**A NOVEL AUTOLOGOUS TISSUE-ENGINEERED HEART VALVE FOR TRANSCATHETER IMPLANTATION**

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**Objective:**Tissue-engineered heart valves are expected to be viable grafts. However, it is unknown whether they fit for transcatheter implantation. We developed a novel autologous stent-valve (stent biovalve) with a unique in-body tissue engineering. In this study, we investigated feasibility of the valve and time-course histological transition in a large animal experiments.

**Method:**We created molds for biovalves using plastic rods and combined them with self-expandable metallic stents. We embedded them in the subcutaneous spaces of adult goats for 1-2 months. After harvesting the implant (a mold with a stent and encapsulated tissue) en-bloc and removing the mold only, biovalves were constituted from completely autologous connective tissues and fibroblasts. Twenty-five cases of stent-valve type were implanted into in situ the aortic and pulmonary valves (17 and 8, respectively) with transcatheter technique. In each animal, the stent biovalve was explanted at 1-month step (from 1 to 6 months) or as long as possible to observe their time-course change.

**Results:**Biovalves were successfully implanted and showed smooth movement of the leaflets with a little regurgitation in angiogram. The maximum duration of implantation reached to 19 months as a result. The biovalves were extracted at each duration and examined. Calcification were not observed in any cases and durations. The tissues showed laminar endothelialization on the surface of the valve leaflets and the cell migration inside the biovalve body even in 1 month after implantation. The recipients’ cells have also spread inside the leaflets to the tip gradually in 19 months without any hyperplasia and finally constructed characteristic 3-layered tissues like the native leaflets.

**Conclusion:**Implanted biovalves can adapt their histological structure to the environment even after implantation. This histological adaptation gives us expectation that they can sufficiently exert the functions as the native valves and purposively increase the flexibility and durability for a long while. They have a potential to be used for viable bioprosthetic valves and to keep better function and biocompatibility longer than current ones.