**DEVELOPMENT OF A NOVEL AUTOLOGOUS HEART VALVE**

**Y. Takewa**, Y. Nakayama, J. Shimamura, E. Tatsumi;
Department of Artificial Organs, National Cerebral and Cardiovascular Center, Osaka, Japan.

**Objective:**We are developing a novel tissue-engineered heart valve (biovalve) with a unique in-body tissue engineering. This valve is expected to be a viable bioprosthesis keeping better biocompatibility and durability. Purpose: In this study, we made 3 types of heart valves with this method and tested their feasibility and time-course histological change in large animal experiments.

**Method:**In this study, we selected 3 types (a conventional type, a full-root type and a valve with a metalic stent for transcatheter implantation). We created plastic molds for each kind of biovalves with 3D printer easily and quickly, and embedded them in the subcutaneous spaces of adult goats for 1-2 months. After extracting the molds with the tissue and removing the molds only, biovalve with tri-leaflets similar to those of the native valves were constituted from completely autologous connective tissues and fibroblasts. Five cases of conventional biovalves were implanted in the aorta under cardiopulmonary bypass (CPB), 10 cases of full-root type were implanted in the pulmonary artery under CPB , and 26 cases of stent-valve type were implanted with transcatheter technique into in situ the aortic and pulmonary valves (17 and 9, respectively). To observe whether the implanted biovalve stunts the host’s growth, we implanted a full-root type valve into a young goat’s pulmonary artery.

**Results:**In each type, Biovalves were successfully implanted and showed smooth movement of the leaflets with a little regurgitation in angiogram, and the maximum duration reached to 30 months in full-root type and 19 months in stent valve type. Histological examination of the Biovalves showed the autologous cells covering the laminar surface of the valve leaflets and also getting into the connective tissues. The young goat in which the biovalve was implanted in the pulmonary artery gained the weight from 26 to 54 kg in 1 year.

**Conclusion:** The biovalves can adapt their histological structure to the environment. They have a potential to be used for viable bioprosthesis and to keep better function and biocompatibility longer than current valve substitutes.