New Spherical Stent Concept for Cancer Occlusion

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Abstract

We propose the world's first spherical stent, which can be deployed in the upstream of an artery to reduce the blood flow to the downstream cancer cells. Computational models were developed to predict the device's mechanical integrity and hemodynamic occlusion performance. Simulation results suggested that devices with the metal density of 14-27% would reduce the average blood flow rate by 30-50%. Conceptual prototypes were made with a series of manufacturing procedures and tested by flow experiments for proof of concept. Experimental results showed that the spherical stent with the metal density of 27% was able to reduce 44% of the flow, which agreed well with the simulation results.

Keywords: Spherical Stent, Cancer, Occlusion, Nitinol, Super-elasticity

Objective

In this paper, we propose a novel nitinol "spherical stent" concept for future cancer treatment options. This device, the first of its kind in the world, also represents the first "spherical" variation or transformation from traditional vascular stents with a cylindrical shape. Finite element analysis (FEA) models were developed to simulate the mechanical performance of the spherical stent during manufacturing and deployment, including a series of expansions and heat treatments, crimping inside a catheter, and release to the artery. Computational fluid dynamics (CFD) models were also developed to evaluate the presence of the spherical stent on the flow changes in arteries. A pulsed-fiber optic laser, along with a series of expansions and heat treatments, were used to make the first prototype of our spherical stent possible. Flow experiments were conducted for concept proof.

Materials and Methods

This spherical stent has to withstand large deformation without fracture during the dramatic shape and size transformations from crimping to expansion and from cylinder to sphere. In order to achieve such a dramatic shape/size transformation via self-expansion, nitinol alloy (NiTi) was chosen as the device's material due to its exceptional super-elasticity and shape-memory properties [1].

Computer simulations including FEA and CFD were implemented to predict the device integrity and hemodynamic performance [2-3]. Various loading conditions were considered in FEA, including multiple stent expansions and their subsequent heat treatments during manufacturing, crimping of the stent inside a catheter, and releasing it into artery. In CFD, a simple bifurcated artery model was built, with an inlet of 6 mm and two outlets of 4 mm in diameter. The spherical stent was placed at the upstream of outlet 2, with two different metal densities of 14 and 27% evaluated.

Manufacturing the spherical stent requires laser-cutting of the designed pattern onto a nitinol hypotube, followed by an alternating series of expansions and heat treatments as it is gradually shaped into a sphere using customized tooling. Through these manufacturing procedures, nitinol spherical stents designed for the purposes of flow occlusion can be produced.

To evaluate the device occlusion performance, flow experiment were conducted. A plastic bifurcated artery model was manufactured and connected to a tubing system (Figure 1). The spherical stent was deployed at the upstream of outlet 2 to evaluate its occlusion performance. Digital particle image velocimetry (DPIV) experiments were conducted to evaluate the occlusion performance as well.

Results and Discussion

Figure 2 demonstrates the FEA contour plots of strain distribution during a series of spherical expansions. The spherical stent has to withstand large deformation without fracture during the dramatic shape and size transformation. FEA results showed that the maximum strain encountered during the entire process was 10% when the stent was crimped inside a catheter of 1.6 mm diameter for delivery. Since the nitinol failure strain is approximately 12%, this shows that our device is able to withstand large deformation safely. CFD results showed that devices with the metal densities of 27% and 14% were able to reduce the blood flow rate by 50% and 30%, respectively (Figure 3). The reduction of the blood flow in the target artery implied that a portion of the blood flow was re-directed towards the other artery branch, according to the conservation of mass.

After simulations, conceptual prototypes were first cut by a pulsed-fiber optic laser, and a series of expansions and heat treatments were used to shape the stent to its final spherical geometry. Figure 4 presents the world's first prototype of the spherical stent for demonstration of our novel concept.

In the occlusion experiments (metal density of 27%), the fluid volumes collected from both outlets were nearly identical before the spherical stent was placed (48.7% vs. 51.3%). However, when the spherical stent was placed at outlet 2, the fluid volumes collected from both outlets changed drastically to 71.1% vs. 28.9%. This shows that 44% of the flow at outlet 2 was successfully reduced by the presence of the spherical stent and re-directed to outlet 1 instead, which agreed well with the CFD predictions. Figure 5 shows a DPIV image taken at the peak point in Figure 3. It clearly shows the formation of a vortex located at the upstream or proximal side of the spherical stent. The particle velocity at outlet 1 increased significantly, while the particle velocity at outlet 2 decreased, which implied that the flow at outlet 2 was re-directed to outlet 1 after the spherical stent was deployed.

Conclusions

A novel treatment option for cancers is proposed. FEA and CFD models were developed to simulate the mechanical integrity and occlusion performance. A conceptual prototype, the first of its kind in the world, was manufactured and tested to demonstrate its occlusion performance. The spherical stent with the metal density of 27% was able to reduce 44% of the flow, which agreed well with the CFD predictions. We believe that this novel spherical stent will add a new dimension to future cancer treatments.

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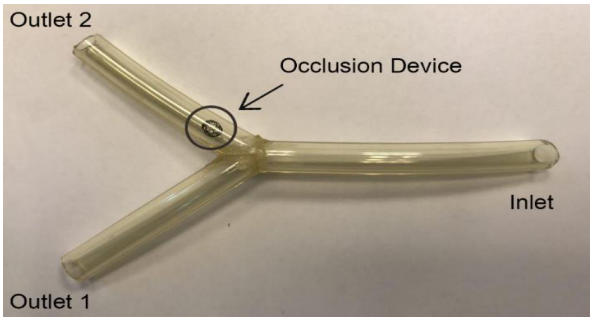

Figure 1. Bifurcated artery model for flow tests.

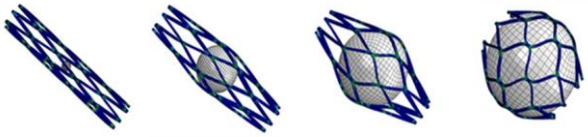

Figure 2. Contour plots of strain distribution during a series of expansions.

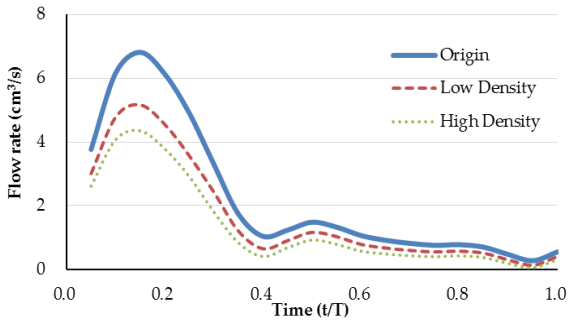

Figure 3. Reduction of blood flow by spherical stent.

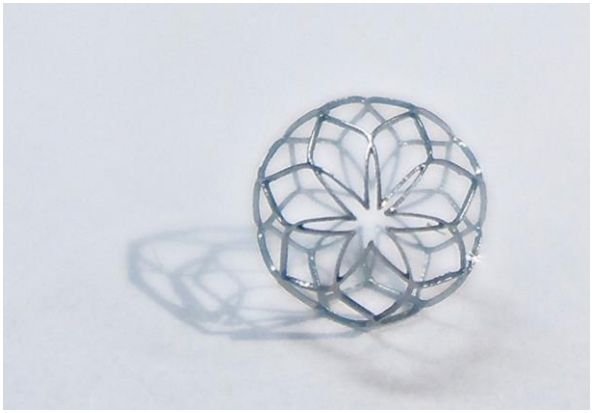

Figure 4. World's first spherical stent.

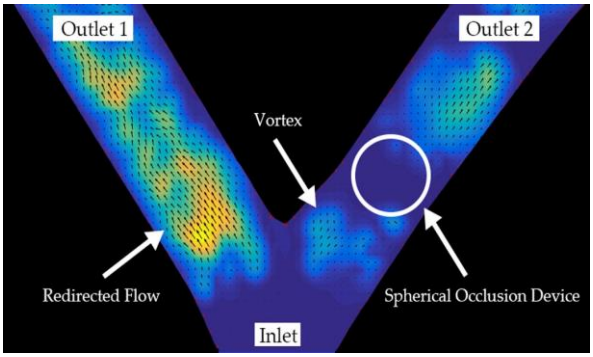

Figure 5. DPIV with successful occlusion.