

SESAME to Treat Subaortic Membrane

First in Human Experience

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Disclosure of relevant financial relationships

Within the prior 24 months, I have had a financial relationship with a company producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients:

Nature of Financial Relationship

Grant/Research Support

Consultant Fees/Honoraria

Individual Stock(s)/Stock Options

Ineligible Company

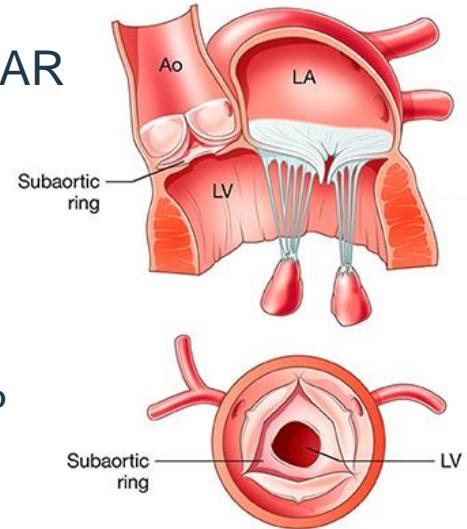
Edwards, Medtronic, Abbott

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Transmural Systems, Excision Medical

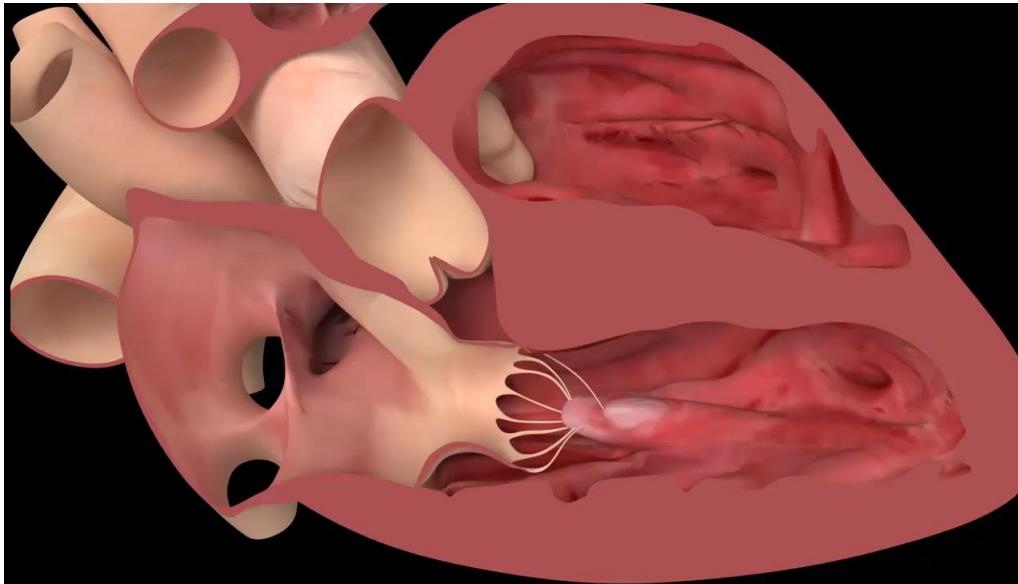
Background

- Subaortic membrane occurs in 6.5% of patients with adult CHD
 - Underappreciated in patients with HOCM
 - It can lead to progressive LVOTO, LV hypertrophy, and AR
- Recurrence rate with surgery of up to 20%
 - *Myectomy may reduce need for reoperation*
 - Progressive AR
 - AV block requiring pacemaker implantation in up to 10%
- For those of high surgical risk:
 - High rate of recurrence after balloon dilation (30%)
 - Anecdotal cases of low implantation of THVs, RF ablation, electrical laceration



SEp_al Scoring Along the Midline Endocardium (SESAME)

- Novel percutaneous myotomy that has been shown to treat LVOTO in patients with oHCM



Design

- Retrospective
- Seven patients across four tertiary cardiac centers in U.S.
- Between 2023 and 2024
- Aim: cut fibromuscular ridge and underlying septal myocardium using transcatheter electrosurgical techniques
- The depth and trajectory of the cut was planned on preprocedure computed tomography

Demographics

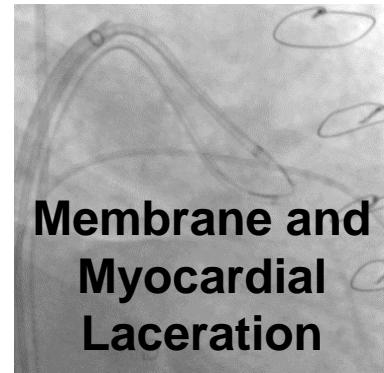
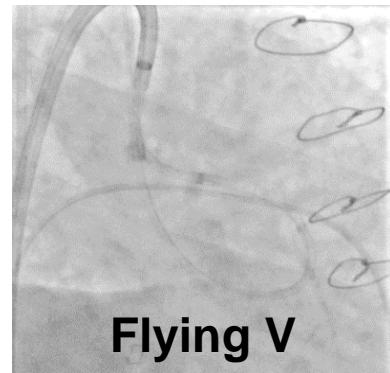
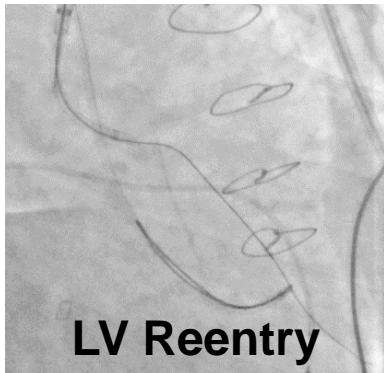
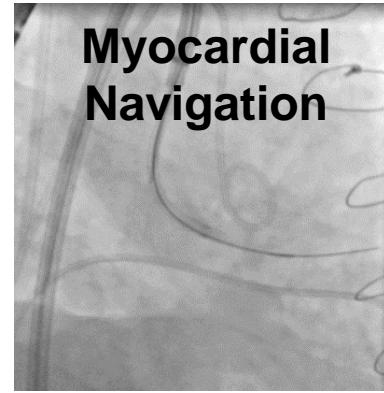
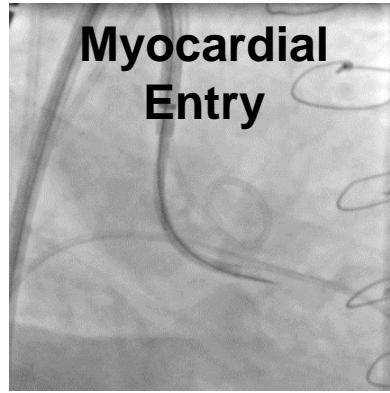
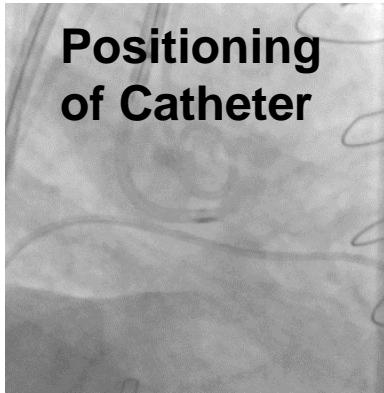
Patient	1	2	3	4	5	6	7
Age, years	29	75	77	60	64	75	82
Sex	F	F	F	F	F	F	M
Prior Surgical Membrane Resection	Y, 2010	Y, 2013	-	-	-	-	-
Prior Valve Surgery	-	Bioprosthetic Mitral Valve Replacement, 2013	-	-	Redo Mechanical Mitral Valve Replacement, Bioprosthetic Tricuspid Valve Replacement, 2021	-	-
≥ Moderate Aortic Stenosis	-	Y	Y	-	Y	-	Y
≥ Moderate Aortic Regurgitation	Y	-	-	-	Y	-	Y
≥ Moderate Mitral Stenosis	-	Y	-	-	-	-	Y
NYHA	1	3	2	3	4	3	3
Left Ventricular Ejection Fraction, %	65	65	60	75	20	70	65

NYHA: New York Heart Association

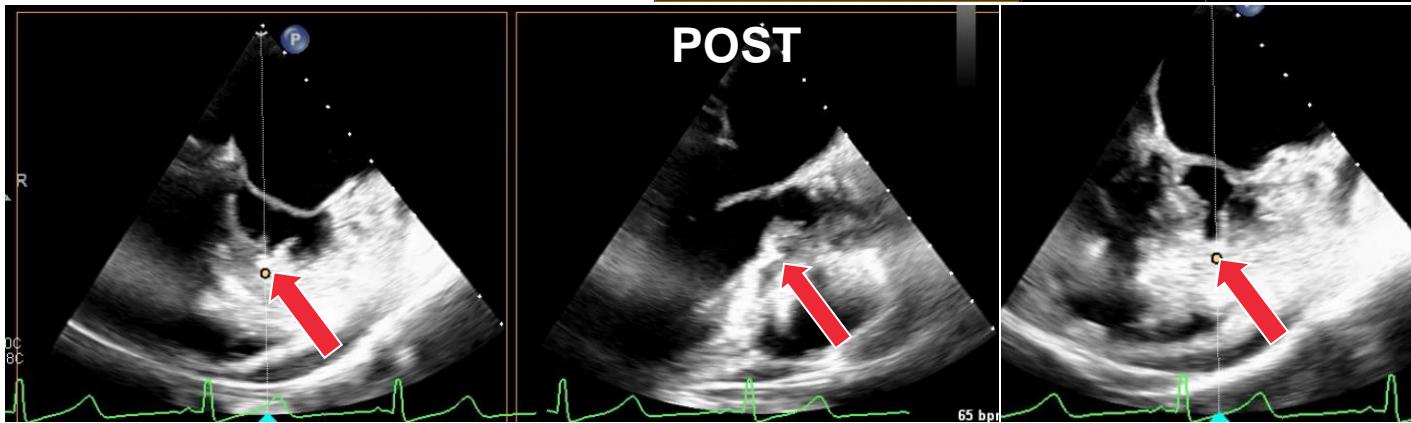
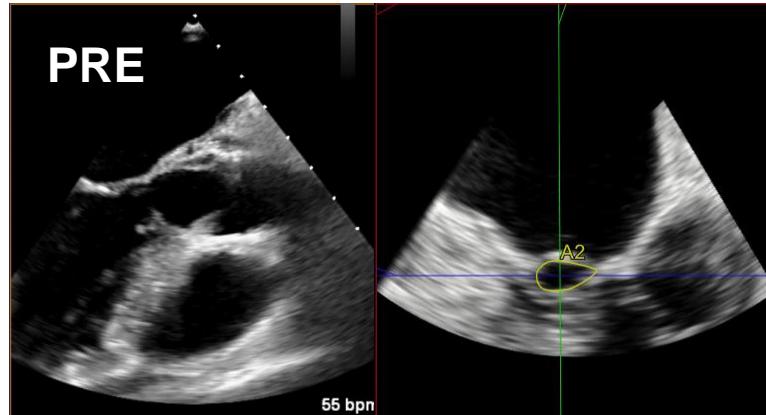
Procedure details

- Median procedure time: 141 minutes
(Range: 81 – 235 minutes)
- Median fluoroscopy dose: 2614 mGy
(Range: 1339 – 14052 mGy)
- Median fluoroscopy time: 41.3 minutes
(Range: 21.8 – 124 minutes)
 - Median contrast volume: 50 mL
(Range: 0 – 65 mL)

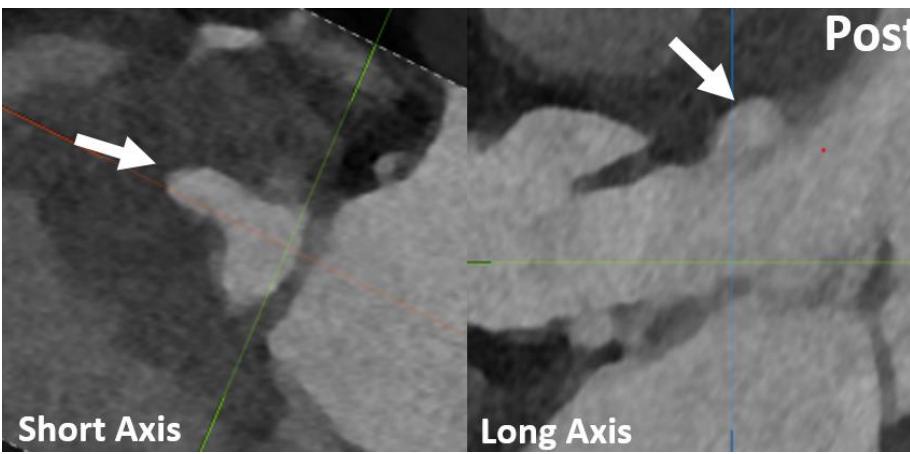
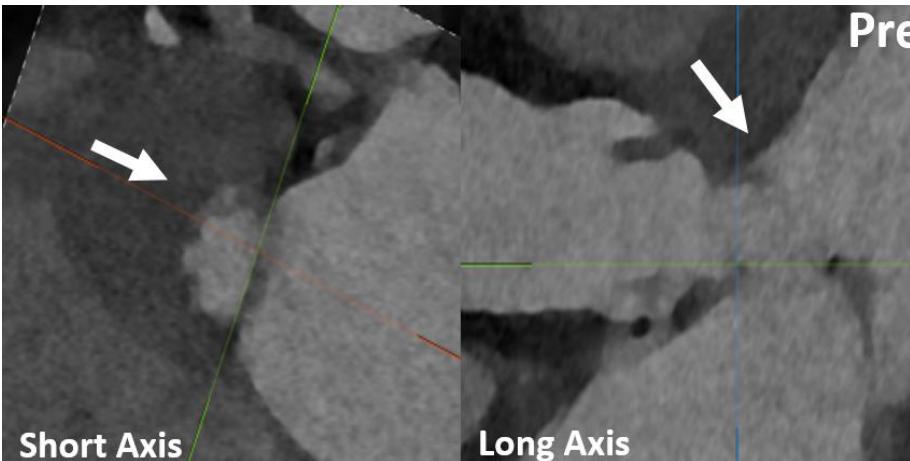
SESAME procedure on fluoroscopy



Echocardiography



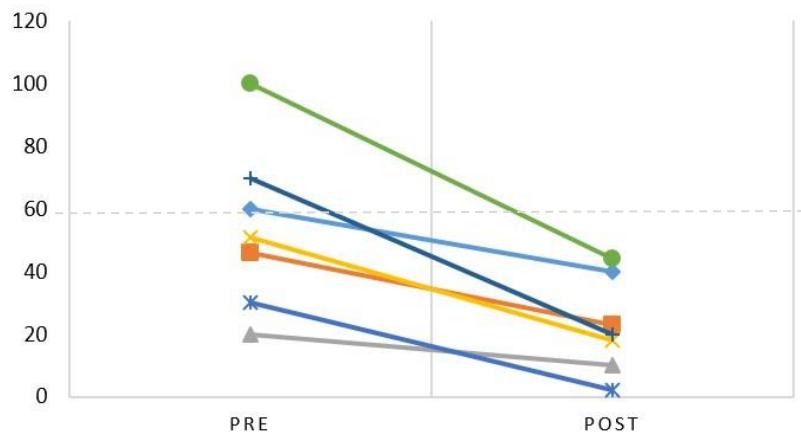
CT



Outcomes

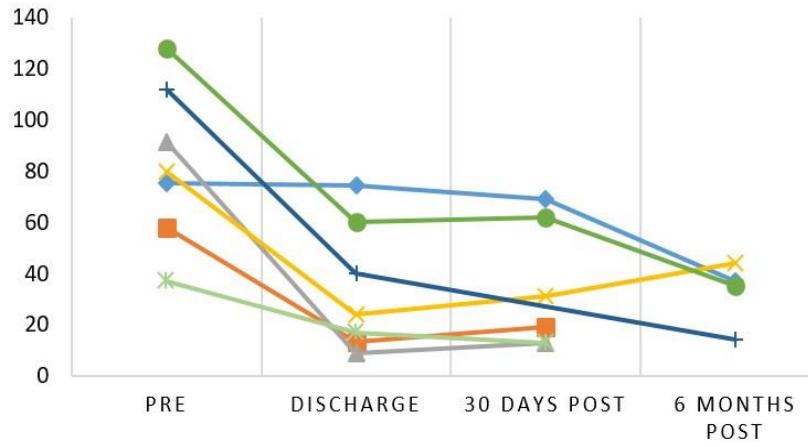
RESTING INVASIVE PEAK TO PEAK GRADIENT (mmHg)

Patient 1 Patient 2 Patient 3 Patient 4
Patient 5 Patient 6 Patient 7



LVOT PEAK GRADIENT AT REST (mmHg)

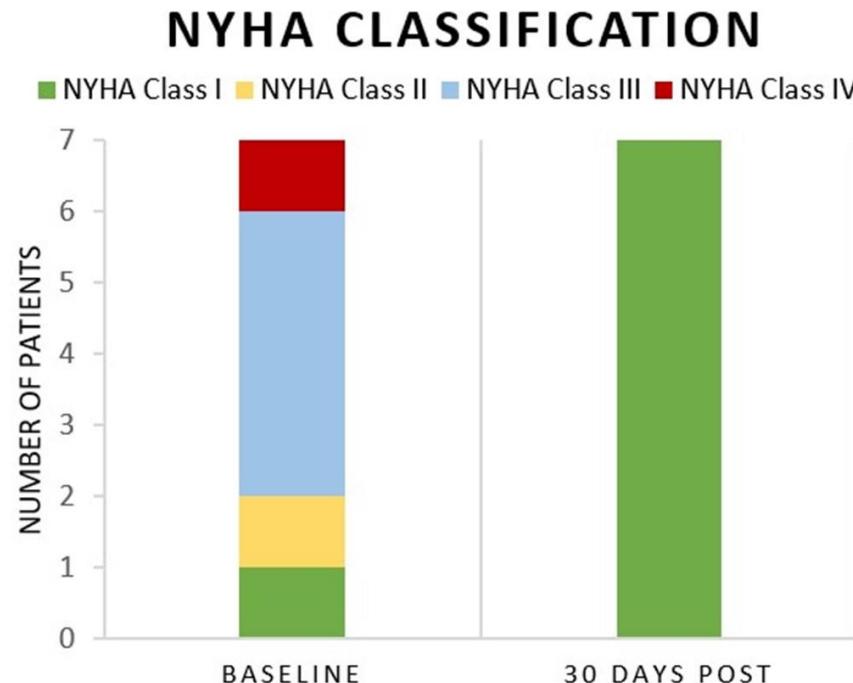
Patient 1 Patient 2 Patient 3 Patient 4
Patient 5 Patient 6 Patient 7



Safety

	<i>30 Day Safety Patient</i>
Death	0
Stroke	0
Procedure-related surgery or intervention	0
Structural complication (Aortic Valve Injury, Aortic Dissection, Mitral Valve Injury, Ventricular Septal Defect, Free Wall Rupture, Pericardial Effusion Requiring Pericardiocentesis)	0
New pacemaker implantation	0
Myocardial Infarction	0
Life-threatening Bleed	0
Major Vascular Complication	0
AKI Stage 3/4	0

NYHA classification at 30-day follow up



Key takeaways

- SESAME was safe and feasible in all seven patients treated with obstructive subaortic membrane, with LVOT gradient and symptom reduction in all
- Progressive muscle splay and remodeling may contribute to further gradient reductions after 30 days
- The procedure does not appear to preclude future surgery or redo SESAME if required

RESEARCH LETTER

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