

# Thirty-day outcomes of a novel transcatheter heart valve to treat degenerated surgical valves - The “VIVALL” multi-center, single-arm, pilot study

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**Speaker's name : Ulrich Schaefer**

I have the following potential conflicts of interest to declare:

**Consultant, proctor and speaker's bureau** for Abbott Vascular, Boston Scientific, Edwards Lifesciences, Medtronic, Gore, Jena Valve Technology, and **New Valve Technology**

**Research support** from Abbott Vascular, Boston Scientific, Jena Valve Technology, Edwards Lifesciences and **New Valve Technology**.

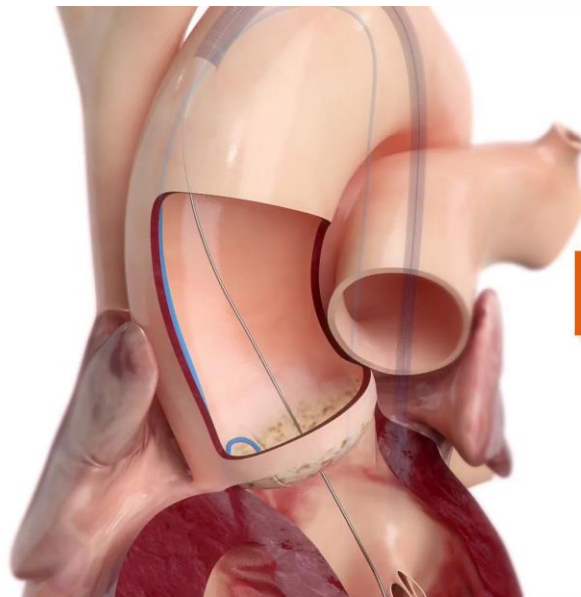
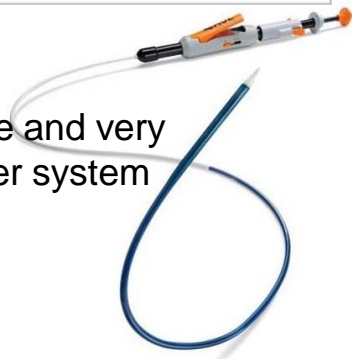
- Worldwide, annually >200.000 surgical aortic valve replacements
- bioprosthetical valves degenerate within 10 to 20 years
- Valve-In-Valve (ViV) treatment appears promising when compared with a redo open-heart operation.
- The ALLEGRA TAVI System seems interesting for ViV

## Three step deployment: “middle first, inflow second, outflow last”

- 3 step “squeeze-to-release” release mechanism

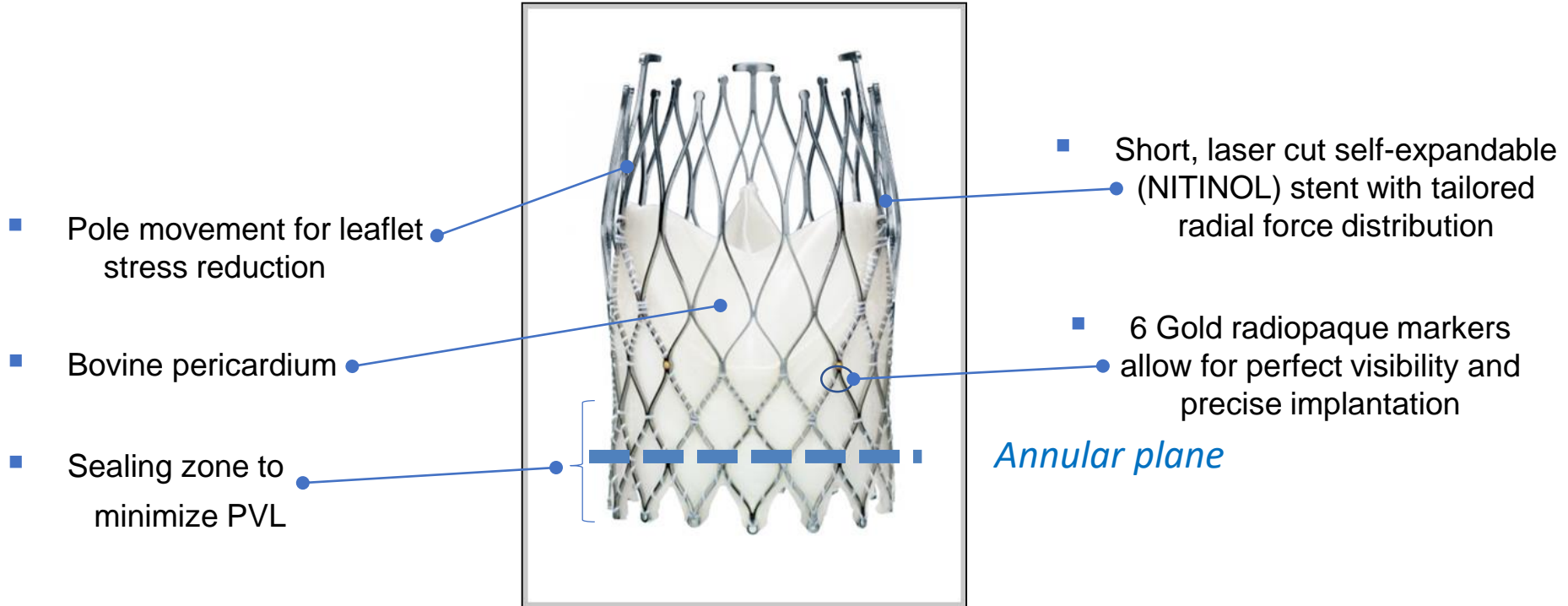


- 18Fr compatible and very flexible catheter system



3 Step deployment

Supra annular design, self-expanding, transvascular access (18Fr)

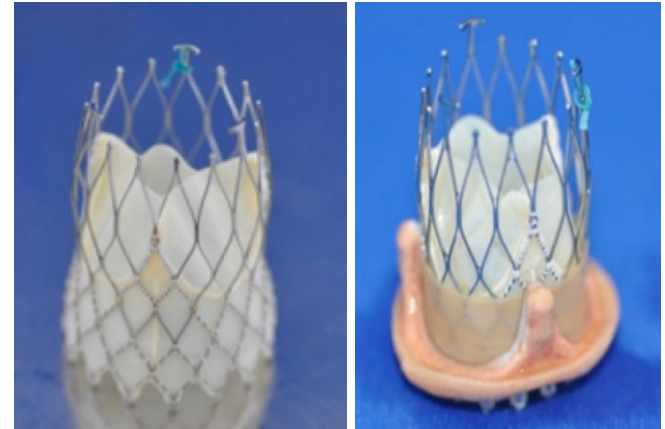


VIVALL study was designed as a prospective, multi-center, single-arm study

Objectives:

- 1.) technical feasibility
- 2.) safety and performance profile

Follow-ups after 30 days, 6 and 12 months.



	Safety	Performance
Primary Endpoints	<ul style="list-style-type: none"> <li>• <b>30-day survival</b>, (expected to be &gt;72.7%), both assessed in the ITT population</li> </ul>	<ul style="list-style-type: none"> <li>• <b>invasively</b> measured postoperative <b>mean pressure gradient</b></li> </ul>
Secondary Endpoints VARC 2	<ul style="list-style-type: none"> <li>• <i>all-cause mortality</i></li> <li>• <i>all stroke (disabling and non-disabling)</i></li> <li>• <i>life-threatening bleeding</i></li> <li>• <i>acute kidney injury - Stage 2 or 3</i></li> <li>• <i>coronary artery obstruction requiring intervention</i></li> <li>• <i>major vascular complication</i></li> <li>• <i>valve-related dysfunction requiring repeat procedure</i></li> </ul>	<ul style="list-style-type: none"> <li>• absence of procedural mortality and correct positioning of a single ALLEGRA</li> <li>• no severe (&lt;0.65 cm<sup>2</sup>/m<sup>2</sup>) patient prosthesis mismatch (PPM)</li> <li>• mean aortic valve gradient &lt;20 mmHg</li> <li>• no moderate or severe prosthetic valve regurgitation</li> <li>• assessments of NYHA class</li> <li>• necessity of new pacemaker implantations</li> </ul>

An independent corelab evaluated all echocardiographic assessments (coreLab Black Forest GmbH, Bad Krozingen, Germany)

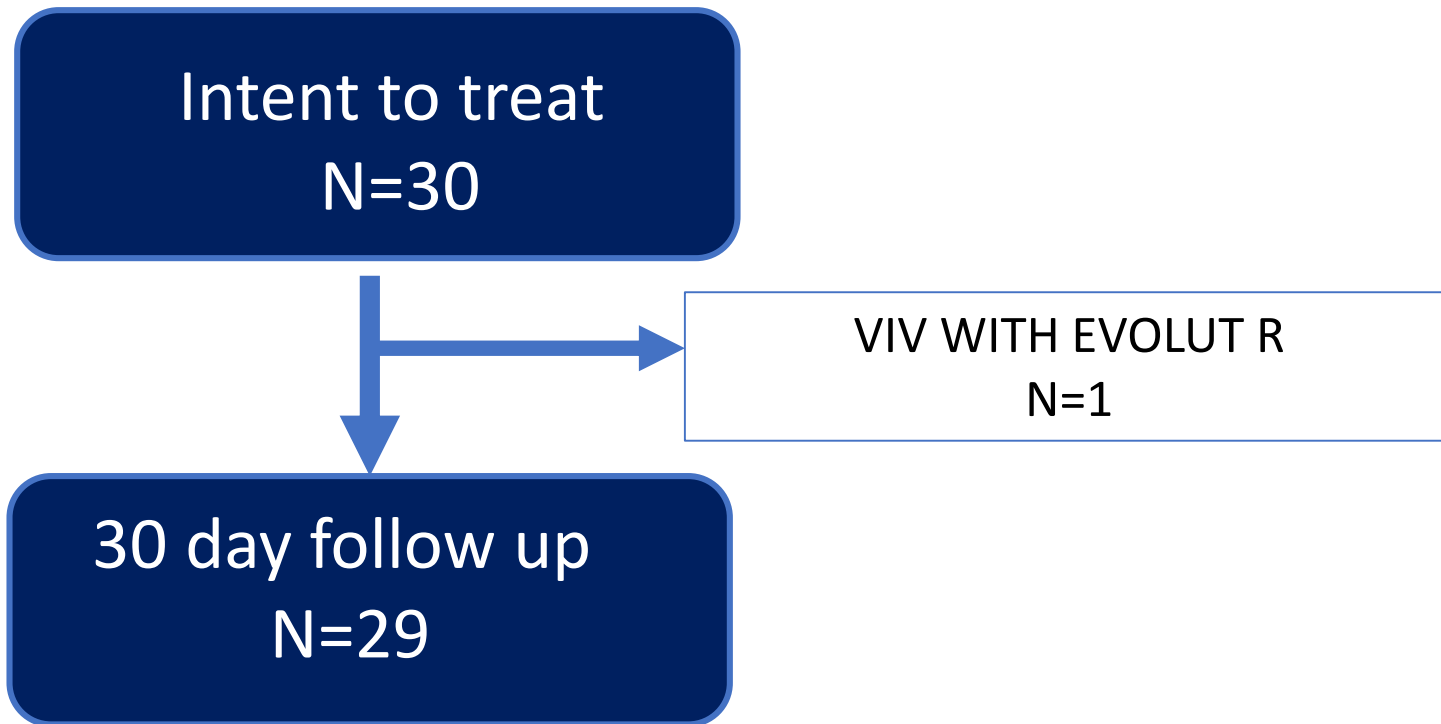
### Inclusion Criteria

- **≥18 years**
  - Symptomatic patients with a **degenerated aortic bioprosthesis (mean aortic gradient >40mmHg or peak jet velocity >4.0m/s and AVA<1.0cm<sup>2</sup>)**
- OR
- Symptomatic patients with **severe bioprosthetic valve insufficiency**
- **High risk for redo surgery** defined by **STS ≥10% / EuroScore II ≥7%**
- OR
- **as assessed by the heart team**
  - Has signed the Patient Informed Consent Form
  - Willing and able to comply with requirements of the study, including all follow-up visits
  - Female patients of childbearing potential have a **negative pregnancy** test ≤7 days before the procedure and are willing to use a reliable method of birth control for the duration of study participation

### Exclusion Criteria

- Low position of the coronary ostia, especially in combination with shallow sinuses
- Echocardiographic evidence of intracardiac mass, thrombus or vegetation
- Significant aortic disease such as severe obstructive calcification or marked tortuosity or kinking which will preclude a safe advancement of the ALLEGRA TAVI System TF
- Iliofemoral vessel conditions such as severe obstructive calcification, severe tortuosity or kinking that would **preclude safe placement of an 18 Fr introducer sheath** or make endovascular access to the aortic valve impossible
- **Severe mitral insufficiency**
- **Internal diameter of the bioprosthesis is ≤16 mm or >28 mm**
- **Patient prosthesis mismatch (EOAi ≤0.65 cm<sup>2</sup>/m<sup>2</sup>)** as the underlying cause of the poor valve function and need for re-intervention
- Non-valvular stenosis as the underlying cause of the poor valve function and need for re-intervention
- Failing pre-existing prosthetic heart valve or prosthetic ring in any other position than aortic
- Partially detached leaflets that in the aortic position may obstruct a coronary ostium.
- Existence of aortic conduit, aortic arch replacement, stentless bioprosthesis and autologous valve replacement
- **Paravalvular leak** of the failing surgical bioprosthesis (between failing surgical bioprosthesis and native annulus)
- **LVEF <20%**
- **Evidence of active endocarditis** or other acute infections
- End stage renal disease requiring chronic dialysis or **creatinine clearance <20 ml/min or serum creatinine >3.0 mg/dl (264 μmol/l)**
- Known hypersensitivity to contrast media, which cannot be adequately pre-medicated or contraindication to anticoagulant or anti-platelet medication or to Nitinol alloy or to bovine tissue
- Evidence of an acute myocardial infarction within the past 30 days
- Cerebral vascular accident (TIA, Stroke) within past 6 months (≤180 days)
- Evidence of active peptic ulcer or upper gastrointestinal bleeding within past 90 days
- Untreated clinically significant coronary artery disease requiring revascularization
- Haemodynamic instability (e.g. cardiogenic shock) requiring inotropic support or mechanical heart assistance (e.g. VAD, IABP), Uncontrolled (therapy resistant) atrial fibrillation
- Life expectancy ≤ 12 months due to other medical illness
- **Currently participating in another investigational drug or device study**

- 1.) Department of Cardiology, University Heart Center, Hamburg, Germany AND  
Heart Surgery Clinic, University Heart Center, Hamburg, Germany
- 2.) Heart Center Brandenburg in Bernau & Brandenburg Medical School, Bernau, Germany
- 3.) Segeberger Clinics, Heart Center, Bad Segeberg, Germany
- 4.) Asklepios Clinic St. Georg, Hamburg, Germany
- 5.) Heart Surgery Clinic, University Heart Center, Halle, Germany



Age (years)	<b>78.6</b>	<b>±6,0</b>
Male	<b>50.0%</b>	(15)
NYHA class III/IV	<b>80.0%</b>	(24)
Coronary artery stenosis >50%	43.3%	(13)
Angina pectoris (stable)	6.7%	(2)
Previous myocardial infarction	16.7%	(5)
Previous cardiac decompensation	<b>30.0%</b>	(9)
Pulmonary hypertension	23.3%	(7)
Previous endocarditis	10.0%	(3)
Atrial fibrillation or flutter	36.7%	(11)
LBBB / RBBB	13.3%	(4)
Previous stroke	10.0%	(3)
Previous TIA	3.3%	(1)

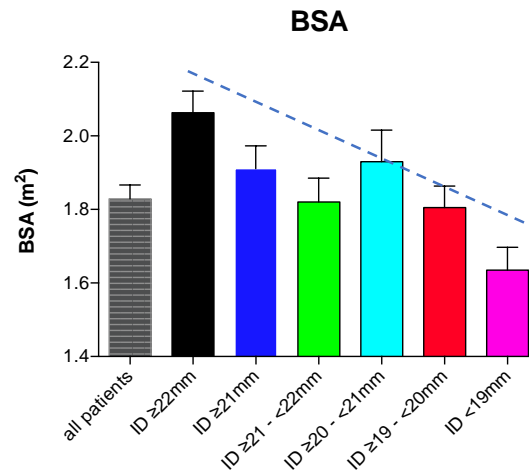
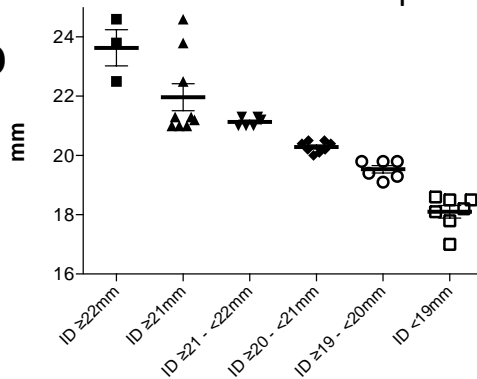
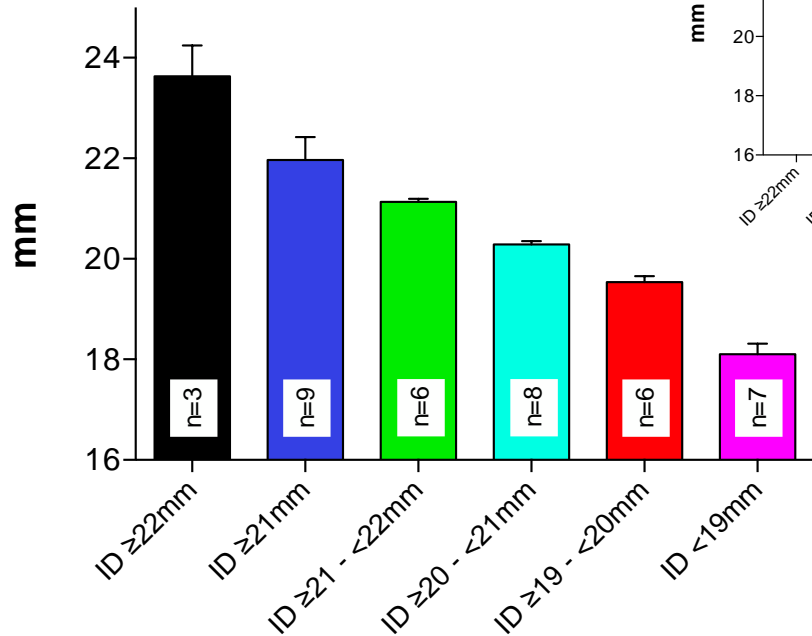
Porcelain aorta		<b>6.7%</b>	(2)
COPD		10.0%	(3)
Chronic renal insufficiency		<b>36.7%</b>	(11)
Cancer / malignant tumor		23.3%	(7)
Diabetes type II		13.3%	(4)
Arterial Hypertension		100%	(30)
Hyperlipedemia/hpercholesterolemi a		56.7%	(17)
Previous PTCA / stenting		36.7%	(11)
Previous CABG		<b>53.3%</b>	(16)
Peripheral artery disease		10,0%	(3)
Previous PTA /stent		23.3%	(7)
Permanent pacemaker		13.3%	(4)
	Insufficiency	<b>33.3%</b>	(10)
Bioprosthesis disease	Stenosis	<b>33.3%</b>	(10)
	Mixed	<b>33.3%</b>	(10)
EuroSCORE II (%)		<b>9.2</b>	<b>±4,3</b>
STS (%)		<b>4.5</b>	<b>±2,1</b>

Patient	Valve Type	Valve Size (mm)	Perimeter derived diameter (mm)	Failure Mode	EOAI Baseline (cm <sup>2</sup> /m <sup>2</sup> )	Mean PG Baseline (mmHg) Echo	Pre-procedure invasive PG (mmHg)	Post-procedure invasive PG (mmHg)	EOAI Discharge (cm <sup>2</sup> /m <sup>2</sup> )	Mean PG Discharge (mmHg) Echo
1	Mitroflow	23	19.8	M	0.53	11	55	12	0.64	15
2	Mitroflow	21	19.3	M	0.52	38	47	13	0.73	20
3	Mitroflow	23	20.5	I	0.86	18	23	6	0.86	12
4	CE SAV	23								
5	Mitroflow	21								
6	Mitroflow	23								
7	Perimount	25								
8	CE SAV	21								
9	Hancock	23								
10	Hancock II	27								
11	Mitroflow	21								
12	Perimount	23								
13	Hancock	25								
14	Mitroflow	21								
15	Magna Ease	23								
16	Mitroflow	21								
17	Hancock II Ultra	25								
18	Hancock	23								
19	Mitroflow	21								
20	Mitroflow	23								
21	Perimount	23								
22	Mitroflow	23								
23	Mosaic	21								
24	Magna Ease	23								
25	Hancock II	23								
26	CE SAV	23	21.2	M	0.73	27	30	20	0.91	22
27	Mosaic	23	18.1	S	0.28	39	37	15	1.20	21
28	Mitroflow	23	21.0	S	0.22	39	51	13	0.69	20
29	Mitroflow	21	19.1	S	0.28	37	54	15	0.30	34
30	Perimount	23	21.3	I	n.d.	20	28	6	0.76*	15

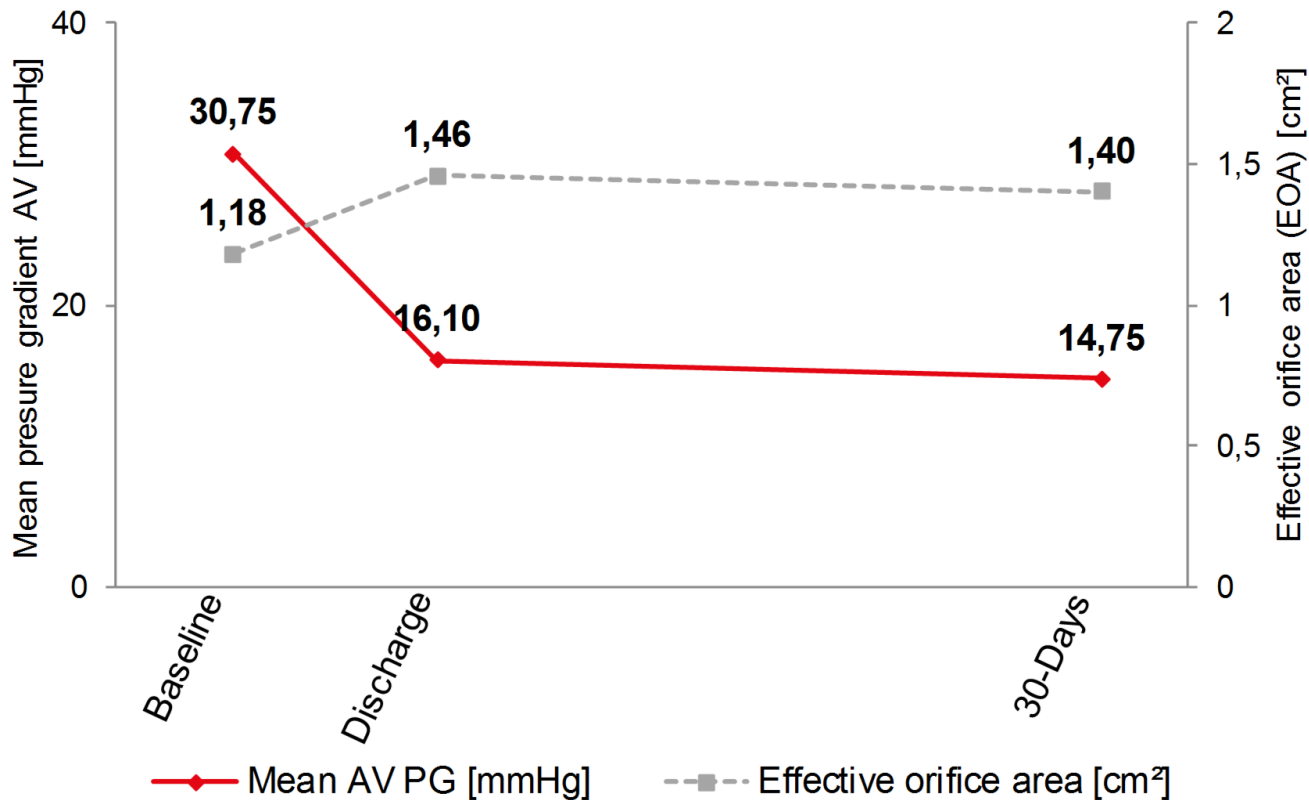
- 80.0% of the surgical valves had an inner diameter of  $\leq 21$  mm and 23.3% of  $\leq 19$  mm.
- Only 4 patients had a surgical bioprosthesis labelled with 25 mm or 27 mm outer diameter
- 43% of the surgical bioprostheses in the study population were Mitroflow valves and 6.7% were Mosaic prostheses with well-known very small inner diameters

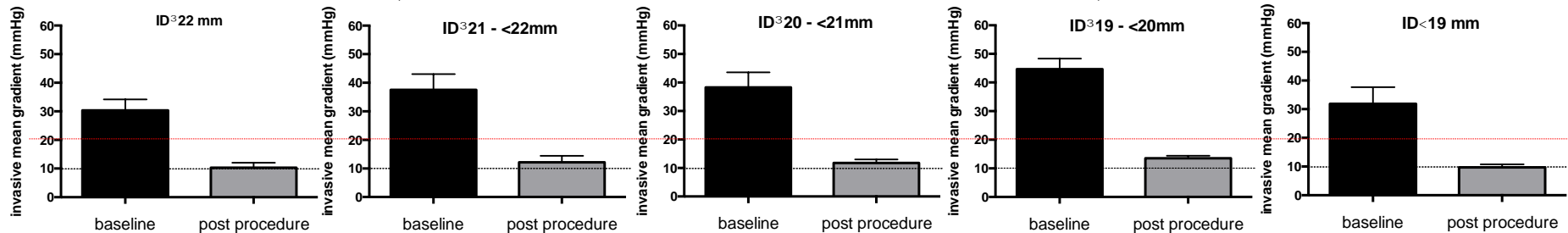
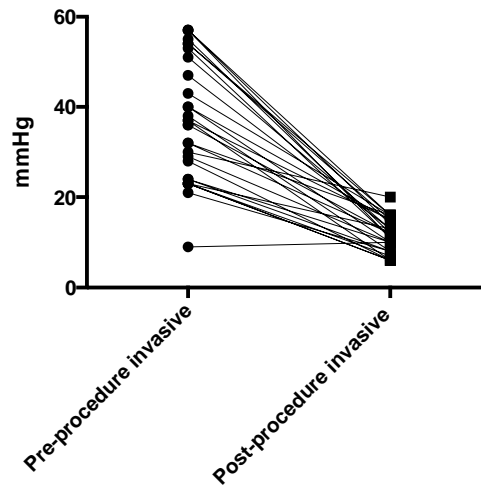
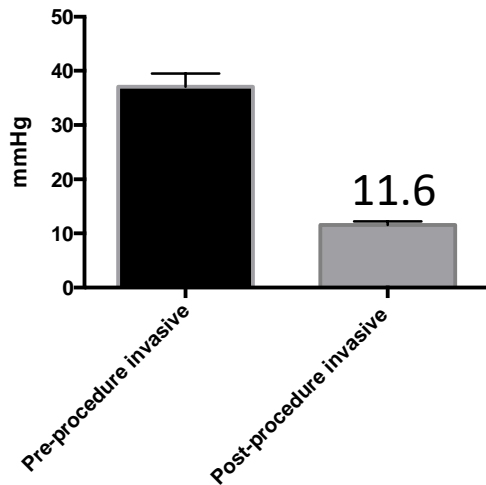
- Mean labelled diameter: **22.7+/- 1.5mm**
- Mean perimeter derived diameter: **20.1+/-1.7mm**

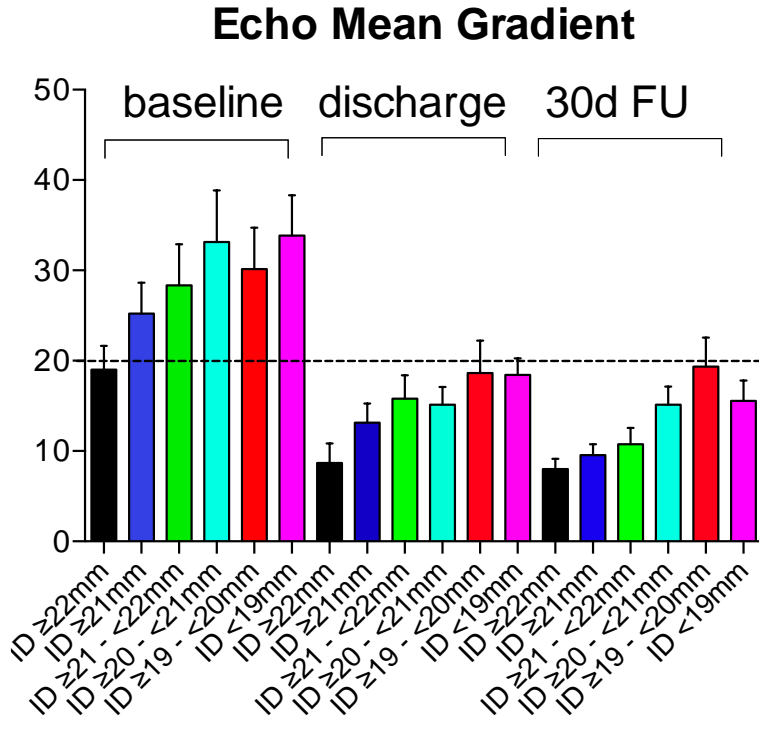
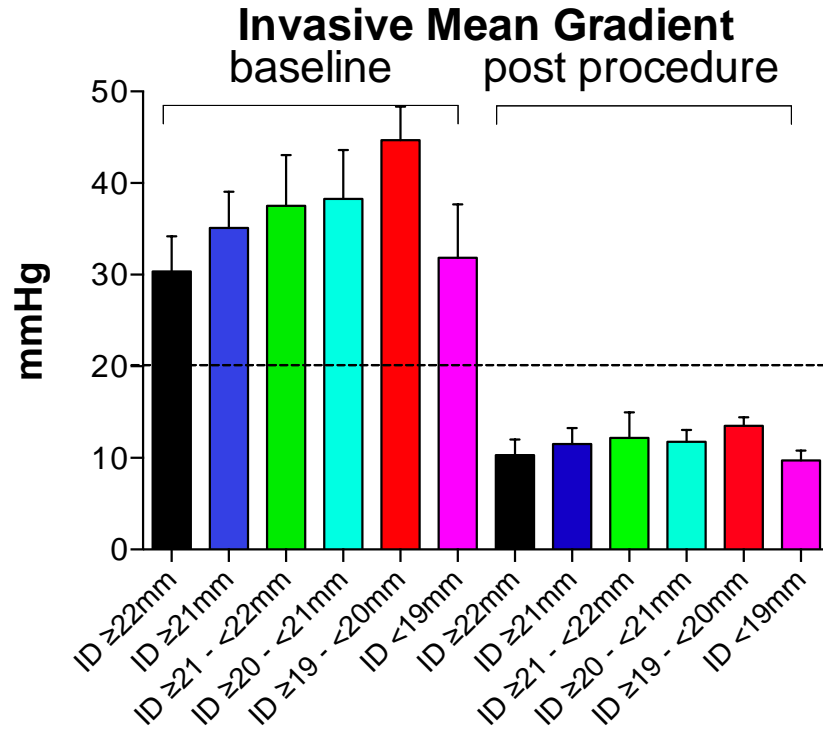
Perimeter-derived ID

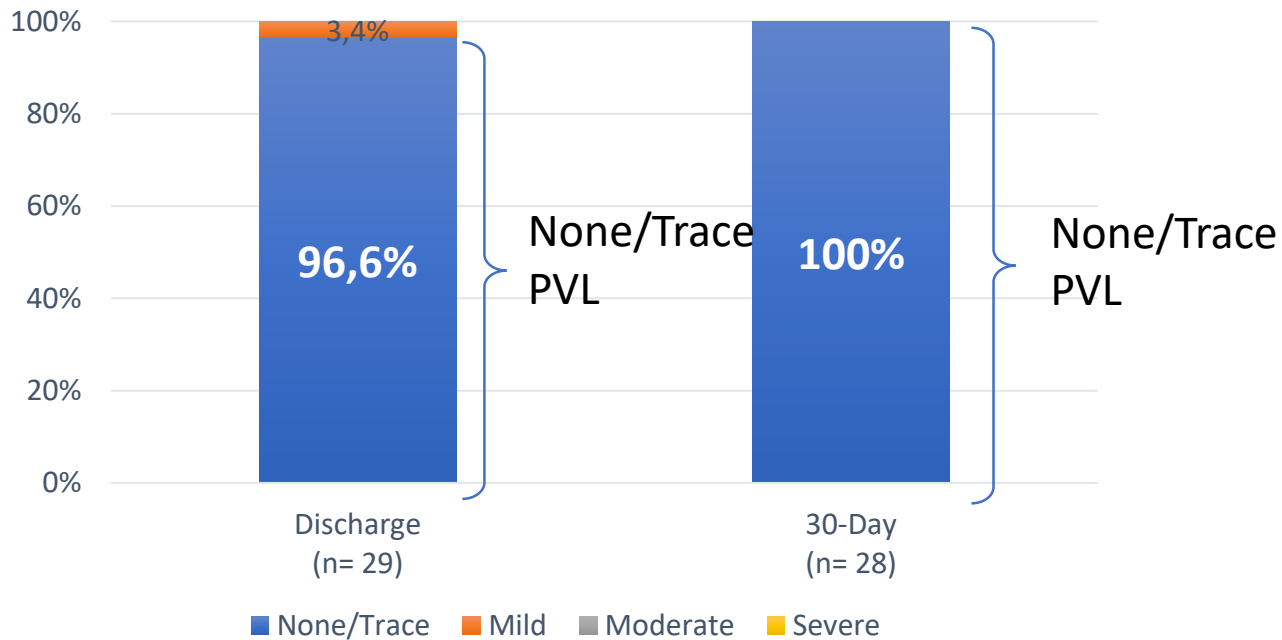


<b>Procedural success</b>		<b>96.6%</b>	<b>(29)</b>
Pre-dilatation		6.70%	(2)
<b>Post-dilatation</b>		<b>56.7%</b>	<b>(17)</b>
<b>ALLEGRA THV retrieved</b>		<b>10%</b>	<b>(3)</b>
<b>Second TAVI implanted</b>		<b>3.3%</b>	<b>(1)</b>
Invasive post-operative mean PG (mmHg)		11.6	±3.7
Fluoroscopy time (min)		24.7	±9,8
Volume contrast medium (ml)		131.9	±52,0
<b>ALLEGRA THV size</b>	23 mm	<b>90.0%</b>	<b>(27)</b>
	27 mm	<b>10.0%</b>	<b>(3)</b>
Data shown in percentages (no.) or mean ± standard deviation.			

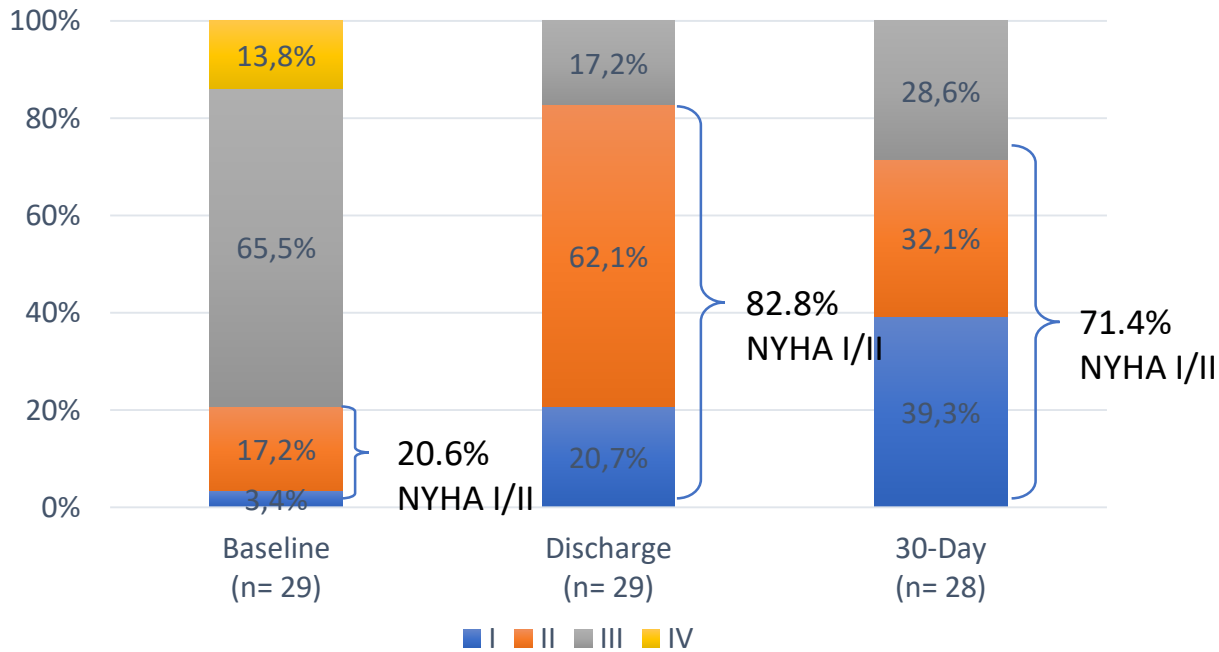








# Change in Functional Capacity (NYHA class)



<b>All-cause mortality</b>	<b>0.0%</b>	<b>(0)</b>
All stroke*	0.0%	(0)
Life-threatening bleeding	0.0%	(0)
Major bleeding	0.0%	(0)
<b>Minor bleeding</b>	<b>16.7%</b>	<b>(5)</b>
Myocardial infarction	0.0%	(0)
AKI stage 1	3.3%	(1)
AKI stage 2	0.0%	(0)
AKI stage 3	0.0%	(0)
Coronary artery obstruction requiring intervention	0.0%	(0)
<b>Major vascular complication</b>	<b>3.3%</b>	<b>(1)</b>
Structural valve deterioration	0.0%	(0)
Valve related dysfunction	0.0%	(0)
Prosthetic valve endocarditis	0.0%	(0)
<b>Prosthetic valve thrombosis</b>	<b>3.3%</b>	<b>(1)</b>
New pacemaker implantation	0.0%	(0)
Data shown in percentages (no.) or mean ± standard deviation. AKI: acute kidney injury.		

\*56% were treated with embolic protection devices (all: Claret Sentinel)

- In this early experience, the **ALLEGRA THV from NVT was safe and performed as intended** for patients with clinically significant degenerated bioprostheses in aortic position
- Hemodynamic properties suggest a **competitive pattern to other supraannular THV designs**
- At 30 days, the **major adverse event rate was very low** (mortality 0%, paravalvular regurgitation 0% - all evaluated as none or trace, implantation of new pacemakers 0%)
- There was no incidence of stroke or myocardial infarction
- At 30 days, the **clinical improvement** was remarkable with **71,4 % in functional class NYHA I/II**
- Continued follow-ups and **additional studies are warranted** to validate these initial promising results

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