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Assessment of two 3-D fluoroscopic systems for articular fracture reduction: a cadaver study

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Abstract

Objective The most commonly used imaging device for assessment of fracture reduction is the two-dimensional X-ray fluoroscope. Two recently introduced 3D fluoroscopic devices, the Siremobil ISO-C3D (Siemens) and the C-InSight (Mazor Surgical Technologies), enable the surgeon to obtain spatial information for the assessment of articular reduction and hardware placement. The purpose of this study was to assess the reliability and accuracy of these two 3D fluoroscopic systems in measuring articular reduction in a cadaveric tibial plateau fracture.

Methods Six cadaveric knee specimens were osteotomized at the lateral tibial plateau and fixed with a maximal articular step-off of 0, 1, 2.5, 5 and 7.5 mm. Each specimen was scanned 10 times with two 3D fluoroscopes, the Siremobil ISO-C3D and the C-InSight. The resulting images were reformatted and interpreted for articular displacements at four different locations at the plateau level and were compared with high-resolution CT scans by an independent observer.

IRB approval was obtained for the cadaveric study in our institution. The work was performed in the Computer Assisted Surgery Laboratory at the Hadassah-Hebrew University Hospital, Jerusalem, Israel.

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Results For the non-displaced fracture, no displacement (mean < 0.1 mm) was observed in either modality. The mean scanning time for the ISO-C3D was 2 min, while each C-InSight scan took 20 s. The readings at four different points along the malreduced fractures were similar for most measurements with either of the two modalities. The C-InSight readings were less accurate than those of the ISO-C3D, relative to the CT scan, but most errors were within clinically acceptable limits (< 2 mm) and used less radiation. *Conclusions* Intraoperative 3D fluoroscopes can detect clinically significant intra-articular step-off with acceptable measurement errors, using newer devices that enable the use of a conventional C-arm and reduced radiation.

Keywords Articular fracture \cdot 3D fluoroscopy \cdot Intraoperative imaging \cdot Tibial plateau fracture

Introduction

Surgical treatment of intra-articular fractures presents a major challenge to the orthopedic surgeon. Traditionally, it has been accepted that the outcome of these fractures is closely correlated with the quality of their reduction [1–3]. The most commonly used intra-operative assessment method of fracture reduction is the two-dimensional fluoroscope. However, this method often fails to detect significant joint incongruencies readily detected by three-dimensional imaging (3D) modalities such as computerized tomography (CT) [4,5]. These more detailed imaging modalities are rarely available in the operating room. Thus, most postoperative CT scans do not impact patient management even with a suboptimal result [5]. In most instances, an unacceptable result on a postoperative CT leads to the need for a second procedure or accepting an articular malreduction.

Recently, three-dimensional (3D) imaging fluoroscopes have been introduced. These devices enable intra-operative CT scan-like imaging, producing axial, sagittal and coronal reformatted images, albeit of an inferior image quality [6]. Early reports of 3D fluoroscopes for the assessment of articular fracture reduction are encouraging [7–9]. However, the cost of these devices remains high, the field of view is limited to 9 inches for most systems, and the amount of radiation produced during each scan remains significant, at about 100 millirem (mrem) [10].

A newly developed software module (C-InSightTM, Mazor Surgical Technologies, Caesarea, Israel) allows for the use of a conventional two-dimensional C-arm fluoroscope, coupled with a target array, to capture and produce 3D fluoroscopic images similar to the ones produced by currently available 3D devices such as the ISO-C3D (Siremobil ISO-C-3DTM, Siemens, Erlanger, Germany). Thus, intra-operative 3D imaging can now be performed via conventional fluoroscopes with the potential advantages of decreased cost and reduced radiation time.

The goal of this study is to assess the reliability and precision of both the ISO-C3D and the C-InSight in detecting articular step-offs in a malreduced cadaveric tibial plateau fracture. Our main hypothesis was that the use of either one of the intra-operative 3D fluoroscopes will accurately detect a clinically relevant (> 2 mm) articular step-off in a simulated cadaveric tibial plateau fracture with clinically acceptable precision. These two intra-operative measures are quantitatively evaluated and compared with high-resolution postoperative CT scans serving as a benchmark.

Methods

We used two 3D fluoroscopic systems for our study. The Siremobil ISO-C 3D is a modified C-arm with a motor unit and a computerized image processing work station for intraoperative visualization. The motor unit transports the C-arm steadily and continuously over a 190° arc around a fixed (iso-centeric) point to visualize a volume of 12 cm^3 . During this orbital rotation, a set of two-dimensional fluoroscopic images in fixed angular steps are recorded. These images are transferred to the work station that provides real-time multiplanar images of axial, sagittal, and coronal reformats. The reader may refer to previous studies describing this modality [6,9,11].

The C-InSight system is comprised of a computer station that feeds directly from the video output of most existing C-Arm units, an image adaptor which mounts onto the C-arm's image intensifier, and a multiple use target, draped in a disposable sterile sheath, which is placed on the patient's body over the anatomical region of interest. A plastic target array is placed and secured by tape over the anatomic region of interest and a continuous 20s fluoroscopic scan is performed while moving the C-arm through its entire arc of motion (Fig. 1). The software analyzes the video stream of images and calculates the position of the scanned anatomic object relative to the target array. During the C-InSight scan, a real-time video stream of X-ray scans is captured by the system and the frames are processed sequentially to determine the target array location. Once all frames are processed, the system can co-locate them in space relative to the target array. Then, the image reconstruction process iteratively builds a CT-like volume. Volume reconstruction and reformatting produces axial, sagittal, and coronal images as well as a 3D model in DICOM format. The target array should be firmly fixed to the anatomic object of interest, even though the manufacturer indicates that a motion of a few centimeters can be tolerated.

The advantages and disadvantages of the two systems are as follows: the C-InSight scan requires roughly 20s of live fluoroscopy versus the 40s of fluoroscopy required with the ISO-C for a slow (100 shot) scan. During a C-InSight scan, the C-Arm operator rotates the C-Arm through its entire arc (approx 120 degrees) around the anatomical region of interest and freely adjusts the C-arm so that it is centered on the anatomy during the scan. This is in contrast to the ISO-C 3D scan which does not require the system to be centered on the target, and therefore, special positioning of the affected limb and/or operating table is not required. Additionally, for the C-InSight, a standard C-arm sterile disposable drape is sufficient, unlike the ISO-C3D, which requires a special drape. Upon completion of the manual C-InSight scan, the system converts the acquired images into a CT-like volume, as described earlier, in about 90-120s. More technical details for the device may be obtained from the manufacturer's Web site [12].

We used six freshly embalmed knee cadaveric specimens to create a tibial plateau fracture. These were paired knee specimens from a 64- year-old female, an 84-year-old male, and a 91-year-old male cadaver. The specimens included the distal femur just proximal to the metaphysis and the proximal tibial and shaft, including all surrounding soft tissues. A standard anterolateral approach was performed, starting from the lateral femoral condyle proximally to Gerdy's tubercle distally. The anterior compartment muscles were elevated and a submeniscal arthrotomy was performed in order to visualize the joint. A vertical osteotomy was done at the mid level of the lateral plateau using drill holes and a half-inch osteotome. The ostetomized fragment was fixed to the tibia using a 3.5-mm anatomically locked pre-contoured proximal tibial plate (Synthes, Bettlach, Switzerland). A line was drawn at the osteotomy level of the intact part of the tibia in order to determine the position of the malreduced fragment. A caliper was used to the measure the maximal step-off.

Fig. 1 The C-InSight 3D fluoroscopy system: a C-arm coupled with a target; b Target array; c The actual scan was acquired with the target wrapped in a sterile plastic sheath





Fig. 2 A cadaveric knee specimen used for the tibial plateau fracture. A standard anterolateral approach was used. After the osteotomy, a 3.5 mm proximal lateral tibial locking plate was used to fix the osteotomy using a 3.5 mm cortex shaft screw, with locking screws placed through the drill sleeves

The first two specimens (designated 1 and 2) were fixed without a step-off and served as the control group. It was planned that the malreduced fractures were to be fixed at a malreduced mid-plateau position of 1, 2.5, 5, and 7.5 mm. However, due to the plates' structure and non-anatomic fit for all specimens, minor shifts at the level of malreduction occurred following fixation. One 50-mm and two 70-mm (each with a 3.5 mm diameter) cortex screws were used for fixation at the plateau level, within 5 mm of the joint line. Additionally, one 3.5-mm cortex screw was placed in the metaphyseal area (Fig. 2). The specimens were designated as follows: Specimens 1 and 2 (no displacement), specimen 3 with a maximal step-off of 5 mm, specimen 4 with a 2.5 mm maximal step-off, specimen 5 with a maximal step-off of 7.5 mm, and specimen 6 a maximal step-off of 1 mm.

Each specimen was scanned ten times with the ISO-C 3D fluoroscope using a 2-min slow-scan protocol. Addition-

ally, all specimens underwent ten scans using the C-InSight software coupled to a 30.5- cm fluoroscope (OEC; GE Healthcare Systems, Chalfont St. Giles, UK). On each scan, both the specimen position and fluoroscope orientation were randomly changed to simulate a different limb position and C-arm orientation, thus simulating normally operating room activity. The displaced fractures underwent high-resolution 64 slice CT scans (Phillips, Cleveland, USA), using a 0.64mm slice protocol as a benchmark test, when the images for both fluoroscopes were with the corresponding CT scans.

All resulting images were reformatted to coronal reconstructions at 1-mm increments respectively using the C-InSight built-in software or ISO-C3D image viewer (Siemens Inc) for the fluoroscopic images and the Centricity PACS systems (GE medical Systems, Milwaukee, USA) for the CT scan images. All measurements were calibrated using the known screw size (3.5 mm) within areas clear of artifacts. The reconstructed images were interpreted by an independent observer (SS) blinded to the dissections and specimens (Fig. 3). Articular step-offs were measured at four different points: The frontal edge of the fracture (front), the most posterior edge of the fracture (back), and at the mid-plateau level (WP). Additionally, the maximal and average displacements were recorded for each measurement. These measurements were performed for all 10 scans of each of the ISO-C3D and C-Insight specimens, as well for the individual CT scans of each specimen.

Statistical analysis

The expected error of $2 \text{ mm} \pm 1$ versus 0 (H₁ hypothesis) was used to calculate the sample size, yielding a power of > 90% using 10 samples of each group with a significance level of < 0.05. A Kolmogorov–Smirnov test was carried out for paired test samples and yielded a normal distribution.

Fig. 3 Resulting coronal reformatted images of a cadaveric tibial plateau fracture specimen fixed in a malreduced position using a ISO-C3D; b C-inSight; and c high-resolution CT



Therefore, a two-sample, double tailed student t test was used to determine the different gap measurements (of each specimen) between the two fluoroscopes. A one sample t test was used to compare each set of either of the fluoroscopic system measurements (10 cases) against the single CT measurement of the corresponding specimen and point of measurement. A p value of < 0.05 was considered statistically significant. SPSS for Windows (v. 15, Chicago, IL) was used for statistical analysis.

Results

For specimens 1 and 2, both imaging modalities accurately detected no displacement with an average measurement error of less than 0.1 mm. No significant differences between the two modalities were detected. The average scanning time for the ISO-C3D was 2 min and for the C-InSight device 20 s. An additional 2 min of processing time was needed before the images could be displayed and reviewed with the C-InSight system. Figure 3 shows images from all three modalities.

The measurements of articular step-off in each malreduced specimen were similar in 15 out of 20 sets of 10 measurements between the ISO-C3D and C-Insight (Table 1). Significant differences in measurements were found between two out of five measurement sets in specimen 4 (2.5 mm stepoff) and three out of five measurement sets in specimen 5 (7.5 mm step-off). However, despite these statistically significant differences, in specimen 4, the overall differences were not high and accounted for less than 1 mm step-off, and in specimen 5 the overall differences account for less than a 2 mm step-off. The average of all measurement points differed significantly in two out of the four specimens, yielding a difference of less than 1 mm in specimen 4 and 2 mm in specimen 5 (Fig. 4).

An additional analysis was performed by measuring the difference between the observed (ISO-C3D and C-InSight) and the expected (CT) values for each specimen. These are presented in Tables 2 and 3. The CT was accurate in predicting the actual maximal step- off in three out of the four specimens with accuracy of less than 0.5 mm. The only exception was specimen 2 which was supposed to be fixed with a 5-mm step-off and measured 7.4 mm by the CT scanner. We suspect that further displacement occurred during the tightening of the shaft screw to the plate and gliding of the fragment distally, causing further displacement. We unfortunately could not physically re-measure this step-off after the scans since the cadavers had to be disposed of.

Table 1 Average measured malreductions of all specimens at four different points, and average displacement measured using ISO-C3D, C-InSight, and CT (numbers are in millimeters, average \pm SD)

Knee specimen modality	Anterior edge	Posterior edge	Widest part of plateau	Maximal displacement	Average displacement
5 mm step-off Specimen 3					
ISO-C	6.9 ± 0.7	6.1 ± 1.9	4.2 ± 0.9	7.6 ± 0.8	6.2 ± 0.7
C-InSight	5.7 ± 0.6	4.6 ± 0.5	6.2 ± 0.7	6.5 ± 0.5	5.7 ± 0.4
2.5 mm step-off Specimen 4	1				
ISO-C	1.5 ± 0.9	1.8 ± 1.1	1.6 ± 0.9	2.5 ± 0.2	1.9 ± 0.3
C-InSight	2.2 ± 0.8	2.0 ± 0.5	$2.1 \pm 0.6^{**}$	2.7 ± 0.4	$2.3 \pm 0.4*$
7.5 mm step-off Specimen 5	5				
ISO-C	$8.3 \pm 1.1^{***}$	3.4 ± 2.1	1.7 ± 1.3	$8.2 \pm 1.3^{***}$	$5.4 \pm 0.8^{***}$
C-InSight	10.4 ± 1.4	3.3 ± 2.2	2.0 ± 1.2	11.2 ± 0.7	6.7 ± 0.9
1 mm step-off Specimen 6					
ISO-C	2.1 ± 0.8	0.7 ± 1.2	0.5 ± 0.5	2.2 ± 0.6	1.4 ± 0.6
C-InSight	3.0 ± 0.9	0.5 ± 0.7	0.5 ± 0.6	3.0 ± 0.9	1.8 ± 0.5

 $p^* = 0.04, p^* = 0.02, p^* < 0.01$

 Table 2
 Measurement
 differences between ISO-C3 and CT scans for all measure points in each specimen

significant (p < 0.05)

differences between ISO-C3D and CT scans for all measured points in each specimen	Specimen	Point of measurement	Mean of displacements in ISO-C	Displacement in CT	p Value
	5 mm step-off Specimen 3	Anterior	6.85 ± 0.7	6.40	0.07
		Posterior	6.08 ± 1.9	7.30	0.07
		Widest plateau	$\textbf{4.18} \pm \textbf{0.9}$	5.0	0.02
		Maximal	7.61 ± 0.84	7.40	0.45
		Average	6.18 ± 0.7	6.52	0.17
	2.5 mm step-off Specimen 4	Anterior	$\textbf{1.53} \pm \textbf{0.93}$	2.30	0.03
		Posterior	1.79 ± 1.05	2.50	0.07
		Widest plateau	$\textbf{1.57} \pm \textbf{0.90}$	2.50	0.01
		Maximal	$\textbf{2.51} \pm \textbf{0.20}$	2.90	0.00
		Average	$\textbf{1.84} \pm \textbf{0.34}$	2.53	0.00
	7.5 mm step-off Specimen 5	Anterior	8.27 ± 1.07	7.58	0.07
		Posterior	3.42 ± 2.08	6.61	0.01
		Widest plateau	1.70 ± 1.31	1.17	0.23
		Maximal	8.17 ± 1.30	7.58	0.18
		Average	5.39 ± 0.81	5.74	0.21
	1 mm step-off Specimen 6	Anterior	$\textbf{2.07} \pm \textbf{0.77}$	1.26	0.01
		Posterior	0.69 ± 1.18	0.19	0.21
		Widest plateau	$\textbf{0.50} \pm \textbf{0.62}$	0	0.01
		Maximal	$\textbf{2.21} \pm \textbf{0.62}$	1.26	0.00
Bold values indicate statistically significant $(p < 0.05)$		Average	$\textbf{1.37} \pm \textbf{0.59}$	0.68	0.01

A significantly larger number of measurement sets were similar between the ISO-C3D and CT (11/20) than between the C-InSight (5/20) and CT which had less similarity between its measurements and the CT scan. However, most of these differences were within 1-2 millimeters, with only two sets (in specimen 5) of measurements exceeding this number.

Discussion

We have evaluated a new modality for intra-operative threedimensional imaging as part of the ongoing effort to obtain CT-like quality imaging in the operating suite. The main finding in our study was that clinically significant articular stepoff in a simulated cadaveric tibial plateau fracture could be

 Table 3
 Measurement

 differences between C InSight
 and CT scans for all measured

 points in each specimen
 between

Specimen	Point of measurement	Mean of displacements in C InSight	Displacement in CT	p Value
5 mm step-off (Specimen 3)	Anterior	$\textbf{5.73} \pm \textbf{0.61}$	6.40	0.01
	Posterior	$\textbf{4.61} \pm \textbf{0.5}$	7.30	0.00
	Widest plateau	$\textbf{6.16} \pm \textbf{0.68}$	5.0	0.00
	Maximal	$\textbf{6.52} \pm \textbf{0.46}$	7.40	0.00
	Average	$\textbf{5.74} \pm \textbf{0.33}$	6.52	0.00
2.5 mm step-off (Specimen 4)	Anterior	2.24 ± 0.74	2.30	0.80
	Posterior	2.26 ± 0.54	2.50	0.20
	Widest plateau	$\textbf{2.0} \pm \textbf{0.59}$	2.50	0.03
	Maximal	2.75 ± 0.44	2.90	0.32
	Average	2.31 ± 0.36	2.53	0.10
7.5 mm step-off (Specimen 5)	Anterior	$\textbf{10.41} \pm \textbf{1.41}$	7.58	0.00
	Posterior	$\textbf{3.28} \pm \textbf{2.16}$	6.61	0.01
	Widest plateau	$\textbf{1.96} \pm \textbf{1.17}$	1.17	0.06
	Maximal	$\textbf{11.2} \pm \textbf{0.73}$	7.58	0.00
	Average	$\textbf{6.72} \pm \textbf{0.89}$	5.74	0.01
1 mm step-off (Specimen 6)	Anterior	$\textbf{2.96} \pm \textbf{0.91}$	1.26	0.00
	Posterior	0.54 ± 0.70	0.19	0.15
	Widest plateau	$\textbf{0.52} \pm \textbf{0.58}$	0	0.02
	Maximal	$\textbf{3.01} \pm \textbf{0.95}$	1.26	0.00
	Average	$\textbf{1.76} \pm \textbf{0.55}$	0.68	0.00

Bold values indicate statistically significant (p < 0.05)



Fig. 4 The average readings for all sets of measurements of Specimens 3, 4, 5 and 6 using ISO-C3D and C-InSight

detected within clinically reasonable accuracy by both the ISO-C3D and the recently introduced C-InSight system.

The ISO-C3D performed better, yielding fewer differences between its readings and the high-resolution CT scan than the C-InSight. However, in most instances, the errors of the latter did not exceed the value of two millimeters, which is considered to be a clinically relevant articular step-off in most fractures [1].

Previous studies have extensively described qualitative experience with similar devices [11,13,14] using different parameters such as image quality, need for revision of the surgical implants and surgeon satisfaction.

Nevertheless, the actual accuracy of these devices was not described in most of the studies. One study compared the accuracy of reading lumbar pedicle screws using both ISO-C3D and CT and concluded that the accuracy of the former did not match the CT reading and recommended against its use as an assessment tool for pedicle screw insertion [15].

Our study evaluation suggests that for both devices, in an intra-articular fracture model, the margin of error (less than 2 mm) enabled us to detect clinically significant articular step-offs [16] (within 2 mm) despite the inferiority to CT image quality. This measurement lies within the clinical significance of anatomic reduction needed for cartilage healing [2]. A similar study using a simulated cadaveric tibial plateau model [17] did not find differences between CT scans and ISO-C3D in detecting minor step-offs in a cadaveric model. However, the authors of this study used a single screw for fixation and we believe that using multiple screws and a plate, as in our study, might have introduced more artifacts, simulating a more realistic clinical situation. We also changed the angle and position of both the fluoroscope and the specimen for each measurement, thus simulating a more realistic scenario commonly seen in the operating room.

Despite its overall image quality inferiority when compared with the ISO-C3D, the potential benefit of using the C-InSight modality is that it obviates the need for an additional machine in the operating room, using a more convenient and readily available 30.5-cm image intensifier, and eliminates the need for special limb positioning in order to achieve an isocentric scan. Although the radiation dose delivered by either fluoroscope was not directly measured in this study, the radiation dose of the C-InSight is reported by the manufacturer in this setting (tibia) to be 15–20 mrem when compared with 50–100 mrem delivered by the ISO-C3D [6]. In addition, the cost of the C-InSight device is significantly lower than the ISO-C3D device.

Technical improvements and better image processing algorithms are needed to overcome image quality shortcomings in both devices. Some newer experimental devices such as the cone-beam CT [18] are promising and should be further investigated.

The limitations of this study include the difficulty in measuring the actual step-off on the cadaveric model due to the complex geometry of the fracture. However, we believe that measuring fracture displacement using four different measuring points did compensate for this inaccuracy. Also, in real fractures, displacement is not always uniform and thus our model is believed to simulate a real fracture. Another limitation is that different software modules were needed for measuring each modality, thereby impeding the "blinded" interpretation of the images. However, our evaluator was blinded to the actual surgeries and measuring techniques. It should also be stressed that the experimental model of the tibial plateau was chosen due to technical convenience and previous work done with similar models. It does not presume to imitate the clinical scenario when some incongruence can at times be accepted with reasonable clinical results [19].

Another limitation was the lack of inter-observer and repeat intra-observer reliability examinations. However, these are reported to be high when dealing with 3D imaging of articular fractures as compared with 2D images [20].

In conclusion, three-dimensional fluoroscopy can contribute to the accuracy of reduction of complex intra-articular fractures. Newer devices, such as the C-InSight system, coupled with conventional C-arm fluoroscopes can obviate the need for more expensive and greater radiation producing 3D fluoroscopes. The advantages of this novel tool might increase the usage of valuable 3D intraoperative fluoroscopy potentially, leading to better fracture reduction.

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