# **Bio-inspired Leaf Stent for Direct Treatment of Cerebral Aneurysms**

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#### Background

Cerebral aneurysm is a weak region in the wall of an artery in the brain, where dilation or ballooning of the artery wall may occur. Its rupture can lead to fatal hemorrhages in the brain. Cerebral aneurysms are common lesions. In the United States, for example, more than 10 million persons have intracranial aneurysms<sup>[1]</sup>. About 27000 people suffer from ruptures of intracranial aneurysms each year, 10% of whom die before they reach the hospital<sup>[2]</sup>. The market for the endovascular treatment of cerebral aneurysms, which currently stands at US\$660 million globally, is expected to double over the next seven years with the newly created flow diverting stents segment providing the main engine for growth<sup>[3]</sup>.

Current methods for treating intracranial aneurysms include surgical clipping and endovascular coiling<sup>[4]</sup>. In the surgical clipping method, the skull of the patient is opened, and a surgical clip is placed across the neck of the aneurysm to stop blood from flowing into the aneurysm sac. The risk of this method is relatively high, especially for elderly or medically complicated patients. Endovascular coiling procedure is a less invasive method involving placement of one or more coils, delivered through a catheter, into the aneurysm until the sac of the aneurysm is completely packed with coils. It helps to trigger a thrombus inside the aneurysm. Although endovascular coiling is deemed to be safer than surgical clipping, it has its own limitations. First, after the aneurysm is filled with the coils, it will remain its original size. As a result, the pressure on the surrounding tissue exerted by the aneurysm will not be removed. Second, this procedure is effective for the aneurysm that involves a well-formed sac with a small neck. When used to treat the wide-neck aneurysm, the coil is likely to protrude into the parent vessels. A solution to prevent coil protrusion is to use a stent in combination with coiling embolization. In the stent-assisted coiling procedure, a stent is first placed across the aneurysm neck, serving as a scaffold inside the lumen. Then, the coils are delivered into the sac of the aneurysm through the interstices of the stent. Although this method can solve some problems of purely coiling, it still has some drawbacks. First, a microcatheter through which the coils are sent into the aneurysm sac has to be navigated through the interstices of the stent. This process is difficult and time-consuming. Second, the coils are still used to fill the sac of the aneurysm. As a result, the aneurysm size remains the same after the treatment. Furthermore, when it comes to the pseudoaneurysm where no fully-formed aneurysm sac can be identified, coiling methods are not applicable<sup>[5]</sup>.

### The concept

Using a stent alone to treat the aneurysm is a promising way to avoid the problems stated above. In this method, a stent with an area of coverage is placed across the aneurysm neck, blocking it sufficiently to restrain blood from flowing into the sac and finally to trigger a thrombus within the aneurysm. Because the aneurysm solidifies naturally on itself, there is no danger of its rupture. Furthermore, because no coil is involved in this method, the aneurysm will gradually shrink as the thrombus is absorbed. Consequently, the pressure applied on the surrounding tissue can be removed.

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The reason why this method has not used is because of the difficulty in designing stent. It has to be flexible enough to pass through and morph the very tortuous blood vessel in brain whereas at the same time to provide sufficient coverage to shut the aneurysm. Current stents made for the stent-assisted coiling, such as Neuroform stent (Boston Scientific), LEO stent (Balt) and Enterprise stent (Corids), have a very open design to allow the coils to pass through the interstices. They do not provide much coverage at all. Therefore, they are inadequate for direct treatment of the aneurysm.

Inspired by the lace fern braches, as shown in Fig. 1, we have developed a new stent, called *leaf stent*, for the direct treatment of the intracranial aneurysms<sup>[6]</sup>. The key idea behind the design is a stent comprising a plurality of "leaves" interconnected by "stems", where the "leaves" provide the coverage to the neck of the aneurysm. The "stems" are connected together in a chain, to which the "leaves" are connected. The stent is made from a single thin-walled nitinol tube by laser cutting. The packaging is achieved by overlapping the "leaves", which leads to a very small delivery diameter. The overall length of the stent hardly changes when it expands.

The leaf stent has sufficient amount of dense areas to provide adequate coverage to the neck of the aneurysm while remaining flexibility and conformability so that it can be easily navigated through tortuous arteries and adopt the path of the vessel after placement, see Fig. 2. The leaf stent can be cut from thin-walled nitinol tubes. Moreover, the covered area can be tailored in order to serve as a right patch in the vicinity of the neck of the aneurysm, and the remainder of the stent can adopt a very open design to prevent blockage of the branch arteries adjacent the aneurysm.

We produced a number of leaf stents using a laser cutting machine. The stent surface was then polished chemically. Both nitinol and polymer "leaves" were used. A folding apparatus was designed to furl the stent from the expanded state to the packaged state. Extensive numerical analysis and mechanical testing showed that the concept does meet the requirement of high flexibility and providing sufficient coverage.



Fig. 1. A lace fern branch. The divided leaves allow it to furl around a curved vessel.



Fig. 2. The leaf stent and its placement inside a bent tube.

## The design

Figure 3 shows a plan view of a single ring of one of the leaf stents notionally unwrapped from its actual tubular shape into a flat shape. The stent comprises a plurality of leaves a interconnected by stem members b. The stem members are connected together in a chain, with the leaves each connected thereto. The stent is formed from a single layer of material cut to define the leaves and the stem members. In one of the designs, the leaves are triangular in outer shape and arranged along a circumferential direction of the stent. The leaves can either be solid plates or modified to each

comprise a frame defining a central aperture, covered by other flexible materials, e.g. a polymer membrane. Figure 3 shows the simulated crimping procedure of a single ring from a fully expanded state to a folded state.



Fig. 3. Crimping procedure of a single ring

Finite element analysis is used to compare the longitudinal flexibility of the leaf stent and the Neuroform Stent (Boston Scientific) which has an extremely open design. Figure 4 shows the bending moment versus curvature curves of both models. It illustrates that the present stent design has similar longitudinal flexibility as the Neuroform Stent. Figures 5 and 6 show the deformed shapes of the present stent and the Neuroform Stent subjected to bending. Note that the leaf stent has quite uniform deformation, while the Neuroform Stent produces large gaps between adjacent rings.



Fig. 4. Bending moment versus curvature cures of the leaf stent and the Neuroform stent



Fig. 5. Deformed shape of the leaf stent subjected to bending



Fig. 6. Deformed shape of the Neuroform stent subjected to bending

## Conclusion

We have proposed a new design for cerebral stent. Numerical modelling and prototypes demonstrate that the concept is viable and promising. A model stent was made using laser cutting followed by chemical polishing. It is flexible and can be folded from an expanded diameter of 5mm to around 1.5mm. It was placed over a punch inside a flexible pipe. When liquid was running, the stent was able to prevent leakage at the punch. Further experiments involving fountain with a brain blood vessel model have been planned.

### References

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