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Self-deployable *origami* stent grafts as a biomedical application of Ni-rich TiNi shape memory alloy foil

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Abstract

This paper describes the design, manufacturing and properties of a new type of stent graft, the origami stent graft. Unlike conventional stent grafts which consist of a wire mesh stent and a covering membrane, the new origami stent graft is made from a single foldable foil with hill and valley folds. The Ni-rich titanium/nickel (TiNi) shape memory alloy (SMA) foil made by the newly developed ultrafine laminates method was used in order to produce the stent graft. The pattern of folds on the foil was produced by negative photochemical etching. The deployment of the stent graft is achieved either by SMA effect at the body temperature or by making use of property of superelasticity. A number of prototypes of the stent graft, which are the same size as standard oesophageal and aortal stent grafts, have been produced successfully. It was demonstrated that the stent graft deploy as expected.
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Keywords: Stent graft; Self-deployable structure; Ni-rich TiNi SMA foil; Photochemical etching

1. Introduction

A stent is a type of flexible tubular device and is capable of being folded to fit into small dimensions for minimum invasive surgery. It is then deployed to open up a blocked lumen and also to protect a weakened lumen in the human body. It is widely used in the treatment of diseases such as coronary artery stenosis, aortic aneurysm or oesophageal cancer [1–4]. There are two types of stents: stents and stent grafts. Most current stents have a mesh structure, whereas a stent graft is composed of a deployable wire mesh stent and a soft covering membrane (graft).

One of the major problems of current stents is restenosis, that is, the blocking of the once opened lumen due to tissue in-growth through the openings of the meshes [5,6]. Stent grafts have been developed as an effective way to prevent restenosis by their graft cover. However, it was reported problems of wire mesh fractures and graft ruptures [7,8]. It is probably due to a geometric incompatibility between the stent and graft when their deployment because the graft is simply attached the mesh stent.

In a previous research, a new single piece stent graft was developed to improve the structural design of currently available stent grafts [9]. The new stent graft has an integrated enclosure without additional covering, therefore preventing tissue in-growth. In addition, it does not have the incompatibility problem between mesh stent and graft during its deployment.

Fig. 1(a and b) show the photographs of one of the new stent graft designs made from a single sheet of card in its fully folded and deployed configurations, respectively. The folding of the new stent graft is achieved by dividing a cylindrical tube into a series of identical elements with hill and valley folds as in origami. Fig. 1(c) shows the pattern of folds. The solid and broken lines represent hill and valley creases, respectively. The folds act as hinges when the stent graft is folded. One of the interesting properties of the folding pattern is that it causes the stent graft to fold and deploy both longitudinally and radially. Therefore, the diameter and length decrease and increase when they fold and deploy, respectively. In addition, the folded configuration of each element also makes the stent graft flexible. These

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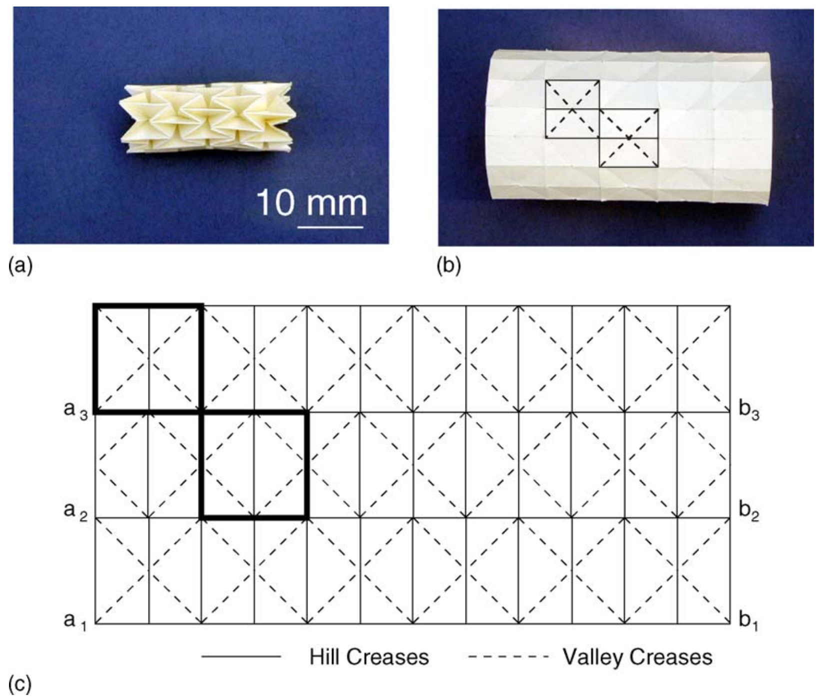

Fig. 1. Photographs of a card model of the origami stent graft in its (a) fully folded, (b) deployed configurations and (c) deployment of the folding pattern. The opposite edge of a sheet, a_1-a_2-a_3 and b_1-b_2-b_3 are joined together to form a cylindrical tube.

properties are suitable for the stent graft design because it can be packaged compactly and ensure flexibility when folded. The new stent graft is named *origami* stent graft since the paper folding patterns used in the Japanese art of origami are employed to fold the stent graft.

TiNi SMA have already been used in stent graft applications [10] because of its shape memory effect [11], as well as its biocompatibility [12,13]. The SMA stent graft is packed inside a sheath so that it can be passed through a narrow space. Once it reaches the intended site, the sheath is withdrawn and the stent graft deploys. Difference between existing SMA stent grafts and origami stent graft the latter is made using a foil instead of wires. Compared to the wire forms, usage of SMA foils is very limited. Complex rolling and annealing methods are required to produce a large and thin foil because of the low plastic workability and high work hardening rate of SMA. Therefore, commercially available SMA foils are still very expensive, resulting in the rarity of SMA foils in industrial products. A new method has recently been developed to produce the foil using ultrafine laminates of pure Ti and Ni [14], which can reduce the cost. This improvement to the production of SMA foils is expected to lead to a significant expansion in the number of applications of SMA.

This paper is organized as follows. Section 2 introduces a new Ni-rich TiNi SMA foil for the origami stent graft. In Section 3, process methods of producing the stent graft including photochemical etching and heat-treatment are described. Etching was used to produce grooves of folds. Heat-treatment was given after etching to store a memory of a cylindrical shape for the stent graft. In Section 4, we demonstrate the self-deployment of the origami stent graft at near body temperature. In addition mechanical property of the stent graft in fully deployed configuration is measured. The conclusions are summarized in Section 5.

2. Material

In this research, two different Ni-rich TiNi SMA foils (Ti–50.7 at% Ni or Ti–51.3 at% Ni) were used in order to produce self-deployable origami stent grafts at body temperature triggered either thermally or mechanically. One is expected to deploy by heating. The other is expected to deploy due to the property of superelastic behaviour of SMA. It is recovered the original deployed configuration of the stent graft on a reduction of stress after the sheath which covers the stent graft is withdrawn.

The foils were produced by a method in which a diffusion treatment (at 1073 K for 72 h) was carried out to the ultrafine laminates foils composed of alternative layers of pure Ti (about 700 nm in thickness) and pure Ni (about 200 nm in thickness). One of the advantages of this TiNi SMA foil is that the foils do not have a rolling direction because the new process does not require rolling, which also reduces manufacturing cost. Detail of this method and properties of the material are given by Tomus et al. [14].

In the present study, Ni-rich TiNi foils were used because martensitic transformation temperature is adjustable to the temperature near human body by appropriate aging. Transformation temperature is very sensitive for the amount of Ni [15,16]. Therefore, the transformation temperature of the Ni-rich TiNi SMA foils with Ti–51.7 at% Ni and Ti–51.3 at% Ni will be different after aging treatment.

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