Measuring Technique for a Lower Limb Load Alarm System

Master’s Thesis in Mechatronical Engineering

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Preface

This master thesis was carried out at Halmstad University in collaboration with Camp Scandinavia AB and the county council of Halland.

We would especially like to thank Håkan Persson, Olle Eklund at Camp Scandinavia, Anders Wykman at Halland county council for their helps and ideas. We would also like to thank our supervisors at Halmstad University Albert-Jan Baerveldt and Wolfgang Svensson. Further thanks are directed to ALMI and THURE for their financial help.

Johan Pettersson & Per Hansson
Halmstad University, January 2006
Abstract

Subsequent to a difficult surgery or a severe injury to the lower part of the body, often partial load bearing is needed to stimulate an optimal rehabilitation. Today, this is achieved by teaching the patient the optimal load by iteration. This has been shown insufficient for many patients, due to their difficulties of remembering the correct amount of load. Furthermore, patients who lack proprioception are unable to feel the load.

A portable measuring system would enhance the patient possibility of optimal loadings. This thesis has two main objects. 1. A study of the state of the art on existing commercial system, related patents and measuring techniques. 2. A new measuring technique, which is the part that most of all determine the system performance, was developed. A new design, using off the shelf, products is proposed.

The design uses a finite number of thin sensors placed onto an insole. By placing the sensors at the plantar pressure points most of the total load is captured by the insole setups. To compensate for the measuring error fitting methods were evaluated. The result depends on the insole calibration methods. The best result without individual calibration is: mean error for the group of 0.5% of the total patient load and a deviation of 24%. With individual calibration reduces the deviation to about 12%.
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1 Introduction

Subsequent to a surgery or severe injury to the lower limb, it can be critical for the rehabilitation that the patient load the injured part partially. Today, existing methods consist of learning the patient by supervised iteration. The patient walks/stands on an ordinary bathroom scale and has to remember the amount of force that is allowed. Patients with diseases such as diabetes, central neurological disturbances or lack of proprioception may not be able to feel and determine the amount of force that is allowed.

By supervised iteration the patient is supposed to learn and remember the amount of acceptable load. If the patient under or overloads the injured part at a longer period it can cause longer rehabilitation time or lead to severe complications such as resurgery or in extreme cases amputation. If the patient could use a constant feedback of the load during the rehabilitation period it would be improved.

Today, there are some existing products on the market, but most of them are to be used by specialist supervision at a clinic and are not for daily use. The main object of this study was to evaluate the possibility of determine the load under the foot by a limited number of thin sensors. The aim is to investigate and develop a measuring technique to find out if it is possible to develop a product at low cost, which gives the patient constant feedback about their lower limb load. The product is to be an insole containing: sensors, CPU and wireless connection to an alarm module. The resulting product should be user friendly and small, for the patient to use it in their everyday life.

This project has been done in a network with representatives from the university, hospital and industry. Collaboration partners were:

Project manager:
Per Hansson (student)
And
Johan Pettersson (student)

Technical supervisor:
Albert-Jan Bearveldt (Professor Mechatronic systems, Halmstad University)
and
Wolfgang Svensson (Research engineer, Ph.D. Student)

Medical supervisor:
Anders Wykman (Consultant, head doctor of orthopedics at county hospital Halmstad)

Market supervisor:
Håkan Persson (Product developer, Camp Scandinavia)
Measuring Technique for a Lower Limb Load Alarm System System
2 Medical background

It is often significant, subsequent to an operation or a severe injury related to the lower limb, to provide a partial load bearing for an optimal rehabilitation. The inability to provide a partial load bearing to the extremity may cause delayed healing, non-healing or in extreme cases amputation.

According to Anders Wykman, the most common way to teach the patient the correct amount of force partial load by supervised iteration. This is done by recognizing the amount of load he is allowed to expose to the extremity by an ordinary bathroom scale. Research has show that healthy people have difficulties to remember the allowed load [1]. It is even more difficult for non healthy people to remember the accepted load. For patients with central neurological disturbances, diabetes, polyneuropati, sciatica or others who lack of proprioception in the leg, which is necessary to determine the amount load on the foot, it may even be impossible. Both Lew et.al[1] and Anders Wykman state that the rehabilitation could be more efficient with an alarm system to help the patient determine the foot load.

Patient with difficulties to feel pain under their feet due to some of the decreases mentioned above have major risk factor of developing sore such as ulcers. To reduce this risk, they need help to feel the force acting on their feet. Fig. 2.1 shows the most exposed fields on the foot. Optimally the sensors should be placed under these locations. [2]

![Figure 2.1: exposed points](image)

Today there are 8000-10000 patients in Sweden who are in need of a partial load bearing. If an alarm could decrease the rehabilitation time and minimize the number of patients who relapse a great economical saving could be made, e.g. one day at the hospital costs approximately 2800SEK and a relapse costs about 88000SEK according to Anders Wykman.
3 Patent and product overview

The project has been granted 15000 SEK by Innovation Halland to carry out a technical search. This is done to ensure that the future product not is trespassing any existing patents. Searches have also been done on existing commercial products and related measurements.

3.1 Patent overview

Some of the technical search was done by Albihns [3] in Malmö. It was carried out for two main reasons; firstly it is needed to know if there are any products or patents like our invention on the market and secondly to obtain the approval for the funding application to THURE.

Albihns researched in the following areas (IPC-classification): [4]

- Measuring devices for testing the shape, pattern, size or movement of the body or parts thereof, for diagnostic purposes. (A61B5/103)
- Footwear with health and hygienic arrangements. (A43B7)
- Orthopedic methods or devices for non-surgical treatment of bones or joints. (A61F5)

Albihns searched for both active and non-active patents, to find out if the patents are still present further investigation are required.

The following patents are the most relevant ones for this project; the summaries are gathered from the technical search report [4]:

3.1.1 Device for measuring force applied to a wearer’s foot
(Pat. No. US 5357696a)

It is a device for monitoring the force provided to a shoe, which contains pressure sensors. When a certain pressure is reached an alarm may appear. The alarm unit could be located either in the shoe or at some other place such on as the arm or in a pocket. An alarm could appear at different levels, which are tunable to match the patient needs. The sensor information may be transmitted wirelessly to a receiver, which could be a separate unit. The alarms could be saved to log the patient’s history. [5]. Fig. 3.1

![Figure 3.1: Picture of the device from patent no US 5357696a.](image)
3.1.2  **Foot weight alarm**  
(Pat. No. US 5619186a)

The device, which is used, for measuring a pressure/weight, of a foot, gives an alarm only if the pressure is too high. By the control unit, the levels and/or intervals may be tuned and the alarm function could be tuned to give different signals on different levels. It has a memory unit to record the patient’s history. [6]. Fig. 3.2

![Figure 3.2: Foot weight alarm model [4]](image)

3.1.3  **Monitoring a recurrent load value on lower extremities**  
(Pat. No. WO 2004/112608a1)

A device detects pressure on a leg. The detection is carried out by a number of pressure sensors in the sole of a shoe. The measurements are transmitted through a transmitter to the receiver, which is placed on an arm as a bracelet. The receiver could be adjusted to give an alarm either when a certain value is exceeded or when a certain value isn’t reached. [7]
3.1.4 **Therapeutic ankle and foot apparatus having a contact sensor mechanism**  
(Pat. No. US 6377178b1)

A device measures the load on a patient’s foot by pressure sensors. Either an audio-signal or a visual-signal could indicate the pressure. The pressure-signal from the sensors could be transmitted wireless to the alarm module. [8]. Fig. 3.3

![Figure 3.3: Model of ankle and foot apparatus](image)

3.1.5 **Device for monitoring loads exerted on parts of the body**  
(Pat. No. US 5042504a)

A load measuring device e.g. for a leg, includes a microprocessor, an alarm system and a memory which stores information about the patient’s history. The alarm system can give either an audio or optical signals. [9]

3.1.6 **Limb load alarm device for part-weight-bearing walking exercise**  
(Medical & biological engineering & computing)

A device, which measures the foot load within treatment after an operation or similar cases, gives alarms in two steps: The first is given when a lower level is exceeded and the second when a higher load level is exceeded. The patient is to load his foot so that he can hear the first alarm level but not the second. [10]
3.1.7 Monitoring and bio-feedback system for lower limb rehabilitation
(Pat. No. US 6273863)

The device includes sensors, which are fitted into a sole, and connected to a CPU that delivers the signal to an alarm system. The alarm system is made so that the patient is encouraged to load the limb at optimal level. It is possible to get a real-time monitoring during physical rehabilitation. [11]

3.1.8 Orthopedic limb load monitoring
(Pat. No. US 5107854)

The device is made of a sensing unit and a control unit. The sensor, which is a liquid filled chamber formed as a sole, is external and measures the pressure in the liquid. The control unit gives an alarm signal when the pressure is higher than a predefined value, which is tunable to fit the patient’s needs. [12]

3.2 Commercial Products

3.2.1 ForceGuard™

ForceGuard™ is the business version of the orthopedic limb load-monitoring patent. ForceGuard™ was produced by a US Company but the product has disappeared from the market. Anders Wykman has used this product at his clinic, and, in his opinion, ForceGuard™ is not reliable and gives no ‘good’ alarm, which could make the patient load his limb to less.

3.2.2 SmartStep

There is little information about this product but it seems like it is an evolution of ForceGuard™, which has been bought by an Israeli company, called Andante Medical Devices Ltd. The product has not been introduced to the market yet but it will be introduced to the Israelis market in 2005. This is probably the reason for the limited information about this product. The product has a sensor insole that is wire connected to the main unit, which is fitted around the patient’s shin, see Fig. 3.4. The alarm can give the patient feedback when he loads his limb correct, and too much.

Figure 3.4: SmartStep model
3.2.3 AccuTread and PedAlert

These products are made exclusively to be used inside a hospital to help the patient get a more realistic feeling for the weight he is allowed to load his foot with. There is not much information to be found about these products.

The AccuTread, Fig. 3.5, is a compliment to the traditional bathroom-scale and the system is suppose to help the rehabilitation personal teach the patient the correct amount of force that is allowed. While the patient walks around the foot load is shown in the display. This gives the patient a better felling about the accepted load while walking. It appears like the AccuTread system is removed from the market by some reason, there was only one site left about the system.

The PedAlert, Fig. 3.6, is a device, which the user wears around the foot or shoe and measure the force under the entire foot. PedAlert has an alarm-signal that you tune to give a sound when accepted load is reached or exceeded. The PedAlert can be ordered and cost about 600 US dollar.

Figure 3.5: AccuTread model

Figure 3.6: PedAlert model
3.3 Related foot pressure measurements

Several studies have used thin sensors, like Force Sensing Resistor (FSR), in an insole, to measure the plantar pressure. All these studies are about; either helping people with diabetics avoid ulcers, or combining the FSR sensors with other types of sensors such as; chock sensor, accelerometer etc. to define the plantar pressure during the phases in a walking sequence.

J. A. Paradiso, et.al. [13] developed a wireless insole, were they combines the FSR sensor with further sensors. The solution is developed for dancers and athletes, to record stress that occur to the foot. Fig.3.7

Wertch, et.al. [14] Also uses an insole with FSR sensors. With a micro controller, carried on the users back, data continuously collected from 14 FSR sensors during 15 minutes. The paper explained the design, data acquisition system and the sensor calibration.

C.S. Nicolopoulos, et.al. [15] Use FRS sensors to investigate the difference in plantar pressure during the different phases in a walking sequence (the pressure shifts from the heel-strike to the push-off). They could also to determine under which of the metatarsal heads the pressure is largest. Unfortunately the accuracy on the total foot load using these tree methods was not published.

One commercial sensor is the F-scan sensor from Tekscan, Inc. Boston, M.A, USA. The sensor covers the whole plantar and gives a pressure spectrum over the foot load, but the sensor underestimates the total force with 30% [16]. Although the underestimated value can be compensated with a gain the output is not reliable enough, due to its sensitivity to temperature, bending and hysteresis [17]. To use the sensor continuously calibration is needed. Another disadvantage is the price.

Figure 3.7: Model of a shoe with sensors and wireless transmission [13]

Figure 3.8: The F-scan insole.
3.4 Conclusions

The monitoring devices described are generally designed as insoles, shoes, or shoe covers. The shoe covers are merely used as an enhanced alternative to the ordinary bathroom scale. This is to give the patient an improved feeling for the accepted load. They are therefore irrelevant for this project. The disadvantage with a whole shoe is that many different shoe-types and sizes will be needed, and the patients can not use their own shoes. To the contrary, an insole would decrease the number of sizes needed drastically and gives the patient the opportunity to use his own shoes.

Major drawbacks with the only commercial product that uses an insole, the Smartstep, are the wires connecting the two units. The cables along the wrist and a unit attached to your shin makes it uncomfortable. In order to eliminate the physical connection between the two units a wireless unit could be implemented into the insole. Furthermore, a movable central unit would give a more flexible and user friendly solution, which will give an advantage on the market.

ForceGuard had a market price of 600$ but are no longer available. The SmartStep is a development of ForceGuard but has not reached the market yet.

Pressure sensors placed in the insole measure the resulting force from the leg. These are often positioned at the adequate pressure points under the foot. An alternative solution is the liquid filled insole, which gives the possibility to sense the pressure under the entire foot. These two methods give different advantages/disadvantages, the liquid-filled insole is sensitive to bending, and using only a few measurement-points will be sensitive to different feet and sizes, while in return it gives the possibility to fit the electronics into the insole. The main contribution of this study was to develop a measuring technique with a finite number of measuring points, which can be used on many different feet and sizes. The main difficulty with this is to make a small number of insole-sizes fit all types of feet and sizes. Further, this gives the opportunity to fit the electronics into the insole and make it wireless.

Half of the described systems are using a one-step alarm system, which only gives an alarm when the patient is overloading. The other half are using a two-step alarm system, which also gives an indication when the patient have the correct load and in that way helps the patient to not load his foot too less or too much, in contrast to one-step, which only indicates an overload. The alarm is generally a sound signal or a vibration. To let the patient choose between these two makes it usable for more patients with disabilities such as hearing damages and lack of proprioception.

Due to the fact that interprets patents claim is difficult and requires special knowledge, Albhns conclusion from the technical search is:
It will be difficult to make any new patent in the area. There is a small risk to trespass the American patent (especially US 5,619,186), if they still are in use. But only a small risk due to the fact that the patents have a narrow field of protection because they are concentrated on different specific technical details.
3.5 Project definition

The objective of this project was to develop a measuring technique for measuring the load on the lower limb and to determine if it is possible to develop a future commercial product. To carry on with a future prototype the measuring technique has the following demands:

The user should be allowed to use his own shoes, which means that the measuring device must be; either outside the shoe or inside the shoe. This project will be concentrated on measuring inside the shoe.

The sensor used to measure the force must be thin and reliable for them to fit inside an insole with other electronics.

The prototype, which should be able to give the wearer instant feedback of the foot load during walk. This means that a short delay is desired.

The measuring device has a demand of a maximum measuring error of about 10%.

The measuring device must be thin enough to fit inside an insole and be comfort to the wearers’ foot.

The measuring devices can not have any external power supply.

The future prototype should consist of two parts; a sensor part and a central unit. These two parts will either communicate be wire or wirelessly. The prototype has to be prepared for a CE-certification.

The sensor part will be placed under the foot of the patient and contain the measuring system; sensors, amplifier, micro controller and a battery source.

The central unit should contain a microprocessor, which will analyze the measurements received from the sensor unit. It will also have an alarm unit with sound, vibration or both. The alarm function will have at least two levels: one ‘good’ signal when the patient reaches the preferred level and one ‘bad’ signal when the patient exceeds the higher limit. The unit will have tuning opportunities for weight and amount of partial load for the patient. The following demand is formulated in cooperation with Anders Wykman and Camp Scandinavia.

Demands on future prototype:
- Easy to adjust the weight and load proportion
- The Sensor part is to be the same size as a regular insole
- Wireless communication
- The accuracy has to match the rehabilitation demands
- Battery time for one day of use
- Two Alarms steps

Desired demands:
- Battery time for one week of use
- Central unit could be placed in different locations
- CE-certified
4 Pressure measurement

The design of an alarm system needs pressure sensors together with amplifying electronics. Different sensors have been evaluated and the test setup and the measuring techniques are presented in this section. Three of the most important parts, the sensor characteristics, the influence of the surrounding material and the sensors placements are shown. Different approaches to fit the sensors output to the true force are presented.

4.1 Reference measurement device

The reference sensor used for measurement in this project is a digital scale, somewhat like a bathroom-scale. The digital scale, is built up from a set of strain sensors mounted on a column in-between a pressure plate and the floor. (Fig 4.1).

To sample the sensor signal on the insole during the tests a DSP board is used. The pressure sensors are connected to analogue ports through an operation amplifier (OP) as shown in Fig. 4.2. A rail to rail OP is used to enable the output from the sensors to span from 0-3V, which is the range of a common analogue port.

The reference sensor gives a linear output. But the sensor does not have a linear output. The output from the reference and the sensor is then computed using Matlab.
4.1.1 Data filter

To reduce the high frequency noise from the sensors the output passes through a data filter. The filter used is calculated using Matlab and is a mean filter of fifth order. In this project sampling frequency of 50 Hz was used but for the future product, to save battery, a slower sampling frequency is preferable. Therefore, a higher filter order would lead to too long delay times on the future product and a lower filter order will not reduce the noise sufficiently.
4.2 Sensor characteristic

InterLink’s Force Sensing Resistor (FSR) sensors were shown, in a previous work at the university of Halmstad [18], to be usable measuring foot pressure. These sensors occur in four different sizes, as shown in Fig. 4.3 and they are formable, which is useful when it comes to fit them to the insoles. There are two round models, which has active areas of $=19.6\text{mm}^2$ for FSRR1 and for FSRR2 $126.7\text{mm}^2$. There are also a square model with active area of FSRSQR=$1451.6\text{mm}^2$ and a long sensor with an active area of FSRL=$3840.5\text{mm}^2$ [13].

![Figure 4.3: FSR sensors. from left: FSRR1, FSRR2, FSRSQR, FSRL](image)

The repeatability has been tested for the four different FSR sensor types. The test was carried out by a repeatable actuation system. A force (11kg on 1 cm$^2$) was placed several times at the same location on the sensors. These results correspond with the manufactures data [19] and the repeatability is between two and five percentage and the tests give the same results.

Due to the fact that human foot not is a flat surface the influence of bending the FSR was investigated. The bending was carried out by reading the output from the sensor while continuous decrease the radius of curvature, until the minimum radius of 5mm was reached. The test was carried out without any other external load on the sensor. The sensor, which was most sensitive to bending, was FSRSQR, Fig. 4.4. At the radius 5mm the output from the FSRSQR equals a force of 21 Newton. Curves with smaller radius than 80mm are not expected under a human foot and can therefore be ignored.

![Figure 4.4: Bending output on FSRSQR without external force.](image)

At t=0 and t=5 the sensor is flat. Decreasing radius(r) when t<2.6 sec.
- $r=15\text{mm}$ at t=1.5, $r=5\text{mm}$ at t=2.6
- Increasing radius while t>2.6
- $r=5\text{mm}$ at t=2.6 $r=15\text{mm}$ at t=3.6
Since the adequate pressure points under the foot are different from foot to foot it is difficult to know where the peak-pressure from the foot will hit the sensor. Therefore the influence of the pressure location has been investigated for FSRSQR, which is the only one were the pressure was assumed to differ on the sensing area. The same force (110N on 1 cm$^2$) was moved around the sensor to find out how the outputs from the sensor differ, Fig. 4.5.

The output from the sensor differs from 22N to 26N but inaccuracy could be a part of the error from the repeatability. According to the FSR datasheet [19] the sensors are not sensitive to noise or vibration.

The output from the FSR sensors is not linear and the output also differs with the firmness of the material surrounding the sensor (Fig 4.6). With a softer material the force will be more concentrated to a specific point on the sensor and with a more firm material surrounding the sensor would make the force more spread out onto the whole active area of the sensor. Therefore it is a trade-off between smoothing the force and the comfort of the foot. Some simple testing has been done on this matter. The material, which has been tested, is closed cells cellular Polyethylene plastic with densities 30, 50, 70 and 150 kg/m$^3$ and hard material such as wood and metal. The material has closed cell, which makes it suitable to ware inside a shoe, closed cells has low water absorption, less than 3 volume percentages [20]. The material was formed like an insole and was tested during one day of normal activity. The comfort and the materials strain, hardening and sensation were then evaluated.

The sensors can measure a pressure of maximum 100N/cm$^2$, which gives FSRSQR a maximum force of about 1450N on the entire area. During the first sequence of a step, the heel-strike, the heel is exposed to the total load of a human and as is shown in Fig. 4.7 (top). The FSRSQR are
not accurate for loads over 800N. It has been shown by Nicolopoulos et.al[15] that by placing hard material around the sensor increases the accuracy at the higher loads. Therefore a hard material was placed under the heel sensor when the FSRSQR are used. This is possible due to the fact that the heel part of the foot is not bending during walking. As one can see in Fig. 4.7 (top right) this increases the sensibility in the upper load region tremendously.

Under the forefoot the pressure is spread out over a larger area, therefore a softer material can be used under the sensors. The softer material is chosen for the comfort of the foot and the ability to bend the insole. The material chosen for the insole is cellular Polyethylene plastic with the density 70 kg/m$^3$. The softer materials are not durable enough, while the stiffer material is uncomfortable for the foot.

Due to the non-linear sensor output a function for each sensor was calculated. The sensor is placed on the reference and a 5 seconds measurement with an increasing force on the sensor was carried out to find a suitable equation. This is made for the different combinations of sensors and surrounding material Fig. 4.7.

The measurement system can not be more accurate than the sensors standard deviation. The deviation is not shown in the figure but has been calculated. The standard deviation of 95% or 2σ is: FSRSQR hard surrounding material = 3% of mean, FSRSQR soft surrounding material = 5% of mean, FSRR2 = 4% of mean and FSRR1 = 10% of mean.
Figure 4.7: Output from the four different sensors when increasing force is applied. Top left: FSRSQR with hard surrounding material. Top right: FSRSQR with 70 kg/m$^3$ Polyethylene plastic as surrounding material. Bottom left: FSRR2 with 70 kg/m$^3$ Polyethylene plastic as surrounding material. Bottom right: FSRR1 with 70 kg/m$^3$ Polyethylene plastic as surrounding material. A third degree function, curve, adaptation is plotted with (-----).
4.3 Insoles measuring method

4.3.1 Sensor positions

One of the most critical parts in this project is the design of the sensor-placements. For this problem a number of sensor configurations are tested. In the first evaluation a small test group is used to determine which of the insoles that are possible solutions. The results from these are not presented in this report but the tests gives the principle of how and where to measure and how much the results differ between the setups.

During rehabilitation the patient are using crutches or in some cases he is limping, either case the step sequence are not the rolling step, which a healthy person is using. Therefore the step sequence of a patient can be seen as a static load, which starts at the heel and moves toward the forefoot while the step is carried out. This reduces the number of considered pressure points, as far as the total load measurement is concerned, from four of the most important pressure points to three. This is because the big toe, which is the main pressure area during the push-off phase, of a normal step, while it dose not influence on the static load as much.

There are studies, which show where the pressure pikes are located [21, 22] but in these cases only one or a few feet are shown and there are no data for the positions. Therefore a simple study was carried out where the approximate pressure areas are measured fore different foot-sizes. The pressure areas were found by sensing and looking at the different feet and may contain some noise. However, due to the large difference between feet the noise will not affect the outcome at all. Linear functions for the pressure pikes were computed, with the foot-size as an argument. Fig. 4.8 shows the pike-locations for different foot-sizes.

These calculations show that the best placements would be as the insole in Fig. 4.8 is configured, with movable sensors at the forefoot, which are moved from size to size. On the other hand the tests show that the movable sensor insole is not accurate enough and the insoles in Fig. 4.9 and Fig. 4.11 give far greater results.

\begin{figure}[h]
\centering
\includegraphics[width=\textwidth]{figure48.png}
\caption{The plantar pressure point showed for sizes 36(o), 39(□), 42(A) and 45(X).}
\end{figure}
The three types of configurations are:

**Fixed sensors:**
Using four FSRSQR to cover as much as possible of the plantar. The purpose of this configuration is to be able to have a reduced number of insole-types, which fits a large number of foot-types (Fig. 4.9).

**Movable sensors:**
This configuration has a fixed FSRSQR at the heel and two movable FSRR2 at the forefoot pressure pad. This is to determine how the result differs when the sensors can be designed to different foot in contrast to the fixed sensors (Fig. 4.10).

**Multiple sensors:**
To determine how well the insole above are performing an insole with a large number of sensors are created. In this case nine sensors are used. The basic idea is to divide the sensors on the fixed sensors into smaller pieces. With help from that evaluate how much the location of the pressure centre influence the results (Fig. 4.11).

### 4.3.2 Algorithms

The load exerted to a foot, can be measured through a finite number of measuring points under the foot. However, due to the differences from foot to foot and the soft irregular surfaces, it will be difficult to make the setup general enough. The idea is to measure the same amount of force for every foot. The fact that the finite number of sensors will miss some of the forces, fitting to compensate for this is needed. This project evaluates three different types of compensating algorithms. Initially studies showed that the movable sensors are not accurate enough; therefore it was rejected for further testing.

**Gain fit**
The most theoretically sound method is to add the measured value from each sensor together and multiply the result with a gain. If the sensors are optimal, measure the total pressure and cover the entire plantar, the gain will be one. Otherwise, in theory a system would work well for different feet if the factor is close to one. The force is then calculated using:
Pressure measurement

\[ \text{Force} = \text{gain} \ast \sum_{i=1}^{n} FSR_i, \quad n = \text{number of sensors}. \]

The gain is determined by minimizing the sum of square error:

One measurement \( i \) from the reference sensor is modeled by linear weighting of the summed sensors.

\[
S(i) = \sum_{j=1}^{n} FSR_j(i), \quad FSR_j = [FSR_1(i) \quad FSR_2(i) \ldots FSR_n(i)]
\]

\[
R(i) = \text{gain} \ast S(i) + e(i), \quad e(i) = \text{error} \quad \quad \quad (1)
\]

\[
e(i) = R(i) - \text{gain} \ast S(i) \quad \quad \quad (2)
\]

Take \( N \) different measurements in matrix form and minimizing the sum of square error.

\[
e = \begin{bmatrix} e(1) \\ \vdots \\ e(N) \end{bmatrix}, \quad R = \begin{bmatrix} R(1) \\ \vdots \\ R(N) \end{bmatrix}, \quad S = \begin{bmatrix} S(1) \\ \vdots \\ S(N) \end{bmatrix}
\]

\[
e = R - \text{gain} \ast S \quad \quad \quad (3)
\]

\[
\min \left( \sum_{i=1}^{N} e(i)^2 \right) = \min(e^T e) \Rightarrow \text{gain} = (S^T S)^{-1} S^T R \quad \quad \quad (5)
\]

**Mean pressure**

To further improve the results from gain fit the influence from foot-size was evaluated. This is done with an algorithm which calculates the mean pressure on each sensor. The mean over all the sensors are then weighted with the foot area. The fact that the sensors are positioned where the pressure is highest the measured force will be higher than average. A fitting can compensate for this, in this case the gain will be <1. The force is calculated using:

\[ \text{Force} = \text{gain} \ast \text{footarea} \ast \frac{1}{n} \sum_{i=1}^{n} \frac{FSR_i}{\text{AREA}_{FSR_i}}, \quad n = \text{number of sensors}. \]

The scale is determined by minimizing the sum of square error:

One measurement \( i \) from the reference sensor is modeled by linear weighting of the summed mean pressure of the sensors times the foot area of the user.

\[
F(i) = \text{footarea} \ast \frac{1}{n} \sum_{j=1}^{n} \frac{FSR_j(i)}{\text{AREA}_{FSR_j}}, \quad FSR_j = [FSR_1(i) \quad FSR_2(i) \ldots FSR_n(i)]
\]

The gain, which is desired, is calculated by replacing \( S \) with \( F \) in equations 1 to 5.
Least square fit
The methods above need the user to adjust the foot size on the device. A method with a mean square error (MSE) fit, were the sensors are individually weighted, could compensate for this. The weights are calculated with a MSE function, which gives the best weighting to each sensor. This method will fit the training data in the best way but it may not be as general as the previous methods. This is due to the fact that this algorithm gives the sensors different importance, which means, if a sensor that is highly weighted is slightly missed by the user it has a high influence on the result. Further, if a less weighted sensor is missed it will not affect the system as much. In some cases it could be good to reduce the influence for certain sensors but to evaluate this in a sound way the test-set has to be very large and normally distributed over foot-types. The force is calculated using:

\[ \text{Force} = FSR_1 \* W_1 + FSR_2 \* W_2 + \ldots + FSR_n \* W_n \]

The weights \((W)\) are determined by minimizing the sum of squared error:

One measurement \(i\) from the reference sensor is modeled by a linear weighing from \(n\) number of sensors.

\[ R(i) = FSR_j (i)W + e(i) \]

\[ FSR_j = [FSR_1(i) \quad FSR_2(i) \ldots FSR_n(i)] \quad W = \begin{bmatrix} W_1 \\ W_2 \\ \vdots \\ W_n \end{bmatrix}, \quad e(i) = error \]

\[ e(i) = R(i) - FSR_j W \]

Take \(N\) different measurements in matrix form and minimizing the sum of square error.

\[ e = \begin{bmatrix} e(1) \\ e(2) \\ \vdots \\ e(N) \end{bmatrix}, \quad R = \begin{bmatrix} R(1) \\ R(2) \\ \vdots \\ R(N) \end{bmatrix}, \quad FSR = \begin{bmatrix} FSR_1(1) \\ FSR_2(1) \\ \vdots \\ FSR_n(N) \end{bmatrix} \]

\[ e = R - FSR \* W \]

\[ \min \left( \sum_{i=1}^{N} e(i)^2 \right) = \min(e^T e) \Rightarrow W = (FSR^T \cdot FSR)^{-1} \cdot FSR^T \cdot R \]
4.3.3 Pressure smoothing

To reduce the differences on different feet to the sensors, a smoothing technique is tried out. This is done by placing a layer of stiff material, e.g. carbon fiber, in this case a wood-plate in-between the foot and the sensors. The insole with static sensors is used and it is placed directly onto the reference sensor with the wood-plate on top. The idea with this experiment is, as Fig. 4.12 shows, to spread the pressure pikes to be a wider pressure and hopefully measure it more correctly. This technique will result in a quite stiff insole; however it would not be a problem due to the static type of step sequence a patient is using during rehabilitation.

Figure 4.12: Pressure smoothing
4.4 Test groups

Each test sequence is 5 seconds long. Three different test sequences were conducted:

- Maximum load in two sets (Fig. 4.13).
- Static continues load.
- Slowly increasing load from zero.

The first sequence is to determine how well the sensors keep up with the reference load in the rises and slopes. The static load is used to determine if the measured load differs in time. Further, the last test sequence, which starts from zero and rises slowly during the entire sampling, is to determine if the measured load differs in different part of the load interval.

Tests were conducted on two test groups, a large and a small.

Large test group:
The large test-group consist of 10 healthy people (age 24-29) mixed with both male and female participants and they have the following foot sizes 38, 39.5, 40, 42, 42, 43, 43, 44, 45 and 45.5.

Small test group:
4 healthy people participate in the small test group. The test person in this group are all male, age 24, 24, 25 and 28, and corresponding foot sizes, 42, 42, 43, 45 and weights 67, 69, 89 and 95kg.

As described above, to get better sensibility a small metallic plate was placed under the heel sensor in the test person’s shoe.

For the tests on smaller group, the test sequences are performed with the insole types in the test person own shoe. For the larger test group the insole where placed directly on the reference device, which reduces the influence of the shoes and gives a more homogeneous results. This is possible due to the fact that during rehabilitation the user will use similar shoe-types.

![Figure 4.13: The test sequence from one person with two pressure peaks.](image-url)
5 Test Results

This chapter shows the results from the tests done on the different insole. Two types of evaluation errors were defined; individual error ($E_i$) and group error ($E_g$).

$$E_i = \frac{1}{N} \sum_{i=1}^{N} \frac{(F_i - \hat{F}_i)}{F_i}, \quad N = 5 \text{sec} \times 50Hz = 250. \quad E_g = \frac{1}{n} \sum_{i=1}^{n} E_i$$

$E_i$ and $E_g$ are shown as a mean error in percentage of the total body weight. This is to be able to compare the different test persons. The tables display $E_g$ while $E_i$ is shown in the figures. Two types of calibrations were used; combined and single calibration. Combined calibration tunes the parameters for the whole group combined while single calibration tunes the parameters for the test persons individually. The main effort is made on the combined calibration because it is a more user friendly model.

5.1 Plantar pressure distribution

One of the ideas with the multiple sensors insole is to determine if the model of the pressure points is correct, and if all the sensors are needed. Tests are made with gain fit and the error showed a minimum at 4 sensors, see Fig. 5.1. The pattern is similar for the test group. These sensors correspond to the four measurement areas at the fixed sensor insole; the heel, the mid-
foot, the mid-outer forefoot and the inner forefoot. When further sensors are added the error increases, which may be caused by the high correlation of the sensor pairs (see Fig. 5.2). This means that the sensor pairs give the same information, thus only noise is added. It also shows that the pressure, at the fixed sensor locations, is similar over the whole sensor areas and therefore can be measured with the larger sensors.

The main idea of this project is to measure the static foot load with a certain accuracy. The performance depends on how well the total pressure can be measured. Due to the difference in pressure point location the part of measured load will differ from foot to foot. For example, two feet of size 42 differs with 6% in part of total load measured. This also differs between the insoles.

5.2 Insole evaluation

Three different insole-types were evaluated; fixed sensors, fixed sensors with a plate and multiple sensors. They were mounted directly onto the reference sensor, removing the influence of different shoe-types. The results show that the total amount measured, differ significantly between the different insoles (see Fig. 5.3). The area of the sensors on the multiple sensors insole is much smaller than that of the fixed sensor insole. The sensors measures higher load when no smoothing plate is used. This is due to the plates averaging effect. In contrary to expected, one can see that the accuracy is not higher for the fixed insole with a plate than without the plate, which may be explained with the theoretical statement that the measured pressure should be close to one.

Line fitting of the insole results and the scale measurement has been done with three different methods; gain, mean value extraction and least square fit. The results from these methods show that the load can be measured with good accuracy. Further, this study has determined if the accuracy can be improved from the total load measurements.
5.2.1 Gain fit

The Gain fit uses the combined values from the sensors and gains them with a certain factor. The results show in table 5.1 that the multiple sensors insole gives smaller mean error, while the fixed sensor insole gives a lower distribution. The individual test results (see Fig. 5.4) show that the group of values for the fixed sensor insole show less variation than for the other two insoles.

<table>
<thead>
<tr>
<th>Sensors</th>
<th>Fixed</th>
<th>Fixed plate</th>
<th>Multiple</th>
</tr>
</thead>
<tbody>
<tr>
<td>$E_g$</td>
<td>-0.5%</td>
<td>-2.2%</td>
<td>-0.1%</td>
</tr>
<tr>
<td>Standard deviation</td>
<td>24%</td>
<td>33%</td>
<td>28%</td>
</tr>
</tbody>
</table>

Table 5.1: The results for Gain fit.

*Figure 5.4: The error $E_i$ when using Gain fit on ten test people, ordered in shoe-size {38 39.5 40 42 42 43 43 44 45 45.5}.*
5.2.2 Mean pressure

The Mean pressure takes the shoe-size into account. Table 5.2 shows that the results for the fixed sensor insole with and without the plate are similar to the Gain fit results, while the error for the multiple sensors insole is larger. This indicates that the shoe-size does not influence the total amount of measured load (see Fig. 5.3). Neither decreasing nor increasing pattern, in relation to shoe-size, can be found. The individual errors are displayed in Fig. 5.5. The group of results from the fixed sensor insole has less variance then the results for the other two insoles.

<table>
<thead>
<tr>
<th>Sensors</th>
<th>Fixed</th>
<th>Fixed plate</th>
<th>Multiple</th>
</tr>
</thead>
<tbody>
<tr>
<td>E_g</td>
<td>-0.9%</td>
<td>-3.1%</td>
<td>-3.1%</td>
</tr>
<tr>
<td>Standard deviation</td>
<td>23%</td>
<td>30%</td>
<td>44%</td>
</tr>
</tbody>
</table>

*Table 5.2: The results for Mean pressure.*

*Figure 5.5: The error $E_i$ when using Mean pressure on ten test people. They are ordered in shoe-size {38 39.5 40 42 43 44 45 45.5}.*
### 5.2.3 Least square fit

This method weights every sensor with an individual weight. As shown in table 5.3 this method works well for the fixed sensor and the multiple sensors insole. However, it differs from the Gain fit as the fixed sensor insole has a lower mean error and the multiple sensors insole has less variation. This may be caused by the fact that Gain fit gives the same gain to all the sensors, while least square fit can give different importance for different sensors. Thus it can tune the weights to only use one of the sensors from each sensor-pair and by that reduce the noise. However, this improvement, in relation to its complexity, is not enough to make it better than the gain method. The results displayed in Fig. 5.7, show that the test error has least variation for the multiple sensors insole.

<table>
<thead>
<tr>
<th>Sensors</th>
<th>Fixed</th>
<th>Fixed plate</th>
<th>Multiple</th>
</tr>
</thead>
<tbody>
<tr>
<td>$E_g$</td>
<td>-0.3%</td>
<td>-1.4%</td>
<td>0.6%</td>
</tr>
<tr>
<td>Standard deviation</td>
<td>20%</td>
<td>23%</td>
<td>17%</td>
</tr>
</tbody>
</table>

*Table 5.3: The results for Least square fit.*

![Figure 5.6: The error $E_i$ when using Least square fit on ten test people. They are ordered in shoe-size {38 39.5 40 42 43 44 45 45.5}.*](image-url)
5.3 Shoe influence

The previous tests have shown how well the insoles are capable of measuring the total amount of force in uniform conditions. To determine if it is possible to use these methods in rehabilitation the shoe influences is studied. People were chosen with matching shoe-type to those used during rehabilitation. These shoes are of firm type with low heel. The result show only small differences between the two conditions (see Fig. 5.7).

The tests with shoes have only been done without the plate on the fixed sensor insole. However, the results for the three different methods show almost identical results with shoe as without shoes. The insoles are equally good in measuring. But due to the simplicity with few sensors the fixed sensor insole with Gain fit give the overall smallest error.

5.4 Single calibration

There is a diversity of the human foot, which makes the part of measured load to differ from person to person. This means that the error $E_i$ will be high for some of the people when using combined calibration. If the calibration is made separately the bias error for each person can be minimized. According to table 5.7 the bias error, which each test person gets when the combined calibration is used is highly reduced with single calibration.

<table>
<thead>
<tr>
<th>Calibration</th>
<th>Combined calibration</th>
<th>Single calibration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test person</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>$E_i$</td>
<td>6.3%</td>
<td>-8.4%</td>
</tr>
<tr>
<td>Standard deviation</td>
<td>8.9%</td>
<td>9.2%</td>
</tr>
</tbody>
</table>

Table 4.7: Combined and single calibration when using Gain fit and the fixed sensor insole.
5.5 Dynamic Load

To evaluate how important it is that the load is static, the insoles have also been tested for dynamic load. The dynamic step, of a healthy person, is a sequence of four phases [18]. Three of these phases are related to plantar pressure. The difficulties with dynamic load are the differences in pressure areas. A step starts at the heel and for a short period the load can be seen as a static load, and at the end it becomes a load at the forefoot pressure areas. If the load can be measured at the time when it can be seen as a static load it would be similar to previous cases. But unfortunately the load is not highest in that part (see Fig 5.8). The load is highest at the beginning and at the end of the step sequence. However the result from this test shows that the load can be measured, during the whole sequence, with good results. The error \( E_t \) over time is 0.50% with an accuracy of 9.5%. This is almost as good as for the static load. However, this is only valid if the least square fit is used. The other two methods are not sufficient for this task.

![Figure 5.8: Dynamic sequence. (-----) Insole (___) Scale](image)
5.6 Conclusions

It has been shown that the intentioned plantar pressure points can be found. Results from minimizing the number sensors, at the multiple sensors insole, show that one sensor from each measurement area on the fixed sensor insole are needed. Using these, pressure models were tested to determine how much of the total load the different insoles are measuring. As stated above, this value should be close to one. The only insole, which corresponds to that, is the fixed sensor insole.

The results show that the fixed sensor insole, without the plate, gives good results, while with the plate the results are poor. This can probably be related to the part of measured load. However, the insole which measures lowest part of the load, the multiple sensors insole, gives good results while being more sensitive to the fitting method. The test group uses the insoles directly onto the weighing machine, while a patient will use it inside their shoes. Therefore the relations between in-shoe and on-scale use is evaluated. This shows that the shoe does not effect the results much. Although this was tested with a smaller test group, the total results from these tests show similar results as the first test.

The best results for the fixed insole without the plate were with the least square fit gives accuracy, $2\sigma$, of 20% of the body weight. But the overall performance from this insole is very good. Gain fit gives accuracy of 24% and accuracy of 23% with Mean pressure. The two other insoles also shows good results, but not for all of the methods. The multiple sensors insole is bad on the Mean pressure with accuracy of 33% but on the other hand it shows the overall best results with Least square fit accuracy of 17%. The fixed insole with the plate is good on the Least square fit with accuracy of 23% but for the other two methods the accuracy is worth than 30%.

All the results above are made with combined calibration for the whole test groups. However, to further improve the test results the system can be calibrated for every single test person, single calibration. With this method the bias error was reduced from about 8% to around 0.5%, which means that $2\sigma$ for the group will be reduced to about 10% for the fixed insole with gain fitting.

As showed above the sensors have accuracy of about 3-4%. Noticing that the best accuracy for the insole tests is around 10%, the sensors may be a big part of the error. Possibly this could be reduced with a set of sensors with lower diffusion, however, such a sensor was not found during this project.
6 Discussion / Conclusion

6.1 Accomplishments

This project studies the possibility to measure the total amount of load, which is exerted to the lower extremity. The insole contains a number of thin pressure sensors, which are placed at the plantar pressure points. Three different insole-types are tested with, fixed sensor, movable sensor and with multiple sensors. The fixed sensor insole is also tested with a plate placed on top of the insole to spread the pressure. To fit the measured load to the real load three approaches are proposed; Gain fit, Mean pressure and Least square fit.

Most of the previous works in this field has had similar ideas on how to measure the foot load and the different plantar pressure points. However the contribution of this project is to determine how well the total load can be measured for a group of people. Design tests have been carried out on a test group of ten people. Further, the influence of shoes has been tested with a group of four people wearing firm low heel shoes.

The tests show promising results. The smallest error overall is achieved with single calibration for the multiple sensors insole and tuned with Least square fit. This setup gives accuracy of 10% and a mean error of 0.5%. If the measuring technique is to be more easy to use for the medical staff the combined calibration can be used. The smallest error achieved for combined calibration is from the test with the multiple sensors insole tuned with Least square fit. The accuracy from this setup is 17% with a mean error of 0.3%. However, to make the measuring setup more economically efficient, low power consuming and general the fixed sensor insole is to be used. The accuracy achieved for the fixed sensor insole tuned with the Gain fit and combined calibration is 24% and a mean error of 0.5%.

One big error source is the sensors themselves, with their standard deviation, $2\sigma$, of about 3-4%; therefore the error could be reduced further with a different type of sensor, which has a higher accuracy. However, during this project such a sensor were not found.
6.2 Product suggestion

The results from this project show that the insole is to be of a material with a density of 70-150 kg/m³ and has to be thinner than 10mm. The insole should also use the fixed sensor configuration with two FSRSQR at the forefoot, one at the mid foot and one at the heel. The sensor at the heel will have a hard material under the sensors, preferably, carbon fiber or metal. These sensors are to be attached to a microcontroller that linearizes the sensor output. An OP amplifier is used in the connection; these are to be driven from an I/O port at the microcontroller.

To reduce the power consumption the microcontroller should calculate if the foot pressure is too high, in the allowed region or if it is to low. Then it has to send the type of alarm, which is to be given to the user, to a wireless unit. Preferably an active RFID tag can be used for this issue. This unit has low power consumption and can be program to only send when it gets a send signal from the processor. The company Free2move has an active RFID tag with an I2C bus, which the microcontroller can communicate over. This tag is also very small and has an I/O port where the microcontroller can be switched on and off. If a small microcontroller and OP amplifier is selected, the electronics can be fitted into an insole of thickness over 6mm. To shield the electronics from the tough environment inside a shoe, it can be encased with hard rubber.

In a daily use with a walking time of 8 hours per day and if the user on average reaches the level of load which is accepted i.e. two transmission per second. In this case with a battery knob battery with a capacity of 300mAh and at 3V, the unit could be used for about 60 days.

The main unit uses the same kind of RFID tag but as a receiver instead. This gives the ability to suite the control unit in a small container, which makes it user-friendly. The main unit should have two potentiometers to tune the weight and weight portion with. The alarm will be given with either a buzzer or a vibrator; these external components are controlled by the same type of microcontroller as is used in the insole. The main unit will need more power, due to the more energy consuming external components. This demand will be met by using a larger rechargeable battery.
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