Partial Weight Bearing

Long-term monitoring of load in patients with a total hip arthroplasty during postoperative recovery

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Verminderd belast lopen

Langdurige belastingsregistratie van patiënten met een totale heupprothese tijdens postoperatief herstel

Proefschrift

ter verkrijging van de graad van doctor aan de
Erasmus Universiteit Rotterdam
op gezag van de
Rector Magnificus

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Voor mijn ouders

Try walking in my shoes
You'll stumble in my footsteps
- DM -

Contents

1.1 Introduction

Physical therapy of hospitalized patients is aimed at optimal functional recovery and to ensure a safe and timely discharge from the hospital. Patients operated on the lower extremity are postoperatively instructed by a physical therapist to independently and safely perform daily activities (such as walking, and getting in and out of a bed or chair) to prevent complications during their postoperative recovery. In general, early postoperative mobilization of patients is stimulated, because immobilization or bed rest can lead to a decrease of muscle mass and bone density, an impairment of cardiovascular and metabolic functions, and an increased risk of deep venous thrombosis.[e.g. 11,23] However, for optimal healing of the operated leg, restriction in lower limb loading, that is partial weight bearing, during mobilization is often necessary.

The relationship between mechanical forces and fracture healing has been assessed in numerous clinical and animal studies.[3,39-41] Early loading causes axial micromotion which has been shown to stimulate fracture healing.[20,39-41] Early full weight bearing, however, delays the healing of fractures and reduces the quality of newly formed tissue compared to restricted weight bearing if too much motion at the fracture site occurs.[3] Fracture healing is also important when a trochanteric osteotomy is performed during a total hip arthroplasty. When performing a trochanteric osteotomy the surgeon detaches the trochanter from the femur before placing the hip prosthesis and reattaches it with a wiring technique (Figure 1). Several factors may influence the healing of the trochanteric osteotomy, including the surgeon's experience, the operative technique, type of wire fixation, and biological factors (quality of bone).[16] Another important factor is the force exerted on the trochanter by abductor muscle pull during weight bearing, which may cause migration of the trochanter and non-union.[2,16,22,29,30,65,69] Severe migration of the trochanter may cause disability as a result of pain, limp, or hip instability and dislocation.[2,16,49] A trochanter migration of more than 2 cm was found to be correlated with a positive Trendelenburg test due to insufficiency of the gluteus medius muscle.[2] Prospective and retrospective clinical studies on trochanteric osteotomy have reported complications rates of 3% to 38%.[2,12,22,25,29,38,55,60,61]

Besides being applied for fracture healing due to trauma events or for healing of the trochanteric osteotomy when performing total hip surgery, partial weight bearing is also prescribed for many other lower limb pathologies, such as cementless implants[e.g.14,52,53,73], osteotomies[e.g 51], amputations[e.g.18,63,64], anterior cruciate ligament reconstruction[e.g.4,34], meniscal repair[e.g.62,68], and Achilles tendon repair.[e.g.15] Thus, a large group of orthopedic and trauma patients have to limit the amount of weight on the operated leg during the healing process.

Therefore, physical therapy instructions to train these patients to perform partial weight bearing during daily activities is an important aspect of the postoperative protocol.

Although there is a relationship between the local forces and the healing process of fractures and trochanteric osteotomies, there is no agreement on what the optimal (i.e. type and magnitude) forces are for these healing processes.[21] An additional problem is that we can not measure the local forces at the healing sites (in vivo) during the patient's postoperative recovery.[21,35] Because the load under the foot is regarded as an indicator for the local forces, the load under the foot (i.e. ground reaction force) during standing and walking is used as an indirect load measure for the local forces in the lower extremity. There are, however, other factors (e.g. muscle forces) which determine the local forces at the healing sites. Despite this, in clinical practice the starting point for reducing the forces at the healing sites is partial weight bearing of the lower extremity. Because there is no consensus regarding the optimal local forces and the relationship between the load under the foot and the local forces, weight bearing restrictions are not standardized in clinical practice but are prescribed based on the individual preference of the surgeon.[13] It is then the task of the physical therapist to instruct the patient to restrict the amount of weight bearing on the operated leg to the target load as prescribed by the surgeon.

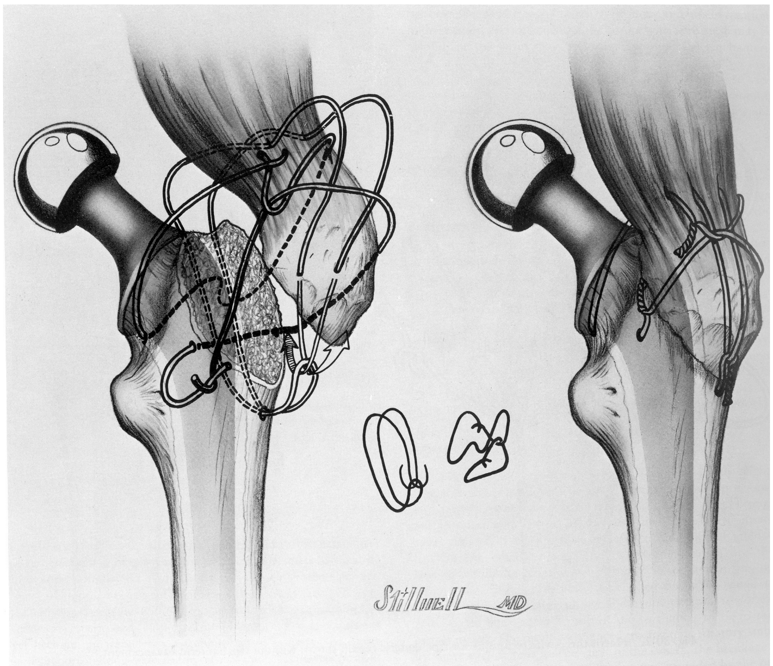

Figure 1. Total hip arthroplasty with trochanteric osteotomy according to Charnley. From: WT Stillwell. The Art of Total Hip Arthroplasty. Copyright © 1986 Elsevier Inc. Reprinted with permission from the Publisher.

1.1.1 Partial weight bearing

Partial weight bearing (PWB) is defined as loading the leg to a certain amount of weight during standing and walking by using a walking aid (e.g. a walker or crutches). The amount of restriction in weight bearing is specified by the surgeon and instructed by a physical therapist. The following classification of weight bearing (target load range from 0 - 100% body weight (BW)) is used by surgeons and physical therapists: *non-weight bearing:* no weight on involved lower extremity (0% BW), *toe-touch / touch-down / foot flat weight bearing:* the lower extremity may rest on the floor but no weight is placed on the extremity (10 - 20% BW), *partial weight bearing:* a weight limit of 20 - 50% BW, *weight bearing as tolerated:* the patient can place as much weight on the extremity as is tolerated within pain limits, and *full weight bearing:* a 100% of BW, with or without walking aids, is allowed. Besides this rather crude classification, the prescribed amount of weight bearing can also be given in distinct target loads, such as 10% or 50% of BW, or 200 Newtons, or 20 kilograms or 60 pounds of load.[31,43,51,56,59,66,67]

In clinical practice different techniques are used to teach patients to perform PWB; however, the method most commonly used is verbal instruction.[9,66] Hereby the physical therapist explains the prescribed weight bearing target in a way that is understandable for the patient. For instance, when the prescribed target load is 10% BW the physical therapist may say to the patient that it is like "walking on egg shells". To control the amount of weight bearing the physical therapist observes the patient's gait pattern, and/or palpates the upper arm muscles (musculus triceps brachii), and/or places a hand under the patient's foot to get an estimate of the amount of weight bearing.[9,31,66]

Another method to teach the patient to put a certain amount of load on the leg is by using a bathroom scale.[10,24,31,44,59,70,74] With this method the patient receives both visual and proprioceptive feedback. Although the bathroom scale provides a quantitative outcome it only gives information of weight bearing in a static situation which differs from weight bearing during walking, because walking produces an extra force due to body acceleration. Besides the biomechanical difference between static and dynamic weight bearing, learning to unload the leg when standing also differs from when walking.

A third method to teach PWB is to use a feedback device that can provide quantitative feedback during standing and walking.[10,31,51,56,59,70] These feedback systems can give audio, and/or vibration, and/or visual feedback. In practice different instruction methods are used which can lead to different weight bearing performances.[10,24,31,44,59,70,74] Until today there is still no consensus as to which method is the best and, therefore, the most common method is verbal instruction and observation of the patient.

1.1.2 Factors affecting partial weight bearing

For the physical therapist it is important to know which factors can influence the patient's weight bearing performance, because this enables the physical therapist to anticipate situations where a risk of incorrect weight bearing may arise. Potential risk factors which could affect the patient's weight bearing performance can be either therapy-related or patient-related. Therapy-related factors include, for instance, the instruction method used (as previously described), as well as the physical therapist who is training the patient, or even the (type of) operation. The operation could disturb the patient's coordination, balance, and propriocepsis and, therefore, it may be difficult for the patient to learn a new sensorimotor skill such as PWB. The literature describes several patient-related factors which are needed to unload the leg with a walking aid. An important factor is the physical condition, because walking with assistive devices (as crutches and a walker) is known to be physically demanding compared to unassisted gait.[6,27,28,33,50] This could be a problem for older less fit patients or for patients with comorbidities to perform PWB. Besides physical aspects, the patient's mental state (e.g. may forget what has been instructed) and social characteristics (e.g. compliance with using a walking aid) can also influence the PWB performance. Only one study has analyzed factors affecting the patient's PWB performance: Chow et al.[19] evaluated elderly patients after operation for a hip fracture, and found that muscle power of the good limbs and the mental state were significant factors, whereas age, BW and type of operation were not significantly related to PWB performance. Because of limited data, the influence of various factors on the patient's PWB performance remains to be established.

1.1.3 Measurement of partial weight bearing

To evaluate whether the patient correctly partially loads the leg to a prescribed target load when recovering from surgery we have to measure the actual amount of loading under the foot (vertical ground reaction force) during daily activities in the hospital and at home. By recording weight bearing in a daily setting during several hours, we are able to measure average peak loads during routine activities and extreme peak loads during occasional activities, in contrast to laboratory measurements. Most studies on PWB measured the load under the foot in a laboratory with mainly healthy subjects.[9,24,31,43,44,70,74] Only a few studies have measured the patient's PWB postoperatively in the hospital.[51,59,67] To our knowledge, no studies have measured PWB at the patient's home or in a nursing home after discharge. However, due to the nowadays short hospital stay, patients recover most of their time at home. Moreover, the home environment differs from the hospital and there is no supervision from a physical therapist or other medical staff which could influence the patient's PWB performance. Therefore, it is important to measure the actual load under the foot not only in the hospital but also at the patient's residence. For this, a measurement instrument is needed which can accurately and with good repeatability measure the vertical ground reaction force over a long-term period outside a laboratory.

In research, the amount of weight placed on the leg while standing or walking is traditionally measured by a force plate because it measures the actual force being applied (i.e. ground reaction force). This system, however, cannot measure weight bearing of patients during daily activities in the clinic and at home, because it is restricted to one location (i.e. the gait laboratory). Also, to obtain reliable and valid data multiple trials are needed and subjects have to hit the force plate correctly, which is difficult for older patients and when walking with assistive devices.[7,42,48,54]

Early work to measure the amount of weight bearing over several steps was done by Schwartz and Heath[58] who designed an instrument in 1939 (the oscillograph) to record the amount of load under the foot by using pressure sensors in the shoe (Figure 2). Over the last decades many devices have been developed to measure weight bearing during several steps within one trial by attaching force or pressure sensors outside a shoe[37,46,47], by building sensors in the sole of a shoe[42], or by placing sensors on the barefoot[8,57,58] or in an insole (pressure-sensitive insole)[1,17,26,32,36,45,66,71,72,75] to be placed in the shoe. Most development occurred with insole pressure systems which led to commercially available devices such as the Fscan (Tekscan Inc., Boston, USA), Footscan (RSscan International, Olen, Belgium), and the Pedar Mobile system (Novel GmbH, Munich, Germany). One important development is that these insole systems became portable so that the subject was no longer attached to a computer by a cable and, therefore, could be measured in their daily environment. However, portable systems need batteries and memory cards to record and download data, which could restrict their use because of limited power supply and/or limited data storage capacity. Although a portable insole pressure system seems to be the best choice for evaluating PWB during daily activities in the hospital and at home, other techniques may be more suitable. Furthermore, questions were raised concerning the validity and repeatability for measuring vertical ground reaction forces over a long-term period (several hours) with insole pressure systems, because these systems are only used and validated for short-measurement periods (i.e. 5-10 minutes).[5,45]

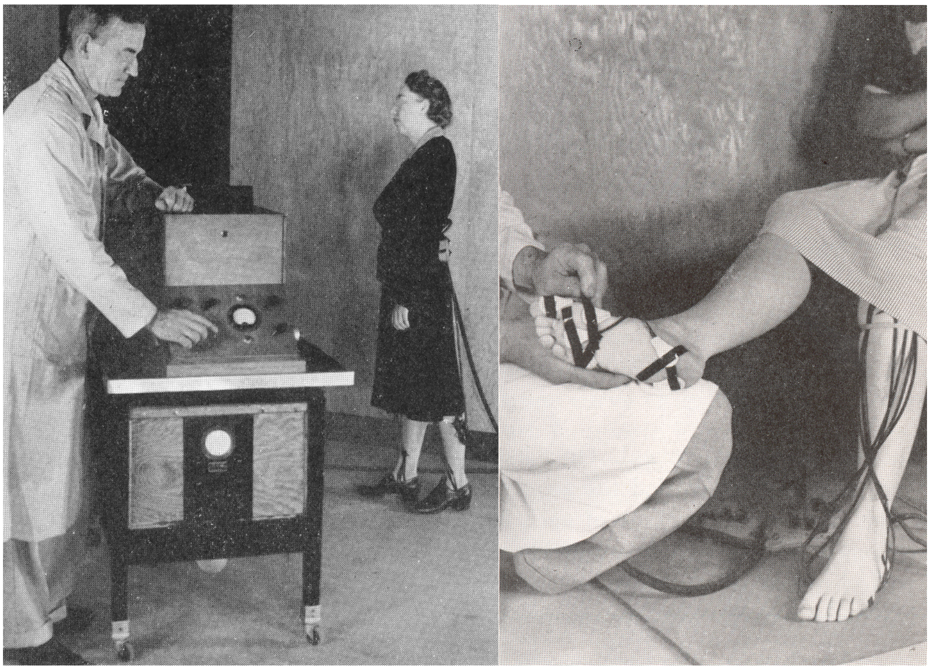

Figure 2. The instrument (oscillograph) designed by Schwartz and Heath in 1932 to record the amount of loading under the foot. Subject walking with pressure sensors in the shoe connected by a cable to the oscillograph (left). Six pressure-sensitive discs are applied to the plantar surface of each foot to measure the load under the foot (right). From: Schwartz RP and Heath AL. J Bone Joint Surg Am 1947;29:203-214. Copyright © 1947 by The Journal of Bone and Joint Surgery, Inc. Reprinted with permission from the Publisher.

1.1.4 Aims of this thesis

The main objective of this thesis is to determine whether patients with a total hip arthroplasty and a trochanteric osteotomy unload their leg to a prescribed target load during their postoperative recovery, and to identify factors that affect the patient's PWB performance. A prior condition for the main objective is to assess the validity and repeatability of an insole pressure system to measure vertical ground reaction forces over a long-term period.

1.2 Outline of this thesis

Chapter 2 presents an overview of the different techniques used to measure weight bearing in a clinical or laboratory setting. A classification and definition are given of the measurement techniques which were subsequently assessed according to methodological quality, application and feasibility criteria.

To use the Pedar Mobile system in a clinical study with long-term weight bearing measurements two validation studies were performed which are presented in **Chapters 3 and 4**. Because the Pedar insoles are worn for several hours in the shoes during long-term measurements, the output of the capacitance sensors in the insoles could be influenced by temperature, humidity and amount and duration of loading. Therefore, the amount and type of drift were examined over a period of 8 hours by comparing the vertical ground reaction force data of the Pedar Mobile system with a Kistler force plate, during hourly standing and walking trials by healthy subjects. In addition a correction algorithm was tested to correct for possible offset drift found (**Chapter 3**). Because the duration of static and dynamic loading in this latter experiment was short and not standardized, a second experiment was performed to examine the validity and repeatability by placing the insoles in testing devices for long-term static and dynamic loading to determine the type and amount of drift during two consecutive days (**Chapter 4**).

Chapter 5 describes the clinical trial on PWB in which the actual amount of weight bearing was compared with the prescribed target load. Two patient groups were evaluated which were verbally instructed by a physical therapist to bear 10% or 50% of their own body weight on the operated leg. Vertical ground reaction forces were measured in the clinic when the patient walked with or without a physical therapist, and again when the patient was at home.

Besides measuring the vertical force during walking, patient characteristics, postoperative status and walking features were also measured to determine their influence on the patient's weight bearing performance; this is described in **Chapter 6.**

Chapter 7 presents a general discussion on PWB and long-term weight bearing measurements using an insole pressure system.

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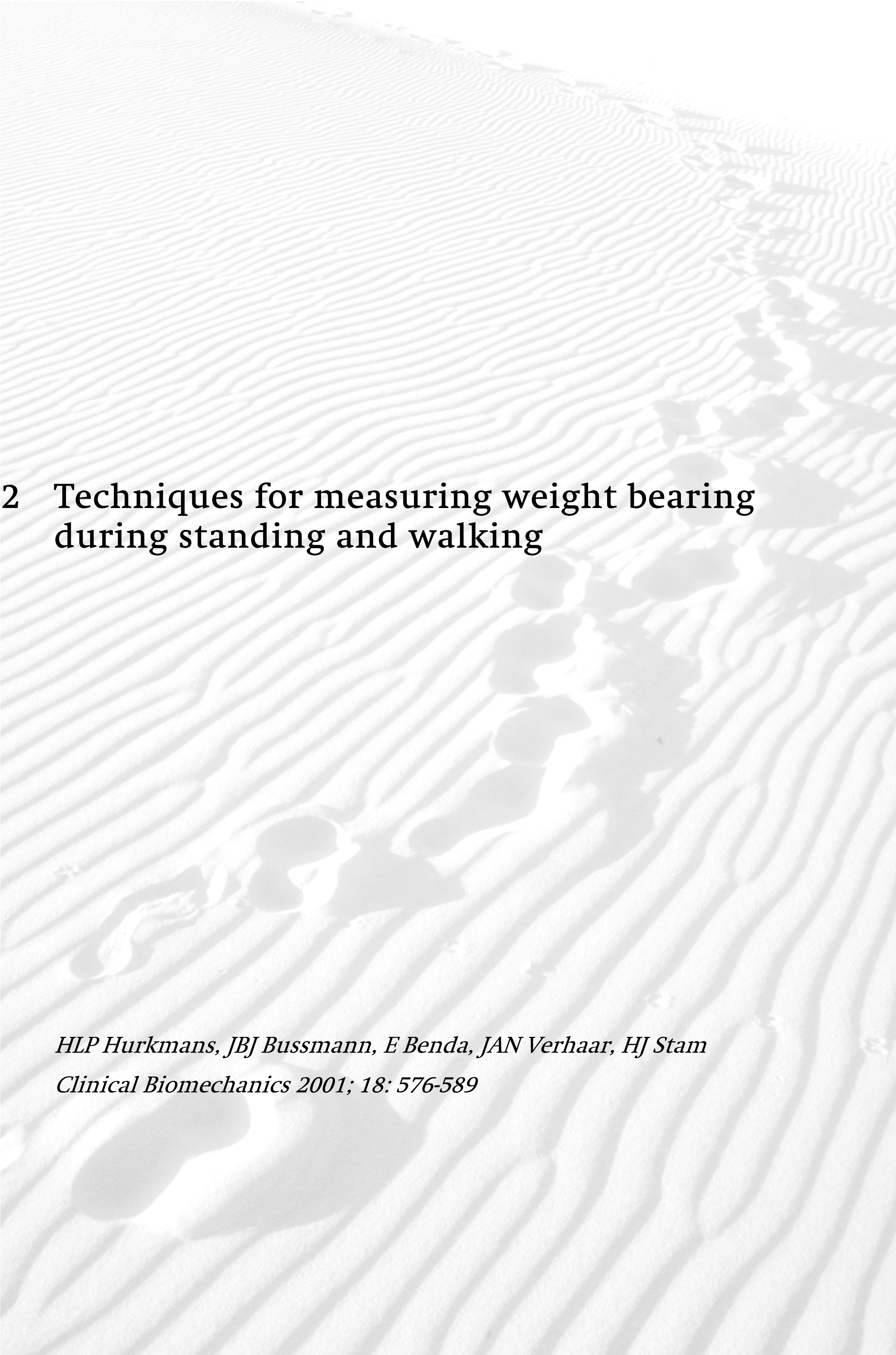

2 Techniques for measuring weight bearing during standing and walking

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Clinical Biomechanics 2001; 18: 576-589

2.1 Abstract

Objective

To classify and assess techniques for measuring the amount of weight bearing during standing and walking.

Background

A large variety of weight bearing measuring techniques exists. This review describes their advantages and limitations to assist clinicians and researchers in selecting a technique for their specific application in measuring weight bearing.

Methods

A literature search was performed in Pubmed-Medline, CINAHL, and EMBASE. Measurement techniques were classified in 'clinical examination', 'scales', 'biofeedback systems', 'ambulatory devices' and 'platforms', and assessed on aspects of methodological quality, application, and feasibility.

Results

A total of 68 related articles was evaluated. The 'clinical examination' technique is a crude method to estimate the amount of weight bearing. Scales are useful for static measurements to evaluate symmetry in weight bearing. Biofeedback systems give more reliable, accurate and objective data on weight bearing compared to 'clinical examination' and 'scales', but the high costs could limit their use in physical therapy departments. The ambulatory devices can measure weight bearing with good accuracy and reliability in the hospital and at home. Platforms have the best methodological quality, but are mostly restricted to a gait laboratory, need trained personnel, and are expensive.

Conclusions

The choice of a technique largely depends upon the criteria discussed in this review; however the clinical utilisation, the research question posed, and the available budget also play a role. The new developments seen in the field of 'ambulatory devices' are aimed at extending measuring time, and improved practicality in data collection and data analysis. For these latter devices, however, mainly preliminary studies have been published about devices that are not (yet) commercially available.

2.2 Introduction

Weight bearing during standing leads to a force exerted by gravity on the subject. In a standing position the amount of this vertical ground reaction force under both feet equals the weight of the subject. During walking, the vertical ground reaction force has a characteristic sinusoid shape during stance phase with two peak forces.[95] The amplitude of these peak forces correlates with the walking speed[69] and stride length[60], and during 'normal' walking and running ranges from 0 to 5 times the body weight.[70,71] It is evident that these forces under the foot during standing and walking generate forces and moments in other structures of the lower extremity, such as the hip. [9,28]

In rehabilitation the amount of weight bearing during standing and walking is crucial in the healing period of orthopaedic patients with various pathologic conditions of the lower extremity, such as uncemented total hip arthroplasty, osteotomies, fractures of the leg, or amputees[3,22,27,32,35,48,52,58,74,79] because immobilisation, non weight bearing, or excessive weight bearing can lead to complications.[10,16,25,31,85,94] Measurement of weight bearing is also essential during rehabilitation of patients with neurological pathologies, e.g. stroke, Parkinson, hemiplegia, and patients with diabetes mellitus and peripheral neuropathy to evaluate symmetry in weight bearing, weight shifting ability, and adequate limb loading.[11-13,53,68,84,87,88] Assessment of the amount of weight bearing is, therefore, important.

Different techniques are used to measure the amount of weight bearing, corresponding to their field of application. Two major fields of application can be distinguished. First, the field of training patients to learn and control partial weight bearing (clinical measurement)[23,33,35,37,73,86,89] and, second, the field of evaluating postoperative weight bearing (research measurement).[42,46,51,55] Within these two fields of application a large variety in measurement techniques and instruments exists, each with their advantages and limitations.

The purpose of this study is, therefore, to classify and assess the different techniques for measuring the amount of weight bearing on the lower extremity during standing and walking. This overview may assist clinicians and researchers to select the most suitable technique for their specific application in measuring weight bearing. The results may also indicate new directions in the development of techniques or instruments for measuring weight bearing.

2.3 Method

A literature search in Pubmed-Medline (1970-2001), CINAHL (1982-2001) and EMBASE (1990-2001) was performed using the following keywords: 'weight', 'bearing', 'load', 'force', 'foot', 'measure', 'walking aid', 'ambulant', 'platform' and 'device'. Of the articles generated, the reference lists were used to find other related articles. Only articles in the English and German language were selected.

2.3.1 Classification and definition of the measurement techniques

To compare the clinical measurement techniques a distinction was made in clinical examination, scales, and biofeedback systems. For the same purpose the research measurement techniques were classified in ambulatory devices and platforms. The following definitions were given to each of the clinical and research measurement techniques.

Clinical examination Clinical examination was defined as observation and/or physical examination of the subject by a therapist during standing and walking with a walking aid, without extra instrumentation. Estimation of weight bearing during walking is done by observation, and/or palpation of the musculus triceps brachii, and/or by placing a hand under the foot of the affected leg.

Scales Standard (analogue or digital) bathroom scales.

Biofeedback systems Load monitoring systems that provide immediate feedback to the subject at a prescribed load level.

Ambulatory devices Portable instruments with sensors attached to the subject, which allow continuous measurement. A division can be made between 'semi-portable' devices which use a long cable, and 'real' portable devices which allow unrestricted movement in the environment. Sensors can be placed under the bare foot, in the shoe, under the shoe, or in an insole.

Platforms Instruments placed in or on the floor, or in a treadmill, for measuring the ground reaction force in one or more planes.

2.3.2 Assessment of measurement techniques

Each clinical and research measurement technique was assessed in order to compare aspects of methodological quality, application, and feasibility for measuring weight bearing. For the methodological quality, information regarding the validity and reliability of the techniques was searched for in the literature. The quantitative criteria used in the literature related to validity were [34]:

error: the difference between measured output value, measured by the system, and the true output value provided by a gold standard, mostly a force platform
accuracy: the true output value minus the measured output divided by the true output value (this ratio is usually expressed in percent)
precision: the number of distinguishable alternatives from which a given result is selected, e.g. 2.400 N is more precise than 2.4 N (a high precision does, however, not imply a high accuracy)
drift: an undesirable change in output value, over time, during a constant input. When the environmental factors temperature and humidity cause an undesirable change in output it is called temperature or humidity drift, respectively
hysteresis: the maximum deviation between ascending and descending output readings taken at the same input value
non-linearity: any deviation of the input-output characteristic from a straight line
creep: the ability of insole material used to resist change under an applied load/pressure over time, quantified as the difference between output value (force) and input value (force) divided by the input value (force)[61,97]

Reliability or reproducibility was defined as the extent to which the instrument yields the same output on repeated measurements with equal input; reproducibility does not imply accuracy.[80]

Aspects related to application were: performance of ‘static’ (during standing) and/or ‘dynamic’ (during walking) measurements; ‘maximum measurement time’: duration of one measurement (e.g. one or multiple steps measured in one session); ‘maximum time resolution’: maximum sample frequency; and ‘measurement range’: the range in which the measurement variable (Newton, % body weight) can be measured. The main aspects regarding feasibility were: simplicity of the technique to measure weight bearing for both the researcher (e.g. time needed, data transfer, data storage) and the subject (e.g. weight/size of the system), and the costs related to the measurements and/or purchase of the technique (information from sales literature).

2.4 Results

2.4.1 Clinical measurement techniques

Clinical examination

The *clinical examination* technique was used in a study by Gray et al.[37] in which the physical therapist estimated what 60 pounds of force felt like when applied to the therapist's hand. They concluded that the amount of weight placed on the therapist's hand is subjective guesswork at best. No studies were found in which the validity of the clinical examination technique to measure weight bearing during standing or walking was determined. Also, no information was found on aspects of application and feasibility of the clinical examination technique.

Scales

The *scale* technique, which provides a quantitative outcome (kilogram) for the amount of weight bearing during standing, is less subjective than the clinical examination technique. Measurement on a standard (bathroom) scale ranges from 0 to approximately 130-150 kg, which usually allows to determine the amount of weight during double leg or single leg standing. Information on the accuracy of measuring the amount of weight for scales was reported by Winstein et al.[93] They mentioned an accuracy of ±0.45 kg being the smallest unit of the analogue scale; the measurement range of the scales was 0-157.5 kg. The digital scales used by Bohannon et al.[12,13], were reported to register weight to a 0.1 pound (0.05 kg) level of precision, and were calibrated before each testing session. Chow et al.[22] stated that accuracy was difficult to achieve and maintain particularly when the weight to be replicated was minimal. As scales are used to measure weight bearing in a static situation, Chow et al.[23] found that the most consistent method to measure the actual weight under the feet during walking was a row of 8 bathroom scales on the floor between parallel bars, but no data were given to confirm this statement.

Biofeedback systems

The first reported biofeedback device was a leg load warning system developed by Endicott et al.[32] in 1974. It consisted of a single load transducer located in the hollowed-out heel of an orthopaedic sandal, and an electronic package that modified the signal from the sensor. It transmitted two audible tones, a low frequency tone when a patient had not exceeded the minimum load and a high frequency tone when the maximum load was exceeded. The authors described good characteristics for the transducer, e.g. no hysteresis and no drifting of the signal over a period of 8 hours, although no specific data were given on the methodological quality.

Miyazaki and Iwakura[66] made a limb load alarm device also using two different audio feedback signals. The low frequency tone was activated when the load exceeded a preset lower threshold and was switched off when the load increased to the upper threshold activating the high frequency tone. Two strain gauge force transducers were attached to the sole of a shoe, one at the metatarsal part and at the heel, by elastic bands and Velcro straps. The device had a 10% accuracy, a temperature drift of ±3 N/^{0}C, and a measurement range of 0-1000 N. The processing unit with rechargeable batteries (12x8x2.5cm, 240g) was fastened at the waist by a belt, allowing the system to work for 15 hours. The costs were about $25, for components only. Limitation of the system was that to obtain the total limb load, by summing the outputs of both transducers, it was necessary that the remaining parts of the sole did not make contact with the floor; this was not feasible in all parts of the stance phase. However, the authors stated that the error due to this was small. In 1986 Miyazaki et al.[64] described a new limb load monitor mentioning the drawbacks of their previous system[66] in terms of accuracy and ease of setting the threshold load levels. This time they used a capacitive transducer, which resembled an insole and was also attached outside the shoe. The accuracy was improved to a 5% error. The device, however, was heavier (320g) and larger (13x9x3cm). A major problem of the system was that gain adjustment had to be made each time the transducer was changed, and to solve this problem expensive pre-calibrated load sensors were needed.[64]

The audio feedback system most referred to is the (Krusen) Limb Load Monitor (LLM).[35,49,87,96] The LLM consists of a pressure transducer built in an insole connected to a control box, which can be worn around the waist. The box emits a tone that may increase or decrease in pitch depending on loading calibration and mode selection. A control knob for adjusting the sound “null” point indicates to the patient that the desired loading has been reached. To calibrate the LLM, the patient loads the limb on a bathroom scale while the null point setting is adjusted.[87] Wolf and Binder-Macleod[96] compared the LLM with a force plate and found statistical significant differences ranging from 8-36% for both force peaks. The loading measurements showed a wide range in the 95 percent confidence intervals and it was therefore concluded that the accuracy of the LLM was insufficient. Intrarater and interrater reliability were determined by Carey et al.[17] They found intra-class correlation coefficients of 0.995 and 0.990 for the first and second force peak, respectively, and concluded that the measurement reliability was high. However, healthy subjects were used in the study and intrarater and interrater reliability are highly dependent on individual peak forces and other gait variables. The authors therefore concluded that additional studies with different patient groups were necessary to establish the clinical utility of the LLM. Wolf and Binder-Macleod[96] described the LLM to be inexpensive and easy to use. However, Gapsis et al.[35] had some criticism regarding the clinical usefulness, i.e. durability, and ease of repair, and opined that certain modifications of the LLM unit would increase the usefulness.

A PMT feedback system with insoles, based on a hydraulic principle, was used by Perren and Matter.[73] The device had a storage capacity of 8000 steps, and software presented the total amount of weight bearing in percentages of 100 N force units. Perren and Matter found that separate recording of the 3 sensors led to measurement errors. They also described having many technical problems, especially with the durability of these insoles. Siebert[79] used a similar feedback device. Size and weight of the system were found to be acceptable. It was carried on the body and stored the weight load of each step which guaranteed the complete registration of the postoperative period of total hip patients. No data were given on methodological quality of the device.

Instrumented walking aids were designed by Bergmann et al.[8] and Engel et al.[33] to train and control weight bearing. Bergmann et al.[8] chose for an indirect measuring technique which was inexpensive and not restricted to a certain place compared to the direct measurement techniques: the platforms and devices with transducers in or outside the shoe. They presented a linear relationship, between the ground reaction force of the walking aid and the partial weight bearing leg, to calculate the amount of weight bearing from the measurement of the walking aid. When the restriction in weight bearing is less than 10% of the body weight this technique becomes less reliable. According to Bergmann et al.[8] the instrumented walking aid was easy to use and inexpensive. Engel et al.[33] described a cane with a vibrating membrane built into the handle, and with two lights which can only be seen by the therapist. Although Engel et al.[33] reported that their instrumented walking cane accurately indicated the amount of weight borne on the affected leg, these data were not validated against data from e.g. a force plate.

2.4.2 Research measurement techniques

Ambulatory devices: Semi-portable with transducers outside the shoe

A commercially available system (CDG) with eight capacitive transducers, covering the surface of the sole in almost every situation, was developed by Hermens et al.[42] This semi-portable system (cable) measured the vertical force (distribution) during a walk of 20 seconds and was designed to be used in the clinical environment. The force transducers, placed in an overshoe, could be easily attached and removed form the patient's shoe. Hermens et al.[42] mainly described the data processing procedures and methods of data presentation and not the methodological quality of the obtained force data (Table 1). The system was used in two clinical trials to measure the vertical ground reaction force during the gait of hip arthroplasty patients walking with crutches.[43,82]

Ambulatory devices: Semi-portable with transducers built in the shoe

The measuring system of Kljajic and Krajnik[53] included five pairs of leather shoes in which eight or nine force transducers were built into each shoe sole. The accuracy (3%) was found to be comparable with force plates of the same cost. The advantage of this system over the force plate was that it enabled measurements of a large number of steps, which the authors mentioned as being of utmost importance in severely impaired patients who cannot undergo the long and exhausting measurements required by force plate testing. Disadvantages were that the patient had to wear special shoes instead of his own footwear, and that measurements were restricted to a walkway.

Ambulatory devices: Semi-portable with transducers in insole

When measuring vertical forces with insoles a distinction can be made between discrete sensor insoles and matrix insoles. With discrete sensor insoles a limited amount of sensors are placed at specific areas under the foot, whereas matrix insoles consist of numerous sensors elements arranged in rows and columns which, unlike discrete systems, can measure the pressure/force under the entire plantar surface.

Gross and Bunch[38] compared the vertical force output of their discrete insole system with a force plate to assess the transducer placement validity. They concluded that the shapes of the force curve were similar, but the units of load differed. The differences between curve endpoints were related to limited number of transducers available for placement beneath the calcaneus and toes. As no description was given of the duration of data storage or use of a data storage card we assume this system is semi-portable.

One of the first matrix insoles was developed by Hennig et al.[41] using 499 piezoelectric transducers in each insole. Besides good sensor characteristics the sampling rate can be set up to 200 Hz. A limitation of the system is that the subject needs to carry a relatively large and heavy backpack, and external power via a cable was necessary because adequate batteries would be too heavy.

Table 1. Aspects on the methodological quality of the ambulatory devices.

System	Transducer type	Error	Creep	Drift	Hysteresis	Non-linearity	Reliability	Calibration
Commercial								
Pedar[42, 65-70]	capacitive	0.8-17%	3.4%	<0.05N/ (cm^2 ^0C)^{a,b}	< 3%	?	0.84-0.98^c 0.6-3%^{d}	air bladder device
Fsscan[42, 43, 68, 69, 71-74]	FSR	4-24%	11.6-19%	?	21%	?	0.52-0.98^c 9.5-20.8%^{d}	subject's weight; air bladder device
Parotec[63]	piezoresistive	?	?	-0.001N/cm$^{2\,e}$ -0.015N/cm^2/K^a	0.05%	0.42%	?	by manufacturer
CDG[38]	capacitive	?	?	?	?	?	?	?
Non-commercial								
Tveit and Kärrholm[36]	strain gauge	?	?	?	?	?	?	subject on force plate
Aranzulla et al.[8]	resistive	<1kg	?	?	?	?	?	testing machine
Abu-Faraj et al.[60]	conductive polymer	7-14%	?	?	5-10%	?	?	device: dynamically at 36^{0}C
Dingwell et al.[62]	capacitive	?	?	?	?	?	?	subject on force plate
Whalen et al.[61]	capacitive	?	?	?	?	?	?	subject on force plate
Wertsch et al.[59]	conductive polymer	?	?	-0.5%/^{0}C^a	8%	yes, ?	?	device: at 36^{0}C
Zhu et al.[58]	conductive polymer	?	?	-0.5%/^{0}C^a	8%	yes, ?	?	device: dynamically at 36^{0}C
Gross and Bunch[54]	piezoelectric	3.1-9.9%	?	?	3.7%	2.3%	?	device: dynamically
Kljajic and Krajnik[27]	strain gauge	3%	?	?	1%	1%	?	subject on force plate
Miyazaki and Ishida[47]	capacitive	5%	?	?	?	yes, ?	?	?
Hennig et al.[55]	piezoelectric	?	?	?	< 1%	< 2%	?	?
Miyazaki and Iwakura[56]	strain gauge	10-15%	?	?	?	?	?	?

? = no data found in the literature; ^{a} Temperature drift; ^{b} Information from standard sales literature (2001); ^{c} ICC; ^{d} CV; ^{e} Humidity drift

Ambulatory devices: Portable with transducers outside the shoe

Miyazaki and Iwakura[65] developed in 1978 a portable device, which could measure the vertical force under the foot continuously during standing and walking. It consisted of two strain gauge force transducers attached to the rear and front part of the sole of a sport shoe. Problems of the device were that a portion of the foot forces bypassed the force transducers due to direct contact between the floor and the sole of the shoe. At slow cadences (under 110 steps/min) the error was within 10%, but at higher cadences the error was 15%. The walking style of the subject was little affected due to the arrangement and thickness of the transducers, and the transducers varied in their sensitivity. Positive aspects were the long measurement time (8 hours) and the relatively small and light weighted unit, which was fastened at the waist by a belt. Using a radio frequency for data transfer, with a transmission range from 15 to 100 m, no cable was needed and therefore the patient's movement was not restricted. To solve the aforesaid problems, Miyazaki an Ishida[63] developed a new device consisting of two large flexible capacitive transducers per shoe. Specifically for patients with a fractured leg, Aranzulla et al.[3] developed an ambulatory system which could continuously measure the amount of weight bearing for over 24 hours. They used four flexible resistance transducers, which were attached to a Tubigrip sock. Custom-made software was used to calculate the mean amount of weight bearing, the mean duration of weight bearing, and the number of weight bearing events.

Ambulatory devices: Transducers in insole

A portable microprocessor-based data-acquisition system developed by Zhu et al.[99] consisted of seven pressure sensors (0.5 mm) which were each dynamically calibrated at 36^{0}C after being placed in the insole to compensate for non-linearity and temperature drift. Data could be continuously collected for 7 minutes at a 20Hz sample rate. The measurement time was extended by Wertsch et al.[91] and Abu-Faraj et al.[1] to 2 hours with a sample frequency of 20 Hz, and to 8 hours at 40 Hz, respectively. Abu-Faraj et al.[1] described that the discrete sensors had thin metal backings which offered a greater stiffness than the rest of the insole by at least a 20:1 ratio. Another aspect was the insole distortion around the sensor edges. A positive aspect of discrete systems (because of their limited use of sensors compared to matrix insoles) is the ability of long-term data collection. Although the system was smaller but heavier than the one used by Zhu et al.[99] and Wertsch et al.[91], Abu-Faraj et al.[1] described it as fully portable, not disrupting the natural gait pattern, and therefore ideal to measure the vertical force during daily living activities. To acquire data of a subject, customised insoles need to be made for each foot.

Whalen et al.[92] developed a force measuring system with one capacitance insole force sensor designed to operate continuously for 2 weeks without the need to retrieve data or replace batteries. Long-term (2 weeks) sensor stability, i.e. no significant change in the sensor force output over time, remained to be determined because after a 15-hour trial the sensor failed due to two short bouts of activity (running and tennis). Data reduction was achieved by filtering the digitised vertical ground reaction force. The processor continuously time-differentiated the force and saved the maximum load rate between each peak and valley. The data logger stored the time of occurrence of these peaks and valleys and the total daily duration of force levels into 0.1 body weight intervals. Dingwell et al.[29] replicated the device of Whalen et al.[92] and measured 4 subjects for 10 hours to quantify daily load bearing activity. Specific Matlab (The Mathworks, Inc) routines were developed to convert the raw data to percent body weight (%BW). Tveit et al.[86] specially made pressure-sensitive insoles to measure the amount of weight bearing after hip surgery. Although no time interval was given, the system enabled long-term collection of data from each patient in his or her environment. The authors stated that further research would be required to evaluate patient compliance and long-term reliability. A commercially available discrete insole system is the Parotec system.[21,78] Chesnin et al.[21] presented bench testing data for the methodological quality of the system with an accuracy of 2.0% and precision of 0.4%, and no discernible drift. The system is portable and can store data for 5 minutes with a sampling frequency up to 200Hz.

Commercially available matrix insoles systems are the Pedar system[14,47,50,61,76,98] (Novel GmbH, Munich, Germany)[4] and the F-Scan system[20,54,61,76,77,97,98] (Tekscan Inc., Boston, MA)[2]. In contrast to the previous described ambulatory devices, much information was found regarding the validity and reliability of measuring pressure/force by these two devices. A comparison between the two devices was made by McPoil et al.[61] where the Pedar system demonstrated a high level of validity and reliability, whereas the results raised serious questions regarding the ability of the F-Scan insole to accurately measure normal force. Woodburn et al.[97] stated that accuracy of the F-Scan was hampered by inaccurate calibration, and poor hysteresis and poor creep properties. Quasada et al.[76] compared the two systems after two new developments of the F-Scan, i.e. new resistive ink sensor insoles and software allowing calibration via an air pressure bladder (like the Pedar system) instead of the subject's body mass. They concurred with previous reports that the Pedar system is likely the system of choice when the greatest accuracy and repeatability are desired. Both systems use a cable for data transfer but the Pedar system also has a Mobile version which can collect data for up to 1 hour on a 40 Mb PCMCIA storage card when both insoles, with 99 sensors each, and a sample rate of 50 Hz are used.

Table 2. Aspects on application and feasibility of the ambulatory devices.

System	Type	Measurement range (unit)	Time resolution	Weight / size	Data transfer	Data storage	Costs
Commercial							
Pedar[42, 67, 70]	insole, matrix	0-60 (N/cm^2)	50 Hz	850 g/ 17.5x10.4x4.4 cm[a]	data logger / 10m cable	1 hr/ 40 Mb PCMCIA card/ PC	$14,230[b]
Fsscan[42, 43, 71-74]	insole, matrix	0-100 (N/cm^2)	165 Hz	180 g	9.25m cable	PC	$12,950[b]
Parotec[63, 64]	insole, discrete	0-62 (N/cm^2)	100-200 Hz	?	data logger / cable	5 min	$?
CDG[38]	overshoe, discrete		100 Hz	19x14x4.5 cm[a]	cable	PC	$18,553[b]
Non-commercial							
Tveit and Kärrholm[36]	insole, discrete	0-250 (kg)	250 Hz	?	cable	PC	?
Aranzulla et al.[8]	Tubigrip sock, discrete	? (kg)	?	500 g / 13x13x7.5 cm	data logger	24 hrs	?
Abu-Faraj et al.[60]	insole, discrete	0-1.2 (MPa)	40 Hz	1250 g / 15x15x10 cm	data logger	8 hrs	?
Dingwell et al.[62]	insole, discrete	? (%BW)	25 Hz	908 g	data logger	10 hrs/4 Mb PCMCIA card	?
Whalen et al.[61]	insole, discrete	? (%BW)	100 Hz	7.5x7.5x2.5 cm	data logger	2 wks/ 2 Mb PCMCIA card	?
Wertsch et al.[59]	insole, discrete	0-2 (MPa)	100 Hz	800 g / 20x18x17cm	data logger	2 hrs (20Hz)	?
Zhu et al.[58]	insole, discrete	0-2 (MPa)	100 Hz	800 g / 20x18x17 cm	data logger	7 min(20Hz)	?
Gross and Bunch[54]	insole, discrete	0-2 (MPa)	333 Hz	6x11x3 cm	?	?	?
Kljajic and Krajnik[27]	in sole of shoe	(N)	100 Hz	?	30m cable	PC	?
Miyazaki and Ishida[47]	sole outside shoe	0-1000 (N)	?	220g / 13x9x25 cm	telemetry	PC	?
Hennig et al.[55]	insole, matrix	1-1.5 (MPa)	200,100,50,25 Hz	2900g/ 25x18x15 cm	cable	PC	?
Miyazaki and Iwakura[56]	outside shoe	0-980 (N)	80 Hz	180g/ 10.5x8x2.3	telemetry	PC	$70[c]

? = no data found in the literature; [a] Information from standard sales literature (2001); [b] Contains standard hardware and software (2001/2002); [c] Costs at that time

The durability of the F-Scan sensor was criticised by Rose et al.[77] and Woodburn et al.[97] The sensors showed consistent measurements for about 30 gait cycles but then the recordings steadily dropped off due to wear of the individual sensor. However, compared to the Pedar system, F-Scan has a higher measurement range, a higher sample frequency and the price of the system is lower (Table 2).

Standard Platforms

The force plate is one of the most important measuring devices in biomechanics, quantifying external forces during human locomotion.[70] As with ambulatory devices, the electromechanical properties of the transducer used in the measuring instrument are of major importance for the quality of the output. The type of sensors used in force platforms, e.g. piezoelectric[15,24] or strain gauge[6,26,45], have very good characteristics resulting in a high accuracy, and precision of force measurements made by these instruments[24,70] (Table 3). The Kistler (Kistler Instrumente AG Winterthur, Switzerland) and AMTI (Advanced Mechanical Technology, Inc, Watertown, MA) force platforms are, due to their characteristics, frequently used as a gold standard against which other systems are evaluated.[4,20,24,40,47] Hughes et al.[44] stated that the reliability[80] of the results depends on the capacity of the equipment to give the same result on consecutive steps, and on the ability of the patient to walk in the same way several times. Therefore, 100% reproducibility can not be expected when measuring a variable related to gait, because gait always varies slightly between walks and subjects. When measuring weight bearing with standard floor platforms, multiple walks are needed to gain reliable results.[5,30,44] Bates et al.[5] used a Kistler platform and found that a minimum of eight trials was needed to obtain reasonable reliable mean vertical force values. However, multiple trials, needed to gain reliable results, can present problems for patients who have a poor physical condition.[53;67] Moreover, the subject needs to hit the force plate correctly, and a measurement protocol is needed to collect data in a standardised way.[19;75] The walking pattern will probably be affected due to targeting of the subject's foot on the platform, especially when the platform has small dimensions.[8] Grabiner et al.[36], however, found that variability of ground reaction force is not significantly affected by targeting the force plate. Wearing et al.[90] also confirmed this by demonstrating that targeting a certain 30 x 24 cm^2 target does not affect ground reaction forces when a gait protocol that fine-tunes the start position is employed. The location of platforms is restricted to a gait laboratory because the platform generally needs to be mounted into the floor.[15,26,45,81,83]

Table 3. Aspects on the methodological quality of the platforms.

System	Transducer type	Error	Creep	Drift	Hysteresis	Non-linearity	Reliability	Calibration
Standard Platforms								
Kistler (type 9281)[a]	piezoelectric	?	n.a.	?	< 0.5%	< 0.5%	?	by manufacturer static in situ
AMTI (type OR6-7)[a]	?	?	n.a.	$0.01\%/^0C^b$	< 0.2%	< 0.2%	?	by manufacturer
EMED F[81, 85]	capacitance	?	n.a.	$0.5k\ Pa/^0C^b$	<5%	?	$0.75\text{-}0.90^c$	by manufacturer
AccuGait (AMTI)[a]	?	?	n.a.	?	?	?	?	by manufacturer
Long Platforms								
Ollson et al.[91]	strain gauge	1%	n.a.	?	<1%	<1%	?	static, discrete known loads
Hynd et al.[39]	strain gauge	0.1%	n.a.	?	0.1%	±0.1	?	static, discrete known loads
Treadmill Platforms								
Gaitway (Kistler)[a]	piezoelectric	?	n.a.	?	see platform	see platform	?	by manufacturer static in situ
Kram and Powell[92]	strain gauge	1%	n.a.	?	?	<5%	?	static, discrete known loads
Kram et al.[93]	strain gauge	1%	n.a.	?	?	0.2%	?	?
Belli et al.[94]	crystal force	?	n.a.	0.140 N/min	?	±0.3	?	artificial leg method

? = no data found in the literature; n.a. = not applicable; [a] Information from standard sales literature (2001/2002); [b] Temperature drift; [c] ICC

Portable platforms do not need to be mounted into the floor but need to be placed in a sufficiently long (6m) walkway.[44,75] Hughes et al.[44] studied the reliability of the EMED F system (Novel GmbH, Munich, Germany) and found that a minimum of three trials was needed to obtain excellent reliability (Table 3). This system uses capacitance transducers and therefore has a relatively low (70 Hz) sample frequency. The AccuGait, a portable platform developed by AMTI, has a sample frequency up to 200 Hz. Generally, the time resolution of force platforms is high compared to ambulatory devices with sample frequencies >100 Hz (Table 2, 4).

Long Platforms

To avoid the earlier mentioned problems of targeting and fatigue of patients, long force platforms were developed for clinical studies.[46,72] Olsson et al.[72] provided a walkway which consisted of two five-meter long platforms, developed in 1966 by Rydell, with additional equipment to give more accurate, efficient, fast and reliable data. The authors pointed out that this force plate walkway cannot record changes in forces that occur over 20 Hz due to its limited frequency range, nor can it study the highest frequencies of gait during initial foot contact. A specially designed computer program called "KI-step" calculated the maximal vertical force in %BW. Although the force plate walkway was designed for clinical studies it was not applicable to all types of gait disturbances. Olsson et al. stated that the subject must also be able to walk unassisted by another person, walk with one foot on each plate, and avoid placing the walking aid on the force plates. Hynd et al.[46] developed a long dual-platform triaxial walkway. The natural frequency of the platform was 92 Hz, and thus above 50 Hz which is, according to the authors, sufficient for measurement of walking. The potential increase in walking base, as a result of having to walk on a different platform for each foot, was not apparent with the pathological gaits for which this platform walkway was designed.

Treadmill Platforms

To measure the ground reaction force for many successive steps and with repeatable constant speed, Kram and Powell[57] developed a treadmill-mounted force platform (Table 3). A commercially available strain gauged AMTI platform was mounted directly under the belt of a motorised treadmill. The 1.21 m long platform is usable up to a running speed of ~7 m/s. The limitation of this treadmill platform was that it could only measure the vertical ground reaction force. Kram et al.[56], therefore, developed in 1998 a force treadmill that could also measure the horizontal ground reaction forces.

Table 4. Aspects on application and feasibility of the platforms.

System	Type	Measurement range	Time resolution	Weight / size	Data transfer	Data storage	costs
Standard Platforms							
Kistler (type 9281)[a]	in floor	20 kN[b]	1000 Hz	40 kg / 60x40x10 cm	cables	PC	$11,640[c]
AMTI (type OR6-7)[a]	in floor	17.8 kN[b]	570 Hz	32 kg / 50.8x46.4x8.3 cm	cables	PC	$11,640[c]
EMED F[85]	portable		70 Hz[a]	43.8x22.6 cm[a]	cables	PC	$9,299[a]
AccuGait (AMTI)[a]	portable	2700 N	50,100,200 Hz	11.4 kg 50x50x4.4 cm	4.5 m cable	PC	$14,340[d]
Long platforms							
Ollson et al.[91]	in floor	?	?	30 kg/ 500x20 cm	cables	PC	?
Hynd et al.[39]	in floor	2500 N	2000 Hz	35 kg / 330x40 cm	cables	PC	?
Treadmill Platforms							
Gaitway (Kistler)[a]	treadmill	2000 N, 6000 N	25-2500 Hz	364 kg/ 139x49.5x21.6[e]	cables	PC	$44,545[c]
Kram and Powell[92]	treadmill	?	400 Hz	121x46 cm	cables	PC	?
Kram et al.[93]	treadmill	?	1000 Hz	180x60	cables	PC	?
Belli et al.[94]	treadmill	?	800 Hz	200mx25 cm	cables	PC	?

? = no data found in the literature; [a] Information from standard sales literature (2001/2002); [b] Range vertical force; [c] Platform only;
[d] Portable platform with amplifier and software; [e] Bed length x width x height

They stated that the force treadmill has many advantages over conventional run-way mounted force platforms: it allows ground reaction forces to be collected far more rapidly, a large number of successive steps can be averaged to determine more representative values, no long laboratory or hallway is needed, and it allows for simultaneous collection of biomechanical and other data such as oxygen consumption and EMG. The treadmill ergometer developed by Belli et al.[7] consists of two parallel treadmills, one for each foot. They used crystal force transducers (Kistler, Wintertur, Switzerland) because of their ability to tolerate wide range of force measurements. The maximum velocity of the treadmill belts is 2.87 m/s, which gives a theoretical maximum foot contact distance of 1.36 m. Comfortable walking requires a belt longer than the contact distance and therefore a 2 m long belt was used. Belli et al.[7] found that low frequency oscillations were present in the force and velocity data collected during treadmill walking, and that future design should specify and reduce the velocity oscillations of the belt. The same phenomenon was also presented by Kram and Powell[57]; they concluded that, compared with a standard Kistler platform, the treadmill force platform provided accurate measurement of vertical ground force.

2.5 Discussion and Conclusions

An extensive literature search was conducted on the different techniques and instruments used to measure weight bearing during standing and/or walking. Because of the large amount of different instruments we chose to classify the techniques into five categories in order to evaluate their advantages and disadvantages with regard to measurement of weight bearing. Not all instruments developed are mentioned in each category. For the biofeedback systems these are: the Accutread system (Chattanooga group, Hixson, USA), the PedAlert (Planet Products Corp., Madison, USA), the Biofeedback Weight Monitor (Enabling Devices, NY, USA), and the Andante Smartstep (Andante Medical Devices Ltd, Beer Sheva, Israel). For the ambulatory devices these are: the Footscan system (RSscan International, Olen, Belgium), the Foot pressure system (T&T Medilogic, Schönefeld, Germany), and the Dinatto in-shoe pressure system (Buratto Advanced Technology, Crocetta, Italy). The main reason is that of these (commercially) instruments no articles were found in the used databases. We also found a large discrepancy in available articles between the five measurement techniques. Especially the limited information on clinical examination made it impossible to give a well-balanced conclusion on the methodological quality of this technique to measure weight bearing. In only a few of the found articles a weight bearing technique was used for a specific patient group. Therefore, we could not link a certain measurement technique to a particular clinical situation, e.g. fracture of the lower extremity or stroke. In most articles, in which a certain technique was evaluated, the authors described in the introduction paragraph that measurement of weight bearing is important in rehabilitation in general.

Clinical measurement techniques

Although *clinical examination* is a commonly used technique to train control weight bearing, it is a crude method estimating the amount of weight bearing during standing and walking, and allows the clinician to give only a qualitative (e.g. too high or too low) description of the outcome; such estimation results in a poor accuracy. Especially in a dynamic walking situation, where the magnitude depends on walking speed and stride length, assessment of the amount of vertical ground reaction force becomes even more complex. Only one article by Gray et al.[37] was found in which the clinical examination technique was used. Although no comparison was made between the weight estimation by the clinician and e.g. a force platform, Gray et al.[37] concluded that measuring the amount of weight by using the therapist's hand is "subjective guesswork at best".

Scales are often used in combination with clinical examination for training of weight bearing.[23,32,79,93] The measurement range of scales (0-150 kg) limits their use to static measurements. Scales have a good accuracy[13], but Chow et al.[22] stated that accuracy is difficult to achieve and maintain, particularly when the weight to be replicated is minimal. The needle of a scale does not have peak and hold capacity so that it is difficult to read and reproduce peak forces.[37] Therefore, this technique is mostly used for static measurements to evaluate symmetry in weight bearing.

Biofeedback instruments give more reliable, accurate and objective data on weight bearing than 'clinical examination' and can measure weight bearing during walking in contrast to 'scales'. However, such data can only be obtained when these instruments are calibrated and correctly applied to the human body. The costs of these devices, however, could limit the use in and outside physical therapy departments.

Research measurement techniques

The methodological quality of the ambulatory devices has only been extensively studied for the commercially available systems, of which the Pedar system has the greatest accuracy and repeatability. These studies, however, are restricted to short-term measurements for which these systems are mostly used. Data on the validity of the other ambulatory systems is limited to one article presented by the authors who developed the system. Measurement quality of the ambulatory devices depends on the type of transducers used. For instance, capacitive transducers have a fairly stable and linear response, but are relatively thick and less flexible compared to force sensing resistors (FSR). Another limitation of the capacity principle is the low sample frequency (100Hz). More detailed descriptions of strain gauges, FSR, piezoresistive and piezoelectric transducers are given by Lord[59], Cavanagh et al.[18], Schaff[78], and Cobb[24]. The performance of the transducers can be influenced by the material used (e.g. wear and deformation) and by temperature changes, which can lead to e.g. hysteresis[24,97,99], creep[20,61] and temperature drift[18,61,65,97,99] of the output signal. Especially when the device is placed inside the shoe the temperature can have an important effect on the sensitivity of the transducers[18]; however, only a few articles address the accuracy related to temperature range.[41;52] Although all systems can be calibrated, only a few systems can calibrate the sensors individually, and at a temperature related to the temperature in the shoe. The reported measurement range is 0-200 N/cm^2 and 0-250 kg, which is sufficient for weight bearing measurements. Only the early reports of Miyazaki report a relatively low measurement range, which may have been sufficient for their patients. Time resolution is 'good', with sample frequencies from 40-150 Hz which is sufficient for walking.[1,19,24]

The instruments can be semi-portable when using a cable, or portable using telemetry or a data logger to store data. These portable instruments can be used to measure weight bearing in the home situation during normal daily activities. Restrictions in collecting data over a longer time period are due to the software, energy consumption/power supply, and/or storage capacity.

Practicability (or simplicity in use) varies depending on whether the essential factors, e.g. attachment to the patient, calibration, data collection and analysis, are easy and not too time-consuming. Standard fixation of the portable devices on the subject or patient is with a belt on the hip. For patients, who have had hip surgery, this type of fixation is less comfortable and could even be painful. As the described systems are still relatively heavy and large for long-term daily measurements of weight bearing, future developments could focus on alternative forms of fixation. The commercially available instruments work with software packages, which simplify calibration and give extensive output information on e.g. (peak) force, step and stride length, and contact time. Weight of the device, location and type of sensors (barefoot, thickness of insole, slipper), and restriction due to cables determine the comfort for the patient and whether the system disrupts the gait pattern.[42;53] The ambulatory devices can be relatively expensive, especially when they require high sensor quality and calibration of the system.

Platforms have a high methodological quality to measure the ground reaction force and are therefore frequently used as a gold standard against which other systems, e.g.

ambulatory devices, are evaluated. The transducers used in platforms are ideally suited for dynamic events, whereas for static measurements drift occurs over time. Quartz is used in the Kistler force transducers, and static measurements are more feasible with quartz than other piezoelectric material. Large forces can be measured for minutes and perhaps even hours; however low-level forces can be measured statically for much shorter intervals. This is why piezoelectric force transducers are often described as “quasi- or semi-static”.

Standard platforms are restricted, compared to ambulatory devices, to single step measurements and therefore multiple trials are needed to gain reliable results. Other limitations are that the subject needs to hit the force plate correctly to obtain valid force data and problems of targeting may occur. To overcome the described limitations of standard platforms, long walkway platforms and treadmill force plates were developed. Another limitation for all platforms is their restriction to mostly a gait laboratory to measure the ground reaction force. To measure the ground reaction force in a rehabilitation environment, i.e. the clinic or home of the patient, an ambulatory device is the only option.

Specifically for measurement of ground reaction forces during (partial) weight bearing with walking aids one has to be aware that the patient does not place the aid on the force plate when collecting data of weight bearing on the foot.[67] Edwards[30] concluded that for this kind of measurement a force shoe system is better than a force plate, because without a force shoe system it is difficult to simultaneously collect ipsilateral cane forces and extremity ground reaction forces because the proximity of the cane is too close to the affected foot and therefore distorts the force plate data. Platforms generally cost more than ambulatory systems, because of the extra equipment and personnel needed for correct placement in a laboratory. Furthermore, measurement costs are also higher because of the time-consuming measurements[62] and the trained personnel required for operating and calibrating these kind of systems.[34,39]

The choice of a technique for measuring weight bearing depends largely upon methodological, application, and feasibility aspects presented in this overview, but also on important aspects such as the clinical utilisation, the research question posed, the clinical set-up, and the available budget. To assess, for example, the amount of (partial) weight bearing after an orthopaedic procedure in the patient’s home situation during one day, the portable ambulatory device technique seems to be the best option available. Commercially available ambulatory devices, however, still have limitations in collecting data over a longer (8-10 hours) time period, and their relatively large size and weight can be strenuous for the patient. The new developments seen in the field of ambulatory devices technique are aimed at extending the measuring time, and at improved practicality for the researcher and clinician in data collection and data analysis. For these latter devices, however, mainly preliminary studies have been published about devices that are not (yet) commercially available.

This overview may support the selection of the most optimal technique to measure weight bearing for a specific application. Future development should focus on the limitations and disadvantages of the available techniques and instruments. Particularly for the clinical examination technique, information is lacking about its methodological quality. As this technique is often used in routine clinical evaluation of weight bearing, further research is needed on the validity and reliability of measuring weight bearing.

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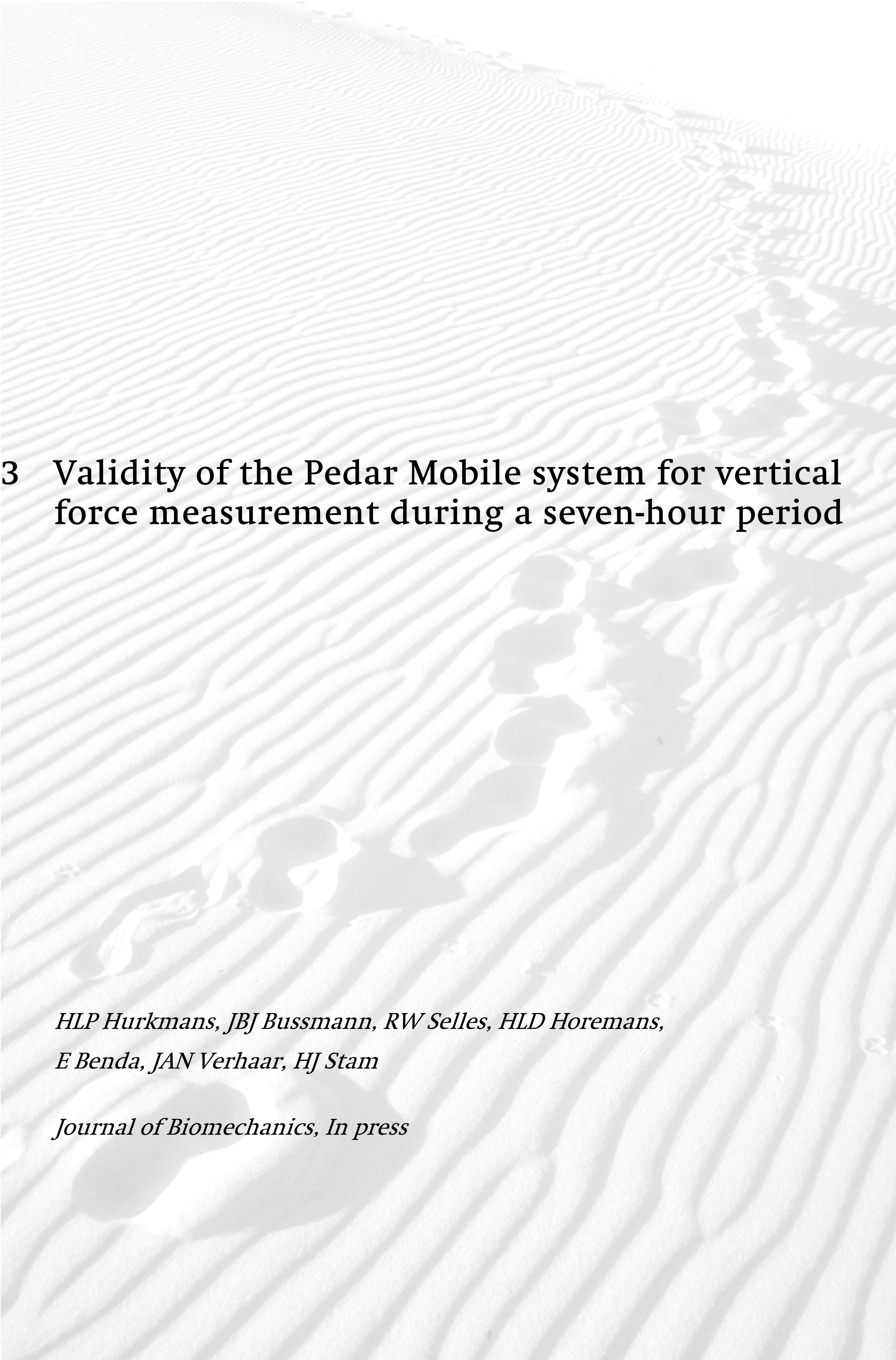

3 Validity of the Pedar Mobile system for vertical force measurement during a seven-hour period

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3.1 Abstract

Objective measurement of weight bearing during a long-term period can give insight into the postoperative loading of the lower extremity of orthopedic patients to avoid complications. This study investigated the validity of vertical ground reaction force measurements during a long-term period using the Pedar Mobile insole pressure system, by comparing it with a Kistler force platform. In addition, the validity of a new sensor drift correction algorithm to correct for offset drift in the Pedar signal was evaluated. Ground reaction force data were collected during dynamic and static conditions from five healthy subjects every hour for 7 h. A mean offset drift of 14.6% was found after 7 h. After applying the drift correction algorithm the Pedar system showed a high accuracy for the second peak in the ground reaction force-time curve (1.1 to 3.4% difference, $p > 0.05$) and step duration (-2.0 to 4.4% difference, $p > 0.05$). Less accuracy was found for the first peak in the ground reaction force-time curve (5.2 to 12.0% difference; $p < 0.05$ for the first 3 h, $p > 0.05$ for the last 4 h) and, consequently, in the vertical force impulse (5.5 to 11.0% difference, $p > 0.05$). The Pedar Mobile system appeared to be a valid instrument to measure the vertical force during a long-term period when using the drift correction program described in this study.

Keywords: Pedar Mobile system; validity; vertical force; drift correction; long-term period

3.2 Introduction

To avoid complications, instruction on partial weight bearing is often given during the rehabilitation of orthopedic patients with various pathologies of the lower extremity.[9,11,12,14,23-26,28,30] It is evident that the ground reaction forces under the foot during weight bearing (i.e. when walking and standing) generate forces and moments in other structures in the lower extremity, such as the hip.[5,10] In daily clinical practice, because the forces in the hip can not be directly measured, the ground reaction force under the foot is used as a load measure, often expressed in percentage body weight. Patients are generally instructed to perform partial weight bearing during a period of 6 to 8 weeks. To evaluate the effectiveness of this instruction and to quantify the loading of the lower limb during the day, objective measurement is needed of the actual amount of loading (vertical ground reaction force) and other aspects of loading (i.e. step duration, vertical force impulse) during weight bearing, both in and outside the clinic and during a long-term period.

Portable insole pressure devices can measure the actual amount of load bearing during daily activities and over a long-term period (hours).[15] However, the validity of vertical force measurements performed by insole systems (especially during long-term periods) may be influenced by temperature or humidity in the shoe, and by loading of the sensors during an entire day.[7] Moreover, insole sensors measure the “normal” force, which is not necessarily similar to the vertical ground reaction force.[16,17,19] Only a few studies have used an insole pressure system for long-term measurements.[1,23,25,26] Perren and Matter[23] concluded that their insole system (based on a hydraulic principle) was not technically reliable enough for routine use in the clinic. Discrete insole pressure systems, developed by Tveit and Kärrholm[26] and Abu-Faraj et al.[1], have some disadvantages compared to matrix insole devices: the transducer may act as a foreign body in the shoe, and inaccuracies may occur due to imprecise positioning of the sensors.[1,7,18] No reports were found on the validity of these insole systems to measure the vertical ground reaction force during long-term measurements.

Arndt[2] performed long-term measurements using Pedar pressure matrix insoles (Novel GmbH, Munich, Germany) and found a 17% sensor creep after 3 h. To correct for this creep, Arndt presented a correction method in which short standing trials were used to reset the signal based on the assumption that the measured body weight does not change during the trial. In that study, no data were presented regarding the validity of the Pedar system after the correction method was used. However, for long-term partial weight bearing measurements, we believe that Arndt’s correction method is not optimal because the patient uses a walker or crutches meaning that the total body weight can not be measured. In the present study, we introduce a drift correction algorithm to correct for the possible offset drift during walking in the Pedar mobile system.

The aim of this study was to investigate the validity of the Pedar Mobile system to measure vertical force during a long-term period. The main research questions were: What is the amount and type of drift when using the Pedar system for 7 hours? How accurate is the Pedar system in measuring vertical force over a long-term period when corrected for possible offset drift?

3.3 Methods

3.3.1 Subjects

Five healthy subjects (3 females and 2 males) with an age range of 21-35 years (mean 26 years) and weight range of 60-89 kg (mean 69 kg), participated in the study. None of the subjects had a history of musculoskeletal trauma or disease of foot or ankle. An overview of the subjects' characteristics is presented in Table 1.

Table 1. Subject characteristics at t = 0 h.

Subject	Gender	**Age** (yrs)	**Weight** (kg)	**Insole** (type)	**Shoe size** (European)
1	Female	28	67	W	40
2	Female	22	59	W	40
3	Female	25	61	W	40
4	Male	35	70	X	42
5	Male	21	89	X	42

W = humidity-proof W-sized insoles; X = humidity-proof X-sized insoles

3.3.2 Material

The Pedar Mobile system (a portable device with matrix insoles containing 99 capacitance sensors) was used to measure vertical force during a long-term period. Three custom-made battery units, consisting of two Sony NP750 Li-ion batteries, were needed to provide the Pedar system with power for an 8-h period. The Pedar start-stop trigger cable was used to record data during the measurement protocol after every hour. The in-shoe pressure data were stored on a 40Mb PCMCIA flash card. Pedar mobile Expert version 8.2 software and a custom written Matlab® correction program were used to analyze the data.

A Kistler (type 9281B12) force plate was used to measure the vertical ground reaction force. Data were collected from the platform via two Kistler type 5001, and two Kistler type 5011 charge amplifiers, and A/D conversion was done with a 12 bits resolution DASH-16 PC board. Custom-made data acquisition software was used to collect the Kistler data.

All subjects wore similar athletic running shoes: the men wore a shoe size 42 (European; UK: 7.5-8; US: 8.5-9) and the women a shoe size 40 (European; UK: 6.5; US: 8.5). For the purpose of this study, Novel GmbH developed humidity-proof versions of the Pedar insoles to decrease sensor drift during long-term measurements (these insoles are now commercially available). The men used humidity-proof X-sized insoles (shoe size 42/43) and the women used humidity-proof W-sized Pedar insoles (shoe size 40/41).

3.3.3 Protocol

The Pedar insoles were calibrated using the Trublu calibration device (Novel GmbH) and a GDH 14 AN digital manometer (Greisinger Electronic GmbH, Regenstauf, Germany). The pressure loads applied were 4, 7, and 10 up to 60 N/cm^2 with intervals of 5 N/cm^2. Pedar data were collected for the right foot only using a sampling frequency of 99 Hz. The Kistler force data were recorded using a sampling frequency of 500 Hz. Before measurement, the Pedar Mobile system was turned on 1 hour in advance (acclimatization period) and zero settings were done at t = 0 and t = 1 h. In preliminary tests we found a negative drift in the Pedar system data, which stabilized after 1 hour; based on this, the Novel company recommended an acclimatization period of 1 hour after which a second zero setting should be performed. After the second zero setting at t = 1 h, dynamic and static measurements were performed every hour for 7 h. For the dynamic measurements each subject walked at their own walking speed and positioned themself in front of the force plate so that the third right footstep was placed on the platform.[20,27] This was repeated 10 times for each subject every hour. For the static measurements, the subjects stood still on the left leg only, followed by standing still on the platform for 10 seconds on the right leg only. To standardize the subject's activities during the 7-h period, most of the time the subjects were sitting behind a computer, but during each hour were asked to stand up at least 5 times and on two occasions each hour to walk about 10 m.

3.3.4. Data analysis

Pedar mobile Expert version 8.2 software was used to calculate the force data from the Pedar system. Then, all Pedar and Kistler data were imported in Matlab® and were filtered using a low-pass Butterworth filter with a cut-off frequency of 40 Hz. In the analysis, drift was defined as an undesired change in output signal (force) over a period of time that is unrelated to the input (load). The drift was expressed as: (1) absolute drift, defined as the increase in force measured during the unloading periods of the insoles (i.e. during swing phase for the walking trials and during the time the right leg was in the air for the standing trials), and as (2) relative drift, defined as the increase in force during unloading periods and expressed as a percentage of the force during loading periods (static and dynamic measurements). Next, the type of drift (offset or gain) was assessed, because our correction method assumes that the drift is an offset drift. Offset drift was defined as a drift in which all output values (during loading and unloading periods) are increased at a certain time by the same value. This offset drift is relatively easy to correct, in contrast to gain drift in which output values are increased by a multiplication factor. To determine the type of drift, the drift measured with the right leg in the air (insole unloaded) was subtracted from the drift measured with the right leg on the force plate (insole loaded). If this difference (insole loaded minus insole unloaded) was constant over time, then the drift would be an offset drift and not a gain drift.

Offset drift during walking was corrected using a custom-made drift correction algorithm. The main steps of the automated correction algorithm are shown in Fig. 1. First, a threshold force value (which has to be above the maximum offset drift; Fig. 1A) was set to detect the first data point of the descending force curve of each step, (referred to as 'cycle detection point') below the threshold force value. This was done to define a unique point in each gait cycle. Secondly, the minimum force during each cycle was determined as the lowest force value between two consecutive cycle detection points (Fig. 1B). After this, a first order polynomial was fitted between two consecutive minima by determining the x-value (time) and y-value (force) of the first (x_1, y_1) and second minima (x_2, y_2), after which the slope coefficient (s) of the first order polynomial was calculated using the following equation: $s = (y_2 - y_1) / (x_2 - x_1)$. The first order polynomial equation was then $y = a + sx$, in which 'a' was the y-value of the first minima point (y_1). Then for each x-value, the y-value of the polynomial was calculated and subtracted from the corresponding raw force data point to get the offset drift corrected vertical force (Fig. 1C). The correction method was based on the following assumptions: (1) the drift is an offset drift, (2) the drift between two subsequent steps is linear, and (3) the force during the swing phase is zero.

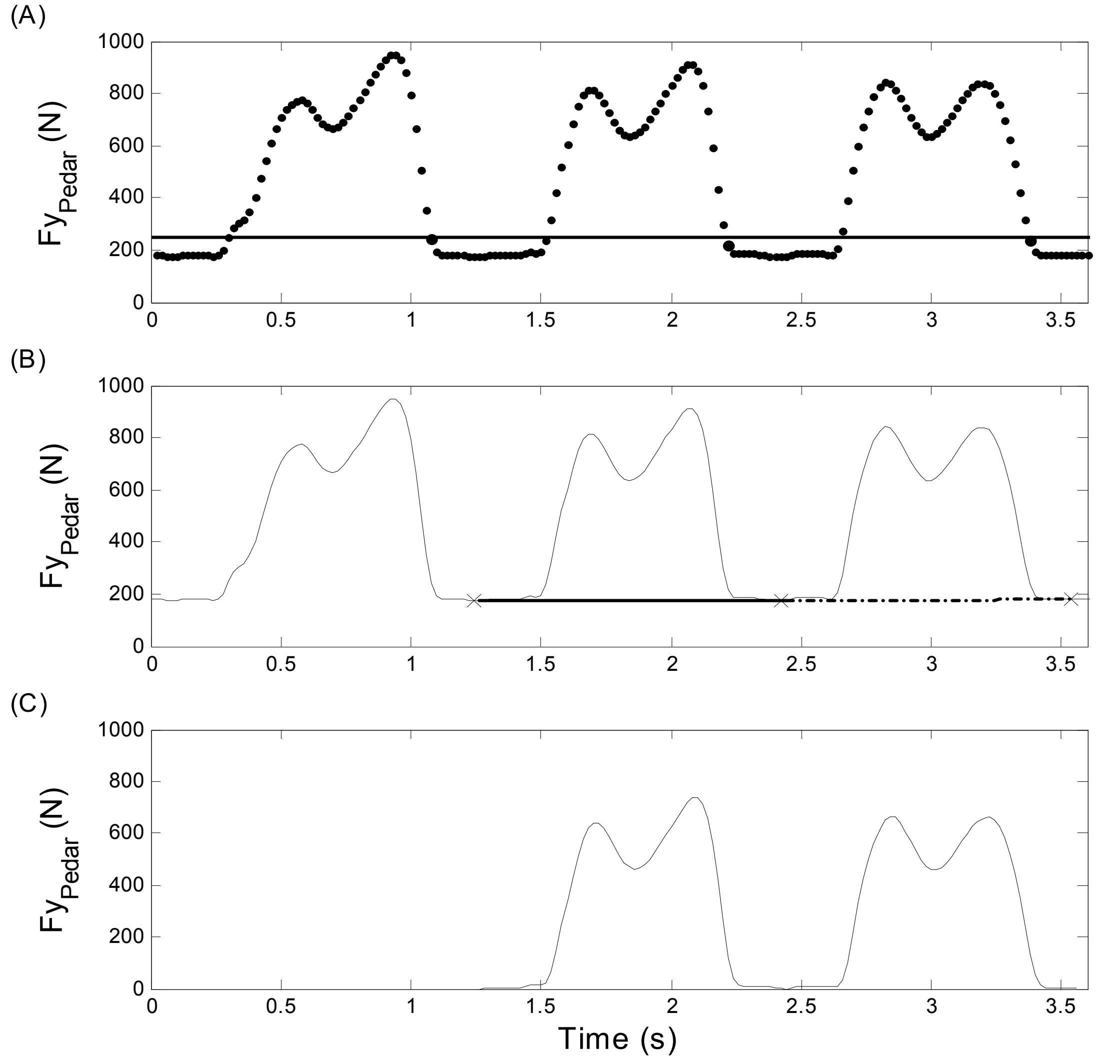

Figure 1. Graphical representation of the algorithm used to correct for offset drift. As an example the Pedar force data of the first three right footsteps of subject 2 recorded at hour 7 are shown. See Methods (Data analysis) for detailed explanation. ***A****: The threshold value (horizontal line) was set at 250 N, which was just above the maximum offset drift of approximately 200 N. The cycle detection point, indicated with • and defined as the first sample of the descending force curve below the threshold, is shown for the three steps.* ***B****: The minimum of each step, indicated with x, was detected as the lowest force between two consecutive cycle detection points. A first order polynomial was fitted between two consecutive force minima (— ; ––·) for step two and step three.* ***C****: For each x-value (time), the y-value (force) of the polynomial was subtracted from the corresponding raw force data point to get the offset drift-corrected vertical force.*

The accuracy of the Pedar Mobile system measurements after correction for offset drift was determined by the absolute and relative error of measurement. The absolute error was calculated as the difference between Kistler output data and Pedar Mobile output data; the relative error expressed the absolute error as a percentage of the force measured with the Kistler platform. Four variables that are important for weight bearing measurements were compared between the Kistler and Pedar system: (1) the first peak force in the M-shaped ground reaction force-time curve (N); (2) the second peak force in the ground reaction force-time curve (N); (3) the vertical force impulse (area under the force-time curve, Ns); (4) the step duration (s). The mean and standard deviation were calculated for each of the paired data from the Pedar system and Kistler force plate. Paired t-tests were done using SPSS 10.1.0 for Windows. The level of significance for all tests was set at 5%.

3.4 Results

Amount and type of drift

The amount of drift found over 7 h for the dynamic and static measurements is presented in Table 2. The data generally showed minor drift for the first 3 h and an increase in drift after hour 4. The individual drift data for the dynamic measurements showed a relatively small drift for the first 4 hours for subjects 1, 2, and 3, while drift increased from hour 4 to hour 7 (Fig. 2); these latter subjects were the three females with insoles W. The two male subjects (4 and 5), wearing insoles X, showed a larger drift which started at the beginning of the measurements. The mean drift after 7 h was 132 N (14%) and 141 N (16%) for the walking and standing experiments, respectively.

Table 2. Mean (standard deviation) of the absolute drift, and the relative drift found over seven hours of the dynamic and static measurements with the Pedar Mobile system.

	Hour 1	Hour 2	Hour 3	Hour 4	Hour 5	Hour 6	Hour 7
Walking							
Absolute drift[1] (N)	10.41	16.68	20.53	36.71	55.07	80.84	132.04
	(20.77)	(29.03)	(33.22)	(35.27)	(41.68)	(39.41)	(40.03)
Relative drift, Fp1 (%)	1.39	2.21	2.68	4.48	6.59	9.33	14.17
Relative drift, Fp2 (%)	1.27	2.06	2.55	4.39	6.48	9.25	13.92
Standing							
Absolute drift[2] (N)	17.74	21.29	30.69	51.01	59.08	100.08	141.57
	(31.41)	(30.39)	(33.24)	(43.10)	(41.85)	(35.04)	(35.14)
Relative drift (%)	2.38	2.85	3.99	6.31	7.28	11.60	15.60

[1] Force measured during swing phase; [2] Force measured during right insole unloaded; Fp1 = first peak force; Fp2 = second peak force

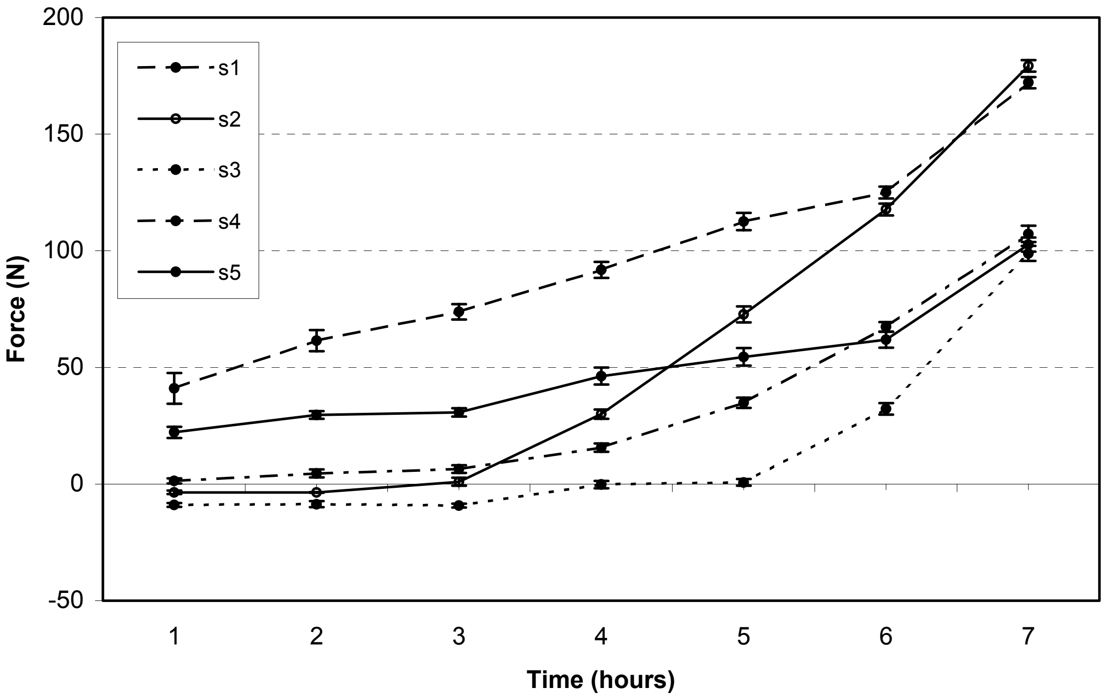

Figure 2. The drift of Pedar force data for the five subjects (s1 to s5) over 7h, measured by the Pedar Mobile system during the swing phase of the dynamic measurements.

The mean force curves for standing on the right leg (insole loaded) and for the right leg in the air (insole unloaded) showed a similar drift over 7 h (Fig. 3). At hour 1 the difference between the insole loaded and the insole unloaded was 728 N. At hour 4 and hour 7 the differences were 757 N and 758 N, respectively; these differences were not significantly different from hour 1 ($p = 0.630$, and $p = 0.203$). Because there was no significant change in the difference between the measured force during loading and unloading of the insole between the measurements, this indicates that the drift was predominantly an offset drift.

Accuracy of the Pedar Mobile system with offset drift correction

After offset drift correction using the drift correction algorithm, the differences between Kistler and Pedar Mobile data were relatively small for the second peak in the ground reaction force-time curve. The relative errors ranged from 1.1 to 3.4%, and were not significantly different for all 7 hours (Table 3; Fig. 4). The first peak force showed larger differences, with relative errors ranging from 5 to 12%. However, only for hours 1, 2, and 3 were these differences significant. All Pedar Mobile force data were lower than the Kistler force data. The vertical force impulse data as well as the calculated step duration were not significantly different from the Kistler data.

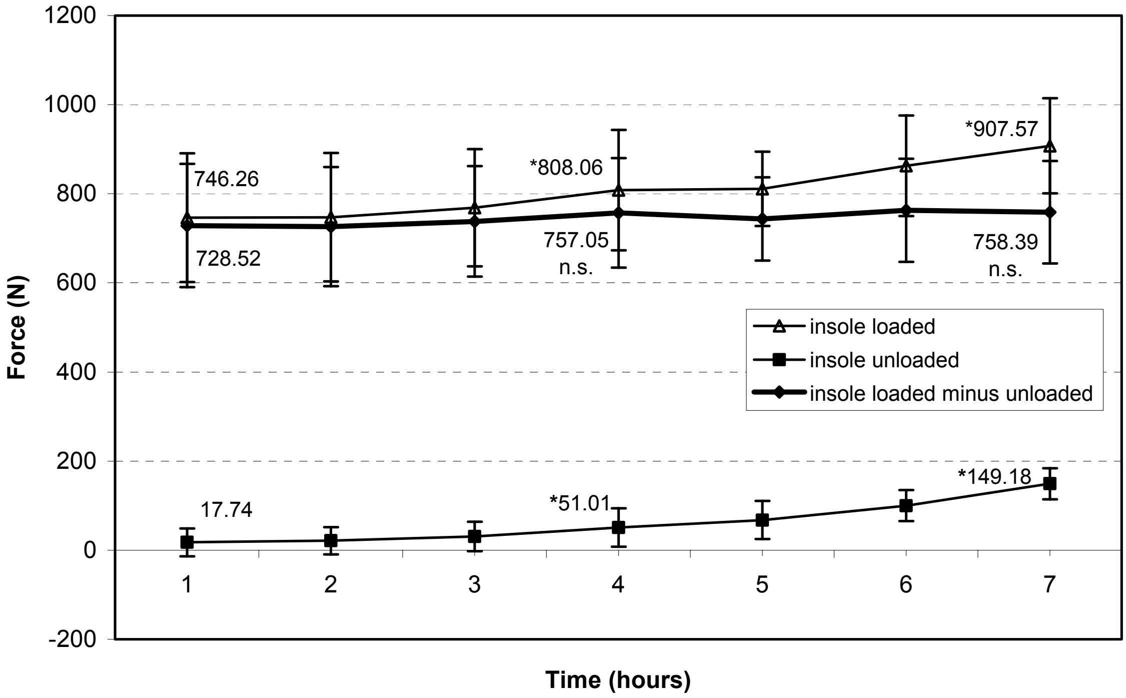

*Fig. 3. The mean force and standard deviation measured by the Pedar Mobile system during standing on the right leg (insole loaded), during right leg in the air (insole unloaded) for the five subjects over seven hours. The difference between the "insole loaded" and the "insole unloaded" curve is presented by the "insole loaded minus insole unloaded" curve. * = significant difference from hour 1; n.s. = non-significant difference from hour 1.*

3.5. Discussion

This study investigated the amount and type of drift when the Pedar Mobile system was active for 7 h, as well as the validity of the Pedar mobile system to measure vertical force over a long-term period when corrected for offset drift.

The Pedar data showed a drift of up to 14% when the system was active for a period of 7 h. During the dynamic measurements, the pair of Pedar insoles used by the three female subjects generally showed less drift for the first 3 h than the pair of insoles used by the two male subjects, while after 3 h the drift increased similarly in both groups (Fig. 2). These differences between insoles might arise because the insoles used by the females were new, whereas those of the males had been used for more than 6 months.[7] Hsiao et al.[13] found that the accuracy and precision of a one-year-old insole were inferior to that of a new pair. In addition, in the present study the small differences between the male and female shoe types and/or the greater body weight of the male subjects may explain the different drift values.[2]

Table 3. Comparison of the mean first and second peak force, vertical force impulse, and step duration over seven hours, measured with a Kistler platform and the Pedar Mobile system. Pedar Mobile force data are corrected for drift using the correction algorithm.

	Hour 1	Hour 2	Hour 3	Hour 4	Hour 5	Hour 6	Hour 7
1st peak force (N)							
Kistler (sd)	833.88 (178.94)	838.54 (185.77)	835.14 (183.98)	847.79 (178.33)	836.23 (172.89)	837.10 (178.44)	843.78 (170.49)
Pedar (sd)	739.42 (150.19)	737.85 (153.30)	744.19 (141.17)	782.02 (131.86)	780.79 (127.81)	785.37 (130.02)	799.70 (118.65)
% difference	11.3	12.0	10.9	7.8	6.6	6.2	5.2
Mean difference (95% C.I.)	94.46 (32.6-156.3)	100.69 (29.1-172.3)	90.95 (31.7-150.2)	65.76 (-3.3-134.9)	55.44 (-9.6-120.5)	51.7 (-15.8-119.3)	44.1 (-29.4-117.5)
p-value[a]	0.013 *	0.017 *	0.013 *	0.057	0.077	0.101	0.171
2nd peak force (N)							
Kistler (sd)	822.48 (188.30)	814.77 (197.60)	812.47 (194.40)	816.10 (190.47)	807.12 (173.28)	805.20 (179.90)	825.71 (190.22)
Pedar (sd)	810.51 (125.33)	793.30 (128.18)	785.13 (120.04)	799.94 (107.19)	794.85 (105.08)	792.75 (108.54)	816.32 (108.54)
% difference	1.5	2.6	3.4	2.0	1.5	1.6	1.1
Mean difference (95% C.I.)	11.97 (-90.8-114.8)	21.47 (-81.4-124.4)	27.34 (-87.9-142.9)	16.16 (-108.5-140.9)	12.27 (-104.3-128.9)	12.45 (-119.8-144.7)	9.39 (-127.7-146.5)
p-value[a]	0.763	0.594	0.546	0.737	0.785	0.807	0.858
Vertical force Impulse (Ns)							
Kistler (sd)	405.78 (85.70)	390.85 (76.07)	397.28 (75.22)	399.57 (78.47)	393.51 (74.96)	391.90 (75.71)	389.64 (81.13)
Pedar (sd)	359.70 (57.69)	350.46 (81.02)	353.57 (82.53)	368.99 (78.19)	365.79 (76.44)	365.87 (74.99)	368.13 (81.64)
% difference	8.1	10.3	11.0	7.7	7.0	6.6	5.5
Mean difference (95% C.I.)	46.08 (-36.9-129.1)	40.39 (-17.0-97.8)	43.7 (-11.8-99.2)	30.6 (-35.0-96.1)	27.7 (-31.4-86.8)	26.0 (-38.5-90.6)	21.5 (-44.0-87.0)
p-value[1]	0.175	0.122	0.094	0.265	0.263	0.326	0.413
step duration (s)							
Kistler (sd)	0.70 (0.03)	0.70 (0.03)	0.71 (0.05)	0.71 (0.04)	0.71 (0.04)	0.71 (0.04)	0.70 (0.03)
Pedar (sd)	0.67 (0.15)	0.70 (0.18)	0.70 (0.18)	0.72 (0.16)	0.72 (0.14)	0.71 (0.15)	0.71 (0.16)
% difference	4.4	0.1	2.5	-1.5	-2.4	-0.1	-2.0
Mean difference (95% C.I.)	0.04 (-0.16-0.24)	0.00 (-0.16-0.16)	0.02 (-0.13-0.17)	-0.01 (-0.16-0.14)	-0.02 (-0.17-0.14)	0.00 (-0.13-0.13)	-0.01 (-0.15-0.13)
p-value[a]	0.598	0.992	0.755	0.860	0.783	0.988	0.794

[a] 5% significance level; * = significant

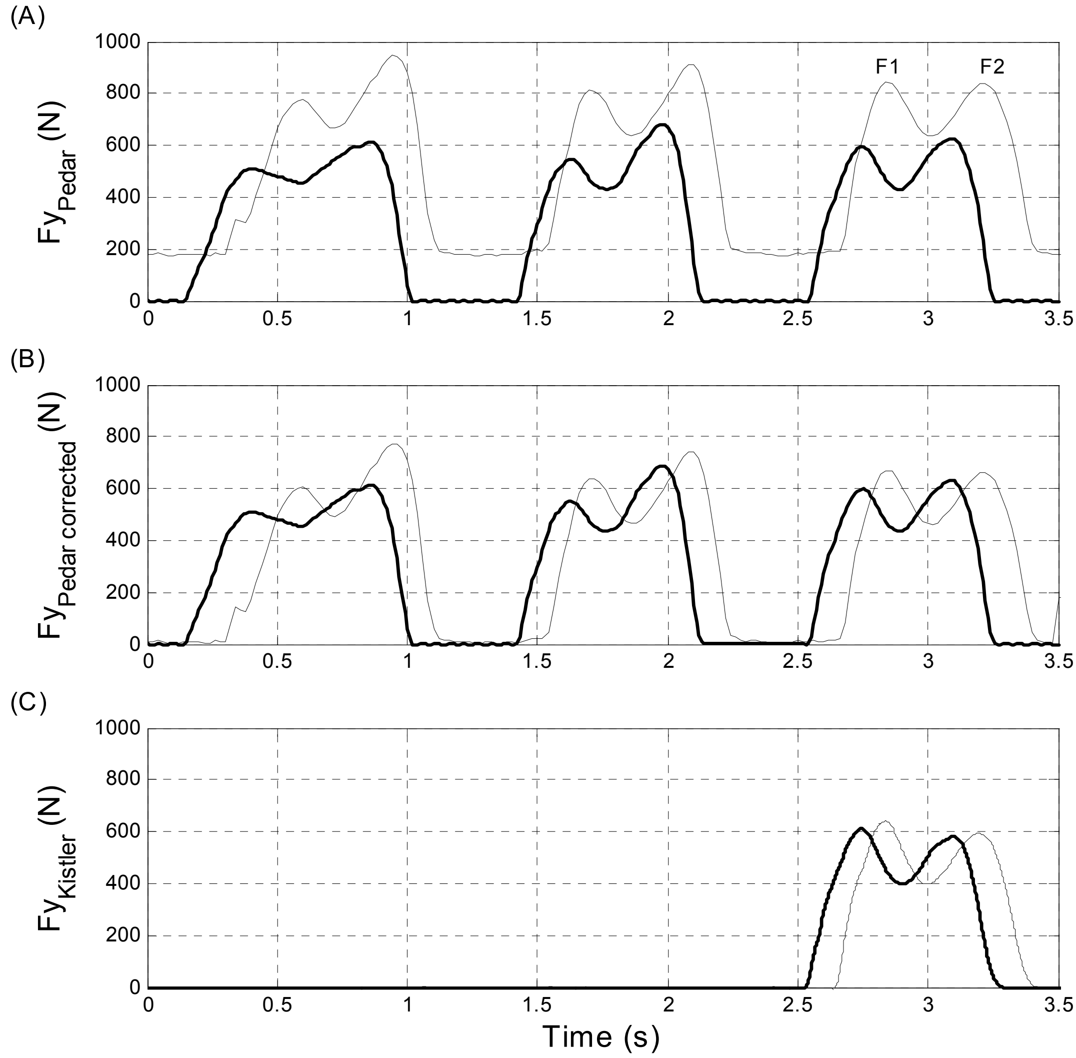

*Figure 4. Example of the offset drift correction of Pedar force data using the correction algorithm. **A**: Pedar force data before offset drift correction of the first three right footsteps of subject 2, recorded at hour 1 (▬) and hour 7 (—). **B**: The same Pedar force data after offset drift correction. **C**: Kistler force data of the third right footstep. F1 = first peak force; F2 = second peak force.*

The somewhat larger drift in the static compared to the dynamic experiments (Table 2) might be explained by the measurement protocol, in which the dynamic trials were performed directly after the subjects had mainly been sitting with minimal sensor loading. The duration of sensor loading could also have influenced the measurements during standing.[13,19] In the present study there was a relative sensor drift after 3 h of 3 to 4%, which is smaller than the 8 to17% reported by Arndt.[2] This might be mainly related to the fact that Arndt studied two subjects walking constantly for 3 h wearing military boots and carrying a heavy load (49% of body weight), while our subjects where predominantly sitting.

Systematic comparison of static loading and unloading throughout the 7-h measurement period showed that the amount of drift was the same in both conditions, and that the difference between the loaded and unloaded condition remained constant. Based on this, we concluded that the drift was predominantly an offset drift, which was essential for the validity of the drift correction algorithm.

The correction algorithm is limited to walking data. We chose this method because the risk of putting too much weight on the lower extremity during partial weight bearing is probably much higher during walking than during standing. Although the measurements in this study were done using a capacitive insole pressure system, the drift correction method is independent of the measurement system.

The present study showed that a good estimate of the vertical force during walking can be obtained with the Pedar Mobile system during a long-term period after using the drift correction algorithm (Table 3). No significant differences were found between the Pedar and the Kistler data concerning the second peak in the ground reaction force, the vertical force impulse, and the step duration. The Pedar Mobile data systematically underestimated the first peak in the ground reaction force (5 to 11 %). This underestimation is in line with studies by Barnett et al.[3] and Boyd et al.[6], who reported 14 to 16% lower Pedar values compared to force plate data. For the second peak in the ground reaction force, the accuracy found in the present study (relative errors of 1.1 to 3.4%) was higher than that reported by Barnett et al.[3] (3 to 11%) and Boyd et al.[6] (6%). The acclimatization period of 1 hour, which we used to correct for negative drift (5 to 8%) before the measurements, might explain the higher accuracy in the present study. Although Barnett et al.[3] mentioned an 'acclimatization' in their study procedure, no specific information was given regarding duration or zero settings.

The underestimation of the first and second peak force in the Pedar Mobile system compared to the Kistler force data might be related to the way matrix sensors measure force compared to force platforms. The matrix sensors of the Pedar Mobile system measure the force perpendicular ('normal force') to each sensor.[16,17,19] Therefore, especially during heel-strike and toe-off, the force vector of each sensor is different from the vertical force vector of the force platform. Generally, the sensors of the insoles are positioned more parallel to the force platform during toe-off compared to heel-strike, which might explain the higher accuracy of the second peak force measurements. The step duration measured by Pedar Mobile showed a high accuracy, comparable with data reported by Barnett et al.[3] The vertical force impulse data were mainly influenced by the differences in the first peak force, because the differences in the second peak force and step duration were relatively small (Table 3).

Insole pressure measurements may be influenced by the type of footwear. For example, Barnett et al.[3] found differences in vertical force data between running shoes (soft sole) and leather shoes (hard sole). However, other studies reported no differences in vertical force measurements between different shoe types.[4,8,21,22] In this study, the male subjects wore a different brand of shoes than the female subjects, but both brands were running shoes. The difference in shoe type would probably only have a major influence on the insole measurements if completely different types of shoes were used.[3] However, because the same type of shoe was used in this study their influence on the force measurements is considered as negligible.

Another aspect is that insole sensors measure the “normal” force, which is not necessarily similar to the vertical ground reaction force.[16,17,19] It might be argued that the resultant force vector (F_r) is more comparable during heel-strike with the Pedar force vector than the vertical force (F_y). However, data presented by Winter[29] show that during walking the mean F_y is 100% of body weight, and the mean F_x is 15 to 20% of body weight. Therefore, the calculated F_r would be 101 to 102% of body weight and thus does not differ much from the vertical force.

The lower force values measured with the Pedar system compared to the Kistler force plate could be due to the lower sampling rate, which was 99 Hz for the Pedar system and 500 Hz for the Kistler force plate. Visual inspection of the ground reaction force-time curves (see Fig. 4) indicated that, despite this difference, the force-time curves of both systems showed similar shapes for the first and second peak force, indicating that the lower sampling frequency of the Pedar system did not influence the measured peak forces.

The present study indicates that the Pedar Mobile system can be used in both clinical and research settings to evaluate vertical ground reaction forces during long-term periods. With the Pedar Mobile system (using humidity-proof insoles, a zero setting after 1 h of usage, and the correction algorithm) we found errors of maximally 12% after a 7-h period (for the first peak in the ground reaction force) compared to Kistler ground reaction force data; the errors were only around 1 to 3% for the second peak in the ground reaction force. We believe that the present system can be used in a wide range of long-term measurement studies, such as studies on postoperative weight bearing measurements of orthopedic patients (e.g. total hip arthroplasty, osteotomies and fractures of lower extremity, cruciate ligament reconstruction).

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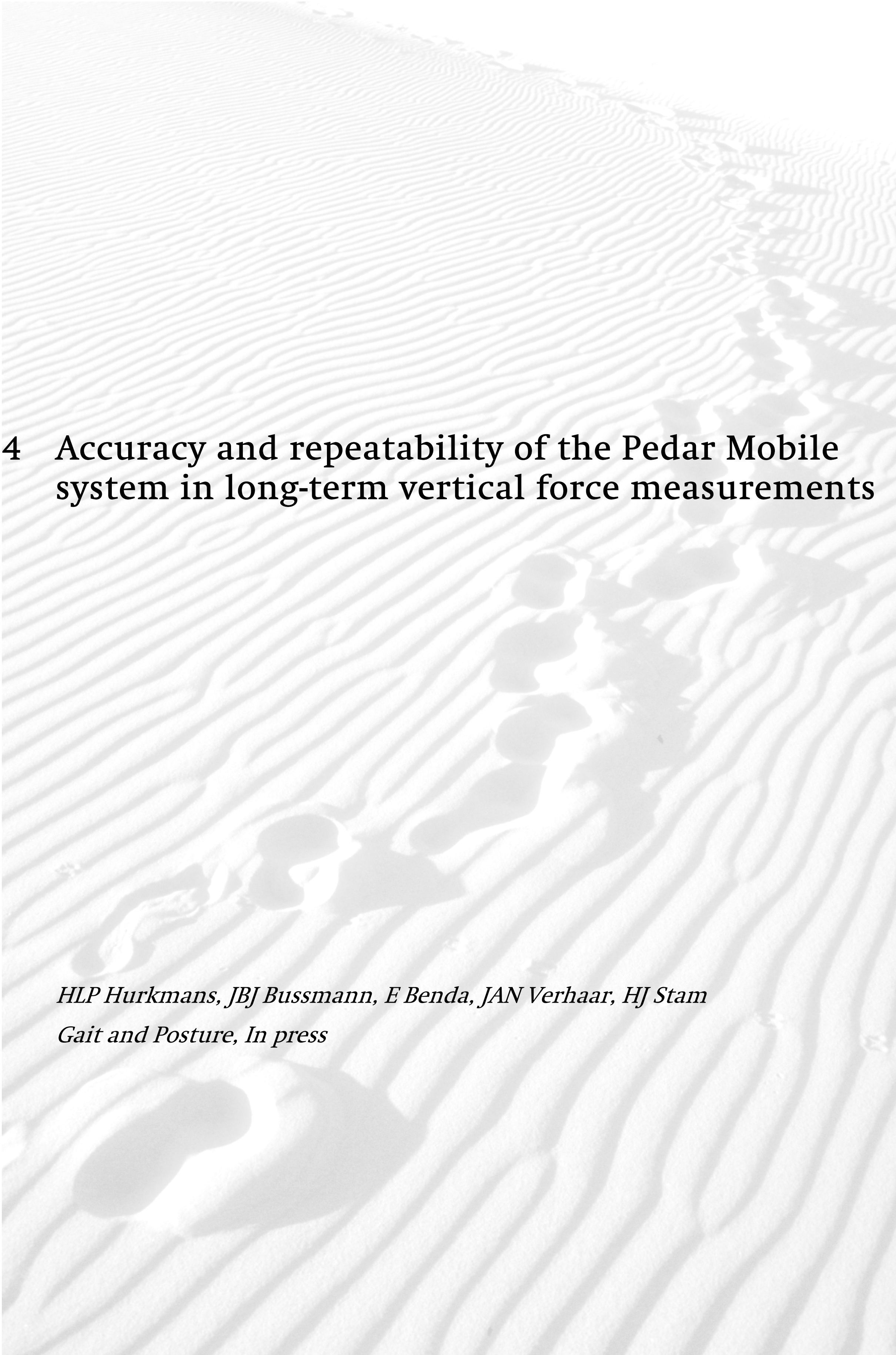

4 Accuracy and repeatability of the Pedar Mobile system in long-term vertical force measurements

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Gait and Posture, In press

4.1 Abstract

Portable insole pressure systems can be used to measure the vertical force during long-term (hours) measurements to determine the patient's amount of weight bearing during daily activities in the hospital and at home. Especially for long-term measurements the amount and duration of loading pressure insoles can have a large influence on the accuracy, as previous studies found a time-dependent behavior after a relatively short period (minutes) of constant loading. Therefore, this study assessed the accuracy and repeatability of a portable capacitive insole system (Pedar, Novel GmbH) to measure vertical force during long-term loading. Static loading experiments were performed during which the Pedar insoles were loaded with 5 N/cm^2 and 10 N/cm^2 for 7 hours. Dynamic loading experiments were performed with one Pedar insole which was cyclically loaded with 300 N, 500 N and 1000 N during two sessions of 1200 load cycles. The static and dynamic experiments were repeated three days later. Accuracy, due to offset drift, decreased in time during the start of the static experiments (% error: -1.9% to 0.3% at hour 0, 26.3% to 34% at hour 7). The % error for the dynamic experiments ranged from -16% to -19%, from -3% to -7%, and from -8% to ~0% when the insole was loaded with 300 N, 500 N, and 1000 N, respectively. The amount of drift ranged from 12 N to 62 N for the 500 N and 1000 N loads, respectively. The mean day-to-day percentage difference for the static and dynamic experiments ranged from -2.3% to 0.5%, and from -2.9% to 3.0%, respectively. The results indicate that drift correction is necessary for accurate assessment of vertical force by the Pedar Mobile system to determine the amount of weight bearing during long-term measurements.

Keywords: Pedar Mobile system; accuracy; repeatability; long-term measurements

4.2 Introduction

Partial weight bearing is commonly instructed for 6-12 weeks for patients with a lower limb fracture or arthroplasty, because weight bearing higher than the treating surgeon has allowed can lead to non-union of bone fragments or instable implants.[3,5,17] Long-term measurement of weight bearing in the hospital and at the patient's home during daily activities can provide more relevant information about the patient's loading pattern (e.g. average or extreme peak loads during a day) than the assessment of weight bearing in a laboratory, where only a few steps can be measured and evaluated.

Portable insole pressure systems can be used to measure the vertical force during weight bearing.[6,11,12,15] However, only a few studies described portable insole devices that can record in-shoe pressures or ground reaction forces over a long-term period.[1,16] To our knowledge, no studies have investigated the validity and reliability of these systems to measure the vertical force over a long-term period. The Pedar Mobile system (Novel GmbH, Munich, Germany), a portable in-shoe pressure system using 99 capacitive sensors per insole, can record vertical force data for a maximum of one hour when continuously measuring with two insoles at a sample rate of 50 Hz. The restrictions of the Pedar system for mobile measurements during several hours are that the recording period is limited due to the maximum data storage capacity of the largest PCMCIA card (40Mb: 60 minutes data collection at 10.000 samples/sec) used by the Pedar system, and because the largest Pedar battery (2100mAh NiMH) provides power for a maximum of one hour. To perform long-term evaluation of weight bearing we adapted the Pedar Mobile system by connecting an electronic device to the Pedar box that works as an automatic start-stop trigger so that data are only recorded during standing and walking, and by using a custom-made battery-unit (consists of two Sony NP750 Li-ion batteries) which supplies the Pedar system power for 3.5 hours.

During long-term insole measurements the accuracy and repeatability may, besides factors such as temperature and humidity, particularly be influenced by the amount and duration of loading.[7-10,13] Previous bench test studies reported time-dependent behavior of capacitive insoles in which sensor values increased by 3.5 - 4.5% after 10 -15 minutes of continuous loading of the insoles.[10,13] Especially when the insoles are continuously loaded for a much longer period (hours) this drift may be even more significant. Besides the amount of drift during long-term measurements, we were also interested in the type of sensor drift. When offset drift occurs the discrepancy between the measured value (Pedar) and the actual value (testing device) is independent from the actual value, thus this difference will be constant. Therefore, offset drift is easy to correct for. This is in contrast with gain drift in which the discrepancy between the measured value (Pedar) and the actual value (testing device) is dependant from the actual value and, therefore, this difference will not be constant. No studies were found regarding the effect of long-term static and/or dynamic loading on the amount and type of sensor drift of capacitive pressure insoles.

The purpose of this study was to assess the accuracy and repeatability of the Pedar Mobile system to measure vertical force during long-term static and dynamic loading by conducting a series of bench tests. In addition, the type of drift was investigated during a long-term static loading experiment.

4.3 Materials and Methods

4.3.1 Materials

The Pedar Mobile system is a matrix insole system in which vertical (columns) and horizontal (rows) metal strips are fixed to either side of a dielectric material. At each intersection point of these rows and columns there is a capacitance sensor. The sensors are placed between two layers of polyethylene, which provides insensitivity to humidity within the shoe, and are covered on both sides with artificial leather. Each insole consists of 99 sensors, which are equally spread over the insole area, and is approximately 2 mm thick. The Pedar humidity-proof left and right insoles type W (insole area of 155.42 cm^2) and type V (insole area of 139.31 cm^2) were used for the tests.

For static loading a Trublu calibration device (Novel GmbH, Munich, Germany) was used. The digital manometer, GDN 14 AN (Greisinger Electronic GmbH, Regenstauf, Germany) placed on the calibration device has an accuracy of 0.01 bar (Fig. 1). For dynamic loading an LRX 2.5 kN single column, bench mounted materials testing system (Lloyd instruments Ltd, Hampshire, UK) was used (Fig. 2).

4.3.2 Methods

The insoles were calibrated before each measurement using the Trublu calibration device. Calibration curves were generated for each sensor using the pressures 4, 7 and 10 to 60 N/cm^2 with intervals of 5 N/cm^2. A zero measurement was performed at t = -1 and at t = 0 hour, which means that the insoles were lying unloaded on a table and the sensors were set to zero by using the Novel GmbH software.

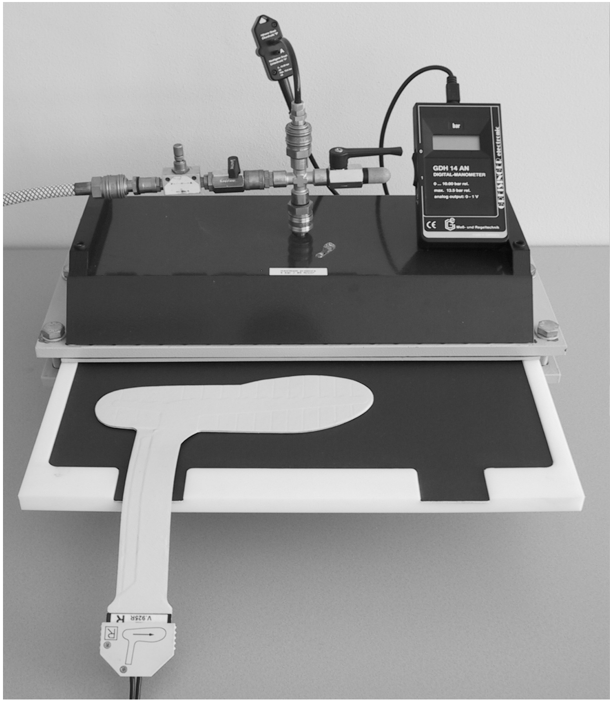

Figure 1. The Trublu rubber bladder calibration Device *(Novel GmbH, Munich, Germany) with the manometer (Greisinger Electronic GmbH, Regenstauf, Germany) and a Pedar insole.*

Figure 2. The dynamic loading device (Lloyd *instruments Ltd, Hampshire, UK) with a Pedar insole placed between two steel plates.*

The second zero measurement (at hour 0) was done and recommended by Novel GmbH because the Pedar system reaches a thermodynamic equilibrium after one hour. After the second zero measurement the static or dynamic measurements were started. Because the measurements were performed in a laboratory we used the Online setup and not the Mobile setup of the system.

Static long-term loading experiment

In the static experiment the accuracy of the Pedar system was investigated by applying a load for 7 hours on the insoles. Left and right insole were placed in the Trublu calibration device and continuously loaded with a pressure of 5 N/cm^2 for 7 hours. Data were collected for two seconds at 0, 10, 20 and 60 minutes, and subsequently every hour. The measurements at 10 and 20 minutes were performed to compare the results with previous insole loading experiments.[10,13] To investigate whether the type of drift is an offset drift the continuous load of 5 N/cm^2 was temporarily increased by 5 N/cm^2 for two seconds every hour, and data were also collected during these two seconds. Although the load is not actually kept constant over the entire 7 hours, we do not think that the 2 seconds increase in load will influence the static test because it is a very short time period to initiate a time-dependant effect. This experiment was repeated three days later, to determine day-to-day repeatability. The same protocol, with the exception of data collection at 10 and 20 minutes, was also used with a load of 10 N/cm^2, which was temporarily increased by 10 N/cm^2 for two seconds every hour. Left and right Pedar insoles type W, with an area of 155.42 cm^2 each, were used in the static measurements with 5 N/cm^2 and 10 N/cm^2 pressure load which equals a total loading force of 777.1 N and 1554.2 N, respectively. Left and right Pedar insoles type V (with an area of 139.31 cm^2 per insole) were used in the static measurements with 10 N/cm^2 pressure load which equals a total loading force of 1393.1 N. During all the static measurements the Pedar data were collected with a sampling frequency of 50 Hz.

Dynamic long-term loading experiment

The accuracy of the Pedar system during long-term dynamic loading was investigated by placing the right Pedar insole, type W, between two steel plates mounted on the Lloyd bench-testing device (Fig. 2). The insole was then loaded for 1200 cycles (session 1) with 300 N (load cycle: two seconds load-on, and one second load-off), using a loading speed of 1 mm/sec. After this the insole was not loaded for 3 hours and then again loaded for 1200 cycles with 300 N (session 2). The Pedar system was active during the entire period of about 8 hours. Data were recorded during the first 10 cycles and then after every 100 cycles (12 data collection periods in total) for 10 cycles at a sampling rate of 50 Hz by the Pedar system, and at 20 Hz by the Lloyd bench-testing device. The measurements of the Lloyd device and the Pedar system were synchronized by a pulse tone which was generated every 100th cycle by a PC connected to the Lloyd device. At that point the Pedar measurement was also started. During the period between the two loading sessions the Pedar force was measured for 10 seconds every hour at 50 Hz. This procedure was repeated three days later. The protocol was also performed with a cyclic load of 500 N and 1000 N.

4.3.3 Data analysis

Both the Pedar Mobile data and the Lloyd bench-testing device data were filtered using a low pass Butterworth filter with a cut-off frequency of 40 Hz. The mean force was calculated from the two seconds of static data recording and the 10 dynamic loading cycles, for both the Pedar system and the test devices.

The *accuracy* of the Pedar system was determined by the per cent error of measurement which was calculated using the following equation: $((\text{Output}_{\text{Pedar}} - \text{Input}_{\text{Test device}}) / \text{Input}_{\text{Test device}}) \times 100\%$; Test device = Trublu calibration device or Lloyd bench-test device. The *drift* was defined as an undesired change in output signal (force) over a period of time that is unrelated to the input (load). The *absolute drift* during the static experiments was determined by the difference between the Pedar values at hour 0 and the Pedar output at hour 1 to 7. The *absolute drift* during the dynamic experiments was determined by the Pedar force values during the unloading periods of the insole. The *relative drift* for the static measurements was calculated according to the equation: ((mean Pedar value at hour x – mean Pedar value at hour 0) / mean Pedar value at hour 0) x 100%, where x is 1 to 7. The *relative drift* for the dynamic measurements was calculated according the equation: ((mean Pedar value of y^{th} 10 cycles – mean Pedar value of 1^{st} 10 cycles) / mean Pedar value of 1^{st} 10 cycles) x 100%, where y is 2 to 12.

Subsequently, the type of drift (*offset* drift or *gain* drift) was assessed because offset drift can easily be corrected for. To determine the type of drift, the absolute drift during the continuous load was subtracted from the absolute drift measured during the temporarily increased load. If this difference was constant over time, then the drift would be an offset drift and not a gain drift.

The repeatability of the Pedar Mobile system was assessed by determining the percentage difference of the Pedar force measurements between day 1 and day 2 at hour 0 to hour 7 for the static experiments, and by determining the percentage difference between day 1 and day 2 at collection period 1 to 12 for the dynamic experiments. The mean percentage day-to-day difference was then calculated from the 7 hours of the static experiment and the 12 collection periods of the dynamic experiments.

4.4 Results

Static long-term loading experiment

The per cent error of measurement of the insoles during the static experiments ranged from -2.2% and 0.3% at hour 0 (Table 1). From hour 1 to 7 the per cent error of measurement varied from 10 to 43% depending on the duration of loading and applied load. The relative drift after ten and twenty minutes was 9 - 9.5% when loading the Pedar insoles with a static load of 5 N/cm^2, after which a more steady increase in drift was found of 12.3% and 12.6% (left and right W type insole) at hour 1 to a drift of 26.3% and 33.8% at hour 7 (Fig. 3). When using a static load of 10 N/cm^2 larger differences were observed in the drift over time between the insoles. The two type V insoles showed less increase in drift than the W type insoles, and also a larger difference in drift was observed between the two V type insoles. The W type insoles showed a similar increase in drift which was larger compared to drift found during the 5 N/cm^2 static load. The mean percentage day-to-day difference was -2.3% (range -3.7 – 0.4) and 0.5% (range -0.3 – 1.14) for the left and right insole W, respectively.

Table 1. Measurement error (%) of the Pedar insoles at hour 0 - 7 for the static loading experiments at day 1 and day 2.

Static Load (N/cm^2)				**5**				
Time (hour)	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**
W-Left insole - day 1 Per cent error (%)	-1.9	10.2	14.1	17.0	18.4	20.0	22.2	23.9
W-Right insole - day 1 Per cent error (%)	-1.5	10.9	15.3	19.7	22.5	25.3	29.0	31.8
W-Left insole - day 2 Per cent error (%)	-2.2	11.3	15.9	20.5	22.7	24.0	26.7	27.0
W-Right insole - day 2 Per cent error (%)	-2.2	10.2	14.0	18.7	22.2	24.7	29.3	31.0
Static Load (N/cm^2)				**10**				
Time (hour)	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**
W-Left insole Per cent error (%)	0.5	18.6	23.8	28.0	31.9	34.6	36.0	41.9
W-Right insole Per cent error (%)	0.0	13.9	21.2	24.9	30.5	34.0	37.3	43.2
V-Left insole Per cent error (%)	0.3	11.1	17.5	22.5	26.2	30.3	32.6	34.6
V-Right insole Per cent error (%)	-1.0	5.8	8.4	10.5	11.7	13.3	14.1	14.6

The difference in measured force between the temporarily increased load and the continuous load (10 minus 5 N/cm^2, and 20 minus 10 N/cm^2, respectively) for all tested insoles was constant over time after hour 1, which indicated that the found drift was an offset drift (Fig. 4). During the first hour the continuous load curves showed a larger increase in force than the temporarily increased load curves. This resulted, therefore, in a larger difference compared to hour 1 to 7.

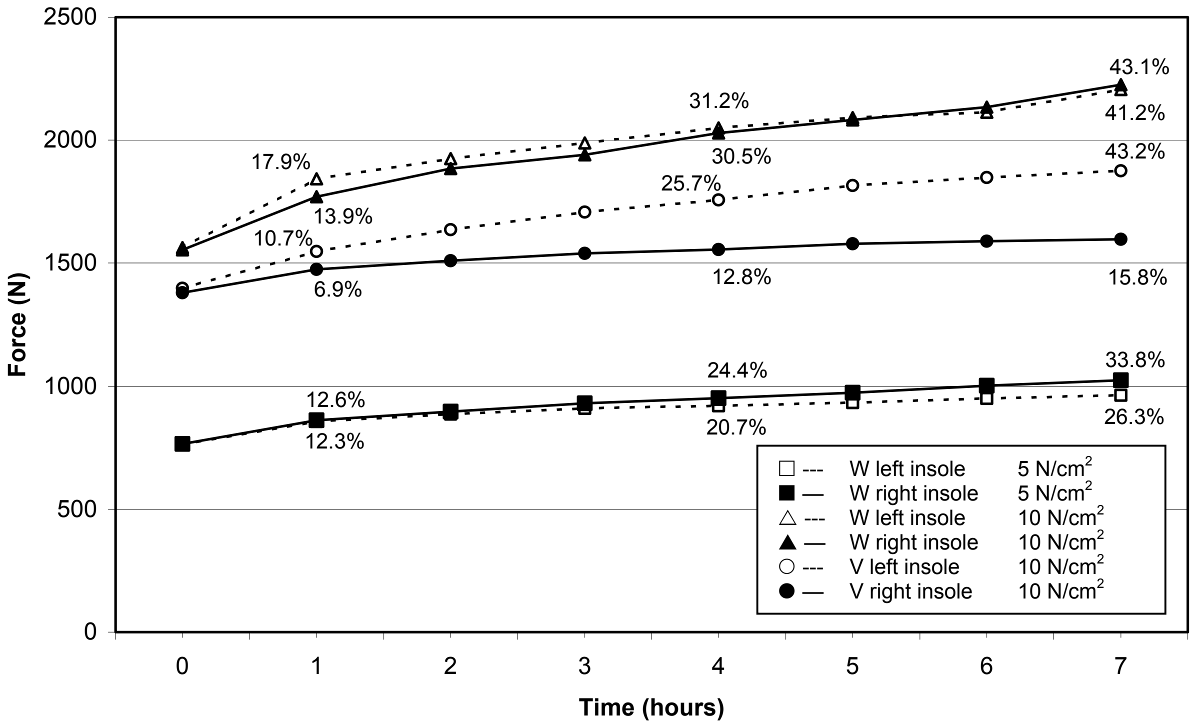

Figure 3. The amount of drift over seven hours for static load 5 N/cm^2 and 10 N/cm^2.

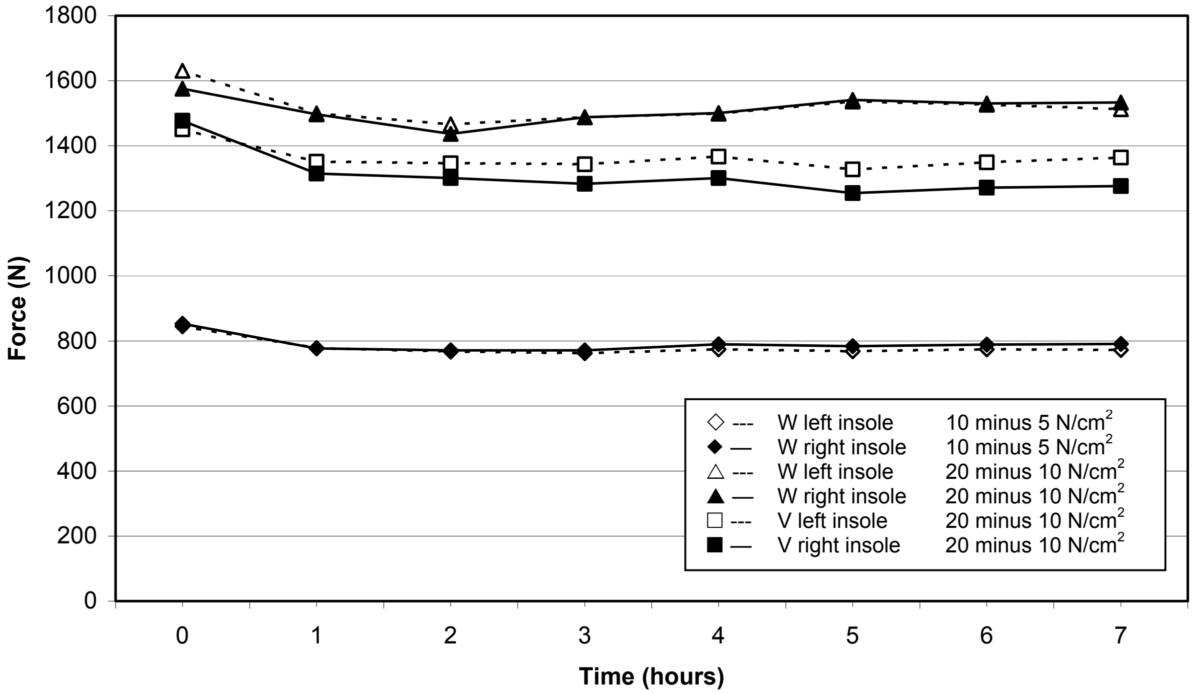

Figure 4. The curves represent the differences between the Pedar output during the two-seconds increase in load and the constant load (10 minus 5 N/cm^2, or 20 minus 10 N/cm^2) for hour 0 to 7, to assess the of type of drift.

Dynamic long-term loading experiment

The per cent errors for the Pedar data during the dynamic loading experiments were much larger for the 300 N load than for the 500 N and the 1000 N cyclic load, during both sessions (Table 2). For the 300 N load the difference between the Pedar data and the loading device data remained more or less the same (Fig. 5). The measured force showed an increase over time with the 500 N load, leading to smaller errors with the applied load. A larger increase in force was observed with the 1000 N cyclic load, which eventually led during session 2 to larger values than applied by the loading device. The measured force showed a more rapid rise during the first 100 cycles with the 500 N and 1000 N cyclic loads, followed by a gradual rise over the remaining load cycles.

Table 2. Measurement errors of the Pedar insoles during the 12 collection periods of the dynamic loading experiment at day 1 and 2, for session 1 and 2, and for the 300 N, 500 N, and the 1000 N load.

Dynamic Load (N)						**0 - 300**						
Collection period (n)	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**
Day 1, session 1												
Per cent error (%)	-19.3	-18.5	-18.4	-18.3	-17.9	-18.0	-17.5	-17.5	-17.1	-16.7	-16.5	-16.4
Day 1, session 2												
Per cent error (%)	-20.3	-18.8	-18.7	-18.0	-18.2	-18.0	-17.5	-17.3	-17.6	-17.5	-17.3	-17.3
Day 2, session 1												
Per cent error (%)	-22.0	-20.9	-20.8	-20.5	-20.3	-20.1	-20.0	-19.8	-19.6	-19.4	-19.0	-19.0
Day 2, session 2												
Per cent error (%)	-22.3	-21.0	-20.5	-20.3	-20.1	-19.9	-19.7	-19.4	-19.4	-19.3	-19.1	-18.9
Dynamic Load (N)						**0 - 500**						
Collection period (n)	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**
Day 1, session 1												
Per cent error (%)	-7.3	-7.7	-6.9	-6.4	-5.8	-5.4	-4.6	-4.5	-4.0	-3.6	-3.1	-2.8
Day 1, session 2												
Per cent error (%)	-8.2	-5.0	-4.1	-3.4	-3.0	-2.6	-2.4	-2.4	-2.1	-1.2	-1.1	-1.1
Day 2, session 1												
Per cent error (%)	-13.7	-10.3	-9.9	-9.1	-8.6	-8.4	-8.0	-7.5	-7.2	no data	-6.2	-5.9
Day 2, session 2												
Per cent error (%)	-9.3	-5.8	-5.1	-4.7	-4.6	-4.4	-3.8	-4.0	-3.6	-3.3	-2.8	-2.3
Dynamic Load (N)						**0 - 1000**						
Collection period (n)	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**
Day 1, session 1												
Per cent error (%)	-7.9	-5.2	-4.8	-3.4	-3.1	-2.7	-2.2	-1.8	-1.1	-0.9	-0.1	-0.3
Day 1, session 2												
Per cent error (%)	-4.9	-2.3	-1.1	-0.4	1.0	1.5	2.1	2.7	3.2	3.5	4.0	4.6
Day 2, session 1												
Per cent error (%)	-7.7	-4.5	-3.1	-2.0	-1.2	-0.5	0.1	0.7	1.5	2.1	2.3	no data
Day 2, session 2												
Per cent error (%)	-3.9	-0.3	no data	2.4	2.8	3.1	3.7	4.4	4.9	5.6	5.8	6.0

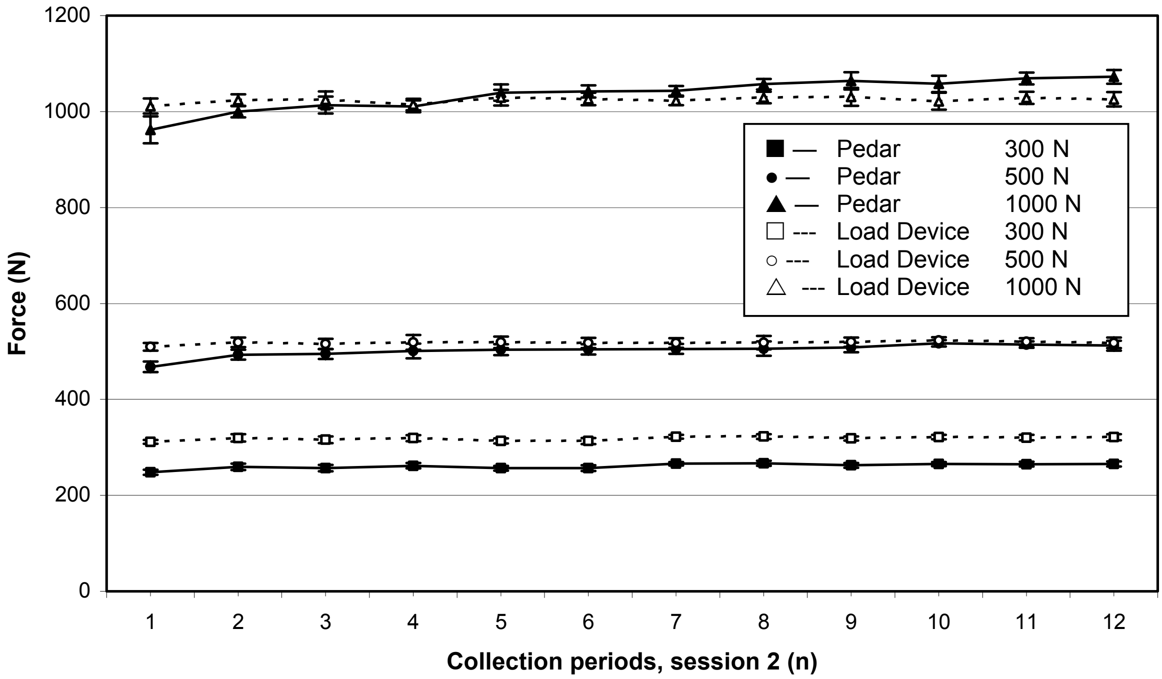

Figure 5. The differences between the measured Pedar force (N) and the Load device force (N) for the 300 N, 500 N, and 1000 N dynamic loading session 2 experiments.

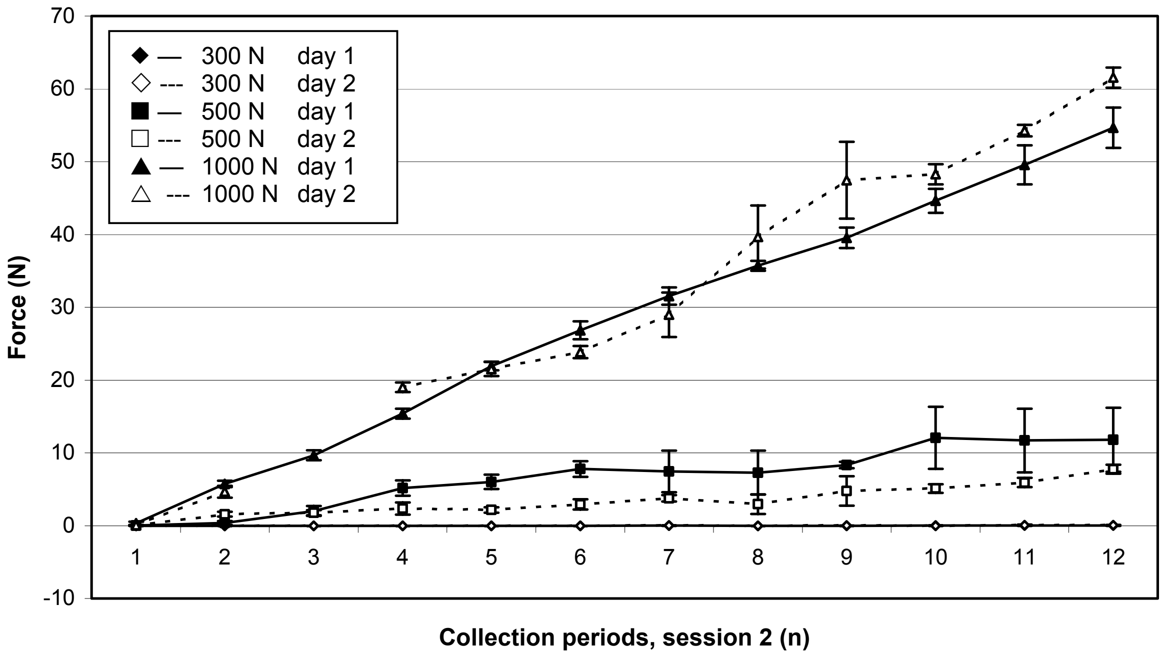

Figure 6. The relative drift found during the load-off periods of the 12 collection periods during session 2 at day 1 and day 2 for 300 N, 500 N, and 1000N presented by the load minima curves. The points excluded from the 1000 N Pedar-minima load curves on day 2 were missing data.

During the load-off periods of the dynamic experiments with 300 N load the mean total force was zero (Fig. 6). An increase in force of 10 -12 N was measured during the load-off periods at the end of session 1 and 2, respectively, for the 500 N cyclic loading experiment. The mean increase during the 1000 N was 22 - 55 N at the end of session 1 and 2, respectively. The measured force was zero during the 3-hour period between the two loading sessions, during which time the insole was not loaded. Missing data during the 500 N and the 1000 N dynamic load experiment (Fig. 6) were caused due to the fact that the Pedar system did not record data at these time events. However, this did not interfere with de testing device and therefore did not effect the loading experiment.

The mean percentage day-to-day differences for the 300 N, 500 N, and the 1000 N load at session 1 were 3% (range 1.9 - 4.4), 2.1% (range 0.5 - 4.4), and -2.9% (range -4.2 to -0.8), respectively. The mean percentage day-to-day differences for session 2 were 1.9% (range 0.1 to 3.9), 0.6% (-1.4 to 2.1), and -1.9 (range -4.0 to -0.7) for the 300 N, 500 N, and the 1000 N load, respectively.

4.5 Discussion

The present study investigated the accuracy and repeatability of the Pedar system to measure vertical force during long-term static and dynamic loading. In addition, we studied the type of drift because if the drift was an offset drift then correction of this drift would be relatively straightforward.

The accuracy of the Pedar system at the start (hour 0) of the static experiments was good with relatively small differences compared to the used loads, but from hour 1 to 7 a substantial amount of drift was found which resulted in larger inaccuracies (Table 1; Fig. 3). The largest increase in sensor output was observed during the first hour, after which the measured force showed a more gradual increase over time. During the static experiment with a 5 N/cm^2 load we also measured the drift after 10 and 20 minutes, which was 9.5% and 9.6%, respectively. This amount of drift is much higher than the 3.4% and 4.4% increase in sensor values as reported by McPoil et al.[13] and Hsiao et al.[10] Comparison of these data, however, is difficult because different measurement protocols were used. The second zero measurement after an acclimatization period of one hour (used in this study to correct for negative drift) is probably the main explanation for this difference, as the negative drift we found in earlier test studies ranged from 5-8%. The logarithmic curve of this negative drift showed the largest decrease in force (2-5%) during the first 10-15 minutes. To our knowledge, no correction for negative drift has been performed in previous studies with the Pedar system. Barnett et al.[4] mentioned an 'acclimatization' in their study procedure; however, no specific information was given regarding duration or zero measurements. If measurements are performed directly after the first zero measurement the negative drift is negligible, but for long-term measurements one should correct for this drift by performing a second zero measurement.

In our study the drift found during the static experiments showed a relatively linear pattern from hour 1 to 7 for all the tested insoles (Fig. 3). This result differed from most of the time-load curves presented by Arndt[2], which were fitted with a second order polynomial. The sensors also showed a larger drift when using a larger constant load which could be explained by creep of the insoles. In the study by Arndt[2], in which the Pedar insoles were loaded for 3 hours by two male subjects who walked on a treadmill, a similar result was found: more sensor drift for the heavier subject. Hsiao et al.[10], however, did not indicate a load effect and reported only one drift value of 4.4% after applying different pressures (30, 50, 300, 500 kPa). The variation in drift between the insoles could be explained by differences in the usage frequency, although in this study we could not make a distinction between insoles which were more or less used.[7,10]

To determine the type of drift we increased the continuous static load every hour for 2 seconds, which means that the load was not actually kept constant during the entire 7 hours and this increase could, therefore, effect the results of the static experiment. However we did not think that this would happen because it is a very short time period to initiate a time-dependant effect. Our presumption was confirmed by the dynamic test results in which the absolute error was 0 N for all used loads during the first 10 cycles of loading the insoles repetitively for 2 seconds (Table 2).

The type of drift during the static experiment was found to be an offset drift because the difference in sensor output measured every hour between the continuous load and the temporarily increased load resulted in an almost straight horizontal line (Fig. 4). From hour 0 to 1 this difference was larger compared to hour 1 to 7, because during the first hour the continuous loads (5 N/cm^2 and 10 N/cm^2) showed more increase in sensor output than the temporarily increased loads (10 N/cm^2 and 20 N/cm^2). The measurements at 10 and 20 minutes during the 5 N/cm^2 continuous load experiment indicated that this increase already occurred within the first 10 minutes, which could be the effect of deformity of the insole material (creep). A limitation in our protocol is that no measurements were done at 10 and 20 minutes during the temporarily increased loads. However, this creep effect could probably not be measured with the temporarily increased load because it only lasted for two seconds. This is supported by the fact that the 10 N/cm^2 continuous load showed the larger increase during the first hour but not the 10 N/cm^2 temporarily increased load. Therefore, from our data it can be concluded that the drift found during the entire period of 7 hours is an offset drift with the exception of the first 10 minutes. When starting long-term measurements with subjects we therefore perform a second zero measurement after the subject has worn the Pedar system for one hour. This is done to correct for the negative drift, but will also correct for creep. The offset drift found during a long-term measurement has to be corrected afterwards, for which we are now developing a drift correction program.

A reasonable degree of accuracy was found when the Pedar insoles were cyclically loaded during a long-term period with a 500 N load (% error: -1% to -8%) and with a 1000 N load (% error: -8% to 5%). The poor accuracy found with the 300 N cyclic load (% error: -22% to -16%), which produced a relatively low pressure on the W insole of 19 kPa, is comparable with the average error of 16% at 50 kPa found by McPoil et al.[13] Hsiao et al.[10] also found a low accuracy when low pressures (< 35 kPa) were applied over a short period of time.

A time-dependent increase was observed in the Pedar sensor response when higher cyclic loads were used. This increase seemed to be larger at the beginning of a cyclic loading session after which a more gradual increase occurred. Creep due to the visco-elastic properties of the insole could explain the initial increase, because almost no increase in force was observed during the load-off periods at the beginning of the loading sessions. Pitei et al.[14] also found an initial rapid rise followed by a more gradual steady increase, when cyclically loading a FSR insole. The gradual increase in sensor response in our study was larger when higher cyclic loads were used, indicating that the drift over time was load dependent (Fig 5, 6). However, when comparing loading session 2 with session 1 the drift occurred earlier at session 2 and was larger for both the 500 N and 100 N loads (Fig. 6). Besides the amount of loading, another factor seemed to have influenced the amount of drift. A temperature rise during the experiments could have influenced the measurements, although the room temperature was constant at 23.5 ^{0}C (300 N, 1000 N), and 26 ^{0}C (500 N) which lies in the recommended operating conditions (0-40 ^{0}C) reported by the Pedar manufacturer.

The Pedar insoles showed a good repeatability in measuring the vertical force as relatively small mean percentage differences were found between the two measurement days. However, one has to be aware that variation in drift between insoles can occur and that correction for offset drift has to be performed for each insole separately (Fig 3).

The present study found that long-term loading of the Pedar insoles leads to an amount of drift which was also found by Arndt.[2] Characterizing the drift as an offset drift was essential because it is relatively easy to correct for offset drift. The Pedar system can be used to perform long-term vertical force measurements in and outside the clinic. In practice this means that you have to use the Pedar Mobile system with humidity proof insoles (specifically made by Novel GmbH for long-term measurements), and a simple adaptation as we described in the Methods regarding power supply and automatic recording of vertical forces during standing and walking. Furthermore, a second zero measurement has to performed after 1 hour of usage (acclimatization period). We are currently developing a correction algorithm to correct for offset drift during data analysis. The presented results and practical issues only apply on long-term measurements. Clinical (pressure) measurements, which are mostly performed with this system, are not hindered by error caused by offset drift because these measurements are mostly performed within 5-10 minutes.

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5 The difference between actual and prescribed weight bearing of total hip patients with a trochanteric osteotomy

- Long-term vertical force measurements in and outside the hospital -

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Submitted for publication

5.1. Abstract

Background

Partial weight bearing (PWB) is generally instructed after orthopedic surgery of the lower extremity to avoid complications during the postoperative recovery period. This study evaluated the difference between actual and prescribed weight bearing for two target loads (10% and 50% of body weight (BW)) during 3 conditions: 1) in the hospital in the presence of a physical therapist (PT) (c1), 2) in the hospital without the presence of a PT (c2), 3) at the patient's home 2 weeks after discharge (c3).

Material and Methods

Fifty patients who had undergone total hip arthroplasty with trochanteric osteotomy were included and verbally instructed by a PT to perform PWB at a 10% BW target load (n = 33) or at a 50% BW target load (n = 17). The vertical force was measured postoperatively during a 5 - 6 h period on day 7 (± 2 days) in the hospital (c1 and c2), and on day 21 (± 5 days) at the patient's home (c3) using a validated insole pressure system. The mean peak load (sd) (% BW) and mean (sd) number/percentage of steps below, equal to, and above the target load were calculated.

Results

With a 10% BW target load the mean peak loads (sd) (% BW) were 19.2 (11.4), 20.0 (9.8), and 26.8 (12.8), and with a 50% BW target load the mean peak loads (sd) (% BW) were 28.1 (16.0), 32.5 (17.9), and 43.3 (15.9), for condition 1, 2, and 3, respectively. The mean (sd) percentages of steps above the 10% BW target load were 38.5% (39.7), 46.5% (36.0), and 63.6% (38.3), and above the 50% BW target load 2.3% (7.7), 8.9% (25.7), and 17.4% (23.4) for condition 1, 2, and 3, respectively. In c3 compared to c2 a larger mean peak load was found for the 10% BW target load ($p = 0.025$) and the 50% BW target load ($p = 0.027$), and more steps above the target load were found for a 50% BW target load ($p = 0.043$). No significant differences were found between c1 and c2.

Conclusions

In 55% of all conditions, patients did not load the operated leg within the instructed weight bearing limits after having received verbal instructions. Especially with a 10% BW target load and at home weight bearing was higher than prescribed.

5.2. Introduction

Partial weight bearing is (PWB) commonly instructed during the rehabilitation of patients with fractures, osteotomies, amputations or arthroplasties of the lower extremity.[3,7,11,20-22,25,26,29,31] For patients with a total hip arthroplasty and a trochanteric osteotomy it is important to restrict the activation of the hip abductors to avoid non-union of the trochanter fragment which may lead to functional disability.[2,5,10,12,24,27] Although the relationship between the load under the foot and the load at the hip is complex, the conventional therapy is to restrict weight bearing. The maximum amount of weight bearing or target load is prescribed by the treating surgeon and given in percentage body weight (BW) or in kilogram load. The goal of physical therapy is to ensure that the patient loads the operated leg at the prescribed target load. The most common method used by the physical therapist (PT) to instruct PWB is to give verbal instructions in combination with observation, palpation of triceps brachii muscle, and/or placing a hand under the foot of the affected leg to estimate the amount of weight bearing.

Factors which may influence the patients' weight bearing performance are the absence of the PT, the setting (hospital or patient's home) and time after surgery. At the start of rehabilitation the patient walks with the PT in the hospital and receives instructions and feedback from the PT. At a certain point during rehabilitation in the hospital the PT decides that the patient is able to perform PWB unsupervised. Although the results of commonly used instruction strategies are reported to be poor[13,25], unsupervised walking without verbal feedback from the PT could probably lead to higher limb loading than when walking with a PT. Higher limb loading is also more likely to occur at the patient's home compared to the more controlled clinical setting. Nowadays, the patient recovers for several weeks at home (or in a nursing home), which is longer than the short hospital stay of 5-7 days. At home the patient performs daily activities without help or supervision from a PT, and probably does more things alone which may distract them leading to inefficient handling of the walking aid[18]. Also, the home environment differs from the hospital environment, which may influence a patient's gait and, therefore, the loading of the operated leg. Because patients generally feel more confident and have less pain several weeks after surgery, they could load the limb above the prescribed target load. Additionally, because patients feel more confident they could become more active, thus increasing the risk of loading the limb above the prescribed target load.

Another factor which may influence the patient's weight bearing performance is the instructed target load prescribed by the surgeon. Studies have shown that lower target loads

(10-15 kg, 10-30% BW) resulted in larger differences between prescribed and actual weight bearing than higher target loads (50% BW).[1,18,20,28]

To gain insight in how much the patient really loads the operated leg during postoperative recovery, long-term weight bearing measurements have to be performed during the patient's stay in the hospital and at the patient's home, instead of short-term gait analyses in a laboratory. In addition, performing measurements over several hours enables us to obtain average and extreme peak loads from routine daily activities. To perform these kinds of measurements we previously adapted and validated an insole pressure system.[15,16]

The present study aimed to evaluate whether patients with a total hip arthroplasty and trochanteric osteotomy unload their operated leg at a prescribed target load after verbal instructions from a PT, by comparing the target load with the actual load which was measured by a valid and reliable insole pressure system. Specifically, we wanted to know what the difference is between the actual load and two target loads (10% and 50% of BW) in three conditions: 1) in the hospital in the presence of a PT, 2) in the hospital without the presence of a PT, and 3) at the patient's home 2 weeks after discharge.

5.3 Materials and Methods

5.3.1 Patients

Between August 2002 and October 2004, 145 consecutive patients received a primary unilateral total hip arthroplasty with trochanteric osteotomy for the treatment of osteoarthritis of the hip at the orthopedic departments of two hospitals participating in this study. All patients between the age of 40-80 years and from whom a written informed consent was obtained were included in the study. Exclusion criteria were: medical conditions or social problems due to which patients could not perform or could not be instructed to perform PWB (e.g. Parkinson's disease, epilepsy, alcoholism), postoperative bed rest for more than 3 weeks, foot orthosis, foot deformities which needed special footwear, and a shoe size (European) smaller than 36 or larger than 45. The institutional review boards at each of the two participating hospitals approved the study.

5.3.2 Protocol

The patients were instructed by a PT to perform PWB with a walker or elbow crutches (3-point gait[15]) depending on the walking ability of the patient. Instructions were given verbally, and verbal feedback was given during and/or after PWB. The patients were generally instructed with a 10% BW target load in one hospital, and with a 50% BW target load in the other participating hospital.

Weight bearing was measured with the Pedar Mobile system (Novel GmbH, Munich, Germany) which was validated to measure the vertical force during walking over a long-term period.[15] The Pedar Mobile system is a portable insole pressure device with matrix insoles (2 mm thick). Each insole contains 99 capacitive sensors. Prior to each measurement the Pedar insoles were calibrated using the Trublu calibration device (Novel GmbH) and a GDH 14 AN digital manometer (Greisinger Electronic GmbH, Regenstauf, Germany). The pressure loads applied were 4, 7, and 10 to 60 N/cm^2 with intervals of 5 N/cm^2. The Pedar system was placed in a custom-made vest together with a custom-made battery unit, consisting of two Sony NP750 Li-ion batteries, which was worn by the patient (Fig. 1). An electronic device with an accelerometer was made to automatically start and stop the Pedar system so that data were recorded only when the patient was standing or walking. The accelerometer was fixated with adhesive tape on approximately the middle front part of the contralateral thigh. The Pedar Mobile system was turned on 1 hour in advance (acclimatization period) and zero settings were done at t = 0 and t = 1 hour.[15] Data collection started after the second zero setting. The weight bearing measurements were performed on day 7 (± 2 days) postoperatively in the hospital when the patient walked with a PT (condition 1) or walked unsupervised (condition 2), and on day 21 (± 5 days) postoperatively at the patient's home (or in a nursing home) 2 weeks after discharge (condition 3). Weight bearing data during walking were collected over a period of 5 hours (from ± 11 am till ± 4 pm) at a sample frequency of 50 Hz.

Data analysis

Pedar-m Expert version 8.2 software was used to calculate the vertical force data from the Pedar system. Then, all Pedar data were imported in a custom-made Matlab® program and were filtered using a low pass Butterworth filter with a cut-off frequency of 40 Hz. The Matlab program was used to select the walking data within the data files, and to correct the walking data for offset drift.[15] For each step the maximum peak load was determined.

Figure 1. The Pedar system with a custom-made battery unit placed in a custom-made vest (right) worn by a patient (left). The accelerometer is connected to the Pedar system and fixated on the middle front part of the contralateral thigh.(a = custom made vest; b = Pedar box; c = battery unit; d =electronic device; e = accelerometer; f = 40 Mb flash card)

From these maximum peak loads, the following variables were calculated for the two target loads (10% and 50% BW) and for each of the three conditions: the mean (sd) peak load (% BW), peak load variance within and between patients, the total number of steps (n), the number and percentage of steps below the target load, equal to the target load and above the target load. We arbitrarily defined “below the target” as less than 5% BW for the 10% target load and less than 40% BW for the 50% target load, and “above the target” as more than 20% BW for the 10% target load and more than 60% BW for the 50% target load. The remaining category was defined as “equal to the target”.

Comparisons between the three conditions for the calculated variables were made using the paired t-test. For each test, the level of significance was set at $p < 0.05$. All statistical analyses were performed with SPSS for windows (version 10; SPSS, Chicago, Illinois, USA).

5.4 Results

Fifty patients were included in the study of which 33 patients performed PWB with a target load of 10% BW and 17 patients with a target load of 50% BW (Fig. 2). Due to mostly logistic reasons not all patients were measured at each condition. From the 33 patients with the 10% BW target load, respectively, 25, 26, and 26 patients, and from the 17 patients with the 50% BW target load, respectively, 11, 11, and 16 patients were measured at condition 1, 2, and 3, respectively. Three patients, which were operated in the hospital which generally prescribes a 50% BW target load, were mobilized on a target load of 10% BW. To assess the amount of weight bearing in the 10% BW and 50% BW target load group for condition 1, 2, and 3 during a long-term period, a total of respectively 1752, 3029, and 10258 steps, and a total of 1120, 1788, and 7498 steps were evaluated.

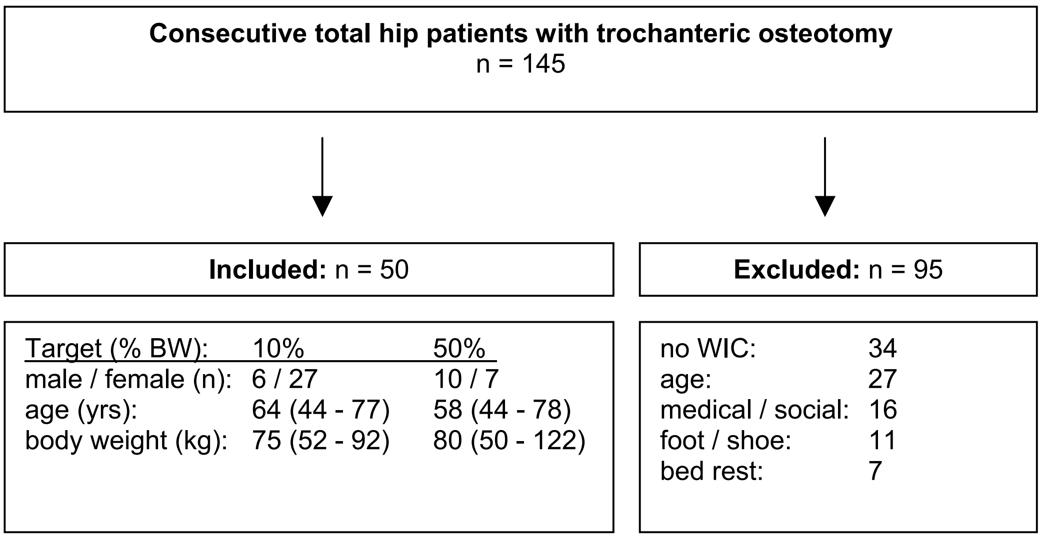

Figure 2. Flow chart of the patients included in the current study which performed partial weight bearing with a 10% and a 50% body weight target load. (WIC = written informed consent)

Partial weight bearing with supervision

When patients walked with the PT, more patients with a 10% BW target load had a mean peak load equal to the prescribed target load compared to the patients with a 50% BW target load (Table 1). However, 32% of the patients with a 10% BW target load and 0% of the patients with a 50% BW target load had a mean peak load above the prescribed target load.

Table 1. Partial weight bearing data of the patients with a 10% and 50% BW target load. Per condition and target load the mean (sd) of the mean peak loads of all the patient steps, and the mean (sd) amount of all steps taken by a patient are presented. Also, the percentage patients (pat) with a mean peak load below (< T), equal (= T), and above (> T) the target load, and the mean (sd) percentage of steps below (< T), equal (= T), and above (> T) the target load are given, for which an overall mean (sd) is presented for all 3 conditions and both target loads.

Condition (n)	T- load (% BW)	Patients (n)	MPL (%BW)	All steps (n)	MPL < T (% pat)	MPL = T (% pat)	MPL > T (% pat)	Steps < T (%)	Steps = T (%)	Steps > T (%)
1	10	25	19.2 (11.4)	70.1 (39.7)	4.0	64.0	32.0	11.4 (20.5)	50.1 (34.4)	38.5 (39.7)
	50	11	28.1 (16.0)	101.8 (58.9)	63.6	36.4	0	66.1 (40.1)	31.6 (37.3)	2.3 (7.7)
2	10	26	20.0 (9.8)	116.5 (79.5)	3.9	53.8	42.3	9.7 (20.8)	43.8 (30.9)	46.5 (36.0)
	50	11	32.5 (17.9)	162.5 (113.1)	63.6	27.3	9.1	63.3 (42.5)	27.8 (35.8)	8.9 (25.7)
3	10	26	26.8 (12.8)	394.5 (251.4)	0	30.8	69.2	3.2 (5.0)	33.2 (34.5)	63.6 (38.3)
	50	16	43.3 (15.9)	486.6 (378.6)	37.5	56.3	6.2	35.4 (35.9)	47.2 (29.0)	17.4 (23.4)
					28.8 (30.2)	44.8 (15.2)	26.5 (26.5)	31.5 (27.9)	39.1 (9.2)	29.6 (23.9)

Body weight ranges: 10% target load: "below target" = 0 - 5% body weight; "equal to target" = 5 - 20% body weight; "above target" = 20 - 100% body weight; 50% target load: "below target" = 0 - 40% body weight; "equal to target" = 40 - 60% body weight; "above target" = 60 - 100% body weight. MPL = Mean peak Load; T = target load. *Significant level set at < 0.05.

The percentage of steps equal to the target load was about the same as the percentage of steps above and below the target load for the 10% BW target load in contrast to the 50% BW target load in which most of the steps were below the target load. In this condition, the distribution of the peak loads showed a large variety in weight bearing, with peak loads up to 55-60% BW for the 10% BW target load and up to 65-70% for the 50% BW target load (Fig. 3; Fig. 4). The patients' within-variance and between-variance in weight bearing was 22.1% and 2.2% BW, respectively, for the 10% BW target load, and 46.2% and 5.1% BW, respectively, for the 50% BW target load.

Partial weight bearing without supervision

When the patients walked unsupervised in the hospital, they walked more than when they walked with the PT (Table 1). The percentage of patients with a mean peak load above the target load was increased with 9-10% in the 10% and 50% BW target load group.

The percentage of steps above the target load was larger for the 10% BW target load compared to the 50% BW target load. As in condition 1, the distribution of the peak loads showed again a large variety in weight bearing, with peak loads up to 55-60% and 90-95% BW for the 10% BW target load and the 50% BW target load group, respectively (Fig. 3; Fig. 4). The weight bearing variance within and between patients was 33.6% and 1.9% BW, respectively, for the 10% BW target load, and 54.8% and 5.7% BW, respectively, for the 50% BW target load.

Partial weight bearing at home 2 weeks after discharge

When the patients walked at their residence, they walked about 3 times more than when they walked unsupervised in the hospital (Table 1). The percentage of patients with a mean peak load above the target load was increased to 69.2% in the 10% BW target load group.

The percentage of steps above the target load was larger for the 10% BW target load compared to the 50% BW target load. In the 10% BW and 50% BW target load group peak loads were measured up to 70-75% BW and 90-95% BW, respectively (Fig. 3; Fig. 4) The weight bearing variance within and between patients was 44.9% and 2.6% BW, respectively, for the 10% BW target load, and 106.1% and 5.8% BW, respectively, for the 50% BW target load.

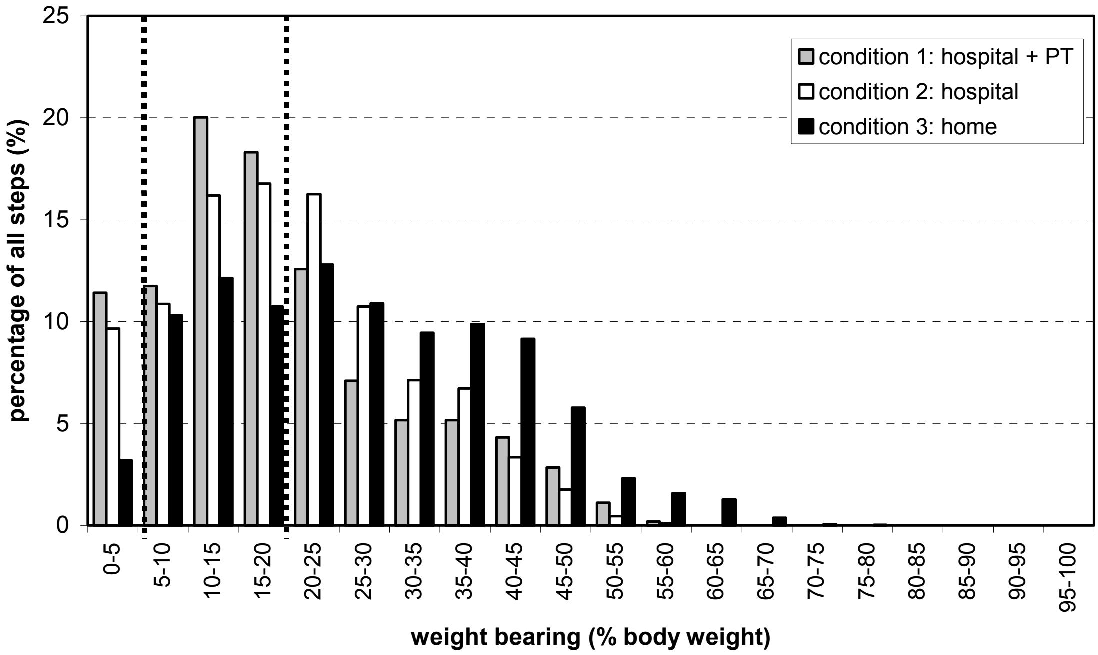

Figure 3. Distribution of the peak forces for the three conditions with the target load set at 10% body weight.(hospital + PT = in hospital with a physical therapist (condition 1); hospital = in hospital without a physical therapist (condition 2); home = at home, or in a nursing home (condition 3)).

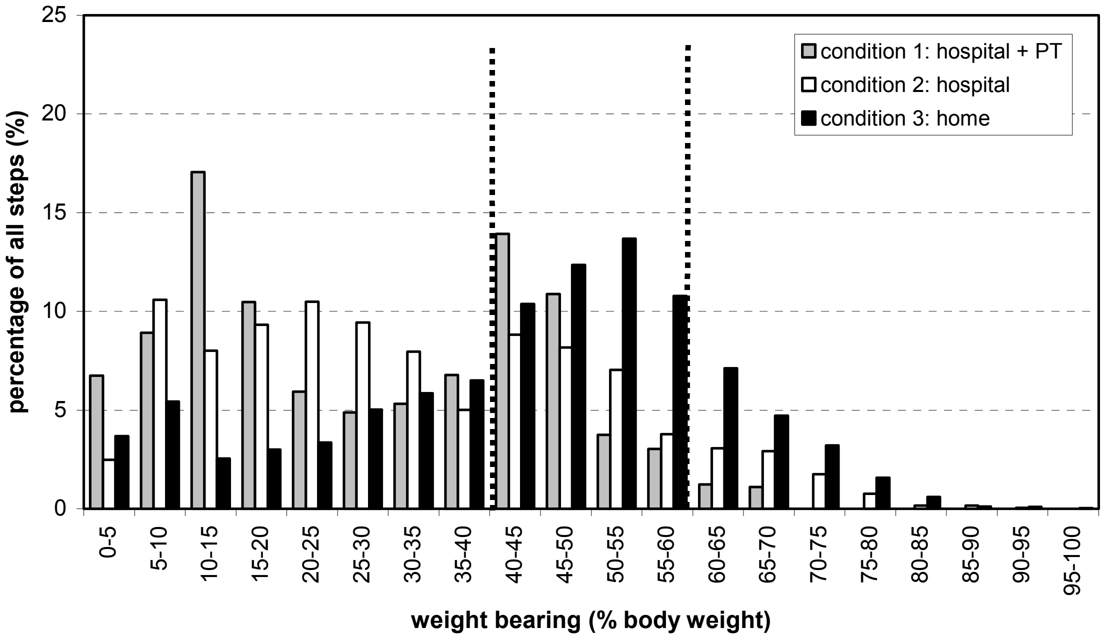

Figure 4. Distribution of the peak forces for the three conditions with the target load set at 50% body weight.(hospital + PT = in hospital with a physical therapist (condition 1); hospital = in hospital without a physical therapist (condition 2); home = at home, or in a nursing home (condition 3)).

Comparing partial weight bearing conditions

When comparing the three PWB conditions, no significant difference was found in the mean peak load between condition 1 (in hospital with PT) and condition 2 (in hospital without PT) in both target load groups (Table 2). In condition 3 (at home) the mean peak load was significantly higher than during condition 2 in both target load groups. No significant differences were found between condition 1 and 2 for the percentage of steps above the target load. When patients walked at home at a 10% BW target load, 17% more steps were above the target load than during unsupervised walking in the hospital, but this difference was not significant (p= 0.074). With a 50% BW target load, 9% more steps (p = 0.043) were above the instructed target load when patients walked at home.

5.5 Discussion

The present study evaluated PWB of patients with a total hip arthroplasty and trochanteric osteotomy during their 6-8 week recovery period by measuring the actual load during walking with a validated insole pressure system over a 5-hour period and comparing it with two instructed target loads in three conditions.

Table 2 Comparison of the partial weight bearing conditions for the 10% BW and 50% BW target load. Per condition the ∆ mean (sd) of the mean peak loads of all the patient steps, the ∆ mean (sd) amount of all steps taken by a patient, and the ∆ mean (sd) percentage of steps below (< T), equal (= T), and above (> T) are presented.

10% BW target load						
Patients (n)	**Condition** (n)	**∆ Mean Peak Load** (%BW)	**∆ All steps** (n)	**∆ Steps < T** (%)	**∆ Steps = T** (%)	**∆ Steps > T** (%)
20	1 - 2	-0.1 p = 0.869	-39.5 p = 0.091	-1.6 p = 0.526	3.5 p = 0.397	-1.8 p = 0.633
23	2 - 3	-7.0 p = 0.025*	-267.7 p = 0.000*	6.7 p = 0.175	10.5 p = 0.216	-17.2 p = 0.074
50% BW target load						
Patients (n)	**Condition** (n)	**∆ Mean Peak Load** (%BW)	**∆ All steps** (n)	**∆ Steps < T** (%)	**∆ Steps = T** (%)	**∆ Steps > T** (%)
8	1 - 2	-3.17 p = 0.409	-30.9 p = 0.359	-1.9 p = 0.686	0.1 p = 0.977	1.8 p = 0.538
10	2 - 3	-11.5 p = 0.027*	-207.4 p = 0.039*	30.3 0.041*	-21.0 p = 0.116	-9.4 p = 0.043*

Body weight ranges: 10% target load: "below target" = 0 - 5% body weight; "equal to target" = 5 - 20% body weight; "above target" = 20 - 100% body weight; 50% target load: "below target" = 0 - 40% body weight; "equal to target" = 40 - 60% body weight; "above target" = 60 - 100% body weight; T = target load. *Significant level set at < 0.05.

In this study we found that after total hip arthroplasty followed by verbal instructions from the PT a substantial amount of patients did not load their operated leg at the prescribed target load when walking with (condition 1) or without (condition 2) supervision of a PT in the hospital and when walking at home (condition 3), and that the results were even worse when looking at the amount of steps taken by the patients. Previous patient-studies on PWB also showed that patients did not load their leg at the prescribed target load, and that a large percentage of steps (40% - 80%) of the patients were above the target load when using either verbal instructions and observation, and/or the hand-under-the foot method and/or a bathroom scale.[13,20,22,25,26,] This indicates, that the commonly used methods are inadequate to obtain the prescribed target load during weight bearing performance. However, our data also showed that the amount (percentage) of steps above the target load was strongly determined by environment/time after discharge (hospital vs home) and by the prescribed target load. When walking in the hospital 0-9% of the patients had a mean peak load above the 50% BW target load and 2-9% of all the steps were above the 50% BW target load. Thus, when the main goal is not to load the operated leg above the target load then verbal instructions seemed to be sufficient for PWB in the hospital at a 50% BW target load.

Although observation with verbal feedback from the PT is a subjective method to control weight bearing, we expected higher limb loads compared to the situation where the patients walked in the hospital without feedback. However, no significant differences were found between the mean peak load and the percentage steps above the target load of condition 1 and 2 (Table 2). This would indicate that the patients learned to limit the load on their leg at a certain level when trained by a PT, although this was not the instructed load. Weight bearing training was done by giving verbal feedback after performing PWB for a few steps. Winstein et al.[30] concluded that this “postresponse feedback” was effective for learning a PWB skill, but that concurrent feedback (e.g. audio feedback during the weight performance) is needed for immediate performance. Another aspect that could explain the similar weight bearing in both conditions is the postoperative pain which may have led the patients to be more cautious in placing the foot on the ground. Koval et al.[17] found that elderly patients who are allowed to bear weight as tolerated after operative treatment of a fracture of the femoral neck or an intertrochanteric fracture appear to voluntarily limit loading of the injured limb.

At home the patients loaded their operated leg significantly higher than during unsupervised PWB in the hospital. A reason for loading the operated leg more per step could be that the patients might be more confident and/or may have less pain. Also, the patients walked significantly more at home than in the hospital which could increase the risk of incorrect loading the leg. In addition, when a patient walks more the patient could also become fatigued as walking with walking aids is physically demanding[8,9,14], and consequently load the leg more than the prescribed target load. Also, the patients’ compliance to weight bearing instructions could influence the loading of the operated leg at home. At the patient’s home we occasionally observed that patients used only one crutch or did not use the walking aids at all e.g. when opening the front door or while making coffee. Several patients stated that they sometimes forgot to use the walking aid when standing up. Unfortunately, we were not able to match the load data with these events.

We found that with a lower prescribed target load (10% BW) more steps were above the target load than with a higher prescribed target load (50% BW). This is in line with previous studies on PWB with different target loads that also found relatively less accuracy when a low target load was used.[1,22,28] It is obvious that when the patient has to place less weight on the operated leg more weight has to be placed on the walking aid and, therefore, more muscle strength of the upper arm is needed.[6,19] Chow et al.[4] found that the muscle power of the upper arm influenced the ability of the patient to perform PWB.

While a substantial amount of the patients did not load the operated leg at the prescribed target loads nearly all patients loaded the leg partially, i.e. less than 100% BW, and the verbal instructions used for the 10% BW target load (i.e. placing the leg on the ground but not putting weight on it, or “like walking on eggshells”) did unload the patient’s leg more than when using the verbal instructions for the 50% BW target load (i.e. place an equal amount of weight on each leg during walking as when standing still on both legs) (Fig. 3, Fig. 4). Also, the within-variance and between-variance in the 10% BW target load group was smaller than in the 50% BW target load group, and higher weight bearing loads (up to 90-95% BW) were measured in the 50% BW target load group which could increase the risk of complications. Therefore, a simple practical solution to decrease weight bearing in the 50% BW target load group could be to use the more strict 10% BW weight bearing verbal instructions. For instructing patients at a 10% BW target load other methods (e.g. audio feedback) should be used by the PT.[20,22,23]

To evaluate PWB it is important to measure not only the amount of loading but also the duration (amount of steps) of loading. Complications can occur due to a occasional full weight bearing, but may also occur as a result of long-term weight bearing just above the target load. Individual patient data in our study show a large variability in amount and duration of loading between separate walking periods, ranging from several seconds to 10-20 minutes. Also, an increase in loading was seen in the longer walking periods which may indicate that patients were getting (more) fatigued because of longer intensive use of the walking aids and/or were becoming less concentrated.[8,9,14,32] This suggests that weight bearing instructions should not only include a restriction in the amount of loading but also emphasize the importance of limiting the duration of walking to, for instance, 5-minute walking sessions.

There is no definition or consensus as to what constitutes “too much” loading, because no data are available which relate complication rates to either the amount or the duration of loading. Gray et al.[13] defined weight bearing as “acceptable” when the subjects loaded the leg within a range of ±15 pounds of the 60-pound target load for at least 60% of the time. However, they also remarked that in a clinical situation it may only be acceptable if the patient loads the leg correctly 90% of the time. The surgeons in our hospital use the arbitrarily chosen weight bearing cut-offs (below, equal, above) for the 10% and 50% BW target load as prescribed in the methods, and considered 10% (or less) of the steps above the target load to be acceptable.

In conclusion, we found that in 55% of all conditions patients with a total hip arthroplasty and trochanter osteotomy did not load their leg within the instructed target load limits during PWB after having received verbal instructions. The weight performance of the patient is strongly determined by the prescribed target load and the setting/time after surgery as more steps were above the target load with a 10% BW target load than with a 50% target load, and more steps were above the target load at home compared to walking unsupervised in the hospital.

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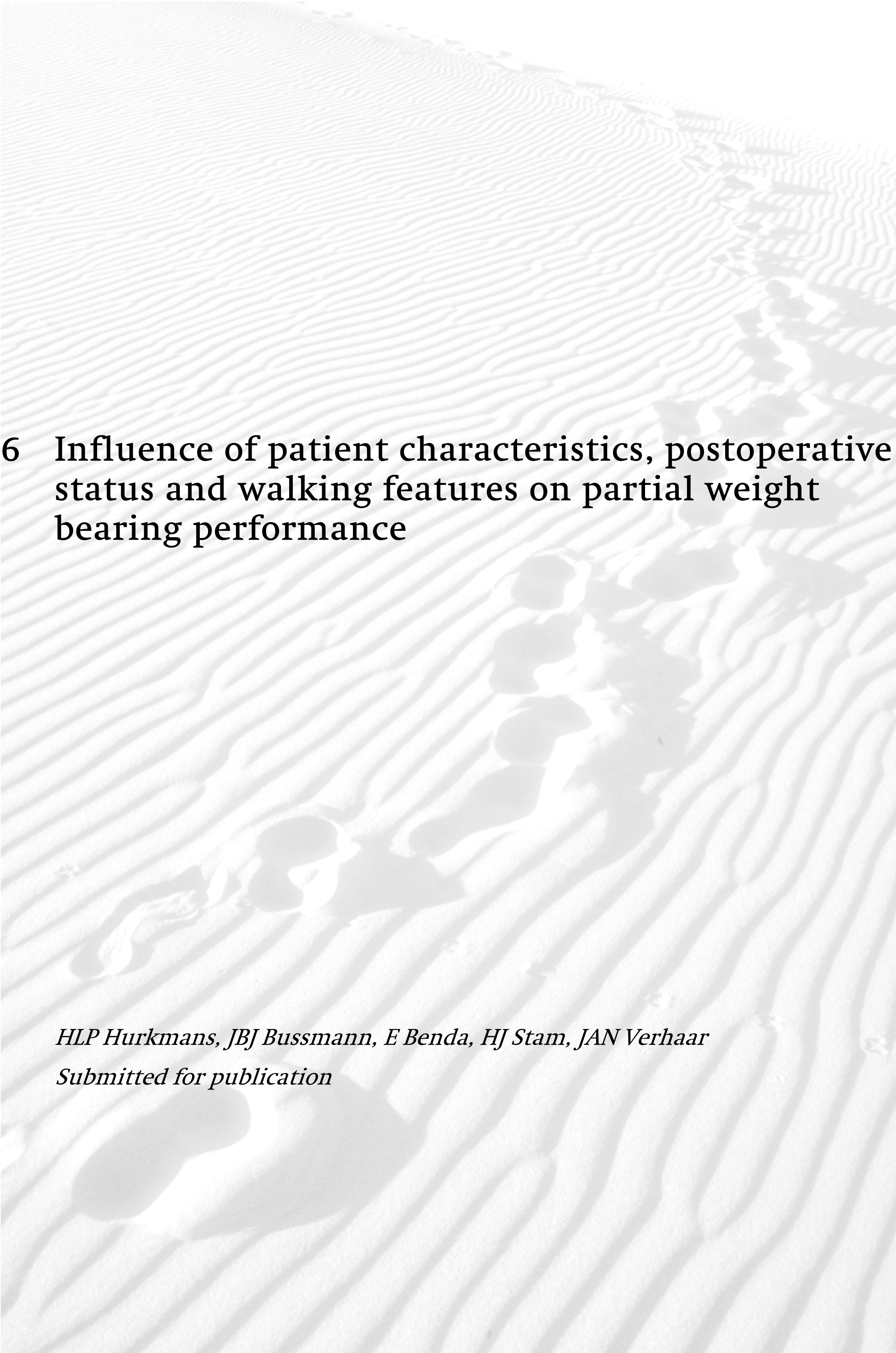

6 Influence of patient characteristics, postoperative status and walking features on partial weight bearing performance

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6.1 Abstract

Background

It is important for the physician and physical therapist to know which factors increase the risk of incorrect loading of the operated leg during the patient's partial weight bearing (PWB) performance. This study evaluated the relationship between patient characteristics, postoperative status and walking features with the patient's PWB performance.

Material and Methods

Fifty patients who had undergone total hip arthroplasty with trochanteric osteotomy were included and performed PWB to either a 10% or 50% body weight (BW) target load. The mean peak load (% BW) and percentage of steps above the target load were used as PWB outcome measures. The patient characteristics age, gender, BW, isometric upper arm force (hand-held dynamometer), the postoperative status items pain [Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), Numeric rating scale (NRS)], fatigue and anxiety [Profile of Mood States (POMS), NRS], and the walking features step frequency, total walking time, total number of steps (insole pressure system), and walking aid were evaluated.

Results

Univariate multilevel regression analyses indicated that gender (women load the leg more than men) ($p = 0.029$), anxiety about falling (NRS) ($p = 0.017$), total walking time ($p = 0.0001$), and total number of steps ($p = 0.0003$) were positively related, and step frequency ($p = 0.030$) was negatively related with the mean peak load (% BW). Pain during walking (NRS) ($p = 0.019$), and anxiety about falling (NRS) ($p = 0.009$) were positively related with the percentage of steps above the target load. Specifically for the 10% BW target load, pain (WOMAC) ($p = 0.047$), and pain during walking (NRS) ($p = 0.037$) were positively related with the mean peak load (% BW); anxiety (POMS) ($p = 0.019$), total walking time ($p = 0.040$), and total number of steps ($p = 0.017$) were positively related with the percentage of steps above the target load.

Conclusions

Higher weight bearing loads were found when the patient is a woman, when the patient has more postoperative pain during walking, is more anxious about falling, walks with a lower step frequency, walks longer and takes more steps. Contrary to our expectations, arm strength did not influence PWB, and an increase in pain or anxiety did not result in a decrease in PWB.

6.2 Introduction

Postoperative gait training after lower limb surgery is often combined with weight bearing restriction of the lower limb to avoid complications during rehabilitation.[3,8,11,12,29,32,37] The level of weight bearing restriction is prescribed by the orthopedic surgeon and can range from 10% to 50% of the patient's body weight (BW). The task of the physical therapist (PT) is to instruct the patient to perform partial weight bearing (PWB) at the prescribed target load. In a previous PWB study we found that the target load, and setting/time after surgery (hospital vs. home) strongly determined the patient's PWB performance.[22] Other studies also showed that loading of the lower limb depends on the instruction method used and the target load.[14,18,29,32,33] It can be assumed that more factors than the instruction method used, target load and setting, influence the load on the operated leg.

Three categories of determinants that may influence the patient's PWB performance can be distinguished; namely, patient characteristics, postoperative status, and patient's walking features. The patient's age, BW and arm strength can affect PWB because aging decreases the condition, and walking with walking aids (compared to normal walking) is known to be physically demanding[4,16,17,19,28], heavier patients have to unload the leg more, and patients with less arm strength can have difficulty to unload the leg. The postoperative state of the patient might also be of importance for the PWB performance. For instance, postoperative pain and anxiety may cause the patient to be more cautious about placing the foot on the ground. Furthermore, higher limb loads could occur when the patient is more fatigued. Certain walking features (e.g. the duration of walking or the type of walking aid used) might also affect the patient's loading of the operated leg. Therefore, when learning to walk with walking aids, patients are instructed to walk slowly and for short distances. However, when patients are feeling better during rehabilitation they may tend to walk for longer periods which may increase the risk of higher limb loading.

The three categories are based more on logical reasoning than on scientific criteria because, to our knowledge, no studies have evaluated the relationship between patient characteristics, or postoperative status, or walking features and the patient's PWB performance. Only one brief report by Chow et al[12]. was found in which patient characteristics and other factors that affected the patient's ability to perform PWB were evaluated. The authors found that muscle power of the good limbs and the mental state were significant factors, whereas, age, body weight and type of surgery were not significantly related to PWB performance. Limitations of that study were that bathroom scales were used to measure weight bearing during walking (which are not suitable for measuring vertical forces during walking[7,11,23]), only a few steps were analyzed, and parallel bars were used instead of commonly used walking aids (i.e. elbow crutches, standard walker). Therefore, in the present study we measure the amount of weight bearing using a validated insole pressure system over a long-term period in the hospital, and at the patient's home/nursing home when patients are using a walker or elbow crutches.

The aim of the present study was to determine which patient characteristics, factors related to the patient's postoperative status, and walking features influence the patient's PWB performance, which was measured over a long-term period in and outside the hospital using a validated insole pressure system. This knowledge can help the physician and PT to address factors which increase the risk of incorrect loading of the operated leg.

6.3 Materials and Methods

6.3.1 Patients

Between August 2002 and October 2004, 145 consecutive patients received a primary unilateral total hip arthroplasty with trochanteric osteotomy for the treatment of osteoarthritis of the hip at the orthopedic departments of two hospitals participating in this study. Of this group of total hip patients, all patients aged 40 to 80 years and from whom a written informed consent was obtained, were included in the present study. Exclusion criteria were: medical conditions or social problems due to which patients could not perform or could not be instructed to perform PWB (e.g. Parkinson's disease, epilepsy, and alcoholism), postoperative bed rest for more than 3 weeks, foot orthosis, foot deformities which needed special footwear, and a shoe size (European) smaller than 36 or larger than 45. The institutional review boards at each of the two participating hospitals approved the study.

Partial weight bearing

The amount of weight bearing was determined by measuring the peak load (N) of each step with the Pedar Mobile system (Novel GmbH, Munich, Germany), a portable insole pressure system of which each insole (2 mm thick) contains 99 capacitance sensors. The Pedar Mobile system was adapted and validated to measure the vertical ground reaction force during walking over a long-term period.[20,21]

Patient characteristics

The patient characteristics age and gender were registered, and BW was measured using a scale. Isometric elbow extension force and isometric shoulder flexion force (N) for the left and right arm were measured with a hand-held dynamometer.[1,2,5,6,26,]

Postoperative status

The patient's postoperative pain intensity of the operated limb was measured with the dimension pain of the Dutch version of the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) which uses a 5-point scale from 0 (= none) to 4 (=extreme).[31] The postoperative fatigue and anxiety were measured with the subscales for fatigue and anxiety of the Profile of Mood States (POMS), of which each scale consists of six mood-related adjectives that are rated on a 5-point scale from 0 (= not at all) to 4 (= extremely).[35] Also, an 11-point numerical rating scale (NRS) was used to evaluate the amount of pain, fatigue and anxiety during the period of the weight bearing measurements.[15] After the weight bearing patients were asked measurements to rate their pain during the periods of standing still (p1) and walking (p2) by giving a number between 0 (no pain at all) and 10 (the worst possible pain), and to rate their fatigue (f1) during walking by giving a number between 0 (not tired at all) and 10 (extremely tired). For anxiety (score 0 = not afraid at all; score 10 = extremely afraid) the questions were: how afraid are you to walk due to the pain of the operated leg (a1), how afraid are you to fall during standing or walking (a2), and how afraid are you that your hip may dislocate while turning around during walking (a3).

Walking features

The step frequency (sec^{-1}), the total walking time (minutes), and the total number of steps (n) were measured with the Pedar system. The information on which type of walking aid was used (elbow crutches or walker) was given by the PT or the patient.

6.3.2 Protocol

The patients were instructed by a PT to perform PWB with a walker or elbow crutches (3-point gait[10]) depending on the walking ability of the patient. Instructions were given verbally, and verbal feedback was given during and/or after PWB. The patients were generally instructed with a 10% BW target load in one hospital, and with a 50% BW target load in the other participating hospital.

Prior to each weight bearing measurement the insoles were calibrated using the Trublu calibration device (Novel GmbH) and a GDH 14 AN digital manometer (Greisinger Electronic

GmbH, Regenstauf, Germany). The pressure loads applied were 4, 7, and 10 to 60 N/cm^2 with intervals of 5 N/cm^2. The Pedar system was placed in a custom-made vest together with a custom-made battery unit, consisting of two Sony NP750 Li-ion batteries, which was worn by the patient.[22] An electronic device with an accelerometer was made to automatically start and stop the Pedar system so that only data were recorded when the patient was standing or walking. The accelerometer was fixated with adhesive tape on approximately the middle front part of the contralateral thigh. The Pedar system was turned on 1 hour in advance (acclimatization period) and zero settings were done at t = 0 and t = 1 hour.[20] Data collection started after the second zero setting. Weight bearing data during walking were collected over a period of approximately 5 hours (from ± 11 am till ± 4 pm) at a sample frequency of 50 Hz.

The weight bearing measurements with the Pedar system were performed on day 7 (± 2 days) postoperatively in the hospital when the patient walked with a PT (condition 1) or walked unsupervised (condition 2), and on day 21 (± 5 days) postoperatively at the patient's home or in a nursing home (condition 3). Postoperatively in the hospital the patient's BW, upper arm force, pain, fatigue, and anxiety were measured on day 7 (± 2 days) . On day 21 (± 5 days) postoperatively these patient variables were measured again at the patient's home (or in a nursing home), with exception of the upper arm force.

6.3.3 Data analysis

Pedar-m Expert version 8.2 software was used to calculate the vertical force data from the Pedar system. Then, all Pedar data were imported in a custom-made Matlab® program and were filtered using a low-pass Butterworth filter with a cut-off frequency of 40 Hz. A Matlab program was used to select the walking data within the data files, and to correct the walking data for offset drift.[20] For each step the maximum peak load was determined. From these maximum peak loads, the mean and standard deviation (sd) peak load (% BW) and the percentage of steps above the target load were calculated for the two target loads (10% and 50% BW) and for each of the three conditions. We arbitrarily defined "above the target" as more than 20% BW for the 10% BW target, and more than 60% BW for the 50% BW target. The mean upper arm force was calculated from the measured left and right arm forces and normalized to BW. The mean and sd were calculated for all of the described variables. Paired t-tests using SPSS for windows (version 10; SPSS, Chicago, Illinois, USA) were applied to detect significant differences (level of significance set at $p < 0.05$) over time and between conditions.

Multilevel regression analysis was performed using MLwiN (version 1, London, UK) to analyze the linear relationship between the factors and the patient's PWB performance. Univariate multilevel analyses were performed to analyze the linear relationship between each of the independent variables age, gender, BW, upper arm force, pain, fatigue and anxiety, and step frequency, total walking time, total number of steps and type of walking aid, and the dependent variables (Y) mean peak load (% BW) and percentage of steps above the target load. For each univariate analysis we used the following 2-level multilevel linear regression model, with conditions set at level-1(j) and individuals set at level-2 (i):

$$\begin{aligned} Y_{ij} = \; & \beta_{0ij}a + \beta_{1ij} \times (\Delta c1 - c2)_{ij} + \beta_{2j} \times (\Delta c2 - c3)_{ij} + \beta_{3ij} \times \text{target}_{ij} + \beta_{4ij} \times \text{variable}_{ij} \\ & + \beta_{4ij} \times \text{target} \times \text{variable}_{ij} + \beta_{5ij} \times (\Delta c1 - c2) \times \text{variable}_{ij} + \beta_{6ij} \times (\Delta c2 - c3) \times \text{variable}_{ij} \\ & + \beta_{7ij} \times (\Delta c1 - c2) \times \text{target}_{ij} + \beta_{8ij} \times (\Delta c2 - c3) \times \text{target}_{ij} \end{aligned}$$

The a in the model is the regression constant, the βs are the regression coefficients, and (Δc1 - c2) and (Δc2 - c3) are dummy variables, which means that their value is 0 or 1 depending on the condition of interest. For condition 1 dummy (Δc1 - c2) was 1 and dummy (Δc2 - c3) was 0, for condition 2 both dummy (Δc1 - c2) and dummy (Δc2 - c3) were 0, and for condition 3 dummy (Δc1 - c2) was 0 and dummy (Δc2 - c3) was 1. The variable target was coded as 0 for the 50% BW target and as 1 for the 10% BW target, the variable gender was coded 0 and 1 for male and female, respectively, and walking aid was coded as 0 and 1 for elbow crutches and walker, respectively. Variables were eliminated from the model using the backwards procedure with the level of significance set at $p < 0.05$. Multivariate multilevel analyses were performed with the variables from the univariate analyses which were found to be significant when $p < 0.1$. For this multivariate analysis also backward regression was used with the level of significance set at $p < 0.05$.

6.4 Results

A total of 50 patients was included in the study of which 33 patients (27 females, 6 males) performed PWB with a target of 10% BW and 17 patients (7 females, 10 males) with a target of 50% BW (Table 1). Ninety-five patients were excluded because of the following reasons: no written informed consent (34), outside the age range (27), medical or social problems (16), problems related to feet or shoes (11), and prolonged bed rest for 3 weeks (7). Not all patients were measured at each condition, mostly due to logistic reasons. From the 33 patients with the 10% BW target, respectively, 25, 26, and 26 patients, and from the 17 patients with the 50% BW target, respectively, 11, 11, and 16 patients were measured at condition 1, 2, and 3, respectively. Three patients, which were operated in the hospital which generally prescribes a 50% BW target load, were mobilized on a target load of 10% BW on postoperative orders of the surgeon.

Table 1. Patient characteristics (mean (sd)) of the total hip patients with a trochanteric osteotomy included in the study with a target load of 10% and 50% BW, with the differences (mean (SEM)) between the 10% and 50% BW target load for each of the patient characteristics.

	10% BW target			50% BW target			10% - 50% BW target			
	Men (n = 6)	Women (n = 27)	p-value	Men (n = 10)	Women (n = 7)	p-value	Men	p-value	Women	p-value
Age (years)	58.0 (7.5)	65.4 (8.4)	0.057	53.1 (6.6)	64.6 (10.4)	0.014	4.9 (3.6)	0.195	0.84 (3.7)	0.825
BW (kg)	79.0 (4.1)	74.6 (9.6)	0.295	87.5 (17.2)	68.7 (12.3)	0.026	-8.5 (5.7)	0.163	5.9 (4.4)	0.183
Extension force left (N)	194.3 (53.7)	116.5 (30.2)	<0.001	178.2 (47.4)	107.3 (24.9)	0.001	16.1 (25.7)	0.540	9.2 (11.2)	0.467
Extension force right (N)	176.8 (33.7)	113.5 (24.5)	<0.001	190.1 (45.4)	135.8 (94.3)	0.132	-13.4 (21.5)	0.544	-22.3 (20.0)	0.272
Flexion force left (N)	166.5 (30.2)	108.7 (36.4)	0.001	158.8 (60.7)	101.8 (18.1)	0.017	7.7 (26.8)	0.779	6.9 (14.3)	0.631
Flexion force right (N)	171.4 (30.4)	105.3 (36.4)	<0.001	166.5 (44.6)	92.9 (31.8)	0.002	4.8 (20.7)	0.817	12.4 (15.1)	0.419
Mean uaf (N)	177.3 (30.6)	111.0 (28.4)	<0.001	173.4 (42.9)	109.4 (16.4)	0.001	3.83 (20.1)	0.852	1.5 (11.3)	0.892
Mean uaf (N) / BW (N)	0.23 (0.03)	0.15 (0.04)	<0.001	0.21 (0.05)	0.17 (0.04)	0.131	0.02 (0.02)	0.336	-0.01 (0.02)	0.375

Extension = elbow extension; Flexion = shoulder flexion; uaf = upper arm force; BW = body weight;
level of significance set at < 0.05

Descriptives

In the 50% BW target group the patient characteristics show that men were younger and heavier than the women (Table 1). In the 10% BW target group the men also had more arm strength, even when corrected for BW.

During the postoperative period from day 7 to day 21 the pain decreased in the 10% BW target group, and the pain during walking decreased in both target groups (Table 2). The patients were in general and during walking less fatigued at home compared to their stay in the hospital. Only in the 50% BW target group a decrease was seen in the patient's postoperative anxiety and the patient's anxiety about falling.

Table 2. Postoperative status (mean (sd)) of the total hip patients with a trochanteric osteotomy with a target load of 10% and 50% BW at day 7 and day 21 postoperatively, with the differences (mean (SEM)) between the 10% and 50% BW target load for the postoperative status at day 7 and day 21.

	10% BW target			50% BW target			10% - 50% BW target			
	d7 (n = 33)	d21 (n = 30)	p-value	d7 (n = 15)	d21 (n = 16)	p-value	d7	p-value	d21	p-value
Pain (WOMAC)	3.5 (3.1)	2.2 (2.5)	0.011	4.3 (1.9)	2.8 (2.8)	0.053	-0.9 (0.7)	0.233	-0.6 (0.8)	0.497
Pain standing (NRS)	1.7 (2.3)	1.1 (2.0)	0.177	2.1 (1.8)	1.1 (2.6)	0.124	-0.3 (07)	0.610	0.0 (0.6)	0.953
Pain walking (NRS)	2.1 (2.2)	1.1 (1.9)	0.004	2.5 (1.7)	1.0 (1.0)	0.008	-0.5 (0.6)	0.461	0.8 (0.5)	0.845
Fatigue (POMS)	5.2 (3.4)	2.9 (4.0)	0.003	5.0 (3.2)	1.7 (1.9)	0.001	0.2 (1.0)	0.884	1.2 (1.0)	0.244
Fatigue walking (NRS)	4.5 (2.1)	2.2 (2.1)	0.000	3.1 (1.8)	1.0 (1.0)	0.002	1.3 (0.6)	0.038	1.2 (0.6)	0.012
Anxiety (POMS)	2.5 (2.4)	2.1 (4.2)	0.254	3.9 (2.7)	2.1 (3.3)	0.002	-1.5 (0.8)	0.062	0.0 (1.2)	0.981
Anxiety walking (NRS)	1.1 (1.8)	0.7 (1.6)	0.402	0.7 (1.2)	0.2 (0.5)	0.223	0.3 (0.5)	0.527	0.5 (0.4)	0.187
Anxiety falling (NRS)	1.7 (2.3)	1.2 (2.0)	0.351	1.3 (1.6)	0.4 (1.0)	0.028	0.5 (0.7)	0.483	0.8 (0.6)	0.156
Anxiety dislocate hip (NRS)	0.4 (2.1)	0.8 (2.0)	0.324	0.9 (2.0)	0.6 (1.6)	0.357	-0.4 (0.5)	0.396	0.2 (0.6)	0.767

d = day; level of significance set at < 0.05

In the 10% BW target group the step frequency increased when the patients walked unsupervised compared to walking with a PT (Table 3). An increase in step frequency was also found in this group when the patients walked at home. Both total walking time and total number of steps during the 5-hour measurement period were larger at 3 to 4 weeks postoperatively.

Univariate relations

The results of the univariate regression analyses are shown in Table 4. The patient characteristic gender and the dummy (Δc1 - c2) x gender were related with the mean peak load. The dummy (Δc1 - c2) x gender was related with the percentage of steps above the target load. These results indicate that women load their leg with a higher mean peak load than men. However, when females are walking with a PT (c2) their mean peak load and percentage of steps above the target load are less than men.

Table 3. Walking features step frequency, total walking time and total number of steps (mean (sd)) of the total hip patients with a trochanteric osteotomy with a target load of 10% and 50% BW for the three conditions, with the differences (mean (SEM)) between the 10% and 50% BW target load for the walking features at the three conditions.

	10% BW target				
	C1 (n = 25)	C2 (n = 26)	C3 (n = 26)	C1 - C2 (n = 20) p-value	C2 - C3 (n = 23) p-value
Step frequency (sec^{-1})	0.36 (0.08)	0.38 (0.06)	0.48 (0.09)	0.010	0.000
Total Walking time (min)	3.9 (2.3)	6.2 (4.4)	15.3 (8.9)	0.135	0.000
Total steps (n)	70.1 (39.7)	116.5 (75.9)	394.5 (251.4)	0.091	0.000
	50% BW target				
	C1 (n = 11)	C2 (n = 11)	C3 (n = 16)	C1 - C2 (n = 8) p-value	C2 - C3 (n = 10) p-value
Step frequency (sec^{-1})	0.41 (0.13)	0.44 (0.15)	0.50 (0.10)	0.683	0.097
Total Walking time (min)	5.0 (3.2)	6.5 (2.8)	17.1 (11.4)	0.528	0.029
Total steps (n)	101.8 (58.9)	162.5 (113.1)	486.6 (378.6)	0.359	0.039

	10% - 50% BW target					
	C1	p-value	C2	p-value	C3	p- value
Step frequency (sec^{-1})	-0.06 (0.04)	0.113	-0.06 (0.05)	0.068	-0.03 (0.03)	0.358
Total Walking time (min)	-1.1 (0.9)	0.262	-0.3 (1.4)	0.841	-1.8 (3.1)	0.573
Total steps (n)	-31.7 (16.7)	0.066	-46.0 (31.7)	0.155	-74.1 (97.0)	0.450

C1 = partial weight bearing in hospital with a physical therapist ; C2 = partial weight bearing in hospital without a physical therapist; C3 = partial weight bearing at home; BW = body weight. level of significance set at < 0.05.

We expected that more pain led to less weight bearing, however, the overall postoperative pain (WOMAC) and the pain during walking (NRS) were positively related with the mean peak load for the 10% BW target load. Pain during walking was also positively related with the percentage of steps above the target load. Contrary to our expectations, fatigue (POMS) was found to be negatively related with the mean peak load when patients performed PWB with a PT. We expected to find a negative relation between anxiety and weight bearing. Nevertheless, anxiety measured with the POMS was positively related with the percentage of steps above the target load for the 10% BW target load. However, at home (c3) anxiety measured with the POMS was negatively related with the percentage of steps above the target load. The anxiety about falling during standing and/or walking (NRS) was positively related with the mean peak load and the percentage of steps above the target load.

The walking features step frequency, total walking time and total number of steps were all positively related with the mean peak load. Total walking time and total number of steps were also positively related with the percentage of steps above the target load for the 10% BW target.

Multivariate relations

Multivariate regression analysis demonstrated that the best predictive variables for the mean peak load were gender, walking with PT x gender, pain during walking (NRS), target x pain during walking (NRS), and anxiety about falling during standing and/or walking (NRS). The best predictive variables for the percentage of steps above the target load were walking with PT x gender, target x anxiety (POMS), and walking at home x anxiety (POMS).

6.5 Discussion

The aim of the present study was to determine whether patient characteristics, postoperative status, and walking features influenced the PWB performance of total hip patients during their recovery. In a previous study in which we measured the PWB of total hip patients during their recovery, we found that the mean peak load differed from the prescribed target load, that more than 27% of the patients had a mean peak load above the target load, and that more than 30% of the steps were above the target load.[22] We also found that the patient's PWB performance was strongly determined by the prescribed target load and the condition (i.e. with or without a PT in the hospital, and at home). These PWB results, however, can also be influenced by other factors. The knowledge that certain factors can influence the patient's PWB performance is important for the PT so that he/she can anticipate to situations which might increase the risk of incorrect loading of the operated leg.

Patient characteristics

The patient characteristics age, BW and upper arm strength were not related with the patient's PWB performance, which was also reported by Chow et al.[12] with exception of the upper arm strength. It is known that aging results in an decrease of physical and mental condition.[5,9,24,30]

Table 4. Univariate regression coefficients (SE) and their p-values for the linear relationship between the patient characteristics, postoperative status, and walking features (independent variables) and the mean peak load (% BW) and the % steps above the target (% BW) (dependent variables).

	Mean peak load (% BW)		% steps > target (% BW)	
	Regression coefficient (SE)	**p-value**	**Regression coefficient (SE)**	**p-value**
Patient characteristics				
Age (years)	0.217 (0.184)	0.238	0.216 (0.457)	0.637
Gender	8.521 (3.888)	0.029	14.039 (9.734)	0.150
(∆c1 - c2) x gender	-5.857 (2.458)	0.017	-12.835 (5.749)	0.027
BW (kg)	-0.039 (0.140)	0.781	-0.090 (0.347)	0.795
Mean uaf (N)	-0.050 (0.040)	0.211	-0.145 (0.099)	0.144
Mean uaf (N) / bw (N)	-43.828 (35.200)	0.211	-138.990 (85.226)	0.103
Postoperative status				
Pain (WOMAC)	-0.762 (0.898)	0.395	2.426 (1.287)	0.059
Target x pain	2.037 (1.024)	0.047	-	-
Pain walking (NRS)	-1.622 (1.230)	0.187	4.406 (1.883)	0.019
Target x pain walking	2.986 (1.428)	0.037	-	-
Pain standing (NRS)	0.551 (0.629)	0.381	1.690 (1.624)	0.298
Fatigue (POMS)	0.538 (0.409)	0.187	1.505 (1.013)	0.136
(∆c1 - c2) x fatigue	-0.661 (0.323)	0.040		
Fatigue walking (NRS)	-0.490 (0.745)	0.511	-0.215 (1.919)	0.911
Anxiety (POMS)	0.752 (0.419)	0.074	2.721 (1.945)	0.162
Target x anxiety	-	-	5.057 (2.157)	0.019
(∆c2 - c3) x anxiety	-	-	-5.205 (1.666)	0.002
Anxiety walking (NRS)	1.221 (0.883)	0.168	3.605 (2.307)	0.118
Anxiety falling (NRS)	1.699 (0.713)	0.017	4.779 (1.826)	0.009
Anxiety dislocate hip (NRS)	1.079 (0.747)	0.150	3.399 (1.896)	0.073
Walking features				
Step frequency (sec^{-1})	-26.974 (12.459)	0.030	10.006 (31.688)	0.752
Total Walking time (min)	0.543 (0.135)	0.0001	0.064 (0.512)	0.901
Target x total walk time	-	-	1.194 (0.582)	0.040
Total steps (n)	0.018 (0.005)	0.0003	0.001 (0.017)	0.953
Target x total steps	-	-	0.050 (0.021)	0.017
Walking aid	-1.732 (2.167)	0.424	-4.538 (4.816)	0.347

uaf = upper arm force; BW = body weight; level of significance set at < 0.05

However, this age effect is mostly seen when comparing younger and older subjects. In our study and that of Chow et al.[12] a group of hip patients was evaluated which had a relatively small age range and, therefore, probably no relation was found between age and weight bearing. We expected that the relation upper arm strength - BW would influence the PWB, i.e. higher limb loads during PWB will probably occur when a patient has poor upper arm strength and is also heavy and that a patient with normal upper arm strength who has a relatively low BW will load the limb less. However, we found no relationship between normalized upper arm strength and mean peak load or percentage of steps above the target. A possible explanation for the lack of relation between upper normalized arm strength and weight bearing could be that the patients who had more arm strength were also heavier. Because patients were instructed to load their leg at a percentage of their BW, heavier patients have to unload their leg more (absolute load) than patients with a lower BW, which costs more upper arm strength. This was confirmed by the fact that arm strength normalized for BW also showed no relationship with the weight bearing outcome measures. The patients in the study of Chow et al.[12] had a much lower BW (43 - 44 kg) than our patients (69 - 88 kg) which might explain why Chow et al.[12] found that arm strength was related to weight bearing. Another explanation could be that our weight bearing measurements were performed in a non-controlled environment (i.e. outside a laboratory), and that although the patient had sufficient arm strength to load the leg correctly he/she did not load the leg at the prescribed target load.

Postoperative status

Within the postoperative status factors, the overall pain and pain during walking were positively related with the mean peak load at a 10% BW target load and with the percentage of steps above the target. However, we expected that patients who have more pain would unload their leg (voluntarily) more than patients who have less to no pain.[25] For this reason, weight bearing as tolerated or pain-guided weight bearing is prescribed in clinical practice to unload the operated leg; however, this type of treatment approach is not supported by the present study. A possible explanation for the finding of a positive and not a negative relation in our study could be that the patient scored a low pain figure because he/she did load the leg at a low load, and scored a high pain figure because he/she had loaded the leg more. Although pain could restrict the loading of the leg, we think that pain intensity is not a good instrument to unload the leg to a specific target load (e.g. 10% BW) during the entire recovery period of 6-8 weeks, because the voluntary unloading of the patients in the study by Koval et al.[25] was 51% BW at one week and 65% BW at three weeks postoperatively. Moreover, pain varies between total hip patients, and most patients in our study had little to no pain three weeks after the total hip operation and still had to restrict weight bearing to either 10% or 50% BW for another three weeks (Table 2).[22] Vasarhelyi et al.[34] stated that increasing levels of load might be a function of postoperative pain as their young patients loaded their leg more when they had a slight decrease in pain; however, in their older patients, a substantial decrease in pain did not change the variance in the magnitude of load bearing.

Patients can become fatigued during PWB which might lead to higher loads because walking with assistive devices is physically demanding.[4,16,17,19,28] However, we did not found a positive relation between fatigue and PWB outcome measures. Fatigue was found to be negatively related with the mean peak load in the presence of a PT. Patients are probably more motivated to unload their leg, even though they become tired, in the presence of a PT than when walking alone.

Postoperative anxiety can influence the patient's weight bearing performance as patients might be more careful in placing their foot on the ground or walk less, which could decrease the risk of high weight bearing loads. This was confirmed by a negative relation between anxiety and the percentage of steps above the target load at home 2 - 3 weeks after discharge. However, contrary to our expectations, a positive relation was found between anxiety and percentage of steps above the target at a 10% BW target load. The positive relation between anxiety about falling and weight bearing could indicate that the patients loaded their operated leg more to gain more balance.

Walking features

From the walking features, a decrease in step frequency and an increase in walking time and total number of steps lead to a higher mean peak load. Also, an increase in walking time and total number of steps lead to a higher percentage of steps above the target for the 10% BW target load. Previous studies found that an increase in step frequency or walking cadence resulted in an increase of the vertical ground reaction force and plantar pressures.[13,36,39] Martin and Marsh[27], however, found little change in ground reaction forces while changing the step frequency, which they explained by the fact that they controlled speed during the measurements. The relationship between walking time and weight bearing, and total number of steps and weight bearing can be explained by a higher chance of loading the leg more when patients are walking more. However, it should be noted that besides the relationship that patients load the leg more due to more walking, patients may also load the leg more because they are more confident and walk more because they are more confident. In this case, there is no direct relation between walking and weight bearing as both, separately, increase due to another factor.

No relation was found between type of walking aid and the mean peak load or the percentage of steps above the target. Youdas et al.[38] found differences in walking speed and cadence with different types of assistive devices; however, they did not evaluate a standard walker or elbow crutches. Our results suggest that PWB with a walker or elbow crutches does not affect the weight bearing performance of the patient.

In our previous study we found that the prescribed target load influenced the weight bearing of the patients; the 10% BW target load had a lower mean peak load and had more steps above the target load than the 50% BW target load.[22] In the regression models we found that target was an effect-modifier for pain, pain during walking and anxiety which means that a significant relation with the dependent variable was found for the 10% BW target load but not for the 50% BW target load. Besides the differences in relationships for the two target loads, we also found that certain independent variables were related with the mean peak load but not with the percentage of steps above the target or vice versa. Therefore, one has to be aware that the interpretation of the relationships found depends on the selected PWB outcome measure.

Limitations of the study

The limitations of our study include the number and selection of patients evaluated. Using multilevel analysis with repeated measurements we efficiently used the number of measurements to increase the data set. Although weight bearing measurements were repeated at three conditions, the relation between the independent and the dependent variable was not equally strong for each of the three conditions, which might explain why certain relations were not found. Also, weight bearing was not assessed for every patient at each of the three conditions, which reduced the number of measurements. Exclusion of less fit patients, resulting in a relatively small homogenous group, could have influenced the results regarding not finding relationships with age, muscle strength and fatigue.

Clinical relevance/conclusions

In clinical practice it is important for the PT to know which factors influence the patient's PWB performance, so that the PT can anticipate situations which might increase the risk of incorrect loading of the operated leg. From this study we can conclude that the PT has to be aware that female patients load the operated leg more than male patients, although the difference between females and males is smaller when females walk with the PT. Also, when patients are more anxious about falling, they load the leg more and more steps could be placed above the target load. Furthermore, an increase in limb load is more likely to occur when a patient walks longer and takes more steps. Additionally, when a 10% BW target load is prescribed more steps will be loaded above the target load when a patient walks more and/or takes more steps. Contrary to our expectations, arm strength did not influence PWB, and an increase in pain or anxiety did not result in a decrease in PWB. In view of our results, we think that pain intensity is not a good instrument to unload the leg to a specific target load during an entire recovery period lasting 6 to 8 weeks.

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7 General discussion

The primary aim of this thesis was to evaluate whether patients with a total hip arthroplasty and a trochanteric osteotomy do load their leg to a prescribed target load during their postoperative recovery, and to identify factors that affect the patient's partial weight bearing (PWB) performance. This aim required an instrument that measures the load placed on the leg (i.e. vertical ground reaction force) during the patient's daily activities. Therefore, we assessed the validity and repeatability of an adapted portable insole pressure system to measure the vertical ground reaction force over several hours. In the present chapter, we first summarize and discuss the main results of the clinical PWB studies described in this thesis. Secondly, the concept of PWB is described and several reasons are given that might explain why there is no consensus on the optimal PWB status. Thirdly, we will discuss some of the limitations of the methodology used, and implications for the clinical physical therapy practice to instruct PWB. Then, the practical possibilities and limitations of an adapted insole pressure system for weight bearing measurements in a daily setting, as well as expected technological developments within this field, are discussed. Finally, some directions for future research on PWB are presented.

7.1 Partial weight bearing of patients during postoperative recovery

To evaluate whether patients perform PWB to a certain target load during their recovery in the hospital and at home, weight bearing measurements have to take place in the patient's natural setting. In the literature, most of the PBW studies performed the measurements in a gait laboratory using healthy subjects and predefined walking trials.[3,16,21,27,28,37,41] From the patient studies on PWB, only two studies investigated patients postoperatively when freely walking in the hospital[30,34]; one of these studies measured patients postoperatively in the hospital but used a predefined gait trial[42], and the other study measured patients outside the hospital but also used a standardized distance and the average time after surgery was four years.[36]

Therefore, we performed a PWB study in which the load placed on the operated leg was objectively measured when total hip patients were walking in their natural setting during postoperative recovery in the hospital and at home (Chapter 5). The results of that PWB study showed that a substantial amount of patients did not load their operated leg to the prescribed target load, and that for a large percentage of measured steps the leg was loaded incorrectly during PWB in the hospital. These findings support the two earlier patient studies in which patients walked freely in the hospital.[30,34] Although the authors from these two latter studies found that biofeedback improved the patient's PWB performance, other studies reported some drawbacks (i.e. overshooting the target load, and decrease in PWB accuracy when biofeedback is removed) of PWB training with biofeedback.[33,37,38] Therefore, further research on the effectiveness of biofeedback regarding the level and duration of biofeedback is needed to implement biofeedback in the clinical practice.

Influence of setting/time after surgery on partial weight bearing

In our PWB study we made a distinction between PWB with or without the presence of a physical therapist (PT) during the patient's stay in the hospital, and between PWB in the hospital and at home to assess a possible setting effect (i.e. with vs. without a PT, and hospital vs. home) and/or time effect (1 week vs. 3-4 weeks after surgery) on the PWB performance, which has not been studied before. One week after surgery there was no difference in PWB when the patient walked with or without the PT. This suggests that after one week the patient does not need the presence of a PT to perform PWB, although the load on the leg was not the correct target load. This could also suggest that other factors (such as postoperative pain) have an effect on the immediate PWB performance, because the measurements were taken on the same day which meant that the patient was equally cautious about placing the foot on the ground in both settings.

At home (3 - 4 weeks after surgery) distinctly higher loads were placed on the operated leg and a larger percentage of steps was above the target load than during the hospital stay (1 week after surgery). Although several reasons are mentioned in Chapter 5 which might explain the higher weight bearing loads at the patient's home (e.g. the difference in environment, or the increase in the patient's confidence), no distinction can be made as to whether these results are mainly determined by factors related to the setting or to the time after surgery. A reduction of the high weight bearing loads at home might be obtained by limiting the number of steps taken throughout the day (Chapters 5 and 6). In Chapter 5 we found that the number of steps taken at home was about 3 times more than in the hospital, and in Chapter 6 a relation was found between weight bearing and the total number of steps taken. However, it should be noted that besides the causal relation that more walking leads to higher weight bearing loads, the walking duration and weight bearing loads may also increase independently due to the patient's increase in confidence. Nevertheless, a simple instruction that the PT might give to the patients is to limit the amount of walking during the day to avoid high limb loads, especially for those patients who already show eagerness to take longer walks in the hospital.

Influence of target load on partial weight bearing

Another characteristic of our PWB study is that we evaluated PWB at two different prescribed target loads, because this could affect the patient's PWB performance. All previous studies use different target loads ranging from 9 - 32 kg or 10 - 50% body weight (BW), making it difficult to compare the results. We found that the target load did influence the weight bearing performance of the patient, resulting in more patients taking more steps above the prescribed target load with a low target load (i.e. 10% BW) than with a high target load (50% BW), especially when the patient was at home. These results indicate that with a lower target there is a higher risk of loading the leg too much; however, we do not know whether this leads to more postoperative complications.

Influence of patient characteristics, postoperative status and walking features on partial weight bearing

Besides the factors which are mainly related to the PWB protocol (i.e. instruction method, setting, target load), other factors that are more patient-related may also influence the patient's PWB performance. In Chapter 6 we showed that women will more likely load the operated leg more than men, and that postoperative pain during walking, anxiety about falling, total walking time and total number of steps taken are positively related and the step frequency is negatively related with the patient's PWB performance. One previous report that evaluated factors affecting PWB found that muscle power of the arm was important for PWB[15], whereas, we did not find a relation between upper arm force and PWB. However, because of the limited information and differences in results in the literature, more research is needed on this topic.

Partial weight bearing measurement in a natural setting

A characteristic of measuring in a natural setting is that the patient's actual performance is measured (i.e. what he/she does) and not the capacity/ability of the patient (i.e. what he/she can do). The explanations for our results (i.e. that a large group of patients did not load the leg at the prescribed target load) can, therefore, be threefold. First, the patients were not physically or mentally able to perform PWB. To know whether patients are able to perform PWB, measurements have to be performed in a controlled laboratory setting in which patients are maximally motivated. When, for instance, the walking distance (number of steps) and the load at every step is measured one can determine what the maximum distance is (or number of steps are) at which no risky overloading of the leg occurs. If one determines that a patient is not able to perform PWB, then perhaps the patient should be operated with a technique that allows full weight bearing. Secondly, it can mean that the patients were able to perform PWB but were not properly instructed. In this case, it may be that the verbal instruction method used is not adequate and other methods have to be evaluated. In the literature better results in the immediate PWB performance were found when using (audio) feedback systems instead of the commonly used verbal feedback.[4,30,34]

Feedback systems provide concurrent feedback which means that the feedback is presented (immediately) during the performance. However, for (long-term) learning of a PWB skill verbal postresponse feedback (which is feedback after the PWB performance) was found to be more effective than concurrent feedback.[38] Although audiofeedback and postresponse feedback seem promising, further study is needed on the effectiveness of these two forms of feedback on the actual weight bearing performance of patients in the clinic (concurrent feedback) and at home several weeks after discharge (postresponse feedback). Thirdly, it can mean that the patients were able to perform PWB and were properly instructed, but did not load the leg at the prescribed target load for other reasons. The patient's compliance with the verbal instructions could be of importance here, especially for PWB at the patient's home. A typical incident before a home measurement was that a patient opened the front door of his/her house and used only one elbow crutch. We suggest that a study designed to measure the usage of the walking aid combined with the recording of the number of steps taken by the patient may provide an answer regarding the patient's compliance.

7.2 Controversy over the optimal partial weight bearing status

Concept of partial weight bearing

The general concept behind PWB is to decrease the forces at the healing site by reducing the external load on the operated leg. For the healing of a trochanteric osteotomy, decreasing the external load on the leg reduces the activity of the abductor muscles and, consequently, the forces on the osteotomy. This means that in clinical practice the operating surgeon and the PT use the amount of (external) load placed on the leg as an indicator for the amount of force at the trochanter osteotomy site. In this thesis the external load on the leg was assessed by measuring the vertical ground reaction force during walking. In previous PWB studies the vertical ground reaction force was also used as an objective measure to assess the amount of load placed on the lower extremity.[16,21,27,28,36,37,41]

Although the concept of PWB seems clear, the optimal postoperative weight bearing status remains an area of confusion and controversy. This is seen in the random variety of target loads (e.g. 32 kg or 30% BW) and variety in duration of weight bearing (6 - 8 weeks or 8 - 12 weeks) described in the literature for the same surgical interventions.[11,26] An example of this controversy is also seen in our study where two different target loads were prescribed for the same total hip operation at two different hospitals (Chapter 5). In one participating hospital, which uses a 50% BW target load, 40% BW was still found to be acceptable, but this was found to be too much in the other participating hospital where the patients are restricted to a 10% BW target load, although they had the same surgical intervention. This leads to the question: when does the patient actually load the leg below, equal to, or above the target load? Until now no clear answer can be given.

Reasons related to the controversy over the partial weight bearing status

One of the reasons for the lack of consensus on PWB is probably because many other factors, besides the local forces, determine the healing process of fractures and implants. For fracture healing (induce bone growth) and for cementless implant fixation (osseointegration) limited micromotion is necessary; however, too much micromotion leads to connective tissue and therefore delayed fracture healing or non-union, and less strong fixation of uncemented implants.[12,31,39] The amount of micromotion depends on the local forces and on several other factors such as the prosthesis' design, the fracture fixation, operation technique, bone quality, and strength of the surrounding tissues, which are factors that are not easy to characterize.[14,24,39] Thus, because of the multiple factors that determine the healing process, and the fact that these factors are not easy to measure, it remains difficult to assess how important the role of PWB is in the occurrence of postoperative complications.

Another aspect which may be related to the controversy over PWB, is that we do not know which type or amount of local force e.g. axial force or torsional force, or peak force (e.g. 1 x 2000 N) or duration of force (e.g. 10 x 200 N) is good or harmful for the healing site. Wirtz et al.[39] stated that although there are many in-vitro, and in-vivo studies, as well as mathematical finite-element simulations models that explored the primary stability of total hip prostheses, it is unknown which micromotion occurs at which local joint forces. However, Wirtz et al.[39] did establishe general guidelines for weight bearing after total hip arthroplasty, by combining the results from in-vivo animal studies[e.g.31] and the hip joint in-vivo studies[e.g.5], in which uncemented implants should be loaded only partially for at least 6 weeks. However, Brander et al.[11] recommended full weight bearing for uncemented implants in their evidence-based review on rehabilitation after total joint replacement, except in the presence of a trochanteric osteotomy. More recent studies also prescribe full weight bearing for uncemented implants, and even for fractures and anterior cruciate ligament reconstructions because of the limited number of complications found.[9,13,18,19,26,40] No reports were found in which complications were studied when early full weight bearing was prescribed for patients with a total hip and trochanteric osteotomy.

Furthermore, in clinical practice we do not know which local forces occur at the healing site during PWB, because we can not measure them. In-vivo studies with sensors in hip prostheses that measure the hip contact forces during standing and walking give an indication of the amount of local forces in the hip.[e.g.5,8] However, to our knowledge no studies have measured axial or shear forces in-vivo at the trochanteric osteotomy site.

Moreover, the relationship between the vertical ground reaction force during PWB and the local forces at the healing site is not clear. Musculo-skeletal models which are currently available seem promising to predict forces at the hip using ground action forces.[e.g.22] However, Heller et al.[22] still found 19% of intra-individual variation in hip moments compared to 4% variation in the ground reaction forces due to the inverse dynamics calculation.

In summary, we conclude that more knowledge is needed on PWB to reach consensus on the optimal postoperative weight bearing status after lower limb surgery. Future studies should focus on either biomechanical research to gain more insight in the relation between local forces or (micro)movement at the healing site and PWB, or focus on clinical/epidemiological research with large patient groups to assess the relation between PWB and postoperative complications. A biomechanical study could, for example, measure postoperatively the movement at the osteotomy site with radiostereometric analysis (RSA) in patients with a total hip and trochanter osteotomy together with the patient's actual weight bearing as prescribed in this thesis. The patients from our study will be followed to assess postoperative complications up to 12 months after surgery. By collecting as much information on other factors that may be related to complications, a multivariate model will be used to find a relation between the amount of weight bearing and the number/type of complications.

7.3 Limitations of the clinical study

Generalization of the results

Differences between the two hospitals in our study and other hospitals may include the PWB protocol (e.g. target load), and factors such as the experience of the PT, the intensity of physical therapy, patient characteristics, and the surgeon and type of surgical intervention, which makes it difficult to generalize the results. However, the main difference between the two hospitals in our study is probably the target load used, and although we did not assess other factors (as mentioned above) we have no indication that the two hospitals differ on these aspects. The generalizibility of our results to other hospitals can not be assessed. However, there seemed to be no distinct reasons why the physical therapy for PWB in these hospitals will be different from other locations. Nevertheless, to establish whether our results are also applicable elsewhere, measurements have to repeated at other hospitals.

In this study, we focused on total hip patients with a trochanteric osteotomy and not on other patient groups for which PWB is prescribed. We chose to evaluate total hip patients with a trochanteric osteotomy mainly because this was the largest homogenous patient group in our hospital. The variance in pathology, type of patient and surgical intervention which affect the patient's postoperative status and, therefore, mainly determine the PWB performance of the patient, makes it difficult to generalize our PWB results to other patient groups. Therefore, the study in Chapter 5 needs to be repeated to determine whether patients with e.g. a femur fracture do unload their operated leg correctly.

Walking and other activities

In the present study the load placed on the operated leg was measured only during walking. Walking is generally regarded as the most important weight bearing activity, because high impact loads can occur due to alternate standing on one leg with acceleration of the total body mass.[17] Also, when walking the abductor muscles are active during single-limb support which induces forces at the greater trochanter that have to be avoided when patients have a trochanteric osteotomy. Furthermore, walking is necessary to perform daily activities and, consequently, frequent loading of the leg occurs when many steps are taken.

Other activities besides level walking could also lead to high loads in the lower extremity, such as ascending/descending stairs and transfers (sit-to-stand, in/out bed).[5,7,17,20,35] Davy et al.[17] implanted a telemeterized total hip prosthesis in one patient and measured forces in the hip during the patient's recovery. They found maximum forces of 1.0 - 1.8 times body weight with straight-leg raising, 1.0 - 1.5 times body weight when getting into or out of bed, 2.6 - 2.8 times body weight during stance phase of gait, and 2.6 times body weight during stair climbing. In other studies with telemeterized hip prostheses, forces raised up to 2.5 times body weight when the leg was actively raised against resistance in bed and 2.0 times body weight in sit-to-stand and stand-to-sit activities.[5,35] This indicates that, besides walking, other weight bearing activities can also create high loads in the hip, and that these loads also can occur due to muscle contraction.

The data of the telemeterized hip prosthesis studies suggest that walking and stair climbing cause the highest hip loads, while sit-to-stand and stand-to-sit activities also lead to relatively high loads in the hip. In our study we were unable to monitor what kind of activity the patient was doing, so no distinction in the data could be made between, for example, level walking or stair climbing. Bergmann et al.[6] found an extremely high load on the hip (i.e. 7 times body weight) when a patient was accidentally stumbling during walking. Therefore, walking can still be seen as the most important activity to measure long-term loading and extreme loads during (occasional) activities in daily life. An addition could be to measure the weight bearing loads placed on the leg during sit-to-stand and stand-to-sit activities when a patient is recovering from surgery. Knowledge on external loads that are harmful will clarify the need for measurement of activities that induce these loads.

Adaptation of the patient to the weight bearing measurement

The weight bearing measurements could be influenced by the fact that the patients were aware that they were measured, and most of them also knew what was measured. Therefore, it is possible that the patient loaded the operated leg better (i.e. less higher loads than he/she would do without the measurement system), because the patient knew that he/she was being “observed”. The influence of this aspect can not be determined from the present data. However, we think it unlikely that the patients were constantly aware of the instrument over a 5 - 6 hour measurement period. Many of the patients already had difficulty using the walking aids and unloading the operated leg, which took most of their attention. It can be argued that the patients might have been less active due to hindrance of the vest with the Pedar box and the battery unit and the weight of these devices. However, most patients stated after the measurement that wearing the vest was less of a burden than they had expected. It should be noted that some patients reported that they did not walk outside during the measurement at home, because the vest did not look very attractive with their own clothes. On the other hand, patients frequently asked whether they should walk more because they were being measured and, although they were specifically asked to do only what they would ordinarily do, some of them proudly said that they had walked a little extra. However, the outcome measure of steps below, equal to or above the target load was expressed as a percentage of the total number of steps taken and, therefore, was independent of the number of steps taken. Therefore, we feel confident that the weight bearing results were not influenced by the change in the patient’s walking behavior.

Choice of measurement system and outcome measure

For objective measurement of the amount of load placed on the leg during walking, the (vertical) ground reaction force is accepted as the ‘gold standard’. Therefore, in most PWB studies force platforms were used to measure the patient’s weight bearing.[16,21,27,28,37,41] Although force platforms have the best methodological quality for measuring the vertical ground reaction force, they are restricted to a laboratory which makes them unsuitable for weight bearing measurements in a natural setting (see Chapter 2). Therefore, in the present study (as well as in some other PWB studies) insole pressure systems were used, because these systems can record weight bearing over many steps during activities of daily living.[30,34,36]

One problem with insole pressure systems is that these systems actually measure the normal force, which is not necessarily similar to the vertical ground reaction force.[2,25,29] The normal force is the force perpendicular to each sensor in the insole and its vector is equal to the vertical ground reaction force when the foot is positioned flat on the floor, but alters during the initial and late portions of the stance phase of the gait cycle. It might be argued that the resultant force vector is more comparable during heel-strike with the insole force vector than the vertical force vector. However, in the discussion of Chapter 3 we showed that the calculated resultant force vector does not differ much from the vertical force vector. Barnett et al.[2] compared the vertical force measured with the Pedar insole system and a force plate, and found a good accuracy for the second peak force and less accuracy for the first peak force during the stance phase. Similar results were obtained in this thesis where vertical force measurements were validated over a long-term period (Chapter 3). This may be explained by the fact that the insole sensors are positioned more parallel to the force platform during toe-off than during heel-strike. Generally, during PWB patients are instructed to place the foot of the operated leg (in which the sensors are placed parallel to the ground) flat on the ground.

In most PWB studies, the primary outcome measure is the average peak force/load in percentage body weight because this is related to the maximum load (or target load) used by the clinician. Besides the maximum (or peak) load, clinicians may also be interested in how long (i.e time or number of steps) the patient correctly performs PWB, because the duration of loading (just) above the target load could be equally important for possible complications as the occasional peak loads. An interesting outcome measure for PWB is the force-time integral or force impulse, which provides both force and time of loading during a step. For instance, Vasarhelyi et al.[42] found higher impulse values in their older patient group than in their young patients. The choice of the main outcome measure for PWB remains difficult, because the relationship between the ground reaction force on the leg and the local forces at the healing site in the leg is not clear.

In the clinical study, for the main outcome measures we used average peak load (% BW), the percentage of patients with an average peak load (% BW) below, equal to and above the target load, and the percentage of steps below, equal to and above the target load, which have, unfortunately, certain limitations. To compare the weight bearing results between three conditions and to compare them with other studies we used the average peak load (%

BW) of a group of patients. This group average peak load was calculated from the average peak load (% BW) of all steps taken by each patient. However, a reduction in weight bearing information would occur when only the group average peak is presented when long-term measurements are performed, because the long-term measurements from the individual patients showed a large variance in weight bearing. We, therefore, also presented the patient's within-variance in weight bearing (Chapter 5). One limitation of the weight bearing cut-offs used for below, equal to and above the target load, is that they are arbitrarily chosen. Other cut-offs for below, equal to and above the target load would lead to different results. However, by presenting a distribution of peak forces (see Figures 3 and 4 in Chapter 5) one can determine the amount of weight bearing for their own chosen cut-offs. A final remark on the choice of a weight bearing outcome measure is that we found that certain factors were correlated with the average peak load and not with the percentage above the target load or vice versa (Chapter 6). Therefore, one has to be aware that interpretation of the relations found depend on the chosen PWB outcome measure.

7.4 Implications for clinical practice

The direct implications for clinical practice are that the PT and operating surgeon should be aware that many patients do not correctly load their leg during postoperative recovery, and that this is primarily the case when a relatively low target load is prescribed and when patients are at home after discharge (Chapter 5). Also, the results in Chapter 6 indicate that the PT must be aware that female patients tend to load the leg more than male patients when they walk without supervision, that patients who are more anxious about falling will load the leg more, and that increased limb load is more likely to occur when a patient walks for a longer time and takes more steps.

Considering our previous discussion regarding the limited knowledge on PWB (see **Controversy over the optimal partial weight bearing status** - *Concept of partial weight bearing* -) the PT is still not sure which load is harmful to the patient, because there is no (or limited) evidence from patient studies regarding the benefit derived from PWB. Furthermore, the PT does not know whether incorrect loading is harmful. Thus, does 40% BW above the target load lead to a non-union of the trochanteric osteotomy when this loading happens only once, or does a non-union occur when 80% of the steps taken by the patient are loaded with 20% BW above the target load? Therefore, further research (biomechanical/epidemiological) is needed to obtain more evidence about the local load/micromotion at the trochanteric osteotomy healing site and PWB, and the relation between complications and PWB (evidence-based medicine/therapy).

Until we have answers to the above-mentioned problems, there are several possible weight bearing strategies that the PT can follow. First, a less strict weight bearing strategy in which some unloading is considered to be sufficient (e.g. weight bearing as tolerated) and only extreme loads have to be avoided, this means all loads above full (i.e. 100%) body weight (e.g. stumbling leads to hip loads of 7x BW[6]). The instructions should focus on the patient's awareness of risky activities and movements. A positive side-effect is that patients do not have to unload the leg too much, which could decrease the stress on the upper extremities and the contralateral limb. A second option is a strict weight bearing strategy with a defined target load. The PT tries to ensure that the patient loads the leg at the prescribed target load. Given the results from this thesis and from other PWB studies, a randomized clinical trial to evaluate the effect of audio feedback on the patient's PWB performance is needed. The third option can be seen as an in-between strategy, which is merely a continuation of the current practice. This means that the PT instructs the patient in the best possible way with the commonly used instruction methods (i.e. verbal instructions with/without use of a bathroom scale). Using this latter strategy the surgeon or PT has no real problem if discrepancies exist between the actual and the prescribed target load. Because of the lack of evidence concerning which strategy is best, the choice of the weight bearing strategy still depends on the surgeon's own preference.

7.5 Long-term measurement of weight bearing in daily living with an insole pressure system

In Chapter 2 we concluded that insole pressure systems are the most suitable instruments for our PWB measurements. Previous studies by Siebert[34] and Tveit and Kärrholm[36] used insole systems to evaluate PWB outside the laboratory, although no information was given regarding the validity and/or reliability of these insole systems. Good validity and reliability were reported for the Pedar insole system.[2,10,23,25,29,32] However, these studies evaluated the Pedar system for only short measurement times because the system was not primarily developed for measurements over several hours. For our purpose we adapted and validated the Pedar system to be used for long-term weight bearing measurements in daily living.

Validity issues for long-term weight bearing measurement with an insole system

One of the first issues of validity when measuring the vertical ground reaction force with an insole system is that these systems measure the normal force, which is not exactly the same as the vertical force. This has already been discussed in a previous section (see **Limitations of the clinical study** - *Choice of measurement system and outcome measure* -).

A new validity issue related to long-term measurements, was the occurrence of offset drift. A study by Arndt et al.[1] reported a drift of up to 17% after 3 hours, for which they developed a correction method; however, these authors did not perform further validity or reliability tests. In Chapters 3 and 4 of this thesis we described the amount and type of drift after long-term loading of the insoles and concluded that the Pedar Mobile system was a valid instrument to measure the vertical force during a long-term period when using the drift correction program specially developed for this. Besides the (positive) offset drift, we also found a negative drift which stabilized after one hour. For this acclimatization period of one hour a practical solution was chosen by performing a second zero setting (i.e. calibration in the shoe) after one hour before starting the actual weight bearing measurements.

Practical issues for long-term measurements with an insole system

A practical limitation of the Pedar Mobile system for continuous data collection over several hours was that the battery (Ni-Cd) of the Pedar system provided power for a maximum of one hour and that the memory card (Intel 2+ flash card) had a limited data capacity (maximum of one hour data collection with 2 insoles at 50 Hz). Therefore, we adapted the Pedar system by using different batteries (Sony NP750 Li-ion) and by including an automatic start-stop device to ensure that data were recorded only when the patient was standing or walking, thus strongly reducing the amount of data (Chapters 3 and 5). When measuring for 5 - 6 hours, two battery units were needed which were changed at home by the patients without any problems reported. We expected that a total of one hour would be sufficient to collect all walking data during a 5 - 6 hour period; however, a few patients walked at home more than the one hour we were able to record. Nevertheless, we think that one hour of walking data should provide enough information to obtain a good impression of the patient's PWB performance.

Other practical aspects are more patient-related, such as the weight of the measurement equipment, the possible hindrance of cables when walking with walking aids, and the shoes used during the measurements. The vest with Pedar box and battery unit weighted about 1.8 kg, however, nearly all patients did not object to wearing the vest for 5 - 6 hours. The importance of the design of the vest was that it fitted around the patient's body such that the Pedar box could not move when activities were being performed; thus, the patient was not hindered by the weight of the Pedar box. When fitting the measurement equipment on the patient it is important to fix the cables properly so that the patient walks unhindered with the walking aids. Therefore, the cables were generally placed under the pants and attached with tape to the patient's bare legs. To avoid possible effects of type of shoe on the insole measurements, the patients wore the same shoes during the measurements in the hospital and at home/nursing home. Although the patients wore comfortable shoes with laces, the feet of some patients were swollen to such an extent that they were unable to wear normal shoes and thus no weight bearing measurements could be performed.

New developments

When considering the limitations of the insole system used for long-term weight bearing measurements, future developments should focus on e.g. automatic drift correction for the positive offset drifts as well as for the negative drift in the first hour (within the electronics of the system), the weight and size of the recording unit and the power supply, and wire-less connection between the recording unit and the insoles.

A new Pedar system (Pedar-X) has recently become available which is smaller and half the weight of the earlier Pedar-M system which we used in our patient study. The system can work in a mobile capacity with Bluetooth™ technology or with a built-in flash memory storage of 8 Mb. The sample frequency is increased from 10,000 to 20,000 sensors/second (i.e. 100 Hz instead of 50 Hz with 2 insoles), and the power supply is provided by Li-ion batteries which can be changed by the subject during measurements without any breaks using a Y-cable. An important new development for long-term force measurements is that the Pedar-X can be programmed such that for each insole the total force per time frame is stored in the internal memory. This means that with 8 Mb of memory the system can store for about 4.5 hours of force data at 100 Hz, and with the 32 Mb version of the Pedar-X force data can be stored for up to 22 hours. In this way the system can be used specifically to monitor load. In the near future, the Pedar system can also be used as a biofeedback device for PWB after surgery. For this, the user can define a force range before the measurement, and when during the measurement the patient is below or above that force range a signal (different versions) will be given.

7.6 Future research on partial weight bearing

Several studies have evaluated whether weight bearing can be instructed. However, the available literature and knowledge on PWB is quite limited. In this last section we summarize previous remarks on and mention some new aspects of future research on PWB.

The two main aspects for future research are: 1) biomechanical studies to gain more insight in the relation between local forces or (micro)movement at the healing site and PWB, and 2) clinical/epidemiological studies to assess the relation between PWB and postoperative complications. In addition, no research has focused on the evaluation of PWB during activities other than walking. Also in this thesis, PWB was assessed only during walking and (as mentioned previously) other activities (e.g. ascending /descending stairs, sit-to stand) can also lead to relatively high forces in the hip. Furthermore, the number of patient studies is limited with regard to PWB, and most of them evaluated total hip patients. Therefore, different patient groups need to be evaluated to establish whether other patients perform better or worse than those already studied. For example, the recent study by Vasarhelyi et al.[42] postoperatively evaluated patients with a fracture of the lower limb and found that younger patients loaded their leg less than the older patients. However, the number of patients evaluated (12 young patients; 11 elderly patients), was relatively small. Further research is also needed to provide the PT with more knowledge on how to instruct patients to perform weight bearing at a specific target load. The effect of audiofeedback seems promising but needs more evidence from clinical trials in which patients are measured in both the hospital and at home. A final option for future research on PWB is to gain more insight into the patient's gait pattern during PWB, which might provide information on which gait aspects are important for the unloading of the lower limb. For instance, does the patient load the leg more during heel-strike or during toe-off, or is the duration of the stance phase related to the limb load? By performing long-term measurements in a daily setting in this thesis we obtained data on several thousands of foot steps taken by patients both in the clinic and at home. This data set will be used for further research on the patient's gait pattern in relation to PWB.

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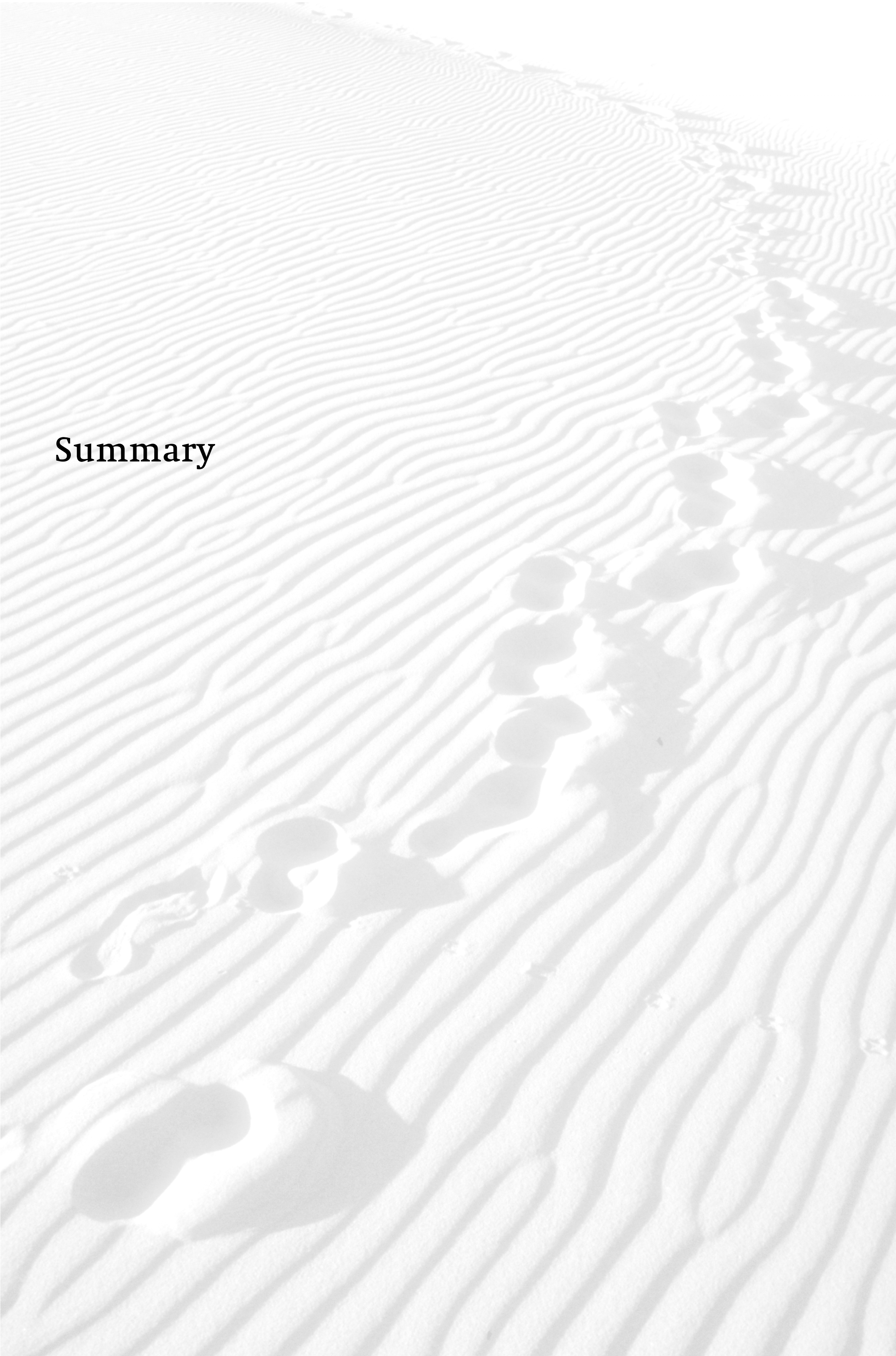
Summary



Partial weight bearing (PWB) is a central aspect within the postoperative physical therapy of orthopedic and trauma patients with pathologies of the lower extremity. Restriction in weight bearing of the operated leg during standing and walking is needed to avoid complications during the postoperative recovery. The task of the physical therapist (PT) is to instruct the patient how to unload the lower extremity during recovery, so that the patient can safely and independently perform activities of daily living. Restriction of the amount of load on the operated leg not only has to take place during the relatively short supervision periods with the PT, but also during the longer and, therefore, more relevant recovery periods without supervision during the hospital stay as well as after discharge.

Although PWB is commonly used, few data are available on the assessment of actual load on the operated leg of the patient during activities of daily living. One reason for this could be the lack of valid and reliable portable instruments which can objectively measure the amount of weight bearing over a period of several hours.

In this thesis the PWB performance of total hip patients with a trochanteric osteotomy is evaluated during their postoperative recovery. For this, a portable insole pressure system was adapted and validated to measure the vertical ground reaction force both in and outside the hospital setting.

Chapter 1 presents a general introduction to PWB. It describes the relationship between the loading and the healing process of the lower extremity during the postoperative recovery period. Specifically, for total hip patients with a trochanteric osteotomy the need to restrict the lower limb load is described. A brief overview is given of the different instruction methods used by the physical therapist in the clinic to restrict the amount of weight bearing prescribed by the surgeon, the factors which may influence the patient's weight bearing performance, and the instruments used to measure weight bearing. The last section of Chapter 1 presents an outline of this thesis.

To measure the amount of weight bearing objectively over several hours during the day we needed an instrument that can measure in a valid and reliable way the vertical ground reaction force during several hours. Therefore, a literature search was performed to gather information on instruments and techniques that measure weight bearing. **Chapter 2** gives an overview aimed to classify, assess and discuss these different techniques to measure weight bearing during standing and walking. Five techniques (clinical examination, scales, biofeedback systems, ambulatory devices, and platforms) were defined and evaluated on aspects of methodological quality, application and feasibility. The main conclusions were

that clinical examination is a crude method to measure weight bearing, and that a scale is only useful for static measurements to evaluate symmetry in weight bearing. Biofeedback systems are more reliable and accurate than clinical examination and scales, but high costs limit their use in daily physical therapy practice. Platforms have the best methodological quality but are restricted to a certain place, whereas ambulatory devices can measure weight bearing with a good accuracy and reliability in and outside the hospital. Besides the criteria used in the review, the choice of a technique also depends on the research question posed and the available budget.

To perform long-term weight bearing measurements in the clinic and at the patient's home the Pedar Mobile system (a portable insole pressure device) is a potential system. However, the validity and repeatability of this system was evaluated in previous studies only during short measurement periods (i.e. 5 - 10 minutes). Temperature and humidity can influence the output of the sensors as these are worn inside a shoe. This might especially apply when the insoles are worn inside the shoes for several hours. Therefore, the validity of the Pedar Mobile system to measure the vertical ground reaction force over a long-term period was investigated by comparing the Pedar data with the data from a Kistler force plate (**Chapter 3**). Vertical ground reaction force data were collected during dynamic (walking) and static (standing) conditions every hour for 7 hours from five healthy subjects. To correct for possible drift in the force data, which was defined as an undesirable change in the output signal (force) over a period of time unrelated to the input (load), we developed a drift correction algorithm. This correction algorithm was based on the fact that the output of the insole sensors should be zero during the swing phase of walking because there is no weight placed on the foot during that time. If force values during the swing phase were measured, then the correction algorithm subtracts the force values from the swing phase from the force values measured during the standing phase of walking. Besides that the force during the swing phase had to be zero, the correction algorithm was also based on another assumption, namely, the drift has to be an offset drift. Therefore, the type of drift (offset or gain drift) was also assessed in that study. A substantial amount of drift (15%) was found, which was mainly an offset drift. After using the correction algorithm the Pedar system showed a high accuracy for the second peak in the ground reaction force-time curve and the step duration. Less accuracy was found for the first peak in the ground reaction force-time curve and, consequently, in the vertical force impulse. We concluded that the Pedar Mobile system is a valid instrument to measure the peak vertical ground reaction force during a long-term period when using the drift correction algorithm.

Besides temperature and humidity, the output of the insole sensors can also be influenced by the amount and duration of loading during long-term measurements. Therefore, we performed a second validation study in which the accuracy and the repeatability of the Pedar system was assessed to measure the vertical force during long-term loading (**Chapter 4**). Static and dynamic vertical loading experiments were performed over 7 hours with laboratory testing devices using, respectively, two and three different load conditions. The experiments were repeated 3 days later to determine the day-to-day repeatability. We found that the accuracy, due to offset drift, decreased over time during static loading. The accuracy during dynamic loading increased when higher loads were used. More drift was found when higher dynamic loads were used. We concluded that drift correction with the correction algorithm is necessary for accurate measurement of the vertical force by the Pedar Mobile system, when the amount of weight bearing during long-term measurements has to be determined.

Chapter 5 presents a clinical study in which the PWB performances of 50 total hip patients with a trochanteric osteotomy were evaluated. Patients were verbally instructed by a physical therapist to load the operated leg at either 10% or 50% of their own body weight (BW), as prescribed by the operating surgeon. The actual load under the foot during walking, measured with the Pedar Mobile system, was compared with the prescribed target load. Weight bearing measurements were performed at three conditions: 1) in the hospital in presence of a physical therapist, 2) in the hospital when the patient walked unsupervised, and 3) when the patient walked at home two weeks after discharge. For each recorded step the maximum peak load was determined. From these maximum peak loads, the following variables were calculated: the mean (sd) peak load (% BW), peak load variance within and between patients, the total number of steps, and - with arbitrarily defined load limits - the number and percentage of steps below the target load, equal to the target load and above the target load. We found that a majority of the patients (55%) did not perform PWB at the prescribed target load. The weight bearing performance of the patient was strongly determined by the described target load and the condition. With a 10% BW target load more steps were above the target than with a 50% BW target load. Also, more steps above the target load and higher weight bearing loads were recorded when the patients were at home 3 - 4 weeks after surgery compared to when the patients walked in the hospital 7 days after surgery.

In **Chapter 6** we analyzed factors which could influence the patient's PWB performance. This may give the physical therapist information on which factors increase the risk of incorrect loading of the operated leg. From the patients presented in Chapter 5 we measured patient characteristics (e.g. age, gender), postoperative status (pain, fatigue and anxiety), and walking features (e.g. step frequency). Univariate and multivariate multilevel regression analyses showed that the weight bearing performance was mainly influenced by the patient's gender (women load the leg more than men), and positive relations were found for the postoperative pain during walking, anxiety about falling, the total walking time, and the total number of steps taken by the patient, whereas a negative relation was found for the step frequency.

In **Chapter 7** the most important findings in this thesis are summarized and further discussed, together with some study limitations, implications for the clinic, and recommendations for future research.

Samenvatting

Verminderd belast lopen vormt een centraal onderdeel van de fysiotherapeutische nabehandeling van orthopedische en trauma patiënten die geopereerd zijn aan de onderste extremiteit. Het beperken van de belasting op het geopereerde been tijdens het staan en lopen wordt noodzakelijk geacht om complicaties tijdens het herstel na een operatie te voorkomen. Het is de taak van de fysiotherapeut om de patiënt te instrueren hoe hij/zij het geopereerde been moet ontlasten, zodat hij/zij veilig en zelfstandig de activiteiten van het dagelijkse leven kan uitvoeren. Dit ontlasten moet niet alleen gebeuren tijdens de relatief kortdurende aanwezigheid van de fysiotherapeut, maar ook tijdens de langere en daardoor meer relevante herstelperiodes zonder supervisie, zowel tijdens opname in als na ontslag uit het ziekenhuis. Als er inzicht moet worden verkregen in de mate van belasten van het geopereerde been moet dit dus tijdens al deze condities worden gemeten.

Hoewel verminderd belast lopen tijdens het herstel na een operatie wordt toegepast, is er maar weinig bekend over hoeveel de patiënt het geopereerde been nu daadwerkelijk belast tijdens dagelijkse activiteiten. Een reden hiervoor kan zijn dat er een gebrek is aan valide en betrouwbare draagbare meetinstrumenten die objectief en gedurende enkele uren de mate van belasten op het been kunnen meten.

In dit proefschrift wordt het verminderd belast lopen van totale heup patiënten met een trochanter osteotomie tijdens hun postoperatief herstel geëvalueerd. Om het verminderd belast lopen te meten is een draagbaar meetsysteem met inlegzolen, die druksensoren bevatten, aangepast en gevalideerd om de verticale grondreactiekrachten te meten binnen en buiten het ziekenhuis.

Hoofdstuk 1 geeft een algemene inleiding over verminderd belast lopen. Allereerst wordt de relatie beschreven tussen de belasting en de genezing van de onderste extremiteit tijdens de postoperatieve herstelperiode. Specifiek wordt uitgelegd waarom het noodzakelijk is dat patiënten met een totale heupprothese en een trochanterosteotomie het been dienen te ontlasten. Een beknopt overzicht wordt gegeven van de verschillende instructiemethoden die in het ziekenhuis gebruikt worden door de fysiotherapeut om de patiënten verminderd belast te leren lopen op het door de chirurg aangegeven belastingsniveau, de factoren die het verminderd belast lopen van de patiënt kunnen beïnvloeden en de meetinstrumenten die de belasting op het been tijdens lopen kunnen bepalen.

Voor het objectief meten van de mate van belasting op het geopereerde been gedurende enkele uren over de dag is een valide en betrouwbaar meetinstrument nodig dat de verticale grondreactiekracht kan meten gedurende een lange periode. Daarom is er in **hoofdstuk 2** een literatuuronderzoek beschreven waarin verschillende technieken, om de mate van belasting tijdens staan en lopen te meten, worden geclassificeerd, beoordeeld en bediscussieerd. Vijf technieken (klinisch onderzoek, weegschalen, biofeedbacksystemen, ambulante meetinstrumenten en krachtenplatforms) werden gedefinieerd en geëvalueerd op de criteria methodologische kwaliteit, toepassing en uitvoerbaarheid. De hoofdconclusies zijn dat klinisch onderzoek een grove methode is om de mate van belasting te meten, en dat een weegschaal alleen geschikt is voor evaluatie van de symmetrie in de mate van belasting tijdens staan. Biofeedbacksystemen zijn nauwkeuriger en betrouwbaarder dan klinische onderzoek en weegschalen, maar hoge kosten van deze apparatuur beperken het dagelijkse gebruik in de fysiotherapeutische praktijk. Hoewel krachtenplatforms de beste methodologische kwaliteit hebben, zijn metingen veelal plaatsgebonden. Dit in tegenstelling tot ambulante meetinstrumenten die met een goede nauwkeurigheid en betrouwbaarheid de mate van belasting in en buiten het ziekenhuis kunnen meten. Naast de beschreven criteria in deze studie zal de keuze van een techniek natuurlijk ook bepaald worden door de onderzoeksvraag en het beschikbare budget.

Voor het langdurig meten van de mate van belasting in het ziekenhuis en bij de patiënt thuis is het Pedar Mobile systeem (een draagbaar meetinstrument met inlegzolen) potentieel geschikt. Echter, de validiteit en betrouwbaarheid van dit systeem is in voorgaande studies alleen over korte meetperioden (d.w.z. 5 tot 10 minuten) bepaald. Temperatuur en vochtigheid kunnen de output van de sensoren in de inlegzool beïnvloeden, in het bijzonder als de inlegzool enkele uren in de schoen word gedragen. Daarom is de validiteit van het Pedar systeem om de verticale grondreactiekracht te meten tijdens een langdurige periode onderzocht, door de Pedar data te vergelijken met de data van een Kistler krachtenplatform (**hoofdstuk 3**). Verticale grondreactiekrachten werden elk uur, gedurende een periode van 7 uur, gemeten bij 5 gezonde proefpersonen tijdens dynamische (lopen) en statische (staan) condities. Voor de correctie van eventuele drift in de krachtdata, gedefinieerd als een niet wenselijke verandering van het outputsignaal (kracht) gedurende een bepaalde tijdsperiode die niet gerelateerd is aan de input van het signaal (belasting), is een correctiealgoritme ontwikkeld. Dit correctiealgoritme is gebaseerd op het gegeven dat tijdens de zwaaifase van het lopen de output van de sensoren van de inlegzool nul is omdat er op dat moment geen belasting geplaatst wordt op de voet. Indien er tijdens de zwaaifase toch krachten worden gemeten, dan corrigeert het correctie algoritme hiervoor door de laagste kracht tijdens de zwaaifase af te trekken van de gemeten kracht tijdens de standfase van het lopen. Behalve de aanname dat de kracht gemeten gedurende de zwaaifase nul dient te zijn, is het correctiealgoritme gebaseerd op nog een ander aanname, namelijk dat de drift een offset drift dient te zijn. Daarom werd in deze studie ook het type drift ('offset' of 'gain' drift) bepaald. Een aanzienlijke hoeveelheid drift (15%) werd gevonden. Deze drift bleek voornamelijk offset drift te zijn. Na toepassing van het correctiealgoritme bleek het Pedar systeem een goede nauwkeurigheid te hebben voor het meten van de tweede piekkracht in de grondreactiekracht-tijdscurve en de stapduur. Het Pedar systeem was minder nauwkeurig in het meten van de eerste piekkracht in de grondreactiekracht-tijdscurve, en daarmee ook in de verticale krachtimpuls. De conclusie is dat het Pedar Mobile systeem een valide meetinstrument is voor het bepalen van de verticale grondreactiekracht gedurende een lange periode indien gebruik gemaakt wordt van het correctiealgoritme.

Het outputsignaal van de sensoren in de inlegzool kan, naast temperatuur en vochtigheid, ook worden beïnvloed door de mate en duur van de belasting. Om deze reden is er een tweede validiteitstudie uitgevoerd waarin de nauwkeurigheid en de herhaalbaarheid werd bepaald van het Pedar systeem om de verticale grondreactiekracht te meten tijdens langdurige belasting (**hoofdstuk 4**). Statische en dynamische verticale belasting-experimenten werden gedurende 7 uur uitgevoerd met behulp van laboratorium-testapparatuur, waarbij gebruikt werd gemaakt van verschillende belastingcondities. Om de test-hertest betrouwbaarheid te bepalen werden de experimenten 3 dagen later herhaald. Door offset drift nam tijdens de statische belastingtests de nauwkeurigheid in de tijd af. De nauwkeurigheid tijdens de dynamische belastingtests nam toe bij hogere belastingen. Tevens werd er bij hogere dynamische belastingen meer drift gevonden. De conclusie is dat driftcorrectie met behulp van het correctiealgoritme noodzakelijk is voor het nauwkeurig meten van de verticale kracht door het Pedar Mobile systeem, indien de mate van belasting bepaald wordt bij langdurige metingen.

Hoofdstuk 5 beschrijft een klinische studie waarin het verminderd belast lopen van 50 totale heuppatiënten met een trochanterosteotomie wordt geëvalueerd. De patiënten werden verbaal geïnstrueerd door de fysiotherapeut om het geopereerde been te belasten met 10% dan wel 50% van het lichaamsgewicht. De mate van belasting werd voorgeschreven door de opererende chirurg. De daadwerkelijke belasting op het geopereerde been, gemeten met het Pedar Mobile systeem, werd vergeleken met de voorgeschreven belasting. De belastingmetingen werden uitgevoerd onder drie condities: 1) in het ziekenhuis in aanwezigheid van de fysiotherapeut, 2) in het ziekenhuis als de patiënt loopt zonder supervisie van de fysiotherapeut, en 3) bij de patiënt thuis twee weken na ontslag uit het ziekenhuis. Van elke geregistreerde stap tijdens het lopen werd de maximale belasting bepaald. Op basis van deze maximale belastingen werden de volgende variabelen berekend: de gemiddelde (standaarddeviatie) maximale belasting (als percentage van het lichaamsgewicht), de patiënt tussen-variantie en binnen-variantie van de maximale belasting, het totaal aantal stappen, en - aan de hand van zelf gedefinieerde belastingsgrenzen - het aantal en percentage stappen onder, gelijk aan en boven het voorgeschreven belastingsniveau. We vonden dat een meerderheid van de patiënten (55%) het geopereerde been niet verminderd belastte op het voorgeschreven belastingsniveau. De mate van belasten op het been door de patiënt tijdens verminderd belast lopen werd sterk beïnvloed door het voorgeschreven belastingsniveau en de eerder beschreven condities. Met een voorgeschreven belastingsniveau van 10% van het lichaamsgewicht werden er meer stappen overbelast dan bij een voorgeschreven belastingsniveau van 50% van het lichaamsgewicht. Ook werd er relatief bij meer stappen overbelast en werden er hogere gemiddelde belastingen gemeten 3 tot 4 weken na de operatie als de patiënt thuis was, dan wanneer de patiënt in het ziekenhuis liep 7 dagen na de operatie.

In **hoofdstuk 6** zijn factoren geanalyseerd die mogelijk de mate van belasten beïnvloeden tijdens verminder belast lopen. Dit verschaft de fysiotherapeut informatie over welke factoren mogelijk het risico verhogen tot te grote belasting van het geopereerde been. Van de patiënten uit de klinische studie uit **hoofdstuk 5** werden patiëntkarakteristieken (b.v. leeftijd, geslacht), postoperatieve status van de patiënt (pijn, vermoeidheid, angst), en loopkarakteristieken (b.v. stapfrequentie) gemeten. Univariate en multivariate multi-level analyses toonden aan dat de mate van belasting tijdens verminder belast lopen voornamelijk beïnvloed wordt door het geslacht van de patiënt (vrouwen belasten meer dan mannen). Tevens waren er positieve verbanden met de postoperatieve pijn tijdens lopen, de angst om te vallen, de totale loopduur en het totaal aantal stappen dat de patiënt neemt en was er een negatief verband met de stapfrequentie.

In **hoofdstuk 7** worden de belangrijkste bevindingen uit dit proefschrift samengevat en verder bediscussieerd. Tevens zijn enkele beperkingen en implicaties voor de klinische praktijk beschreven en zijn aanbevelingen voor verder onderzoek aangedragen.

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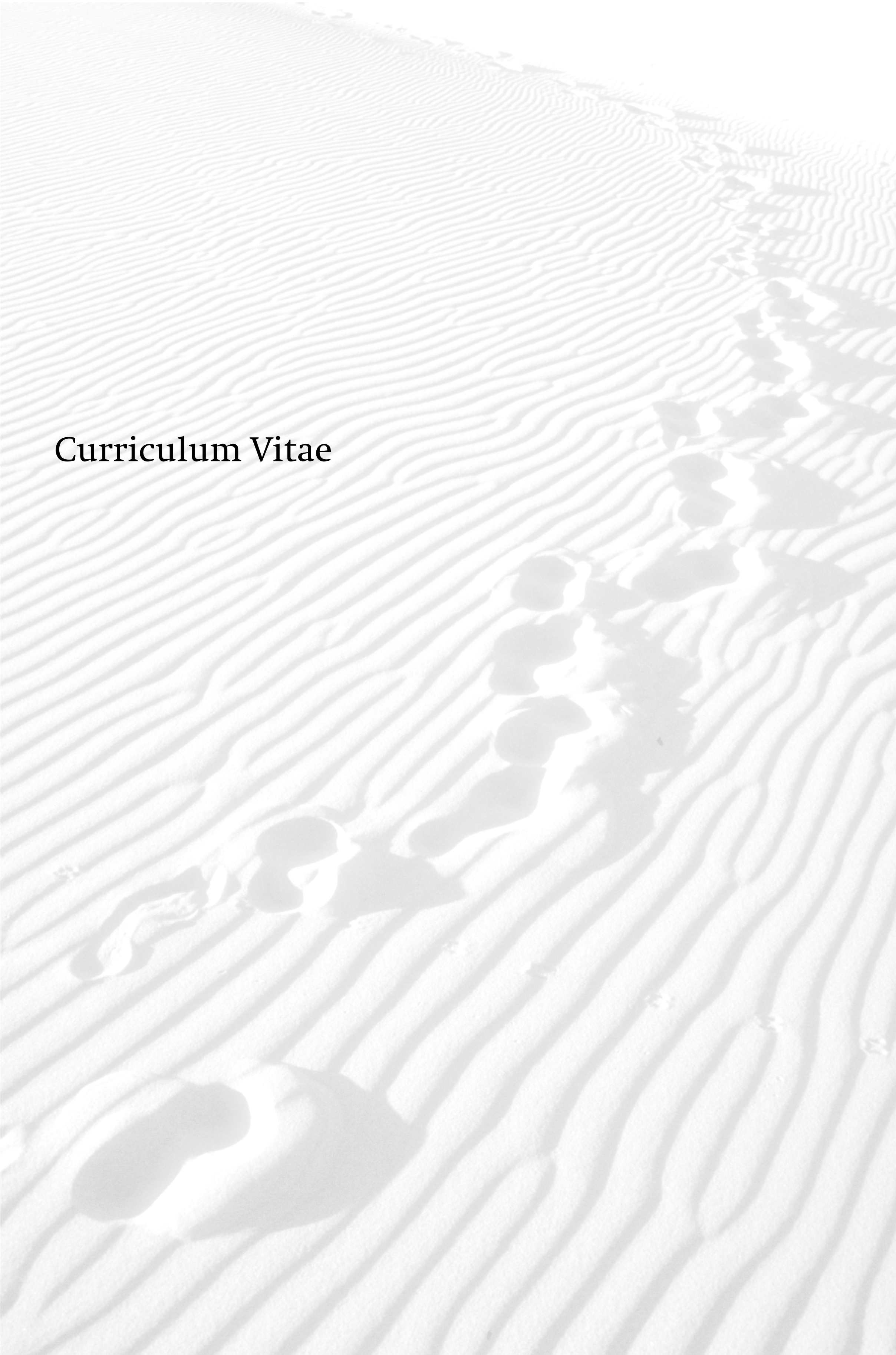
Curriculum Vitae



Henri Hurkmans werd geboren op 8 maart 1968 in Veghel. Na het behalen van het Atheneum-B diploma studeerde hij een jaar Biologie in Utrecht waarna hij zijn militaire dienstplicht grotendeels vervulde bij de Landmacht als Korporaal binnen de Geneeskundige formatie van het 11e TKBAT in Oirschot. In 1989 startte hij met de studie Gezondheidswetenschappen aan de Katholieke Universiteit van Nijmegen (KUN), met als afstudeerrichting Bewegingswetenschappen. Tijdens deze studie verrichtte hij onderzoek naar het schokdempend vermogen van het hielkussen bij het Centrum TNO Leder en Schoenen te Waalwijk. In een tweede onderzoeksproject bij de vakgroep Anatomie en Embryologie van de KUN onderzocht hij de carpale instabiliteit bij scapho-lunaire dissociatie in het polsgewricht. Na het behalen van het doctoraal examen in 1994 was hij enkele jaren werkzaam als wetenschappelijk medewerker aan de afdeling Orthopedie van het Academisch Ziekenhuis Groningen.

In 2000 startte Henri op de afdeling Fysiotherapie van het Academisch Ziekenhuis Rotterdam Dijkzigt (inmiddels samen met de medische faculteit van de Erasmus Universiteit Rotterdam het Erasmus MC, Universitair Medisch centrum Rotterdam) onder leiding van E. Benda met zijn promotieonderzoek naar het verminderd belast lopen, wat in nauwe samenwerking werd uitgevoerd met de afdelingen Revalidatie en Orthopedie onder begeleiding van dr. J.B.J. Bussmann, prof. dr. H.J. Stam en prof. dr. J.A.N. Verhaar. De resultaten hiervan staan vermeld in dit proefschrift. Naast zijn promotieonderzoek werkte Henri als docent van de Transfergroep Rotterdam waar hij de bij- en nascholingscursus 'Evidence Based Medicine' gaf aan fysiotherapeuten.

Momenteel werkt Henri bij de afdeling Fysiotherapie van het Erasmus MC als wetenschappelijk onderzoeker aan een vervolgstudie van zijn promotieonderzoek. In deze randomized clinical trial wordt er gekeken naar de meerwaarde van audiofeedback bij vermindert belast lopen, en wordt er tevens gekeken naar de relatie van verminderd belast lopen met ontstane complicaties en het functioneel herstel van patiënten met een totale heupprothese.