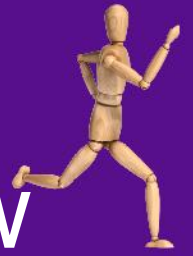


This Paper Will Change Your
Practice, It Changed Mine: New
Information That You Need to
Know
OTA Specialty Day March



Kenneth A. Egol, M.D.

I (and/or my co-authors) have something to disclose.

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Closed Contact Casting Vs Surgery for Initial Treatment of Unstable Ankle Fractures in Older Adults: A Randomized Clinical Trial



- Randomized Clinical Trial
- Published IN JAMA
- Took place at 24 centers in the UK

Research

JAMA | Original Investigation

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

Keith Willett, MB,BS, FRCS, David J. Keene, DPhil, Dinesh Misra, PhD, Julian Nam, MSc, Elizabeth Tutton, PhD, Robert Handley, FRCS, Lesley Morgan, Emma Roberts, Andrew Briggs, DPhil, Ranjit Lal, PhD, Timothy J. S. Chesser, FRCS, Ian Pallister, FRCS, Sarah E. Lamb, DPhil, for the Ankle Injury Management (AIM) Trial Collaborators

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 RESULTS 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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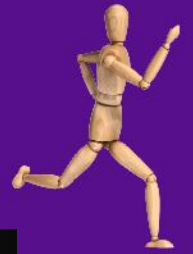
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Author Affiliations: Author affiliations are listed at the end of this article.

Group Information: The Ankle Injury Management (AIM) Trial Collaborators members are listed at the end of this article.

Corresponding Author: Keith Willett, MB,BS, FRCS, Kadoorie Centre for Critical Care Research and Education, Level 3, John Radcliffe Hospital, Oxford, OX3 9DU, United Kingdom (keth.willett@rjh.ox.nhs.uk).

Design



- Patients over 60
- Randomized to receive cast or surgery
 - Via telephone 24 hrs a day
- 6 week assessments not blinded all others were
- Min 6 months FU



Intervention



- ORIF

- Standard Principles
- Post op care per surgeon

- Close Contact Cast

- IN OR under anesthesia
- Specific protocol
- All had 1 hour training session

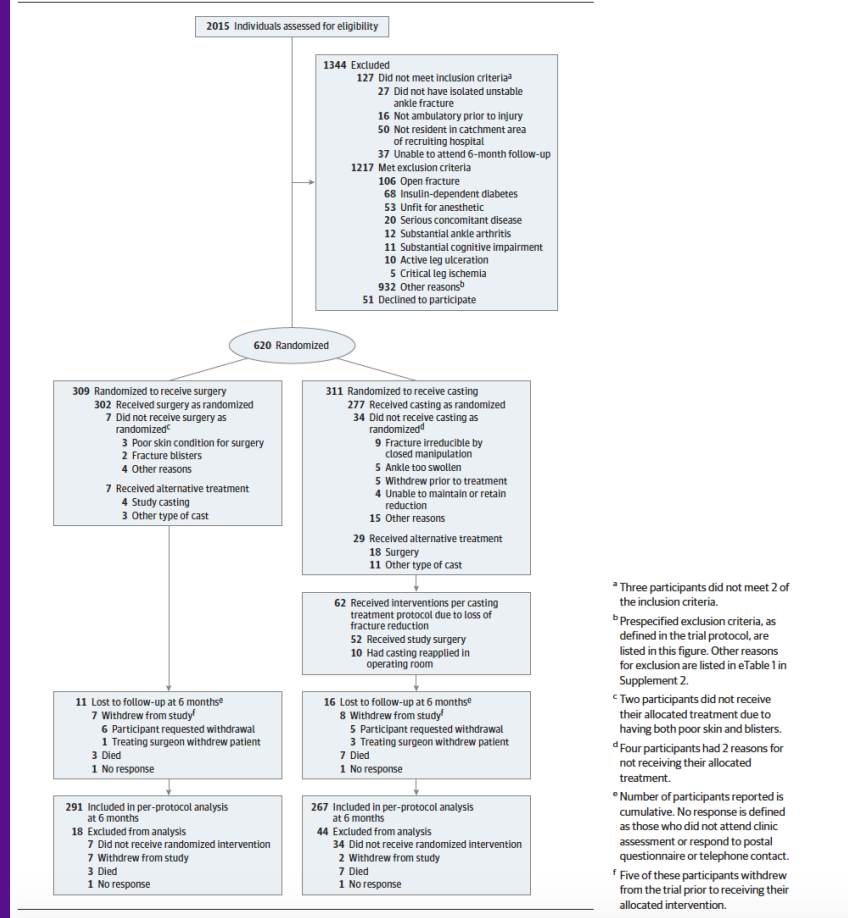


Outcomes



- 620 patients randomized
 - Over 300 in each group
- Follow up at 6 weeks and 6 months
- Olerud -Molander Score
- SF-12
- Euro-Quol 5
- Pain from subscales of OM

Figure. Trial Profile of Casting vs Surgery for Ankle Fracture in Older Adults¹



Outcomes



- Patient reported time to WB
- Timed get up and go test at 6 mos
- Radiographic
 - Union
 - Ankle mortise
- Complications recorded



Results



- Baseline demos demonstrated equivalent groups
- 19% of casted patients were converted to ORIF due to loss of reduction
- 4% re-casted (second anesthetic)

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. (%)		
Infrasyndesmotoc/trans-syndesmotoc	272 (88.0)	270 (86.8)
Suprasyndesmotoc	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.

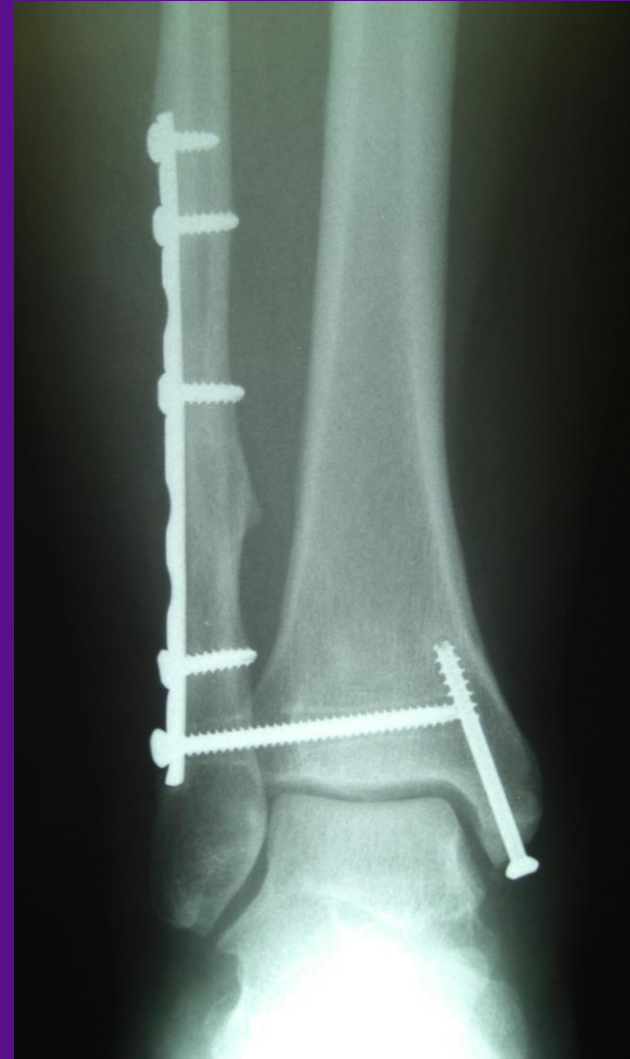
^e Range typically from 0 (death) to 1 (perfect health); negative scores can be obtained, reflective of a patient's quality of life being worse than death.

^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.

Results



- At 6 months successfully casted and ORIF had equivalent outcomes
- 10% of ORIF patients had a wound problem or infection (1% in cast)



Limitations



- 6 months follow up
- Definition of Older?
- Learning curve to casting
- Ankle fractures are a wide range of injury
- A reduced mortise at healing is the key- not new



So Why is it Important?



- Provides level 1 evidence to what we know
- Provides treating surgeons with information to discuss with patients and families
- Provides cover from malpractice attorneys



Conclusion



- In properly selected older patients with unstable ankle fractures
- Casting with a reduced ankle mortise can be successful 75% of the time
- If this treatment is chosen, patients need close follow up



Thank You

