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Successful implantation of autologous valved conduits with self-expanding stent (stent-biovalve) within the pulmonary artery in beagle dogs

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KEYWORDS
Heart valve replacement;
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Abstract *Objectives:* To evaluate the functionality of an autologous heart valve with stent (Stent-biovalve or SBV) after implantation in the pulmonic valve position in beagle dogs.
Animals: Five beagle dogs.
Methods: A mold with an aperture of a tri-leaflet structure was constructed from a pair of concave and convex rods to which a nitinol (NiTi) stent was mounted. This mold was embedded in a dorsal subcutaneous pouch in beagle dogs for 4 weeks. At

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Self-expandable stent;
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the time of the removal, the surfaces of the molds were completely covered with connective tissues, tri-leaflet valves were formed and the NiTi stent was tightly connected to the structure.
Results: The mean burst strength of the SBV leaflet was 2710 mmHg (range 2280—3116 mmHg), which was approximately equal to that of the native pulmonic valve leaflet. After implantation in the pulmonary position, the SBV showed good functionality as a pulmonic valve. At 84 days after implantation, the SBV was replaced with autologous fibroblasts and collagenous tissues, and showed organization similar to that of native heart valves.
Conclusion: Stent-Biovalves achieved good valvular function with laminar flow in the pulmonic valve position of beagle dogs.
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Abbreviations

3D	three dimensional
αSMA	α-smooth muscle actin
eVG	elastica van gieson
HE	hematoxylin and eosin
NiTi	nitinol
SBV	Stent biovalve

Introduction

Pulmonic stenosis is one of the most common congenital heart diseases in veterinary medicine and has been associated with severe clinical signs including sudden death.[1] Surgical valvulotomy, balloon dilatation and open or closed patch-graft have become the treatment of choice for congenital pulmonic stenosis.[2—7] However, in humans, heart valve replacement is an efficient treatment option for valvular diseases and has become the treatment of choice for patients with obstructive lesions.[8—10] Additionally, less invasive procedures such as percutaneous pulmonic valve implantation have become a mainstream treatment. The hemodynamic performance of the percutaneously placed valve has been shown to be similar to the surgically replaced pulmonic valve. Although valve replacement has demonstrated good efficacy in human patients with pulmonic valvular diseases, there are presently no effective artificial valves available for use in veterinary medicine. The ideal artificial valve should mimic the characteristics of a normal native valve such as hemodynamics, durability, thromboresistance and biocompatibility.[11]

We previously reported the development of an autologous heart valve using the "in-body tissue architecture" technology,[12—15] which had characteristics similar to native heart valves. The autologous heart valve used the "in-body tissue architecture" technology, which was a novel and practical technique for regenerative medicine based on the tissue encapsulation phenomenon of foreign materials in patients. The advantages of this autologous heart valve are the capabilities of self-restoration and growth as well as the lack of immunological rejection after implantation. Most importantly, this autologous heart valve has many sizes and shape options by simply adjusting the mold before implantation. Although this autologous heart valve indicated good hemodynamics in the pulmonic valve position,[16] the main issue was the implantation technique of end-to-end anastomosis. This technique is time consuming and requires well-trained vascular surgical techniques. To overcome this limitation, we developed the autologous heart valve with stent using the "in-body tissue architecture" technology, named stent-biovalve (SBV). Stent-biovalve may simplify the implantation procedure and facilitate the treatment of stenosis. Our eventual goal is that SBV provides the new percutaneous treatment options for pulmonic valve stenosis. The purpose of this study was to develop the SBV and investigate its functionality in a pulmonary position.

Materials and methods

Animal studies

All animals received care according to the Principles of Laboratory Animal Care (formulated by the National Institutes of Health, Publication No. 56-23, received 1985). The research protocols were approved by the ethics committee of National Cerebral and Cardiovascular Center Research Institute (No.12602) and College of Bioresource Science, Nihon University (No. AP11B004).

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