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Contribution to the Improvement of Textile Vascular Prostheses Crimping

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ABSTRACT

Textile vascular prostheses implantation is today a common surgical procedure in the management of patients having severe blood circulation difficulties. The development of the "ideal" synthetic graft has been a challenge in vascular surgery throughout the years. Mainly related to the biological behavior of the used materials, the process of prosthetic graft failure is attributed to multiple factors. The textile graft complications can be, in part, due to the reliability of prosthesis finishing processes, especially wall crimping step. In the present study, a new thread-winding process for prosthesis crimping is described. A cord winding operation realized at controlled tension has been added to the crimping process. This new technique is applicable to almost all woven or knitted vascular prostheses. A microscopic study permits to confirm the regular crimps configuration necessary to preserve regular blood flow and easy prosthesis flexion essential for particular implantation sites such as at knee level.

Key words: Vascular prosthesis, crimping, polyethylene terephthalate, tubular fabric

INTRODUCTION

Cardiovascular surgical devices are commonly used for patients suffering from the hardening and narrowing of arteries generally known as atherosclerotic heart disease which can be treated using coronary artery bypass graft surgery. During this surgery, a deviation is created around clogged arteries to improve blood flow through the heart (Safaei *et al.*, 2010). The world market for traditional cardiac surgical devices is estimated at $7 billion in 2010 and is expected to reach $12 billion in 2015 (Lehr, 2010). This market is expected to be driven by demographic and epidemiological patterns, the availability of new technologies and improved products, such as vascular prostheses, stents and heart valves and a rise in affordability levels especially for China people.

Vascular prostheses have been in routine clinical use for six decades. A large variety of synthetic textile fibers including Ivalon, Orlon, Nylon and Dacron, as well as non-textile materials (Teflon) have been tested for prosthetic applications. Moreover, several textile structures including woven, knitted (both warp and weft-knitted) and velour fabrics have been developed and implanted in millions of patients, but they suffer from various complications, associated with structural defects such as lack of compliance, dilatation and resistance to the blood and obstruction of prostheses (Pourdeyhimi, 1986). Both surgical and manufacturing techniques have evolved concurrently. Nowadays, the textile watertight implants of polyethylene terephthalate (PET) share the market with those moulded in one single piece of expanded polytetrafluoroethylene (ePTFE) (Mantovani *et al.*, 2003). Other investigations (Yang *et al.*, 2009; Grasl *et al.*, 2010) have been devoted in recent years to the use of polyurethane prostheses, as well. The reconstructive vascular surgery uses extruded PTFE grafts for small diameters (6mm and less), while textile PET prostheses are widely implanted when grafts of medium and large-caliber arterial bypass (more than 8mm in diameter) are required as they perform better in high blood flow. Biocompatibility, biostability and high tensile strength of PET, used for a long time as suture threads or artificial ligaments, have long-been well documented (Ben Abdessalem *et al.*, 1999; Medical, 2001; Rajendran and Anand, 2002; Marzougui *et al.*, 2009).

The first vascular prostheses were very primitive, made from industrial fabrics and materials generally intended for use in clothing (Chakfe *et al.*, 2004). Now-a-days, textile vascular grafts, commercially available (Table 1), are produced under specific controlled conditions and in very small quantities.

After removal from the knitting-machines or looms, the tubular fabrics undergo special treatments before being packaged. Since textile structures, especially knitted ones, are initially too permeable to liquids for direct application, they have to be subjected to compaction to reduce their porosity to acceptable levels. This is accomplished by either thermal or chemical treatments. For imparting kink resistance and increasing their flexibility, textile vascular prostheses are also crimped by using thermal treatments. Finally, the grafts must be sterilized prior to implantation to free them of micro-organisms that could lead to infection (Guidoin *et al.*, 1982). Although these prostheses are generally considered to be reliable, reports in the medical literature have revealed incidents where these grafts have failed (Dieval *et al.*, 2003; Van Damme *et al.*, 2005; Scharn *et al.*, 2006). These failures have been attributed, in part, to the post-manufacturing processes briefly described above (Chakfe *et al.*, 2001). It has been suggested that the failure of the grafts may be due to alterations caused by thermal treatments such as compaction and crimping (Ben Abdessalem *et al.*, 2009). Further attention should be then drawn to prostheses manufacturing and finishing procedures.

Table 1: Main commercially available textile vascular prostheses

Manufacturer	Prostheses trademarks	Specifications
C. R. Bard, Inc., US	Wovex®, Dialine®, DeBakey®, Bard®, Velex®	Collagen impregnated knitted or woven grafts, either smooth-walled or velour with texturized outer wall and flat-yarn inside graft
Vascutek Ltd, UK; Terumo Corporation, US	Fluoropassiv®, Gelsoft®, VP1200K®, Gelseal®, Gelweave®, Twillweave®	Woven or warp-knitted, zero porosity, gelatin impregnated, crimped or externally reinforced vascular prostheses with "floating yarns" on external surface
Atrium Medical Corporation, US	Ultramax®	Gel impregnated and zero porosity knitted double velour vascular prostheses
Perouse Medical, FR stretch	Polythèse®, Polymaille®	Collagen impregnated woven velour and extra thin knitted prostheses with helical reinforcement
Meadox Medicals; Boston Scientific Corp., US	Microvel®	Knitted double velour prosthesis
B. Braun Melsungen, GE	Protegraft®, Uni-Graft®	Woven and knitted double microvelour low porosity prostheses

The first generation of vascular grafts was made of woven fabrics that were hand-sewn with the edges cuffed in order to prevent fraying (Pourdeyhimi, 1986). These early grafts demonstrated difficulties after the implantation because of their lack of compression resistance and their tendency to kink and collapse. In fact, kinking creates a major problem, especially when the graft is applied at bone joints that bave an extensive range of movement, such as hip joints.

The problem appears to have been solved by the works of Tapp who patented an original method of prosthesis crimping (Tapp, 1958). His discovery occurred when braided-nylon tubes placed over a glass rod were being soaked in formic acid in order to weld the edges and thereby prevent fraying. When he removed the tube from the glass rod, he noticed the formation of an "accordion" pleat. Tapp's crimping method consisted then in applying stiffening treatment to a braided nylon tube mounted upon a glass mandrel. The whole device was treated in a 73% concentrated aqueous solution of formic acid during 20 sec. One end of the tube, still retained by tying cotton cords, had been initially pushed along the smooth mandrel until a compressed circular pleat effect was produced. The circular crimps thus formed were made permanent by heat setting in an oven at 130°C during 30 min. Although the patent specifications referred to the applicability of this technique to any synthetic fiber, it has been found useful mostly for polyamides (Pourdeyhimi, 1986). Several other patents (Jeckel, 1967; Koch and Demarest, 1990) tried to improve Tapp's crimping method, but the subsequently universal developed manufacturing techniques are owing to Roberts (1957) for "mould-crimping technique" and Starks (1962) for the "thread-winding process".

In mould-crimping technique, wavy form is created by the application of internal steam pressure in a mould designed according to the required configuration. The process normally produces a circular crimp, although the mould may be modified to produce a helical crimp configuration. The mould includes a rigid elongated shape having to be inserted into the textile tube, an inflatable radially-stretchable cylindrical body extending there-over, several spaced rigid rings encircling the rigid form within the flexible body and being secured at equi-spaced intervals to the inflatable body to prevent its radial expansion at spaced intervals and thereby form the troughs of crimps once the body is inflated (Roberts, 1957). This complex apparatus is specially suited to high bulk texturized yarns and velour that have to be delicately treated.

The thread-winding process, by contrast, produces a helical-crimp configuration and tends to flatten the filamentous feature of velour. In the thread-winding process, crimping is obtained by spirally winding a thread around the tubular fabric previously fitted on a smooth surfaced mandrel, the graft being compressed at both ends until small wrinkles are formed throughout the length of the textile tube. After fabric wrinkling, the mandrel with textile tube is introduced into an oven to give the fabric a permanent set (Starks, 1962). It is significant that the mandrel has to be smaller than the textile tube itself to permit this fabric wrinkling upon the mandrel. Despite the use of a double wind with reverse helix as suggested by Starks (1962), problems of slippage between winding thread and fabric can not be properly controlled. This slippage involves variations in crimping dimensions throughout the same prosthesis portion. Hence, the regularity of blood flow would not be guaranteed. The crimping process confers radial resistance to external compression and longitudinal compliance to the polyester tube wall and improves the grafts flexibility (Ben Abdessalem *et al.*, 2005). It is clear that these advantages might be compromised if crimping is not correctly performed.

The present study was aimed to conceive and develop a new crimping method for woven and knitted PET prostheses that preserves the textile structure and realizes regular crimps. For this purpose, a new device was built to improve prosthesis crimping quality and preserve the graft performances.

MATERIALS AND METHODS

For crimping experiments, plain weave samples were manufactured. A woven fabric is a textile structure formed when two sets of yarns are interlaced. The longitudinal yarns are known as the warp and widthwise yarns are known as the weft. Plain weave is the simplest of all weaves: the warp yarns lie alternately over and under the weft ones. Despite their simplicity, plain woven fabrics have the highest number of interlacing and are, therefore, the most dimensionally stable structures. They exhibit high bursting strength, minimum tendency to fatigue, and low permeability to liquids (Mokhtar *et al*., 2009).

The specimens were produced as PET seamless tubes on an ARM shuttle handloom (Switzerland). The weft yarns were produced by Setila S.A. (Setila®) and the warp ones by Diolen Industerial Fibers Inc. (Diolen®) (Table 2).

A standard drawing of 149 ends, taken-up on one warp beam, had been fulfilled through 8 healds and a 20 dents cm^{-1} reed. The obtained fabric presents a width of 32×2 mm, a warp count equal to 23.3 ends cm^{-1}, a pick count equal to 32.8 fillings cm^{-1} and 0.21 mm as thickness.

The primary idea was to use weft yarns that have a very high shrinkage (68% at 200°C-2 min) in order to involve crimping formation only by heat setting and avoid mechanical solicitations applied to the textile structure as in classical crimping techniques (Le Magnen *et al*., 2001). This high shrinkage is not common for ordinary polyester yarn applications. In fact, this high shrinkage is specific to partially-oriented yarns generally intended to be texturized. We have thermally stabilized the warp yarns in order they tolerate the weaving load without rupture. The tubular structure was fitted on a helically threaded mandrel made of copper which is an inert material that has a good thermal conductibility. Then the woven fabric was heat set with hot air by using a Roaches fixing stenter (England) at 200°C-2 min. After heat setting and free relaxation, a 22% shrinkage in weft direction was registered, but polyester samples did not show franc crimping. Despite their very high shrinkage character, weft yarns did not come close to mandrel threads. Therefore, we manufactured an internally threaded cylinder axially divided into two equal parts tightened with nuts on the tubular fabric fitted on an externally threaded mandrel (Fig. 1). We tested various thread dimensions, but only irregular crimping was obtained. In order to better apply crimping shape, we wound a cord around the threaded mandrel. This closely guided the fabric into the thread and gave thereby a regular crimping configuration.

We tested various thread dimensions (depth and frequency) for different mandrel diameters. It is worth noting that before crimping, the woven tubes had been treated in a washing

Table 2: General properties of PET yarns used in samples weaving

Yarns	Linear density	Yarn structure	$\mathrm{HAS}_{200^\circ\mathrm{C}\text{-}2\mathrm{min}}$	Tenacity (mN/tex)
Warp	280dtex, 48F	FOY, simple, Z130 tours m^{-1}	1.7%	650
Weft	170dtex, 88F	POY, simple, flat	68%	200

HAS: Hot Air Shrinkage, FOY: Fully Oriented Yarn, POY: Partially Oriented Yarn, F: Filaments count

Fig. 1: Two threaded mandrels crimping device

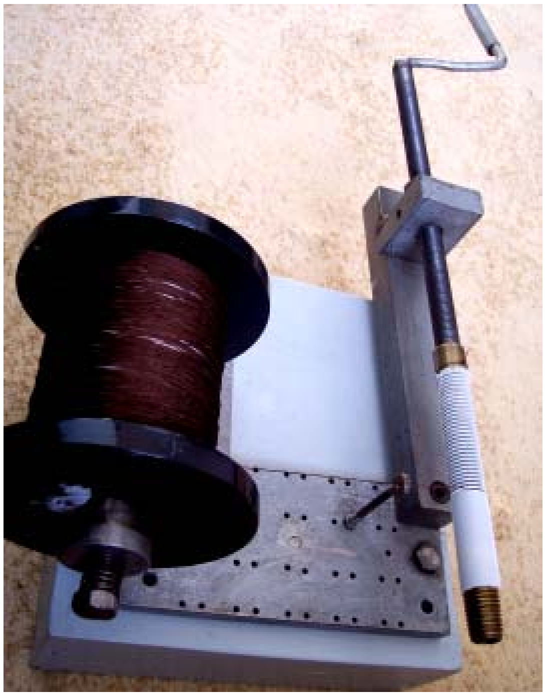

Fig. 2: The new cord-winding device

machine at 40°C-30 min with a detergent (Materge AP, 1 g/l) and then atmospheric dried. This treatment involved a small shrinkage due to the relaxation of textile structure and permitted the fabric to free from the oiling previously applied to yarns before weaving.

It is obvious that manual cord winding involves irregular cord tension and consequently irregular crimping shape. In order to apply a regular tension to the cord during winding around the threaded mandrel, we conceived a new device insuring constant winding tension. The threaded mandrel is firstly introduced inside the relaxed woven tube. The cord is wound around a spool in contact with a spring placed at its side and playing the role of a brake. The cord tension is set by using a bolt which regulates the spring compression. The cord is tied to the copper mandrel and the mandrel is fixed to a threaded rod which is rotated with a crank. When the crank is turned, the cord is regularly wound bringing thus tubular fabric close to the thread troughs (Fig. 2).

Table 3: General characteristics of tested winding cords

Crimping cord	Melting point (°C)	Linear density/diameter	Breaking load/tenacity
Copper wire	1085	0.45 mm	44N
Fish-hook PP monofilament	165	0.55 mm	129N
Three-ply polyester yarn	255	180 tex 0.40 mm	64N 36 cN/tex
Two-ply polyester yarn	255	115 tex 0.30 mm	52N 45 cN/tex
Braided polyester yarn	255	64 tex 0.25 mm	33N 52 cN/tex

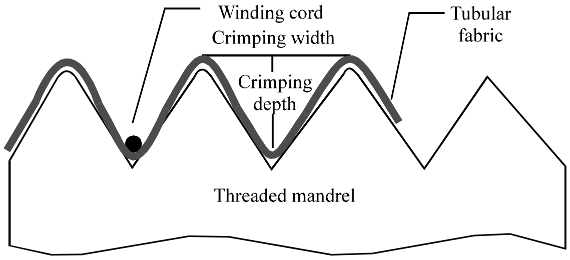

Fig. 3: Configuration of threaded mandrel and tubular fabric (axial section)

The cord has to be made of inert material and resist to elevated heat setting temperatures applied to PET tubes. Several cords have been tested: a copper wire, a fish-hook polypropylene monofilament, plied multifilament polyester yarns (currently used for leather stitching) and a braided cord composed of eight polyester yarns (Table 3).

It is noticeable that the polypropylene fish-hook monofilament was difficult to handle when wound around the mandrel because of its great slippage. The convenient cord has to show a balance between both fineness and high tensile strength. In fact, this cord is inserted into tight conical threads, therefore thinner, the cord is, easier it would closely drive the fabric into thread cavities (Fig. 3) and more flexible will be the textile tube. At the other hand, the cord must have enough tenacity to endure, without rupture, the high tension that would be applied during winding procedure.

The tubular polyester samples wound with the different kinds of cords were heat set in a stenter at 200°C during 3 min except the fabric wound with polypropylene monofilament which was treated at 140°C during 5 min because of its relatively low melting point in comparison to the polyester one (Table 3). Then, samples were cooled by using water in order to provoke a thermal shock necessary for crimped walls to keep permanent their wavy form.

RESULTS AND DISCUSSION

All crimped tubes corresponding to the different winding cords showed regular crimp shapes and good flexibility (Fig. 4). At present, there is no any standard or official procedure permitting to measure prosthesis flexibility. The surgeon generally appreciates the prosthesis flexibility by observing the prosthesis tendency to collapse after manually curving the graft. As can be seen in Fig. 4, the crimped prosthesis can be easily curved at about 180° without collapsing. However, we noticed that copper wire damaged woven fabric at contact points and multi-plied as well as braided polyester yarns involved particularly interesting crimping results.

Fig. 4: Crimped tubes obtained with the new crimping process

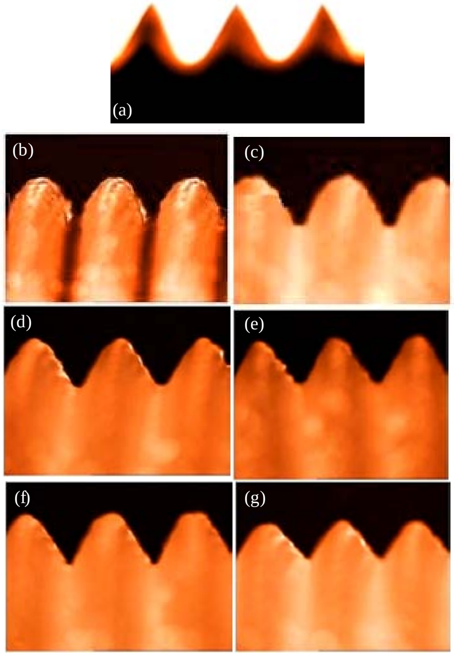

Fig. 5: Crimping configurations and dimensions (width/depth) obtained with different winding cords after heat setting: microscopic view (x20), (a): Mandrel thread form (mandrel major-diameter = 20 mm), (b): Copper wire wound on woven tube, (c): Crimping shape obtained with copper wire (3.1/1.6 mm), (d): Crimping shape obtained with fish-hook PP monofilament (2.8/1.6 mm), (e): Crimping shape obtained with three-ply polyester yarn (2.6/1.4 mm), (f): Crimping shape obtained with two-ply polyester yarn (2.7/1.7 mm), (g): Crimping shape obtained with braided polyester yarn (2.4/1.3 mm)

After heat setting, the obtained specimens showed different crimping shapes and dimensions. Crimping looks flattened at the bottom for specimens wound with thick cords (wire copper, fish-hook and three-ply yarn) (Fig. 5 c-e) and sharp and deep for those wound with either braided or two-ply yarns (Fig. 5 f,g). We measured crimping dimensions (width/depth) by using an optical microscope and an image processing software.

Crimping dimensions greatly influence the general behavior of the prosthesis (Le Magnen *et al.*, 2001). It affects not only the prosthesis extensibility and flexibility but also the blood flow and the deposit of thrombotic materials in crimp cavities especially in deep crimping case which often leads to prosthesis occlusion (Ben Abdessalem *et al.*, 1999). Crimping geometry and thereby both threaded mandrel dimensions and the nature of winding cord used in crimping procedure depend on crimping configuration required by surgeons according to the zone where the graft would be applied. Consequently, the crimping configuration depends on a big number of parameters such as graft diameter, required flexibility and compliance, thrombogenicity risk, blood flow, etc.

CONCLUSION

The development of the "ideal" synthetic graft has been a challenge in vascular surgery throughout the years. Most crimping processes described in literature have specific weaknesses and greater interest has to be directed to the improvement of manufacturing and finishing processes, especially crimping technique which deeply affects textile vascular prostheses biofunctionality.

A new winding process has been described in this paper. A cord-winding operation realized at controlled tension was described. The winding tension applied to PET fabric and the fineness of the cord are fundamental parameters to obtain the crimping shape and dimensions required by surgeons. This crimping process is applicable to woven and knitted textile vascular prostheses and permits to obtain regular crimps and perfectly flexible textile vascular graft.

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