

VALVULAR AND STRUCTURAL HEART DISEASES

Original Studies

Transapical Implantation of a Self-Expandable Aortic Valve Prosthesis Utilizing a Novel Designed Positioning Element

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Objectives: To evaluate a new transapical system which utilizes a novel designed positioning element and a two-step positioning mechanism for easy and accurate implantation of transcatheter valves. **Background:** Transcatheter aortic valve implantation is an important treatment option for non-surgical patients with severe aortic stenosis. However, accurate placement of the transcatheter valve remains challenging. **Methods:** Self-expandable aortic valve prosthesis with a flexibly connected, annulus-like positioning element was implanted through a transapical approach in 12 pigs. The positioning element was separated and can be released independent of the valve prosthesis. During valve implantation, firstly, the positioning element was unsheathed and fixed into the aortic sinus. Then, the prosthetic valve was guided to an anatomically oriented position and deployed. Six animals were followed up to 180 days. **Results:** With the help of the positioning element, all 12 valves were successfully deployed at the anticipated site. The valve release procedure took an average of 7.3 ± 2.5 min. The mean transvalvular pressure gradient was 2.8 ± 1.1 mm Hg at valve deployment. Of the six chronic animals, the mean transvalvular pressure gradient was 3.0 ± 1.0 mm Hg on day 7, and 2.9 ± 1.6 mm Hg on day 180 ($P = 0.91$). No migration, embolization, or coronary obstruction was observed during surgery and at necropsy. Pathological examination showed anatomically correct positioning of the prosthetic valve without signs of thrombosis or calcification. **Conclusions:** In this study, we confirmed the feasibility of the J-Valve transapical system for transapical implantation through a two-step process. Satisfactory hemodynamic and pathological performance during a follow-up of 180 days was demonstrated. © 2016 Wiley Periodicals, Inc.

Key words: transapical aortic valve implantation; anatomically correct positioning; two-step positioning mechanism; preclinical evaluation

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INTRODUCTION

Transcatheter aortic valve implantation (TAVI) has gained worldwide recognition in treating inoperable or high-risk patients with severe aortic stenosis. The feasibility and effectiveness of this novel technique have already been confirmed by many large multicenter registries and the prospective, randomized Placement of Aortic Transcatheter Valves (PARTNER) trial [1–3]. Nevertheless, TAVI is a complicated procedure. The incidence of paraprothestic regurgitation is relatively high, and the periprocedural complications can be severe [4]. Since these adverse events are closely related to increased perioperative mortalities and morbidities, further improvement of transcatheter device remains crucial [5].

In the past few years, transcatheter devices have experienced a rapid development that greatly improves the accuracy of valve positioning, while simplifies the implantation procedures [6]. One of the most important design considerations for a good TAVI device is easy and anatomically correct implantation of the prosthetic valve. Anatomically correct positioning demands: (1) the prosthetic valve locates at the annulus level and (2) it maintains both coaxial and commissural-correct alignment with the aortic root. These properties are also of paramount importance for reducing the risks of paravalvular leakage and coronary obstruction.

Nowadays, most of the new generation transcatheter valves intend to use auxiliary positioning structures or markers to assist valve positioning [7–9]. The J-Valve transapical system (JieCheng Medical Technologies, Suzhou, China) for the first time introduces a separated, specially designed positioning element and a two-step positioning mechanism to help with valve implantation. The positioning element is supposed to guide the valve prosthesis an anatomically oriented position through a simple operation. In the present study, we explored the feasibility of J-Valve transapical system as well as its long-term hemodynamic and pathological performances in a porcine model.

MATERIALS AND METHODS

Experimental assessment of the J-Valve transapical system was performed on 12 Chinese miniature pigs weighing between 40 and 60 kg (49.0 ± 6.8 kg). The Animal Care and Use Committee of Fuwai Hospital approved the study protocol, and all animals received humane care in compliance with the National Institutes of Health Guide for the Care and Use of Laboratory Animals (revised 1996). All 12 implantation procedures were performed in a hybrid operating room at the Animal Experiment Center in Fuwai Hospital, Beijing, China.

All procedures were performed with animals in the dorsal recumbent position. General anesthesia was induced with intramuscular administration of ketamine (35 mg/kg) and diazepam (1.5 mg/kg) and followed by an intravenous continuous infusion of propofol [2.29 mg/(kg h)], midazolam [1.14 mg/(kg h)], and fentanyl [0.009 mg/(kg h)]. After intubation, animals were mechanically ventilated. The diameter of the aortic annulus was measured by transthoracic echocardiography (Philip Sonos 7500, 3M probe), and the size of the prosthetic valve was determined 6–15% larger than the aortic annulus. Hemodynamic performance of the prosthetic valve was assessed by transesophageal echocardiography (Philip Sonos 7500, transesophageal probe) during surgery and by transthoracic echocardiography during the follow-up. Angiographic imaging of the aortic root was obtained using a monoplane digital imaging system (OEC 9800 Plus, GE Healthcare, Waukesha, WI, USA).

Self-Expandable Prosthetic Valve

The J-ValveTM prosthetic valve consists of two components, the valve body and the positioning element, which can be released separately (Fig. 1A). The valve body is made up of a trifoliate porcine aortic valve mounted on a self-expandable nitinol stent. There is a polyester skirt covering the outer surface of the valve stent, thereby avoiding direct contact between the biologic tissue and the metallic stents. Besides, the polyester skirt seals the space between the nitinol stent and the aortic wall, and minimizes the risk of paraprothestic leakage. The valve body comes in 4 sizes, 21, 23, 25, and 27 mm, designed to fit the aortic annulus diameter between 19 and 26 mm.

The positioning element is made up of three highly elastic, U-shaped, and nitinol graspers, which are joined together by three sliding tracks and arranged into a shape similar to that of the natural aortic annulus (Fig. 1B). The valve body and the positioning element are movable attached by three connecting sutures, with one ending fixed at the bottom of the valve body where the leaflet commissures locate, and the other ending flexibly attached on the sliding tracks (Fig. 1A, red circle). During valve implantation, the connecting sutures can slide along the tracks as the valve body moved relative to the positioning element. Additionally, the positioning element can provide operator tactile feedbacks after fixating on the aortic leaflets.

Delivery System

The J-Valve Ausper-AS delivery system is composed of an operation handle and a 27F delivery catheter (Fig. 1C). On the operation handle, there are four rotary knobs controlling the position and release of the positioning element

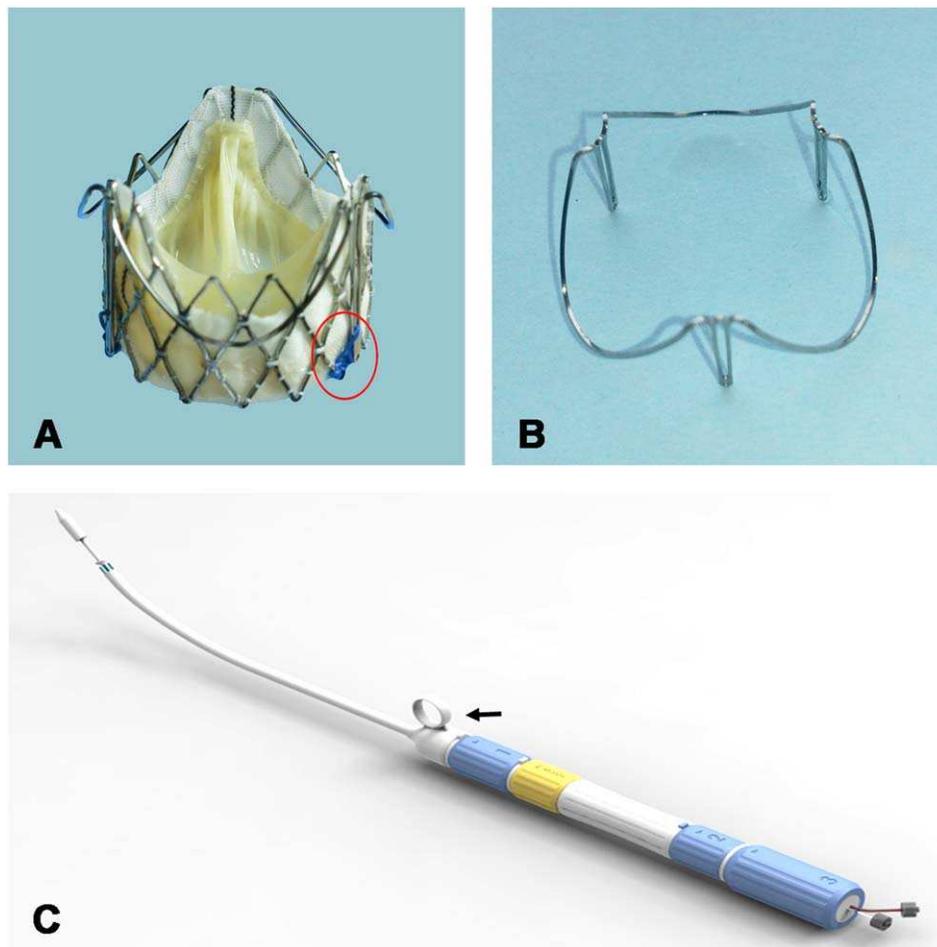


Fig. 1. The J-Valve transapical system. (A) J-Valve bioprosthesis valve showing the stent valve and the annulus-shaped positioning element (black arrow) that are flexibly connected (red circle); (B) a close-up photograph of the positioning element (C) J-Valve Ausper-AS delivery catheter showing the indicating ring (black arrow).

and the valve stent. When the prosthetic valve is crimped into the delivery catheter, the valve body is placed distal to the positioning element with the connecting sutures locating at the upper-ending of the sliding tracks. After unsheathing of the positioning element, the valve body would be pulled back to the positioning element until all connecting sutures slid to the lower-ending of the slide tracks and became straightened (Fig. 2 and Supporting Information Video S2). At the former head of the operation handle, there is an indicating ring corresponds to one leaflet commissure of the prosthetic valve, monitoring the orientation of the valve after entering the heart (Fig. 1C, black arrow).

Surgical Procedure

After anticoagulation with 400 IU/kg heparin, a 7F pigtail catheter was introduced from the left femoral artery for hemodynamic monitoring and angiography.

A Swan–Ganz catheter was introduced from the left femoral vein and placed within the pulmonary artery for measurement of cardiac output. An inferior partial median sternotomy and longitudinal incision of the pericardium was performed to access the left ventricular apex. Valve implantation was performed without ventricular unloading through cardiopulmonary bypass or rapid pacing. Usually, a left anterior oblique 60deg angle was used to clearly locate the coronary arteries and aortic sinuses. To better visualize the implantation site, the angiographic projection could be slightly inclined in the cranial or caudal direction to obtain an optimal perpendicular view of the aortic annulus. Since the J-Valve transapical system has auxiliary positioning element, projections exactly perpendicular to the aortic annulus were not strictly demanded in the present study. However, this is recommended for clinical patients, as the positioning elements may have troubles

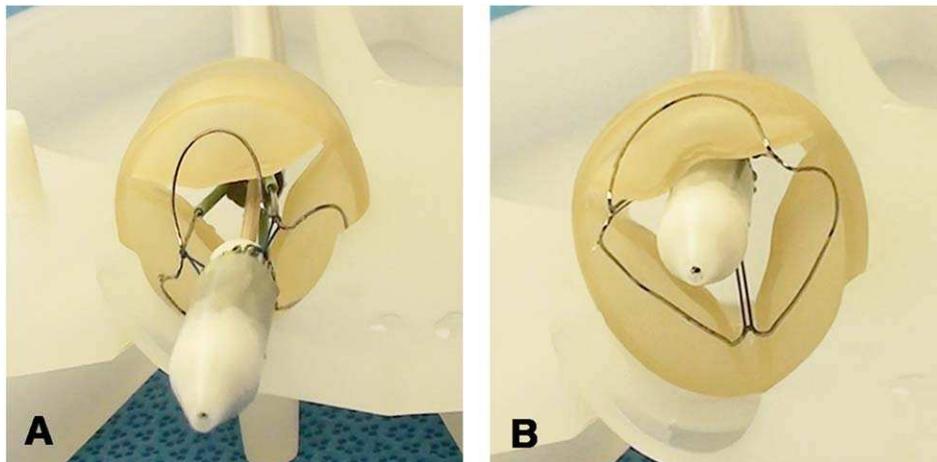


Fig. 2. Relative position between the valve body and the positioning element is adjustable during valve implantation, demonstrated on an *in vitro* aortic valve model.

in cases of a calcified annulus which was discussed below. After angiography, a 0.035-in. super-stiff guide-wire was placed across the aortic valve into the descending aorta under fluoroscopic guidance. The 24F delivery catheter was introduced “over-the-wire” into the left ventricle and the ascending aorta. Valve positioning and release were then followed under fluoroscopic guidance, as described below. After valve deployment, the delivery catheter was closed and retrieved, and the apex was closed with a purse string suture. Six animals were killed after angiography and ultrasonic examination. The remaining six ones were followed up to 180 days and detailed pathological examinations were performed at autopsy.

Valve Implantation

Implantation of J-Valve was showed in Fig. 3, Supporting Information Video S1 and S2. The two-step release process began after the positioning element completely passed the sinotubular junction. In the first step, the positioning element was released and guided to an anatomically oriented position within the aortic annulus. After released, the elastic graspers could quickly restore to the annulus-like shape. Then, the delivery catheter was carefully retreated and slightly rotated to ensure that all the three graspers capture the native leaflets and fall down to the bottom of the aortic sinus (Fig. 3A and D). Correct positioning was identified on fluoroscopies as well as transesophageal echocardiography. In the next step, the valve body was pulled back towards the aortic annulus until all three connecting sutures reached the lower ending of the sliding tracks and straightened (Fig. 3B and E). At this point, the valve body became coaxial with the position-

ing element, which also meant with the aortic root. After confirming the position, the prosthetic valve was deployed with no needing for rapid ventricular pacing (Fig. 3C and F). Length of the connecting sutures was presented before system assembling. The relative position between the valve body and the positioning element was therefore fixed after the sutures became straightened. Usually, the bottom of the valve body was 8.0–10.0 cm under the graspers.

Statistical Analyses

Categorical variables are described as frequency rates (%), while continuous variables are described as mean \pm standard deviation. The Student’s *t* test and analysis of variance (ANOVA) were used to determine statistical differences between two or multiple groups. A $P < 0.05$ was considered significant. Data analysis was performed with a statistical software package (SPSS for Windows, Version 19.0).

RESULTS

Valve Implantation

All 12 prosthetic valves were successfully implanted. No coronary obstruction, valve migration, or other serious adverse event was observed, and no conduction block or other type of arrhythmia was recorded during implantation. With the help of the positioning element, the valve release procedure (all steps between the delivery catheter entering and exiting the ventricle) took only 7.3 ± 2.5 min. Valve position was confirmed by angiography immediately after deployment. In one animal, the valve was slightly oblique ($<10^\circ$) to the mitral valve with a mild paravalvular leakage, however, there

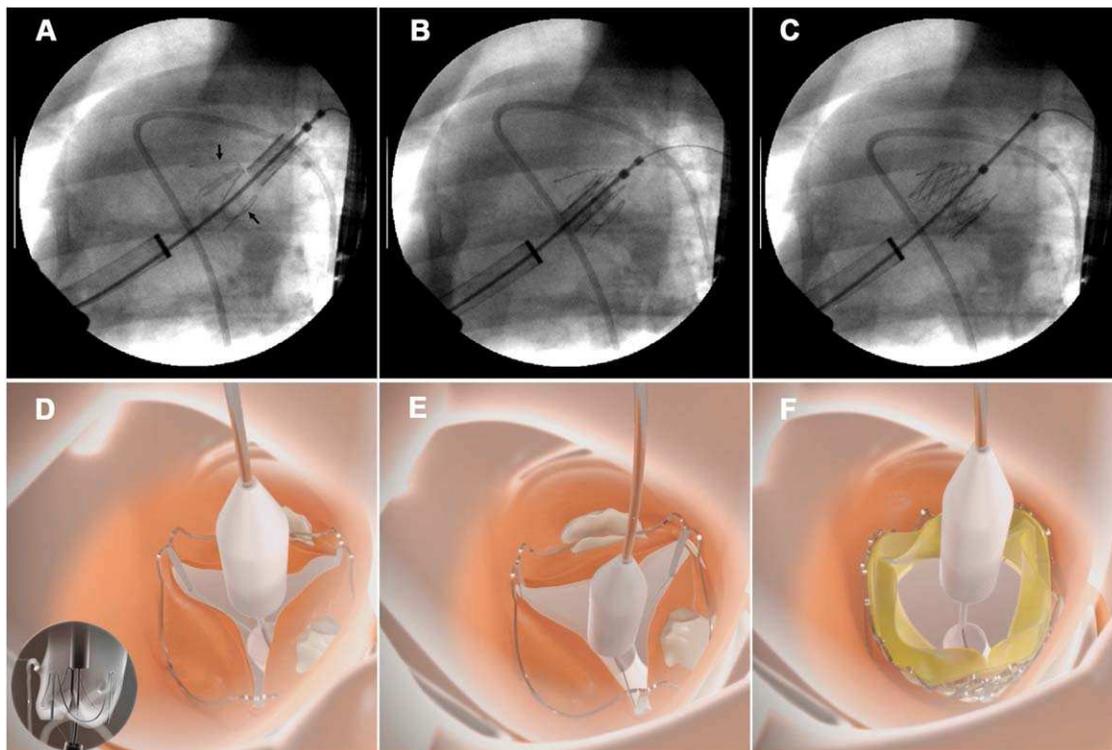


Fig. 3. Intraoperative fluoroscopy angiogram and the animation showing the two-step release procedure of J-valve. (A) and (D) The positioning element (black arrow) was unsheathed and fixed into the aortic sinus; (B) and (E) the valve body was pulled downwards to the native annulus till all the three sutures became tightened; (C) and (F) the valve was deployed.

was no effect on mitral valve function. In another procedure, a second positioning was performed because one of the positioning graspers failed to capture the aortic cusp during the first attempt.

Hemodynamic Performance

The hemodynamic performance of the prosthetic valves was assessed immediately after implantation and at 7 and 180 days follow-up (Table I). The mean transvalvular pressure gradient (MTPG) was 2.8 ± 1.1 mm Hg and the effective orifice area (EOA) was 3.1 ± 0.6 cm² after valve deployment. Of the six chronic animals MTPG and EOA remained stable during the 180-day follow-up: MTPG, 3.0 ± 1.0 mm Hg and 2.9 ± 1.6 mm Hg on days 7 and 180, respectively, $P = 0.91$; EOA, 3.2 ± 0.4 and 3.3 ± 0.3 cm² on days 7 and 180, $P = 0.74$. Cardiac function was assessed based on cardiac output as recorded by a Swan–Ganz catheter. No difference was observed between the output before (3.2 ± 1.2 L/min) and after (3.7 ± 1.7 L/min) valve deployment ($P = 0.1$). Three of the 12 animals showed mild paravalvular leakage after valve deployment. Of the six chronic animals, one showed mild paravalvular leakage immediately after valve deployment and remained unchanged till the study

end. At the end of the follow-up, another two animals developed mild-to-moderate paravalvular leakage. However, no severe paravalvular leakage was observed during the study period.

Pathological Examination

The final postmortem analysis at necropsy revealed a firm and stable fixation of the prosthetic valve and most importantly, the valve was orientated in an anatomically correct position at the annulus level, covering the native leaflets without coronary artery obstruction in all of the six chronic animals (Fig. 4A). Surface of the valve stent and the valve leaflets were covered by a layer of neoendothelium, which was further confirmed under microscopy (Fig. 4B–D). There was no evidence of calcification, thrombosis or any kind of valvular deterioration observed. Furthermore, no sign of thromboembolism was found in the brain, kidneys or other vital organs either.

DISCUSSION

High mortalities and morbidities have restricted extensive clinical application of TAVI, especially in

TABLE I. Characteristics of Valve Implantation and Hemodynamic Performance

		Baseline	Postimplantation	7 d	180 d
	Sample size	$n = 12$	$n = 12$	$n=6$	$n=6$
Adverse events	Coronary obstruction	–	0	0	0
	Ventricular fibrillation/other arrhythmias	–	0	0	0
	Valve migration	–	0	0	0
	Valve obliqueness	–	1	0	0
Hemodynamic performance	Cardiac output (L/min)	3.2 ± 1.2	3.7 ± 1.7	—	—
	Mean transvalvular pressure gradient (mm Hg)	1.0 ± 0.5	2.8 ± 1.1	3.0 ± 1.0	2.9 ± 1.6
	Paraprosthetic leak	0	3 (mild)	1 (mild)	3 (2 mild, 1 moderate)
	Orifice area of the prosthetic valve (cm ²)	0	3.1 ± 0.6	3.2 ± 0.4	3.3 ± 0.3
	Mitral regurgitation	0	3 (mild)	1 (mild)	0

low-risk patients [10,11]. There is growing evidence that the poor prognosis of TAVI is closely associated with malpositioning of the prosthetic valves [5,12]. Therefore, accurate positioning remains one of the most important design issues that should be improved. In the present study, we confirmed the feasibility and long term safety of the J-Valve transapical system, which employs a separated positioning element to facilitate accurate and easy valve implantation. Optimal hemodynamic and pathological performances during a follow-up of 6 months were demonstrated.

Nowadays, most of the new generation transcatheter systems have employed auxiliary positioning structures (e.g., arms and feelers) to assist valve positioning, such as the JenaValve™ (JenaValve, Munich, Germany), the Engager™ valve (Medtronic, Minneapolis, MN, USA) and the J-Valve [13,14]. These positioning structures anchor into the aortic sinus during valve implantation, helping to locate the prosthetic valve at annulus level and prevent supra-annular deployment. After fixating into the aortic annulus, the positioning structures can guide the prosthetic valve a correct alignment with the aortic root. These designs greatly improved the accuracy of positioning and simplify the implantation procedure.

Different from the other valves, the positioning structure of the J-Valve system is separated from the valve body that enables the positioning element to be released independent of the valve body. Once released, the positioning element can quickly restore to the annulus-like shape, ensuring better capture and fitting of the aortic leaflets. Moreover, this design enables the relative position between the valve body and the positioning element adjustable before final release. Situations do exist that the positioning grasper cannot get to the bottom of the aortic sinus in patients with bulky calcific degenerative aortic stenosis, and yet can hardly become coaxial with the aortic root. This situation was also simulated using the *in vitro* aortic valve model. In such a case, the connecting sutures can be slightly loosened and the angle between the valve body and the positioning element can be modulated accordingly. It is worth noting that, in such cases,

length of the connecting sutures should be preset longer to avoid supra-annulus valve implantation and coronary obstruction. Another advantage of the separation design is that the positioning process has little disturbance on the blood flow. The valve body was fully compressed and located highly above the annulus level during the positioning process (Fig. 3). So, there is no need for rapid ventricular pacing during valve implantation.

In the present study, all valves were successfully implanted within 90 min, mainly due to the help of the positioning elements. Operators did not have to rely heavily on angiographic images to confirm the position and orientation of the valves. This greatly simplified the operative procedures and shortened the operative time, consequently reduced the risk of periprocedural complications. Actually, the release process only took an average of 7.3 ± 2.5 min in our study, which was very short. In another animal study aimed at training doctors for clinical trials, three senior surgeons all successfully deployed the valve during their first attempt. Two of them only received a brief video training before real practice.

In addition to the guiding function, the positioning structures of the JenaValve, the Engager valve, and the J-Valve system provide the prosthetic valves strong axial support from falling into the ventricles, making them suitable for patients with aortic insufficiency which was considered as a relative contraindication for early transcatheter valves. Several pilot studies have provided the initial experience of using these devices in patients with pure aortic regurgitation and showed optimal initial outcome [15,16]. TAVI may therefore become a treatment option for Behcet's disease, which is rather hard to deal with traditional surgical methods. At present, the J-Valve system is only available for implantation via the transapical approach. A retrograde version of this device is currently under initial feasibility investigation with results expected in the near future. Different from the retrograde systems, the antegrade systems are not restricted by the diameter of the artery. The antegrade valve is therefore less compressed, which may be helpful in improving the durability of the valve prosthesis.

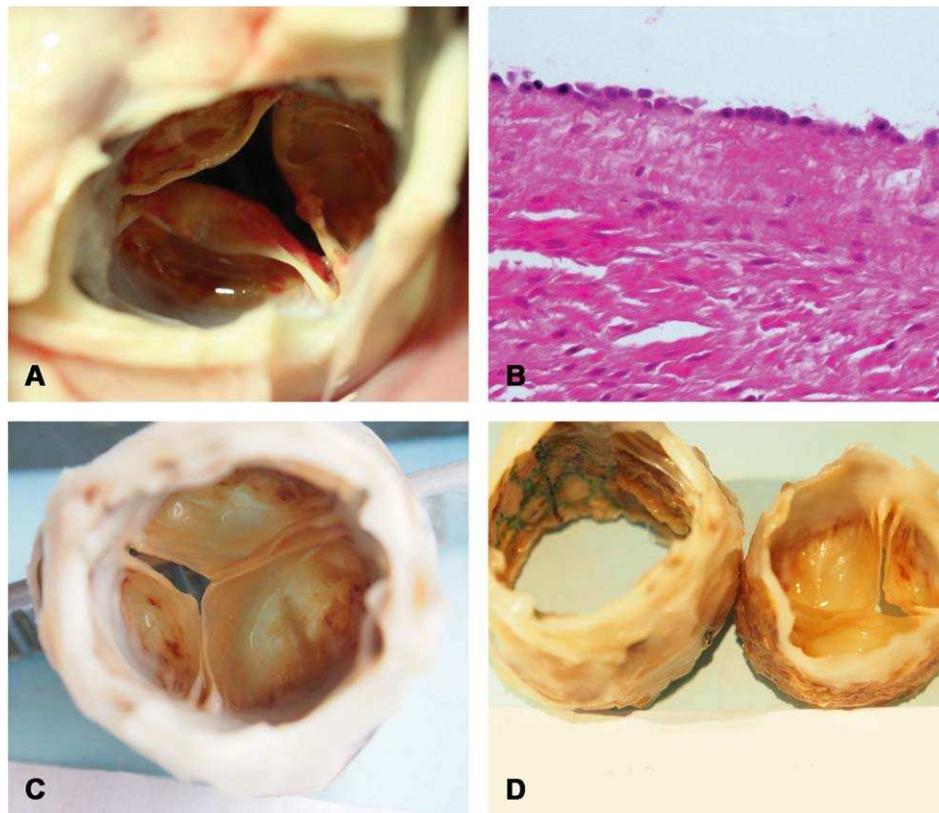


Fig. 4. Pathological examination at autopsy. (A) The prosthetic valve was orientated in an anatomically correct position without coronary artery obstruction; (B–D) microscopic and macroscopic examination revealed a layer of endothelium covering the surface of the prosthetic valve.

In the present study, one of the tested valves was slightly oblique to the mitral valve with no effect on mitral valve function after deployment. This was due to early deployment of the prosthetic valve before descending to the desired position. To avoid this situation happening again, the control handle has been redesigned. The valve bodies cannot be deployed before descending to the target location. In another procedure, a second positioning was performed because one of the positioning grasper failed to capture the aortic cusp during the first attempt. This was because the positioning element was unsheathed before it had completely passed the sinotubular junction. Similar mistakes can be avoided as the operators' experience increasing. Paraprothetic leakage ranged from mild to moderate in the six chronic animals during the follow-up, despite the use of a polyester skirt. This may be, at least partly, due to the fact that in healthy animals the vascular tissue is more flexible throughout the cardiac cycle. Besides, pig's aortic annulus is more flat than that of human. Nevertheless, no severe paravalvular leakage was observed.

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CONCLUSION

In this study, we demonstrated the feasibility, safety, and good hemodynamic performance of the J-Valve transapical system. We established that the positioning elements of the J-Valve device are capable of providing anatomically correct positioning and alignment for the prosthetic valve.

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