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Posted Date: 18 October 2024

doi: 10.20944/preprints202410.1464.v1

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Exploring Technical Insights into the Mechanical Adaptation-Behavior of the Intuity Elite Bioprosthesis: A Single-Center Experience

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Abstract: Objectives: Sutureless aortic valve replacement (Su-AVR) is gaining popularity due to its simplified implantation technique and advantages such as shorter operative time. We evaluated the Intuity aortic bioprosthesis and investigated the mechanical adaptation of its prosthetic stent and its susceptibility to cusp fibrosis, dysfunction, flutter, and obstruction after implantation, if any. Methods: N=19 patients received a Su-AVR with the Intuity bioprosthesis at our institution between 2018 and 2020. We analysed the clinical outcomes, anatomical and stereotactical features using the OSIRIX DICOM Pixmeo software CT images, and the radial force (RF) profile using the RX Machine apparatus (Machine Solutions Inc., located in Flagstaff, AZ), for evaluating the valve's stent according to ISO standards. Results: In all three-dimensional reconstructions, the Intuity stent showed no degree of deformation or ovalisation. Annulus ovality was 0 and 10.4%, respectively, and ovality of the skirt at its open edge was 2 and 19.9%, respectively. Intuity's RF was significantly higher than other transcatheter aortic devices, exceeding the tester's measurement range. Conclusions: The Intuity Elite bio-prosthesis demonstrates remarkable ovality, RFs, and rigidity that could relate to a potential for dynamic adjustment to the hemodynamic patterns in the aortic root postoperatively. Its high RFs at the annulus may explain the resistance to deformation, ensuring harmonious, natural-like cusp mobility. This may reduce the risk of turbulence-induced fibrosis and increased transvalvular pressure gradients, and may clinically translate into less hemolysis. To validate the clinical impact of our findings, if any, additional research with larger sample and extended follow-up is essential.

Keywords: intuity bioprosthesis; annulus ovality; crush forces; radial forces; stent mechanical adaptation behaviour; rap-id deployment valve

1. Introduction

The aortic heart valve (HV) is a complex structure in a challenging dynamic anatomical and mechanical environment. The blood flow exerts diverse stresses on the valve tissue during each cardiac cycle, which can trigger biological responses such as gene expression, protein activation, and cell phenotype. This plethora of forces may also impact valve remodeling or pathological changes. Understanding the complex mechanobiology of the aortic HV involving stress-strain distribution within the leaflet thickness, remodeling cascades during the cardiac cycle and complex biomechanics pathways of stimulus transmission from the organ to cellular microcosm remains a challenging endeavor (1, 2). Understanding the geometric and biomechanical adaptation of different bioprostheses after implantation is of great clinical interest and needs to be addressed. Severe aortic valve stenosis is still the most common heart valve disease (HD) in the world (3-5). For decades, conventional surgical AVR has been the gold standard of care (6-8). Conventional AVR in patients

 doi:10.20944/preprints202410.1464.v1

without serious comorbidities is widely considered to be a safe procedure with a low risk of mortality (9, 10). However, as patients' age and comorbidities continue to rise, conventional AVR procedures increasingly associated with complications, particularly when combined with other procedures such as CABG (11-14). The correlation between prolonged aortic cross-clamp and CPB times and increased mortality has been shown (15, 16). Consequently, rapid deployment sutureless (RDS) AVR is gaining ground due to its established simplified implantation technique, proven safety and reduced bypass and cross-clamp time. due to its established simplified implantation technique, proven safety, and reduced bypass and cross-clamp time (17-20). Compared to conventional valves, the Intuity delivers comparable initial clinical outcomes, with significantly better hemodynamics and clinical benefits on long-term morbidity and mortality(16, 21, 22).

The Intuity sutureless aortic valve (Edwards Lifesciences Inc., Irvine, CA, USA) is one of the two commercially available and mostly used RDS bioprostheses and is implanted using the Edwards Intuity rapid-deployment application system.

AVR with the Intuity valve is similar to conventional surgical AVR, which requires open-heart surgery with cardiopulmonary bypass to remove the calcified valve and decalcify the annulus. Unlike conventional AVR, the anchoring of the implanted Intuity valve in the annulus is not dependent on circumferential annular sutures. The Intuity design is based on the Magna Ease valve (Edwards Lifesciences), but with the addition of a balloon-expandable stainless steel stent frame covered by a polyester fabric that is attached to the inflow. Balloon inflation causes the stent frame to expand and seal against the adjacent subvalvular left ventricular outflow tract and ventriculoarterial junction (23). The tapered, fabric-covered expanded stent anchors and seals a properly placed valve in such an ideal position that the suture ring is located directly over the attachment of the native aortic leaflets to the aortic annulus over almost 90% of its circumference (23). The pericommissural region is the only area that extends beyond the level of the suture ring and accounts for the remaining 10% of the circumference. Three additional guide sutures placed at the nadir of each sinus help to orient the suture ring and valve prosthesis (23). The prosthesis is carefully guided into the correct position, after which the metal skirt is dilated in the left ventricular outflow tract (LVOT) (24-26). RD SuAVR is an attractive alternative in combined procedures, and in fragile aortas especially in elderly patients with multiple comorbidities. Multiple studies have validated and confirmed the safety and hemodynamic efficacy of the Intuity valve (27). Numerous technical aspects have to be considered such as a careful leaflet excision and decalcification with preservation of the aortic annulus being of paramount importance. Avoiding oversizing or undersizing is crucial, particularly when dealing with bicuspid or unicuspid valves, where extra caution is warranted. Precise placement prior to inflating the balloon is essential, especially in instances involving preexisting Right Bundle Branch Block (RBBB). In addition, when conducting mitral valve surgery, it is crucial to exercise care due to the fact that the sub-annular aortic region is frequently the focus of prosthetic mitral implants and suture material. This can impact the sub-annular landing region for the Intuity valve, resulting in a disrupted anatomy that could complicate the implantation process (23).

The Intuity valve offers several advantages over conventional alternatives, but associated with a greater frequency of new conductive system abnormalities (25). This applies to recently inserted pacemakers and the occurrence of new left bundle branch block (LBBB). When a right bundle branch block (RBBB) preexists, the emergence of an additional LBBB will require the insertion of a pacemaker. Therefore, the Intuity valve should be avoided in such cases. Several publications have shown that the hemodynamic characteristics of the Intuity valve exceed those of conventional aortic valve prostheses (18, 22). Our objective was to conduct a thorough analysis of the morphological and functional adaptation of the Intuity Prosthesis through a comprehensive evaluation that included in vitro testing and in vivo 3D analysis following AVR.

2. Materials and Methods

2.1. Data Source

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Retrospectively, patient data, clinical information prior, during, and after surgery were gathered and examined through our institution's database. Our research was granted approval by the local ethics committee (Ethics Commission RWTH Aachen) with an Institutional Review Board (IRB) authorization: EK 151/09 version 1.2.3, dated March 2016. As a result of the retrospective nature of the research, informed consent was not required. Patient data included medical history, postoperative echocardiographic examinations, cardiac CT scans, intraoperative data, as well as the 30-day postoperative outcomes.

2.2. Study Cohort

This is a single-center, retrospective observational study. Data of patients who received a SuAVR in our Department of cardiothoracic surgery at RWTH Aachen University Hospital between January 2018 and December 2020were retrieved from the institutional database and then screened. The CT scans of patients who received sutureless surgical aortic valve replacement (SuAVR), clinical, operative, echocardiographic, and radiographic data of patients who underwent isolated or combined SAVR with the Intuity bio-prosthesis were included. Inclusion parameters were elective cases of isolated or combined SuAVR with the Intuity bio-prosthesis. exclusion criteria included cases that were of emergent or urgent nature, presence of bicuspid aortic valve, anatomical contraindications to suAVR such as dilated aortic root, endocarditis, hypertrophic cardiomyopathy with LV outflow tract obstruction, redo cases, poor quality of the outflow tract, poor echocardiographic images or incomplete data. All patients received a standardized evaluation and management, prior, during and after surgery by the same team of highly experienced experts.

2.3. Operative Technique

All patients underwent a standardized surgical procedure performed by the consistent team of cardiac surgeons. CPB was established by central aorto-caval cannulation. The best site for cross-clamp and aortotomy for the given surgical access was chosen based on the anatomy and the pathological changes of the ventriculoarterial junction, aortic root, and ascending aorta. Antegrade cardioplegia Bretschneider was administered. The aortotomy was carefully performed to ensure precise placement of the Intuity valve directly above the aortic annulus. These included variations such as a lazy-S, lazy-U, hockey-stick, strict longitudinal, and transverse types of aortotomy. In this cohort, no cases appeared with the diameter of the sinotubular junction (STJ) smaller or equal to the aortic annulus, so that no opening of the aortic root for implantation was required. No high transverse incisions were required. Focal exophytic calcifications projecting into the lumen of the aortic root were delicately excised, and any damage to the aortic wall was meticulously repaired with sutures, resulting in a seamless aortic wall surface. This ensured the smooth insertion of the prosthesis into the ideal position without dislodging any remaining calcific particles.

2.4. The Intuity Edwards Bio-Prosthesis

The Intuity aortic valve is built upon the Perimount valve technology, with the addition of a stainless steel frame at the inflow section that is covered by a textured sealing cloth. The leaflets consist of bovine pericardium. After positioning the prosthesis in the correct position, the stent is expanded with a balloon in the LVOT, which helps to seal the prosthesis and secures the prosthesis in the correct position. The prosthesis is available in the sizes 19, 21, 23, 25 and 27 mm (25, 26).

2.5. Computed Tomography Analysis

A meticulous technical assessment was conducted for each instance to evaluate the positioning, orientation, and integration of the valve with the adjacent anatomy utilizing advanced cardiovascular 3D reconstruction software (OSIRIX DICOM Viewer © 2024 (Pixmeo SARL, Switzerland)). Two postoperative computed tomography scans were utilized for visualization and analysis. This evaluation was conducted to assess whether the Intuity valve is prone to deformation in its natural placement. In order to gain a deeper comprehension of the mechanical characteristics of the Intuity

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valve, the radial forces of the valve were assessed in an in vitro setting as well. This also enables a more intricate comparison to the evaluation of its biomechanics.

3D analysis of the CT images after Intuity Implantation were conducted using the software OSIRIX DICOM Viewer © 2024 (Pixmeo SARL, Switzerland). Figures S3-S6, and Videos S1-S3.

Ovality measurements were performed at the annulus level and the distal end of the skirt. Stent ovality O was used as a metric for stent deformation. The percentage ovality O can be calculated mathematically using the length of the major axis L_{max} and the length of the orthogonal minor axis $L_{\perp}$ of an ellipse according to the following formula:

$$O = \frac{2 * (L_{max} - L_{\perp})}{(L_{max} + L_{\perp})} * 100\%$$

2.6. In Vitro Radial Force Assessment

Radial force (RF) is a parameter utilized to gauge the resistance of a stent structure to external radial deformation, as this most accurately replicates the in situ conditions (18). Measuring of the RF is a common practice in the design of heart valves, and analyzing this data can provide valuable insights into the performance and behavior of a valve prosthesis in vivo (28). RF measurements were conducted using the commercial RF tester RX650 from Machine Solutions in Flagstaff, Arizona, USA, which is also utilized in regulatory assessments in accordance with ISO 5840-3, see Figure 1. A crimping mechanism consisting of 12 triangular crimping jaws opens and closes around the stent to crimp it down and let it expand, respectively. Intuity prosthesis with a diameter 27mm were introduced into the tester. The tester was programmed to crimp down and compress gradually from 35 mm to 25 mm while consistently measuring the exerted RF. The manufacturer has specified the measurement accuracy of the tester as 0.06%.

2.7. Transthoracic and Trans-Esophageal Echocardiography Assessments

Echocardiographic assessment included at least one preoperative TTE the day before surgery, an intraoperative TEE prior to CPB establishment and after CPB weaning, as well as a postoperative TTE control during the early postoperative period and the day of admission. All TTE evaluations were conducted in adherence with the guidelines set forth by both the European Society of Cardiovascular Imaging and the American Society of Echocardiography (29-31). Echocardiographic assessments were conducted with the aid of the Vivid E9 device (GE Vingmed Ultrasound AS, Horten, Norway).

2.8. Statistical Analysis

The statistical analysis was conducted utilizing the software Minitab (version 19). The assessment involved utilizing both Graphical Summary and individual variables table tools. The Graphical Summary tool was utilized to provide a summary of numerical data, incorporating various statistics such as sample size, mean, standard deviation, confidence interval, minimum and maximum values. Meanwhile, the Individual Variable Table tool was employed to summarize categorical data with counts and percentages. It is important to note that certain variables contained missing values (N*) due to missing information within the dataset; these missing values were not included by Minitab during statistical calculation processes.

3. Results

3.1. Clinical Findings

Between March 2018 and June 2020, a total of 19 patients (57% females) with a mean age of 76.2 years received an AVR using the Intuity bio-prosthesis (Table 1). Thirteen patients (n=13, 68.4%) underwent simultaneous surgery in addition to the aortic valve replacement (AVR). The

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postoperative mortality rate was 10.5 %, none death was cardiac related. The postoperative rate of permanent pacemaker implantation was 5.5%.

Table 1. Patient characteristics.

Variable	Total Count	N	N*	Mean	SD	Minimum	Maximum	Confidence Interval 95%
EuroscoreII	19	19	0	2.197	0.771	0.930	4.600	1.8253- 2.5684
STS SCORE (risk for mortality)	19	19	0	1.660	0.722	0.760	3.460	1.3125 – 2.0083
Age	19	19	0	76.26	6.51	64.00	85.00	73.124 -79.403
Thrombocytes preoperative	19	19	0	261.4	66.2	132.0	379.0	229.45 – 293.29
Thrombocytes postoperative	19	19	0	178.6	45.8	83.0	257.0	156.55 – 200.71
LDH preoperative	19	19	0	254.8	129.3	136.0	680.0	192.53 – 317.15
LDH postoperative	19	19	0	373.0	146.7	216.0	793.0	302.28 – 443.72
HLM time in minutes	19	19	0	157.5	50.4	88.0	300.0	133.25 – 181.80
Cross Clamp Time in minutes	19	19	0	106.53	29.90	60.00	169.00	92.11 – 120.94
Length of stay in days	19	17	4	13.87	9.63	0.00	41.00	8.535 – 19.198
ICU Stay in days	19	17	3	8.75	8.96	1.00	30.00	3.9780 – 13.5220
Hight (cm)	19	19	0	169.11	9.09	152.00	184.00	164.72 – 173.49
Weight (Kg)	19	19	0	79.74	11.56	60.00	103.00	74.167 – 85.307
BSA	19	19	0	1.9219	0.1470	1.6000	2.1300	1.8436 – 2.002

BSA body surface area, ICU: intensive care unit, LDH: Lactate dehydrogenase

Table 2. Operative and postoperative characteristics.

Cohort (n = 19)	Number (n)	Percent (%)
30-day mortality	2	10.5
In-hospital mortality	2	10.5
KD	1	5.2
COPD	2	10.5
IDDM	5	26.3
HLP	4	21
PAD	1	5.2
Prior AF	5	26.3
Prior stroke	1	5.2
AV block with PM implant	1	5.2
Delirium	5	26.3

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Ischemic stroke	0	0
AF	2	10.5
Mild PVL	2	10.5
Moderate PVL	1	5.2
Severe PVL	0	0

AF: atrial fibrillation; AV: atrioventricular; AVR: aortic valve replacement; COPD: chronic obstructive pulmonary disease; CPB: cardiopulmonary bypass; HLP: hyperlipoproteinaemia; IDDM: insulin-dependent diabetes mellitus; KD: kidney disease; PAD: peripheral artery disease; PM: Pacemaker; PVL: paravalvular leak; SD: standard deviation.

Echocardiographic findings are presented in Table 3.

Table 3. Echocardiographic analysis.

Variable	Total	N	N*	Mean	StDev	Minimum	Maximum	Confidence Interval 95%
MPG (mmhg)	19	15	4	10.552	3.581	5.000	18.000	8.569 – 12.535
PPG (mmHg)	19	15	4	19.42	6.08	10.00	32.00	16.058 – 22.792
Velocity Ratio	19	15	4	0.4813	0.0892	0.3700	0.7000	0.43194 – 0.53073
AVAI=EOAI (VTI) cm^2/ml2	19	15	4	0.8000	0.1885	0.6000	1.3000	0.69560 – 0.90440
ET ms	19	15	4	250.67	17.78	215.00	283.00	240.82 – 260.51
AT ms	19	15	4	75.73	7.15	58.00	88.00	71.776 – 79.691

AT: acceleration time; DVI: Doppler velocity indices; EOAI: effective orifice area index; ET: ejection time; MPG: mean pressure gradient; PPG: peak pressure gradient.

3.2. Computed Tomography Analysis

Stent ovality at the annulus level was 0 and 10.4%, respectively. Stent ovality at the distant edge of the skirt was 2 and 19.9%, respectively.

3.3. Radial Force RF Measurements

Figure 1 shows the results of the RF measurements. For the Intuity prosthesis, the radial force increased gradually starting at a diameter of 33 mm during compression. Below a diameter of 31 mm, the RF increased quickly until it reached 200 N at 29 mm. The test had to be halted upon reaching 200 N, as this exceeded the load cell's maximum capacity in the radial force tester and risked damaging the equipment.

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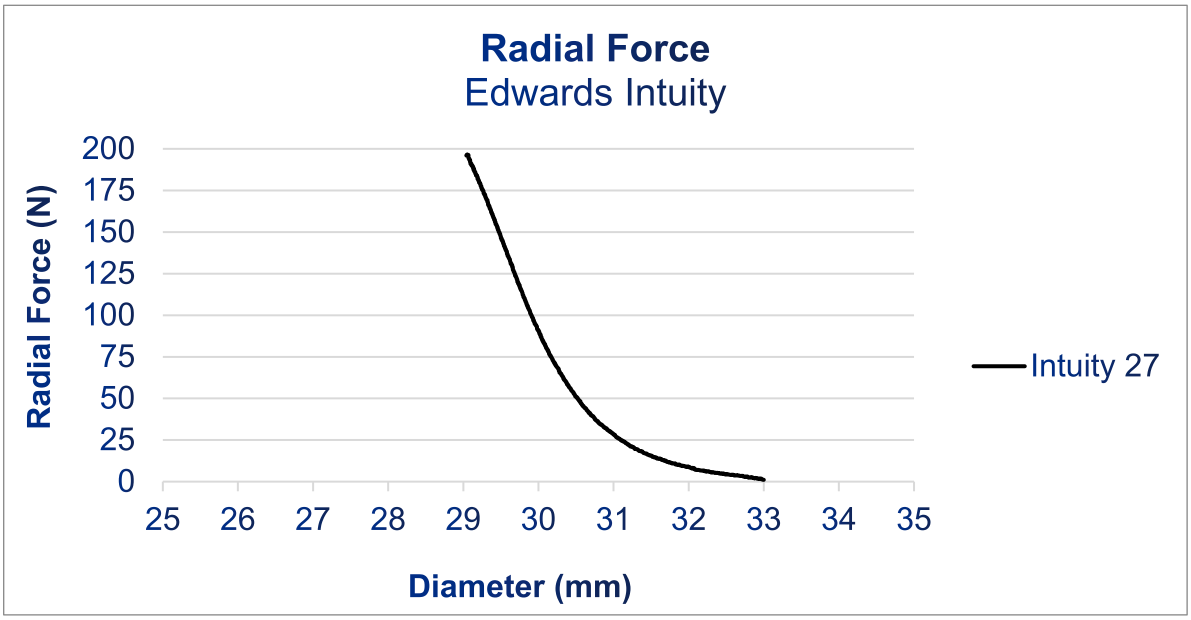

Figure 1. Radial Force Profile of the Edwards Intuity Bioprosthesis.

4. Discussion

RD prostheses are often considered a safe alternative to traditional aortic valve replacement, albeit at a considerably higher cost compared to the standard option. The main noticeable benefit over conventional procedures is the decrease in both bypass and aortic clamp time in the majority of cases. SuAVR demonstrated lower pressure gradients compared to traditional AVR in individuals receiving prosthetic valves of equivalent dimensions (32).

Reports of 12,000 patients and comparing the Intuity RDAVR to TAVR procedures, or conventional AVR with other sutured and sutureless bioprostheses, have shown that the Intuity Su-AVR exhibits a 30-day mortality of only 3.8%, with no reported incidence of paravalvular leak or myocardial infarction. Furthermore, an Intuity-related PPM rate of 11.11 % and a stroke frequency of 2.2% are reported (33). Compared to other sutured bioprostheses, the mortality rate with the Intuity valve ranged from 0% to 3.9%, while for conventional it ranged from 0% to 6.9%. The short-term mortality rate for Intuity ranged from 0.9% to 12.4%. This is comparable to our outcomes. The long-term cardiovascular mortality rate for the Intuity valve varied from 0.9% to 1.55%.

The human aortic annulus is not absolutely circle-shaped(34). It is also described that the ellipticity of the aortic annulus can influence the results of some prosthesis implantation while not affecting other alternatives(35). Sutured, stented valves enforce the human annular plane into its desired circular shape, providing proper long-term performance of the cusps. However, there are only few studies regarding the prosthesis-annular plane adaptation in case of sutureless valves. In our previous study we analyzed the biomechanics of the Perceval prosthesis. In this single-center study our objectives were to provide insights into the technical attributes of the widely used Intuity prosthesis. The RF results obtained from our in vitro testing indicate that the Intuity valve exhibits a high degree of rigidity, suggesting a reduced susceptibility to deformation. This is also confirmed by the low degrees of ovality found at the annulus level in the analyzed CT images. The RF of the Intuity valve at 29 mm, which is 2 mm above the upper end of its intended implantation range, (200 N). Within its implantation range, the Intuity valve is potentially even more rigid, but the RF tester maxed out at 200 N and did not allow for additional measurements. 200 N of radial force, however, corresponds to putting a load of 20 kg on the stent frame, which should be sufficient for its intended purpose. The Intuity bioprosthesis seems sufficiently rigid to sustain a round contour in vivo. This could explain the satisfying results, good hemodynamic performance, and low rate of patient-prosthesis mismatch even in patients with a small aortic root (36).

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An explanation of our findings may be attributed to the expandable stainless double-crimped frame steel cloth-covered skirt's role in facilitating a larger orifice area for the prosthesis, that is flexible enough to be implanted and favour gentle surgical approaches. The skirt section showed higher degrees of ovality than the stent section housing the valve. This allows the skirt to adapt well to the native anatomy decreasing the risk of paravalvular leakage. At the same time the skirt is rigid enough to maintain its structure and provide good haemodynamic response to the remodelling of the left ventricular outflow tract due to the infra-annular frame and freedom from Teflon supported sutures, thus reducing turbulent flows in the left ventricular outflow tract.

Limitations of the Study

To the best of our knowledge, this is one of the few studies investigating the biomechanical adaptation of the Intuity valve; however, one potential limitation of our study is the small cohort size. Additionally, the data focuses on short-term measures, gathered mainly directly and up to 30 days after surgery, and does not include long-term follow-up to assess patient outcomes and valve-related data such as structural valve deterioration. It should be noted that individual characteristics and parameters, such as aortic root distensibility and aortic root stiffness, may impact the geometrical orifice area (GOA) and aortic valve kinematics, thereby affecting the mechanical load on the aortic valve cusps. Further investigation is required to determine whether these alterations have a significant impact on the onset of structural valve deterioration and the valve's longevity (1, 37) as well as to further determine the potential clinical implications of these findings in long-term survival and prognosis.

5. Conclusion

The Intuity bioprosthesis demonstrates remarkable structural rigidity, and thus, the potential capacity to dynamically adjust to the hemodynamic patterns in the aortic root. Its high RFs may explain the resistance to deformation, ensuring harmonious, natural-like cusp mobility. This may reduce the risk of turbulence-induced fibrosis and increased transvalvular pressure gradients, and may clinically translate into less hemolysis. However, the generated radial forces may invite high-grade postoperative conduction system disorders. Additional research with larger sample sizes and longer follow-up periods is needed to confirm our findings and their impact in longterm.

Supplementary Materials: The following supporting information can be downloaded at the website of this paper posted on Preprints.org.

Conflicts of Interest: none declared.

Abbreviations

AF atrial fibrillation
AV atrioventricular
AVR aortic valve replacement
COPD chronic obstructive pulmonary disease
CPB cardiopulmonary bypass
EOA effective orifice area
GOA geometrical orifice area
HVD heart valve disease
HLP hyperlipoproteinaemia
IDDM insulin-dependent diabetes mellitus
ICU intensive care unit
KD kidney disease
LBBB left Bundle Branch Block
MPG mean pressure gradient
PAD peripheral artery disease
PM Pacemaker

PVL para-valvular leak
RBBB Right Bundle Branch Block
RDAVR Rapid Deployment Aortic Valve Replacement
RDS rapid deployment sutureless
RD-SAVR Rapid deployment sutureless aortic valve replacement
RF radial force
SuAVR sutureless aortic valve replacement
SD standard deviation
TTE transthoracic echocardiography
PPG peak preassure gradient
PVL paravalvular leakage
TEE trans-esophageal echocardiography
3D three dimension

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