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Biofeedback in Partial Weight Bearing: Validity of 3 Different Devices

Restrictions of lower-limb weight bearing (WB) are frequently prescribed to patients after orthopaedic trauma or surgery, such as lower-limb fractures or osteotomy.¹² Weight bearing is often restricted, based on the fear that too much load can lead to failure of fixation devices, delayed fracture healing, and nonunion of bone fragments.^{5,17,18} Conversely, the rationale for gradually advancing WB is that repetitive loads can stimulate osteoblast activity in fracture patterns and fixation constructs.^{12,17,18} Consequently, the difficulty in rehabilitation

of patients with an affected lower limb is the dual desire to protect the fracture or fixation construct by limiting WB and simultaneously stimulate bone growth by increasing WB. Therefore, it is commonly recommended that WB restrictions be gradually reduced as healing occurs.^{6,12}

Usually, physical therapists train patients to comply with prescribed WB instructions using verbal instructions, tactile feedback, or bathroom scales.^{10,12} However, these methods do not represent dynamic activities, such as walking, and are not accurate in training patients to comply with partial-WB instructions.^{3,6,7,10,25} Feedback during dynamic activities is important, as earlier research has shown that it is difficult for patients to comply with WB instructions.^{3,6,9,11-13,24,25} Reasons for noncompliance with partial-WB instructions include the difficulty in judging load placed on the lower extremities and the lack of adequate training methods or biofeedback systems.^{3,9,12,24}

Technological advances have resulted in the development of several commercially available biofeedback devices that are fully portable and capable of monitoring and offering real-time feedback on partial WB in dynamic situations.^{6,9,10,12} The OpenGo *science* (Moticon GmbH, Munich, Germany), SmartStep (Andan-

● **STUDY DESIGN:** Controlled laboratory study to assess criterion-related validity, with a cross-sectional within-subject design.

● **BACKGROUND:** Patients with orthopaedic conditions have difficulties complying with partial weight-bearing instructions. Technological advances have resulted in biofeedback devices that offer real-time feedback. However, the accuracy of these devices is mostly unknown. Inaccurate feedback can result in incorrect lower-limb loading and may lead to delayed healing.

● **OBJECTIVES:** To investigate validity of peak force measurements obtained using 3 different biofeedback devices under varying levels of partial weight-bearing categories.

● **METHODS:** Validity of 3 biofeedback devices (OpenGo *science*, SmartStep, and SensiStep) was assessed. Healthy participants were instructed to walk at a self-selected speed with crutches under 3 different weight-bearing conditions, categorized as a percentage range of body weight: 1% to 20%, greater than 20% to 50%, and greater than 50% to 75%. Peak force data from the biofeedback

devices were compared with the peak vertical ground reaction force measured with a force plate. Criterion validity was estimated using simple and regression-based Bland-Altman 95% limits of agreement and weighted kappas.

● **RESULTS:** Fifty-five healthy adults (58% male) participated. Agreement with the gold standard was substantial for the SmartStep, moderate for OpenGo *science*, and slight for SensiStep (weighted $\kappa = 0.76, 0.58, \text{ and } 0.19$, respectively). For the 1% to 20% and greater than 20% to 50% weight-bearing categories, both the OpenGo *science* and SmartStep had acceptable limits of agreement. For the weight-bearing category greater than 50% to 75%, none of the devices had acceptable agreement.

● **CONCLUSION:** The OpenGo *science* and SmartStep provided valid feedback in the lower weight-bearing categories, and the SensiStep showed poor validity of feedback in all weight-bearing categories. *J Orthop Sports Phys Ther* 2016;46(11):993-1001. doi:10.2519/jospt.2016.6625

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te Medical Devices, Ltd, Omer, Israel), and SensiStep (Evalan BV, Amsterdam, the Netherlands) are examples of such biofeedback devices. The OpenGo *science* and SensiStep have recently been developed, and SmartStep has been on the market for over 10 years. These devices differ in the technology used to measure WB, but they all intend to enable physical therapists to assess, train, and monitor patients' WB, and they intend to provide patients with feedback during daily activities.

Although OpenGo *science*, SmartStep, and SensiStep seem like promising devices to improve training and compliance with WB instructions, to date, it is unknown how accurate these biofeedback devices are in providing feedback on partial WB. Inaccurate feedback can result in incorrect lower-limb loading and may lead to complications or delayed healing. For deciding which biofeedback devices could be useful in research or clinical practice, it is important to know the level of agreement between the peak force measurements under the foot of the biofeedback devices and a force plate (used as gold standard). Although instruments should normally be validated in the target population (ie, patients with orthopaedic conditions who have been prescribed with restricted WB), in this study, this was considered undesirable, because not knowing the accuracy could unnecessarily expose patients to health risks. The aim of this study was to investigate criterion validity of peak force measurements obtained using 3 different commercial biofeedback devices under varying levels of partial-WB categories.

METHODS

Design and Study Setting

THE CRITERION VALIDITY OF PEAK force measurements under the foot of 3 biofeedback devices (SmartStep, OpenGo *science*, and SensiStep) was investigated by comparing them with the peak vertical ground reaction

force under the foot measured with an embedded AMTI force plate (model OR6-7; Advanced Mechanical Technology, Inc, Watertown, MA), used as a gold standard, in a cross-sectional within-subject design. Measurements took place at the Movement Analysis and Rehabilitation Technology Laboratory of Fontys University of Applied Sciences-Eindhoven (Eindhoven, the Netherlands).

Participants

As recommended by the COSMIN initiative, the minimum sample size in studies investigating criterion validity is at least 50 participants.²³ A convenience sample of healthy adults was recruited at Fontys University of Applied Sciences-Eindhoven. Inclusion criteria were overall good health, age of 18 to 70 years, and shoe size between 36 and 46 on the Continental European system. Excluded were persons with balance disorders, with current injuries or pathologies of the lower extremities that interfered with normal gait performance, diagnosis by a doctor or podiatrist of foot deformities (eg, flatfoot), a foot orthosis prescription (in the past or at the time), use of walking aids, and, finally, being unable to use forearm crutches because of a pathology.

Biofeedback Devices

The OpenGo *science* consists of wireless sensor insoles for data measurement, analysis software for a personal computer, a radio stick for wireless transmission, and a WB application for a smartphone. Each insole has 13 pressure sensors that cover 60% of the insole area, a triaxial acceleration sensor, and a temperature sensor. The WB application for the smartphone is used to preset an upper threshold for WB and to provide real-time audio or haptic feedback.

The SmartStep consists of flexible insoles containing 2 separate air pockets (one for the forefoot and one for the hindfoot). Tubes are used to inflate/deflate each pocket and to connect the

pockets to a wireless microprocessor control unit, which is worn around the ankle. The microprocessor control unit contains 2 pressure sensors and also functions as a feedback unit by producing an audio signal when a preset WB value is reached. A software application on a personal computer is used to preset upper and lower WB thresholds.

The SensiStep consists of an insole force sensor placed in the heel of a sandal and a feedback unit that collects and stores data from the sensor and provides feedback through light and audio signals. The feedback unit can be worn on the wrist or belt. A software application for a tablet is used to preset upper and lower WB thresholds. The characteristics of the 3 biofeedback devices are presented in **TABLE 1**.

Measurement Procedure

Participant characteristics (eg, age, sex, body length, shoe size) were collected and proper-size insoles (OpenGo *science* and SmartStep) or sandals (SensiStep) were fitted to their right and left feet. Participants wore their own athletic shoes when insoles were used. Each measurement day started with a calibration of the AMTI OR6-7 force plate. Before WB measurements started, the participant's body weight (BW) was measured in Newtons by the force plate. Biofeedback devices were calibrated in accordance with the procedures recommended by the manufacturer. For the OpenGo *science*, the insoles were placed in the athletic shoes at least 10 minutes before WB measurement started. This temperature acclimatization period was necessary to optimize calibration. Because of the longer preparation time for the OpenGo *science*, a fixed testing order was chosen: OpenGo *science*, SmartStep, SensiStep. Testing order effects were not expected, because the WB trials were controlled by the force plate (so WB performances were according to the instructed WB conditions). First, participants were instructed to walk with 2 forearm crutches in 3-point gait

TABLE 1

CHARACTERISTICS OF THE 3 BIOFEEDBACK DEVICES

Characteristic	OpenGo science	SmartStep	SensiStep
Sensor type	Capacitive pressure sensor	Silicon pressure sensor	Force sensor
Number of sensors	13	2	1
Load range per sensor	0-40 N/cm ²	0-25 N/cm ²	0-150 kg
Feedback type	Audio or haptic	Audio	Lights and audio (optional)
Connectivity sensor to FB unit	Wireless to smartphone	NA*	Wireless to FB unit
Sampling frequency, Hz	5-50 [†]	40	50
Data transfer	Wireless or cable to PC	Wireless to PC	Wireless to tablet and cloud
Data storage time	5-48 h [‡]	10 min	Several days

Abbreviations: FB, feedback; NA, not applicable; PC, personal computer.
**Both sensors and FB unit are integrated into the control unit.*
[†]Maximum sampling frequency with all 13 pressure sensors operating.
[‡]Data storage time depends on the chosen sampling frequency.

at a self-selected speed under 3 different partial-WB conditions, expressed in percentage ranges of BW: (1) 1% to 20%, (2) greater than 20% to 50%, (3) greater than 50% to 75%. During practice trials, one of the researchers provided the participants with verbal feedback on WB by using the force-plate data. Peak force recording started when participants were able to walk 2 successive practice trials in agreement with the selected WB condition. The testing order of the different WB conditions was the same for each participant and biofeedback device: (1) 1% to 20% BW, (2) greater than 20% to 50% BW, (3) greater than 50% to 75% BW. This order is in line with the clinical setting in which patients are first trained in lower-WB conditions, and WB restrictions are gradually reduced as healing occurs.

A 2-step protocol was used: each participant was positioned in front of the force plate so that the right foot (second right footstep) landed on the force plate. Peak force data of a single right footstep were recorded using both the biofeedback device and the force plate simultaneously. A measurement was valid if only the right foot landed on the force plate and the amount of WB measured by the force plate was in agreement with the selected WB condition. A single valid measurement was obtained for each WB condition and

biofeedback device. The force-plate data were recorded using a sampling frequency of 1000 Hz. For each biofeedback device, the maximum sampling rate was selected. The sampling frequencies for the SmartStep, OpenGo science, and SensiStep were 40 Hz, 50 Hz, and 50 Hz, respectively.

Data Analysis

Descriptive statistics were used to describe the research population. The difference in percentage of BW between the measurement of each biofeedback device and that of the force plate was calculated. Criterion validity of agreement per WB category was estimated using Bland-Altman 95% limits of agreement (basic method).² Agreement was considered acceptable if the lower limit of agreement did not exceed the range of the instructed WB category, so the biofeedback device could be preset on a safe percentage of BW (to prevent overload) within the instructed WB category. To give insight in the trend in agreement across the range of WB categories per biofeedback device, a regression-based limits-of-agreement method² using linear mixed-model analyses was used to correct for dependency of observations within subjects (each participant underwent 3 measurements). In case of a non-linear relationship, a squared term of the mean of the 2 measurements was added

to the regression of difference on average, resulting in curved 95% limits of agreement.¹ To evaluate agreement of classification within instructed WB categories between the biofeedback devices and the force plate, weighted Cohen kappas were calculated over 3 categories (1% to 20%, greater than 20% to 50%, greater than 50% to 75%). Kappa values were interpreted according to the classifications of Landis and Koch¹⁶: 0.00 or less, poor; 0.01 to 0.20, slight; 0.21 to 0.40, fair; 0.41 to 0.60, moderate; 0.61 to 0.80, substantial; and 0.81 to 1.00, almost perfect. When missing data remained below 5%, no further actions were taken and available data were analyzed.

Ethics

The Medical Ethics Research Committee of the University Medical Center Utrecht (the Netherlands) approved the study. The study was conducted according to the principles of the Declaration of Helsinki (version: 64th World Medical Association General Assembly, Brazil, October 2013) and is in accordance with the Personal Data Protection Act. Written informed consent was obtained from all participants. The study was funded by the Scientific College of Physiotherapy of the Royal Dutch Society for Physical Therapy, but that organization did not play a role in the investigation.

RESULTS

Participant Characteristics

FIFTY-FIVE HEALTHY ADULTS (58% male) aged 18 to 70 years participated in the study. The percentage of missing data was 4% or less. Characteristics of the study population are presented in **TABLE 2**.

Agreement of Classification in WB Categories

All biofeedback systems show decreas-

ing agreement by increasing WB categories. The agreement of classification in WB categories between the OpenGo *science*, SmartStep, and SensiStep and the force plate was, respectively, moderate, substantial, and slight (see **TABLE 3**). The absolute agreement between the biofeedback devices and force plate varied between 78.7% and 10.4%.

Mean Difference and 95% Limits of Agreement

TABLE 4 shows the mean difference and

the lower and upper limits of agreement between the biofeedback devices and the force plate per WB category. For the purpose of giving feedback using predefined ranges of WB, **TABLE 4** shows an acceptable agreement in the first 2 successive WB categories (0% to 20% and greater than 20% to 50%) for the SmartStep and OpenGo *science*. For the WB category greater than 50% to 75% BW, the lower limit of agreement exceeded the range of the instructed WB category in the SmartStep and OpenGo *science*. The SensiStep device showed no acceptable agreement in all WB categories. Additionally, in the WB category 1% to 20% BW, the SensiStep measured no force at all in 91% of the participants, and the other WB categories show a large underestimation of peak forces. The estimated trend of the mean differences and the regression-based limits of agreement per biofeedback device are shown in **FIGURES 1** through **3**. The SmartStep and OpenGo *science* showed a relatively horizontal trend line for the mean differences, although the systematic bias increased slightly to moderately in successive WB categories. The SensiStep showed a large systematic bias (underestimation), which increased in successive WB categories.

DISCUSSION

FOR THE PURPOSE OF GIVING FEEDBACK using predefined ranges of WB, the results showed acceptable criterion validity for the OpenGo *science* and

TABLE 2		CHARACTERISTICS OF THE STUDY POPULATION*	
Characteristic	Value		
Sex (male), n (%)	32 (58)		
Age, y	32.3 ± 15.6		
Body height, cm	175.7 ± 8.4		
Body weight, kg	76.0 ± 11.2		
Shoe size [†]	42.0 (38-46)		

*Values are mean ± SD unless otherwise indicated.
[†]Shoe size was measured in the units of the Continental European system. Values are median (range).

TABLE 3			AGREEMENT OF CLASSIFICATION IN WEIGHT-BEARING CATEGORIES BETWEEN THE BIOFEEDBACK DEVICES AND THE GOLD STANDARD		
Biofeedback Device	Overall Score				
	Weighted Kappa*	Absolute Agreement, %			
SmartStep	0.76 (0.68, 0.83)	78.7			
OpenGo <i>science</i>	0.58 (0.49, 0.67)	65.2			
SensiStep	0.19 (0.14, 0.25)	10.4			

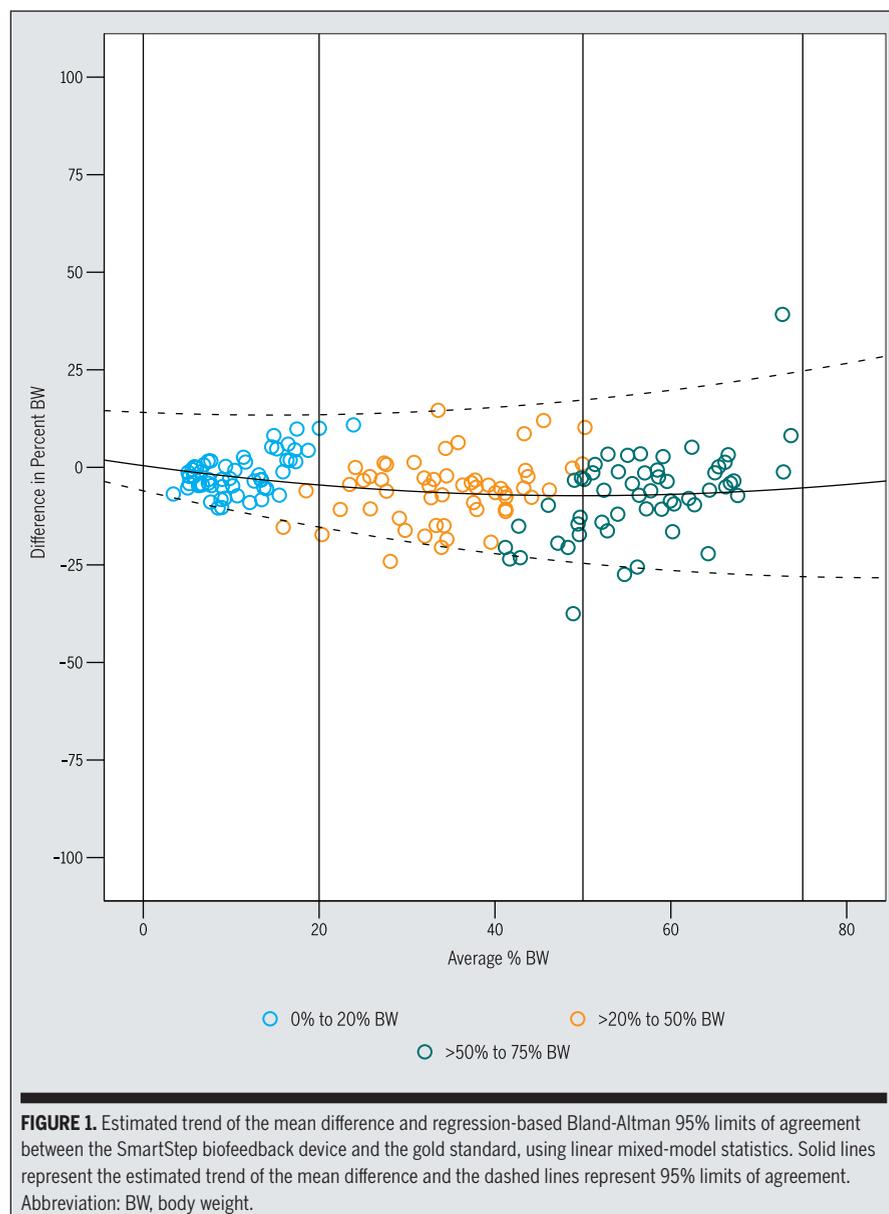
*Values in parentheses are 95% confidence interval.

TABLE 4		MEAN DIFFERENCE BETWEEN THE BIOFEEDBACK DEVICES AND THE GOLD STANDARD*		
Biofeedback Device	Weight-Bearing Category			
	1%-20% BW	>20%-50% BW	>50%-75% BW	
SmartStep	-1.6 (-11.7, 8.5)	-5.8 (-21.6, 10.1)	-7.4 (-29.8, 15.0)	
OpenGo <i>science</i>	-2.8 (-13.0, 7.6)	-10.0 (-25.8, 5.8)	-14.8 (-31.6, 2.1)	
SensiStep [†]	...	-19.7 (-41.7, 2.4)	-31.4 (-57.6, -5.3)	

Abbreviation: BW, body weight.
 *Values are mean difference (lower, upper bounds of limits of agreement).
[†]Values could not be calculated for the 1% to 20% weight-bearing category because SensiStep measured no force in 50 of the 55 participants.

SmartStep. However, in the highest WB category (greater than 50% to 75% BW), the lower limit of agreement slightly exceeded the range of the instructed WB category in the SmartStep and OpenGo *science* (with 4.8% and 6.6% BW on average, respectively). Therefore, to be confident that no overload will occur, it is recommended that the SmartStep and OpenGo *science* devices be preset to a few percentage points below the greater than 50% to 75% BW category. The SensiStep gave a large underestimation of peak force values in all WB categories. Additionally, in the lowest WB category, the SensiStep measured no force in 91% of participants. An explanation for this large underestimation by the SensiStep might be the single sensor position under the heel. A study by Pauser et al²⁰ showed that hindfoot force does not represent complete foot loading. Moreover, a commonly used technique to achieve low WB loads is the toe-touch WB technique, in which the toes touch the ground first and the forefoot is loaded instead of the hindfoot. This was also supported by the post hoc visual analyses of the foot-strike pattern based on foot-motion data collected simultaneously during the WB trials. This post hoc qualitative analysis showed that during peak force, the hindfoot was not in contact with the ground and that in the lowest WB category, the hindfoot of most participants did not make contact with the ground during the entire stance phase. This could explain why the SensiStep measured no force at all in the 1% to 20% BW category in most cases. Differences in peak force values compared to the force plate showed increasing deviation in successive WB categories for all devices. This relationship between differences and the magnitude depends on the specific characteristics of the sensors used in the WB devices.

Despite the numerous insole biofeedback devices on the market, there is a lack of studies investigating criterion validity of these biofeedback devices. Criterion validity of the SmartStep was investigated earlier by Isakov¹⁴ in 2007,



by comparing full-WB data during walking with the data obtained by a force plate in a sample of 11 healthy volunteers. It was concluded that the SmartStep is a valid device, because of the high correlation with the force plate ($r = 0.952$, $R^2 = 0.91$, $P = .004$). Comparison with our study is, however, hampered because we investigated partial WB instead of full WB and used other outcome measures, that is, absolute agreement instead of relative agreement. Absolute agreement was chosen because agreement param-

eters are expressed on the actual scale of measurements, which is more useful for clinical interpretation.

It can be questioned how accurate biofeedback devices need to be to successfully give feedback on partial WB. An exact answer cannot be given. It should be taken into account that the defined criteria for an acceptable level of agreement between the biofeedback devices and the force plate (used as gold standard) in this study were arbitrarily chosen, as no clear criteria exist. Looking at the ob-

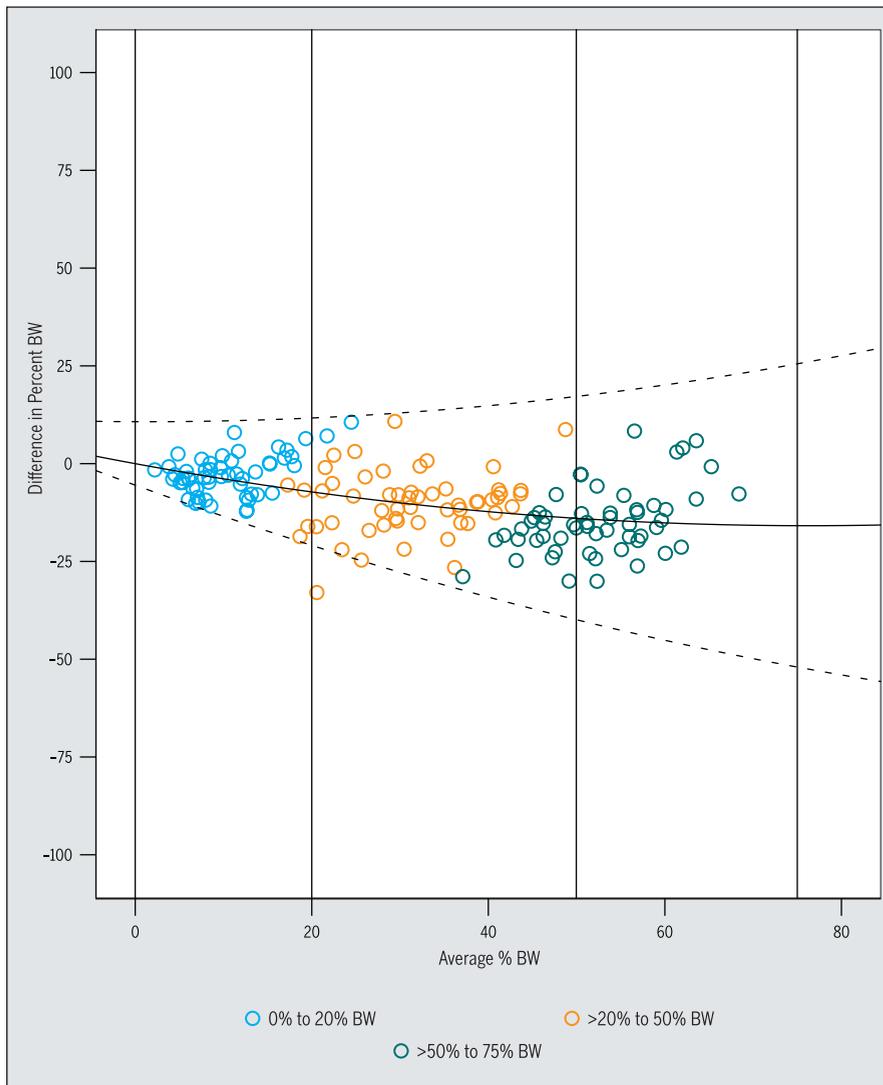


FIGURE 2. Estimated trend of the mean difference and regression-based Bland-Altman 95% limits of agreement between the OpenGo science biofeedback device and the gold standard, using linear mixed-model statistics. Solid lines represent the estimated trend of the mean difference and the dashed lines represent 95% limits of agreement. Abbreviation: BW, body weight.

served agreement results, all biofeedback devices had, at best, limits of agreement around 10%. Based on the commonly used relatively large WB ranges in partial-WB regimens, these agreements seem acceptable. However, it can be argued that biofeedback devices should be more precise. For instance, if devices are more precise, it will enhance insight into optimal WB for bone healing. Moreover, although prescribing partial WB is a common and accepted part of clinical practice, there is some controversy regarding the clinical

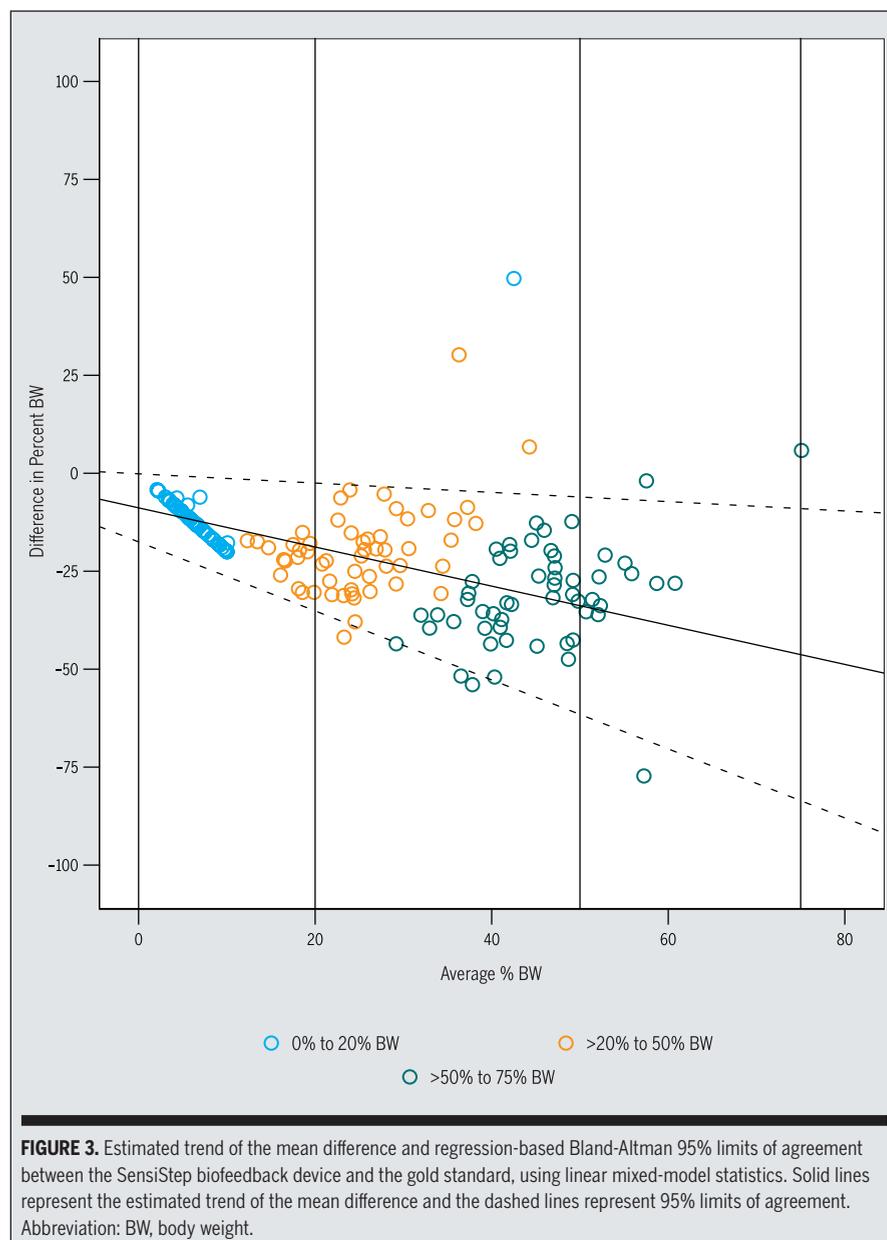
benefits. To date, no studies of high methodological quality have investigated the consequences of noncompliance with partial-WB recommendations or compared rehabilitation programs with and without WB restrictions. Therefore, it remains unclear how effective partial WB is and how important it is to comply with partial-WB instructions.^{12,15} However, what we do know from earlier research is that in the absence of adequate feedback, patients have difficulties in complying with low prescribed target loads, espe-

cially when load prescriptions are below approximately 30% BW.^{8,9,11,13,24} In most studies, without adequate feedback, patients loaded the lower limb more than 2 times as high as prescribed.^{8,13,24}

Some of the choices made in the study protocol of the current study might have influenced the results. First of all, because of the limited evidence for restricted-WB regimens and the absence of international consensus about classification systems for restricted WB, we chose to express restricted WB in commonly prescribed categories of percentage BW: (1) 1% to 20%, (2) greater than 20% to 50%, (3) greater than 50% to 75%.¹² As recommended by Rubin et al,²¹ WB instructions were expressed in percentage BW, because normalizing WB categories to percentage BW makes it easier to interpret the results. Second, validity of the biofeedback devices was assessed by comparing peak force measurements of a single step. Peak forces were chosen based on the idea that peak forces under the foot represent forces produced in other lower-limb structures. However, observing peak force as the only biomechanical parameter could be a study limitation. Although peak strain magnitude in the bone is the single most important component of the strain stimulus that correlates with loading-related bone formation, emerging evidence indicates that bone adaptation is also responsive to other factors.^{17,19,26} Besides peak strain magnitude, type of loading (static or dynamic loading) and the number of loading cycles and bouts are important for bone formation.^{17,19,26} Based on these findings, examining criterion validity of these other parameters seems important as well. However, clinical guidelines on optimal mechanical load for bone healing still provide patients with WB instructions in terms of maximum allowed peak force. Moreover, the current generation of biofeedback devices also provide only real-time feedback based on peak force under the foot. Therefore, the study was designed to provide findings that would be imme-

diately beneficial to daily clinical practice and would conform to the current practice guidelines. In future research, validating other biomechanical parameters should be considered. Furthermore, a single-step comparison instead of a multi-step comparison was chosen based on the assumption that complication can already occur by occasional excessive WB (1 step),¹¹ implying that each step has to be measured accurately. Another study limitation that has to be acknowledged when interpreting our results is that what was measured was not criterion validity of the feedback, but rather the ability of the devices to measure WB accurately. Although there were no signs of discrepancy between measured values and the provided feedback by the devices, the ability to measure accurately and to provide feedback accurately are different variables and could differ. In our study, we chose to provide participants with feedback on WB by using the force plate so that WB conditions could be controlled, and each of the participants underwent 3 measurements in accordance with the 3 WB conditions. Thereby, we gave priority to properly controlling the WB conditions instead of using the feedback of the devices, which would mean we could not control the WB conditions. Although some of these choices may have influenced the results, the current study is the first to investigate criterion validity of biofeedback devices in different partial-WB categories, instead of in full WB. In our opinion, validity has to be investigated under the same conditions as the biofeedback device used.

Although both the OpenGo *science* and SmartStep seem to be valid and promising biofeedback devices to train and monitor adherence to prescribed WB instructions, it should be mentioned that participants in this study were healthy volunteers and had no lower-limb injuries. Their WB kinematics may not be representative of patients with lower-limb injuries. Nevertheless, healthy participants were chosen because criterion validity of 3 biofeedback devices in partial



WB has not been previously investigated, and the authors considered validating the devices in the target population as undesirable, because not knowing the accuracy could unnecessarily expose patients to health risks. Furthermore, although the OpenGo *science* and SmartStep seem to be valid and promising, the use of technology is often not as successful as predicted. For successful implementation of assistive technology in daily practice, it is important that the biofeedback systems

have good usability and intended users' (patients and therapists) acceptance.^{4,22} Therefore, further research is needed to investigate the usability in training and monitoring adherence to WB instructions and the acceptance of this technology.

CONCLUSION

THE RESULTS OF THE CURRENT STUDY provide insight into the validity of biofeedback devices when used in

dynamic situations. The criterion validity of the OpenGo *science* and SmartStep is acceptable for the purpose of giving feedback in the lower WB categories (1% to 20% and greater than 20% to 50% BW). For the SensiStep, criterion validity is poor in all WB categories.

For successful implementation of the 2 valid biofeedback devices in daily practice, further research is needed to investigate the usability and technology acceptance of these devices from users' perspectives. ●

KEY POINTS

FINDINGS: In a sufficiently powered sample ($n = 55$) of healthy adults, we found that agreement of classification in WB categories with the force plate (used as a gold standard measure) was substantial for the SmartStep, moderate for the OpenGo *science*, and slight for the SensiStep (weighted $\kappa = 0.76, 0.58,$ and 0.19 , respectively). For the 1% to 20% and greater than 20% to 50% BW categories, both the OpenGo *science* and SmartStep have an acceptable limit of agreement. The SensiStep did not show an acceptable limit of agreement in any of the WB categories.

IMPLICATIONS: Noncompliance with WB instructions is a risk factor for failure of fixation devices and delayed fracture healing. Biofeedback devices are increasingly used to train and monitor patients' WB in postoperative regimens. Our study provides insight into the validity of 3 different biofeedback devices. The study results showed that criterion validity of the OpenGo *science* and SmartStep is acceptable for the purpose of giving feedback in lower WB categories. Knowing the accuracy of these devices, clinicians and researchers can decide which biofeedback devices seem useful in clinical practice and research.

CAUTION: Clinicians and researchers should be cautious in generalizing the validity findings of the biofeedback devices beyond a population of healthy individuals. Validity of the biofeedback devices was studied in a sample of healthy adults without recent lower-

limb trauma or surgery. Their WB kinematics may not be representative of patients with a recent lower-limb trauma or surgery.

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