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Close Contact Casting vs Surgery for Initial Treatment of Unstable Ankle Fractures in Older Adults
A Randomized Clinical Trial

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IMPORTANCE Ankle fractures cause substantial morbidity in older persons. Surgical fixation is the contemporary intervention but is associated with infection and other healing complications.

OBJECTIVE To determine whether initial fracture treatment with close contact casting, a molded below-knee cast with minimal padding, offers outcome equivalent to that with immediate surgery, with fewer complications and less health resource use.

DESIGN, SETTING, AND PARTICIPANTS This was a pragmatic, equivalence, randomized clinical trial with blinded outcome assessors. A pilot study commenced in May 2004, followed by multicenter recruitment from July 2010 to November 2013; follow-up was completed May 2014. Recruitment was from 24 UK major trauma centers and general hospitals. Participants were 620 adults older than 60 years with acute, overtly unstable ankle fracture. Exclusions were serious limb or concomitant disease or substantial cognitive impairment.

INTERVENTIONS Participants were randomly assigned to surgery (n = 309) or casting (n = 311). Casts were applied in the operating room under general or spinal anesthesia by a trained surgeon.

MAIN OUTCOMES AND MEASURES The primary 6-month, per-protocol outcome was the Olerud-Molander Ankle Score at 6 months (OMAS; range, 0-100; higher scores indicate better outcomes and fewer symptoms), equivalence prespecified as ±6 points. Secondary outcomes were quality of life, pain, ankle motion, mobility, complications, health resource use, and patient satisfaction.

RESULTS Among 620 adults (mean age, 71 years; 460 [74%] women) who were randomized, 593 (96%) completed the study. Nearly all participants (579/620; 93%) received allocated treatment; 52 of 275 (19%) who initially received casting later converted to surgery, which was allowable in the casting treatment pathway to manage early loss of fracture reduction. At 6 months, casting resulted in ankle function equivalent to that with surgery (OMAS score, 66.0 [95% CI, 63.6-68.5] for surgery vs 64.5 [95% CI, 61.8-67.2] for casting; mean difference, −0.6 [95% CI, −3.9 to 2.6]; *P* for equivalence = .001). Infection and wound breakdown were more common with surgery (29/298 [10%] vs 4/275 [1%]; odds ratio [OR], 7.3 [95% CI, 2.6-20.2]), as were additional operating room procedures (18/298 [6%] for surgery and 3/275 [1%] for casting; OR, 5.8 [95% CI, 1.8-18.7]). Radiologic malunion was more common in the casting group (38/249 [15%] vs 8/274 [3%] for surgery; OR, 6.0 [95% CI, 2.8-12.9]). Casting required less operating room time compared with surgery (mean difference [minutes/participant], −54 [95% CI, −58 to −50]). There were no significant differences in other secondary outcomes: quality of life, pain, ankle motion, mobility, and patient satisfaction.

CONCLUSIONS AND RELEVANCE Among older adults with unstable ankle fracture, the use of close contact casting compared with surgery resulted in similar functional outcomes at 6 months. Close contact casting may be an appropriate treatment for such patients.

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Supplemental content

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The number of older adults sustaining ankle fractures is increasing,[1] and they experience disproportionately poor outcomes.[2] Ankle fractures cause loss of independence and quality of life, incurring substantial health costs.[3-5] Treatment of unstable fractures is either surgical, using open reduction and internal fixation, or nonsurgical, using externally applied casts. Neither method yields an entirely satisfactory outcome in older adults. Traditional casting techniques are associated with poor fracture alignment and healing, as well as plaster sores.[6] Surgery is often complicated by poor implant fixation, wound problems, and infection.[7] A Cochrane review of surgery vs casting for ankle fractures was unable to make recommendations because of poor-quality studies.[8]

A modified casting technique has been developed, close contact casting, which uses minimal padding compared with traditional casting and achieves fracture reduction by distributing contact pressure by close anatomic fit. The clinical strategy of close contact casting was to use this as the first-line treatment, recognizing that if reduction were not possible during the procedure or could not be retained in the immediate postoperative phase (up to 3 weeks), the treatment protocol allowed surgery. The intention of the Ankle Injury Management Trial was to investigate in older adults with unstable ankle fractures whether initial fracture management with close contact casting resulted in an outcome equivalent to that with immediate surgery, with fewer complications and less resource use.

Key Points

Question Does close contact casting (a molded below-knee cast with minimal padding) compared with internal fixation surgery result in an equivalent functional outcome for adults older than 60 years with an unstable ankle fracture?

Findings In this randomized equivalence clinical trial that included 620 adults from 24 hospitals, ankle function measures, which included postfracture symptoms, quality of life, pain, ankle motion, and mobility, were equivalent at 6 months in both groups. Infection and wound breakdown were more common with surgery.

Meaning Close contact casting may be an appropriate alternative treatment to surgery for older adult patients with unstable ankle fracture.

Methods

Study Design and Eligibility Criteria

This pragmatic, multicenter, equivalence randomized clinical trial with blinded outcome assessors was conducted at 24 UK trauma centers and district general hospitals. Participants were adults older than 60 years presenting with acute malleolar fracture(s) and an unstable ankle joint on the initial radiograph who would normally be offered surgery. Patients requiring stress radiographs to elicit talar instability were excluded. Patients were included if they were ambulatory before injury, able to provide informed consent and follow instructions, and lived near a recruiting hospital and could attend the 6-month follow-up. Patients with critical limb ischemia, insulin-dependent diabetes mellitus, active leg ulceration, open fractures, serious concomitant disease (ie, terminal illness), substantial ankle arthritis, or substantial cognitive impairment (Mini-Mental State Examination score <16/30),[9] or who were unfit for anesthesia, were excluded. All participants provided written informed consent.

The study was approved by the National Research Ethics Service Oxfordshire Committee. The trial protocol is available in Supplement 1.[10] The trial was overseen by independent steering and data and safety monitoring committees.

Randomization and Blinding

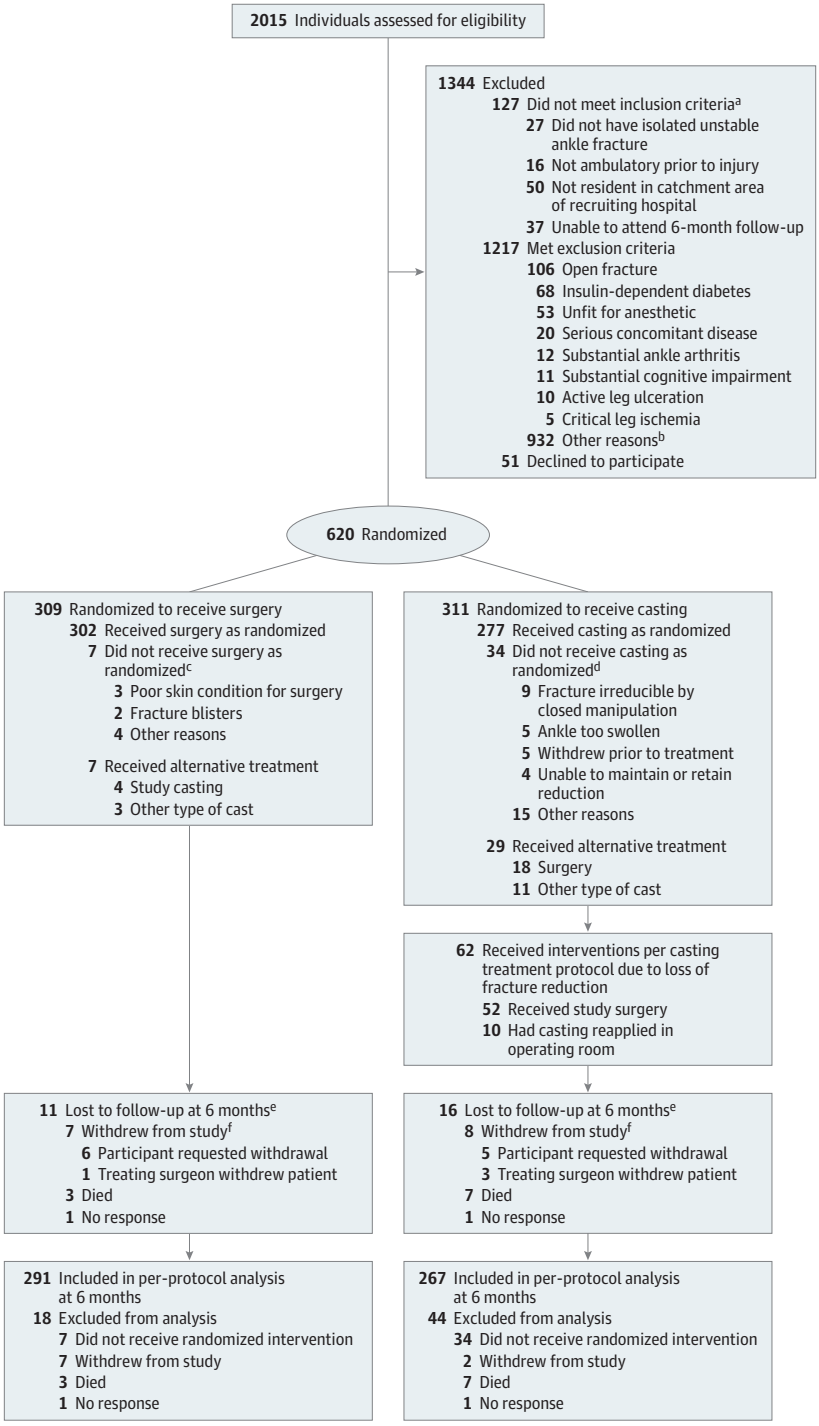
After providing consent and undergoing baseline assessments, participants were individually randomized to receive surgery or close contact casting (**Figure**) in a 1:1 allocation by hospital staff, using a 24-hour telephone service at an independent organization (Aberdeen University). Concealment was ensured by registering participants before computer generation of the allocation. Randomization was stratified by center and fracture pattern (infrasyndesmotic/trans-syndesmotic vs suprasyndesmotic) and used random permuted blocks of lengths 2 and 4.

A blinded health professional performed outcome assessments at the primary end point (6 months). Before assessments, opaque ankle bandages were applied to obscure the ankle. The James blinding index was used to assess success of blinding (0 [total lack of blinding] to 1 [complete blinding]).[11] The assessments at 6 weeks were not blinded because the assessor needed knowledge of postoperative instructions for weight bearing and movement. It was not possible to mask the surgeons or participants because of the nature of the interventions, nor was it possible to mask the radiograph assessors.

Interventions

Surgery was internal fixation conducted with internationally recognized principles and techniques.[12] Selection of implants, postoperative splinting, immediate or delayed weight bearing, and clinical follow-up were according to usual local practice and the surgeon's preference. The close contact cast was applied in an operating room under general or spinal anesthesia by an orthopedic surgeon immediately after closed fracture reduction. Instructions were to achieve joint congruence with no talar shift or tilt. The close contact casting application was first a stockinette bandage (BSN Medical GmbH) and then shaped, self-adhesive foam pads (Fleecy Foam 5 mm; Hapla) placed over prominences (tibial crest, fibular head, calcaneum, Achilles tendon, and metatarsal heads) and medial and lateral sides of the ankle, where molding pressure was applied to hold the fracture reduction. The exact molding points for each participant were at the surgeon's discretion. Then 2 self-adhesive strips were applied to the full length of the cast (Fleecy web roll 5 cm; Hapla) to prevent plaster saw injury during removal. Finally, a single nonoverlapping synthetic wool layer (Soffban Plus; BSN Medical GmbH), plaster of paris (Gypsona; BSN Medical GmbH), and a reinforcing topcoat of synthetic casting material (Soft Cast Casting Tape; 3M Health Cate Ltd) were applied below the knee. All surgeons who applied casting had completed a 1-hour training session, supplemented

Figure. Trial Profile of Casting vs Surgery for Ankle Fracture in Older Adults



[a] Three participants did not meet 2 of the inclusion criteria.

[b] Prespecified exclusion criteria, as defined in the trial protocol, are listed in this figure. Other reasons for exclusion are listed in eTable 1 in Supplement 2.

[c] Two participants did not receive their allocated treatment due to having both poor skin and blisters.

[d] Four participants had 2 reasons for not receiving their allocated treatment.

[e] Number of participants reported is cumulative. No response is defined as those who did not attend clinic assessment or respond to postal questionnaire or telephone contact.

[f] Five of these participants withdrew from the trial prior to receiving their allocated intervention.

with a video (https://www.youtube.com/playlist?list=PL2Gg_an4nwPfIUC9RQV54Y2lbD76HiWcV) or were supervised by a surgeon who had completed training. Joint congruence was monitored with radiographs in the weeks after initial close contact cast application and after any reapplications for cast loosening. Reapplications did not require anesthesia. The protocol specified that if during clinical follow-up there was, in the treating surgeon's opinion, an unacceptable loss of fracture position before clinical union, he or she could remanipulate and reapply a cast in the outpatient clinic or operating room or convert to surgery. Guidance was that the casting group should touch or nonweight bear for 4 weeks and increase to full weight bearing by 6 to 8 weeks from intervention at the surgeon's discretion and patient volition.

The treatment protocol anticipated and allowed scenarios in which allocated treatment might have to be modified. Participants in the casting allocation could proceed to surgery when reduction could not be achieved or held with close contact casting in the operating room. Participants in the surgical allocation could proceed to traditional casting or external fixation when incision was considered unsafe, but not to close contact casting. For both allocations, a temporary treatment could be undertaken in the operating room (manipulation and splinting or external fixation) until it was appropriate to receive the allocated treatment. Each hospital followed its own protocols for thromboprophylaxis, surgical antibiotic prophylaxis, and rehabilitation.

Data Collection and Outcome Measures

Follow-up was at 6 weeks and 6 months after randomization, using patient-reported questionnaires and performance tests at a clinic visit. When participants could not attend the clinic, questionnaires were collected by telephone or mail.

The primary outcome measure was the Olerud-Molander Ankle Score (OMAS; scale 0-100, with higher scores indicating better function), a measure of ankle fracture symptoms.[13] Secondary outcomes were the 12-Item Short Form Health Survey (SF-12 version 1)[14] (scale 0-100, with higher scores indicating better quality of life) and EuroQol 5 dimensions questionnaire, 3 levels (EQ-5D-3L) (scale 0 [death] to 1 [perfect health]; negative scores are reflective of a patient's quality of life being worse than death).[15] Pain was estimated using relevant subscales of the OMAS (rated 1-5, with 1 indicating "none" and 5 indicating "constant and severe") and EQ-5D (rated 1-3, with 1 indicating "no pain or discomfort" and 3 indicating "extreme pain or discomfort"). We also collected assessments of patient satisfaction (rated 1-5, with 1 indicating "very dissatisfied" and 5 indicating "very satisfied") and health care resource use (operating room time, surgical implants, casting, hospital stay, and follow-up care). Patient-reported time to weight bearing was recorded. Ankle range of motion (plantar and dorsiflexion) was measured with a standardized handheld goniometer.[16] Mobility was measured at 6 months with the Timed Up and Go test (walking distance, 8.6 m).[17] Fracture nonunion and malunion at 6 months was assessed with anteroposterior or mortise and lateral radiographs collected during the course of routine practice. Radiographs were analyzed at Oxford University by 2 experienced orthopedic surgeons (K.W. and R.H.). Assessors had no access to clinical data or patient reports. Malunion was defined as one or a combination of the following: talar subluxation or shift (>2 mm), talar tilt (>2°), or diastasis (tibiofibular clear space ≥5 mm). Nonunion was assessed for lateral and medial malleoli. Absolute measures corrected for magnification were obtained when there were Digital Imaging and Communications in Medicine data, which included the majority of images.

Expected complications, harms, or additional surgery related to study treatments were recorded as adverse events, including operative complications; wound, implant, and cast complications; venous thromboembolism; and additional procedures, including implant removal. In addition, unexpected adverse events were reported. Serious adverse events were defined as any untoward medical occurrence that was both unexpected and related to the study treatments, resulting in death, life- or limb-threatening complication, and/or rehospitalization. Treatment relatedness was determined by surgeons at sites and confirmed by the chief investigator. We estimated costs of the procedures, including time in the operating room, staff, facilities, implants, materials, and acute and community care costs linked to the admission. Additional health resource use was captured in patient-reported questionnaires at 6 weeks and 6 months. A cost-effectiveness analysis will be reported separately.

At baseline, we collected data on demographic and clinical characteristics. Participants were asked to recall their status before fracture with questionnaires used during follow-up and to complete the EQ-5D on the day of assessment. The ASEPSIS wound score (Additional treatment, Serous discharge, Erythema, Purulent exudate, Separation of the deep tissues, Isolation of bacteria, duration of inpatient Stay)[18] at 10 days after surgery, described in the first version of the protocol, was not collected after an amendment approved by the ethics committee.

Statistical Analysis

The sample size of 620 provided 80% power to perform tests of an equivalence margin of ±6 OMAS points, at α = .05 and allowing 10% loss to follow-up. Estimates of the standard deviation were confirmed from a single-site pilot phase (n = 95; SD 16.2 OMAS points in the operative group). The design was modified between pilot and full trial from a noninferiority design using a binary end point to an equivalence design using a continuously scaled equivalence margin. This modification was not based on analysis of data but was in response to guidance from the independent funder, funder peer review, independent steering and data and safety monitoring committees, and advances in accepted approaches to equivalence trial design.[19] The choice of equivalence margin was informed by a multidisciplinary expert panel and, in the absence of better evidence, a review of minimum clinically important differences for similar scores. The 6-point margin was consistent with the minimum clinically important differences reported in a recent psychometric evaluation of the OMAS, which also confirmed other psychometric properties of the score sufficient for use as an outcome measure in ankle fracture trials.[20] The participants from the pilot phase were included in the final sample because the full trial protocol was otherwise modified only by adding cost-effectiveness outcomes. We performed a sensitivity analysis by including a pilot membership term in the random-effects model used for the primary analysis to assess whether including participants from the pilot study introduced bias.

The primary analysis was per protocol,[21] in which only the data from patients who received their allocated treatment were analyzed. If the allocated treatment was received but a second intervention was required, provided this was a prespecified allowable event, these participants remained in the per-protocol analysis. An intention-to-treat analysis including all randomized participants was also conducted, aiming to demonstrate equivalence with both approaches.[22] The primary end point was 6 months.

A statistical analysis plan was preapproved by the data and safety monitoring committee. We used random-effects mod-

Table 1. Baseline Demographic and Clinical Characteristics of Randomized Participants by Treatment Group

Characteristic	Surgery (n = 309)	Casting (n = 311)
Age, mean (SD), y	69.8 (6.9)	71.4 (7.6)
Sex, No. (%)		
Male	82 (26.5)	78 (25.1)
Female	227 (73.5)	233 (74.9)
Ankle fracture classification, No. (%)		
Infrasyndesmotic/trans-syndesmotic	272 (88.0)	270 (86.8)
Suprasyndesmotic	37 (12.0)	41 (13.2)
Olerud-Molander Ankle Score, preinjury, mean (SD)[a,b]	89.8 (17.0)	87.7 (17.7)
SF-12 mental score preinjury, mean (SD)[a,c]	53.7 (8.1)	54.5 (7.5)
Missing data	2	0
SF-12 physical score preinjury, mean (SD)[a,c]	51.2 (8.8)	49.6 (10.3)
Missing data	2	0
EQ-5D score preinjury, mean (SD)[a,d,e]	0.91 (0.16)	0.87 (0.19)
Missing data	31	30
EQ-5D score day of randomization, mean (SD)[d,e]	0.04 (0.26)	0.07 (0.26)
Missing data	49	47
Mini-Mental State Examination score, mean (SD)[d]	28.2 (2.1)	27.9 (2.3)
Missing data	32	31
Medical history, No. (%)		
Heart disease	38 (12.3)	44 (14.1)
Hypertension	126 (40.8)	140 (45.0)
Asthma/chronic obstructive pulmonary disease	46 (14.9)	39 (12.6)
Non-insulin-dependent diabetes	31 (10.0)	26 (8.4)
Parkinson disease	0	0
Epilepsy	4 (1.3)	5 (1.6)
Renal disease	5 (1.6)	7 (2.3)
Liver disease	2 (0.7)	4 (1.3)
Cerebrovascular accident/transient ischemic attack	14 (4.5)	21 (6.8)
Peptic ulcer	5 (1.6)	13 (4.2)
Malignancy	37 (12.0)	36 (11.7)
Venous thromboembolism	10 (3.2)	19 (6.2)
Osteoarthritis	84 (27.2)	100 (32.4)
Rheumatoid arthritis	12 (3.9)	14 (4.5)
Depression	35 (11.3)	38 (12.3)
Dementia	1 (0.3)	0
Current smoker, No. (%)	25 (8.1)	32 (10.4)
Alcohol consumption per week, median (IQR), units[f]	4 (0-45)	2 (0-42)
Admitted from own home, No. (%)	302 (97.7)	297 (96.0)
No walking aid used before injury, No. (%)	271 (87.7)	258 (83.5)

Abbreviations: EQ-5D, EuroQol 5 dimensions questionnaire; IQR, interquartile range; SF-12, 12-Item Short Form Health Survey.

[a] Participants recalled preinjury status.

[b] Range 0-100, with higher scores indicating better ankle function.

[c] Range 0 to 100, with higher scores indicating better functioning.

[d] The majority of missing scores relate to early study participants before the measure's being introduced.

[e] Range typically from 0 (death) to 1 (perfect health); negative scores can be obtained, reflective of a patient's quality of life being worse than death.

[f] One unit of alcohol in the United Kingdom is 10 mL, or 8 g of pure alcohol. Equivalent public estimates are 250 mL of beer, 76 mL of wine, and 25 mL of whisky.

els to estimate the mean difference and 95% CI between treatments adjusted for age, sex, fracture pattern, and baseline score. The center variable was included in this model as a random effect to account for center differences. Categorical outcomes were analyzed with logistic regression models to estimate the odds ratio and 95% CI. When data were not normally distributed, we used Hodges-Lehmann and Fisher exact tests for continuous and categorical variables, respectively.

Only the primary analyses assessed equivalence, in which the null hypothesis was that the 2 groups were not equivalent. The alternative hypothesis was therefore that the treatment groups were equivalent (ie, the 95% CIs were totally within the equivalence margin), so if the *P* value was significant ($P < .05$), the conclusion was that there was significant evidence to suggest that the 2 treatments were equivalent. According to CONSORT and other groups, secondary outcomes can be managed by a superiority or equivalence framework.[22] We assessed secondary end points with a superiority hypothesis rather than an equivalence because this technique, recognized as legitimate, avoided the need to set multiple equivalence margins when such margins were not available. Superiority testing is also more statistically efficient, which was an important consideration for this trial. Sensitivity analyses using multiple imputation techniques to assess the effect of missing data were planned. It is well recognized that surgical techniques can take some time to learn and that the number

Table 2. Primary and Secondary Outcomes at 6-Month Follow-up (Per-Protocol Analysis)

	Surgery		Casting		
Measure	No.	Mean (95% CI)	No.	Mean (95% CI)	Adjusted Difference (95% CI)[a]
OMAS[b]	291	66.0 (63.6 to 68.5)	267	64.5 (61.8 to 67.2)	−0.6 (−3.9 to 2.6)
SF-12 score[c]					
Mental	291	52.1 (50.9 to 53.3)	267	52.2 (51.0 to 53.4)	−0.2 (−1.7 to 1.2)
Physical	291	45.6 (44.4 to 46.7)	267	44.0 (42.7 to 45.3)	−0.8 (−2.3 to 0.7)
EQ-5D[d]	264	0.76 (0.73 to 0.79)	241	0.76 (0.73 to 0.78)	−0.004 (−0.04 to 0.04)
Ankle range, degrees					
Dorsiflexion	282	11.9 (10.7 to 13.1)	256	11.6 (10.2 to 13.1)	0.2 (−1.5 to 1.9)
Plantar flexion	282	33.7 (32.1 to 35.3)	256	31.1 (29.5 to 32.7)	−2.5 (−4.6 to −0.5)
Eversion, % compared with uninjured ankle	282	88.0 (78.3 to 97.7)	251	86.1 (79.6 to 92.6)	−2.0 (−13.5 to 9.6)
Inversion, % compared with uninjured ankle	282	83.4 (75.8 to 91.0)	256	83.4 (78.2 to 88.5)	−0.3 (−9.4 to 8.8)
EQ-5D pain rating[e]	265	1.6 (1.5 to 1.7)	241	1.6 (1.5 to 1.6)	−0.00009 (−0.09 to 0.09)
OMAS pain rating[f]	291	2.0 (1.9 to 2.1)	267	1.9 (1.8 to 2.1)	−0.1 (−0.2 to 0.1)
Patient satisfaction[g]	248	4.5 (4.4 to 4.6)	224	4.5 (4.3 to 4.6)	−0.05 (−0.2 to 0.1)
Timed Up and Go mobility test, s[h]	276	18.0 (14.5 to 22.6)	242	18.4 (15.2 to 24.0)	−0.9 (−1.9 to 0.1)

Abbreviations: EQ-5D, EuroQol 5 dimensions questionnaire; OMAS, Olerud-Molander Ankle Score; SF-12, 12-Item Short Form Health Survey.

[a] Differences were adjusted for baseline outcome values, age, sex, recruitment hospital, and fracture pattern (trans-syndesmotic and infrasyndesmotic vs suprasyndesmotic). A negative value implies that the treatment effect is in favor of surgery.

[b] Range 0-100, with higher scores indicating better ankle function. Shown are primary analysis results.

[c] Range 0 to 100, with higher scores indicating better functioning.

[d] Range typically from 0 (death) to 1 (perfect health); negative scores can be obtained, reflective of a patient's quality of life being worse than death.

[e] Scores were from 1 to 3, with 1 indicating "no pain or discomfort" and 3 indicating "extreme pain or discomfort."

[f] Scores were from 1 to 5, with 1 indicating "none" and 5 indicating "constant and severe."

[g] Patient satisfaction with treatment was rated from 1 to 5, with 1 indicating "very dissatisfied" and 5 indicating "very satisfied."

[h] Collected at 6 months only. Data not normally distributed; hence, median (interquartile range) is presented instead of mean (SD). Hodges-Lehmann estimate (95% CI) reported for the treatment comparison.

of procedures undertaken can be important in determining outcome.[23] Learning curves were assessed with a longitudinal random model. For each surgeon, operation time was ordered sequentially by date, and a time variable was created. This time variable was fitted as a random effect into a longitudinal model, with the operation time as the response variable. The surgeon was included as a random effect. All tests were 2-sided at the 5% significance level. Secondary end point analyses should be considered exploratory because they were not adjusted for multiple comparisons. Analyses were conducted with Stata version 13.1 and SAS version 9.3.

Results

Recruitment to the pilot study started in May 2004, moving to the multicenter phase from July 2010 to November 2013. A total of 2015 patients were assessed for eligibility; 671 were eligible and 620 consented to randomization (Figure and eTable 1 in Supplement 2). Baseline characteristics were well matched between groups (**Table 1**). Participants were aged an average of 71 years, and 460 of 620 (74%) were women. Ankle fractures were trans-syndesmotic or infrasyndesmotic (542/620; 87%) and suprasyndesmotic (78/620; 13%). Six-month assessments were conducted mostly in clinic (572/593; 97%). Follow-up data were obtained for 593 of 620 participants (96%) at 6 months; the remainder had been lost to follow-up (2/620; 0.3%), had withdrawn (15/620; 2%), or had died (10/620; 2%). Analyses included 90% of participants (558/620) for per protocol and 96% (593/620) for intention to treat.

The majority of participants (579/620; 93%) received allocated treatment. In the casting arm, 34 of 620 participants (6%) did not receive the casting and so were not included in the per-protocol analysis. Of these participants, 17 proceeded to internal fixation surgery, 1 received external fixation surgery, 5 had traditional casting, 6 had an alternative form of casting, and 5 withdrew before receiving treatment. In the surgery arm, 7 of 620 participants (1%) did not receive internal fixation and so were not in the per-protocol analysis. Of these participants, 4 received casting against protocol and 3 received another form of casting. The remainder of participants received their treatment per protocol, including 13 of 298 (4%) who received a temporary treatment before surgery and 2 of 275 (0.7%) who received one before close contact casting.

For participants in the casting arm who received treatment according to allocation, later loss of fracture reduction resulted in conversion to internal fixation for 52 of 275 (19%) or remanipulation and casting applied in the operating room for 10 of 275 (4%). These events in the weeks after initial casting application were allowable and expected as part of the close contact casting intervention pathway, so these participants were included in per-protocol analysis. One hundred surgeons applied close contact casting in the trial, and 45 of them performed 2 procedures; only 13 surgeons conducted 5 or more procedures. There was no evidence of a learning curve among the surgeons (F test = 1.45; P = .09).

There was no difference in OMAS scores between close contact casting and surgery at 6 months after randomization (**Table 2**). In the per-protocol analysis, the mean difference at

6 months was -0.6 OMAS points (95% CI, -3.9 to 2.6; P = .001). In the intention-to-treat analysis (eTable 3 in Supplement 2), the mean difference was -0.2 OMAS points (95% CI, -3.3 to 2.9; P < .001). A post hoc analysis was performed in which participants who did not receive their allocated casting intervention but received surgery instead were included in the surgery group; there was no difference between groups (mean difference, -0.7 OMAS points; 95% CI, -3.84 to 2.42; P = .66). Sensitivity analyses using imputation were not conducted because missing data were minimal. For the primary outcome and end point, there were no missing data for the per-protocol analysis and 0.2% missing data for the intention-to-treat analysis. Inclusion of participants from the pilot study did not introduce bias in the primary per-protocol analysis; the treatment effect estimate was unchanged and the pilot membership indicator in the model was not significant (P = .71). The James blinding index was 0.8 (95% CI, 0.78-0.84).

Table 2 shows data for secondary outcomes. There were no differences between the secondary outcomes of quality of life (mental and physical), ankle pain, and patient satisfaction at either 6 weeks or 6 months. The Timed Up and Go mobility test score was only completed at 6 months. There were small differences in ankle motion at 6 weeks (eTable 2 in Supplement 2), but no differences at 6 months.

Six-month radiographs were missing for 24 of 298 participants (8%) in the surgery group and 26 of 275 (10%) in the casting group. Radiologic malleolar nonunion was low overall and lower in the surgery group compared with casting for the lateral malleolus (data were missing for 1 participant: 0/274 vs 8/248; 3%) and medial malleolus (3/274 vs 18/248 [1% vs 7%]), yielding an odds ratio of 0.1 (95% CI, 0.04-0.5). Radiologic malunion occurred in 38 of 249 participants (15%) in the casting group compared with 8 of 274 (3%) in the surgery group, yielding an odds ratio of 6.0 (95% CI, 2.8-12.9). The most disabling form of malunion was a combination of talar shift, tilt, and a diastasis. There were few cases of this type of malunion, and these were equally spread between the trial groups (eTable 4 in Supplement 2).

Adverse events are detailed in **Table 3**. There were no unexpected, treatment-related, serious adverse events. The number of participants who experienced an infection and/or wound breakdown in those with follow-up data available for the surgery group was 29 of 298 (10%) compared with 4 of 275 (1%) for close contact casting, yielding an odds ratio of 7.3 (95% CI, 2.6-20.2). eTable 4 in Supplement 2 shows OMAS scores at 6 months for these participants. The number of additional operating room procedures for treatment-related complications was 18 of 298 participants (6%) in the surgery group and 3 of 275 (1%) in the close contact casting group, yielding an odds ratio of 5.8 (95% CI, 1.8-18.7).

Resource use for the interventions is shown in eTable 5 in Supplement 2. Casting resulted in a meaningful mean reduction in overall operating room time and implant use and small increases in casts, orthopedic outpatient or office consultations, and hospital transport use. There was no difference in length of hospital stay or time to weight bearing. There were no differences in other aspects of health resource use during the follow-up period.

Table 3. Treatment-Related Adverse Events: Complications and Additional Procedures in the Operating Room by Treatment Group (Per-Protocol Analysis)

	No. (%)	
	Surgery (n = 298)[a]	Casting (n = 275)[a]
Complications		
Intraoperative fracture	1 (0.3)	0
Neurovascular injury	3 (1.0)	3 (1.1)
Wound complications		
Infection	8 (2.7)[b]	2 (0.7)[b]
Breakdown	27 (9.1)[b]	3 (1.1)[b]
Nonwound lower limb skin complication	11 (3.7)	9 (3.3)
Internal fixation complications		
Implant failure	5 (1.7)	0
Other clinical issue	4 (1.3)	0
Casting complications	12 (4.0)	16 (5.8)
Pain from cast		
Plaster sore	13 (4.4)	18 (6.5)
Plaster saw laceration	1 (0.3)	5 (1.8)
Venous thromboembolism	4 (1.3)	12 (4.4)
Additional operating room procedures		
Revision of internal fixation	3 (1.0)	1 (0.4)
Wound washout	2 (0.7)	0
Wound debridement	1 (0.3)	0
Incision and drainage of hematoma	1 (0.3)	0
Removal of internal fixation implants		
Syndesmosis screws	6 (2.0)	1 (0.4)
Other metalwork	4 (1.3)[b]	1 (0.4)

[a] Excluded are all participants who did not receive their allocated treatment or did not provide any follow-up data.

[b] One or more participants experienced both infection and wound breakdown.

Clinical outcomes and resource use were consistent between the per-protocol and intention-to-treat populations (Tables 2 and 3; eTables 2, 3, and 6-9 in Supplement 2).

Discussion

In older adults with unstable ankle fractures, a strategy of commencing fracture management with close contact casting resulted in ankle function equivalent to that with immediate surgery, with fewer wound complications and reduced intervention costs. Close contact casting was delivered successfully for most participants, substantially reducing the number of patients requiring invasive surgical procedures at the outset and additional operations during a 6-month period. These findings are strengthened by consistency between per-protocol and intention-to-treat analyses, excellent retention of participants during follow-up, minimal missing data, a robust scientific design, and adequate numbers of study participants.

In recent decades, orthopedic surgical practice has favored open surgical implant fixation of fractures of the ankle to restore exact joint congruence. This approach is considered to improve outcomes and reduce postinjury arthritis.

However, in older patients with lower demand, shorter life expectancy, lesser bone and tissue quality, and diminished capacity for healing, the rates of delayed or infected wound healing and loss of implant fixation become greater. More complicated types of clinical presentation were not included in the study sample, in which abnormalities of skin and risk of infection were substantially greater. Previous research has demonstrated the effectiveness of contact casting for management of significant skin ulceration in diabetes and related conditions.[24] The sample was consistent with the age, sex representations, and levels of disability of clinical populations and samples in other trials.[7,25,26] There were higher rates of radiologic malunion with close contact casting, indicating that maintaining position was more difficult. The overall equivalence in clinical outcome, however, challenges the importance of restoring exact joint congruence in older adults and suggests that function and pain are not as closely related to malunion as many clinicians believe. Alternatively, the grades or types of malunion observed after close contact casting may be of little functional significance.

The evidence base for nonsurgical fracture management is limited. To our knowledge, this clinical trial is the first to report the effectiveness of close contact casting for this indication. The findings are consistent with a recent smaller trial of younger persons with similar injuries that compared traditional casting techniques and surgery and reported no functional differences but more malunion with casting.[27]

This was a pragmatic trial recruiting from major trauma centers and smaller district hospitals following their usual practices for assessment and management. The trial protocol allowed aspects of care, except the intervention, to continue unchanged and enabled the results to be generalizable to a range of settings. The design allowed for different decisions being made in the operating room, as is the case in everyday practice. The results represent a well-controlled comparison of the 2 intervention strategies of starting fracture management with surgery or casting.

Limitations have to be recognized. Longer-term outcomes would have yielded greater certainty of the safety and effectiveness of treatment, particularly the development of posttraumatic osteoarthritis. However, the weight of evidence showed that physical function at 6 months was a robust intermediary measure for long-term outcome.[28] There is a fundamental uncertainty about causative factors of posttraumatic osteoarthritis. The limited published evidence implicates direct damage caused by the initial trauma, complications, and patient-related factors rather than joint alignment during the fracture reduction.[29-31] A learning curve was not identified for close contact casting, but this might have been difficult to detect, given the limited number of close contact casting procedures conducted by each surgeon during the trial. There were a large number of secondary analyses, and although they should be considered exploratory, all are consistent in direction and nature.

Conclusions

Among older adults with unstable ankle fracture, the use of close contact casting compared with surgery resulted in similar functional outcomes at 6 months. Close contact casting may be an appropriate treatment for such patients.

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