

‘DESIGN AND MANUFACTURING PROCESS FOR A VASCULAR GRAFT’

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Vascutek Company Business

Manufacture of high quality vascular prostheses for human implant.

Abdominal Aortic Aneurysms (AAA), a life-threatening disease occurs when a section of the abdominal aorta, the body's main circulatory vessel, weakens and bulges outwards. Endovascular grafts such as the Anaconda (manufactured by Vascutek Ltd) are used to treat AAA using a minimally invasive surgery approach.

Project Aims and Drivers for Development



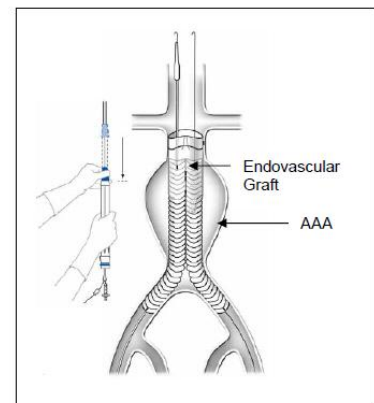
Aims: To develop an endovascular device with stent attachment and the associated manufacturing methods for the device in order to complete a qualified manufacturing unit.

The project was centred around the development of automated manufacturing procedures using novel joining techniques for a vascular graft.

The endovascular device worked on in the project consisted of a tube of polyester fabric with Nitinol wire support rings positioned and attached at intervals along the length.

The challenges currently faced in the production of the endovascular grafts were as follows:

- Labour intensive procedures with time-consuming manual assembly using complex and difficult manual sewing.
- High manufacturing costs.
- High production times (approximately 9 hours for each unit of the stent-graft system).

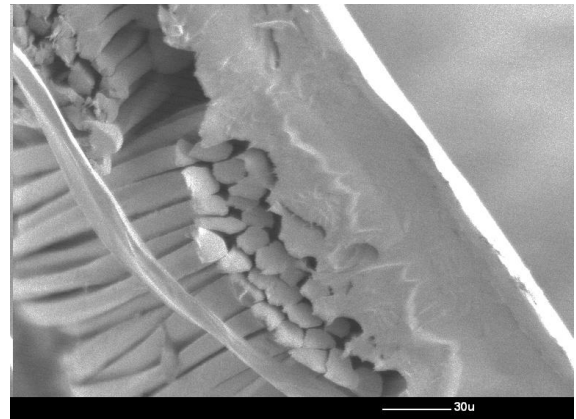
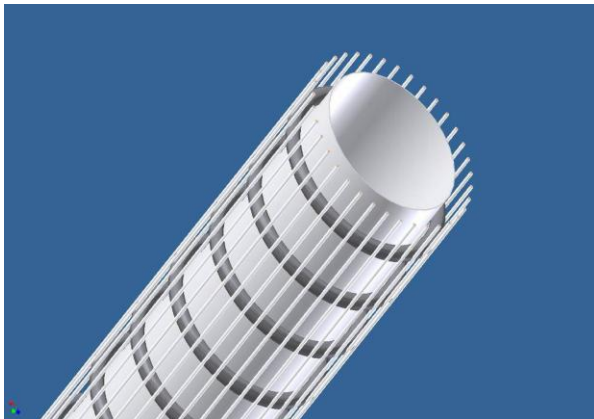


- Rising quality control issues.
- Quality dependent on the operator - e.g. suture thread sewn too tightly or loosely can alter the behaviour of Nitinol stents during deployment and subsequent use within the patient body.
- Variability in the final product.
- Increasing prevalence of cardiovascular diseases and higher demands for these devices directly result in increasing labour and associated costs leading to higher quality control issues and a narrow profit margin.

Achievements

The main steps, events and achievements in finding solutions to these problems were as follows:

- A review of current and potential manufacturing processes was conducted and a report was written for the endovascular device.
- Alternative designs and materials were specified for the endovascular device. A method using laser cut strips of PET film to support the Nitinol wire stent was ultimately selected which facilitated automated manufacture whilst also reducing the profile (bulk) of the device for easier deployment by the surgeon.
- Following an exhaustive process selection procedure, laser welding was indentified, developed and tested for attachment of the wires to the fabric tubing. A manufacturing procedure was specified.
- A manufacturing analysis, supported by technical and economic justification, was prepared for the new manufacturing method.
- An evaluator manufacturing unit was specified, built and tested at TWI. Tubular endovascular devices were prepared using the new techniques, which reduced the stent attachment time to less than 10 minutes from 9 hours.



New stent design using rings supported by external tapes, and micrograph of weld between fabric and tape.