A NOVEL ORIGAMI STENT

Zhong You and Kaori Kuribayashi

Department of Engineering Science
University of Oxford
Parks Road
Oxford, OX1 3PJ
U. K.

INTRODUCTION

Stent is a flexible tubular structure capable of being folded into small dimensions allowing its passage into the problematic locations in the body and then being expanded. Use of stents has shown an important advance in the treatment of various diseases. For example, oesophageal stents have been widely used in the gastrointestinal tract to treat cancers in the oesophagus and bile duct. For oesophageal and pancreato-biliary cancers stent placement has become the most common form of treatment because these tumours are often inoperable at the time of diagnosis and are not particularly responsive to radiotherapy or chemotherapy. Stenting technique has been regarded as simple, safe and most effective in comparison with other non-surgical treatment (Guitron A et al, Domschke W. et. al.). In theory stenting can instantly restore swallowing function or bile flow for patients with severe dysphagia or jaundice due to cancer and the treatment can sometimes be carried out even without requiring hospital admission.

Although the advent of expandable metal stents has made their insertion diameter smaller and consequently these stents are far more comfortable for oesophageal use than the rigid tubular stents that were previously used, there are still many problems due to deficiency of the existing designs. Present expanding stents are made from metal wire mesh with or without outer covering membrane. The common problems of uncovered stent include bolus obstruction, tumour in-growth, gastro-oesophageal reflux, migration/slippage, erosion into aorta and mediastinal structures and difficulties in delivery especially for high oesophageal malignancies and angulated cardio-oesophageal lesions (Adam et. al., Grund et. al.). Covered stent was developed by simply attach a membrane sleeve around a wire mesh stent to prevent tumour in-growth. The flexible membrane neatly folded in-between the wire mesh normally does not affect the expansion of the stent but its existence significantly reduces frictional forces and enhances the risk of migration/slippage. Thus, for both types of stents, re-intervention is often required (Katherine, S. et. al.). As the result, many patients get a sub-optimal response to this type of treatment. Furthermore, a majority of the current expandable stents are made of Nitanol wire, an expensive shape memory alloy. They commonly produce a severe inflammatory reaction which causes stenosis at either end of the stent or between the interstices and require expensive plastic coatings to cover the gaps (Kozarek et al, Kynim et al). The high cost has reduced their widespread use. Often doctors opt for cheaper, semi-rigid plastic tubular stents even though they carry a higher risk of oesophagus perforation and are more easily blocked with bile and biofilm than the expandable stents.

The objective of our study presented here is to develop a new type of expandable stents to eliminate these drawbacks.

CONCEPT OF ORIGAMI STENT

The concept of the origami stent is originated from the way of packaging a thin-walled tube with the introduction of folding patterns.

To obtain these patterns, We first looked into the buckling pattern of a tubular structure under torsion. Figure 1 shows such a pattern generated by ABAQUS (HKS), which consists of a set of helical folds. This led us to believe that properly engineered folds, like origami patterns, could make folding of a tubular stent possible. As the result, a family of such patterns have been found.

The patterns are made from three type of folds: two sets of helical folds orthogonal to each other and cross folds, as shown in Fig. 2 (Kuribayashi and You). The existence of long helical folds enables a highly synchronised deployment process. The primary characteristics of the novel stents can be aummarised as follows:

- Small packaging volume for easy delivery.
- Integrated enclosure without additional covering to prevent problems associated with existing stents.
- Simple structural forms for reliable expansion.
- Greater generality based on generic solutions enabling them to be easily modified for applications at specific locations and different anatomic shape where the current ones are unable to work.

The concept is a geometrical one, i.e. it can be realised using different materials. We are currently work on the material selection, manufacturing technology which may be used to produce origami stents, and structural analysis. We have looked into the possibility of using stainless steel, shape memory alloys and polymers for stents and related technique to produce folds, e.g. chemical etching, controlled laser cutting and stamping. Two types of metal stents have been produced. Associated expending mechanisms have been designed. A complete structural analysis of the expansion process has been conducted. We hope to complete engineering work and start pre-clinical study shortly.

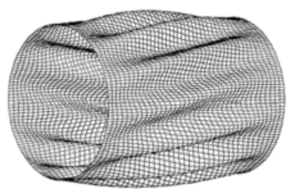
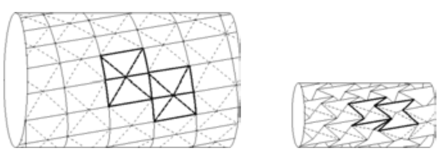


Figure 1. Buckling pattern of a thin-walled tube under torsion.



(a) (b)

Figure 2. One of the folding patterns with helical folds for tubular stents. (a) It is fully expanded and (b) completely folded.

CONCLUSION

The paper presents a novel type of stents developed for use in gastrointestinal tract. It can be conveniently applied to other large organs as biliary stents, urinary tract stents or stent grafts for aorta. The concept is a generic one allowing its use on other sites of the human body with necessary modification. The full potential of such stents is still to be explored.

REFERENCES

1. Adam A. et. al., 1998, “A New Design for the Esophageal Wallstent Endoprosthesis Resistant to Distal Migration,” AJR, 170, 1477-1481
2. Domschke W. et. al., 1990, “Self-expanding Mesh Stent for Esophageal Cancer Stenosis, Endoscopy,” 22(3), 134-6,
3. Grund, K. E., et. al., 1995, “Highly Flexible Self-expanding Meshed Metal Stents for Palliation of Malignant Esophagogastric Obstruction, Endoscopy,” 27(3), 486-494
4. Guitron A. et. al., 1998, “Self-expanding Metal Prosthesis as Palliative Treatment in Esophageal Cancer,” Rev Gastroenterol Max, 63(4), 198-203
5. HKS, 2000, ABAQUS 5.8
6. Katherine, S. et. al., 1998, “Self-expanding Metal Oesophageal Endoprostheses Covered and Uncovered: a Review of 30 Cases,” European Journal of Gastroenterology and Hepatology, 10, 371-4
7. Kozarek R A, Ball T J, Brandabur, J J et al, 1996, “Expandable versus conventional esophageal prostheses: easier insertion may not prelude stent related problems,” Gastrointest Endosc, 43, 204-208
8. Kuribayashi K. and You Z., 2002, Deployable stents, Patent: WO-02/078572
9. Kynim K, Wagner H J et al. 1993, “A controlled trial of an expandable metal stent for palliation of esophageal obstruction due to inoperable cancer,” N Engl J Med, 329, 1302-1307