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Development of diameter-change type accelerated durability tester and preliminary assessment of CP stent

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***Abstract*— We developed an accelerated durability test system which can apply radial diameter-change load to stents by producing physiologic aortic pulsatile pressure differences.**

***Clinical Relevance*— The durability test system worked at the frequency of 20Hz without any problems. We confirmed that no stent fracture was observed in the initial durability study of 1 year equivalent duration.**

I. Introduction

The CP (Cheatham Platinum) stent, which consisted of platinum / iridium alloy, are targeted for treatment of pediatric coarctation of the aorta and pulmonary artery[1]. The stent can be repeatedly expanded as children grow and vessel diameters become larger. In this study, we developed an accelerated durability test system that can apply diameter-change load to the stents by producing physiologic aortic pulsatile pressure differences. We investigated that the accelerated durability test system worked stably. Moreover, we conducted an initial durability test of the CP stent under an aortic diameter-change environment to investigate the initial one-year equivalent durability of the CP stent.

II. Methods

The durability test system composed of a voice coil motor, a silicone blood vessel model, and polymer elastic chamber (Figure 1). The polymer elastic chamber was connected to the voice coil motor. By cyclically changing volume inside the elastic chamber, a physiologic pulsatile pressure of 120/80mmHg were generated in the blood vessel model. The voice coil motor was driven at the frequency of 20 Hz. Generally, implantable devices need to ensure 10 year's durability in a simulated in vivo condition, before clinical trials. Therefore, development of durability test system which can reasonably test medical devices at accelerated conditions are essential. In this study, the blood vessel model was made of silicone that matches to the dimensions and stiffness parameters of the human aorta. By applying the internal pulse pressure, the diameter change rate of the models was 7.3%, which was within the range of human aorta (5.3 ± 2.6%)[2] . Physiologic saline was used, and the temperature was adjusted within 37±2°C. The CP stent was deployed in the blood vessel model (Figure 2). We investigated whether the test system works stably, and after the confirmation, we conducted the accelerated durability tests of the CP stent for one-year equivalent duration.

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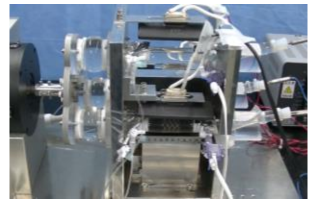

Figure 1 Radial pressure-change load type accelerated durability tester.

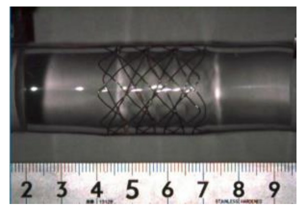

Figure 2 The CP stent place in the aortic vessel model

III. Results

In the durability tests, the pressure differences, and temperature were stable throughout one-year equivalent duration (Figure 3). The mean diameter change rate was 6.8%. No stent fracture was observed.

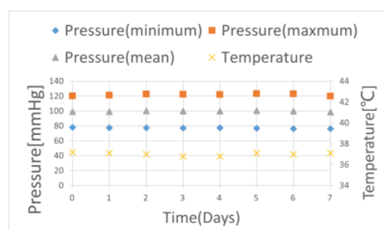

Figure 3 Pressure and temperature

IV. Discussion & Conclusion

We successfully developed the accelerated durability tester which can produce physiologic aortic diameter-change and pressure difference at the frequency 20 Hz. We confirmed that the system worked stable. In the accelerated durability test of the CP stent, no stent fracture was observed in the one-year equivalent duration. As a future work, we will confirm 10-year equivalent durability of the CP stent.

References

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[2] Tina M. Morrison et al, "Circumferential and longitudinal cyclic strain of the human thoracic aorta: Age-related changes", Journal of Vascular Surgery(2009), Vol.49, No.4, 1029- 1036.