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Thin membranes based on FBG sensors for real-time sub-bandage pressure monitoring

F. Spini, D. Rigamonti, P. Aceti, and P. Bettini

***Abstract* — This work focuses on the manufacturing and testing of a new device for medical bandages monitoring. An excessive pressure exerted from the compression bandage can block the blood flow of the patient, causing different medical complications to skin, nerves and to the circulatory system. On the contrary, if the pressure applied is low, the therapy is not effective. The utility therefore arises of a device capable of quantitatively indicating the correct adjustment of the bandage. The technological demonstrators developed consist of a polyurethane elastomeric shell with a thin composite supporting core. Fiber Bragg Grating Sensors (FBGS) embedded within this core permit the detection of the sub-bandage pressure applied during compression therapy. The two prototypes were applied under arm bandages to evaluate their capability to transmit the applied pressure to the embedded FBGS. We demonstrated the ability to monitor the bandaging action measuring the level of pressure exerted with the rounds of bandages. Moreover, the thin membranes permit the monitoring of the heartbeat of the patient, giving feedback about blood irroration. The device developed is therefore promising to improve the results of compression therapy.**

***Index Terms*— Compression Therapy, FBG, Fiber optic, Heartbeat monitoring, Pressure Sensors, Smart Bandages**

I. Introduction

Fiber Bragg Grating Sensors (FBGS) based pressure sensors are a subject of much current interest in different engineering sectors, including biomedical, petrochemical, water management system [1]. More in general, FBGS are known to measure several parameters such as strain, temperature, pressure, displacement. Considering pressure measurement, Xu *et al*. demonstrated that a bare Fiber Bragg Grating (FBG) pressure sensor placed in a high-pressure vessel and pressurized up to 70 MPa had a low sensitivity [2]. For this reason, sensitivity enhancement methods are needed, and several examples based on different mechanical structures (i.e., polymer-based and diaphragms-based pressure transducers) were proposed [3]-[7].

Lightweight, possibility of incorporation in small medical catheters and needles, biocompatibility, chemical and biological inertness, instantaneous response to biophysical variation and immunity to electromagnetic interference are properties that make optical fibers interesting in the biomedical field [8].

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F. Spini, D. Rigamonti, P. Aceti, P. Bettini are with the Department of Aerospace Science and Technology, Politecnico di Milano, 20156 Milano, Italy (e-mail: francesca.spini@polimi.it, daniela.rigamonti@polimi.it, pietro.aceti@polimi.it, paolo.bettini@polimi.it)

Different biomedical devices were developed using FBG pressure sensors (e.g., manometers for gastroscopy and colonoscopy [8], smart bed for the monitoring of sleeping postures [9], retractor for neurosurgical operations [10]).

Compression therapy is a prevention and treatment technique frequently used in venous and lymphatic insufficiency in the lower limbs (e.g., varicosities, lymphedema, venous eczema and ulceration, deep vein thrombosis and post thrombotic syndrome). Compression therapy involves the application of different devices, such as elastic and nonelastic bandages, boots, hosiery, or stockings [11] [12].

The application and maintenance of a certain level of the interface pressure is of great importance to ensure successful results. In fact, a low pressure under compression bandages can lead to inadequate treatment. On the other hand, an excessive interface pressure can imply harmful side effects, such as injury to the skin, phlebitis, arterial complications, leg ulcer formation, necrosis, gangrene, and local damage to the peroneal nerve [13]. For this reason, the results of compression therapy could be improved with the development of a non-invasive device capable of measuring the sub-bandage pressure.

The possibility to exploit FBGS for the monitoring of the sub-bandage pressure is under study. Bradbury *et al.* developed a pressure sensor for compression therapy by embedding the FBG in a polymer material and using a textile housing. However, the device produced was able to monitor locally the pressure exerted in a specific point of the bandage [14]. On the contrary, in our study we exploited the wavelength division multiplexing capability of FBGS, that permits to have multiple sensors engraved in a single fiber and discriminate their signals. The aim was the obtainment of multiple points of measurement. An array of three FBGS was used in this research work, ensuring therefore to measure locally the pressure in a large enough area of the bandage. In compression therapy is indeed fundamental to guarantee a correct pressure distribution, avoiding regions with low or excessive sub-bandage pressure. Wang *et al*. studied an optical fiber force sensor for compression therapy based on two arrays of FBG entwined in a double helix. They used rigid metal disc substrates to fix each FBG pair and strips of tape to fabricate the device [15]. In contrast with the latter study, we used a different configuration. In this research, the two manufactured technological demonstrators consist of a polyurethane elastomeric shell with a thin composite supporting core. These, together with the embedded fiber optic, create thin membranes, that we used for the investigation of the interface pressure under medical bandages.

The device can provide the local measurement of the pressure variation, which is related to a strain-induced wavelength shift in the FBG sensor engraved inside the fiber. The thin membranes enable to monitor the bandaging action and to indicate the level of pressure exerted from the bandage. Moreover, the monitoring of the heartbeat of the patient is another advantage of this device. Section 2 of this work introduces the design, sensing principle and the main steps of the technological process developed for the manufacturing of the device. The procedure of functional testing of the device is also presented in this section. Section 3 describes results of functional tests as well results obtained when the thin membranes are used under medical bandages. Finally, section 4 presents the discussion and the conclusions that can be drawn about the device developed.

II. Methods of Fabrication and Testing of the Device

A. Design and sensing principle

The main goals during the design of the device were the obtainment of multipoint pressure measurements with high sensitivity and the subsistence of the flexibility of the membrane. The first requirement was related to the need to monitor the sub-bandage pressure in different areas during the medical treatment. An array of three sensors to obtain as many points of measurement was used. The plan size of the membranes is 190 x 100 mm^2. A high sensitivity of the sensors can be reached by embedding the FBGS in an elastomeric material, as demonstrated in previous studies [3]. An elastomeric protrusion, called “button” contains the FBG sensor. The aim of its shape is the amplification of the solicitation on the sensor. The thin composite core is necessary to provide a certain stiffness to the membrane. To avoid that the presence of the composite core prevents the correct transfer of the pressure from elastomer to sensors, we created a circular hole of diameter 10 mm for each one of them in the composite core. The hole also guarantees a second aim of the composite core, that is to create a constrain to the fiber optic at both sides of the FBG sensor increasing in this way its sensitivity and accuracy. Also, the mutual decoupling in presence of several FBGS within the device can be achieved in this way. In fact, the application of a local pressure to one of the sensors do not influence the response of the others FBGS in the membrane.

Finally, a low thickness of the composite core is necessary to guarantee the adaptability of the device to the human body and a certain flexibility of the membrane.

The schematic design of a section of the thin elastomeric membrane is shown in Fig.1.

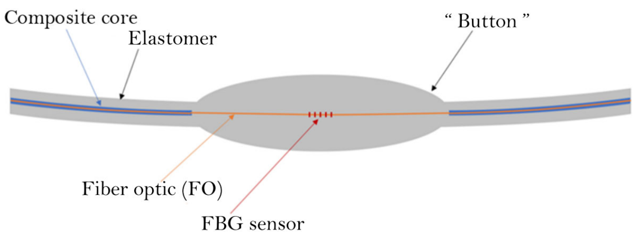


Fig. 1. Schematic design of a section of the thin elastomeric membrane designed for medical bandages monitoring. The FBG sensor is embedded in an elastomeric material to obtain high sensitivity, whereas the composite core provides the necessary stiffness.

The spectrum of the light reflected by the FBG sensor is characterized by a peak centered at the Bragg wavelength, which depends on the FBG grating parameters (i.e., refractive index and pitch). The direct quantity measured by the FBG sensor is the wavelength shift of this reflected peak, that depends straight away on strain and temperature (1).

$$\Delta\lambda_B = \lambda_B\,(1-p_e)\,\Delta\varepsilon + \lambda_B\,(\alpha+\zeta)\,\Delta T \qquad (1)$$

Other types of external stimuli, such as a pressure variation, can be transduced into a strain variation to exploit this dependency. This is the principle adopted here, where the pressure applied to the “button” causes a tension in the fiber.

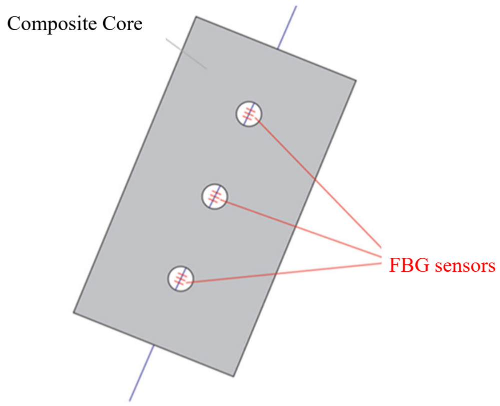
B. Technological development of the device

The process of manufacturing of the thin membranes can be divided in two different phases. In the first one (Fig.2a), we produced the composite core, in which the fiber optic is embedded, whereas in the second phase (Fig.2b) we cast the elastomeric shell. Each FBG sensor is at the centre of the corresponding hole of the composite core and is 50 mm distant from the others. We designed a mold that was used for both the two phases of production of the membranes. We manufactured different samples using optical fibers without sensors, to define and set-up the correct procedure for the fabrication of the technological demonstrators.

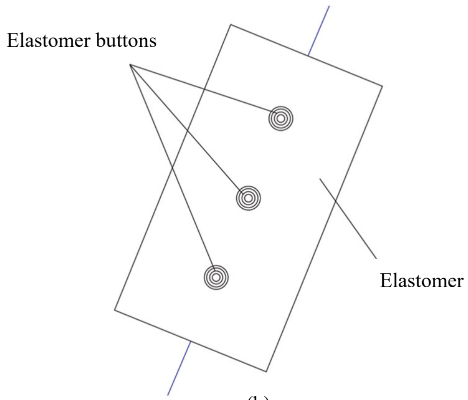
For the manufacturing of the first samples, composite core consisted of two plies of a thin pre-preg fabric, made of a glass fiber reinforced epoxy matrix (Table I). This choice was motivated by the need to minimize the thickness of the composite core to obtain a device capable of adapting to the human body. In fact, an excessive thickness of the core would have implied non-flexible membranes. However, the fiber optic was subjected to failures during the production of the first samples, caused by the pressure applied during the curing cycle in presence of reinforcing fibers crossing.

In order to maintain the integrity of the optical fiber, an additional layer of unidirectional glass fiber was added (Table I) to accommodate and to protect the optical fiber against the pressure during the manufacturing, as suggested by Bettini *et al*. [16]. Unidirectional glass fiber was used over the entire length of the membranes aligned with the optical fiber, except for the composite holes.

We realized the three holes in the composite plies through a die-cutter, whereas the unidirectional glass fiber was cut into strips. We placed in sequence: the peel-ply, a first ply of glass fiber fabric, the strips of unidirectional glass fiber, the Ormocer ® coated optical fiber with the array of three FBGS centered in the holes, the second ply of glass fiber fabric, another peel-ply layer, and a rubber pad to distribute the pressure applied during the manufacturing. Finally, we prepared the vacuum bag and we processed the composite core in the oven at a temperature of 125°C under vacuum. The composite core obtained is shown in Fig. 3a.



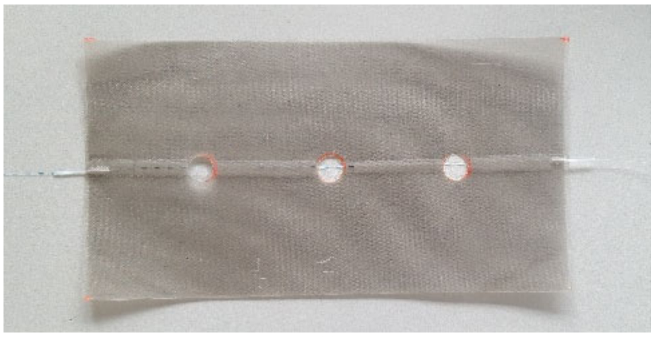
(a)



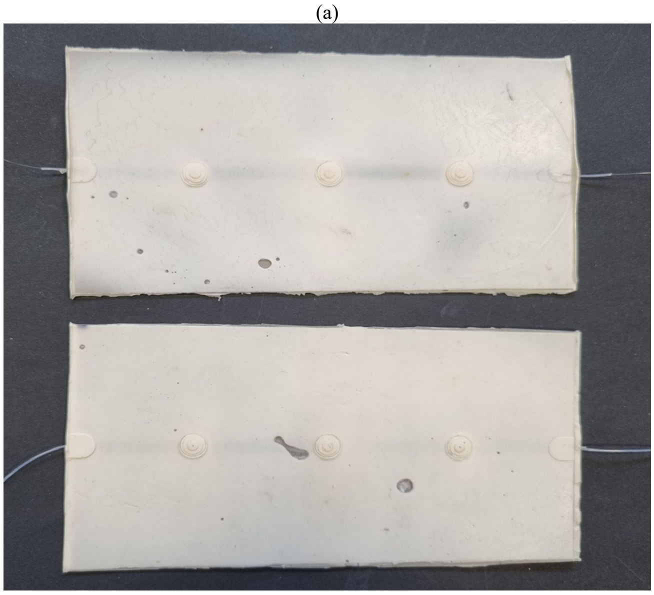
(b)

Fig. 2. (a) First phase of production of the composite core, in which the optical fiber is embedded and (b) second phase of casting of the elastomer

The final phase of the manufacturing of the thin membranes was the casting of the elastomeric shell. We chose a polyurethane rubber (Table I) suitable for the casting application and easy to operate. A devoted rigid counter mold was adopted in this phase to obtain a closed mold for the casting. In Fig.3b are shown the two final prototypes produced (ID1 and ID2). The thickness of the membranes is approximately 1 mm. The two technological demonstrators present bubbles generated by the laboratory process used. However, the quantity and the positions of the bubbles do not compromise the working of the sensors.



(a)



(b)

Fig. 3. (a) Composite core with the array of three FBGS embedded and (b) two final membranes obtained after the casting of the polyurethane rubber

TABLE I
MATERIALS

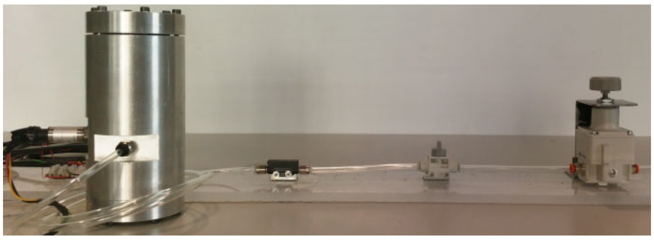
Component	Material	Supplier
Composite core	pre-preg E- glass fabric, Areal weight 48 g/m^2 (EE48 ET445)	Seal SAATI S.r.l
Protective strip	pre-preg S-glass UD Areal weight 280 g/m^2 (SP250 S29A)	3M
Elastomeric shell	polyurethane rubber Polimold NT 30	Poolkemie S.r.l.
Fiber optics	125 nm cladding fiber, Ormocer® coated	FBGS Technologies GmbH
FBG sensors	array of 3 FBG sensors 50 mm spaced and 3 mm long Bragg wavelength: 1530 – 1537.5 – 1545 nm	FBGS Technologies GmbH

C. *Functional tests*

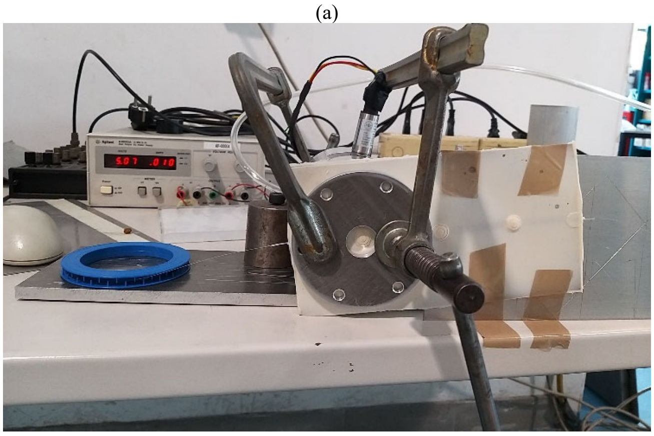
The aim of these first tests was the verification of the elastomeric shell capability to transmit the pressure to the embedded FBG sensors, the composite core capability to ensure mutual decoupling, as well a preliminary evaluation of sensors level of sensitivity. We performed the tests on the first prototype produced (ID1). The system used for functional tests

(Fig.4a) was developed by Pernigoni *et al*. [17] and consists of a hollow cylinder having an upper part with a central hole that blocks the elastomeric membrane allowing the pressurization of the internal cavity of the cylinder with respect to the external ambient, avoiding any leakage. The system is equipped with a pressure transducer Pressure Sensor Limited PSC217-B-4-5-A, which provides a differential measurement (i.e., difference between the pressure in the cylinder and ambient pressure), a SMC® PFMV530-1 flow meter, a precision pressure regulator SMC® IR2000-F02 and a finger valve SMC® VHK2-06F-06F.

The set-up (Fig. 4b) enabled the placing of one side of the elastomeric sensitive "button" inside the pressurized cavity of the cylinder, whereas the other side was in contact with the ambient pressure. Two clamps were used to close the system with the upper cap, avoiding leakages during the measurements. Moreover, we fixed a plate to the membrane in correspondence of the other two sensitive "buttons" not subjected to the test. This operation was necessary because of the low stiffness of the device, that would have implied significant deformations of the membrane caused by its own weight during the measurements, leading to a non-correct data acquisition. Finally, we connected the membrane to the Micron Optics SM130 optical sensing interrogator. We performed static measurements correlating each pressure value set by the testing system with the corresponding values of variation of wavelength measured by the FBG sensors, once the value of variation of wavelength was stable.



(a)



(b)

Fig. 4. (a) System used for the functional tests and (b) experimental set-up

D. Validation tests

We applied the thin membranes under arm bandages to evaluate the ability of the devices to monitor the bandaging action, giving feedback about the pressure level exerted from the bandages. We connected the thin membranes to the Micron Optics SM30 optical sensing interrogator, to monitor the application and the wearing of the bandages. Two patients participated in the tests, while a physical therapist was involved directly to apply the bandages, aligning the FBGS along the lower arm, as shown in Fig.5.

Fig. 5. Application of the bandage positioning the thin membrane with the three FBGS aligned along the lower arm

TABLE II
TYPES OF VALIDATION TESTS

ID1	ID2
Intensity of the bandage (soft and tight) patient 1	Intensity of the bandage (soft and tight) patient 1
Intensity of the bandage (soft and tight) patient 2	Intensity of the bandage (soft and tight) patient 2
Heartbeat monitoring	

We performed different tests, in order to monitor the variation of wavelength related to the application and removal of the bandage. The physical therapist varied the intensity of bandages according to her professional experience by changing the overlap and the tension of the band, verifying the response of the sensors to different sub-bandage pressures. The physical therapist used two different types of elastic bandages: the first one is a single-stretch elastic adhesive gauze, the second is a cotton elastic band typically used in phlebological bandages. For a clear comparison of the results related to the intensity of the bandages, we considered the second FBG sensor placed in the central area of the bandage. Finally, we tested the capability of the device to monitor the heartbeat of the person at rest. We used a pulse oximeter to validate the heart rate measurements. The optical sensing interrogator provides the measure of the variation of wavelength of the FBGS, which is related to the pressure applied from the bandage. Table II presents the summary of the tests conducted with ID1 and ID2 membranes.

III. RESULTS

A. Functional tests results

Fig.6 shows the relationship between variation of wavelength and pressure variation obtained during the functional test for the first FBG sensor of ID1 membrane. The results of the other two FBGS are similar to those of the first sensor.

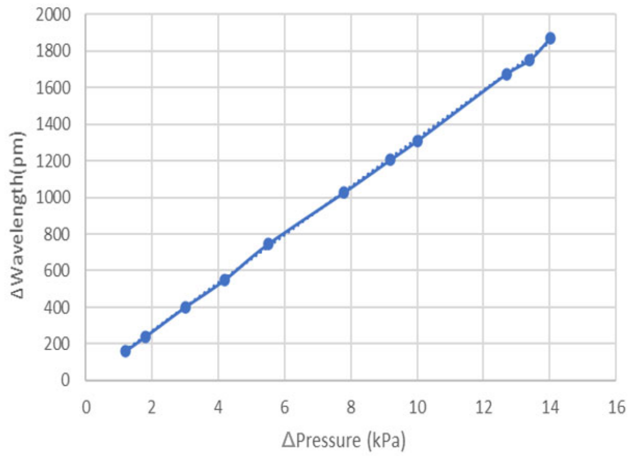


Fig. 6. Relationship between variation of wavelength and pressure variation obtained during functional test for the first FBG sensor. The sensor exhibits a good linearity and a high sensitivity

The FBG sensors present a linear response in the range of pressure variation tested and a high sensitivity (e.g., 132 pm/kPa for the first FBG sensor).

From the point of view of the speed in the response of the sensors, this is almost instantaneous during loading (increasing pressure), whereas it is very slow (tens of seconds) in unloading (decreasing pressure).

TABLE III
SENSORS NORMALIZED RESPONSE

	Response of sensor 1	Response of sensor 2	Response of sensor 3
Pressure applied to sensor 1	1.000	0.013	0.018
Pressure applied to sensor 2	0.012	0.989	0.019
Pressure applied to sensor 3	0.016	0.004	1.008

Note: The matrix was obtained considering a pressure of 10 kPa and normalizing the wavelength variation values with respect to those of the first sensor.

Finally, we demonstrated the mutual decoupling of the FBGS embedded in the membrane. The matrix in Table III shows this result. We obtained the matrix applying a pressure variation of 10 kPa and normalizing the wavelength shift values with respect to the one of the first sensor.

B. Validation tests results

The variation of wavelength related to the bandage application and removal is shown in Fig.7. The first green rectangle represents the bandaging action. After a short period of wearing, we removed the bandage. This is clearly visible in the violet rectangle.

Focusing on the removal of the bandage illustrated in Fig.8, in the initial stage, we removed the bandage only from the third FBG sensor. Then, we continued this operation, removing the bandage from the second FBG sensor and finally from the first one. The instantaneous decrease of the variation of wavelength values is highlighted by the first, second and third arrow that indicate the removal sequence of the bandage. Moreover, the step-like behavior related to the removal of each round can be easily visualized.

Regarding the ability to indicate sub-bandage pressure intensities, the comparison between two soft bandages and two tight bandages is illustrated in Fig. 9. For reasons of clarity of the graph, we show the results obtained for the central FBG sensor. We can demonstrate that the values of variation of wavelength related to the tight bandages are higher than those of the soft bandages.

Another advantage of the device is the capability to monitor on demand the heartbeat when the pressure applied by the band is under the systolic pressure of the patient, as shown by A. Benmira *et al.* in [18]. The heartbeat measured by the FBG embedded in the ID1 membrane showed in Fig.10 has been validated using a pulse oximeter showed in Fig.11. Both the instruments gave a heart rate of 60. The heartbeat is an index of the tissues perfusion of the bandaged body part and so it gives a local feedback of the proper blood circulation in tissues. This feature permits to have a local and on-demand measurement throughout the treatment: from the application of the bandage until its removal. It's important to monitor the heartbeat for the entire time the bandage is worn, because the pressure could change due to a bandage relaxation or a body part swelling [13]. The system permits also to measure heartbeat when, due to the bandages, is not possible to measure the radial pulse (e.g., wrist and ankle plaster).

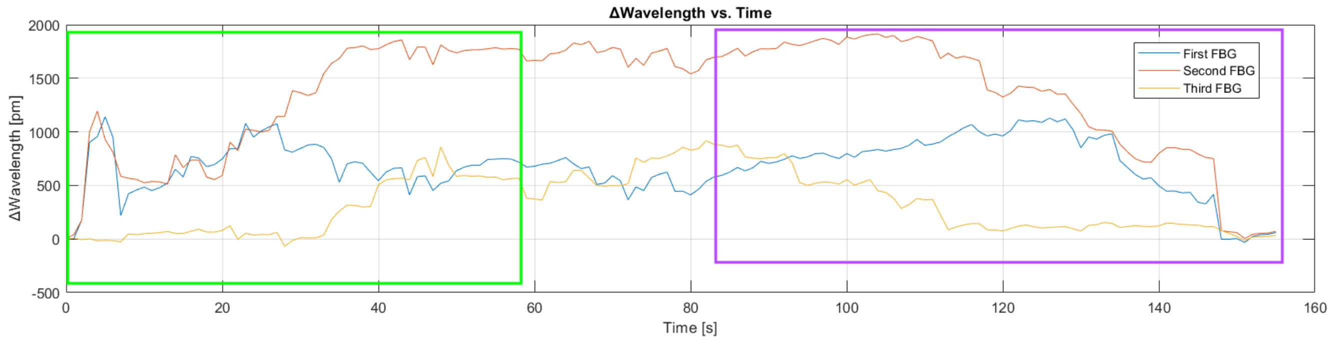


Fig. 7. Wavelength shift related to the bandage application and removal. The green rectangle represents the bandaging action, whereas the violet one the removal.

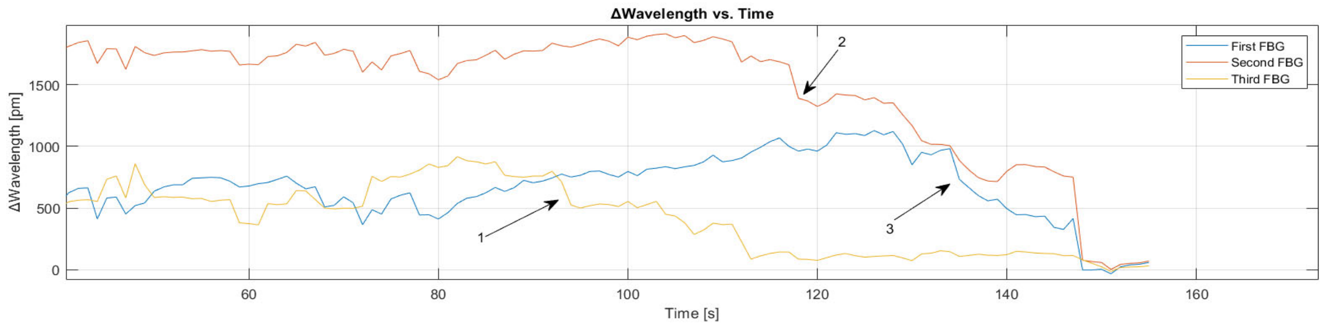


Fig.8. Bandage removal. The removal sequence of the bandage is highlighted by the first, second and third arrow.

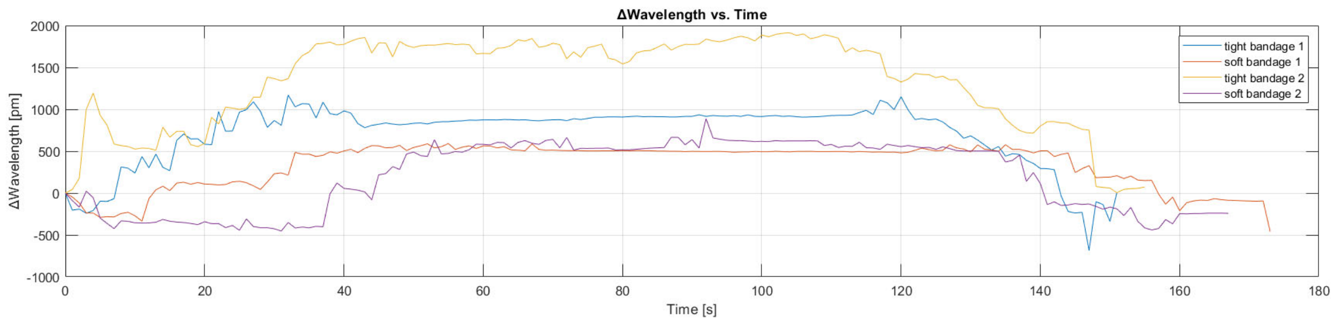


Fig. 9. Variation of wavelength related to the application of two soft bandages and two tight bandages. For the comparison we considered the values obtained from the central sensor of the membrane.

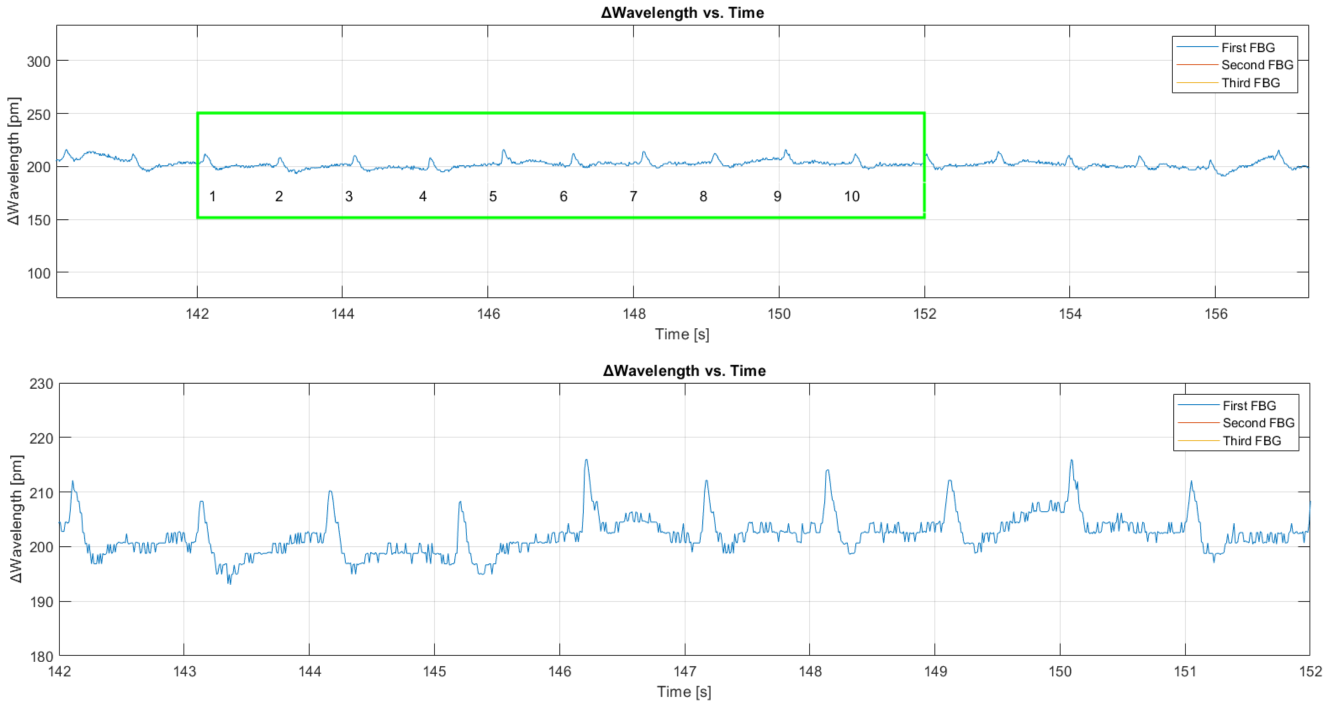


Fig. 10. Variation of wavelength with respect to time during the monitoring of the heartbeat of the person at rest. The green rectangle indicates ten heartbeats obtained in ten seconds of monitoring. The graph below is the green rectangle zoomed.

Fig. 11. Validation of the heartbeat measurement through pulse oximeter.

IV. Discussion and conclusions

This work focuses on the design, manufacturing and testing of thin membranes able to adapt to the human body and to monitor the sub-bandage pressure during compression therapy. We used Fiber Bragg Grating Sensors (FBGS) to detect the pressure applied during the medical treatment. The device can provide the local measurement of the pressure variation, which is related to a strain-induced wavelength shift in the FBG sensor engraved inside the fiber. We exploited the multiplexing capability of FBGS to obtain three points of measurement in the membranes. We achieved a high sensitivity of sensors by embedding them in an elastomeric material, whilst the presence of the inner composite core was fundamental to guarantee the mutual decoupling of the sensors. Indeed, the functional tests confirmed that the application of a local pressure to one of the sensors do not influence the response of the others FBGS in the membrane.

We applied the manufactured membranes under arm bandages to evaluate the capability to transmit the pressure applied to the FBGS. The measurement of the interface pressure is fundamental to achieve good results after the medical treatment. The results obtained with the positioning of thin membranes under arm bandages are promising. The wavelength shift during the bandage application is proportional to the number of rounds of the bandage and therefore to the sub-bandage pressure. We demonstrated that the membranes can perform a real-time monitoring of the pressure applied. The removal of the bandage from one of the FBG sensors causes in fact the instantaneous decrease of the wavelength shift values. The removal sequence of the bandage can be easily monitored. Moreover, the application of soft bandages and tighter ones demonstrates that the device is a valid quantitative indicator of the quality of the treatment. The device is therefore proven to be able to measure the interface pressure exerted from the medical bandage. The capability to indicate the right level of pressure to apply would enable to avoid incorrect bandages. In addition, the monitoring of the variations of interface pressure during the wearing of the bandage following its initial application could be also useful to indicate if an adjusting of the bandage is necessary, especially in compressive bandages for lymphoedema treatment. The monitoring of the heartbeat is another advantage of this device, giving feedback to the clinician about the tissues perfusion under the bandage.

In future work, we will use a suitable rubber material, instead of polyurethane to develop a biocompatible device. Moreover, we will investigate the possibility to have a portable and energy autonomous (exploiting human energy harvesting devices [19]) interrogation system able to monitor the variation of the interface pressure and heartbeat after the application of the bandage in carrying out daily activities. A deep study of the influence of the temperature during the measurements will be also necessary. Finally, we will consider the shape of the elastomer in contact with the FBGS to seek the best performances in terms of sensitivity. Numerical analysis will be therefore required. A further development is the design of a blood pressure measurement device exploiting both pressure and Korotkoff sounds [18] given by the FBG sensors.

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