

CHAPTER 7

FINAL REMARKS

7.1 Main achievements

This dissertation concerns the structural design of stent grafts. A new type of stent graft has been developed which incorporates into a single piece both the wire mesh and the covering membrane which are found in traditional stent grafts. The new design consists of a folded sheet of material, and has its basis in the ancient Japanese art of origami, and is therefore termed the origami stent graft. The principal findings are summarised in the following paragraphs.

Firstly, a detailed symmetric design of a foldable cylindrical tube for the new stent graft has been presented. Folding is achieved by dividing the structure into a series of identical foldable elements. Particular attention has been paid to two types of elements: rectangular elements and general elements. Folding patterns for each type of element was obtained. Both patterns allow the stent graft to be folded and expanded both radially and longitudinally.

The relationships among the design of the elements, the number of elements in the circumferential and longitudinal directions and the folded dimensions of the stent graft have been derived. It has been found that compact folding in the radial direction can be achieved by increasing the number of circumferential elements. However, a large number of elements may cause manufacturing difficulty. A compromise can be found to address both concerns. It has also been found that the stent graft can be folded compactly in the longitudinal direction as both the number of the circumferential and

longitudinal elements increase, and that the ratio of its constriction depends on the design of the element.

We have also identified a geometric mismatch during deployment. The elements have to deform when the structure is expanded. Optimum designs which minimise the deformation have been found.

Variations to the general folding patterns of both cylindrical and conical tubes have also been discussed, though without detailed geometric calculation.

Secondly, we have found that it is possible to make a foldable cylindrical tube with helical folds. Helical folds are introduced by adjusting the joining position of the two edges of a sheet that had been symmetrically jointed in the symmetric design. The main advantages of the stent graft with helical folds over the symmetric ones are improvement to the radial strength of the stent graft and ease of the deployment process by synchronizing the deployment of each element. The relationships among the number of elements in one complete circumference of a helix, the helical angle and the radius of the helical type stent graft have been derived.

The locations for the helical folds are optimised for easy folding by considering both the geometric aspects of folding and the buckling patterns of a thin-walled tube under torsion, which have been found analytically. Physical models of the tube with prefabricated helical folds have been produced and then twisted by applying torques at both ends. The model confirms that the tube with the helical folds resembling buckling patterns could be folded more easily under torsion.

Thirdly, we carried out numerical analysis using FEM in order to understand the strain of the fold with respect to the different widths of fold. From the results, it is found that the circumferential strain becomes smaller as the width of the groove increases. However, the reduction of the strain becomes less obvious when the width is greater than 1.2 mm.

The FE analysis has also been used to identify the deformed pattern of a thin cylindrical tube under certain prescribed loads (displacements). The geometry of the

deformed pattern resembles the pattern of the folds of the designed foldable cylindrical tube. Therefore, the stent graft can be folded into the desirable shape easily if the groove is produced.

The FE analysis is also used to identify the accuracy of the geometric analysis in the presence of a mismatch. It is found that the geometric analysis and FEM techniques strongly agree with one another with regard to deployment radius, but weakly agree in assessing overall length.

Finally, the stent graft has been manufactured to verify the concept. A number of demonstration models of the stent graft, which are of the same size as standard oesophageal and aortal stent grafts, have been produced successfully. The same materials as used in current stent grafts, stainless steel and shape memory alloy were used, but the sheet form was used rather than the wire form.

The patterns of folds on the stainless steel sheet are produced by photochemical etching. It is found that folding of the models in its fully folded configuration is easily accomplished if the folds are pre-folded to the preferred direction of deformation. Process techniques of SMA, such as photochemical etching to engrave folds into both sides of the sheet and heat-treatment to add ductility and re-shape from sheet to tubular shape are established. Optimal condition for production of the stent grafts were obtained in terms of the type of photoresist and its thickness; UV exposure intensity and time; baking temperatures; proportion of HF/HNO₃/H₂O of the etchant and the temperature of heat-treatment.

It has been demonstrated that stent grafts with Ti-rich and Ni-rich TiNi SMA self-expanded smoothly and gradually by heating. The stent graft with Ni-rich TiNi SMA sheet was designed to expand at near body temperature. The work has proved that the concept of a foldable cylindrical tube can be applied to produce the stent graft using existing biocompatible materials such as stainless steel and SMA sheets.

7.2 Future work

The concept of the origami stent graft is novel and has raised considerable interest. However, the design must be improved in order to produce a marketable and reliable product. The next step for development of this concept involves the production of a prototype for clinical trials. It is recommended that the initial work on the design be directed towards oesophageal applications, since the oesophagus is relatively large, with relatively easy access. The currently obtainable size of the origami stent graft would also make it useful for abdominal aortic aneurysms (AAA) and thoracic aortic aneurysms (TAA). Coronary stent grafts are much smaller, and the difficulties of miniaturising the present design for use in coronary arteries would be too great for the near future.

We have noted that the current design lacks flexibility. The fully deployed stent graft with both stainless steel and SMA are rigid. Instead of producing the stent graft with only metal, using other biocompatible materials such as Dacron (a polyester) or PTFE with reinforcement may improve flexibility. A metal reinforcing frame could be attached to one of these flexible materials along the folds of the origami stent graft so that the expansion behaviour is identical to that of single-piece stent graft. Material thickness and mechanical properties also need to be considered in order to obtain adequate mechanical support. Thicker material can provide higher stiffness but would reduce flexibility.

Adhesive has been used to connect the ends of a sheet in order to form a cylindrical tube. Instead of adhesive, spot welding may also be used. Another option may be to use a tube instead of a sheet. Several existing techniques for etching a cylindrical tube (Jackman, et al. 1999; Mineta, et al. 2001) can be applied to produce the origami stent graft. However, producing the grooves inside of the tube by etching may prove to be complicated. Future work should include the development of a fold pattern that would produce a stent from a single-sided etch. In this research, photochemical

etching is used to produce the stent graft since the etching is inexpensive, and the facility is available at Oxford University. However, there may be advantages of using other processing methods for the manufacture of stent grafts, such as laser cutting. The laser method may produce smooth edges, but the costs are relatively high. It is also possible to polish sharp edges using advanced etching techniques. Advantages and disadvantages for both processes should be investigated.

Techniques for folding and expansion of the stent also need to be considered and improved. For stainless steel stent grafts, an existing balloon expansion tool could be used. Further development involves manufacturing of a new Ni-rich TiNi SMA sheet whose reverse transformation temperature of A_f is lower than the body temperature to produce a self-expanding stent graft with superelastic behaviour. Radial force and strengths of the stent graft with various A_f during and after expanding need to be examined to produce the SMA stent graft which has enough force to open and hold a blocked organ and weaken wall in the human body.

For this research the focus has been on the use of the structure as a medical stent. However, consideration should be given to other foldable/expandable medical devices that could make use of this design, such as vena cava filters and resetting tools in orthopaedics.

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Appendix

The design of the stent graft presented in this dissertation has been submitted for a patent to cover the U.K, U.S.A, EU and Japan supported by ISIS Innovation Ltd. (Kuribayashi and You, PCT/GB02/01424 – "Deployable Stent", filing date: 27 March 2002). A spin out company from the University of Oxford called "Origami Instruments Ltd." will be set up in 2004 to explore this invention.

