# Percutaneous transvascular aortic valve replacement with a self-expanding stent-valve device

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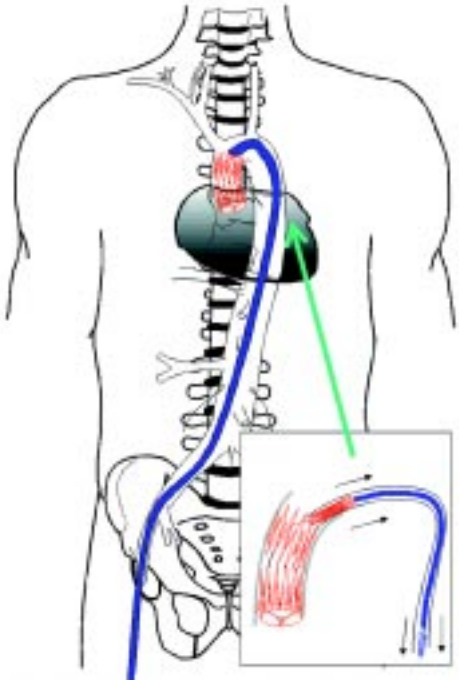

Fig. 1:
Impantation of the stent-valve device

Fig. 2:
Prototype of the stent-valve device

Besides surgical replacement for treatment of aortic valve stenosis or insufficiency sufficient alternatives still lack. Due to high risks of open heart operation especially in elderly and multi-morbid patients a minimal invasive therapeutically approach would be favorable.
A possible solution of these problems can be seen in a transvascular implantation of a so-called bio-valve which is made of porcine heart valve by chemical fixation. This bio-valve is attached to the distal end of a Nitinol-stent. The stent valve device can be implanted with a catheter by folding it to a diameter of 6 mm. The self-expanding stent deflates the bio-valve in an orthotopic position in the left outlet tract pushing the old valve into the aortic vessel wall.
A newly designed self-expanding Nitinol- stent was designed as the result of a cooperation of Friedrich-Schiller-University and Fraunhofer Institute in Jena. The Nitinol- stent was designed to stabilize the bio-valve after deflation in a physiological manner. Its construction was optimized for high flexibility as well as stiffness to provide a optimum placement in the outlet tract of the beating heart.
For correct placement of the commissures the coronary ostials should be marked by guiding catheters. Fluoroscopy and transesophageal echo are useful for optimal implantation of the valve-stent device.

We tested the self-expanding stent valve device in an artificial circulation model achieving the following results:

- no dislocation occurred up to pressure load of > 200 mmHg
- maximum transvavular pressure gradient was < 22 mmHg under flow rate of 5 l/min
- leakage flow was < 500 ml/min under pulsatile pressure load of 120/80 mmHg
- diameter of the folded device below 6.5 mm

Due to these promising results in vitro we intend to perform animal experiments with the self-expanding stent valve device.

## References

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