The added value of routine radiographs in wrist and ankle fractures

Gerven, P. van

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Routine radiography following the initial 2 weeks of follow-up of ankle fracture patients does not have added value. The WARRIOR trial: a multicenter randomized controlled trial

P. van Gerven
P. Krijnen
W.P. Zuidema
M. El Moumni
S.M. Rubinstein
M.W. van Tulder
I.B. Schipper
M.F. Termaat
and the WARRIOR Trial Study Group*

* Warrior study group (other than those already mentioned as authors):
L van Bodegom-Vos, R.S. Breederveld, R.J. Derksen, B. van Dijkman, J.C. Goslings, J.H. Hegeman, J.M. Hoogendoorn, C. van Kuijk, S.A.G. Meylaerts, F.R. Rosendaal, N.L. Weil, K.W. Wendt

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ABSTRACT

Background

The clinical consequences of routine follow-up radiographs for patients with ankle fractures are unclear, and their usefulness is disputed. The aim of the present study was to determine if routine radiographs made at weeks 6 and 12 can be omitted without compromising clinical outcomes.

Methods

This multicenter randomized controlled trial with a noninferiority design included 246 patients with an ankle fracture, 153 (62%) of whom received operative management. At 6 and 12 weeks of follow-up, patients in the routine care group (n=128) received routine radiographs whereas patients in the reduced imaging group (n=118) did not. The primary outcome was the Olerud-Molander Ankle Score (OMAS). Secondary outcomes were the American Academy of Orthopaedic Surgeons (AAOS) foot and ankle questionnaire, health-related quality of life (HRQoL) as measured with the EuroQol-5 Dimensions-3 Levels (EQ-5D-3L) and Short Form-36 (SF-36), complications, pain, health perception, self-perceived recovery, the number of radiographs, and the indications for radiographs to be made. The outcomes were assessed at baseline and at 6, 12, 26, and 52 weeks of follow-up. Data were analyzed with use of mixed models.

Results

Reduced imaging was noninferior compared with routine care in terms of the OMAS (difference [β], −0.9; 95% confidence interval [CI], −6.2 to 4.4). AAOS scores, HRQoL, pain, health perception, and self-perceived recovery did not differ between groups. Patients in the reduced imaging group received a median of 4 radiographs, whereas those in the routine care group received a median of 5 radiographs ($p < 0.05$). The rates of complications were similar (27.1% [32 of 118] in the reduced imaging group, compared with 22.7% [29 of 128] in the routine care group, $p = 0.42$). The types of complications were also similar.

Conclusion

Implementation of a reduced imaging protocol following an ankle fracture has no measurable negative effects on functional outcome, pain, and complication rates during the first year of follow-up. The number of follow-up radiographs can be reduced by implementing this protocol.

INTRODUCTION

Ankle fractures are one of the most common skeletal injuries. Approximately 10% of all fractures involve the ankle, and the reported incidence of ankle fractures is between 101 and 187 per 100,000 per year.[1-3] Over the last decade, this incidence has risen because of increasing participation in athletic activities and aging of the population.[4] About half of these fractures are managed operatively because of incongruity of the joint or primary instability.[5] Following ankle fracture treatment, routine radiographic assessment of the ankle is a common practice both for operatively and nonoperatively managed patients worldwide.[4, 6, 7] Screening for incongruity of the joint is a common reason for making follow-up radiographs. Incongruity can lead to uneven joint loading, osteoarthritis, and a poor functional outcome. Other reasons for radiographs include monitoring of bone healing, assessing osteosynthesis material, identifying complications, reassuring the patient and physician, educating residents, and medicolegal motives.[6] Recent studies have debated the usefulness of routine follow-up radiographs for patients with ankle fractures.[8-13] In a previous retrospective study, we found that the treatment strategy was modified in only 11 (1.2%) of 936 instances in which a radiograph was made routinely after >3 weeks of follow-up.[5] This finding suggests that omitting these radiographs does not lead to worse clinical outcomes. However, that analysis was based on data that were collected retrospectively, and, therefore, was subject to various forms of bias that may have influenced the outcomes and conclusions. Therefore, the purpose of the present study was to evaluate whether routine radiography after the initial 2 weeks of follow-up can be omitted without compromising functional and clinical outcomes for patients with ankle fractures.

METHODS

Setting and Design

This research was designed as a multicenter randomized controlled trial (RCT) with a noninferiority design for the primary outcome.[14] The study was performed in 7 hospitals in the Netherlands, including 4 level-I trauma centers, 2 level-II trauma centers, and 1 level-III trauma center. Patients were included between July 2014 and October 2017. Noninferiority trials assess whether an intervention is not worse (noninferior) compared with routine care. If so, other outcomes, such as lower costs, fewer side effects, or improved feasibility, should then be considered.[15] More detailed information, such as study design, can be found in our protocol, which was published prior to the start of patient inclusion.[16] The trial was approved by the Medical Ethics Committee of the Leiden University Medical Center (project number: P14.086). The Consolidated Standards of

Reporting Trials (CONSORT) guidelines for noninferiority trials were followed when reporting our results.[15] The trial was registered in the Netherlands Trial Register (NL4477).

Inclusion Criteria

Patients were eligible if they were ≥18 years of age, had adequate Dutch language understanding, had a closed or Gustilo grade-1 open fracture of the ankle (Lauge-Hansen classification types: supination-adduction [SA] 2, supination-external rotation [SE] 2 to 4, pronation-external rotation [PE] 1 to 4, or pronation-abduction [PA] 1 to 3), and provided written informed consent.[17] Ankle sprains and isolated Danis-Weber type A[18] (Lauge-Hansen SA1) fractures were not eligible for inclusion as radiographic follow-up is not routinely performed in such cases.

Exclusion Criteria

We excluded patients who had a pathological fracture, an open fracture (Gustilo grade 2 or 3), or multiple fractures involving the extremities. Patients deemed unable to comply with follow-up and patients who were assigned to a nonparticipating hospital for treatment or follow-up were also excluded.

Sample-Size Calculation

To demonstrate noninferiority with a power of 0.85 and an alpha of 0.05, 142 participants were necessary on the basis of the margin of noninferiority of 9 points on the Olerud-Molander Ankle Score (OMAS).[19] The sample-size calculation has been described in detail elsewhere.[16] To be able to perform a subgroup analysis for nonoperatively and operatively managed patients, 284 participants had to be included. To account for a 10% rate of loss to follow-up, 312 participants were needed in total.

Randomization

Participants were randomized to either the routine care group or the reduced imaging group in a 1:1 ratio, stratified by hospital and treatment (i.e., operative or nonoperative management). Neither participants nor physicians were blinded.[16]

Routine Care Group

Patients who were randomized to the routine care group received radiographic follow-up according to the local trauma protocol.[7] The first weeks of follow-up were similar for both groups. Follow-up of the routine care group after these initial 2 weeks consisted of outpatient clinic visits that includes a routine radiographic evaluation at 6 and 12 weeks after trauma or operative management. The start of weight-bearing mobilization and the initiation of physical therapy were at the discretion of the treating physician, and additional follow-up evaluations and radiographs could be scheduled at any time.

Reduced Imaging Group

Follow-up in the reduced imaging group was similar to that in the routine care group, except that routine radiographic evaluation was omitted at weeks 6 and 12. Radiographs were made at those intervals only if a clinical indication was present or at the treating physician's discretion. Clinical indications included new trauma involving the affected ankle, a score of >6 on the 0-to-10-point visual analog scale (VAS) for pain, loss of range of motion, or neurovascular symptoms. Clinicians had the discretion to order another radiograph for several reasons. For example, if a specific fracture pattern was regarded as highly unstable, if delayed bone-healing was expected (e.g., because of older age, diabetes mellitus, smoking habits, or osteoporosis), or if the patient wished to have a radiographic examination at the time of follow-up. As in the routine care group, the start of weight-bearing mobilization and the initiation of physical therapy were at the discretion of the treating physician, and additional follow-up evaluations and radiographs could be scheduled at any time.

Primary Outcome Measure

The primary outcome was patient-reported functional outcome according to the OMAS.[19]

Secondary Outcome Measures

Foot and ankle-related disability was assessed with the American Academy of Orthopaedic Surgeons (AAOS) foot and ankle questionnaire for ankle fractures, including the optional AAOS shoe module.[20] Health-related quality of life (HRQoL) was assessed with use of the EuroQol-5 Dimensions-3 Levels (EQ-5D-3L) questionnaire[21] and the Physical Component Summary (PCS) and Mental Component Summary (MCS) scores of the Short Form-36 (SF-36) questionnaire.[22, 23] VAS scores were used to measure pain at rest and when the affected ankle was moved. Overall health status was also scored with use of a VAS. Self-perceived recovery and return of ankle function were scored with use of a 5-point Likert scale. All patient-reported outcomes were gathered at baseline (pre-injury status) and after 6, 12, 26, and 52 weeks of follow-up. Information on the number of radiographs, and reasons to obtain these radiographs were derived from the medical charts. Information on complications, including implant failure, nonunion, malunion, surgical site infections, and chronic pain, was also derived from the medical charts, which were independently reviewed by 2 investigators.

Statistical Analysis

Data were analyzed with use of SPSS Statistics for Windows (version 25; IBM Corp., Armonk, NY). Baseline characteristics were compared with use of descriptive statistics. The Mann-Whitney U test was used to compare the median number of radiographs. The

χ^2 test was used to compare complication rates between groups. Linear mixed models were used to analyze repeated patient-reported outcomes and to handle missing values. The models had a longitudinal 2-level structure in which questionnaires over time were clustered within patients. Differences in outcome in these analyses are reported as the intervention's regression coefficient (difference [β]), with the associated 95% confidence interval (CI). The primary outcome was compared with the noninferiority margin. All secondary outcome measures were analyzed using a superiority design. The analyses were corrected for the patients' pre-injury status and potentially confounding patient characteristics (Table I). Missing values in potential confounders were multiply imputed. For all statistical tests, significance was assumed at $p < 0.05$.

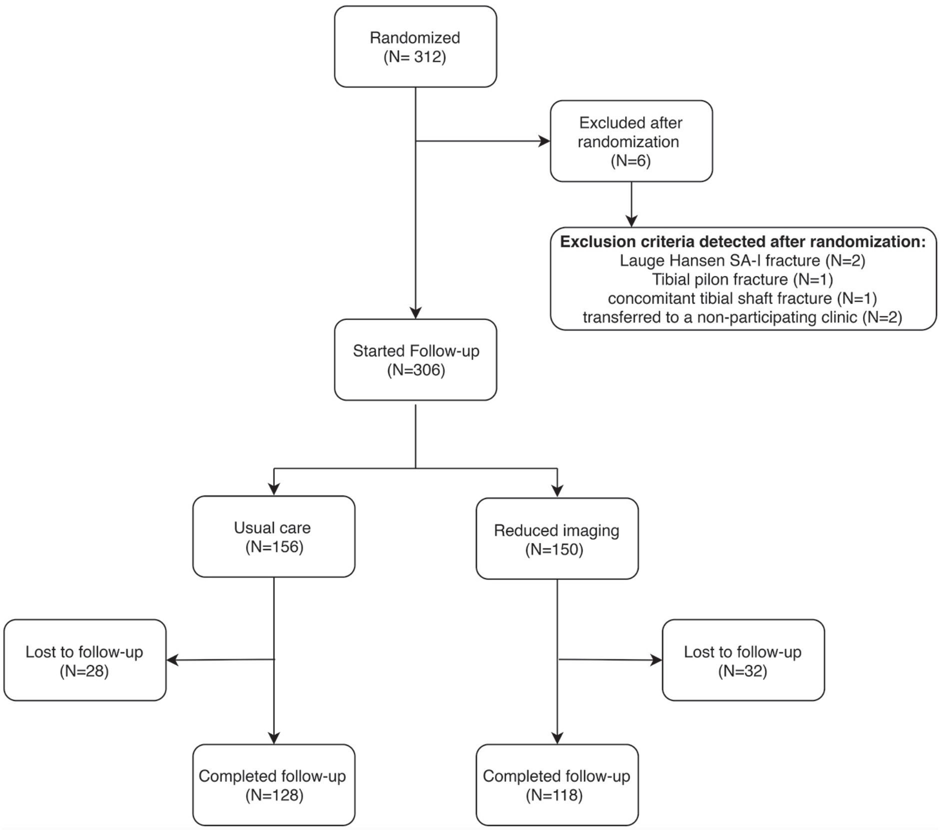

Figure 1. Flowchart of patients.

RESULTS

Participants

In total, 312 eligible patients with an ankle fracture were included in the study. 6 were excluded following randomization, and 60 patients (19.2%) were lost to follow-up because none of the questionnaires were returned during follow-up and therefore no data were available for analysis (Fig. 1). The study group consisted of 246 patients, of whom 128 were randomized to the routine care group and 118 were randomized to the reduced imaging group. No differences were observed in baseline characteristics apart from a higher mean body mass index (BMI) in the reduced imaging group (Table I). Overall, 153

Table I. Patient characteristics by treatment allocation

		Routine care (n=128)		Reduced imaging (n=118)		*p*-value
Male sex,	n (%)	69	(53.9)	58	(48.7)	0.42
Age	mean (SD)	47.7	(18.5)	50.8	(18.2)	0.18
BMI	mean (SD)	25.8	(4.3)	27.3	(6.0)	**0.02**
Alcohol >10 U/week	n (%)	22	(17.2)	16	(13.4)	0.42
Smoking >10/day	n (%)	10	(7.8)	9	(7.6)	0.94
Operative treatment	n (%)	77	(60.2)	76	(64.4)	0.46
Lauge-Hansen classification SA	n (%)	2	(1.6)	2	(1.7)	0.60
SE		94	(73.4)	94	(79.0)	
PA/PE		31	(24.2)	23	(19.3)	
missing		1	(0.8)	0	(0.0)	
Weber classification A	n(%)	2	(1.6)	2	(1.7)	0.49
B		93	(72.7)	94	(79.0)	
C		27	(21.1)	21	(17.6)	
missing		6	(4.7)	2	(1.7)	
Malleolar involvement Uni-	n(%)	66	(51.6)	64	(53.8)	0.79
Bi-		27	(21.1)	21	(17.6)	
Tri-		35	(27.3)	34	(28.6)	
ASA classification 1	n(%)	53	(41.4)	47	(39.5)	0.83
2		60	(46.9)	55	(46.2)	
≥3		15	(11.7)	12	(7.7)	

Legend for Table I:
SD: Standard deviation
SA: Supination-adduction
SE: Supination-external rotation
PA: Pronation-adduction
PE: Pronation-eversion
BMI: Body Mass index
ASA: American Society of Anesthesiologists
Bold = a significant difference between groups (*p* <0.05)

patients (62%) received operative management, including 77 in the routine care group and 76 in the reduced imaging group. In total, 1,096 (89%) of 1,230 questionnaires were completed by the patients in the study group.

Table II: outcome scores per treatment allocation per timepoint, and adjusted differences(β)

	Routine care n=128 median (IQR)	**Reduced imaging** n=118 median (IQR)	**RC vs RI** Adjusted β (95%CI)
OMAS (0-100)			
BL	100 (100-100)	100 (100-100)	-
W6	40 (25-60)	45 (25-65)	-3.3 (-8.4 to 1.9)
W12	65 (45-80)	65 (46-80)	-0.9 (-5.9 to 4.2)
W26	85 (68-95)	80 (65-95)	1.74 (-3.4 to 6.9)
W52	90 (80-100)	90 (80-100)	-0.9 (-6.2 to 4.4)
AAOS (0-100)			
BL	100 (98-100)	100 (98-100)	-
W6	73 (59-82)	76 (63-84)	-2.8 (-6.6 to 1.0)
W12	85 (74-92)	83 (73-92)	1.1 (-2.4 to 4.7)
W26	93 (87-97)	94 (84-98)	0.1 (-3.5 to 3.7)
W52	96 (91-99)	97 (89-100)	0.8 (-2.9 to 4.5)
AAOS shoe (0-100)			
BL	100 (100-100)	100 (75-100)	-
W6	50 (25-100)	50 (25-94)	-2.4 (-113 to 6,5)
W12	60 (37-100)	50 (25-100)	-2.2 (-9.8 to 5.4)
W26	100 (100-100)	80 (43-100)	-4.8 (-12.5 to 2.8)
W52	100 (50-100)	80 (50-80)	0.1 (-7.6 to 7.9)
EQ-5D-3L (0-1)			
BL	1.0 (0.9-1.0)	1.0 (0.84-1.0)	-
W6	0.78 (0.57-0.81)	0.78 (0.65-0.86)	**-0.05 (-0.09 to -0.004)**
W12	0.83 (0.78-1.0)	0.81 (0.78-1.0)	-0.02 (-0.06 to 0.03)
W26	1.0 (0.81-1.0)	0.84 (0.78-1.0)	0.03 (-0.02 to 0.07)
W52	1.0 (0.84-1.0)	1.0 (0.81-1.0)	-0.00 (-0.05 to 0.04)
SF36 PCS (0-100*)			
BL	57.2 (54.8-59.3)	56.9 (52.7-58.9)	-
W6	36.3 (29.6-44.8)	34.8 (28.8-41.7)	0.5 (-1.6 to 2.6)
W12	45.5 (38.5-51.5)	43.2 (36.9-51.1)	0.3 (-1.8 to 2.4)
W26	53.1 (46.9-56.4)	50.8 (41.7-55.6)	1.3 (-0.9 to 3.5)
W52	54.1 (49.1-57.3)	53.5 (47.4-57.0)	0.1 (-2.1 to 2.3)

Table II: outcome scores per treatment allocation per timepoint, and adjusted differences(β) (continued)

	Routine care n=128 median (IQR)	**Reduced imaging** n=118 median (IQR)	**RC vs RI** Adjusted β (95%CI)
SF36 MCS (0-100*)			
BL	53.8 (48.1-58.5)	54.1 (48.3-56.5)	-
W6	53.5 (44.2-58.9)	53.3 (45.1-41.7)	-0.6 (-2.6 to 1.5)
W12	55.0 (49.8-60.1)	56.8 (47.9-60.1)	-0.2 (-2.2 to 1.9)
W26	54.7 (49.1-58.3)	55.6 (50.3-59.1)	-1.0 (-3.2 to 1.1)
W52	54.3 (49.3-58.5)	55.6 (50.3-58.3)	-0.4 (-2.6 to 1.7)
pain rest (0-10)			
BL	0.0 (0.0-1.0)	0.0 (0.0-1.0)	-
W6	1.0 (0.3-2.9)	1.0 (0.0-2.3	0.3 (-0.1 to 0.8)
W12	1.0 (0.0-2.0)	1.0 (0.0-2.0)	-0.0 (-0.5 to 0.4)
W26	0.4 (0.0-1.2)	0.5 (0.0-2.0)	0.2 (-0.2 to 0.7)
W52	0.5 (0.0-1.0)	0.1 (0.0-1.0)	0.1 (-0.4 to 0.5)
pain movement (0-10)			
BL	0.0 (0.0-1.0)	0.1 (0.0-1.0)	-
W6	3.0 (2.0-5.0)	2.5 (1.0-4.8)	0.4 (-0.1 to 1.0)
W12	2.0 (1.0-3.2)	2.0 (1.0-4.0)	-0.2 (-0.7 to 0.4)
W26	1.0 (0.1-2.0)	1.0 (0.1-2.0)	0.1 (-0,5 to 0.7)
W52	1.0 (0.0-1.9)	1.0 (0.0-2.0)	-0.0 (-0.6 to 0.6)
Health status (0-10)			
BL	8.2 (7.5-9.0)	8.0 (7.0-9.0)	-
W6	8.0 (6.8-9.0)	7.5 (7.0-8.8)	-0.1 (-0.5 to 0.4)
W12	8.0 (7.0-9.0)	8.0 (7.0-8.0)	0.0 (-0.5 to 0.5)
W26	8.0 (7.3-9.0)	8.0 (7.0-8.8)	0,4 (-0,0 to 0,9)
W52	8.0 (7.1-9.0)	8.0 (7.0-9.0)	0,1 (-0.4 to 0.6)
Recovered (1-5)‡			
W6	3.0 (3.0-4.0)	3.0 (3.0-4.0)	0.1 (-0.1 to 0.3)
W12	4.0 (4.0-4.0)	4.0 (3.0-4.0)	0.1 (-0.1 to 0.3)
W26	4.0 (4.0-4.0)	4.0 (4.0-4.0)	0.0 (-0.2 to 0.2)
W52	4.0 (4.0-5.0)	4.0 (4.0-5.0)	0.2 (-0.1 to 0.4)
Regained function (1-5)‡			
W6	2.0 (1.0-3.0)	2.0 (1.0-3.0)	-0.1 (-0.4 to 0.1)
W12	4.0 (2.0-4.0)	3.0 (2.0-4.0)	0.1 (-0.1 to 0.4)
W26	4.0 (3.3-4.0)	4.0 (3.0-5.0)	0.1 (-0.2 to 0.3)
W52	4.0 (4.0-5.0)	4.0 (4.0-5.0)	0.0 (-0.2 to 0.3)

Legend Table II
*: 50 = average score
‡: Higher = better
Bold = a significant difference between groups (p <0.05)

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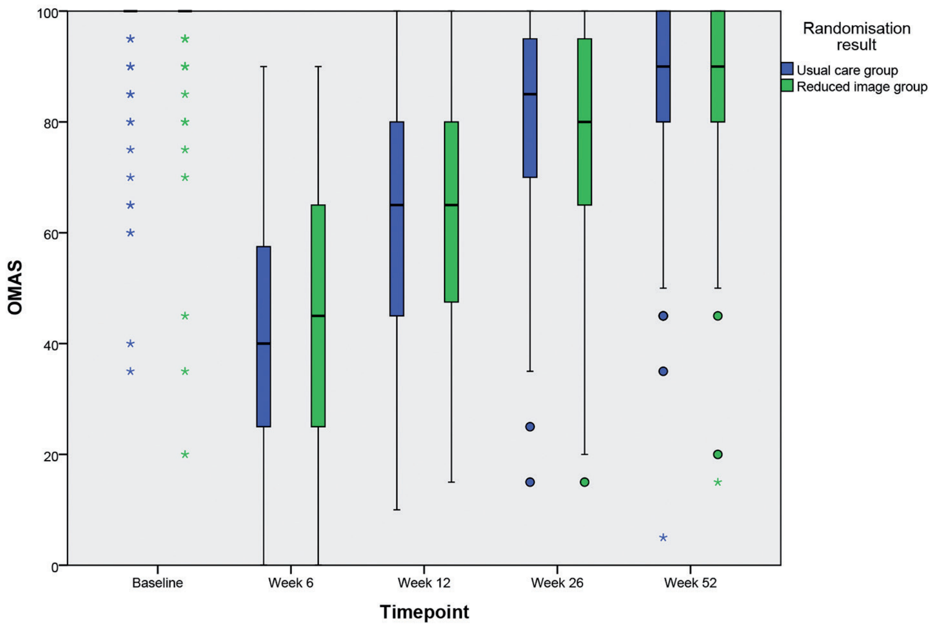

Figure 2: Box plot of OMAS over time. Horizontal line in box = median, top and bottom of box = interquartile range, whiskers = 1.5 times the interquartile range, circles = outliers, and asterisks = extreme outliers

Primary Outcome

The difference in the OMAS between groups was within the margin of noninferiority at all time points (Table II). At 52 weeks, the OMAS for the reduced imaging group (median, 90; interquartile range [IQR], 80 to 100) was noninferior in comparison with that for the routine care group (median, 90; IQR, 80 to 100) (Fig. 2). The difference in the OMAS and its 95% CI were within the margin of noninferiority of 9 points (β, –0.9; 95% CI –6.2 to 4.4).

Secondary Outcomes

At 52 weeks, the patient-perceived functional status of the injured ankle was comparable between the groups according to the AAOS foot and ankle questionnaire (β, 0.8; 95% CI, –2.9 to 4.5) (Table II). Scores per time point were similar in both groups (Fig. 3). The scores for the AAOS shoe questionnaire were comparable as well (Table II). No differences between the groups were found at week 52 in terms of HRQoL. The EQ-5D-3L scores were similar at 52 weeks (β, –0.00; 95% CI, –0.05 to 0.04) and at all other individual time points except for week 6, at which the EQ-5D-3L scores for the reduced imaging group were significantly higher than those for the routine care group (β, –0.05; 95% CI, –0.09 to –0.004) (Fig. 4, Table II). Neither the PCS and MCS scores of the SF-36 questionnaire nor pain were inferior in the reduced imaging group as compared with the routine

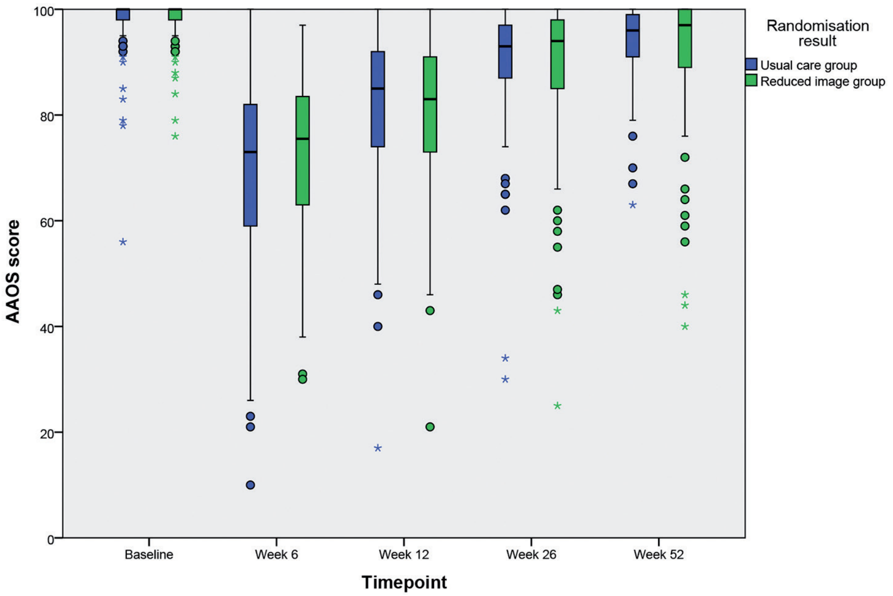

Figure 3: Box plot of AAOS ankle scores over time. Horizontal line in box = median, top and bottom of box = interquartile range, whiskers = 1.5 times the interquartile range, circles = outliers, and asterisks = extreme outliers

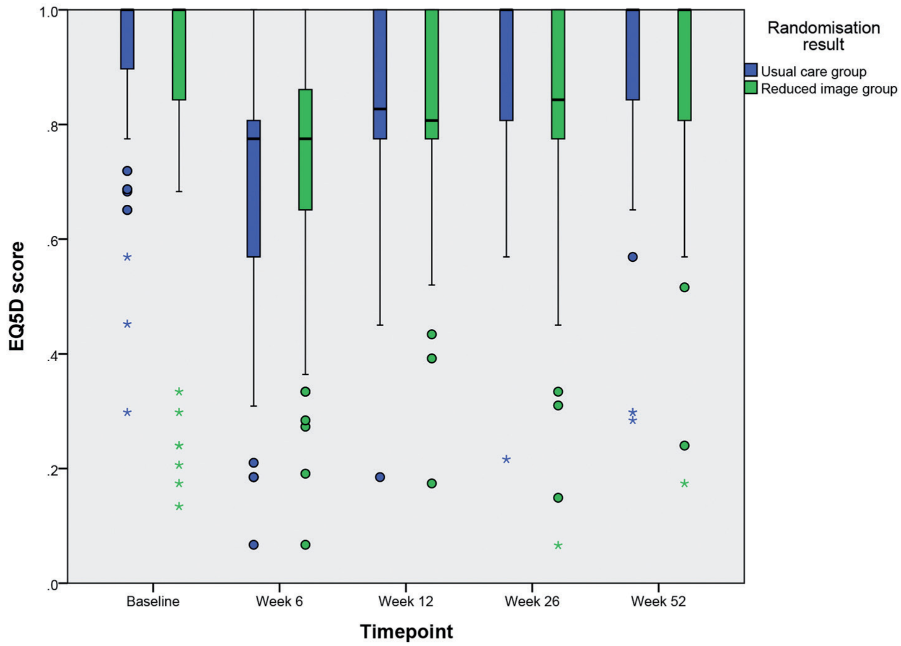

Figure 4: Box plot of EQ-5D-3L scores over time. Horizontal line in box = median, top and bottom of box = interquartile range, whiskers = 1.5 times the interquartile range, circles = outliers, and asterisks = extreme outliers

care group at any time point (Figs. 5 and 6, Table II). Both groups had similar scores for median health status at week 52 (β, 0.1; 95% CI, −0.4 to 0.6), median self-perceived recovery at week 52 (β, 0.2; 95% CI, −0.1 to 0.4), and return of ankle function (β, 0.0; 95% CI, −0.2 to 0.3) (Table II). Complications did not occur more often in the reduced imaging group (27.1% [32/118]) than in the routine care group (22.7% [29/128], $p = 0.42$). Specific types of complications were also equally common (Table III).

Radiographs

During treatment of all patients, 1,204 sets of 3-view radiographs were made (Table IV). Patients in the routine care group received a median of 5 radiographs (IQR, 4 to 6 radiographs) during the entire treatment period, which was significantly higher than the number in the reduced imaging group (median, 4 radiographs; IQR, 3 to 5 radiographs) ($p < 0.05$). More radiographs were made to assess bone-healing in the routine care group in comparison with the reduced imaging group (295 [43%] versus 181 [35%], $p < 0.05$). More radiographs were made to assess a painful ankle in the reduced imaging group than in the routine care group (14 [2.7%] versus 9 [1.3%], $p < 0.05$). A significantly lower percentage of patients in the reduced imaging group had a radiograph made after 2 weeks when compared with patients in the routine care group (77 [65%] versus 105 [82%], $p < 0.05$).

Subgroup Analyses

The OMAS at week 52 for the reduced imaging group were noninferior to those for the routine care group within the subgroups of operatively treated and nonoperatively treated patients (see Appendix). For nonoperatively treated patients, all patient-reported secondary outcome measures were comparable at all time points and for the entire follow-up period, apart from the SF36 MCS score at 6 weeks, which was higher for the routine care group (see Appendix). For operatively treated patients, the AAOS score, EQ-5D-3L score, and SF36 MCS score were higher for the reduced imaging group than for the routine care group at 6 weeks. In contrast, pain at rest and self-perceived recovery were lower for the reduced imaging group at 6 weeks. All other outcome measures showed similar results in the routine care and reduced imaging groups at all time points (see Appendix).

Per-Protocol Analysis

A per-protocol analysis was performed to assess the influence of protocol violations. This analysis resulted in outcomes like the main analysis. Reduced imaging was noninferior to routine care for the OMAS at week 52 (β, −0.5; 95% CI, −7.5 to 6.6) (see Appendix).

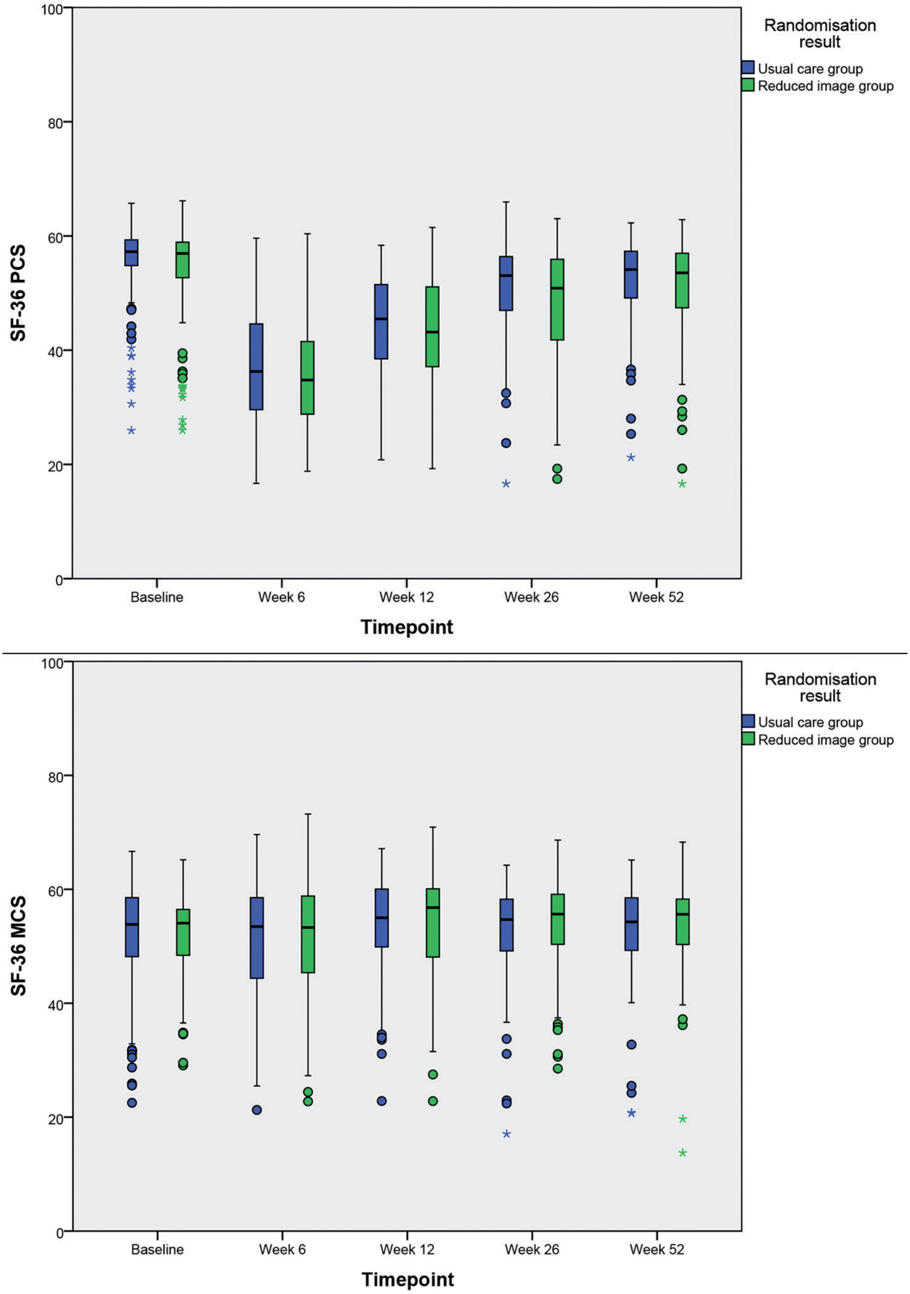

Figure 5: Box plots of SF-36 PCS and MCS over time. Horizontal line in box = median, top and bottom of box = interquartile range, whiskers = 1.5 times the interquartile range, circles = outliers, and asterisks = extreme outliers

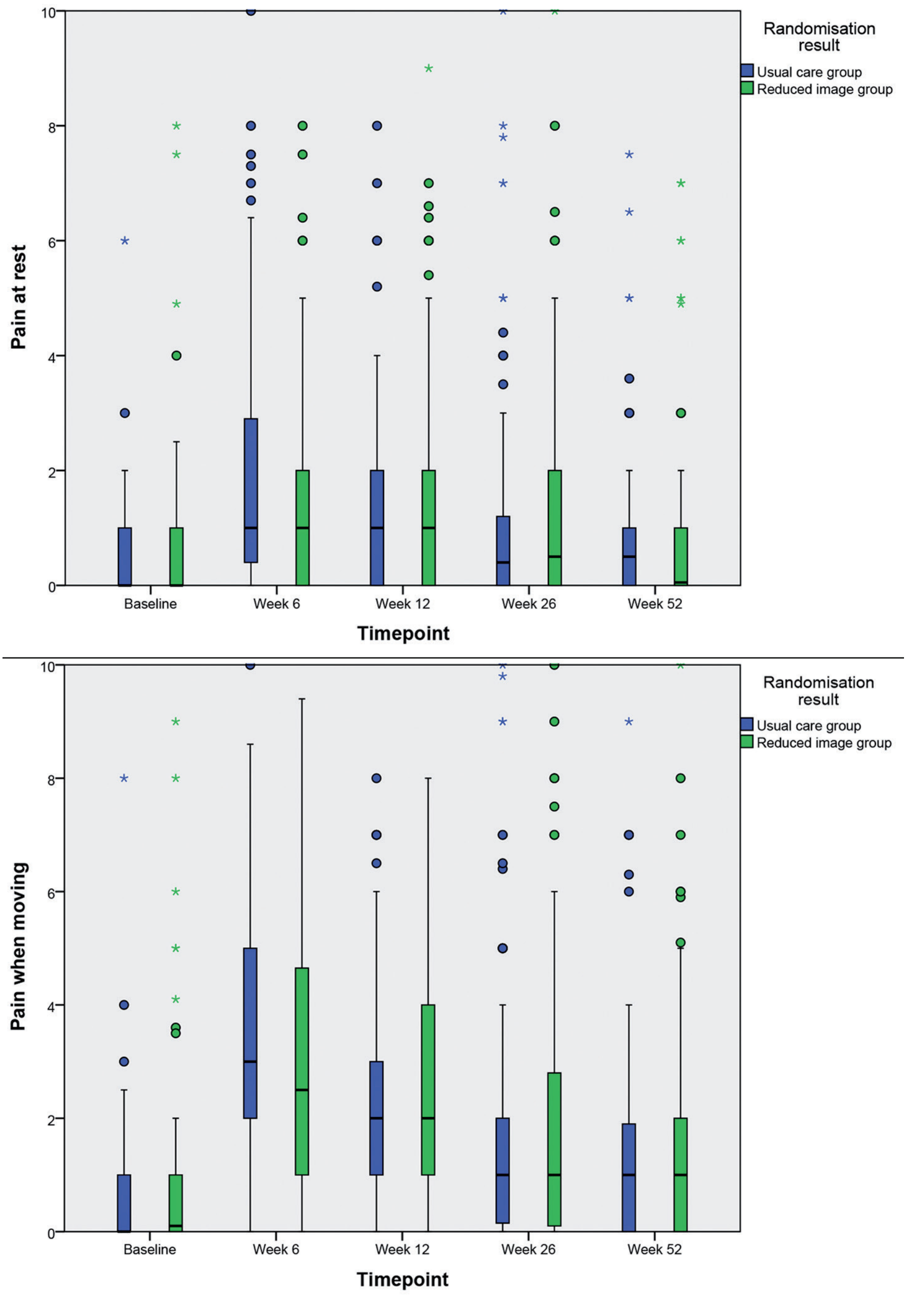

Figure 6: Box plots of VAS for pain at rest and when moving over time. Horizontal line in box = median, top and bottom of box = interquartile range, whiskers = 1.5 times the interquartile range, circles = outliers, and asterisks = extreme outliers

Table III. Complications

Complication:	Routine care (n=128)	Reduced imaging (n=118)	*p*-value
Nonunion	2	3	0.59
Malunion	3	1	0.35
Surgical site infection	7	10	0.35
Failure of fixation	3	1	0.35
Neurological	5	2	0.30
Osteoarthritis	0	3	NA
Hardware Complaints	3	7	0.15
Talar osteonecrosis	2	0	NA
Chronic pain	4	5	0.64
Total	**29 (22.7%)**	**32 (27.1%)**	**0.42**

Table IV. Radiographs and indications

	Routine Care (n=128)	Reduced Imaging (n=118)	*p*-value
Number of radiographs	681	523	
Radiographs per patient, median (IQR)	5 (4-6)	4 (3-5)	**<0.05**
Radiograph after two weeks follow-up, N (%)	105 (84.3)	77 (65.3)	**<0.05**
Indication, *N (%)*			
Fracture	136 (20)	118 (22.6)	0.3
Dislocation	488 (71.7)	356 (68.1)	0.2
Consolidation	295 (43.3)	181 (34.6)	**<0.05**
Routine	5 (0.7)	1 (0.2)	0.2
Pain	9 (1.3)	14 (2.7)	**<0.05**
Impaired function	1 (0.1)	0 (0)	0.4
Evaluate hardware	134 (19.7)	101 (19.3)	1.0
Before implant removal	11 (1.6)	9 (1.7)	0.9
Suspected complication	11 (1.6)	9 (1.7)	0.9
Unknown	3 (0.4)	1 (0.2)	0.5

Bold = a significant difference between groups ($p < 0.05$)

DISCUSSION

This large, multicenter RCT demonstrates that routine radiographs that are made after the first 2 weeks of follow-up do not affect outcomes in the first 12 months for patients with ankle fractures. Omitting routine radiographs led to a significant decrease of 1 radiograph per patient (median), whereas other outcomes such as functional status, HRQoL, pain levels, and complications were comparable. The decrease in the number of radiographs could provide a cost-saving opportunity.[8] For example, the cost for 1 radiograph (3 views) in the Netherlands is €52. With the incidence of 30,000 ankle fractures per annum, the cost saving potential in the Netherlands would add up to €1.5 million annually while leading to a small (0.003-mSv) reduction in ionizing radiation per patient.[24] These findings are consistent with those of previous retrospective studies that have suggested that routine follow-up radiographs have limited added value for patients with ankle fractures. Harish et al. [9], McDonald et al.,[12] Ovaska et al.,[11] Ghattas et al.,[8] and Miniaci-Coxhead et al.,[10] all concluded that routine radiographs made at the first postoperative outpatient clinic visit were of little value. Schuld et al. [13] reported a similar result for radiographs made after splinting nonoperatively managed fractures. In our previous retrospective cohort study of 528 participants,[5] we found that routine follow-up radiographs seldom influenced the treatment strategy.

The present study had some limitations. The number of protocol violations, especially in the reduced imaging group, was high. In the reduced imaging group, the protocol was followed for 59 (50%) of 118 patients. Of these, 51 patients had no radiographs at weeks 6 and 12 and 8 patients had a radiograph for which an indication was registered. The fact that protocol violations were more common in the reduced imaging group is in contrast with our previous randomized trial concerning reduced imaging in the follow-up period after wrist fractures.[25] In that study, protocol violations occurred mainly in the routine care group when a radiograph was not made at week 6 or 12. This finding might indicate that physicians put more value on follow-up radiographs for patients with an ankle fracture than for those with a distal radius fracture. This finding is in accordance with our retrospective studies,[5, 26] in which radiographs were more frequently made after >2 weeks of follow-up for patients with an ankle fracture[5] as compared with those with a distal radius fractures.[26] The high number of protocol violations also might be related to the possibility that clinical indications for radiographs were not recorded in the medical file. To determine whether these protocol violations influenced our results, a per-protocol analysis was conducted. As the per-protocol analysis showed results like the main analysis, we concluded that protocol violations did not introduce bias.

A second limitation might be related to performance bias as participants and physicians were not blinded to the treatment allocation. Because of the nature of the intervention, blinding of physicians was not possible and blinding of patients was impractical.

A third limitation is related to the high number of outcome measures and multiple time points at which data were collected. Multiple testing might have introduced a type-I error. We found some significant differences between the routine care group and the reduced imaging group at 6 weeks, particularly in the subgroup analyses. These differences are unlikely to be a result of the intervention as follow-up was similar for both groups up until that time point. All significant differences that were found were inconsistent over time and presumably represented random findings. Fourth, as the minimum clinically important difference for the OMAS is unknown, the margin of noninferiority was set at 9 points. This value was based on the minimum clinically important difference for the Disabilities of the Arm, Shoulder and Hand (DASH) score, which we used in a similar study for patients with distal radius fractures.[25] Importantly, our margin of noninferiority is consistent with other trials involving the OMAS such as the Ankle Injury Management (AIM) trial[27] and the Routine versus On DEmand removal Of the syndesmotic screw (RODEO) trial.[28] As the present trial was only powered to demonstrate noninferiority for the OMAS but not for the complication rate, it was possibly underpowered to detect a clinically relevant difference in adverse events such as malunions. Our previous retrospective study showed that conversion to operative care based on a routine radiograph was rare (0.2%).[5] This leads to a high number needed to treat. Whether this is justified in local healthcare and legal systems is up to policymakers and physicians. The study was performed in compliance with the published research protocol, thereby decreasing the risk of selective outcome reporting bias.[29]

In conclusion, this study demonstrates that omitting routine follow-up radiographs for patients with ankle fractures does not negatively affect outcomes or increase the risk of complications in the first 12 months of follow-up in comparison with routine care.

REFERENCES

1. Court-Brown CM, Caesar B. Epidemiology of adult fractures: A review. Injury. 2006 Aug;37(8):691-7. Epub 2006/07/04.
2. Daly PJ, Fitzgerald RH, Jr., Melton LJ, Ilstrup DM. Epidemiology of ankle fractures in Rochester, Minnesota. Acta orthopaedica Scandinavica. 1987 Oct;58(5):539-44. Epub 1987/10/01.
3. Thur CK, Edgren G, Jansson KA, Wretenberg P. Epidemiology of adult ankle fractures in Sweden between 1987 and 2004: a population-based study of 91,410 Swedish inpatients. Acta orthopaedica. 2012 Jun;83(3):276-81. Epub 2012/03/10.
4. Koehler S, Eiff P. Overview of ankle fractures in adults. UpToDate2016 [cited 2017 23-06-2017]; Available from: https://www.uptodate.com/contents/overview-of-ankle-fractures-in-adults.
5. van Gerven P, Weil NL, Termaat MF, Rubinstein SM, El Moumni M, Zuidema WP, et al. Routine Follow-Up Radiographs for Ankle Fractures Seldom Add Value to Clinical Decision-Making: A Retrospective, Observational Study. The Journal of foot and ankle surgery : official publication of the American College of Foot and Ankle Surgeons. 2018 Sep - Oct;57(5):957-60. Epub 2018/07/19.
6. Chaudhry S, DelSole EM, Egol KA. Post-splinting radiographs of minimally displaced fractures: good medicine or medicolegal protection? The Journal of bone and joint surgery American volume. 2012 Sep 05;94(17):e128(1)-(5). Epub 2012/09/21.
7. Schipper IB, Termaat MF, Rhemrev S, Meylaerts SAG, Bartlema K, Stichter W, et al. Richtlijnen voor behandeling van letsels van het steun en bewegingsapparaat (Clinical guidelines for the treatment of trauma to the musculoskeletal system). Rotterdam: Optima grafische communicatie; 2016.
8. Ghattas TN, Dart BR, Pollock AG, Hinkin S, Pham A, Jones TL. Effect of initial postoperative visit radiographs on treatment plans. J Bone Joint Surg Am. 2013 5/1/2013;95 e57(9):1-4.
9. Harish S, Vince AS, Patel AD. Routine radiography following ankle fracture fixation: a case for limiting its use. Injury. 1999 Dec;30(10):699-701.
10. Miniaci-Coxhead SL, Martin EA, Ketz JP. Quality and Utility of Immediate Formal Postoperative Radiographs in Ankle Fractures. Foot & ankle international. 2015 Oct;36(10):1196-201. Epub 2015/05/23.
11. Ovaska MT, Nuutinen T, Madanat R, Makinen TJ, Soderlund T. The role of outpatient visit after operative treatment of ankle fractures. Injury. 2016 Nov;47(11):2575-8. Epub 2016/11/05.
12. McDonald MR, Bulka CM, Thakore RV, Obremskey WT, Ehrenfeld JM, Jahangir AA, et al. Ankle radiographs in the early postoperative period: do they matter? Journal of orthopaedic trauma. 2014 Sep;28(9):538-41. Epub 2014/01/01.
13. Schuld JC, Volker ML, Anderson SA, Zwank MD. Postsplinting x-rays of nondisplaced hand, wrist, ankle, and foot fractures are unnecessary. The American journal of emergency medicine. 2016 Aug;34(8):1625-6. Epub 2016/05/30.
14. D'Agostino RB, Sr., Massaro JM, Sullivan LM. Non-inferiority trials: design concepts and issues - the encounters of academic consultants in statistics. Statistics in medicine. 2003 Jan 30;22(2):169-86. Epub 2003/01/10.
15. Piaggio G, Elbourne DR, Pocock SJ, Evans SJ, Altman DG. Reporting of noninferiority and equivalence randomized trials: extension of the CONSORT 2010 statement. Jama. 2012 Dec 26;308(24):2594-604. Epub 2012/12/27.
16. Weil NL, Termaat MF, Rubinstein SM, El Moumni M, Zuidema WP, Derksen RJ, et al. WARRIOR-trial - is routine radiography following the 2-week initial follow-up in trauma patients with wrist

and ankle fractures necessary: study protocol for a randomized controlled trial. Trials. 2015 Feb 27;16:66. Epub 2015/04/16.

17. Lauge-Hansen N. Fractures of the ankle. II. Combined experimental-surgical and experimental-roentgenologic investigations. Arch Surg. 1950 May;60(5):957-85.
18. Weber BG. Die Verletzungen des oberen Sprunggelenkes. Bern: Huber Verlag; 1966.
19. Olerud C, Molander H. A scoring scale for symptom evaluation after ankle fracture. Archives of orthopaedic and trauma surgery. 1984;103(3):190-4. Epub 1984/01/01.
20. Johanson NA, Liang MH, Daltroy L, Rudicel S, Richmond J. American Academy of Orthopaedic Surgeons lower limb outcomes assessment instruments. Reliability, validity, and sensitivity to change. The Journal of bone and joint surgery American volume. 2004 May;86(5):902-9. Epub 2004/05/01.
21. Lamers LM, Stalmeier PF, McDonnell J, Krabbe PF, van Busschbach JJ. [Measuring the quality of life in economic evaluations: the Dutch EQ-5D tariff]. Nederlands tijdschrift voor geneeskunde. 2005 Jul 09;149(28):1574-8. Epub 2005/07/26.
22. Aaronson NK, Muller M, Cohen PD, Essink-Bot ML, Fekkes M, Sanderman R, et al. Translation, validation, and norming of the Dutch language version of the SF-36 Health Survey in community and chronic disease populations. Journal of clinical epidemiology. 1998 Nov;51(11):1055-68. Epub 1998/11/17.
23. Ware JE, Jr., Sherbourne CD. The MOS 36-item short-form health survey (SF-36). I. Conceptual framework and item selection. Medical care. 1992 Jun;30(6):473-83. Epub 1992/06/11.
24. Lin EC. Radiation Risk From Medical Imaging. Mayo Clinic Proceedings. 2010;85(12):1142-6.
25. van Gerven P, El Moumni M, Zuidema WP, Rubinstein SM, Krijnen P, van Tulder MW, et al. Omitting Routine Radiography of Traumatic Distal Radial Fractures After Initial 2-Week Follow-up Does Not Affect Outcomes. The Journal of bone and joint surgery American volume. 2019 Aug 7;101(15):1342-50. Epub 2019/08/09.
26. Weil NL, El Moumni M, Rubinstein SM, Krijnen P, Termaat MF, Schipper IB. Routine follow-up radiographs for distal radius fractures are seldom clinically substantiated. Archives of orthopaedic and trauma surgery. 2017 Jul 22;137(9):1187-91. Epub 2017/07/25.
27. Keene DJ, Mistry D, Nam J, Tutton E, Handley R, Morgan L, et al. The Ankle Injury Management (AIM) trial: a pragmatic, multicentre, equivalence randomised controlled trial and economic evaluation comparing close contact casting with open surgical reduction and internal fixation in the treatment of unstable ankle fractures in patients aged over 60 years. Health technology assessment (Winchester, England). 2016 Oct;20(75):1-158. Epub 2016/10/14.
28. Dingemans SA, Birnie MFN, Sanders FRK, van den Bekerom MPJ, Backes M, van Beeck E, et al. Routine versus on demand removal of the syndesmotic screw; a protocol for an international randomised controlled trial (RODEO-trial). BMC musculoskeletal disorders. 2018 Jan 31;19(1):35. Epub 2018/02/02.
29. Rongen JJ, Hannink G. Comparison of Registered and Published Primary Outcomes in Randomized Controlled Trials of Orthopaedic Surgical Interventions. The Journal of bone and joint surgery American volume. 2016 Mar 2;98(5):403-9. Epub 2016/03/05.

APPENDICES

Appendix 1: Outcome scores per treatment allocation per timepoint, and adjusted differences(β) for the nonoperatively treated subgroup

	Routine care n=128 median (IQR)	**Reduced imaging** n=118 median (IQR)	**RC vs RI** Adjusted β (95%CI)
OMAS (0-100)			
BL	100 (90-100)	100 (100-100)	-
W6	50 (35-65)	55 (30-70)	1.9 (-6.3 to 10.1)
W12	70 (60-85)	75 (60-85)	1.2 (-6.9 to 9.3)
W26	90 (75-100)	90 (76-100)	5.3 (-2.9 to 13.4)
W52	95 (85-100)	100 (85-100)	2.7 (-5.9 to 11.2)
AAOS (0-100)			
BL	100 (98-100)	100 (99-100)	-
W6	77 (62-87)	76 (63-82)	3.8 (-1.6 to 9.1)
W12	89 (83-95)	86 (75-94)	5.0 (-0.3 to 10.2)
W26	96 (90-99)	98 (93-100)	2.4 (-3.1 to 7.8)
W52	95 (95-100)	99 (96-100)	2.5 (-3.1 to 8.0)
AAOS shoe (0-100)			
BL	100 (81-100)	100 (88-100)	-
W6	38 (25-100)	29 (25-100)	5.4 (-7.0 to 17.8)
W12	64 (50-100)	50 (33-100)	-1.4 (-12.0 to 9.1)
W26	100 (50-100)	100 (50-100)	-3.6 (-15.2 to 8.0)
W52	100 (62-100)	80 (55-100)	8.9 (-2.6 to 20.4)
EQ-5D-3L (0-1)			
BL	1.0 (0.85-1.0)	1.0 (0.84-1.0)	-
W6	0.78 (0.65-0.86)	0.78 (0.78-0.86)	-0.01 (-0.08 to 0.05)
W12	0.85 (0.78-1.0)	0.84 (0.78-1.0)	-0.01 (-0.07 to 0.06)
W26	1.0 (0.84-1.0)	1.0 (0.81-1.0)	0.02 (-0.05 to 0.09)
W52	1.0 (0.89-1.0)	1.0 (0.84-1.0)	0.01 (-0.06 to 0.09)
SF36 PCS (0-100*)			
BL	57.0 (52.8-59.3)	56.7 (53.4-58.7)	-
W6	38.7 (32.1-48.1)	36.3 (30.5-42.2)	2.6 (-0.6 to 5.9)
W12	49.9 (39.6-54.7)	47.9 (39.5-53.6)	0.8 (-2.6 to 4.1)
W26	55.2 (49.2-58.4)	52.9 (49.3-57.2)	2.7 (-0.8 to 6.1)
W52	54.7 (50.7-58.0)	54.6 (50.4-57.3)	1.6 (-2.0 to 5.1)

Appendix 1 (continued)

	Routine care n=128 median (IQR)	**Reduced imaging** n=118 median (IQR)	**RC vs RI** Adjusted β (95%CI)
SF36 MCS (0-100*)			
BL	52.8 (46.4-59.2)	54.2 (48.6-56.6)	-
W6	54.0 (46.9-60.3)	51.4 (44.2-59.1)	**3.6 (0.1 to 5.6)**
W12	56.0 (53.4-60.7)	58.1 (45.3-60.1)	2.2 (-1.0 to 5.3)
W26	54.0 (48.9-59.2)	55.5 (49.8-58.6)	-0.4 (-3.6 to 2.9)
W52	52.6 (48.8-58.0)	56.4 (50.8-58.5)	-0.3 (-3.6 to 3.1)
pain rest (0-10)			
BL	0.0 (0.0-1.0)	0.0 (0.0-1.0)	-
W6	1.0 (0.4-2.0)	1.7 (0.4-4.0)	-0.4 (-1.2 to 0.4)
W12	1.0 (0.0-1.8)	0.1 (0.0-1.5)	-0.0 (-0.8 to 0.8)
W26	0.0 (0.0-1.0)	0.0 (0.0-1.7)	0.0 (-0.8 to 0.8)
W52	0.0 (0.0-1.0)	0.0 (0.0-1.0)	-0.0 (-0.8 to 0.8)
pain movement (0-10)			
BL	0.0 (0.0-1.0)	0.0 (0.0-1.0)	-
W6	3.1 (2.0-5.3)	3.7 (1.0-5.0)	0.2 (-0.6 to 1.1)
W12	1.4 (1.0-2.9)	2.0 (0.5-4.2)	-0.4 (-1.2 to 0.5)
W26	1.0 (0.0-1.2)	0.4 (0.0-2.0)	0.2 (-0.7 to 1.1)
W52	0.2 (0.0-1.0)	0.0 (0.0-1.0)	0.1 (-0.8 to 1.1)
Health status (0-10)			
BL	8.9 (7.6-9.1)	8.0(7.0-9.0)	-
W6	8.0 (7.0-9.0)	7.2 (7.0-8.0)	0.2 (-0.5 to 1.0)
W12	8.0 (7.0-9.0)	8.0 (7.0-8.4)	-0.1 (-0.8 to 0.7)
W26	8.1 (7.0-9.0)	8.0 (7.0-9.0)	0.5 (-0.3 to 1.2)
W52	8.0 (7.0-9.0)	8.0 (6.8-9.0)	0.4 (-0.4 to 1.2)
Recovered (1-5)‡			
W6	3 (3-4)	3 (3-4)	0.1 (-0.2 to 0.4)
W12	4 (4-4)	4 (4-4)	0.2 (-0.1 to 0.5)
W26	4 (4-5)	4 (4-5)	0.1 (-0.3 to 0.4)
W52	5 (4-5)	5 (4-5)	0.2 (-0.1 to 0.5)
Regained function (1-5)‡			
W6	2 (2-3)	2 (2-3)	0.1 (-0.4 to 0.5)
W12	4 (3-4)	4 (3-4)	0.3 (-0.1 to 0.7)
W26	4 (4-5)	5 (4-5)	0.0 (-0.4 to 0.5)
W52	5 (4-5)	5 (4-5)	0.1 (-0.4 to 0.5)

Legend Appendix 1
*: 50 = average score
‡: Higher = better
Bold = a significant difference between groups ($p < 0.05$)

Appendix 2: Outcome scores per treatment allocation per timepoint, and adjusted differences(β) for the operatively treated subgroup

	Routine care n=128 median (IQR)	**Reduced imaging** n=118 median (IQR)	**RC vs RI** Adjusted β (95%CI)
OMAS (0-100)			
BL	100 (100-100)	100 (100-100)	-
W6	35 (24-55)	43 (25-60)	-5.4 (-12.1 to 1.3)
W12	60 (40-75)	55 (45-75)	1.5 (-7.9 to 5.0)
W26	80 (63-90)	78 (55-90)	0.5 (-6.1 to 7.0)
W52	85 (78-100)	85 (75-100)	-2.1 (-8.9 to 4.6)
AAOS (0-100)			
BL	100 (98-100)	100 (95-100)	-
W6	70 (55-82)	74 (63-88)	**-6.0 (-11.3 to -0.8)**
W12	80 (72-91)	80 (71-89)	0.0 (-4.6 to 4.7)
W26	92 (94-96)	90 (78-96)	0.0 (-4.7 to 4.8)
W52	94 (90-98)	96 (86-98)	1.1 (-3.7 to 5.8)
AAOS shoe (0-100)			
BL	100 (100-100)	100 (71-100)	-
W6	50 (25-100)	50 (25-100)	-5.8 (-17.8 to 6.1)
W12	50 (33-100)	50 (25-100)	-2.6 (-12.8 to 7.5)
W26	75 (40-100)	71 (40-100)	-6.1 (-16.0 to 3.7)
W52	100 (50-100)	88 (50-100)	-3.8 (-13.8 to 6.3)
EQ-5D-3L (0-1)			
BL	1.0 (1.0-1.0)	1.0 (0.84-1.0)	-
W6	0.69 (0.52-0.78)	0.78 (0.59-0.85)	**-0.07 (-0.1 to -0.0)**
W12	0.81 (0.78-0.89)	0.81 (0.78-0.89)	-0.02 (-0.1 to 0.0)
W26	0.90 (0.79-1.0)	0.84 (0.76-1.0)	0.03 (-0.0 to 0.1)
W52	1.0 (0.83-1.0)	0.93 (0.81-1.0)	-0.01 (-0.1 to 0.0)
SF36 PCS (0-100*)			
BL	57.7 (55.3 -59.2)	57.1 (52.2 -59.1)	-
W6	34.2 (28.9-40.1)	34.5 (28.1-38.6)	-0.5 (-3.1 to 2.2)
W12	44.3 (37.6-50.2)	40.4 (35.6-49.7)	0.2 (-1.2 to 1.5)
W26	51.6 (46.1-54.9)	48.7 (39.5-54.3)	0.8 (-0.6 to 2.2)
W52	53.7 (48.6-56.5)	53.3 (46.0-56.7)	-0.2 (-2.9 to 2.6)
SF36 MCS (0-100*)			
BL	54.0 (48.8-58.2)	54.0 (47.5-56.5)	-
W6	51.3 (42.8-58.0)	53.6 (47.6-58.9)	-**2.6 (-5.3 to -0.0)**
W12	52.6 (49.5-59.9)	56.1 (49.4-60.1)	-1.1 (-3.7 to 1.6)
W26	55.3 (49.6-58.3)	55.7 (50.3-59.2)	-1.2 (-3.9 to 1.5)
W52	55.6 (50.6-58.9)	54.5 (49.3-57.5)	-0.3 (-1.7 to 1.1)

Appendix 2 (continued)

	Routine care n=128 median (IQR)	**Reduced imaging** n=118 median (IQR)	**RC vs RI** Adjusted β (95%CI)
pain rest (0-10)			
BL	0.0 (0.0-1.0)	0.2 (0.0-1.0)	-
W6	1.2 (0.2-3.0)	1.0 (0.0-2.0)	**0.8 (0.3 to 1.4)**
W12	1.0 (0.2-2.0)	1.0 (0.0-2.0)	0.0 (-0.6 to 0.6)
W26	1.0 (0.0-2.0)	1.0 (0.0-2.0)	0.5 (-0.1 to 1.0)
W52	0.7 (0.0-1.5)	0.5 (0.0-1.4)	0.2 (-0.4 to 0.8)
pain movement (0-10)			
BL	0,1 (0,0-1,0)	0,2 (0,0-1,0)	-
W6	3.0 (2.0-5.0)	2.0 (1.0-4.0)	0.5 (-0.1 to 1.2)
W12	2.1 (1.0-3.7)	2.0 (1.0-4.0)	-0.0 (-0.7 to 0.7)
W26	2.0 (0.5-3.0)	1.0 (0.7-3.2)	0.2 (-0,5 to 0.8)
W52	1.0 (0.5-2.1)	1.0 (0.6-2.4)	-0.1 (-0.8 to 0.6)
Health status (0-10)			
BL	8.0 (7.0-9.0)	8.0 (7.0-9.0)	-
W6	8.0 (6.0-9.0)	7.5 (6.9-9.0)	-0.1 (-0.7 to 0.4)
W12	8.0 (6.8-8.8)	7.9 (6.5-8.0)	0.2 (-0.4 to 0.7)
W26	8.0 (7.5-9.0)	8.0 (6.5-8.5)	0.5 (-0.0 to 1.1)
W52	8.0 (7.6-9.0)	8.0 (7.0-8.7)	0.1 (-0.5 to 0.7)
Recovered (1-5)‡			
W6	3 (3-4)	3 (2-4)	**0.2 (0.0 to 0.3)**
W12	4 (3-4)	3 (3-4)	0.1 (-0.1 to 0.4)
W26	4 (4-4)	4 (4-4)	0.0 (-0.3 to 0.3)
W52	4 (4-5)	4 (4-5)	0.1 (-0.1 to 0.4)
Regained function (1-5)‡			
W6	2 (1-2)	2 (1-3)	-0.2 (-0.6 to 0.1)
W12	3 (2-4)	3 (2-4)	0.0 (-0.3 to 0.4)
W26	4 (3-4)	4 (3-4)	0.1 (-0.3 to 0.4)
W52	4 (4-4)	4 (4-5)	0.0 (-0.3 to 0.4)

Legend Appendix 2
*****: 50 = average score
‡: Higher = better
Bold = a significant difference between groups (p <0.05)

Appendix 3: Outcome scores per treatment allocation per timepoint, and adjusted differences(β) for the per-protocol analysis

	Routine care n=128 median (IQR)	**Reduced imaging** n=118 median (IQR)	**RC vs RI** Adjusted β (95%CI)
OMAS (0-100)			
BL	100 (100-100)	100 (100-100)	-
W6	40 (25-55)	55 (38-70)	**-9.4 (-16.2 to -2.6)**
W12	65 (45-75)	70 (55-85)	-6.8 (-13.5 to 0.01)
W26	80 (65-90)	85 (70-100)	-0.2 (-7.0 to 6.5)
W52	85 (80-100)	90 (80-100)	-0.5 (-7.5 to 6.6)
AAOS (0-100)			
BL	100 (99-100)	99 (97-100)	-
W6	74 (59-81)	78 (66-87)	**-7.9 (-12.9 to -2.9)**
W12	83 (74-92)	85 (75-94)	-3.5 (-8.3 to 1.3)
W26	92 (84-96)	96 (88-99)	-2.8 (-7.7 to 2.0)
W52	95 (90-99)	99 (93-100)	-1.5 (-6.4 to 3.3)
AAOS shoe (0-100)			
BL	100 (100-100)	100 (95-100)	-
W6	33 (25-100)	50 (25-100)	-9.0 (-19.8 to 1.8)
W12	50 (33-81)	60 (33-100)	-8.6 (-18.6 to 1.4)
W26	67 (40-100)	100 (58-100)	**-15.9 (-26.1 to -5.6)**
W52	75 (50-100)	100 (52.5-100)	-6.7 (-16.8 to 3.4)
EQ-5D-3L (0-1)			
BL	1.0 (0.89-1.0)	1.0 (0.81-1.0)	-
W6	0.69 (0.52-0.78)	0.78 (0.72-0.86)	**-0.09 (-0.16 to -0.04)**
W12	0.81 (0.78-0.97)	0.84 (0.78-1.0)	-0.03 (-0.10 to 0.03)
W26	0.89 (0.81-1.0)	0.89 (0.75-1.0)	0.01 (-0.05 to 0.07)
W52	1.0 (0.84-1.0)	1.0 (0.81-1.0)	0.03 (-0.04 to 0.09)
SF36 PCS (0-100*)			
BL	58.3 (55.0-59.3)	57.0 (49.8-59.6)	-
W6	35.3 (28.5-42.6)	37.2 (30.0-43.3)	-1.1 (-3.9 to 1.7)
W12	44.8 (38.1-51.6)	45.6 (37.4-53.3)	0.9 (-0.6 to 2.4)
W26	51.5 (46.0-55.4)	51.3 (42.5-56.1)	0.5 (-2.5 to 3.4)
W52	53.8(49.1-57.2)	53.4 (48.8-57.1)	0.4 (-2.6 to 3.4)
SF36 MCS (0-100*)			
BL	53.8 (48.8-58.6)	52.0 (45.1-55.5)	-
W6	52.3 (44.0-58.4)	53.0 (43.3-57.3)	-0.2 (-2.8 to 2.4)
W12	55.5 (49.6-60.7)	56.2 (45.3-60.1)	0.5 (-2.2 to 3.2)
W26	55.7 (49.5-58.4)	54.3 (49.4-58.5)	0.1 (-2.6 to 2.8)
W52	54.4 (49.4-59.3)	54.5 (48-8-57.7)	**1.7 (0.3 to 3.1)**

Appendix 3 (continued)

	Routine care n=128 median (IQR)	**Reduced imaging** n=118 median (IQR)	**RC vs RI** Adjusted β (95%CI)
pain rest (0-10)			
BL	0.0 (0.0-1.0)	0.0 (0.0-1.0)	-
W6	1.4 (0.3-2.9)	1.0 (0.0-2.3)	0.2 (-0.4 to 0.8)
W12	1.0 (0.1-2.0)	0.9 (0.0-1.4)	0.1 (-0.6 to 0.7)
W26	1.0 (0.0-2.0)	0.2 (0.0-2.0)	0.3 (-0.3 to 1.0)
W52	0.6 (0.0-1.2)	0.0 (0.0-1.0)	0.2 (-0.5 to 0.8)
pain movement (0-10)			
BL	0.0 (0.0-1.0)	0.1 (0.0-1.0)	-
W6	3.1 (2.0-5.0)	2.5 (1.1-4.3)	0.5 (-0.3 to 1.2)
W12	2.0 (1.0-3.9)	1.5 (0.6-4.0)	0.2 (-0.5 to 1.0)
W26	1.2 (0.4-3.0)	1.0 (0.0-3.0)	0.3 (-0.5 to 1.0)
W52	1.0 (0.5-2.0)	0.9 (0.0-1.7)	0.2 (-0.5 to 0.9)
Health status (0-10)			
BL	8.5 (7.5-9.0)	8.0 (7.0-9.0)	-
W6	8.0 (6.5-9.0)	7.3 (6.8-8.2)	0.2 (-0.1 to 0.4)
W12	8.0 (7.0-9.0)	7.5 (6.6-8.0)	**0.6 (0.02 to 1.2)**
W26	8.0 (7.2-9.0)	8.0 (7.0-8.9)	0.4 (-0.2 to 1.0)
W52	8.0 (7.2-9.0)	8.0 (6.0-9.0)	0.4 (-0.2 to 1.0)
Recovered (1-5)‡)			
W6	3 (3-4)	3 (3-4)	-0.0 (-0.3 to 0.2)
W12	4 (3-4)	4 (4-4)	-0.0 (-0.3 to 0.2)
W26	4 (4-4)	4 (4-5)	-0.1 (-0.4 to 0.2)
W52	4 (4-5)	5 (4-5)	0.1 (-0.2 to 0.4)
Regained function (1-5)‡			
W6	2 (1-3)	2.5 (2-3)	**-0.4 (-0.8 to -0.1)**
W12	3 (2-4)	4 (3-4)	-0.1 (-0.4 to 0.3)
W26	4 (3-4)	4 (4-5)	-0.0 (-0.4 to 0.3)
W52	4 (4-5)	5 (4-5)	-0.2 (-0.5 to 0.2)

Legend Appendix 3
*: 50 = average score
‡: Higher = better
Bold = a significant difference between groups (p <0.05)