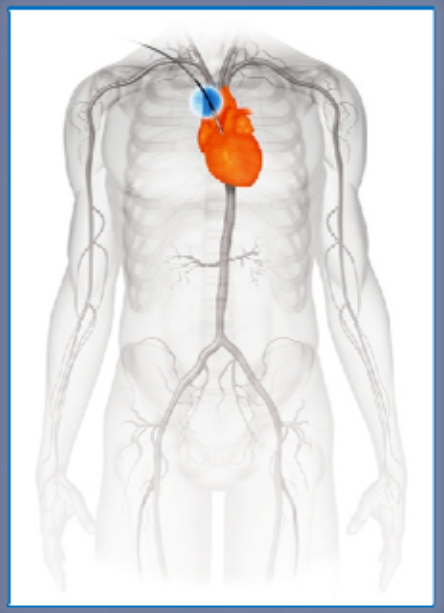
3rd TAVI Summit
Seoul, August 9/10, 2013

The Medtronic Core Valve System Direct Aortic Approch



Eberhard Grube MD, FACC, FSCAI
Michael Reardon MD

Michael Reardon MD

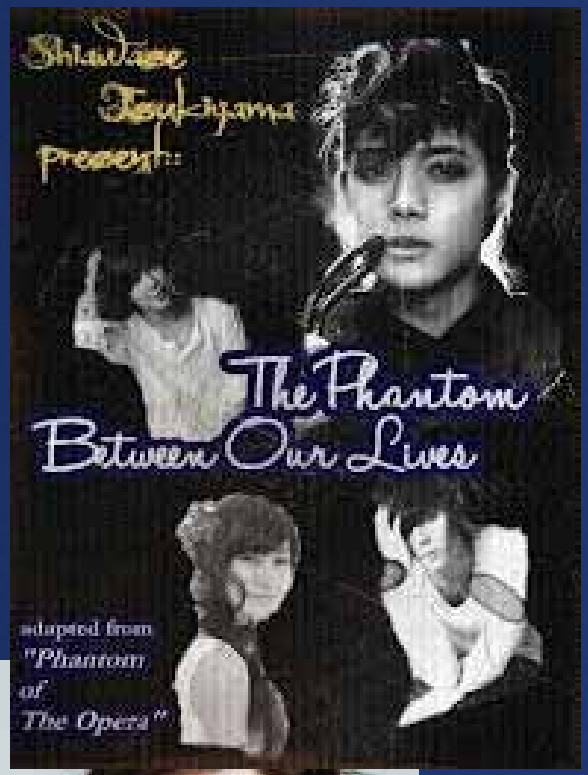
Michael J. Reardon, M.D.
Senior Member The Methodist Hospital Research Institute
Chief, Division of Cardiac Surgery The Methodist Hospital, Houston TX
Clinical Professor, Department of Surgery Baylor College of Medicine

Seung-Jung Park MD

Thank You and…

Congratulations !

Seung Jung Park MD



Eberhard Grube MD

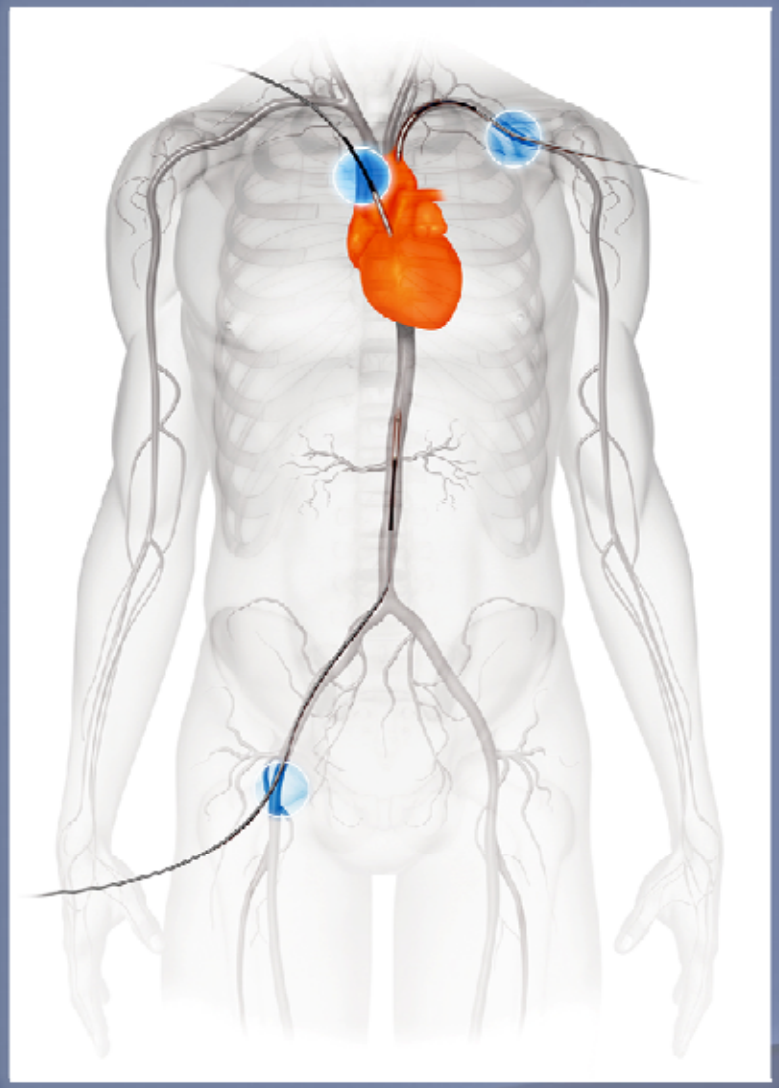
Within the past 12 months, the presenter or their spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

Physician Name	Company/Relationship
Eberhard Grube, MD	Medtronic, CoreValve: C, SB, AB, OF Sadra Medical: E, C, SB, AB Direct Flow: C, SB, AB Mitralign: AB, SB, E Boston Scientific: C, SB, AB Biosensors: E, SB, C, AB Cordis: AB Abbott Vascular: AB Valtech: E, SB, Claret: SB Keystone Medical: SB

TAVI Access Routes
Medtronic CoreValve System

- The Medtronic CoreValve System is approved for three transarterial access options
  - Transfemoral
  - Subclavian
  - Direct Aortic

- All sizes and access routes use an 18FR catheter delivery system



Direct Aortic TAVI

A familiar approach to treat more patients

Direct Aortic implantation expands patient access to TAVI

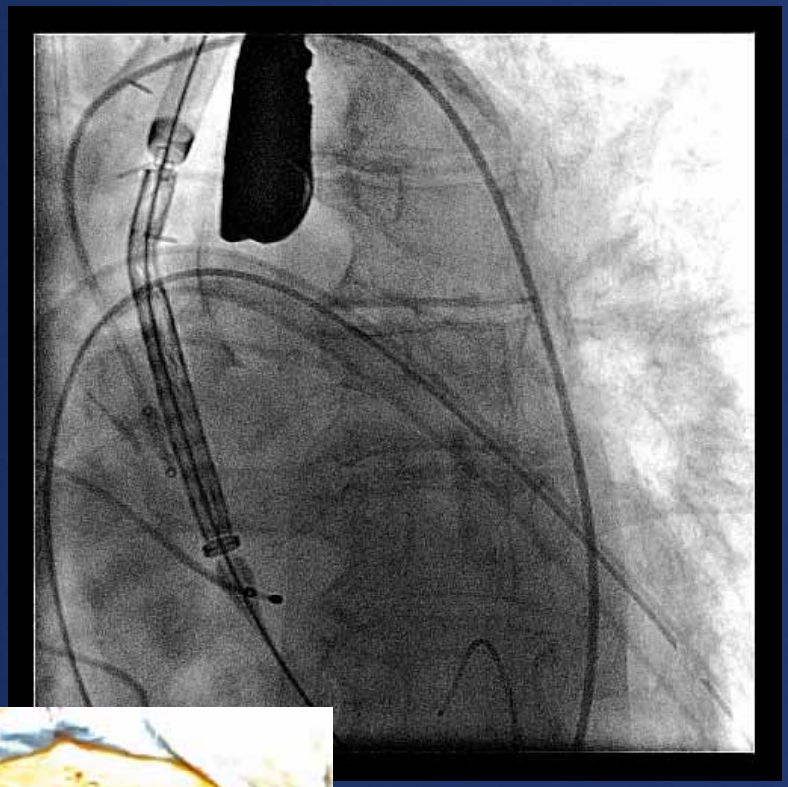
- Familiar access through a mini-sternotomy or mini-thoracotomy
- Pericardial dissection and direct heart muscle manipulation are not required

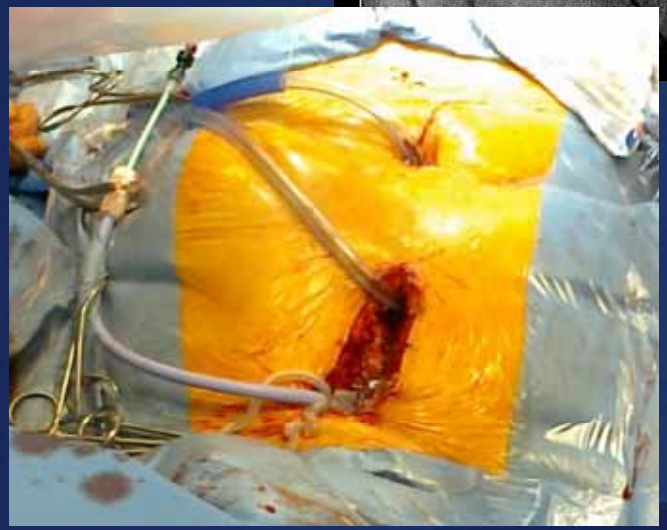
Bruschi G, et al. Direct Aortic Access Through Right Minithoracotomy for Implantation of Self-Expanding Aortic Bioprosthesis Valves [1]

"The direct aortic approach technique provides a direct access to the aortic annulus, allowing an easier manipulation and delivery of the device."

Bruschi G, De Maro F, Fratto P, et al.[1]

Alternative Access
Trans-Aortic Approach

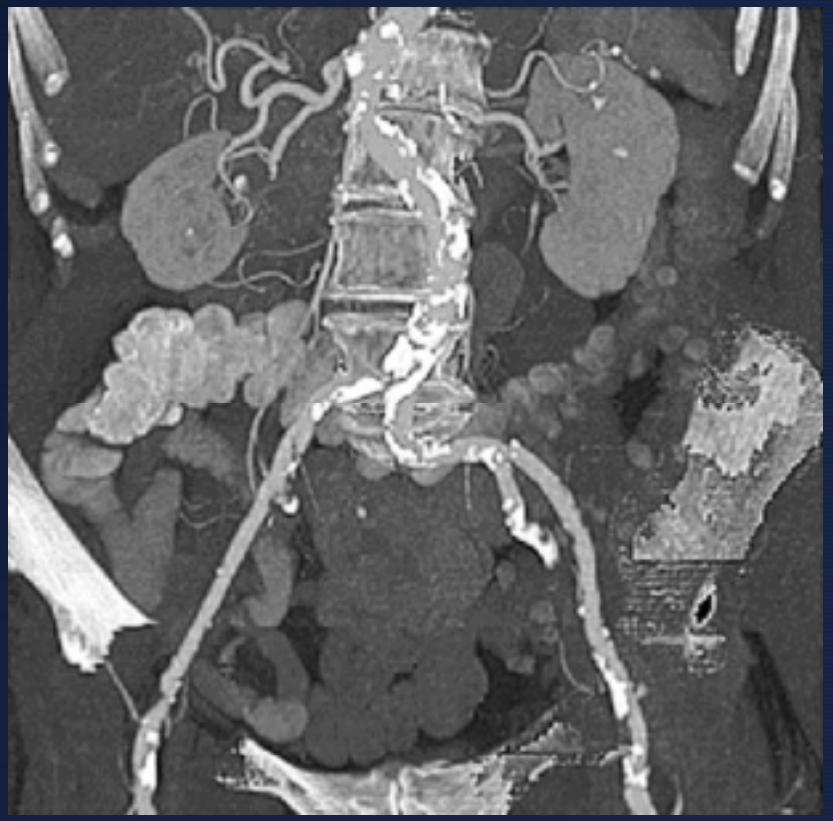


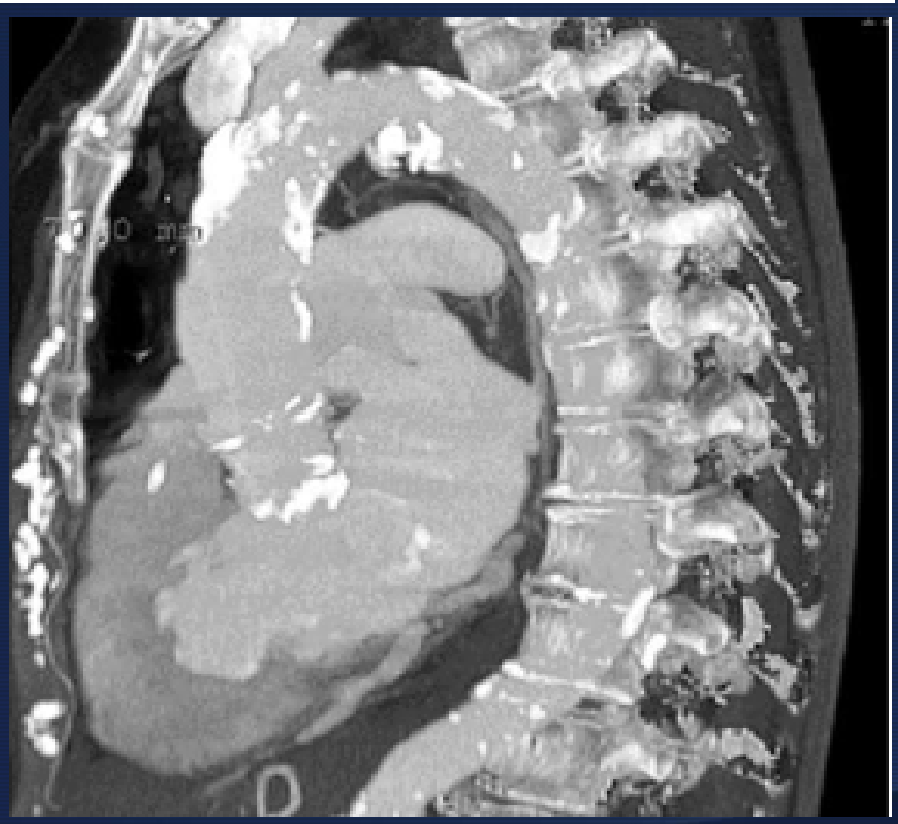


Alternative Access: Direct Aortic

Transaortic Transcatheter Aortic Valve Implantation: A Novel Approach for the Truly "No-Access Option" Patients

George Latsios,* MD, Ulrich Gerckens, MD, and Eberhard Grube, MD





Latsios et al CCI 2010; 75:1129–1136

Direct Aortic Operative Technique
Medtronic CoreValve® System

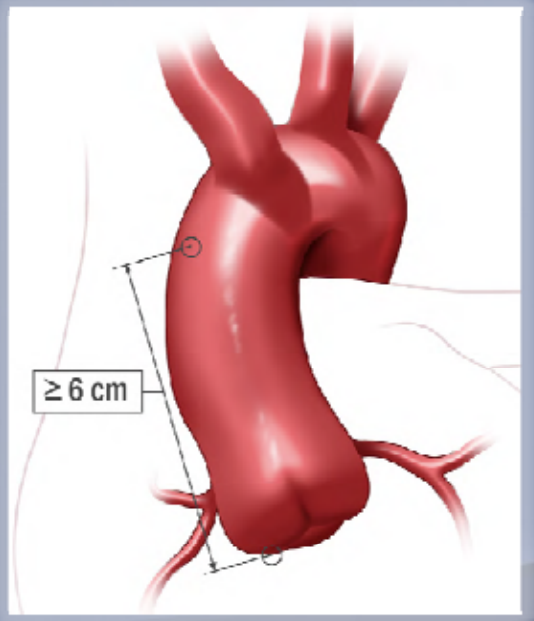
Pre-operative Planning

A pre-operative CT scan is essential to guide in the selection of the:

- Thoracic Access Location
  - Delivery trajectory should optimize coaxial alignment with native valve and avoid critical vessels
- Aortic Access Site
  - Site should be free of calcification and greater than 6 cm from the basal plane to facilitate valve deployment

CoreValve® Size	26 mm	29 mm	31 mm
Valve Height	55 mm	53 mm	52 mm

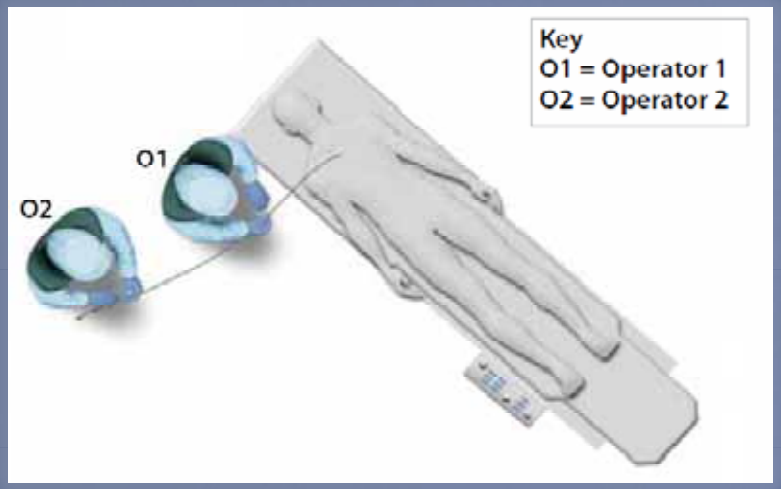
Image courtesy of Dr. Giuseppe Bruschi



Room Setup

- The direct aortic procedure must be performed in a hybrid room that supports both interventional and surgical procedures (e.g. Hybrid OR)

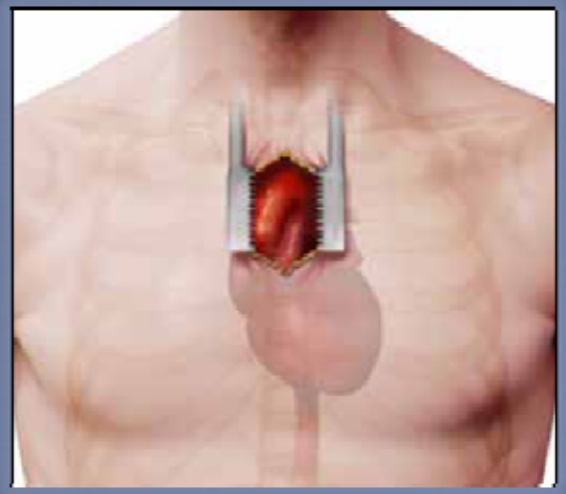
- The operative team should evaluate the following prior to the procedure:
  - Location of the imaging screens, image intensifier, and other equipment
  - Operator positions to ensure control of the access site and delivery catheter
  - Consider use of third operator on patient's left side to maintain dedicated control of introducer sheath throughout procedure in order to avoid access site complications.



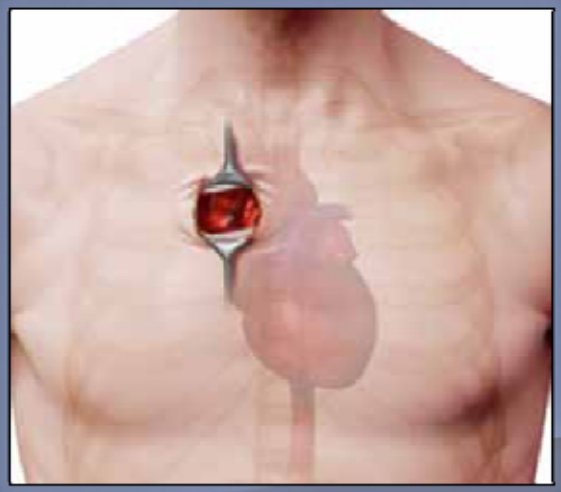
Surgical Approaches

- Access aorta through an upper partial mini-sternotomy or right anterior mini-thoracotomy
- Access route selection based on:
  - Anatomy
    - Distance between access site and basal plane
    - Aortic root angulation
    - Location of access site relative to surrounding anatomical structures (e.g. LIMA or RIMA graft)
  - Clinical preference
    - Familiarity with approach

Mini-Sternotomy



Mini-Thoracotomy



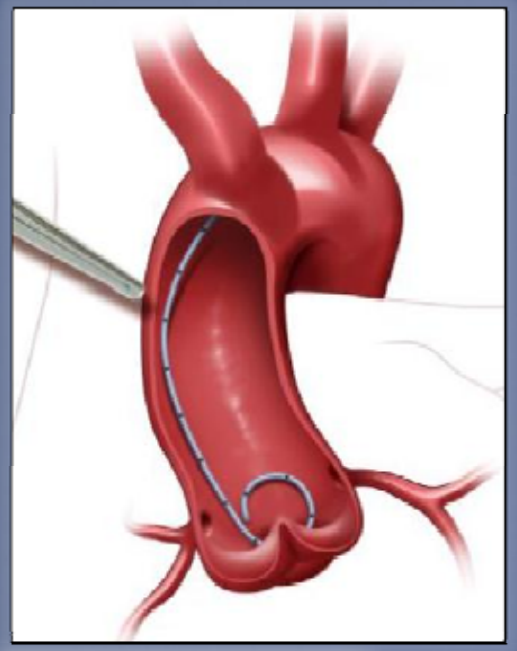
Mini-sternotomy

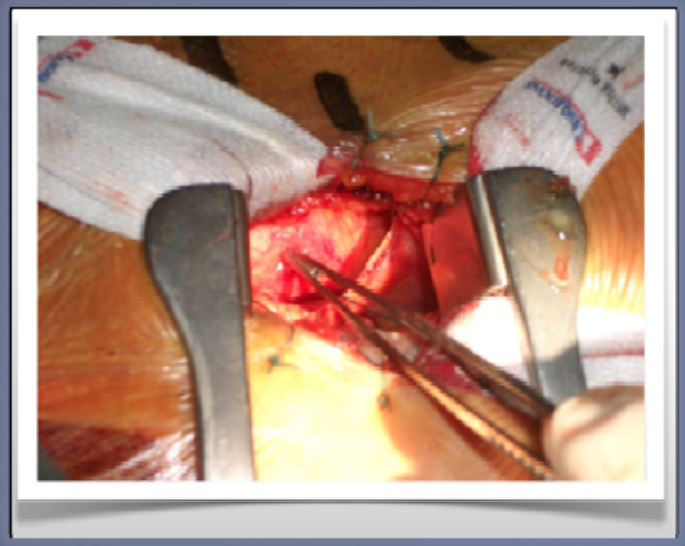
Video courtesy of Dr. Michael Reardon

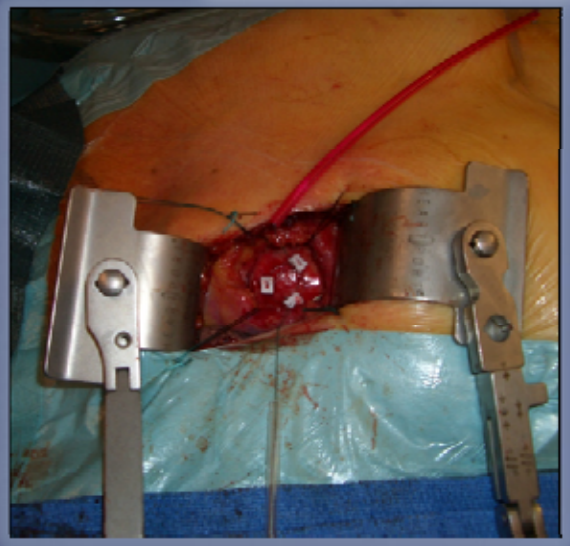
Aortic Access

- Perform aortography with forceps placed directly on the intended access site and use graduated pigtail to confirm ≥ 6 cm distance from the basal plane

- Place two standard double purse-string sutures and gain arterial access via the Seldinger technique or direct cannulation via scalpel puncture.







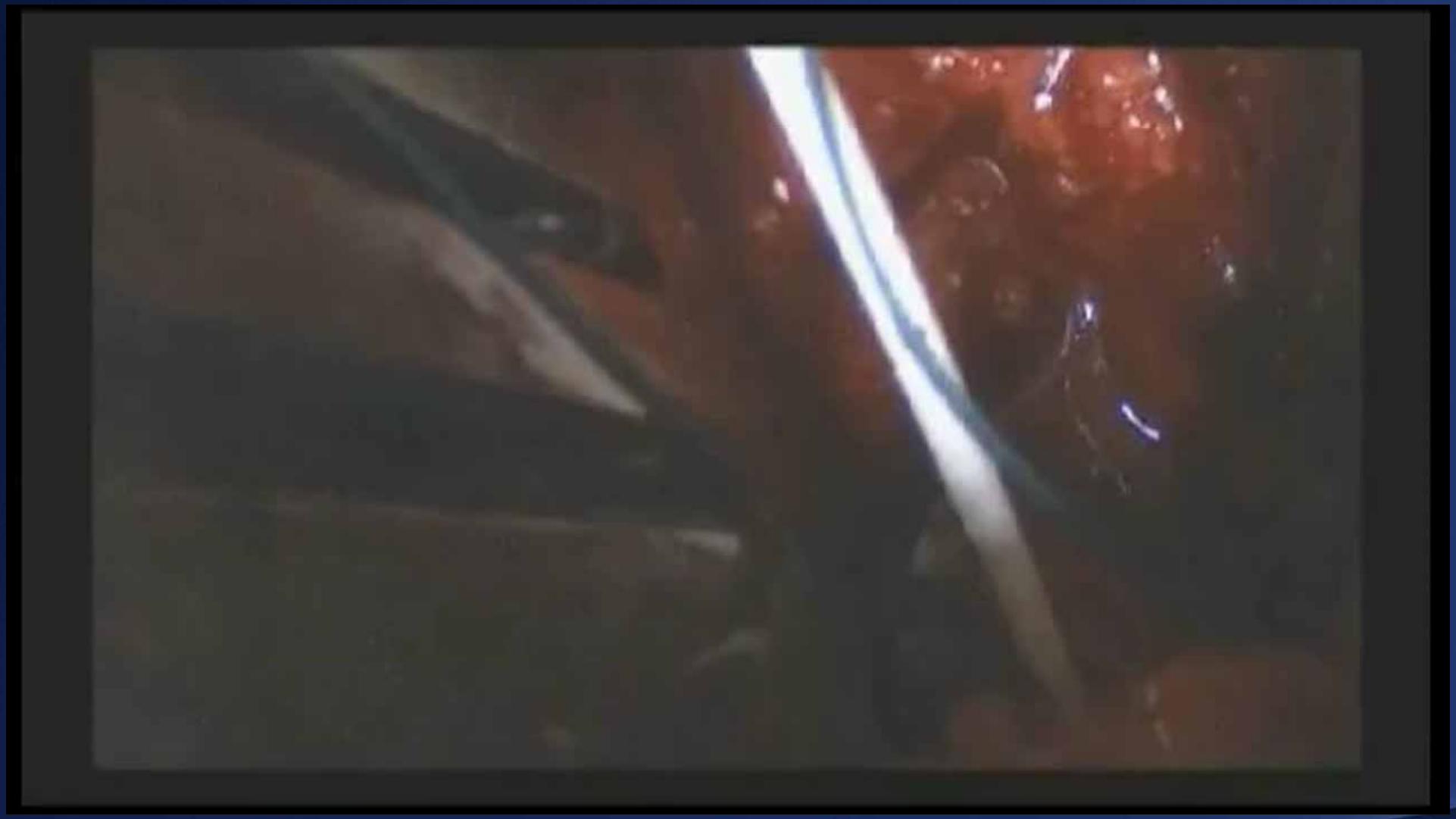
Courtesy of Dr. Giuseppe Bruschi

Aortic Access

Video courtesy of Dr. Michael Reardon

Guidewire Insertion

- Follow standard CoreValve guidewire-catheter exchange sequence to cross the native valve and place the super stiff guidewire



Video courtesy of Dr. Michael Reardon

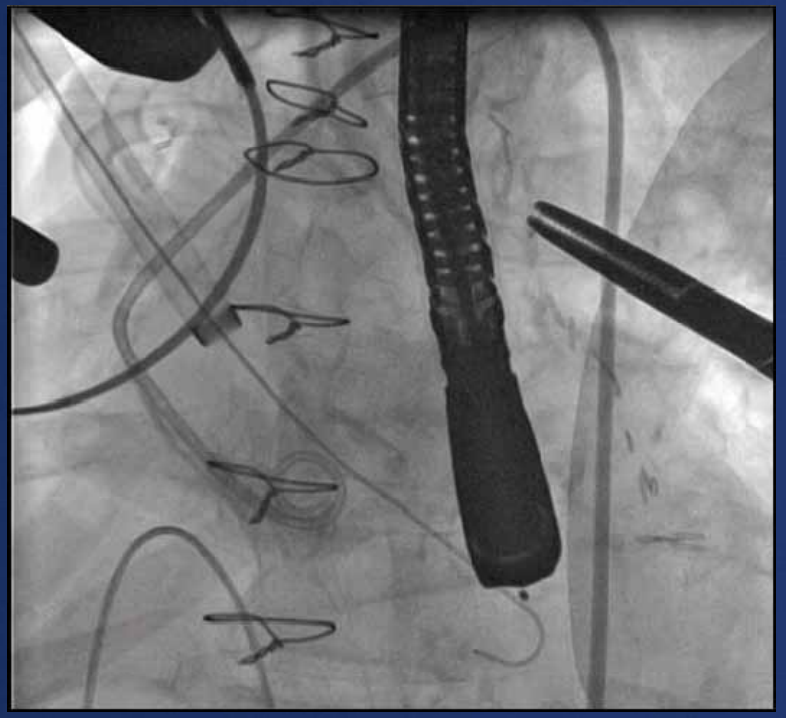
Introducer Access & Positioning

- Insert 18-Fr introducer over a super stiff guidewire approximately 2 cm into the aortic lumen

Video courtesy of Dr. Michael Reardon

Controlling the Introducer

- It is critical to maintain the recommended introducer position throughout the procedure to avoid “pop-out” or interaction with the aortic root anatomy
- Position control may be accomplished by:
  - Securing introducer with sutures
  - Tunneling the introducer through a skin incision
  - A dedicated hand or operator to manually hold introducer in place.



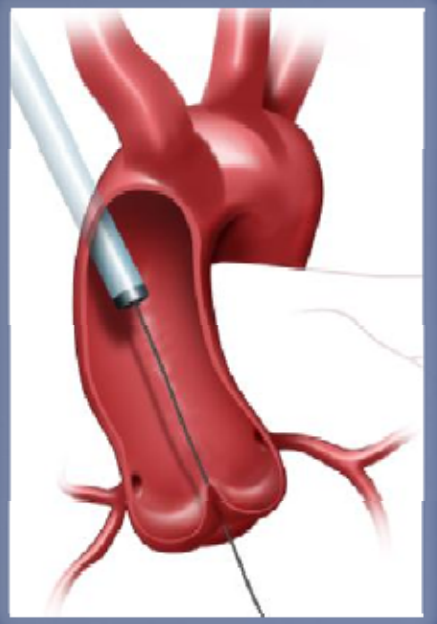
Courtesy of Mr. Neil Moat

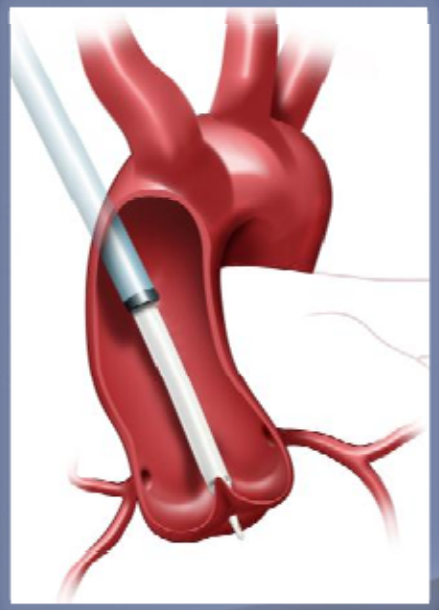
BAV & Valve Deployment

Video courtesy of Dr. Michael Reardon

Valve Deployment

- Perform a standard balloon valvuloplasty
- The Direct Aortic procedure provides direct delivery catheter system response due to the short & straight approach to the native aortic valve
- CoreValve Direct Aortic implantation utilizes the same proven retrograde delivery system with an atraumatic, tapered tip to cross the native valve
- Full valve function and partial repositionability prior to final release provides time for evaluation and adjustment





Delivery System Retrieval

- Capture tip of the delivery system in the sheath prior to withdrawal

Video courtesy of Dr. Michael Reardon

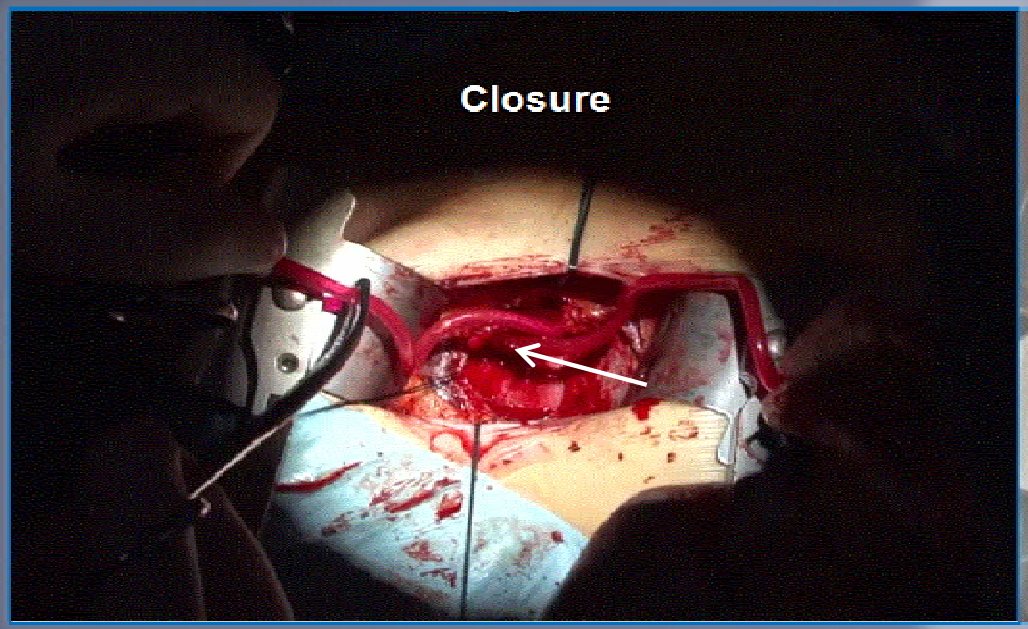
Post Deployment Evaluation

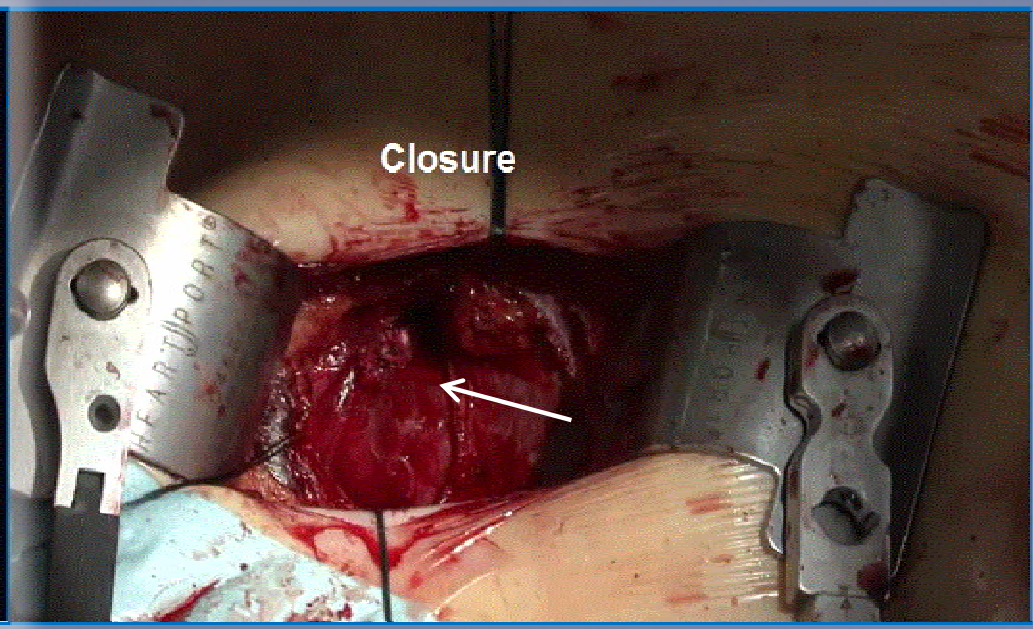
- Advance pig-tail catheter into LV to measure the transvalvular gradient
- Utilize angiography and echo to assess implantation depth

Video courtesy of Dr. Michael Reardon

Closure

- Carefully manage purse-string sutures to maintain effective hemostasis during introducer removal
- Consider fast pacing (120-140 bpm) or pharmacologic agent to reduce systolic blood pressure below 100 mm Hg

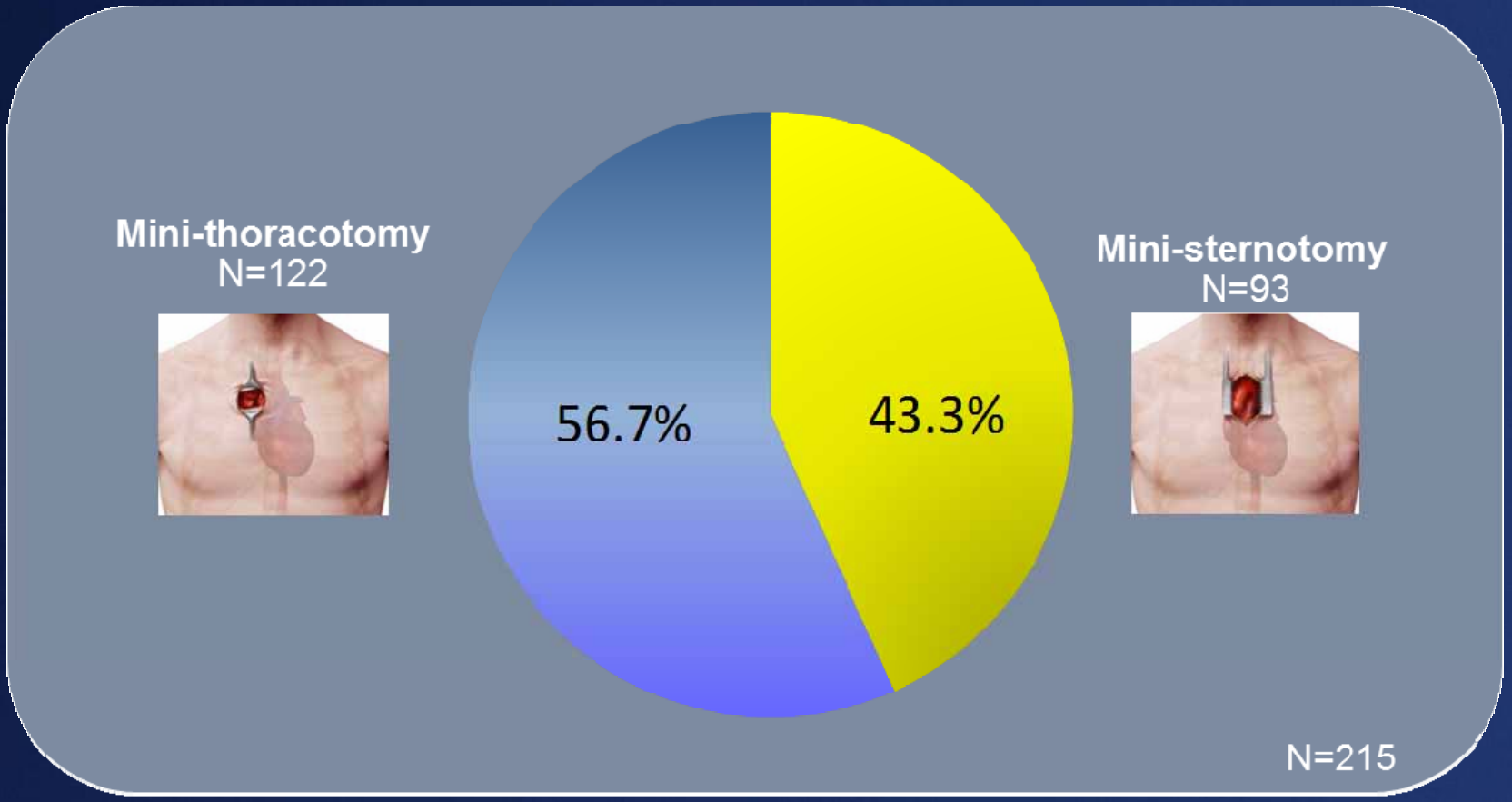




Courtesy of Dr. Giuseppe Bruschi

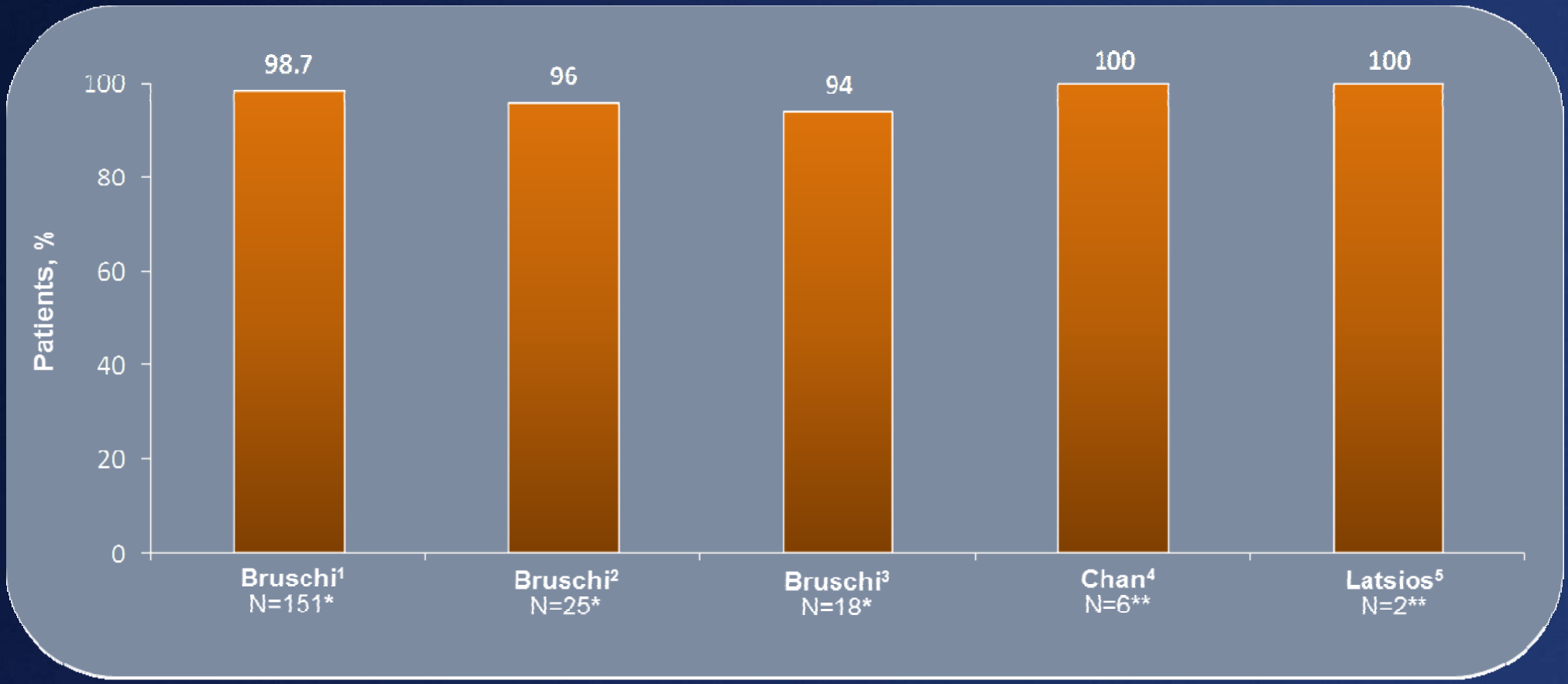
Medtronic CoreValve® System
Direct Aortic Approach
Summary of CoreValve Clinical Experience

Access Approach
Direct Aortic



[1] Bruschi G, Jahangiri M, Trivedi U, et al. EACTS 2012; [2] Bruschi G, De Marco F, Botto L, et al. STS 2012; [3] Brushi G, De Marco F, Botta L, et al. JACC. 2011; 58: b208-209; [4] Chan HP, DiMario C, Davies SW, et al. *European Heart Journal* . August 2011; 32 suppl 1: 895; [5] Latsios G, Gerckens U, Grube E. *Catheterization & Cardiovascular Interventions*. 2010;75:1129-1136; [6] Cockburn J, Trivedi U, Hildick-Smith D. *Catheterization & Cardiovascular Interventions*. 2011;dio: 10.1002/ccd.23044; [7] van der Lienden BTG, Swinkels BM, Heijman RH et al. JACC: *Cardiovascular Innervations*. 2011;4(9):1049-1050; [8] Danenberg H, Elami A, Rudis E, et al. Presented at: 58th Annual Conference of Israel Heart Society; May 4-5, 2011; Tel-Aviv, Israel; [9] Bauernschmitt R, Schreiber C, Bleiziffer S, et al. The Heart Surgery Forum. 2009.

Procedural Success
Direct Aortic



*** Procedural Success defined as adequate placement and normal performance of bioprostheses, and survival of implantation**
**** Procedural Success defined as technical success of the procedure**

Initial Experiences (one case) reported 100% procedural success for their one patient:
Cockburn, van der Lienden, Danenberg, and Bauernschmitt

.

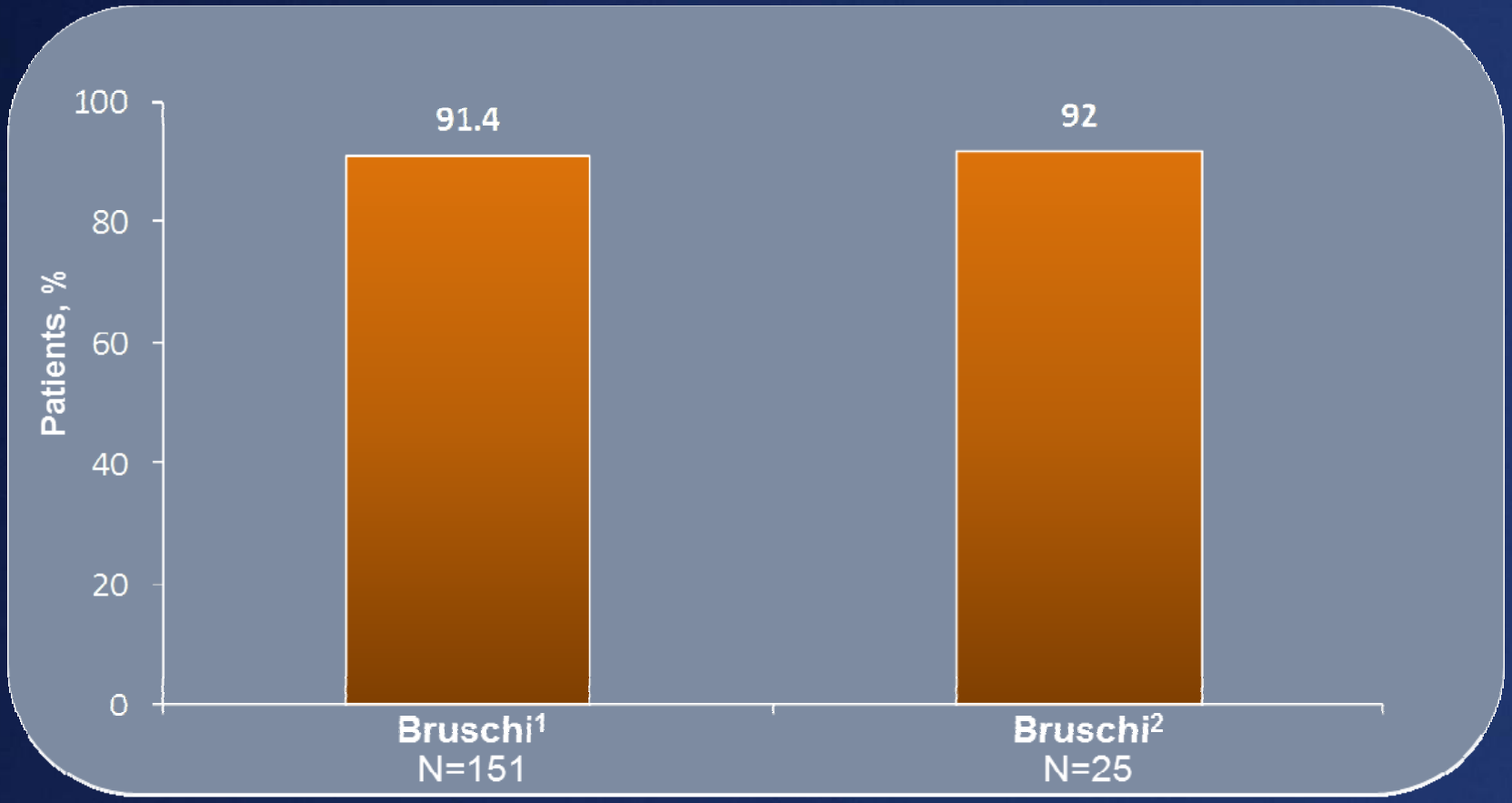
[1] Bruschi G, Jahangiri M, Trivedi U, et al. EACTS 2012; [2] Bruschi G, De Marco F, Botto L, et al. STS 2012; [3] Brushi G, De Marco F, Botta L, et al. JACC. 2011; 58: b208-209; [4] Chan HP, DiMario C, Davies SW, et al. *European Heart Journal* . August 2011; 32 suppl 1: 895; [5] Latsios G, Gerckens U, Grube E. *Catheterization & Cardiovascular Interventions*. 2010;75:1129-1136

Procedural Results
Direct Aortic

	Bruschi[1] N=151	Bruschi[2] N=25	Bruschi[3] N=18	Chan[4] N=6	Latsios[5] N=2	Cockburn[6] N=1	van der Lienden[7] N=1	Danen-berg[8] N=1	Bauern-schmitt[9] N=1
Stroke, %	3.3	0	0	NR	0	NR	NR	NR	NR
Pacemaker Implantation %	13.9	16	16	NR	50	0	0	0	NR
Vascular Complications %	3.3	0	NR	0	0	0	0	0	NR
Second CoreValve Implanted, %	1	NR	0	0	0	0	0	0	0

[1] Bruschi G, Jahangiri M, Trivedi U, et al. EACTS 2012; [2] Bruschi G, De Marco F, Botto L, et al. STS 2012; [3] Brushi G, De Marco F, Botta L, et al. JACC. 2011; 58: b208-209; [4] Chan HP, DiMario C, Davies SW, et al. *European Heart Journal* . August 2011; 32 suppl 1: 895; [5] Latsios G, Gerckens U, Grube E. *Catheterization & Cardiovascular Interventions*. 2010;75:1129-1136; [6] Cockburn J, Trivedi U, Hildick-Smith D. *Catheterization & Cardiovascular Interventions*. 2011;dio: 10.1002/ccd.23044; [7] van der Lienden BTG, Swinkels BM, Heijman RH et al. JACC: *Cardiovascular Innervations*. 2011;4(9):1049-1050; [8] Danenberg H, Elami A, Rudis E, et al. Presented at: 58th Annual Conference of Israel Heart Society; May 4-5, 2011; Tel-Aviv, Israel; [9] Bauernschmitt R, Schreiber C, Bleiziffer S, et al. The Heart Surgery Forum. 2009.

30-day Survival
Direct Aortic

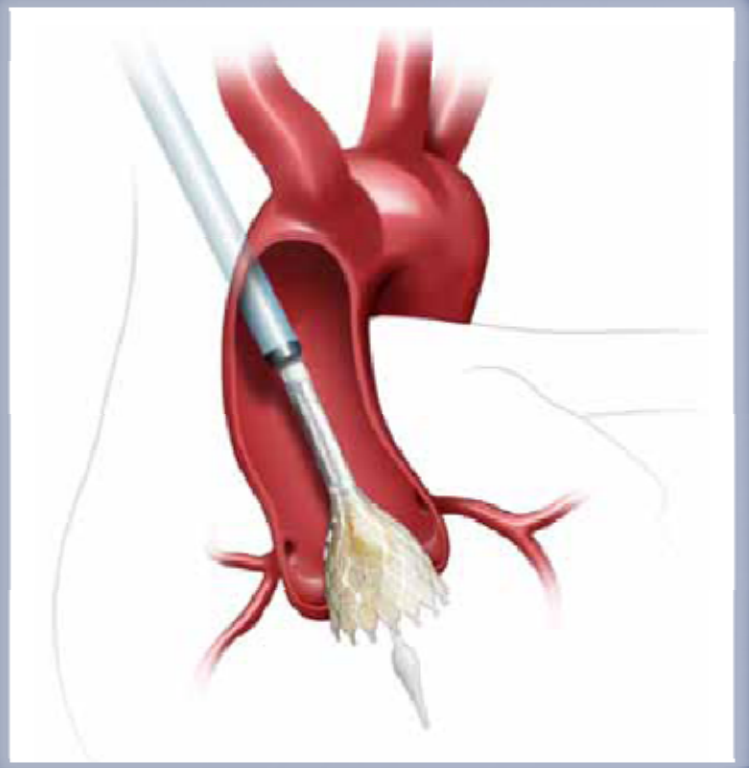


[1] Bruschi G, Jahangiri M, Trivedi U, et al. EACTS 2012; [2] Bruschi G, De Marco F, Botto L, et al. STS 2012

Bruschi[1] and Bruschi[2] are the only published literature reporting 30-day Survival data to date.

Direct Aortic TAVI: Summary

- Direct Aortic is a familiar approach providing more patients access to transcatheter aortic valve implantation
- No direct heart muscle manipulation required
- CoreValve uses a proven retrograde delivery system with consistent valve loading process for direct aortic procedures



Thank you very much!

References

1. J Brushi G, De Marco F, Fratto P, Oreglia J, Colombo P, Botta L, Klugmann S, Martinelli L. *Alternative approaches for trans-catheter self-expanding aortic bioprosthetic valves implantation: single-center experience*. Euro J Cardio-Thoracic Surg. 2011; 39: e151-e158.

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3. Latsios G, Gerckens U, Grube E. "Transortic Transcatheter Aortic Valve Implantation: A Novel Approach for the Truly No-Access Option Patients." Catheterization and Cardiovascular Interventions. 2010;75:1129-36.

4. Etienne PY, Papadatos S, Khoury E, Pieters D, Price J, Glineur D. "Transoartic Transcatheter Aortic Valve Implantation With the Edwards Sapien Valve: Feasibility, Technical Considerations, and Clinical Advantages." Ann Thorac Surg. 2011;92:746-8.

5. Bruschi et. Al. "Direct aortic access through right minithoracotomy for implantation of self-expanding aortic bioprosthetic valves." J Thoracic and Cardiovascular Surgery. 140, 715-16. September 2010

6. Romano M et. al. "Transaortic aortic valve implantation using the Edwards Sapien valve for patients with no optional artery access. A promising alternative approach." Presented at PCR London Valve 2011. October 18 2011.

7. Moat N et. al. "European Experience of Direct Aortic TAVI With a Self-Expanding Prosthesis." Presented at STS. January 30, 2012.