DEVELOPMENT AND TEST RESULTS OF A SYSTEM FOR THE RECOVERY OF THE LOWER LIMBS

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Abstract
According to medical research,[1] exertion of a certain level of loading to injured lower limbs is considered as important from the point of view of their recovery. Total unloading would decelerate coalescing of bones just like their permanent overloading. In order to avoid it, patients must be trained to walk with optimal load on lower limbs. A data logger with built-in load cell is designated both to sustain this process and to store data on load values exercised to limbs during recovery as well. The report below tells how this device was developed.

Keywords: load cell, lover limb, partial weight bearing, recovery, feedback, rehabilitation

Introduction

An important condition for the recovery of the lower limbs is optimal loading distribution during walking. The goal of the development is to realize a system to train and control walking leading to limb loading prescribed by the physician. This article describes the development of the system measuring the loading of the lower limbs, criteria taken into account during development, the performed experiments, and the developed solutions. We review the patients who need rehabilitation and whose efficient recovery is assisted by the system.

Methods

In course of rehabilitation related to lower limbs and walking it is necessary to know when and how much load the patient exposed the affected limbs or side to, what difference can be measured between the load of the healthy and rehabilitated limbs. An indispensable condition of the right recovery of the injured lower limb is partial release from load because full release may delay the setting (recovery) of the bone in the same way as overload1. During recovery the limbs are increasingly loaded up to 70% of full load, then the patient himself gets to full load at more or less suitable rate. Final goal of the rehabilitation of those with nervous system injury is to develop symmetrical walking and load therefore the patient must be urged to load the weaker limb to a greater extent. Similar is the case with patients walking long time with pain and load releasing devices. We can see that following the implantation of the prosthesis symmetrical limb loading is not restored[4] therefore symmetry of walking must be corrected through separate rehabilitation.

Current solution

Training partial unloading is carried out by teaching the patient after he is standing to realize how much pain belongs to the desired load. It is usually carried out by a personal scale in hospital but the use of foot-board with force measurement possibility or instrumented treadmill are also possible. This load is periodically controlled and new level of load is determined during control examination. The deficiency of the procedure is that the patient exerts load from memory, there is no continuous measurement and feedback on the right and wrong load. Data are not recorded to indicate to the physician how many steps the patient took under what load and whether kept the physician's advice.

Goal

The goal is to develop force transducer-data collection-feedback device continuously usable during full recovery.[2,3] The force transducer shoe may continuously help the patient to learn and practice right limb loading. Thy physician and the physical therapist may set the next load level according to the improving condition of the patient on the basis of the unloaded data.

Selection of force components characterizing the load of the lower limb

In course of normal walking only ground reaction force component is calculated during the measurement of lower limbs load because forces in the plane of the ground, in the direction of walking and perpendicular to it may take place only in case of significant acceleration like among professional football players. Among the occurring moments the torsion moment of the limb may be significant, but in case of patient requiring rehabilitation this value can be neglected because of slow, considered movement.

Ground reaction force during normal walk

During normal walking there are more phases of movement of foot while contacted to the ground from heel strike while toe-off. The ground reaction force has two maximum points like peaks of heel and forefoot loading (*Figure 1*). It is suitable to measure the ground measuring force under the heel if the patient is able to walk in normal way. In that case the first peaks are measured and stored.

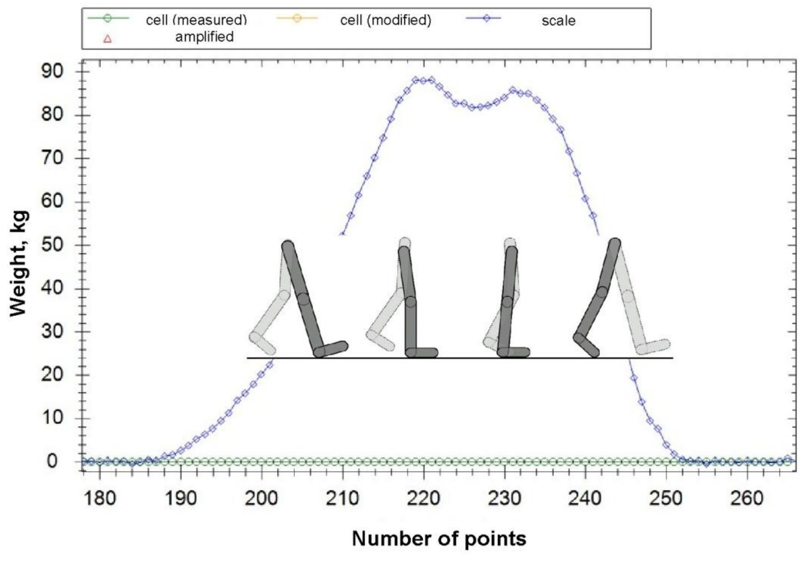

Figure 1. Walking phases and ground reaction force was recorded by scale platform (x axis – time with 50Hz sampling rate; y axis – load in kg)

If the patient is unable for rolling walk, does not load clearly his heel the action line of the maximum of the reaction force is shifted towards toes. The walking image of patients is measurable with a scale having big walking surface on which several steps can be taken. The shape of the force diagram can show that the walking image of the patient does not change therefore it is enough to measure reaction force on the heel. When measurement is started when force transducer shoe is adjusted to the patient, the extent of force shift can be set with the scale platform, in this way the measured values comply with the actual load. If the patient is unable to load his heel, forces must be measured on several points of the sole, on the heel, on the inner and outer sides of the first part of the foot, and on the big toe.

Results

Development of suitable shoes

Three criteria must be taken into account during the development of force transducer shoes: comfort, safety and accurate measurement results. Our experiments proved that comfortable force transmitting surfaces cannot be developed into flexible shoes between the force transducer and the sole because the roll of fat of the human sole and the flexible heel-sole of the shoes can cause great deformation during walking. The hard force transducer cell placed in the foot-shoe system on the one hand makes the use of shoes uncomfortable because of local pressure peaks; on the other hand flexible condition does not ensure that full load may be shifted to the force transducer cell because of the force components taken up by the flexible condition. Human sole cannot be made more rigid therefore a rigid pair of shoes was developed. Wooden sole clogs are comfortable and safe. Its wood frame is properly rigid, ensures comfortable force transducer surface and provides enough space for force transducer cell. The wooden frame of the clogs must have two parts: the upper part having contact with the foot and the lower part having contact with the ground. The lower and upper parts are connected with the force transducer cell or cells. Necessary measurement accuracy can be achieved with this development. Use of strap increases safety (*Figure 2*).

Figure 2 Force transducer shoes on the scale platform

Force measurement

Force transducer sensor

As the first step of our development on the basis of literature and market research we decided to develop our own force transducer sensor and electronics since any device meeting the target is not available on the market. The following parameters were decided in the technical description: low consumption, thin construction, pressure directed load capacity, long term stability and accuracy, robust construction, usable up to 150 kg mass. We could not choose from insole-like pressure measuring sensors, which can be placed into shoes since everyday use would be unaffordable because of the high price and computer of high capacity and size to handle the great quantity of data is also necessary and it cannot be integrated into the shoes.

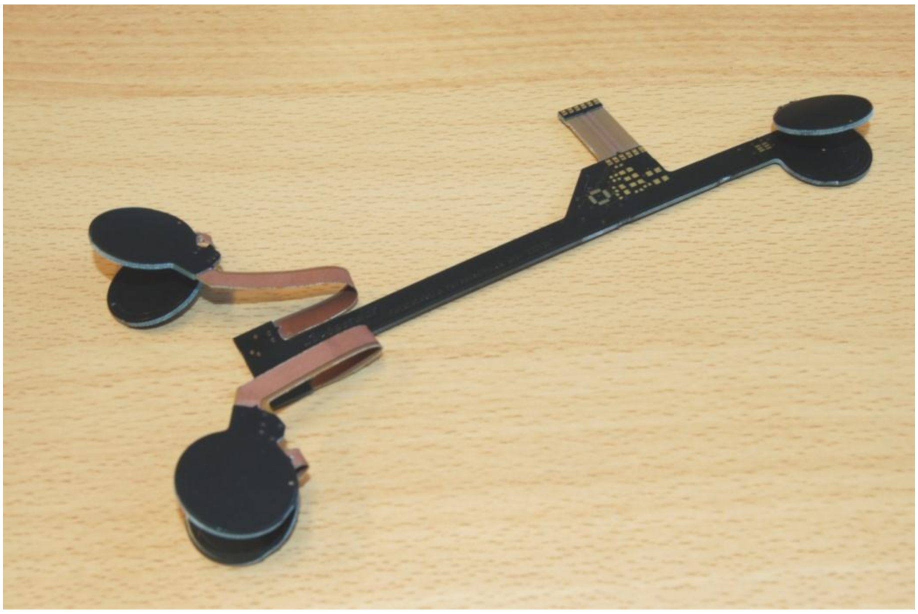

Figure 3. Electric board of system with three sensors

Therefore force measurement was reduced to measure one force only with optimum construction. Capacitive force transducer sensor was chosen (*Figure 3*). The "soul" of the capacitive sensor is dielectric and the spring element, which determine force shift, the force-electric signal characteristics and their dependencies on different conditions (temperature, humidity, etc.). Since sensors with these required characteristics are not available, we carried out our own development. We have developed a cell working with steel membrane; in that case dielectric is air, which is between measuring unit and spring element. The load bearing capacity of the cell with steel membrane, remaining deformation, and hysteresis were tested under laboratory conditions. The sizes of fitting parts taking part in springs and construction of their fitting surfaces were optimized, in this way hysteresis measurable during up load and release was reduced to minimum, the failure range of measurement fell within 2% (*Figure 4*). The disadvantage of the steel membrane cell is its weight and relatively high production cost because of several precision parts.

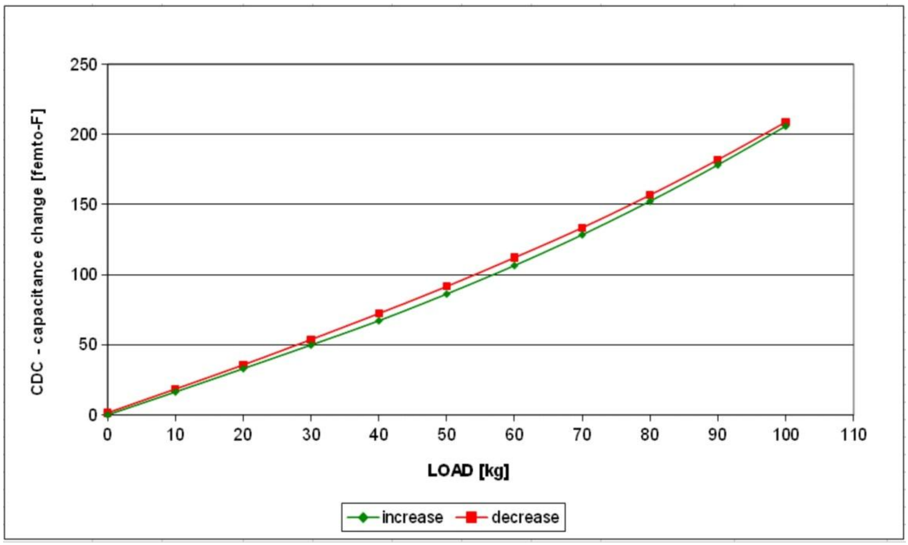

Figure 4. Hysteresis of steel spring

Capacitive force transducer using artificial rubber (silicone, polyurethane, PDMS) spring element was developed because of its simpler solution and lighter weight. In this sensor the artificial rubber spring is dielectric at the same time. On the basis of literature and market research several artificial rubber materials deemed suitable were chosen and the change of dielectric characteristics under pressure change, the change of force deformation functions under the effect of temperature, the limit load whose long term use does not cause remaining deformation in the artificial rubber were examined in laboratory.

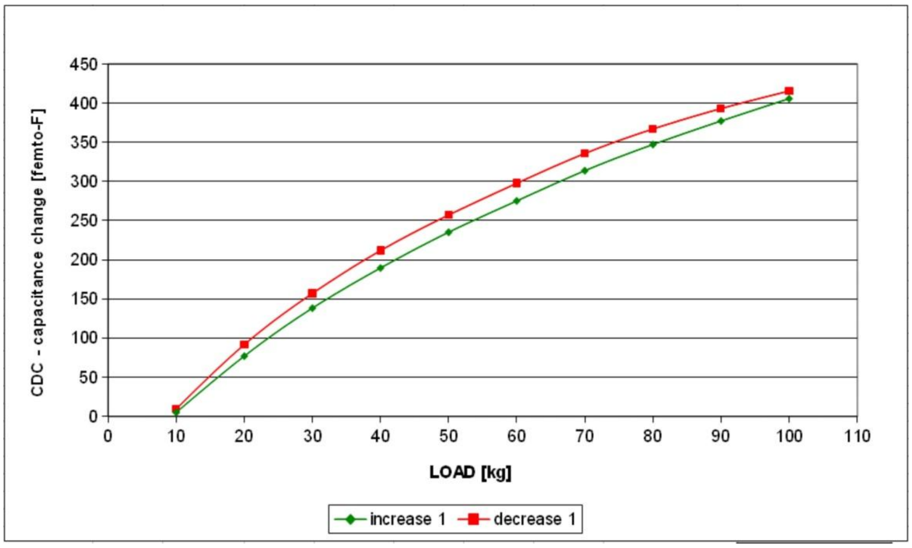

Figure 5. Hysteresis of PDMS spring

In addition we examined what geometric construction can minimize hysteresis typical of artificial rubber because of the relatively high inside friction of the material. The use of PDMS material could keep the 5 % failure range (*Figure 5*).

Data processing

To determine the load peaks during walking with appropriate accuracy a data processing algorithm was developed for the dynamic measurements results based on force measurement with the frequency of 50/second. Continuous evaluation of the measurement data is necessary because the patients need feedback on each step. The evaluation algorithm working continuously during the measurement procedure is looking for maximum value or values during the given steps according to optimised parameters. We have to distinguish normal walking – when force decreases to zero – from the stamp and lounge, when the force does not decreases to zero between two maximum force values.

Feedback

On the basis of the results of the evaluation algorithm the force transducer shoes give feedback to the patient, according to load levels determined to the given treatment period, which can be modified arbitrarily during the whole treatment period by the physical therapist or the physician. A proper procedure for the feedback can be the use of stimulus by sound, light and vibration. Tests have verified that the most efficient way is the sound signal is, because the mostly elderly people cannot listen to a lamp during walking, or have difficulties to interpret the vibration signal of the force transducer shoes.

The force transducer shoes themselves can give sound signal with their built beepers, but outer signal devices can improve the efficiency of the feedback, in case of hard of hearing patients. Two outer feedback instruments have been developed, with which the force transducer shoes are communicating on wireless channel. One of them is a sound signal attached on belt, it has its own power supply, loudspeaker and earphone (*Figure 6*), the other one is a watch which in addition to sound signals also shows measurement results on its display (*Figure 7*).

Figure 6. Use of wireless external feedback instrument with earphone

Figure 7. Use of wireless watch as feedback instrument

Two possibilities were developed for the way of feedback. On the one hand, based on the calculated maximum values the patient gets different sound signal after the step in case of load release or overload, it is called “punishing” feedback, because shoes beep only in case of error and with phase delay since maximum value is obtained only after finishing the step and sound signal can be started then. On the other hand “rewarding” sound signal, which gives different buzzer sound at the moment when the measured force value reaches the desired range, in this way indicates that the patient should not weigh on his foot to a greater extent since load is just right! The two feedbacks can be used simultaneously and separately, but clinical tests proved that elderly patients have difficulties to interpret three types of sound signals. “Personalization” procedure during measurement and data collection observes the efficiency of feedback, which is different person by person. It continuously modifies the feedback levels that the patient should remain in the load range defined by the physical therapist/physician.

Calibration of force measurement

The relation between the value measured by the shoes and the value measured on the ground depends on the number of force transducer sensors, location in the shoes and the walk image of the patient, therefore the force measurement shoes must be set on force transducer platform by control measurement in case of all patients. A folding scale platform was constructed on which the patient can take several steps with only the affected foot on the surface, the other one and load releasing device are not (*Figure 8*). The measurement results of the scale platform along with the results of force transducer shoes appear in the application running on the joined computer. The measurement of the force transducer shoes can be corrected on the basis of the results (*Figure 9*). Simultaneously with the current article the construction of a force transducer treadmill, which is suitable for continuous measurement of the ground reaction of both feet is going on (*Figure 10*). The treadmill is equipped with load releasing elements and fall restricting pending strap in this way it is not only suitable for the calibration of the force transducer shoes, but is also usable for rehabilitation therapy and examination. Joint measurement of the ground load of the two feet provides the physician accurate image about the asymmetrical walking of the patient.

Figure 8. Calibration of force transducer shoes on the scale platform

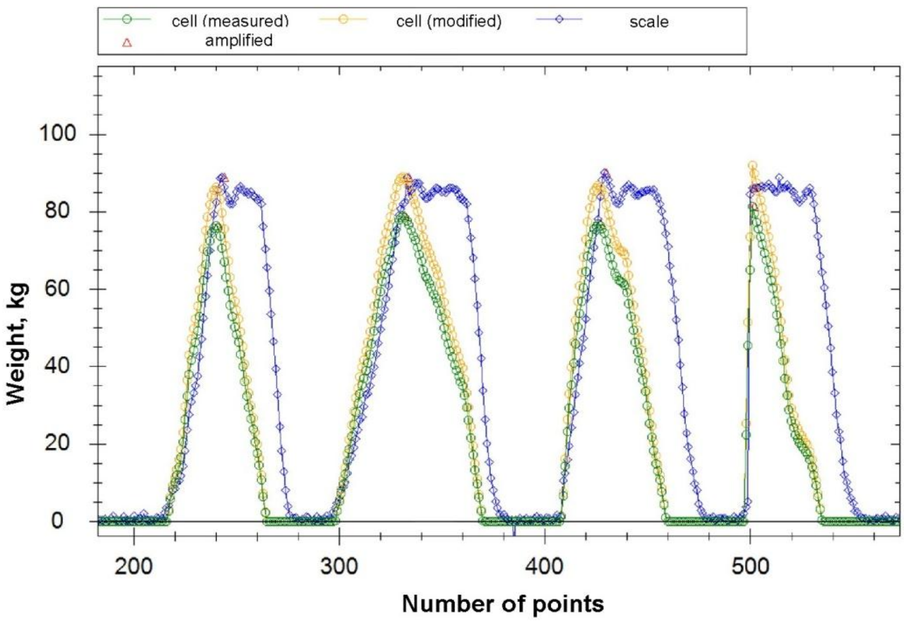

Figure 9. Results of calibration of force transducer shoes on the scale platform (green – shoes original; orange – shoes calibrated; blue – scale platform; x axis – time with 50Hz sampling rate; y axis – load)

Power supply

The force transducer shoes must operate for at least 30 days safely with minimum handling. To this end there are three ways: battery and everyday charging, high capacity battery and self-charging system. Although several promising power supplies resulting from the force of steps during walking are published in periodicals, not one usable as real solution could be found. As final solution high capacity batteries were chosen, which are able to operate the force transducer shoes for at least 30 days even in cold weather. In addition to adequate power supply energy demand decreasing solutions were developed as the sleeping and measurement operation of electronics.

Figure 10. 3D view of force transducer treadmill

Software, data base

Following the log in to the server new patients and walk improving devices can be entered, new treatments can be started and measurement results from treatments can be unloaded. All the data and measurements related to the treatment get to the server and in case of proper entitlement the entitled user can have access to all data from anywhere with the help of internet browser.

Elements of the realised system

- force transducer data collecting-feedback shoes
- feedback instrument with wireless communication
- scale to train walking, to calibrate shoes
- treadmill to train walking, to calibrate shoes

- wireless communicator to PC for data movement between PC and scale, PC and treadmill, PC and shoes
- PC program
- server program

Discussion

Results of clinical tests

The clinical testing of the system is carried out with TUKEB license at three hospital departments. The clinical test was not finished when the manuscript was sent.

Results up to now:[5]
The system was tested on 10 healthy volunteers and 72 patients. The majority of patients in the test used the force transducer shoes following implantation of arthritis prostheses, the others after different fractures. The average age of the examined persons was 65 years, the average weight 76 kg. Test periods are traditional training of load release by physical therapist, the use of the device without feedback then with feedback.

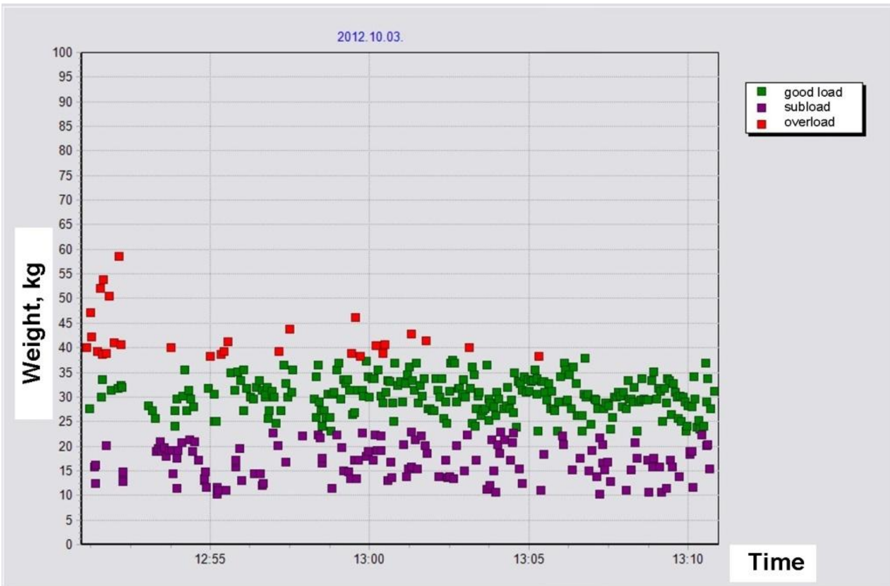

Figure 11. Measuring results in the data evaluation section of software (red – overload; green – load in the range; violet – load under the range)

On the basis of aggregate results we could conclude that the device must be used with feedback (sound signal, light signal or in vibrating mode). In this case the results showed 40 % reduction of overload in the clinical tests. Simultaneously with sending this article clinical tests are going on with patients affected by problems of the nervous system.

Possibilities for further development

The Angel Heel slippers can be made suitable to measure also walk pattern, that is, the distance-time-angle parameters of walk, for the complex kinematic and dynamic examination of walking under natural conditions. These continuously wearable measurement- data collection systems can provide more accurate data than case by case control measurements since statistical mass of real results recorded under stress free environment can be obtained.

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