

National Textile Center

FY 2003 (Year 12) Project Proposal

Project No.

F03-AE02

Competency: Fabrication

TEXTILE PROSTHESES FOR VASCULAR APPLICATIONS

Project Team:

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Objective:

The objective of this project is to develop a new class of implantable endoluminal prosthesis for biomedical applications based on advanced textile technology. The most likely initial application will be in the field of arterial circulation. Fundamental research in the area of textile base endoluminal devices has been initiated in Germany, Japan, and Argentina. An integrated program involving academic and industrial centers of textile engineering has yet to be initiated in the United States. As a result of this project, applications of textiles in medical technology will be expanded in the U.S.

Relevance to NTC Mission:

On an annual basis, the number of vascular surgical procedures performed in the U. S. is estimated at 600,000. On the basis of these figures, the projected U. S. market for vascular prostheses by the year 2005 is expected to exceed half a billion dollars annually. The growth of low-volume, high performance specialty markets represents an increasingly important segment of the textile industry. The focus of this project on the development of a high-precision textile formulation will establish fundamental principles for both the manufacturing techniques and material selection in the creation of an important class of life-saving biomedical devices.

State of the Art:

In order to avoid major surgery, catheter delivered metallic stents have been utilized with increasing frequency to mechanically expand narrowed arterial segments. However, the current generation of metallic devices do not have the necessary flexibility to be utilized for the treatment of extended lengths of arterial diseases. Nor can they be utilized if the artery is dilated and at risk of rupture. We believe that current textile based technological approaches can be extended to the design and fabrication of a catheter delivered device, precisely integrating textile with metal and/or polymer components. Specifically, this work will focus on the design and fabrication of circumferentially supported devices of varying configuration and length which are self anchored at each end after implantation. Critical design requirements include: high radial compressibility for catheter delivery, self expansion to serve a large range of internal luminal diameters, device flexibility to accommodate routes, and appropriate tensile properties to prevent tubular collapse and migration.

According to the medical doctors, the best treatment is to avoid a bypass surgery. Many kinds of stents have been used for years in Europe, but only two metallic stents are approved for use by the U.S. Food and Drug Administration for coronary arteries. The Palmaz-Shatz metallic stent, manufactured by Johnson and Johnson, is used as a primary treatment alternative to angioplasty, for the express purpose of trying to reduce re-stenosis or narrowing of the arteries (Figure 1).

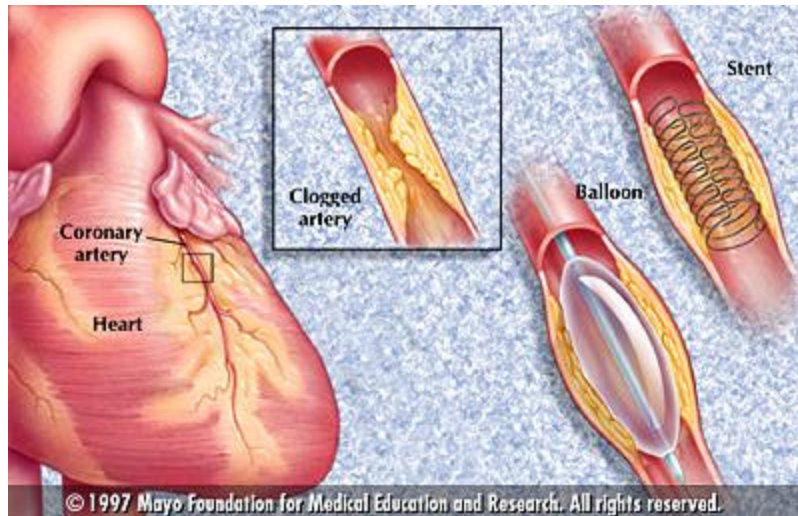


Figure 1. Application of stent for clogged artery (www.mayohealth.org)

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Approach:

The design principle for a catheter delivered vascular prosthesis consist of integrated sealing and reinforcing components. The sealing component will comprise a seamless tube braided, woven or knitted from textile fibers that contains the blood flow. The reinforcing component adds structural integrity to the sealing component and ensures that the device remains open after it is initially expanded following delivery. The reinforcing component will also serve to prevent device migration. Unlike stents alone or stent-graft hybrids, which consist of two separate devices fastened together, our approach will develop these components concomitantly so that both will move isotropically together. Cyclic stresses due to the pulsatile nature of arterial blood flow will inevitably cause mechanical failure at the connection points. The desired 30-year performance period will subject the device to almost 1 billion uninterrupted cycles. Thus, the approach outlined has the inherent advantage of reducing the concentration of mechanical stress that will be responsible for device failure.

The base case will consist of reinforcing polymer component braided into a tube, and overbraided or interbraided with several layers of textile fiber (e.g. polyester). The ends of the reinforcing component are flared so as to prevent migration of the device. Both component braids will have the same geometry so as to afford isotropic movement of the two components. Based upon these suppositions a rational design requires an integrated approach involving three distinct areas: (i) material selection (ii) textile processing, and (iii) characterization of biomedical performance.

Reinforcing and sealing component: The optimal reinforcing component will consist of a very flexible material that can be woven or braided and then rendered sufficiently elastic and stiff via post processing such as thermal annealing. The reinforcing component will have sufficiently high modulus so as to remain expanded and

prevent migration in the blood vessel. The sealing component will consist of a textile or modified textile fiber that can be woven or braided into a seamless tube.

Interbraiding or interweaving of components: The integrated assembly must be accomplished so that both components move isotropically with the periodic expansion and contraction of the blood vessel. The sealing component must also have sufficiently low porosity to prevent blood loss. Optimal weave or braid geometry that satisfies these constraints will be determined.

Degradation and mechanical performance: Creep, fatigue properties, and tubular bursting measurements will be characterized at each iterative step of the design process. Circumferential and longitudinal tensile strengths should exceed those measured in arteries (1.47 and 5.29 MPa respectively), and the compliance of the device will be matched to typical arterial values. Porosity of the device will be balanced between mechanical and hemostatic constraints.

Device migration: Migration of the device will be characterized by applying traction to test devices in human aortic specimens in vitro. Surface induced blot clots: Abnormal flow patterns can precipitate clot formation. Devices that meet the mechanical constraints outlined above will be implanted into animals and clot formation will be characterized using radio-labeled platelets and non-invasive nuclear scintillation techniques.

This Year's Goal:

Textile Goals: A catalog of all potential materials for use as the sealing component will be established and include known physical and biocompatibility properties. This list will be reviewed for further evaluation with regard to braiding and weaving constraints. Several candidate materials for the reinforcing components will be chosen and fashioned into preliminary geometries. For example, if high temperature carbon fibers are recommended as a candidate for the sealing components, metal materials will be considered for the reinforcing component.

We will determine the recommended textile technique for the integrated assembly of the sealing and reinforcing component (i.e., braiding, weaving). A critical property comparison of woven, braided, and knit structures will be performed in order to identify the best structure. Additionally, we will work out the optimum geometric and fabric parameters of the recommended braid or weave (i.e., plain versus twill weave, warp or weft knit, biaxial or triaxial braid, etc.) so as to produce a highly isotropic device. Auburn University has the necessary braiding, weaving, and knitting equipment to produce prototype fabric preformed structures.

Biomedical Goals: The first year biomedical goals will be to assemble a tensiometer device to quantify migration as a function of the axial load. In addition, a device will be built to measure static compliance as well as the creep and tubular bursting strength. As the project progresses, its emphasis will shift from material selection to the textile technology area and finally to the biomedical area.

Outreach to Industry:

Medical device companies which have expressed an interest in the proposed design include: Cordis Corporation (a branch of Johnson&Johnson), Meadox Medicals Inc., Bard Inc., National Medical Technologies, Inc., and Intervascular Inc. However these companies have limited resources for textile research and development. Given that these devices can be produced by natural extensions of current textile manufacturing processes, textile companies are in a unique position to develop such devices. The optimal industrial calibration will involve this NTC supported research with both textile and medical device companies.

New Resources Required:

This project will unite three distinct areas of expertise in the textile, material and medical fields. Dr. Adanur will provide expertise in textile engineering including industrial and medical textile manufacturing. Dr. Warner will cover the area of material processing and characterization. Dr. Chaikof is both a professor of vascular surgery at Emory University and on the biomedical and chemical engineering faculties at Georgia Tech. Mr. Kirk Johnson is the Director of Product Development at Cordis Corporation, a division of Johnson & Johnson and manufacturer of medical devices. No major capital equipment purchases is necessary. Two graduate students are needed for the project.