

Off-pump transapical mitral valve-in-ring implantation

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Abstract

OBJECTIVES: The study aimed to evaluate the feasibility of off-pump transapical mitral valve-in-ring implantation and to test the performance of a custom-made self-expandable stent valve, in comparison with the standard SAPIEN valve.

METHODS: Acute experiments were performed in five pigs. Animals (mean weight 58.4 ± 7.3 kg) underwent mitral valve annuloplasties under cardiopulmonary bypass using 26-mm rings (SJM™). Then, a 30-mm custom-made self-expandable stent valve or a 23-mm balloon-expandable transcatheter heart valve (Edwards SAPIEN XT™) was deployed within the annuloplasty rings through a transatrial access and under direct vision. Subsequently, the stent valves were inserted transapically under fluoroscopic guidance and off pump.

RESULTS: The procedural success of transatrial and transapical mitral valve-in-ring procedures was 100% (10 of 10). Mean transatrial and transapical procedure time was 2.0 ± 1.1 and 22.0 ± 5.7 min, respectively. Haemodynamic status during transapical implantation remained stable, and differences in data collected before and after the stent-valve deployment were not statistically significant. Mean mitral annulus diameter and mean mitral orifice area in the group of self-expandable stent valves were 2.60 ± 0.02 cm and 4.16 ± 0.48 cm², respectively, whereas in the SAPIEN group they were 1.95 ± 0.18 cm and 2.26 ± 0.20 cm², respectively. Trace or mild regurgitation was detected only in the self-expandable stent-valve group. Mean gradients were 4.1 ± 4.5 mmHg across the self-expandable stent valves and 1.0 ± 0 mmHg across the SAPIEN valves. Postmortem examination confirmed adequate positioning of the self-expandable valves and the SAPIEN valves within the annuloplasty ring.

CONCLUSIONS: Off-pump transapical mitral valve-in-ring implantation is safe and feasible. Transapical access may represent the ideal option for valve-in-ring procedures in cases of recurrent mitral regurgitation after mitral valve repair, in high-risk patients. Owing to the supra-annular profile of the valve components, our custom-made nitinol stent valve provides nearer to normal functional area than the SAPIEN valve.

Keywords: Transcatheter • Mitral valve • Transapical • Valve-in-ring

INTRODUCTION

Mitral valve repair using an annuloplasty ring is the optimal surgical therapy for mitral regurgitation (MR). Some clinical studies have revealed the superiority of mitral valve repair over replacement [1, 2], including elderly patients [3]. Although acceptable early mitral valve repair results were demonstrated, recent studies have called into question the durability of mitral valve repair in some patients. They have documented the development of recurrent MR after repair for degenerative aetiologies to be 2–4% per year [4, 5]. Some centres reported that recurrence of severe mitral valve regurgitation following valve repair is up to 30% at 6 months [4, 6, 7], and some of them require redo cardiac surgery. However, not only the surgeons but also the patients have to take into consideration the challenge of redo surgery, especially in the case of elderly high-risk patients.

Recently, transcatheter valve replacement techniques have been developed to offer patients less invasive alternatives to open heart surgery. Transfemoral and transapical implantation of aortic and pulmonary stent valves have shown promising clinical results. Moreover, transcatheter mitral valve replacement is also under evaluation and, based on this development, some recently published clinical reports and animal studies have confirmed the feasibility of transcatheter mitral valve-in-valve or valve-in-ring implantation [8–11]. Thus, the valve-in-ring technique turns out to be a potential therapeutic technique for high-risk patients with mitral repair failure.

This study was designed to confirm the feasibility of transapical transcatheter mitral valve-in-ring replacement without cardiopulmonary bypass (CPB) support using a custom-made self-expandable nitinol stent valve, and to evaluate the haemodynamic performances compared with the conventional SAPIEN heart valve (Edwards Lifesciences, Irvine, CA, USA), in a porcine model.

MATERIALS AND METHODS

The stent valve

Two different stent valves were employed, as follows.

- (i) A 30-mm self-expandable stent with a double-crown design was manufactured as described in a previous article [12]. It is composed of two self-expandable nitinol Z-stents covered by an ultra-thin polytetrafluoroethylene membrane, that were sutured together like two opposite crowns, for the annular fixation. A 30-mm diameter Dacron tube is attached at the centre of the fixation system and it accommodates a unidirectional trileaflet semilunar valve created in-house with commercial porcine pericardium (Vascutek, Swillington, UK; Fig. 1A). All stent valves were tested *in vitro* prior to the experiment *in vivo* and then stored in glutaraldehyde solution.
- (ii) A 23-mm Edwards SAPIEN XT™ balloon-expandable transcatheter heart valve (Edwards Lifescience, Irvine, CA, USA; Fig. 1B).

The delivery system

- (i) A self-constructed Teflon sheath delivery system was employed *in vivo*. It consisted of a 30-cm-long sheath and a pusher with a blunt tip. The sheath, including the stent-loading capsule, was made based on a modified 18 French commercial introducer sheath (B. Braun Melsungen Ag, Melsungen, Germany). The distal end of the sheath was

dilated up to a 30 French inner lumen diameter by inflating a 10-mm balloon (Boston Scientific Corp., Watertown, MA, USA). On the basis of the length of the stent, a 40-mm capsule was created [13]. Then, the stent valve was compressed with a commercial crimper and loaded into the capsule. The valve deployment in the appropriate position was performed with a pusher into the sheath and without balloon catheters (nitinol stent). The folded valve measured 10 mm in diameter and 40–43 mm in length (Fig. 2A).

- (ii) Ascendra2 transapical delivery system (Edwards Lifescience, Irvine, CA, USA; Fig. 2B).

Animal preparation

Animals received care in compliance with the Principles of Laboratory Animals formulated by the National Society of Medical Research and the Guide for the Care and Use of Laboratory Animals prepared by the Institute of Laboratory Animal Resources and published by the US National Institutes of Health (NIH publication no. 85-23, revised 1985). The protocol was approved by the Institutional Committee on Animal Research.

Five pigs (mean weight 58.4 ± 7.3 kg, 9–12 weeks, female) were included in our study for acute evaluation. After induction

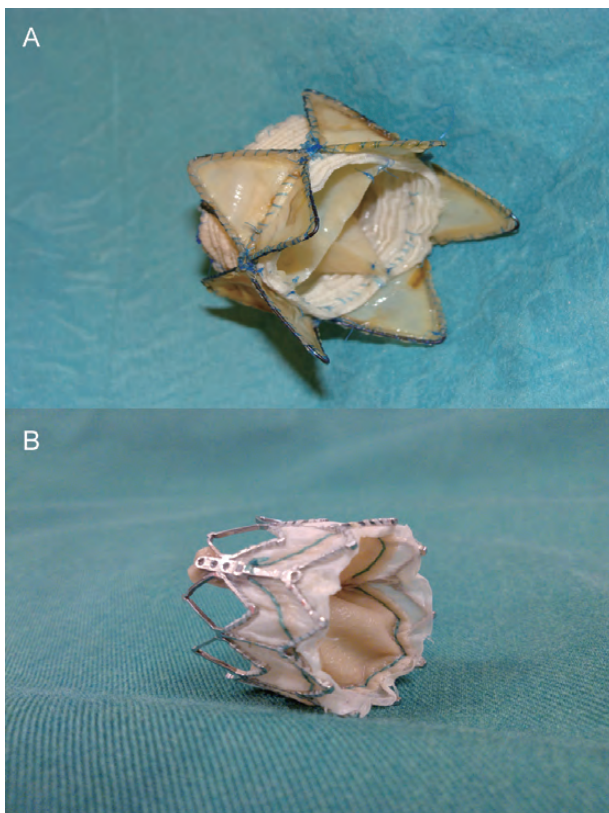


Figure 1: Two different stent valves were used: a self-expandable stent valve (A) and the Edwards SAPIEN balloon-expandable transcatheter heart valve (B).

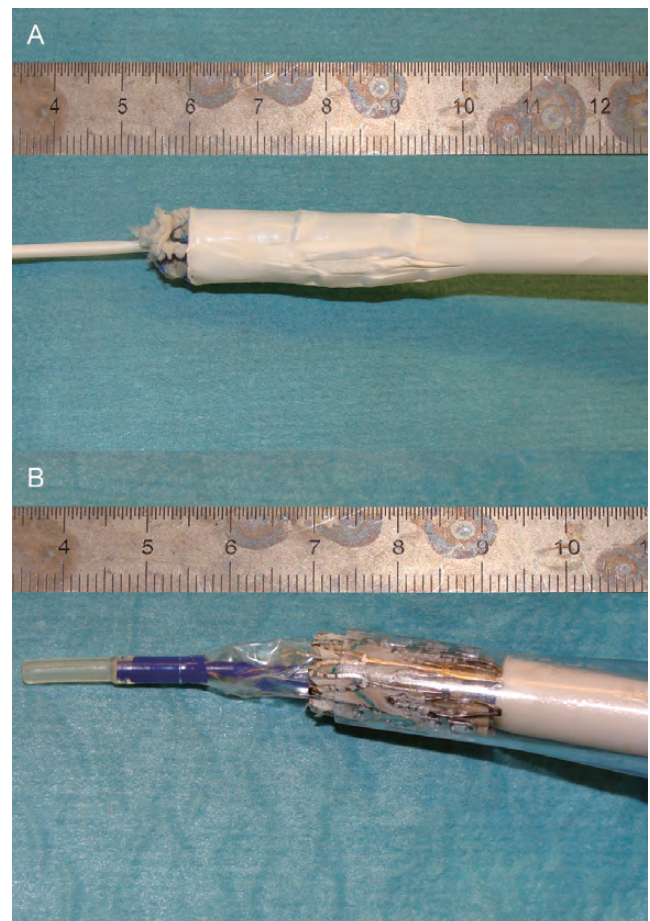


Figure 2: The custom-made delivery system, which loads the self-expandable stent valve (A), and the Ascendra2 transapical delivery system, which loads the Edwards SAPIEN valve (B).

of general anaesthesia, with tracheal intubation and mechanical ventilation (ketamine 22 mg/kg and atropine 0.8 mg/kg intramuscularly; thiopental 15 mg/kg intravenously for induction; and isoflurane 2.5% for maintenance of anaesthesia), the right carotid artery and internal jugular vein were exposed, and catheters were introduced to monitor the blood pressure (BP) and the central venous pressure (CVP), and for blood sampling and infusion. The left carotid artery and the external jugular vein were prepared for cannulation for CPB. The right femoral vein was also exposed for insertion of an intracardiac ultrasonic probe (ICUS; Accuson Navigate, Acuson, Siemens, Munich, Germany). Continuous monitoring of electrocardiography, arterial pressure, central venous pressure and oxygen saturation was routine.

Annuloplasty ring implantation and transatrial stent-valve implantation

After standard sternotomy and heparinization (Liquemine; La Roche Ltd, Basel, Switzerland; 100 IU/kg), the native mitral annular diameter was measured by ICUS. CPB was instituted with cannulation of the left carotid artery and external jugular vein. After aortic cross-clamping, antegrade cardioplegia was administered and the heart arrested. After opening of the left atrium from the left side, a 26-mm SJM™ Séguin semi-rigid annuloplasty ring (St Jude Medical Inc., St Paul, MN, USA) custom-marked by titanium clips was sutured at the standard position of the mitral annulus (Fig. 3). Saline injection tests were performed to evaluate the mitral valve closure. Transatrial stent-valve implantation was performed under direct vision. The ventricular side of the self-expandable stent valve was released by sliding the pusher once the delivery system was placed across the ring; then, we gently pulled the introducer back in order to deploy the atrial side. Regarding the balloon-expandable valve, the delivery system was introduced within the ring and then inflated at the proper position. The heart was de-aired, and the aortic cross-clamp was removed after atrial closure. Once off pump, the ICUS was performed. The trans-stent and left ventricular outflow tract (LVOT) pressure gradient were measured with a needle. After all measurements were completed, a second cardiac arrest was induced on pump with cardioplegic solution,

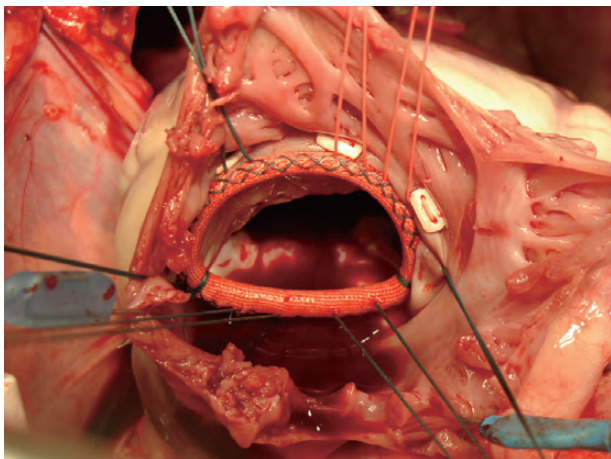


Figure 3: The 26 mm semi-rigid annuloplasty ring was sutured at the mitral annulus under cardiopulmonary bypass (viewed and implanted from the left side). Clips were placed to the ring to be visualized under fluoroscopy.

and the stent valve was removed. The left atrium was closed, the aortic cross-clamp removed and the CPB stopped with stable haemodynamics.

Transapical mitral stent-valve implantation

Self-expandable stent-valve implantation (n = 4). A double 2-0 purse-string monofilament pledgeted felt suture was placed at the left ventricular apex. The apex was punctured with a needle followed by a guide wire and an 8 French introducer system (Arrows, Reing, PA, USA) inserted into the left ventricle. Several titanium clips placed on the ring were seen as a dotted circle under fluoroscopy. A soft-tipped, stiff guidewire (0.89 mm, 180 cm; Boston Scientific, Natick, MA, USA) was introduced into the left ventricle, through the ring, and positioned in a left pulmonary vein. A pigtail catheter was advanced for exchanging the stiff wire. Then, a super-stiff guidewire (TSMG-35-26O-LES; Cook Medical, Limerick, Ireland) was exchanged using the pigtail catheter. A 30 French Ascendra2 Introducer Sheath Set (Edwards Lifescience) was used to dilate the transapical access and then removed, and the bleeding was controlled by tightening the purse-string sutures. The custom-made delivery system loaded with the self-expandable stent valve was pushed along the rigid guidewire, until the middle of the stent valve reached the mitral ring. Without rapid ventricular pacing, the atrial side of the stent partly expanded by advancing the pusher. We withdrew the delivery system gradually until the fixation portion of the stent was at the level of the ring, and then we gently pulled back the delivery sheath to deploy the ventricular side (Fig. 4A-D).

Edwards SAPIEN valve implantation (n = 1). The transapical access was established as described above. A 23-mm SAPIEN valve was mounted on the delivery balloon and introduced through the ring under ICUS and fluoroscopy guidance. Once in position, the stent was deployed following the standard technique (Fig. 4E and F).

After implantation, the ICUS was used to evaluate the function and competence of the stent valve for at least 30 min. The trans-stent and LVOT pressure gradients were measured directly with a needle. Thereafter, haemodynamic parameters were continuously recorded for at least 1 h. The animals were then killed by an iv injection of Phenobarbital to permit inspection of the position of the stent valves in the rings.

Statistical analysis

Data were analysed with SPSS19 software for Windows. Variables are reported as means \pm standard deviation (SD), and Student's paired *t*-test was used for comparison.

RESULTS

Annuloplasty rings were successfully implanted in all animals. Mean heart arrest time and CPB time were 19.0 ± 3.1 and 53.6 ± 4.9 min, respectively. The procedural success of transatrial and transapical mitral valve-in-ring was 100%. Custom-made self-expandable nitinol stent valves (30 mm) and 23-mm Edwards SAPIEN XT balloon-expandable transcatheter heart valves were used for comparison. The number of implanted stent valves and

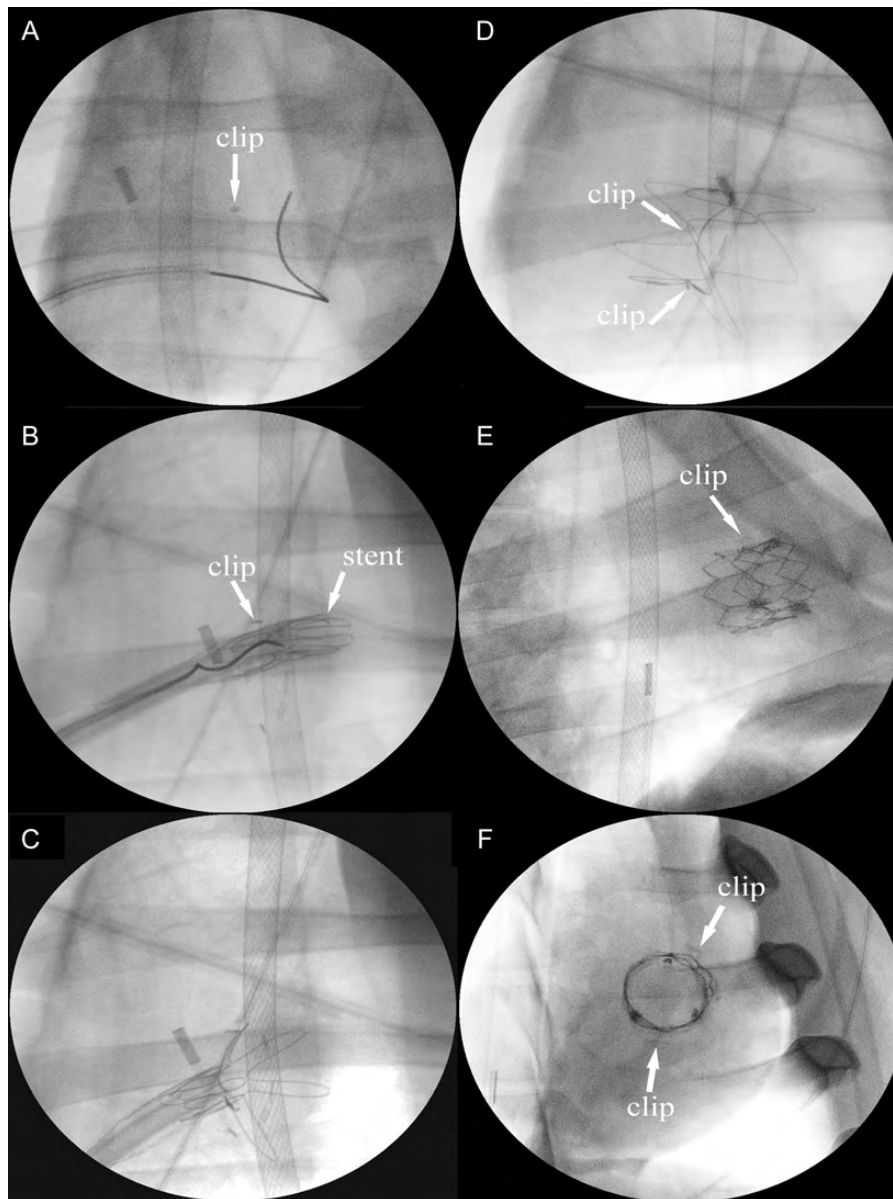


Figure 4: The custom-made self-expandable stent valve was delivered (A–C) and anchored to the annuloplasty ring (white arrows; D). The Edwards SAPIEN valve was accurately positioned within the annuloplasty ring, marked with a titanium clip (white arrows; E and F). The stent retained the ‘round’ shape (F).

the implanted access are showed in Table 1. Mean transatrial and transapical procedure times were 2.0 ± 1.1 and 22.0 ± 5.7 min, respectively. Haemodynamic data before and after transapical valve deployment are showed in Table 1.

The mean diameter of the native mitral annulus was 2.54 ± 0.13 cm, and the mean mitral valve area was 4.81 ± 0.52 cm² in ICUS evaluation. Comparatively, they were 2.60 ± 0.20 cm and 4.16 ± 0.48 cm² in the group of self-expandable stents and 1.95 ± 0.18 cm and 2.26 ± 0.20 cm² in the group of SAPIEN valves, respectively, after implantation. All valves within the stents opened and closed completely and functioned well (Fig. 5). In the self-expandable stents, trace or mild central regurgitation was detected. A mild leak between the stent and the ring also existed in one of them. No regurgitation was observed in the SAPIEN valves (Table 2). The mean pressure gradient across the self-expandable stent was 4.1 ± 4.5 mmHg, and across the SAPIEN valve the gradient was 1.0 ± 0 mmHg. The

corresponding gradients across the LVOT were 3.0 ± 1.0 and 2.5 ± 2.1 mmHg, respectively (Table 2).

Postmortem examinations confirmed good positioning of the stents within the annuloplasty rings in all animals, without LVOT obstruction (Fig. 6).

DISCUSSION

With the development of transcatheter aortic valve replacement, transapical access has become a routine approach for the implantation of transcatheter aortic valve prostheses because of its safety, reproducibility and low complication rate. Allowance for implantation of large devices and short access to both the mitral and the aortic valve are considered to be its main advantages [14]. Despite these superior attributes, the interference of the mitral valve apparatus with the delivery system still has a

Table 1: Procedural and haemodynamic data

Animal no.	Weight (kg)	Stent		HR ^a (beats/min)		BP ^a (mmHg)		CVP ^a (mmHg)		ECG		Arrest time (min)	CPB time (min)	Tap time (min)
		Tat	Tap	B	A	B	A	B	A	B	A			
1	50	C	C	50	47	56/23	47/12	6	5	NS	NS	20	57	30
2	55	C	C	92	102	76/31	76/38	5	8	NS	NS	23	53	25
3	65	S	C	102	120	73/44	92/35	10	7	NS	NS	15	48	20
4	55	C	S	103	56	81/45	91/23	6	12	NS	NS	17	50	20
5	67	S	C	132	50	82/29	71/26	5	5	NS	NS	20	60	15

^aDifferences between haemodynamics before and after the valve-in-ring implantation were not statistically significant. A: after transapical implantation; B: before transapical implantation; BP: blood pressure; CPB: cardiopulmonary bypass; C: custom-made stent valve; CVP: central venous pressure; ECG: electrocardiography; HR: heart rate; NS: normal sinus; S: SAPIEN valve; Tap: transapical; Tat: transatrial.



Figure 5: An intracardiac ultrasonic probe (ICUS) was employed to evaluate the performances of the implanted self-expandable stent valve (A) and the Edwards SAPIEN valve (B). Both valve types were functioning well.

negative influence in spreading this access to transcatheter mitral valve replacements [15]. Several teams did some work on it and reported their clinical and animal studies, including replacement of native mitral valves and mitral valve-in-valve procedures for degenerated bioprostheses [8, 16, 17]. Nevertheless, up to now no experimental studies have been published on a transapical mitral valve-in-ring procedure.

In our study, we successfully performed transapical mitral valve-in-ring implantations using two different types of stent valves, and there were no significant differences in terms of haemodynamics, heart rate, blood pressure and CVP before and after the valve implantation ($P > 0.05$). This finding attests to the feasibility of transapical mitral valve-in-ring implantations without CPB.

So far, the available balloon-expandable Edwards SAPIEN transcatheter heart valve has been the only valve used in reports on mitral valve-in-valve or valve-in-ring procedures, and this reflects its promising results and its excellent low profile and performing delivery system. The main problem of the valve-in-ring technique is matching the size between the stent valve and the mitral ring. Joerg Kempfert and colleagues reported in their tests that the 23- and 26-mm SAPIEN valves fitted well within annuloplasty ring sizes up to 26 and 28 mm, respectively. An oversized ring may result in median or severe central MR because the stent may expand excessively and may become dislodged [9]. In our study, the 23-mm SAPIEN valve matched the 26-mm ring very well. No central or perivalvular regurgitation was recorded, and dislodgement of the stent valve never happened. On the contrary, a conformational change of shape in SAPIEN valves from 'round' to 'oval' when implanted into the ring was described in previous studies, but this was not observed in our series [9, 10]. In fact, when the stent expanded, its shape remained 'round', whereas the 'D'-shaped annuloplasty ring became circular (Fig. 4F). Postmortem examination also confirmed this finding (Fig. 6C), and this contradiction is probably due to the use of semi-rigid annuloplasty rings in our study. A benefit resulting from this change of shape is the maintenance of normal valve haemodynamics and a reduction in the risk of perivalvular and/or intravalvular regurgitation.

We also found that the stent-valve orifice area ($2.26 \pm 0.20 \text{ cm}^2$) after the implantation of a SAPIEN valve into the ring was significantly lower compared with the surface area of the native mitral valve ($4.80 \pm 0.60 \text{ cm}^2$; $P < 0.05$). This result is a relative valve undersizing and could appear to be suboptimal in clinical cases.

There are some advantages in a self-expanding valve design, such as the potential for the positioning of stent-valve components in a supra-annular fashion, allowing for a larger orifice area. In our study, the resulting orifice area was indeed superior to the ones measured through the SAPIEN valves, but the transvalvular gradient pressures were suboptimal because of the

Table 2: Implanted stent-valve function

	Self-expandable valves		Edwards SAPIEN valves	
Stent number	<i>n</i> = 7		<i>n</i> = 3	
Pressure gradient across the valve (mmHg)	4.1 ± 4.5		1.0 ± 0	
Pressure gradient across the left ventricular outflow tract (mmHg)	3.0 ± 1.0		2.5 ± 2.1	
Mitral regurgitation	Trace or mild		No	
Valve diameter (cm)	Native	Stent	Native	Stent
Valve area (cm ²)	2.54 ± 0.13	2.60 ± 0.02	2.53 ± 0.13	1.95 ± 0.18
	4.81 ± 0.52	4.16 ± 0.48	4.80 ± 0.60 ^a	2.26 ± 0.20 ^a

^aThere was a significant difference between the area of the implanted Edwards SAPIEN valves and the native mitral valve orifice area.

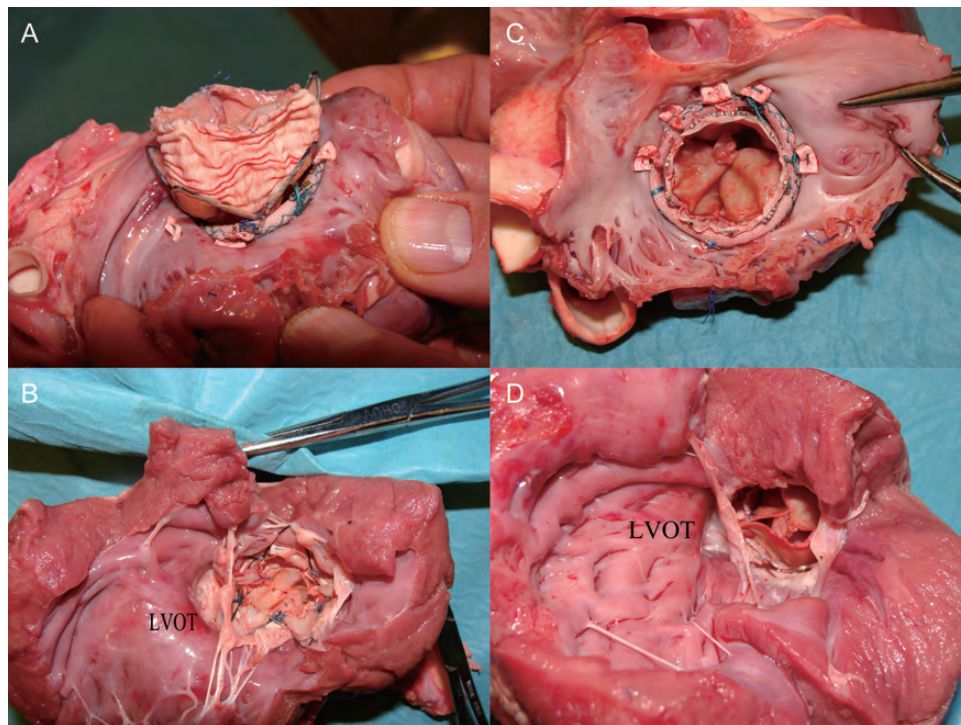


Figure 6: At postmortem examination, the custom-made self-expandable stent (A, left atrial side; B, left ventricular side) and the Edwards SAPIEN valve (C, left atrial side; D, left ventricular side) were positioned accurately within the annuloplasty ring, without left ventricular outflow tract (LVOT) obstruction. The 'D'-shaped annuloplasty ring became near to circular in the presence of the fully expanded SAPIEN stent valve (C).

amount of material within the stent. As described in the previous paragraph, a Dacron tube for accommodating a valve was an extra component in our stent compared with the SAPIEN valve. Moreover, this tube was soft and might be partly deformed while the blood flow went through. All of these factors resulted in higher transvalvular gradient pressures. We will further optimize the design of the stent in future experiments.

Based on our previous experience [12], the double-crown self-expandable valve was modified using porcine pericardium to replace the previous aortic and pulmonary valve homografts, and several advantages appeared when this prototype was compared with the SAPIEN valve, as follows: (i) a larger (diameter > 28 mm) stent could be applied; (ii) the structure of the double crown fits extremely well into the annuloplasty ring, and the ring offers an appropriate position for the fixation of the stent valve; (iii) no rapid pacing is required during the

implantation; and (iv) the orifice valve area after the implantation ($4.16 \pm 0.48 \text{ cm}^2$) approximated the native valve area ($4.81 \pm 0.52 \text{ cm}^2$; $P = 0.297 > 0.05$). We think that our custom-made double-crown stent valve is more suitable for valve-in-ring procedures than the SAPIEN valve. However, in one case we detected a mild central and persistent regurgitation with high transvalvular pressures (15 mmHg); the probable reason for high gradients in this case was that the regurgitation resulted in an increase in the left ventricular end-diastolic pressure.

In conclusion, the present study demonstrated the feasibility of transapical mitral valve-in-ring implantations without extracorporeal circulation. The transapical technique developed for the Edwards SAPIEN stent-valve implantation shows promising performances in valve-in-ring procedures. Moreover, new self-expandable stent valves implanted through transapical access show good haemodynamic results with better functional valve areas.

LIMITATIONS

The study was an acute test in animals. The long-term durability and haemodynamics of both stent valves in rings are unknown. The fixation stability of stents in mitral rings needs to be confirmed by long-term studies.

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Conflict of interest: none declared.

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