

Pressure Offloading Device for Diabetic Footwear Based on Magnetorheological Fluids

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Abstract—Diabetes is a rapidly growing disease, with important complications that decrease the quality of life of patients. Diabetic Foot Ulceration is a major complication of diabetes and can lead to gangrene and amputation. It is related to high pressure developed on the plantar surface and can be prevented and treated with pressure offloading footwear. Current solutions are either mechanic insoles and shoes or smart devices that perform only plantar pressure measurements. This paper presents the design of a device that performs pressure offloading using magnetorheological fluids. The device consists of a magnetorheological valve that controls the offloading and a force sensor. An electronic board is used for force measurements and control of the valve. The experimental results validate the offloading capabilities of the device. Due to their size, multiple such devices, and the electronic board, can be integrated into diabetic footwear to achieve active offloading.

Index Terms—Magnetorheological valves, pressure offloading

I. INTRODUCTION

Diabetes is a metabolic condition characterized by high blood glucose levels. The number of people suffering from diabetes worldwide increases steadily, while it is predicted that the disease will affect 693 million adults by 2045 [1]. Diabetic patients develop several major complications leading to high morbidity and mortality rates, including peripheral neuropathy [2]. The latter is responsible for peripheral nerve dysfunction, causing sensorimotor abnormalities that affect the biomechanics of diabetic foot [3]. This results in different plantar pressure distributions compared to healthy persons. High load areas on the foot surface, in combination with the loss of pain sensation due to neuropathy, lead to Diabetic Foot Ulceration (DFU) [4]. DFUs deteriorate easily in diabetic patients, leading to gangrene and establishing diabetes as the leading cause of lower limb amputation [5].

Plantar pressure distribution in diabetic patients with neuropathy has been studied extensively [6], [7] due to its relationship to tissue breakdown and ulcer creation [8]. It has been observed that the regions the most affected by ulcers include the combined metatarsals, the hallux, and the heel, with higher plantar pressure appearing especially on the first region [9]. Thus, according to the aforementioned studies, plantar pressure offloading of risky areas seems an effective ulceration prevention and healing method.

Up to the present time, there exist two types of preventive and treating solutions. The first one includes purely mechanical setups, such as total contact casts, cast-walker shoes, and custom-made orthopedic shoes [10]–[12] that present high effectiveness in terms of ulcer healing. However, they exhibit the following disadvantages: they are cumbersome, resulting in low adherence of patients to the footwear, and very frequently, they only displace the high-pressure region on the plantar surface, leading to ulcer recurrence on different spots [13]. The second solution type includes electronic systems that perform active plantar pressure measurements. They have either been already commercialized or remain at the research level and exist in the form of insoles, shoes or socks [14], [15]. Yet, none of them provides active plantar pressure offloading after the measurement, but only notifications to the patients for potential ulceration risk.

Previous studies [16], [17] have investigated the possibility of using magnetorheological (MR) fluids in the valve operation mode to create modules that can offload plantar pressure. MR fluids are smart materials consisting of micron-sized iron particles in oil. The application of an external magnetic field leads to the formation of particle chains and to the increase of viscosity of the fluid. This principle is exploited in the aforementioned studies using MR valves.

This paper presents the design and experimental validation of a complete MR device for pressure offloading, together with its driving electronics. The device consists of a MR valve that controls the vertical fluid flow between two fluid chambers. The upper chamber is in the form of a metallic bellow, which can be compressed when the valve is open, allowing fluid flow and pressure offloading. On the contrary, when the valve is closed, the fluid flow is negligible and the device can sustain the applied plantar load. The functionality of the device is validated experimentally. An electronic system that can control multiple of such MR devices is suggested, too. Both the MR device and the electronic circuit are designed considering minimization of size. In this way, multiple such devices and the circuit will be able to be integrated into a future wearable insole. The latter will measure the plantar force and pressure on the whole foot surface, and it will offload the high-pressure regions by turning off the MR devices under these regions.

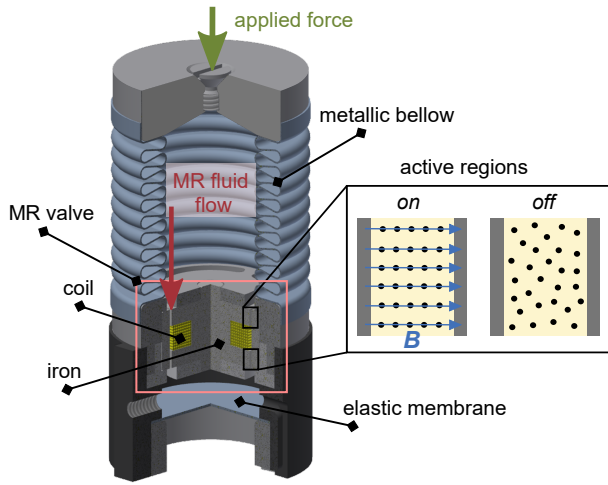


Fig. 1. Cutaway drawing of the MR device consisting of a MR valve, a metallic bellow, and an elastic membrane. The MR fluid particles in the active regions form chain-like structures in the existence of a magnetic field. In this way, the viscosity of the MR fluid increases and the valve closes.

II. MR DEVICE

Magnetorheological fluids are smart materials consisting of micron-sized iron particles dispersed in a carrier medium, such as oil. The application of an external magnetic field leads to the creation of chains of particles in parallel with the field lines (see Fig. 1). The formation of chains is linked with an increase in fluid viscosity. Thus, the MR fluid transits from the liquid to the semi-solid state. The transition is reversible, and when the external magnetic field is removed the particles rearrange randomly in the carrier medium, forming loose bonds with each other, and the fluid returns back to the liquid state.

The MR fluid principle is used in this paper for the control of MR valves. A MR valve is the fundamental element of the proposed device. It is inserted in the inner part of the device, as in Fig. 1, and is used for controlling the flow of the MR fluid. More specifically, the valve is cylindrical and consists of an inner ferromagnetic core. A coil is wound around the inner core, while a second ferromagnetic piece in the form of a cylindrical ring is placed around the inner core. A gap is formed between the inner and the outer piece through which the MR fluid can flow. The coil functions as an electromagnet. When a DC current flows in it, a magnetic field is created. The latter is perpendicular to the flow in the active regions of the valve (Fig. 1) and it is closing the valve. When it is removed the valve is open again. This leads to the conclusion that the valve can function in two states: the closed when there is current in the coil (the device is on), and the open when there is no current (the device is off).

The MR device also consists of a metallic bellow, as in Fig. 1, that can be compressed with an applied force, as well as of an elastic membrane at the bottom part. The metallic bellow and the space between the membrane and the valve are filled with MR fluid. When the valve is closed, there is ideally no flow, and, since the MR fluid is incompressible, the bellow cannot be compressed even when an external force is exerted

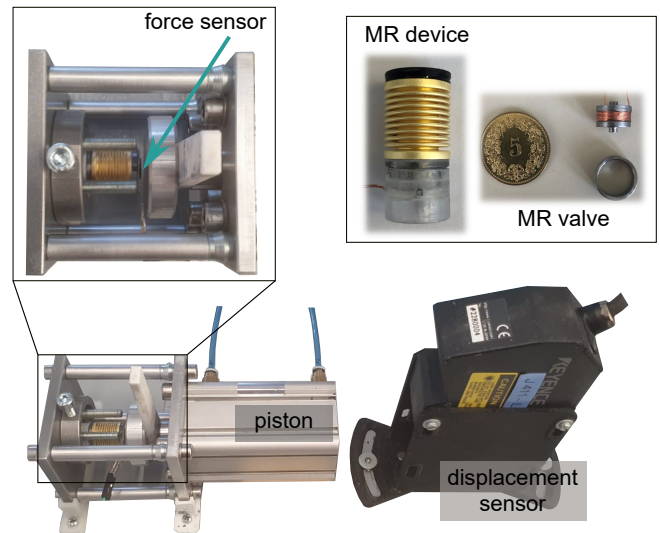


Fig. 2. The experimental setup includes a pneumatic piston applying force on the MR device and a displacement sensor that measures the piston displacement. A force sensor is placed on top of the bellow. The figure includes the prototypes of the MR device and valve.

on it. In case the valve is open, an external vertical force will cause the compression of the bellow and the fluid flow from the bellow to the bottom space. The elastic membrane will expand due to the increase in the fluid volume.

The above paragraph describes the two states, in which the MR device can function. The device can be controlled only by supplying or not the coil with a DC current. The addition of a force sensor on top of the metallic bellow is necessary to detect high applied forces. If the device is integrated into a shoe and the sensed force corresponds to a plantar pressure value higher than 350 kPa [18], then the current supply must stop and the valve must open. In this case, the bellow will be compressed leading to a regional offloading of the plantar pressure. In case the applied plantar force is not high enough, the valve can remain closed and the device can sustain the load, ideally without any compression of the bellow.

III. EXPERIMENTAL VALIDATION

This section presents the setup used for the experimental validation of the MR device, the device fabrication process, the electronic circuit used for reading the applied force and controlling the MR device, and the obtained experimental results.

A. Experimental Setup

In order to validate the functionality of the proposed MR device, force must be applied on the top of the module. Moreover, it must be applied vertically, in the same way the force is applied by the human foot. For this reason, the setup of Fig. 2 was used during the experimental process. It consists of a metallic support piece where the device is placed and immobilized, and of a pneumatic piston (SMC CDQ2A32TF-50DZ) to apply the force to the device. On top of the device,

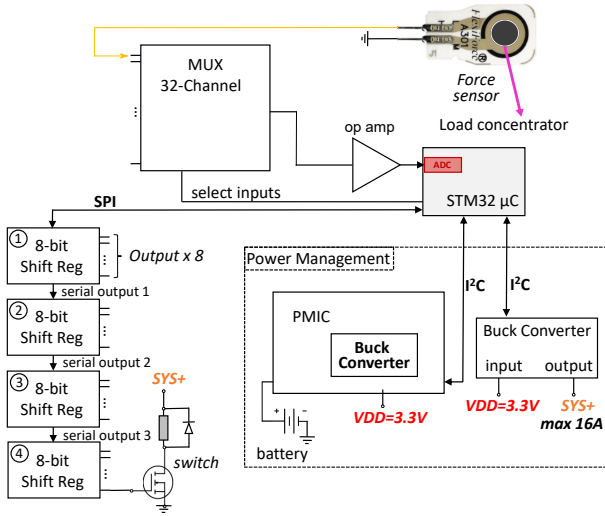


Fig. 3. The block diagram of the PCB for force measurements and control of the MR device.

a force sensor was placed. A laser displacement sensor (*LK-G150 with LK-G3001PV all-in-one-controller*) was used to measure the displacement of the pneumatic piston in each application of pressure. The obtained signals of force and displacement were acquired with an oscilloscope (*Teledyne LeCroy LT224*). Compressed air was provided directly to the pneumatic piston through tubes. The device was supplied with 0.77 A current.

B. MR Device Fabrication

In previous studies [19], the MR valve design was optimized to increase the sustained load and minimize its volume. The fabrication of the valve was based on this design. For the ferromagnetic parts of the valve, we used pure iron (*ARMCO Telar*). MR fluid *MRF132DG* by *Lord Corporation* was used to fill the device. The elastic membrane was fabricated using a latex sheet with 0.2 mm thickness, while the metallic bellow was fabricated by *Mera Bellows*. The holes needed for filling the device with MR fluid were sealed with screws. The height of the device is 30 mm and the volume is 4618 mm³.

C. Control Electronics

The electronics for controlling the functionality of the MR device consist of a custom-made board that can fit in an insole and a force sensor. The force measurements are performed with off-the-shelf force sensors with a range of 0-111 N (*Flexifoce A301, Tekscan*). The selection took place according to two criteria: the size of the sensor that must fit on top of the MR module and the force range which can reach up to 110 N on the diabetic foot surface [18]. Each sensor is placed on the top part of the metallic bellow. A load concentrator of an 8-mm diameter is placed on top of each sensor (Fig. 3). The sensors are calibrated following a 5-point calibration process, using a motorized pull tester that can also apply forces, in the desired range.

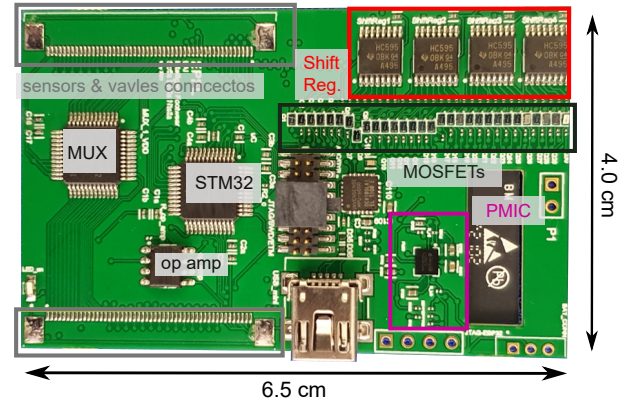


Fig. 4. Different blocks of the PCB: power management unit, valve switches and control shift registers, microcontroller, amplifier for force measurements, sensors and valves connectors. The buck converter is mounted at the other side of the PCB.

The proposed electronic board driving the system is shown in Fig. 3 and Fig. 4. The sensor has two connectors, connected to the PCB. The board includes a 32-Channel analog multiplexer (*ADG732BSUZ*) for future connection of multiple sensors and multiple devices. The multiplexer's output is connected to an amplifier. The analog output of the amplifier is connected to one analog channel of the low-power microcontroller *STM32L151CCT6* where the force readings are collected.

The micro-controller's goal is to measure the force, calculate the pressure and turn the valve on or off according to the pressure reading. Since the board is capable of controlling a maximum of 32 devices, four 8-bit serial-in-parallel-out shift registers (*SN74HC595PWR, Texas Instruments*) are used for simultaneous turning the devices on or off. In order to select the state of the valves simultaneously, we connect the serial output of each register to the serial input of the next one. Like that we can have a simultaneous output of a maximum of 32 channels. In every digital output we connect a valve switch implemented with a minimal footprint N-MOSFET transistor (*CSD17381F4*), as in Fig. 3 and Fig. 4. The footprint minimization is imperative considering that in the existing architecture each valve must be controlled independently, thus, one switch is needed for every valve.

A dedicated power management unit was designed and added to the PCB. This consists of the highly integrated, configurable, low quiescent current *PMIC DA9070* by *Dialog Semiconductors* that integrates a linear charger, several LDOs, a buck converter, analog battery monitor and can be configured through I²C communication. This can facilitate future battery integration and the power supply of the existing components. In parallel, a buck converter (*MAX77874, Maxim Integrated*) is used to power up the valves. This buck converter is a 16A output high-performance regulator aimed at powering up multicore CPUs and GPU Processors. It can also be programmed through I²C communication since the selected STM32 microcontroller is provided with two such communication channels.

The schematic and the layout of the PCB were designed

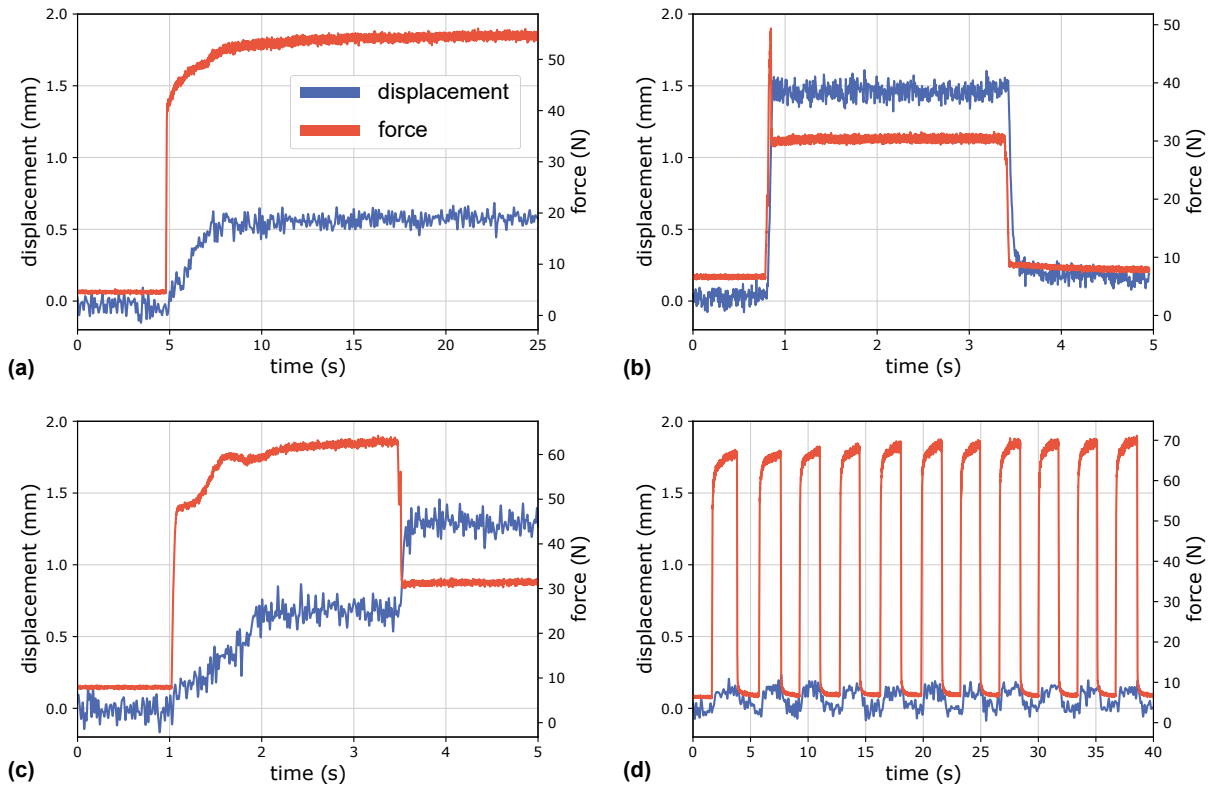


Fig. 5. Experimental validation of the MR device (a) with a closed valve, (b) with an open valve, (c) with a valve that is initially closed and then it opens, and (d) with a closed valve where the load is applied repetitively.

using Altium Designer. The PCB consists of 6 layers and was fabricated as an High Density Interconnector (HDI) board in order for a higher number of vias, thinner connection traces, and more components to be allowed on the board. In addition, components were soldered on both sides of the PCB. These facts facilitated the minimization of the board size. Large polygon pours were created on the valve supply line so that it can sustain high current supply of multiple MR devices. The PCB dimensions are 4 x 6.5 cm, a size small enough to fit in a wearable insole.

D. Experimental Results

The functionality of the MR device was tested using the setup of Fig. 2. Four different types of tests were performed. The experimental results are presented in Fig. 5 and depict the displacement of the piston and the force applied to the device over time. Firstly, the device was switched on with a current supply of 0.77 A. As shown in Fig. 5(a), the piston displacement reached a maximum 0.6 mm, and then it remained constant until the end of the experiment. This means that the valve was in the closed state. At the same time, the applied force reached 55 N, which corresponds to 357 kPa. Thus, the device can sustain at least 357 kPa. Higher values are not of interest in our case, since for values higher than 350 kPa the device must be switched off and the pressure must be offloaded. In Fig. 5(b) the current supply was removed and the device was turned off, having an open valve. As a result,

the displacement reached immediately 1.5 mm, which was the limit of the piston stroke. It is evident that since the valve was open, the fluid did not face any resistance and freely flowed from the metallic bellow part to the bottom part of the device through the valve. In parallel, the measured force reached only 30 N, almost half of the force measured when the valve was closed. At $t=3.5$ s the piston movement was disabled and it moved backwards, towards its origin.

Fig. 5(c) depicts the case where the valve was initially closed and opened at $t=3.5$ s. A combination of the behaviors of the MR device in Fig. 5(a) and (b) is presented here. Initially the device was turned on and the valve was closed. The piston started moving at $t=1$ s, achieving only a small displacement of 0.6 mm and a force of 60 N. On the contrary, at $t=3.5$ s, when the device was switched off, the displacement increased abruptly close to 1.5 mm and the force decreased to 30 N. This result shows the transition of the device from one state to the other. Finally, in Fig. 5(d) the valve was closed and the piston was repetitively moving towards the module. The displacement was 0.2 mm in every repetition, which proves that the valve was closed and the behavior was repetitive. The measured force reached 70 N. The piston displacement was smaller and measured force was higher compared to the closed state of the device in Fig. 5(a). This is justified by the initial position of the piston. The piston was activated towards the device and then deactivated without retraction. After that, the

measurement began. This means that without retracting the piston, the metallic bellow was not allowed to return back to its original state at 0.0 mm of piston displacement. As a consequence, the piston displacement reached only 0.2 mm instead of 0.5 mm and encountered higher vertical resistance by the device. The latter led to an increase in measured force.

IV. CONCLUSIONS

DFUs is a major health issue, caused by high plantar pressure and peripheral neuropathy. Current state-of-the-art solutions are bulky, passive mechanical systems. This paper presents the design of a device based on magnetorheological fluids that can be used for plantar pressure offloading, reducing the size of the current treatment and prevention solutions and allowing active control of offloading. The device can work in two states for both sustaining and offloading plantar pressure. An electronic system for driving the device is presented in this work, too. The circuit is in a size that can fit in a wearable insole and it controls the force measurements and the device's functionality. The experimental results demonstrate the capability of the MR device to sustain the plantar load when supplied with 0.77 A and to offload the load when the current supply stops. Future steps will include the fabrication of multiple identical MR devices and their integration into a shoe insole. This will allow the creation of a wearable insole that will offload dynamically high plantar pressure regions and prevent DFUs, without further deteriorating the patients' quality of life.

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