Intraoperative Three-Dimensional Imaging With a Motorized Mobile C-Arm (SIREMOBIL ISO-C-3D) in Foot and Ankle Trauma Care

A Preliminary Report

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Objective: The aim of the study was to assess the feasibility and benefit of the intraoperative use of a mobile C-arm with 3-dimensional imaging (ISO-C-3D).

Design: Prospective consecutive clinical study.

Setting: University hospital, level I trauma center.

Methods: The ISO-C-3D was used for intraoperative visualization in foot and ankle trauma care. Conventional C-arms were used to judge the reduction and implant position before the ISO-C-3D was used. Time spent, changes resulting from use of the ISO-C-3D, and surgeons' ratings (visual analogue scale, 0–10 points) were recorded.

Patients: Between January 1, 2003 and March 15, 2004, the ISO-C-3D was used in 62 cases (factures: pilon, n = 1; Weber-C ankles, n = 7; isolated dorsal Volkmann, n = 1; talus, n = 3; calcaneus, n = 20; navicular, n = 1; cuboid, n = 1; Lisfranc fracture-dislocation, n = 6; hindfoot arthrodesis with or without correction, n = 12).

Results: On average, the operation was interrupted for 440 seconds (range 330–700); 120 seconds, on average, for the ISO-C-3D scan and 210 seconds, on average, for evaluation of the images by the surgeon. In 39% of the cases (24 of 62), the reduction and/or implant position was corrected during the same procedure after the ISO-C-3D scan. The ratings of the 8 surgeons who used the ISO-C-3D were 9.2(5.2–10) for feasibility, 9.5 (6.1–10) for accuracy, and 8.2 (4.5–10) for clinical benefit.

Conclusion: Intraoperative 3-dimensional visualization with the ISO-C-3D can provide useful information in foot and ankle trauma care that cannot be obtained from plain films or conventional C-arms. During the same procedure, after conventional C-arm scans judged the positioning to be correct and an ISO-C-3D scan was done, the reduction and/or implant position was corrected in 39% of the cases in this study, although not unnecessarily prolonging the operation. The ISO-C-3D appears to be most helpful in procedures with a closed reduction and internal fixation, and/or when axial reformations provide information that is not possible to obtain with a conventional C-arm and/or direct visualization during open reduction and internal fixation.

Key Words: computer-assisted surgery, deformities, hindfoot, mid-foot, fracture-dislocation

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When using intraoperative fluoroscopy in foot and ankle trauma care, incorrect positioning of extraosseous and intra-articular screws and gaps or steps in joint lines frequently remain undiscovered and are only recognized on postoperative computed tomography (CT) scans.[1] A mobile C-arm with 3-dimensional (3D) imaging (ISO-C-3D™, Siemens AG, Germany) is available to better enhance the intraoperative recognition of problems with fracture reduction and/or fixation. Earlier experimental studies and research studies on patients showed that the use of this device improved the evaluation of reduction and implant positioning compared to plain films or C-arms alone and was comparable to CT scans.[1–6] Other options for intraoperative 3D imaging are open magnetic resonance imaging (MRI) or CT.[7–10] However, high costs and limited mobility associated with these devices has narrowed their use.[1–3,5,6] As a result of these limitations, the ISO-C-3D was developed as a cost-effective and easier-to-use mobile device for intraoperative 3D visualization in orthopaedic surgery.

The aim of the study was to evaluate the feasibility and benefits of the intraoperative use of the ISO-C-3D for foot and ankle trauma care. The study was designed to discover if the technical features of the ISO-C-3D leads to modifications or corrections during 1 single surgical procedure. The hypothesis was that the ISO-C-3D could intraoperatively detect failures of reduction or implant position that had not been detected with a conventional C-arm.

MATERIAL AND METHODS

Device

The ISO-C-3D™ is a motorized mobile C-arm that provides fluoroscopic images during a 190° orbital rotation, resulting in a 119-mm data cube (Fig. 1). Multiplanar and

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FIGURE 1. ISO-C-3D device in the operating room and carbonfracture table.

2-dimensional reconstructions can be obtained from these 3D data sets (Fig. 2).

Setting

This clinical study was performed in a level I trauma center, which is also a university hospital. The surgical staff involved in the study consisted of experienced orthopaedic trauma surgeons as well as interns, residents, and fellows in training. The surgical procedures were not exclusively performed by the head of the trauma department or the attending surgeons, but also by residents.

The device was always used after reduction and positioning of implants were judged to be correct by the surgeon using a conventional C-arm. When incorrect reduction and/or implant positions were detected with the conventional C-arm, a correction of the reduction and/or implant was performed. The correction was then again checked by the conventional C-arm. These steps were repeated until the reduction and implant position was judged to be correct using the conventional C-arm.

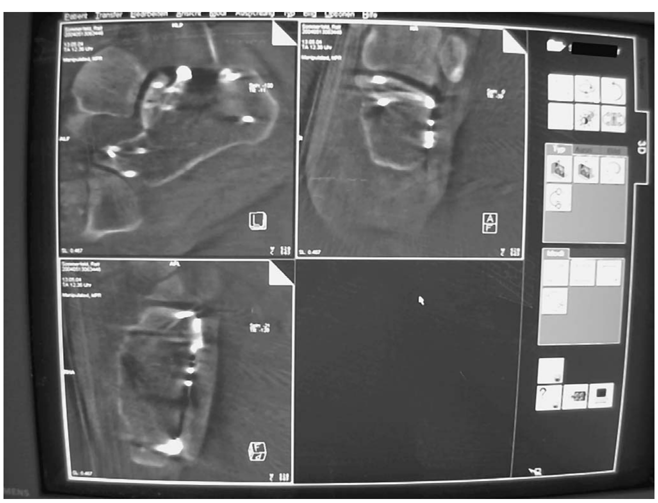

FIGURE 2. Monitor view of ISO-C-3D device showing multiplanar reformations of a calcaneus after open reduction and internal fixation with a plate and screws. Top left, parasagittal reformation; top right, coronal reformation, bottom left, axial/horizontal reformation.

The surgical staff performed the conventional C-arm imaging. The ISO-C-3D imaging was done either by the surgical staff or a medical student who attended the ISO-C-3D study as part of his MD thesis. Eight surgeons were involved in the study (1 head of department, 4 attending surgeons, 2 senior residents, and 1 junior resident). Their level of experience with acute trauma and reconstructive foot and ankle surgery ranged from 15 cases (junior resident) to 500 cases (head of department). None of the surgeons had prior experience with the ISO-C-3D. A sterile towel or a sterile plastic bag was used as a drape when the scanning procedure was performed.

After using the ISO-C-3D, the surgeon decided if changes needed to be made when incorrect reduction and/or implant positions were detected. The necessary changes were made to achieve the goals of the surgical procedure, ie, anatomic reduction and optimal implant position. Based on the surgeonś experience, corrections were always made if there would be a direct effect on the clinical outcome; that is, optimization of the reduction and/or repositioning of the implant might improve the clinical outcome. After the corrections, a second ISO-C-3D scan was performed if any uncertainty remained regarding the correct reduction and/or implant position.

Inclusion Criteria

The following inclusion criteria were defined:

- Patients. All patients who were treated at the institution between January 1, 2003 and March 15, 2004 were considered for inclusion.
- Cases. Fractures of the pilon, isolated dorsal Volkmann triangle, talus, calcaneus, navicular, cuboid, Chopart fracture-dislocation, Lisfranc fracture-dislocation, isolated Weber C ankles, and posttraumatic ankle and hindfoot arthrodeses were designated for inclusion.
- Availability of the device. The device was not always available for the study because it was also being used for procedures other than foot and ankle. Also, the device was not available during software updates and repairs.
- No exclusion criteria were defined.

Evaluation

The previously mentioned medical student recorded the times needed for each of the steps of the procedure, which were as follows (Table 1):

- Preparation for the use of the ISO-C-3D in the operating room (ie, transfer of the device to the operating room, establishing connections, turning on)
- Adjustment of the ISO-C-3D to the patient, including draping
- Scan time (exclusively the scanning process)
- Calculation time of the ISO-C-3D device after the scan, before the images were visible on the screen

TABLE 1. Time Spent for Intraoperative ISO-C-3D Use

		Time Spent Seconds Minutes.seconds		
Step	**Description of Step**	**Average**	**Minimum**	**Maximum**
Preparing	Transfer of the device to the operating room, establishing of connections, turning on	300 5.00	150 2.30	600 10.00
Adjustment	Draping with sterile towel or plastic bag adjustment of device to the foot for the scan	180 3.00	100 1.40	360 6.00
Scanning	ISO-C-3D scan alone	120 2.00	100 1.40	130 2.10
Calculation	Calculating time of device after the scan, before the images were visible on the screen	35 0.35	30 0.30	600 10.00
Evaluation	Choosing the views and planes on the screen and analyzing the reduction and implant position by the surgeon	210 3.30	120 2.00	360 6.00
Interruption of surgical procedure	Adjustment + scanning + evaluation	440 7.20	330 5.30	700 11.40

- Evaluation time, that is, time spent by the surgeon choosing the views and planes on the screen and analyzing reduction and implant position
- Interruption time during the procedure for use of the ISO-C-3D (time for adjustment, scanning, and evaluation without preparing and calculating) including problems with the device

Finally, the surgeons analyzed the consequences of the ISO-C-3D scan on the procedure (changes of reduction and/or implant position) using a visual analogue scale (VAS, 0–10 points, for feasibility, accuracy, and clinical benefit).

RESULTS

Patients

Between January 1, 2003 and March 15, 2004, the ISO-C-3D was used in 62 cases (Table 2).

Time Spent

Table 1 shows the time spent for the different steps of ISO-C-3D use. The operation was interrupted for adjustment, scanning, and evaluation for 440 seconds (7 minutes, 20 seconds) on average (range 330–700 seconds). This does not include preparing (before operation) and calculation (during operation).

Radiation Contamination

The net radiation was 39.3 seconds during a 100-image ISO-C-3D scan.

Problems

In 1 case (2%), the software crashed during calculation and was restarted (summarized total calculation time: 600 seconds). The reason for the crash could not be determined. The crash happened before the first software update at the very beginning of the study.

Consequences of ISO-C-3D Scan

Reduction and/or implant position was corrected in 39% (24 of 62) of cases at the same procedure after using the ISO-C-3D scan (Table 2). The position of implants was corrected in 26% of cases (16 of 62), the reduction was corrected in 19% of cases (12 of 62), and both implant position and reduction were corrected in 6.5% of cases (4 of 62). A second ISO-C-3D scan was performed in 12 cases after the corrections (50% of cases in which corrections were performed). No further corrections were made in those 12 cases after the second scan.

Correlation of Consequences of ISO-3-3D Use With Surgeons' Experience

Table 3 indicates that the changes made correlated with the surgeon's experience. The head of the department performed corrections in 31% of his 13 cases after ISO-C-3D use. The 4 attending surgeons who were involved in the study performed between 3 and 7 cases each and corrected reduction and/or implant position in 38% of their total cases. The 2 senior residents (1 of whom was the author, who contributed 26 cases) performed a correction in 44% of their total 27 cases. The junior resident performed 1 case (without changes after ISO-C-3D use). The percentage of correction did not significantly differ between these groups (head of department, attending surgeon/senior resident; χ^2 test, $P > 0.05$).

Surgeon's Ratings (Visual Analogue Scale)

The ratings of the 8 involved surgeons were 9.2 (5.2–10) for feasibility, 9.5 (6.1–10) for accuracy, and 8.2 (4.5–10) for clinical benefit. Figures 3 to 7 show illustrative cases.

DISCUSSION

A major problem in foot and ankle trauma care is the high percentage of joint fractures,[11,12] especially in the hind- and midfoot region.[12,13] Long-term results in these cases are directly related to the accuracy of the initial reduction of the joint lines.[11,13] During operative foot and ankle trauma care, intraoperative visualization is a problem, especially during closed procedures.[12,14,15] Different intraoperative C-arm views are standard and are as sufficient or insufficient as plain radiographs.[11,14] However, postoperative CT scans sometimes show joint line steps or gaps and/or malpositioning of implants

TABLE 2. Cases With ISO-C-3D Use

Diagnosis (no.)	No. Changes After ISO-C-3D Use In Total	Implant Position	Reduction	Description of Procedures and of Changes After ISO-C-3D Use
Fracture (n = 50)				
Pilon(11)	4/11	2/11	3/11	All cases ORIF with plates and screws
				Case 1, 1 screw that penetrated ankle corrected
				Case 2, 1 screw that penetrated ankle corrected and step in joint line corrected
				Case 3, 4, step of the ankle joint line corrected
Weber C(7)	3/7	2/7	2/7	All cases CRIF with syndesmosis screw
				Case 1, reduction of distal fibula corrected
				Case 2, syndesmosis screw corrected
				Case 3, reduction of distal fibula and syndesmosis screw corrected
Dorsal Volkmann (1)	1/1	—	1/1	CRIF with 2 screws Step and gap in joint line corrected
Talus (3)	1/3	1/3	—	All cases ORIF with screws, 1 screw that penetrated alkle joint corrected
Calcaneus (20)	7/20	5/20	3/20	ORIF with plate and screws
				Case 1, 2, 3, 1 screw that penetrated posterior facet corrected
				Case 4, 1 screw that penetrated calcaneocuboid joint corrected
				Case 5, 6, step in the posterior facet corrected
				Case 7, 1 screw that penetrated posterior facet and step in the posterior facet corrected
Navicular (1)	1/1	1/1	—	CRIF with screw
				One screw that penetrated talonavicular joint medially and plantarly corrected
Cuboid (1)	—	—	—	ORIF with screws
Lisfanc fracture-dislocation (6)	2/6	1/6	1/6	2 cases ORIF with tricortical bone autograft, plate and screw, 4 cases ORIF with screws/wires
				Case 1, 1 screw that penetrated talonavicular joint corrected
				Case 2, reduction of 4th and 5th metatarsal corrected to reduce flattening of the transverse arch
Posttraumatic osteoarthritis at the hindfoot with or without deformity (n = 12)				
Subtalar osteoarthritis (2)	1/2	1/2	—	Open cartilage removal, cancellous bone autograft, 7.3-mm screws
				One screw that penetrated the ankle joint corrected
Subtalar osteoarthritis with deformity (10)	4/10	3/10	2/10	Open cartilage removal, correction, tricortical bone autograft, 7.3-mm screws
				Case 1, 1 screw that penetrated the ankle joint corrected
				Case 2,1 screw that penetrated joint between cuboid and 4th metatarsal corrected
				Case 3, hindfoot varus corrected
				Case 4,1 screw that penetrated joint between cuboid and 4th metararsal corrected; hindfoot varus corrected
In total (62)	24/62 (39%)	16/62 (26%)	12/62 (19%)	

ORIF, open reduction and internal fixation; CRIF, closed reduction and internal fixation.

that had not been previously recognized intraoperatively.[1] A repeat procedure might be necessary to correct reduction and/or implant position.[11] It is in these cases that an intraoperative 3D imaging device that is comparable to a CT would improve the clinical outcome. Based on this study and others included in the literature, the ISO-C-3D appears to provide this necessary information.[1,3–6]

Clinical Benefit

In more than one-third of the cases in the study, intraoperative use of the ISO-C-3D, in foot and ankle fracture care and corrections of posttraumatic deformities in the hindfoot region, led to changes of reduction and/or implant position. However, we did not evaluate the impact of the changes on patient outcome. In that regard, a clinical follow-up

TABLE 3. Changes Made in Relation to Surgeons' Experience

Surgeon Status	No. Cases Contributed to Study, Single Surgeon and in Total	No. Changes After ISO-C-3D Use		
		In Total	Implant Position	Reduction
Head (n = 1)	13	4/13 (31%)	3/13 (23%)	2/13 (15%)
Attending surgeon (n = 4)	7/6/5/3 = 21	8/21 (38%)	5/21 (24%)	4/21 (19%)
Senior resident (n = 2)	26/1 = 27	12/27 (44%)	8/27 (29%)	6/27 (22%)
Junior resident (n = 1)	1	0/1	0/1	0/1
Total surgeons (n = 8)	62	24/62 (39%)	16/62 (26%)	12/62 (19%)

study will be performed based on those patients evaluated in this study. The follow-up study will focus on patient satisfaction, clinical outcome, and will have a sufficient follow-up time of at least 2 years. To analyze the impact of the ISO-C-3D, we are planning to perform a matched-pair analysis with patients that were treated earlier at our institution with the use of only a C-arm.

Illustrative of the clinical benefit of our use of the ISO-C-3D versus conventional C-arm use intraoperatively is the report by Zwipp. He reported a malposition of the distal fibula after closed reduction and fixation with a syndesmosis screw in 5 of 18 Weber C fractures, which was recognized with a postoperative CT.[16] He used a conventional C-arm and did not detect these malpositions intraoperatively. Revision surgery was performed in those 5 cases to improve the reduction.[18] We recognized comparable malpositions in 2 of 7 Weber C fractures when using the ISO-C-3D intraoperatively and were able to correct the reduction during the same procedure.

Another important finding in our study was the high percentage of screws penetrating joints when open reduction and internal fixation of calcaneus fractures was performed. Although the posterior facet and the calcaneocuboid joint were visible from the lateral side, we found screws penetrating these joints medially when we performed an intraoperative ISO-C-3D scan in 5 of 20 cases. Both joints are oblique and the posterior facet is especially difficult to visualize with a C-arm (Broden view).[12,14,15] In 3 of 20 cases, significant steps in the joint line of the posterior facet were also recognized with ISO-C-3D, and correction during the same operative procedure was possible. The ability to make corrections during the same surgical procedure may improve the clinical outcome because Song et al[17] found nonanatomic reduction of the posterior facet, ie, steps in the joint line, in 7 of 21 fractures using postoperative CT scans of Sanders type II calcaneus fractures.[18] They found a worse clinical outcome in those fractures in comparison to the remaining 14 fractures with anatomic reduction of the posterior facet without any steps.[17]

In summary, the ISO-C-3D appears to be most helpful in procedures with closed reduction and internal fixation and/or when axial reformations provide information that is not possible to obtain with a conventional C-arm and/or direct visualization during open reduction and internal fixation. Weber C fractures and calcaneus fractures are examples of these special situations. The ISO-C-3D is less useful when easy visualization with a conventional C-arm or direct vision is possible, as in open reduction and internal fixation of Weber B ankle fractures.

Time Spent

A major concern for new technical devices is always the time factor. In our study, the operation was interrupted for 7.20 minutes on average for ISO-C-3D use. After the end of the study, 6 of the 8 users in our department, including the first and the senior author, used the ISO-C-3D exclusively (and not the C-arm at all) in specific cases such as calcaneus fractures or Weber C ankle fractures. This reduces the time spent for radiologic imaging (C-arm and/or ISO-C-3D), and consequently the extra time spent for the ISO-C-3D use if a C-arm had been also used. Importantly, 2-dimensional images for documentation are easy to obtain using the ISO-C-3D data.

Cost Factors

The biggest disadvantage of the ISO-C-3D is the cost. The ISO-C-3D is twice as expensive as a conventional digital C-arm (price of ISO-C-3D is approximately 120,000 Euro,

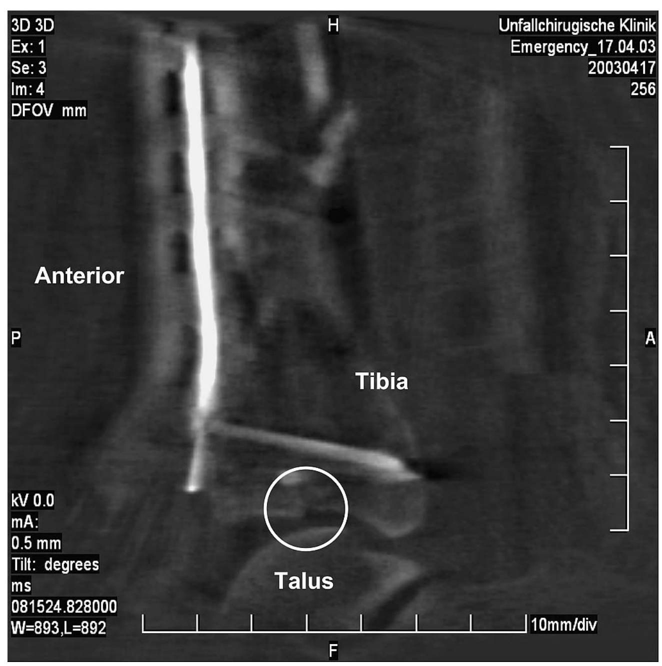

FIGURE 3. Pilon fracture after open reduction and internal fixation with plates and screws, with a significant step in the joint line that was not recognized using the conventional C-arm. After the ISO-C-3D scan, the reduction was corrected during the same procedure.

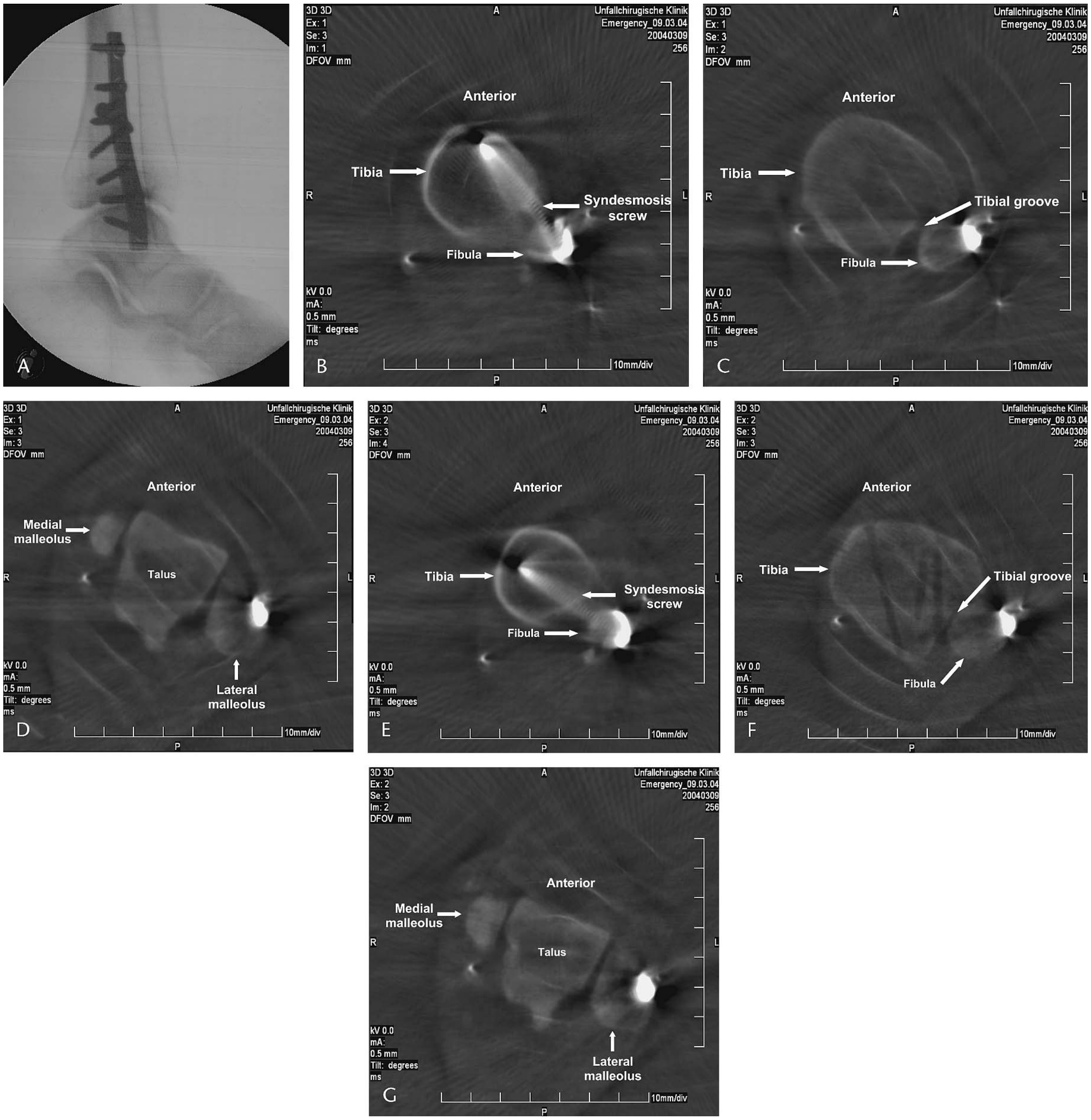

FIGURE 4. Weber C fracture after open reduction and plate fixation of the fibula without a syndesmosis screw. The indication existed for a closed reduction of the distal tibiofibular joint and insertion of a syndesmosis screw through a stab incision (A, lateral C-arm fluoroscopic view after first attempt of syndesmosis screw insertion). An ISO-C-3D-scan after the first attempt showed the screw position too far anteriorly (B, anterior, top of pictures), an anterior shift of the distal fibula with consequent incongruence at the groove of the distal tibia (C), and inadequately increased internal rotation of the distal fibula (D). After correction of the reduction and implant position, a second ISO-C-3D-scan confirmed a correct implant position (E), a correct congruent position of the distal fibula in the groove of the tibia (F), and a correct rotation of the distal fibula (G).

or $146,000 US). In addition, a carbon table for patient positioning in the operating room is necessary for optimal image quality with the ISO-C-3D (price of carbon table is approximately 30,000 Euro, or $37,000 US). The higher financial expenditure for the use of the ISO-C-3D may be offset by the likely reduction in the number of postoperative CT scans.

In this study, we did not obtain postoperative CT scans on a regular basis, as we did before the ISO-C-3D was available. Earlier studies have proven the comparable resolution of the ISO-C-3D and the CT.[1,3–5,19] Because the technical features of the ISO-C-3D had been shown in previous studies, a comparison between ISO-C-3D and CT was not performed during our study. The study was designed to discover the technical possibilities of the ISO-C-3D and how its use leads to modifications or corrections during a single surgical procedure. A decrease in subsequent procedures was expected due to the discovery and correction of malreduction

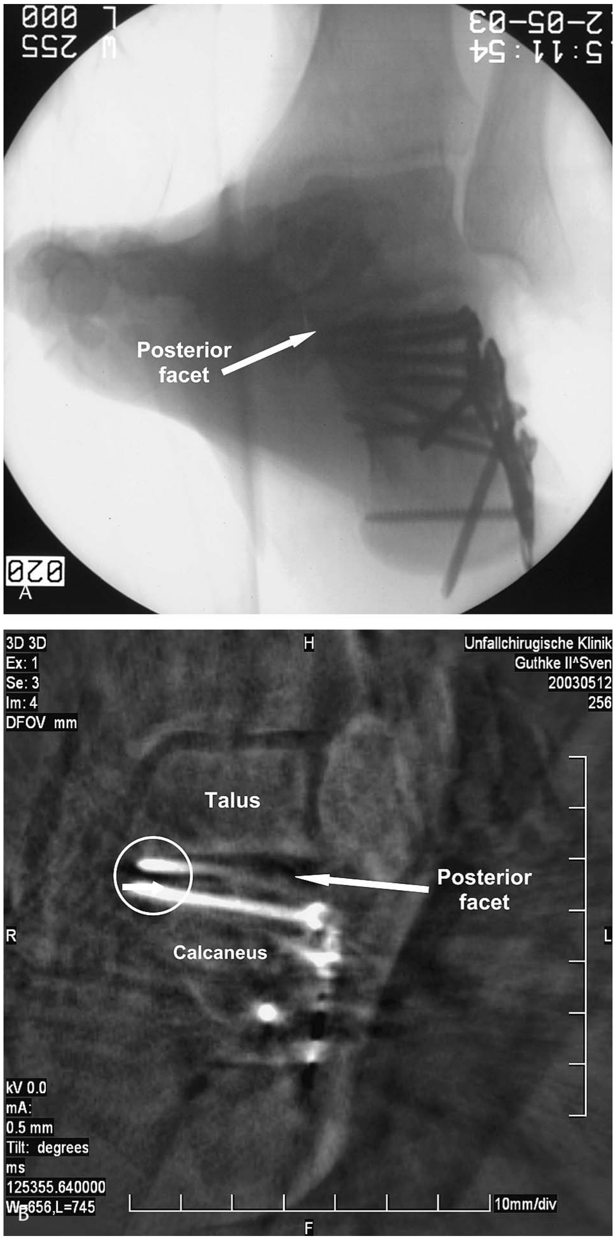

FIGURE 5. Calcaneus fracture after open reduction and internal fixation with plate and screws. After evaluation with C-arm including a Broden view (A), a correct reduction and implant position was confirmed by the surgeon. The ISO-C-3D scan showed a screw penetrating the posterior facet medially (B) that was corrected during the same procedure.

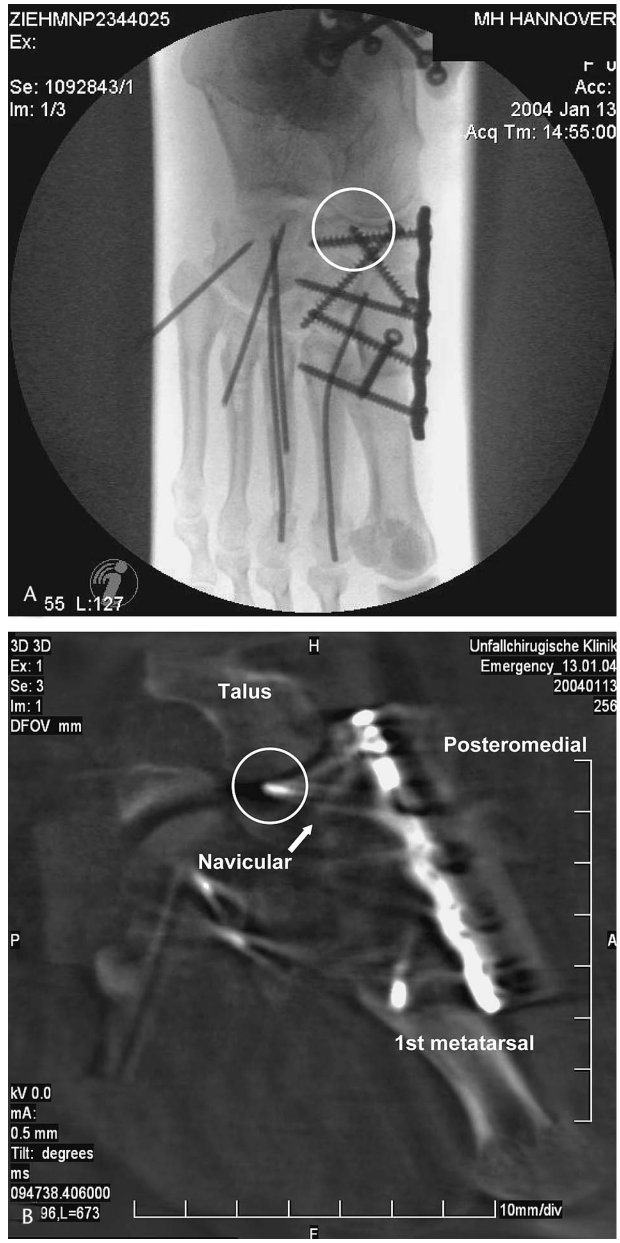

FIGURE 6. Lisfranc fracture-dislocation and neck fractures of second and third metatarsal after open reduction and internal fixation at the Lisfranc joint with insertion of a tricortical bone autograft from the pelvic rim for substitution of the extremely comminuted medial cuneiform, Lisfranc joint arthrodesis of the medial column including first, second, and third metatarsal, Lisfranc joint transfixation of the lateral column including fourth and fifth metatarsal, and antegrade K-wire fixation of the metatarsal neck fractures. Correct reduction and implant position was confirmed with the C-arm. The ISO-C-3D scan showed a screw penetrating the talonavicular joint (circle) that was corrected during the same procedure.

and malpositioning of implants by using the ISO-C-3D in the original procedure.

Radiation Contamination

The net radiation time in our study was 39.3 seconds during a 100-image ISO-C-3D scan. The device measures radiation time. The amount of radiation contamination during that time depended on the volume and density of the radiated body and could not be determined. The protocol for a standard ISO-C-3D foot and ankle scan comprises an effective slice thickness of 0.46 mm, 59 kV, 1.9 mA, and 22.8 mAs. The radiation dose for this standard protocol is 39.9 mGy × cm, compared to 37mGy × cm for a standard spiral CT (2 mm,

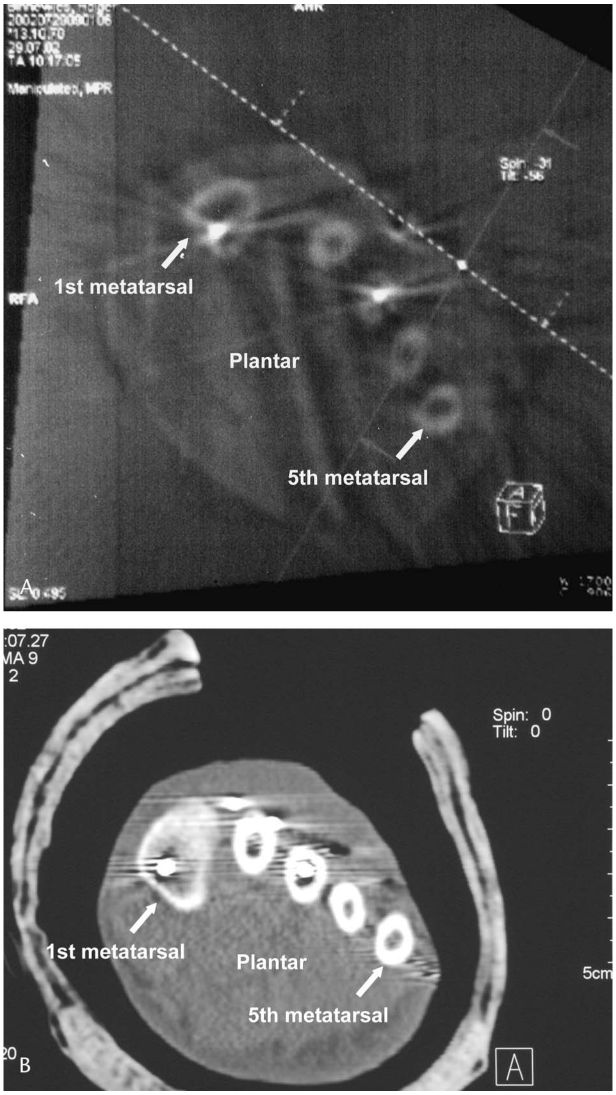

FIGURE 7. Lisfranc fracture-dislocation after open reduction and internal fixation. This procedure was performed after insufficient closed reduction with consecutive flattening of the transverse arch that was confirmed in a postoperative CT after the first procedure (not shown). The figure shows the comparable quality of the intraoperative ISO-C-3D scan (A) and the postoperative CT scan (B).

120 kV, 50 mA, 1.950 mAs).[4,5] Therefore, the radiation contamination of an ISO-C-3D scan is comparable to a standard CT scan and corresponds to the fluoroscopic use of a conventional digital C-arm for 39.3 seconds.[4,5]

CONCLUSION

In conclusion, the intraoperative 3D visualization with the ISO-C-3D can provide useful information in foot and ankle trauma care that cannot be obtained from plain films or conventional C-arms. The ISO-C-3D appears to be most helpful in procedures with closed reduction and internal fixation and/or when axial reformations provide information that is not possible to obtain with a conventional C-arm and/or direct visualization during open reduction and internal fixation. The ISO-C-3D has the possibility of replacing a postoperative CT scan, as 2-dimensional images for documentation can also be done. The radiation contamination is comparable to a standard CT scan and corresponds to 39 seconds fluoroscopy time with a conventional digital C-arm.

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