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Research article

The correlation between intra-operative 2D- and 3D fluoroscopy with postoperative CT-scans in the treatment of calcaneal fractures

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ABSTRACT

Objectives: The aim of this study was to determine the correlation of the intra-operative fluoroscopic 2D- and 3D-images compared with a postoperative CT-scan, in terms of quality of reduction and fixation of calcaneal fractures.

Methods: Patients requiring open reduction and internal fixation (ORIF) of a calcaneal fracture were recruited as part of the EF3X-trial. During surgery, intra-operative images of fluoroscopic 2D- and 3D-imaging were obtained to assess the quality of the reduction and implant position. All patients received a postoperative CT-scan within one week.

The operating surgeon evaluated intra-operatively both 2D- and 3D-images according to a 23-item scoring protocol on a 3-point Likert scale. A scoring panel, consisting of three clinical experts, evaluated all images in a blinded and independent fashion. Intraclass correlation coefficients (ICC) with their 95% confidence intervals (CI) were calculated using a two-way-random model with absolute agreement.

Results: A total of 102 calcaneal fractures were included. Agreement of 3D-imaging for the quality of reduction was better than 2D-imaging, although still fair, but for fixation moderate to good. Agreement between the 2D-images and the CT-scans was poor to fair. Intra-operative 2D-imaging received the highest ratings for image quality and interpretability, followed by CT-scanning.

Conclusion: Implant position can be evaluated satisfactory with the aid of intra-operative 3D imaging. Although intra-operative 3D imaging had a better agreement with postoperative CT-scanning than 2D-imaging, there is a need to improve image quality and suppress scattering from implants to improve the additional value of intra-operative 3D imaging in calcaneal fracture reduction and fixation.

1. Introduction

The quality of reduction and accurate implant positioning in patients treated operatively for calcaneal fractures are considered important factor predictors for functional outcome [1–6]. To facilitate assessment of the reduction and implant positioning during surgery, intra-operative 3D-fluoroscopy (3D-imaging) was introduced in addition to conventional intra-operative 2D-fluoroscopy (2D-imaging).

Diagnostic accuracy of intra-operative 3D-imaging is assessed similar to CT-scanning in cadaver studies [7–11]. However, these studies evaluated a single screw implanted and fractures consisting of two fragments. This is not in concordance with clinical practice; commonly fractures are comminuted and require multiple screws and a plate. As the number of implants negatively affects the image quality due to scattering, the interpretability and consequently the diagnostic accuracy of the images decreases with multiple implants.

The aim of this study was to correlate the surgeons' intraoperative evaluation of intra-operative fluoroscopic 2D- and 3D images with postoperative CT-scans in terms of quality of fracture reduction and implant position in operatively treated calcaneal fractures. Secondly, the same correlations were calculated when judged by an independent scoring panel.

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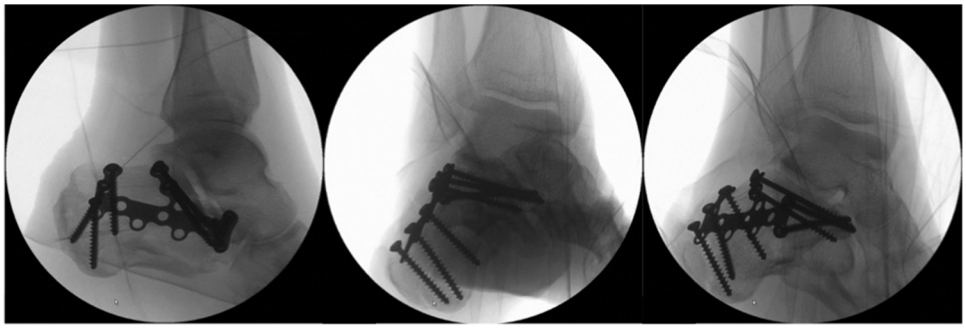

Fig. 1. Intra-operative 2D-images.
Final intra-operative 2D-images. From left to right: Lateral, axial and Brodén view.

2. Methods

This study was performed in accordance with the Quality Assessment of Diagnostic Accuracy Studies (QUADAS)-2 statement [12].

2.1. Patients

Patients were participants of a randomised clinical trial, the EF3X-trial [13]. In this trial the clinical effectiveness of the additional use of intra-operative 3D-imaging to 2D-imaging in the operative treatment of calcaneal, wrist and ankle fractures was studied. Approval was obtained from the medical ethics committee and all patients provided written informed consent. The study was registered under Dutch Trial Register NTR 1902.

All patients with a calcaneal fracture were included between December 2010 and July 2015, if they met the following inclusion criteria: Adult patients with a calcaneal Sanders classification I-IV fracture requiring surgery (ORIF of CRIF); no pathological fracture; no rheumatoid osteoarthritis; not pregnant; able to understand trial features and having signed informed consent.

2.2. Index test

Both 2D- and 3D-imaging techniques were used intra-operatively. For this purpose the BV Pulsera (Philips Healthcare, Best, the Netherlands) with 3D-RX (3-Dimensional Rotational X-ray) was used. The use of 2D-imaging was at the disposal of the surgeon until he was satisfied with the reduction and implant position. Final images were obtained consisting of at least three views (lateral, axial and Brodén) to represent the result of the reduction and implant position (Fig. 1). Hereafter, 3D-imaging was performed. All scans acquired 225 projection images over a period of 30 s during a 200° rotation of the C-arm. The projection images were used to reconstruct a 3D data set. Both volume rendering and slice images in 3 different directions (coronal, axial and sagittal planes) were available (Fig. 2). The images could be enhanced by automatic colouring the implants (Titanview®) (Fig. 3).

The radiation exposure of each image in the scanning run is dynamically adjusted to provide the best combination of low dose and optimal image quality.

Randomisation determined whether the intra-operative images of 3D imaging were available to the surgeon. If 3D-imaging was available to the surgeon, corrections in both reduction and implant position were allowed. After the surgeon was satisfied with the reduction and implant position, final 3D imaging was performed. Only the final 3D images were used for this study. 2D-images were used when 3D imaging was not available to the surgeon or no corrections were performed after 3D imaging.

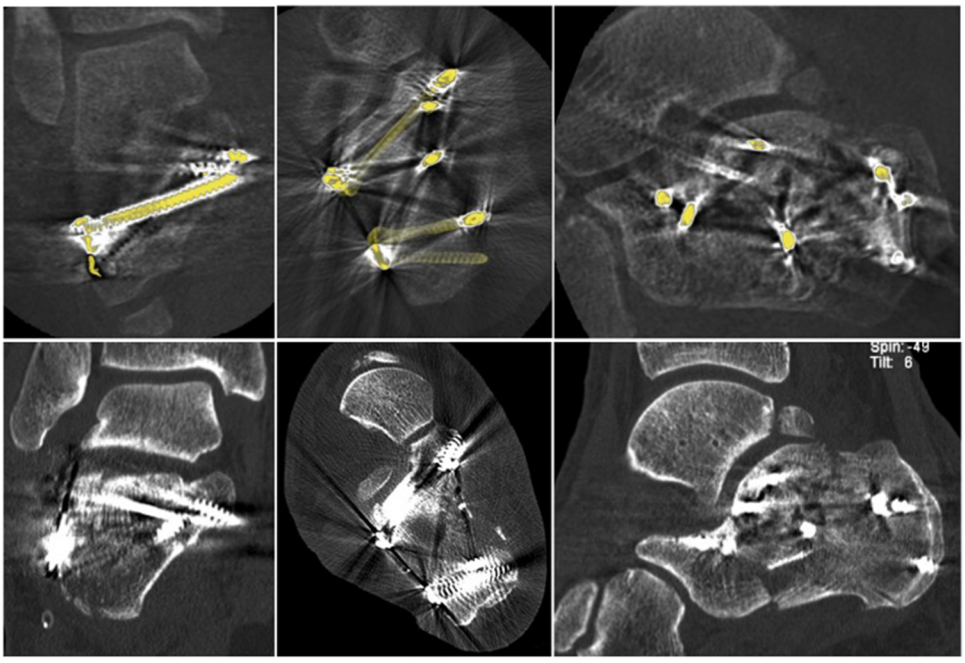

Fig. 2. Intra-operative 3D-reconstructions and postoperative CT-scan.
Final intra-operative 3D-reconstructions and postoperative CT-scan.
Upper row intra-operative 3D-scan with, from left to right, coronal, axial and sagittal reconstructions.
Lower row postoperative CT-scan with, from left to right, coronal, axial and sagittal reconstructions.

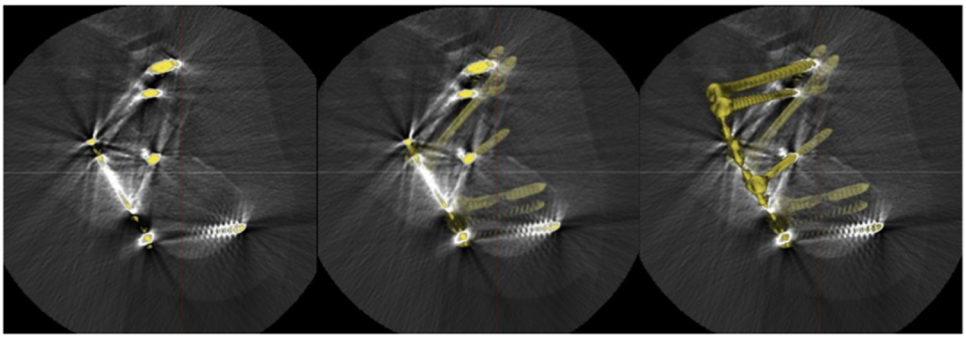

Fig. 3. Titanview®.
Titanview® is software that coloures the implants automaticly
Left image: Implants in the current plane are coloured
Middle image: Implants in both the current plane as well as the background are coloured
Right image: Implants in the current plane as well as the fore- and background are coloured

2.3. Reference standard

All patients underwent postoperative CT-scanning within one week after surgery. This postoperative CT-scan was used as a reference standard. CT-scans were performed using 64-slice CT-scanners with a maximal axial slice thickness of 1 mm. Standard multiplanar reconstructions (coronal, axial and sagittal plane) were available (Fig. 2).

2.4. Assessment of quality of reduction and implant position of calcaneal fractures

The quality of reduction and implant position was evaluated according to a standard scoring protocol based on a Delphi consensus of international experts in calcaneal fracture surgery [14,15]. The inter- and intra-observer reliability of this scoring protocol is similar to the measurements of Böhlers' and Gissanes' angles on conventional X-rays and 3D-CT-reconstructions [15,16].

This scoring protocol consists of 23 items evaluating the quality of reduction, implant (mal) positioning and quality of imaging. Reduction of the articulating surfaces of the calcaneus (the calcaneocuboid (CC), the posterior talocalcaneal (PTC) and anterior talocalcaneal (ATC) joint) consisted of assessment of the symmetry and width of the joint, presence of step-offs, gaps and intra-articular bone fragments. These items were scored on a 3-point Likert scale in the categories: 'anatomic'; 'not anatomic but acceptable'; 'not anatomic and not acceptable'; or 'not judgeable'. Implant position was evaluated for screw protrusion in the articular surface of the CC, PTC or ATC-joints and/or medial wall. Additionally, plate position and correct positioning of screws in the sustentaculum and anterior process were evaluated.

All images available to the operating surgeon were evaluated intra-operatively. In order to provide an objective and independent evaluation, without interference of clinical information of direct sight on the fracture or information of perioperative images, all images were anonymized and systematically evaluated by a scoring panel consisting of 3 clinical experts (one trauma surgeon, one radiologist, one orthopaedic resident). The average scores of this scoring panel were used for the analyses.

2.5. Statistical analyses

Descriptive statistics were used to report image quality (SPSS version 23, IBM, Armonk, NY, USA). Usually diagnostic accuracy is expressed as sensitivity and specificity, requiring dichotomous outcomes of the radiologic evaluation. However, the scoring protocol, based on a Delphi consensus, consisted of a 3-point Likert scale. Therefore, intraclass correlation coefficients (ICC) with their 95% confidence intervals (CI) were calculated with a two-way-random model with absolute agreement. This model was used to enable generalisation of the results to a wider population. As for diagnostic accuracy purposes, scores have to be similar and not only consistent hence absolute agreement was used. Only single measures were reported for the clinical evaluation as well as the average evaluation of the scoring panel of both 2D- and 3D-fluoroscopy compared to average evaluation of the postoperative CT-scan. This was decided because in clinical practice the of 2D- and 3D-fluoroscopy will be rated by one person (i.e. the operating surgeon) [17]. Items scored as 'not judgeable' were excluded from the analysis.

Cut-offs were used as provided by Cicchetti et al. The reliability was considered 'poor' for ICC values less than 0.40, 'fair' for values between 0.40 and 0.59, 'good' for values between 0.60 and 0.74, and 'excellent' for values between 0.75 and 1.0 were used. An ICC of 0.60 was set as the minimal acceptable level of agreement [18].

3. Results

102 calcaneal fractures in 100 patients were included for analysis. The fractures were classified on a pre-operative CT-scan as Type I (3); type II (36); type III (47); and type IV (16) according to the Sanders classification. Based on the postoperative CT-scan at least one of the reduction items was scored as 'not anatomical, not acceptable' in 19%, and one of the implant positioning items was 'not acceptable' in 26% of the calcaneal fractures, compared to 6% and 17%, respectively, based on evaluation of the 3D-images by the scoring panel.

The median radiation dose intra-operatively, including both 2D- and 3D-imaging, differed significantly between the two randomisation groups. When the intra-operative 3D-scan was not available to the surgeon the median radiation dose was 570 mGy/cm^2 (range 286–1290 mGy/cm^2). If the 3D-scan was available to the surgeon, the median radiation dose was 726 mGy/cm^2 (range 304–2110 mGy/cm^2).

The 2D-images of 74 calcaneal fractures were included in the analysis, as these were the final images because 3D-imaging was not available due to randomisation or no corrections were performed after 3D-imaging. The surgeon was allowed to intra-operatively evaluate 3D-images in 50 cases. In six patients 3D-images were not saved correctly and could therefore not be evaluated by the scoring panel, 1 post-operative CT-scan was missing. The scoring panel evaluated all 3D-images of the 95 calcaneal fractures included in the trial. Postoperative CT-scans were obtained in all but one patient and evaluated by the scoring panel. Therefore correlation could be determined for 95 calcaneal fractures.

3.1. Intraclass correlation of intra-operative fluoroscopic 2D-imaging with computed tomography

The evaluation of reduction and fixation by the scoring panel

Table 1
Intraclass correlation coefficient of intra-operative fluoroscopic 2D-imaging a nd postoperative CT-scan. (For interpretation of the references to colour in this table, the reader is referred to the web version of this article.)

	Intraoperative 2D FLUOROSCOPY			Scoring panel 2D FLUOROSCOPY		
	ICC 3-items single [95% CI]	N=74	Not judgeable 2D/CT	ICC 3-items single [95% CI]	N=74	Not judgeable 2D/CT
Böhlers angle	-0.01 [-0.15-0.16]	71	0/2	0.20 [-0.05-0.42]	58	6/2
Gissanes angle	0.18 [-0.03-0.38]	71	0/2	0.19 [-0.06-0.43]	58	6/2
Length of the calcaneus	0.19 [-0.02-0.39]	73	0/0	0.53 [0.32-0.69]	61	5/0
Varus/varus of the tuber	0.06 [-0.16-0.28]	73	0/0	0.68 [0.42-0.83]	29	37/0
CC-joint	0.04 [-0.15-0.24]	73	0/0	0.04 [-0.15-0.24]	65	1/0
PTC-joint	0.22 [-0.03-0.44]	73	0/0	0.19 [-0.06-0.42]	65	1/0
ATC-joint	0.15 [-0.05-0.35]	72	1/0	0.12 [-0.07-0.32]	65	1/0
Overall quality of reduction	0.07 [-0.09-0.24]	70	1/2	0.11 [-0.07-0.31]	64	8/1
Position of fixation plate	0.23 [0.02-0.43]	72	1/0	0.22 [-0.02-0.43]	64	2/0
Grip of screws in sustentaculum	0.36 [0.13-0.55]	72	1/0	0.03[-0.16-0.23]	63	3/0
Intra-articular screws	0.00 [-0.19-0.21]	73	0/0	0.05 [-0.19-0.29]	66	1/0
Medial protrusion screws	-0.17 [-0.38-0.05]	73	0/0	0.07 [-0.14-0.29]	62	4/0
Overall quality of implant position	0.20 [-0.02-0.41]	72	1/0	0.16 [-0.08-0.39]	64	5/0
Overall quality of ORIF	0.12 [-0.07-0.32]	70	2/2	0.02 [-0.09-0.16]	54	10/1
Overall revision required				0.09 [-0.11-0.29]	66	0/0

Cut-offs are as provided by Cicchetti et al., with reliability being 'poor' for ICC values less than 0.40, 'fair' for values between 0.40 and 0.59, 'good' for values between 0.60 and 0.74, and 'excellent' for values between 0.75 and 1.0 were used.

showed a 'fair' ICC with the evaluation of the postoperative CT-scan except for the length of the calcaneus and varus/valgus position, which showed a 'moderate' ICC. (Table 1). For correlation of the surgeon's intra-operative evaluation showed a 'fair' ICC for all the items of reduction and fixation.

3.2. Intraclass correlation of intra-operative fluoroscopic 3D-imaging with computed tomography

The ICC of the fracture reduction as judged by the scoring panel, as well as intra-operatively, was 'fair', except for the evaluation of the CC-joint, which was 'moderate' (Table 2). The scoring panel scored the position of the fixation plate and intra-articular screws as 'good'. Correct screw positioning in the sustentaculum and tuber and medial protrusion of screws showed a 'moderate' correlation with CT. Overall quality of implant position evaluated by the scoring panel had a 'moderate' ICC and overall quality of reduction and implant position also score 'moderate'. The requirement of a revision had a 'fair' correlation with CT-images.

3.3. Image quality

Both the surgeon's intra-operative evaluation and the evaluation of the scoring panel of image quality, scattering and interpretability of 2D-

Table 2
Intraclass correlation coefficient of intra-operative fluoroscopic 3D-imaging and postoperative CT-scan. (For interpretation of the references to colour in this table, the reader is referred to the web version of this article.)

	Intraoperative 3D FLUOROSCOPY			Scoring panel 3D FLUOROSCOPY		
	ICC 3-items single [95% CI]	N=50	Not judgeable 3D/CT	ICC 3-items single [95% CI]	N=95	Not judgeable 3D/CT
Böhlers angle	0.10 [-0.11-0.33]	46	2/1	0.36 [0.16-0.52]	91	2/2
Gissanes angle	0.16 [-0.08-0.40]	46	2/1	0.31 [0.11-0.48]	91	1/2
Length of the calcaneus	-0.04 [-0.24-0.19]	47	2/0	0.16 [-0.04-0.35]	93	2/0
Varus/varus of the tuber	-0.06 [-0.33-0.23]	47	2/0	0.06 [-0.14-0.26]	93	2/0
CC-joint	0.42 [0.16-0.63]	46	3/0	0.40 [0.21-0.56]	92	3/0
PTC-joint	0.19 [-0.08-0.45]	47	2/0	0.39 [0.10-0.60]	93	1/0
ATC-joint	0.26 [-0.02-0.50]	47	2/0	0.08 [-0.07-0.25]	94	0/0
Overall quality of reduction	0.22 [-0.07-0.49]	46	2/1	0.35 [0.00-0.59]	91	2/2
Position of fixation plate	0.37 [0.10-0.59]	46	2/1	0.68 [0.55-0.78]	92	1/1
Grip of screws in sustentaculum	0.18 [-0.07-0.43]	46	3/0	0.42 [0.24-0.57]	92	2/0
Intra-articular screws	0.15 [-0.12-0.41]	46	2/0	0.66 [0.53-0.76]	93	1/0
Medial protrusion screws	0.25 [-0.02-0.49]	47	2/0	0.51 [0.34-0.64]	92	2/0
Overall quality of implant position	0.30 [0.01-0.54]	46	2/0	0.48 [0.31-0.63]	93	1/0
Overall quality of ORIF	0.19 [-0.09-0.46]	45	2/1	0.37 [0.09-0.58]	89	1/4
Overall revision required				0.27 [0.08-0.44]	66	0/0

Cut-offs are as provided by Cicchetti et al., with reliability being 'poor' for ICC values less than 0.40, 'fair' for values between 0.40 and 0.59, 'good' for values between 0.60 and 0.74, and 'excellent' for values between 0.75 and 1.0 were used.

imaging was considered 'good' in more than 90% of the images (Fig. 4). As for 3D-imaging the intra-operative evaluation differed from the blinded evaluation by the scoring panel. Scattering was considered more of an issue for the scoring panel (11%) than intra-operatively for the surgeons (2%): the surgeons scored image quality in 85% as 'good' versus only 18% by the scoring panel. Interpretability of CT-images were rated 'good' in 92% of cases versus only 22% for the 3D-images.

4. Discussion

In this study, we found a poor to good correlation between intra-operative evaluation of 2D- and 3D-imaging and the post-operative CT as to fracture reduction and fixation. The scoring panel showed an acceptable intraclass correlation for two reduction items (length and position of the tuber) of 2D-imaging and all items regarding fixation of 3D-imaging.

Image quality, scattering and interpretability of intra-operative fluoroscopic 2D-imaging was valued even higher than the CT-scan as current reference standard. The image quality of 3D-fluoroscopic imaging was lowest with a large difference between the intra-operative evaluation and the scoring panel. In contrast, agreement for the quality of reduction was better, although still fair, and still better for fixation.

Similar to previously reported results from Euler et al. and Wirth et al. about image quality, 2D-imaging was valued best on image quality, scattering and interpretability of images [7,19,20]. Probably, intra-operative evaluation of the image quality was higher due to the

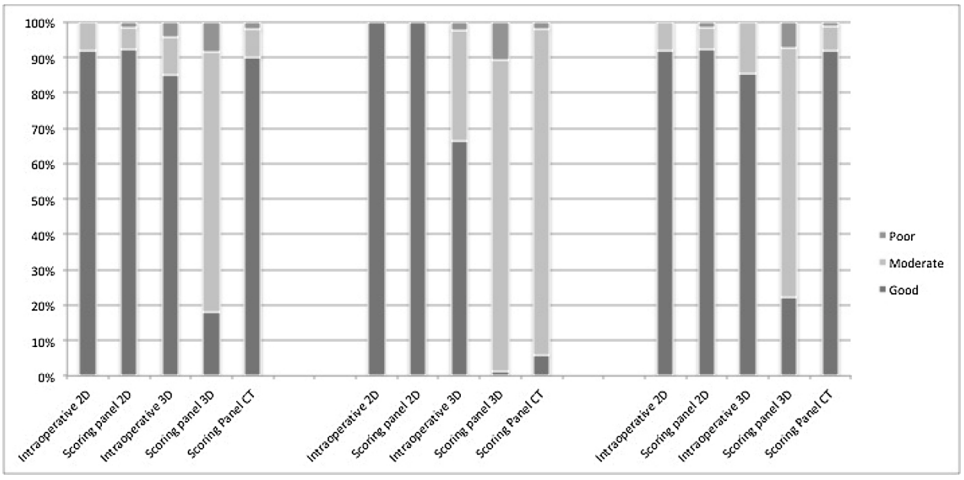

Fig. 4. Subjective image quality.
Intraoperative 2D: Intra-operative evaluation of 2D-fluoroscopy by the operating surgeon.
Scoring panel 2D: Consensus of evaluation of 2D-fluoroscopy by the scoring panel.
Intraoperative 3D: Intra-operative of 3D-fluoroscopy by the operating surgeon.
Scoring panel 3D: Consensus of evaluation of 3D-fluoroscopy by the scoring panel.
Scoring panel CT: Consensus of evaluation of the CT-scan by the scoring panel.

additional information the surgeon had at hand (e.g. evaluation of pre-operative imaging, direct sight of the fracture fragments). This could have lowered the surgeons' demands of the interpretability and quality of the images available.

Ideally, to determine diagnostic accuracy of intra-operative 2D- and 3D-imaging, sensitivity and specificity should be calculated. In order to calculate these, a binary evaluation of the reduction and implant position is required (e.g. acceptable or not-acceptable). In case of only two fracture fragments or one implant a binary evaluation is feasible. However, in case of a comminuted fracture with multiple implants there are more nuances, with a grey area in which reduction and/or implant position might not be perfectly anatomical but acceptable, and no need for revision. Therefore, we used a scoring system with a 3-point Likert scale for the postoperative evaluation of reduction and fixation, to reflect the evaluation of fracture reduction and fixation in clinical practice [15].

Intraclass correlation between the evaluation of intra-operative fluoroscopic images and the postoperative CT-evaluation was better for the scoring panel than the operating surgeons. A reason for this could be that the scoring panel performed the evaluation of the 3D-images and the CT-evaluation, while the operating surgeons only performed evaluation of the 3D-images. Thus, in case of the operating surgeons only inter-observer variation could have played a role, whereas in the scoring panel also intra-observer variance could have been a contributing factor [15].

Although cadaver studies showed a sensitivity of 81–100% and specificity of 80–99%, we found only fair agreements for most of the evaluated items [7–11]. Clinical practice seems more intricate than a cadaver setting. The clinical study from Kendoff et al showed that, even though intra-operative 3D-imaging was used, in 4% of the patients revision surgery was performed due to a clinically important malreduction or implant misplacement visible on the postoperative CT-scan [21]. The authors concluded that the inconsistency between the intra-operative 3D-images and postoperative CT-scan was mainly the result of poor 3D image quality due to scattering of the implants. In the current study, 62% of the fractures were Sanders type III-IV requiring a plate with multiple screws. The subsequent scattering probably lowered the image quality, resulting in a lower correlation between 3D imaging and CT-scanning. However, this probably reflects the actual accuracy of intra-operative 3D imaging in clinical practice. For CT-scanning metal artefact reduction techniques have been introduced, but during this study these techniques were not available.

Only one comparative study of 3D-C-arms has been performed, comparing the Iso-C-3D (Siemens) and the Vario 3D (Ziehm) [22]. As this was a cadaver study, a reliable comparison with the diagnostic performance of the BV Pulsera (Philips) used in this clinical trial is not possible.

Ideally, for the calculation of intra-observer agreement outcomes should be more or less equally divided among the outcomes. However, in this study, only 19% of the reductions were not acceptable and implant position was misplaced in 26%, divided over the different scoring items. When compared to the postoperative CT-scan, the intra-operative 3D images showed a better correlation in terms of evaluating implant positioning than the evaluation of fracture reduction. This could explain a low correlation, as well as a lower correlation for the reduction items than for the fixation items.

This is the first study describing the correlation between intra-operative 3D imaging and postoperative CT-evaluation of calcaneal fractures of both reduction and implant position in a clinical setting. Even though this study is a good reflection of clinical practice, this setting also has limitations. Because it is unethical not to strive for the best reduction and fixation possible it is very difficult to obtain variety in the quality of reduction and fixation on every item in this CT-based scoring protocol. On the other hand, these types of multifragmentary fractures are difficult to mimic in a cadaver setting. In addition, the operating surgeons and scoring panel were asked to give their overall opinion of the different fragments within one joint. Hence, they could have different opinions about which fragment dominated their judgement.

Imaging and software techniques develop rapidly and future research should aim to adequately compare the diagnostic accuracy of intra-operative imaging devices in a clinical setting. Furthermore, in order to compare imaging devices, a further development and evaluation of the scoring protocol is necessary to determine which of the items truly predict clinical outcome and whether the current thresholds of intra-articular gaps and step-offs of 2 mm are clinically feasible and relevant in the various fracture types.

In conclusion, implant position can be evaluated satisfactory with the aid of intra-operative 3D-imaging. Although 3D-imaging showed a better agreement than 2D-imaging, there is a need to improve image quality and suppress scattering from implants to improve the correlation in the evaluation of fracture reduction. Moreover, because minimally invasive approaches have become more popular [23], intra-operative imaging is a necessity for adequate reduction and fixation.

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