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DEVELOPMENT OF A THERAPEUTIC DEVICE SUPPORTING REAL-TIME DYNAMIC VERTICAL FORCE UNLOAD

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ABSTRACT

The general goal of the present work was the development and the evaluation of efficiency and safety performance of a designed therapeutic device, which is aimed at a patient's dynamic unloading during walking, combined with a plantar pressure storage system.

The proposed device overcomes the lack of a dynamic vertical unload force enabling the patients to walk at random speed. The software interface allows downloading a patient's data for archiving, reporting or exporting as an ASCII-file for additional analysis. As part of a rehabilitation technology for the purpose of miscellaneous training conditions and of a variety of training intensity a treadmill and mechanical steps are used.

The developed rehabilitation system ensures: operational safety, positional adjustment, choice of unload level, automatic load control in a real-time operation mode and provides a visual feedback of the current walking process.

Index Terms - Therapeutic device, rehabilitation, plantar pressure, walking, vertical force

1. INTRODUCTION

One of the priority directions of motion rehabilitation process optimization and analysis is the simultaneous application of different physical therapeutic methods. The regular training using therapeutic devices promotes stimulation and improvement of the muscular tonus. Intensive training can improve or recover motor functions of people with lower extremities traumas.

Today on the medical equipment market the weight-supported systems have been established and extensively used in restorative therapy. Weight-supported systems with a vertical displacement of the force application point of gravity make a physiological load-induced gait training possible. Specially made dynamic overhead rail systems provide to uniformly unload the mass of a patient's body, thereby assisting the arrangement of conditions for an optimal physiological walking process and sensory stimulation. Body weight support level can be adapted to needs of every patient. The aforementioned machines apply two different approaches to gait rehabilitation [1]: the exoskeleton type systems, which are used in combination with a treadmill, and systems, which apply the principle of movable footplates.

The primary goal of body-weight-supported treadmill training (BWSTT) [2] has been to improve the temporal and spatial characteristics of unsupported overground walking. The LiteGait System [3] and AutoAmbulator [1] are gait training devices that simultaneously control weight bearing, posture, and balance over a treadmill or over ground. The Biodex Unweighting System [4] enables partial weight-bearing therapy and works like a simple patient lift device. It incorporates a dynamic suspension system that accommodates the vertical displacement of the force application point of gravity that occurs during normal gait. The above systems do not have a function of automated patient's weight unload and harness' position control. The function of weight's value regulation facilitates training for children and lightweight patients and guarantees an optimal training framework. Among such systems are the products below. The Lokomat system (Lokomat Basic) [2, 5] consists of a robotic gait orthosis Lokomat and a body weight support system Lokobasis with patient unloading possibilities and utilizes high quality semiconductor controlled motor drives, which are integrated in the gait orthosis at each hip and knee joint. All aforementioned systems are used in combination with a treadmill. Young summarized [6], that intensive exercises, especially when using weight-supported ambulation training on treadmills, can remarkably restore locomotor performance of people who have been long paralyzed due to spinal cord injury or stroke.

The electro-mechanical devises Gait Trainer GT I and HapticWalker [1] enable subjects to practice a gait-like movement with minimal assistance, where each of the patient's feet is positioned on a separate footplate whose movements are controlled by a planetary gear system.

Ample quantity of scientific investigations are aimed at an analysis of body weight support influence on human gait by using techniques for recording and stimulation of the electrical muscles activity [7, 8, etc.]. Our approach consists in the consolidation of a body-weight-supported system with plantar pressure registration during the training.

At the present time the foot pressure analysis is extensively used in the dynamic and kinematic evaluation of human's gait [9, 10, 11]. This method of testing makes possible the analysis of plantar pressure distribution under different areas of feet and provides information about the foot structure and its function. Therefore, foot's deformation and malfunction can easily be detected during the pressure data analysis.

2. MATERIAL AND APPROACH

During development of our body-weight-supported equipment, we had taken into account several approaches [12], which were determined through prior clinical experience, consultation of anthropometric tables, and application of engineering principles.

The unloading system provides relief to decrease the amount of weight the patient must uphold. The unloading system must be able to support at least 40 percent of the subject's body weight during a training session. However, for safety reasons, the body weight support must also prevent patient injury due to falls. The system must also allow sufficient vertical movement of the subject's center of gravity to permit normal gait, but limited to avoid the patient to lose posture.

In order to increase the safety of the therapy, the system must provide 100 percent patient's weight as the support of the fall prevention system. Using a limit of 115 kg for the heaviest subject, the system must be able to unload 45 kg for gait training and provide up to 115 kg of support to prevent falls.

The unloading system must also have controls that are easily accessible and support levels that allow for easy adjustments to the amount of body weight support as the subject improves or fatigues during a training session.

It is also important that the unloading system supports the harness and the patient by two support-points, separated by approximately shoulder width, to allow a natural weight shift in comparison to a one-point suspension permits. A single point support leads to excessive twisting movements and instability of patients with diminished voluntary postural control.

Two types of unloading systems exist [12]. The first is a counterweight system, which is relatively simple and provides a constant amount of body weight support over a large range of vertical displacements.

The other option is a spring-based system, which can be further subdivided by the type of spring used. The systems are categorized based on function; therefore, this group is not only limited to simple springs, per se, but also includes pneumatic, elastic, and other systems that exhibit similar behavior.

Separately should be noted motorized systems of load control, which allow automated control of load value and at which we reckoned our product.

The suggested equipment has been developed on the base of a MintDrive*II*® [13] versatile intelligent drive with an integrated motion controller. The MintDrive*II*® combines a powerful fully featured motion controller and brushless servo control in a compact package. This provides a flexible and powerful motion control solution for single axis rotary and linear positioning systems.

The components which have been used for design and development of the basic version of our device are depicted on figure 1. Standard features include: the motor that is connected to the MintDrive*II*®, a motor power cable, a resolver or encoder feedback cable and a regeneration resistor for dynamic brake.

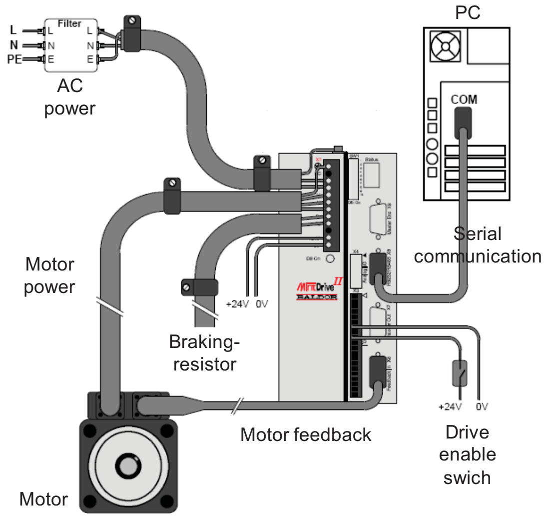


Figure 1. Standard MintDriveII® connection scheme

Appropriate software has been developed using the structured multitasking BASIC-like programming language Mint®.

For in-shoe pressure distribution measurement a Tekscan F-Scan VersaTek® system [9, 14] is used. The hardware part consists of a computer, sensors, cuffs, a hub and a power supply. For connecting cuffs and the hub an Ethernet cable is used, which can be replaced for length adjustment. Computer and hub are connected using an USB cable (figure 2).

The in-sole sensor contains 960 sensor cells and is 0.2 mm thick. It is based on strain gauges so that the difference in the electrical resistance of the sensor material is measured. The sensor cells are organized as a matrix. Each row has up to 21 and each column up to 60 sensor cells. Pressure data can be measured with a maximum sampling frequency of 850 Hz for each sensor cell. For adjustment to different sizes of the patient's feet the sensors can be trimmed by using a pair of scissors. The four-sided area of each sensor cell is 2.5 mm^2, the standard in-sole maximum width is 106.7 mm and the maximum height is 304.8 mm. This equals the European shoe size 48. There are two sensor models with different pressure sensing ranges available. The standard sensors saturation pressure is 861.8 kPa and the sensitive sensors saturation pressure is 517.1 kPa. As operation range for all sensors a pressure range of 15:1 is recommended by the manufacturer. Regarding the sensitivity of the sensors this equals a measurement range from 34.5 kPa to 517.1 kPa. Resolution the measurement range is a 1.89 kPa.

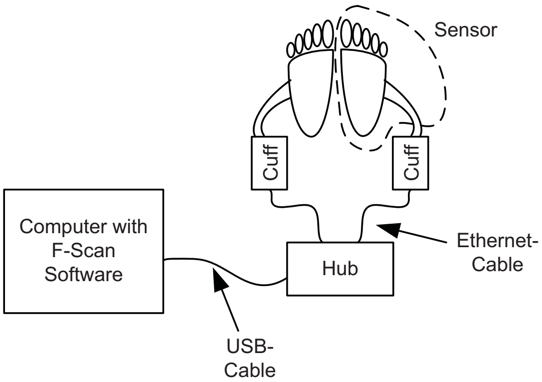


Figure 2. Hardware components of the in-sole sensor system

Among other plantar pressure distribution measurement systems the novel pedar® system [15] should be mentioned. This sensor system contains up to 99 sensor cells per foot depending on the sensor size. The F-Scan sensor system is chosen because of adjustability of the sensors to the patients shoe sizes. Compared to the Novel system, where individual sensors for each shoe sizes are needed, the Tekscan sensor can easily be trimmed by scissors to the appropriate size.

3. MEDICAL BALANCER SYSTEM

The presented BWS-device Medical Balancer includes a body weight support system, which allows automated patient crane-, balancer- and unloading functions. Technologically the device consists of a motorized rope winch, a supported at 4 points rope and a separate control system. The winch is driven by a motor with adapted planetary gear with integrated sensor. Supplementary a treadmill and mechanical steps are used. The general view of Medical Balancer system is depicted on figure 3.

The crane-function makes it possible to locate a comfortable position of the harness, lift patients out of the wheelchair and partially unloaded from their body weight. Maximal patient weight for this function is 150 kg. The balancer function allows an effective and precise patient's unloading during the therapy. The permanent dynamic body weight support optimizes physiological gait training and gives the opportunity of an unloading during reference phase of the walk. The automated processes of patient's lifting and weight unloading facilitate set-up and training.

The load relieving function provides a dynamic electronic control of the unloading weight. Today's body weight support systems do not provide a constant weight support due to inertia forces. The weight support is therefore a subject of fluctuations. During therapy emerging vertical movements by the patient are controlled and translated into an appropriate force. The actual force measured by an external sensor is fed back to the MintDrive*II*® in order to assure to stay below a predefined maximal weight bearing. Programmed functional dependences between system voltage, torque and load values have been evaluated experimentally. The developed algorithms of safety load's increase and reduction provide comfort and an efficient execution of therapeutic sessions.

Figure 3. General view of Medical Balancer system

The Medical Balancer software consists of a controller-version and a PC-version. The controller-version uses CAN (Controller Area Network) interface. In our device the CAN keypad is used to enter information and control moves (figure 4, a). The operation of the keypad is controlled by the Mint program running on the Mint*DriveII*®. The program uses the keypad buttons marked F1-F6 for navigation through a simple menu. The numeric buttons are used to enter values. For the patients comfort a mobile control console (figure 4, b), which gives an opportunity of independently using the crane- and balancer functionality, has been developed.

a) b)

Figure 4. Balancer-software UI service unit

For more flexible usage of the device the Balancer PC-version was created. Interrelation between both versions implements by means of the supplied Mint ActiveX component, which enables complete machine control from a PC-application and communicates with the controller firmware.

The control software realizes the functionality through the main window of the application and through the dialog elements according to the Microsoft Windows regulations. The subconscious comprehension and the switching speed between the tasks are the important criteria of GUI efficiency, therefore as master element the task-oriented ribbon-interface conception had been chosen. Crane and Measurement tabs of the Balancer PC-application are depicted on figure 5.

a) Crane-panels

b) Measurement-panels

Figure 5. Balancer-software GUI

The application offers a choice of slow or quick crane's movement parameters, and features an opportunity to change calibration parameters and input information about current treatment. The system includes the possibilities of load's value and measurement parameters selection. The controller feedback data is displayed on the PC-screen for the therapist's control and for load analysis and can be recorded for further analysis.

Within the harness selection several requirements [12] had to be considered. The harness should have support across the buttocks and around the thighs, as well as around the ribcage, while allowing free movement of the arms and legs. It is important for the harness not to interfere with normal gait. Also it must fit sufficiently to minimize upward slipping of the harness during unloading and it should be comfortable to wear. The most important consideration for the harness is that it promotes an upright stance.

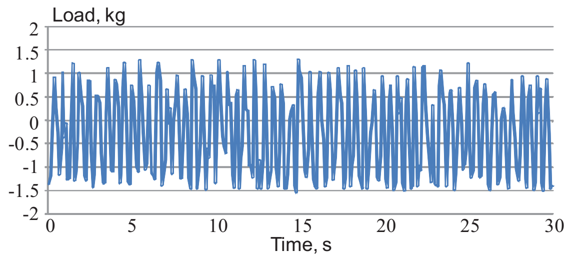
For the patients comfort the 695 SHBD MAGS Suspension Vest from Maine Anti Gravity Systems Company has been used [16].

Preliminary studies done with test subjects at the Institute of Materials Science(1), provide objective data to quantify the successes of the product. Thirty healthy subjects (26-50 years of age) were studied under different conditions of loading and unloading. Each measurement consisted of a recorded 30-seconds walk at a normal pace on the treadmill with 0, 45, 30 and 15 kg of body weight unloading. Statistical characteristics of the difference between given and received values of load in kg with significance level 0.05 [17] for all tests are presented in table 1.

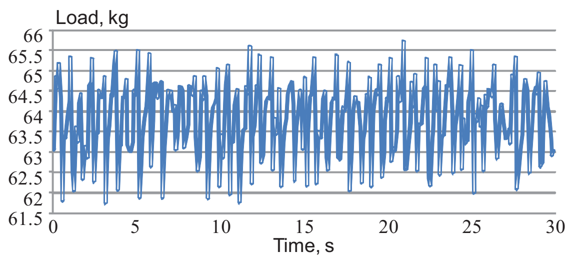
Table 1. The difference between given and received values of load

Unloading, kg	Average	Confidence interval	Sample variance
0	0.84	(0.39;1.3)	0.88
45	1.37	(0.77;1.98)	1.22
30	1.3	(0.68;1.92)	1.64
15	1.05	(0.52;1.59)	1.22

In figure 6 oscillations of the unload force during treadmill walking at normal gang velocity for a patient with 78.6 kg weight are depicted.



a) 0 kg loading



b) unloading to 15 kg

Figure 6. Example of load recording from a single subject during normal gait

The data analysis shows a load variation during walking of +/- 1.5 to 2 kg. For the standing patient this value is +/- 0.5 kg.

A similar Medical Balancer device for dogs' therapy had been developed in the Institute of Materials Science(1) in collaboration with the Clinic for Small Animals of the University of Veterinary Medicine Hannover [18].

4. EXPERIMENTAL SETUP

For the kinematic and dynamic characterization of the human walking description wide spread occurrence got the method of survey, which bases on the plantar pressure measurement for the functional diagnostics [9, 11]. In the present work the plantar pressure registration during walking has been realized with the diagnostic system F-Scan [9, 14]. The insoles (figure 7) are of universal size. Before start of measurement it is necessary to cut the sensors insole to the shape of a human's foot and shoe.

Figure 7. A foot sensors insole

Before starting the recording process a calibration step for every patient should be implemented. After pressure data recording the pressure distribution data can be displayed as false colour footprints. Measurements have been performed with a frequency of 100 footprint/s.

The FastScan Clinical software (Version 6.3.1) is running on an Windows XP PC equipped with a Intel Core 2 Duo CPU @ 2,53 GHz and 3 GB RAM. The software manages the measurement data for each patients measurement trials. Before starting the measurement a calibration procedure has to be passed. The calibration has realised by Tekscan Software. In recent experiments the step calibration was used. During the calibration the patient has to stand on one foot at time. The output of the sensor cells is then converted to the corresponding body weight. To avoid sensor drift due to thermal influences the sensor are put into the shoes two minutes before starting the calibration and measurement process. The software also allows adjustment of sampling rate, measurement period and event based triggering of the measurement process. The standard measurement procedure for every patient consists from the following steps:

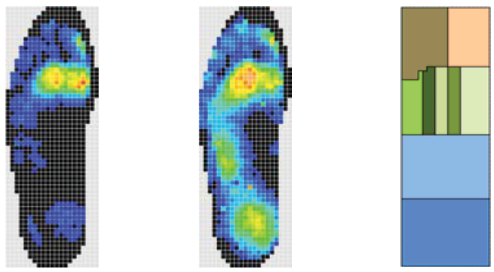
1. implement the calibration in balancer-software;
2. dress the patient in the harness;
3. actual patient weight measure;
4. fix a value of load;
5. wait till the load value comes to the necessary value;
6. implement the calibration in F-scan software;
7. run the treadmill;
8. wait about 30 sec for a gait‘s stabilization;
9. start the data saving during training or therapy time;
10. stop the treadmill;
11. free the patient.

Follow-up data processing and data analysis have been realized as separate tasks.

5. RECORDING WALKING CYCLES AND INITIAL RESULTS ANALYSIS

In several previous studies about foot-anatomy and analysis of foot's motion during the walking, the foot has been divided into several parts, corresponding to foot anatomy. Thus in [9, 19] the results of gait process researches with foot-partitioning on 3 areas: hindfoot, midfoot and forefoot, or accordingly on 6 areas, have been shown. In the second case every area has been divided on the side part and central part. In [10] the method of analysis, which bases on the 10 areas foot-partitioning: hindfoot, midfoot, 5 areas of the metatarsal bones, area of first, area of second, area of third-fifth fingers, had been proposed.

An example of a footprint with the superimposed mask according to foot-partition on 10 anatomical areas of load is presented in figure 8. The visualized data of a captured frame is shown in a). For further analysis a detection of step phases is needed. By detecting the beginning and end of a step the maximum pressure picture shown in b) can be generated by visualizing the maximum load of each sensor cell occurred during a step. The mask for partitioning of the foot is shown in c). It is described within an ASCII file to achieve easy readability for the users and computer systems to be able to automate the data conversion and analysis process.



a) b) c)

Figure 8. Example of a footprint and a mask

A research of unloading influences on humans walking through the plantar pressure data analysis goes beyond the scope of present work. For further analysis and statistics the data is converted into ASCII format. Sensor data is captured with an 8-bit resolution, so that the RAW data ASCII representation values range is from 0 to 255. The conversion and data analysis software is performed with a Java Framework developed at the Institute of Microelectronic Systems(2), which allows adaption and expansion for satisfying future requirements. For example, in combination with step, detection the maximum force within the areas for each step in a measurement trial can be calculated to compare variations in the pressure distribution during walking.

6. CONCLUSION AND FUTURE RESEARCH

Combining the Medical Balancer therapeutic device and plantar pressure storage system is a new approach in rehabilitation, which has been developed according to the modern principles of BWS-design and can be extensively used in restorative therapy.

Possible further enhancements include a redesign of the suspension vest to achieve an increased comfort for the patients and improvement of a design in order to get less weight and less system inertia. Future research topics are the real-time feedback of the pressure values measured by the in-sole system to the motor management. By this approach local pressure maxima above the therapeutically allowed maximum pressure can be avoided. A clinical trial should evaluate the benefits of this approach. Thereto a computer configuration and appropriate control software could be developed to estimate the necessary computing power for real-time measurement and unload force calculation. A later approach would be the development of a dedicated hardware platform for sensor data retrieval and calculation of the motor parameters to achieve a tiny energy efficient system capable of real-time operation.

For the patient‘s safety additional possibilities of accident prevention for small load values and automatic upward movement restriction by means of additional sensor have been planned.

Presented work has been done within the scope of collaboration between Institute of Materials Science, Leibniz Universität Hannover, Prof. Dr.-Ing. habil. Dr.-Ing. E.h. Dr. h.c. Fr.-W. Bach; Institute of Microelectronic Systems, Leibniz Universität Hannover, Prof. Dr.-Ing. habil. H. Blume; Clinic of Traumatic Surgery, Hannover Medical School, Univ.-Prof. Dr. med. C. Krettek and Clinic for Small Animals, University of Veterinary Medicine Hannover, Prof. Dr. med. vet. I. Nolte.

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