

BMJ Open Surgery for Type B Ankle Fracture Treatment: a Combined Randomised and Observational Study (CROSSBAT)

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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: A pragmatic, multicentre, single-blinded, combined randomised controlled trial and observational study. Setting 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 postinjury. Primary analysis was intention to treat; the randomised and observational cohorts were analysed separately.

Results: From 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.

Trial registration number: NCT01134094.

Strengths and limitations of this study

- The strengths of CROSSBAT (Combined Randomised and Observational Study of Surgery for type B Ankle fracture Treatment) include allocation concealment.
- In the randomised cohort, loss to follow-up and cross-over 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 1 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 Association for the Study of Internal Fixation (AO) or Orthopaedic Trauma Association (OTA) 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 to 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*¹³ showed that the average costs of non-surgical and surgical management of an unstable, isolated, lateral malleolar fracture were US\$1892 and US\$6404, respectively.

A national survey of 358 orthopaedic surgeons in Australia revealed that surgical management of this common fracture is preferred by ~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 postinjury 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 online 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 supplementary material 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 10 days of injury were screened for eligibility. Significant talar shift was defined as medial clear space being at least 2 mm wider than the superior clear space on a 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

preinjury; and willing to be followed up for 12 months. Exclusion criteria were participants who were medically unfit for anaesthesia/surgery; skeletally immature; previous trauma or surgery to the fractured ankle; inability to consent; pregnancy; the presence of comorbidities 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 10 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 6 weeks were not required as they were unlikely to demonstrate any osteoarthritic changes and because late malalignment 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 intraoperative or postoperative events were recorded. Postoperatively, 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 m 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 6 weeks postinjury 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 postinjury by the treating surgeon who assessed the patient with new ankle radiographs. The treating surgeon reviewed the participant 6 weeks postinjury 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 postinjury. 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 an SD 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 end points included any adverse events in the 12 months postinjury; return to work at 6 weeks and 3, 6 and 12 months postinjury; the PCS and FAOQ at 3 and 6 months postinjury; and the mental component score of the SF-12v2 at 3, 6 and 12 months postinjury. 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 postinjury. Follow-up assessments were conducted by telephone. Physiotherapy use (number of visits) was measured.

Statistical analysis

The PCS has an SD of 10 points and a 5-point difference (equivalent to a 0.5 SD) 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 five-point difference in the PCS between the two groups at a significance level of 0.05, allowing for a 20% loss to follow-up. The normative FAOQ score has an SD of 10, with a 5-point difference (0.5 SD) regarded as the minimum clinically important difference.¹⁹ The same sample size (160) would provide the same power to detect a 0.5 SD difference in the FAOQ. There was no sample size target for the observational cohort as this cohort was to provide online 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 Student's t-test was used to compare continuous variables between groups. Missing data were not imputed. The χ^2 or Fisher's exact test was used for categorical data analysis as appropriate. Statistical analysis was conducted using SAS V.9.4 (Cary, North Carolina, 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} They were not involved in the development or conduct of the study. Publication details will be disseminated to study participants who expressed an interest in knowing the results of this study. All participants were thanked in Acknowledgements statement 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 15 August 2010 to 3 October 2013, 436 participants who 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 flow chart 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 intention-to-treat 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

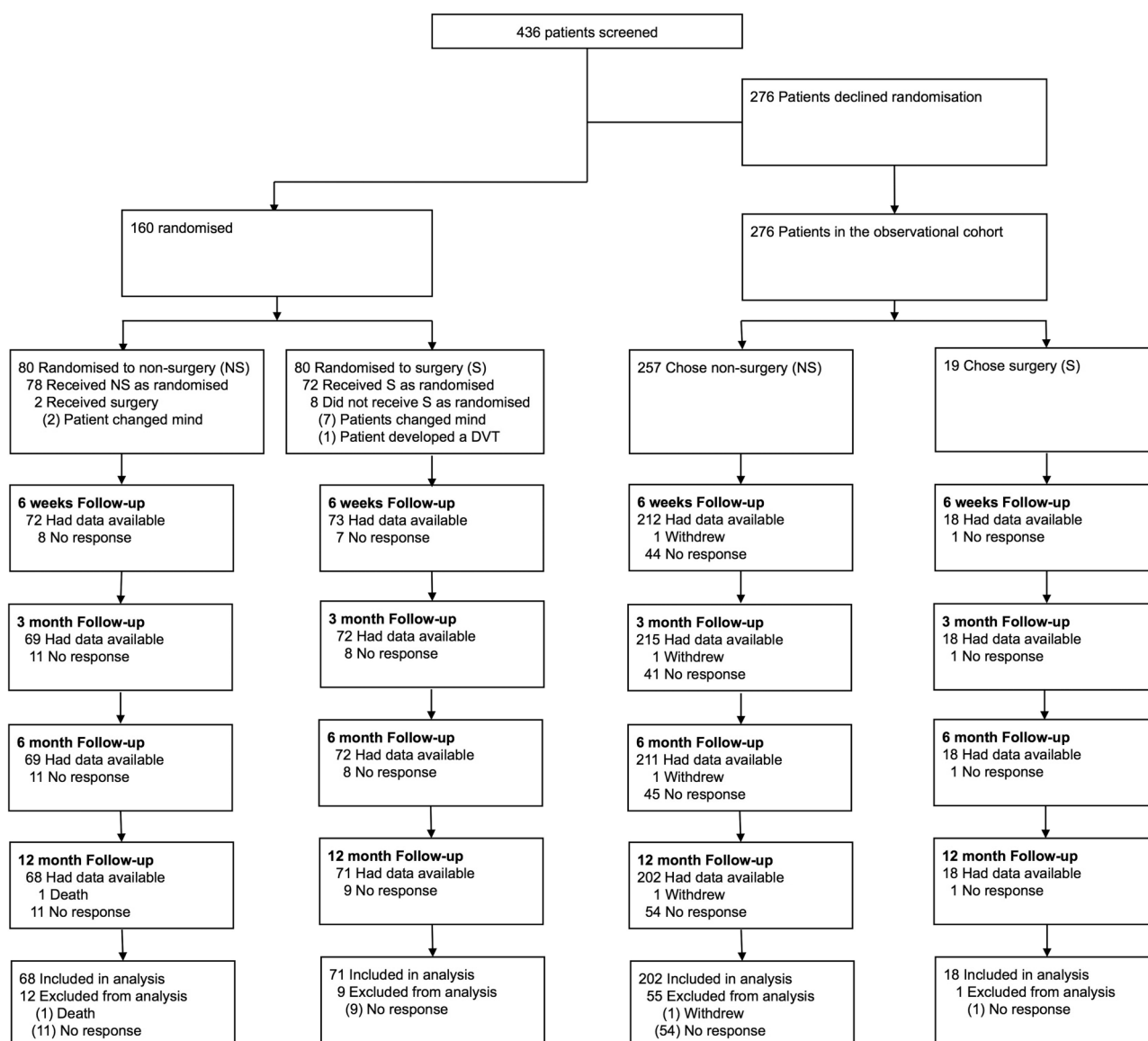


Figure 1 Cohort ascertainment and retention. DVT, deep vein thrombosis.

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)*	39.4 (13.7)*
Female, n (%)	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, n (%)	41 (51)	46 (58)	11 (58)	120 (47)
Mechanism, n (%)				
Fall <1 m	70 (90)	67 (84)	17 (90)	232 (92)
Fall >1 m	6 (8)	8 (10)	0 (0)	9 (4)
Motor vehicle accident	2 (3)	5 (6)	2 (11)	11 (5)
Education, n (%)				
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, n (%)	3 (4)	4 (5)	0 (0)	10 (4)
Peripheral vascular disease, n (%)	1 (1)	0 (0)	0 (0)	1 (1)
Alcohol, n (%)†	60 (78)	63 (79)	15 (79)	177 (69)
Smoker, n (%)‡	29 (36)	28 (35)	9 (47)	74 (29)
Working, n (%)	64 (80)	65 (81)	15 (79)	197 (77)
Insurance status, n (%)				
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)

*Surgical group was significantly younger than non-surgical group in the observational cohort ($p=0.007$).

†A patient was described as consuming alcohol if they were drinking one or more standard drinks per month.

‡A patient was described as a smoker if they were smoking one or more cigarettes per month.

BMI, body mass index; CROSSBAT, Combined Randomised and Observational Study of Surgery for type B Ankle fracture Treatment; TAFE, Technical and Further Education.

and observational cohorts showed that both cohorts had similar demographic profiles.

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 5.8–55.6 and 32.6–55.6 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 online 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 preinjury) 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.

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 presurgery) 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 online supplementary appendix. Results for the observational cohort are presented in the online 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 postinjury. Furthermore, surgical management was not superior to

Table 2 Results for the intention-to-treat analysis

Variable	Randomised cohort (intention-to-treat analysis)			
	Surgical n=72	Non-surgical n=69	Difference (95% CI)	p Value
3 months				
FAOQ, mean (SD)	43.8 (12.0)	44.7 (12.2)	0.9 (−3.1 to 5.0)*	0.65
PCS, mean (SD)	47.1 (10.5)	46.8 (11.6)	0.24 (−3.9 to 3.5)*	0.90
MCS, mean (SD)	55.0 (10.3)	56.4 (7.4)	1.4 (−1.6 to 4.4)*	0.37
Working, n (%)†	55/64 (86%)	57/61 (93%)	0.47 (0.15 to 1.4)‡	0.17
6 months				
FAOQ, mean (SD)	49.1 (8.4)	51.9 (5.6)	2.7 (0.4 to 5.1)*	0.025
PCS, mean (SD)	50.4 (8.9)	52.3 (7.4)	1.9 (−0.90 to 4.6)*	0.18
MCS, mean (SD)	56.6 (7.2)	57.2 (7.9)	0.6 (−2.0 to 3.1)*	0.66
Working, n (%)†	62/63 (98)	61/61 (100)	NA	1.00
12 months				
FAOQ, mean (SD)	49.8 (10.6)	53.0 (5.2)	3.2 (0.4 to 5.9)*	0.028
PCS, mean (SD)	53.7 (7.1)	53.2 (6.7)	0.6 (−1.8 to 2.9)*	0.63
MCS, mean (SD)	55.2 (11.1)	56.5 (9.7)	1.3 (−2.2 to 4.8)*	0.47
Working, n (%)†	62/63 (98)	60/60 (100)	NA	1.00
Any adverse event, n (%)	23/73 (32)	10/74 (14)	2.3 (1.2 to 4.5)‡	0.009
Major adverse event, n (%)	6/73 (8)	3/74 (4)	2.0 (0.5 to 7.8)‡	0.33
Minor adverse event, n (%)	20/73 (27)	7/74 (10)	2.8 (1.3 to 6.4)‡	0.006
Physiotherapy use, n (%)	44/73 (60)	28/72 (39)	1.5 (1.1 to 2.2)‡	0.010

*Mean difference (95% CI).

†Based on the number of participants working preinjury.

‡Risk ratio (95% CI).

FAOQ, American Academy of Orthopaedic Surgeons Foot and Ankle Outcomes Questionnaire; MCS, mental component scores; NA, not available; PCS, physical component scores.

non-surgical management for any secondary outcomes and it was associated with a 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 that 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*¹ showed that there was insufficient evidence to justify surgical management of type B ankle fractures. 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 a significant lateral talar shift).³³ Despite the presence of slight talar

malalignment 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 malalignment at 1 year, but it was likely to have been sub-clinical 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 cross-over 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 who were approached were willing to be recruited to either the randomised or

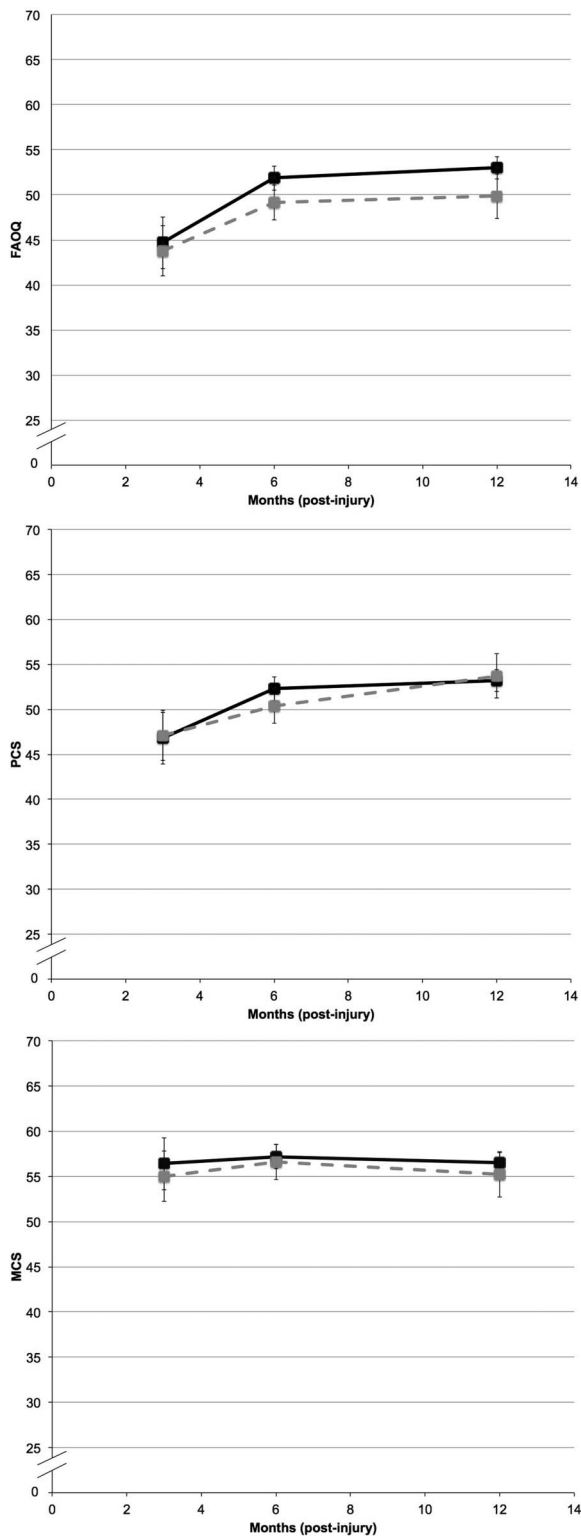


Figure 2 Differences between surgical and non-surgical groups with respect to ankle function and general health for the randomised cohort. FAOQ, PCS and MCS are the scores of the SF-12v2 general health survey for the randomised and cohort. Higher value represents better function. Error bars represent 95% CI. Solid black line represents the non-surgical group while the dashed grey line represents the surgical group. FAOQ, American Academy of Orthopaedic Surgeons Foot and Ankle Outcomes Questionnaire; MCS, mental component scores; PCS, physical component scores.

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 Chung-Wei *et al*⁸⁴ showed no evidence of improved outcomes with physiotherapy-based rehabilitation following ankle fractures. 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 1-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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Contributors RM and IAH 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. RM, IAH, SA, JMN and CROSSBAT Study Group were involved in study, concept, design, acquisition, critical revision of the manuscript for important intellectual content. RM and IAH conducted statistical analysis and are responsible for the data analysis.

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- ▶ Central Regional Ethics Committee. Reference Number: CEN/12/06/030
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- ▶ Flinders Clinical Research Ethics Committee. Reference Number: 358.10
- ▶ Hunter New England Human Research Ethics Committee. Reference Number: 09/12/16/5.02
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