

ICT-enabled Medical Compression Stocking for Treatment of Leg Venous Insufficiency

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Abstract: This paper presents a novel approach to the treatment of leg venous insufficiency. This approach consists of an ICT-enabled medical compression stocking that aims at mitigating the requirement for daily assistance and increasing the patient's self-sufficiency. More specifically, this paper presents the wearable subsystem of this solution. In addition this paper discusses the different prototypes that have been produced to demonstrate that this new approach is technically feasible.

1 INTRODUCTION

Leg venous insufficiency is a serious medical condition with severe impact on the mobility and self-sufficiency of patients, chiefly elderly people. The most practical and efficient non-invasive treatment to counteract and prevent leg venous problems is compression therapy by means of bandages or Graded Compression Stockings (GCSs) (Parsch, 2003). GCSs, however, suffers from a number of drawbacks: Poor conformance to the individual patients' legs as their size and volume changes over time, degrading elasticity over time due to washing and stretching, and difficult to handle. The overall consequence of this is poor levels of therapeutic compliance and consequently less effective treatment. This, in turn, may lead to ineffective and prolonged treatment, and reduced quality of life. Moreover, as GCSs are often difficult to put on by patients by themselves, the patients often depend on a visit by home caretakers in the morning and evening to help put the GCSs on and take them off. Apart from being of obvious inconvenience for the patients, it is a demanding and time-consuming task for the caretakers, and of substantial expense to society.

In this paper we present the current state of the Stocking Assembly (SA) subsystem (Figure 2) of

the e-Stocking EU Ambient Assisted Living project. The aim of this project is to develop an intelligent, Information and Communication Technology (ICT)-enabled graded compression stocking solution that addresses the aforementioned shortcomings of existing GCSs. Key features of the novel stockings are easy application and operation, compliance with individual patient's clinical needs; and enhanced mobility and self-sufficiency.

Section 2 presents the state of the art in GCSs and ICT-enabled compression solutions. Sections 3 to 5 yield an overview of the entire e-Stocking architecture, pertaining requirements, and the design of the SA adopted to meet these requirements. Sections 6 to 7 yield a description of SA prototypes, obtained results, future work and conclusions.

2 STATE OF THE ART

Current approaches to treatment of leg venous insufficiency focus on the compression of the affected limb through different mechanisms. Existing compression therapy treatment is delivered by the application of either compression bandages, compression stockings or Intermittent Pneumatic Compression (IPC) (Hegarty

et al., 2010). IPC is targeted primarily for the treatment of venous leg ulcers and is delivered in hospitals and daycare centers (Hegarty et al., 2008). While related in nature to the problem under study the IPC approach does not address the patients' self-sufficiency and the characteristics of the treatment are different as IPCs provide dynamic compression while this study aims at static compression at lower pressure levels.

Application of a graded pressure distribution by means of GCS is a complex task and previous work describes how this is true, even for ideal scenarios (Liu et al., 2005). Additional studies have shown that muscle movement during walking results in a variation of up to 30 mmHg in exerted pressure (Godoy et al., 2010; Partsch et al., 2006), making the study of the pressure distribution over the leg even more challenging. However, from a medical point of view such variations are positive as they provide a measure of dynamic compression that massages the leg.

In order to measure the compression exerted at specific locations, resistive force sensors have been extensively evaluated (Khaburi et al., 2011a; Kawano et al., 2005) and to some extent pneumatic force sensors e.g. in the shape of the commercially available Microlab PicoPress pressure sensor instrument (Khaburi et al., 2011b). Finally, monitoring the swelling process of the leg as the treatment progresses has also been previously addressed using bioimpedance techniques (Hegarty et al., 2008) and strain gauges (Lebosse et al., 2011).

Even though extensive work has been conducted on different aspects of the treatment of leg venous insufficiency such as sensing technologies, sensor placement and analysis of existing approaches, to our knowledge an electronic wearable device that delivers quality compression treatment and enhances the patient's self-sufficiency has not yet been developed.

3 SYSTEM ARCHITECTURE

The e-Stockings system consists of several physically separated subsystems shown on Figure 1.

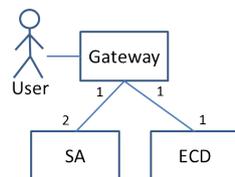


Figure 1: e-Stockings System Architecture.

The SA provides the compression to the patient's leg. Through the use of several air chambers the com-

pression applied to the patient's leg can be graded from ankle level to just below the knee. The compression delivered to the leg is continuously regulated through measurement of the air pressure in the air chambers or the on-skin pressure. The compression applied is calibrated to each individual patient by means of the E-stockings Calibration Device (ECD).

The ECD provides calibration data to the SA control unit and interfaces pressure sensors which can be applied with the SA. The ECD is used to obtain on-skin pressure values against which the SA can calibrate its target pressure values.

The Gateway consists of a smartphone device which runs a gateway application. This provides bridging services when the SA and ECD should be connected as well as the graphical user interface for use in the calibration process. The Gateway connects wirelessly to the SA and ECD, respectively, and forwards sensor data requests and responses to the counterpart. In the future, the Gateway is envisioned to provide a means of remotely configuring and obtaining system and medical diagnostics data from the SA.

4 SYSTEM REQUIREMENTS

The requirements for the system as a whole, to which the SA must adhere, are specified in detail in the pertaining SysML-based Systems Requirement Specification, in which functional requirements are specified using a set of use cases. The most important requirements for the SA are informally listed below. The e-Stocking shall...

- R1 promote self-sufficiency; the user shall be able to apply and remove the stocking without assistance.
- R2 apply the correct compression profile, typically with the highest compression in the foot section and decreasing in compression towards the knee.
- R3 apply the correct compression throughout the usage scope of the stocking, even in the face of changing leg size.
- R4 be user-friendly in its operation.
- R5 be battery powered and operable for 14 hours without charging.
- R6 be breathable and washable.
- R7 be as lightweight and noiseless as possible.
- R8 have a compression mechanism and control box which is easily attached and detached.
- R9 be configurable, enabling changes in compression configurations.

R10 have an aesthetically pleasing design.

R11 be certifiable as a medical device.

As the e-Stocking will compete with normal GCSs in the market, which are very thin with a look and feel as normal knitted stocking, and as the requirements are contradictory (e.g. lightweight, but battery-powered, breathable but airtight), these requirements give rise to substantial challenges.

5 SA DESIGN

The SA consists of four main parts as shown on Figure 2: an inner stocking (item 1), the compression stocking itself (item 2), an actuator board (item 3), and an Electronic Control Unit (ECU) (item 4). Each of these are described in the following subsections.

5.1 Inner Stocking

The inner stocking is a commercial, knitted stocking, which has an antibacterial property (Ag). The purpose of this stocking is to provide a smooth, comfortable surface to the skin. Furthermore, as this is the part of the stocking assembly which is in immediate contact with the patient's skin, it alleviates the stocking itself from the majority of washing required to maintain proper hygiene.



Figure 2: Stocking Assembly prototype 3.

5.2 Stocking

The stocking, as shown on Figure 2 item 2, covers the lower leg of the patient from just behind the toes to

immediately under the knee. A nonseparable zipper, extending the full length of the front of the stocking save for the last centimeter on the foot, provides a closing mechanism which allows the stocking to be applied and removed with relative ease, much like a softer version of a knee-long boot, while ensuring a snug fit. The top of the stocking consists of a soft, elastic band which prevents the stocking from sagging when it is zipped but not yet compressed. The stocking has 3 individual compression sections mounted laterally to cover the entire length of the stocking. Each compression section consists of two air chambers mounted at same height on the adaxial and abaxial sides of the leg, respectively. The air chambers are sewn to an elastic, permeable garment on the anterior and posterior sides of the leg to form the integral stocking. Each air chamber consists of two layers of airtight material which are high-frequency welded at the edges to achieve air tightness. A special air channel is welded from the foot section along the front of the middle compression section to allow a shorter tube to connect the actuator board and the foot section. The two layers of which each air chambers consists differ in rigidity, the outer layer being more rigid than the inner one, ensuring that expansion of the air chamber is primarily directed towards the patient's leg which increases the compression applied to the leg per unit volume of air in the compression section.

By controlling the compression of each compression section individually, the requirement for graded compression can be accommodated. The expandable compression sections provide the stocking with a certain dynamic range which is foreseen to alleviate the need for individual tailoring of the stockings. Instead, this may allow for the production of only a limited number of different shapes and sizes, which will simplify sizing, ordering and distributing of the stockings.

5.3 Electronic Control Unit

Compression is managed by an Electronic Control Unit (ECU). The ECU controls sensors, actuators, user input and other external interfaces by means of a software application running atop a FreeRTOS (RT Engineers Ltd., 2013) Operating System (OS).

The nature of the experimental work conducted in this project requires frequent changes in sensors and actuators interfaced by the ECU. In order to ease this process and shorten development time and cost we use the Programmable System-on-Chip Cypress PSoC5 as hardware platform. This platform implements an ARM Cortex-M3-based processor which provides sufficient processing power to run the appli-

cation and OS, apart from a number of programmable hardware blocks which provides the necessary flexibility, e.g. for conditioning sensors and actuators signals. Using custom hardware blocks implemented in the PSoC5 allows a small form-factor to be maintained, yet preserves an open interface for experimenting with different sensors and actuators. Furthermore, the ECU features a dedicated Bluetooth module to connect to remote devices, a 3-axis accelerometer for motion detection and power for the complete Stocking Assembly.

C++ was selected as implementation language. The use of an object-oriented (OO) language promises to minimize the gap between the employed OO design process and the implementation. Furthermore, C++ paves the way for flexible and interchangeable implementations, a desirable feature in light of the experimental nature of the prototyping and subsequent frequent alterations and additions to source code, e.g. when testing a new sensor or actuator, or a new compression strategy. Finally, the use of C++ allows source code to be tested early, often and systematically as an integrated quality-enhancing activity throughout software development.

While not strictly necessary, the inclusion of an OS was desired. It was envisioned that the ECU application would benefit from running a number of concurrent threads, and the task abstraction, timing and synchronization facilities, etc. provided by an OS would be of substantial value. A number of OS's were investigated and FreeRTOS subsequently chosen due to its flexibility, customizability, widespread use and small footprint. An abstraction layer was put atop FreeRTOS to allow the application to interface and abstract away the specific OS, and thus facilitate a change of OS if so desired later, e.g. to SafeRTOS (WHIS, 2013) as required in a certification process.

5.4 Sensors and Actuators Board

The sensors and actuators board, mounted on the front of the stocking as shown on Figure 2 item 3, is equipped with four miniature solenoid valves, one air pump and an electronic manometer, mounted on a prototyping PCB and placed in a plexiglas housing. The actuators and manometer are connected inside this housing using short pieces of tubing. Three short tubes protrude from each side of the actuator board and are inserted into the flanges of the stocking compression sections prior to compression. This allows the ECU to measure pressure in, and control inflation or deflation of the individual compression sections.

6 PROTOTYPES AND RESULTS

This section presents three preliminary system prototypes and the results that have been achieved so far.

6.1 Prototype 1: Resistive Sensor Solution

In Prototype 1 resistive force sensors were used to measure the on-skin pressure. In preparation for this, a number of tests were conducted to screen for suitable sensors. This was done using a cardboard tube of est. 10 cm diameter upon which the sensor was mounted. On top of this, the sensor pad of a PicoPress compression measurement system was positioned for reference readings. To apply pressure to the sensors, the cuff of a sphygmomanometer was wrapped around the cardboard tube, covering the sensors.

It was evident from these experiments that a suitable resistive force sensor should have certain properties, most notably a large sensing area to mitigate edge effects. It was also evident that, regardless of the sensor used, pressure measurements below 10-15 mmHg were not consistent and could not be trusted.

As a result of the screening process, the InterLink Electronics FSR 406 Square Force Sensing Resistor (Interlink Electronics, 2013) was selected for use in the prototype.

For the experiments on the prototype, three FSR 406 sensors were used to measure on-skin pressure. One sensor was positioned on the back of the leg and on the calf, respectively, corresponding to positions B1 and C recommended in (Partsch et al., 2006), and one sensor was positioned above the tuberosity of the third metatarsal bone on the foot. Each pressure sensor was connected to the ECU by discrete wires. A number of compression-regulation-decompression cycles were executed: The ECU controlled compression build-up until the specified compression level was reached, at which point the ECU commenced periodic regulation of the compression level, supplementing compression as made necessary by any air leakage from the sections. When commanded to do so, the ECU controlled decompression of the stocking until the compression reached a level at which the SA was considered deflated.

A number of results were drawn from these experiments. First, it was evident that the exact positioning of the pressure sensors was crucial to the repeatability of the experiments; placing the sensors even 1 cm off caused intolerable deviations in the measured compression. Second, the airtightness of the compression sections was insufficient.

The requirement for very exact positioning of the

resistive force sensors was considered an unacceptable task to put on the patients which were to apply the stocking on a daily basis. To alleviate this, it was considered to permanently attach the sensors to the inside of the stocking. This would require the sensors to be washable, however, which they are not by default. Thus, they would have to be coated in watertight material. Experiments using coated sensors showed that the coating caused its own set of problems, as it clogged the small breathing hole in the sensor necessary for air to escape from the sensor when it is compressed.

It was also clear that the airtightness of the compression sections was insufficient, as the ECU had to supplement the compression by running the pump and valves every 5-10 seconds. This caused an audible periodic noise disturbance and significantly higher power consumption over time, both of which were unacceptable.

Based on these results it was decided to discard resistive sensors altogether, and create and test a new prototype which would be more airtight, and which would use an electronic manometer to measure the pressure in the compression sections and use this to determine the compression on the patient's leg.

6.2 Prototype 2: Manometer Solution

Prototype 2 was constructed to be more airtight and using a Smartec SPD002GAsil manometer (Smartec sensors, 2013) to gauge pressure in the air chambers. This would have the benefit that the sensor would not need to be permanently attached at skin level and could thus be removed along with other electronic and pneumatic devices prior to washing.

As experiments progressed it became evident that the air chambers were indeed more airtight due to improvements achieved in the high-frequency welding process, but not entirely so. It also became evident that the pressure measured in the compression sections did not correspond to the applied compression on the skin as measured on-skin by the PicoPress reference sensor. It was possible to derive a second order compression section-to-skin pressure transfer function, but such a transfer function proved susceptible to changes in the volume and shape of the test person's leg - changes which were expected as a consequence of the compression treatment itself. Considering the desire for not having to tailor the stockings to individual patients, and considering that even if tailored, any change in leg shape or volume, e.g. as result of compression therapy, would render a transfer function erroneous, the use of the manometer-and-transfer-functions combination was discarded.

6.3 Prototype 3: Hybrid Solution

Prototype 3 was constructed to leverage the experience gained from prior prototypes; to use on-skin calibration periodically, e.g. monthly, to obtain accurate reference results, and to use the corresponding ECU manometer values as target values on a day-to-day basis.

The ECD was introduced to provide a means of gauging the on-skin pressure through the use of three FSR 406 resistive force sensors, identical to the ones used in Prototype 1 and placed in the same positions. The stand-alone ECD was to be operated by skilled personnel which would mitigate the risk of false compression readings due to erroneous positioning of the sensors. The ECU would be commanded into a special "calibration" mode in which it would control the compression of the leg as hitherto, but take its compression readings from the ECD over a Bluetooth connection established by a Gateway device (Smartphone app). When the on-skin compression level as read by the ECD was in accordance with the target compression configured for the ECU, the ECU would stop compression of the leg, gauge the level of compression in the individual compression sections by means of its own electronic manometer and store these in non-volatile memory for future use when operating in its "normal" mode. Thus, using the ECD and ECU in conjunction, the stocking could be calibrated by the help of skilled personnel periodically (e.g. monthly) to accommodate changes in the shape and volume of the patient's leg, but be used with relative ease by the patients themselves, as there would be no need for accurate placement of sensors on a day-to-day basis.

Experiments were conducted using this strategy and, while the principle appeared sound, it again became evident that the spot measurements given by the resistive sensors were not sufficiently reliable. It was therefore decided that a number of flat stand-alone air chambers (dubbed "calibration pads") each the size of a compression sections, should be produced. For calibration, the calibration pads would be slightly inflated, connected to electronic manometers on the ECD and placed under the stocking before it was closed. When compression was initiated, the same pressure would be exerted on the calibration pads as on the skin. Thus, by measuring the pressure in the calibration pads, a measure for the on-skin pressure could be derived. While similar to the resistive sensors in application, the prominent advantage of the calibration pads is their larger area; pressure readings taken from a calibration pad corresponds to the mean compression exerted on the area covered by the pad

and thus mitigates the requirement for very exact positioning of the sensors.

7 FUTURE WORK AND CONCLUSIONS

Initial tests have been conducted using the calibration pads. The results indicate a correlation between compression measured with the pads and with a PicoPress reference, but further experiments must be conducted to fully understand and have confidence in the correlations, especially in terms of consistency over time.

Clinical testing is planned to take place during the final year of the project. This test shall primarily reveal if the stocking has the required clinical effect on the patient's legs. Before this testing phase can take place, however, certification by legal authorities in the country where the test is to be performed - in our case in Switzerland - must be obtained. Another similar task, end-user testing, is planned to be conducted in three different countries to investigate and accommodate for cultural differences and habits. The end-user testing shall primarily test the main requirements of enabling independent living and usability aspects. End-user tests also require certification to be obtained prior to the tests.

Based on the results of clinical and end-user tests, the prototype will be further developed and, at the end of the project period, result in a workable prototype which fulfils the stated set of requirements. At this time, the experiences obtained and the final prototype will form the foundation for further product development and maturing, in which manufacturing and production issues will be addressed and CE-marking obtained for the end product, paving the way to introduction into the market.

This paper has listed the main requirements of an ICT-controlled medical compression stocking, and described the design, implementation, and tools applied in the development of a stocking assembly to meet these requirements. Furthermore, it has described the technical challenges posed and how they were overcome.

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