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Novel methods for the mechanical characterization of patches used in carotid artery repair

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ABSTRACT

Carotid endarterectomy (CEA) is one of the approaches available for the treatment of carotid artery disease, with carotid patch angioplasty the pertinent technique mostly preferred by vascular surgeons. This technique entails an arteriotomy succeeded by closure with a textile, polymer or biological tissue patch. In this work, we propose microbuckling and microindentation as novel methodologies for acquiring the mechanical properties of patches used in carotid artery repair. Regarding microbuckling, the patch is loaded by a sensitive dynamometer at one end and its motion is recorded, at three different levels of axial deformation: $\delta/\ell = 0.1$, 0.3 and 0.5 (in the post-buckling regime). The corresponding experimental loads are recorded, as well. Following pertinent closed-from equations, various material metrics are obtained, such as the Young's modulus of elasticity and the so-called frictional couple of the material. Regarding microindentation, the material's hardness number is measured with the aid of a durometer. Similar to microbuckling, indentation analytical expressions allow for the determination of key material properties, such as the modulus of elasticity, indentation forces and depths. Where possible, we perform microtension to verify acquired results. Results demonstrate that measured properties may vary substantially for materials which are of the same type, due to variations of the material microstructure, as observed with optical and scanning electron microscopes (SEM). Several commercial patches were tested in this work. To shortly present the main results, the microbuckling technique furnished (for the Young's modulus) 40.17 MPa for the B/Braun Aesculap cardiovascular patch and 71.49 MPa for the Vasutek Terumo, while the microindentation technique, for bovine patches, provided 6.356 MPa for the Xeno Sure and 4.701 MPa for the Vascu-Guard. A test type recommendation is provided, relating the type of the patch material to the method more plausible in each case, in order to achieve better measurement accuracy. Results of this study can contribute in establishing guidelines and criteria determining material selection in CEA.

1. Introduction

Mechanical forces regulate multiple aspects of carotid vascular physiology and function and play a key role in vascular development and homeostatic mechanisms as well as during carotid arterial disease [1]. Carotid artery disease is an important public health issue. Moderate and severe (50%–99%) carotid artery stenosis affects approximately 10% of the general population by their 8th decade and causes about 10% of all strokes [2]. Thus, carotid endarterectomy (CEA), carotid artery stenting (CAS) or best medical treatment are the current treatment options [3]. Currently, the three principal approaches to CEA are: i) primary arteriotomy closure, ii) patch angioplasty and iii) eversion CEA (eCEA). Patch angioplasty and eCEA have been more popular among vascular surgeons, in contrast to primary arteriotomy closure, because of reportedly reducing the incidence of restenosis and including theoretical technical advantages [4–7].

Carotid patch angioplasty is the most popular technique among vascular surgeons and entails a longitudinal arteriotomy which extends beyond the plaque, both proximally and distally. This is typically followed by the use of a patch angioplasty closure technique. Closure of the arteriotomy with a patch minimizes the effect of neointimal hyperplasia and scarring, maintaining the arterial lumen diameter after

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the procedure. A broad variety of materials, each bearing its own advantages and disadvantages, is available. Currently, there are no guidelines concerning the selection of the material to be used in the quotidian practice of carotid endarterectomy, thus material selection primarily depends on the material availability at the host Vascular Department [8–10].

The objective of the study is to investigate the mechanical properties of various materials used as carotid artery patches, as well as to propose a methodology for accurately measuring them.

In this work, we propose two new methods that can be suited better for patch materials: Microbuckling for textile patches and microindentation for tissue patches. Polymer patches can be tested with microtensile devices.

2. Materials and methods

The most commonly used prosthetic patching materials are polytetrafluoroethylene (PTFE) and Dacron [10]. PTFE is a fluoride resin composed of carbon and fluoride only. Expanded PTFE (ePTFE) has a porous structure with 20 μm to 30 μm fibril distance and is also commonly used as a vascular graft. Its properties include resistance to thrombosis and the ability to support re-endothelialization. More recently, an elastomeric coating such as polyurethane has been applied to the outside surface of ePTFE patches to minimize suture hole bleeding. Dacron is a polyester fiber, a condensation polymer of ethylene glycol and terephthalic acid, showing high tensile strength and resistance to stretching. Woven or knitted sheets of Dacron are commonly used in vascular surgery, including use as vascular grafts [10]. Synthetic arterial prosthetics are expected to be about ten times less distensible than the host arteries [11]. Dacron's elastic modulus varies depending on its thickness and microstructure: double velour is about three times softer than the knitted counterpart [11,12]. Moreover, Dacron seems to sustain a high stress concentration of the suture line.

During the past 20 years, bovine pericardium has also emerged as an alternative material patch for arterial closure after vascular surgery. Vascular surgeons adopted the use of bovine pericardium due to various technical advantages, including easy handling, less suture bleeding and the ability to immediately perform arterial duplex examination at the site of angioplasty [13,14].

Recently, several studies have compared the materials used for patch angioplasty, concluding that more data are required to clarify differences among different patch materials [4–6]. Nowadays, there is a great controversy regarding the precise role of patch angioplasty widely used for the performance of the operation. Although the basic aims of surgery are always the same, the exact techniques utilized vary among surgeons. The differences in the postoperative morphological and hemodynamic conditions of carotid arteries of patients undergoing CEA have been observed and emphasized by numerous researchers [15–21] but the quantification of the associated blood flow indexes has been employed only by few groups [22–25].

Patch materials used in carotid artery repair fall mainly into three categories: textiles, polymers and tissues. These materials are very thin and have very small dimensions. Use of microtensile devices can run into several problems such as griping of the specimens and assessment of homogeneous stress fields. We should also emphasize the size dependency of the elastic properties of vascular patches. Contrary to the cylindrical grafts, fabric patches are tailored cut to the particular CEA operation. The edges of the cut could release the locked prestress of the fabric and this affects directly its elastic modulus (generally reduces it). It is therefore important to have ways of assessing the elastic modulus of textile patches of different sizes. Not all patch material can be tested with the same technique. For example, biological tissue, such as bovine pericardium, cannot be tested with a simple tensile device, since the gripping procedure could destroy it, owing to its softness and sensitivity, unless special custom-made devices are to be used, see for example [26].

2.1. Observations

Several commercial vascular patches have been examined in the context of this study. They were examined with a Scanning Electron Microscope (SEM model: JEOL JSM 5310) in order to pinpoint differences in their microstructure, a factor that seems to influence mechanical properties. The samples were sputtered with a special coating of gold, 10 Å thick (ion sputtering device JEOL JFC-1100E), so as to enhance conductivity and provide better observations results. Acquired images are illustrated in the Results section (Figs. 9 to 14). Images were also acquired with a common camera, in order to capture microstructure visible at the macroscopic level.

2.2. The microtensile testing methodology

This simple and "traditional" methodology has evolved for testing biomaterials, such as bioprosthetic heart valve tissue, see for instance [27] and references therein, or human arteries of various types, as per [28]. Nevertheless, it has been seldom employed for specifically characterizing vascular patches [29].

An MTS load frame with grips specially designed to handle the small thickness patches was used in the context of this work to test polyester fabrics. This methodology's measurements also served as a comparison for values acquired with the microbuckling methodology, as will be presented in the following. The following patches where tested in this manner: Bard Sauvage Filamentous, Gore Acuseal and Vasutek Terumo. The gauge length was adjusted to 7 cm for all measurements.

2.3. The microbuckling testing methodology

In this section, microbuckling is presented as a testing technique for measuring overall elastic moduli of patches in the form of woven or knitted fabrics. The B/Braun Aesculap and the Vasutek Terumo patch were tested in this fashion.

Grosberg's method [30] is implemented in order to obtain the textile bending rigidity, B, which is the prime unknown parameter of this methodology. This method assumes that the bending moment, M, due to bulking must first overcome a threshold value, the so called frictional couple M_0 [31,32], which is to be determined, as well.

Fig. 1 presents the microbuckling configuration. The textile patch is loaded by a sensitive dynamometer at the upper end, with the patch dimensions known prior to the test. The vertical motion of the loaded tip, $\delta\ell$ is also recorded. No special type of gripping is required and the specimen length ℓ can be small.

$$M \to \infty \quad \text{for } M \le M_o \tag{1}$$

$$M = BK + M_o \quad \text{for} \quad M > M_o \tag{2}$$

The overall buckling response (Eqs. (1) and (2) is depicted in Fig. 2.

With regard to the notation of Fig. 1, the basic equations of Grosberg's analysis are as follows:

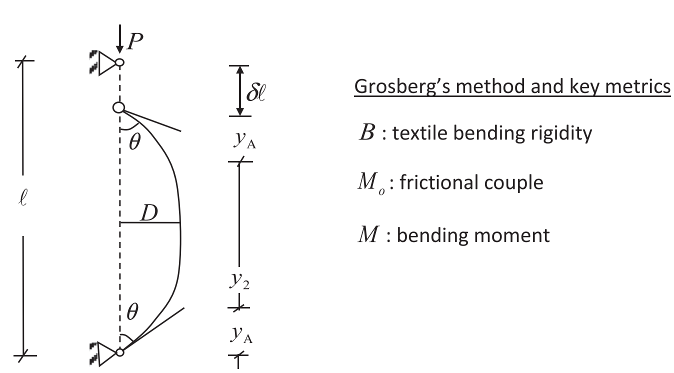

Fig. 1. The microbuckling configuration.