

Study about animal (NZW Rabbit, Juvenile pig) test to secure safety and effectiveness of thermoplastic polyurethane stent graft & graft using electrospinning

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Background. A stent is a cylindrical medical device used to normalize the flow of blood or body fluids, such as blood vessels, gastrointestinal tract, and bile duct, by inserting it into a narrowed or blocked area under image fluoroscopy without performing a surgical operation when the flow is not smooth. In particular, stents applied to blood vessels are divided into stents for coronary arteries, stents for blood vessels, stents for blood vessels in the brain, stents for iliac arteries, and stents made of absorbent materials. It is used to improve blood flow.

Coronary artery disease refers to a lesion in which blood flow to the myocardium is impaired due to stenosis of the coronary arteries due to atherosclerosis. Atherosclerotic coronary artery disease has long been known as the most common cause of death in the West. Although it has not yet occurred frequently in the East, including Korea, it is reported that coronary artery disease is on the rise with the recent change in eating habits. Coronary artery disease is clinically manifested in one of three aspects: angina pectoris, myocardial infarction, and sudden death. Double myocardial infarction is usually caused by sudden thrombus in a coronary artery with atherosclerotic stenosis, resulting in complete blockage of myocardial blood flow. Myocardial infarction, which was supplied by blood vessels from blocked blood vessels, leads to necrosis. In order to improve blood flow in blood vessels blocked from blood supply due to myocardial infarction, stenting is in the spotlight along with surgical methods. Among the causes of blocking the flow of blood vessels, thrombus is seen as the main cause, so the frequency of using vascular stents with suppressed thrombus formation is increasing.

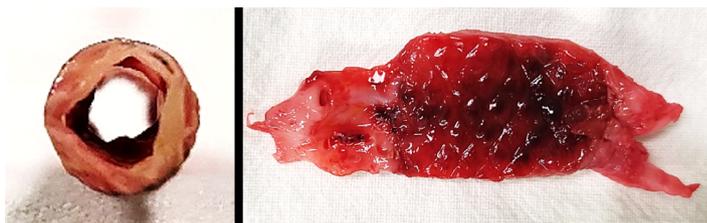


Fig. 1. Thrombus observation and internal blood vessel evaluation

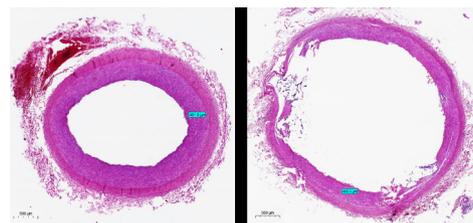


Fig. 2. Biopsy

Results. A coronary stent is a medical device used to improve blood flow by expanding a coronary artery narrowed by the formation of a thrombus, and is an intermediary procedure that minimizes side effects through surgery. Among the causes of blocking the flow of blood vessels, thrombus fish are seen as the main cause, so the frequency of using vascular stents with suppressed thrombus formation is increasing. S&G Biotech Research Institute is developing a self-expanding Nitinol stent graft that can ensure patency while suppressing the formation of blood clots. The graft material used here is a material that hardly decomposes in bodily fluids such as blood by using a thermoplastic polyurethane material, and is loaded with an antithrombotic agent. Our research team produced a stent graft by spinning the TPU graft onto the self-expanding Nitinol stent skeleton with an electrospinning device, and confirmed its safety and effectiveness by conducting a biological safety evaluation and animal testing. In addition to the vascular stent for the coronary artery for the treatment of coronary artery disease, the frequency of application of the aortic vascular stent graft for the treatment of aortic vascular disease is also increasing. The aortic vascular stent graft is a stent composed of a metal stent skeleton and a graft and suture made of a biocompatible polymer material and is used for aortic dissection and aneurysm treatment.

Conclusion. After blood vessel extraction, the surface of the inserted stent and the inside of the blood vessel were checked, and the result was grade 0 (no thrombus observed). No other peculiarities were identified inside the blood vessels. As a result of checking the H&E results of 3 parts (distal part, middle part, and proximal part) of each blood vessel, in the stent group. Neointimal proliferation was not confirmed.

Keywords: biopsy; blood vessels; grafts; polyurethane; stents; thermoplastic; thrombus

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