



I prefer the 2nd generation
beating heart mitral valve
repair with E-PTFE chordae



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Harpoon Mitral Valve Repair System



21-Gauge Needle
with pre-wound ePTFE suture
in preformed knot configuration



Delivery System
with a low profile (3 mm, 9 Fr)
to deliver device to the valve

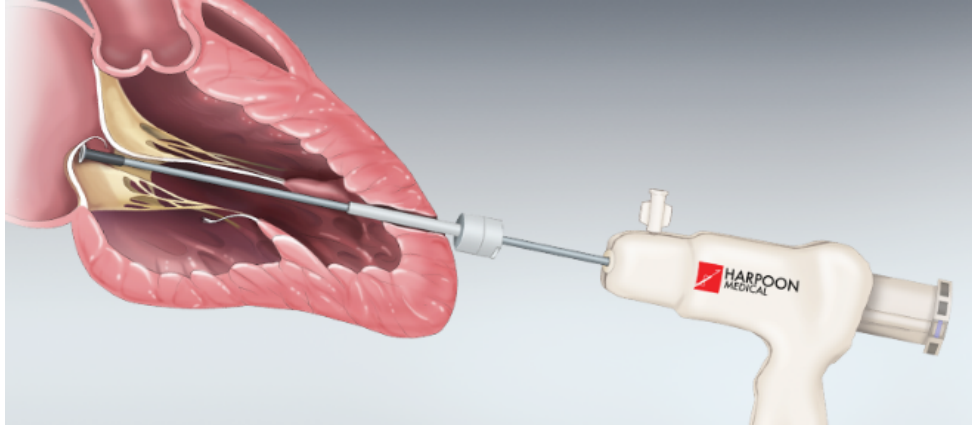


Hemostatic Introducer
to reduce blood loss and improve
tactile feedback

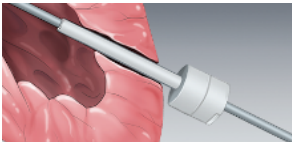
Proprietary Anchor
with an ePTFE suture as the only
element left in the heart



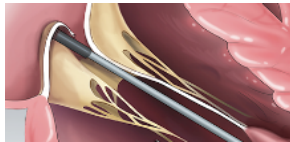
Harpoon Mitral Valve Repair System



- ✓ Simple, minimally-invasive, beating-heart, off pump repair
- ✓ Echo-guided chordal placement



Hemostatic Introducer

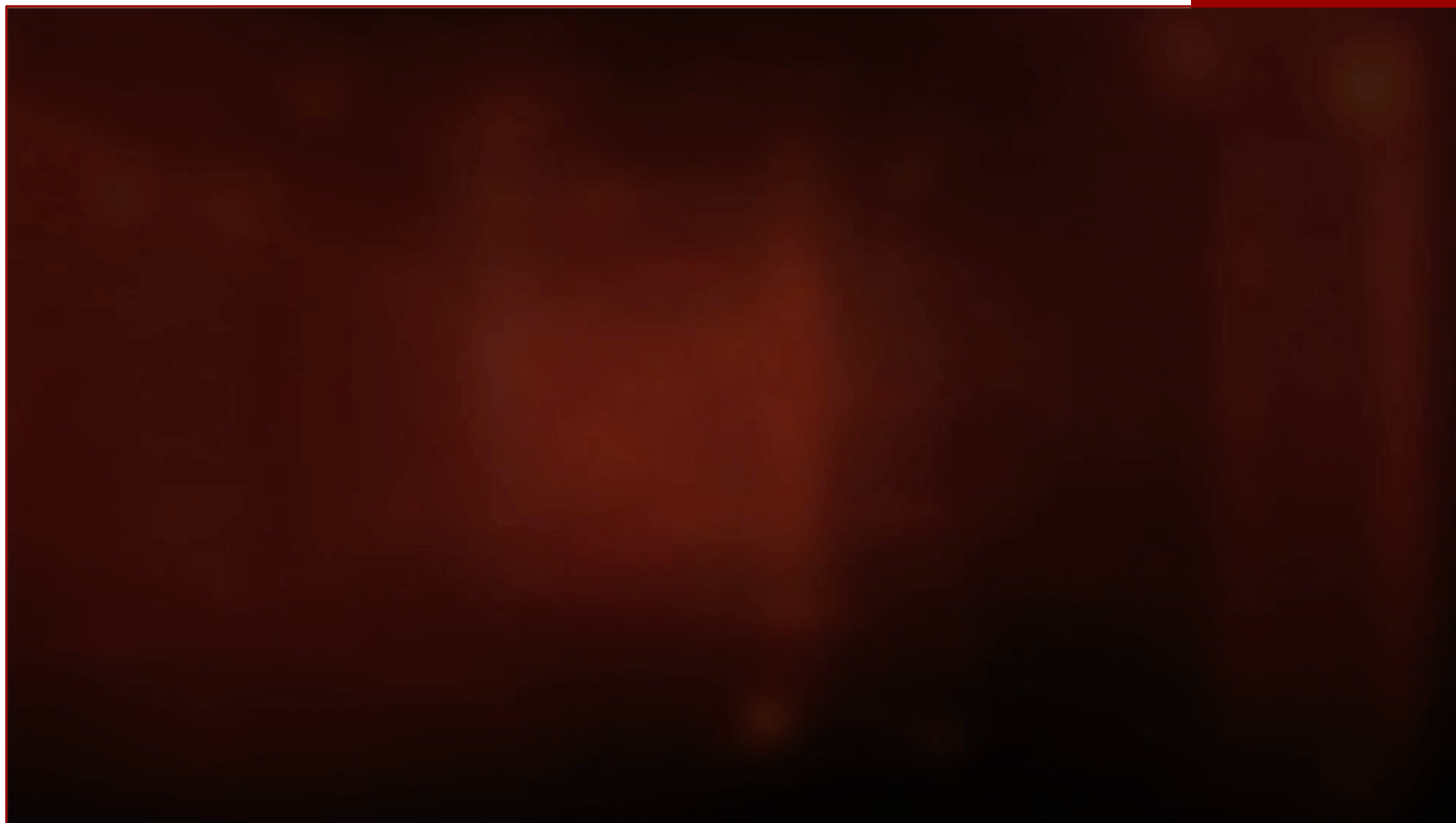


Low-Profile Delivery System
9 Fr shafted instrument



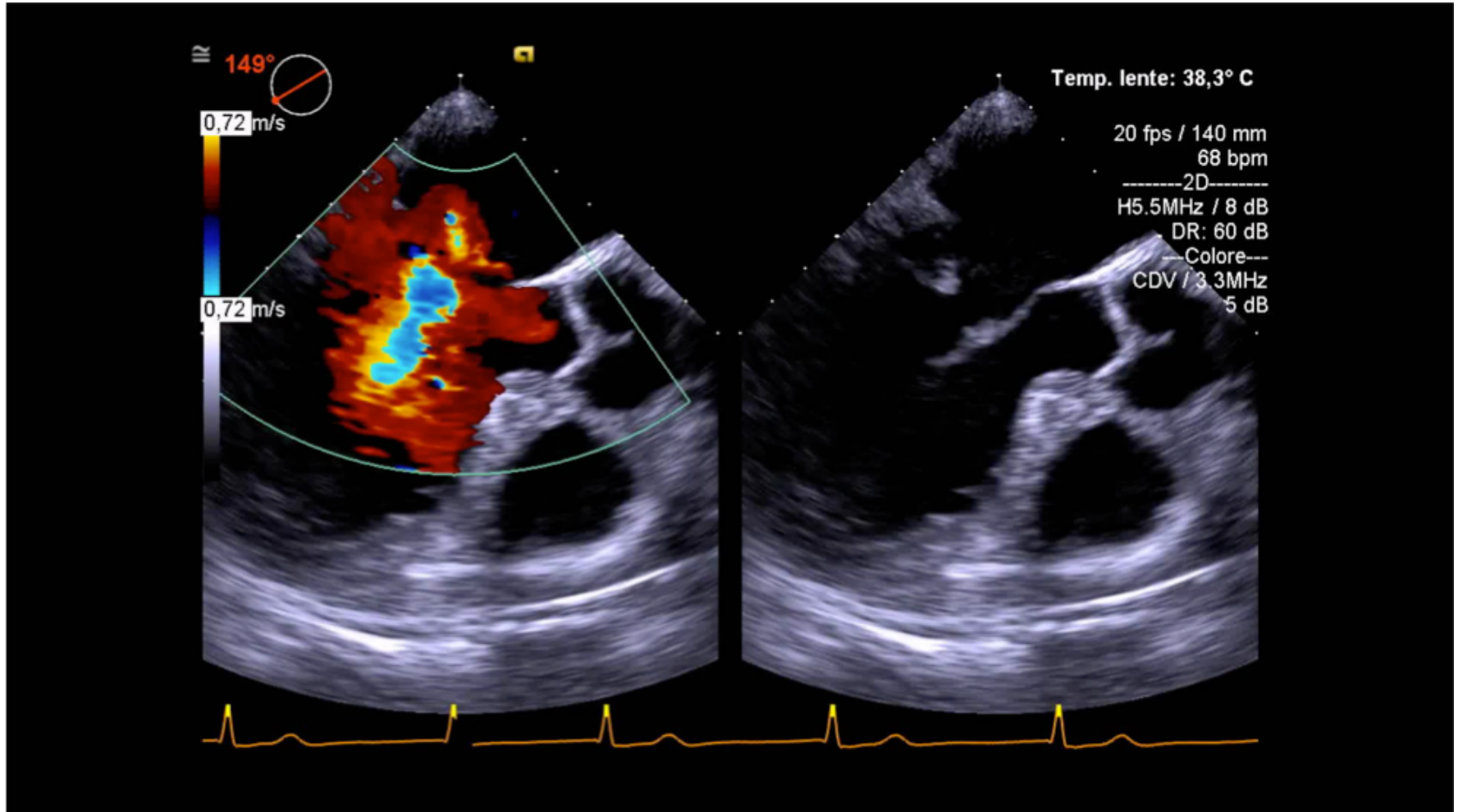
Secure Anchoring
Self-forming ePTFE knot





HARPOON Procedure Key Steps

Delivery System Positioning



Beating-Heart Mitral Valve Repair Using a Novel ePTFE Cordal Implantation Device

A Prospective Trial

James S. Gammie, MD,^a Krzysztof Bartus, MD, PhD,^b Andrzej Gackowski, MD, PhD,^b Michael N. D'Ambra, MD,^c
Piotr Szymanski, MD, PhD,^d Agata Bilewska, MD, PhD,^d Mariusz Kusmierczyk, MD, PhD,^d
Bogusław Kapelak, MD, PhD,^b Jolanta Rzucidlo-Resil, MD,^b Neil Moat, MBBS,^e Alison Duncan, MBBS, PhD,^e
Rashmi Yadev, MBBS, PhD,^e Steve Livesey, MBChB,^f Paul Diprose, MBChB,^f Gino Gerosa, MD, PhD,^g
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89 patients
screened

Isolated posterior
leaflet (Mainly P2)

30 enrolled

6 sites in 3 countries

TABLE 1 Baseline Characteristics of the Patients	
Age, yrs	61 ± 13
Males	23 (77)
BMI, kg/m ²	26.2 ± 3.7
NYHA Class, %	
I	15 (50)
II	10 (33)
III	5 (17)
IV	0 (0)
STS PROM, %	0.69 ± 0.72
EuroSCORE II, %	1.2 ± 1.3
Atrial fibrillation	9 (30)*
Hypertension	22 (73)
Diabetes mellitus	3 (10)
Glomerular filtration rate, ml/min/m ²	79.1 ± 15.5
Cardiac structure and function	
Mean LV ejection fraction, %	69 ± 7
LA diameter, cm	46 ± 7
LV end-diastolic diameter, cm	53 ± 6
LV end-systolic diameter, cm	32 ± 6
sPAP, mm Hg	42 ± 13
Isolated P2 prolapse	28 (93)
Isolated P3 prolapse	1 (3)
P2/P3 prolapse	1 (3)

Technical success rate
of (28/30), 93%

Mean n°of Chords
3.9±1

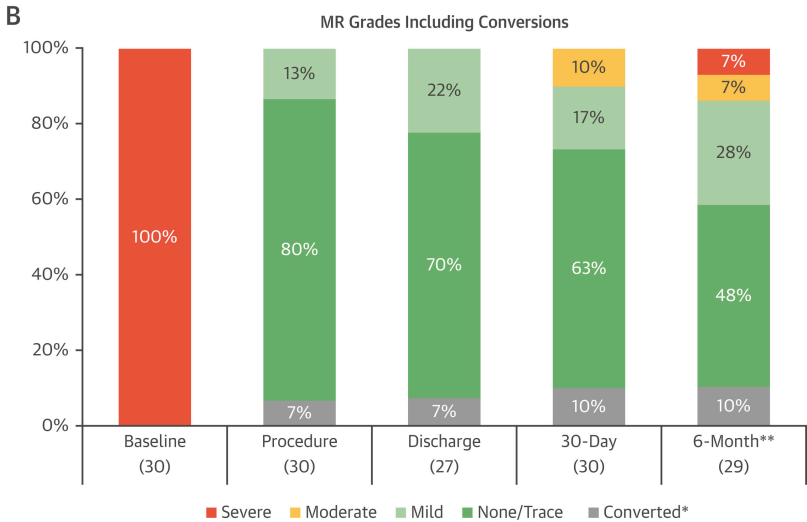
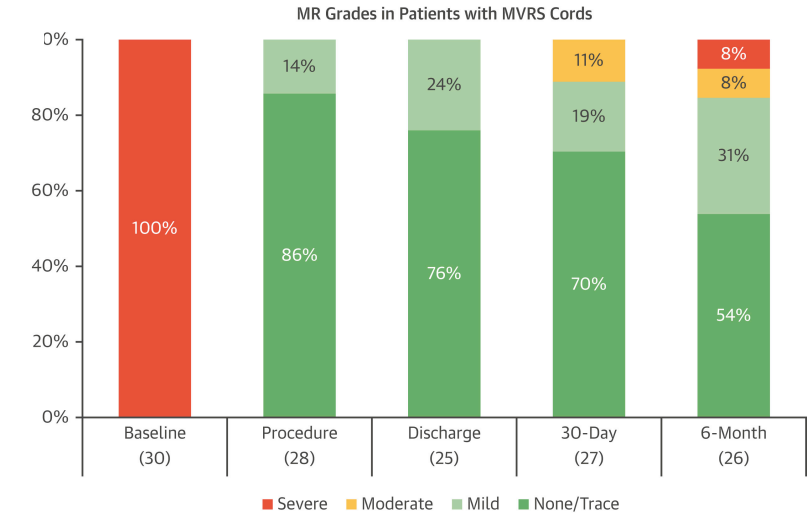
Intraoperative blood
loss 276±196 ml

Length of stay 6.7±1.6
days

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TABLE 2 Echocardiographic Results

	Screening	30 Day	6 Month	p Value
LVEDD, mm	53 ± 6	49 ± 5*	48 ± 6*	<0.001
LVESD, mm	33 ± 6	33 ± 5	32 ± 5	0.31
LA volume, ml	106 ± 36	72 ± 26*	69 ± 24*	<0.001
→ LV EDV, ml	161 ± 36	123 ± 28*	122 ± 30*	<0.001
LV ESV, ml	52 ± 20	49 ± 13	45 ± 14	<0.001
LVEF, %	69 ± 7	61 ± 6*	66 ± 7	<0.001
→ MV annular diameter, mm	34.7 ± 5.8	31.2 ± 4.0	28.2 ± 5.1*	<0.001
→ Mitral annular area, cm ²	10.0 ± 2.7	8.4 ± 2.0†	6.9 ± 2.0*	<0.001
Mean MV gradient, mm Hg	NA	1.3 ± 0.5	1.5 ± 0.6	0.30

Values are mean ± SD. *p < 0.001 vs. baseline. †p < 0.05 compared to baseline.

LA = left atrial; LV EDV = left ventricular end-diastolic volume; LV ESV = left ventricular end-systolic volume; LVEDD = left ventricular end-diastolic dimension; LVESD = left ventricular end-systolic dimension; MV=mitral valve.



Potential benefits over 1^o generation
device

Single entry in the LV-No «In & Out»



Reduced blood loss



Anesthetic Management and Procedural Outcomes of Patients Undergoing Off-Pump Transapical Implantation of Artificial Chordae to Correct Mitral Regurgitation: Case Series of 76 Patients

www.anesthesia-analgesia.org

March 2018 • Volume 126 • Number 3

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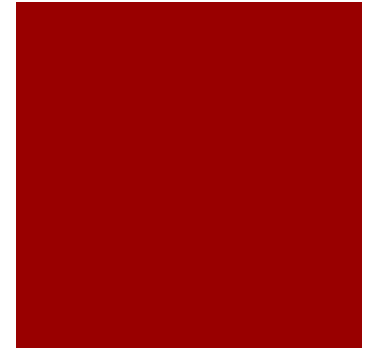
Table 3. Perioperative Data (n = 76)

Intraoperative variables	
Duration of surgery (min), median (IQR)	120 (115–145)
Intraoperative fluid balance (mL), median (IQR)	1510 (1050–2005)
Blood loss during surgery (mL), median (IQR)	500 (350–700)
Patients with intraoperative blood loss >1000 mL, n (%)	10 (13)
Retransfusion of washed erythrocytes (mL), median (IQR)	250 (180–395)
Retransfusion of washed erythrocytes, n (%)	46 (61)
Intraoperative blood loss in patients who had retransfusion (mL), median (IQR)	600 (440–930)
Intraoperative blood loss, in no retransfused patients (mL), median (IQR)	400 (250–500)

Smaller entry site (9 Fr.)



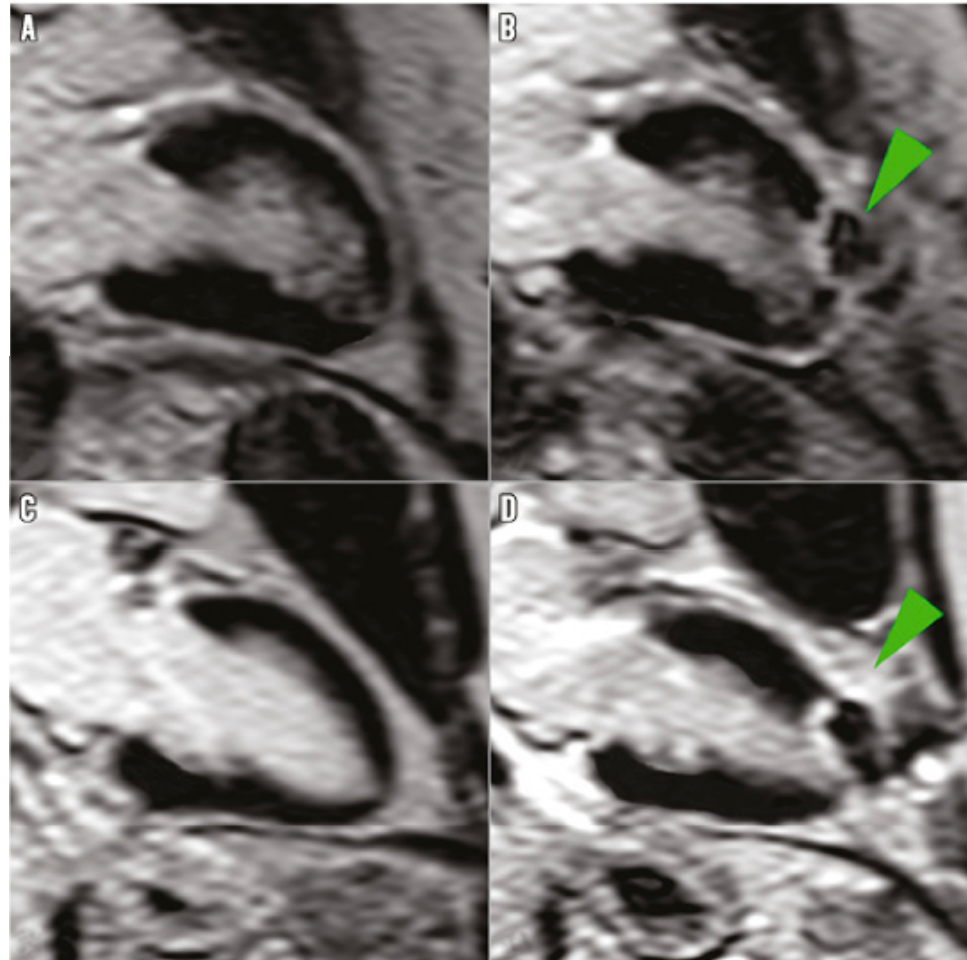
Reduced LV scar



Myocardial injury following transcatheter aortic valve implantation: insights from delayed-enhancement cardiovascular magnetic resonance

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Conclusions

- Harpoon enables echo-guided beating heart anchoring of e-PTFE artificial chords
- It is a truly micro-invasive procedure (9 Fr. Delivery system, beating heart, off-pump, advanced imaging)
- Procedural traumatism and bleeding are limited
- It allows for real time confirmation of the intra-operative results
- It does not preclude future reinterventions



WHEN I WAS A PUP



**I HAD ONE TOY AND
IT WAS A STICK**

