

Sutureless Aortic Valve Perceval



Catania experience

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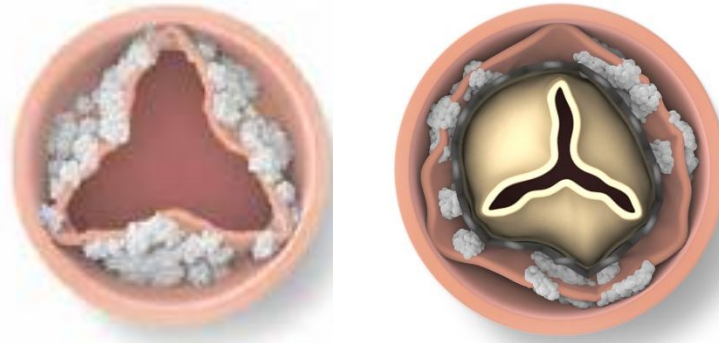
CURRENT GUIDELINES

2014 AHA/ACC Guideline for the Management of Patients With Valvular Heart Disease: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines

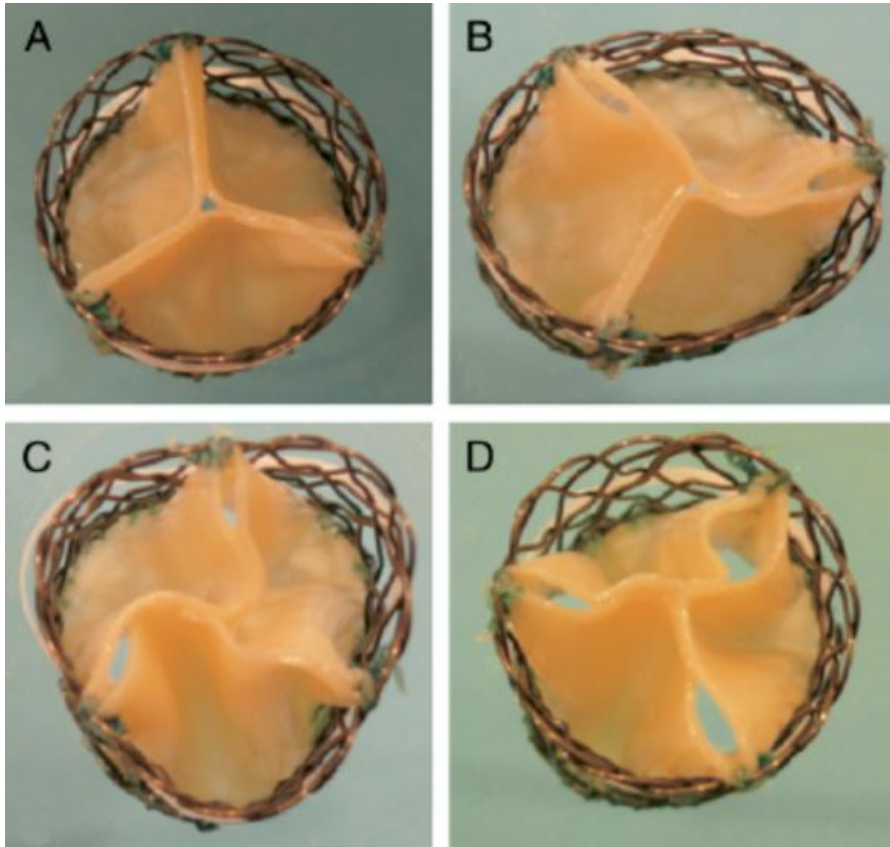
Rick A. Nishimura, Catherine M. Otto, Robert O. Bonow, Blase A. Carabello, John P. Erwin III, Robert A. Guyton, Patrick T. O'Gara, Carlos E. Ruiz, Nikolaos J. Skubas, Paul Sorajja, Thoralf M. Sundt III and James D. Thomas

| | | |
|---|-----------------|---|
| Surgical AVR is recommended in patients who meet an indication for AVR (Section 3.2.3) with low or intermediate surgical risk | I | A |
| For patients in whom TAVR or high-risk surgical AVR is being considered, members of a Heart Valve Team should collaborate to provide optimal patient care | I | C |
| TAVR is recommended in patients who meet an indication for AVR for AS who have a prohibitive surgical risk and a predicted post-TAVR survival >12 mo | I | B |
| TAVR is a reasonable alternative to surgical AVR in patients who meet an indication for AVR (Section 3.2.3) and who have high surgical risk (Section 2.5) | IIa | B |
| Percutaneous aortic balloon dilation may be considered as a bridge to surgical or transcatheter AVR in severely symptomatic patients with severe AS | IIb | C |
| TAVR is not recommended in patients in whom existing comorbidities would preclude the expected benefit from correction of AS | III: No Benefit | B |

THE DRAWBACK OF TAVI



THE DRAWBACK OF TAVI



Zegdi et al showed that the implantation of a **percutaneous bioprosthesis within a "left-in-place" severely calcified valve** might lead to incomplete or irregular expansion of the prosthetic valve.

JACC 2008;51:579-84.

2012 - THE GREYSCALE OF AORTIC VALVE STENOSIS

Conventional AVR

TAVI

<75y

75-80y

>80y

Sutureless aortic valves

Mignosa C. presented at Valve Summit 2012

2014 – CE APPROVAL

Conventional AVR

TAVI

<75y

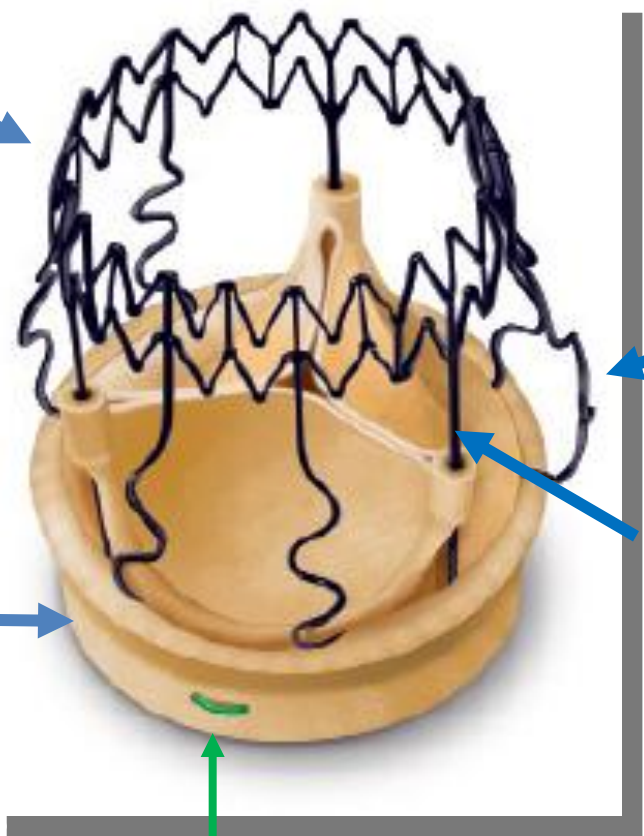
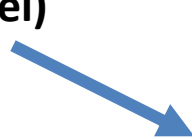
75-80y

>80y

Perceval

PERCEVAL: ESSENTIAL ELEMENTS

OUTFLOW RING
(@ STJ level)



Sinusoidal struts
(Valsalva sinuses)

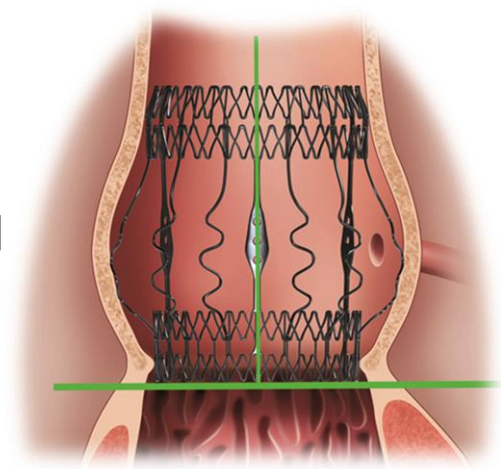


Straight commissural struts

INFLOW RING
(@ Annulus level)



3 Eylets for guiding sutures

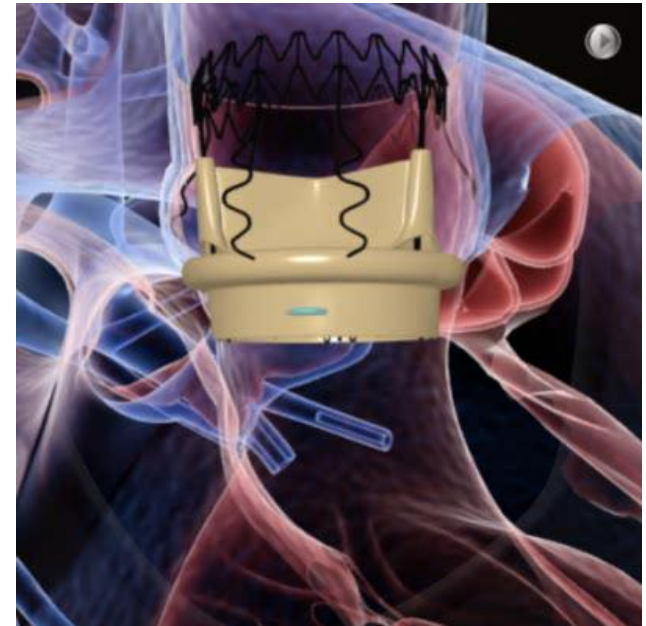


PERCEVAL: KEY FEATURES

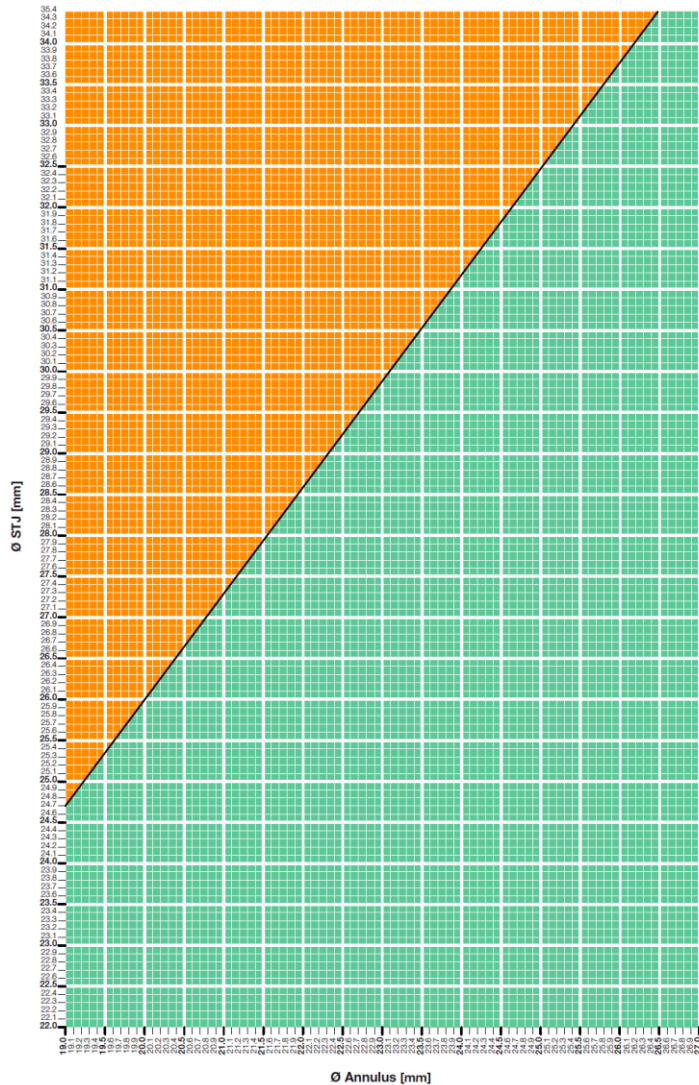
Heritage of a proven bovine pericardium valve

Excellent aortic fit

- ▶ Unique self anchoring system
- ▶ Exclusive double ring design and structural shape
- ▶ Tapered outflow ring design

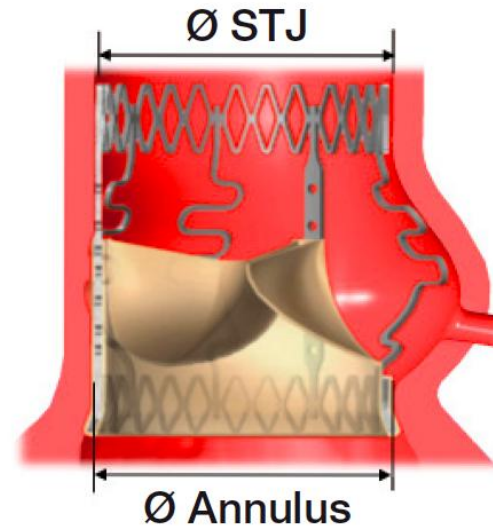


KEY ANATOMICAL MEASUREMENTS



Patient Exclusion Area

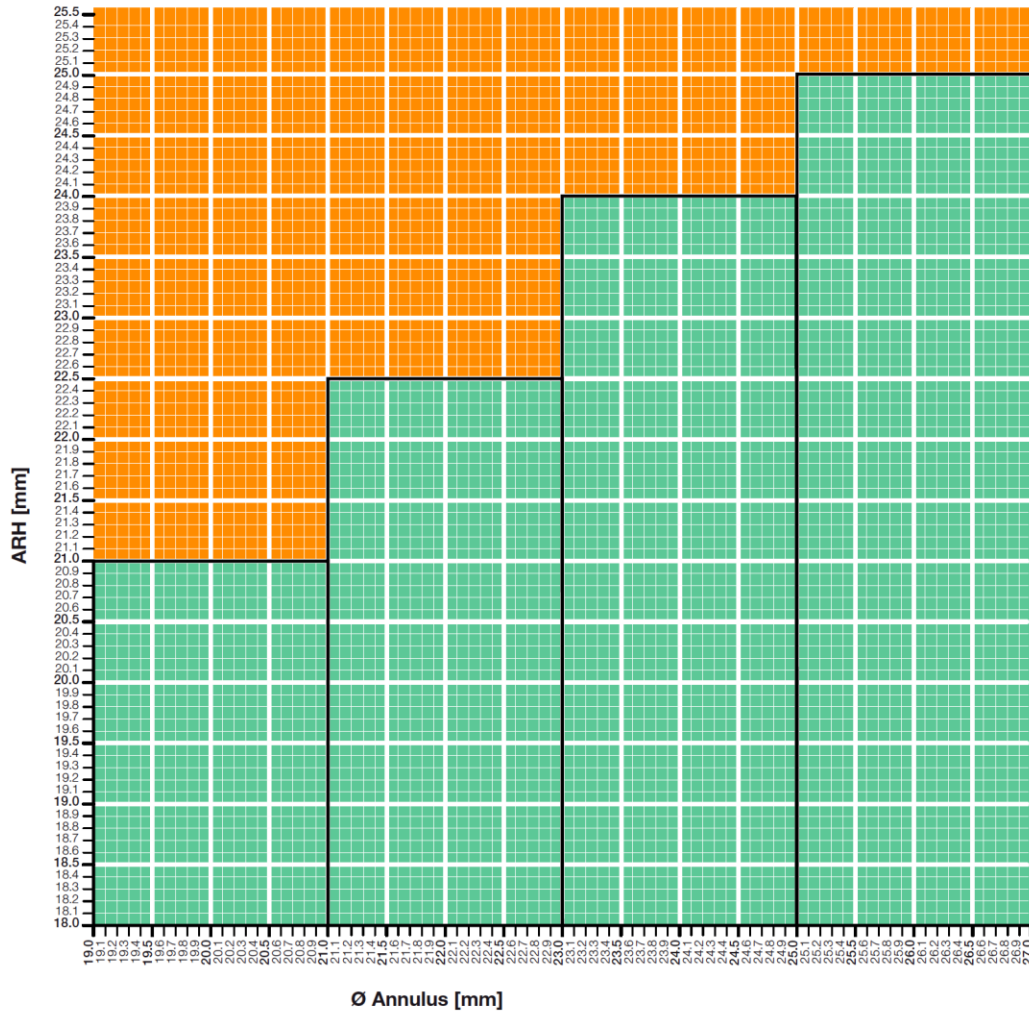
Patient Inclusion Area



The patient is Suitable if

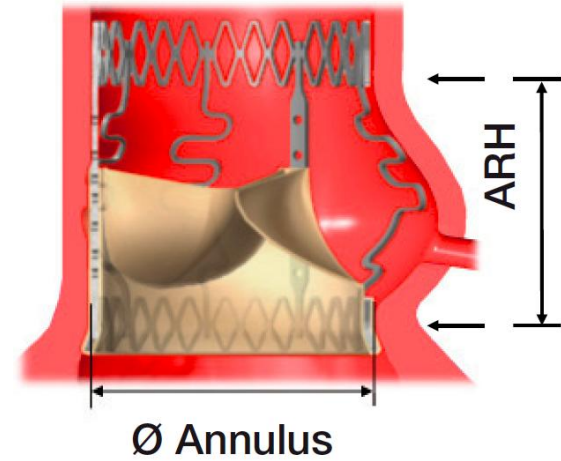
$$\frac{\text{Ø STJ}}{\text{Ø Annulus}} \leq 1.3$$

KEY ANATOMICAL MEASUREMENTS



Patient Exclusion Area

Patient Inclusion Area



Patient is Suitable if

- size S/21: $19 < \text{Ø} < 21$ mm and $\text{ARH} < 21$ mm
- size M/23: $21 \leq \text{Ø} < 23$ mm and $\text{ARH} < 22.5$ mm
- size L/25: $23 \leq \text{Ø} < 25$ mm and $\text{ARH} < 24$ mm
- size XL/27: $25 < \text{Ø} < 27$ mm and $\text{ARH} < 25$ mm

OPTIMAL CANDIDATES FOR SUTURELESS AVR

Biological Valve Patient candidates

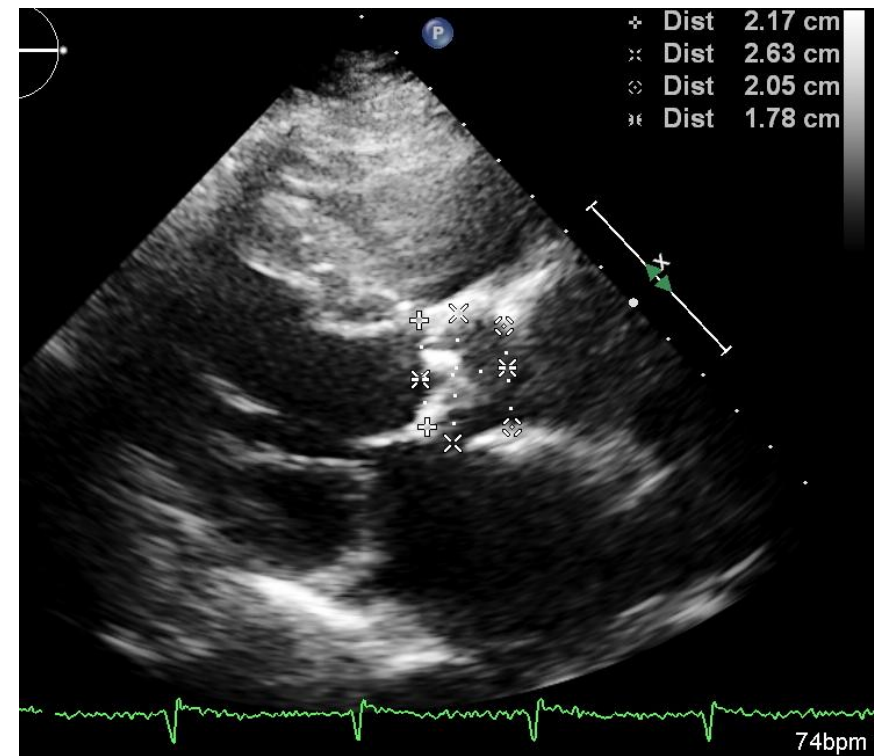
ideal for:

- ▶ Patients requiring CABG and/or multiple procedures
- ▶ Minimally Invasive approaches
- ▶ Medium-high risk patients
- ▶ Patients with small annuli and/or calcified annuli
- ▶ Calcified aortic root/sinotubular junction
- ▶ Redo
- ▶ Rescue tool for TAVI

PERCEVAL: TTE/TEE ASSESMENT

Preop / Intraop

- ▶ LVOT
- ▶ Aortic root (Annulus, Sinuses, STJ, ARH)
- ▶ AV morphology
- ▶ AVA and gradients



ANATOMICAL IMPLICATIONS FOR AV IMAGING

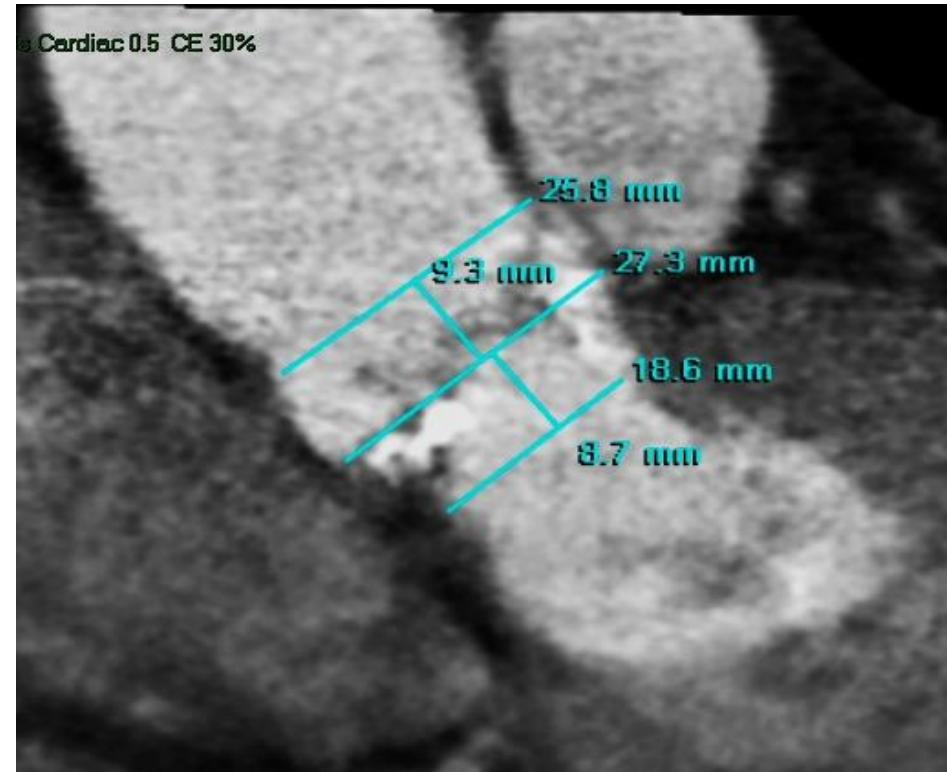
The aortic annulus is clearly a complex structure and requires imaging that can take into account its elliptical and irregular shape

Single diameter methods can provide misleading results

PERCEVAL: MULTISLICE CT SCAN ASSESSMENT

Preop

- ▶ Area, perimeter, diameters
- ▶ High spatial resolution
- ▶ Calcification assessment



PERCEVAL: IMPLANT TECHNIQUE

- ▶ Full sternotomy – MIS
- ▶ Transverse aortotomy, 1.5 cm above the STJ
- ▶ The aortic valve is removed and the annulus decalcified, to achieve a circular geometry
- ▶ Sizing (*yellow fits – white doesn't*)
- ▶ Collapsing of the Perceval S sutureless prosthesis

PERCEVAL: IMPLANT TECHNIQUE

- ▶ Three 4/0 polipropilene guiding sutures are passed through the nadirs of the aortic annulus and through the three eyelets at the inflow ring of the prosthesis
- ▶ The valve is released and the holder is gently removed
- ▶ Ballooning at 4 atm and rinsing with hot saline for 30 s
- ▶ Assessment of a correct placement: see the anterior leaflet of the MV and do not see the aortic annulus

PERCEVAL: IMPLANT TECHNIQUE



Cardiac Surgery Unit, A.O.U. "Policlinico-
Vittorio Emanuele"
University of Catania, Catania, Italy

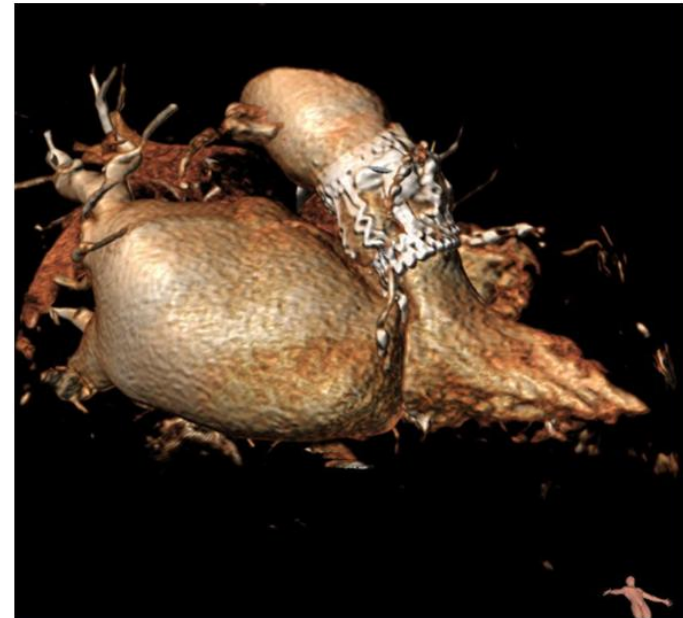
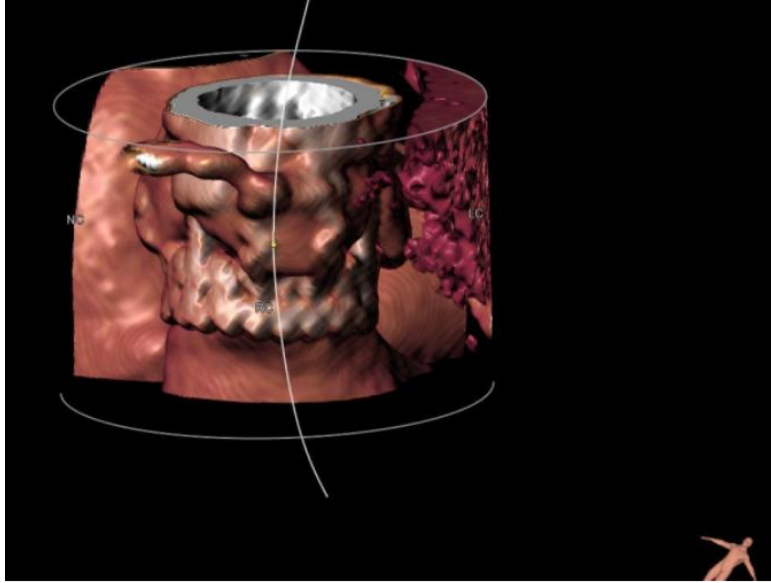


Implantation technique of aortic sutureless valve *PERCEVALS* in ministernotomy

Carmelo Mignosa, MD, FECTS



PERCEVAL: IMPLANT TECHNIQUE



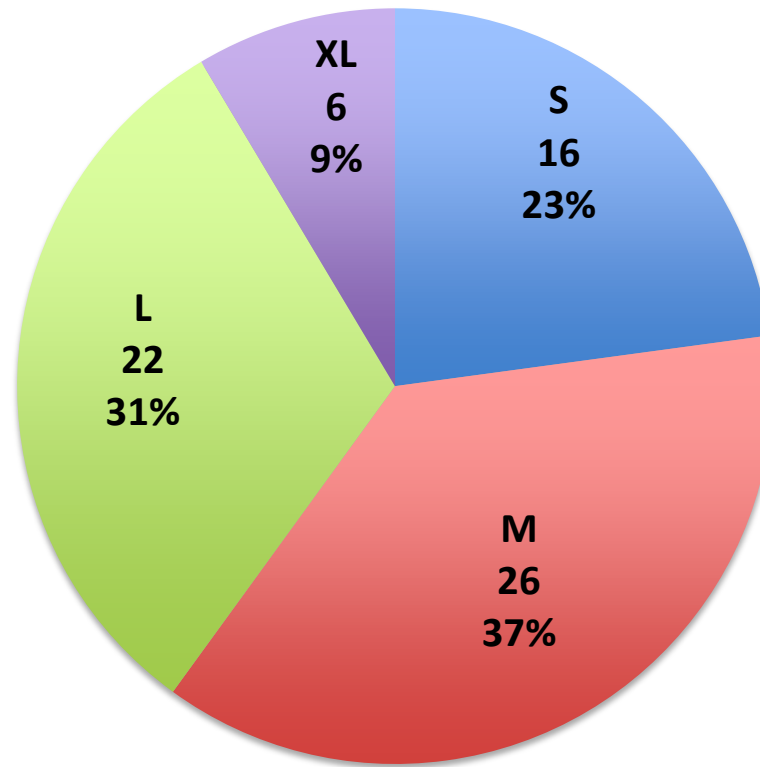
OUR EXPERIENCE AT FERRAROTTO HOSPITAL

April 2011 – April 2014

70 patients

| Variables | n=70 |
|---------------------|-----------------------------------|
| Age | 75.3 ± 4.9 yrs (58-92 yrs) |
| Female | 48 (68.6%) |
| NYHA(3/4) | 50 (71.4%) |
| IDDM | 22 (31.4%) |
| COPD | 17 (24.3%) |
| Redo | 3 (4.3%) |
| EuroSCORE II | 7.6 ± 8.2% (1.1%-45.1%) |
| EF | 56 ± 8.6% (31%-76%) |
| Annulus | 21.4 ± 1.8 mm (17-26 mm) |

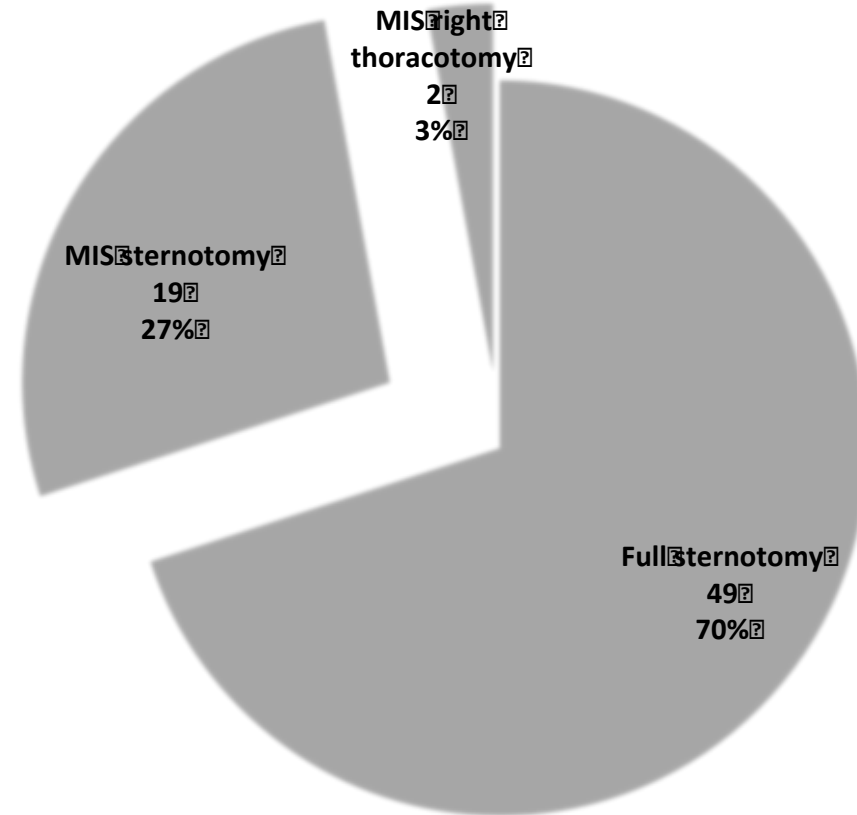
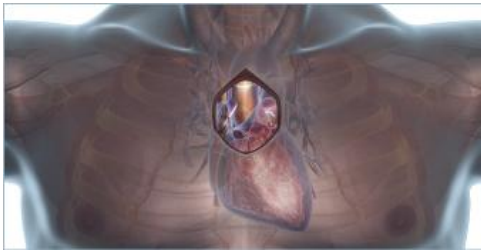
FERRAROTTO HOSPITAL: SURGERY



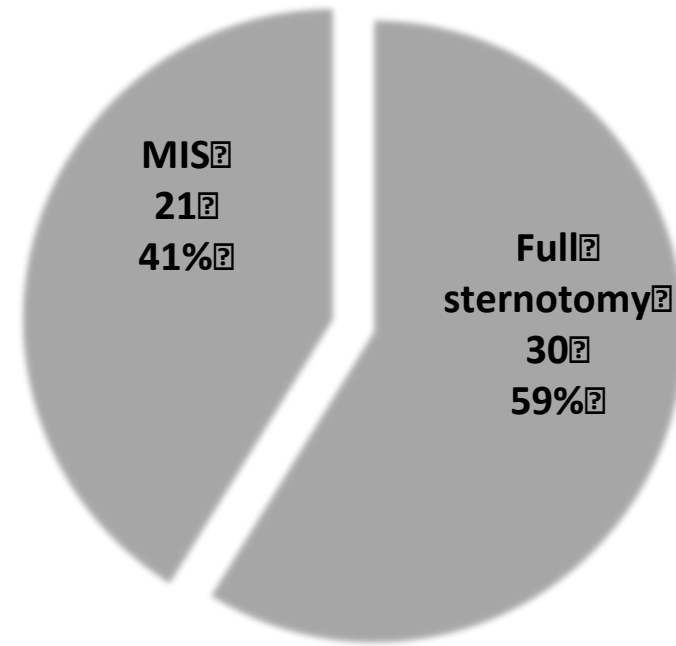
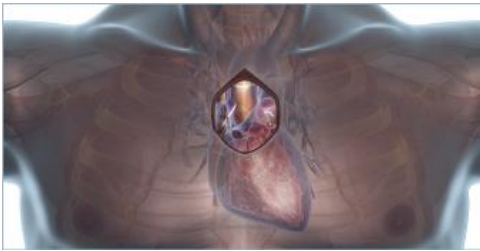
FERRAROTTO HOSPITAL: SURGERY

- ▶ **21 (30.0%) combined procedures**
 - ▶ 19 (28.8%) CABG
 - ▶ 2 (3.0%) MV Repair
 - ▶ 1 (1.5%) TV repair
 - ▶ 1 (1.5%) AF ablation
- ▶ **23 (32.9%) LVOT septal myectomy**
- ▶ **CPB 70.9 ± 31.1 min (isolated AVR 52.3 ± 13.7 min)**
- ▶ **XCT 45.1 ± 18.2 min (isolated AVR 27.3 ± 6.8 min)**

Surgical approach – overall series



Surgical approach – isolated AVR



FERRAROTTO HOSPITAL: DISCHARGE

| Variables | n=70 |
|--------------------------|------------------------|
| Peak gradient | 22.2 ± 8.2 mmHg |
| Mean gradient | 11.8 ± 4.6 mmHg |
| Paravalvular leak | 1 (1.4%) |
| Central leak | 0% |
| PMK | 3 (4.3%) |

OUR IMPRESSION WITH PERCEVAL

- ▶ **Traditional AVR is still the gold standard for the treatment of aortic valve stenosis**
- ▶ **Perceval S represented a powerful breakthrough in case of high-risk patients**

OUR IMPRESSION WITH PERCEVAL

PERCEVAL

- ▶ It is **easy, safe** and **reproducible** to implant
- ▶ Minimizes Aortic Cross Clamping Time
- ▶ Provides excellent hemodynamic
- ▶ Delivers excellent clinical outcome

OUR IMPRESSION WITH PERCEVAL

- ▶ In general, Perceval is the ideal device for:
 - concomitant procedures
 - high risk patients
 - minimally invasive techniques
 - calcified aortic root / sinotubular junction
 - rescue tool for TAVI

Our Impression With Perceval

► In a word:



Versatility