An optical fibre tape sensor for monitoring sub-bandage pressures: Progress towards an "ideal sensor"

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Key words

Compression therapy, graduated compression, lymphoedema, sub-bandage pressure monitoring, venous insufficiency

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Declaration of interest: None.

Abstract

A fibre optic sensing array in the form of a thin, flexible tape is described and tested for the monitoring of sub-bandage pressures. The sensing array consists of 36 discrete sensing elements spaced at 1-cm intervals along the tape and provides real-time feedback of applied pressures. It has been used to assist an experienced wound care nurse to achieve the targeted pressure gradient when applying a multilayer compression product. Results of working pressures achieved during simple exercises and when walking on a treadmill are also presented.

In 2006 an international committee of leading experts in the field of compression therapy developed a Consensus Statement on the measurement of lower leg compression *in vivo* (Partsch et al, 2006). In this Statement the preferred characteristics of an "ideal sensor" for monitoring sub-bandage pressures were presented to set a standard for device manufacturers to aspire to for future device development. The Consensus Statement further recommends a series of standardised protocols and measurements aimed at unifying compression therapies between centres.

The ideal characteristics listed in the Consensus Statement included physical parameters such as size, flexibility, durability and reliability to ensure ease of use and comfort for the patient, and also performance criteria such as overload tolerance (resistance to excessive pressures), simplicity, low hysteresis and creep, linearity, resolution and precision, and sufficient resolution and frequency response to allow real-time monitoring, preferably including locomotive studies. A further cited parameter was the ability to have sensors of variable sizes to cover different aspects of the limb being monitored. The final parameter cited by Partsch et al was cost, which needs to be commensurate with the application. All of these characteristics are challenging but important to achieve if sub-bandage monitoring is to become accepted within the compression therapy community. As designers of instrumentation for a variety of industries, we would add that convenience, ease of use and an easy-to-understand display are critical for the success of a new device.

In this article we first briefly describe the principles behind fibre optic sensing and how they have been applied to sub-bandage monitoring, we then describe the methods applied to record pressures during the application of various compression bandage products and the results from recent tests in which the subject wearing the bandage performed a variety of simple movements. We conclude with a discussion of how closely this new sensor approaches the ideals set out in the Consensus Statement (Partsch et al, 2006).

Methods

Optical fibre sensing

Optical fibres are increasingly being used across many industry sectors because of their ability to gather and transmit very large amounts of information over long distances, and their immunity to electromagnetic interference (Yin, 2008; Albert, 2011). They are made from ultra-pure glass and are typically 125 μm in diameter with an outer protective layer that increases the diameter to 200–250 μm. Optical fibres are extremely flexible and have high tensile strength, making them interesting candidates for many forms of *in vivo* measurement. At CSIRO, we have been pioneering the use of distributed fibre optic sensors for monitoring muscular activity and peristalsis in the human gastrointestinal tract (Arkwright et al, 2009a; 2009b). These devices are now being used to provide detailed information about the pressures and contractile forces in the human colon and small bowel, and are currently being prepared for regulatory approval in Europe and the US (Dinning et al, 2012). The devices are fabricated from arrays of fibre Bragg gratings (FBGs) (Chojetzki et al, 2005), which, in their simplest form, can be thought of as wavelength selective optical strain gauges.* These FBG strain gauges are typically 3 mm long and can be bonded to a variety of custom-designed transducer housings to allow measurement of parameters such as temperature, force, pressure, and of course, strain. The inherent wavelength selectivity of FBGs allows large numbers of these optical strain gauges to be contained along a single length of fibre, each of which can be uniquely identified and interrogated by a different optical wavelength or colour. This makes it possible to form distributed sensing arrays of up to ~40 closely spaced transducers (≥10 mm between sensors) along a single optical fibre.

For monitoring interface pressures underneath compression therapy products, we have modified our gastrointestinal catheters to form a flattened sensing array that is sandwiched between two lengths of flexible strapping tape (*Figure 1*). As a result of the width and low profile (~25 mm width × 1.5 mm depth) of the tape, the sensor array cannot be felt beneath a typical compression product and does not present any risk of creating pressure "hot spots" that could exacerbate localised impairment of venous flow.

Sub-bandage pressure monitoring

The need for accurate feedback of pressures applied under compression bandages and garments has been discussed widely in the literature, and the discussions range two predominant areas. First, whether the correct pressures are being achieved in practice and second, the amount of pressure required at given anatomical locations such as ankle, calf, or knee, to achieve a desired therapeutic outcome. Both issues are intimately linked to the ability to accurately record applied pressures along the full length of the region undergoing therapy, hence the need to develop a distributed sensor array that can span the full region of interest.

*The wavelength of light is synonymous with the colour of light. In this application, the wavelengths used are all infrared and so are not in the visible region of the spectrum; however, the concept is still valid. The FBG strain gauges are each designed to reflect a different wavelength or "colour" of light and can then be independently monitored by observing the subtle changes in these different colours.

The prevalent belief is that the compression bandages should exert a graduated pressure profile decreasing linearly from ~40 mmHg at the ankle to ~20 mmHg below the knee (Moore, 2002); however, more recent studies indicate that maximal pressures applied to the mid-calf may provide more beneficial therapeutic outcomes (Mosti and Partsch, 2012). Regardless of the variations in opinion on the correct therapeutic pressures, or perhaps because of these variations, the ability to monitor and track the pressures in both resting and active states is clearly important for the optimisation of any compression therapy.

The fibre optic sensing array recently developed at CSIRO shows promise for achieving the ideal characteristics defined in the Consensus paper by Partsch et al (2006) and may be of particular use for analysing data during exercise. The following section describes the use of the sensor for the monitoring of resting and working pressures achieved under compression products.

Results

Graduated pressure bandaging trials

To demonstrate the benefits of using feedback from a distributed sensing array spanning the full length of the limb, a four-layer compression bandaging system (PROFORE multi-layer compression system; Smith & Nephew) was applied to the leg of a healthy volunteer with the sensor array positioned on top of the first protective layer. The first layer of the bandaging system is intended to provide protection to the wound without supplying any significant compression, hence placing the sensor array on top of this layer allowed the subsequent pressure inducing layers to be monitored. The sensor array was placed along the fleshy side of the shin (tibialis anterior), extending from the ankle to just below the knee, taking care to avoid any bony prominences or tendons that could influence the measured pressure. Of the 36 available sensors, 33 were sufficient to cover the region of interest, hence results given below are restricted to these active sensor locations. The compression layers were then applied to the limb by one of the authors (Vicki Patton), a consultant nurse specialist with over 10 years experience in chronic wound care nursing, but who was not familiar with the specific bandaging product used for the trial.

In the first instance, the practitioner was not allowed to view the measured pressure profile during application of the compression bandage. She was then asked to conduct a further three applications on the same subject and results were provided in the form of a histogram displaying pressures recorded by the sensor array.

The first blinded run achieved a resting sub-bandage pressure profile that had maxima in both proximal and distal sections of the limb and did not provide the desired pressure gradient. The result of this first attempt is shown in *Figure 2* (grey bars). During application, a rolling average was applied to the data, providing virtual sensing regions of approximately 7 cm to avoid the effects of local high pressure spots and also to make the display easier to interpret by the bandager. A seven-point rolling average is generated for each

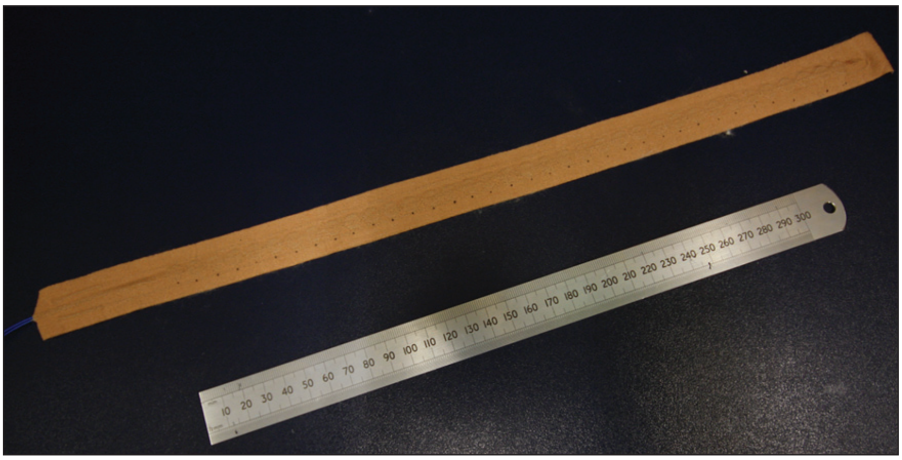


Figure 1. Photograph of the fibre optic sensing array. The black dots indicate the locations of the sensing regions.

sensor location by adding the three nearest neighbour measurements on either side of the sensor and the sensor measurement itself, and then dividing the total by seven. A further three bandage applications were then carried out using feedback to guide the applied pressure; on the final run a pressure gradient of approximately 45 mmHg–20 mmHg was achieved, demonstrating a considerable improvement over the first blinded run. The red bars in *Figure 2* indicate the pressure gradient achieved on the final run.

Working pressure trials

In a separate series of measurements using a three-layer compression bandage (SurePress High Compression Bandage), the sensor array was again positioned on top of the primary protective layer and used to monitor the working pressures as the volunteer performed a series of simple exercises. *Figure 3* shows the averaged result measured from five consecutive sensors located at the medial gaiter area during the activities. The following features matching each physical activity were observed:

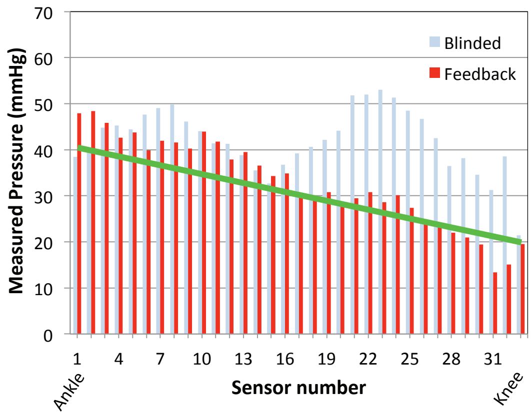
- Following application, the pressure increased to the targeted working pressure and was maintained while the subject was in the seated upright position.
- Repeated dorsiflexion caused a phasic variation in measured pressure.
- The static pressure increased to a new level when the patient stood up.
- Standing on tip-toe and performing knee bends further increased the measured pressure in a synchrony with the movements.
- Sitting down again reduced the measured value.
- Additional dorsiflexion produced a similar phasic response to that initially observed.

These features match well with the previously reported data measured with localized single point sensors (Partsch et al, 2006).

Ambulatory trials

In a final measurement, the sensor array was positioned between the first and second layers of a two-layer 3M™ COBAN™ product and the volunteer was asked to walk at a comfortable speed on a treadmill. The data from a 10-second section of this test are shown in *Figure 4*. The data are displayed as an intensity plot with overlayed line plots from discrete sensors near the ankle, gaiter, and calf. The intensity plot was generated by first removing the baseline pressures so that only the variations in pressure were displayed, then interpolating the measured pressures from the whole sensor array for each time interval (recorded at 10 measurements per second). The interpolated values formed a pseudo-continuous variation in pressure along the limb, which could then be displayed on a two-dimensional colour plot with time along the x-axis, sensor location along the y-axis and variations in colour indicating the changes in pressure. Displaying the data in this way clearly shows a retrograde trend in the sub-bandage pressure profiles running from ankle to knee as the foot is planted and then lifted during a stride. Data shown in *Figure 4* also indicate the ability of the sensor to record and display the time-varying sub-bandage pressures recorded along the full length of the limb.

Figure 2. Sub-bandage pressures measured after an initial blinded application, and after the third application using feedback from the fibre optic sensor array.



Discussion

The ability to measure and monitor sub-bandage pressures are clearly pre-requisites to any form of quantitative analysis of the application and subsequent effects of compression therapy. While a number of devices exist that can measure sub-bandage pressures at one or a few locations, we believe that our fibre optic approach is the first that can monitor the entire length of the limb simultaneously and provide feedback to the practitioner.

The sensor and the histogram representation of applied pressures has proved to be popular with both experienced and novice practitioners as a feedback mechanism to guide the application of a compression product. The addition of a user-defined visual guiding line to the display (shown in green in *Figure 2*) to indicate the desired pressure profiles allows the sensor to be easily configured to target different pressure profiles depending on the nature of the intended therapeutic outcome.

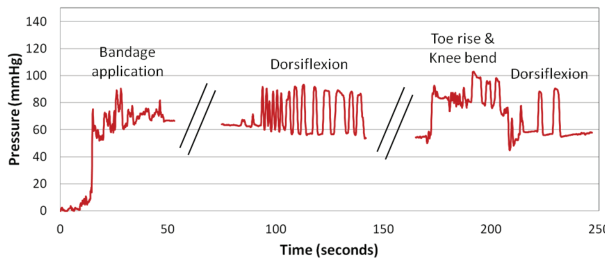


Figure 3. Working pressure measurement at the medial gaiter during simple movement by the volunteer. Timings of each movement are noted above the plot. The data was averaged from five consecutive sensor regions to simulate a 5 cm sensing region.

Comparison with the "ideal sensor"

In returning to our initial intent of fabricating a device that approaches the needs recommended by Partsch et al (2006), it is instructive to compare the results from the fibre optic sensor array with the characteristics defined above.

The tests carried out on the prototype fibre optic sensors and reported herein easily satisfy the requirements of size (of both discrete sensors and of averaged "virtual" sensors), flexibility, thin profile, continuous output and high sampling rates necessary for locomotion studies, and biologically significant pressure ranges. In addition, although not reported in this article, the fibre optic sensors have a high overload tolerance (>2000 mmHg equivalent pressures), electronic simplicity, low creep and hysteresis, inherently high sensitivities, and are insensitive to temperature fluctuations. The remaining physical parameters still require further elucidation, and as with all fibre optic devices, the issue of cost will be strongly dependant on volumes and on the market uptake of the technology, and will be further clarified as market interest is determined.

Conclusion

Compression bandaging has long been considered the main therapy for venous leg ulcers with the success of treatment largely depending on the amount and the distribution of the pressure applied. However, the reported treatment outcomes vary markedly because the actual sub-bandage pressure profile is difficult to achieve in clinical settings.

In this article we have reported a new fibre optic sensor made from FBG arrays, packaged in a flexible tape format suitable for positioning underneath a compression bandage. The sensor array has many of the idealised functions described by a previous consensus study (Partsch et al, 2006), and as a result enables more quantitative monitoring of the application of compression bandages and garments, and the subsequent analysis of pressures generated during exercise.

The sensor was tested by a senior nurse consultant with over 10 years experience in chronic wound care, and has been shown to improve the pressure profile achieved by providing direct feedback of the applied pressure during bandaging. The sensor array was able to record both resting and working pressures, and the results accurately represent the performed activities and match well to the findings from previous independent studies. The small size and flexibility of the optical fibres and their ability to transmit data over long distances makes them ideal for monitoring subjects undergoing various forms of exercise and for visualising sub-bandage pressures during gait analysis.

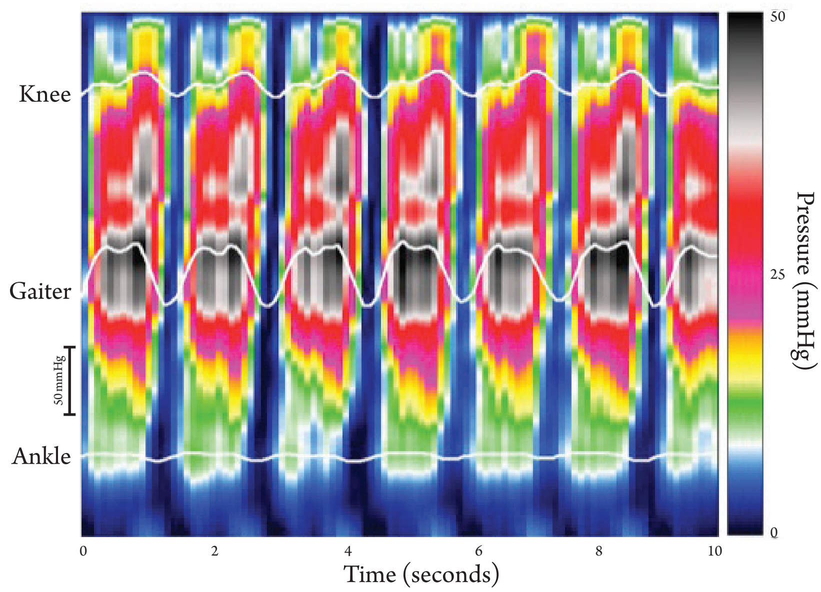


Figure 4. A 10-second section of data recorded while the volunteer was walking on a treadmill. The white lines show data recorded by discrete sensors located near the ankle, gaiter, and knee (a 50-mmHg scale bar for these data is shown on the lower left of the figure). The intensity plot shows the data recorded from the full sensor array with time along the x-axis, sensor location on the y-axis, and variations in pressure recorded as changes in colour.

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