Omitting Routine Radiography of Traumatic Ankle Fractures After Initial 2-Week Follow-up Does Not Affect Outcomes The WARRIOR Trial

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Omitting Routine Radiography of Traumatic Ankle Fractures After Initial 2-Week Follow-up Does Not Affect Outcomes

The WARRIOR Trial: A Multicenter Randomized Controlled Trial

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Investigation performed at Leiden University Medical Center, Leiden; University Medical Center Groningen, Groningen; VU University Medical Center, Amsterdam; and Haaglanden Medical Center, The Hague, the Netherlands

Background: The clinical consequences of routine follow-up radiographs for patients with ankle fracture are unclear, and their usefulness is disputed. The purpose 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 treatment. 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 OMAS scores (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.

Conclusions: 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.

Level of Evidence: Therapeutic Level I. See Instructions for Authors for a complete description of levels of evidence.

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

*A list of the WARRIOR Trial Study Group members is given in a note at the end of the article.

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A **data-sharing statement** is provided with the online version of the article (http://links.lww.com/JBJS/F991).

half of these fractures are treated surgically 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 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.

Materials and 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

TABLE I Patient Characteristics by Treatment Allocation

	Usual Care (N = 128)	Reduced Imaging (N = 118)	P Value
Male sex *(no. of patients)*	69 (53.9%)	58 (49.2%)	0.42
Age* *(yr)*	47.7 ± 18.5	50.8 ± 18.2	0.18
Body mass index* *(kg/m²)*	25.8 ± 4.3	27.3 ± 6.0	0.02†
Alcohol >10 U/week *(no. of patients)*	22 (17.2%)	16 (13.6%)	0.42
Smoking >10/day *(no. of patients)*	10 (7.8%)	9 (7.6%)	0.94
Operative treatment *(no. of patients)*	77 (60.2%)	76 (64.4%)	0.46
Lauge-Hansen[17] classification *(no. of patients)*			0.60
Supination-adduction	2 (1.6%)	2 (1.7%)	
Supination-external rotation	94 (73.4%)	93 (78.8%)	
Pronation-adduction/pronation-eversion	31 (24.2%)	23 (19.5%)	
Missing	1 (0.8%)	0 (0.0%)	
Weber[18] classification *(no. of patients)*			0.49
A	2 (1.6%)	2 (1.7%)	
B	93 (72.7%)	93 (78.8%)	
C	27 (21.1%)	21 (17.8%)	
Missing	6 (4.7%)	2 (1.7%)	
Malleolar involvement *(no. of patients)*			0.79
Unimalleolar	66 (51.6%)	64 (54.2%)	
Bimalleolar	27 (21.1%)	20 (16.9%)	
Trimalleolar	35 (27.3%)	34 (28.8%)	
ASA classification‡ *(no. of patients)*			0.83
1	53 (41.4%)	46 (39.0%)	
2	60 (46.9%)	55 (46.6%)	
≥3	15 (11.7%)	17 (14.4%)	

*The values are given as the mean and the standard deviation. †Significant. ‡ASA = American Society of Anesthesiologists.

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 [LH] 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] (LH 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). 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 treatment. 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.

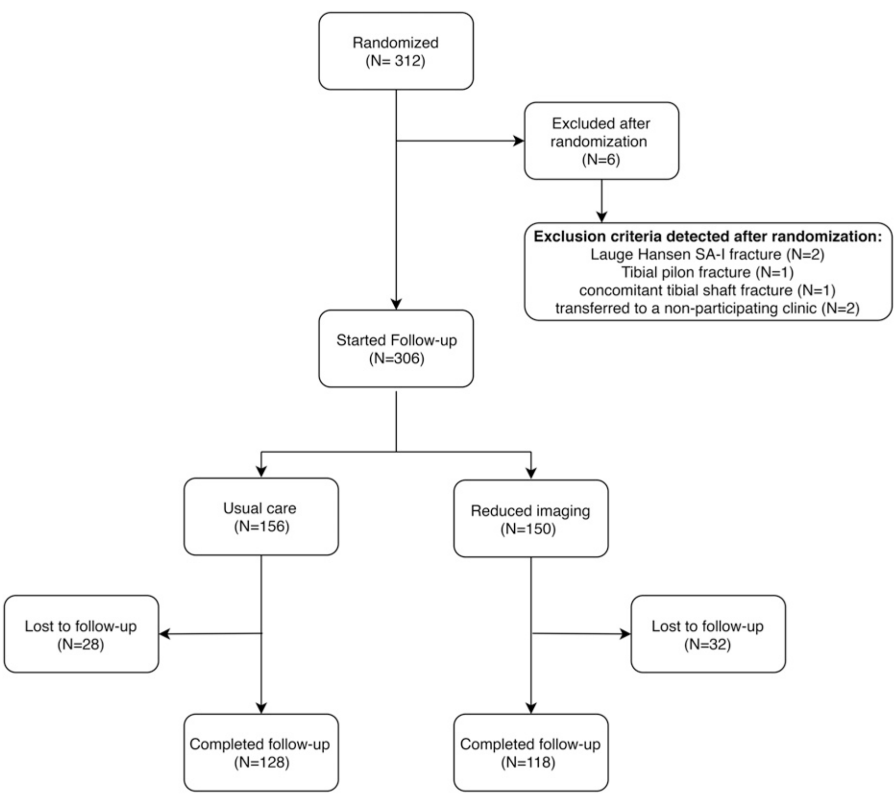

Fig. 1

CONSORT (Consolidated Standards of Reporting Trials) diagram.

TABLE II Outcome Scores per Treatment Allocation per Time Point, with Adjusted Differences (β)

	Usual Care* (N = 128)	Reduced Imaging* (N = 118)	Usual Care Versus Reduced Imaging, Adjusted β†
OMAS (0-100 points)			
Baseline	100 (100-100)	100 (100-100)	—
Week 6	40 (25-60)	45 (25-65)	−3.3 (−8.4 to 1.9)
Week 12	65 (45-80)	65 (46-80)	−0.9 (−5.9 to 4.2)
Week 26	85 (68-95)	80 (65-95)	1.74 (−3.4 to 6.9)
Week 52	90 (80-100)	90 (80-100)	−0.9 (−6.2 to 4.4)
AAOS (0-100 points)			
Baseline	100 (98-100)	100 (98-100)	—
Week 6	73 (59-82)	76 (63-84)	−2.8 (−6.6 to 1.0)
Week 12	85 (74-92)	83 (73-92)	1.1 (−2.4 to 4.7)
Week 26	93 (87-97)	94 (84-98)	0.1 (−3.5 to 3.7)
Week 52	96 (91-99)	97 (89-100)	0.8 (−2.9 to 4.5)
AAOS shoe (0-100 points)			
Baseline	100 (100-100)	100 (75-100)	—
Week 6	50 (25-100)	50 (25-94)	−2.4 (−11.3 to 6.5)
Week 12	60 (37-100)	50 (25-100)	−2.2 (−9.8 to 5.4)
Week 26	100 (100-100)	80 (43-100)	−4.8 (−12.5 to 2.8)
Week 52	100 (50-100)	80 (50-80)	0.1 (−7.6 to 7.9)
EQ-5D-3L (0-1)			
Baseline	1.0 (0.9-1.0)	1.0 (0.84-1.0)	—
Week 6	0.78 (0.57-0.81)	0.78 (0.65-0.86)	−0.05 (−0.09 to −0.004)‡
Week 12	0.83 (0.78-1.0)	0.81 (0.78-1.0)	−0.02 (−0.06 to 0.03)
Week 26	1.0 (0.81-1.0)	0.84 (0.78-1.0)	0.03 (−0.02 to 0.07)
Week 52	1.0 (0.84-1.0)	1.0 (0.81-1.0)	−0.00 (−0.05 to 0.04)
SF-36 PCS (0-100; average = 50)			
Baseline	57.2 (54.8-59.3)	56.9 (52.7-58.9)	—
Week 6	36.3 (29.6-44.8)	34.8 (28.8-41.7)	0.5 (−1.6 to 2.6)
Week 12	45.5 (38.5-51.5)	43.2 (36.9-51.1)	0.3 (−1.8 to 2.4)
Week 26	53.1 (46.9-56.4)	50.8 (41.7-55.6)	1.3 (−0.9 to 3.5)
Week 52	54.1 (49.1-57.3)	53.5 (47.4-57.0)	0.1 (−2.1 to 2.3)
SF-36 MCS (0-100; average = 50)			
Baseline	53.8 (48.1-58.5)	54.1 (48.3-56.5)	—
Week 6	53.5 (44.2-58.9)	53.3 (45.1-41.7)	−0.6 (−2.6 to 1.5)
Week 12	55.0 (49.8-60.1)	56.8 (47.9-60.1)	−0.2 (−2.2 to 1.9)
Week 26	54.7 (49.1-58.3)	55.6 (50.3-59.1)	−1.0 (−3.2 to 1.1)
Week 52	54.3 (49.3-58.5)	55.6 (50.3-58.3)	−0.4 (−2.6 to 1.7)
VAS pain at rest (0-10)			
Baseline	0.0 (0.0-1.0)	0.0 (0.0-1.0)	—
Week 6	1.0 (0.3-2.9)	1.0 (0.0-2.3)	0.3 (−0.1 to 0.8)
Week 12	1.0 (0.0-2.0)	1.0 (0.0-2.0)	−0.0 (−0.5 to 0.4)
Week 26	0.4 (0.0-1.2)	0.5 (0.0-2.0)	0.2 (−0.2 to 0.7)
Week 52	0.5 (0.0-1.0)	0.1 (0.0-1.0)	0.1 (−0.4 to 0.5)
VAS pain with movement (0-10)			
Baseline	0.0 (0.0-1.0)	0.1 (0.0-1.0)	—
Week 6	3.0 (2.0-5.0)	2.5 (1.0-4.8)	0.4 (−0.1 to 1.0)
Week 12	2.0 (1.0-3.2)	2.0 (1.0-4.0)	−0.2 (−0.7 to 0.4)

continued

TABLE II (*continued*)

	Usual Care* (N = 128)	Reduced Imaging* (N = 118)	Usual Care Versus Reduced Imaging, Adjusted β†
Week 26	1.0 (0.1-2.0)	1.0 (0.1-3.0)	0.1 (−0.5 to 0.7)
Week 52	1.0 (0.0-1.9)	1.0 (0.0-2.0)	−0.0 (−0.6 to 0.6)
VAS health status (0-10)			
Baseline	8.2 (7.5-9.0)	8.0 (7.0-9.0)	—
Week 6	8.0 (6.8-9.0)	7.5 (7.0-8.8)	−0.1 (−0.5 to 0.4)
Week 12	8.0 (7.0-9.0)	8.0 (7.0-8.0)	0.0 (−0.5 to 0.5)
Week 26	8.0 (7.3-9.0)	8.0 (7.0-8.8)	0.4 (−0.0 to 0.9)
Week 52	8.0 (7.1-9.0)	8.0 (7.0-9.0)	0.1 (−0.4 to 0.6)
Recovered (1-5; higher = better)			
Week 6	3.0 (3.0-4.0)	3.0 (3.0-4.0)	0.1 (−0.1 to 0.3)
Week 12	4.0 (4.0-4.0)	4.0 (3.0-4.0)	0.1 (−0.1 to 0.3)
Week 26	4.0 (4.0-4.0)	4.0 (4.0-4.0)	0.0 (−0.2 to 0.2)
Week 52	4.0 (4.0-5.0)	4.0 (4.0-5.0)	0.2 (−0.1 to 0.4)
Regained function (1-5; higher = better)			
Week 6	2.0 (1.0-3.0)	2.0 (1.0-3.0)	−0.1 (−0.4 to 0.1)
Week 12	4.0 (2.0-4.0)	3.0 (2.0-4.0)	0.1 (−0.1 to 0.4)
Week 26	4.0 (3.3-4.0)	4.0 (3.0-5.0)	0.1 (−0.2 to 0.3)
Week 52	4.0 (4.0-5.0)	4.0 (4.0-5.0)	0.0 (−0.2 to 0.3)

*The values are given as the mean, with the interquartile range in parentheses. †The 95% CI is given in parentheses. ‡Significant.

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

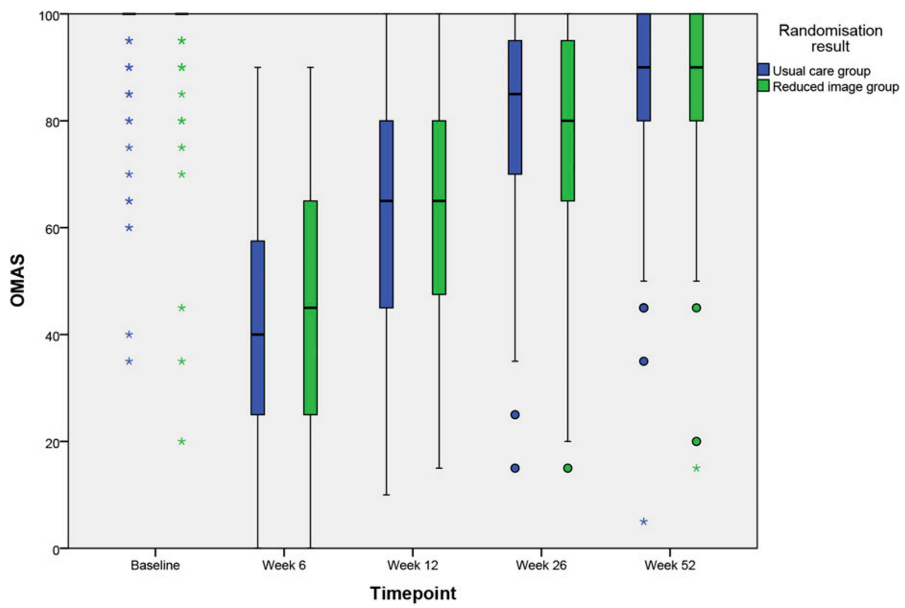

Fig. 2

Box plots of OMAS 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.

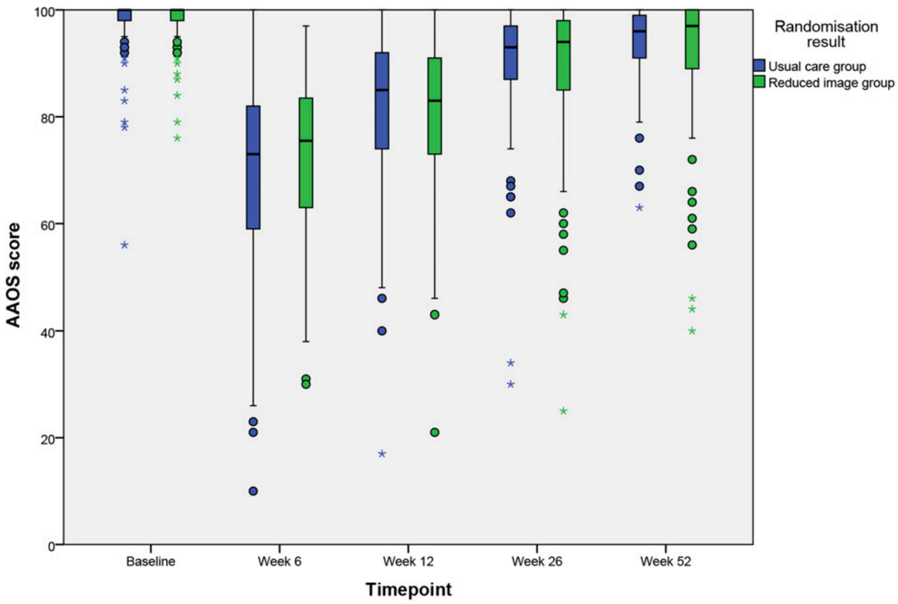

Fig. 3
Box plots of AAOS scores over time. Horizontal line in box = median, top and bottom of box = interquartile range, whiskers = 1.5 times the interquartile range, circles = outliers, and asterisks = extreme outliers.

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 a number of 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.

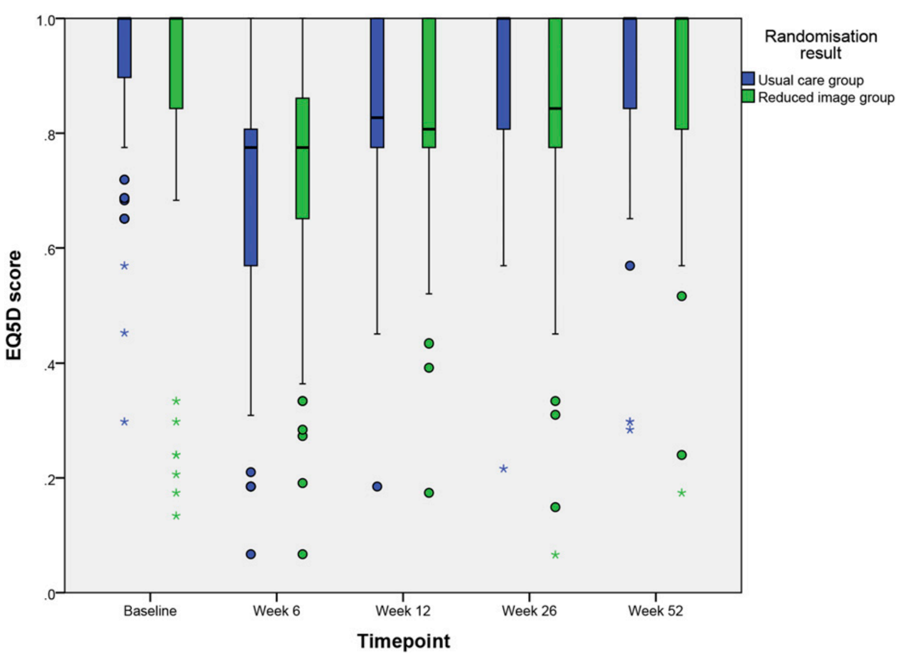

Fig. 4
Box plots of EQ-5D-3L scores over time. Horizontal line in box = median, top and bottom of box = interquartile range, whiskers = 1.5 times the interquartile range, circles = outliers, and asterisks = extreme outliers.

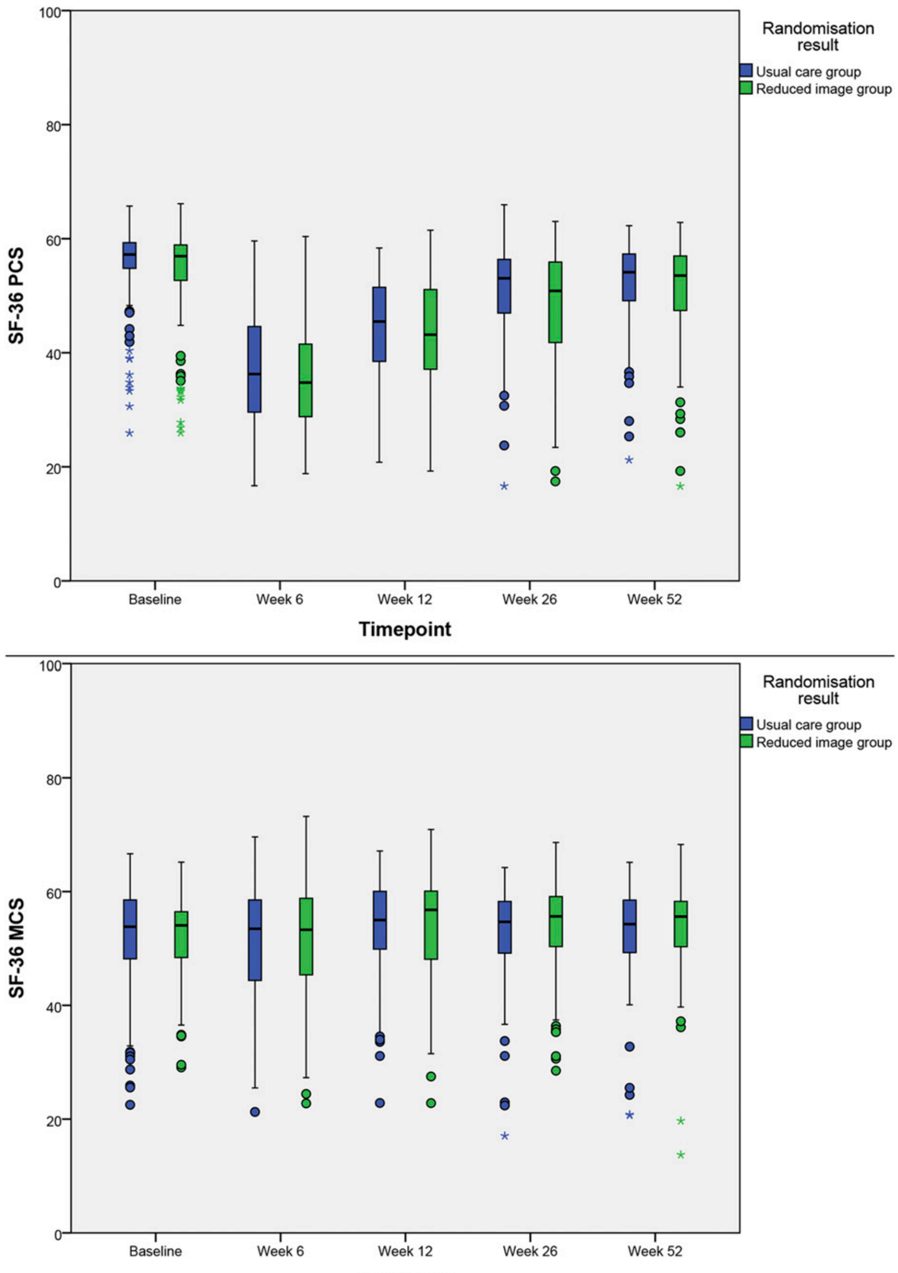

Fig. 5

Box plots of SF-36 PCS and MCS 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

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

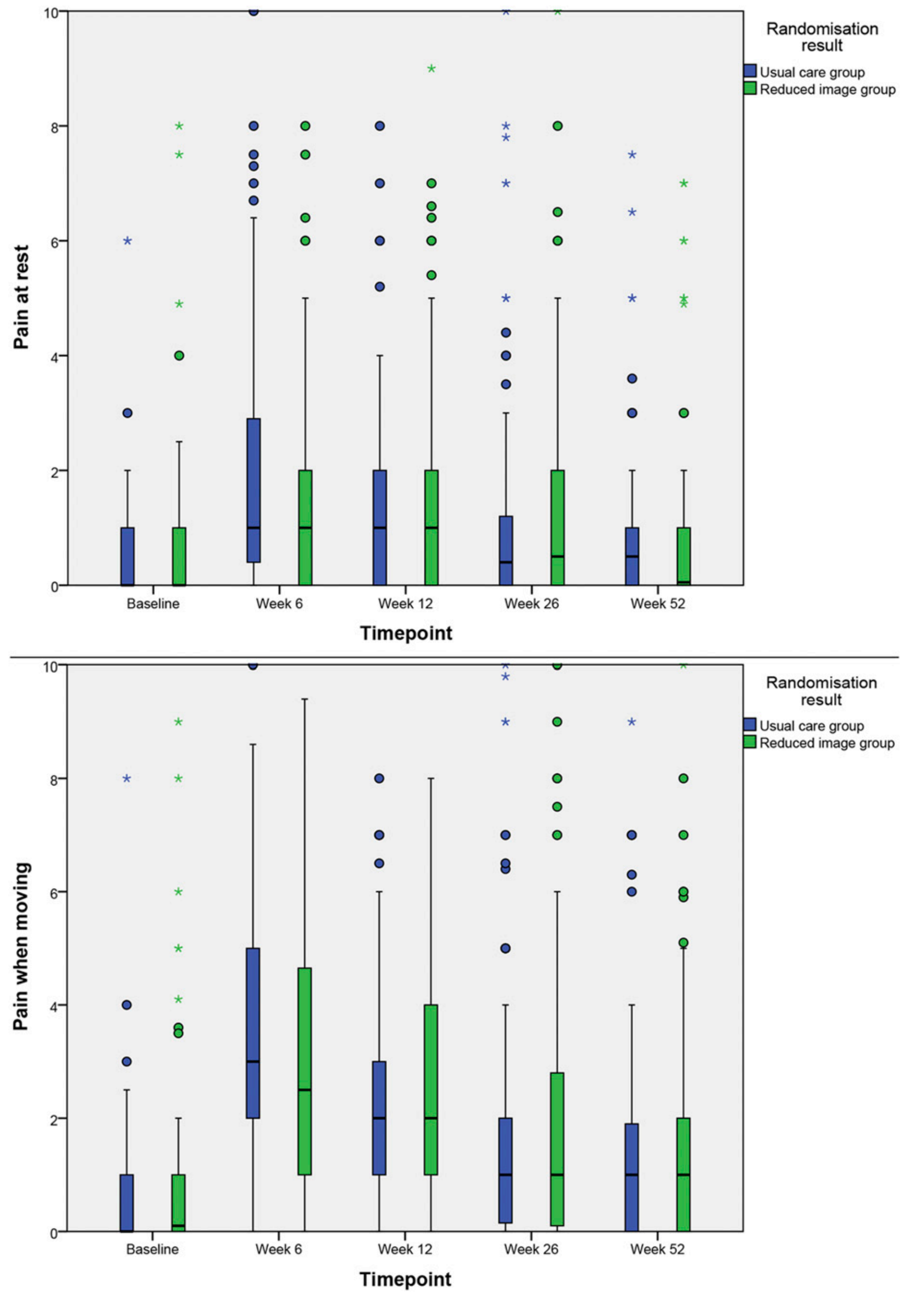

Fig. 6

Box plots of VAS scores 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.

derived from the medical charts. Information on complications, including implant failure, nonunion, malunion, surgical site infections, and chronic pain, was 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). Baseline characteristics were compared with use of descriptive statistics. The Mann-Whitney U test was used to compare the median number of radiographs. The chi-square 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

TABLE III Complications

	Usual Care (N = 128) *(no. of patients)*	Reduced Imaging (N = 118) *(no. of patients)*	P Value
Complication			
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*
Implant-related 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

*NA = not applicable; as 1 of the groups had 0 complications, no p value could be calculated.

status and potentially confounding patient characteristics (Table I). Missing values in potential confounders were multiply imputed[24]. For all statistical tests, the level of significance was set at $p < 0.05$.

Results

Participants

In total, 312 eligible patients with an ankle fracture were included in the study. Six 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 patients (62%) received operative treatment, 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.

Primary Outcome

The difference in 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 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 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 AAOS shoe scores 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)

TABLE IV Radiographs and Indications

	Usual Care (N = 128)	Reduced Imaging (N = 118)	P Value
No. of radiographs	681	523	
No. of radiographs per patient*	5 (4-6)	4 (3-5)	<0.05†
Radiograph made after 2 weeks of follow-up *(no. of patients)*	105 (82.0%)	77 (65.3%)	<0.05†
Indication‡ *(no. of radiographs)*			
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 implant	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

*The values are given as the median, with the interquartile range in parentheses. †Significant. ‡The percentages are based on the number of radiographs, not the number of patients.

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-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 of 118]) than in the routine-care group (22.7% [29 of 128], $p = 0.42$). Specific types of complications were also equally common (Table III).

Radiographs

During the course of 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 scores 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, with the exception of the SF-36 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 SF-36 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 similar to the main analysis. Reduced imaging was noninferior to routine care for the OMAS at week 52 (β, −0.5 points; 95% CI, −7.5 to 6.6 points) (see Appendix).

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 ($56 USD). With the incidence of 30,000 ankle fractures per annum, the cost saving potential in the Netherlands would add up to €1.5 million ($1.6 million USD) annually while leading to a small (0.003-mSv) reduction in ionizing radiation per patient[25]. 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 of nonoperatively treated fractures. In our previous retrospective cohort study of 528 participants[5], we found that routine follow-up radiographs seldom influenced 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[26]. 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 radial fracture. This finding is in accordance with our retrospective studies[5,27], 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 radial fracture[27]. 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 similar to 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 radial fractures[26]. Importantly, our margin of noninferiority is consistent with other trials involving the OMAS such as the Ankle Injury Management (AIM) trial[28] and the Routine versus On DEmand removal Of the syndesmotic screw (RODEO) trial[29]. As the present trial was only powered to demonstrate noninferiority for the OMAS (primary outcome) 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 on the basis of 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[30].

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.

Appendix

eA Supporting material provided by the authors is posted with the online version of this article as a data supplement at jbjs.org (http://links.lww.com/JBJS/F990). ■

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References

1. Court-Brown CM, Caesar B. Epidemiology of adult fractures: a review. Injury. 2006 Aug;37(8):691-7. Epub 2006 Jun 30.

2. Daly PJ, Fitzgerald RH Jr, Melton LJ, Ilstrup DM. Epidemiology of ankle fractures in Rochester, Minnesota. Acta Orthop Scand. 1987 Oct;58(5):539-44.

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 Orthop. 2012 Jun;83(3):276-81. Epub 2012 Mar 8.

4. Koehler S, Eiff P. Overview of ankle fractures in adults. 2016. Accessed 2017 Jun 23. 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, Hoogendoorn JM, van der Meulen HGWM, van Tulder MW, Schipper IB. Routine follow-up radiographs for ankle fractures seldom add value to clinical decision-making: a retrospective, observational study. J Foot Ankle Surg. 2018 Sep - Oct;57(5):957-60. Epub 2018 Jul 13.

6. Chaudhry S, DelSole EM, Egol KA. Post-splinting radiographs of minimally displaced fractures: good medicine or medicolegal protection? J Bone Joint Surg Am. 2012 Sep 5;94(17):e128.

7. Schipper IB, Termaat MF, Rhemrev S, Meylaerts SAG, Bartlema K, Stichter W, Embden D, van de Bremer J, Krug E, Hoogendoorn JM, Alleman J, van der Meulen H, van der Elst M, Greeven A, Niggebrugge A, Richie E, van der Linden F, de Vries M, Nagels J, Turkcan K, Cheragwandi A, Dijkstra S. Richtlijnen voor behandeling van letsels van het steun en bewegingsapparaat. 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 May 1;95(9):e57.

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 Int. 2015 Oct;36(10):1196-201. Epub 2015 May 21.

11. Ovaska MT, Nuutinen T, Madanat R, Mäkinen TJ, Söderlund T. The role of outpatient visit after operative treatment of ankle fractures. Injury. 2016 Nov;47(11):2575-8. Epub 2016 Sep 7.

12. McDonald MR, Bulka CM, Thakore RV, Obremskey WT, Ehrenfeld JM, Jahangir AA, Sethi MK. Ankle radiographs in the early postoperative period: do they matter? J Orthop Trauma. 2014 Sep;28(9):538-41.

13. Schuld JC, Volker ML, Anderson SA, Zwank MD. Postsplinting x-rays of non-displaced hand, wrist, ankle, and foot fractures are unnecessary. Am J Emerg Med. 2016 Aug;34(8):1625-6. Epub 2016 May 4.

14. D'Agostino RB Sr, Massaro JM, Sullivan LM. Non-inferiority trials: design concepts and issues - the encounters of academic consultants in statistics. Stat Med. 2003 Jan 30;22(2):169-86.

15. Piaggio G, Elbourne DR, Pocock SJ, Evans SJ, Altman DG. CONSORT Group. Reporting of noninferiority and equivalence randomized trials: extension of the CONSORT 2010 statement. JAMA. 2012 Dec 26;308(24):2594-604.

16. Weil NL, Termaat MF, Rubinstein SM, El Moumni M, Zuidema WP, Derksen RJ, Krijnen P, van Bodegom-Vos L, Wendt KW, van Kuijk C, Rosendaal FR, Breederveld RS, Goslings JC, Schipper IB, van Tulder MW. 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.

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; 1966.

19. Olerud C, Molander H. A scoring scale for symptom evaluation after ankle fracture. Arch Orthop Trauma Surg. 1984;103(3):190-4.

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. J Bone Joint Surg Am. 2004 May;86(5):902-9.

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]. Ned Tijdschr Geneeskd. 2005 Jul 9;149(28):1574-8. Dutch.

22. Aaronson NK, Muller M, Cohen PD, Essink-Bot ML, Fekkes M, Sanderman R, Sprangers MA, te Velde A, Verrips E. Translation, validation, and norming of the Dutch language version of the SF-36 health survey in community and chronic disease populations. J Clin Epidemiol. 1998 Nov;51(11):1055-68.

23. Ware JE Jr, Sherbourne CD. The MOS 36-Item Short-Form Health Survey (SF-36). I. Conceptual framework and item selection. Med Care. 1992 Jun; 30(6):473-83.

24. White IR, Royston P, Wood AM. Multiple imputation using chained equations: issues and guidance for practice. Stat Med. 2011 Feb 20;30(4):377-99. Epub 2010 Nov 30.

25. Lin EC. Radiation risk from medical imaging. Mayo Clin Proc. 2010 Dec;85(12): 1142-6; quiz 1146.

26. van Gerven P, El Moumni M, Zuidema WP, Rubinstein SM, Krijnen P, van Tulder MW, Schipper IB, Termaat MF. Omitting routine radiography of traumatic distal radial fractures after initial 2-week follow-up does not affect outcomes. J Bone Joint Surg Am. 2019 Aug 7;101(15):1342-50.

27. 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. Arch Orthop Trauma Surg. 2017 Sep;137(9):1187-91. Epub 2017 Jul 22.

28. Keene DJ, Mistry D, Nam J, Tutton E, Handley R, Morgan L, Roberts E, Gray B, Briggs A, Lall R, Chesser TJ, Pallister I, Lamb SE, Willett K. 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 Technol Assess. 2016 Oct;20(75):1-158.

29. Dingemans SA, Birnie MFN, Sanders FRK, van den Bekerom MPJ, Backes M, van Beeck E, Bloemers FW, van Dijkman B, Flikweert E, Haverkamp D, Holtslag HR, Hoogendoorn JM, Joosse P, Parkkinen M, Roukema G, Sosef N, Twigt BA, van Veen RN, van der Veen AH, Vermeulen J, Winkelhagen J, van der Zwaard BC, van Dieren S, Goslings JC, Schepers T. Routine versus on demand removal of the syndesmotic screw; a protocol for an international randomised controlled trial (RODEO-trial). BMC Musculoskelet Disord. 2018 Jan 31;19(1):35.

30. Rongen JJ, Hannink G. Comparison of registered and published primary outcomes in randomized controlled trials of orthopaedic surgical interventions. J Bone Joint Surg Am. 2016 Mar 2;98(5):403-9.