Surgical Implants using the Techniques of Embroidery

This report describes our breakthrough research into our patented method for the rapid design and manufacture of textile surgical implants using embroidery.

Project Report Prepared on behalf of the Project collaborators by:
    Julian Ellis
    Project Manager

Summary
1. Introduction
2. The Demonstration component
3. Embroidery Techniques
   3.1 Cornely
   3.2 Schiffli
   3.3 Lockstitch
4. Embroidery Software
5. Endovascular Aneurysm Graft Stent
6. Implant Materials
7. Reinforcement Patterns
8. Processing
9. Project collaborators
   9.1 Ellis Developments
   9.2 Pearsalls Sutures
   9.3 Division of Vascular Surgery, University of
   9.4 Anson Medical Limited
   9.5 Contributions of each Partner
   9.6 Interaction of collaborators
10. Design Control
11. Endoleak Research
Summary

The objective of the project was to investigate the use of embroidery techniques for the manufacture of surgical implants. The project developed a technical demonstrator in the form of a graft stent for the repair of abdominal aortic aneurysms using endovascular techniques.

The project used the demonstrator to show that fibre placement using embroidery could be applied not only to textile fibres using the CADCAM techniques of modern embroidery systems, but the placement of metallic shape memory alloy wire.

Existing fibre placement techniques were developed through the use of software and stimulated development of associated methodologies and design techniques.

In the rapidly moving world of endovascular surgery, a product requirement specification that changed throughout the project demonstrated that the technology could keep pace with the fast changing demands of the surgeons. The project has also stimulated an enhanced understanding of the problems of endovascular techniques and an MD thesis is now in preparation as a result of an underlying programme to understand attachment of the endovascular graft stent to human aortae.

1. Endovascular surgery is a comparatively new technique for the repair of abdominal aortic

Of the population over 65 years old, 2.4% of men have aortic aneurysms, some 0.29% of women. Using current techniques there are approximately 3,000 cases of surgical intervention each year in England and Wales. There is a 5-10% mortality rate on elective surgery, but there is a greater risk from rupture if un-operated. 10,000 per year die of ruptured Abdominal Aortic Aneurysms (AAA) in
England and Wales Many patients with aortic aneurysms are too old or frail to be able to withstand open surgery. The development of satisfactory vascular stents to line the aorta that can be inserted using endoscopic techniques was essential to allow operative intervention on this group of patients.

When the project commenced in 1996, a 44 patient series of endovascular stents had been run by Professor Hopkinson at the Queen's Medical Centre, Nottingham. There had been approximately a 25% failure rate for the current endoscopic techniques, when a change of plan during the operation required open surgery, putting the patient at significantly greater risk. Failure had generally been over an inability to maintain an effective seal between the inner surface of the artery and the outer surface of the endoscopic stent.

There had been very limited development of a number of endovascular implants in other centres in the UK, despite the potential for 12,000 - 13,000 endovascular implants per year in England and Wales subject to a satisfactory method being developed. Preliminary studies had indicated that endovascular surgery is associated with less haemodynamic derangement, which has the advantage of minimising cardiovascular morbidity and mortality.

The requirement was for an implant that would be thin enough to be introduced through a 7.3mm catheter, and having walls made from fibres that were sufficiently densely packed to provide low porosity (although this did not need to be as high as a conventional vascular prosthesis). It should also incorporate radio-opaque markers. It was required that the graft stent be arranged so as to obtain a seal against the artery wall. It was suggested that this be achieved by forming polyester strip springs at the top and bottom of the stents.

2. The Demonstration component

The development of an abdominal aortic aneurysm graft stent was chosen as a demonstrator of this technology for several reasons. One of these was that endovascular surgery is a fast developing area in which one of the project collaborators had already established an international reputation. Secondly, the specification for a satisfactory graft stent provided a demanding target to be met using this new technology. Thirdly, because the novel method of manufacture (embroidery technology), overcame many of the limitations imposed by patents of other manufacturers.

3. Embroidery Techniques

3.1

There are several machine embroidery techniques in existence. Cornely embroidery uses a single needle head with a substrate material held in a pantograph, which is moved under computer control. One application of this technique in the garment industry is the tacking of heavy cord to the substrate by coiling the cord in a wrapping yarn, then stitching the wrapping yarn to the substrate with a chain stitch. This method was deemed unsatisfactory because of the lack of stitch security, (a characteristic of chain stitching).

3.2

This method of embroidery uses rows of needles held on a horizontal rack, with a substrate material mounted in a vertically held pantograph. The primary yarn runs partially through the thickness of the substrate and is held in place by a second interlocking yarn at the rear of the work. This approach was rejected because Schiffl machines are extremely large, high output units. A 21-yard long machine costing in the order of £1 million would produce nearly a million aneurysm graft stents per month.

3.3

These embroidery machines are the most common type of commercially available equipment and
are essentially adaptations of a standard lockstitch sewing machine. Lockstitching is particularly appropriate for surgical implants because the security of the stitching is very high. The machines are competitively priced, and there is a good range of software available. This commercial software for decorative embroidery is usually very much more powerful than is needed for the comparatively simple stitching needed for surgical implant applications.

Lockstitch machines are available ranging from a single embroidery head to 36 head machines. The selection of an appropriately sized machine for future mass production can therefore be made according to particular volume demands. Lockstitch embroidery machines are also highly portable. Additional capacity, should the need arise, can be provided at very short notice. As a result of this and other advantages of embroidery lockstitch machines, this route was selected for this project.

**4. Embroidery Software**

A number of commercially available embroidery packages were examined. The package that was eventually selected is, as are all other available packages, designed for aesthetic embroidery. Similarly there are a number of levels of complexities of the software package available, typically five. The level two software was sufficiently powerful for use in this project and provided good value for money. Many of the stitch patterns used in this project required individual stitch placement rather than complex algorithms: many of the features of the software were infrequently used.

Work carried out at the University of Nottingham indicates that to satisfy the majority of patients requiring endovascular aneurysm repair, some 1,700 size variations of implant would be required. One objective of the project was to develop approaches to produce different sizes of implant using software. This was not done for two reasons: the first being that aneurysm graft sizing is the subject of an ongoing study, and it has recently been learned that a considerably smaller number of grafts would need to be customised to satisfy all the patients than was previously thought. Secondly, the design of the graft stent was continually changing during the project for a number of reasons. It was decided to leave the development of very rapid design methods, using computer macros, until the design and sizing of the graft stents have reached a more stable state of development and understanding. However, a new size graft can already be developed in less than 2 hours, but it is hoped to reduce this to less than half an hour.

It has been demonstrated successfully that once a design has been completed for a stent the software design code can be transmitted by e-mail from one site to another, and manufacturing of a surgical implant may commence in less than 10 minutes.

**5. Endovascular Aneurysm Graft Stent Specification**

The science of endovascular aneurysm repair is a rapidly evolving one. Professor Hopkinson and his team are in continual contact with other pioneering teams in this technology. Throughout the project, the requirement specification for the implant was continually updated in the light of this. However, many of the original requirements remained constant throughout the project, although the importance and the detail of some of these requirements was amended and revised. The main features of the specification are as follows:

1. A base material of fine woven polyester. Industrial grade (i.e. unpigmented) polyester yarns have long been used for vascular repair and other implant materials. Microfibre polyesters, that is fibres with filaments having a count of less than 1 decitex have comparatively recently been developed, and are a preferred fibre for use in endovascular stents because of their ability to pack closely in a woven fabric and provide a high degree of leak resistance. A source of supply of a suitable fabric was identified in Italy and ultimately a large single batch of checked and certified fabric was acquired. This was sufficient to provide several years manufacturing output of the finished implant. The fabric is scoured before use to remove all spinning lubricants and other contaminants.
2. A bio-inert material for the reinforcement. Conventional vascular repair textiles are reinforced using a crimping technique to concertina the fabric. However, this produces a high bulk product, which is unsuitable for insertion through a catheter. Therefore the fabric must be straight walled with a reinforcement material. This prevents the lumen closing if the graft is required to pass through a tortuous diseased artery.

3. High columnar strength. Concern was expressed that the graft might collapse under pulsatile blood pressure and move within the artery. Such columnar strength would also aid insertion and minimises any possibility of lengthways collapse of the graft. Similarly, it was expected that the strength of the column would reduce the possibility of the occlusion of the lumen in a twisted artery.

4. A simple but effective anchoring system at the top of the graft against the healthy artery above the diseased section to prevent the device migrating. The method of achieving this fit should be either a hook or similar system or a tight spring fit against the artery wall.

5. A bulk sufficiently low that the whole device would pass through a 22 French catheter (7 mm diameter).

6. A device that would emerge from within the catheter and deploy rapidly as required within the aneurysm, and provide a seal against the vessel wall to prevent blood leakage around the device (an endoleak).

6. Implant Materials

It was originally envisaged that all the embroidery work would use conventional suture materials for use as the implant embroidery thread. These products, manufactured by one of the collaborators, were considered to be ideal because of the ready acceptance by surgeons of such materials. Materials used during the project included conventional braided polyester suture thread together with nylon and polyethylene monofilament. Additionally, non-implant grade polypropylene was used to try to attain the required stiffness. These aforementioned materials were not fully successful, so superelastic alloy was used. Nitinol alloy has been used with considerable success in other implant devices. Although there is ongoing discussion about its biocompatibility, the extremely rapid oxidation of the metal provides an oxide barrier between the metal and the bio-system. Any long-term risks associated with nickel ion release are thought to be minimal in this patient group.

7. Reinforcement Patterns

There were a very considerable number of ideas for reinforcement. Some of these were much more successful than others; the final design for the implant was arrived at by an iterative process that resulted in 153 designs having been produced. Many of the design ideas are shown in the patent for the endovascular stent.

The design eventually adopted was a "ladder pattern" which not only provided sufficient reinforcement of the polyester textile to prevent the lumen collapsing, but also provided sufficient columnar strength to achieve what was required in that direction. The Nitinol wire was preshaped and set, and then precisely stitched in place on the base cloth using conventional lockstitch embroidery methods. It was found later in the project that the spring fit of the device against the wall of the healthy aneurysm above and below the damaged section of artery could be better achieved if the spring section was placed inside the completed stent. By stopping the embroidery programme at an appropriate stage, the Nitinol wire is readily fed through the base cloth to emerge externally before continuing the stitching process.

After the embroidery takes place, including attaching wire and hooks to the base cloth, the tube of the finished stent is completed by hand stitching. Because of the low diameter of the finished stent, it is very difficult to use secure stitching methods to form a narrow tube. Some research has been
carried out to attempt to identify a method of machine attachment. It is noteworthy that no secure stitching method that can be applied to this problem has been patented in the last 160 years.

8. Processing

After the graft stent is closed into a tube, the device is scoured and sterilised using gamma -irradiation. It is then ready for loading into the implantation device.

9. Project collaborators

The consortium comprises a manufacturer experienced in the high volume production of textile surgical applications, a small research orientated manufacturer experienced in the interface between textiles and clinical surgery; and research orientated clinicians with experience of the applications for the demonstration product planned.

9.1 Ellis Developments

Ellis Developments Limited was founded in 1985, and specialises in advanced textile technology, particularly the development of textiles for engineering and surgical applications. The company was responsible for the textile design of Europe’s best selling artificial ligament, the Leeds-Keio Ligament for the replacement of anterior cruciate ligament of the knee. They previously had administered a £700,000 LINK Structural Composites project, to apply embroidery to composite preform production and have won SMART awards in 1988 and 1999. Ellis Developments Limited is an SME.

9.2 Pearsalls

Pearsalls Sutures were a division of Bridport Gundry plc and were founded in 1795. They were subsequently owned by the US based Mamon Corporation. Pearsalls have been making suture threads for over 100 years, and supply most independent suture companies, including Davis and Geck, B. Braun and US Surgical. Over 90% of their work is exported and they have won a Queen's Award for Export.

9.3 Division of Vascular Surgery, University of

The Division of Vascular Surgery under the leadership of Professor Brian Hopkinson at the University of Nottingham is part of the Department of Medical and Surgical Sciences. Professor Hopkinson has an international reputation for his work in endovascular surgery and has carried out the largest number of endovascular procedures in the world.

9.4 Anson Medical Limited

Anson became actively involved in the project in May 1997, when they were brought in to advise on the use of shape-memory alloy. Although they did not become an official partner, Anson attended project meetings as well as becoming heavily involved in the project. An agreement was signed in July 1998 whereby Anson committed development resources to commercialise the AAA graft stent. They have been approached by a number of leading companies who wish to distribute the product in specific territories.

Anson Medical provided technical input in the form of providing pre-shaped ladders of shape memory alloy and a large variety of technical advice and assistance. They also provided significant funding for parts of the project for which the budget was insufficient. Anson Medical Limited is an SME.

9.5 Contributions of each

Ellis Developments Limited have considerable expertise of textile surgical implants and embroidery.
They acted as interface between textile and clinical disciplines, and to lead intellectual property aspects, as well as being project managers.

Pearsalls Sutures provided controlled facilities for the operation of embroidery machinery and know-how on the handling, production and application of textile materials. They installed a class H clean room during the project and are now registered to ISO 9001 and EN 46001.

The Division of Vascular Surgery at the University of Nottingham provided expertise in endovascular stenting, having run the world's largest series of endovascular surgical procedures. They had previously developed an understanding for the requirements of effective stent that can be applied to patients who are too old or too frail to withstand abdominal surgery to treat aortic aneurysms.

9.6 Interaction of

There were formal project meetings held each quarter for the duration of the project, which reviewed work carried out during the previous period, and planned future work. Each 6 months a full project meeting was attended by representatives of the programme managers, Quotec and project monitors from the Department of Health. These minuted meetings were supported by regular meetings, telephone calls, faxes, e-mails, and informal meetings between partners.

10. Design Control

By September 1999 good evidence had been provided that the Nitinol-polyester graft combination goes into a normal sheep aorta satisfactorily. It fixes well with hooks, and seals satisfactorily as far as experimental aneurysms are concerned. The limited amount of histology carried out then shows no adverse reaction at all. At that time there were 7 sheep with stent-graft and aneurysms in place and an additional 2 sheep had stent grafts in their aorta, one without an aneurysm and one with an aneurysm had been sealed off, despite having made an attempt to produce a forced endoleak.

The next stage was to prove that the graft would follow tortuous vessel paths without kinking which was one of the first requirements for the graft. A 20 cm long graft was made and put in as an open procedure through an ateriotomy with a 3600 curl in it. Full patency of this graft was maintained in two sheep for over 24 hours.

11. Endoleak Research

From one of the animals sacrificed, extremely good evidence was provided that a small endoleak can enable systolic pressure to enter the aneurysm. The presence of clot within the aneurysm prevents the blood getting back into the aorta and maintains a mean intra-aneurysm pressure much higher that the systemic mean arterial pressure. This very interesting observation provides an explanation as to why a small endoleak is very often fatal to patients, sometimes within a week of surgery. Endoleaks have been a major problem in endovascular surgery and as they are the greatest source of morbidity and mortality a much better way of sealing was thought essential.

It may be that combinations of thin nylon or polyester sacks inserted within the graft and then inflated with silicone rubber could help provide a very good seal. Alternatively sacks of thin compliant nylon or polyester could be fed into the endoleak from the lumen of the aorta and then inflated to seal off the affected area. A request was therefore put in to enable the study of another 3 sheep with the 3600 curled graft in them and 3 more with endoleaks that could be sealed by an intra-aneurysmal bag of silicone rubber. This work, outside the project, continues.

Before proceeding to the endoleak experiments in animals, a bench model was developed to try to demonstrate what size of endoleak is required to raise pressure in the aneurysm above the mean arterial pressure. It is proposed that implantable pressure sensors will then be put inside the
experimental aneurysms. External monitoring will be used over a period of several months to check the pressure and pressure wave within the aneurysm in live sheep.

12. Cost Evaluation

There is an ongoing debate about the comparative cost benefits of endovascular aneurysm repair techniques as against conventional open repair. The cost of current endovascular repair devices is very high, but it is expected that partly as a result of the comparative speed and simplicity with which customised devices can be produced using embroidery techniques, the Nottingham Graft Stent will be available to the NHS at a marked discount to current prices.

13. Achieved Project Deliverables

1. An understanding of the design rules for embroidered surgical graft
2. An understanding of design rules for other textile surgical
3. The development of validated manufacturing methods for the design and manufacture of custom made implants.
4. A demonstration of extremely rapid prototyping and manufacturing
5. Structural design methods for embroidered textile
6. Demonstration for potential for embroidery as a method of manufacture of customisable surgical implants
7. Manufacturing method for surgical implants which is highly flexible, has improved structural performance and has high consistency compared with conventional textile implant manufacturing techniques.
8. Established design control
9. Established manufacturing control
10. Apparently successful animal trials of the demonstration
11. Apparently successful laboratory testing of the demonstrated
12. Developed protocol and software design
13. Validated implant design.
14. Product almost ready for submission to Medical Devices

14 Dissemination

14.1 Published Conference

Ellis J.G, Wallace W.A, Neumann L, Textile For the Repair of The Rotator Cuff of the Shoulder, Medical Textiles’ 96, Bolton UK


14.2 Conference

Ellis J.G *Surgical Implants Using Embroidery Techniques* UK liaison committee for Sciences Allied to Medicine and Biology, Medical and Biology New Technology, 4th International Conference, Brunel, 1999


14.4 Thesis


14.5 Display at *Tomorrow’s World Live* Exhibition, NEC Birmingham, July 1999


European Patent application - *Device for the Reinforcement of the Rotator Cuff of the Shoulder*

US Patent 5990378 - *Textile Surgical Implants*

European Patent Application 96303741.1 - *Textile Surgical Implants*

European Patent 074416282 "*Textile surgical Implants"*

US Patent 98/652316 "*Textile Surgical Implants"*

"*Vascular Graft Stent*"

15. Exploitation

15.1 Achievements and Further

Anson Medical Ltd have taken rights to distribute the AAA Graft Stent across the world. They have been approached by a number of leading companies who wish to distribute the product in specific territories.

Once the product has been submitted to and approved by the Medical Device Agency, the product will be available for clinical tests. Initially these will be carried out at Queen's Medical Centre, Nottingham.

A number of other embroidered implants are in various stages of development in parallel with this
project. These include several shoulder repair devices, which have already been used on a small number of patients, and a prosthesis for the replacement of an intervertebral disc of the cervical spine.

16. Parallel Projects

Concurrent with the project, there have been a number of developments taking place using embroidery techniques. These include the following:

16.1 A device for the Repair of the cervical spine

This is the embroidery of a complex textile shape, which fits around a silicone cervical spinal disc prosthesis. The textile is designed to replace the spinal ligaments and hold the disc prosthesis firmly in place. Ten million cycle testing has demonstrated that the device retains its patency after such a repeated load and unload cycle. The device was developed in conjunction with Mr Andre Jackowski of the Royal Orthopaedic Hospital, Birmingham. A patent has been filed and published for this device.

16.2 Shoulder

Three shoulder products developed in conjunction with Professor W A Wallace and Mr Lars Neumann of the Shoulder and Elbow Unit, at Nottingham City Hospital/University of Nottingham. There have already been a number of implantations made under special exemption rules, although CE marking have not yet being possible on the product. Two other shoulder devices are in an advanced stage of development, one of which has been patented.

16.3 Orbital Floor

Designs have been developed for the repair of the orbital floor for use by Maxillofacial surgeons. Some of this work has been done in conjunction with the AMPICS project funded by the EPSRC and based at the University of Nottingham. The device, made from polyester yarn, meets all the criteria of the surgeon, Mrs Sheila Fisher of the Oral Maxillofacial Unit, Nottingham, with the exception that she requires a biodegradable raw material. Existing biodegradable raw materials such as polylactic acid and polyglycolic acid degrade far too quickly for use in this particular application. Following a successful trial using Ethicon's slowly biodegradable Panacryl fibre in the shoulder, it is hoped that Ethicon will release sufficient fibre for tests to be carried out using this product.

17. Recommendations for Further Research

- Development of an embroidered graft without
- Development of an endoleak model bench-
- Development of system of external monitoring of pressures inside the aneurysmal
- Study on filling the aneurysmal sac with various thrombogenic substances as a way to prevent endoleak as well as provide external support for the stent graft
- Study on deformation of graft during and after
- Development of other surgical implants using embroidery
- Development of a seam closure sewing machine for small diameter
- Development of software for the rapid design of AAA graft

18.
This project which took rather longer than originally planned, mainly because of circumstances beyond the control of the collaborators, has developed a demonstration device which shows every prospect of being technically highly successful. The technical success is likely to be reflected in the commercial success of the device, the signs for which are extremely encouraging at the time of writing. There are still many unsolved surgical problems for the endovascular repair of abdominal aortic aneurysms, but plans exist to meet these by continued development programmes. Many of the further developments are expected to be funded through income generated by sale of the first stage graft design.

19. Acknowledgements

We acknowledge with thanks the help of all members of the team that made this project so successful. These include:

University of Nottingham
Dr Jean-Noel Albertini
Mr Bruce Braithwaite
Mr David Edwards
Dr Nabil El-Marasy
Dr Stravros Kaliapor
Dr Jan Macierewicz
Mr Mark Parry
Mr Ron Walker
Mr Stuart
Mr Waquar

Pearsalls Limited
Mrs Elizabeth
Dr Alan
Mr Lawson

Ellis Developments Limited
Miss Pauline Ellis

Anson Medical Limited
Dr Peter Philips
Dr Gail Beaton

Department of Health
Mr Anthony N
Mr Jonathan

Quo-Tec Limited
Mr Matthew

Appendix

Collaborator
Pearsalls Sutures
Dr Alan McLeod

Mr D Lawson

Ellis Developments Limited (SME)

Julian G Ellis

Mr Peter W

University of Nottingham, Department of Vascular Surgery

Professor Brian R

(Anson Medical Limited, Didcot, Oxfordshire joined the project informally, providing expertise in shape memory alloys and as the preferred company to market the product)

Appendix 2

Project

To produce a validated method for the design and cost effective production of low and medium volume production textile surgical implants.

To develop a specific application in the area of vascular surgery in order to demonstrate the technique

A set of design rules for embroidery of
Reproducible method of manufacture to meet the requirements of good manufacturing practice

Development of manufacturing conditions and process appropriate to implant

Method validated through clinical tests

All these targets have been achieved, although time has not permitted the clinical testing of the device produced. This was mainly due to a considerable delay in obtaining Home Office approval for the animal work. However, the device is almost ready for submission to the Medical Devices Agency for approval for clinical test to commence.
Julian Ellis at Ellis Developments Ltd will be delighted to hear from you. Telephone on +44 (0) 7976 425899

e-mail: info@ellisdev.co.uk We are based at Far Close, Rolleston Road, Fiskerton, Southwell, Nottinghamshire, NG25 0UJ, United Kingdom