The adverse events were collected at 6 weeks and 3, 6 and 12 months post-injury. Follow-up assessments were conducted by telephone. Physiotherapy use (number of visits) was measured.

Statistical Analysis

The PCS has a standard deviation (sd) of 10 points and a 5-point difference (equivalent to a 0·5sd) is considered to be the minimum clinically important difference (20,21,25). A sample size of 160 in the randomised cohort was used to provide 80% power to detect a 5-point difference in the PCS between the two groups at a significance level of 0·05, allowing for 20% loss to follow-up. The normative FAOQ score has a sd of 10, with a 5 point difference (0.5sd) regarded as the minimum

clinically important difference (19). The same sample size (160) would provide the same power to detect a 0·5sd difference in the FAOQ. There was no sample size target for the observational cohort as this cohort was to provide supplementary information for the randomised cohort. The randomised and observational cohorts were analysed separately. The primary analysis, conducted using intention-to-treat principles, was performed on the randomised cohort; an as-treated analysis was also performed on the randomised cohort for sensitivity testing. Student's t-test was used to compare continuous variables between groups. Missing data was not imputed. Chi-squared or Fisher's exact test was used for categorical data analysis as appropriate. Statistical analysis was conducted using SAS 9·4 (Cary, NC, USA). Both primary outcomes were required to be significantly better in the surgical arm in order for surgery to be regarded as superior. The trial was registered with clinicaltrials.gov (NCT01134094).

Patient involvement

Patients were involved in the development of the outcome measures (17,19-21). Patients were not involved in the development or conduct of the study. Publication details will be disseminated to study participants that expressed an interest in knowing the results of this study. All participants were thanked in acknowledgements for participating in this study. The burden of intervention on patients was assessed and considered to be low by the ethics committee that assessed the research project (given that both the intervention and control arms are routine practice); no patients were involved in that assessment. This was done as part of a survey of patient factors influencing participation in surgical randomised trials, embedded within CROSSBAT. The embedded study is currently under review.

Role of the funding source

This trial was supported in part by a grant from the Australian Orthopaedic Association Research Foundation. RM was supported with: a postgraduate scholarship from the National Health and Medical Research Council, Avant Doctors-in-training research scholarship and the Foundation for Surgery John Loewenthal Research Fellowship from the Royal Australasian College of Surgeons. The funding organisations of the study had no role in the study design, data collection, data analysis, data interpretation, or writing of the report. The corresponding author had full access to all the data in the study and had final responsibility for the decision to submit for publication.

RESULTS

From August 15, 2010 to October 3, 2013, 436 participants that presented with an isolated, closed AO type 44-B1 distal fibula fracture with minimal talar shift were screened and all were recruited; 160 participants were randomised to the randomised cohort and all 276 participants who declined randomisation were included in the observational cohort. The cohort ascertainment and retention flowchart is presented in Figure 1.

In the randomised cohort, 80 participants were randomised to non-surgical management and 80 were randomised to surgical management. At 12 months, 68 (85%) and 71 (89%) participants were followed up in the non-surgical and surgical groups, respectively. The ITT analysis kept participants in the groups to which they were randomised, but the numbers are incomplete due to missing data.

In the observational cohort, 257 participants were treated non-surgically and 19 were treated surgically as most patients declined surgery when informed of equipoise regarding the two treatment arms. At 12 months, 202 (79%) participants were followed up in the non-surgical group, and 18 (95%) participants were followed-up in the surgical group.

Baseline participant characteristics were similar between the two groups in the randomised cohort. In the observational cohort, the surgical group was significantly younger than the non-surgical group (mean difference 8·3, 95% CI: 2·6 to 14·0; p=0·007). There were no other significant differences in baseline demographics between the two groups in the observational cohort. Baseline characteristics are shown in Table 1. Comparison of baseline data between the randomised and observational cohorts showed that both cohorts had similar demographic profiles.

Table 1: Baseline demographics for CROSSBAT

Variable	Randomised Cohort		Observational Cohort	
	Surgical (n=80)	Non-Surgical (n=80)	Surgical (n=19)	Non-Surgical (n=257)
Age, mean (SD), years	38·1 (13·0)	39·8 (13·7)	31·1 (11·5)[a]	39·4 (13·7)[a]
Female, no. (%)	42 (53)	41 (51)	5 (26)	115 (45)
BMI, mean (SD), kg/m^2	27·7 (5·2)	28·4 (6·6)	26·2 (2·9)	27·6 (5·5)

Left Side, no. (%)	41 (51)	46 (58)	11 (58)	120 (47)
Mechanism, no. (%)				
Fall < 1m	70 (90)	67 (84)	17 (90)	232 (92)
Fall > 1m	6 (8)	8 (10)	0 (0)	9 (4)
Motor vehicle accident	2 (3)	5 (6)	2 (11)	11 (5)
Education, no. (%)				
High School or Lower	31 (39)	44 (55)	11 (58)	100 (39)
TAFE/Diploma	30 (38)	23 (29)	4 (21)	78 (30)
University or above	17 (21)	12 (15)	4 (21)	73 (29)
Diabetes Mellitus, no. (%)	3 (4)	4 (5)	0 (0)	10 (4)
Peripheral vascular disease, no. (%)	1 (1)	0 (0)	0 (0)	1 (1)
Alcohol, no. (%)[b]	60 (78)	63 (79)	15 (79)	177 (69)
Smoker, no. (%)[c]	29 (36)	28 (35)	9 (47)	74 (29)
Working, no. (%)	64 (80)	65 (81)	15 (79)	197 (77)
Insurance Status, no. (%)				
Public	50 (63)	57 (71)	7 (37)	160 (63)
Private	18 (23)	19 (24)	9 (47)	75 (30)
Compensation	10 (13)	3 (4)	3 (16)	18 (7)

[a] Surgical group was significantly younger than non-surgical group in the observational cohort (p=0·007)

[b] A patient was described as consuming alcohol if they were drinking one or more standard drink per month

[c] A patient was described as a smoker if they were smoking one or more cigarettes per month

For the randomised cohort, at 12 months, intention-to-treat analysis demonstrated that the surgical group was not superior to the non-surgical group. With respect to the FAOQ, there was a statistically significant difference favouring the non-surgical group (mean difference 3·2; 95% CI: 0·4 to 5·9; p=0·028), but this difference was not clinically meaningful. The minimum and maximum values of FAOQ scores were 5·8 to 55·6 and 32·6 to 55·6 for the surgical and non-surgical groups, respectively. The surgical group was not superior to the non-surgical group with respect to the PCS (mean difference 0·6, favouring the non-surgical group; 95% CI: -2·9 to 1·8; p=0·63). The surgical group had a significantly higher proportion of participants with overall adverse events (Risk ratio [RR]=2.3; 95% CI: 1.2 to 5.4; p=0.01) and minor adverse events (RR=2.9; 95% CI: 1.3 to 6.4; p=0.009). No significant differences in the proportion of participants with major adverse events were found (RR=2.0; 95% CI: 0.5 to 7.8; p=0.30). A breakdown of the adverse events is provided in the supplementary appendix. There was one death in the non-surgical group. This participant was an intravenous drug user who overdosed and died between 6 and 12 months post injury. The length of hospital stay was shorter in the non-surgical group (mean difference 1·5 days; 95% CI: 0·9 to 2·0; p<0·001). A significantly higher proportion of participants from the surgical group used outpatient physiotherapy (RR=1.5; 95% CI: 1.1 to 2.2; p=0.01). There was no significant difference between the surgical and non-surgical groups with respect to the proportion of participants (of those who were working pre-injury) returning to work at 6 weeks (RR=0.87; 95% CI: 0.62 to 1.2; p=0.41). A summary of the outcomes is presented in Table 2 and Figure 2.

Table 2: Results for the Intention to treat analysis

Variable	Randomised Cohort (Intention to Treat Analysis)			
	Surgical	Non-Surgical	Difference (95% CI)	P value
3 months	**n=72**	**n=69**		
FAOQ, mean (SD)	43·8 (12·0)	44·7 (12·2)	0·9 (-3·1 to 5·0)[a]	0·65
PCS, mean (SD)	47·1 (10·5)	46·8 (11·6)	0·24 (-3·9 to 3·5)[a]	0·90
MCS, mean (SD)	55·0 (10·3)	56·4 (7·4)	1·4 (-1·6 to 4·4)[a]	0·37
Working, no. (%)[c]	55/64 (86%)	57/61 (93%)	0·47 (0·15 to 1·4)[b]	0·17
6 months	**n=72**	**n=69**		
FAOQ, mean (SD)	49·1 (8·4)	51·9 (5·6)	2·7 (0·4 to 5·1)[a]	0·025
PCS, mean (SD)	50·4 (8·9)	52·3 (7·4)	1·9 (-0·90 to 4·6)[a]	0·18
MCS, mean (SD)	56·6 (7·2)	57·2 (7·9)	0·6 (-2·0 to 3·1)[a]	0·66
Working, no. (%)[c]	62/63 (98)	61/61 (100)	N/A	1·00
12 months	**n=71**	**n=68**		
FAOQ, mean (SD)	49·8 (10·6)	53·0 (5·2)	3·2 (0·4 to 5·9)[a]	0·028
PCS, mean (SD)	53·7 (7·1)	53·2 (6·7)	0·6 (-1·8 to 2·9)[a]	0·63
MCS, mean (SD)	55·2 (11·1)	56·5 (9·7)	1·3 (-2·2 to 4·8)[a]	0·47
Working, no. (%)[c]	62/63 (98)	60/60 (100)	N/A	1·00
Any Adverse Event, no. (%)	23/73 (32)	10/74 (14)	2·3 (1·2 to 4·5)[b]	0·009
Major Adverse Event, no. (%)	6/73 (8)	3/74 (4)	2·0 (0·5 to 7·8)[b]	0·33
Minor Adverse Event, no. (%)	20/73 (27)	7/74 (10)	2·8 (1·3 to 6·4)[b]	0·006
Physiotherapy Use, no. (%)	44/73 (60)	28/72 (39)	1·5 (1·1 to 2·2)[b]	0·010

[a] Mean difference (95% CI)

[b] Risk ratio (95% CI)

[c] Based on the number of participants working pre-injury

There were 10 protocol violations; 8 patients randomised to the surgical group were treated non-surgically (7 later declined surgery; 1 was diagnosed with a deep vein thrombosis pre-surgery) and

2 patients randomised to the non-surgical group were treated surgically due to protocol violations by treating surgeons.

An as-treated analysis of the randomised cohort was also conducted. It also showed that the surgical group was not superior to the non-surgical group for any outcomes. These results are presented in the supplementary appendix.

With respect to the observational cohort, at 12 months, the surgical group was not superior to the non-surgical group with respect to the FAOQ (mean difference 5·5, favouring the non-surgical group; 95% CI: -2·4 to 13·3; p=0·16) or PCS (mean difference 0·55, favouring the non-surgical group; 95% CI: -4·8 to 5·9; p=0·83). The surgical group had a significantly higher proportion of participants with overall (RR=5.1; 95% CI: 2.7 to 9.3; p<0.001), major (RR=5.9; 95% CI: 2.3 to 15.4; p=0.003) and minor (RR=6.3; 95% CI: 2.9 to 13.9; p<0.001) adverse events. A breakdown of the adverse events is provided in the supplementary appendix. The length of stay in hospital was shorter in the non-surgical group (mean difference 1·7 days; 95% CI: 0·6 to 2·9; p=0·006). More participants from the surgical group used outpatient physiotherapy (RR=1.5; 95% CI: 1.1 to 2.1; p=0.045). There was no significant difference between the surgical and non-surgical groups with respect to the proportion of participants (of those who were working pre-injury) returning to work at 6 weeks (RR=0.82; 95% CI: 0.46 to 1.5; p=0.047). A summary of the outcomes is presented in the supplementary appendix and Figure 2.

DISCUSSION

Principal findings

In adult patients aged from 18 to 65 years with an isolated type B ankle fracture with minimal talar shift, surgical management was not superior to non-surgical management in terms of ankle function and health-related quality of life at 12 months post-injury. Furthermore, surgical management was not superior to non-surgical management for any secondary outcomes and it was associated with longer length of hospital stay and a higher rate of adverse events.

CROSSBAT was a randomised controlled trial with a parallel observational cohort. The randomised cohort provides a robust comparison of effectiveness between the two treatment groups while the observational cohort provides a concurrent cohort subjected to routine clinical

practice. The two cohorts had largely similar baseline characteristics indicating that the results of the randomised trial are generalisable to similar patients who decline randomisation. Further details of baseline comparisons are provided in the appendix. For these reasons, we believe dissemination of the results of CROSSBAT will help address the practice variation that exists in this area (14,26).

Comparison with other studies

A recent systematic review conducted by Donken *et al* showed there was insufficient evidence to justify surgical management of type B ankle fractures (1). This is because the prevailing RCTs identified by the review included patients with either different patterns of ankle fractures and/or with significant talar shift that potentially confounds the need for surgery (7,27-31). A recent study consented 81 patients to either surgical or non-surgical management for potentially unstable type B ankle fractures (type B ankle fractures that had a positive external rotation stress test indicating significant lateral talar shift) (32). Despite the presence of slight talar misalignment in 20% of the non-surgical group at 1 year, patients managed surgically did not have superior functional outcomes to those managed non-surgically (32). It is possible that a minority of patients in the non-surgical group studied within CROSSBAT also had some misalignment at 1 year, but it was likely to have been subclinical given the good clinical scores. To assess the longer-term implications of surgical and non-surgical management of these ankle fractures, we plan to conduct longer-term follow-up of the participants using both radiographic and functional measures.

Strengths and Limitations

The strengths of CROSSBAT include allocation concealment, which was assured through employment of a third party overseeing randomisation and allocation. In the randomised cohort, loss to follow-up and crossover rates were low, and the as-treated analysis supported the findings of the intention-to-treat analysis. Outcome tools were validated and relevant, and assessors were blinded. The addition of the observational arm added to generalisability of the findings and addressed selection bias.

Limitations include the lack of blinding of the surgeons and participants which is unavoidable with this trial design. It is also possible that some eligible participants were missed, as recruitment fluctuated over time and between sites, given that dedicated research officers were not present

at the sites due to funding constraints. However, all participants that were approached were willing to be recruited to either the randomised or observational cohort. The physiotherapy practices post-injury were not controlled, as participants were free to access physiotherapy services as desired. It was noted that a higher proportion of participants managed surgically sought physiotherapy. This, however, did not result in improved patient reported outcomes for the surgical group. Further, a recent review by Lin *et al* showed no evidence of improved outcomes with physiotherapy-based rehabilitation following ankle fractures (33). Future research would include further follow-up of this cohort to assess the longer-term effect of surgical and non-surgical management of these 44-B1 ankle fractures.

CONCLUSION

The results of this study demonstrate that surgical management is not superior to non-surgical management in type B ankle (fibula) fractures with minimal talar shift in the short-term and is associated with increased adverse events. Further follow-up is needed to assess the difference between the two groups in the longer term.

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Author Contributions: Mittal R and Harris I had full access to all of the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis and act as guarantors.

Study, concept, design, acquisition, critical revision of the manuscript for important intellectual content: RM, IH, SA, JN and CROSSBAT Study Group

Statistical analysis: Mittal R and Harris I conducted and are responsible for the data analysis.

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Competing interests: All authors have completed the ICMJE uniform disclosure form at www.icmje.org/coi_disclosure.pdf and declare: funding and support was received for this study as described; no financial relationships with any organisations that might have an interest in the submitted work in the previous three years; no other relationships or activities that could appear to have influenced the submitted work.

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Ethical approval: This study was approved by the following ethics committees:

- Central Regional Ethics Committee. Reference Number: CEN/12/06/030
- Ethics of Human Research Committee (TQEH and LMH). Reference Number: 2010130
- Flinders Clinical Research Ethics Committee. Reference Number: 358.10
- Hunter New England Human Research Ethics Committee. Reference Number: 09/12/16/5.02
- Melbourne Health Human Research Ethics Committee. Reference Number: 2010.027
- Metro South Human Research Ethics Committee. Reference Number: HREC/11/QPAH/145
- Royal Adelaide Hospital Research Ethics Committee. Reference Number: 100705
- Sir Charles Gairdner Group Human Research Ethics Committee. Reference Number: 2010-092
- University of New South Wales Human Research Ethics Committee. Reference Number: HC12187

Data sharing: Additional data from the study can be obtained from the corresponding author at rajatmittal.syd@gmail.com

Transparency: The lead authors (the manuscript's guarantors) affirm that the manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

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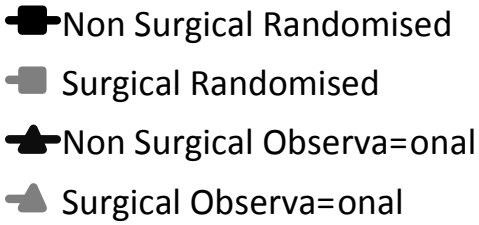
Figure 1: Cohort ascertainment and retention

Figure 2: Differences between surgical and non-surgical groups with respect to ankle function and general health for the randomised and observational cohorts



American Academy of Orthopaedic Surgeons Foot and Ankle Outcomes Questionnaire (FAOQ), physical component scores (PCS) and mental component scores (MCS) of the SF-12v2 general health survey for the randomised and observational cohorts. Higher value represents better function. Error bars represent 95% confidence interval.

436 patients screened

276 Patients declined randomization

160 randomized

276 Patients in the observational cohort

80 Randomised to non-surgery (NS)
78 Received NS as randomized
2 Received surgery
(2) Patient changed mind

80 Randomized to surgery (S)
72 Received S as randomized
8 Did not receive S as randomized
(7) Patients changed mind
(1) Patient developed a DVT

257 Chose non-surgery (NS)

19 Chose surgery (S)

6 weeks Follow-up
72 Had data available
8 No response

6 weeks Follow-up
73 Had data available
7 No response

6 weeks Follow-up
212 Had data available
1 Withdrew
44 No response

6 weeks Follow-up
18 Had data available
1 No response

3 month Follow-up
69 Had data available
11 No response

3 month Follow-up
72 Had data available
8 No response

3 month Follow-up
215 Had data available
1 Withdrew
41 No response

3 month Follow-up
18 Had data available
1 No response

6 month Follow-up
69 Had data available
11 No response

6 month Follow-up
72 Had data available
8 No response

6 month Follow-up
211 Had data available
1 Withdrew
45 No response

6 month Follow-up
18 Had data available
1 No response

12 month Follow-up
68 Had data available
1 Death
11 No response

12 month Follow-up
71 Had data available
9 No response

12 month Follow-up
202Hhad data available
1 Withdrew
54 No response

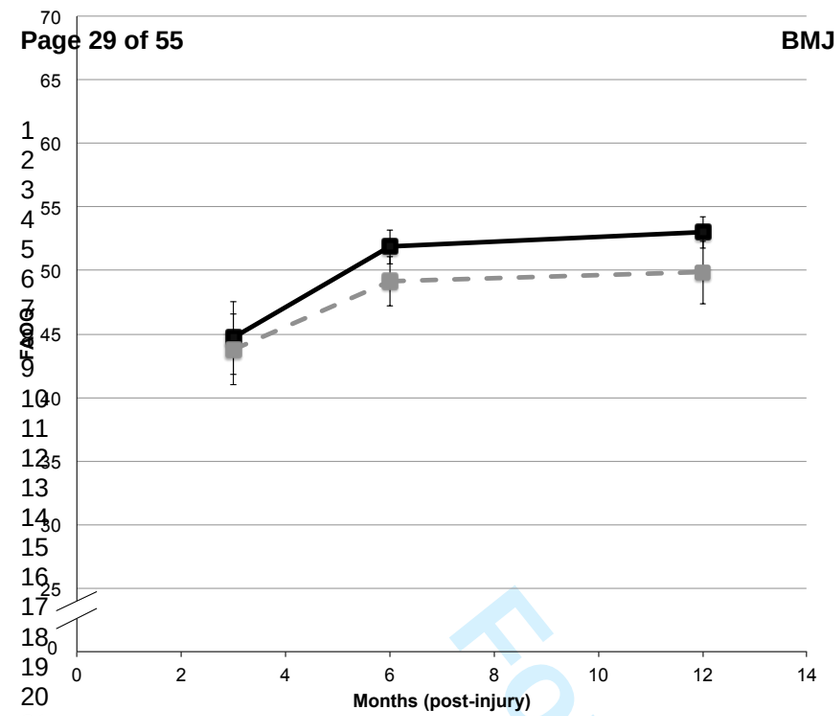
12 month Follow-up
18 Had data available
1 No response

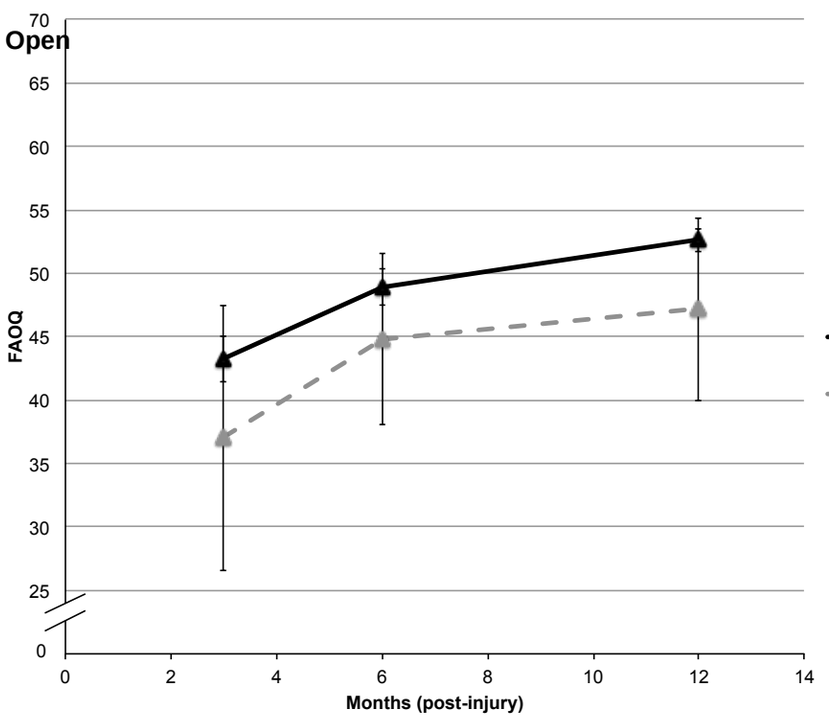
68 Included in analysis
12 Excluded from analysis
(1) Death
(11) No response

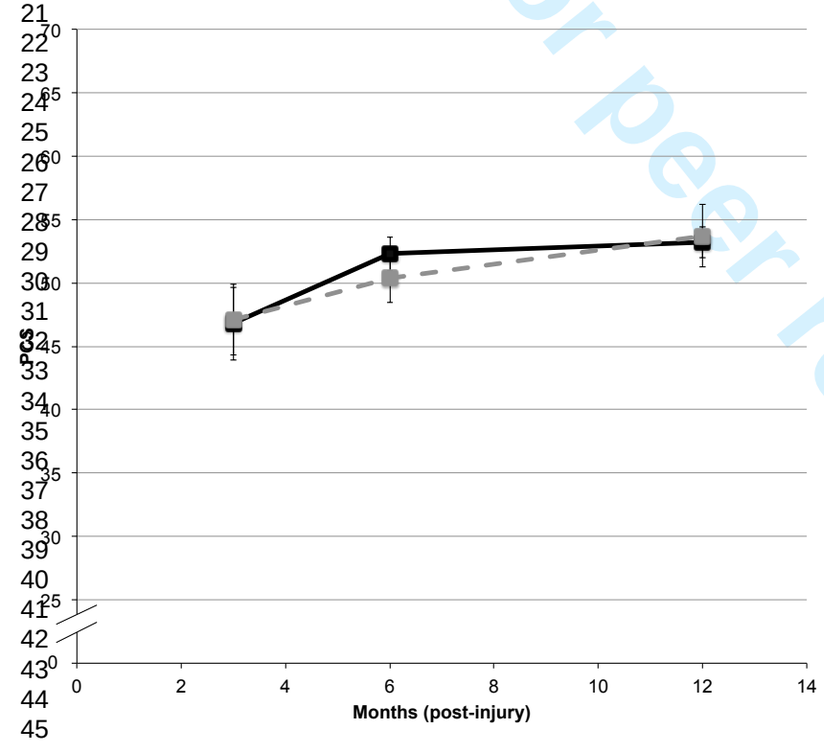
71 Included in analysis
9 Excluded from analysis
(9) No response

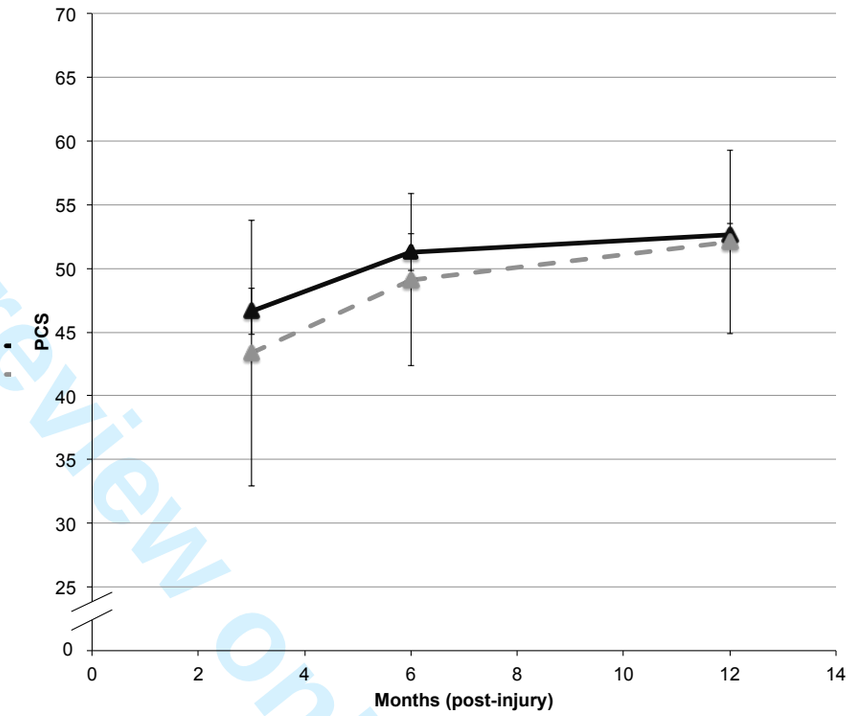
202 Included in analysis
55 Excluded from analysis
(1) Withdrew
(54) No response

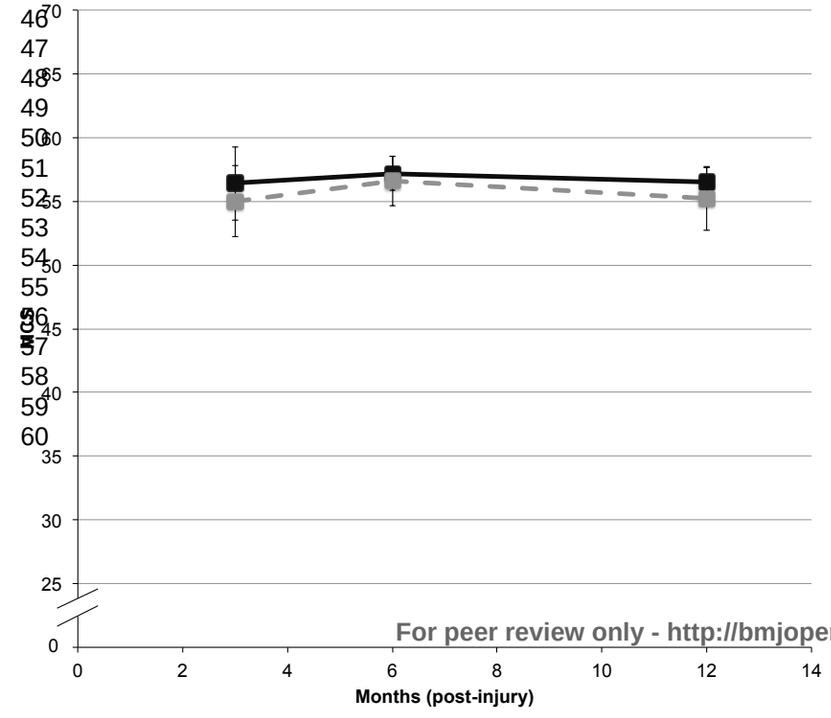
18 Included in analysis
1 Excluded from analysis
(1) No response

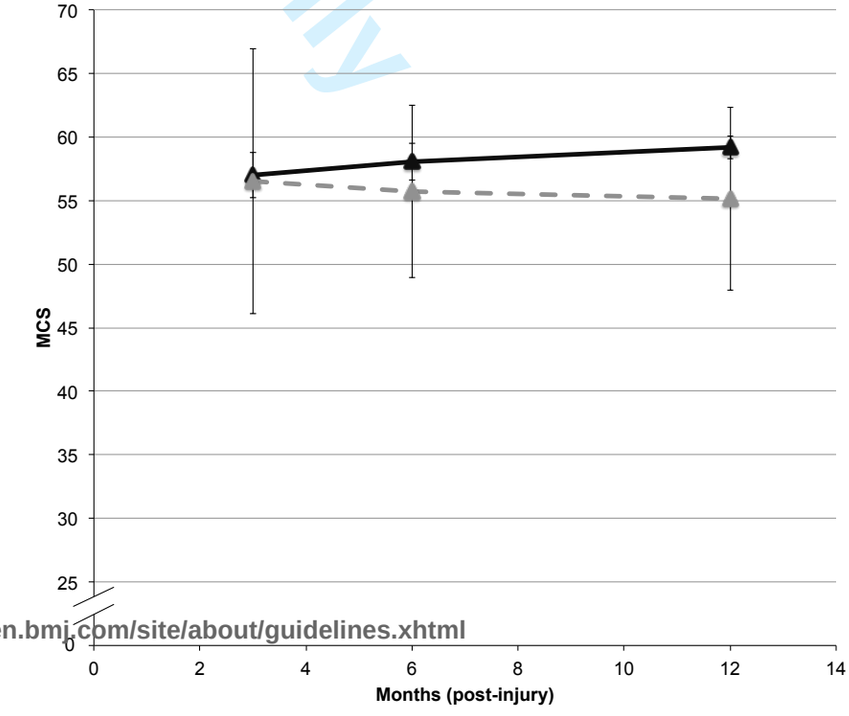












Supplementary Appendix

S1: As treated analysis of the randomised cohort

At 12 months, the surgical group was not superior to the non-surgical group with respect to the FAOQ (mean difference 2·4, favouring the non-surgical group; 95% CI: -0·5 to 5·3; p=0·099) or the PCS (mean difference 0·07, favouring the surgical group; 95% CI: -2·4 to 2·3; p=0·95). The surgical group had a higher proportion of participants with overall adverse events (32% vs. 14%; p=0·008) and minor adverse events (27% vs. 11%; p=0·019). No significant differences in major adverse events were found (10% vs. 6%, p=0·08). More participants from the surgical group used outpatient physiotherapy (59% vs. 42%, p=0·038). There was no significant difference between the surgical vs. non-surgical groups with respect to the proportion of participants (who were working pre-injury) returning to work at 6 weeks (47% vs. 60%; p=0·18) respectively. A summary of the outcomes is presented in Table S1.

Table S1·1: As treated analysis

Variable	Randomised Cohort (As Treated Analysis)			
	Non-Surgical	Surgical	Difference (95% CI)	P value
3 months	**n=74**	**n=67**		
FAOQ[a]	44·7 (12·0)	43·7 (12·2)	1·0 (-3·1 to 5·0)	0·64
PCS[a]	46·6 (11·4)	47·3 (10·5)	0·6 (-3·1 to 4·3)	0·74
MCS[a]	56·4 (7·3)	54·9 (10·5)	1·5 (-1·6 to 4·6)	0·33
Working[bc]	60/64 (94)	52/61 (85)	0·4 (0·1 to 1·3)	0·12
6 months	**n=73**	**n=68**		
FAOQ[a]	51·3 (6·3)	49·5 (8·1)	1·8 (-0·6 to 4·2)	0·15
PCS[a]	52·1 (7·3)	50·6 (9·1)	1·5 (-1·2 to 4·3)	0·27
MCS[a]	57·2 (8·2)	56·5 (6·7)	0·7 (-1·8 to 3·2)	0·59
Working[bc]	63/63 (100)	60/61 (98)	N/A	0·48
12 months	**n=71**	**n=68**		
FAOQ[a]	52·6 (5·8)	50·2 (10·5)	2·4 (-0·5 to 5·3)	0·099
PCS[a]	53·4 (6·4)	53·5 (7·3)	0·1 (2·4 to -2·3)	0·95
MCS[a]	56·9 (9·4)	54·7 (11·5)	2·2 (-1·4 to 5·7)	0·24
Working[bc]	62/62 (100)	60/61 (98)	N/A	0·50
Any Adverse Event[c]	11/79 (14)	22/68 (32)	1·3 (1·1 to 1·5)	0·008
Major Adverse Event[c]	2/79 (3)	7/68 (10)	1·1 (1·0 to 1·2)	0·081
Minor Adverse Event[c]	9/79 (11)	18/68 (27)	1·2 (1·0 to 1·4)	0·019
Physiotherapy Use[c]	32/77 (42)	40/68 (59)	1·4 (1·0 to 2·0)	0·038

[a] Values are mean (standard deviation). Difference is mean difference (95% CI)

[b] Based on the number of participants working pre-injury

[c] Values are number (%). Difference is relative risk (95% CI)

S2: Observational Cohort

Table S2·1: Analysis of observational cohort

Variable	Observational Cohort			
	Non-Surgical	Surgical	Mean Difference	P value
3 months	**n=215**	**n=18**		
FAOQ[a]	43·3 (13·6)	37·0 (22·6)	6·3 (-5·1 to 17·6)	0·26
PCS[a]	46·6 (10·8)	43·4 (16·2)	3·3 (-5·2 to 11·7)	0·42
MCS[a]	57·0 (8·5)	56·5 (9·0)	0·5 (-4·3 to 5·2)	0·84
Working[b]	147/164 (90)	15/17 (88)	0·9 (0·2 to 3·5)	0·69
6 months	**n=211**	**n=18**		
FAOQ[a]	48·9 (10·7)	44·9 (14·6)	4·1 (-3·3 to 11·5)	0·26
PCS[a]	51·3 (8·1)	49·1 (10·2)	2·2 (-2·8 to 7·2)	0·38
MCS[a]	58·1 (6·9)	55·7 (9·5)	2·4 (-2·3 to 7·0)	0·30
Working[b]	158/164 (96)	16/17 (94)	0·6 (0·08 to 4·9)	0·51
12 months	**n=202**	**n=18**		
FAOQ[a]	52·6 (6·6)	47·2 (15·6)	5·5 (-2·4 to 13·3)	0·16
PCS[a]	52·6 (7·3)	52·1 (10·6)	0·6 (-4·8 to 5·9)	0·83
MCS[a]	59·2 (6·6)	55·1 (12·5)	4·0 (-2·2 to 10·3)	0·19
Working[b]	141/144 (98)	14/16 (88)	0·2 (0·03 to 1·0)	0·079
Any Adverse Event[c]	21/212 (10)	9/18 (50)	1·8 (1·1 to 2·9)	<0·001
Major Adverse Event[c]	10/212 (5)	5/18 (28)	1·3 (1·0 to 1·8)	0·003
Minor Adverse Event[c]	13/212 (6)	7/18 (39)	1·5 (1·1 to 2·2)	<0·001
Physiotherapy Use[c]	98/206 (48)	13/18 (72)	1·9 (0·9 to 4·0)	0·045

[a] Values are mean (standard deviation). Difference is mean difference (95% CI)

[b] Based on the number of participants working pre-injury

[c] Values are number (%). Difference is relative risk (95% CI)

S3: Adverse Events

Table S3·1: Adverse events for the randomised cohort

Variable	Randomised Cohort (Intention to Treat Analysis)		
	Non-Surgical (n=72)	Surgical (n=73)	P value
Any adverse event	10 (14)	23 (32)	0·009
Unplanned surgery	2 (3)	5 (7)	0·28
Neurological injury	2 (3)	5 (7)	0·28
Major infection	0 (0)	2 (3)	0·25
Minor infection	1 (1)	11 (15)	0·002
Deep vein thrombosis	3 (4)	5 (7)	0·49
Pulmonary Embolus	0 (0)	0 (0)	
Other[a]	2 (3)	1 (1)	1·00
Death	1 (1)	0 (0)	1·00

Values are n (%)

[a] 1 participant each from the non-surgical and surgical group had stress a fracture in their foot. Both were treated without surgery or admission to hospital. 1 participant in the non-surgical group had Achilles tendonitis that was treated without surgery.

Table S3·2: Adverse events in the observational cohort

Variable	Observational Cohort		
	Non-Surgical (n=212)	Surgical (n=18)	P value
Any adverse event	21 (10)	9 (50)	<0·001
Unplanned surgery	9 (4)	5 (28)	0·002
Neurological injury	5 (2)	3 (17)	0·018
Major infection	0 (0)	2 (11)	0·006
Minor infection	1 (1)	3 (17)	0·002
Deep vein thrombosis	5 (2)	1 (6)	0·39
Pulmonary embolus	1 (1)	0 (0)	1·00
Other[a]	2 (1)	1(6)	0·22
Death	0 (0)	0 (0)	

Values are n (%)

[a] In the non-surgical group, one participant had a torn gastrocnemius muscle and the other had a stress fracture in their foot. One participant in the surgical group felt the cast was too tight and that had to be replaced with a boot.

S4: Comparison of baseline demographics of surgical participants between the randomised and observational cohorts

Table S4·1: Baseline demographics of surgical participants

Variable	Surgical Participants		
	Randomised (n=80)	Observational (n=19)	p value
Age, mean (SD), years	38·1 (13·0)	31·1 (11·5)	0.03
Female, no. (%)	42 (53)	5 (26)	0.045
BMI, mean (SD), kg/m^2	27·7 (5·2)	26·2 (2·9)	0.10
Left Side, no. (%)	41 (51)	11 (58)	0.68
Mechanism, no. (%)			0.15
Fall < 1m	70 (90)	17 (90)	
Fall > 1m	6 (8)	0 (0)	
Motor vehicle accident	2 (3)	2 (11)	
Education, no. (%)			
High School or Lower	31 (39)	11 (58)	0.29
TAFE/Diploma	30 (38)	4 (21)	
University or above	17 (21)	4 (21)	
Diabetes Mellitus, no. (%)	3 (4)	0 (0)	1.00
Peripheral vascular disease, no. (%)	1 (1)	0 (0)	1.00
Alcohol, no. (%)[a]	60 (78)	15 (79)	0.92
Smoker, no. (%)[b]	29 (36)	9 (47)	0.42
Working, no. (%)	64 (80)	15 (79)	0.68
Insurance Status, no. (%)			0.07
Public	50 (63)	7 (37)	
Private	18 (23)	9 (47)	

Compensation	10 (13)	3 (16)	

[a] A patient was described as consuming alcohol if they were drinking one or more standard drink per month

[b] A patient was described as a smoker if they were smoking one or more cigarettes per month

S5: Comparison of baseline demographics of non-surgical participants between the randomised and observational cohorts

Table S5·1: Baseline demographics of non-surgical participants

Variable	Non-Surgical Participants		
	Randomisation (n=80)	Observational (n=257)	p-value
Age, mean (SD), years	39·8 (13·7)	39·4 (13·7)	0.82
Female, no. (%)	41 (51)	115 (45)	0.31
BMI, mean (SD), kg/m^2	28·4 (6·6)	27·6 (5·5)	0.37
Left Side, no. (%)	46 (58)	120 (47)	0.27
Mechanism, no. (%) Fall < 1m Fall > 1m Motor vehicle accident	 67 (84) 8 (10) 5 (6)	 232 (92) 9 (4) 11 (5)	0.055
Education, no. (%) High School or Lower TAFE/Diploma University or above	 44 (55) 23 (29) 12 (15)	 100 (39) 78 (30) 73 (29)	0.018
Diabetes Mellitus, no. (%)	4 (5)	10 (4)	0.75
Peripheral vascular disease, no. (%)	0 (0)	1 (1)	1.00
Alcohol, no. (%)[a]	63 (79)	177 (69)	0.11
Smoker, no. (%)[b]	28 (35)	74 (29)	0.33
Working, no. (%)	65 (81)	197 (77)	0.35
Insurance Status, no. (%) Public Private	 57 (71) 19 (24)	 160 (63) 75 (30)	0.30

Compensation	3 (4)	18 (7)	

[a] A patient was described as consuming alcohol if they were drinking one or more standard drink per month

[b] A patient was described as a smoker if they were smoking one or more cigarettes per month

S6: List of recruiting sites

Table S6·1: List of recruiting hospitals

Hospital	City	State	Country
Bankstown Hospital	Bankstown	New South Wales	Australia
Cairns Base Hospital	Cairns	Queensland	Australia
Campbelltown Hospital	Campbelltown	New South Wales	Australia
Canberra Hospital	Garran	Australian Capital Territory	Australia
Flinders Medical Centre	Bedford Park	South Australia	Australia
John Hunter Hospital	New Lambton	New South Wales	Australia
Liverpool Hospital	Liverpool	New South Wales	Australia
Lyell McEwin Hospital[a]	Elizabeth Vale	South Australia	Australia
Mackay Base Hospital	Mackay	Queensland	Australia
Nambour Base Hospital	Nambour	Queensland	Australia
Prince of Wales Hospital	Randwick	New South Wales	Australia
Princess Alexandra Hospital	Woolloongabba	Queensland	Australia
Royal Adelaide Hospital	Adelaide	South Australia	Australia
Royal Brisbane and Women's Hospital	Herston	Queensland	Australia
Royal Melbourne Hospital	Parkville	Victoria	Australia
Royal Prince Alfred Hospital	Camperdown	New South Wales	Australia
Sir Charles Gairdner Hospital	Nedlands	Western Australia	Australia
St. George Hospital	Kogarah	New South Wales	Australia
Sutherland Hospital	Caringbah	New South Wales	Australia
Wellington Hospital	Newtown	Wellington	New Zealand
Westmead Hospital	Westmead	New South Wales	Australia
Wollongong Hospital	Wollongong	New South Wales	Australia

[a] Lyell McEwin hospital contributed only to the observational arm due to lack of surgeon equipoise

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist Item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	3-4
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	5
	2b	Specific objectives or hypotheses	6
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	6, 7
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	N/A
Participants	4a	Eligibility criteria for participants	7
	4b	Settings and locations where the data were collected	6-7
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	8-10
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	10
	6b	Any changes to trial outcomes after the trial commenced, with reasons	N/A
Sample size	7a	How sample size was determined	11
	7b	When applicable, explanation of any interim analyses and stopping guidelines	N/A
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	7-8
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	7-8
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	7-8
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	7-8

Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	8
	11b	If relevant, description of the similarity of interventions	8-10
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	11
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	11
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	12
	13b	For each group, losses and exclusions after randomisation, together with reasons	12
Recruitment	14a	Dates defining the periods of recruitment and follow-up	12
	14b	Why the trial ended or was stopped	N/A
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	14
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	17-18
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	17-18
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	17-18
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	N/A
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	17-18
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	21-22
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	22
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	22
Other information			
Registration	23	Registration number and name of trial registry	4
Protocol	24	Where the full trial protocol can be accessed, if available	7
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	23

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

CROSSBAT (Combined Randomised and Observational Study of Surgery for Type B Ankle Fracture Treatment): Protocol

Background

Ankle fractures are common, with one in 800 people fracturing their ankle every year.[1-4] The most common pattern involves a fracture of the distal fibula (lateral malleolus) at the level of the tibiofibular syndesmosis, otherwise known as a Weber, AO (Association for the Study of Internal Fixation) or OTA (Orthopaedic Trauma Association) type B ankle fracture.[5-8] If combined with displacement of the ankle mortise or a fracture of the medial malleolus, surgical fixation is the preferred treatment. However, the most common type of ankle fracture involves a type B lateral malleolus fracture without substantial injury to the medial side of the joint or displacement of the talus (AO/OTS type 44-B1).[9]

Management options for these minimally displaced type B ankle fractures include surgical stabilization by internal fixation using a plate and screws or non-surgical management using a cast or a walking boot.[3] Advocates for surgical management emphasize the importance of achieving an anatomic reduction with internal fixation thereby limiting the potential for displacement and instability.[9] Advocates for non-surgical management argue that functional outcomes are not superior with surgical stabilization and is associated with significant related costs and possible adverse

events.[10-12] These include the general risks of anesthesia and surgery such as venous thromboembolism, infection, failure of fixation or the need for revision surgery.

A national survey of 358 orthopedic surgeons in Australia revealed that surgical management of this common fracture is preferred by approximately 40% of surgeons, despite a lack of evidence to support this approach. Recognizing the costs and risks associated with surgery, the lack of evidence supporting the benefit of surgery and the considerable practice variation, we designed a randomized trial to determine the comparative effectiveness of surgical and non-surgical management.

In this study (CROSSBAT: Combined Randomized and Observational Study of Surgery for Type B Ankle Fracture Treatment), involving participants with an isolated type B lateral malleolar ankle fracture, we sought to determine whether surgical management provided superior ankle function and quality of life at 12 months post-injury when compared to non-surgical management. The concurrent observational cohort study was included to provide further evidence regarding the outcomes obtained in routine practice and to address possible selection bias (therefore improving the generalizability of the results).

Study Objective

This study aims to determine whether surgical management confers improved outcomes for participants with isolated AO (Association for the Study of Internal Fixation) or OTA (Orthopaedic Trauma Association) type 44-B1 distal fibula fractures when compared with non-surgical management.

Primary aim

To compare, ankle function and quality of life at 12 months following an isolated AO type 44-B1 distal fibula fracture without significant talar shift, between participants treated surgically and non-surgically.

Secondary aims

To compare the following outcomes between the two groups of participants including

1. Ankle function at 3 and 6 months
2. General health at 3, 6 and 12 months
3. Adverse events
4. Work status
5. Length of stay in hospital

Research plan

Study Design

This trial will be an international, multi-centre, randomized controlled trial with an observational cohort. Randomization will be stratified by site. The protocol will be approved by the relevant ethics committees associated with each site. The trial is registered with clinicaltrials.gov (NCT01134094).

Recruitment of participants

All consecutive participants who present to a recruiting hospital that meet the inclusion criteria during the study period will be screened for eligibility.

Inclusion criteria

- Participants aged between 18 and 65 inclusive.
- AO type 44-B1 fibula fracture with no significant talar shift – significant talar shift was defined as medial clear space being 2mm or more wider than the superior clear space on mortise x-ray view of the ankle
- No other concomitant fractures/dislocations
- Closed injury
- Mobilising unaided/independently pre-injury
- Willingness to be followed up for 12 months

Exclusion criteria

- Medically unfit for general anaesthesia/surgery

- Skeletally immature participants
- Previous trauma or surgery to the affected ankle
- Inability to consent
- Pregnancy
- Other injuries that impede mobilisation e.g. stroke, neurovascular deficit at presentation
- Non-English speaking

Participants will be given a participant information sheet by a researcher at the institution. Written, informed consent will be obtained. Participants' rights to a second opinion or withdrawal from the study will not be affected. Age, gender and clinical details of the fracture will be recorded for eligible participants who decline to participate, so that the generalizability of the study can be assessed.

Baseline measures

The following information will be ascertained:

- Demographic details: Age, gender, height, weight
- Treating surgeon, treatment group, institution
- Side of injury
- Mechanism of injury
    - Fall <1m
    - Fall >1m
    - Motor vehicle injury
- Significant history at time of presentation

- Diabetes Mellitus
- Peripheral Vascular Disease
- Smoking
- Alcohol

- Work status
  - Working
  - Not working
- Insurance status
  - Uninsured (Medicare)
  - Private
  - Compensation

Treatment allocation

If consent is given, the researcher will call a telephone-based service for participant allocation that will be available 24 hours a day, 7 days a week. If the participant declines randomisation, but is willing to be followed-up, treatment will be determined after surgeon-participant discussion.

Interventions

As part of protocol development, authors RM and IH consulted with orthopedic surgeons at meetings of the Australian Orthopedic Trauma Society regarding current practice for the management of type B ankle fractures so that the surgical and non-surgical groups represented acceptable practice. At the same time, surgeon willingness to participate was ascertained. Participating sites were therefore,

identified through this consultation process. Most surgeons at recruiting sites had equipoise and will contribute to the RCT; one recruiting site declined to randomize participants due to lack of equipoise and will contribute to the observational cohort only.

Surgical intervention

The surgical technique for each participant managed surgically will include fixation using a plate and screws. Surgeries will be performed by orthopedic surgeons or by orthopedic trainees under the supervision of orthopedic surgeons following AO principles of fracture fixation. Plate placement and reduction techniques will be left to the discretion of the surgeon. Any adverse intra-operative or post-operative events will be recorded. Post operatively, all participants will be NWB (non-weight bearing) and placed in a POP (plaster of paris) below knee cast or walking boot. Discharge from hospital will determined by the participant's ability to walk 25 meters unaided by standby assistance as determined by a physiotherapist (usual discharge criteria). The treating surgeon will review the participant after 10-14 days for a wound assessment and change of cast to a walking cast or walking boot (cam walker). The participant will be allowed full weight bearing. The participants will be reviewed again at six weeks post-injury with ankle radiographs and the cast or walking boot will be removed.

Non-Operative management

Participants who are treated non-operatively will be treated with a walking boot and allowed WBAT. Discharge from hospital will be determined as for the surgical group.

All participants will be reviewed within 10-14 days post injury by the treating surgeon, who will review the participant with new ankle radiographs. The participants will be reviewed again at six weeks post-injury with ankle radiographs and the walking boot will be removed.

Referral to physiotherapy for all participants will be at the discretion of the treating surgeon. All participants will be followed up regularly and various outcomes will be measured as outlined below.

Outcomes

The primary end-points address functional outcomes and quality of life. Follow-up assessments will be conducted by telephone. Outcome assessors will be blinded to participant intervention.

1. Ankle function will be measured using the American Academy of Orthopaedic Surgeons Foot and Ankle Outcomes Questionnaire (FAOQ) at 12 months post injury. The FAOQ uses the Global Foot and Ankle Scale that assesses overall function and pain. The FAOQ is a validated, participant reported outcome that assesses ankle function with a higher score indicating better function.[13,14]
2. The physical component score (PCS) of the General Health Survey will be measured at 12 months post injury using the Medical Outcomes Study Short Form (SF-12v2). The SF-12v2 is a validated participant reported outcome with a higher score indicating better function that has been used for the assessment of people with ankle fractures.[15-17]

	Time post injury			
Outcomes measured	6 weeks	3 months	6 months	12 months
AAOS Foot and Ankle Instrument		Yes	Yes	Yes
SF-12v2		Yes	Yes	Yes
Adverse Events	Yes	Yes	Yes	Yes
Work		Yes	Yes	Yes

Table 1: Timeline of outcomes measured

Secondary outcomes

1. FAOQ at 3 and 6 months
2. PCS at 3 and 6 months
3. The mental component score (MCS) of the General Health Survey will be measured at 3, 6 and 12 months post injury using the (SF-12v2)
4. Adverse events: Overall adverse events will be measured. Adverse events will be further classified as major (unplanned/repeat surgery; major infection; pulmonary embolus, death or other adverse event requiring hospital admission) or minor (neurological injury not requiring further intervention; minor infection; deep vein thrombosis or other adverse events not requiring hospital admission). Adverse events will be collected at 6 weeks; and 3, 6 and 12 months post-injury to minimise recall bias.

a. Infection: defined as any therapeutic intervention (including the administration of antibiotics beyond or in addition to the initial prophylactic period of 48 hours) provided for infection, whether or not infection is proven by specimen cultures. Infection will be further divided into major infection (requiring hospital admission) or minor infection (not requiring hospital admission)
b. Unplanned surgery: defined as any subsequent procedure relating to the original surgery (or any procedure on the distal fibula in a participant that was initially treated non-operatively)
c. Patient reported neurolovascular symptoms including pins and needles, dysaesthesia/numbess or poor blood circulation in the affected lower limb
d. Clinically diagnosed deep vein thrombosis subsequently confirmed on ultrasound
e. Clinically significant pulmonary embolus confirmed on computed tomographic pulmonary angiogram (CTPA)
f. Death
g. Any other adverse events

5. Work status will be measured as: Returned to usual work, reduced/modified work, not back to normal work, N/A (Not working pre-morbid)
6. Length of inpatient stay: This will be measured from the day of admission to the day participant is considered safe for discharge

Sample Size

The PCS has a standard deviation (sd) of 10 and a 5-point difference (equivalent to a 0.5sd) in the PCS is widely considered to be the minimum clinically important difference.[15,16,18] A sample size of 160 in the randomized cohort will provide 80% power to detect a 5-point difference in the PCS between the two groups at a significance level of 0.05, allowing for 20% loss to follow-up. The same sample size will provide the same power to detect a 0.5sd difference in the FAOQ. A difference of at least 0.5sd needs to exist between the two groups to justify subjecting participants to the risk and complications associated with surgery.[19] There is no sample size target for the observational cohort as this cohort will provide supplementary information for the randomized cohort.

Statistical Analysis Plan

The randomized and observational cohorts will be analyzed separately. The primary analysis, conducted using intention-to-treat principles, will be performed on the randomized cohort; an as treated analysis will also be performed on the randomized cohort for sensitivity testing. Student's t-test will be used to compare continuous variables between groups. Chi-squared or Fisher's exact test will be used for categorical data analysis as appropriate. Statistical analysis will be conducted using SAS X.X (Cary, NC, USA). Both primary outcomes are required to be significantly better in the surgical arm in order for the latter to be regarded as superior.

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Surgery for type B Ankle fracture Treatment (CROSSBAT): Combined Randomised and Observational Study

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Title

Surgery for type B Ankle fracture Treatment (CROSSBAT): Combined Randomised and Observational Study

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ABSTRACT

Background

Isolated type-B ankle fractures with no injury to the medial side are the most common type of ankle fracture.

Objective

This study aimed to determine if surgery is superior to non-surgical management for the treatment of these fractures.

Methods

Design

A pragmatic, multicentre, single-blinded, combined randomised controlled trial and observational study.

Setting/Participants/Interventions

Participants between 18 and 65 years with a type B ankle fracture and minimal talar shift were recruited from 22 hospitals in Australia and New Zealand. Participants willing to be randomised were randomly allocated to undergo surgical fixation followed by mobilisation in a walking boot for 6 weeks. Those treated non-surgically were managed in a walking boot for 6 weeks. Participants not willing to be randomised formed the observational cohort. Randomisation stratified by site and using permuted variable blocks was administered centrally. Outcome assessors were blinded for the primary outcomes.

Primary Outcomes

Patient-reported ankle function using the American Academy of Orthopaedic Surgeons Foot and Ankle Outcomes Questionnaire (FAOQ) and the physical component score (PCS) of the SF-12v2 General Health Survey at 12 months post-injury. Primary analysis was intention-to-treat; the randomised and observational cohorts were analysed separately.

Results

Between August 2010 to October 2013 160 people were randomised (80 surgical and 80 non-surgical); 139 (71 surgical and 68 non-surgical) were analysed as intention-to-treat. 276 formed

the observational cohort (19 surgical and 257 non-surgical); 220 (18 surgical and 202 non-surgical) were analysed. The randomised cohort demonstrated that surgery was not superior to non-surgery for the FAOQ (49·8 vs. 53·0; mean difference 3·2 [95% CI: 0·4 to 5·9], p=0·028), or the PCS (53·7 vs. 53·2; mean difference 0·6 [-2·9 to 1·8], p=0·63). 23 (32%) and 10 (14%) participants had an adverse event in the surgical and non-surgical groups, respectively. Similar results were found in the observational cohort.

Conclusions

Surgery is not superior to non-surgical management for 44-B1 ankle fractures in the short term, and is associated with increased adverse events.

Funding

Australian Orthopaedic Association Research Foundation; National Health and Medical Research Council; Avant Mutual Group; the Royal Australasian College of Surgeons.

Trial Registration

The study was registered on www.clinicaltrials.gov (NCT01134094)

Article Summary

Strengths and limitations of this study

- The strengths of CROSSBAT include allocation concealment.
- In the randomised cohort, loss to follow-up and crossover rates were low, and the as-treated analysis supported the findings of the intention-to-treat analysis.
- Outcome tools were validated and relevant, and assessors were blinded.
- The addition of the observational arm added to generalisability of the findings and addressed selection bias.
- Limitations include the lack of blinding of the surgeons and participants which is unavoidable with this trial design and the use of subjective scoring only.

Ankle fractures are common, with one in 800 people fracturing their ankle every year (1-3). The most common pattern involves a fracture of the distal fibula (lateral malleolus) at the level of the tibiofibular syndesmosis, otherwise known as an AO (Association for the Study of Internal Fixation) or OTA (Orthopaedic Trauma Association) type B ankle fracture (4-7). If combined with displacement of the ankle mortise or a fracture of the medial malleolus, surgical fixation is the preferred treatment. However, the most common type of ankle fracture involves a type B lateral malleolus fracture without fracture of the medial malleolus or displacement of the talus (AO/OTA type 44-B1) (8).

Management options for these AO 44-B1 ankle fractures include surgical stabilisation by internal fixation using a plate and screws or non-surgical management using a cast or a walking boot (1). Advocates for surgical management emphasise the importance of achieving an anatomic reduction with internal fixation thereby limiting the potential for displacement and instability (9). Advocates for non-surgical management argue that functional outcomes are not superior with surgical stabilisation and surgery is associated with significant costs and possible adverse events (8,10-12). These include the general risks of anaesthesia and surgery, such as death, venous thromboembolism, infection, failure of fixation and the need for revision surgery (12). Slobogean *et al* showed that the average costs of non-surgical and surgical management of an unstable, isolated, lateral malleolar fracture were $1,892 and $6,404 (US dollars) respectively (13).

A national survey of 358 orthopaedic surgeons in Australia revealed that surgical management of this common fracture is preferred by approximately 40% of surgeons, despite a lack of evidence to support this approach (14). Recognising the costs and risks associated with surgery, the lack of evidence supporting the benefit of surgery and the considerable practice variation, we designed a randomised trial to determine the comparative effectiveness of surgical and non-surgical management.

In this study involving participants with a 44-B1 ankle fracture, we sought to determine whether surgical management provided superior ankle function and quality of life at 12 months post-injury when compared with non-surgical management. A concurrent observational cohort study was included to provide further evidence regarding the outcomes obtained in routine practice and to improve the generalisability of the results.

METHODS

Study Design

CROSSBAT (Combined Randomised and Observational Study of Surgery for type B Ankle fracture Treatment) was a pragmatic, multicentre, parallel-group, superiority, randomised controlled trial with an observational cohort that recruited participants from August 2010 to October 2013. It involved 22 hospitals in Australia and New Zealand that were a mix of rural, regional and metropolitan centres (a list of recruiting hospitals is provided in the supplementary appendix). The main study was the randomised group, and participants declining randomisation were invited to participate in the observational cohort. The protocol was approved by the ethics committees relevant for each site. The full protocol can be accessed as an online supplement on the BMJ website.

Participants

Consecutive adult patients presenting to a recruiting hospital during the study period with an isolated, closed AO type 44-B1 distal fibula fracture without significant talar shift presenting within ten days of injury were screened for eligibility. Significant talar shift was defined as medial clear space being at least 2mm wider than the superior clear space on mortise x-ray view of the ankle. Further inclusion criteria were patients aged between 18 and 65 years inclusive with no other concomitant fractures/dislocations; mobilising unaided/independently pre-injury; and willing to be followed up for 12 months. Exclusion criteria were participants that were medically unfit for anaesthesia/surgery; skeletally immature; previous trauma or surgery to the fractured ankle; inability to consent; pregnancy; the presence of or co-morbidities that impede mobilisation; and non-English speaking. Written, informed consent was obtained from all patients willing to participate.

Randomisation and blinding

Eligible participants willing to be randomised were randomly allocated in a 1:1 ratio to either the surgical or non-surgical intervention. The National Health and Medical Research Council Clinical Trials Centre (not otherwise involved in the study) generated the randomisation schedule using a permuted block approach with variable block size and stratified by site. Randomisation was administered using an automated telephone-based system that provided allocation concealment. Owing to the nature of the interventions, neither the investigators nor the participants were

blinded. Outcome assessors were independent of the treating teams, and collected data using a standardised telephone interview. As part of the opening conversation, patients were advised not to disclose their treatment so that the assessor could remain blind to treatment. After randomisation, the surgical group received surgery within ten days of injury. Eligible participants who declined randomisation were invited to enter the observational cohort. Treatment for the observational cohort was determined by participant and surgeon preference.

Procedures

During protocol development, members of the Australian Orthopaedic Trauma Society were consulted regarding the best practice for the surgical and non-surgical management of 44-B1 ankle fractures as well as the primary and secondary outcomes. Patient eligibility centred on the presence of the fracture of interest. An external rotation stress test to assess the stability of the ankle was not performed as it was not routine practice in Australia owing to uncertainty about its validity and clinical utility (15,16). The focus for the effectiveness of the interventions was patient-reported outcomes. Radiological measures beyond six weeks were not required as they were unlikely to demonstrate any osteoarthritic changes and because late mal-alignment was considered rare (with both methods of treatment) and unlikely to influence management without clinical symptoms. One recruiting site declined to randomise participants due to lack of equipoise within the orthopaedic department and contributed to the observational cohort only.

The technique for surgical management was surgical fixation using a plate and screws. Surgeries were performed by orthopaedic surgeons or by orthopaedic trainees under the supervision of consultant orthopaedic surgeons following the AO principles of fracture fixation. Plate placement and reduction techniques were left to the discretion of the surgeon. Adverse intra-operative or post-operative events were recorded. Post-operatively, all participants were non-weight bearing and placed in a below-knee plaster cast or walking boot. Discharge from hospital was determined by the participant's ability to walk 25 meters unaided with standby assistance as determined by a physiotherapist (usual discharge criteria). The treating surgeon reviewed the participant after 10-14 days for wound assessment and change of cast to a walking cast or a walking boot (cam walker). The participant was then allowed full weight bearing. The treating surgeon reviewed the participant six weeks post-injury with ankle radiographs and removed the cast or walking boot.

Participants who were treated non-surgically were managed with a walking boot and allowed full weight bearing. Discharge from hospital was determined as for the surgical group. All participants were examined within 10-14 days post-injury by the treating surgeon who assessed the patient with new ankle radiographs. The treating surgeon reviewed the participant six weeks post-injury with repeat ankle radiographs and removed the cast or walking boot.

Referral to physiotherapy for all participants was at the discretion of the treating surgeon.

Outcomes

The primary outcome measures were patient-reported ankle function using the American Academy of Orthopaedic Surgeons Foot and Ankle Outcomes Questionnaire (FAOQ) and the health-related quality of life using the physical component score (PCS) of the SF-12v2 General Health Survey at 12 months post injury. The FAOQ is a validated, patient reported outcome measure that assesses ankle function with a higher value indicating better function (17,18). Normative FAOQ scores were used, with a score of 50 representing the mean in the general population, and a standard deviation of 10 (19). Similarly, the SF-12v2 is a validated patient reported outcome measure that has been used for the assessment of people with ankle fractures, with a higher value indicating better health (20-22). Both the SF-12v2 and the FAOQ have been used previously for patients with ankle fractures (22,23). Secondary endpoints included any adverse events in the 12 months post-injury; return to work at 6 weeks, and 3, 6 and 12 months post-injury; the PCS and FAOQ at 3 and 6 months post-injury; and the mental component score (MCS) of the SF-12v2 at 3, 6 and 12 months post-injury. Adverse events were classified as major (unplanned/repeat surgery; infection requiring admission to hospital; pulmonary embolus or death) or minor (neurological injury not requiring further intervention; infections not requiring hospital admission; deep vein thrombosis or other adverse events not requiring hospital admission or surgery) (24). The adverse events were collected at 6 weeks and 3, 6 and 12 months post-injury. Follow-up assessments were conducted by telephone. Physiotherapy use (number of visits) was measured.

Statistical Analysis

The PCS has a standard deviation (sd) of 10 points and a 5-point difference (equivalent to a 0·5sd) is considered to be the minimum clinically important difference (20,21,25). A sample size of 160 in the randomised cohort was used to provide 80% power to detect a 5-point difference in the PCS

between the two groups at a significance level of 0·05, allowing for 20% loss to follow-up. The normative FAOQ score has a sd of 10, with a 5 point difference (0.5sd) regarded as the minimum clinically important difference (19). The same sample size (160) would provide the same power to detect a 0·5sd difference in the FAOQ. There was no sample size target for the observational cohort as this cohort was to provide supplementary information for the randomised cohort. The randomised and observational cohorts were analysed separately. The primary analysis, conducted using intention-to-treat principles, was performed on the randomised cohort; an as-treated analysis was also performed on the randomised cohort for sensitivity testing. Normality was assessed and the Student's t-test was used to compare continuous variables between groups. Missing data was not imputed. Chi-squared or Fisher's exact test was used for categorical data analysis as appropriate. Statistical analysis was conducted using SAS 9·4 (Cary, NC, USA). Both primary outcomes were required to be significantly better in the surgical arm in order for surgery to be regarded as superior. The trial was registered with clinicaltrials.gov (NCT01134094).

Patient involvement

Patients were involved in the development of the outcome measures (17,19-21). Patients were not involved in the development or conduct of the study. Publication details will be disseminated to study participants that expressed an interest in knowing the results of this study. All participants were thanked in acknowledgements for participating in this study. The burden of intervention on patients was assessed and considered to be low by the ethics committee that assessed the research project (given that both the intervention and control arms are routine practice); no patients were involved in that assessment. This was done as part of a survey of patient factors influencing participation in surgical randomised trials, embedded within CROSSBAT (26).

Role of the funding source

This trial was supported in part by a grant from the Australian Orthopaedic Association Research Foundation. RM was supported with: a postgraduate scholarship from the National Health and Medical Research Council, Avant Doctors-in-training research scholarship and the Foundation for Surgery John Loewenthal Research Fellowship from the Royal Australasian College of Surgeons. The funding organisations of the study had no role in the study design, data collection, data analysis, data interpretation, or writing of the report. The corresponding author had full access to all the data in the study and had final responsibility for the decision to submit for publication.

RESULTS

From August 15, 2010 to October 3, 2013, 436 participants that presented with an isolated, closed AO type 44-B1 distal fibula fracture with minimal talar shift were screened and all were recruited; 160 participants were randomised to the randomised cohort and all 276 participants who declined randomisation were included in the observational cohort. The cohort ascertainment and retention flowchart is presented in Figure 1.

In the randomised cohort, 80 participants were randomised to non-surgical management and 80 were randomised to surgical management. At 12 months, 68 (85%) and 71 (89%) participants were followed up in the non-surgical and surgical groups, respectively. The ITT analysis kept participants in the groups to which they were randomised, but the numbers are incomplete due to missing data.

In the observational cohort, 257 participants were treated non-surgically and 19 were treated surgically as most patients declined surgery when informed of equipoise regarding the two treatment arms. At 12 months, 202 (79%) participants were followed up in the non-surgical group, and 18 (95%) participants were followed-up in the surgical group.

Baseline participant characteristics were similar between the two groups in the randomised cohort. In the observational cohort, the surgical group was significantly younger than the non-surgical group (mean difference 8·3, 95% CI: 2·6 to 14·0; p=0·007). There were no other significant differences in baseline demographics between the two groups in the observational cohort. Baseline characteristics are shown in Table 1. Comparison of baseline data between the randomised and observational cohorts showed that both cohorts had similar demographic profiles.

Table 1: Baseline demographics for CROSSBAT

Variable	Randomised Cohort		Observational Cohort	
	Surgical (n=80)	Non-Surgical (n=80)	Surgical (n=19)	Non-Surgical (n=257)
Age, mean (SD), years	38·1 (13·0)	39·8 (13·7)	31·1 (11·5)[a]	39·4 (13·7)[a]

Female, no. (%)	42 (53)	41 (51)	5 (26)	115 (45)
BMI, mean (SD), kg/m^2	27·7 (5·2)	28·4 (6·6)	26·2 (2·9)	27·6 (5·5)
Left Side, no. (%)	41 (51)	46 (58)	11 (58)	120 (47)
Mechanism, no. (%)				
Fall < 1m	70 (90)	67 (84)	17 (90)	232 (92)
Fall > 1m	6 (8)	8 (10)	0 (0)	9 (4)
Motor vehicle accident	2 (3)	5 (6)	2 (11)	11 (5)
Education, no. (%)				
High School or Lower	31 (39)	44 (55)	11 (58)	100 (39)
TAFE/Diploma	30 (38)	23 (29)	4 (21)	78 (30)
University or above	17 (21)	12 (15)	4 (21)	73 (29)
Diabetes Mellitus, no. (%)	3 (4)	4 (5)	0 (0)	10 (4)
Peripheral vascular disease, no. (%)	1 (1)	0 (0)	0 (0)	1 (1)
Alcohol, no. (%)[b]	60 (78)	63 (79)	15 (79)	177 (69)
Smoker, no. (%)[c]	29 (36)	28 (35)	9 (47)	74 (29)
Working, no. (%)	64 (80)	65 (81)	15 (79)	197 (77)
Insurance Status, no. (%)				
Public	50 (63)	57 (71)	7 (37)	160 (63)
Private	18 (23)	19 (24)	9 (47)	75 (30)
Compensation	10 (13)	3 (4)	3 (16)	18 (7)

[a] Surgical group was significantly younger than non-surgical group in the observational cohort (p=0·007)

[b] A patient was described as consuming alcohol if they were drinking one or more standard drink per month

[c] A patient was described as a smoker if they were smoking one or more cigarettes per month

For the randomised cohort, at 12 months, intention-to-treat analysis demonstrated that the surgical group was not superior to the non-surgical group. With respect to the FAOQ, there was a statistically significant difference favouring the non-surgical group (mean difference 3·2; 95% CI: 0·4 to 5·9; p=0·028), but this difference was not clinically meaningful. The minimum and maximum values of FAOQ scores were 5·8 to 55·6 and 32·6 to 55·6 for the surgical and non-surgical groups, respectively. The surgical group was not superior to the non-surgical group with respect to the PCS (mean difference 0·6, favouring the non-surgical group; 95% CI: -2·9 to 1·8; p=0·63). The surgical group had a significantly higher proportion of participants with overall adverse events (Risk ratio [RR]=2.3; 95% CI: 1.2 to 5.4; p=0.01) and minor adverse events (RR=2.9; 95% CI: 1.3 to 6.4; p=0.009). No significant differences in the proportion of participants with major adverse events were found (RR=2.0; 95% CI: 0.5 to 7.8; p=0.30). A breakdown of the adverse events is provided in the supplementary appendix. There was one death in the non-surgical group. This participant was an intravenous drug user who overdosed and died between 6 and 12 months post injury. The length of hospital stay was shorter in the non-surgical group (mean difference 1·5 days; 95% CI: 0·9 to 2·0; p<0·001). A significantly higher proportion of participants from the surgical group used outpatient physiotherapy (RR=1.5; 95% CI: 1.1 to 2.2; p=0.01). There was no significant difference between the surgical and non-surgical groups with respect to the proportion of participants (of those who were working pre-injury) returning to work at 6 weeks (RR=0.87; 95% CI: 0.62 to 1.2; p=0.41). A summary of the outcomes is presented in Table 2 and Figure 2.

Table 2: Results for the Intention to treat analysis

Variable	Randomised Cohort (Intention to Treat Analysis)			
	Surgical	Non-Surgical	Difference (95% CI)	P value
3 months	**n=72**	**n=69**		
FAOQ, mean (SD)	43·8 (12·0)	44·7 (12·2)	0·9 (-3·1 to 5·0)[a]	0·65
PCS, mean (SD)	47·1 (10·5)	46·8 (11·6)	0·24 (-3·9 to 3·5)[a]	0·90
MCS, mean (SD)	55·0 (10·3)	56·4 (7·4)	1·4 (-1·6 to 4·4)[a]	0·37
Working, no. (%)[c]	55/64 (86%)	57/61 (93%)	0·47 (0·15 to 1·4)[b]	0·17
6 months	**n=72**	**n=69**		
FAOQ, mean (SD)	49·1 (8·4)	51·9 (5·6)	2·7 (0·4 to 5·1)[a]	0·025
PCS, mean (SD)	50·4 (8·9)	52·3 (7·4)	1·9 (-0·90 to 4·6)[a]	0·18
MCS, mean (SD)	56·6 (7·2)	57·2 (7·9)	0·6 (-2·0 to 3·1)[a]	0·66
Working, no. (%)[c]	62/63 (98)	61/61 (100)	N/A	1·00
12 months	**n=71**	**n=68**		
FAOQ, mean (SD)	49·8 (10·6)	53·0 (5·2)	3·2 (0·4 to 5·9)[a]	0·028
PCS, mean (SD)	53·7 (7·1)	53·2 (6·7)	0·6 (-1·8 to 2·9)[a]	0·63
MCS, mean (SD)	55·2 (11·1)	56·5 (9·7)	1·3 (-2·2 to 4·8)[a]	0·47
Working, no. (%)[c]	62/63 (98)	60/60 (100)	N/A	1·00
Any Adverse Event, no. (%)	23/73 (32)	10/74 (14)	2·3 (1·2 to 4·5)[b]	0·009
Major Adverse Event, no. (%)	6/73 (8)	3/74 (4)	2·0 (0·5 to 7·8)[b]	0·33
Minor Adverse Event, no. (%)	20/73 (27)	7/74 (10)	2·8 (1·3 to 6·4)[b]	0·006
Physiotherapy Use, no. (%)	44/73 (60)	28/72 (39)	1·5 (1·1 to 2·2)[b]	0·010

[a] Mean difference (95% CI)

[b] Risk ratio (95% CI)

[c] Based on the number of participants working pre-injury

There were 10 protocol violations; 8 patients randomised to the surgical group were treated non-surgically (7 later declined surgery; 1 was diagnosed with a deep vein thrombosis pre-surgery) and

2 patients randomised to the non-surgical group were treated surgically due to protocol violations by treating surgeons.

An as-treated analysis of the randomised cohort was also conducted. It also showed that the surgical group was not superior to the non-surgical group for any outcomes. These results are presented in the supplementary appendix. Results for the observational cohort are presented in the supplementary appendix as well.

DISCUSSION

Principal findings

In adult patients aged from 18 to 65 years with an isolated type B ankle fracture with minimal talar shift, surgical management was not superior to non-surgical management in terms of ankle function and health-related quality of life at 12 months post-injury. Furthermore, surgical management was not superior to non-surgical management for any secondary outcomes and it was associated with longer length of hospital stay and a higher rate of adverse events.

CROSSBAT was a randomised controlled trial with a parallel observational cohort. The randomised cohort provides a robust comparison of effectiveness between the two treatment groups while the observational cohort provides a concurrent cohort subjected to routine clinical practice. The two cohorts had largely similar baseline characteristics indicating that the results of the randomised trial are generalisable to similar patients who decline randomisation. Further details of baseline comparisons are provided in the appendix. For these reasons, we believe dissemination of the results of CROSSBAT will help address the practice variation that exists in this area (14,27).

Comparison with other studies

A recent systematic review conducted by Donken *et al* showed there was insufficient evidence to justify surgical management of type B ankle fractures (1). This is because the prevailing RCTs identified by the review included patients with either different patterns of ankle fractures and/or with significant talar shift that potentially confounds the need for surgery (7,28-32). A recent study consented 81 patients to either surgical or non-surgical management for potentially unstable type B ankle fractures (type B ankle fractures that had a positive external rotation stress

test indicating significant lateral talar shift) (33). Despite the presence of slight talar misalignment in 20% of the non-surgical group at 1 year, patients managed surgically did not have superior functional outcomes to those managed non-surgically (33). It is possible that a minority of patients in the non-surgical group studied within CROSSBAT also had some misalignment at 1 year, but it was likely to have been subclinical given the good clinical scores. To assess the longer-term implications of surgical and non-surgical management of these ankle fractures, we plan to conduct longer-term follow-up of the participants using both radiographic and functional measures.

Strengths and Limitations

The strengths of CROSSBAT include allocation concealment, which was assured through employment of a third party overseeing randomisation and allocation. In the randomised cohort, loss to follow-up and crossover rates were low, and the as-treated analysis supported the findings of the intention-to-treat analysis. Outcome tools were validated and relevant, and assessors were blinded. The addition of the observational arm added to generalisability of the findings and addressed selection bias.

Limitations include the lack of blinding of the surgeons and participants which is unavoidable with this trial design. It is also possible that some eligible participants were missed, as recruitment fluctuated over time and between sites, given that dedicated research officers were not present at the sites due to funding constraints. However, all participants that were approached were willing to be recruited to either the randomised or observational cohort. The physiotherapy practices post-injury were not controlled, as participants were free to access physiotherapy services as desired. It was noted that a higher proportion of participants managed surgically sought physiotherapy. This, however, did not result in improved patient reported outcomes for the surgical group. Further, a recent review by Lin *et al* showed no evidence of improved outcomes with physiotherapy-based rehabilitation following ankle fractures (34). Future research would include further follow-up of this cohort to assess the longer-term effect of surgical and non-surgical management of these 44-B1 ankle fractures.

CONCLUSION

The results of this study demonstrate that surgical management is not superior to non-surgical management in type B ankle (fibula) fractures with minimal talar shift in the short-term and is associated with increased adverse events. Further follow-up is needed to assess the difference between the two groups in the longer term.

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Study, concept, design, acquisition, critical revision of the manuscript for important intellectual content: RM, IH, SA, JN and CROSSBAT Study Group

Statistical analysis: Mittal R and Harris I conducted and are responsible for the data analysis.

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Ethical approval: This study was approved by the following ethics committees:

- Central Regional Ethics Committee. Reference Number: CEN/12/06/030
- Ethics of Human Research Committee (TQEH and LMH). Reference Number: 2010130

- Flinders Clinical Research Ethics Committee. Reference Number: 358.10
- Hunter New England Human Research Ethics Committee. Reference Number: 09/12/16/5.02
- Melbourne Health Human Research Ethics Committee. Reference Number: 2010.027
- Metro South Human Research Ethics Committee. Reference Number: HREC/11/QPAH/145
- Royal Adelaide Hospital Research Ethics Committee. Reference Number: 100705
- Sir Charles Gairdner Group Human Research Ethics Committee. Reference Number: 2010-092
- University of New South Wales Human Research Ethics Committee. Reference Number: HC12187

Data sharing: Additional data from the study can be obtained from the corresponding author at rajatmittal.syd@gmail.com

Transparency: The lead authors (the manuscript's guarantors) affirm that the manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

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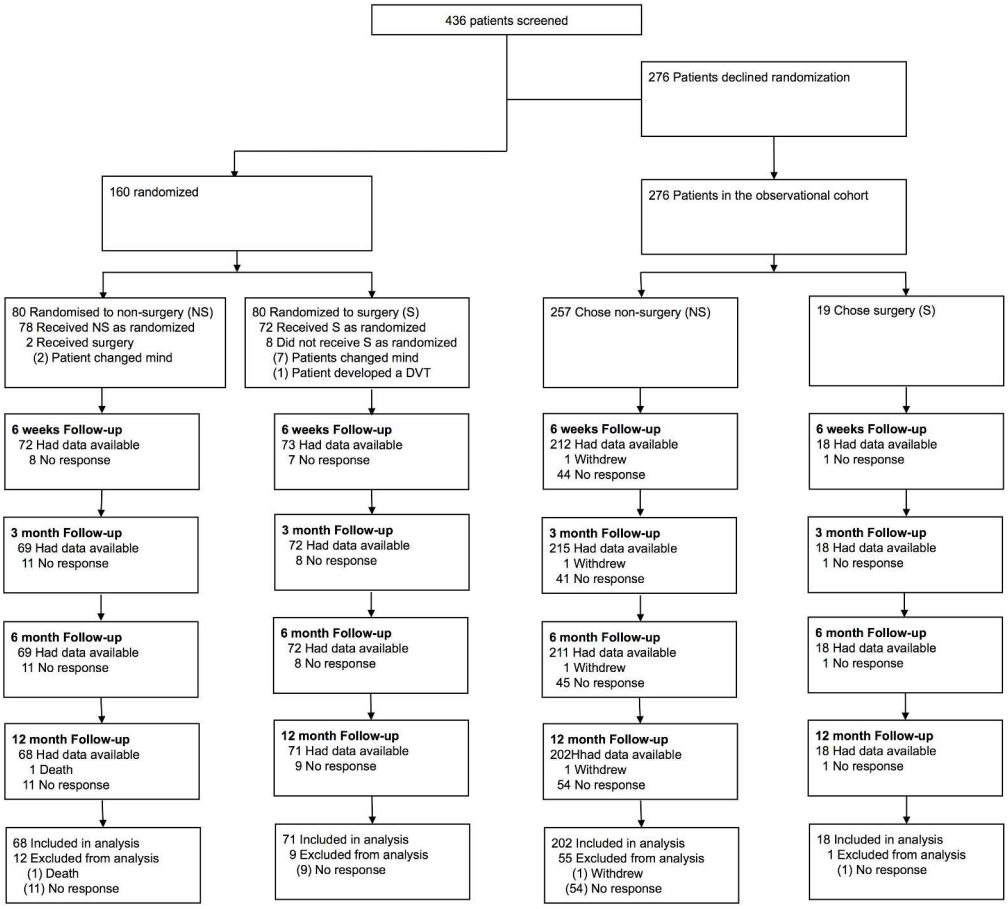
Figure 1: Cohort ascertainment and retention

Figure 2: Differences between surgical and non-surgical groups with respect to ankle function and general health for the randomised cohort

American Academy of Orthopaedic Surgeons Foot and Ankle Outcomes Questionnaire (FAOQ), physical component scores (PCS) and mental component scores (MCS) of the SF-12v2 general health survey for the randomised and cohort. Higher value represents better function. Error bars represent 95% confidence interval. Solid black line represents the non-surgical group while the dashed grey line represents the surgical group



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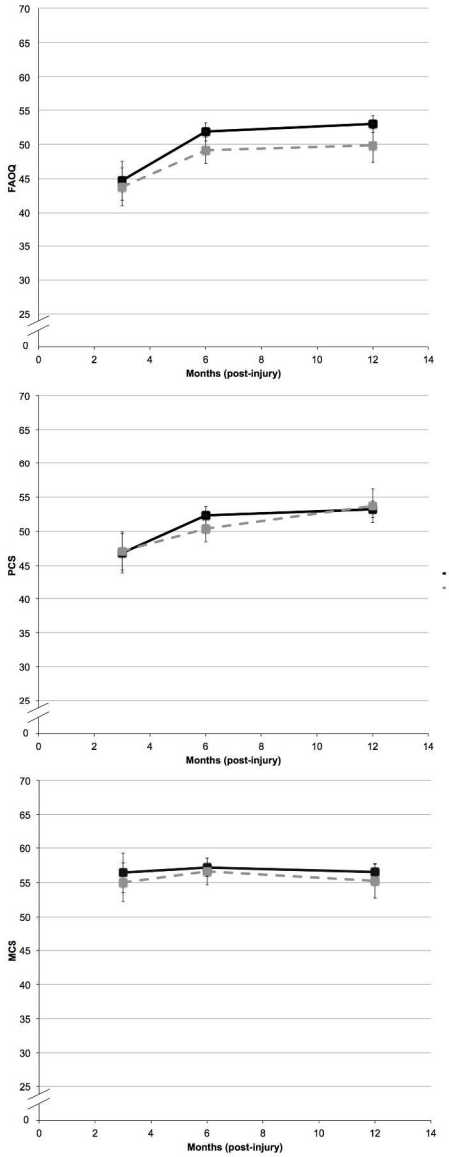

Differences between surgical and non-surgical groups with respect to ankle function and general health for the randomised cohort

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Supplementary Appendix

S1: As treated analysis of the randomised cohort

At 12 months, the surgical group was not superior to the non-surgical group with respect to the FAOQ (mean difference 2·4, favouring the non-surgical group; 95% CI: -0·5 to 5·3; p=0·099) or the PCS (mean difference 0·07, favouring the surgical group; 95% CI: -2·4 to 2·3; p=0·95). The surgical group had a higher proportion of participants with overall adverse events (32% vs. 14%; p=0·008) and minor adverse events (27% vs. 11%; p=0·019). No significant differences in major adverse events were found (10% vs. 6%, p=0·08). More participants from the surgical group used outpatient physiotherapy (59% vs. 42%, p=0·038). There was no significant difference between the surgical vs. non-surgical groups with respect to the proportion of participants (who were working pre-injury) returning to work at 6 weeks (47% vs. 60%; p=0·18) respectively. A summary of the outcomes is presented in Table S1.

Table S1·1: As treated analysis

Variable	Randomised Cohort (As Treated Analysis)			
	Non-Surgical	Surgical	Difference (95% CI)	P value
3 months	**n=74**	**n=67**		
FAOQ[a]	44·7 (12·0)	43·7 (12·2)	1·0 (-3·1 to 5·0)	0·64
PCS[a]	46·6 (11·4)	47·3 (10·5)	0·6 (-3·1 to 4·3)	0·74
MCS[a]	56·4 (7·3)	54·9 (10·5)	1·5 (-1·6 to 4·6)	0·33
Working[bc]	60/64 (94)	52/61 (85)	0·4 (0·1 to 1·3)	0·12
6 months	**n=73**	**n=68**		
FAOQ[a]	51·3 (6·3)	49·5 (8·1)	1·8 (-0·6 to 4·2)	0·15
PCS[a]	52·1 (7·3)	50·6 (9·1)	1·5 (-1·2 to 4·3)	0·27
MCS[a]	57·2 (8·2)	56·5 (6·7)	0·7 (-1·8 to 3·2)	0·59
Working[bc]	63/63 (100)	60/61 (98)	N/A	0·48
12 months	**n=71**	**n=68**		
FAOQ[a]	52·6 (5·8)	50·2 (10·5)	2·4 (-0·5 to 5·3)	0·099
PCS[a]	53·4 (6·4)	53·5 (7·3)	0·1 (2·4 to -2·3)	0·95
MCS[a]	56·9 (9·4)	54·7 (11·5)	2·2 (-1·4 to 5·7)	0·24
Working[bc]	62/62 (100)	60/61 (98)	N/A	0·50
Any Adverse Event[c]	11/79 (14)	22/68 (32)	1·3 (1·1 to 1·5)	0·008
Major Adverse Event[c]	2/79 (3)	7/68 (10)	1·1 (1·0 to 1·2)	0·081
Minor Adverse Event[c]	9/79 (11)	18/68 (27)	1·2 (1·0 to 1·4)	0·019
Physiotherapy Use[c]	32/77 (42)	40/68 (59)	1·4 (1·0 to 2·0)	0·038

[a] Values are mean (standard deviation). Difference is mean difference (95% CI)

[b] Based on the number of participants working pre-injury

[c] Values are number (%). Difference is relative risk (95% CI)

S2: Observational Cohort

With respect to the observational cohort, at 12 months, the surgical group was not superior to the non-surgical group with respect to the FAOQ (mean difference 5·5, favouring the non-surgical group; 95% CI: -2·4 to 13·3; p=0·16) or PCS (mean difference 0·55, favouring the non-surgical group; 95% CI: -4·8 to 5·9; p=0·83). The surgical group had a significantly higher proportion of participants with overall (RR=5.1; 95% CI: 2.7 to 9.3; p<0.001), major (RR=5.9; 95% CI: 2.3 to 15.4; p=0.003) and minor (RR=6.3; 95% CI: 2.9 to 13.9; p<0.001) adverse events. A breakdown of the adverse events is provided in the supplementary appendix. The length of stay in hospital was shorter in the non-surgical group (mean difference 1·7 days; 95% CI: 0·6 to 2·9; p=0·006). More participants from the surgical group used outpatient physiotherapy (RR=1.5; 95% CI: 1.1 to 2.1; p=0.045). There was no significant difference between the surgical and non-surgical groups with respect to the proportion of participants (of those who were working pre-injury) returning to work at 6 weeks (RR=0.82; 95% CI: 0.46 to 1.5; p=0.047). A summary of the outcomes is presented in the supplementary appendix.

Table S2·1: Analysis of observational cohort

Variable	Observational Cohort			
	Non-Surgical	Surgical	Mean Difference	P value
3 months	**n=215**	**n=18**		
FAOQ[a]	43·3 (13·6)	37·0 (22·6)	6·3 (-5·1 to 17·6)	0·26
PCS[a]	46·6 (10·8)	43·4 (16·2)	3·3 (-5·2 to 11·7)	0·42
MCS[a]	57·0 (8·5)	56·5 (9·0)	0·5 (-4·3 to 5·2)	0·84
Working[b]	147/164 (90)	15/17 (88)	0·9 (0·2 to 3·5)	0·69
6 months	**n=211**	**n=18**		
FAOQ[a]	48·9 (10·7)	44·9 (14·6)	4·1 (-3·3 to 11·5)	0·26
PCS[a]	51·3 (8·1)	49·1 (10·2)	2·2 (-2·8 to 7·2)	0·38
MCS[a]	58·1 (6·9)	55·7 (9·5)	2·4 (-2·3 to 7·0)	0·30
Working[b]	158/164 (96)	16/17 (94)	0·6 (0·08 to 4·9)	0·51
12 months	**n=202**	**n=18**		
FAOQ[a]	52·6 (6·6)	47·2 (15·6)	5·5 (-2·4 to 13·3)	0·16
PCS[a]	52·6 (7·3)	52·1 (10·6)	0·6 (-4·8 to 5·9)	0·83

MCS[a]	59·2 (6·6)	55·1 (12·5)	4·0 (-2·2 to 10·3)	0·19
Working[b]	141/144 (98)	14/16 (88)	0·2 (0·03 to 1·0)	0·079
Any Adverse Event[c]	21/212 (10)	9/18 (50)	1·8 (1·1 to 2·9)	<0·001
Major Adverse Event[c]	10/212 (5)	5/18 (28)	1·3 (1·0 to 1·8)	0·003
Minor Adverse Event[c]	13/212 (6)	7/18 (39)	1·5 (1·1 to 2·2)	<0·001
Physiotherapy Use[c]	98/206 (48)	13/18 (72)	1·9 (0·9 to 4·0)	0·045

[a] Values are mean (standard deviation). Difference is mean difference (95% CI)

[b] Based on the number of participants working pre-injury

[c] Values are number (%). Difference is relative risk (95% CI)

S3: Adverse Events

Table S3·1: Adverse events for the randomised cohort

Variable	Randomised Cohort (Intention to Treat Analysis)		
	Non-Surgical (n=72)	Surgical (n=73)	P value
Any adverse event	10 (14)	23 (32)	0·009
Unplanned surgery	2 (3)	5 (7)	0·28
Neurological injury	2 (3)	5 (7)	0·28
Major infection	0 (0)	2 (3)	0·25
Minor infection	1 (1)	11 (15)	0·002
Deep vein thrombosis	3 (4)	5 (7)	0·49
Pulmonary Embolus	0 (0)	0 (0)	
Other[a]	2 (3)	1 (1)	1·00
Death	1 (1)	0 (0)	1·00

Values are n (%)

[a] 1 participant each from the non-surgical and surgical group had stress a fracture in their foot. Both were treated without surgery or admission to hospital. 1 participant in the non-surgical group had Achilles tendonitis that was treated without surgery.

Table S3·2: Adverse events in the observational cohort

Variable	Observational Cohort		
	Non-Surgical (n=212)	Surgical (n=18)	P value
Any adverse event	21 (10)	9 (50)	<0·001
Unplanned surgery	9 (4)	5 (28)	0·002
Neurological injury	5 (2)	3 (17)	0·018
Major infection	0 (0)	2 (11)	0·006
Minor infection	1 (1)	3 (17)	0·002
Deep vein thrombosis	5 (2)	1 (6)	0·39
Pulmonary embolus	1 (1)	0 (0)	1·00
Other[a]	2 (1)	1(6)	0·22
Death	0 (0)	0 (0)	

Values are n (%)

[a] In the non-surgical group, one participant had a torn gastrocnemius muscle and the other had a stress fracture in their foot. One participant in the surgical group felt the cast was too tight and that had to be replaced with a boot.

S4: Comparison of baseline demographics between the randomised and observational cohorts

Table S4·1: Baseline demographics of participants

Variable	Randomised (n=160)	Observational (n=276)	p value
Age, mean (SD), years	39·0 (13·3)	38·8 (13.7)	0.91
Female, no. (%)	83 (52)	120 (44)	0.09
BMI, mean (SD), kg/m^2	28.1 (5·5)	27.5 (5.3)	0.36
Left Side, no. (%)	87 (55)	131 (48)	0.32
Mechanism, no. (%)			0.049
Fall < 1m	137 (87)	249 (92)	
Fall > 1m	14 (9)	9 (3)	
Motor vehicle accident	7 (4)	13 (5)	
Education, no. (%)			0.067
High School or Lower	75 (48)	111 (41)	
TAFE/Diploma	53 (34)	82 (30)	
University or above	29 (18)	77 (29)	
Diabetes Mellitus, no. (%)	7 (4)	10 (4)	0.70
Peripheral vascular disease, no. (%)	1 (1)	1 (1)	1.00
Alcohol, no. (%)[a]	123 (78)	192 (70)	0.062

Smoker, no. (%)[b]	57 (36)	83 (31)	0.24
Working, no. (%)	134 (85)	219 (80)	0.18
Insurance Status, no. (%)			0.27
Public	107 (68)	167 (61)	
Private	37 (24)	84 (31)	
Compensation	13 (8)	21 (8)	

[a] A patient was described as consuming alcohol if they were drinking one or more standard drink per month

[b] A patient was described as a smoker if they were smoking one or more cigarettes per month

S5: Comparison of baseline demographics of surgical participants between the randomised and observational cohorts

Table S5·1: Baseline demographics of surgical participants

Variable	Surgical Participants		
	Randomised (n=80)	Observational (n=19)	p value
Age, mean (SD), years	38·1 (13·0)	31·1 (11·5)	0.03
Female, no. (%)	42 (53)	5 (26)	0.045
BMI, mean (SD), kg/m^2	27·7 (5·2)	26·2 (2·9)	0.10
Left Side, no. (%)	41 (51)	11 (58)	0.68
Mechanism, no. (%)			0.15
Fall < 1m	70 (90)	17 (90)	
Fall > 1m	6 (8)	0 (0)	
Motor vehicle accident	2 (3)	2 (11)	
Education, no. (%)			
High School or Lower	31 (39)	11 (58)	0.29
TAFE/Diploma	30 (38)	4 (21)	
University or above	17 (21)	4 (21)	
Diabetes Mellitus, no. (%)	3 (4)	0 (0)	1.00
Peripheral vascular	1 (1)	0 (0)	1.00

disease, no. (%)			
Alcohol, no. (%)[a]	60 (78)	15 (79)	0.92
Smoker, no. (%)[b]	29 (36)	9 (47)	0.42
Working, no. (%)	64 (80)	15 (79)	0.68
Insurance Status, no. (%)			0.07
Public	50 (63)	7 (37)	
Private	18 (23)	9 (47)	
Compensation	10 (13)	3 (16)	

[a] A patient was described as consuming alcohol if they were drinking one or more standard drink per month

[b] A patient was described as a smoker if they were smoking one or more cigarettes per month

S6: Comparison of baseline demographics of non-surgical participants between the randomised and observational cohorts

Table S6·1: Baseline demographics of non-surgical participants

Variable	Non-Surgical Participants		
	Randomisation (n=80)	Observational (n=257)	p-value
Age, mean (SD), years	39·8 (13·7)	39·4 (13·7)	0.82
Female, no. (%)	41 (51)	115 (45)	0.31
BMI, mean (SD), kg/m^2	28·4 (6·6)	27·6 (5·5)	0.37
Left Side, no. (%)	46 (58)	120 (47)	0.27
Mechanism, no. (%)			0.055
Fall < 1m	67 (84)	232 (92)	
Fall > 1m	8 (10)	9 (4)	
Motor vehicle accident	5 (6)	11 (5)	
Education, no. (%)			0.018
High School or Lower	44 (55)	100 (39)	
TAFE/Diploma	23 (29)	78 (30)	
University or above	12 (15)	73 (29)	
Diabetes Mellitus, no. (%)	4 (5)	10 (4)	0.75
Peripheral vascular	0 (0)	1 (1)	1.00

disease, no. (%)			
Alcohol, no. (%)[a]	63 (79)	177 (69)	0.11
Smoker, no. (%)[b]	28 (35)	74 (29)	0.33
Working, no. (%)	65 (81)	197 (77)	0.35
Insurance Status, no. (%)			0.30
Public	57 (71)	160 (63)	
Private	19 (24)	75 (30)	
Compensation	3 (4)	18 (7)	

[a] A patient was described as consuming alcohol if they were drinking one or more standard drink per month

[b] A patient was described as a smoker if they were smoking one or more cigarettes per month

S7: List of recruiting sites

Table S7·1: List of recruiting hospitals

Hospital	City	State	Country
Bankstown Hospital	Bankstown	New South Wales	Australia
Cairns Base Hospital	Cairns	Queensland	Australia
Campbelltown Hospital	Campbelltown	New South Wales	Australia
Canberra Hospital	Garran	Australian Capital Territory	Australia
Flinders Medical Centre	Bedford Park	South Australia	Australia
John Hunter Hospital	New Lambton	New South Wales	Australia
Liverpool Hospital	Liverpool	New South Wales	Australia
Lyell McEwin Hospital[a]	Elizabeth Vale	South Australia	Australia
Mackay Base Hospital	Mackay	Queensland	Australia
Nambour Base Hospital	Nambour	Queensland	Australia
Prince of Wales Hospital	Randwick	New South Wales	Australia
Princess Alexandra Hospital	Woolloongabba	Queensland	Australia
Royal Adelaide Hospital	Adelaide	South Australia	Australia
Royal Brisbane and Women's Hospital	Herston	Queensland	Australia
Royal Melbourne Hospital	Parkville	Victoria	Australia
Royal Prince Alfred Hospital	Camperdown	New South Wales	Australia
Sir Charles Gairdner Hospital	Nedlands	Western Australia	Australia
St. George Hospital	Kogarah	New South Wales	Australia
Sutherland Hospital	Caringbah	New South Wales	Australia
Wellington Hospital	Newtown	Wellington	New Zealand
Westmead Hospital	Westmead	New South Wales	Australia
Wollongong Hospital	Wollongong	New South Wales	Australia

[a] Lyell McEwin hospital contributed only to the observational arm due to lack of surgeon equipoise

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist Item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	3-4
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	5
	2b	Specific objectives or hypotheses	6
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	6, 7
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	N/A
Participants	4a	Eligibility criteria for participants	7
	4b	Settings and locations where the data were collected	6-7
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	8-10
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	10
	6b	Any changes to trial outcomes after the trial commenced, with reasons	N/A
Sample size	7a	How sample size was determined	11
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Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	11
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Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	12
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Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	14
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Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	17-18
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*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

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Surgery for type B Ankle fracture Treatment (CROSSBAT): Combined Randomised and Observational Study

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Title

Surgery for type B Ankle fracture Treatment (CROSSBAT): Combined Randomised and Observational Study

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ABSTRACT

Background

Isolated type-B ankle fractures with no injury to the medial side are the most common type of ankle fracture.

Objective

This study aimed to determine if surgery is superior to non-surgical management for the treatment of these fractures.

Methods

Design

A pragmatic, multicentre, single-blinded, combined randomised controlled trial and observational study.

Setting/Participants/Interventions

Participants between 18 and 65 years with a type B ankle fracture and minimal talar shift were recruited from 22 hospitals in Australia and New Zealand. Participants willing to be randomised were randomly allocated to undergo surgical fixation followed by mobilisation in a walking boot for 6 weeks. Those treated non-surgically were managed in a walking boot for 6 weeks. Participants not willing to be randomised formed the observational cohort. Randomisation stratified by site and using permuted variable blocks was administered centrally. Outcome assessors were blinded for the primary outcomes.

Primary Outcomes

Patient-reported ankle function using the American Academy of Orthopaedic Surgeons Foot and Ankle Outcomes Questionnaire (FAOQ) and the physical component score (PCS) of the SF-12v2 General Health Survey at 12 months post-injury. Primary analysis was intention-to-treat; the randomised and observational cohorts were analysed separately.

Results

Between August 2010 to October 2013 160 people were randomised (80 surgical and 80 non-surgical); 139 (71 surgical and 68 non-surgical) were analysed as intention-to-treat. 276 formed

the observational cohort (19 surgical and 257 non-surgical); 220 (18 surgical and 202 non-surgical) were analysed. The randomised cohort demonstrated that surgery was not superior to non-surgery for the FAOQ (49·8 vs. 53·0; mean difference 3·2 [95% CI: 0·4 to 5·9], p=0·028), or the PCS (53·7 vs. 53·2; mean difference 0·6 [-2·9 to 1·8], p=0·63). 23 (32%) and 10 (14%) participants had an adverse event in the surgical and non-surgical groups, respectively. Similar results were found in the observational cohort.

Conclusions

Surgery is not superior to non-surgical management for 44-B1 ankle fractures in the short term, and is associated with increased adverse events.

Funding

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Trial Registration

The study was registered on www.clinicaltrials.gov (NCT01134094)

Article Summary

Strengths and limitations of this study

- The strengths of CROSSBAT include allocation concealment.
- In the randomised cohort, loss to follow-up and crossover rates were low, and the as-treated analysis supported the findings of the intention-to-treat analysis.
- Outcome tools were validated and relevant, and assessors were blinded.
- The addition of the observational arm added to generalisability of the findings and addressed selection bias.
- Limitations include the lack of blinding of the surgeons and participants which is unavoidable with this trial design and the use of subjective scoring only.

Ankle fractures are common, with one in 800 people fracturing their ankle every year (1-3). The most common pattern involves a fracture of the distal fibula (lateral malleolus) at the level of the tibiofibular syndesmosis, otherwise known as an AO (Association for the Study of Internal Fixation) or OTA (Orthopaedic Trauma Association) type B ankle fracture (4-7). If combined with displacement of the ankle mortise or a fracture of the medial malleolus, surgical fixation is the preferred treatment. However, the most common type of ankle fracture involves a type B lateral malleolus fracture without fracture of the medial malleolus or displacement of the talus (AO/OTA type 44-B1) (8).

Management options for these AO 44-B1 ankle fractures include surgical stabilisation by internal fixation using a plate and screws or non-surgical management using a cast or a walking boot (1). Advocates for surgical management emphasise the importance of achieving an anatomic reduction with internal fixation thereby limiting the potential for displacement and instability (9). Advocates for non-surgical management argue that functional outcomes are not superior with surgical stabilisation and surgery is associated with significant costs and possible adverse events (8,10-12). These include the general risks of anaesthesia and surgery, such as death, venous thromboembolism, infection, failure of fixation and the need for revision surgery (12). Slobogean *et al* showed that the average costs of non-surgical and surgical management of an unstable, isolated, lateral malleolar fracture were $1,892 and $6,404 (US dollars) respectively (13).

A national survey of 358 orthopaedic surgeons in Australia revealed that surgical management of this common fracture is preferred by approximately 40% of surgeons, despite a lack of evidence to support this approach (14). Recognising the costs and risks associated with surgery, the lack of evidence supporting the benefit of surgery and the considerable practice variation, we designed a randomised trial to determine the comparative effectiveness of surgical and non-surgical management.

In this study involving participants with a 44-B1 ankle fracture, we sought to determine whether surgical management provided superior ankle function and quality of life at 12 months post-injury when compared with non-surgical management. A concurrent observational cohort study was included to provide further evidence regarding the outcomes obtained in routine practice and to improve the generalisability of the results.

METHODS

Study Design

CROSSBAT (Combined Randomised and Observational Study of Surgery for type B Ankle fracture Treatment) was a pragmatic, multicentre, parallel-group, superiority, randomised controlled trial with an observational cohort that recruited participants from August 2010 to October 2013. It involved 22 hospitals in Australia and New Zealand that were a mix of rural, regional and metropolitan centres (a list of recruiting hospitals is provided in the supplementary appendix). The main study was the randomised group, and participants declining randomisation were invited to participate in the observational cohort. The protocol was approved by the ethics committees relevant for each site. The full protocol can be accessed as an online supplement on the BMJ website.

Participants

Consecutive adult patients presenting to a recruiting hospital during the study period with an isolated, closed AO type 44-B1 distal fibula fracture without significant talar shift presenting within ten days of injury were screened for eligibility. Significant talar shift was defined as medial clear space being at least 2mm wider than the superior clear space on mortise x-ray view of the ankle. Further inclusion criteria were patients aged between 18 and 65 years inclusive with no other concomitant fractures/dislocations; mobilising unaided/independently pre-injury; and willing to be followed up for 12 months. Exclusion criteria were participants that were medically unfit for anaesthesia/surgery; skeletally immature; previous trauma or surgery to the fractured ankle; inability to consent; pregnancy; the presence of or co-morbidities that impede mobilisation; and non-English speaking. Written, informed consent was obtained from all patients willing to participate.

Randomisation and blinding

Eligible participants willing to be randomised were randomly allocated in a 1:1 ratio to either the surgical or non-surgical intervention. The National Health and Medical Research Council Clinical Trials Centre (not otherwise involved in the study) generated the randomisation schedule using a permuted block approach with variable block size and stratified by site. Randomisation was administered using an automated telephone-based system that provided allocation concealment. Owing to the nature of the interventions, neither the investigators nor the participants were

blinded. Outcome assessors were independent of the treating teams, and collected data using a standardised telephone interview. As part of the opening conversation, patients were advised not to disclose their treatment so that the assessor could remain blind to treatment. After randomisation, the surgical group received surgery within ten days of injury. Eligible participants who declined randomisation were invited to enter the observational cohort. Treatment for the observational cohort was determined by participant and surgeon preference.

Procedures

During protocol development, members of the Australian Orthopaedic Trauma Society were consulted regarding the best practice for the surgical and non-surgical management of 44-B1 ankle fractures as well as the primary and secondary outcomes. Patient eligibility centred on the presence of the fracture of interest. An external rotation stress test to assess the stability of the ankle was not performed as it was not routine practice in Australia owing to uncertainty about its validity and clinical utility (15,16). The focus for the effectiveness of the interventions was patient-reported outcomes. Radiological measures beyond six weeks were not required as they were unlikely to demonstrate any osteoarthritic changes and because late mal-alignment was considered rare (with both methods of treatment) and unlikely to influence management without clinical symptoms. One recruiting site declined to randomise participants due to lack of equipoise within the orthopaedic department and contributed to the observational cohort only.

The technique for surgical management was surgical fixation using a plate and screws. Surgeries were performed by orthopaedic surgeons or by orthopaedic trainees under the supervision of consultant orthopaedic surgeons following the AO principles of fracture fixation. Plate placement and reduction techniques were left to the discretion of the surgeon. Adverse intra-operative or post-operative events were recorded. Post-operatively, all participants were non-weight bearing and placed in a below-knee plaster cast or walking boot. Discharge from hospital was determined by the participant's ability to walk 25 meters unaided with standby assistance as determined by a physiotherapist (usual discharge criteria). The treating surgeon reviewed the participant after 10-14 days for wound assessment and change of cast to a walking cast or a walking boot (cam walker). The participant was then allowed full weight bearing. The treating surgeon reviewed the participant six weeks post-injury with ankle radiographs and removed the cast or walking boot.

Participants who were treated non-surgically were managed with a walking boot and allowed full weight bearing. Discharge from hospital was determined as for the surgical group. All participants were examined within 10-14 days post-injury by the treating surgeon who assessed the patient with new ankle radiographs. The treating surgeon reviewed the participant six weeks post-injury with repeat ankle radiographs and removed the cast or walking boot.

Referral to physiotherapy for all participants was at the discretion of the treating surgeon.

Outcomes

The primary outcome measures were patient-reported ankle function using the American Academy of Orthopaedic Surgeons Foot and Ankle Outcomes Questionnaire (FAOQ) and the health-related quality of life using the physical component score (PCS) of the SF-12v2 General Health Survey at 12 months post injury. The FAOQ is a validated, patient reported outcome measure that assesses ankle function with a higher value indicating better function (17,18). Normative FAOQ scores were used, with a score of 50 representing the mean in the general population, and a standard deviation of 10 (19). Similarly, the SF-12v2 is a validated patient reported outcome measure that has been used for the assessment of people with ankle fractures, with a higher value indicating better health (20-22). Both the SF-12v2 and the FAOQ have been used previously for patients with ankle fractures (22,23). Secondary endpoints included any adverse events in the 12 months post-injury; return to work at 6 weeks, and 3, 6 and 12 months post-injury; the PCS and FAOQ at 3 and 6 months post-injury; and the mental component score (MCS) of the SF-12v2 at 3, 6 and 12 months post-injury. Adverse events were classified as major (unplanned/repeat surgery; infection requiring admission to hospital; pulmonary embolus or death) or minor (neurological injury not requiring further intervention; infections not requiring hospital admission; deep vein thrombosis or other adverse events not requiring hospital admission or surgery) (24). The adverse events were collected at 6 weeks and 3, 6 and 12 months post-injury. Follow-up assessments were conducted by telephone. Physiotherapy use (number of visits) was measured.

Statistical Analysis

The PCS has a standard deviation (sd) of 10 points and a 5-point difference (equivalent to a 0·5sd) is considered to be the minimum clinically important difference (20,21,25). A sample size of 160 in the randomised cohort was used to provide 80% power to detect a 5-point difference in the PCS

between the two groups at a significance level of 0·05, allowing for 20% loss to follow-up. The normative FAOQ score has a sd of 10, with a 5 point difference (0.5sd) regarded as the minimum clinically important difference (19). The same sample size (160) would provide the same power to detect a 0·5sd difference in the FAOQ. There was no sample size target for the observational cohort as this cohort was to provide supplementary information for the randomised cohort. The randomised and observational cohorts were analysed separately. The primary analysis, conducted using intention-to-treat principles, was performed on the randomised cohort; an as-treated analysis was also performed on the randomised cohort for sensitivity testing. Normality was assessed and the Student's t-test was used to compare continuous variables between groups. Missing data was not imputed. Chi-squared or Fisher's exact test was used for categorical data analysis as appropriate. Statistical analysis was conducted using SAS 9·4 (Cary, NC, USA). Both primary outcomes were required to be significantly better in the surgical arm in order for surgery to be regarded as superior. The trial was registered with clinicaltrials.gov (NCT01134094).

Patient involvement

Patients were involved in the development of the outcome measures (17,19-21). Patients were not involved in the development or conduct of the study. Publication details will be disseminated to study participants that expressed an interest in knowing the results of this study. All participants were thanked in acknowledgements for participating in this study. The burden of intervention on patients was assessed and considered to be low by the ethics committee that assessed the research project (given that both the intervention and control arms are routine practice); no patients were involved in that assessment. This was done as part of a survey of patient factors influencing participation in surgical randomised trials, embedded within CROSSBAT (26).

Role of the funding source

This trial was supported in part by a grant from the Australian Orthopaedic Association Research Foundation. RM was supported with: a postgraduate scholarship from the National Health and Medical Research Council, Avant Doctors-in-training research scholarship and the Foundation for Surgery John Loewenthal Research Fellowship from the Royal Australasian College of Surgeons. The funding organisations of the study had no role in the study design, data collection, data analysis, data interpretation, or writing of the report. The corresponding author had full access to all the data in the study and had final responsibility for the decision to submit for publication.

RESULTS

From August 15, 2010 to October 3, 2013, 436 participants that presented with an isolated, closed AO type 44-B1 distal fibula fracture with minimal talar shift were screened and all were recruited; 160 participants were randomised to the randomised cohort and all 276 participants who declined randomisation were included in the observational cohort. The cohort ascertainment and retention flowchart is presented in Figure 1.

In the randomised cohort, 80 participants were randomised to non-surgical management and 80 were randomised to surgical management. At 12 months, 68 (85%) and 71 (89%) participants were followed up in the non-surgical and surgical groups, respectively. The ITT analysis kept participants in the groups to which they were randomised, but the numbers are incomplete due to missing data.

In the observational cohort, 257 participants were treated non-surgically and 19 were treated surgically as most patients declined surgery when informed of equipoise regarding the two treatment arms. At 12 months, 202 (79%) participants were followed up in the non-surgical group, and 18 (95%) participants were followed-up in the surgical group.

Baseline participant characteristics were similar between the two groups in the randomised cohort. In the observational cohort, the surgical group was significantly younger than the non-surgical group (mean difference 8·3, 95% CI: 2·6 to 14·0; p=0·007). There were no other significant differences in baseline demographics between the two groups in the observational cohort. Baseline characteristics are shown in Table 1. Comparison of baseline data between the randomised and observational cohorts showed that both cohorts had similar demographic profiles.

Table 1: Baseline demographics for CROSSBAT

Variable	Randomised Cohort		Observational Cohort	
	Surgical (n=80)	Non-Surgical (n=80)	Surgical (n=19)	Non-Surgical (n=257)
Age, mean (SD), years	38·1 (13·0)	39·8 (13·7)	31·1 (11·5)[a]	39·4 (13·7)[a]

Female, no. (%)	42 (53)	41 (51)	5 (26)	115 (45)
BMI, mean (SD), kg/m^2	27·7 (5·2)	28·4 (6·6)	26·2 (2·9)	27·6 (5·5)
Left Side, no. (%)	41 (51)	46 (58)	11 (58)	120 (47)
Mechanism, no. (%)				
Fall < 1m	70 (90)	67 (84)	17 (90)	232 (92)
Fall > 1m	6 (8)	8 (10)	0 (0)	9 (4)
Motor vehicle accident	2 (3)	5 (6)	2 (11)	11 (5)
Education, no. (%)				
High School or Lower	31 (39)	44 (55)	11 (58)	100 (39)
TAFE/Diploma	30 (38)	23 (29)	4 (21)	78 (30)
University or above	17 (21)	12 (15)	4 (21)	73 (29)
Diabetes Mellitus, no. (%)	3 (4)	4 (5)	0 (0)	10 (4)
Peripheral vascular disease, no. (%)	1 (1)	0 (0)	0 (0)	1 (1)
Alcohol, no. (%)[b]	60 (78)	63 (79)	15 (79)	177 (69)
Smoker, no. (%)[c]	29 (36)	28 (35)	9 (47)	74 (29)
Working, no. (%)	64 (80)	65 (81)	15 (79)	197 (77)
Insurance Status, no. (%)				
Public	50 (63)	57 (71)	7 (37)	160 (63)
Private	18 (23)	19 (24)	9 (47)	75 (30)
Compensation	10 (13)	3 (4)	3 (16)	18 (7)

[a] Surgical group was significantly younger than non-surgical group in the observational cohort (p=0·007)

[b] A patient was described as consuming alcohol if they were drinking one or more standard drink per month

[c] A patient was described as a smoker if they were smoking one or more cigarettes per month

For the randomised cohort, at 12 months, intention-to-treat analysis demonstrated that the surgical group was not superior to the non-surgical group. With respect to the FAOQ, there was a statistically significant difference favouring the non-surgical group (mean difference 3·2; 95% CI: 0·4 to 5·9; p=0·028), but this difference was not clinically meaningful. The minimum and maximum values of FAOQ scores were 5·8 to 55·6 and 32·6 to 55·6 for the surgical and non-surgical groups, respectively. The surgical group was not superior to the non-surgical group with respect to the PCS (mean difference 0·6, favouring the non-surgical group; 95% CI: -2·9 to 1·8; p=0·63). The surgical group had a significantly higher proportion of participants with overall adverse events (Risk ratio [RR]=2.3; 95% CI: 1.2 to 5.4; p=0.01) and minor adverse events (RR=2.9; 95% CI: 1.3 to 6.4; p=0.009). No significant differences in the proportion of participants with major adverse events were found (RR=2.0; 95% CI: 0.5 to 7.8; p=0.30). A breakdown of the adverse events is provided in the supplementary appendix. There was one death in the non-surgical group. This participant was an intravenous drug user who overdosed and died between 6 and 12 months post injury. The length of hospital stay was shorter in the non-surgical group (mean difference 1·5 days; 95% CI: 0·9 to 2·0; p<0·001). A significantly higher proportion of participants from the surgical group used outpatient physiotherapy (RR=1.5; 95% CI: 1.1 to 2.2; p=0.01). There was no significant difference between the surgical and non-surgical groups with respect to the proportion of participants (of those who were working pre-injury) returning to work at 6 weeks (RR=0.87; 95% CI: 0.62 to 1.2; p=0.41). A summary of the outcomes is presented in Table 2 and Figure 2.

Table 2: Results for the Intention to treat analysis

Variable	Randomised Cohort (Intention to Treat Analysis)			
	Surgical	Non-Surgical	Difference (95% CI)	P value
3 months	**n=72**	**n=69**		
FAOQ, mean (SD)	43·8 (12·0)	44·7 (12·2)	0·9 (-3·1 to 5·0)[a]	0·65
PCS, mean (SD)	47·1 (10·5)	46·8 (11·6)	0·24 (-3·9 to 3·5)[a]	0·90
MCS, mean (SD)	55·0 (10·3)	56·4 (7·4)	1·4 (-1·6 to 4·4)[a]	0·37
Working, no. (%)[c]	55/64 (86%)	57/61 (93%)	0·47 (0·15 to 1·4)[b]	0·17
6 months	**n=72**	**n=69**		
FAOQ, mean (SD)	49·1 (8·4)	51·9 (5·6)	2·7 (0·4 to 5·1)[a]	0·025
PCS, mean (SD)	50·4 (8·9)	52·3 (7·4)	1·9 (-0·90 to 4·6)[a]	0·18
MCS, mean (SD)	56·6 (7·2)	57·2 (7·9)	0·6 (-2·0 to 3·1)[a]	0·66
Working, no. (%)[c]	62/63 (98)	61/61 (100)	N/A	1·00
12 months	**n=71**	**n=68**		
FAOQ, mean (SD)	49·8 (10·6)	53·0 (5·2)	3·2 (0·4 to 5·9)[a]	0·028
PCS, mean (SD)	53·7 (7·1)	53·2 (6·7)	0·6 (-1·8 to 2·9)[a]	0·63
MCS, mean (SD)	55·2 (11·1)	56·5 (9·7)	1·3 (-2·2 to 4·8)[a]	0·47
Working, no. (%)[c]	62/63 (98)	60/60 (100)	N/A	1·00
Any Adverse Event, no. (%)	23/73 (32)	10/74 (14)	2·3 (1·2 to 4·5)[b]	0·009
Major Adverse Event, no. (%)	6/73 (8)	3/74 (4)	2·0 (0·5 to 7·8)[b]	0·33
Minor Adverse Event, no. (%)	20/73 (27)	7/74 (10)	2·8 (1·3 to 6·4)[b]	0·006
Physiotherapy Use, no. (%)	44/73 (60)	28/72 (39)	1·5 (1·1 to 2·2)[b]	0·010

[a] Mean difference (95% CI)

[b] Risk ratio (95% CI)

[c] Based on the number of participants working pre-injury

There were 10 protocol violations; 8 patients randomised to the surgical group were treated non-surgically (7 later declined surgery; 1 was diagnosed with a deep vein thrombosis pre-surgery) and

2 patients randomised to the non-surgical group were treated surgically due to protocol violations by treating surgeons.

An as-treated analysis of the randomised cohort was also conducted. It also showed that the surgical group was not superior to the non-surgical group for any outcomes. These results are presented in the supplementary appendix. Results for the observational cohort are presented in the supplementary appendix as well.

DISCUSSION

Principal findings

In adult patients aged from 18 to 65 years with an isolated type B ankle fracture with minimal talar shift, surgical management was not superior to non-surgical management in terms of ankle function and health-related quality of life at 12 months post-injury. Furthermore, surgical management was not superior to non-surgical management for any secondary outcomes and it was associated with longer length of hospital stay and a higher rate of adverse events.

CROSSBAT was a randomised controlled trial with a parallel observational cohort. The randomised cohort provides a robust comparison of effectiveness between the two treatment groups while the observational cohort provides a concurrent cohort subjected to routine clinical practice. The two cohorts had largely similar baseline characteristics indicating that the results of the randomised trial are generalisable to similar patients who decline randomisation. Further details of baseline comparisons are provided in the appendix. For these reasons, we believe dissemination of the results of CROSSBAT will help address the practice variation that exists in this area (14,27).

Comparison with other studies

A recent systematic review conducted by Donken *et al* showed there was insufficient evidence to justify surgical management of type B ankle fractures (1). This is because the prevailing RCTs identified by the review included patients with either different patterns of ankle fractures and/or with significant talar shift that potentially confounds the need for surgery (7,28-32). A recent study consented 81 patients to either surgical or non-surgical management for potentially unstable type B ankle fractures (type B ankle fractures that had a positive external rotation stress

test indicating significant lateral talar shift) (33). Despite the presence of slight talar misalignment in 20% of the non-surgical group at 1 year, patients managed surgically did not have superior functional outcomes to those managed non-surgically (33). It is possible that a minority of patients in the non-surgical group studied within CROSSBAT also had some misalignment at 1 year, but it was likely to have been subclinical given the good clinical scores. To assess the longer-term implications of surgical and non-surgical management of these ankle fractures, we plan to conduct longer-term follow-up of the participants using both radiographic and functional measures.

Strengths and Limitations

The strengths of CROSSBAT include allocation concealment, which was assured through employment of a third party overseeing randomisation and allocation. In the randomised cohort, loss to follow-up and crossover rates were low, and the as-treated analysis supported the findings of the intention-to-treat analysis. Outcome tools were validated and relevant, and assessors were blinded. The addition of the observational arm added to generalisability of the findings and addressed selection bias.

Limitations include the lack of blinding of the surgeons and participants which is unavoidable with this trial design. It is also possible that some eligible participants were missed, as recruitment fluctuated over time and between sites, given that dedicated research officers were not present at the sites due to funding constraints. However, all participants that were approached were willing to be recruited to either the randomised or observational cohort. The physiotherapy practices post-injury were not controlled, as participants were free to access physiotherapy services as desired. It was noted that a higher proportion of participants managed surgically sought physiotherapy. This, however, did not result in improved patient reported outcomes for the surgical group. Further, a recent review by Lin *et al* showed no evidence of improved outcomes with physiotherapy-based rehabilitation following ankle fractures (34). Some may consider the use of subjective scoring to be a limitation, however, both the SF-12v2 and the FAOQ have been validated and used previously for patients with ankle fractures (22,23). It can also be argued that clinical decisions about treating patients should be based on symptoms rather than radiographs. Although this study presents one-year results, future research would include further follow-up of this cohort to assess the longer-term effect of surgical and non-surgical management of these 44-B1 ankle fractures.

CONCLUSION

The results of this study demonstrate that surgical management is not superior to non-surgical management in type B ankle (fibula) fractures with minimal talar shift in the short-term and is associated with increased adverse events. Further follow-up is needed to assess the difference between the two groups in the longer term.

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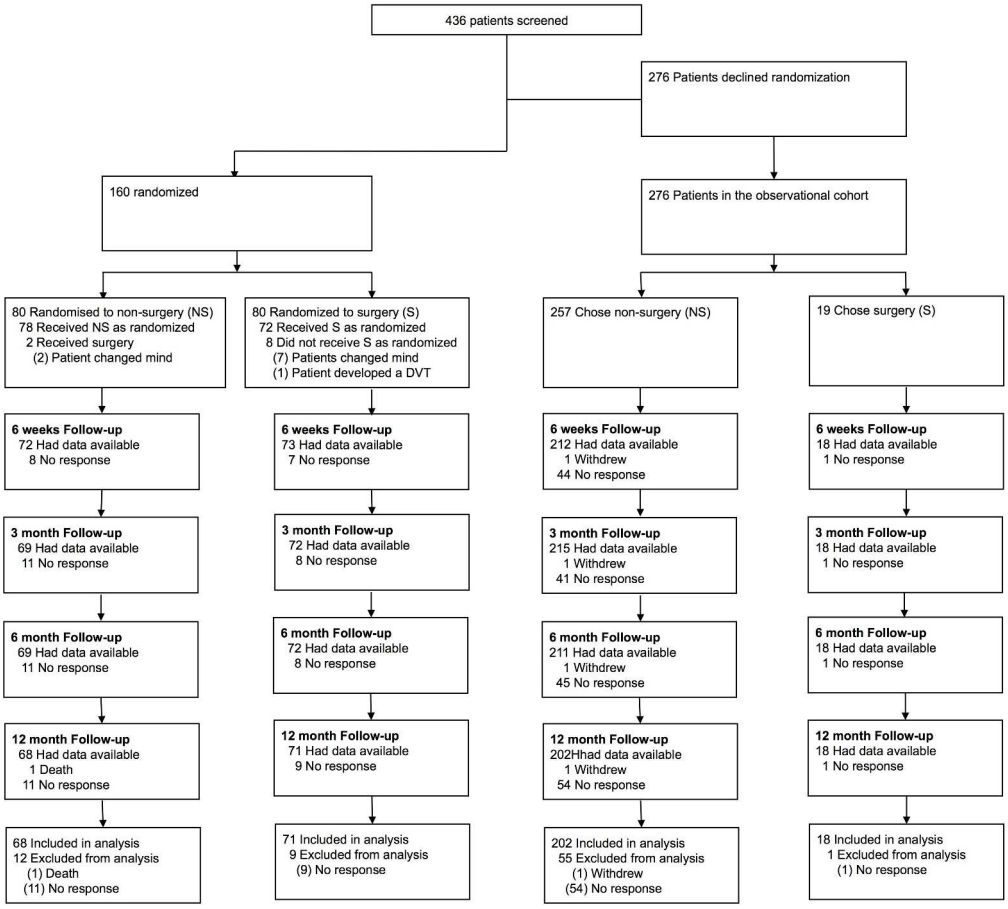
Figure 1: Cohort ascertainment and retention

Figure 2: Differences between surgical and non-surgical groups with respect to ankle function and general health for the randomised cohort

American Academy of Orthopaedic Surgeons Foot and Ankle Outcomes Questionnaire (FAOQ), physical component scores (PCS) and mental component scores (MCS) of the SF-12v2 general health survey for the randomised and cohort. Higher value represents better function. Error bars represent 95% confidence interval. Solid black line represents the non-surgical group while the dashed grey line represents the surgical group



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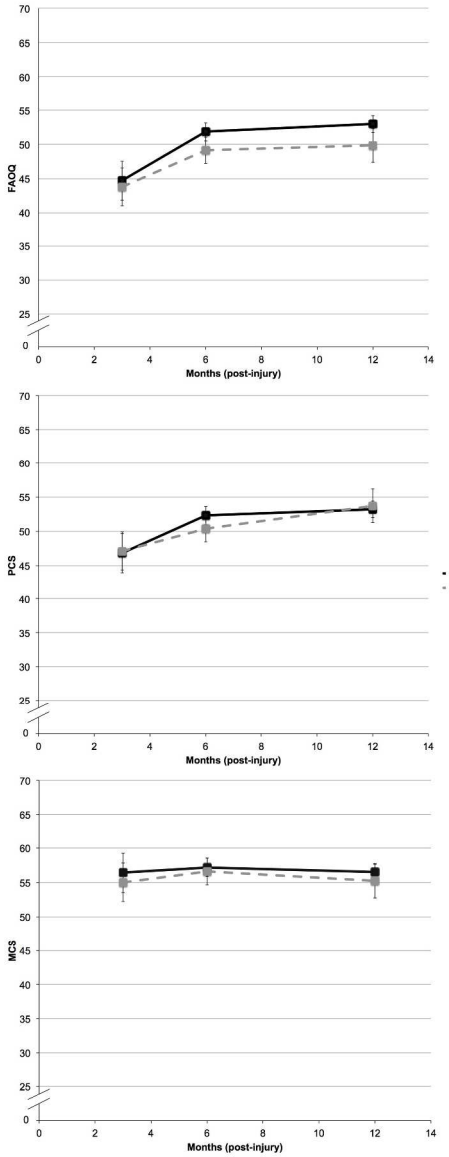

Differences between surgical and non-surgical groups with respect to ankle function and general health for the randomised cohort

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Supplementary Appendix

S1: As treated analysis of the randomised cohort

At 12 months, the surgical group was not superior to the non-surgical group with respect to the FAOQ (mean difference 2·4, favouring the non-surgical group; 95% CI: -0·5 to 5·3; p=0·099) or the PCS (mean difference 0·07, favouring the surgical group; 95% CI: -2·4 to 2·3; p=0·95). The surgical group had a higher proportion of participants with overall adverse events (32% vs. 14%; p=0·008) and minor adverse events (27% vs. 11%; p=0·019). No significant differences in major adverse events were found (10% vs. 6%, p=0·08). More participants from the surgical group used outpatient physiotherapy (59% vs. 42%, p=0·038). There was no significant difference between the surgical vs. non-surgical groups with respect to the proportion of participants (who were working pre-injury) returning to work at 6 weeks (47% vs. 60%; p=0·18) respectively. A summary of the outcomes is presented in Table S1.

Table S1·1: As treated analysis

Variable	Randomised Cohort (As Treated Analysis)			
	Non-Surgical	Surgical	Difference (95% CI)	P value
3 months	**n=74**	**n=67**		
FAOQ[a]	44·7 (12·0)	43·7 (12·2)	1·0 (-3·1 to 5·0)	0·64
PCS[a]	46·6 (11·4)	47·3 (10·5)	0·6 (-3·1 to 4·3)	0·74
MCS[a]	56·4 (7·3)	54·9 (10·5)	1·5 (-1·6 to 4·6)	0·33
Working[bc]	60/64 (94)	52/61 (85)	0·4 (0·1 to 1·3)	0·12
6 months	**n=73**	**n=68**		
FAOQ[a]	51·3 (6·3)	49·5 (8·1)	1·8 (-0·6 to 4·2)	0·15
PCS[a]	52·1 (7·3)	50·6 (9·1)	1·5 (-1·2 to 4·3)	0·27
MCS[a]	57·2 (8·2)	56·5 (6·7)	0·7 (-1·8 to 3·2)	0·59
Working[bc]	63/63 (100)	60/61 (98)	N/A	0·48
12 months	**n=71**	**n=68**		
FAOQ[a]	52·6 (5·8)	50·2 (10·5)	2·4 (-0·5 to 5·3)	0·099
PCS[a]	53·4 (6·4)	53·5 (7·3)	0·1 (2·4 to -2·3)	0·95
MCS[a]	56·9 (9·4)	54·7 (11·5)	2·2 (-1·4 to 5·7)	0·24
Working[bc]	62/62 (100)	60/61 (98)	N/A	0·50
Any Adverse Event[c]	11/79 (14)	22/68 (32)	1·3 (1·1 to 1·5)	0·008
Major Adverse Event[c]	2/79 (3)	7/68 (10)	1·1 (1·0 to 1·2)	0·081
Minor Adverse Event[c]	9/79 (11)	18/68 (27)	1·2 (1·0 to 1·4)	0·019
Physiotherapy Use[c]	32/77 (42)	40/68 (59)	1·4 (1·0 to 2·0)	0·038

[a] Values are mean (standard deviation). Difference is mean difference (95% CI)

[b] Based on the number of participants working pre-injury

[c] Values are number (%). Difference is relative risk (95% CI)

S2: Observational Cohort

With respect to the observational cohort, at 12 months, the surgical group was not superior to the non-surgical group with respect to the FAOQ (mean difference 5·5, favouring the non-surgical group; 95% CI: -2·4 to 13·3; p=0·16) or PCS (mean difference 0·55, favouring the non-surgical group; 95% CI: -4·8 to 5·9; p=0·83). The surgical group had a significantly higher proportion of participants with overall (RR=5.1; 95% CI: 2.7 to 9.3; p<0.001), major (RR=5.9; 95% CI: 2.3 to 15.4; p=0.003) and minor (RR=6.3; 95% CI: 2.9 to 13.9; p<0.001) adverse events. A breakdown of the adverse events is provided in the supplementary appendix. The length of stay in hospital was shorter in the non-surgical group (mean difference 1·7 days; 95% CI: 0·6 to 2·9; p=0·006). More participants from the surgical group used outpatient physiotherapy (RR=1.5; 95% CI: 1.1 to 2.1; p=0.045). There was no significant difference between the surgical and non-surgical groups with respect to the proportion of participants (of those who were working pre-injury) returning to work at 6 weeks (RR=0.82; 95% CI: 0.46 to 1.5; p=0.047). A summary of the outcomes is presented in the supplementary appendix.

Table S2·1: Analysis of observational cohort

Variable	Observational Cohort			
	Non-Surgical	Surgical	Mean Difference	P value
3 months	**n=215**	**n=18**		
FAOQ[a]	43·3 (13·6)	37·0 (22·6)	6·3 (-5·1 to 17·6)	0·26
PCS[a]	46·6 (10·8)	43·4 (16·2)	3·3 (-5·2 to 11·7)	0·42
MCS[a]	57·0 (8·5)	56·5 (9·0)	0·5 (-4·3 to 5·2)	0·84
Working[b]	147/164 (90)	15/17 (88)	0·9 (0·2 to 3·5)	0·69
6 months	**n=211**	**n=18**		
FAOQ[a]	48·9 (10·7)	44·9 (14·6)	4·1 (-3·3 to 11·5)	0·26
PCS[a]	51·3 (8·1)	49·1 (10·2)	2·2 (-2·8 to 7·2)	0·38
MCS[a]	58·1 (6·9)	55·7 (9·5)	2·4 (-2·3 to 7·0)	0·30
Working[b]	158/164 (96)	16/17 (94)	0·6 (0·08 to 4·9)	0·51
12 months	**n=202**	**n=18**		
FAOQ[a]	52·6 (6·6)	47·2 (15·6)	5·5 (-2·4 to 13·3)	0·16
PCS[a]	52·6 (7·3)	52·1 (10·6)	0·6 (-4·8 to 5·9)	0·83

MCS[a]	59·2 (6·6)	55·1 (12·5)	4·0 (-2·2 to 10·3)	0·19
Working[b]	141/144 (98)	14/16 (88)	0·2 (0·03 to 1·0)	0·079
Any Adverse Event[c]	21/212 (10)	9/18 (50)	1·8 (1·1 to 2·9)	<0·001
Major Adverse Event[c]	10/212 (5)	5/18 (28)	1·3 (1·0 to 1·8)	0·003
Minor Adverse Event[c]	13/212 (6)	7/18 (39)	1·5 (1·1 to 2·2)	<0·001
Physiotherapy Use[c]	98/206 (48)	13/18 (72)	1·9 (0·9 to 4·0)	0·045

[a] Values are mean (standard deviation). Difference is mean difference (95% CI)

[b] Based on the number of participants working pre-injury

[c] Values are number (%). Difference is relative risk (95% CI)

S3: Adverse Events

Table S3·1: Adverse events for the randomised cohort

Variable	Randomised Cohort (Intention to Treat Analysis)		
	Non-Surgical (n=72)	Surgical (n=73)	P value
Any adverse event	10 (14)	23 (32)	0·009
Unplanned surgery	2 (3)	5 (7)	0·28
Neurological injury	2 (3)	5 (7)	0·28
Major infection	0 (0)	2 (3)	0·25
Minor infection	1 (1)	11 (15)	0·002
Deep vein thrombosis	3 (4)	5 (7)	0·49
Pulmonary Embolus	0 (0)	0 (0)	
Other[a]	2 (3)	1 (1)	1·00
Death	1 (1)	0 (0)	1·00

Values are n (%)

[a] 1 participant each from the non-surgical and surgical group had stress a fracture in their foot. Both were treated without surgery or admission to hospital. 1 participant in the non-surgical group had Achilles tendonitis that was treated without surgery.

Table S3·2: Adverse events in the observational cohort

Variable	Observational Cohort		
	Non-Surgical (n=212)	Surgical (n=18)	P value
Any adverse event	21 (10)	9 (50)	<0·001
Unplanned surgery	9 (4)	5 (28)	0·002
Neurological injury	5 (2)	3 (17)	0·018
Major infection	0 (0)	2 (11)	0·006
Minor infection	1 (1)	3 (17)	0·002
Deep vein thrombosis	5 (2)	1 (6)	0·39
Pulmonary embolus	1 (1)	0 (0)	1·00
Other[a]	2 (1)	1(6)	0·22
Death	0 (0)	0 (0)	

Values are n (%)

[a] In the non-surgical group, one participant had a torn gastrocnemius muscle and the other had a stress fracture in their foot. One participant in the surgical group felt the cast was too tight and that had to be replaced with a boot.

S4: Comparison of baseline demographics between the randomised and observational cohorts

Table S4·1: Baseline demographics of participants

Variable	Randomised (n=160)	Observational (n=276)	p value
Age, mean (SD), years	39·0 (13·3)	38·8 (13.7)	0.91
Female, no. (%)	83 (52)	120 (44)	0.09
BMI, mean (SD), kg/m^2	28.1 (5·5)	27.5 (5.3)	0.36
Left Side, no. (%)	87 (55)	131 (48)	0.32
Mechanism, no. (%)			0.049
Fall < 1m	137 (87)	249 (92)	
Fall > 1m	14 (9)	9 (3)	
Motor vehicle accident	7 (4)	13 (5)	
Education, no. (%)			0.067
High School or Lower	75 (48)	111 (41)	
TAFE/Diploma	53 (34)	82 (30)	
University or above	29 (18)	77 (29)	
Diabetes Mellitus, no. (%)	7 (4)	10 (4)	0.70
Peripheral vascular disease, no. (%)	1 (1)	1 (1)	1.00
Alcohol, no. (%)[a]	123 (78)	192 (70)	0.062

Smoker, no. (%)[b]	57 (36)	83 (31)	0.24
Working, no. (%)	134 (85)	219 (80)	0.18
Insurance Status, no. (%)			0.27
Public	107 (68)	167 (61)	
Private	37 (24)	84 (31)	
Compensation	13 (8)	21 (8)	

[a] A patient was described as consuming alcohol if they were drinking one or more standard drink per month

[b] A patient was described as a smoker if they were smoking one or more cigarettes per month

S5: Comparison of baseline demographics of surgical participants between the randomised and observational cohorts

Table S5·1: Baseline demographics of surgical participants

Variable	Surgical Participants		
	Randomised (n=80)	Observational (n=19)	p value
Age, mean (SD), years	38·1 (13·0)	31·1 (11·5)	0.03
Female, no. (%)	42 (53)	5 (26)	0.045
BMI, mean (SD), kg/m^2	27·7 (5·2)	26·2 (2·9)	0.10
Left Side, no. (%)	41 (51)	11 (58)	0.68
Mechanism, no. (%)			0.15
Fall < 1m	70 (90)	17 (90)	
Fall > 1m	6 (8)	0 (0)	
Motor vehicle accident	2 (3)	2 (11)	
Education, no. (%)			
High School or Lower	31 (39)	11 (58)	0.29
TAFE/Diploma	30 (38)	4 (21)	
University or above	17 (21)	4 (21)	
Diabetes Mellitus, no. (%)	3 (4)	0 (0)	1.00
Peripheral vascular	1 (1)	0 (0)	1.00

disease, no. (%)			
Alcohol, no. (%)[a]	60 (78)	15 (79)	0.92
Smoker, no. (%)[b]	29 (36)	9 (47)	0.42
Working, no. (%)	64 (80)	15 (79)	0.68
Insurance Status, no. (%)			0.07
Public	50 (63)	7 (37)	
Private	18 (23)	9 (47)	
Compensation	10 (13)	3 (16)	

[a] A patient was described as consuming alcohol if they were drinking one or more standard drink per month

[b] A patient was described as a smoker if they were smoking one or more cigarettes per month

S6: Comparison of baseline demographics of non-surgical participants between the randomised and observational cohorts

Table S6·1: Baseline demographics of non-surgical participants

Variable	Non-Surgical Participants		
	Randomisation (n=80)	Observational (n=257)	p-value
Age, mean (SD), years	39·8 (13·7)	39·4 (13·7)	0.82
Female, no. (%)	41 (51)	115 (45)	0.31
BMI, mean (SD), kg/m^2	28·4 (6·6)	27·6 (5·5)	0.37
Left Side, no. (%)	46 (58)	120 (47)	0.27
Mechanism, no. (%)			0.055
Fall < 1m	67 (84)	232 (92)	
Fall > 1m	8 (10)	9 (4)	
Motor vehicle accident	5 (6)	11 (5)	
Education, no. (%)			0.018
High School or Lower	44 (55)	100 (39)	
TAFE/Diploma	23 (29)	78 (30)	
University or above	12 (15)	73 (29)	
Diabetes Mellitus, no. (%)	4 (5)	10 (4)	0.75
Peripheral vascular	0 (0)	1 (1)	1.00

disease, no. (%)			
Alcohol, no. (%)[a]	63 (79)	177 (69)	0.11
Smoker, no. (%)[b]	28 (35)	74 (29)	0.33
Working, no. (%)	65 (81)	197 (77)	0.35
Insurance Status, no. (%)			0.30
Public	57 (71)	160 (63)	
Private	19 (24)	75 (30)	
Compensation	3 (4)	18 (7)	

[a] A patient was described as consuming alcohol if they were drinking one or more standard drink per month

[b] A patient was described as a smoker if they were smoking one or more cigarettes per month

S7: List of recruiting sites

Table S7·1: List of recruiting hospitals

Hospital	City	State	Country
Bankstown Hospital	Bankstown	New South Wales	Australia
Cairns Base Hospital	Cairns	Queensland	Australia
Campbelltown Hospital	Campbelltown	New South Wales	Australia
Canberra Hospital	Garran	Australian Capital Territory	Australia
Flinders Medical Centre	Bedford Park	South Australia	Australia
John Hunter Hospital	New Lambton	New South Wales	Australia
Liverpool Hospital	Liverpool	New South Wales	Australia
Lyell McEwin Hospital[a]	Elizabeth Vale	South Australia	Australia
Mackay Base Hospital	Mackay	Queensland	Australia
Nambour Base Hospital	Nambour	Queensland	Australia
Prince of Wales Hospital	Randwick	New South Wales	Australia
Princess Alexandra Hospital	Woolloongabba	Queensland	Australia
Royal Adelaide Hospital	Adelaide	South Australia	Australia
Royal Brisbane and Women's Hospital	Herston	Queensland	Australia
Royal Melbourne Hospital	Parkville	Victoria	Australia
Royal Prince Alfred Hospital	Camperdown	New South Wales	Australia
Sir Charles Gairdner Hospital	Nedlands	Western Australia	Australia
St. George Hospital	Kogarah	New South Wales	Australia
Sutherland Hospital	Caringbah	New South Wales	Australia
Wellington Hospital	Newtown	Wellington	New Zealand
Westmead Hospital	Westmead	New South Wales	Australia
Wollongong Hospital	Wollongong	New South Wales	Australia

[a] Lyell McEwin hospital contributed only to the observational arm due to lack of surgeon equipoise

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist Item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	3-4
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	6
	2b	Specific objectives or hypotheses	6
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	7-8
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	N/A
Participants	4a	Eligibility criteria for participants	7-8
	4b	Settings and locations where the data were collected	7
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	8-9
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	9-10
	6b	Any changes to trial outcomes after the trial commenced, with reasons	N/A
Sample size	7a	How sample size was determined	10-11
	7b	When applicable, explanation of any interim analyses and stopping guidelines	N/A
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	7
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	7-8
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	7
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	7

Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	8
	11b	If relevant, description of the similarity of interventions	8-9
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	9-10
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	10-11
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	12
	13b	For each group, losses and exclusions after randomisation, together with reasons	27
Recruitment	14a	Dates defining the periods of recruitment and follow-up	12
	14b	Why the trial ended or was stopped	N/A
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	13-14
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	15-16
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	16
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	16
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	N/A
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	15-16
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	16
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	15-16
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	15-16
Other information			
Registration	23	Registration number and name of trial registry	4
Protocol	24	Where the full trial protocol can be accessed, if available	7
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	19

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.