Different in-shoe devices for partial weight bearing

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Abstract
Partial weight bearing is often part of the instructions during rehabilitation of patients with fractures or after reconstructive surgery of the lower extremity. To define the optimal weight-bearing load and maximize compliance is difficult. Biofeedback is an option, and can be done in various ways by using scales, weighing feel by hand or weight-measuring insoles. Over the last few years many insoles have been developed. The purpose of this study is to compare the different devices that are currently used. A literature search was performed and a list of criteria was designed to see which insoles have the best specifications. Pedar, OpenGo, F-scan and Opryx LogR had the best specifications and are discussed in more detail. It can be concluded that the Pedar and F-scan are the most reliable, but they are also extremely expensive. The OpenGo and Opryx LogR are slightly less reliable than the Pedar and F-scan, but can still be used for research and clinical use. These devices are much cheaper, but still are expensive for daily use. We conclude that various measuring insoles with biofeedback are in use, with different levels of reliability. The most reliable insoles are very costly, but even the less reliable insole due to the price are not yet available for common use.

Keywords: gait analysis, partial weight bearing, plantar pressure, in-shoe device, insole, rehabilitation

1. Introduction
In-shoe pressure measurement systems are useful tools to acquire plantar pressure and force data during dynamic movements (Pui W. Kong, 2009). Such systems are widely used in gait analysis (Benedikt J. Braun, 2016), running analysis (Robert Mann, 2016) and adjuvant in partial weight bearing (Henri L. Hurkmans, 2012).

To load the leg up to a pre-set, particular amount of weight during standing and walking, when using crutches or another walking aid, is defined as “partial weight bearing” (PWB). It is commonly used during rehabilitation for patients with fractures or after reconstructive surgery of the lower extremity (Attila Vasarhelyi, 2006). The idea of PWB is that limiting the amount of body weight during rehabilitation will enable better ingrowth of prosthesis or prevent dislocation and promote healing in fracture care. (H.L.P Hurkmans, 2003). Partial Weight bearing starts on the first day after surgery with low weight bearing on the affected limb and increases until full weight bearing is accomplished (Attila Vasarhelyi, 2006). The treating surgeon or physiotherapist prescribes the maximum kgs or % of weight bearing (D.C Wirtz, 1997). Surgeons and physical therapists use a classification of weight bearing. By using non-weight bearing no weight is involved on the lower extremity. During foot flat weight bearing only 10-20% of the body weight may be used on the lower extremity. By partial weight bearing, 20-50% of the body weight is tolerated. 100% of the body weight is allowed with full weight bearing (H.L.P Hurkmans, 2003) (Joshua W. Hustedt, 2012).

2. Method
A literature search was performed using the following keywords: gait analysis, partial weight bearing, plantar pressure, in-shoe device, insole, and rehabilitation. Of the articles generated, the preference lists were used to find other related articles. Only articles in English were selected.
Selection of devices
A table is made with all the devices that exist at this moment, in order to obtain a clear overview of the existing devices. As many features available per device are placed in the table. To define which devices have the best features a criteria and wishing list was made.

Classification
To find out which device (or devices) is the best option available now, a criteria list is made. At least six criteria should be available in the data. The devices that received a score of 70% or higher are going to be discussed enhanced. The devices that meet the requirements will be compared.

Criteria list
1. The device has to be an insole, not a shoe or force plate.
2. Data transfer has to be wireless
3. It has to be available for consumers, not only clinicians and researchers
4. It is available in 5 or more different sizes
5. The insole contains at least 8 sensors
6. The price of the device is below $2500
7. The insole weights less than 100g
8. Error of the insole is lower than 10%

Wishing list
1. The insole is wireless
2. The device is easy to work with, meaning every user is able to use the insole on the basis of the manual
3. The product is durable

3. Results

3.1 Methods to measure partial weight bearing
It is difficult to define the best weight-bearing strategy to optimise compliance and support clinical outcomes. No standardized guidelines exist for specific clinical conditions. Researchers and clinicians use different methods to teach patients applying the partial weight bearing instructions.
Clinical examination is a feedback training method where physical therapists place a hand under the foot of the patients and estimate the weight of the patient's lower extremity (H.L.P Hurkmans, 2003). Grey et al. studied this method and concluded that this techniques is 'subjective guesswork at best (F.B Gray, 1998).

A different method is using scales to offer quantitative feedback to the patient. Researchers have studied if this technique is accurate. Patients were instructed how to achieve partial weight bearing loading at 20%, 40%, 60% and 80% of their individual body weight using a bathroom scale. They concluded that patients were unable to replicate the static and dynamic weight bearing restrictions within a range of 5% of the body weight after using the scale (Jay R. Ebert, 2008).
Another method is the use of biofeedback devices. Different biofeedback devices have been developed that give a constant feedback to patients as they are walking (Joshua W. Hustedt, 2012). Over the years many different biofeedback devices have been developed. The first biofeedback device presented was a leg load warning system developed by Endicott et al. (D. Endicott, 1974) in 1974. Miyazaki and Iwakura also made a limb load alarm device (S. Miyazaki, 1978). Nowadays different ambulatory devices are developed such as Smartstep (Andante Medical Devices Ltd, Beer Sheva, Israel) and Sensistep (Evalan, Netherlands), Pedar (Novelgmbh, Munich, Germany) and F-Scan (Tekscan Inc., Boston, MA, USA).

3.2 Current biofeedback devices
Table 1 shows definitions of the words using to describe the quality of the different biofeedback devices. Table 2 and 3 show the obtained specifications about the different devices. All devices available will be shortly described.

<table>
<thead>
<tr>
<th>Repeatability</th>
<th>The ability of an operator to consistently repeat the same measurement of the same part under the same conditions.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Validity</td>
<td>The state or quality of being valid</td>
</tr>
<tr>
<td>Reliability</td>
<td>Significant results must be more than a one-off finding and be inherently repeatable</td>
</tr>
<tr>
<td>Accuracy</td>
<td>It refers to the closeness of a measured value to a standard or known value.</td>
</tr>
</tbody>
</table>

Table 1, definitions
Table 2, aspects on the quality of the biofeedback devices.

<table>
<thead>
<tr>
<th>Name</th>
<th>Measurement range (kPa)</th>
<th>Time Resolution</th>
<th>Mean pressure error</th>
<th>Creep (kPa)</th>
<th>Drift (kPa/K)</th>
<th>Hysteresis</th>
<th>Calibration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pedar Mobile System</td>
<td>15-600</td>
<td>300Hz</td>
<td>mean 4.5%, maximum 16.2%</td>
<td>&lt;0.5</td>
<td>&lt;7</td>
<td></td>
<td>Air bladder</td>
</tr>
<tr>
<td>OpenGo</td>
<td>0-400</td>
<td>5-100Hz</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>F-scan</td>
<td>345-517 (sensitive) 862 (standard)</td>
<td>0-169Hz</td>
<td>mean 60.5%, maximum 135.7%</td>
<td>12.2-18.5%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PedAlert 100</td>
<td>10.5-21</td>
<td>100Hz</td>
<td>6%log</td>
<td>-2%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Orpyx LogR</td>
<td>6-640</td>
<td>60Hz</td>
<td>mean 10.7%, maximum 20.77%</td>
<td></td>
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<td></td>
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</tr>
<tr>
<td>Walkinsense</td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Smartstep</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sensistep</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>10%</td>
</tr>
<tr>
<td>Digit Sole</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>smart insole</td>
<td></td>
<td></td>
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<td></td>
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</tr>
<tr>
<td>Arion smart insole</td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Carv</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>IOFit</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Flexisense</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Name</td>
<td>Data Storage</td>
<td>Transfer Type</td>
<td>Weight/Size</td>
<td>Insole Thickness (mm)</td>
<td>Number of Sensors</td>
<td>Transducer Type</td>
<td>Power Supply Type</td>
</tr>
<tr>
<td>---------------</td>
<td>--------------</td>
<td>---------------</td>
<td>-------------</td>
<td>-----------------------</td>
<td>-------------------</td>
<td>----------------</td>
<td>------------------</td>
</tr>
<tr>
<td>Pedal Mobile System</td>
<td>SD card</td>
<td>USB</td>
<td>150 x 100 x 40</td>
<td>1.9 85-99</td>
<td>2 capacitive, coin cell</td>
<td>36/37-44/45</td>
<td>NIMH</td>
</tr>
<tr>
<td>OpenGo</td>
<td>Flash</td>
<td>Wireless</td>
<td>&lt;80g</td>
<td>960</td>
<td>13 capacitive, coin cell</td>
<td>45</td>
<td>NIMH</td>
</tr>
<tr>
<td>F-Scan</td>
<td>Flash</td>
<td>Wireless</td>
<td>&lt;80g</td>
<td>3</td>
<td>15 variable</td>
<td>8 upto 14</td>
<td>NIMH</td>
</tr>
<tr>
<td>Medisole</td>
<td>USB</td>
<td>Wireless</td>
<td>180g</td>
<td>0</td>
<td>180mah</td>
<td>1.5</td>
<td>9v</td>
</tr>
<tr>
<td>Walksense</td>
<td>USB</td>
<td>Wireless</td>
<td>68g</td>
<td>0</td>
<td>180mah</td>
<td>1.5</td>
<td>9v</td>
</tr>
<tr>
<td>Smartstep</td>
<td>Bluetooth</td>
<td>Low Energy (ble)</td>
<td>71g</td>
<td>3</td>
<td>180mah</td>
<td>1.5</td>
<td>9v</td>
</tr>
<tr>
<td>Sandstep</td>
<td>Bluetooth</td>
<td>Low Energy (ble)</td>
<td>540g</td>
<td>3</td>
<td>180mah</td>
<td>1.5</td>
<td>9v</td>
</tr>
<tr>
<td>Allin smart</td>
<td>Bluetooth</td>
<td>Low Energy (ble)</td>
<td>100-125g</td>
<td>3</td>
<td>180mah</td>
<td>1.5</td>
<td>9v</td>
</tr>
<tr>
<td>Orthofit</td>
<td>Bluetooth</td>
<td>Low Energy (ble)</td>
<td>100-125g</td>
<td>3</td>
<td>180mah</td>
<td>1.5</td>
<td>9v</td>
</tr>
<tr>
<td>Flexsense</td>
<td>Bluetooth</td>
<td>Low Energy (ble)</td>
<td>100-125g</td>
<td>3</td>
<td>180mah</td>
<td>1.5</td>
<td>9v</td>
</tr>
</tbody>
</table>

Table 3. Aspects on application of the ambulatory devices
The Pedar system is one of the most commonly used systems for in-shoe pressure measurement. The Pedar in-shoe system is an insole with 99 capacitive sensors. The system works with Bluetooth wireless telemetry system in a wide range. The system connects to highly conforming, elastic sensor insoles that cover the entire plantar surface of the foot (Novel). A disadvantage of the system is that it is very expensive.

The OpenGo science system (Moticon, Munich, Germany) incorporates 12 capacitive sensors, a 3D accelerometer and a temperature sensor, measuring peak pressures, pressure distribution, acceleration, motion sequences, gait patterns and temperatures. It operates wireless and the data is stored on a flash drive. The insole can be placed in any shoe and the system has an automated zeroing system so the shoes can be changed at random (Benedikt J. Braun, 2016) (Moticon).

The F-scan mobile system is a commercial in-shoe force/pressure measurement system. The in-shoe system has been used in clinical studies focused mainly on the evaluation of various therapeutic measurements (J Woodburn, 1996). The system uses ultra-thin in-shoe sensors and provides pressure information about the foot function and gait analysis. Another advantage is that the system utilizes relatively low cost sensors and pressure data is stored in a data-logger, so field tests are made possible and the subject can move freely (Pui W. Kong, 2009) (Tekscan).

Orpyx LogR is a solution designed for the accurate, efficient, and real-time measurement of foot and plantar pressure analysis (Orpyx). The system is available on a limited basis to select human performance labs, biomechanics and athletic researchers. The system uses eight SSR sensors and is less expensive than Pedar and OpenGo, because of the few sensors.

Medilogic is also a relatively cheaper one. The system can have sensors up to 240, it depends on the type of insole (Noraxon).

The Walkinsense is a portable system to collect information relating to in-shoe plantar pressure measurement and lower limb activity (Nordicortopedica). The system contains eight sensors.

At the moment several sport insoles and running shoes with an insole have been developed or are in development. Those systems have been developed to provide a more accurate feedback of athletic performances and enhance these. Digitsole smartsole and Flexisense are tracker insoles to measure real steps and it offers accurate activity measurement. It helps to improve the running technique, prevents injuries and it allows to get the most out of running (Digitsole) (HCI Viocare). The IOFit device is a start up supported by Samsung. This device is a smart-shoe with accelerometer, pressure sensors and can be combined with an app to read the obtained data. The shoe is produced by Salted Venture, but it is unclear when the product will be on the market. Carv is an insole that helps you ski better. It measures motion, pressure distributions and it relays feedback through your earphones in real-time. Also this product is not available yet.
3.3 Classification
To find out which device (or devices) is the best option available now, a criteria list was made. Table 4 shows if the devices meet the criteria's on the criteria list. The devices that meet the requirements will be compared.

<table>
<thead>
<tr>
<th>Pedar Open-Go F-scan PedAler t100 /120 Orpyx LogR™ Medilog Walkinsense Smartstep Sensistep DigitSole Arion smart Insole Carv IO Fit Flexisense</th>
<th>yes</th>
<th>Yes</th>
<th>yes</th>
<th>no</th>
<th>yes</th>
<th>yes</th>
<th>yes</th>
<th>no</th>
<th>no</th>
<th>yes</th>
<th>yes</th>
<th>-</th>
<th>no</th>
<th>yes</th>
</tr>
</thead>
<tbody>
<tr>
<td>The device is an insole</td>
<td>no</td>
<td>yes</td>
<td>no</td>
<td>no</td>
<td>no</td>
<td>yes</td>
<td>no</td>
<td>no</td>
<td>no</td>
<td>yes</td>
<td>no</td>
<td>-</td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td>Datatranfer is wireless</td>
<td>yes</td>
<td>yes</td>
<td>no</td>
<td>yes</td>
<td>yes</td>
<td>-</td>
<td>no</td>
<td>-</td>
<td>no</td>
<td>yes</td>
<td>yes</td>
<td>not</td>
<td>not</td>
<td>-</td>
</tr>
<tr>
<td>It is available for consumers</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
<td>-</td>
<td>yes</td>
<td>yes</td>
<td>-</td>
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<td>yes</td>
<td>-</td>
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</tr>
<tr>
<td>It is in 5 or more different sizes</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
<td>-</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
<td>no</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Contains at least 8 sensors</td>
<td>no</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
<td>no</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>yes</td>
<td>-</td>
<td>-</td>
<td>yes</td>
<td>-</td>
</tr>
<tr>
<td>The price is below $2500</td>
<td>-</td>
<td>yes</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>no</td>
<td>yes</td>
<td>yes</td>
<td>no</td>
<td>no</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Weights less than 100g</td>
<td>yes</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>yes</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>yes</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

Table 4, Comparison of devices with the criteria list.
The systems that are listed without a percentage did not meet at least 6 requirements, meaning they are not included in the comparison. Table 5 shows that Pedar, OpenGo, F-scan and Orpyx have an outcome above 70%. Medilogic, Walkingsense and Sensistep were included in the comparison, but didn’t satisfy the requirement of 70%.

### 3.4.1 Pedar
The Pedar Mobile system is a portable in-shoe pressure system that uses 99 capacitive sensors per insole. The Pedar Mobile system cannot transfer the data wireless to a PC. The obtained data can be transferred to a PC via a fiber optic/USB cable. The system is available for consumers, but the disadvantage is that the system is very expensive. The price of the device is € 15,450.00, which makes it a device that is mostly used in clinical and research settings. The device contains 99 capacitive sensors, which leads to a sensor density of 0.57-0.78 per cm². The capacitance transducer matrix has the advantage of the ability to calibrate each individual sensor in the matrix. The insole top surface consists of soft foam. A recent study shows that systems which use soft foam have a greater contact area than systems using a thin plastic film, which is the case with F-scan. A different study showed that the Pedar Mobile system has a high validity for pressure (Carine Price, 2016). Also the assessment of the ability of the system to accurately measure vertical force gives a valuable insight into the accuracy of the force data gathered with Pedar (Abdul H.A. Razak, 2012).

### 3.4.2 OpenGo
The OpenGo is an insole that has 13 capacitive pressure sensors, a 3D accelerometer and a temperature sensor incorporated. The system is able to measure peak pressures, pressure distribution, acceleration, motion sequences, gait patterns and temperatures. The insole weights less than 80 grams and operates completely wireless. The patient can
remove the insole freely from the shoe and place it in any other shoe at any time due to an automated zeroing system (Benedikt J. Braun, 2016). The OpenGo has fewer sensors that the Pedar of F-scan, which results in a reduced sensor capability. Despite that, the OpenGo shows a good correlation between the insole and the force plate system for temporospatial. A study showed that the system could be used in broad clinical trials that require step by step or gait analysis over a long period of time (Benedikt J. Braun, 2015).

### 3.4.3 F-scan

The F-Scan system is one of the most commonly used in-shoe pressure measurement systems for gait analysis (Pui W. Kong, 2009). The insole consists of two polyester sheets whose inner surfaces are printed with electrical circuits. The insole consists of 860 individual pressure-sensing locations, which leads to a sensor density of 4 per cm² (J Woodburn, 1996). The F-scan system is available in different connection types depending on the user. The F-scan Base and the F-scan Datalogger transfers data to a PC via a wire. Scanning rates up to 750 Hz are available with the Base or Datalogger. Tekscan also provides the F-scan Wireless, which transfers data directly from the subject to the computer; however wireless data transfer reduces scanning rates to 100 Hz (Tekscan). Although the system uses relatively low-cost and thin in-shoe sensors the F-scan still is as expensive as the Pedar Mobile system. The total mass of all external devices of the F-scan system is approximately 1.8 kg. This includes two in-shoe sensors, two receiver units attached to the subject’s lower leg, one data-logger unit attached at the waist level and several connection cables (J Woodburn, 1996). Different studies show that the system not only responds to the applied pressure, but also can be influenced by other variables, such as surface contact hardness conditions, creeping and temperature (Zong-Ping Luo, 1998) (J Woodburn, 1996). A study compared the F-scan, Medilogic and the Pedar and found that the F-scan had higher average errors, but a lower repeatability for contact area, especially at lower pressures. This is due to an interaction between the inherent noise in the resistive system and the larger number of sensors (Carine Price, 2016).

### 3.4.4 Orpyx logR

A relatively cheaper option is the Orpyx LogR. The resolution is low because of the low number of sensors. The system incorporates 8 pressure sensors per insole. The insole fits inside any running or walking shoe. There are no wires or plugs necessary for data transfer, because the system runs on Bluetooth Low Energy. Due to the low number of sensors, the accuracy of plantar pressure mapping is limited and may not be able to capture important details. Although the Orpyx LogR is cheaper than those with high resolutions; they are not necessarily affordable to the public as well (Ading M Tan, 2015).

### 4. Discussion

F-scan and Pedar seem to be the best option for research and clinical use. They have a better accuracy and validity than the Orpyx logR and OpenGo. This is mostly because of the many sensors. A disadvantage is that the devices are very expensive and not affordable for the public. The Orpyx logR and OpenGo seem to be a better option for consumers because the price is much lower, but still they are quite expensive. The
systems have a low number of sensors, which results in a lower resolution. Yet the devices give a good biofeedback and can also be used for research and gait analysis. So the biggest problem of the devices is that the price is too high for customers. A company called VTEC is designing an insole that is affordable for the mass.

5. Limitations
For many devices there were only a few publications / studies available, so the lack on information made it impossible to judge them. Also, for many devices only old publications were available, probably that information is no longer current at the moment. It was therefore not possible to have a complete overview of all existing devices at this time.

6. Conclusions
The F-scan and Pedar Mobile system came out best in our analysis. The disadvantage is that they are too expensive. The Orpyx Log Rand OpenGo also seemed a good option to be used for clinicians and researchers. Those devices are cheaper than de F-scan and Pedar Mobile system, but still too expensive for consumers. It is important that a new device is being developed, that still has a good accuracy and validity, but also is affordable for the public. Digit Smartsole and Flexisense are devices that are developed for consumers. The prices are much lower and affordable for the public. Those devices are not on the market, and the price of the flexisense is not available yet, but it seems to be that they are much cheaper options, with still a good accuracy and validity for measurements.

References


