Immediate outcomes of a rapid-deployment sutureless cuff for heart valve prostheses versus standard sutured prostheses in the treatment of degenerative aortic valve disease: prospective single-centre non-randomised pilot study

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Received 18 April 2026. Revised 22 June 2026. Accepted 4 August 2026.

How to cite: Zhurko S.A., Osipov A.M., Gamzaev A.B., Kalinina M.L., Sukhova M.B., Kurmanbek uulu E., Golubev A.A., Lashmanov D.I. Immediate outcomes of a rapid-deployment sutureless cuff for heart valve prostheses versus standard sutured prostheses in the treatment of degenerative aortic valve disease: prospective single-centre non-randomised pilot study. *Patologiya krovoobrashcheniya i kardiokhirurgiya = Circulation Pathology and Cardiac Surgery*. 2026;30(3):65-77. (In Russ.)
https://doi.org/10.21688/1681-3472-2026-3-65-77

Informed consent
The patient's informed consent to use the records for medical purposes is obtained.

Funding
The study did not have sponsorship.

Conflict of interest
The authors declare no conflict of interest.

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Abstract

Introduction: Sutureless valves represent an alternative approach to aortic valve replacement, enabling rapid prosthesis implantation without placement of multiple interrupted sutures.

Objective: To compare prostheses with a rapid-deployment sutureless cuff with standard sutured prostheses in patients with degenerative aortic valve disease.

Methods: This prospective, single-centre, non-randomised pilot study included 105 patients who underwent aortic valve replacement between January 2022 and March 2024. Patients were allocated to three groups: a rapid-deployment sutureless cuff with mechanical or biological valve cartridges ($n = 35$), the Medeng-2 mechanical prosthesis ($n = 41$), and the UniLine biological prosthesis ($n = 29$). The primary endpoints were all-cause and prosthesis-related mortality within 30 days. Secondary endpoints included mean transprosthetic pressure gradients at discharge and the frequency and nature of complications.

Results: The groups were comparable for most preoperative characteristics, including EuroSCORE II ($p = 0.213$). Statistically significant differences were observed in age and left ventricular ejection fraction, reflecting clinical selection rather than systematic differences in operative risk. Cardiopulmonary bypass and aortic cross-clamp times were significantly shorter in the sutureless cuff group ($p < 0.001$). Thirty-day all-cause mortality was 8.6% (3/35) in the RDSC group, 7.3% (3/41) in the Medeng-2 group, and 3.3% (1/29) in the UniLine group ($p = 0.78$). Permanent pacemaker implantation rates were 8.8%, 0%, and 3.3%, respectively ($p = 0.18$). At discharge, mean pressure gradients were lower in the sutureless cuff group than in the mechanical prosthesis group.

Conclusion: Preliminary findings from this pilot study suggest that a rapid-deployment sutureless cuff reduces operative time and provides satisfactory early haemodynamic outcomes. Further studies are required to confirm safety with respect to rare complications and to evaluate long-term outcomes.

Keywords: aortic cross-clamp time; aortic valve replacement; attachable cuff with sutureless fixation; cardiopulmonary bypass duration; rapid-deployment valves; sutureless prostheses

Непосредственные результаты использования бесшовной присоединяемой манжеты протезов клапанов сердца в сравнении со стандартными шовными протезами при коррекции дегенеративных аортальных пороков: проспективное одноцентровое нерандомизированное пилотное исследование

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Поступила в редакцию 18 апреля 2026 г.
Исправлена 22 июня 2026 г. Принята к печати 4 августа 2026 г.

Цитировать: Журко С.А., Осипов А.М., Гамзаев А.Б., Калинина М.Л., Сухова М.Б., Курманбек уулу Э., Голубев А.А., Лашманов Д.И. Непосредственные результаты использования бесшовной присоединяемой манжеты протезов клапанов сердца в сравнении со стандартными шовными протезами при коррекции дегенеративных аортальных пороков: проспективное одноцентровое нерандомизированное пилотное исследование. *Патология кровообращения и кардиохирургия.* 2026;30(3):65-77. https://doi.org/10.21688/1681-3472-2026-3-65-77

Информированное согласие
Получено информированное согласие пациентов на публикацию и использование медицинских данных в научных целях.

Финансирование
Исследование не имело спонсорской поддержки.

Конфликт интересов
Авторы заявляют об отсутствии конфликта интересов.

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Исправление статьи: С.А. Журко, А.М. Осипов, А.Б. Гамзаев
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Аннотация

Актуальность. Применение бесшовных клапанов представляет собой альтернативный подход к протезированию аортального клапана, обеспечивающий быструю имплантацию протеза без наложения множества узловых швов.

Цель. Сравнение применения протезов с бесшовной присоединяемой манжетой и стандартных шовных протезов у пациентов с дегенеративными аортальными пороками.

Методы. В проспективное одноцентровое нерандомизированное пилотное исследование включено 105 пациентов, перенесших протезирование аортального клапана в период с января 2022 г. по март 2024 г. Пациенты были распределены на три группы: с бесшовной присоединяемой манжетой с механическими или биологическими протезами-картриджами (n = 35), с механическим протезом «Меднинж-2» (n = 41) и биологическим протезом «ЮниЛайн» (n = 29). Первичными конечными точками исследования являлись общая и протез-ассоциированная летальность в течение 30 дней. Вторичными конечными точками служили значения средних градиентов давления при выписке, частота и характер осложнений.

Результаты. Группы были сопоставимы по большинству предоперационных характеристик, включая EuroScore II (p = 0,213). Статистически значимые различия выявлены по возрасту и фракции выброса левого желудочка, что отражает особенности клинического отбора, а не систематическое различие в операционном риске. Время искусственного кровообращения и длительность пережатия аорты были статистически значимо короче в группе с бесшовной манжетой (p < 0,001). Общая 30-дневная летальность составила 8,6 % (3/35) в группе с БПМ, 7,3 % (3/41) в группе с «Меднинж-2», 3,3 % (1/29) в группе с «ЮниЛайн» (p = 0,78). Частота имплантации электрокардиостимулятора – 8,8; 0 и 3,3 % (p = 0,18). При выписке в группе с бесшовной манжетой отмечены более

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низкие средние градиенты давления по сравнению группой с механическими протезами.

Заключение. Предварительные данные пилотного исследования показывают, что использование бесшовной присоединяемой манжеты позволяет сократить время операции и обеспечивает удовлетворительные ранние гемодинамические результаты. Для подтверждения безопасности по редким осложнениям и оценки отдаленных исходов требуются дальнейшие исследования.

Ключевые слова: бесшовные протезы; время пережатия аорты; длительность искусственного кровообращения; клапаны быстрого развертывания; присоединяемая манжета с бесшовной фиксацией; протезирование аортального клапана

Introduction

Degenerative aortic valve disease is the most common cause of aortic stenosis and aortic regurgitation in developed countries. Aortic valve replacement remains the gold standard treatment for aortic valve disease [1]. Approximately 8,000 aortic valve replacement procedures are performed annually in Russia. Mechanical prostheses predominate; biological prostheses account for only 27.1%. According to data reported by L.A. Bokeria for 2024 [2], transcatheter aortic valve implantation was used in only 2,276 cases (27.4%).

Sutureless valves, also known as rapid-deployment valves, enable rapid prosthesis implantation without placement of multiple interrupted sutures in the aortic annulus [3]. This may shorten operative time, facilitate complete removal of calcified tissue, and allow concomitant coronary artery bypass grafting [4; 5].

Currently, the main sutureless or rapid-deployment prostheses available internationally are Perceval S (Corcym, United Kingdom) and Edwards INTUITY (Edwards Lifesciences, USA) [6; 7]. Another sutureless prosthesis, the 3f Enable valve manufactured by Medtronic (USA), was discontinued in 2015 [8].

RDSC on delivery system

Medeng-BIO

Medeng-ST

Medeng-EC

Fig. 1. An attachable cuff with sutureless fixation and cartridge-type prostheses.

Note. RDSC, rapid-deployment sutureless cuff.

The Russian device developed by Medeng Research and Production Company (Penza) – an attachable cuff with sutureless fixation, patented in 2017 (Russian Patent No. 2632516, 5 October 2017) – has been insufficiently studied; only one case-series publication is currently available [9]. A distinctive feature of this device is its availability and the option to select either a mechanical or biological cartridge without age restrictions, a feature not offered by international analogues.

Objective: To compare outcomes of an attachable cuff with sutureless fixation, designed for implantation of mechanical or biological prostheses, with standard sutured prostheses.

Methods

Study design

This was a prospective, single-centre, longitudinal, non-randomised pilot study. The study was approved by the local ethics committee of the Korolev Specialized Cardiovascular Clinical Hospital, Nizhny Novgorod Region (Protocol No. 1 dated 26 January 2022). The study was conducted in accordance with Good Clinical Practice standards and the principles of the Declaration of Helsinki. All patients provided written informed consent to participate and to the processing of personal data.

No sample-size calculation was performed because of the pilot nature of the study and ethical limitations associated with introducing a new medical device. The study group comprised patients who received a rapid-deployment sutureless cuff (RDSC) with one of several valve cartridges: the Medeng-EC bileaflet mechanical cartridge, the Medeng-ST full-flow mechanical cartridge, or the Medeng-BIO biological cartridge (Fig. 1).

The RDSC consists of a conventional cuff incorporating the Easy Change mechanism. The cuff is secured to the aortic annulus using three guide sutures to prevent displacement; sealing is achieved by balloon dilation of the infrannular stented portion.

The control groups comprised patients receiving conventional sutured valves: the UniLine biological xenopericardial valve (NeoCor JSC, Kemerovo) and the Medeng-2 bileaflet mechanical disc valve (Medeng Research and Production Company, Penza).

Inclusion criteria: age >18 years; haemodynamically significant degenerative aortic valve disease (stenosis or regurgitation).

Fig. 2. Placement of U-shaped mattress sutures at the nadirs of the sinuses of Valsalva

Exclusion criteria: age <18 or >80 years; a competing disease or concomitant condition substantially affecting postoperative prognosis or quality of life; infective endocarditis; concomitant surgery on the ascending aorta; haemodynamically significant disease of another valve requiring surgical correction; progressive non-cardiac disease expected to reduce life expectancy to one year; unacceptably high risk associated with aortic valve replacement; or haemodialysis.

The primary endpoint was all-cause mortality and prosthesis-related mortality, defined as acute prosthetic valve thrombosis resulting in sudden cardiac death or fatal arrhythmia; prosthetic endocarditis resulting in sepsis and multiorgan failure; rupture of the aortic root with cardiac tamponade; or paravalvular regurgitation with haemodynamic instability.

Secondary endpoints were the transprosthetic pressure gradient at discharge and the nature and frequency of complications.

The choice of a mechanical or biological sutured prosthesis or cartridge for the RDSC was made in accordance with the 2021 ESC/EACTS recommendations. The choice between RDSC and a sutured prosthesis was

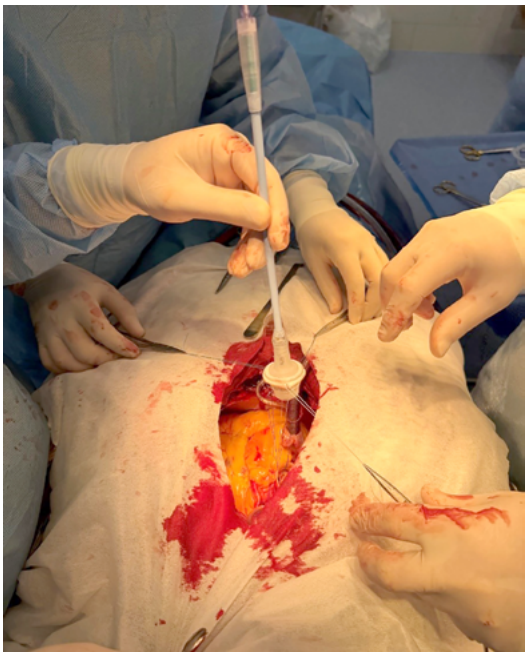

Fig. 3. Advancement of the cuff on the delivery system over the guide sutures

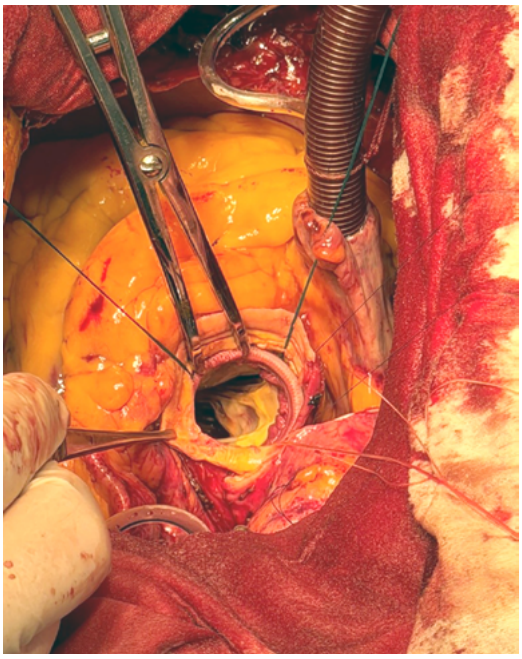

Fig. 5. Surgical step: assessment of cuff seating against the left ventricular outflow tract and annulus after removal of the delivery system

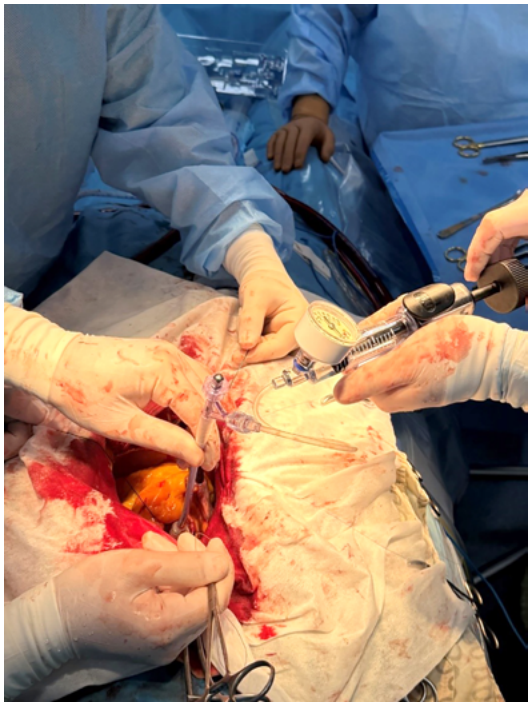

Fig. 4. Deployment of the infrannular stented portion of the cuff using a standard indeflator

based on surgeon preference. There were no anatomical contraindications related to the aortic root or other exclusion criteria that precluded RDSC implantation. Most operations were performed by one cardiac surgeon with more than 15 years of experience in prosthetic heart valve implantation.

Concomitant coronary artery bypass grafting, including internal mammary artery grafting, was performed using a standard technique without sequential grafts. Distal anastomoses preceded aortic valve replacement; proximal anastomoses were constructed on the side-clamped aorta after release of the main cross-clamp. Procedures were performed with normothermic cardiopulmonary bypass using right atrium-to-ascending aorta cannulation. Antegrade pharmacological cold cardioplegia with Bretschneider solution was used.

RDSC implantation technique

A transverse aortotomy was made at the standard level used for conventional aortic valve replacement, 2.0–2.5 cm above the annulus. The native valve leaflets were excised and the annulus was meticulously decalcified. Cuff size was determined using the manufacturer's sizer. Three U-shaped guide sutures were then placed at the

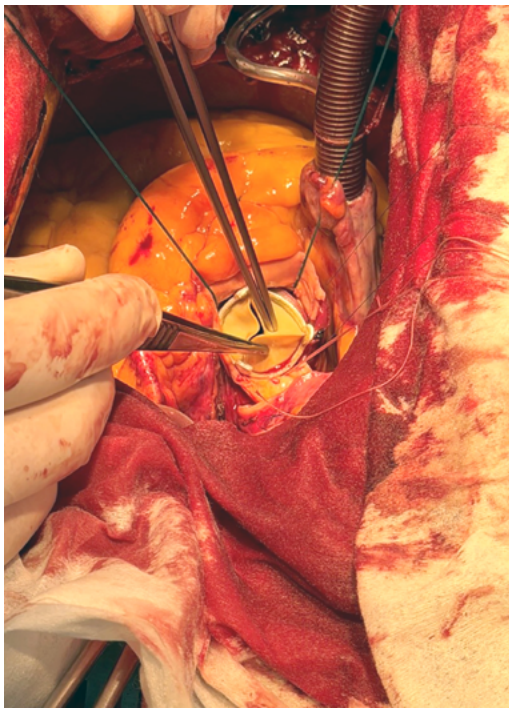

Fig. 6. Implantation of the biological cartridge prosthesis.

nadirs of the aortic annulus using 2-0 USP non-absorbable braided suture with felt pledgets on the left-ventricular side (Fig. 2).

The cuff was implanted using a supra-annular technique over the guide sutures (Fig. 3).

Stepwise balloon dilation of the cuff's stented portion was then performed to ensure a sealed fixation in the infrannular region (Fig. 4).

After dilation, the delivery system was removed. The degree of stent expansion, apposition to the left ventricular outflow tract, and absence of frame migration or deformation were assessed (Fig. 5).

Only after secure cuff fixation had been confirmed was a mechanical cartridge (Medeng-EC or Medeng-ST) or biological cartridge (Medeng-BIO) implanted and secured in the cuff using the Easy Change system (Fig. 6).

Warfarin was prescribed immediately after surgery, with a target international normalized ratio of 2.0–3.0. In the early postoperative period, all patients received low-molecular-weight heparin prophylaxis until the target INR was reached. Transthoracic echocardiography was performed preoperatively using a GE Vivid E95 system (GE Healthcare, Norway) to assess prosthesis function and left ventricular parameters. Intraoperative transoesophageal

Table 1. Comparability of subgroups within the RDSC group

Variable	Medeng-BIO (*n* = 14)	Medeng-EC (*n* = 13)	Medeng-ST (*n* = 8)	*p*
Age, years, median [IQR]	71.0 [69.2; 72.8]	64.0 [58.0; 70.5]	70.0 [59.5; 71.0]	0.109
Male sex, *n* (%)	3 (21.4)	9 (69.2)	2 (25.0)	0.042*
Hypertension, *n* (%)	14 (100)	13 (100)	8 (100)	1.000
Coronary artery disease, *n* (%)	4 (28.6)	6 (46.2)	1 (12.5)	0.312
COPD, *n* (%)	0 (0)	3 (23.1)	3 (37.5)	0.042*
Type 2 diabetes, *n* (%)	8 (57.1)	5 (38.5)	2 (25.0)	0.360
CPB time, min, median [IQR]	65.5 [60.0; 76.5]	63.5 [58.0; 80.0]	94.0 [63.5; 111.5]	0.500
Cross-clamp time, min, median [IQR]	48.5 [40.5; 56.8]	42.0 [36.0;49.8]	43.0 [41.5;80.5]	0.186
LVEF before surgery, %, median [IQR]	51.0 [41.0; 56.2]	43.0 [35.5; 51.8]	53.0 [48.0; 56.5]	0.504
Mean pressure gradient before surgery, mmHg, median [IQR]	45.0 [38.5; 58.0]	45.0 [40.0; 60.0]	46.0 [37.5; 48.5]	0.756
Mean pressure gradient at discharge, mmHg, median [IQR]	7 [4; 9]	8 [5; 10]	8 [6; 10]	0.569

Note. Data are presented as median [25th;75th percentiles] for continuous variables and number (percentage) for categorical variables. Comparisons used the Kruskal – Wallis and Pearson $\chi 2$ tests. COPD, chronic obstructive pulmonary disease; CPB, cardiopulmonary bypass; IQR, interquartile range; LVEF, left ventricular ejection fraction; RDSC, rapid-deployment sutureless cuff.

Table 2. Preoperative characteristics of patients undergoing aortic valve replacement (*n* = 105)

Variable	RDSC	Medeng-2	UniLine	*p*
Male/female, *n* (%)	14 (40.0)/21 (60.0)	21 (51.2)/20 (48.8)	17 (58.7)/12 (41.3)	0.383
BMI, kg/m^2, mean (SD)	29.48 (5.13)	29.47 (6.23)	29.53 (4.02)	0.999
Age, years, median [IQR]	70.00 [62.00; 72.00]	62.00 [53.00; 66.00]	70.00 [68.00; 72.00]	<0.001
Hypertension, *n* (%)	35 (100.0)	35 (85.4)	28 (96.5)	0.026
Coronary artery disease, *n* (%)	11 (31.4)	10 (24.4)	8 (27.6)	0.786
COPD, *n* (%)	6 (17.1)	2 (4.9)	7 (24.1)	0.073
Type 2 diabetes, *n* (%)	15 (42.9)	6 (14.6)	5 (17.2)	0.014; RDSC vs Medeng-2 *p*=0.018
EuroSCORE II, %, median [IQR]	1.94 [1.34; 3.17]	1.73 [1.28; 2.47]	1.43 [1.08; 2.80]	0.213
LVEDV, mL, median [IQR]	125.00 [89.50; 158.50]	120.00 [90.00; 190.00]	96.00 [86.00; 131.75]	0.182
LVESV, mL, median [IQR]	60.00 [43.00; 94.50]	55.00 [42.00; 85.00]	48.50 [37.50; 60.00]	0.153
LVEF, %, mean (SD)	47.29 (11.58)	54.68 (7.24)	54.03 (8.09)	0.006
Bicuspid aortic valve, *n* (%)	11 (31.4)	18 (45.0)	12 (40.0)	0.482
Mean pressure gradient, mmHg, median [IQR]	45.00 [38.50; 54.25]	42.00 [12.50; 61.00]	46.50 [40.00; 55.00]	0.267
Aortic valve area, cm^2, median [IQR]	0.7 [0.7; 0.9]	0.8 [0.7; 0.9]	0.8 [0.7; 0.9]	0.979

Note. BMI, body mass index; COPD, chronic obstructive pulmonary disease; IQR, interquartile range; LVEDV, left ventricular end-diastolic volume; LVEF, left ventricular ejection fraction; LVESV, left ventricular end-systolic volume; SD, standard deviation.

Table 3. Intraoperative Characteristics and Postoperative Clinical Outcomes of Patients Undergoing Aortic Valve Replacement (*n* = 105)

Variable		RDSC	Medeng-2	UniLine	*p*
J-shaped sternotomy, *n* (%)		3 (8.6)	7 (17.1)	2 (6.8)	0.323
Coronary artery bypass grafting, *n* (%)		7 (20.0)	5 (12.2)	8 (27.5)	0.299
Prosthesis size, mm, *n* (%)	21	9 (25.7)	12 (29.3)	9 (31.0)	0.595
	23	12 (34.3)	14 (34.1)	12 (41.3)	
	25	12 (34.3)	15 (36.6)	9 (31.0)	
	27	2 (5.7)	0	0	
Permanent pacemaker implantation, *n* (%)		3 (8.8)	0	1 (3.4)	0.18
Stroke, *n* (%)		1 (2.9)	1 (2.5)	0	0.53

Note. RDSC, rapid-deployment sutureless cuff.

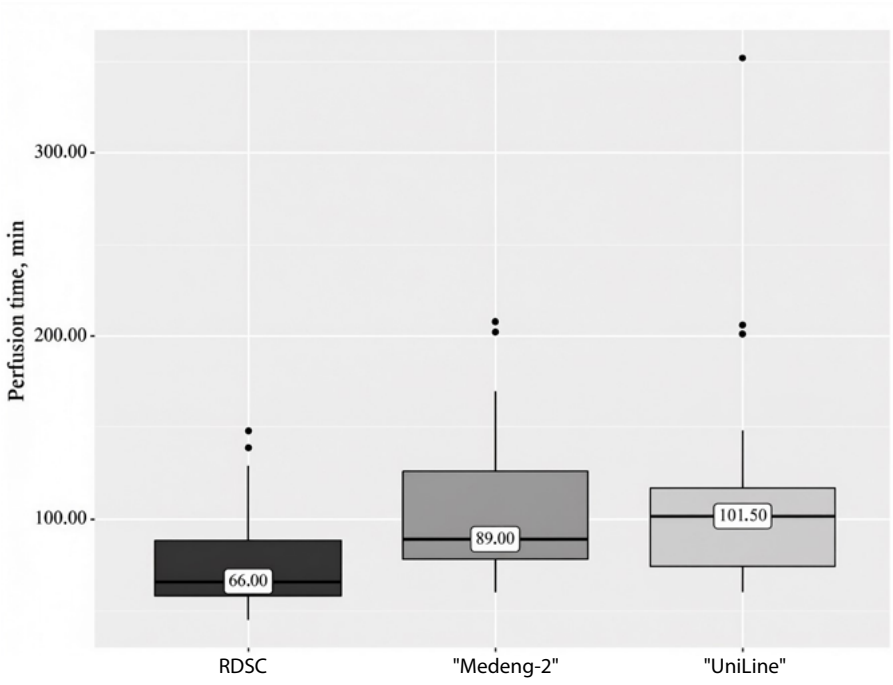

Fig. 7. Cardiopulmonary bypass duration by group

Note. RDSC, rapid-deployment sutureless cuff.

echocardiography was used to measure end-systolic volume, end-diastolic volume, left ventricular ejection fraction, peak and mean pressure gradients, native-valve regurgitation, peak and mean transprosthetic gradients after cardiopulmonary bypass, and the presence or absence of paravalvular regurgitation. Follow-up transthoracic echocardiography was performed at discharge.

Statistical analysis

Statistical analyses were performed using R (version 4.3.2; RStudio, Posit Software, PBC, USA) and Python (version 3.11). Continuous variables were assessed for normality using the Shapiro–Wilk test and visual inspection of histograms. Categorical data are presented as absolute values and percentages. Ninety-five-percent

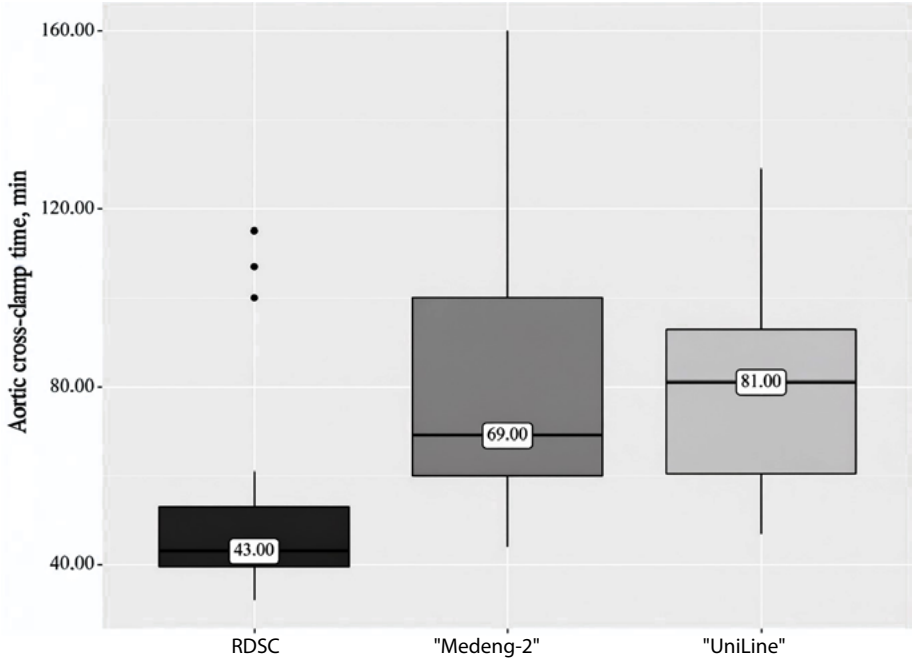

Fig. 8. Aortic cross-clamp time by group

Note. RDSC, rapid-deployment sutureless cuff.

Table 4. Echocardiographic and haemodynamic valve characteristics at discharge

Variable	RDSC	Medeng-2	UniLine	*p*
LVEDV, mL, median [IQR]	94.00 [75.50; 126.00]	93.00 [80.00; 120.00]	104.00 [80.00; 120.00]	0.997
LVESV, mL, median [IQR]	47.00 [38.00; 70.00]	44.50 [36.50; 60.00]	44.50 [35.00; 60.00]	0.480
LVEF, %, median [IQR]	48.00 [41.00; 52.50]	54.00 [50.00; 56.00]	54.50 [50.00; 57.50]	<0.001
Peak pressure gradient, mmHg, median [IQR]	15.00 [11.00; 18.00]	22.00 [18.00; 27.50]	17.00 [13.00; 19.00]	<0.001
Mean pressure gradient, mmHg, median [IQR]	7.50 [5.00; 10.00]	10.00 [9.75; 15.00]	7.50 [5.25; 9.00]	<0.001
Paravalvular regurgitation grade I, *n* (%)	5 (14.3)	0	0	0.004
Paravalvular regurgitation grade II or higher, *n*	0	0	0	–

Note. IQR, interquartile range; LVEDV, left ventricular end-diastolic volume; LVEF, left ventricular ejection fraction; LVESV, left ventricular end-systolic volume; RDSC, rapid-deployment sutureless cuff.

confidence intervals were used to describe the precision of estimates; for proportions, intervals were calculated using the Clopper–Pearson method. Continuous variables are presented as mean ± standard deviation for normally distributed data, or as median and 25th and 75th percentiles for non-normally distributed data. Proportions in contingency tables were compared using Fisher's exact test because of small expected frequencies for rare outcomes, including mortality, stroke, pacemaker implantation, and paravalvular regurgitation. The Freeman – Halton extension was used for tables larger than 2×2. Post hoc pairwise comparisons were adjusted using the Holm – Bonferroni method.

Results

Thirty-five patients underwent surgery with an RDSC. Patients receiving different cartridge types – mechanical, full-flow mechanical, or biological – were analysed as one group. Because this was a pilot study with a limited sample size, stratification by cartridge type would have produced very small subgroups, critically reducing statistical power, preventing representative between-group comparisons, and increasing the risk of type II error. Differences in sex and chronic obstructive pulmonary disease between RDSC subgroups (p=0.042) did not remain statistically significant after adjustment for multiple comparisons and did not affect the principal outcomes, supporting pooled analysis (Table 1).

The primary objective was to evaluate the safety and effectiveness of the surgical platform and fixation technology – the RDSC – rather than a specific occluder material or prosthesis configuration. Key advantages, including reduced ischaemia and cardiopulmonary bypass times, are attributable to the sutureless fixation mechanism (Easy Fix) and do not depend on the cartridge type. A preliminary analysis of the three RDSC subgroups showed no significant differences in major early clinical outcomes. Three 30-day postoperative deaths occurred, one in each subgroup; the difference was random ($\chi^2 = 0.207$, $p = 0.902$). Thus, cartridge type did not appear to confound assessment of the RDSC itself, supporting pooled analysis.

The biological xenopericardial prosthesis group (UniLine) included 29 patients, and the mechanical bileaflet disc prosthesis group (Medeng-2) included 41 patients. Baseline characteristics are shown in Table 2.

Baseline demographic and clinical characteristics were comparable for most variables. Patients in the Medeng-2 group were significantly younger, consistent with the clinical recommendations for mechanical prosthesis use. Baseline LVEF was lower in the RDSC group than in the Medeng-2 and UniLine groups. Peak and mean native-valve gradients and valve area did not differ significantly between groups (p>0.05), indicating comparable haemodynamic severity at surgery.

Significant between-group differences were observed in CPB and aortic cross-clamp times. CPB duration was sig-

nificantly shorter in the RDSC group than in the Medeng-2 and UniLine groups (both $p < 0.001$; Fig. 7). Aortic cross-clamp time was also significantly shorter in the RDSC group than in both control groups (both $p < 0.001$; Fig. 8).

Data are shown as box plots with median, interquartile range (25th–75th percentiles), and range. Kruskal – Wallis test: $H = 16.914$, $p < 0.001$. Post hoc analysis showed significantly shorter CPB time in the RDSC group than in the Medeng-2 and UniLine groups (both $p < 0.001$). RDSC, rapid-deployment sutureless cuff; CPB, cardiopulmonary bypass.

Box plots show the median, IQR, and whiskers (1.5×IQR). Kruskal – Wallis test: $H = 39.227$, $p < 0.001$. Significant differences were found between RDSC and Medeng-2 ($p < 0.001$) and between RDSC and UniLine ($p < 0.001$).

Thirty-day all-cause mortality was 8.6% (3/35) in the RDSC group, 7.3% (3/41) in the Medeng-2 group, and 3.3% (1/29) in the UniLine group ($p = 0.78$). No prosthesis-related deaths occurred. Causes of death unrelated to valve disease included two cases of persistent heart failure with low cardiac output, one case of respiratory and multiorgan failure due to COVID-19, and one acute inferior transmural myocardial infarction that occurred after hospital discharge.

Intraoperative and postoperative data are shown in Table 3.

No statistically significant differences were found in pacemaker implantation, stroke, or mortality ($p = 0.18$, $p = 0.53$, and $p = 0.78$, respectively; Fisher's exact test). No prosthesis explantations due to dislocation or severe paravalvular regurgitation were required. In the RDSC group, five cases (14.3%) of mild, haemodynamically insignificant paravalvular regurgitation (grade 0–I) were recorded. No paravalvular regurgitation was documented with sutured prostheses.

Discharge echocardiographic findings are shown in Table 4. Peak and mean gradients were significantly lower in the RDSC and UniLine groups than in the Medeng-2 group. LVEF at discharge was lower in the RDSC group.

Discussion

Modern cardiac surgery offers a broad range of prostheses for heart valve replacement [9]. Aortic valve prostheses can be classified as sutured, transcatheter, or sutureless/rapid-deployment valves. Conventional sutured prostheses require placement of numerous interrupted sutures (15–25) and remain the gold standard for open aortic valve replacement [1].

Transcatheter aortic valve implantation was developed for patients with severe, decompensated aortic stenosis [10]. The PARTNER and PARTNER II studies demonstrated the benefits of these techniques in patients at high and intermediate-to-high risk [11; 12]. Transcatheter valves are now also being studied in low-risk patients [13; 14].

Sutureless valves can reduce surgical risk by shortening cardiopulmonary bypass and aortic cross-clamp times [15–17]. Internationally available models include Perceval S (Corcym, United Kingdom) and Edwards INTUITY (Edwards Lifesciences, USA) [18; 19]. The principal difference is the fixation mechanism. Perceval S consists of a self-expanding nitinol frame positioned in the sinuses of Valsalva and the proximal ascending aorta, with bovine pericardial leaflets [20; 21]. This allows complete removal of the guide sutures after deployment, providing genuinely sutureless fixation [22; 23].

Edwards INTUITY represents another approach, often referred to as rapid deployment. It requires three fixation sutures for initial positioning, whereas final sealing is achieved by a balloon-expandable skirt located in the infrannular region [7; 24].

The Russian sutureless valve technology was developed by Medeng (Penza). Its Easy Change technology, originally designed for rapid replacement of the cartridge prosthesis, was supplemented with a mechanism enabling rapid cuff fixation and placement of a mechanical, biological, or full-flow cartridge [25]. Easy Fix resembles the implantation technique of Edwards INTUITY and, combined with Easy Change, may permit rapid replacement in cases of bioprosthetic cartridge degeneration [9]. In the first published case series ($n = 10$), the cuff demonstrated safe implantation and satisfactory early haemodynamic results. The present study extends these findings to a larger cohort.

In our study, 30-day mortality in the RDSC group was 8.6% (3/35); this is higher than rates reported for sutureless and rapid-deployment prostheses in international studies: 0.8% in TRANSFORM (Edwards INTUITY) [7], 2.1% in the SURD Registry [16], and 2.5% in a meta-analysis of Perceval S [18]. The higher rate in our cohort may be explained by the lower baseline LVEF in the RDSC group [18]. The median cross-clamp time in the RDSC group was 42 minutes, shorter than the pooled estimate in the meta-

analysis by Berretta et al. (median 49 minutes; IQR 36–63) [16], potentially reflecting an optimised implantation technique and surgeon experience. The discharge mean transprosthetic gradient was 7.5 mmHg, comparable to or lower than values reported for Edwards INTUITY in TRANSFORM (10.3±3.8 [3.1–28.7] mmHg) [7].

Grade I paravalvular regurgitation occurred in five RDSC patients (14.3%); all episodes were haemodynamically insignificant and required no intervention. This complication, observed exclusively in the sutureless cuff group, is an important safety signal. Its likely mechanism is related to infrannular balloon dilation and adaptation of the rigid cuff frame to an unevenly calcified annulus. Although clinically insignificant in the early period, this finding warrants mandatory long-term echocardiographic surveillance to assess fixation stability and exclude progression of regurgitation.

The immediate results indicate that this approach is feasible and effective. Shorter ischaemia and perfusion times may reduce total operative time and facilitate concomitant procedures. The option of implanting either a mechanical or biological cartridge could theoretically broaden the population eligible for sutureless aortic valve replacement by removing age restrictions associated with some international analogues. This potential advantage requires confirmation in further studies. No published clinical data are currently available regarding Easy Change in redo procedures. The present study included no reimplantation cases, underscoring the need for further experience to assess the practical feasibility of this function.

Study limitations

This study has several important limitations. First, it was a single-centre, non-randomised pilot study, increasing the risk of selection bias and limiting causal interpretation of between-group differences. Second, the sample size was insufficient to reliably detect differences in rare outcomes, including 30-day mortality, pacemaker implantation, stroke, and clinically significant paravalvular regurgitation. Therefore, the absence of statistically significant differences should not be interpreted as evidence of equivalence or non-inferiority. Third, allocation was based on clinical judgement and surgeon preference rather than randomisation, potentially resulting in residual confounding despite comparable EuroSCORE II values. This is supported by baseline differences in age, LVEF, hypertension, and type 2 diabetes. Fourth, the RDSC group was heterogeneous with respect to cartridge type, which may have influenced haemodynamic measures and the complication profile. Fifth, most procedures were performed by one surgeon; therefore, the effects of individual expertise and the learning curve on operative time and early outcomes cannot be excluded. Finally, follow-up was limited to the hospital stay and 30 days, precluding assessment of device durability, the time course of paravalvular regurgitation, and late reoperation rates.

Conclusions

Preliminary data from this pilot study suggest that aortic valve replacement using a rapid-deployment sutureless cuff significantly reduces aortic cross-clamp and cardiopulmonary bypass times while providing comparable early haemodynamic outcomes. However, the limited sample size does not provide adequate statistical power to establish equivalence of safety profiles for rare clinical outcomes. Further adequately powered studies are needed to assess long-term outcomes, device durability, and the course of paravalvular regurgitation.

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