



**Aortic Valve Neo-Cuspidization**

# Who is Professor Ozaki?



## Dr. Shigeyuki Ozaki

Professor and Chairman, Department of  
Cardiovascular Surgery  
Toho University Ohashi Medical Center  
Meguro-ku, Tokyo, Japan  
2008 – To date

While in Belgium studying for his PhD, he tested prosthetic valves on several sheep. All calcified within 6 months. This motivated him create a procedure that would decrease calcification.

**2011** - Performed the first Aortic Valve Reconstruction using pericardium

**2012** - Our CEO, Takahiro Uchida, discussed with Dr. Ozaki on its commercialization

**April 2014** -The OzakiVRecS (reusable version) launched in Japan and the US.

**January 2017** - Ozaki AVNeo (single use version) launched in US.

# What is JOMDD?

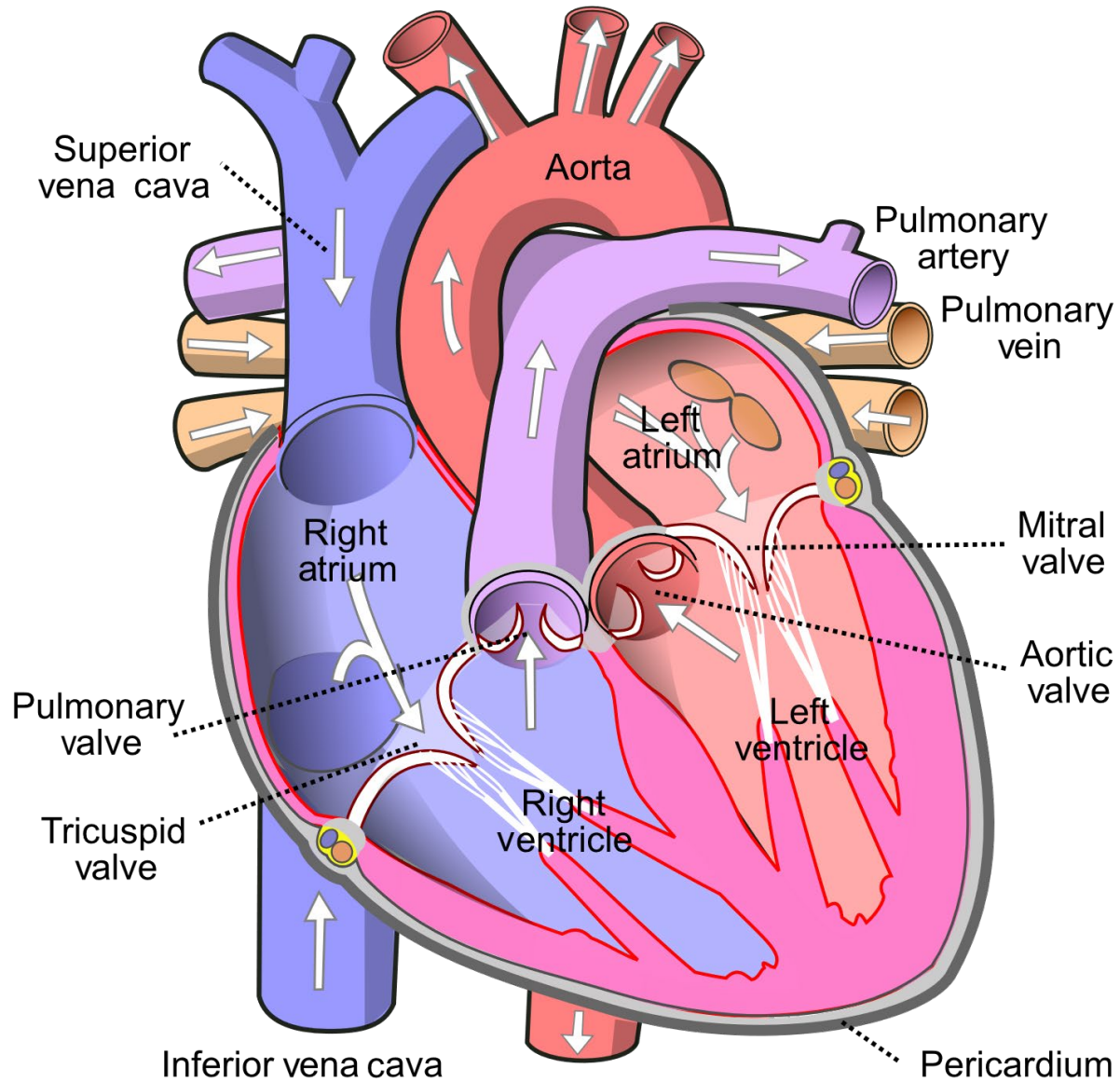
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*Japanese Organization for Medical Device Development, Inc.*

- A medical device incubator and innovator
- Founded in 2012
- Based in Tokyo, Japan

# Normal Cardiac Anatomy



## Aortic Stenosis

- Narrowing of the valve
- Causes
  - Calcification
  - Rheumatic Fever
  - Bicuspid valve

## Aortic Insufficiency

- Aortic regurgitation or “leaky valve”
- Causes
  - 80% Idiopathic in nature
  - Aortic root dilation
  - Connective tissue disorders
    - Marfan Syndrome
    - Ehlers-Danlos Syndrome

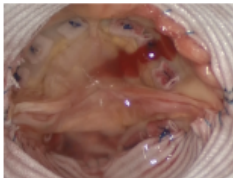
# Treatment Options for Aortic Valve Disease

**Stenosis**

**Insufficiency**



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*Aortic Valve Neo-Cuspidization is a surgical technique that uses autologous pericardium to treat aortic valve disease*

- Primary Features

- Standardized and reproducible
- No anticoagulation
- Less calcification
- Cost efficient
- PPM, nearly zero

- Suitable For

- Narrow aorta
- Hemodialysis ([Kawase et al., 2013](#))
- All ages
- Connective tissue disease
- Tricuspid, Bicuspid, or Unicuspid

# Isn't Conventional AVR Satisfactory?

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“The aortic valve surgery should preserve the cooperation with ascending aorta, sinus of Valsalva, and left ventricle.”

- Prof. Ozaki



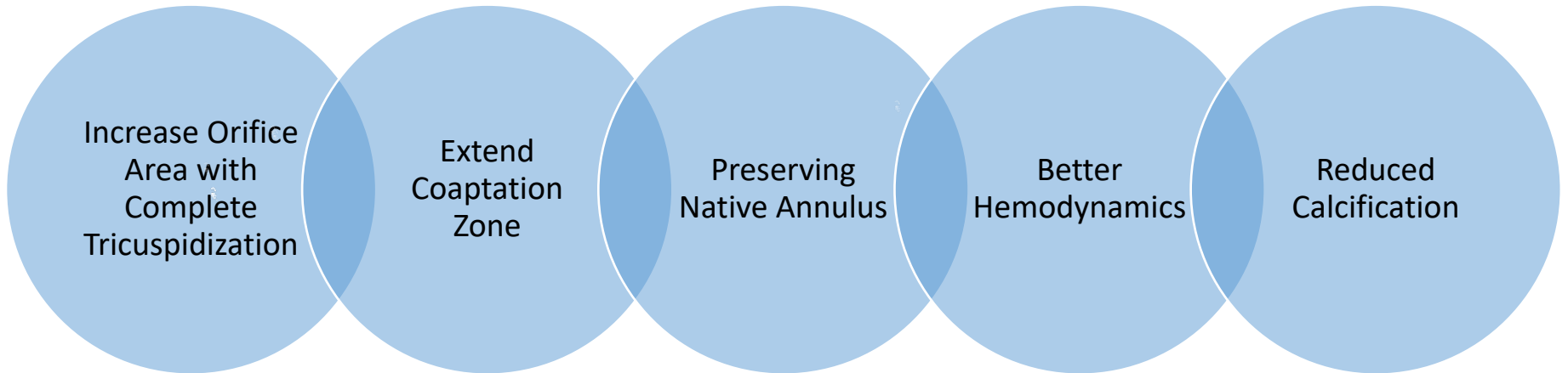


# What makes AVNeo™ Different?

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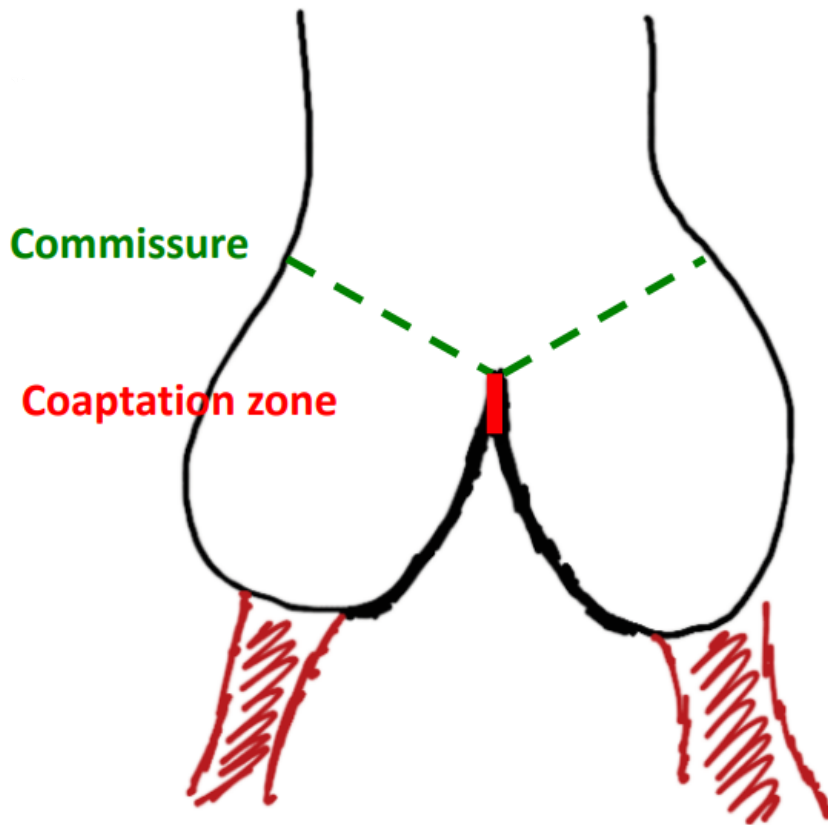


*AVNeo™ allows for the ability to retain the native aortic annulus and its functionality ([Yoshitaka et al., 2016](#))*

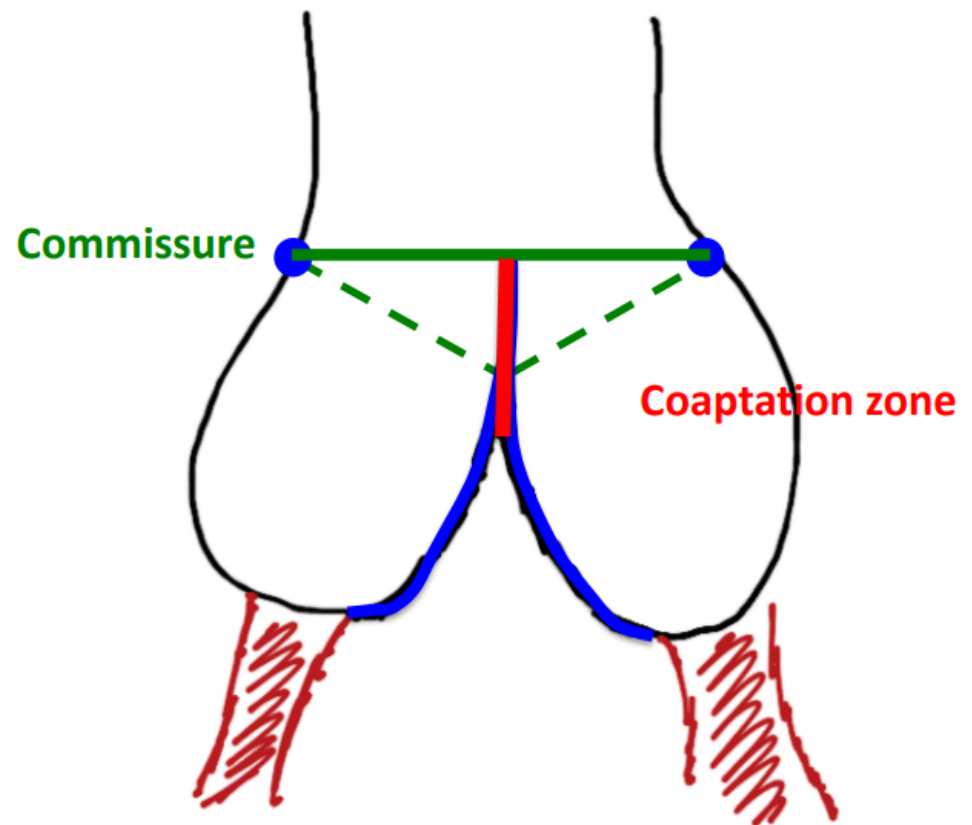


# Increased Coaptation Zone

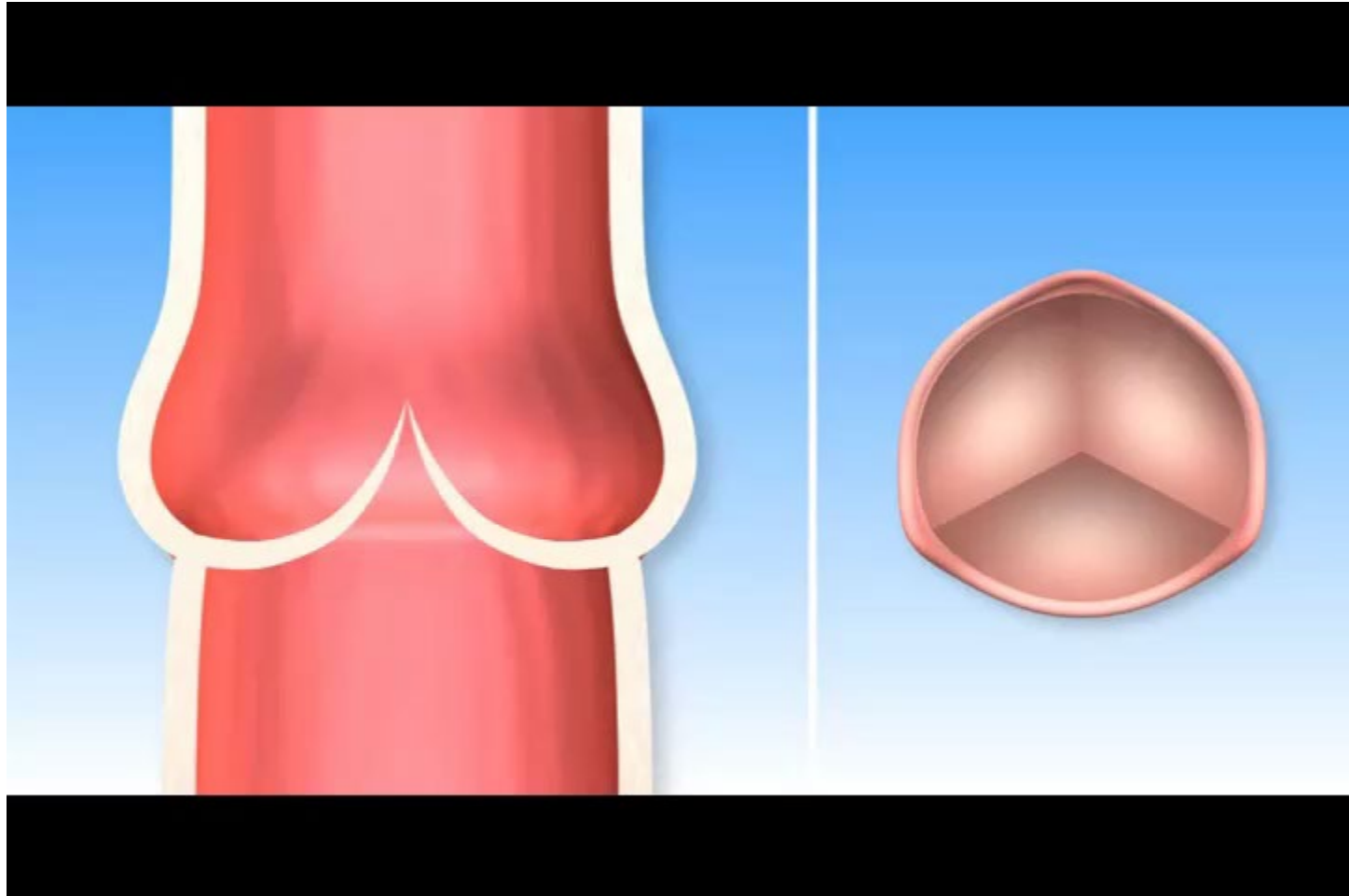
*Native valve*



*Reconstructed valve*



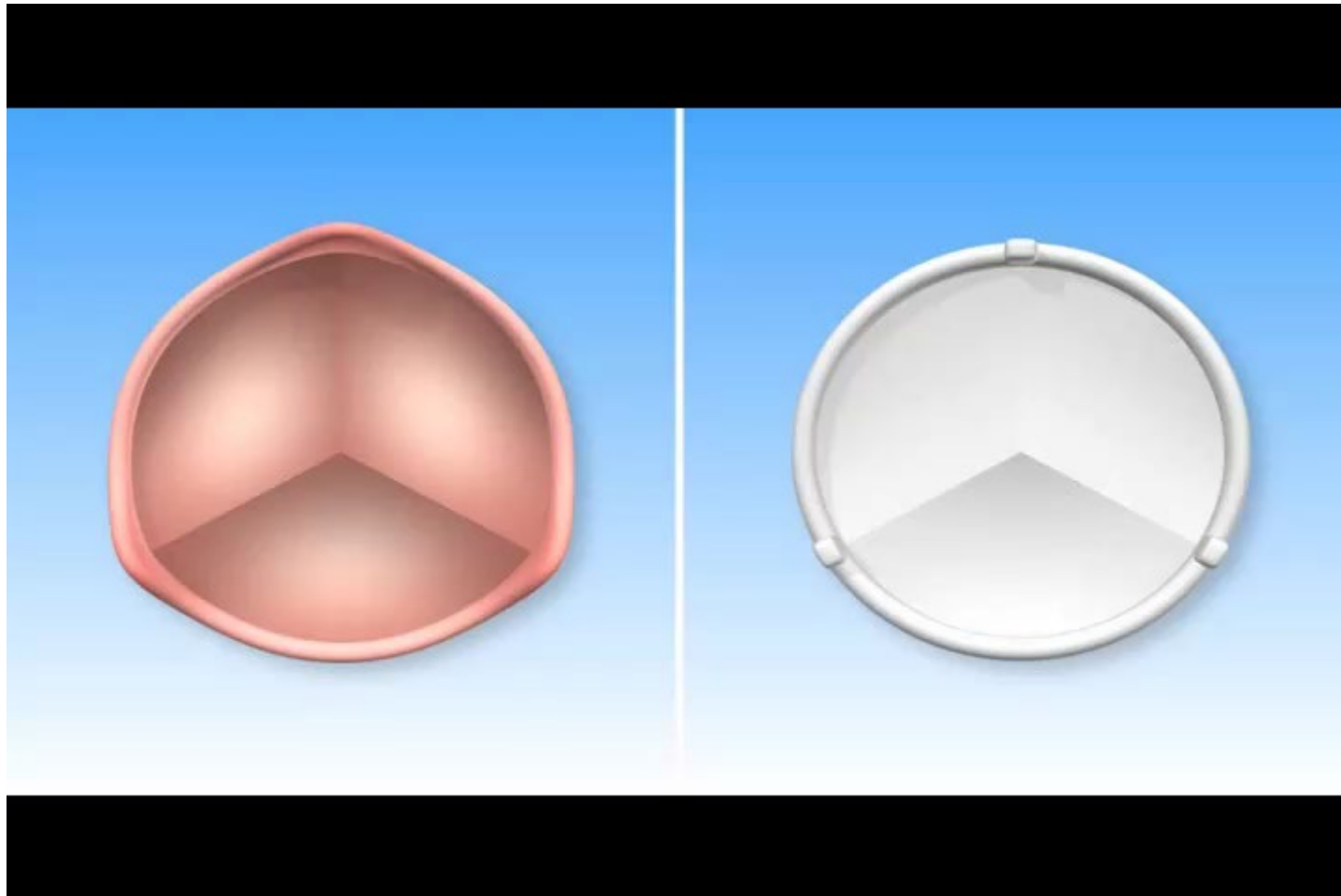
# Movement of Native Aortic Valve



# Native Aortic Valve vs Prosthesis

Native Aortic Valve

Prosthesis with Fixed Ring



## Laboratory Investigation

Wen-Jian Jiang, MD  
Yong-Chao Cui, MD  
Jin-Hua Li, MD  
Xiu-Hui Zhang, MD  
Huan-Huan Ding, MD  
Yong-Qiang Lai, MD  
Hong-Jia Zhang, MD

**Key words:** Aortic valve/pathology/surgery; calcinosis/pathology/prevention & control; disease models, animal; pericardium/pathology/transplantation; rabbits; reconstructive surgical procedures/methods; time factors; transplantation, autologous; transplantation, heterologous

**From:** Department of Cardiac Surgery (Drs. Ding, Jiang, Lai, Li, and H.-J. Zhang), Beijing Anzhen Hospital, Capital Medical University, Beijing Institute of Heart, Lung and Blood Vessel Diseases (Drs. Ding, Jiang, Lai, Li, and H.-J. Zhang); Key Laboratory of

## Is Autologous or Heterologous Pericardium Better for Valvuloplasty?

### A Comparative Study of Calcification Propensity

*Pericardial calcification is detrimental to the long-term durability of valvuloplasty. However, whether calcification susceptibility differs between heterologous and autologous pericar-*



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European Journal of Cardio-thoracic Surgery 28 (2005) 200-205

EUROPEAN JOURNAL OF  
CARDIO-THORACIC  
SURGERY

[www.elsevier.com/locate/ejcts](http://www.elsevier.com/locate/ejcts)

### Up to 16 years follow-up of aortic valve reconstruction with pericardium: a stentless readily available cheap valve?★

Zohair Al Hales<sup>a,\*</sup>, Maie Al Shahid<sup>a</sup>, Aly Al Sanei<sup>a</sup>, Ahmed Sallehuddin<sup>a</sup>, Carlos Duran<sup>b</sup>

<sup>a</sup>King Faisal Heart Institute at King Faisal Specialist Hospital and Research Centre, P.O. Box 3354, MBC-16, Riyadh 11211, Saudi Arabia

<sup>b</sup>The International Heart Institute of Montana Foundation, Missoula, MT, USA

Received 27 December 2004; received in revised form 20 April 2005; accepted 20 April 2005

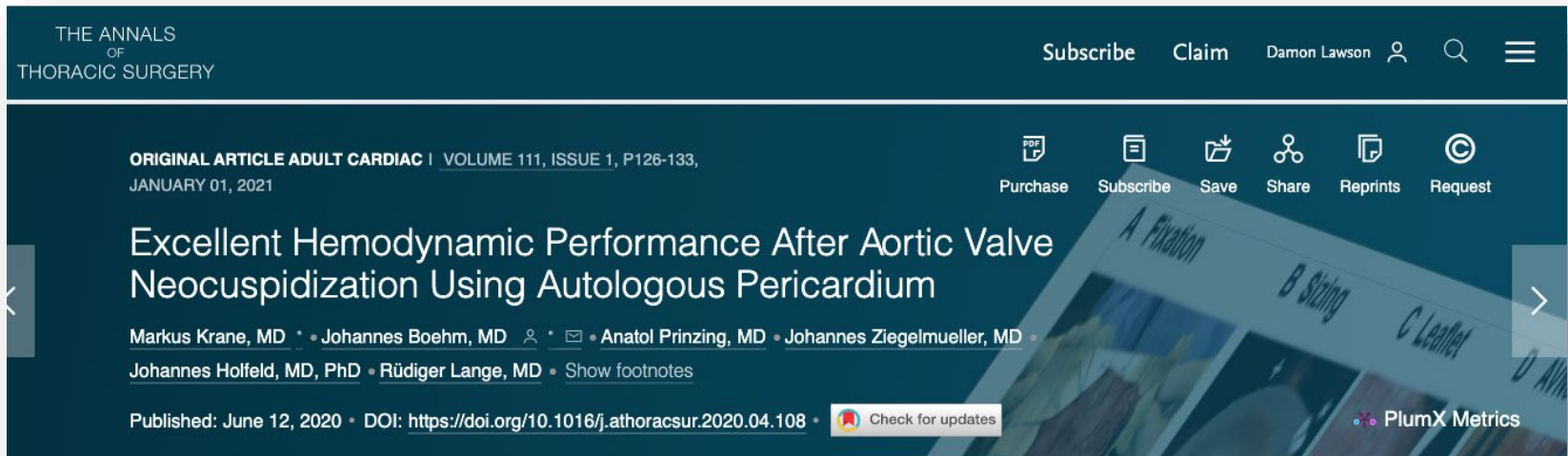
#### Abstract

**Objective:** There is lack of information regarding the long-term behavior of aortic valve reconstruction with pericardium (AoR). A 16-year follow-up is reported here. **Methods:** Between 1988 and 1995, 92 consecutive patients had AoR with bovine (Group I,  $n=27$ ) or glutaraldehyde-treated autologous pericardium (Group II,  $n=65$ ). The mean age was 30 years (range 12-68). There were 65% males, 92% in sinus rhythm, 84% had rheumatic etiology and 36% had 'other valve' surgery. Mitral valve replacement with a mechanical prosthesis is a contraindication to the operation. **Results:** Hospital mortality was 2%. The reconstructed aortic valve performed well with excellent hemodynamics. The mean follow-up interval was  $10.5 \pm 4$  years, range 9-16 years (longer for group I, 12 versus 10 years) with 4% late deaths and seven patients lost to follow-up. Survival rate was  $85 \pm 4\%$ . There were no episodes of thromboembolism. Freedom from reoperation for the whole group was  $68 \pm 5\%$  at 10 years and  $47 \pm 6\%$  at 16 years. For group I, it was  $68 \pm 9\%$  at 10 years and  $48 \pm 10\%$  at 16 years, while for group II it was  $72 \pm 6$  and  $45 \pm 8\%$  at 10 and 16

*Autologous pericardium shown to have reduced calcification when compared to heterologous pericardium*

***“Aortic bioprosthetic leaflet calcification is strongly and independently associated with hemodynamic valve deterioration and the risk of death or aortic valve re-intervention, (Zang et al., 2020).”***

Author	publ. year	Location	Operating years	Pts. No.	Mean age	Echo FU	Peak pressure gradient	Mean pressure gradient
Ozaki et al.	2018	Tokio, Japan	2007 - 2015	850	71	8 years	<b>15,2 mmHg</b>	
Koechlin et al.	2020	Basel, Switzerland	2015 - 2017	35	72	21,5 months	<b>12 mmHg</b>	<b>6 mmHg</b>
Iida et al.	2020	Tokio, Japan	2010 - 2019	36	55	Mid-term (48months)	<b>19 mmHg</b>	
Krane et al.	2021	Munich, Germany	2016 - 2019	103	54	12 months	<b>16,1 mmHg</b>	<b>8,8 mmHg</b>
Benedetto et al.	2021	Bristol, Coventry, UK	2018 - 2020	55	58	12,5 months	<b>16 mmHg</b>	<b>9 mmHg</b>
Pirola et al.	2021	Milan, Italy	2014 - 2020	71	52	3 months	<b>10.9 mmHg</b>	<b>7.5 mmHg</b>



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## Excellent Hemodynamic Performance After Aortic Valve Neocuspidization Using Autologous Pericardium

Markus Krane, MD • Johannes Boehm, MD • Anatol Prinzing, MD • Johannes Ziegelmüller, MD • Johannes Hoffeld, MD, PhD • Rüdiger Lange, MD • Show footnotes

Published: June 12, 2020 • DOI: <https://doi.org/10.1016/j.athoracsur.2020.04.108> • Check for updates • PlumX Metrics

**Results:** Tri-leaflet aortic valve reconstruction was achieved in all patients. In 38 patients, neo-commissures were created (36,9%). Mean cross clamp time was  $135 \pm 20$  min. Four patients underwent reoperation; the overall freedom from reoperation was 96.1%. Echocardiographic 6-12 months follow-up after surgery was available in 93.8% of the patients and did not show any change in hemodynamic parameters compared to discharge. **Comparison between AVNeo and virtually implanted Trifecta Bioprosthesis revealed a significantly lower mean pressure gradient ( $8,5 \pm 3,7$  mmHG versus  $10,2 \pm 2,0$ ,  $p < 0,0001$ ) and higher mean effective orifice area (EOA) ( $2,2 \pm 0,7$  cm<sup>2</sup> versus  $2,1 \pm 0,4$ ,  $p = 0,037$ ) for AVNeo.**

**Conclusions:** AVNeo shows low reoperation rates after surgery within the first two years. The hemodynamic performance is excellent and effective orifice area and pressure gradients remain stable within the first year.

# Excellent Hemodynamics



	AVNeo, n = 20	Medtronic HANCOCK®II T505 CINCH® II, n=41	Carpentier-Edwards PERIMOUNT, n=35	P (ANOVA)
Mean gradient, mmHg	5.2±2.38	9.9±3.18	8.4±3.29	0.001
Peak gradient, mmHg	10.8±3.78	21.7±6.09	17.3±5.83	0.001
Effective orifice area, cm <sup>2</sup>	3.8±0.77	1.5±0.24	1.65±0.40	0.001
Effective orifice area index, cm <sup>2</sup> /m <sup>2</sup>	1.99±0.43	0.86±0.23	0.91±0.35	0.001

*According to Rosseykin et al. (2016), in the immediate postoperative period the Ozaki procedure had lower mean and peak gradients, a larger effective orifice area, and a larger orifice area index when frame-mounted biological aortic prostheses Medtronic HANCOCK®II T505 CINCH® II and the Carpentier-Edwards PERIMOUNT.*





Mid-term Outcomes in 850 Patients Treated with Aortic Valve Neo-Cuspidization Using Glutaraldehyde-Treated Autologous Pericardium

Freedom from recurrence of moderate AR after AVNeo (850)



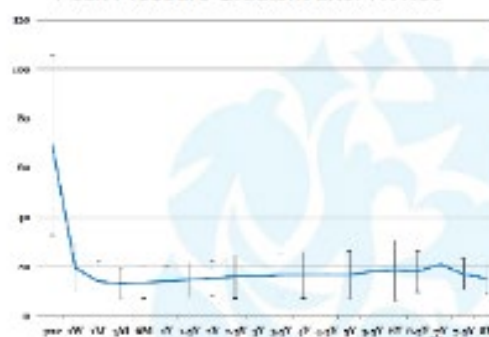
Over all Survival



Freedom from Re-operation



Echocardiographic Evaluation of Peak Pressure Gradient after AVNeo



*Prof. Ozaki Presented his 10 year data at AATS in 2017*

## Key Findings

- Freedom for AR 92.7%
- Peak pressure gradient decreased after AVNeo
- Overall survival 85.9%
- Freedom from Re-operation 95.8%

## Prof Ozaki Reports 12 year Follow-up on 1100 Patients


Turkish Journal of Thoracic and Cardiovascular Surgery 2019;27(4):454  
<http://dx.doi.org/doi: 10.5606/tgkdc.dergisi.2019.01904>



*Editorial Comment / Editorial Yorum*

### Ozaki Procedure: 1,100 patients with up to 12 years of follow-up

*Ozaki prosedürü: 12 yıla varan takipte 1100 hasta*

Shigeyuki Ozaki 

Department of Cardiovascular Surgery, Toho University, Ohashi Medical Center, Tokyo, Japan

Ozaki procedure or aortic valve neo-cuspidization basically includes replacement of aortic valve cusps by three native autologous pericardial cusps. Its midterm outcomes have been published previously.<sup>[1]</sup> This video article presents the operative technique in a stepwise method.<sup>[2]</sup>

In our clinic, this operation was performed during 12 years from April 2007 to March 2019, and more than 1,100 patients were operated. The mean age of the patients was  $67.7 \pm 14.9$  years. The etiology was aortic stenosis in 61.7%, aortic insufficiency in 31.1%, and both in 7.2% of the patients. The mean aortic cross-clamp and cardiopulmonary bypass times were  $106.1 \pm 30.3$  and  $151.3 \pm 36.9$ , respectively. The overall survival rate is 84.6% and freedom from reoperation is 95.8% at 12 years.

2. A bovine pericardium can also be used in selected patients, if native pericardium is not available. No calcification issue was experienced in our series.
3. A learning period usually includes the first 20 patients for such operation; therefore, the set up and technique should be supervised in the beginning.
4. If the difference between the sizing of each cusps is more than 2 mm, a new commissure should be created to prevent misalignment between the cusps.

#### Declaration of conflicting interests

The authors declared no conflicts of interest with respect to the authorship and/or publication of this article.

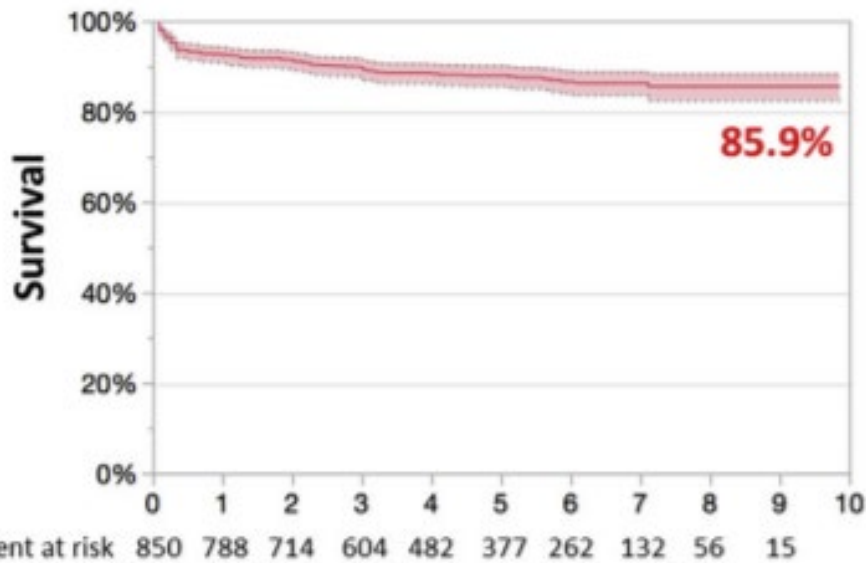
### Key Findings

- Overall survival 84.6%
- Freedom from Re-operation 95.8%

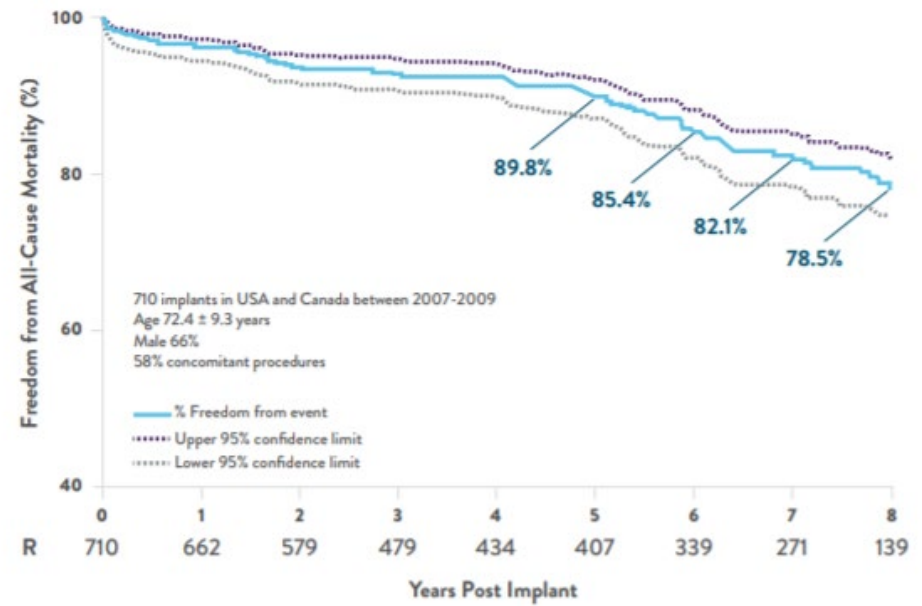
# How Does AVNeo™ Compare?



## AVNeo™ vs Trifecta™ Valve Late Survival



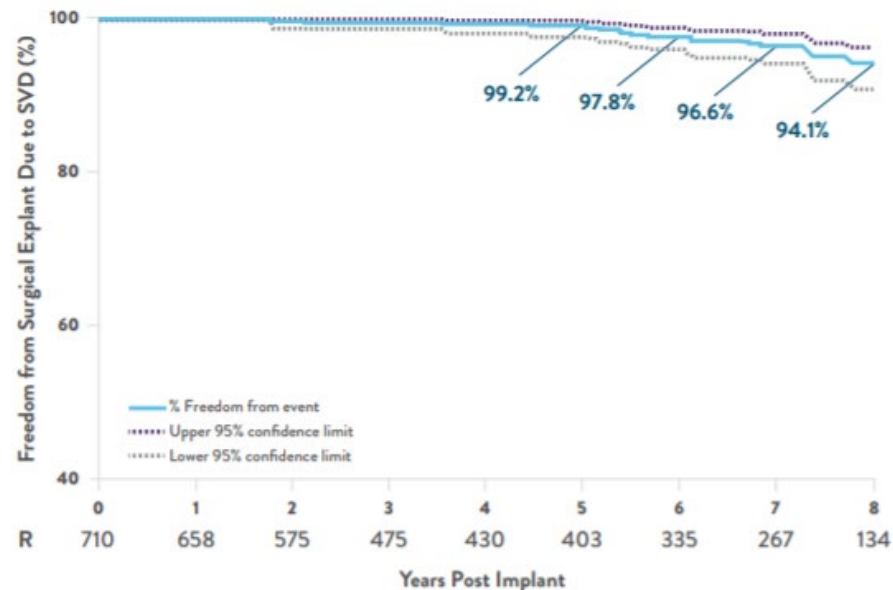
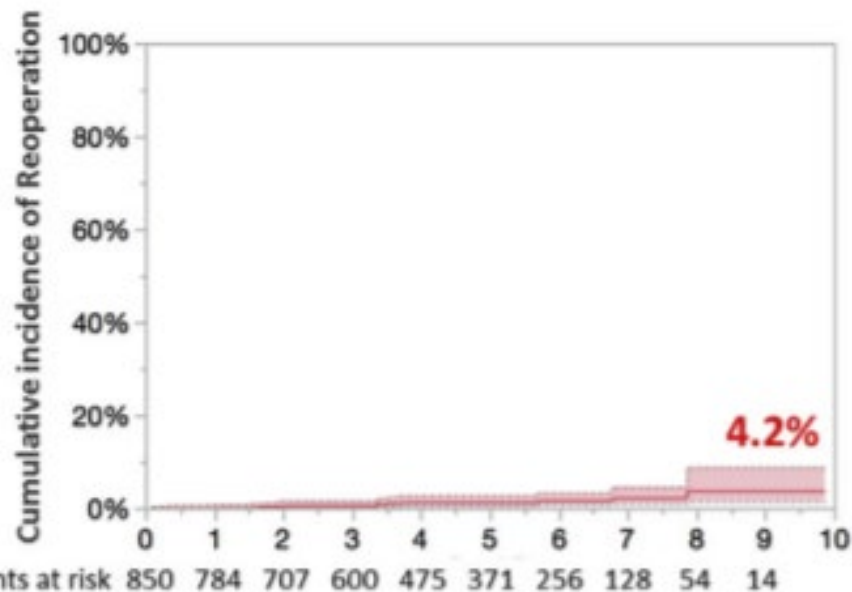
**Figure 1: Trifecta LTFU Survival**



# How Does AVNeo™ Compare?



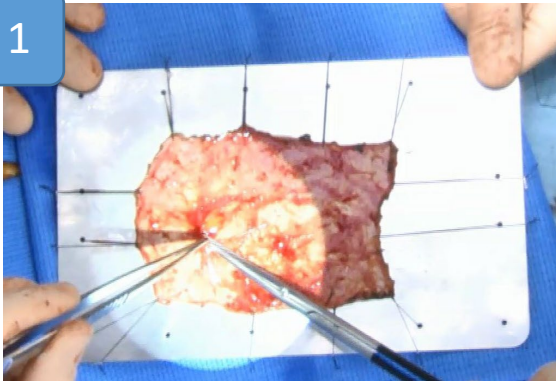
## AVNeo™ vs Trifecta™ Valve Freedom from Reoperation



AVNeo™ **cumulative** incidence of reoperation 4.2% vs Trifecta™ reoperation for **only SVD** at 5.9%

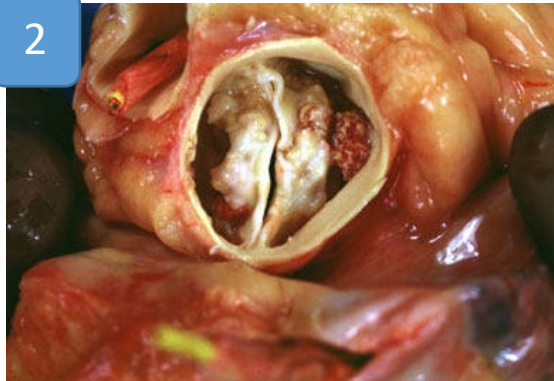
# Highlights of the AVNeo™ Procedure

1



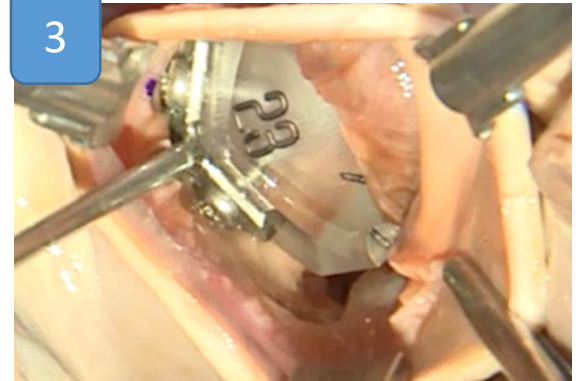
Harvest and prepare pericardium. Fix in 0.6% Glutaraldehyde solution and thoroughly rinse in saline.

2



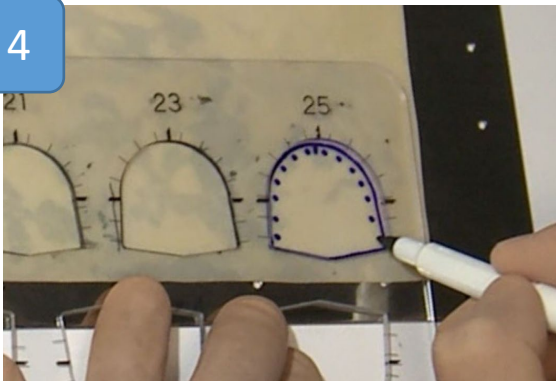
Resect the native valve

3



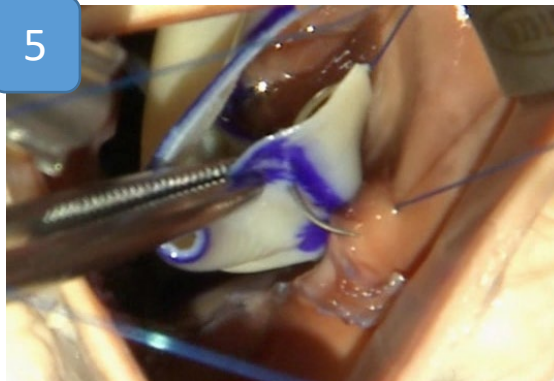
Measure between each commissure, using the AVNeo™ Sizer, to determine the proper leaflet size

4



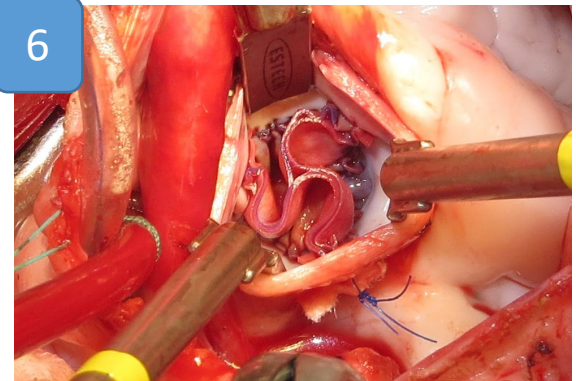
Use the respective sized AVNeo™ leaflet tracing template to draw and trim the pericardium to the correct size.

5



Use the standardized sequence to implant the leaflets into the native annulus

6



New autologous pericardium aortic valve with all three commissures and the distal coaptation zone on the same level.

# The AVNeo™ System

AVNeo™  
Sizers  
come in a  
variety of  
sizes to  
treat  
patients of  
all ages



Standard (21/23/25/27/29)  
Pediatric (13/15/19)  
Large (31/33/35)



## Learning 2007-2011

### 2007

- 1st Case of AVNeo by Prof. Ozaki at Toho Univ.

### 2011

- 404 AVNeo cases by Prof. Ozaki at Toho University

## Adaption 2012-2015

### 2013

- AATS Mid Term Result

### 2014

- FDA Approved
- Ozaki VRec
- (Re-serializable kits)

### 2015

- US 1<sup>st</sup> AVNeo @ Cleveland Clinic
- >750 cases by Prof. Ozaki

## Growth > 2016

### 2016

- FDA Approved
- AVNeo Sizer System (Disposable kits)
- US AVNeo Commercialization

### 2017

- AATS 850 Cases

### 2019

- >1100 Cases by Prof. Ozaki & 12 yr follow-up

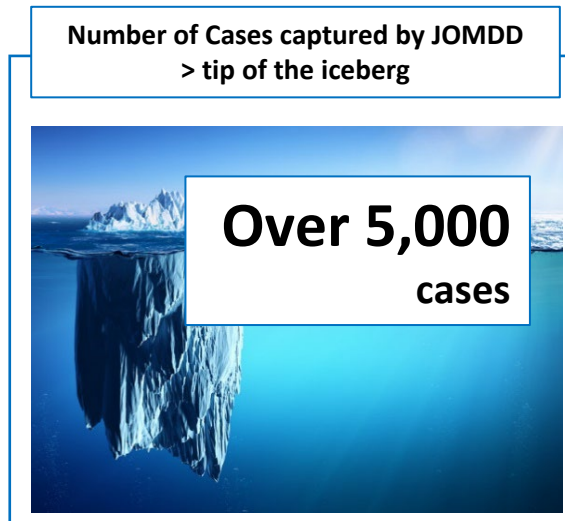
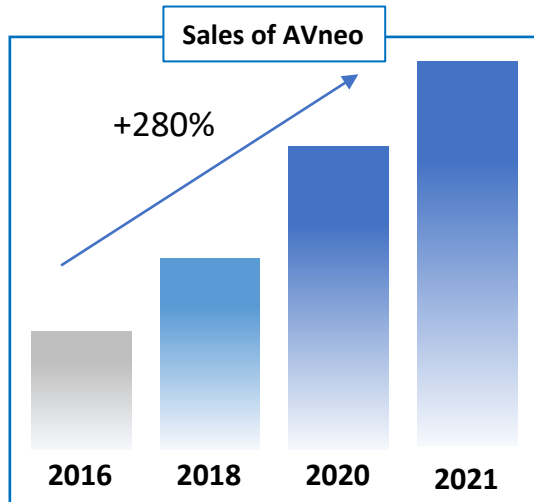
### 2021

- >5,000 globally
- 5 year follow-up from multiple centers

# Global Increase of AVNeo™ Facilities

## Strong Demand:

We are facing significant global demand by the number of surgeons and countries that are implementing AVNeo.



**Distribution Network of AVNeo**  
now in over **50** countries

### Europe

- Austria
- Belgium
- Czech Republic
- Denmark
- Estonia
- France
- Georgia
- Germany
- Hungary
- Italy
- Latvia
- Lithuania
- Netherlands
- Norway
- Portugal
- Romania
- Russia
- Slovakia
- Slovenia
- Spain
- Sweden
- Switzerland
- Turkey
- Ukraine
- UK

### Americas

- USA
- Colombia
- Ecuador
- Peru
- Panama
- Paraguay
- Chile
- Brazil
- Venezuela

### Asia

- China
- Japan
- Vietnam
- Malaysia
- Hong Kong
- Thailand
- Taiwan
- India
- Nepal
- Australia
- Bangladesh

### Middle East/Africa

- Egypt
- Israel
- Qatar
- South Africa
- Saudi Arabia (2021)
- Morocco (2022)



# Training Process to Perform AVNeo™ Procedure



## Stage 1

Didactic  
introduction into  
AVNeo™  
procedure



## Stage 2

Hands-on Dry Lab  
for both tricuspid  
and bicuspid  
valves



## Stage 3

Clinical training  
with designated  
proctor and direct  
observation



## Stage 4

Proctor visit to  
your hospital to  
assist with your  
first cases

## Goals

- Obtain a basic understanding AVNeo™ procedure
- Understanding the benefits from the AVNeo™ procedure
- Review publications for insights on types of patients which have undergone the AVNeo™ procedure

## Responsibilities

- Review publication using AVNeo™ procedures
- “Step by Step” instructions for AVNeo™ procedure
- 1.5-hour video of full AVNeo™ procedure overview
- Independent dry lab practice (optional)
- **Review AVNeo™ webinar series**

> [Ann Thorac Surg.](#) 2021 Jan;111(1):126-133. doi: 10.1016/j.athoracsur.2020.04.108. Epub 2020 Jun 12.

### Excellent Hemodynamic Performance After Aortic Valve Neocuspidization Using Autologous Pericardium

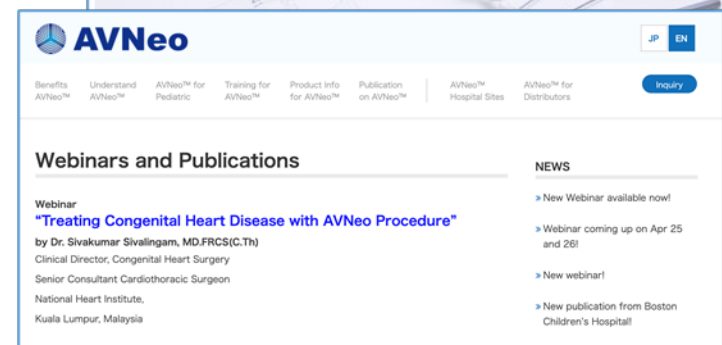


### Step by Step for AVNeo™ Procedure

- Tricuspid/Bicuspid cases -



Overview of the aortic valve reconstruction

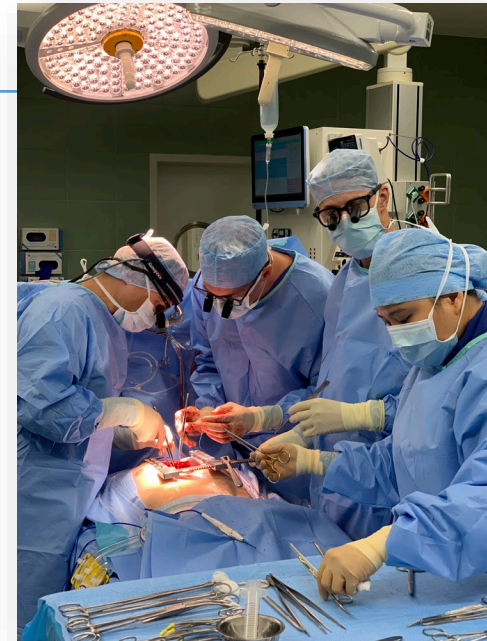
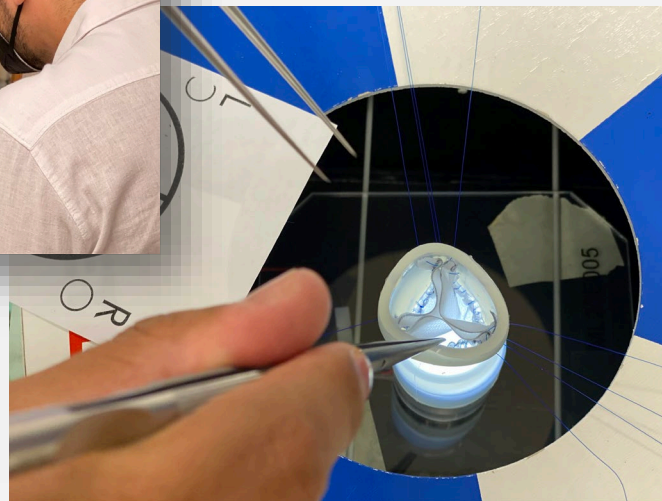


The screenshot shows the AVNeo™ website interface. At the top, there are navigation links for Benefits, Understand, AVNeo™ for Pediatric, Training for, Product Info, Publication, AVNeo™ Hospital Sites, and AVNeo™ for Distributors. Below this, there is a section titled "Webinars and Publications" with a featured webinar: "Treating Congenital Heart Disease with AVNeo Procedure" by Dr. Sivakumar Sivalingam, MD, FRCS(C, Th). To the right, there is a "NEWS" section with updates on new webinars and publications.

# AVNeo™ Training – Onsite

## Day 1

- Lecture on AVNeo™
- Q&A
- Dry Lab Training



## Day 2

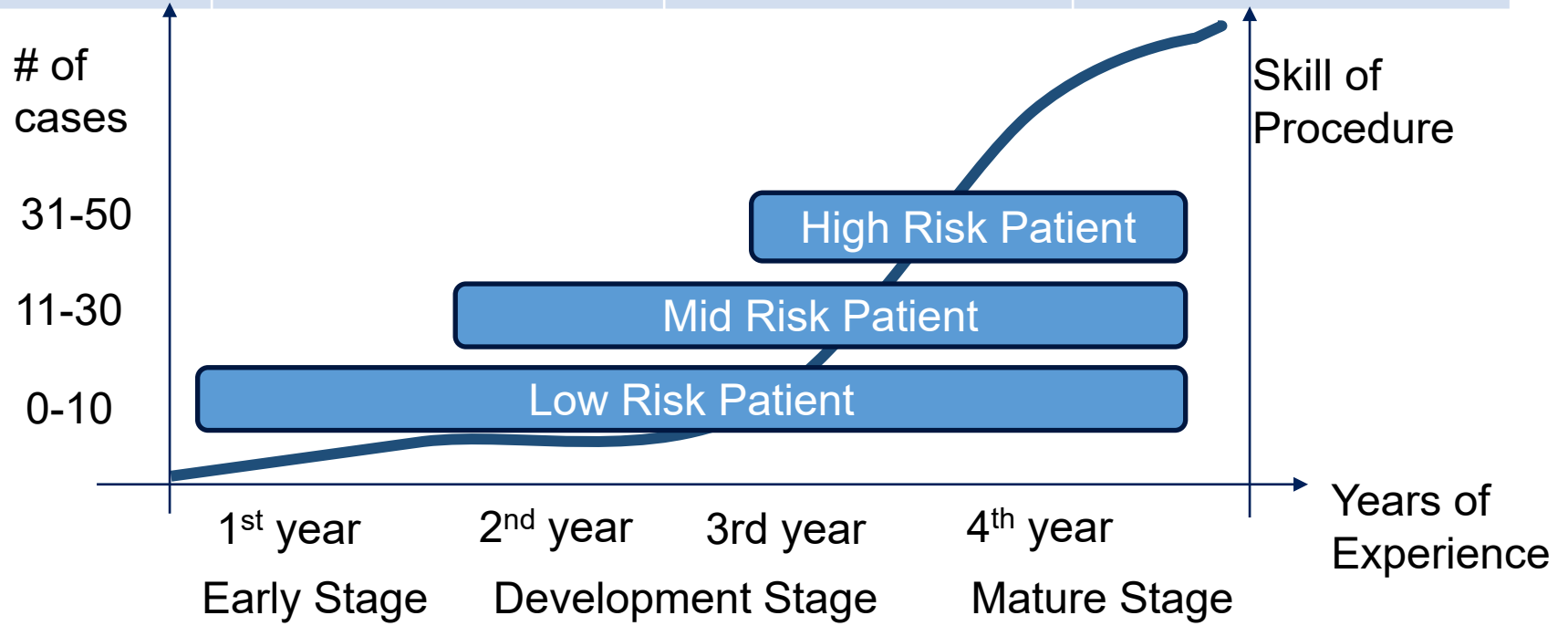
- Review of the AVNeo™ procedure
- Observation of live case
- Question & Answer session

***Final feedback and procedure review session***

# Learning Curve and Patient Selection



	Early Stage	Development Stage	Mature Stage
Patient Selection	Younger Normal EF Tricuspid AV Minimal sinus calcifications Isolated AVR Generous sinus size	Higher risk profile Concomitant procedures	All Patients



# Key Medical Centers Across the Globe

## United States

Cleveland Clinic

UPMC  
University of Pittsburgh Medical Center

THE HEART HOSPITAL  
Baylor Plano

Rady Children's  
Hospital San Diego

Texas Children's Hospital

Children's Hospital LOS ANGELES

VA

Lucile Packard Children's Hospital Stanford

Children's Hospital Colorado

Boston Children's Hospital  
Until every child is well

COLUMBIA UNIVERSITY MEDICAL CENTER

G.S. MOTT CHILDREN'S HOSPITAL

Etc.

## Europe

University of Basel

KATHOLIEKE UNIVERSITEIT LEUVEN

GVM CARE & RESEARCH

Hadassah Medical Center

Centro Cardiologico Monzino

SCCS ZABRZE

Royal Brompton & Harefield  
NHS Foundation Trust

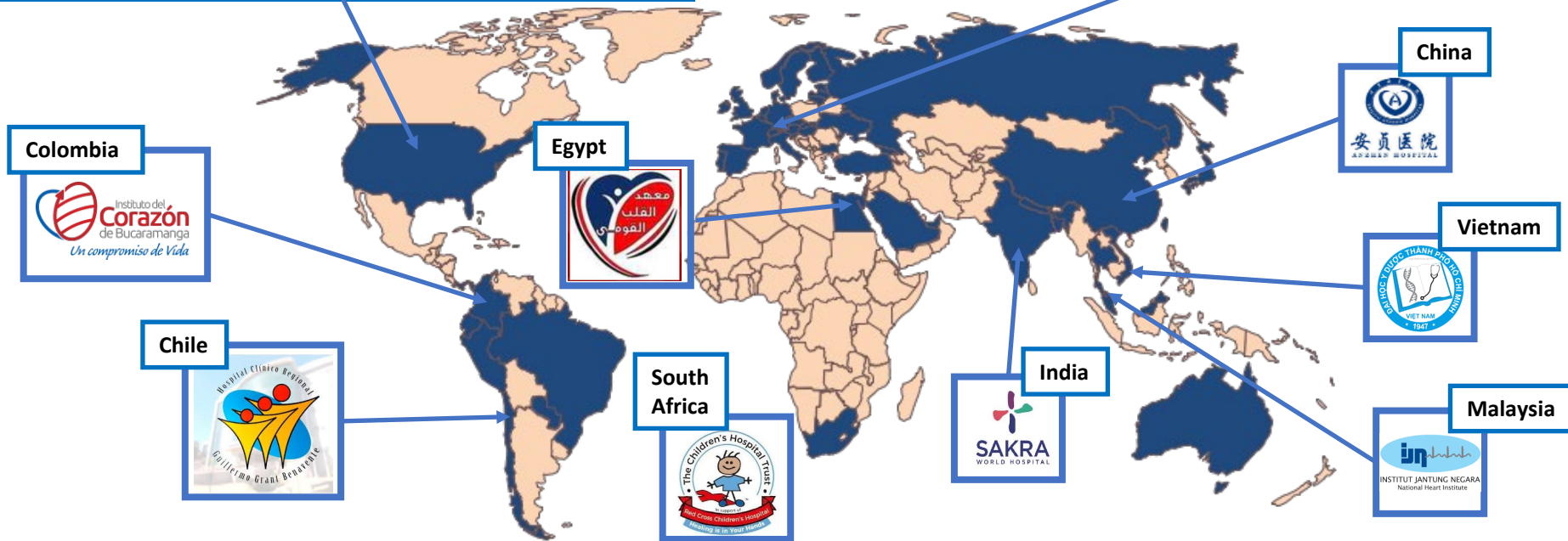
NHS

INSTITUTE HEART  
Ministry of Health of Ukraine

German Heart Centre of the State of Bavaria and the Technical University Munich

Edinburgh Children's Hospital Charity  
child first. patient second.

Etc.



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