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DEVELOPMENT AND PRE-CLINICAL INVESTIGATION OF A MASSAGE DEVICE FOR THE LOW BACK

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ABSTRACT

The low back pain is one of the most widespread pathologies in the world. Several treatments can be adopted to reduce the pain; one of these is the low back massage. Typically, the massage treatment is carried out by the manual manipulation of the lumbar spine. Moreover, some devices are commercially available. In this paper, a new pneumatic massage device for the lower back is presented. Silicone rubber actuators can exert compression forces by the air inlet inside them. An overall amount of 48 actuators covers all the low back of the user, according to the anatomy characteristics of him. A suitable structure supports the actuator and allows them to adhere to the user. The repetitive sequence of air inlet/outlet, from the mid to the low back or from left to right, is able to reproduce the manual massage treatment. The design, the prototype and the performance of the pneumatic actuator are described. A pre-clinical investigation was carried out to collect the level of perception and acceptance of the massage treatment and to collect information about the massage device. Experimental results, obtained by laboratory tests on healthy people, showed the effectiveness of the device.

Keywords: Low back massage, soft actuators, variable stiffness actuation, bio-mechatronic device.

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1. INTRODUCTION

The spine is a flexible structure for sustaining the upper part of the human body. It is made of bony components, called vertebrae, and elastic and soft ones, called intervertebral disks. Spinal nerves and ligaments are placed between the vertebra and the intervertebral disks. Strongly correlated to the age, spine is subjected to irreversible changes: starting from 30 years old, the intervertebral disks begin to lose their elasticity; spinal nerves begin to be compressed and cause pain. The final result is an increase of postural pathologies and pain. One of the changes of the spine is responsible of the low back pain: the 80% of the world population suffers low back pain, regardless the sex. The main causes are the too sedentary lifestyle or, on the contrary, the performing of stressful physical activities. Actually, due to the lack of spare time, the pharmaceutical treatment is the most widespread solution for the low back pain: medicinal painkillers, sold as capsules or medical patches, are commercially available. Moreover, in very serious cases, the surgical treatment is necessary. Nevertheless, an alternative method to the previous ones is the treatment by the massage therapy [1]: a mechanical manipulation of the muscles of the human body. Directly on the local area where massage is carried out, the manipulation develops heat and provides for a therapeutic and relaxing effect on the body; indirectly, the manipulation acts on the nervous and the vegetative system [2].

The low back pain requires the manipulation of the back; typically, patient is lying on the massage table and the therapist provides for the manipulation. Several massage techniques can be applied [3]. They differ from several parameters: the motion direction of the hands (longitudinal as regards the spine, transversal, diagonal or circular); the time of the motion of the hands or, in other terms, the time interval between two successive passes on the same area; the type of grasping of the muscles; the parts of the hands involved in the massage (fingertips, knuckle, punch, palm); the intensity of the massage intended as the pressure level to be applied to the muscles; the application mode of the massage (continuous along the surface of the back or intermittent by means of percussion actions).

Several devices are commercially available for the massage treatment without the assistance of a medical or a therapist expertise. Such devices can be classified according to the application mode of the massage: vibration devices, pressure devices, electrical devices and pneumatic devices. These devices can be autonomously used; they are general purpose devices not conceived for a particular massage. Typically, such devices are not therapeutic but only relaxing.

Only few researchers worked about the development of therapeutic massage devices, corresponding to robotic devices developed for the massage treatment. Not for the massage of torso and limbs, a machine to perform precise massage therapy to maxillofacial region was developed [4]. A massage robot, equipped with an adaptive and learning mechanism, was developed in order to realize the kneading massage. A position/force hybrid controller is at the basis of the performing massage action [5]. The industrial robot Puma 652 was equipped with a properly controlled end-effector following the desired trajectories necessary to practice a therapeutic massage [6]. More recently, some researchers [7] developed bio-mechatronic modules in order to adapt an industrial robot, not conceived to interact with the human tissues.

On one hand, commercial devices perform only a relaxing massage, but no therapeutic; on the other one, robotic devices can perform a therapeutic massage, but they cannot be used in a domestic environment, require a specialized team and a proper space to be used. Moreover, robotic devices are too bulky and too expensive. Finally, no device focused on the low back massage was developed or is commercially available.

In the present work an innovative pneumatic device for the massage treatment of the low back is presented. Pneumatic actuators were chosen due to the high power/weight ratio, typical of pneumatic actuators, compliance and intrinsic safety. Moreover, pneumatic actuators were assessed to be suitable for suit to be worn [8], for intermittent compression acting on humans [9] and to exert a 3-dimensional system of thrusts inside a brace for the scoliosis treatment [10]. The proposed massage device uses pneumatic actuators with the same behavior of the bellow pneumatic muscles. A set of 48 actuators provides for the application of the massage as a compression force applied on the low back. The design of the actuator, its prototyping and the experimental activity to achieve the performances of the actuator will be described. The massage device will be detailed. A questionnaire was prepared for a pre-clinical investigation of the massage device. The questionnaire will be detailed and the experimental results will be also discussed.

2. MATERIALS AND METHOD

2.1. Design of the actuator

The idea at the basis of the massage device was to use a pneumatic actuator whose behavior is similar to the one of the bellow pneumatic muscles [11, 12]: actuators made of an elastic deformable membrane that, when air is inflated inside the internal chamber, develop a force resulting in an axial membrane extension. This kind of actuators can exert a variable stiffness actuation (VSA), typically required for safety purpose: applications where human body and mechanical devices, as robots [13] and surgery instruments of minimally robotic invasive surgery [12], go in contact.

The first step of the design of the actuator was to assess a solution in order to satisfy:

- a restrained axial dimension at rest;
- an extension of only one side of the membrane;
- defined dimensions of the deformable membrane similar to the dimensions of the human fingers.

Two preliminary solutions, shown in Figure 1, were conceived. In both solutions, only the upper membrane can extend. The base side of the air chamber cannot move by the presence of a metal plate or by the increase of the thickness.

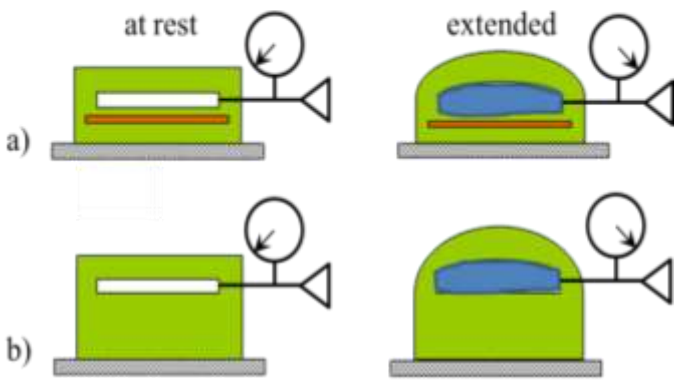


Figure 1 Schemes of the bellow muscles to adopt as actuators: a) with the metal plate; b) with the increased thickness

A silicone rubber for molding was chosen as elastic deformable material for the actuator. The silicone rubber has a non-linear constitutive law and the behavior of the extended membrane depends on the air pressure: the thickness of the membrane and the external load acting on the deformable membrane. For this reason the second step of the design of the actuator was, hence, the definition of a non-linear finite element model. It was constructed with the same procedure followed for a McKibben muscle [14]: the model is based on geometrical parameters (silicone rubber thickness over and under the air chamber; silicone rubber around the air chamber; thickness of the metal plate; overall dimension of the actuator) and functional parameters (desired extension of the membrane; air pressure; external load applied to the membrane). Silicone rubber was modeled as an hyperelastic material; metal plate was modeled as aluminum; pressure was applied perpendicularly to all the faces of the air chamber. A fixed constraint was applied at the basis of the model and, finally, a 2D model with shell elements was implemented. The outputs of the finite element analysis were: the optimal thickness of the membrane, the developed force and the extension of the membrane as a function of the air pressure value and of an external load, respectively. Iterative models were implemented in order to achieve optimal results satisfying two requirements: the maximum exerted force developed by the actuator must be equal to 23-24 N; the surface of the actuator must be in the range 280 – 336 mm^2 (as the surface of the thumb).

The first one was achieved by an experimental measurement of the pressure applied by the fingers during a high intensity (a deep compression on the muscles by the thumbs) massage treatment. A pad made of a 4x2 array of pressure sensors was adopted. Each sensor has a rectangular shape whose dimensions are equal to 10 x 15 mm. The pad was placed inside a rubber square, Figure 2a, with the same thickness of the pad (3 mm): the massage treatment was simulated through the application of the pressure by the thumbs, starting from the rubber square, passing on the sensors and finishing on the rubber square. The test was repeated 20 times by a physiotherapist. Figure 2b shows the mean values of the exerted pressure detected by the eight sensors and the overall mean value, for both the hands. The maximum value of the exerted pressure was equal to 0.6 MPa, corresponding to a force equal to 23.5 N.

The second requirement was achieved by the measurement of the mold of the thumbs on a bed of flour. The highlighted area, shown in Figure 2c, represents the contact surface between the thumbs of the physiotherapist and the body to be massaged. Resulting measurements were taken into account for the dimensioning of the actuators.

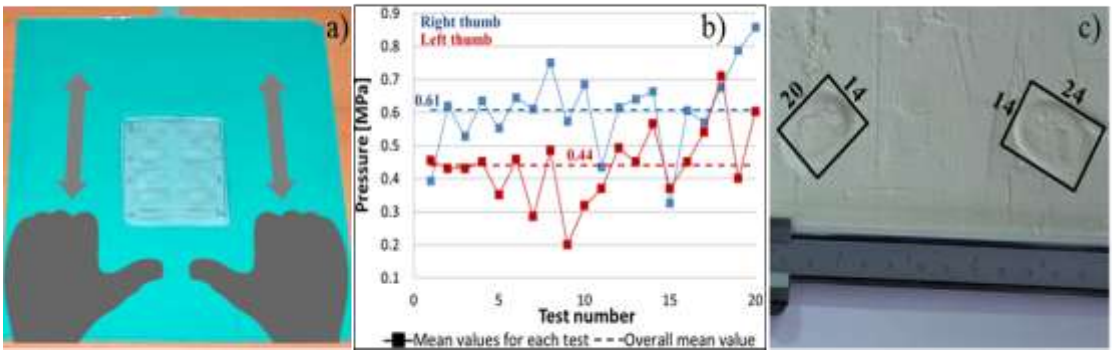


Figure 2 a) Sensors pad for the measurement of the massage pressure; b) experimental values of the massage pressure for both the thumbs; c) experimental values of the contact surface between the thumbs and the body to be massaged

Both solutions were modeled: the second one was neglected because the resulting minimum thickness under the air chamber was equal to 15 mm, too thick to be adopted in a massage device. The optimal geometrical dimensions of the designed actuator, according to the solution 1, are reported in Table 1.

Table 1 Geometrical dimension of the designed actuator achieved by FEM

Dimension	[mm]
Thickness of the silicone rubber under the air chamber	3.0
Thickness of the metal plate	1.0
Thickness of the silicone rubber between the metal plate and the air chamber	1.0
Thickness of the deformable membrane	3.0
Height of the air chamber	0.1
Length of the air chamber	34.0
Width of the air chamber	26.0
Length of the metal plate	34.0
Width of the metal plate	26.0
Length of the actuator	44.0
Width of the actuator	36.0

The maximum extension of the membrane is 10 mm, the maximum exerted force is equal to 24 N and the maximum air pressure value is in the range 0.08 – 0.1 MPa.

2.2. Prototype of the actuator

Since the single actuator has too restrained dimensions and in order to optimize the required contact surface between the actuators and the low back of the user, a set made of a 3x2 array of independent actuators was conceived. Eight sets were realized, for a total amount of 48 actuators. Each set has the following dimensions: 83 x 104 x 9 mm. The prototyping of the set of actuators required the construction of a casting mold for the silicon rubber. Inside the mold, six pins were placed in order to realize the duct for the air inlet/outlet. The casting procedure passed through the following step:

Step 1: casting of the layer (3 mm) of silicone rubber to be placed under the metal plate;

Step 2: after waiting for two hours (necessary for the catalization of the silicone rubber), placement of the metal plate over the previous layer of silicone rubber;

Step 3: casting of the layer (1 mm) of silicone rubber to be placed between the metal plate and the air chamber;

Step 4: after waiting for half an hour, placement of six sheets of paper having the dimensions of the air chamber (34 x 26 mm) on the previous layer of silicone rubber;

Step 5: casting of the last layer (3 mm) of silicone rubber, corresponding to the deformable membrane.

The height of each casted layer is assured by the application of subsequent frames on the casting mold, as shown in Figure 3a. A prototype of the actuator is shown in Figure 3b.

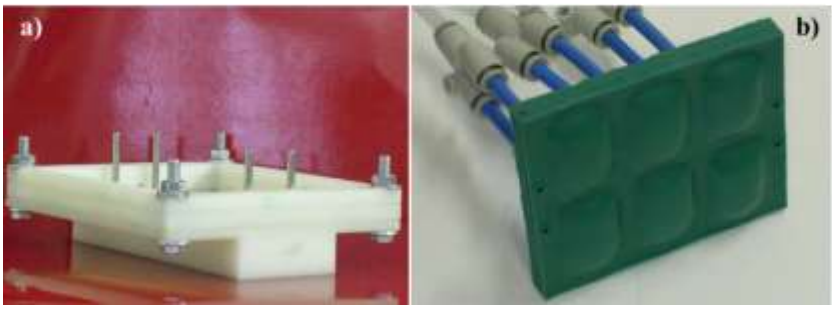


Figure 3 Prototyping of the actuator: a) the casting mold; b) the final prototype

2.3. Performance of the actuator

Hence, each actuator was subjected to two kinds of experimental tests: isotonic tests (for a constant external load, the deformation of the actuators is measured as a function of the inner pressure inside the air chamber) and isometric tests (for a fixed deformation of the actuator, the developed force is measured as a function of the inner pressure inside the air chamber). Isotonic tests were carried out by placing a fixed mass on the actuator and measuring, by a caliper (resolution 0.02 mm), the lift of the mass from the rest position; the adopted testbed for isometric tests, shown in Figure 4, is a portal frame equipped with a CTCA10K5 load cell (full scale 10 kg; nominal sensitivity 2mV/V): the actuator develops a force acting as compression load on the load cell. A precision pressure regulator was adopted to adjust the inner pressure inside the air chamber. A manometer (full scale 6 bar; resolution 0.05 bar) completes the testbed.

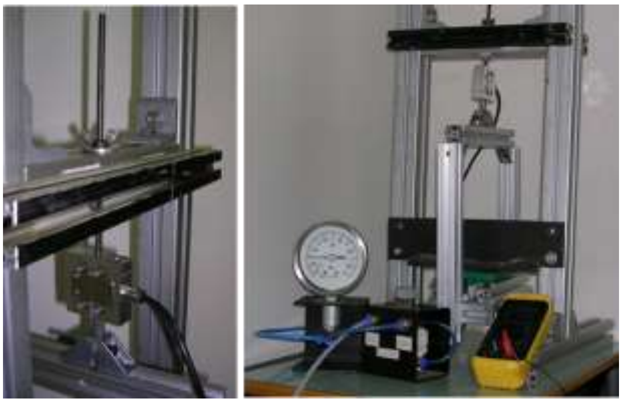


Figure 4 The experimental testbed for isometric tests

Figure 5 shows the average results of the isotonic and isometric tests computed on the basis of the 48 results of each actuator.

2.4. The massage device

With reference to Figure 6, the massage device is equipped with a main structure made of three polymeric modules: the upper (1), the central (2) and the lower module (3), respectively. The main structure is inspired to the rachis segment corresponding to the low back. In order to reproduce the natural curvature of the rachis of many users, the upper and the lower modules have one degree of freedom (dof1): a rotation around two pins (4), adopted to connect the upper and the lower module to the central one.

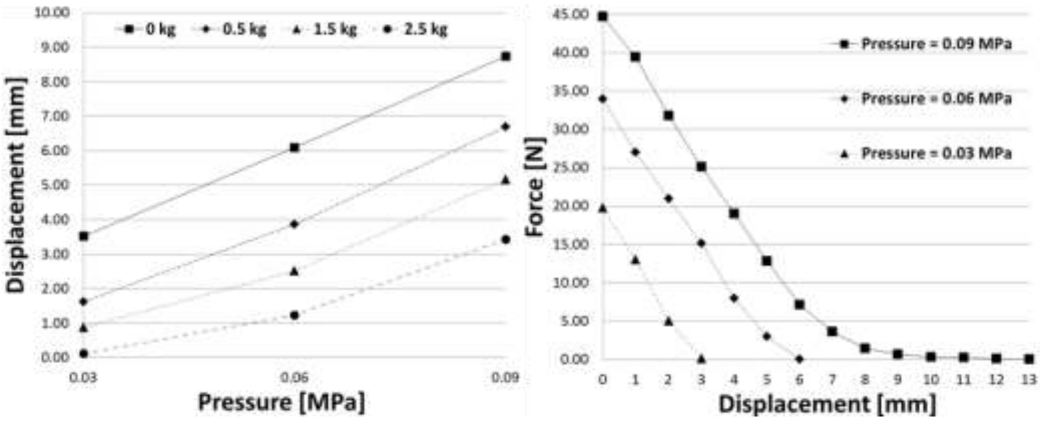


Figure 5 Displacements vs. pressure in isotonic tests, a), and developed forces vs. displacements in isometric tests, b)

With the exception of the central module, the upper and lower ones are equipped with a loop: inside the loop, two aluminum shafts (5) can translate and rotate. At the ends of each shaft, an internal aluminum frame (6), supporting a set of actuators (7), is connected on one edge by a pin. Each internal aluminum frame has three dofs: a translation due to the translation of the shaft inside the loop (dof2), a rotation around an horizontal axis (dof3) due to the rotation of the shaft around its symmetrical axis and the rotation around a vertical axis (dof4), due to the rotation of the frame around the axis of the connection pin with the shaft. On the other edge of each internal aluminum frame, an external aluminum frame (8) is connected by a pin. External frames have one more dof (dof5), due to the rotation around the connection pin with the internal frames. The dofs allow the aluminum frames to adhere to the low back of the user and reproduce a defined anatomy. A set of manual nuts (9) provides for fixing and maintaining the specific configuration of the device, depending on the anatomy of the user. Each actuator has a pneumatic fitting (10) for the air inlet/outlet. An handmade harness, made of belts of fabric (11), was adopted to wear the device to the user.

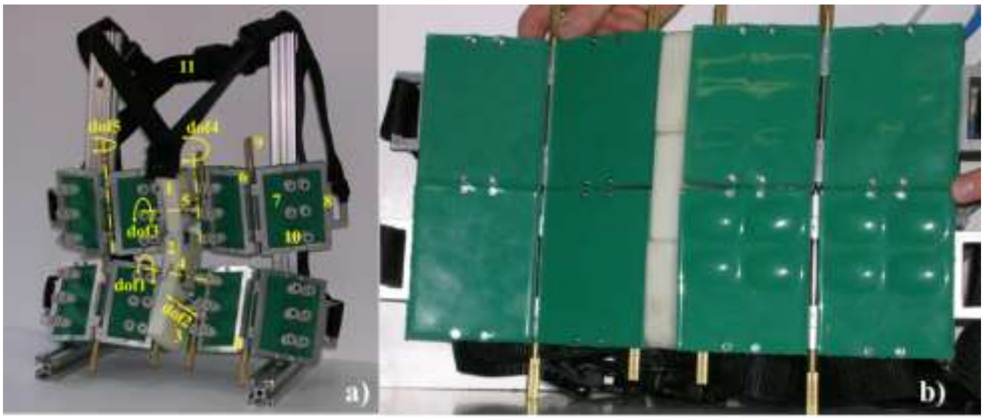


Figure 6 The prototype of the massage device: a) rear view and main components; b) front view and particular of some pressurized actuators

The massage treatment can be carried out along the longitudinal (from the mid to the low back) and transversal (from left to right, or viceversa) directions. When the device adheres to the user, the displacement of each actuator provides for a compression force on the low back. The massage treatment is applied by a succession of air inlets and outlets to and from the actuators: the swinging of the compression forces reproduces the manual massage. The air flow is provided by pneumatic mono-stable electrovalves 3/2, commanded by a S7-200 Siemens PLC, connected to an air compressor. For the longitudinal direction, 6 electrovalves should be adopted: each of them is connected to the actuators belonging to the same row of the 6x8 resulting array of actuators. On the contrary, 8 electro-valves are required for the transversal direction: each of them is connected to the actuators belonging to the same column. Any kind of massage technique can be carried out. It firstly depends on the number of electrovalves to be adopted: if the massage technique requires a concentrated force application, 48 electrovalves are necessary. Then, it depends on the frequency of the massage technique, defined as the number of air inlet/outlet per second, inside each actuator. Finally, it depends on the required pressure to be applied. Figure 7 shows the device worn by a user.

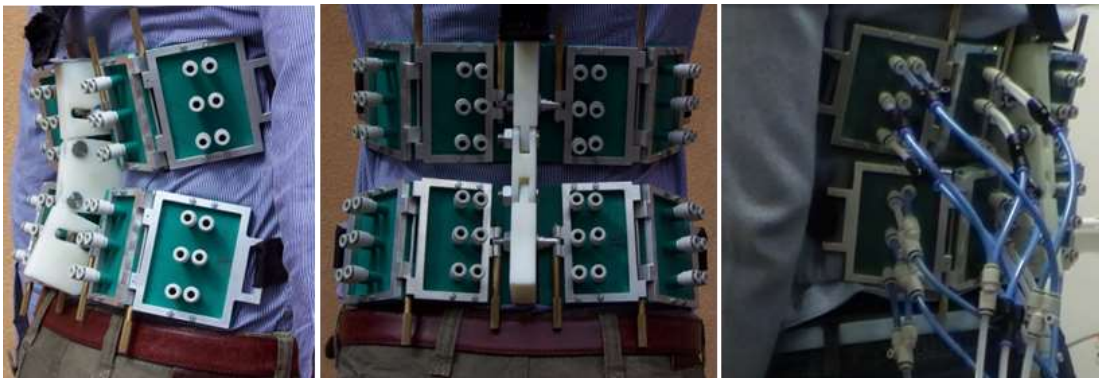


Figure 7 The massage device worn by a user without and with pneumatic tubes

3. PRE-CLINICAL INVESTIGATION

3.1. Aims and parameters of the massage treatment

The pre-clinical experimental investigation was carried out in a laboratory environment by healthy users. The aim of the experimental activity was to collect:

- the level of perception of the massage treatment;
- the level of acceptance of the massage treatment;
- the perception of the users in terms of comfort or bother, easiness of use and noise (due to the commutation of the electrovalves and to the exhaust of air) of the massage device.

Only the massage treatment along the longitudinal direction was tested in the experimental activity. The PLC software was developed as a function of three different levels of frequency, as previously defined:

- low frequency: f=0.22 Hz;
- medium frequency: f=0.33 Hz;
- high frequency: f=0.66 Hz.
- Moreover, tests were carried out for two air pressure levels:
- low pressure: 0.05 MPa, corresponding to a developed force equal to about 15 N;
- high pressure: 0.09 MPa, corresponding to a developed force equal to about 27 N.

3.2. The questionnaire

A proper questionnaire, developed as suggested in [15], was prepared and submitted to the users. The Likert-Type response format [16], whose scale is based on five levels from “Absolute Agree” to “Absolute Disagree” as regards the proposed question, was adopted for the answers. The questionnaire, shown in Figure 8, was divided in three sections:

Section 1: explanation of the Likert scale and collection of personal data from the user;

Section 2: questions about the level of perception and acceptance of the massage treatment. This Section is divided in 6 sub-sections, according to the six combinations of frequency and pressure levels: 1. low pressure and low frequency; 2. low pressure and medium frequency; 3. low pressure and high frequency; 4. high pressure and low frequency; 5. high pressure and medium frequency; 6. high pressure and high frequency.

Section 3: questions to collect indications about the massage treatment and the massage device.

In order to check the effectiveness of a massage device developed in the Department laboratory, we would like to collect your opinion. Please, underline your favourite answer and, where it is required, point out your preference scale to the proposed questions according to the following scale:

***AD**- Absolute Disagree*
***D**- Disagree*
***N**- Neutral*
***A**- Agree*
***AA**- Absolute Agree*

Section 1

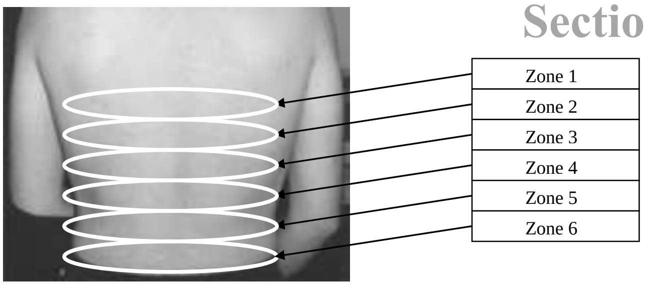
Name: ***Surname:***
Gender: **F** **M** ***Age:***

1. Give a vote from 1 to 10 to the last massage treatment 1 2 3 4 5 6 7 8 9 10

2. I feel the massage treatment in the overall contact region of the massage device **AD D N A AA**

3. If you disagree the last sentence, point out the zones where the massage treatment was not felt

Section 2



4. Point out the zones where you felt the more beneficial effect of the massage treatment
Zone 1 Zone 2 Zone 3 Zone 4 Zone 5 Zone 6

25. Massage device is easy to be worn	**AD D N A AA**
26. After wearing it, I felt low back pain	**AD D N A AA**
27. If you agree the last sentence, point out the zones where you felt the low back pain	
Zone 1 Zone 2 Zone 3 Zone 4 Zone 5 Zone 6	
28. The belts of the harness cause me a sense of compulsion	**AD D N A AA**
29. It is useful to adjust the frequency level	**AD D N A AA**
30. Point out your favourite frequency level	*Low Medium High*
31. It is useful to adjust the pressure level	**AD D N A AA**
32. Point out your favourite pressure level	*Low High*
33. I felt low back pain during the massage treatment	**AD D N A AA**
34. If you agree the last sentence, point out the zones where you felt the low back pain	
Zone 1 Zone 2 Zone 3 Zone 4 Zone 5 Zone 6	
35. The noise bothered me	**AD D N A AA**
36. Massage treatment has relaxed me (regardless of noise)	**AD D N A AA**
37. I want to repeat the massage treatment	**AD D N A AA**
38. I'd like to buy the massage device if it was commercially available	**AD D N A AA**

Comments:

Section 3

For research use, I consent to use the questionnaire.

Signature ___________________________

Figure 8 The submitted questionnaire

Each user followed the same procedure, according to five steps:

Step 1: user is informed about the massage device, the massage technique and the zone of the back involved by the massage treatment; then, user fills the Section 1 of the questionnaire;

Step 2: user wears the massage device;

Step 3: user carries out the massage treatment at low pressure and fills the first three sub-sections of the Section 2 of the questionnaire;

Step 4: user carries out the massage treatment at high pressure and fills the last three sub-sections of the Section 2 of the questionnaire;

Step 5: user removes the massage device and fills the Section 3 of the questionnaire.

The duration of each massage treatment was equal to 2 minutes; the overall duration of the experimental activity, carried out by each user, was equal to 15 minutes.

Two samples of the population were submitted to experimental tests:

Sample 1: 10 healthy people with an average age equal to 24 years;

Sample 2: 4 healthy people with an average age equal to 30 years.

3.3. Results of the investigation

In the following, a comparison between the Sample 1 and the Sample 2 results are shown and discussed.

As regards to question number 1 (votes to the massage treatment), according to the resulting mean values shown in Figure 9, it results:

Sample 1: for a low pressure, a high frequency is appreciated; for a high pressure, a medium frequency is appreciated. The maximum satisfaction was recorder in a low pressure-medium frequency massage treatment; the minimum one, in a low pressure-low frequency massage treatment.

Sample 2: for both pressure levels, a high frequency is appreciated.

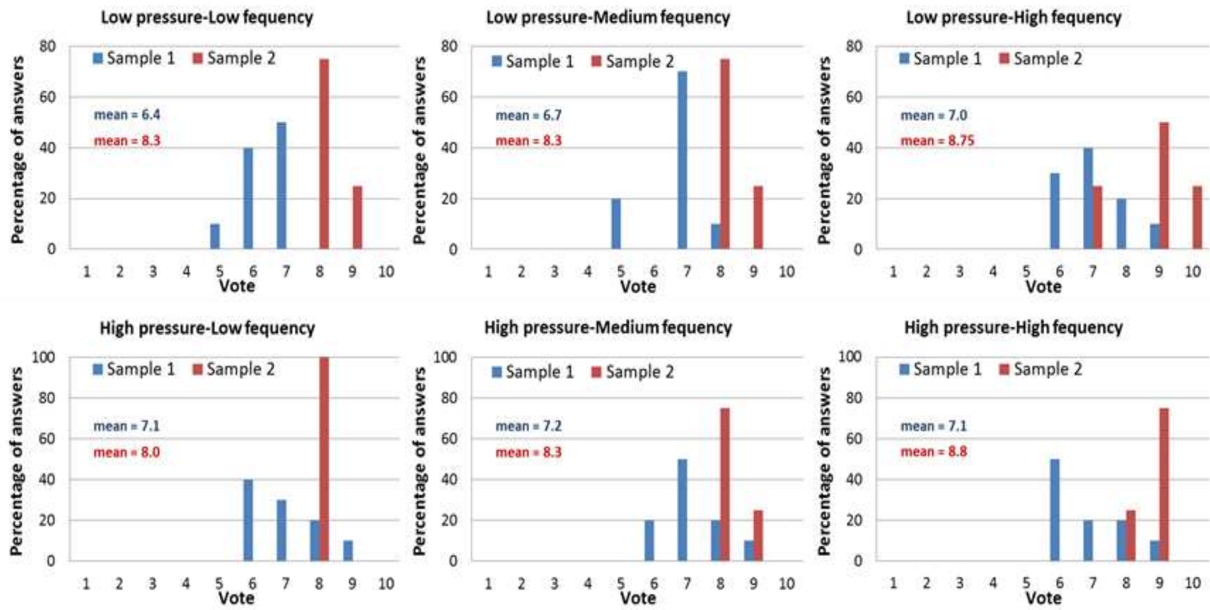


Figure 9 Votes to the massage treatment: comparative results

As regards to question number 4, as shown in Figure 10, the more beneficial effect of the massage treatment is much more felt in zones 3 and 4 with a light diffusion to zones 2 and 5, for both the Samples.

As regards to question number 30 (favorite frequency level), it results:

Sample 1: low frequency = 0%; medium frequency = 70%; high frequency = 30%;

Sample 2: low frequency = 25%; medium frequency = 0%; high frequency = 75%.

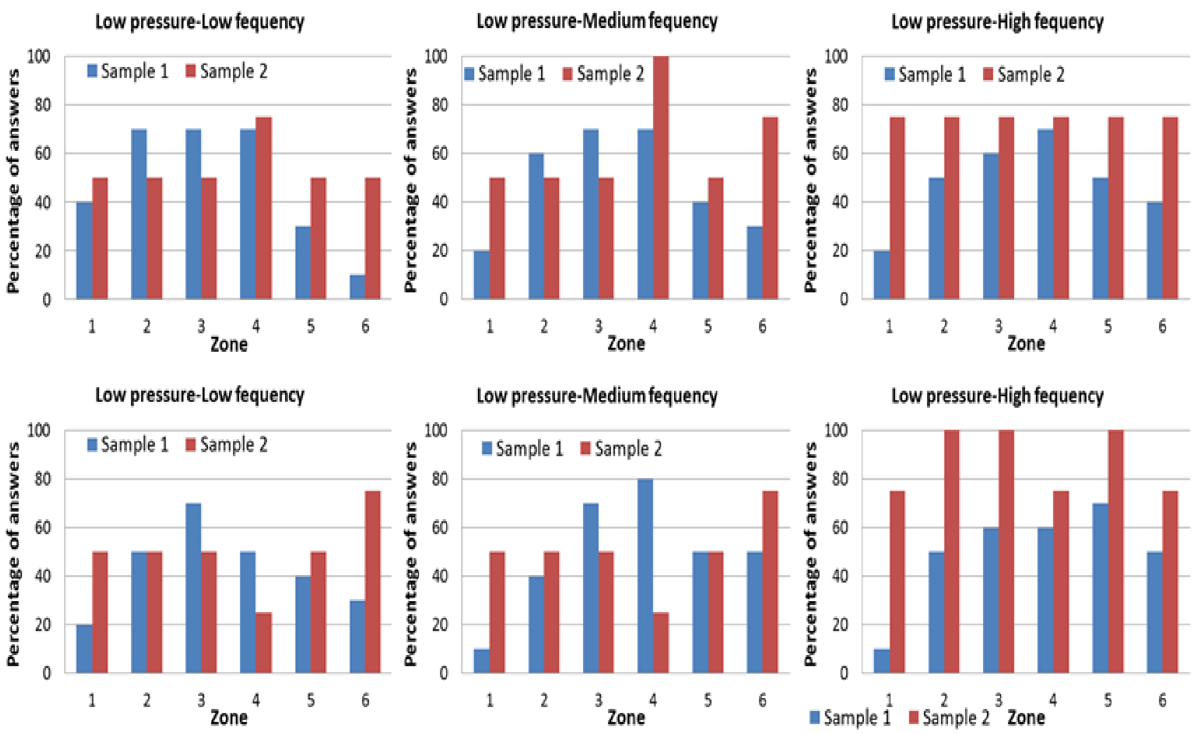


Figure 10 Zones with more beneficial effect of the massage treatment: comparative results

As regards to question number 32 (favorite pressure level), it results:

Sample 1: low pressure = 30%; high pressure = 70%;

Sample 2: low pressure = 0%; high pressure = 100%.

As regards the questions to be answered according to the Likert scale, a score was given to the answers as follows: “Absolute Disagree” corresponds to 1; “Absolute Agree” corresponds to 5. Comparative results, computed as the average values of the corresponding values of the Likert scale, are reported in Table 2.

Table 2 Comparative results of the mean values referring to the questions based on the Likert scales

Questions	Sample 1	Sample 2 of Life
2. I feel the massage treatment in the overall contact region	3.8	3.8
25. Massage device is easy to be worn	3.3	4.3
26. After wearing it, I felt low back pain	1.0	1.0
28. The belts of the harness cause a sense of compulsion	2.2	2
29. It is useful to adjust the frequency level	4.4	4.3
31. It is useful to adjust the pressure level	4.4	4.3
33. I felt low back pain during the massage treatment	1.0	1.0
35. The noise bothered me	2.6	1.5
36. Massage treatment has relaxed me	3.3	4.3
37. I want to repeat the massage treatment	4	4.5
38. I’d like to buy the device device if it was	2.5	3.3

The analysis of the answers shows that:

- it is useful to adjust the frequency level of the massage treatment;
- it is useful to adjust the pressure level for a massage treatment;
- the massage treatment provides for a therapeutic and relaxing effect;
- the noise of the electrovalves should be addressed.

Moreover, the experimental activity provided for further indications about the actuators: in particular, starting from 3500 operative cycles of air inlet/outlet, silicone rubber showed a progressive failure by means the manifestation of cuts, whose variable length was in the range 2 – 5 mm, at the contour of the air chambers.

4. CONCLUSIONS

An innovative pneumatic massage device for the treatment of the low back and a pre-clinical investigation of it was presented. The massage device can adapt to the anatomy of the user by means of sets of pneumatic actuators with 4 degrees of freedom. Each actuator is made by a chamber in silicone rubber: the air inlet/outlet to and from the chamber provides for the displacement of the actuator towards the low back. The sequences of air inlet/outlet reproduces the manual massage. By a PLC code, it is possible to practice several types of massage treatments along the longitudinal and transversal directions. The pre-clinical investigation, to collect the level of perception of the massage treatment, the level of acceptance of the massage treatment and information about the massage device, was carried out with two samples of healthy people different for the number and the age. It resulted that the developed massage device effectively provides for a relaxing effect; moreover, the users deemed useful the availability to adjust the frequency and the pressure levels. Almost the overall low back region, covered by the massage device, was involved in the treatment; no pains were felt by users after the treatment; the noise of the electrovalves seems to be easily tolerated. In the next future, silicone rubber should be replaced by a more resistant material and the PLC must be replaced by a microcontroller. Finally, a set of micro-electrovalves should replace the current ones.

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