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Intraoperative Pedography: A Validated Method for Static Intraoperative Biomechanical Assessment

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ABSTRACT

Background: **A new device was developed to perform intraoperative static pedography. The purpose of this study was to validate the introduced method by a comparison with the standard method for dynamic and static pedography.** ***Methods:*** **A device known as Kraftsimulator Intraoperative Pedographie® (KIOP®) was developed for intraoperative placement of standardized forces to the sole of the foot. Pedographic measurements were done with a custom-made mat that was inserted into the KIOP® (Pliance®, Novel Inc., St. Paul, MN, USA). Validation was done in two steps: (1) comparison of standard dynamic pedography walking on a platform, standard static pedography in standing on a platform, and pedography with KIOP® in supine position in 30 healthy volunteers, and (2) comparison of static pedography in standing position, pedography with KIOP® supine awake, and pedography with KIOP® supine with 30 patients under anesthesia. Individuals who had operative procedures at the knee or distal to the knee were excluded. The different measurements were compared (one-way ANOVA, t-test; significance level 0.05).** ***Results:*** **No significant differences were found among all measurements for the hindfoot compared to midfoot-forefoot force distribution. For the medial compared to lateral force distribution and the 10-region-mapping, significant differences were found when comparing all measurements (steps 1 and 2) and when comparing the measurements of step 1 only. No differences were found for these distributions when comparing the measurements of step 2 alone or when comparing the measurements of step 1 and 2 without the platform measurements of step 1 (dynamic walking pedography and static standing pedography). No significant differences in the force distributions were found in step 2 when comparing subjects without anesthesia, with general anesthesia, and with spinal anesthesia.** ***Conclusions:*** **The KIOP device allows a valid static intraoperative pedography measurement. No statistically significant force distribution differences were found between standing subjects and anesthetized subjects in the supine position.**

Key Words: Biomechanical Assessment; Intraoperative Pedography; Pedography; Validation

INTRODUCTION

For any kind of reduction or corrective procedures of the foot and ankle, an immediate biomechanical assessment after the reduction or correction would be desirable.[1,7,13,15,16,19,23–25,28,30] Analyzing the position of the bones radiographically allows conclusions regarding the biomechanics of the foot.[9,15,17,27,29,20] However, static and dynamic pedography is more effective for the analysis of the biomechanics of the foot.[4,5,21] Pedography for biomechanical assessment has been available only during clinical followup.[18] An intraoperative static pedography may be useful for immediate intraoperative biomechanical assessment.[18] A new device was developed to perform intraoperative pedography. The purpose of this study was to validate this method by a comparison with standard methods for dynamic and static pedography.

MATERIALS AND METHODS

KIOP® – Kraftsimulator Intra-operative Pedographie®

For intraoperative introduction of standardized forces to the sole of the foot, a device named Kraftsimulator Intraoperative Pedographie® (KIOP®, manufactured by the Workshop of the Hannover Medical School, Hannover, Germany; Registered Design No. 20 2004 007 755.8 by the German Patent Office, Munich, Germany & St. Paul, MN, USA) was developed (Figure 1). This device allows

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an introduction of force to the sole of the foot by applying force to the knee in the flexed position (Figure 2). The pedographic measurement is made with a custom-made mat with capacitive sensors (model Pliance®, Novel Inc., Munich, Germany, and St. Paul, MN, USA). The mat is connected to a standard IBM compatible laptop computer with the standard adaptor (model Pliance-X, Novel Inc., Munich, Germany, and St. Paul, MN, USA). Standard software was used for the measurements (model Pliance Expert®, version 10.2.20, Novel Inc., Munich, Germany, and St. Paul, MN, USA). The system allows real-time pedography and comparison to the contralateral side intraoperatively (Figure 3). The introduced total force and force distribution are displayed in real-time to control the amount and distribution of the force.

The total force in standing position of the tested volunteer determined the introduced total force with the KIOP® for the validation process. The aimed force distribution hindfoot:midfoot-forefoot was 60:40, the medial:lateral was 50:50 as described for a standing position.[5] The force distribution was controlled by positioning of the foot and tibia for the medial:lateral distribution and by flexion and extension of the knee and ankle for the force distribution hindfoot:midfoot-forefoot. A more flexed knee and more dorsally extended ankle resulted in a higher percentage of force at the midfoot-forefoot and a lower percentage of force at the hindfoot. A less flexed knee and less dorsally extended ankle resulted in a higher percentage of force at the hindfoot and a lower percentage of force at the midfoot-forefoot. The achieved distributions were analyzed during the validation process. The flexion-extension angles at the knee and ankle during the measurements were not registered.

Fig. 1: Kraftsimulator Intra-operative Pedographie® (KIOP®). The custom made mat for force registration is covered intraoperatively with a sterile plastic bag and is placed on the KIOP®. The size of the mat is 16 × 32 cm, and it contains 32 × 32 sensors with a sensor size of 0.5 × 1 cm.

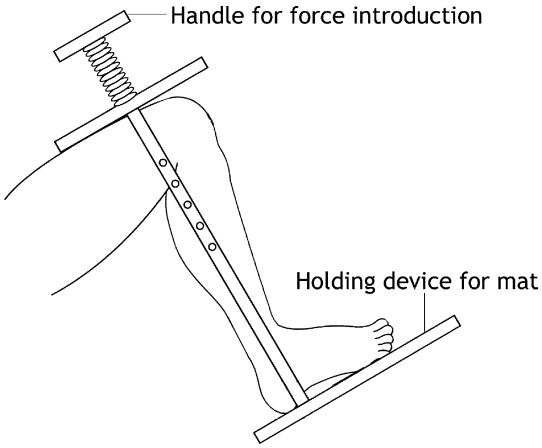

Fig. 2: Method for intraoperative pedography.

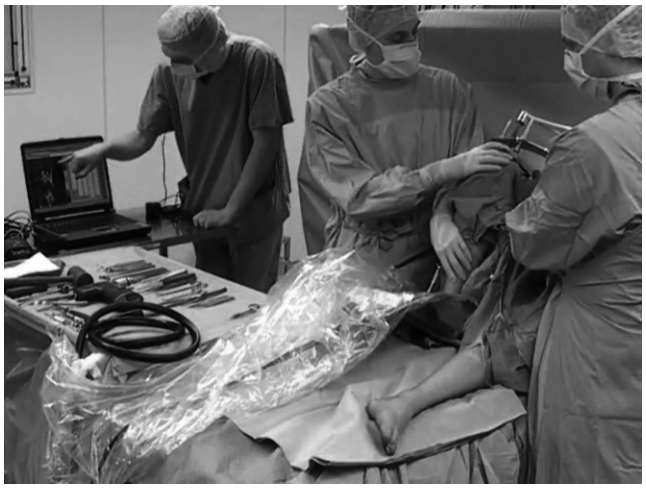

Fig. 3: Intraoperative pedography during a correction arthrodesis at the talonavicular joint (performed during a feasibility prestudy): 300 N, 400 N, and 500 N were applied with the KIOP®, The force measurements were displayed in real-time on the screen of the pedography-system. During intraoperative pedography, KIOP® is entirely sterile and the force measurement mat is covered by a sterile plastic bag.

Validation Process

To allow validation of the method, objectivity, and reliability of the method were first analyzed in detail as a basis for the validation process.

Objectivity

The objectivity of the technical system was analyzed and approved by an introduction of standardized forces to the mat with a standard calibration device (Trublu Calibration Device®, Novel Inc., Munich, Germany, St. Paul, MN, USA).[20] A statistical analysis of the differences of introduced forces and the measured forces showed no significant differences (Table 1).

Table 1: Analysis of objectivity and reliability

	Different Measurements										Mean	STD	t-test
Measurement No.	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**			
OBJECTIVITY													
Introduced force (N)	.50	1.00	3.00	5.00	6.00	8.00	10.00	15.00	20.00	25.00	9.350	8.23	
Measured force (N)	.51	1.00	3.06	5.02	6.07	8.20	9.96	14.99	19.90	24.80	9.350	8.17	
Standardized introduced force (N)	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	.00	
Standardized measured force (N)	1.020	1.000	1.020	1.004	1.010	1.025	.996	. 999	.995	.992	1.00613	.01188	.137
RELIABILITY													
Introduced force (N)	196.2	196.2	196.2	196.2	196.2	196.2	196.2	196.2	196.2	196.2	196.2	.00	
Measured force (N)	196	197	197	194	196	197	197	197	195	195	196.1	1.1005	.780

For the testing of objectivity, equal forces were introduced to each cm^2 of the mat and were measured at each cm^2 of the mat. For the testing of reliability, a weight of 20 kg (196.2N) was placed on different areas of the mat. The total force on the entire mat was measured. (Abbreviations: Mean, mean value; STD, standard deviation; t-test, p-value of one sample t-test, confidence interval 95%, test value was 1.00 for objectivity and 196.2 for reliability).

Reliability

The reliability of the technical system was analyzed and approved by a repeated introduction (10 times) of standardized forces to the mat with a standard calibration device.[20] A statistical analysis of the differences of the repeated measurements showed no significant differences (Table 1).

Validity

The validation was performed in two steps. A statistician determined the number of subjects for both steps necessary after a review of the study design and before starting the study by a power analysis. The calculated power of all used statistical tests for the determined sample size was greater than 0.8.

Step 1 included 30 healthy volunteers without past history of injury or surgery to either lower extremity (Table 2). A comparison was made between standard dynamic pedography (three trials walking, third step, mid-stance force pattern)[2,11] static in standing position (three trials), and pedography with KIOP® in supine position (three trials, total force determined by total force in standing position comparable to half the body weight) (Table 2, Figure 4). For dynamic pedography and pedography in standing position, a standard platform (Emed AT®, Novel Inc., Munich, Germany, and St. Paul, MN, USA) and software (model Emed ST®, version 12.3.18, Novel Inc., Munich, Germany, and St. Paul, MN, USA) were used. Both sides were measured. Step 2 included a comparison of 30 patients who were having surgery (above the hip) but who had no history of injury or surgery of the lower extremities below the knee (Table 2). Pedography in standing position and pedography with KIOP® in nonanesthetized and anesthetized volunteers (three trials, total force determined by total force in standing position comparable to half the body weight) were performed (Figure 5). For all measurements including the pedography in standing position the mat and standard mat software were used. Both sides were measured. Individuals with operative procedures at the knee or distal to the knee were excluded. Only those with general ($n = 17$) or spinal ($n = 13$) anesthesia were included. The anesthetized individuals were measured in the anesthesia room before entering the operating room. The mat was covered with a plastic bag as described above.

The purpose of the comparison of the three groups in step 1 was to find out if the introduced system with a mat-based measurement in the supine position is comparable to a platform measurement in a standing position or walking. The purpose of the comparison of the three groups in step 2 was to compare static pedography in the standing position with the introduced method in awake and anesthetized individuals in the supine position.

For both steps, a standard computerized mapping was done to create a distribution into the following foot regions:

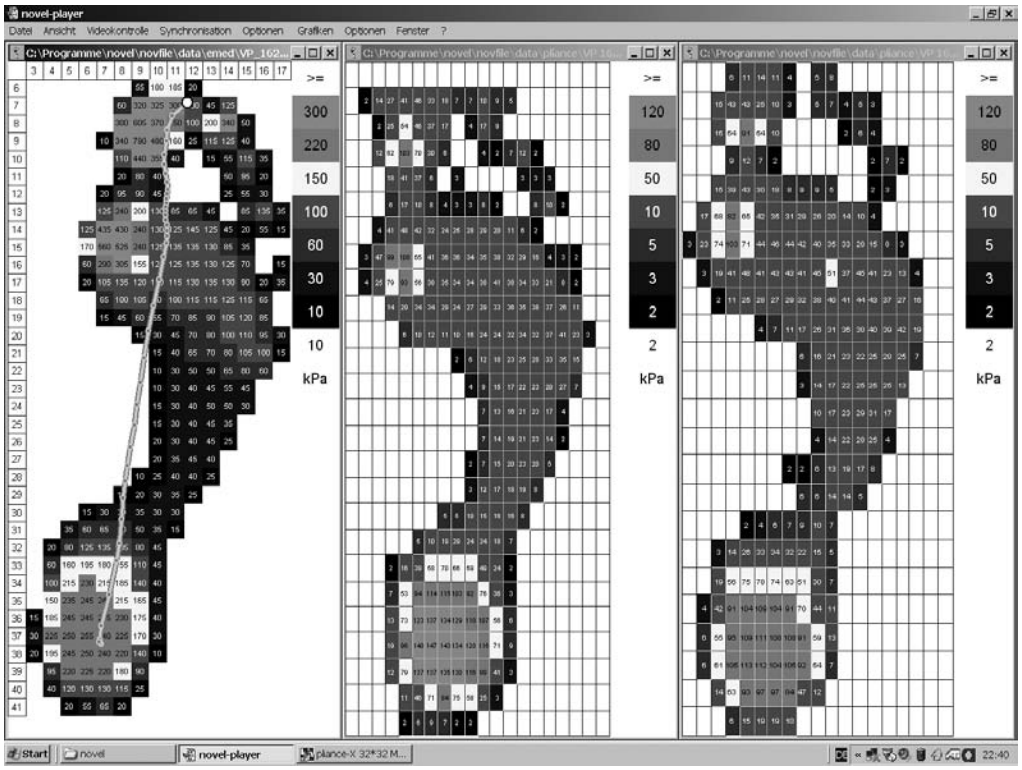

Fig. 4: Images from step 1 of the validation study (conscious individual): left, standard dynamic pedography; middle, static pedography in standing position; right, pedography with KIOP®. All three images show increased forces beneath the first metatarsal head and the first toe.

Table 2: Demographic data of subjects for steps 1 and 2. Mean values and standard deviations are shown

	Step 1	Step 2
Age (years)	26.1 ± 8.6	55.2 ± 15.6
Gender (male:female)	24 : 6	12 : 18
Weight (kg)	81.5 ± 12.0	80.6 ± 16.8
Height (m)	1.78 ± 0.07	1.73 ± 0.09
Body Mass Index	25.9 ± 3.4	26.9 ± 5.0
Shoe size (European)	43.0 ± 2.0	41.3 ± 2.5

hindfoot, midfoot, first metatarsal head, second metatarsal head, third metatarsal head, fourth metatarsal head, fifth metatarsal head, and first through fifth foes (Figure 6, Table 3). This mapping process did not include manual determination of landmarks. The outlines of the foot and the different regions were determined by the software using an algorithm.[6] This software algorithm is based on geometric characteristics of a maximal pressure picture using an individual sensing threshold. In our study this threshold was $1N/cm^2$ for the platform and $2N/cm^2$ for the mat. The lower threshold for the mat is based on the higher sensitivity of the mat sensors than the platform sensors. The percentages of the overall forces at the different regions were compared according to the different measurements (Table 3).

Statistical Analysis and Hypothesis Testing

Statistical analysis included oneway ANOVA with Post-Hoc-Scheffé-test and t-test. The following comparisons were made: comparison of the six different measurements of step 1 and 2, comparison of the four different measurements of step 1 and 2 involving the mat and not the platform, comparison of the three different measurements of step 1, comparison of the three different measurements of step 2 (Table 3).

The study was approved by the Ethical Commission of the Hannover Medical School, Hannover, Germany. Informed consent was obtained from all volunteers included in the study.

RESULTS

Table 3 indicates force distributions of step 1 and 2 and the results of the statistical analysis. No significant differences among the six measurements of step 1 and 2 were found for the hindfoot compared to the midfoot-forefoot force distribution. For the medial compared to the lateral force distribution and the 10-region-mapping, significant differences were found when comparing all measurements (steps 1 and 2), and when comparing the measurements of step 1 only. No differences were found for these distributions when comparing the three measures of isolated step 2 and when comparing the four measurements of steps 1 and 2 without the mat without platform measurements of

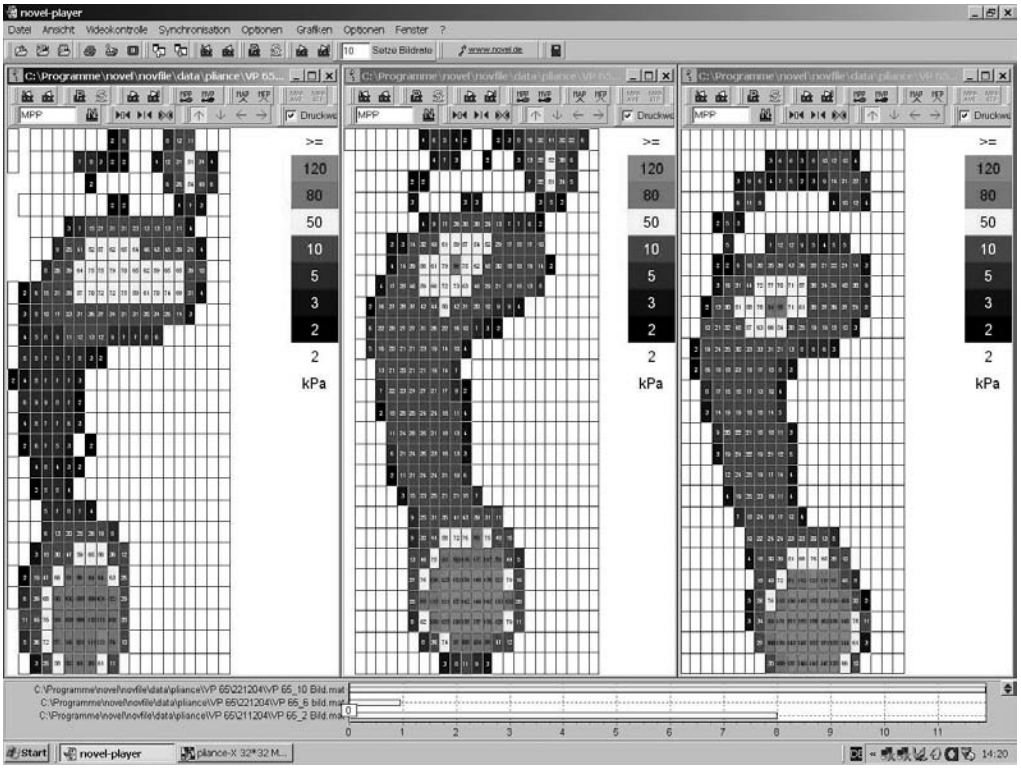

Fig. 5: Images from step 2 of the validation study in nonanesthetized and anesthetized individuals: left, pedography in standing position; middle, pedography with KIOP® in nonanesthetized subject; right, KIOP® in anesthetized subject. All three images show increased forces beneath the third and fourth metatarsals.

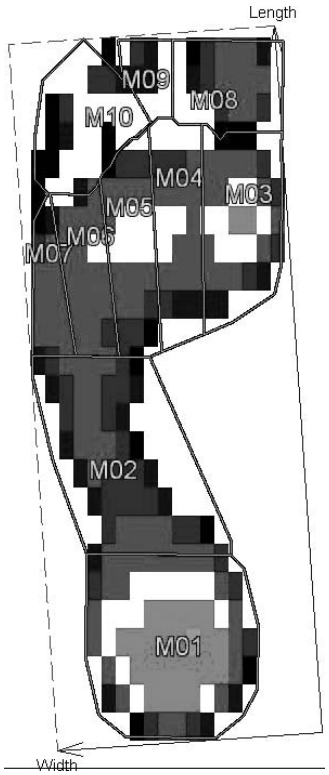

Fig. 6: Image from intraoperative pedography after computerized mapping. The following regions are defined by the mapping process: M1, hindfoot; M2, midfoot; M3, first metatarsal head; M4, second metatarsal head; M5, third metatarsal head; M6, fourth metatarsal head; M7, fifth metatarsal head; M8, first toe; M9, second toe; M10, third through fifth toe.

step 1 (dynamic walking pedography and static standing pedography) (Table 3).

No significant differences in the force distributions were found in step 2 when comparing subjects with general anesthesia to subjects with spinal anesthesia (data not shown; t-test, $p > 0.05$).

DISCUSSION

Pedography is, by definition, a measurement of the force distribution under the sole of the foot and can be done in a static and dynamic way.[10,11] The objective documentation of foot function before and after therapeutic intervention is greatly enhanced by the use of devices capable of measuring dynamic foot force distribution.[2] Efforts to develop this technology date back to the late 19th century, but only with recent advances in computers has it been possible to produce quantitatively accurate high resolutions of foot force distribution with high sampling rates and easily interpreted graphic displays.[2] Over the years, a variety of methods have been used to study foot pressure.[2,3,6] Many of these techniques have already improved our understanding of the foot and its function and have had an impact on the way we practice.[2,4,22]

This investigation was driven by the idea of applying the advantages of pedography-based functional analysis not only preoperatively and postoperatively but also intraoperatively.[18] The main idea was to use the data from an intraoperative pedography to detect nonoptimal biomechanical conditions and to have the opportunity for immediate changes in the correction or reduction in the same procedure, which may improve biomechanical function postoperatively.

The main problem in the design of a system for intraoperative pedography was an adequate introduction of force to the sole of the foot in an anesthetized individual in the supine position. This introduced force needed to be as similar as possible to static pedography in the standing position or, even better, to dynamic pedography during the stance phase of walking. For that purpose, the described device was developed. Measurements were made in near-neutral ankle position, because the influence of the missing muscle activity in an anesthetized individual was considered to be minimal, because electromyographic studies in conscious standing subjects with a comparable ankle position have been demonstrated to be silent.[8,12,26] Our main concern was that there were significant differences in the force distribution patterns between standard pedography and intraoperative pedography. Therefore, statistical analysis was designed to detect differences between the different pedography methods.

Two steps for the validation of the method were planned. Before these steps were taken, the technical objectivity and reliability of the introduced system were approved. In the first step, standard dynamic pedography during the stance phase of walking and a static pedography were both performed with standard platform for dynamic pedography and compared to pedography in supine position with the KIOP® and the mat. This step was done in a gait laboratory on healthy volunteers. The intention of this trial was to find out whether the KIOP® was able to simulate dynamic or static pedography in conscious subjects. We were aware that dynamic pedography force distribution patterns are not comparable to static pedography, neither standing nor supine, because pedography is not a dynamic measurement by definition.[10,11] Pedography should be performed static and dynamic if possible. However, the static measurement alone is also useful if the dynamic measurement is impossible.[2,3,6] We believed that a comparison of the maximal forces of the entire stance phase in dynamic pedography to the static measurements might lead to a better understanding of the mechanisms during the validation process. The second step was performed on patients without a history of injury or surgery of the lower extremities below the knees who were having orthopaedic operations on the hips or on a higher level, including upper extremities. For this step, only the mat was used for the measurements. Static pedographic measurements in conscious individuals in standing and supine positions and measurements in anesthetized patients were made and compared.

Table 3: Percentages from total force for different foot regions for steps 1 and 2

	Step1 (n = 30 subjects, n = 60 feet)			**Step 2 (n = 30 subjects, n = 60 feet)**			**ONEWAY ANOVA (p-values shown)**
	Dynamic (walking, platform)	**Static (standing, platform)**	**KIOP® (cons-cious)**	**Static (standing, mat)**	**KIOP® (cons-cious)**	**KIOP® (anaesthe-tized)**	**1st *p*-value, step 1 & 2; 2nd *p*-value, step 1 & 2 involving mat without platform; 3rd *p*-value, three measurements of step 1 only; 4th *p*-value, three measurements of step 2 only**
Percentages from total force							
Hindfoot versus midfoot							
Hindfoot	61.78 ± 8.3	59.81 ± 8.3	60.95 ± 4.8	62, 79 ± 8.8	60.28 ± 6.1	62.31 ± 6.4	**0.184; 0.156; 0.331; 0.144**
Midfoot/forefoot	38.22 ± 8.3	40.19 ± 8.3	39.05 ± 4.8	37.21 ± 8.8	39.72 ± 6.1	37.68 ± 6.4	**0.184; 0.156; 0.331; 0.144**
Medial versus lateral							
Medial	57.01 ± 7.2	56.48 ± 9.6	50.82 ± 7.0	49.60 ± 8.4	49.73 ± 6.3	50.40 ± 6.5	<0.05; **0.765**; <0.05; **0.819**
Lateral	43.99 ± 7.2	43.52 ± 9.6	49.18 ± 7.0	50.40 ± 8.4	50.27 ± 6.3	49.60 ± 6.5	<0.05; **0.765**; <0.05; **0.819**
10-region-mapping							
Hindfoot	61.73 ± 8.3	57.87 ± 7.3	56.08 ± 6.4	57.2 ± 11.1	52.66 ± 9.0	54.5 ± 10.4	<0.05; **0.550**; <0.05; **0.053**
Midfoot	4.68 ± 2.6	9.58 ± 5.8	7.96 ± 5.9	9.59 ± 5.5	12.09 ± 6.3	8.48 ± 5.7	<0.05; **0.061**; <0.05; **0.063**
1st metatarsal head	6.51 ± 2.7	5.71 ± 2.7	9.36 ± 3.3	6.33 ± 2.9	6.75 ± 3.3	8.28 ± 3.6	<0.05; **0.068**; <0.05; **0.124**
2nd metatarsal head	6.31 ± 2.2	6.03 ± 2.4	7.20 ± 1.9	6.94 ± 2.9	7.15 ± 2.1	8.39 ± 2.5	<0.05; **0.075**; <0.05; **0.087**
3rd metatarsal head	6.87 ± 2.2	6.83 ± 2.3	7.55 ± 1.9	7.99 ± 2.9	8.32 ± 2.0	8.60 ± 2.8	<0.05; **0.097; 0.120; 0.387**

(*Continued*)

Table 3: (*Continued*)

	Step1 (n = 30 subjects, n = 60 feet)			Step 2 (n = 30 subjects, n = 60 feet)			ONEWAY ANOVA (p-values shown)
	Dynamic (walking, platform)	**Static (standing, platform)**	**KIOP® (conscious)**	**Static (standing, mat)**	**KIOP® (conscious)**	**KIOP® (anaesthetized)**	**1st *p*-value, step 1 & 2; 2nd *p*-value, step 1 & 2 involving mat without platform; 3rd *p*-value, three measurements of step 1 only; 4th *p*-value, three measurements of step 2 only**
Percentages from total force							
4th metatarsal head	4.3 ± 1.4	5.41 ± 1.7	5.14 ± 1.4	6.24 ± 2.2	6.53 ± 2.0	6.06 ± 2.5	<0.05; **0.072**; <0.05; **0.567**
5th metatarsal head	2.12 ± 0.7	3.07 ± 1.2	2.31 ± 0.9	2.92 ± 1.6	3.06 ± 1.5	2.75 ± 1.5	<0.05; **0.143**; <0.05; **0.556**
1st toe	5.55 ± 2.4	1.81 ± 1.9	3.26 ± 2.9	1.60 ± 2.0	1.77 ± 1.6	1.78 ± 1.4	<0.05; **0.219**; <0.05; **0.775**
2nd toe	0.92 ± 0.4	0.54 ± 1.6	0.46 ± 0.4	0.33 ± 0.3	0.52 ± 0.4	0.42 ± 0.4	<0.05; **0.081; 0.220; 0.067**
3rd-5th toe	1.01 ± 0.8	3.14 ± 5.4	0.68 ± 0.6	0.87 ± 1.0	1.16 ± 1.4	0.74 ± 0.7	<0.05; **0.157**; <0.05; **0.117**

Mean values (from three measurements of each method for both sides in 30 subjects) and standard deviation are shown. For dynamic pedography and pedography in standing position of step 1, a standard were used. For pedography in standing position of step 2, and all measurements with KIOP® a mat and standard mat software were used. The following comparisons were performed: comparison of the six different measurements of steps 1 and 2 (first *p*-value); comparison of the four different measurements of steps 1 and 2 involving the mat and not the platform (second *p*-value); comparison of the three different measurements of step 1 (third *p*-value); comparison of the three different measurements of step 2 (fourth *p*-value).

The analysis was focused on the force distribution and not on the force values. To allow a validation of the method, objectivity and reliability of the method were analyzed in detail as a basis for the validation process. An analysis of the intraobserver reliability and the interobserver objectivity during the validation process was not done, because the evaluation process was not observer- or investigator-independent. The differences of the force distribution among the different methods were analyzed by the software without the interaction of observers or investigators. During this analysis, the mapping of the pedographic force patterns into different regions was done by software, as well as the calculation of the percentages from the total force in the single regions. The mapping process has been demonstrated to allow a better standardized analysis of force patterns than an observer based subjective analysis.[14] The initial force distribution was adjusted by an investigator (see methods). The aimed force distributions were hindfoot:midfoot-forefoot 60:40, and medial:lateral 50:50, as described for a standing position.[5,11] This adjustment by an investigator is comparable to the adjustment of the force distribution of a standing subject trying to stand on a platform or mat.[11] The distribution of 8 of 10 regions (all regions except hindfoot and midfoot) in the 10-region-mapping was not directly influenced by the described adjustment of the foot.

Because we measured a static quality of the foot, this is not directly related to the dynamic mechanics of the foot, but we do not consider this a methodological weakness, because the purpose of the study was to compare KIOP® measurements to standard methods for dynamic and static pedography. KIOP® was not designed to mimic dynamic pedography. Static pedography has been shown to allow conclusions about the biomechanics of the foot.[10,11]

Our main concern was that the force induction with KIOP® to the sole of the foot was insufficient. We also considered the supine position and the anesthesia as important causes for an nonphysiological pedographic force distribution pattern. To minimize the influence of the missing muscle activity, we measured with the ankle in near neutral position because electromyography in conscious, standing individuals with comparable ankle positions has been demonstrated to be silent.[8,12,28] Still, we could not eliminate the other potentially disturbing factors. Therefore, the statistical analysis was designed to detect potential differences between standard pedography and KIOP® that were affected by these factors.

Because only individuals without known foot pathologies were included in the validation process, it could be argued that this validation is sufficient only for "healthy" feet. However, we also detected nonphysiological force distribution patterns in the volunteers, as shown in Figure 5. Consequently, we consider the KIOP® to be comparable to standard pedography for detection of pathologies.

Finally, we did not really measure intraoperatively but in the anesthesia room before the subjects entered the operating room. However, the setting for the validation process was comparable to intraoperative pedography because the same devices, including the plastic bag covering the mat, were used.

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