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Safety, Feasibility and Acute Performance of the Leaflex™ Performer when Used Pre-TAVI in Aortic Stenosis Patients

The Leaflex™ Performer Feasibility Study

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Potential conflict of interest

Speaker's name: **Andreas Baumbach**

I have no conflict of interest to declare regarding this presentation

General:

- Institutional Research Support from Abbott Vascular
- Consultation and Speaker Fees from Astra Zeneca, Sinomed, Microport, Abbott Vascular, Cardinal Health, KSH

The Leaflex™ Performer

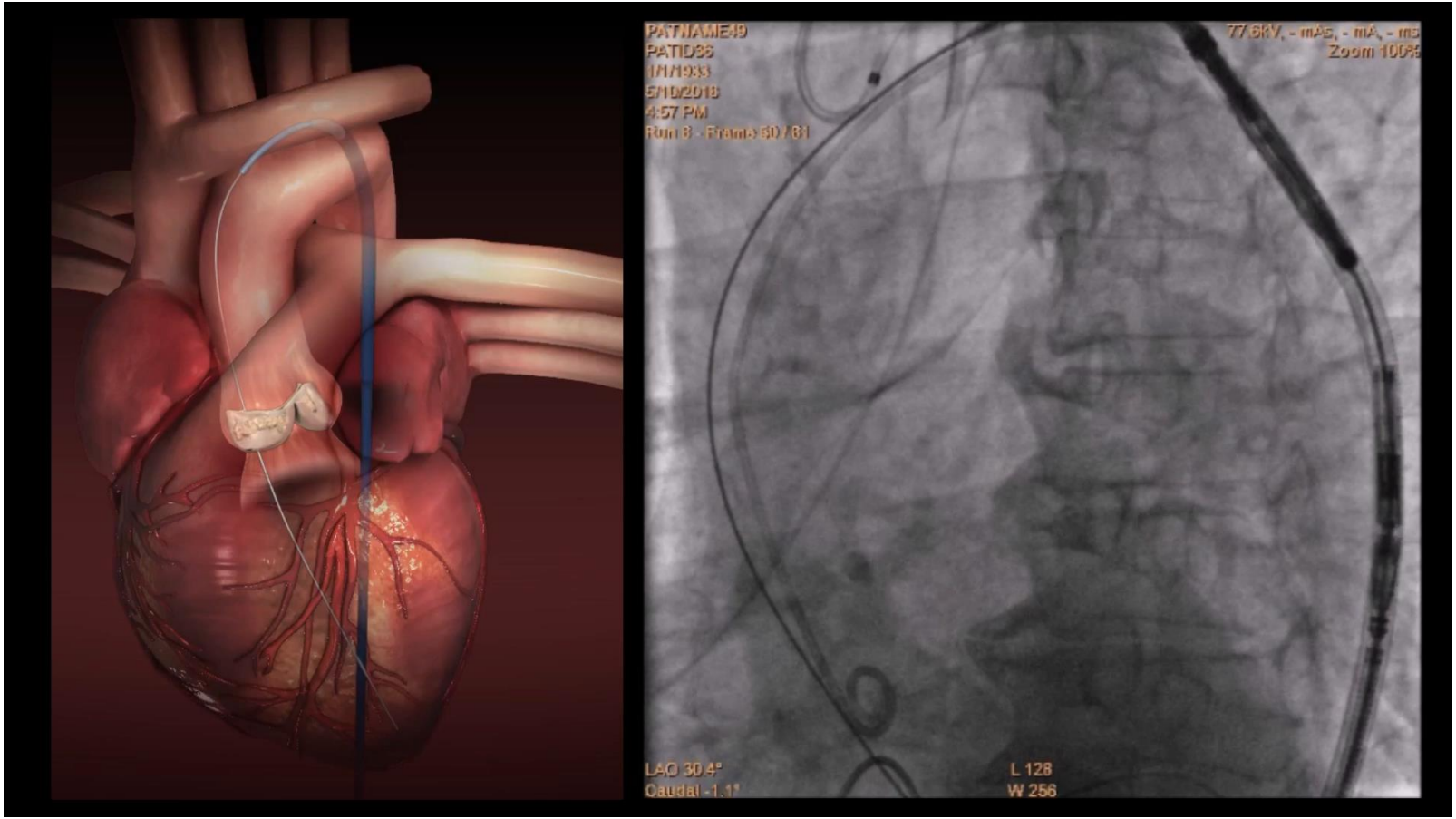
Non-implant based treatment for AS

Principle Segmentation of calcium bridges (Scoring)

Effect Increased leaflet mobility, resulting in substantial improvement in valve area

Goal To provide a short and simple standalone procedure alongside TAVI

The Leaflex™ Procedure

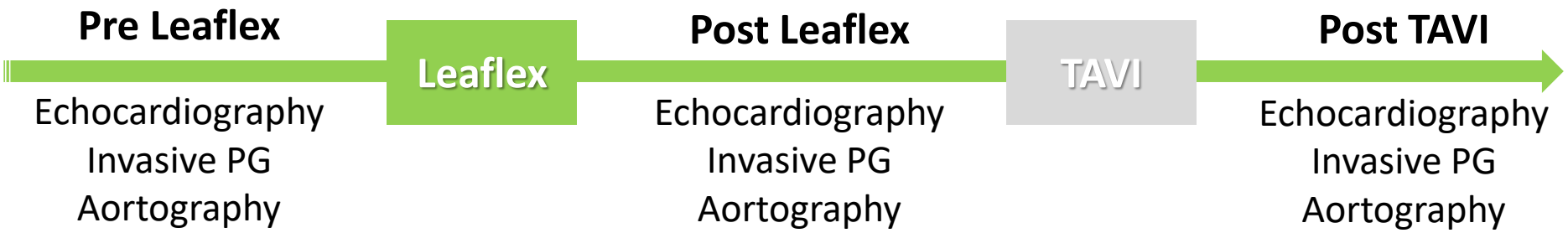


Study Design

Study goal	**Assess the safety, feasibility and acute performance of the Leaflex™ Performer**
Patient population	Aortic stenosis patients scheduled for TAVI procedure
Performance Endpoints	Leaflex™ procedure success
	Leaflex™ hemodynamic/AVA improvement (assessed post Leaflex™, pre-TAVI)
	Final valve implantation assessment
Safety Endpoints	All-cause mortality @ 30 days
	Stroke @ 30 days (VARC II)
	Leaflex™ procedural complications (assessed prior to TAVI)
Follow-up	Pre-discharge, 1 month and 3 months

Study Details

- Leaflex procedure performed pre-TAVI
- Procedure performed under general anesthesia*
- TTE and TEE used for performance and safety assessments*
- Embolic protection device (Sentinel™) used in all cases



* One case done using deep sedation and without TEE

Main Eligibility Criteria

Main Inclusion Criteria

- Native aortic valve
- Degenerative calcified aortic stenosis
- Patient planned to undergo a trans-femoral TAVR procedure

Main Exclusion Criteria

- **Congenitally unicuspid, bicuspid or quadricuspid native aortic valve**
- **Severe aortic regurgitation**
- **LVEF < 25%**
- CVA or TIA in the past 6 months
- MI in the past 3 months
- Severe carotid artery disease requiring intervention
- Percutaneous intervention or other invasive cardiac or peripheral procedure, in past month
- **Severely calcified aorta** or significant atheroma on the aorta / significant aortic disease
- Severe and difficult to control cardiac arrhythmia
- Malignancy or other major illness that might require surgery in the next 1 month
- Significant hypertrophic cardiomyopathy
- Active peptic ulcer or acute GI bleeding in the past 90 days
- Renal insufficiency (SCr>2.5mg/dl / CrCl<30ml/min / end stage renal disease req chronic dialysis)

Enrolling Sites and Core Labs

Site	Investigator	Pts.
Budapest, Hungary	P. Andreka, G. Fontos	6
London, UK	A. Baumbach, S. Kennon	3
Brighton, UK	D. Hildick-Smith, U. Trivedi, J. Cockburn	3
Krakow, Poland	K. Bartus, J. Trebacz	2
Galway, Ireland	D. Mylotte, A. Neylon	1
Rehovot, Israel	M. Jonas, G. Gandelman	1

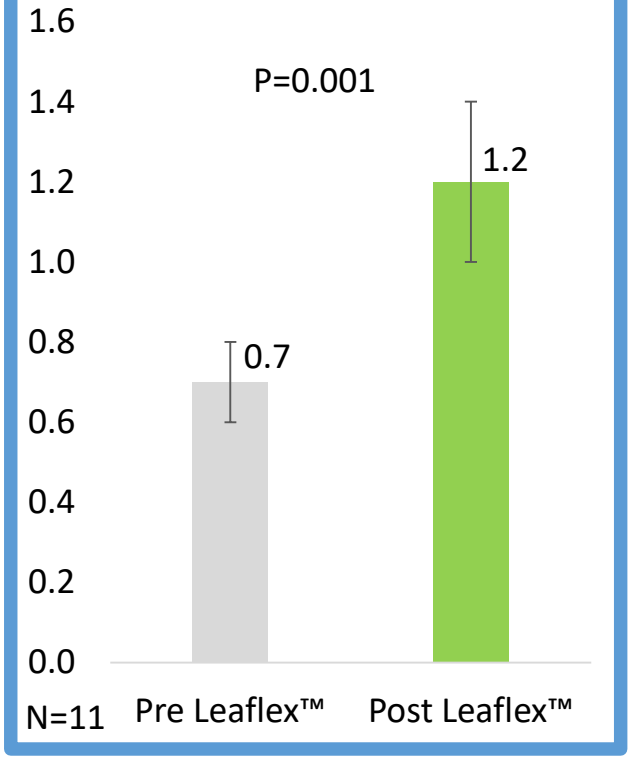
Core Labs	
CT	A. Hamdan, Israel
Echocardiography	B. Scott, Belgium
Safety Monitor	D. Halon, Israel

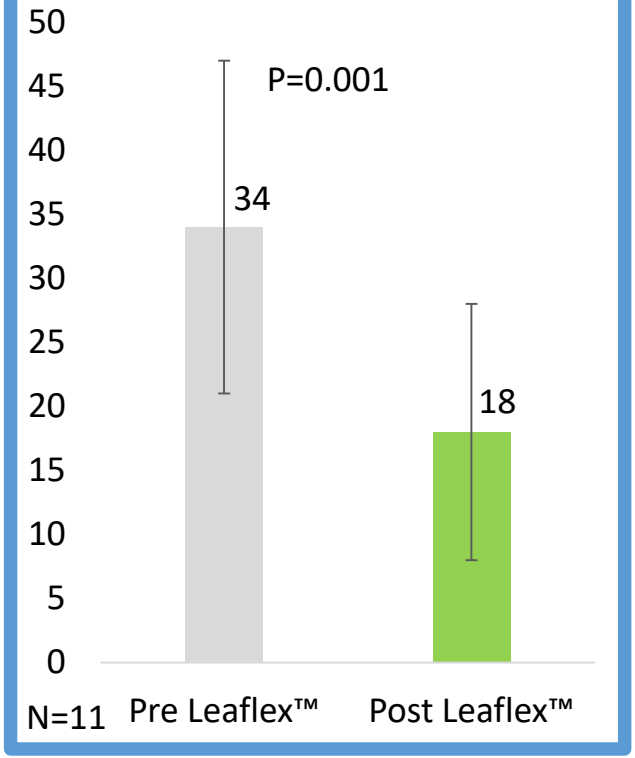
Patients Baseline Characteristics

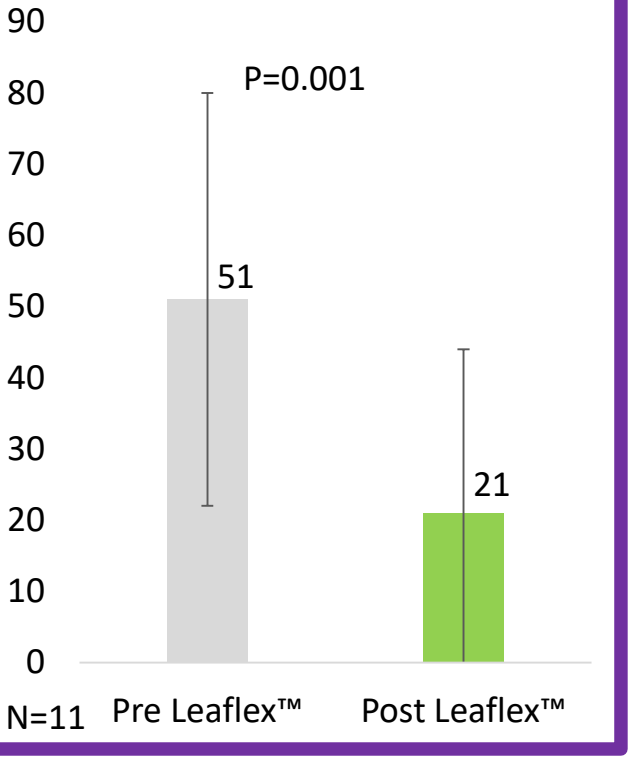
Characteristics (N=16)		**N (%) or Mean± Stdev**	
Gender male		11	(69)
Age (years)		83.5	± 4.6
NYHA	**II**	**7**	**(44.0)**
	III	**9**	**(56.0)**
LVEF (%)		**57.8**	**± 7.3**
AVA (cm^2)		0.7	± 0.2
Mean Pressure Gradient (mmHg)		40	± 12
Aortic Regurgitation	Moderate	2	(12.5)
	Mild	8	(50.0)
	None/Trace	6	(37.5)
Logistic Euroscore I		**16.6**	**± 7.1**
Euroscore II		**4.4**	**± 2.9**

Characteristics (N=16)		**N (%)**	
Stable angina		8	(50.0)
Hypertension		13	(81.3)
Hyperlipidemia		12	(75.0)
Diabetes		6	(37.5)
Coronary artery disease		10	(62.5)
Congestive heart failure		3	(18.8)
Cerebrovascular disease		3	(18.8)
Previous BAV		3	(18.8)
Renal impairment	Moderate	7	(43.8)
	Severe	4	(25.0)
Chronic lung disease		2	(12.5)
Pulmonary hypertension	Moderate	5	(31.3)
	Severe	2	(12.5)

Performance Endpoints - Results

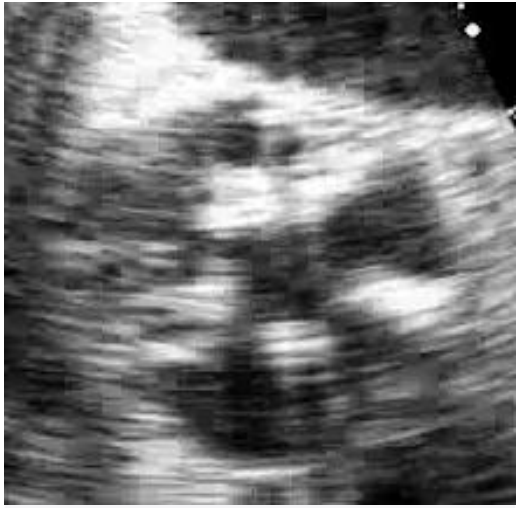


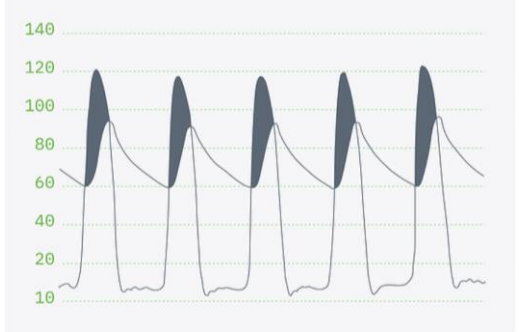




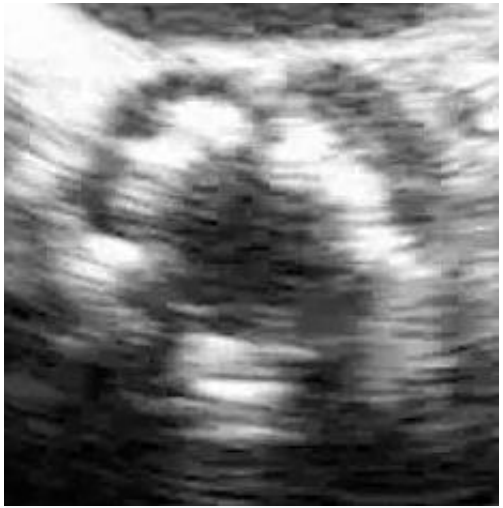
Procedure Results Example

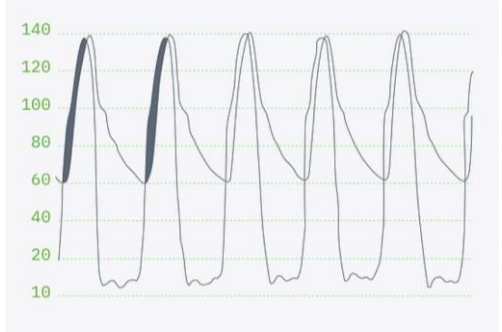
Pre Leaflex™



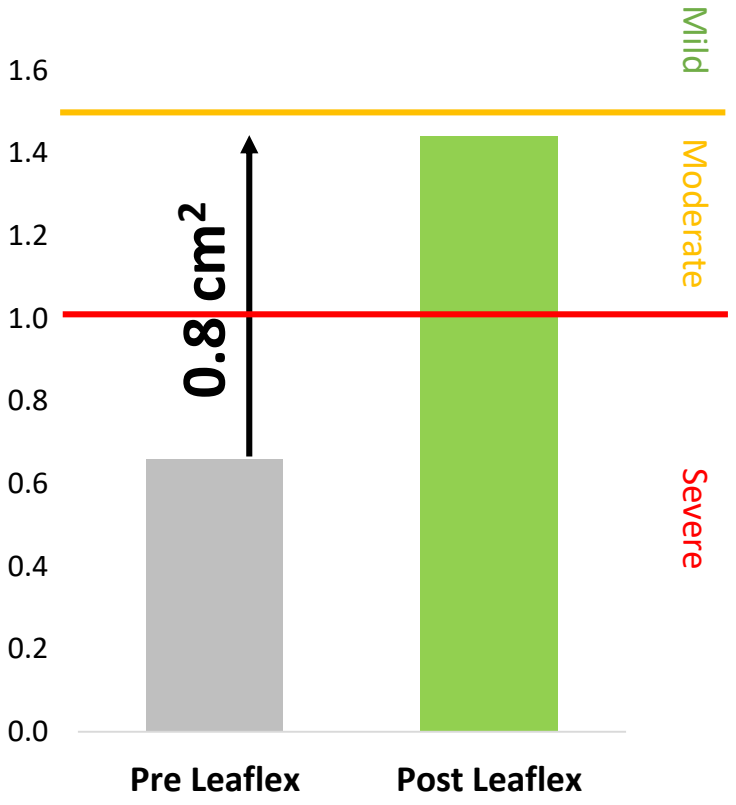


Post Leaflex™





Aortic Valve Area (cm^2)



Performance Endpoints - Results

Leaflex™ Procedure Endpoints		N (%)
Procedural success (N=16)	Device introduction	16 (100)
	Device positioning	15 (93.8) Deflection failure in 1 case
	Device scoring performed	11 (68.8) Device iteration after 4 cases fixed expansion issue
	Device withdrawal	16 (100) Sheathed by introducer sheath in 2 cases

Post TAVR Endpoints		N
Final valve implantation post scoring (N=11)	PVL > mild	2
	Post dilatation	3

Safety Endpoints - Results

Endpoint (N=16)			**N**
All-cause mortality (@ 30 days)			1 (non-cardiac, 16 days post procedure, not related)
Stroke (@ 30 days, VARC II)			2 (non embolic, result of prolonged procedure/ emergency surgery following LV perforation)
Procedural complication	Aortic regurgitation (>1 grade difference)		1
	Conduction disturbances		2
	Structural injury	Aortic rupture	0
		Aortic valve leaflet injury	0
		Annular rupture	0
		LV perforation	1
		Mitral valve injury	0

Summary

- In this early clinical evaluation, the Leaflex™ procedure showed a significant effect on aortic valve area
  - Shift from significant to moderate aortic stenosis
  - Greater than in comparable series with BAV
- The procedure is feasible
- This first series was planned in the context of TAVI and GA to provide a stable environment for hemodynamic testing and allow for necessary device iterations.

Outlook

- The Leaflex™ as a stand-alone procedure has the potential of filling a gap and expanding treatment options for patients with aortic stenosis
- Clinical studies are planned for the evaluation of acute and long-term results following treatment with the Leaflex™ Performer