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学 位 論 文 内 容 の 要 旨
DISSERTATION ABSTRACT

博士の専攻分野の名称　博士（工学）　氏名　Achmad Syaifudin

学 位 論 文 題 名
Title of dissertation submitted for the degree

Development of balloon-expandable stents for treatment of eccentric plaque considering surface roughening
(偏心プラークのための表面性状を考慮したバルーン拡張ステントに関する研究)

Stent, a tiny mesh tube that is well known to treat narrow or blocked artery due to plaque obstruction, remain relevant to investigate after decades of development. Researchers are still trying to solve the problems, such as in-stent restenosis, vessel wall inflammation, and plaque rupture. Prior to stent investigation, reviewing literature to map the problems surrounding stent deployment is a non-negligible stage of study. Numerous developments have been conducted, which can be classified into development on stent material, mechanism of stent expansion, and mesh structure of stent geometry. In the case of the balloon expandable stent (BES), there is a possibility of the development related to both the material properties and the cost. Therefore, BES is the main choice of treatment around the world. Nowadays, the development of BES should be conducted considering the results of clinical trials and/or experimental data. From the clinical trials, deep injury of arterial tissue is a more potent stimulus for neointima formation than stretch. From this point of view, the author presumes that the stent developments considering specific plaque type and the appropriate material model of the arterial tissue are effective to minimize the vascular injury.

The physical properties of the stent surface influence the effectiveness of vascular disease treatment after stent deployment. During the expanding process, the stent subject to high-level deformation that could alter either its microstructure or the magnitude of surface roughness.

In chapter 2, the structural transient dynamic analysis was performed using ANSYS R15.0, to identify the deformation after the stent is placed in a blood vessel. Two types of bare metal stents are studied: a Palmaz type and a Sinusoidal type. The relationship between plaque length and the changes in surface roughness was investigated by utilizing three different length of plaque; plaque length longer than the stent, shorter than the stent, and the same length as the stent. In order to reduce computational time, 3D cyclical and translational symmetry was implemented into the FE model. The material models was defined as a multilinear isotropic for the stent and hyperelastic for the balloon, plaque, and vessel wall. The correlation between the plastic deformation and the changes in surface roughness was obtained by the intermittent pure tensile test using specimens. The plastic strain obtained by FE simulation can be used to estimate the surface roughness of the expanded stent using the relationship between the plastic deformation and the changes in surface roughness. The study showed that the plaque size relative to stent length significantly influenced the changes in surface roughness. It was also found that the stent having the same length as the plaque is preferable because of the small surface roughness after expansion.

Both the stent and balloon types are key factors in the stenting process. In the treatment of the eccentric plaque obstruction, the symmetric expansion of the stent generates non-uniform stress distribution, which may aggravate the fibrous cap that is prone to rupture.

In chapter 3, a non-symmetric structural geometry of stent is constructed to obtain a reasonable stress distribution. To derive the novel structural geometry, the Sinusoidal stent is modified by varying the struts length and width, adding bridges and varying the curvature width of struts. An end ring of stent struts was also modified to reduce the Ectropion angle. Two balloon types were used to deploy the stent, i.e. the ordinary cylindrical and the offset balloon. Analyses of the deformation characteristics, surface roughness changes, and induced stresses were subsequently examined using structural transient dynamic analysis in ANSYS R15.0. The Palmaz and Sinusoidal stent were used for comparative study. This study indicated that the Asymmetric stent type has effect on reducing the central radial recoiling and the dog-boning phenomenon. As for the surface roughness changes and stresses, the Asymmetric stent results were similar to those of the Sinusoidal stent.

Mechanical characteristic assessment of the new stent design is important to improve the performance during the stenting process. Stent with good performance in geometric assessment should pass several tests in the unexpanded and expanded condition. FEM assessment is expected to replace the actual mechanical assessment to save the cost and time of the manufacturing.

In chapter 4, the FEM assessment is conducted using structural nonlinear analyses in ANSYS R15.0. Four assessments are included in this study: two flexibility tests on unexpanded condition (single-load and multi-load) and the other tests on expanded condition (single-load and multi-load). The stent type used in the simulation is the Asymmetric stent and the Sinusoidal stent. This study indicated that Asymmetric stent has higher flexibility compared to Sinusoidal stent in both configurations, i.e. unexpanded or expanded conditions. In the case of Asymmetric stent, its inflated-side is more flexible than the fixed-side.

In chapter 5, plaque obstruction that mainly appears in an eccentric shape, should be treated carefully to avoid severe vascular injury. As a series of the new stent development, the rupture analysis after stent deployment was conducted. Namely, the structural transient nonlinear analysis was constructed in ANSYS R15.0 to investigate the plaque vulnerability and arterial tissue rupture. An idealized human carotid artery and eccentric fibroatheroma plaque type are chosen as a FEM model. The large lipid pool and the fibrous cap are accommodated in the plaque model to simulate the rupture. Arterial tissue with multilayer material parameters, including intima, media and adventitia, was modeled as the isotropic hyperelastic material. All material parameter constants for the arterial tissue are extracted from the experimental data using the hyperelastic curve fitting in ANSYS R15.0. Sinusoidal stent was included in the simulation to be used as a comparative tool in analyses. For the expansion mechanism, ordinary cylindrical and offset balloon types were incorporated to inflate the stents alternately. The simulation results show that the four expansion combination did not produce the residual stress and stretch within diseased adventitia, diseased media, and the fibrous plaque cap. The residual stress effected the intact of arterial wall opposite of the plaque. The fibrous plaque cap brakes due to the critical residual stress though the stretch remains under safety region.

This study indicated the importance of choosing appropriate stent type and length in the treatment of atherosclerotic diseases. This result also supports the idea that a specific stent type cannot be used for all atherosclerotic plaque shape.