

The Effect of Stent Coating on the Stent Flexibility: Comparison of Covered Stent and Bare Metal Stent

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Abstract : Carotid artery stenting (CAS) is the standard procedure for patients with severe carotid stenosis at high risk for carotid endarterectomy (CAE). A major drawback of CAS is the higher incidence of procedure-related stroke compared with traditional open surgical treatment for carotid stenosis - CEA, even with the use of the embolic protection devices (EPD). As the currently available bare metal stents cannot address this problem, our research group developed a novel preferential covered-stent for carotid artery aims to prevent friable fragments of atherosclerotic plaques from flowing into the cerebral circulation, and yet maintaining the flow of the external carotid artery. The preliminary animal studies have demonstrated the potential of this novel covered-stent design for the treatment of carotid atherosclerotic stenosis. The purpose of this study is to evaluate the effect of membrane coating on the stent flexibility in order to improve the clinical performance of our novel covered stents. A total of 21 stents were evaluated in this study: 15 self expanding bare nitinol stents and 6 PTFE-covered stents. 10 of the bare stents were coated with 11%, 16% and 22% Polyurethane(PU), 4%, 6.25% and 11% EE, as well as 22% PU plus 5 μ m Parylene. Different laser cutting designs were performed on 4 of the PTFE covert stents. All the stents, with or without the covered membrane, were subjected to a three-point flexural test. The stents were placed on two supports that are 30 mm apart, and the actuator is applying a force in the exact middle of the two supports with a loading pin with radius 2.5 mm. The loading pin displacement change, the force and the variation in stent shape were recorded for analysis. The flexibility of the stents was evaluated by the lumen area preservation at three displacement bending levels: 5mm, 7mm, and 10mm. All the lumen areas in all stents decreased with the increase of the displacement from 0 to 10 mm. The bare stents were able to maintain 0.864 ± 0.015 , 0.740 ± 0.025 and 0.597 ± 0.031 of original lumen area at 5 mm, 7 mm and 10mm displacement respectively. For covered stents, the stents with EE coating membrane showed the best lumen area preservation (0.839 ± 0.005 , 0.7334 ± 0.043 and 0.559 ± 0.014), whereas, the stents with PU and Parylene coating were only 0.662, 0.439 and 0.305. Bending stiffness was also calculated and compared. These results provided optimal material information and it was crucial for enhancing clinical performance of our novel covered stents.

Keywords : carotid artery, covered stent, nonlinear, hyperelastic, stress, strain

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