DANISH MEDICAL JOURNAL

Protocol Article

Outpatient versus inpatient surgery for ankle fractures – a protocol for a randomised controlled trial

Christian G.R. Rasmussen[1], Peter Larsen[1, 2], Christian Pedersen[1] & Rasmus Elsoe[1]

1) Department of Orthopaedic Surgery, Aalborg University Hospital, 2) Department of Physiotherapy, Aalborg University Hospital, Denmark

Dan Med J 2025;72(7):A10240746. doi: 10.61409/A10240746

ABSTRACT

INTRODUCTION. In recent years, outpatient surgical treatment for ankle fractures has been introduced for selected fracture types and patients with a low degree of comorbidity. Limited evidence is available to guide the choice between inpatient and outpatient care for ankle fractures. This randomised controlled trial aims to investigate the effect of inpatient versus outpatient surgery of ankle fractures on patient-reported outcomes at 12 weeks.

METHODS. This study is a single-centre non-inferiority randomised controlled trial investigating outpatient care for surgically treated ankle fractures. A total of 86 patients will be included in the study and randomised 1:1 to either outpatient or inpatient care. The primary outcome is the Foot and Ankle Outcome Score at three months after surgery. Secondary outcomes will include patient satisfaction, pain, physical function and adverse events.

CONCLUSIONS. Conducting a randomised controlled trial investigating inpatient versus outpatient surgery for ankle fractures on both patient-reported outcomes, patient satisfaction, adverse events, pain, function and bone healing will provide evidence to guide future recommendations in the planning of surgical treatment for ankle fractures.

FUNDING. The study is partially funded by Helsefonden and the North Denmark Region.

TRIAL REGISTRATION. The study was pre-registered on Clinicaltrials.gov ID: NCT05389436, 20 May 2022.

Ankle fractures are very common injuries, with an incidence of 169-174 per 100,000 persons per year [1, 2]. The trauma mechanism is most often related to participating in sports and falling from a standing height [1]. Shifting demographics and an increase in participation in sports are expected to lead to a rise in the incidence of ankle fractures in the years to come [3-5]. The treatment of ankle fractures may be conservative or surgical, depending on fracture classification, fracture stability and patient comorbidities [6]. The surgical treatment is offered to patients with unstable fracture types and aims to restore the anatomy and stability of the ankle joint while facilitating early mobilisation [6, 7]. Surgical treatment for ankle fractures has historically required inpatient care for several days [8-10]. The recommendation for inpatient care is largely based on the assumption that monitoring post-operative pain, soft tissue conditions and early mobilisation is best achieved during inpatient care [8-10].

In recent years, outpatient surgical treatment for ankle fractures has been introduced for selected fracture types and patients with a low degree of comorbidity [11]. A retrospective analysis of 256 ankle fractures from Germany shows that surgical treatment of isolated ankle fractures as an outpatient procedure is a safe and resource-efficient concept that was not associated with an increased complication rate [8]. Several studies have reported

that outpatient surgery for ankle fractures is safe and less expensive than inpatient surgery [10-13].

However, the existing literature is predominantly observational or retrospective in nature. The literature lacks a high-quality randomised controlled trial comparing inpatient and outpatient surgery for the treatment of ankle fractures. Conducting a randomised controlled trial investigating inpatient versus outpatient surgery for ankle fractures on patient-reported outcomes, patient satisfaction, adverse events, pain, physical function and bone healing will provide evidence to guide future recommendations in the planning of surgical treatment for ankle fractures.

The primary aim of this trial is to investigate the effect of inpatient versus outpatient surgery of ankle fractures on patient-reported outcomes utilising the Foot and Ankle Outcome Score (FAOS) at 12 weeks.

The secondary aims are to report patient satisfaction, adverse events, pain, physical function and bone healing between inpatient and outpatient surgical care.

We hypothesise that patients receiving outpatient care have a FOAS score which is less than 14 points (the minimal clinically important difference) poorer than those receiving inpatient care.

PATIENTS AND METHODS

Trial design

This study will use a non-inferiority, prospective randomised controlled trial design in which outpatient care for surgically treated ankle fractures will be compared 1:1 to standard inpatient care. The trial adheres methodologically to the CONSORT guideline [14]. The study's feasibility was tested and proven before initiating the trial.

Participants

Patients will be included from the Department of Orthopaedic Surgery at Aalborg University Hospital, Denmark. An orthopaedic resident will assess the patients for eligibility based on consecutive sampling and the inclusion and exclusion criteria presented in **Table 1**.

TABLE 1 Inclusion and exclusion criteria.

Inclusion criteria
Age ≥ 18 yrs
Ankle fracture requiring surgery
Satisfactorily reduced in lower leg cast
Able to ambulate with cast and perform ADL at home, possibly with the help of relatives
Exclusion criteria
Impaired physical function, mental or social capacity; incapable of participating in the study
Not reading or understanding spoken Danish
Does not wish to participate
Concurrent major fracture to the lower extremity: ipsi- and/or contralateral
Pathologic fracture
ASA score ≥ 3
Pregnancy
Open fracture
Infectious disease requiring isolation

ADL = activity of daily living; ASA = American Society of Anesthesiologists.

Recruitment

Upon acceptance of participation and signing of the consent forms, patients will be enrolled in the study.

Randomisation and blinding

Patients are randomly assigned to either inpatient or outpatient care (1:1); the surgeon requests a digital randomisation key whereby the treatment option is revealed. Due to the study design, blinding of patients, staff and the treating surgeon is not possible. However, the data assessor will be blinded.

Interventions

Outpatient: Before discharge from the emergency room, the patient is provided with written information on the intended treatment plan. Surgery is planned for the following weekday. Until surgery, a regimen of elevation for the casted ankle is recommended. On the day of the planned surgery, the patient arrives at the outpatient ward at

9 a.m. The surgeon assesses and informs the patient. A physiotherapist provides an individual rehabilitation plan, and an anaesthesiologist assesses the patient. Once anaesthetised, peripheral single-shot nerve blocks are administered perineurally in saphenous and sciatic popliteal areas. The surgical procedure is determined by the fracture, based on local guidelines and the surgeons' preferences. At the end of the surgical procedure, perineural catheters are placed in the saphenous and sciatic popliteal areas and connected to disposable mechanical infusion pumps with a standard infusion of ropivacaine 0.2% at a rate of 6 ml/h and a capacity of approximately 55 hours. When the patient is alert and mobilised without weightbearing, they are discharged. The patient is instructed to remove the perineurial catheters on their own.

Inpatient: The patient is transferred to the inpatient ward. The timing of surgery depends on the operating capacity on the day(s) following admission. Until surgery, a regimen of elevation for the casted ankle is recommended. Once surgery is likely, the surgeon assesses and informs the patient, and an anaesthesiologist also assesses the patient. Once anaesthetised, peripheral single-shot nerve blocks are administered perineurally in the saphenous and sciatic popliteal areas. The surgical procedure is determined by the fracture, based on local guidelines and the surgeons' preferences. These patients do not receive perineurial pain catheters. Post-operatively, the patient is mobilised and a physiotherapist provides an individual rehabilitation plan. The patient is discharged when mobilised and the pain becomes manageable with oral pain medication.

Data collection and outcome assessment

The follow-up procedure includes a telephone interview two days after surgery and visits to the orthopaedic outpatient clinic at two, six and 12 weeks. All data will be kept in a password-protected electronic database managed by Aalborg University Hospital (REDCap). A full overview of the follow-up procedure is presented in **Table 2.**

TABLE 2 Assessment of outcomes.

			Time after surgery			
Outcome collection instrument	**Inclusion**	**Surgery**	**2 days**	**14 days**	**6 weeks**	**12 weeks**
Baseline	√					
Surgery		√				
Day's objective			√			
Pain VAS			√	√	√	√
Range of motion				√	√	√
X-ray					√	√
PASS					√	√
Satisfaction/experience				√	√	√
Workforce status				√	√	√
Workforce status, before fracture				√		
EQ5D-5L				√	√	√
FAOS						√
Tegner activity level				√		√
Patient self-payment						√

EQ5D-5L = European Quality of Life 5 Dimensions, 5 Level Version; FAOS = Foot and Ankle Outcome Score; PASS = Patient-Acceptable Symptom State; VAS = visual analogue scale.

Primary outcome and endpoint

The primary outcome will be measured by the $FAOS_5$ at 12 weeks following surgery, comparing mean $FAOS_5$ between inpatient and outpatient surgery. The $FAOS_5$ is the mean score of the five subscales derived from the FAOS questionnaire. The FOAS is a patient-reported, body-region-specific questionnaire comprising five subscales: pain, symptoms, activities of daily living (ADL), function in sport and recreation (sport/rec) and foot- and ankle-related quality of life (QOL). A score of 100 indicates no symptoms, and 0 indicates extreme symptoms [15]. The FAOS is validated as a patient-reported outcome questionnaire for patients with ankle fractures [7]. To

facilitate in-depth clinical interpretation, the primary outcome ($FAOS_5$) will be complemented by the five individual subscales.

Secondary outcomes

Pain intensity, measured as the present and worst pain experienced during the past 24 hours, will be evaluated on a visual analogue scale (VAS) of 0-10, with 0 indicating no pain and 10 indicating the worst imaginable pain [16]. Concurrently, the use of analgesics will be collected. Pain VAS will be obtained at two days, two weeks, six weeks and 12 weeks.

The range of passive ankle motion (ROM) will be measured with the patient in the supine position, using a goniometer [17]. ROM will be obtained for the uninjured side at two, six and 12 weeks, and for the injured side at six and 12 weeks.

Bone union will be evaluated using anterior-posterior, lateral and Mortise view X-rays. Bone union will be classified as 1) no visible callus/visible fracture lines on all views – no union, 2) callus visible on one or two cortices/fracture line visible on one or two views – some union or 3) callus visible on three or four cortices/no visible fracture line – united [18]. Bone union will be evaluated at six and 12 weeks.

The European Quality of Life 5 Dimensions, 5 Level Version (EQ5D-5L) questionnaire is a standardised generic health-related patient-reported outcome questionnaire. An index of 1.0 indicates full health, 0 indicates death and −0.59 denotes a condition worse than death [19]. The EQ5D-5L will be obtained at two, six and 12 weeks.

Work force status/continued sick leave will be assessed at two, six and 12 weeks.

Patients' experience and satisfaction will be evaluated by interview based on two questions:

1) Based on your experience, how likely is it that you would choose this treatment again?

2) Based on your experience, how likely is it that you would recommend this treatment to friends/relatives?

Possible answers are: very likely, likely, neither/nor, unlikely and very unlikely. For both questions, the patients are asked to describe the influence of pain, personal mobility, transportation time, waiting time to surgery and information received on a five-point Likert scale (no influence, little influence, some influence, big influence, very big influence). The patients can elaborate in free text. With these questions, we aim to examine the patients' combined experience with the treatment, while also allowing them to elaborate on their reflections regarding the level of pain, personal mobility, transportation time, waiting time for surgery and the information received. Patient satisfaction will be obtained at two, six and 12 weeks.

The Tegner activity scale is used to assess patient-reported pre-injury and post-injury activity levels [20]. A score of 10 indicates an activity level equivalent to professional sports, and a score of 0 signifies retirement or sick leave due to injury [20]. At two weeks, the patient will be asked to complete the pre-injury score, and at 12 weeks, the score will be recorded for the actual date.

At 12 weeks, patients will be asked whether they have utilised a private healthcare insurance or paid for private healthcare by other means.

The Patient-Acceptable Symptom State (PASS) will be included to express the highest level of symptoms beyond which patients consider themselves well. The PASS question will be as follows: Based on your current symptoms, would you seek professional treatment if you were not part of this study? PASS will be obtained at six and 12 weeks.

Adverse events will be recorded throughout the study. Adverse events are defined as any negative or unwanted reactions to both treatment arms that could affect treatment or outcome. Adverse events will be categorised as

(but not limited to) infection (skin only), deep infection (involving plates/screws), deep venous thromboembolism, failure of osteosynthesis, prolonged skin healing, compartment syndrome and other.

Sample size calculation

The reported FAOS minimal clinically important difference for ankle fractures of 14 was used as a non-inferiority margin [7]. Based on a standard deviation (SD) of 21, a ratio of 1:1 and an allowable difference of 0, a sample size of 86 patients was established to achieve a power of 90%, with a one-sided significance level of 5% and allowing for a 10% drop-out rate [7].

Statistics

All statistical tests conducted to explore between-group effects will use a 5% significance level ($p \leq 0.05$). Confidence intervals will be reported two-sided at 95%. The primary analysis will adhere to the intention-to-treat principle and will be supplemented by per-protocol analysis. No imputation will be performed.

Descriptive statistics

The inpatient and outpatient baseline characteristics will be presented as means or frequencies with standard deviation (SD) or as percentages in a table (**Table 3**).

TABLE 3 Baseline characteristics for the included patients.

	Inpatient	Outpatient
Age		
Gender (f/m)		
S825 – Medial malleolus		
S826 – Lateral malleolus		
S827A – Bimalleolar		
S827B – Trimalleolar		
S828B – Malleolus		
S828D – Ankle		
S829 – Lower leg		
BMI		
No smoking		
Smoking		
Alcohol		
Diabetes		
Peripheral neuropathy		
Peripheral vessel disease		
Charlson Comorbidity Score		
ASA score		

ASA = American Society of Anesthesiologists.

Primary analysis

The primary analysis will be calculated for the $FAOS_5$ and complemented by FAOS subscales (pain, symptoms, ADL, sport/rec and QOL) at the 12-week follow-up. A linear mixed regression model will be used to estimate the

mean difference in FAOS scores between inpatient and outpatient care. Mean scores, SD, mean differences, 95% confidence intervals and p-values will be reported.

Secondary analysis

Secondary analyses will be conducted for the FAOS subscales (pain, symptoms, ADL, sport/rec and QOL), EQ-5D index and subscales (mobility, self-care, usual activity, pain and anxiety), EQ-VAS, ankle ROM and self-reported pain reactions. The difference between inpatient and outpatient care will be estimated using a linear mixed-effects regression model. Mean scores, SD, mean differences, 95% confidence intervals and p-values will be presented in a table. The following aspects will be incorporated into the model: the effects of the treatment arm, follow-up time and interaction. Adverse events, PASS, bone union and patient satisfaction will be compared between inpatient and outpatient care.

Ethical considerations

The surgical procedure is not affected by participation. Based on existing evidence and our pilot and feasibility data, participation is unlikely to result in inferior treatment compared with standard inpatient surgical care. The study was approved by the Committee for Science Ethics for Northern Denmark (N-20220012) and will be conducted in accordance with the principles of the Declaration of Helsinki.

Data sharing statement

1) Individual participant data will not be shared. 2) The study protocol and informed consent forms will be shared. 3) The data are available immediately following publication and remain accessible for three years after publication. 4) The data will be available to researchers providing sound methodological reasons. 5) The purpose of data sharing is to achieve the researcher's aims. 6) The data will be made available via correspondence with the corresponding author.

Trial registration: The study is pre-registered on Clinicaltrials.gov NCT05389436.

DISCUSSION

To the authors' knowledge, this is the first randomised study to investigate the effect of inpatient versus outpatient surgical care for ankle fractures on patient-reported outcomes, adverse events and patient satisfaction.

Correspondence *Christian G.R. Rasmussen*. E-mail: christian.rasmussen@rn.dk

Accepted 1 May 2025

Published 26 June 2025

Conflicts of interest CGRR reports financial support from or interest in Helsefonden and Region Nord. All authors have submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest. These are available together with the article at ugeskriftet.dk/dmj

Acknowledgements Department of Orthopaedic Surgery, Aalborg University Hospital, Denmark, for patient assessment, recruitment and randomisation. Department of Physiotherapy, Aalborg University Hospital, Denmark, for patient treatment

References can be found with the article at ugeskriftet.dk/dmj

Cite this as Dan Med J 2025;72(7):A10240746

doi 10.61409/A10240746

REFERENCES

1. Elsoe R, Ostgaard SE, Larsen P. Population-based epidemiology of 9767 ankle fractures. Foot Ankle Surg. 2018;24(1):34-39. https://doi.org/10.1016/j.fas.2016.11.002
2. Goost H, Wimmer MD, Barg A, et al. Fractures of the ankle joint: investigation and treatment options. Dtsch Arztebl Int. 2014;111(21):377-388. https://doi.org/10.3238/arztebl.2014.0377
3. Court-Brown CM, Heckman JD, McQueen MM, et al., eds. Rockwood and Green's fractures in adults. 8th ed. Walters Kluwer, 2015
4. Court-Brown CM, McBirnie J, Wilson G. Adult ankle fractures - an increasing problem? Acta Orthop Scand. 1998;69(1):43-47. https://doi.org/10.3109/17453679809002355
5. Bengnér U, Johnell O, Redlund-Johnell I. Epidemiology of ankle fracture 1950 and 1980: increasing incidence in elderly women. Acta Orthop Scand. 1986;57(1):35-37. https://doi.org/10.3109/17453678608993211
6. Tengberg PT, Ban I. Treatment of ankle fractures. Ugeskr Laeger. 2018;180:V11170883
7. Larsen P, Al-Bayati M, Elsøe R. The Foot and Ankle Outcome Score (FAOS) during early recovery after ankle fracture. Foot Ankle Int. 2021;42(9):1179-1184. https://doi.org/10.1177/10711007211002811
8. Weckbach S, Flierl MA, Huber-Lang M, et al. Surgical treatment of ankle fractures as an outpatient procedure. A safe and resource-efficient concept? Unfallchirurg. 2011;114(10):938-942. https://doi.org/10.1007/s00113-011-2066-y
9. Murray AM, McDonald SE, Archbold P, Crealey GE. Cost description of inpatient treatment for ankle fracture. Injury. 2011;42(11):1226-1229. https://doi.org/10.1016/j.injury.2010.08.023
10. Lloyd JM, Martin R, Rajagopalan S, et al. An innovative and cost-effective way of managing ankle fractures prior to surgery - home therapy. Ann R Coll Surg Engl. 2010;92(7):615-618. https://doi.org/10.1308/003588410X12699663904358
11. Malik AT, Quatman CE, Khan SN, et al. Outpatient versus inpatient surgical fixation of isolated ankle fractures: an analysis of 90-day complications, readmissions, and costs. J Foot Ankle Surg. 2020;59(3):502-506. https://doi.org/10.1053/j.jfas.2019.09.030
12. Qin C, Dekker RG, Blough JT, Kadakia AR. Safety and outcomes of inpatient compared with outpatient surgical procedures for ankle fractures. J Bone Joint Surg Am. 2016;98(20):1699-1705. https://doi.org/10.2106/JBJS.15.01465
13. Qin C, Dekker 2nd RG, Helfrich MM, Kadakia AR. Outpatient management of ankle fractures. Orthop Clin North Am. 2018;49(1):103-108. https://doi.org/10.1016/j.ocl.2017.08.012
14. Piaggio G, Elbourne DR, Pocock SJ, et al. Reporting of noninferiority and equivalence randomized trials: extension of the CONSORT 2010 statement. JAMA. 2012;308(24):2594-2604. https://doi.org/10.1001/jama.2012.87802
15. FAOS. A user's guide to: Foot and Ankle Outcome Score FAOS. www.koos.nu/FAOSGuide2003_RC.pdf (14 Dec 2022)
16. Thong ISK, Jensen MP, Miró J, Tan G. The validity of pain intensity measures: what do the NRS, VAS, VRS, and FPS-R measure? Scand J Pain. 2018;18(1):99-107. https://doi.org/10.1515/sjpain-2018-0012
17. Marcano-Fernández F, Prada C, Johal H. Physical outcome measures: the role of strength and range of motion in orthopaedic research. Injury. 2020;51(suppl 2):S106-S110. https://doi.org/10.1016/j.injury.2019.11.017
18. Shih CA, Jou IM, Lee PY, et al. Treating AO/OTA 44B lateral malleolar fracture in patients over 50 years of age: periarticular locking plate versus non-locking plate. J Orthop Surg Res. 2020;15(1):112. https://doi.org/10.1186/s13018-020-01622-9
19. EuroQol. EQ-5D-5L. https://euroqol.org/eq-5d-instruments/eq-5d-5l (14 Dec 2022)
20. Tegner Y, Lysholm J. Rating systems in the evaluation of knee ligament injuries. Clin Orthop Relat Res. 1985;(198):43-49

