Project no. COOP-CT-2005-016868

LOOSEandTIGHT

Development of a superelastic material that enables its cost-effective application in highly compliant compression hosiery for the over 18 millions European citizens suffering from Chronic Venous Insufficiency

Co-operative research Project

Publishable Final Activity Report

Period covered: 1st September 2006 / 31st December 2007 Date of preparation: 11/02/2008

Start date of project: 01/09/2005 Duration: 28 Months

Project coordinator name: Dante Galli
Project coordinator organisation name: D'Appolonia first revision

TABLE OF CONTENT

1 Project Execution

Main objective of the project was to develop a novel hybrid fabric based on superelastic fibres to manufacture a new concept of compression hosiery that overcomes current limitations, hence by guaranteeing the following improvements (in decreasing order of importance):

1. to reduce wearing forces;
2. to prevent damage of the elastane yarn and fabric due to or overstretching while putting the hosiery on;
3. to guarantee as much as possible constant compression stress levels during normal day activities (constant dynamic stiffness index during wearing, that is one of the real add-on in modern compression hosiery);
4. to increase the compliancy, hence to guarantee as much as possible the desired compression stress levels for patients with different leg dimensions.

During the 28 months' project time partners have progressed remarkably in each work-package and the final compression hosiery demonstrator was successfully manufactured and tested.

In order to design the innovative compression hosiery, a preliminary scientific analysis has been carried out to analyze the properties of several superelastic alloys (Nickel-Titanium based binary alloys and Copper based ternary alloys) and complementary textile fibres to be used in order to manufacture the hybrid textile structure. Furthermore, also an investigation on methodologies and technologies to cover the superelastic wires were performed as well. The investigation on Shape Memory Alloys has led to the conclusion that the NiTinol is the best alloy for the envisaged application. It is interesting to notice that the performed scientific analysis allowed to the selection of practically only a type of NiTi wire, considered as the best choice, but provided in two different state: as drawn or straight annealed, depending on when the final heat treatment to the hybrid textile structure has to be applied.

Finally, the as drawn state was chosen as the best choice, having developed a novel heat treatment method to shape set the wire in the desired shape. The original principal reason behind the application of the shape set NiTi yarns was the need to extend the elasticity of NiTi yarns from

~5% to beyond 130% taking advantage of the geometrical deformation of the shape set structure (due to superelastic unbending). Furthermore the super-elastic behaviour of the shape set NiTi wire allows the winding on different spools (cylindrical or conical) and the processing in a conventional circular knitting machine without damaging the material and without affecting the shape set by the developed novel shape setting process.

As far as the hybrid yarn (superelastic wire plus complementary textile fibres) is concerned, the performed scientific analysis allowed the selection as best manufacturing method the hollow spindle yarn covering, which is one of the most important production techniques to achieve multi-component yarns with various characteristics depending from the application. In hollow spindle covering, the covering yarn is spooled around a spool with a hollow centre, the hollow spindle, and wrapped spiral-wise around a core yarn, which is drawn through the hollow spindle. The core yarn results thereby wrapped by the covering yarn(s) and is then taken up on cross wound bobbins.
This method was successfully tested to manufacture several samples of covered superelastic yarns, as presented in following figures.

Figure 1: Hybrid coretwist NiTi yarn

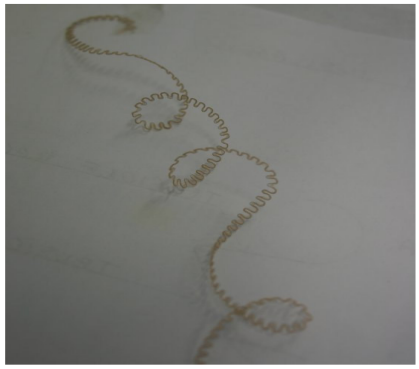

Figure 2: Shape set hybrid NiTi/PA yarn

The second part of the project was dedicated to the development of the hybrid textile structure constituting the basis for the detailed design of the novel compression hosiery. It has to be noticed that the approach towards the design of the superelastic medical hosiery has significantly evolved during the course of the project. Finally, a semi-integrated approach consisting in knitting an interlay NiTi yarn in a form of shape set wire structure into the common elastane knitted fabric was selected as the most promising approach. The technology to produce the NiTi snaked yarns

from as drawn NiTi wires 0.05mm diameter was developed by IoP ASCR, D'Appolonia and GZE Espace and several medical hosiery samples were produced at TEA.

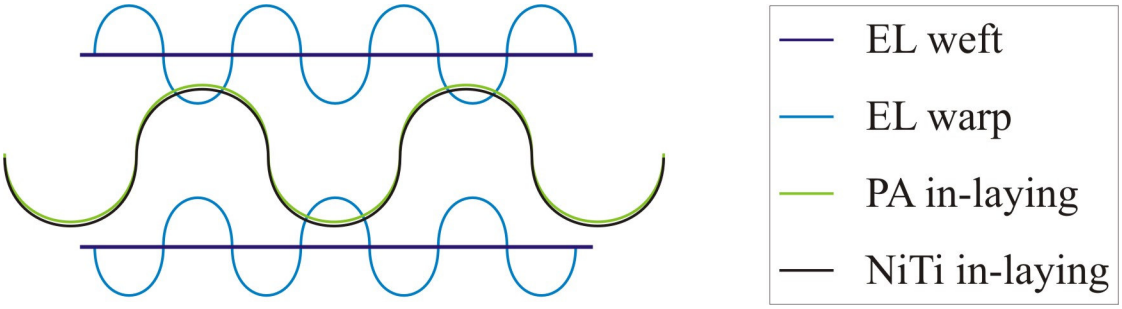

Figure 3: Loose&Tight Hybrid Textile Structure

In later stages of the hosiery development, it was empirically found that even if straight annealed NiTi wire is loosely integrated into the knitted fabric, it will form into a snake like structure by the neighboring elastan yarns and it will still conform the requirements on the development of gradual compression stresses. However, there is crucial difference between the shape set snake yarn and straight wire formed into-snake shape by the fabric. Due to the peculiar features of the superelasticity of NiTi yarns in bending (wire creates sharp edges upon bending over small radii), the NiTi wire knitted as interlay yarn into fabric causes extreme discomfort for patients even if it has been cotton spun. The only solution to avoid this discomfort due to the sharp edges was hence to use the NiTi wire already shape set into snaked yarn with controlled radii.

This result was successfully achieved thanks to the complementary efforts of all project partners which lead to the development of an innovative manufacturing process of continuous snake shape set superelastic wires, then covered with complementary textile fibres and inserted into the compression hosiery.
The final demonstrator was hence manufactured with the following steps:

1. unwinding of the "as drawn" Nitinol wire from the commercial biconical spool;
2. knitting the NiTi wire with KDK process;
3. production of a tubular structure and placement of the tubular fabric on a continuous spiral support which allows to maintain the tubular design during the thermosetting, and further steps

4. shape setting of continuous snake Nitinol wire at (with proper temperature and time settings) in air atmosphere and cooled in air with the use of a tunnel furnace that would allow the heat treatment of a virtually infinite-long knitted fabric;
5. unravelling of the knits and winding of the wire under proper tension on a conical spool;
6. double covering of the snake shape set, before in S turn and then in Z turn, using for each sample the beige polyamide yarn covered by elastomer with a count of 40/2 and collection in three cylinders
7. rewinding into 4 conical spools having size suitable to be inserted in the feeder system of the circular knitting machine at TEA;
8. after an analysis of the possible knitting options, it was observed that the most suitable solution was to couple the snake shape set hybrid NiTi/PA yarn together with the nylon yarn and inserting them by in-laying technique obtaining at the end the production of the final “Loose&tight” compression stocking as presented in the following figure.

Figure 4: Loose&Tight final compression hosiery demonstrator

The demonstrators were tested according to standard norm CEN-ENV 12718, showing a compression class of 1, hence respecting standards and guaranteeing that the articles are ready to be commercialised.

Consortium

The LOOSEandTIGHT consortium consists of three RTD performers and six SMEs. Contractors Contacts are given in Table 1:

Table 1: List of participants of LOOSEandTIGHT Project

Partner name	Web site (contacts)	Country
D'Appolonia S.p.A.	www.dappolonia.it e-mail: dante.galli@dappolonia.it	I
TWISTA	www.marioboselli.it e-mail: salvo.vielmi@twista.sk	SK
Diameter Ltd	www.diameterltd.co.uk e-mail: tony.anson@diameterltd.co.uk	UK
TEA S.n.c.	www.medicaltea.it e-mail: medical@medicaltea.it	I
ELLA-CS s.r.o.	www.ellacs.eu e-mail: karel.volenec@ellacs.cz	CZ
Elettronica Applicata all'Automazione S.p.A.	www.eaa.it e-mail: traverso.ubaldo@eaa.it	I
Jé-Bé International Textiles b.v.b.a.	www.viafil.com e-mail: jef.viaene@pandora.be	B
Grado Zero Espace S.r.l.	www.gzespace.com/new/ita e-mail: looseandtight@gzespace.com	I
Institute of Physics Academy of Sciences of the Czech Republic v.v.i.[2]	www.fzu.cz e-mail: sittner@fzu.cz	CZ

LOOSEandTIGHT project was financed by the Sixth Framework Programme of European Commission.

2 Dissemination and Use

In LOOSEandTIGHT, the following innovations have been developed:

- a novel **manufacturing process** to produce virtually infinite length superelastic wires properly shape set (in the frame of the project the chosen shape is the “snake shape”, but the methodology can be extended to different shapes according to the envisaged application), and the associated processes to wind and un-wind the so produced superelastic wires on proper spools by controlling the tensioning during the winding process;
- a **novel hybrid superelastic yarn** composed by Nickel-Titanium Alloy (Nitinol) wires (both straight or in the snake shape set from) covered with different complementary textile fibres (elastane, cotton) with the desired superelastic properties and improved aesthetic and comfort properties for wearing purposes; ;
- a **novel hybrid textile structure** represented by a semi-integrated approach consisting in knitting an interlay NiTi yarn in a form of shape set wire structure (snake form), properly covered with complementary textile fibres, into the common elastane knitted fabric. This structure is able to exhibit a double effect very effective in compression hosiery application: a geometric elongation effect, thanks to which it is possible to consistently reduce the wearing force and a superelastic effect that guarantees the constant compression level during wearing

A mathematical model (design tool) for the prediction of the compression level exerted by the compression hosiery has been developed as well. Within the proposed concept of the Design Tool, the behaviour of the knitted elastan fabric is taken as an input (determined experimentally). The superelastic force-elongation response of the NiTi snaked yarn (bundle of No N of snaked yarns) is simulated and both mechanical responses are deemed to be connected in parallel (the snaked NiTi yarn is integrated as interlayed yarn into the elastan fabric). The model is able to predict with good results the behaviour of the compression hosiery in terms of compression profile, and, from the following figure, it is possible to see the great difference between standard compression hosiery (red curve, high force required during wearing) and the novel developed compression hosiery (blue curve), in which is evident the advantage in terms of very low force required to obtain the necessary elongation for wearing, but at the same time the right compression force exerted during usage.

Furthermore, during the development of such tasks, a novel heat treatment method has been conceived and developed (the already demonstrated proof of concept has facilitated a GB patent application, “Heat Treatment Method for a Composite Textile”, with Patent Application number GB0617613.5). This novel heat treatment method is really very interesting for a number of applications (from compression hosiery and medical stents, to technical and geo-technical textiles, hybrid composites structures, etc.) because it would highly simplify the production process, only adding this final heat treatment at the end of the cycle. In this way, the superelastic wire, once covered with complementary textile fibres, can be inserted into the usual knitting machines without any changes to the cycle, and in the desired architecture, with no stresses and alteration of its behaviour.

Result Description	**Possible market applications**	**Stage of development**	**Collaboration sought or offered**	**Collaborator details**	**IPR granted or published**	**Contact Details**
Novel manufacturing process (continuous superelastic yarn shape set)	Composite reinforcement for high energy absorbing applications	Demonstrator	Collaboration	Sandonini	None	elena.turco@gzespace.com
Novel hybrid superelastic yarn	Technical textiles, sport textiles, medical textiles	Demonstrator	None	None	None	elena.turco@gzespace.com dante.galli@dappolonia.it
Novel hybrid textile structure	Technical textiles, sport textiles, medical textiles	Demonstrator	None	None	None	elena.turco@gzespace.com dante.galli@dappolonia.it
Novel heat treatment method	Technical textiles, sport textiles, medical textiles, advanced composites	Demonstrator	None	None	Draft patent GB0617613.5	tony.anson@diameterltd.co.uk dante.galli@dappolonia.it
Design tool	Compression hosiery, medical stents	Demonstrator	None	None	None	sittner@fzu.cz dante.galli@dappolonia.it