A Novel Foldable Stent Graft

Kaori Kuribayashi

St. Catherine's Collage Oxford

Thesis submitted for the degree of Doctor of Philosophy
in the Department of Engineering Science
at University of Oxford
Trinity Term, 2004

To my parents

ABSTRACT

A Novel Foldable Stent Graft

Kaori Kuribayashi

St. Catherine's College
A dissertation submitted for the degree of Doctor of Philosophy
in Department of Engineering Science at University of Oxford, Trinity Term 2004

This dissertation concerns the structural design of medical stent grafts. A new type of an innovative stent graft has been developed. Unlike the conventional stent grafts which consist of a wire mesh and a covering membrane, the proposed stent graft can be made from a single folded sheet of material.

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 elements with hill and valley folds as in origami (Japanese art of paper folding). The folding 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. A geometric mismatch during deployment has also been identified. The elements have to deform when the structure is expanded. Optimum designs which minimise the deformation have been found.

Secondly, a new stent graft with helical folds has also been designed to improve radial strength and ease the deployment process. 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 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 established. The locations for the helical folds are optimised for easy folding by considering both geometric aspects of folding and the buckling patterns of a thin-walled tube under torsion, which are found analytically.

Thirdly, using numerical analysis of the finite element method (FEM) the strain level and overall deformation of the stent graft during deployment has been calculated.

Finally, the stent graft has been manufactured to verify the concept. A number of prototypes of the stent graft, which are the same size as standard oesophageal and aortal stent grafts, have been produced successfully using the same materials as current stent grafts of stainless steel and shape memory alloy (SMA) sheets. The patterns of folds on the materials are produced by photochemical etching. It has also been demonstrated that the SMA stent grafts self-expand smoothly and gradually by a near body temperature.

Keywords: stent graft, structural design, foldable structure, helical structure, geometric analysis, numerical analysis, shape memory ally sheet, photochemical etching.

ACKNOWLEGEMENT

This work described in this dissertation was carried out in the Department of Engineering Science at the University of Oxford. I really enjoyed my research. This dissertation could not be accomplished without the co-operations of so many people. I extend my sincerest thanks and gratitude.

The long list of acknowledgement must begin with Dr. Zhong You. He gave me a lot of wonderful opportunities at the University of Oxford. He directed me into the field of deployable structures. I enjoyed our discussion, which always brought me many interests.

I would like to thank Professor Gilliane Sills, my college advisor, for her support and encouragement. Many people at the Department of Engineering Science helped me with my work at various stages. I have had wonderful colleagues from 18 different countries, which is amazing. In particular, my thanks must go to Gwyn Lintern. Thanks to Richard Kelly, Nguyen Giang Kenneth Kar, Nguyen Lam, Yan Chen, Jackie Sim, Andras Lengyel, Davide De Focatiis, Miguel Pena, Gert Bartholomeeusen, John Pickhaver, Sotiris Psomas, Claus Wisser, Mark Poter, Clive Baker and Alison Payne. Their great friendships, and contribution to many memorable and enjoyable occasions are appreciated.

I would also like to extend my gratitude to Mr. Cyril Band who assisted me on photochemical etching on top of his already busy schedule. Also, he and his partner Penny Gledhill make me feel that England is my second home. I will never forget their warm support. I would like to acknowledge Dr. Koichi Tsuchiya for supplying shape memory alloy sheets, his useful discussions and encouragement. I also would like to thank Dr. Neil Morgan, Dr. Peter Leigh for having useful discussions and helps.

In Oxford, I had met so many interesting, energetic and ambitious people. Thanks to Stephen Lui, Mei Yi Lok, Alex Hearn, Bob Goodson and Jenna Phillips and Michelle Chew.

Financial support of Kobe-Oxford scholarship is gratefully acknowledged. I would also like to thank the British Council for supporting my research in Japan. Thanks to St. Catherine's College for the support of several travel funds to attend conferences and workshops. I also thank ISIS innovation for the support the application of an international patent.

Most importantly, I express my greatest gratefulness to my parents, my brother and sister and all my family members for their tremendous support. I am also extremely grateful to my boyfriend, Takafumi Shigetomi for his huge support and encouragement from Japan. To all of them I cannot thank you enough.

I hope that the idea of the new stent graft will become a real product and it could help many patients in the future.

Kaori Kuribayashi

CONTENT

CHAPTER 1 INTRODUCTION

CHAPTER 2 REVIEW OF PREVIOUS WORK

PART I DESIGNS AND ANAYSIS

CHAPTER 3 FOLDABLE CYRINDRICAL TUBES AS A NEW STENT GRAFT

PART II MANUFACTURE

CHAPTER 6 MANUFACTURING AN ORIGMI STENT GRAFT

CHAPTER 7 FINAL REMARKS

NOATION

Some symbols for the variable s and parameters used in this dissertation are provided here.

Capital letters:

A:	Width of line in the developed photoresist.
A_f:	Temperature of finishing of austenite crystal structure.
A_s:	Temperature of starting of austenite crystal structure.
B:	Width of the line after etching.
E:	Young's modulus.
H_A:	Helical lines of a single long fold spirally around the circumference of the helical-type cylindrical tube.
H_B:	Helical lines of the helical-type cylindrical tube run diagonally from one open end to the other.
M:	Mean value of $\|y\|$ during deployment.
M_f:	Temperature of finishing of martensite.
M_s:	Temperature of starting of martensite.
M^*:	B19' martensitic transformation temperature.
N_{yx}:	Buckling shear stress.
L:	Total length of the foldable cylindrical tube.
L^*:	Radio of the value of L in the fully folded configuration respect to in the fully expanded configuration.
R:	Radius of the specimen after heating.
R_0:	Radius of the roller for the bending test.
R_{o1}:	Outer radius between node O_0 and B of the foldable cylindrical tube.
R_{o2}:	Outer radius between node O_0 and A of the foldable cylindrical tube.
R_f:	Temperatures of finishing of R phase martensite crystal structure.
R_i :	Inner radius between node O_0 and O of the foldable cylindrical tube.
R_s:	Temperature of starting of R phase martensite crystal structure.
R^*:	Radio of the value of R_{o1} in the fully folded configuration respect to in the fully expanded configuration.

R^{*}_{m}:	R phase martensitic transformation temperature.
U:	Undercut.

Small letters:

d:	Etching depth.
h:	Effective thickness of the shell $h = t/\sqrt{1-\nu^2}$.
m:	Number of the element in horizontal or circumference directions of the foldable cylindrical tube.
m_b:	Number of the buckling line of peak folds.
n:	Number of the element in vertical or longitudinal directions of the foldable cylindrical tube.
n_A:	Position of the nods at the centre folds of FE model.
n_b:	Slope of the buckling lines.
n_h:	Number of hill folds.
n_t:	Total number of folds.
n_x:	Number of the elements at the groove in the x - axis.
n_y:	Number of the elements at the groove in the y - axis.
n_z:	Number of the elements at the groove in the z - axis.
n_v:	Number of valley folds.
l:	Length between nodes A and B.
l_a:	Length between nodes $E_2A_1$and F_2B_1.
l_o:	original length between nodes A_1 and B_1
t:	Thickness of the cylindrical tube.
y:	Value of $(R_{o1}-R_{o2}) / l$.
w_g:	Width of the groove at the centre of the FE model.
w:	Displacement in the radial direction under torsion.

Greek letters:

α_1:	Angle, $\angle DAO$.
α_2:	Angle, $\angle DAB$.
β_A:	Angle of H_A with respect to the horizontal base line.
β_B:	Angle of H_B with respect to the horizontal base line.
δ:	Central angle, $\angle AO_0C/2$.

δ_b:	Angle between the buckled line and the x - axis.
ε:	Strain of bended surface.
ϕ:	Angle, $\angle AO_oC'/2$.
φ:	Angle, $\angle BQO'$.
ν:	Poison's ratio.
θ:	Deployment angle, $\angle ABC/2$.
Θ_i :	Angles between the folding line with respect to the horizontal $i = 1, 2, 3 \cdots$.
θ_0:	Deployment angle when the cylindrical tube is fully folded.
θ_1:	Deployment angle when the cylindrical tube is fully expanded.
ξ:	Angle between the folds between nodes O and B and nodes O and P.