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Special Issue Review

PedCAT for Radiographic 3D-Imaging in standing position

PedCAT für 3D-Röntgenbildgebung im Stehen

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KEYWORDS
Radiograph;
Computer tomography (CT);
3D-imaging;
Pedography;
Weight bearing

Summary

Background: PedCAT (Curvebeam, Warrington, USA) is a new technology that allows radiographic 3D imaging with full weight bearing which is be not influenced by projection and/or foot orientation (as radiographs). The aim of two different studies was a comparison of specific bone position (angle) measurements between three imaging methods (radiographs, CT, pedCAT), and the correlation of bone position and force/pressure distribution.

Methods: **Study 1.** In a prospective consecutive controlled study starting July 2013, 30 patients in which standard digital radiographs with full weight bearing in standing position, CT without weight bearing, and pedCAT scan with full weight bearing in standing position were included. The following angles were measured and compared: 1st - 2nd intermetatarsal angle, talo-metatarsal 1-angle (TMT) both dorsoplantar and lateral projection, hindfoot angle, calcaneal pitch (ANOVA with Post Hoc Scheffe test).

Study 2. In a prospective consecutive study starting July 2014, 50 patients were included. A pedCAT scan with simultaneous pedography with full weight bearing in standing position was performed. The following parameters were measured: PedCAT: lateral talo-1st metatarsal-angle (TMT), calcaneal pitch angle, minimum height of 5th metatarsal base, 2nd - 5th metatarsal heads and medial sesamoid. Pedography: midfoot contact area, maximum force midfoot, maximum force midfoot lateral, maximum force entire foot, maximum pressure 1st to 5th metatarsal. The corresponding pedCAT and pedography parameters were correlated (Pearson).

Results: **Study 1.** The angles differed between radiographs, CT and pedCAT (ANOVA, all $p \leq .01$). The angles differed between pedCAT and both radiographs and CT (Post Hoc Scheffe test, each $p \leq .05$ except for TMT dorsoplantar and calcaneal pitch angels versus radiographs).

Study 2. No sufficient correlation was found between pedCAT and pedography parameters ($r < 0.05$ or $r > -0.38$).

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Conclusions: The angles differed between radiographs, CT and pedCAT, indicating that only pedCAT is able to detect the correct angles. PedCAT includes weight bearing in contrast to CT. PedCAT prevents inaccuracies of projection and foot orientation in contrast to radiographs.
3D bone position did not correlate with force and pressure distribution under the foot sole during simultaneous pedCAT scan and pedography. Consequently, the bone positions measured with pedCAT do not allow conclusions about the force and pressure distribution and vice versa.

SCHLÜSSELWÖRTER
Röntgenbild;
Computertomographie (CT);
3D-Bildgebung;
Pedographie;
Vollbelastung

Zusammenfassung

Einleitung: PedCAT (Curvebeam, Warrington, USA) ist eine neue Technologie für 3D-Röntgenbildgebung im Stehen mit Belastung ohne Einfluss von Projektion und/oder Fußposition wie bei der 2D-Röntgenbildgebung. Das Ziel von zwei Studien war ein Vergleich von Messwerten typischer Winkel zwischen standardisiertem Röntgen mit Belastung, CT ohne Belastung und PedCAT; und die Analyse der Korrelation zwischen PedCAT-Parametern zur Knochenposition und Pedographieparametern.
Methoden: **Studie 1.** In einer prospektiven konsekutiven Studie wurden 30 Patienten eingeschlossen, bei denen ab 01.07.2013 Röntgen mit Belastung, CT ohne Belastung und PedCAT-Scan durchgeführt wurden. Folgende Winkel wurden am rechten Fuß von drei Untersuchern jeweils dreimal gemessen: Intermetatarsalwinkel, Talo-Metatarsale-1-Winkel dorsoplantar und seitlich, Rückfußachse, Kalkaneusinklination. Diese Winkel wurden hinsichtlich der intra- und interobserver Reliabilität und zwischen den Methoden verglichen (ANOVA).
Studie 2. In einer prospektiven konsekutiven Studie mit Beginn am 28.07.2014 wurden 50 Patienten eingeschlossen. Ein PedCAT-Scan mit gleichzeitiger statischer Pedographie von beiden Füßen im Zweibeinstand erfolgte. Die folgenden Parameter wurden gemessen: Talo-Metatarsale-1-Winkel (TMT) seitlich, Kalkaneusinklination, minimale Höhe mediales Sesambein, Metatarsale-2-4-Köpfchen und Metatarsale 5 proximal, Kontaktfläche Mittelfuß, Maximalkraft Mittelfuß, Mittelfuß lateral, Maximalkraft gesamter Fuß, Maximaldruck Metatarsale 1 distal/Sesambeine, Metatarsale 2-5 distal. PedCAT-Parameter wurden mit Pedographieparametern korreliert (Pearson).
Ergebnisse: **Studie 1.** Die Winkel unterschieden sich zwischen Röntgen mit Belastung, CT ohne Belastung und PedCAT (ANOVA, alle $p \leq 0{,}01$). Die Winkel unterschieden sich zwischen PedCAT und Röntgen/CT (Post Hoc Scheffe Test, jedes $p \leq 0{,}05$ außer TMT dorsoplantar und Kalkaneusinklination versus Röntgen).
Studie 2. Keine suffiziente Korrelation bestand zwischen PedCAT und Pedographieparametern ($r < 0{,}05$ oder $r > -0{,}38$).
Schlussfolgerungen: Die Winkel unterschieden sich zwischen Röntgen mit Belastung, CT ohne Belastung und PedCAT, was impliziert, dass nur mit PedCAT die korrekten Winkel gemessen werden. PedCAT inkludiert Vollbelastung im Gegensatz zum CT. PedCAT verhindert Ungenauigkeiten durch Einfluss von Projektion und/oder Fußposition wie beim Röntgen.
Die 3D-Knochenposition korrelierte nicht mit Druck- und Kraftverteilung unter der Fußsohle wie zuvor vermutet. Folglich kann von der Knochenposition nicht auf die Druck- und Kraftverteilung unter der Fußsohle geschlossen werden. Anders herum erlaubt die Druck- und Kraftverteilung unter der Fußsohle keine Rückschlüsse auf die Knochenposition.

Introduction

The standard for diagnostic radiographic imaging in foot and ankle surgery is radiographs with full weight bearing [12]. Analysing the position of the bones radiographically allows conclusions regarding the biomechanics of the foot [4,11,13,17,19,24,26,27]. The three-dimensional relationships of the bones in the foot are difficult to assess with standard radiographs due to superimposition of the different bones [5]. Angle measurements with standard radiographs could be inaccurate due to inaccuracies of the projection (orientation of central beam) and/or foot orientation [8,14,15]. 3D-imaging with conventional computed tomography (CT) allows for

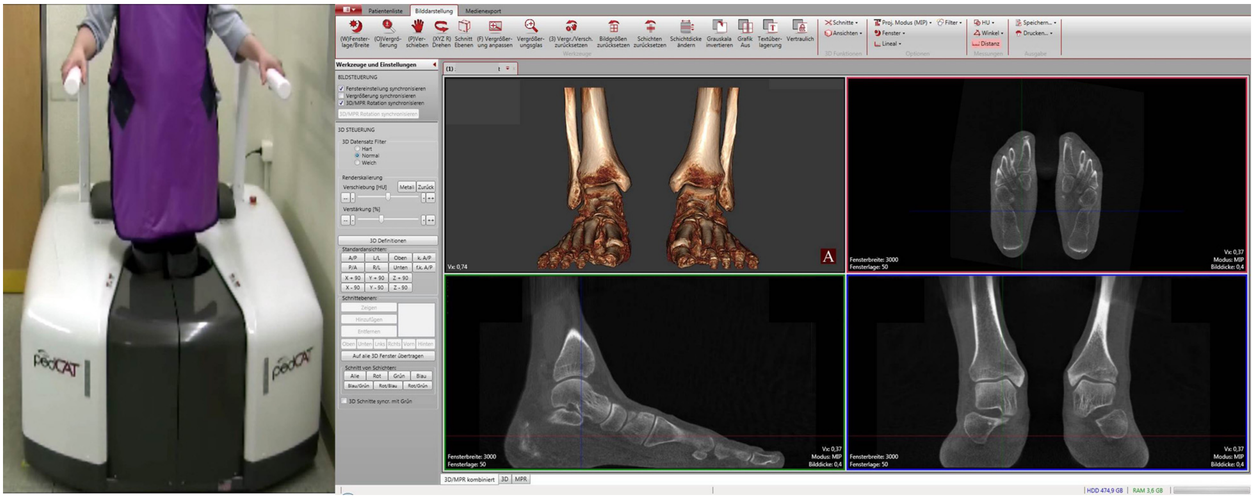

Figure 1. [17]. PedCAT-scan and software screen. An x-ray emitter and a flat-panel-sensor on the opposite side are rotating horizontally around the feet. Resolution and contrast which are the principal parameters for image quality are comparable with modern conventional CT. Left, patient positioned in pedCAT® during scan. Sitting position is also possible for patients that are not allowed or able to stand. The grey part is a sliding door that is opened before and after the scan. The patient can walk into the device of the door is open. Right, software screen view with 3D-reformation (top left), axial reformation (top right, red frame), parasagittal reformation (bottom left, green frame) and coronal reformation (bottom right, blue frame). The standard view is with 1 mm slice thickness, shown by the red, green and blue lines. The red lines are corresponding to the axial reformation in the red frame, the green lines are corresponding to the parasagittal reformation in the green frame, and the blue lines are corresponding to the coronal reformation in the blue frame.

exact analysis within the 3D data that is not influenced by projection and/or foot orientation but lacks weight bearing [5,9]. PedCAT (Curvebeam, Warrington, USA) is a new technology that allows 3D-imaging with full weight bearing which should be not influenced by projection and/or foot orientation (Figures 1 and 2). The aim of the first study was to compare time spent of the image acquisition, and comparison of specific angle measurements between the three methods (radiographs, CT,

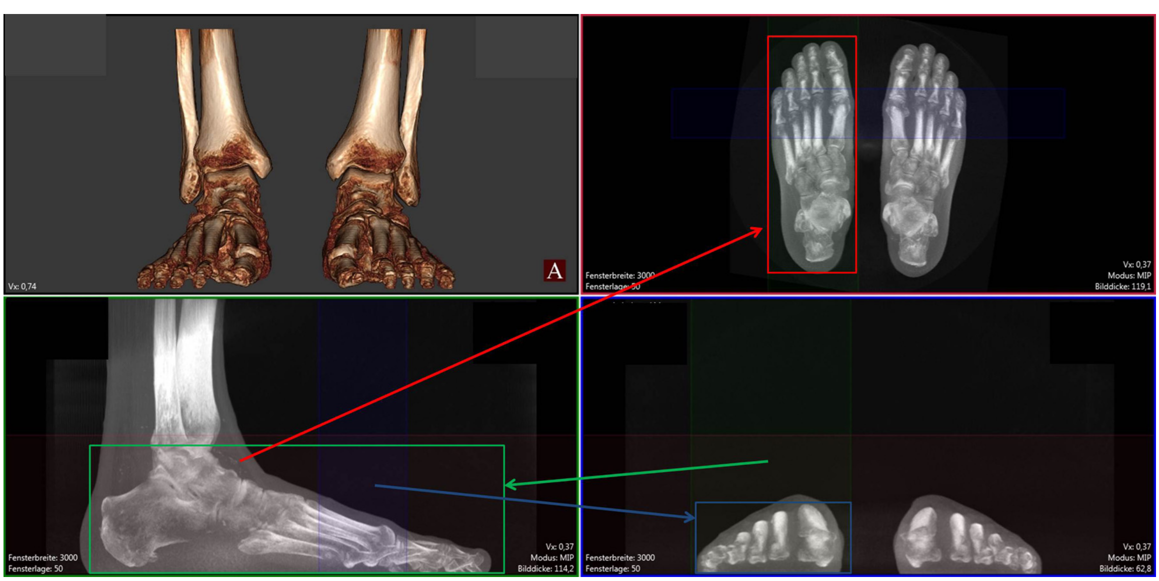

Figure 2. [17]. PedCAT software screen view with increased slice thickness to create virtual radiographs. Top right, in red frame, virtual dorsoplantar radiograph created by increased slice thickness that contains entire foot (red arrow). Bottom left, in green frame, virtual lateral radiograph created by increased slice thickness that contains entire foot (green arrow). Bottom right, in blue frame, virtual metatarsal head skyline view radiograph created by increased slice thickness that contains the metatarsal heads (blue arrow).

pedCAT), and to analyse and compare inter- and intraobserver reliability [17].

Pedography is a measurement of the force distribution under the sole of the foot which can be performed in a static or dynamic way [1,2,6,7,19,21]. The correlation between 3D bone position and pedographic measurements, i.e. force and pressure (distribution) has not been shown so far. For the second study a customized pedography sensor (EMED, Novel, Munich, Germany) was inserted into the pedCAT. The aim of the second study was analyse the correlation of bone position and force/pressure distribution.

Methods - PedCAT versus CT versus radiographs [17]

In a prospective consecutive study, 30 patients in which standard digital radiographs with full weight bearing in standing position, CT without weight bearing in supine position, and pedCAT with full weight bearing in standing position were included, starting July 1, 2013. The potential pathologies of the feet were registered but not further analysed.

Inclusion and exclusion criteria, ethics [17]

The inclusion criteria were age ≥ 18 years, presentation at the local foot and ankle outpatient clinic, and indication for radiographs and 3D-imaging (CT, pedCAT). The indication for Radiograph and 3D-imaging (CT, pedCAT) was defined following the local standard. For example no indication for 3D imaging (CT, pedCAT) was given for isolated forefoot deformities, whereas indication for 3D imaging (CT, pedCAT) was given for deformities in the midfoot and/or hindfoot region.

The exclusion criteria were age < 18 years, no indication for radiograph and/or 3D imaging (CT, pedCAT), and participation in other studies.

All three methods (Radiographs, CT, pedCAT) were approved by the relevant authority for diagnostic use at the local institution. Approval from the local ethical committee was granted for simultaneous use of all three methods (Radiograph, CT, pedCAT) based on the indications as described above. Informed consent was obtained from all subjects.

Image acquisition [17]

The radiographic image acquisition followed a standardized protocol with a fully digital device (Model Buck Diagnost, Philips, Hamburg, Germany) [12,22]. The patient was positioned on a special step with a holding apparatus for the digital film, the x-ray emitter was adjusted and the images were taken (dorsoplantar bilateral radiograph, feet with neutral rotation, central beam in the centre between both feet and 20° oblique anterior from perpendicular; lateral single foot radiograph, foot with neutral rotation, central beam horizontal in the middle of the foot; Saltzman view bilateral radiograph, ankle/feet with neutral rotation, central beam in the center between both feet and 20° oblique posterior from perpendicular [12,22]). The radiation exposure time was approximately 1/10th of a second for each image. For CT (Model Optima 520, General Electric Healthcare, Solingen, Germany; helical technique, 20 lines), the patient was positioned in supine position, and the feet were placed in a special holding device to ensure neutral foot and ankle position [18]. Both feet and ankles were scanned from 10 cm proximal to the ankle level. The slice thickness was adjusted to 1 mm and the pure scanning time was 60 seconds. For pedCAT (Model pedCAT, Curvebeam, Warrington, USA), the patient walked into the device, and was positioned in bipedal standing position as shown in Figure 1. Technically, an x-ray emitter and a flat-panel-sensor on the opposite side are rotating horizontally around the feet. Resolution and contrast which are the principal parameters for image quality are comparable with modern conventional CT. The scanning time was 68 seconds.

Time spent [17]

The time spent of the image acquisition was registered. Time spent was defined as the sum of the time needed for positioning the patient for the imaging and the time needed for the imaging as such as described above. The time for epidemiological data entry was not included. For the radiograph group the times for all four images (feet bilateral dorsoplantar, right foot lateral, left foot lateral, Saltzman hindfoot view bilateral) were added up to a total time.

Angle measurements [17]

The angles were digitally measured with specific software (Radiographs, Jivex, Visus, Bochum, Germany; CT, Syngo XS version VE31GSL19P21VC10ASL129P167SP1, Siemens, Erlangen, Germany; pedCAT, Cubevue, version 2.4.0.5, Curvebeam, Warrington, USA).

The following angles were measured for the right foot by three different investigators three times (data was reloaded and planes redefined for each set of measurements): 1st - 2nd intermetatarsal angle, talo-metatarsal 1-angle (TMT) dorsoplantar and lateral projection, hindfoot angle, calcaneal pitch angle [20,22].

The 1st - 2nd intermetatarsal angle was defined as the angle created between the axis of the 1st and the 2nd metatarsal in the dorsoplantar view (Radiograph) or axial / horizontal reformation (CT, pedCAT). For CT and pedCAT the plane for the measurement was virtually rotated within the 3D-datase to achieve an exact congruency to the bone axes of 1st^{t} and 2nd metatarsals.

The TMT angle was defined as the angle created between the axis of the 1st metatarsal and the talus [20] (Figure 3). The dorsoplantar TMT angle was measured in the dorsoplantar view (Radiograph) or axial / horizontal reformation (CT, pedCAT) (Figure 3). The lateral TMT angle was measured in the lateral view (Radiograph) or parasagittal reformation (CT, pedCAT) (Figure 3). For CT and pedCAT the plane for the measurement was virtually rotated within the 3D-datase to achieve an exact congruency to the bone axis of talus and 1st metatarsal.

The hindfoot angle was defined as the angle created between the axis of the distal tibia and the line between the centre of the talar dome and the posterior calcaneal process (Figure 3). This angle is defined to be positive for hindfoot valgus and negative for hindfoot varus. It is measured Saltzman view (Radiograph) or coronal reformation (CT, pedCAT) (Figure 3). For CT and pedCAT the plane for the measurement was virtually rotated within the 3D-dataset to achieve an exact congruency to the bone axis of the tibia and the axis of the hindfoot (Figure 3, image bottom right). This was typically the case when this plane was congruent with the axis of the ankle, i.e. a line between medial and lateral malleolus comparable to a Mortise orientation but within a 3D-space. Figure 3 (image bottom right) shows the orientation within the 3D dataset as described above with the adjusted rotation with the fibula and tibia aligned in the same virtual plane comparable to a Mortise view.

The calcaneal pitch angle was defined as the angle created between line between the lowest part of the posterior calcaneal process and the lowest part of the anterior calcaneal process, and a horizontal line. The calcaneal pitch was measured in the lateral view (Radiograph) or parasagittal reformation (CT, pedCAT). For CT and pedCAT the plane for the measurement was virtually rotated within the 3D-datase to achieve an exact congruency to an exactly parasagittal plane.

All bone axes (Tibia, talus, metatarsals) were defined as the straight line between the centres of the bones proximally and distally. These bone centres were defined by linear measurements (Figure 3). The TMT angles were defined to be negative for abduction in the dorsoplantar radiograph and for dorsiflexion in the lateral radiographs [20].

Statistics [17]

The parameters were compared intra- and interobserver, and between the different methods (Radiograph, CT, pedCAT) (ANOVA with Post Hoc Scheffe test). The null hypothesis at a significant level of 0.05 was formulated that the different angles did not differ between the three methods. For non-significant findings, a power analysis was indicated. Sufficient power was defined as $\geq .8$.

Methods - Correlation pedCAT with pedography

In a prospective consecutive study starting July 28, 2014, 50 patients were included. A pedCAT scan with simultaneous pedography of both feet under full weight bearing in standing position was performed. A customized pedography sensor (Pliance, Novel, Munich, Germany) was inserted into the pedCAT and connected to a PC with the standard software installed (Expert, Novel, Munich, Germany). The potential pathologies of the feet were registered but not further analysed.

Inclusion and exclusion criteria, ethics

The inclusion criteria were age $\geq$ 18 years, presentation at the local foot and ankle outpatient clinic, and indication for pedCAT. The indication for pedCAT was defined following the local standard [17]. For example no indication for 3D imaging with pedCAT was given for isolated forefoot deformities, whereas indication for was given for deformities in the midfoot and/or hindfoot region.

The exclusion criteria were age < 18 years, no indication for pedCAT imaging and participation in other studies.

Approval from the local ethical committee was granted based on the indications as described above. Informed consent was obtained from all subjects.

Image acquisition

The patient walked into the device, and was positioned in bipedal standing position as shown in Figure 1. Technically, an x-ray emitter and a flat-panel-sensor on the opposite side are rotating horizontally around the feet. Resolution and contrast which are the principal parameters for image

Figure 3. [17]. PedCAT software screen showing an example of some angle measurements. The 3D-reformation (top left), shows how the 3D-dataset was virtually rotated to allow for exact congruency of the plane of the reformations with the bone axes as described in the methods section. Top right, measurement of the dorsoplantar TMT angle; bottom left, measurement of the dorsoplantar TMT angle; bottom right, measurement of the hindfoot angle also as described in the methods section. The hindfoot angle measurement was typically performed in another plane which cannot be displayed simultaneously with planes for the dorsoplantar and lateral TMT angles. This modified presentation was chosen for this figure for to allow simultaneous presentation of three angles within one figure. The lines that define the centres of the bones proximally or distally are exactly 50% of the measured entire bone thickness.

quality are comparable with modern conventional CT [17]. The scanning time was 68 seconds.

Pedography

The data of the pedography sensor (Figure 4) was gathered for the first 30 seconds of the pedCAT scan.

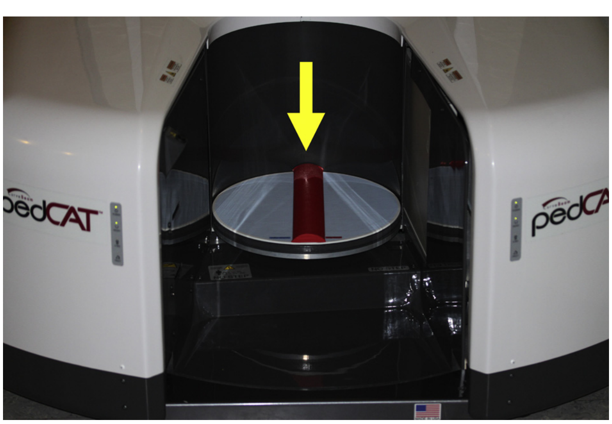

Figure 4. PedCAT with pedography sensor. PedCAT with the sliding door open and the customized pedography sensor in place (yellow arrow).

Measurements of bone position (angles and distances)

The bone positions (angles and distances) were digitally measured with standard pedCAT software (Cubevue, Curvebeam, Warrington, USA).

The following angles and distances were measured for the right foot by three different investigators three times (data was reloaded and planes redefined for each set of measurements): lateral talo-1st metatarsal angle (TMT), calcaneal pitch angle, minimum height of 5th metatarsal base, 2nd - 5th metatarsal heads and medial sesamoid. The medial sesamoid was chosen instead the 1st metatarsal head because it is regularly closer to the foot sole / ground. The medial sesamoid was chosen instead of the lateral sesamoid because it is less likely to completely dislocate from underneath the 1st metatarsal head in forefoot deformities such as hallux valgus [23,25].

The lateral TMT angle was defined as the angle created between the axis of the 1st metatarsal and the talus (Figure 5a) [17,20]. The plane for the measurement was virtually rotated within the 3D-dataset to achieve an exact congruency to the bone axis of talus and 1st metatarsal.

The calcaneal pitch angle was defined as the angle created between a horizontal line a line

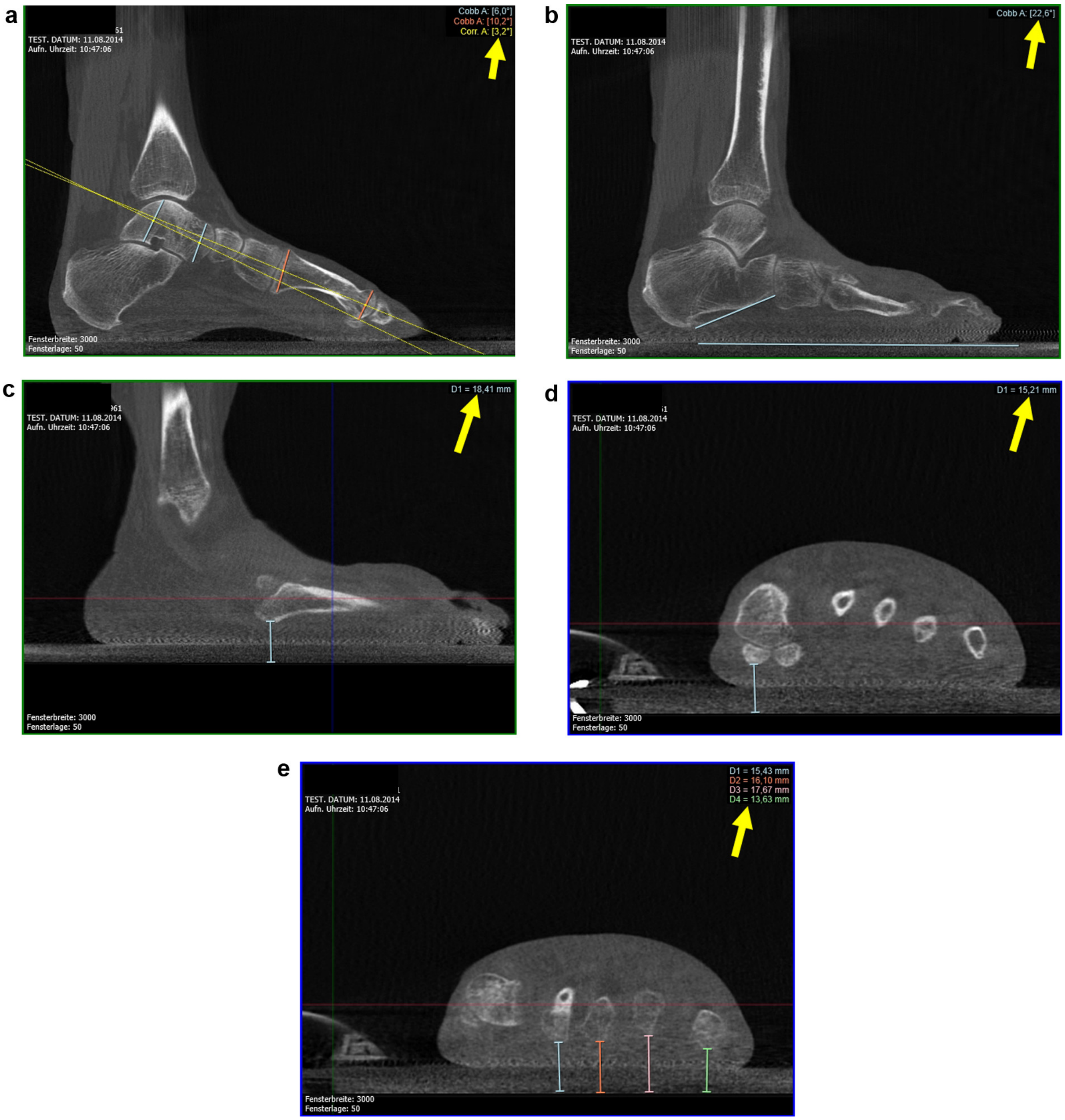

Figure 5. a - e. PedCAT software screens showing examples of some angle and distance measurements. Figure 5a, lateral TMT angle (arrow); Figure 5b, calcaneal pitch angle; Figure 5c, minimum height 5th metatarsal base to footplate; Figure 5d, height medial sesamoid; Figure 5e, height 2^{nd} - 5^{th} metatarsal heads. The lines that define the centres of the bones proximally or distally are exactly 50% of the measured entire bone thickness.

between the lowest part of the posterior calcaneal process and the lowest part of the anterior calcaneal process (Figure 5b) [17]. The plane for the measurement was virtually rotated within the 3D-dataset to achieve an exact congruency to an exactly parasagittal plane.

Bone axes (Talus, 1^{st} metatarsal) were defined as the straight line between the centres of the bones proximally and distally. These bone centres were defined by linear measurements (Figure 5a). The TMT angles were defined to be negative for angle corresponding to a dorsiflexion [20].

The minimum height of 5^{th} metatarsal base, 2^{nd} - 5^{th} metatarsal heads and medial sesamoid was defined as the minimum distance between the footplate and the 5^{th} metatarsal base (Figure 5c), medial sesamoid (Figure 5d), and 2^{nd} - 5^{th} metatarsal heads and (Figure 5e). The plane for the measurement was virtually shifted within the 3D-dataset to display the lowest part of the relevant bone (part).

Measurement of pedographic parameters

A standard computerized mapping to create a distribution into the following foot regions was performed with the standard software (Automask, Novel, Munich, Germany): hindfoot, midfoot, 1st metatarsal head/sesamoids area, 2nd metatarsal head, 3rd metatarsal head, 4th metatarsal head, 5th metatarsal head, 1st toe, 2nd toe, 3rd-5th toe (Figure 6) [16]. This mapping process does not include manual determination of landmarks [16]. The outlines of the foot and the different regions are determined by the software using an algorithm as reported [3]. This software algorithm is based on geometric characteristics of a maximum pressure picture using an individual sensing threshold [16]. The following parameters were registered within the defined foot regions: midfoot contact area, maximum force midfoot, maximum force midfoot lateral, maximum force entire foot, maximum pressure 1st to 5th metatarsal head area. The parameter maximum force midfoot was defined as the maximum force in the entire midfoot region (Figure 6). The parameter maximum force midfoot lateral was defined as maximum force in the lateral sensor row of the midfoot region (Figure 4).

Correlation analysis of pedCAT parameters with pedography parameters

Lateral TMT, calcaneal pitch angle, and minimum height of 5th metatarsal base were each correlated with midfoot contact area, maximum force midfoot, maximum force midfoot lateral and maximum force entire foot. The minimum height of 2nd - 5th metatarsal heads and medial sesamoid were correlated with the maximum pressure of the corresponding 1st to 5th metatarsal head area.

Statistics

The statistical analysis was performed in cooperation with the Institute for Biometry and Statistics of the affiliated university with IBM® SPSS® Statistics (Version 22.0.0.0, IBM, Armonk, NY, USA). The pedCAT parameters were compared for intra- and interobserver (ANOVA with Post Hoc Scheffe test). The correlation of the pedCAT parameters with the pedography parameters was performed with Pearson test. Significant correlation was considered as $p < 0.05$. Sufficient correlation was considered as $r > 0.8$ or < -0.8.

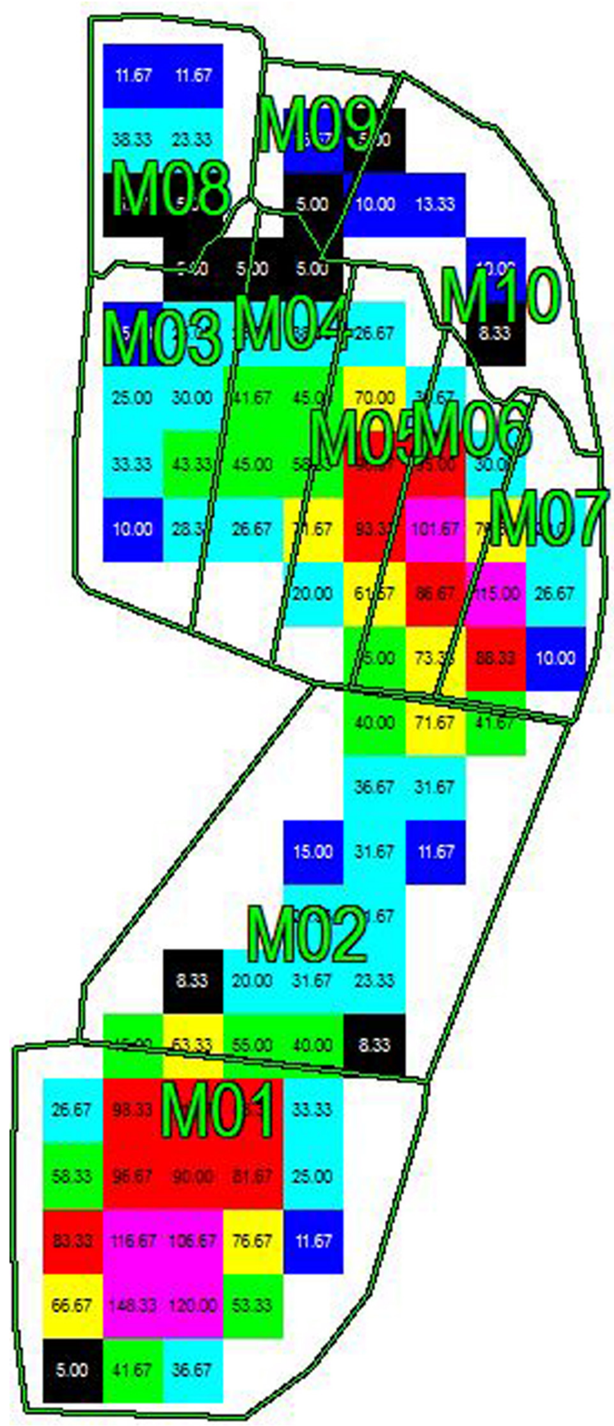

Figure 6. Image from the pedography after computerized mapping. The following regions are defined by the mapping process: M1, hindfoot; M2, midfoot; M3, 1st metatarsal head/sesamoids area; M4, 2nd metatarsal head; M5, 3rd metatarsal head; M6, 4th metatarsal head; M7, 5th metatarsal head; M8, 1st toe; M9, 2nd toe; M10, 3rd-5th toe.

Table 1 ONEWAY ANOWA Radiographs versus CT versus PedCAT and post Hoc Test PedCAT versus Radiographs and CT.

ONEWAY ANOVA

Parameter	Radiographs		CT		PedCAT		p
	mean	STD	mean	STD	mean	STD	
IM-angle	7.7	3.3	7.8	3.9	9.3	3.5	<0.001
TMT dorsoplantar	-6.2	12.4	4.3	10.0	-5.0	12.0	<0.001
TMT lateral	-5.2	8.2	0.5	8.4	-7.6	8.2	<0.001
Hindfoot angle	2.4	6.9	5.4	5.6	10.1	7.1	<0.001
Calcaneal pitch angle	17.5	6.3	16.5	5.0	17.8	5.4	0.01

Pos Hoc Scheffe Test

Parameter	PedCAT vs.	p
IM-angle	Radiographs	<0.001
	CT	<0.001
TMT dorsoplantar	Radiographs	0.561
	CT	<0.001
TMT lateral	Radiographs	0.003
	CT	<0.001
Hindfoot angle	Radiographs	<0.001
	CT	<0.001
Calcaneal pitch angle	Radiographs	0.701
	CT	0.013

IM, 1st - 2nd intermetatarsal angle; TMT, talo - 1st metatarsal - angle; STD, standard deviation.

Results - PedCAT versus CT versus radiographs Richter, 2014 537 /id}

Time spent [17]

The time spent for the image acquisition was 902 ± 70 seconds for radiographs, 415 ± 46 seconds for CT and 270 ± 44 seconds for pedCAT on average (ANOVA, $p < .001$).

Angle measurement - differences between methods [17]

The angles differed between radiographs, CT and pedCAT (ANOVA, all $p \leq .01$) (Table 1). The angles differed between pedCAT and both radiographs and CT (Post Hoc Scheffe test, each $p \leq .05$) except for TMT dorsoplantar and calcaneal pitch angles for pedCAT versus radiographs). The null hypothesis was rejected for all angles except for TMT dorsoplantar and calcaneal pitch angles between pedCAT and Radiograph.

Angle measurement - intra- and interobserver reliability [17]

Regarding intraobserver reliability, the angles did not differ between measurement 1, measurement 2 and measurement 3 for all three investigators and for all three methods (Radiograph, CT, pedCAT) (ANOVA, each $p > .9$, power >.8).

Regarding interobserver reliability, the angles did not differ between the three investigators for measurement 1, measurement 2 and measurement 3 for all three methods (Radiograph, CT, pedCAT) (ANOVA, each $p > .9$, power > .8).

Results - Correlation pedCAT with pedography

Table 2 shows the descriptive statistics of all pedCAT and pedography parameters.

Measurements of bone position (angles and distances) - intra- and interobserver reliability

Regarding intraobserver reliability, the angles and distances did not differ between measurement 1, measurement 2 and measurement 3 of all measured pedCAT parameters for all three investigators (ANOVA, each $p > .8$, power >.8).

Regarding interobserver reliability, the angles and distances did not differ between the three investigators for measurement 1, measurement 2

Table 2 Descriptive statistics of all measured pedCAT and pedography parameters.

	TL (°)	C (°)	H5P (mm)	H1 (mm)	H2 (mm)	H3 (mm)	H4 (mm)	H5 (mm)	MC (cm^2)	MF (N)	MFLAT (N)	FMAX (N)	P1 (kPa)	P2 (kPa)	P3 (kPa)	P4 (kPa)	P5 (kPa)
Mean	-8.3	18.1	21.5	16.4	19.1	18.2	17.5	16.0	18.7	41.7	33.6	375.3	56.5	50.7	50.0	43.8	34.5
Min	-38.0	5.4	15.7	12.8	14.5	13.2	13.6	12.4	3.4	2.8	1.5	52.4	0.0	0.0	0.0	0.0	0.0
Max	14.3	33.5	47.4	28.2	25.9	26.6	25.8	25.4	44.0	203.5	112.8	563.2	355.0	120.0	103.3	100.0	256.7
Std	9.3	5.4	5.2	2.9	2.5	2.1	2.1	2.2	8.5	41.8	28.4	98.2	58.7	27.2	23.4	22.5	38.0

TL, lateral talo-1st metatarsal angle (TMT) angle; C, calcaneal pitch angle; H5P, minimum height 5th metatarsal base; H1, height medial sesamoid; H2 - H5, height 2nd - 5th metatarsal heads; MC, midfoot contact area, MF, maximum force midfoot; MFLAT, maximum force midfoot lateral; FMAX, maximum force entire foot; P1 - P5, maximum pressure 1st to 5th metatarsal; Min, minimum; Max, maximum, Std, standard deviation.

and measurement 3 of all measured pedCAT parameters (ANOVA, each $p > .8$, power > .8).

Correlation of pedCAT parameters with pedography parameters

Table 3 shows the correlation of pedCAT parameters with pedography parameter. The correlation between angles / heights from the pedCAT data with force/pressure distribution from the pedography data was not significant (each $p > 0.05$) except for lateral talo-1st metatarsal angle (TMT) angle versus midfoot contact area ($p = 0.02$) and maximum force entire foot ($p = 0.01$), and minimum height 5th metatarsal base versus maximum force midfoot lateral ($p = 0.05$). The correlation coefficient for these correlations was not sufficient (lateral talo-1st metatarsal angle (TMT) angle versus midfoot contact area ($r = -0.32$) and maximum force entire foot ($r = 0.38$), and minimum height 5th metatarsal base versus maximum force midfoot lateral ($r = -0.27$)). In conclusion, no sufficient correlation was found.

Discussion

These were the first studies comparing bone position (angle) measurements between standard radiographs with weight bearing, standard CT without weight bearing and 3D imaging with weight bearing (PedCAT), and analysing the direct correlation of bone position and force/pressure distribution with simultaneous radiographic 3D-imaging and pedography and full weight bearing [17]. This correlation as such seems to be logical but it has not been shown from a scientific point of view.

Time spent [17]

The image acquisition with pedCAT (270 seconds) was 70% faster than with radiographs (902 seconds) and 35% faster than with CT (450 seconds). This difference was not caused by the scanning time as such which is much lower for radiographs (4 times 1/10 of a second) than for CT (60 seconds) or pedCAT (68 seconds). The positioning of the patient and the adjustment of the x-ray emitter comprised the majority of the time spent for radiographs and the positioning of the patient and the adjustment of the device with specifying the scan area and sliding the patient to the correct position for the scan for CT. For the pedCAT the patient positioning was the fastest and no further adjustments are needed so that only pushing a button is necessary to perform the scan.

Table 3 Correlation of pedCAT parameters with pedography parameters.

		MC (cm^2)	MF(N)	MFLAT (N)	FMAX (N)
TL (°)	**r**	-0.32	-0.14	-0.14	-0.38
	p	**0.02**	0.34	0.33	**0.01**
C (°)	**r**	-0.11	-0.13	-0.11	0.00
	p	0.46	0.37	0.44	0.98
H5P (mm)	**r**	-0.24	-0.26	-0.27	0.06
	p	0.09	0.07	**0.05**	0.68

		P1 (kPa)	P2 (kPa)	P3 (kPa)	P4 (kPa)	P5 (kPa)
H1 (mm)	**r**	-0.02				
	p	0.90				
H2 (mm)	**r**		-0.22			
	p		0.13			
H3 (mm)	**r**			-0.11		
	p			0.45		
H4 (mm)	**r**				-0.22	
	p				0.12	
H5 (mm)	**r**					-0.14
	p					0.35

Parameters, TL, lateral talo-1st metatarsal angle (TMT) angle; C, calcaneal pitch angle; H5P, minimum height 5th metatarsal base; H1, height medial sesamoid; H2 - H5, height 2nd - 5th metatarsal heads; MC, midfoot contact area, MF, maximum force midfoot; MFLAT, maximum force midfoot lateral; FMAX, maximum force entire foot; P1 - P5, maximum pressure 1st to 5th metatarsal.

Angle measurement - differences between methods [17]

The angles differed between radiographs, CT and pedCAT (Multifactorial analysis). The difference of that multifactorial analysis as such is a fact but the difference does not show if one of the methods measures correct and which one. However, when considering technical issues it is obvious that only pedCAT is able to detect the correct angles because pedCAT obtains a 3D-dataset which is independent of foot position and projection under weight bearing conditions. Consequently, the significant different angles (Table 1) measured with radiographs or CT in comparison with pedCAT imply that radiographs or CT do not allow for correct angle measurement. The incorrect angles measured with radiographs are probably caused by inaccuracies of projection and foot orientation, and the incorrect angles measured with CT by missing weight bearing (see detailed discussion below). PedCAT includes weight bearing in contrast to CT. PedCAT countervails inaccuracies of projection and foot orientation in contrast to radiographs due to the 3D dataset which is principally independent from projection and foot orientation. If a malposition of the foot during image acquisition exists, the planes of the pedCAT- reformations (also CT) could be rotated as described above to ensure exact angle measurement despite foot malposition. We did not quantitatively assess the extent of plane rotation needed but the investigators´ interpretation was that the least extent of plane rotation was needed for dorsoplantar TMT and calcaneal pitch angles and more extent of plane rotation for the other angles. This reflects the results that radiographs were not different for calcaneal pitch angle and dorsoplantar TMT angles that are obviously less likely to be influenced by inaccurate foot position, and/or projection which is the key issue for radiographs. Inaccuracy of the projection, i.e. the central beam is obviously an underestimated problem for radiographic imaging. We were not able to isolate the factors inaccurate foot position or inaccurate projection. The resulting different angles in comparison with pedCAT reflect probably a combination of both inaccuracies.

1st - 2nd intermetatarsal angle

This angle was lower for radiographs (7.7) and CT (7.8) than for pedCAT (9.3). We believe that the different angles for radiographs in comparison with pedCAT reflect a combination of both factors inaccurate foot position or inaccurate projection of the radiographic image acquisition. A slight supination of the foot might cause this as well as the bilateral dorsoplantar imaging that is performed with a central beam in the middle between both feet and minimally oblique beams at both feet. For CT, the missing weight bearing will probably cause a true lower angle because CT is independent of foot position and projection as pedCAT.

TMT dorsoplantar

This angle was lower for radiographs (-6.2) and pedCAT (-5.0) than for CT (4.3). The higher or better less negative angles for CT than for radiographs and pedCAT are obviously caused by the missing weight bearing. For radiographs, inaccuracies of foot position and projection are either not relevant or might abrogate each other. We believe that these inaccuracies are more likely not relevant because the investigators´ interpretation was that the least plane rotation for measurement within the pedCAT data was needed for this angle (see above).

TMT lateral

This angle was higher for radiographs (-5.2) and much higher for CT (0.5) than for pedCAT (-7.6). The much higher of much less negative angles for CT than for radiographs and pedCAT are obviously caused by the missing weight bearing. For radiographs, a slight supination of the foot could possibly increase the angle or better decrease the negative value of this angle. More probable seems to be that the axis of the talus is "sticking out" of the plane of the 2D-radiograph based on the abduction of the mid- and forefoot in a flatfoot which is then positioned with the mid- and forefoot parallel to the film but the talus in slight internal rotation and not parallel to the film.

Hindfoot angle

This angle was lower for radiographs (2.4) and CT (5.4) than for pedCAT (10.1). Again, the higher angles for CT than for radiographs and pedCAT are obviously caused by the missing weight bearing. For, radiographs, the foot position with both feet parallel to each other and the longitudinal foot axes perpendicular to the film might be the most important reason for the lower angles. This position is typically not a Mortise view which would be more internal rotation of the ankle and foot. For pedCAT the plane for the measurement was virtually rotated within the 3D-dataset to achieve an exact congruency to the bone axis of the tibia and the axis of the hindfoot. This was typically the case when this plane was congruent with the axis of the ankle, i.e. a line between medial and lateral malleolus comparable to a Mortise orientation but within a 3D-space. This is virtually more internally rotated than in the radiograph group resulting in a higher angle at least for all hindfeet with valgus position which were the majority of the cases as shown by the positive values on average.

Calcaneal pitch angle

This angle was higher for radiographs (17.5) and pedCAT (17.8) than for CT (16.5). The lower angles for CT than for radiographs and pedCAT are probably caused by the missing weight bearing. For radiographs, inaccuracies of foot position and projection are either not relevant or might abrogate each other. We believe that these inaccuracies are more likely not relevant because the investigators´ interpretation was that the least plane rotation for measurement within the pedCAT data was needed for this angle (see above).

Angle measurement - intra- and interobserver reliability [17]

The intra- and interobserver reliability is sufficient for all three methods. This is probably based on the digital software based measurements, and the experience of all three investigators regarding these kind of digital measurements. Based on the sufficient intra- and interobserver reliability for all three methods, differences between the methods are not influenced by differences of intra- and interobserver reliability. In the future, an automatic software based angular measurement between bones in the 3D dataset will be implemented. This will allow for investigator independent analysis of these angles. The advantage of investigator independent definition of parameters have been shown for the pedography as described above [3].

Correlation of pedCAT parameters with pedography parameters

The correlation between angles / heights from the pedCAT data with force/pressure distribution from the pedography data not significant except for lateral talo - 1st metatarsal angle (TMT) angle versus midfoot contact area and maximum force entire foot, and minimum height 5th metatarsal base versus maximum force midfoot lateral. However, the correlation coefficient for these correlations was not sufficient with -0.32, -0.38 and -0.27. In conclusion, no sufficient correlation was found. When analysing all single cases in more detail, some typical association between bone position and pressure or force distribution were observed as for example shown in Figure 5. Still, these case limited parameters did not lead to statistical significant ($p < 0.05$) and sufficient ($r > 0.8$ or < -0.8) correlation. This finding is very surprising and disturbing. Everybody would expect, as we did before the study, that there must be a high correlation between bone position and force/pressure distribution. We did extensively a b

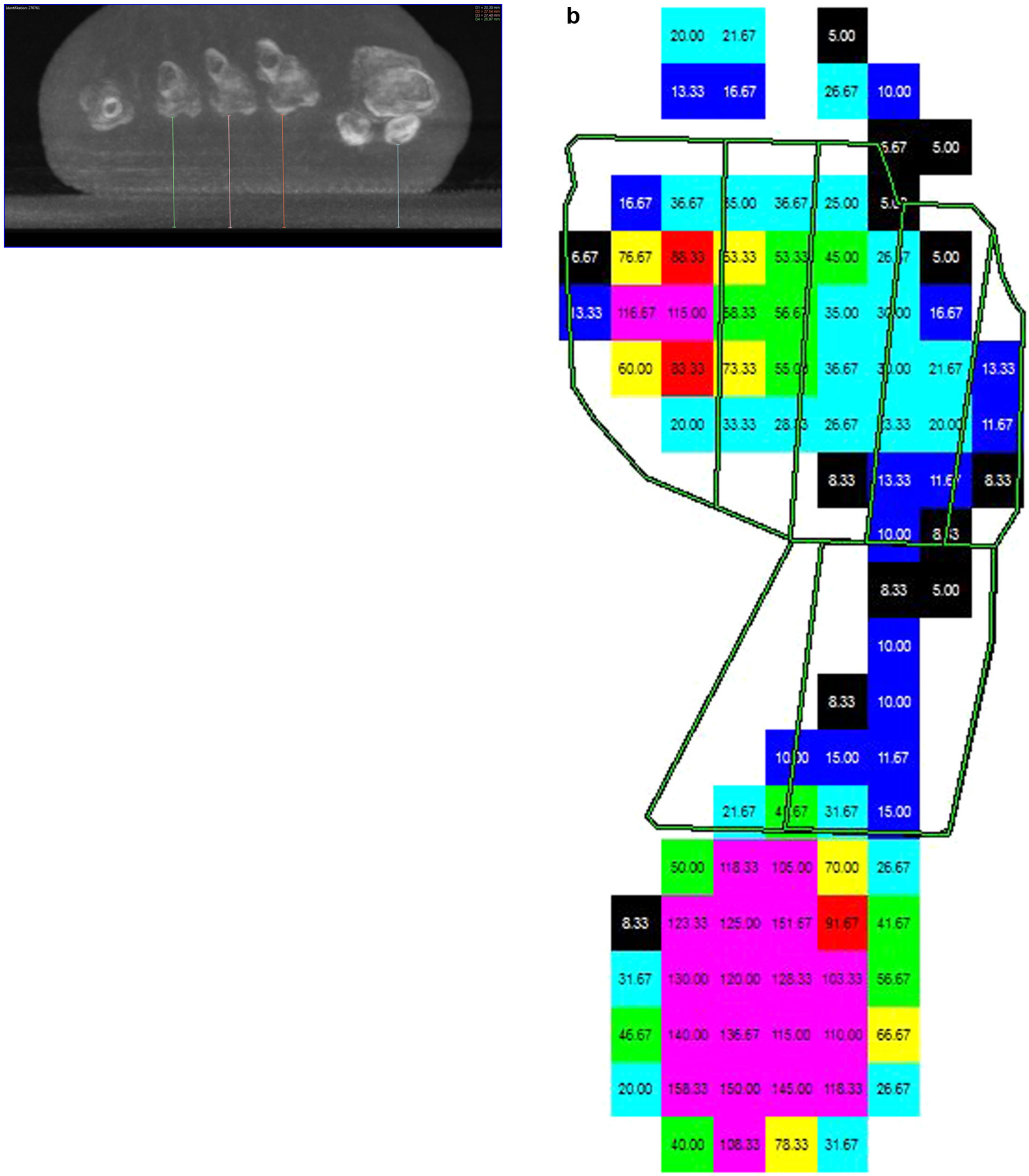

Figure 7. a and b. Correlation of pedCAT (Figure 7a, slice thickness increased for better visualisation) and pedography (Figure 7b). The height of the medial sesamoid was 20.3 mm (mean), and the height of the 2nd - 5th metatarsals was higher (2nd, 27.6 mm; 3rd, 27.4 mm; 4th, 27.0 mm; 5th, 26.4 mm, measurement not shown). The maximum pressures were 116.7 kPa for the first metatarsal, and lower for the 2nd - 5th metatarsals (2nd, 73.3 kPa; 3rd, 45.0 kPa; 4th, 30.0 kPa; 5th, 13.3 kPa). In conclusion, the lower first metatarsal / medial sesamoid resulted in higher pressure than the higher 2nd - 5th metatarsals.

discuss the reasons for the missing statistical correlation within our study group. We could not find a convincing explanation. We wondered if we possibly choose the wrong parameters. One could argue that parameters like lateral TMT angle or calcaneal pitch angle might not be appropriate. However, the height of the metatarsal heads, medial sesamoid, or proximal 5th metatarsal seem to be very comprehensive parameters to correlate with forces and pressures under these bony structures. We thought that different body weight might influence the results. So we also used individual multiplication factors to standardize all pedography parameters patients to a standard weight or better total force (data not shown). However, this did also not lead to any statistical sufficient correlation.

There is no comparison of our results with results from the literature possible because no such measurement has been performed and reported so far.

Shortcomings of the studies [17]

The shortcomings of this study are not the typical ones like missing analysis of intra- and/or interobserver reliability or missing power analysis of the statistical test. The low case number might be a shortcoming. We feel that a (much) higher case number would have led to significant differences of the dorsoplantar TMT and calcaneal pitch angles comparing radiographs with pedCAT. All other angles differed already which led to the conclusions, so a higher case number would probably not change the conclusions. The angular measurement as such could possibly be influenced by the investigators in that manner that the investigators would have desired that one method, for example the pedCAT, would perform better than the other methods. However, this kind of influence principally results in a low intra- and/or interobserver reliability which were sufficient for all three methods. We did not measure how difficult and time consuming the measurements was. The reason for this is that the type of software and version and above all the experience of the investigator might influence this time much more than the method as such. Another shortcoming might that we were not able to isolate the factors inaccurate foot or inaccurate projection of the radiographs group. The radiographic image acquisition followed a standardized protocol which was not further assessed [12]. Finally, the potential foot pathologies of the subjects were registered but not analysed. The pathological angles (not neutral or 0 for TMT dorsoplantar and lateral, hindfoot and calcaneal pith angle on average) imply that relevant pathologies were present which is also based on the inclusion criteria. However, we did not want to investigate different pathologies but the technical parameters of the different imaging methods.

With 50 patients, we "reached" very low correlation coefficients of less than 0.4 (or more than -0.4, respectively), which questions if any higher case number may lead to a sufficient correlation of > 0.8 or < -0.8. We did not measure how difficult and time consuming the pedCAT measurement was. The reason for this is that the type of software and version and above all the experience of the investigator might influence this time much more than the method as such. Finally, the potential foot pathologies of the subjects were registered but not analysed. The pathological angles (lateral TMT angle, -8.3°, calcaneal pitch angle, 18.1° on average) imply that relevant pathologies were present which is also based on the inclusion criteria. However, we did not want to investigate different pathologies but the correlation of pedCAT parameters with pedography parameters. Pedography to date is a dynamic method utilized for the detection and analysis of the entire stance phase during gait and not only for standing position, i.e. static pedography. We measured a static quality of the foot and we are aware that this is not directly related to the dynamic mechanics of the foot [17]. We did not design the introduced method to mimic a dynamic pedography [17]. It has been previously shown and was discussed above that a static pedography also allows conclusion about the biomechanics of the foot [6,7,17,19].

Radiation dose [17]

A comparison of the radiation dose of the pedCAT with radiographs and a standard CT-scan was not performed in our study. The applied energy (product of amperage, voltage and time) is typically adjusted and registered during a CT scan, radiographs or pedCAT. However, the dose as such depends on the structure of the scanned object and is not measured during the imaging. Recently, the dose of foot/ankle radiographs, CT and pedCAT was *measured* and analysed using a foot and ankle phantom [10]. The dose for adults for three radiographs from one foot (Anteroposterior/dorsoplantar + lateral + oblique) was 0.7 μSv, the dose for a bilateral pedCAT scan 4.3 μSv, and the dose for conventional CT of one foot/ankle 25 μSv [10]. The means that a bilateral pedCAT scan has a comparable dose as 18 unilateral radiographs of the foot, and 17% of an unilateral CT of the foot and ankle [10]. This study did also measure the dose of an unilateral pedCAT scan which was 1.4 μSv comparable to 6 unilateral radiographs of the foot, and 5.6% of an unilateral CT of the foot and ankle [10]. For the later clinical use this radiation dose is relativized because virtual radiography could be created from the pedCAT data as shown in Figure 8. We have created the following virtual radiographs from the pedCAT-scan data: entire foot dorsoplantar and lateral views, ankle dorsoplantar, Mortise and lateral views, Saltzman views, metatarsal head skyline views, Broden's views (all views bilateral) [17].

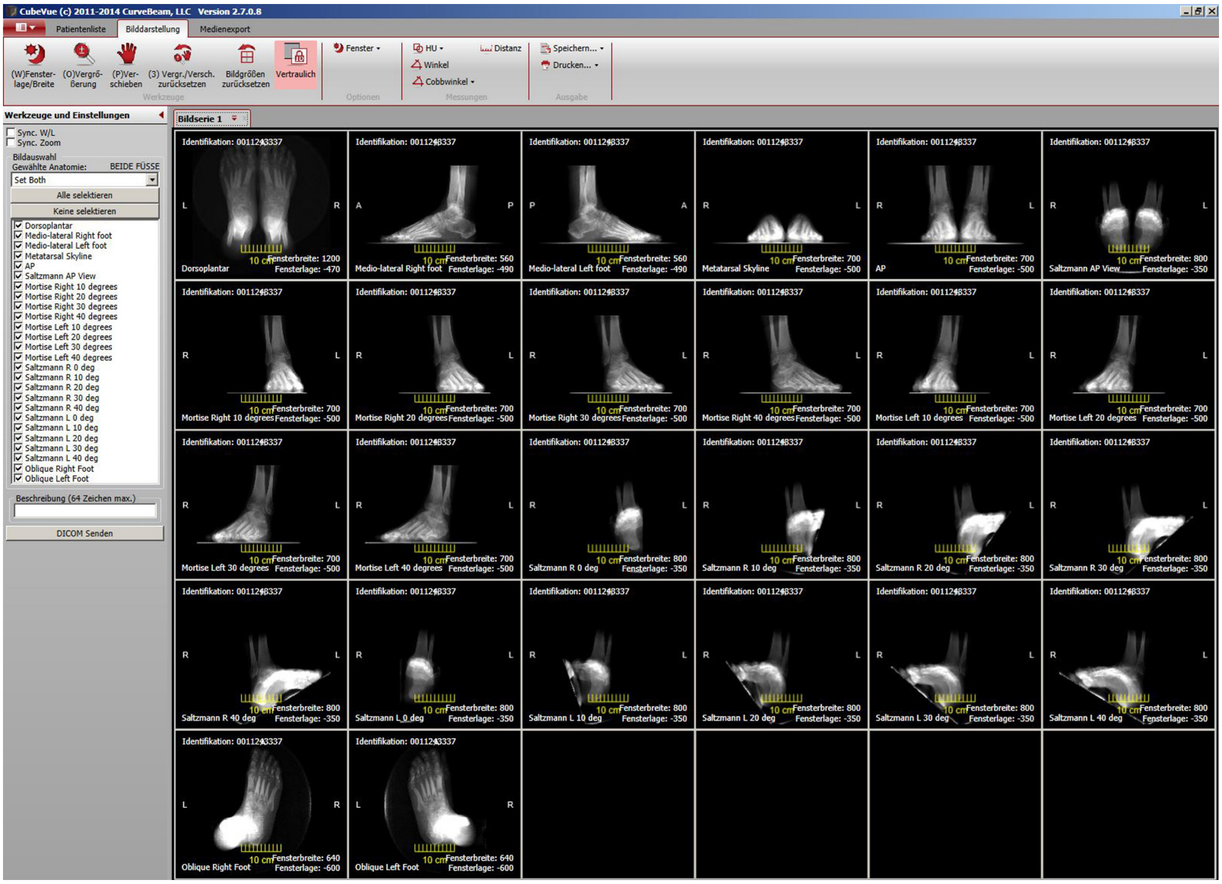

Figure 8. Generation of virtual standard radiographs from 3D-pedCAT-data. First row from left to right, feet bilateral dorsoplantar, right foot lateral, left foot lateral, metatarsal skyline view bilateral, ankle ap bilateral, Saltzman view bilateral. Second row from left to right, Mortise right 10° internal rotation, Mortise right 20° internal rotation, Mortise right 30° internal rotation, Mortise right 40° internal rotation, Mortise left 10° internal rotation, Mortise left 20° internal rotation. Third row from left to right, Mortise left 30° internal rotation, Mortise left 40° internal rotation, Saltzman right 0° internal rotation, Saltzman right 10° internal rotation, Saltzman right 20° internal rotation, Saltzman right 30° internal rotation. Fourth row from left to right, Saltzman right 40° internal rotation, Saltzman left 0° internal rotation, Saltzman left 10° internal rotation, Saltzman left 20° internal rotation, Saltzman left 30° internal rotation, Saltzman left 40° internal rotation. Fifth row from left to right, foot right oblique, foot left oblique. Other images can be defined as desired. The images can be automatically exported to the local PACS system.

Cost [17]

Another issue is cost as always. A device for radiography is around 75,000 Euro, a pedCAT is 150,000 Euro and a CT is starting at 200,000 Euro (all prices excluding VAT). However, devices for radiographs and CT can be used for other body regions also whereas the pedCAT can only be used for the foot and ankle region. The reimbursement is different for different countries and types of insurance. In the country in which this study has taken place the reimbursement for a pedCAT scan is comparable with a CT scan and 15 radiographs. Time spent is also a cost factor. In our study the time spent for the pedCAT scan was 70% faster than radiographs and 35% faster than a CT scan. Still, a pedCAT might be cost-effective for institutions with one foot and ankle surgeon but we think that group with two or more foot and ankle surgeons or foot and ankle departments might be able to run a pedCAT not only cost-effectively but with creating profit even when the quality of the imaging is not taking into consideration. It has been demonstrated in many U.S. institutions and private practices that a single foot & ankle surgeon can operate the pedCAT cost effectively and generate a sizable surplus. The same should apply to other parts of the world. This can also be established by comparing the pedCAT' s typical lease or finance cost (between 3,000 and 4,000 Euros per month depending on the lease terms) and reimbursement per scan (around 200 Euros). These example figures would permit a practice to justify the cost with 15 to 20 scans a month, which should be achievable even with a single surgeon.

This model has been well established for almost similar CBCT devices for dental/maxillofacial/ENT imaging, with hundreds of such devices installed with single practitioners in Germany and across Europe.

Approval for use [17]

Approval for imaging is specific for the pedCAT. Actually, most countries classify the device as a CT. However, a more common trend is to differentiate between conventional CT and Cone Beam CT, and apply exemptions for CBCT from typical CT requirements due to its specialized and limited applications, coupled with low dose and dramatically less complexity. This same model is very common and already established with CBCT devices for maxillofacial & ENT imaging.

In some countries like the one where the institution of authors is located, this device is not classified as a CT which allows non-radiologists to prosecute a pedCAT in their institution in contrast to CT which is mostly only approved for prosecution by radiologists. In conclusion, everybody who is approved to run his or her radiograph device will be allowed to run a pedCAT.

Standard imaging? [17]

When considering the potential of the pedCAT as faster image acquisition and more accurate bone position representation than radiographs and CT with acceptable radiation dose and cost-effectiveness, one could conclude the pedCAT might have the potential to become the standard diagnostic imaging in foot and ankle surgery. When a pedCAT is available as in our institution, CT which has no better image quality (resolution and contrast) but 10 times radiation dose, 1.5 times time spent for image acquisition, higher device cost, and radiologist needed is almost obsolete. Since September 2013, we limited the use of a conventional CT to patients with acute injury that are not able to stand or sit in the pedCAT. We compared the numbers of CT and pedCAT over a six month period in which both were available at our institution (September 2013 to February 2014) with a six month period in which only CT was available (September 2012 to February 2013). In the period with only CT, 148 CT scans were obtained, and in the period with both 16 CT scans and 135 pedCAT scans. This corresponds to a reduction of conventional CT scans of almost 90%. We have also started to generate all radiographs from the pedCAT data (Bilateral dorsoplantar, oblique, lateral views of the foot; bilateral ankle ap, and Saltzman and Mortise views in different rotations (0°, 10°, 20°, 30, and 40° internal rotation) (Fig. 8). The images could be automatically exported to the local PACS system. At the same time we stopped the acquisition of conventional radiographs when a pedCAT scan was obtained (Patient 18 years and older) which decreased the number of conventional radiographs by 95%.

The results of this study call into question if the existing standard angles of angles for pathology classification are also correct for the pedCAT. The answer is no and the reason is obvious because the pedCAT measures different angles as measured with radiographs. For example the 1st-2nd-intermetatarsal angles were 7.7° on average for radiographs and 9.3° on average for pedCAT with a difference of 1.6° (Table 1). What caused this difference? Again, we believe that the different angles in comparison with pedCAT reflect a combination of both factors inaccurate foot position or inaccurate projection of the radiographic image acquisition as discussed above in detail. What does this mean? Are we able to perform a distal osteotomy of the first metatarsal for hallux valgus correction in cases with 1st-2nd-intermetatarsal angle 17.6° measured with pedCAT comparing with 16° with radiographs? What about the significant differences of the hindfoot angles? When it comes to implantation of total ankle replacements and/or surgical corrections of the hindfoot, this might be important information. We cannot answer all questions at this stage but we believe that the standard angles and angles for classification of pathologies need to be defined specifically for pedCAT comparable technologies. Another important part of the discussion based on the results of this study is whether conventional radiographs could still serve as standard diagnostic imaging. The logical answer from a scientific point of view is no because the angles that are measured with conventional radiographs are not correct. Nevertheless, we believe that conventional devices for radiographs will not disappear for a long time and this will be the same with all the non-validated foot and ankle scores that are used again and again even though everybody knows that they are not validated, i.e. they are not correctly measuring. At the end conventional devices for radiographs might disappear as non-validated scores but nobody knows when validated scores and new imaging technologies like pedCAT might be used instead as already in our institution.

In conclusion, the bone position represented by the measured angles differed between radiographs, CT and pedCAT, indicating that only pedCAT is able to detect the correct angles. PedCAT includes weight bearing in contrast to CT. PedCAT prevents inaccurate angle measurement due to inaccuracies of projection and foot orientation in contrast to radiographs due to the 3D-dataset which is principally independent from projection and foot orientation. PedCAT or a similar technology has potential to become the standard diagnostic imaging. 3D bone position did not correlate with force and pressure distribution under the foot sole during simultaneous pedCAT scan and pedography. Consequently, the bone positions measured with pedCAT do not allow conclusions about the force and pressure distribution. Vice versa static pedography parameters do not allow conclusions about the 3D bone position. Further investigations with higher case number and more parameters should be carried out to further validate these surprising findings.

Conflict of interest

None of the authors or the authors´ institution received funding in relation to this study. The corresponding author is consultant of Stryker, Intercus, and Curvebeam, proprietor of R-Innovation, and joint proprietor of 1st Worldwide Orthopaedics.

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