

As shown Figure 6.28(a) and (b), the origami stent graft has been folded successfully without forming any cracks. The radius and length of the stent graft is 6.25 and 25 mm, respectively, in the fully folded configuration. Figures 6.28(c)-(f) show a series of frames from a video recording, demonstrating the deployment process of the Ti-rich SMA stent. The folded origami stent graft was heated at 393K from the bottom, and it deployed gradually and recovered almost to the original cylindrical tube shape. It took about 14 seconds to expand to its fully expanded configuration. This demonstrates that it is possible to make a self-deployable stent graft using a Ti-rich TiNi SMA sheet. However, as shown in Figure 6.28(f) the origami stent graft could not recover completely to the original cylindrical tubular size. Several reasons can be considered.

Firstly, from the result shown in Figure 6.26, the recovery ratio of Ti-rich TiNi SMA reduces after annealing at 773K. Therefore, it is expected that the origami stent graft produced by the annealed SMA sheet could not recover completely when heated. Secondly, Figure 6.29(a) shows the photograph of the cross section of the folds of a stent. The surface strain of the fold is 13%, which is calculated by $(t/2R) \times 100$, where t is a thickness of the folds of 0.04 mm and R is a radius of 0.154 mm. The value is beyond the maximum value of the strain for which SMA is able to go back to its original shape. Thirdly, from the results of the bending test in Section 6.3.5, the etching line width is preferably more than 0.5 mm and in a direction either perpendicular or 45° to the rolling direction. However, in this model the line width was 0.3 mm and it could not be etched in the ideal directions due to the design of the pattern of the folds of the origami stent graft. Furthermore, we now draw attention back to the value of the shortening of folds during deployment calculated in Chapter 3 and use the result in Figure 3.29. Going from one unstrained configuration to the other during deployment requires larger deformation and needs to have a force to jump from one to the other. Therefore, it could be assumed that the SMA stent graft did not have enough force to

expand it completely. Further investigation will be needed to understand behavior of folds during deployment.

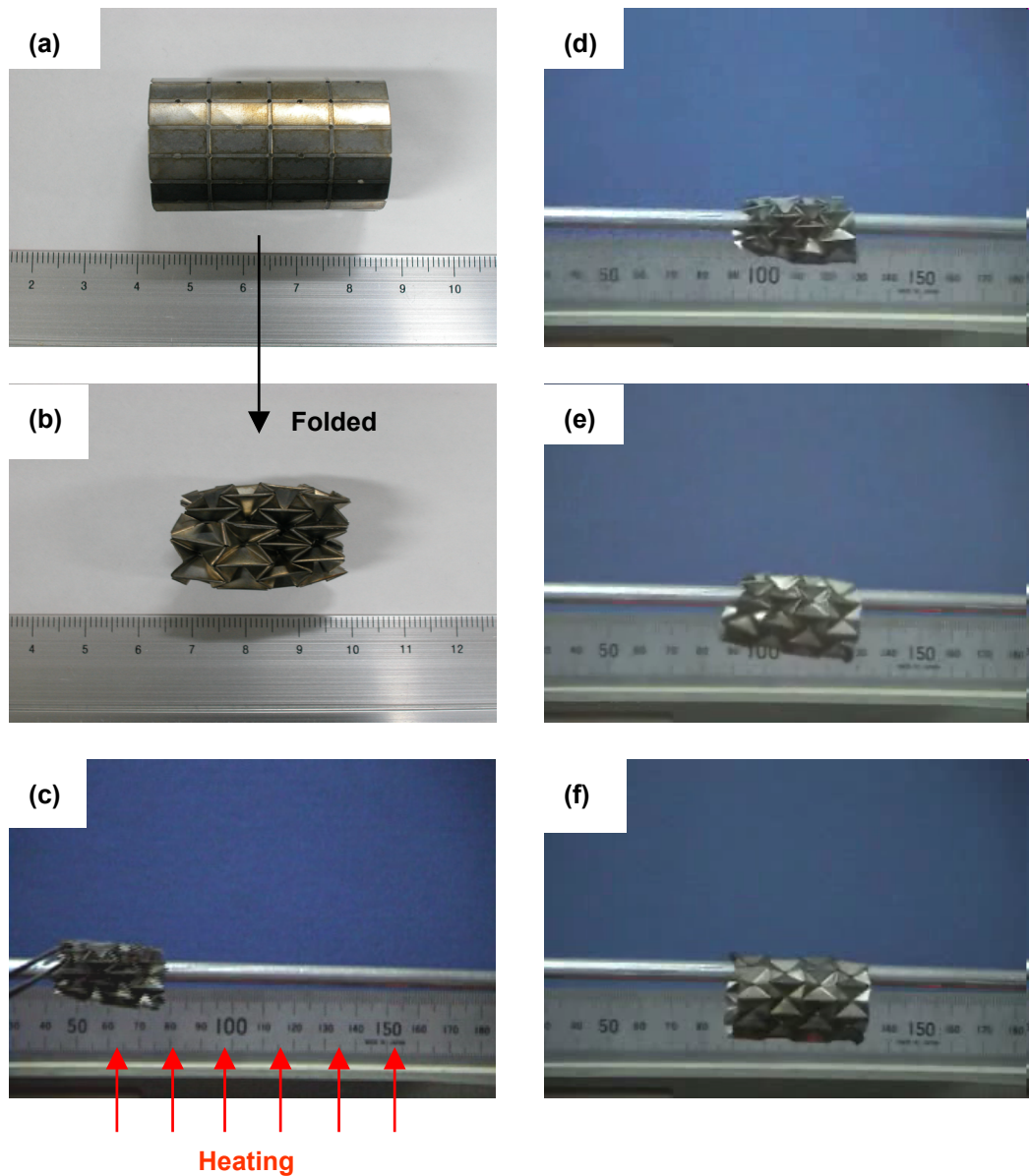


Figure 6.28 Shape change of the model stent. (a) The stent prior to being folded up; (b) folded at room temperature; and (c)–(f) development by heating at 393K.

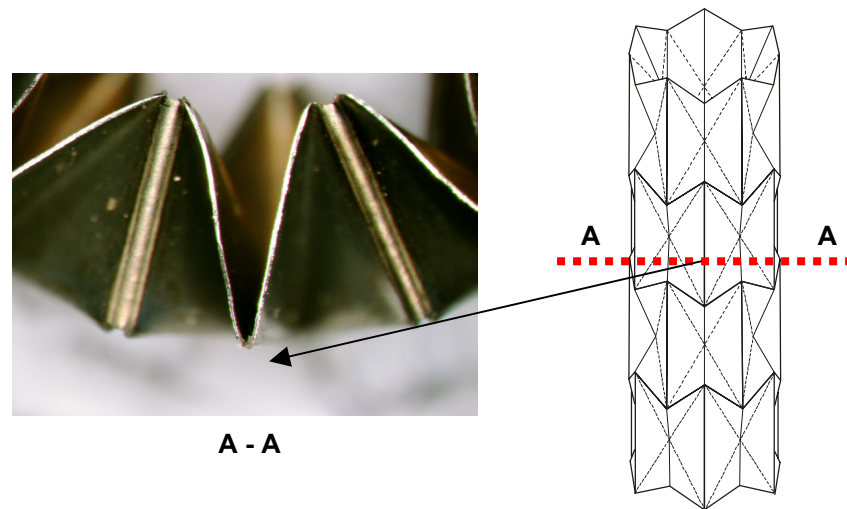


Figure 6.29 (a) Magnification of cross-section A-A.

6.5 Ni-rich TiNi shape memory alloy stent graft

Self-expansion of the stent graft using a commercially available Ti-rich TiNi SMA sheet has been demonstrated successfully, though with restrictions, in the previous section. However, the reverse transformation temperature, A_f of 383K is much too high. In medical applications, it should be near body temperature (about 309K). The use of TiNi SMA sheet with a Ni-rich composition solves this problem because the transformation temperature of Ni-rich SMA is adjustable to the temperature near that of a human body as described in Section 2.2.6, Chapter 2.

A sheet of Ni-rich (Ti-50.7at%Ni) TiNi alloy was supplied by Dr. Tsuchiya at Toyohashi University of Technology, Japan. The size of the sheet was 40 mm x 100 mm x 0.05 mm. It was produced by a new method of diffusion treatment (at 1073K for 72 hours) of ultrafine laminate sheet composed of 179 alternative layers of pure Ti (of 0.2 mm thickness) and pure Ni (of 0.12 mm thickness). A further advantage of this Ni-rich TiNi shape memory alloy sheet is that the sheet does not have a rolling direction

because the new process does not require rolling, which also reduces manufacturing cost. Details of this process and properties of the material are given by Tomus, et al (2003).

Using the negative etching method described in Section 6.2.1, the pattern of the folds for the stent graft was etched into the Ni-rich TiNi SMA sheet. The folding patterns are the same as in Figure 6.7 except for the number of elements. The number of elements in vertical and longitudinal directions are 6 and 4, respectively. The size of the element was 10 mm x 10 mm and the central holes were 0.5 mm x 0.5 mm. The width of the folds was 0.3 mm. The etchant was the same mixture of HF:HNO₃:H₂O as the etchant used to etch Ti-rich TiNi SMA sheet, but in the different proportion of 1:1:6 by volume because the etching process seemed to act more aggressively on the Ni-rich than it did on the Ti-rich TiNi SMA sheet. The thickness of the sheet of 0.05 mm was halved at the folds by the etching process.

After the etching, aging treatment was given at 773K for 40 hours to bring the transformation temperatures close to the body temperature. The transformation temperatures were measured by DSC with a cooling/heating rate of 0.17Ks⁻¹. During the aging process, the sheet was constrained by an aluminum tube to store the memory of a cylindrical shape, so that the stent graft would return back to the cylindrical tube when heated.

The opposite edges of the sheet were connected by adhesive. The stent graft was cooled below M_f , then was folded and inserted into an acrylic tube of 13 mm diameter imitating a catheter. The folded stent was heated by warm air and its deployment was recorded using a digital video camera.

Figure 6.30 shows the results of the DSC profile of the Ni-rich TiNi SMA sheet after diffusion and aging treatments. There are transformation peaks on cooling and one on heating. The first peak, R_m^* at 290K, and the second one, M^* at 278K, on cooling can

be assigned for R phase and B19⁵ martensitic transformation temperature, respectively. Transformation temperatures are found to be determined as $R_s=291\text{K}$, $M_f=261\text{K}$, $A_s=304\text{K}$ and $A_f=319\text{K}$. Therefore, the shape recovery will occur near body temperature.

The total etching time to reduce the thickness to half of its initial value was 16 minutes. Good folding patterns were produced by the negative etching technique. After etching, the sheet formed the cylindrical tubular shape subjected to the aging treatment. When the stent graft was folded, it had to be in martensite phase which is under M_f . As shown in Figure 6.30, M_f is 261K. Nitrogen was used to cool the stent graft to this temperature. Then folding of the origami stent was easily accomplished with no cracking. Before folding, the radius of the stent was 9.55 mm, which again, is suitable for use as an oesophageal or aorta stent graft.

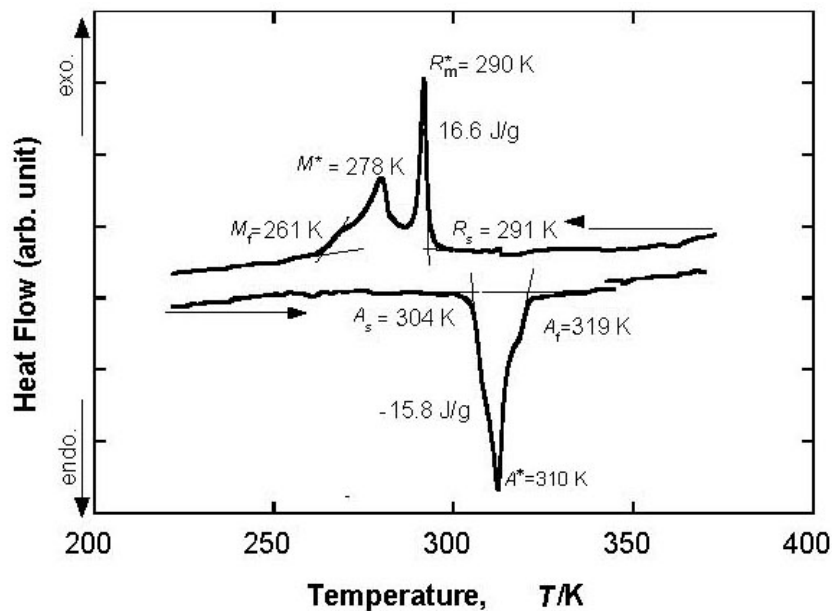


Figure 6.30 DSC profile of Ni-rich TiNi SMA after diffusion treatment at 1073K for 72 hours and aging process at 773K for 40 hours.

⁵ B19' represents monoclinic crystal structures of martensite phase.

Figures 6.31 and 6.32 show two series of frames from the video recording, demonstrating the deployment process of the Ni-rich TiNi SMA stent. The folded origami stent graft was pushed into the acrylic tube of a larger radius (12.5 mm) imitating the oesophageal or aorta lumen. The inside of the larger radius tube was heated by warm air above A_f before the stent graft was inserted and it was heated from top and bottom as shown in Figure 6.31(b) during the deployment of the stent graft. As can be seen in Figure 6.31, both radius and length of the origami stent graft increase gradually. The end view of the deployment of the stent is shown in Figure 6.32. It took 32 seconds for it to expand to its fully expanded configuration after the small acrylic tube (i.e. catheter) was removed completely (Figure 6.32c). Again, it can be seen that the radius increase gradually and the expansion is roughly uniform. However, in the middle stage of the deployment, it becomes slightly distorted (Figure 6.32d and e). It may be a temporary distortion caused by uneven heating of the stent. In living tissue, a stent would be heated relatively evenly, thus uneven heating would be less of a concern.

This demonstrates that it is possible to make a self-expanding stent graft which can expand at near body temperature using a Ni-rich TiNi SMA sheet. However, as shown in Figures 6.31(i) and 6.32(i) the origami stent graft could not recover to the original cylindrical tubular shape completely. The maximum value of the strain of Ni-rich TiNi SMA where it is able to go back to the original shape is 3% (Tomus, et al. 2003). Therefore, it is assumed that the value of the strain of the stent graft is beyond the maximum recoverable strain.

All of the existing self-expanding stents are made from TiNi tubes and the mesh patterns are machined by laser cutting (Duerig, et al. 1999) and processing of TiNi tubes and laser cutting are both complex and expensive processes (Reynaerts, et al. 1996). However, in this study, the stent graft has been produced from TiNi sheet made by the ultrafine laminate method, and the folds have been patterned by a photochemical etching method, which are both simpler and cheaper.

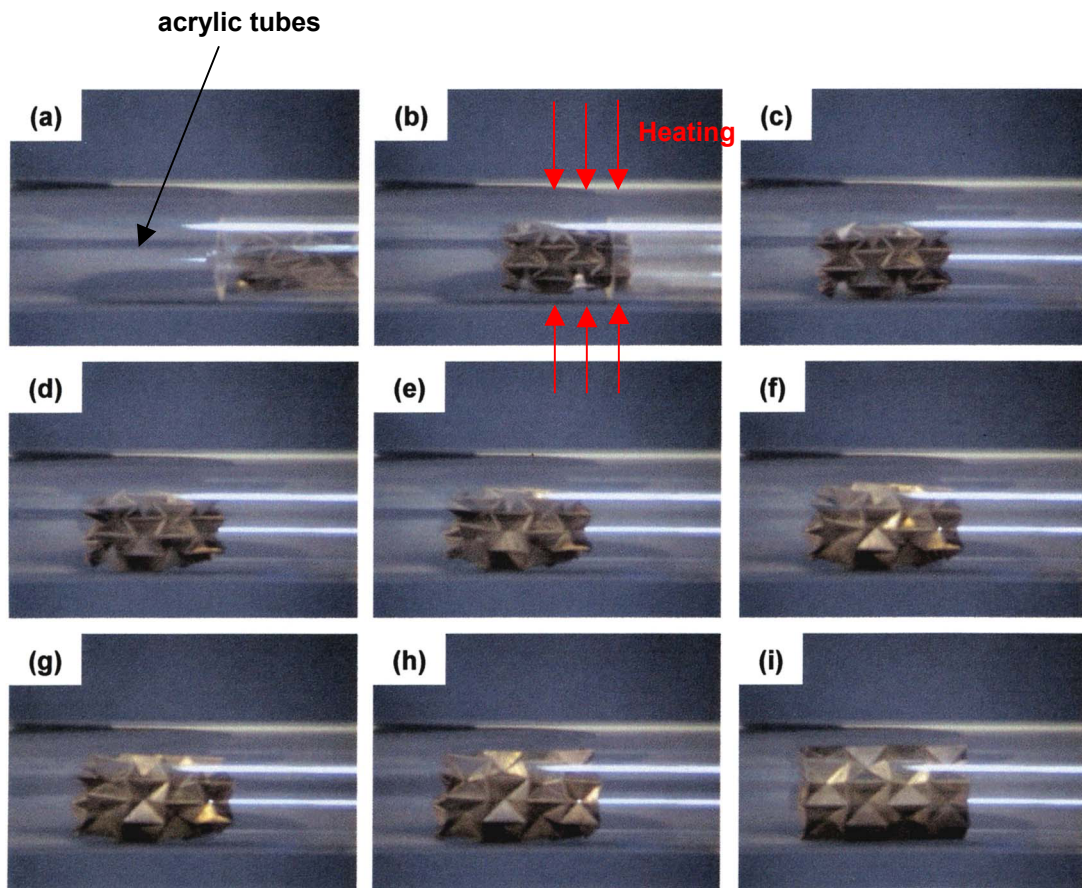


Figure 6.31 Series of video image showing: (a) Stent graft which is folded and backed into a small acrylic tube of 7.5 mm radius was inserted into another acrylic tube of 12.5 mm radius, (b) the small acrylic tube was removed and (c)-(i) the stent graft was self-expanding at above A_f (319K).

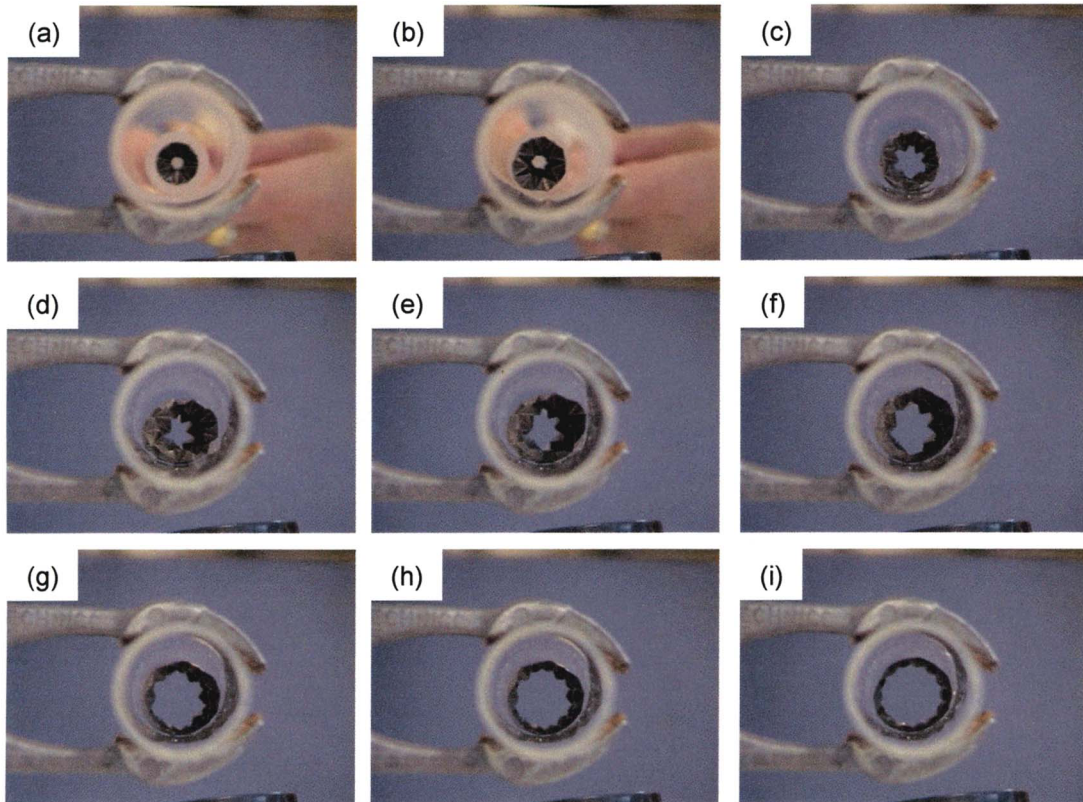


Figure 6.32 Self-deployment of the origami stent graft at end view. (a) Stent graft which is folded and backed into a small acrylic tube of 7.5 mm radius was inserted into another acrylic tube of 12.5 mm radius, (b) the small acrylic tube was removed and (c)-(i) the stent graft was self-expanding at above A_f (319K).

6.6 Conclusions

In this chapter methods to produce models of the origami stent graft using both stainless steel and SMA sheets have been established. The models have been produced successfully. Details of the results are as follows.

The chapter started by using stainless steel sheets, and testing methods to make folds in the metal. It has been found that grooves for the folds can be produced easily using photochemical etching which is a cost effective technique. It was also found using these stainless steel models that folding of the stents to its fully folded configuration could be easily accomplished by using a combination of well-directed radial forces, as well as a longitudinal compression. Such forces have been achieved (for other applications) using a press.

The second part of this chapter has been investigated using techniques such as etching and heat treatment on the development of stents from TiNi SMA sheets. It has been found that the both positive and negative photoresists with the chemical solution of HF/HNO₃/H₂O can be applied. More dilute ratios of this solution (i.e. 1:1:4 or 1:1:6 by volume) are preferred, as the stronger solution (1:1:2) can cause lifting of the photoresist and undercutting of the grooves. From the results of heat-treatment, it has been found that ductility of the SMA sheet can be improved, although this has effects on the ability of the SMA to recover completely to its remembered shape

It has been demonstrated that both Ti-rich and Ni-rich TiNi SMA stent grafts will smoothly self-expand by heating. This is particularly relevant for the Ni-rich TiNi SMA sheet, since it will expand at near body temperature. However, both models could not recover to their original cylindrical tubular shapes completely, which was mainly because the folded stent graft is strained beyond the maximum recoverable strain of TiNi SMA sheets. Some improvement could be made by modifying the folding pattern, and depth and width of the etched grooves.

The working models presented here have shown that the concept of the origami stent graft can be achieved using existing biocompatible materials such as stainless steel and SMA sheets, and using readily available technologies such as photochemical etching.