Emerging Issues



New Era of Impella 5.5 in Korea

Jae-Seung Jung, MD, PhD

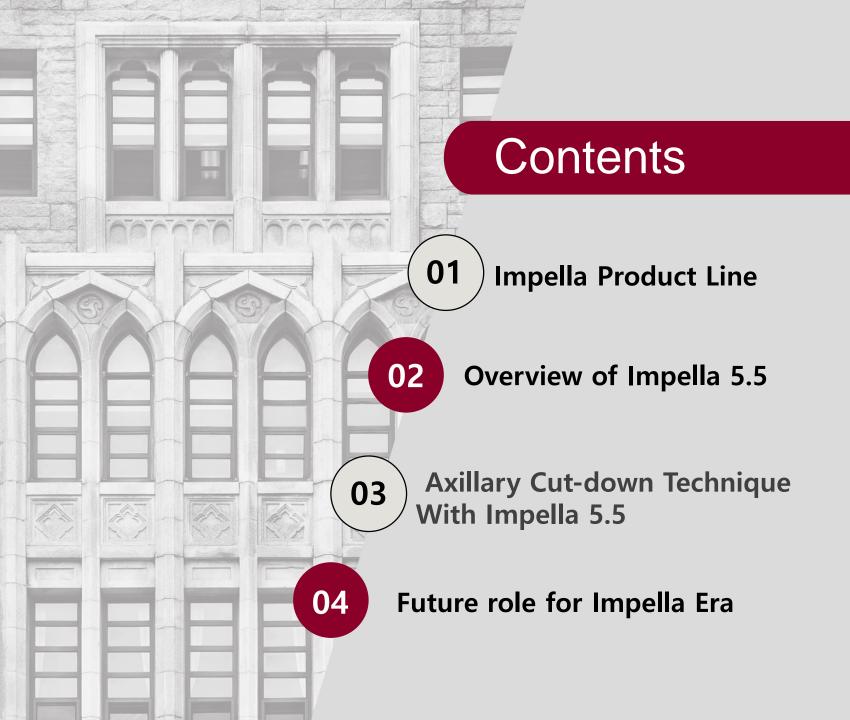
Professor

Depart of Thoracic and Cardiovascular Surgery, Director of ECMO team Director of Bloodless Medicine and Surgery Center Anam-Hospital, Korea University Medicine

ENABLING FUTURE MEDICINE



No disclosure



Impella Product ()1line



Confidential - Restricted use only. Do not distribute.

ABIOMED Product lines

Abiomed is committed to leading in technology and innovation, and improving patient outcomes by developing smaller, smarter and more connected technology

Impella Heart Pumps	2.5	Impella CP (with SmartAssist)	Impella 5	Impella LD	Impella 5.5 (with SmartAssist)	Impella RP (with SmartAssist)	Abiomed Breethe Oxy-1 system
Pics					L	$\left\langle \right\rangle$	- 17-0 - 17-0
Indications	HRPCI & CS	HRPCI & CS	CS	CS	CS	RHF or decompensation	
Access	Percutaneous femoral or Axillary	Percutaneous femoral or Axillary	Femoral cutdown or Axillary	Direct insertion into AA	Axillary cutdown or Direct insertion into AA	Percutaneous femoral Vein(to PA)	
Maximum average flow (I/min)	2.5	4.3 (Maximum mean 3.7L/min)	5	5.3	5.5	4.4	A portable external res piratory assistance de
Fr	12Fr	14Fr	21Fr		23Fr	23Fr	vice in patients with C S, Respiratory Failure(2
Speed		0 – 46,000 rpm	0 – 33,000 rpm	0 – 33,000 rpm	0 – 33,000 rpm		0'FDA clearance)
Maximum duration of support	HRPCI : ≤6hrs CS : ≤4days	HRPCI : ≤6hrs CS:≤4days (FDA) CS:≤5days (CE)	14 days	14 days	14 days(FDA) 29 days(CE)	l4 days	

J&J MedTech *Ref. ABIOMED Website



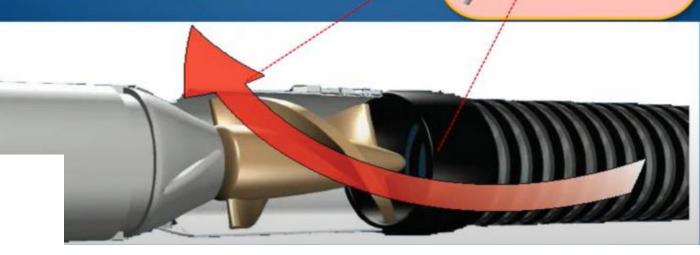
MOVING THE BLOOD

Rotating impeller pulls blood through the cannula

Automated Impella Controller controls how fast the impeller rotates

Rotation speed is proportional to flow:

Faster rotation = Higher flow





Meta-analyses (Impella vs. IABP)

Study	Studies (N)	Patients (N)	Impella versus IABP		
Ouweneel <i>et al²¹</i> JACC 2017	3 ^{10–12}	95	 No difference in 30-day mortality (RR 0.99, 95% CI 0.62 to 1.58, p=0.95) or 6-month mortality (RR 1.15, 95% CI 0.74 to 1.48, p=0.53) 		
Wemly <i>et al</i> ²⁴ Clin Res Cardiol 2019	4 ^{10 11 22 23}	588	 No difference in in-hospital or 30-day mortality (RR 0.84, 95% CI 0.57 to 1.24, p=0.38) No difference in stroke risk (RR 1.00, 95% CI 0.36 to 2.81, p=1.00) Major bleeding increased in Impella group (RR 3.11, 95% CI 1.50 to 6.44, p=0.002) Peripheral ischaemia complications increased in Impella group (RR 2.58, 95% CI 1.24 to 5.34, p=0.01) 		

- IABP에 비해 survival benefit이 없음.....
- 오히려 Bleeding risk, peripheral ischemia complication 증가

McGovern L. Heart 2021;0:1–6.



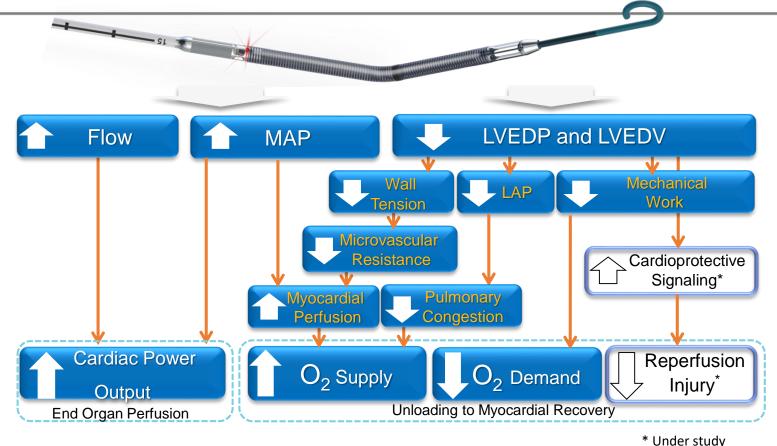
Impella platform

	Impella 2.5	Impella CP		
Access technique	Percutaneous	Percutaneous		
Access artery	Femoral artery	Femoral artery		
Output (max)	2.5 L/min	4.3 L/min		
Catheter diameter	9F	9F		
Motor pump size	12F	14F		
	Impella 5.0/ LD	Impella 5.5		
	Surgical	Surgical		
	Axillary or femoral artery	Axillary or femor	al artery	Or Ascending Aort
	5.0 L/min	6.0 L/min	,	with sternot
	9F	9F		
Impella RP	21F	19F		
Percutaneous				
Femoral vein				
4.0 L/min				
11F				
22F				

McGovern L. Heart 2021;0:1-6.



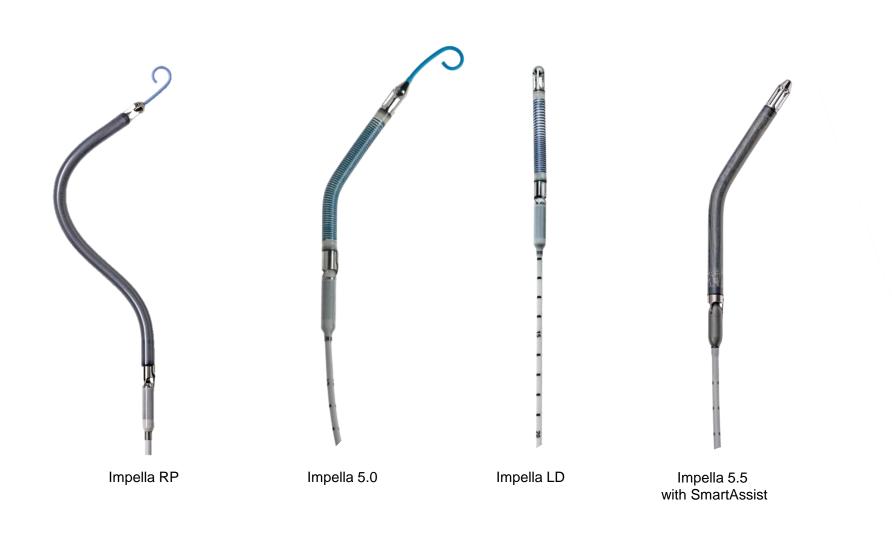
Hemodynamic Effects of Impella Devices



Fincke J, et al. J Am Coll Cardiol 2004 den Uil CA, et al. Eur Heart J 2010 Mendoza DD, et al. AMJ 2007 Torgersen C, et al. Crit Care 2009 Torre-Amione G, et al. J Card Fail 2009 Suga H. et al. Am J Physiol 1979 Suga H, et al. Am J Physiol 1981 Burkhoff D. et al. Am J Physiol Heart Circ 2005 Burkhoff D. et al. Mechanical Properties Of The Heart And Its Interact ion With The Vascular System. (White Paper) 2011 Sauren LDC, et al. Artif Organs 2007 Meyns B, et al. J Am Coll Cardiol 2003 Remmelink M, et al. Catheter Cardiovasc Interv 2007 Aqel RA, et al. J Nucl Cardiol 2009 Lam K_v, et al. Clin Res Cardiol 2009 Reesink KD, et al. Chest 2004 Esposito M, et al JACC 2018 Remmelink M. et al. Catheter Cardiovasc Interv 2010 Naidu S. et al. Novel Circulation.2011 Weber DM, et al. Cardiac Interventions Today Supplement Aug/Sep 2009



IMPELLA SURGICAL SUITE OF PRODUCTS







Improved clinical outcomes associated with the Impella 5.5 compared to the Impella 5.0 in contemporary cardiogenic shock and heart failure patients

Danny Ramzy, MD, PhD,^a Edward G. Soltesz, MD, MPH,^b Scott Silvestry, MD,^c Mani Daneshmand, MD,^d Manreet Kanwar, MD,^e and David A. D'Alessandro, MD^f



J Heart Lung Transplant 2023;42:553–557



	AMICS		Car	diomyopathy		PCCS			
	Impella 5.5 (N=156)	Impella 5.0 (N=278)	p-value	Impella 5.5 (N=270)	Impella 5.0 (N=225)	p-value	Impella 5.5 (N=117)	Impella 5.0 (N = 88)	p-value
Successfully weaned or bridged to heart replacement therapy	110/156 (70.5)	158/278 (56.8)	0.005	238/270 (88.1)	173/225 (76.9)	0.001	89/117 (76.1)	49/88 (55.7)	0.003
Successfully weaned	78/156 (50.0)	118/278 (42.4)	0.133	91/270 (33.7)	79/225 (35.1)	0.776	82/117 (70.1)	46/88 (52.3)	0.013
Bridged to therapy	32/156 (20.5)	40/278 (14.4)	0.108	147/270 (54.4)	94/225 (41.8)	< 0.001	7/117 (6.0)	3/88 (3.4)	0.521
Expired on support or withdrawal of care	46/156 (29.5)	120/278 (43.2)	0.005	32/270 (11.9)	52/225 (23.1)	0.001	28/117 (23.9)	39/88 (44.3)	0.003
Expired on support	21/156 (13.5)	58/278 (20.9)	0.069	10/270 (3.7)	15/225 (6.7)	0.152	13/117 (11.1)	27/88 (30.7)	< 0.001
Withdrawal of care	25/156 (16.0)	62/278 (22.3)	0.134	22/270 (8.1)	37/225 (16.4)	0.005	15/117 (12.8)	12/88 (13.6)	>0.99
Hemolysis	5/156 (3.2)	10/278 (3.6)	>0.99	8/270 (3.0)	21/225 (9.3)	0.003	2/117 (1.7)	1/88 (1.1)	>0.99
CVA	5/156 (3.2)	3/278 (1.1)	0.143	6/270 (2.2)	2/225 (0.9)	0.301	2/117 (1.7)	1/88 (1.1)	>0.99
Bleeding	1/156 (0.6)	5/278 (1.8)	0.426	3/270 (1.1)	5/225 (2.2)	0.478	3/117 (2.6)	6/88 (6.8)	0.177
Vascular injury	1/156 (0.6)	0/278 (0.0)	0.359	0/270 (0.0)	1/225 (0.4)	0.455	0/117 (0.0)	0/88 (0.0)	>0.99
Duration of support, days									
Mean \pm SD (N)	13.2 ± 20.2 (156)	8.7 ± 9.5 (278)	0.008	15.1 ± 13.4 (270)	11.4 ± 10.6 (225)	< 0.001	10.2 ± 23.5 (117)	6.6 ± 8.3 (88)	0.127
Median (range)	9.2 (0.04-233.3)	6.1 (0.01-87.1)		10.7 (0.03-71.1)	8.1 (0.3-64.1)		6.0 (0.0007-245.9)	4.4 (0.02-49.2)	

Table 2 Clinical Outcomes through Device Explant in AMICS, Cardiomyopathy, and PCCS Patients Treated with the Impella 5.5 or 5.0

모든 군에서 Impella 5.5가 5.0에 비해 평균 4일을 더 유지 모든군에서 생존율이 유의하게 Impella 5.5 군이 우수



Impella - SmarAssist[®]



 Real-time displays of critical hemodynamic metrics indicative of left ventricular end-diastolic pressure (LVEDP), mean arterial pressure (MAP), and cardiac power output (CPO). Impella CP with SmartAssist is the only mechanical circulatory support device that calculates and displays pressure signals indicative of LVEDP, MAP and CPO.



SMARTASSIST[®] HEMODYNAMIC SENSORS

Intelligent pump metrics¹ on console to position, manage, wean

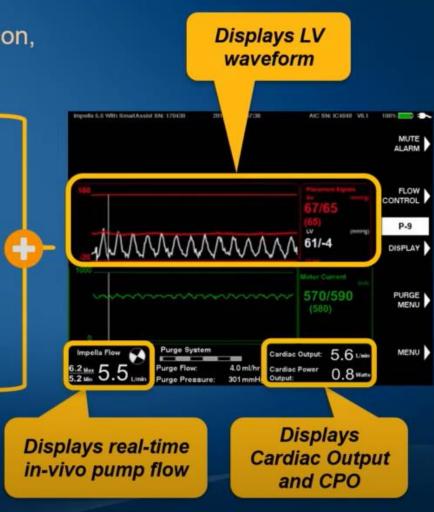


Optical Sensor

Senses Aortic pressure (Ao)

Micro-axial motor

Senses pressure difference between Aorta and Left Ventricle





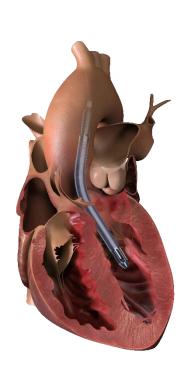
Overview of ()Impella 5.5

Impella 5.5 with SmartAssist Comparison

Feature	Impella 5.0	Impella 5.5 with SmartAssist	Benefit	
Flow	5.0 L/min	5.5 L/min	Full Hemodynamic Support	
Catheter Length	135cm	70cm* *55cm implantable length	Ambulation	
Catheter Construction	Nitinol Wire	Steel Coil	Kink Resistance	
Cannula Rigidity	-	3.5x More Rigid	Deliverability & Torque Resp onse	
Cannula Diameter	21Fr	21Fr	Maintains High Flow	
Motor Diameter	21Fr	19Fr	Deliverability	
Rigid Length (Motor Housing & Outlet)	42mm	27mm	Deliverability	
Motor Bearings	Motor Bearings Stainless Steel		Durability	
Pigtail	Yes	No	Torque Response; in-dwell without adhesion	
Sensor	Differential Pressure	Fiber-Optic	Placement Accuracy	



Hemodynamic Stabilization with Impella Devices



Unloads Left Ventricle

& Coronary Perfusion

Seyfarth et al., JACC, 2008 Remmelink M et al., Cath Card Interv. 2007



Lam K. et al,. Clin Res Cardiol, 2009 Casassus et a., JOIC, 2015

Anderson MB. et al., J Ht Lg Transplant. 2015

Right Side

Support

Escalation & Ambulation



Lima B. et al., Am J Cardiol 2016



ADVANTAGES OF IMPELLA 5.5

- Full hemodynamic support –peak flows >6.2L/min
- Incorporates Impella SmartAssist Technology
- Ease of implantation
 - Axillary or Direct
 - Early ambulation



IMPELLA 5.5 WITH SMARTASSIST

Minimally invasive heart pump that delivers full support, allowing the heart to rest; enabling heart recovery



The Surgeon's Heart Pump

Ease of insertion via the axillary artery or the anterior aorta

Full Support with Maximum Unloading Reduces the heart's oxygen demand and workload

Forward Flow

Provides the patient with coronary and end organ perfusion

Minimally Invasive

Eliminates the need for a sternotomy or coring of the left ventricle

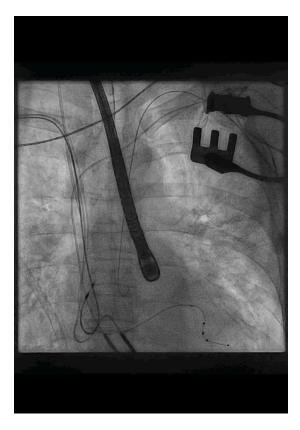
Equipped with SmartAssist

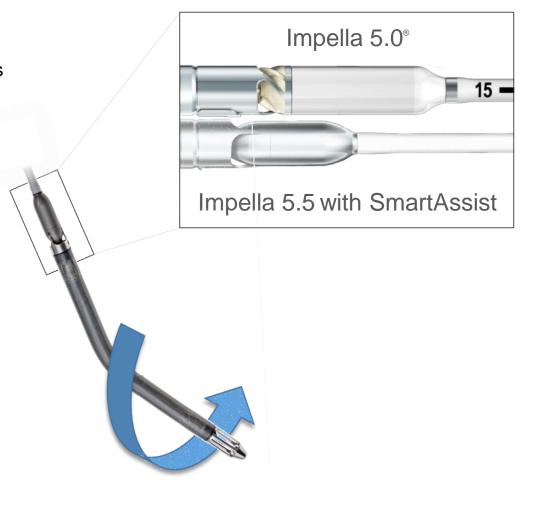
Designed to optimize survival and native heart recovery



IMPROVED DELIVERABILITY AND TORQUE RESPONSE

- Ease of insertion
- Torque response
- Long duration support without adhesions





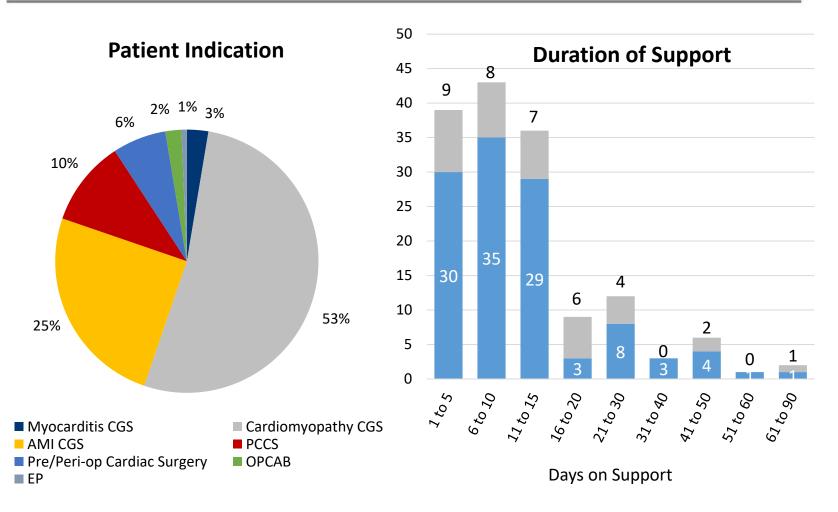


^{oo}ABIOMED[®]

Recovering hearts. Saving lives.



EARLY EXPERIENCE



■ Completed ■ On Support

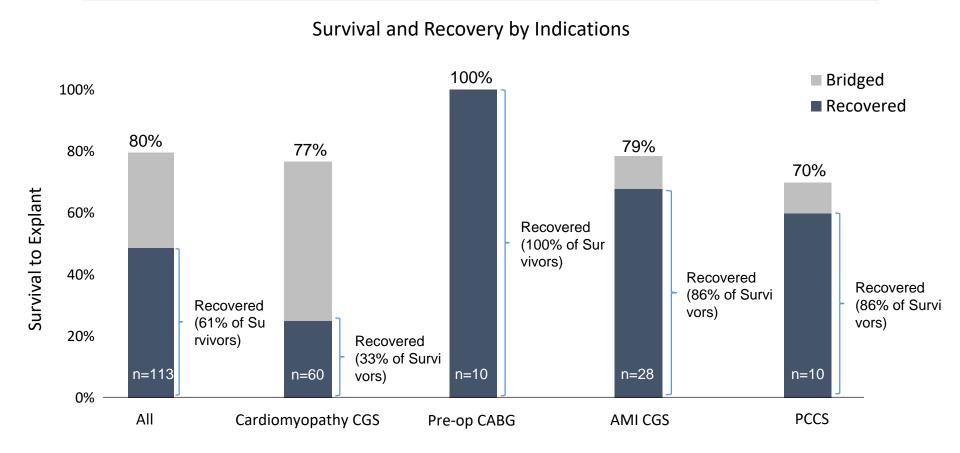


IMPELLA 5.5 EARLY EXPERIENCE SUMMARY

Survival and Recovery by Indications 100% 83% 80% 80% Bridged 77% Recovered Survival to Explant 60% Recovered 40% (91% of Survi vors) Recovered (61% of Su 20% rvivors) Recovered (33% of Survi n=113 n=60 vors) n=53 0% All Cardiomyopathy CGS Recoverable



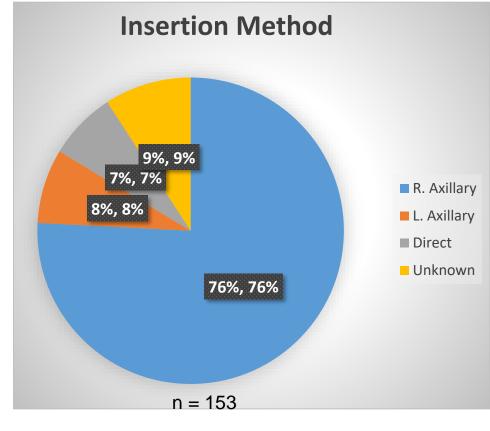
IMPELLA 5.5 EARLY EXPERIENCE SUMMARY





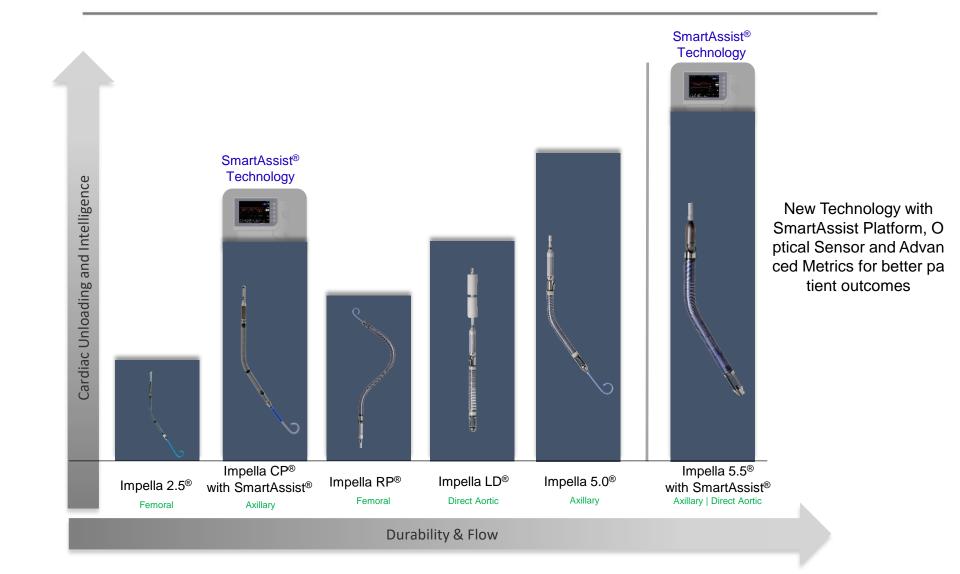
Impella 5.5 Site Access

- Right Axillary Artery: 76%
- Left Axillary Artery: 8%
- Anterior Aortic Root (Open Chest): 7%
- Multiple sub- 7mm axillary arteries successfully impla nted





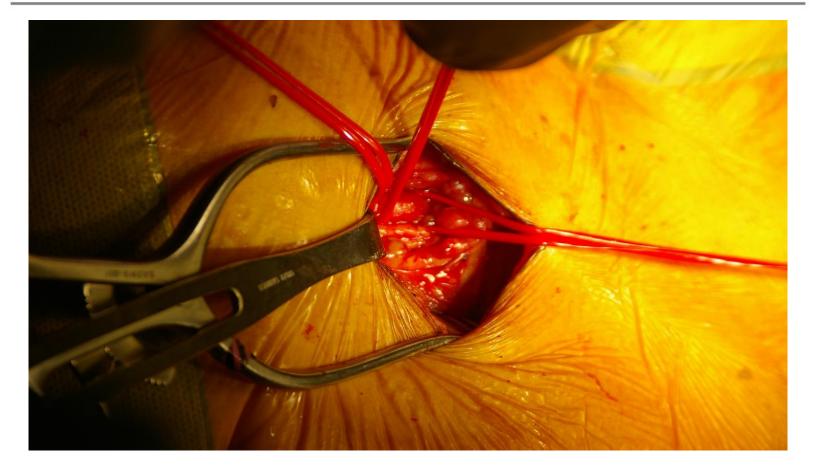
INNOVATION DESIGNED FOR HEART SURGEONS



Axillary Cut-Down UB **Technique With** Impella 5.5

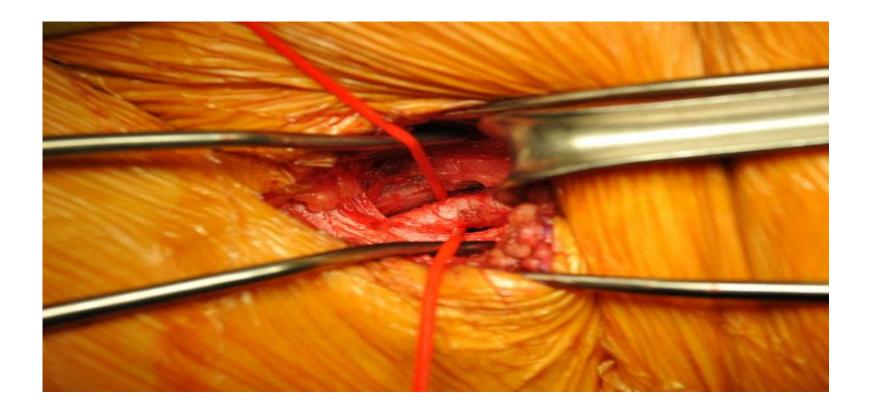


Dissecting out the Axillary Artery



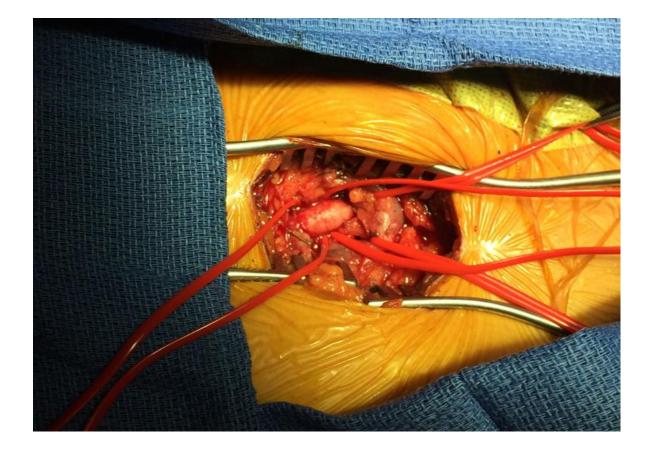


Exposing the Axillary Artery



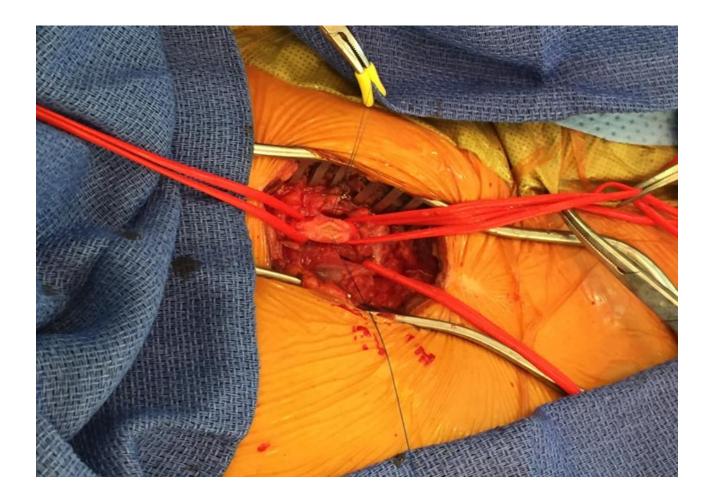








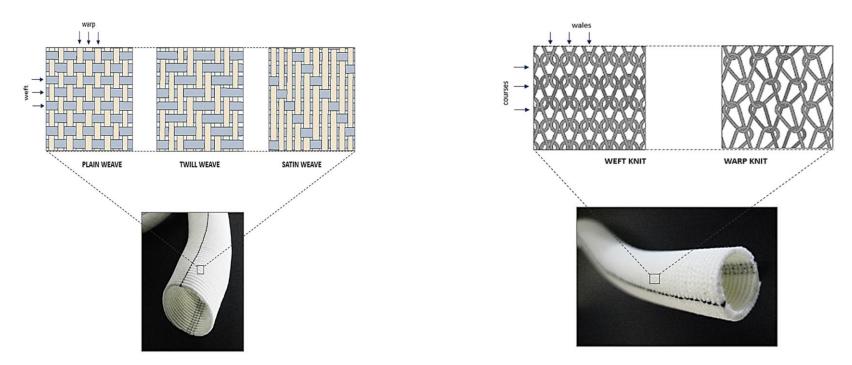
Arteriotomy





Choice of Dacron Graft

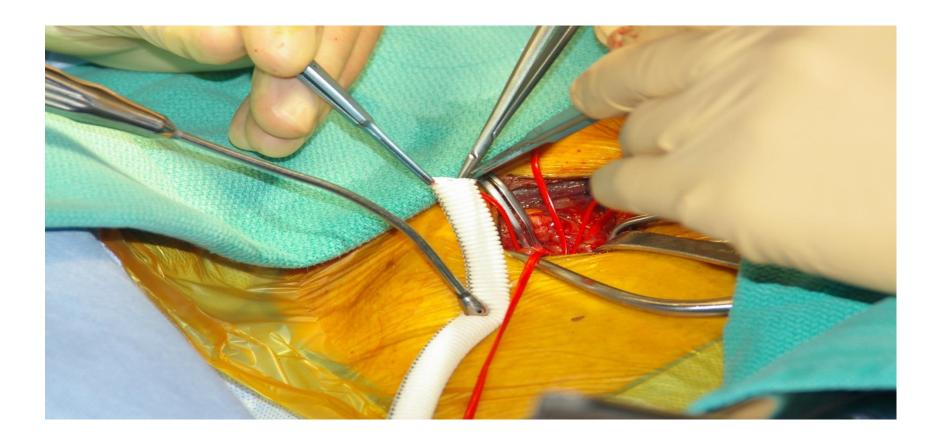
Woven – Nonporous/Doesn't Leak



10mm Woven DACRON graft is our recommendation. Hemashield platinum or Vascutek GelWeave. K nitted grafts, while cheaper, are more porous and will leak. In axillary arteries < 7mm, a 6mm graft may be utilized for Impella CP[®] insertion

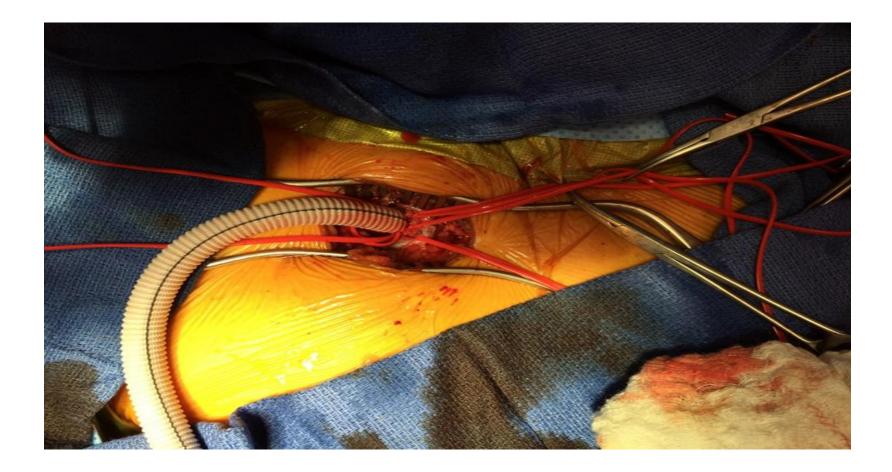


Preparing the Graft



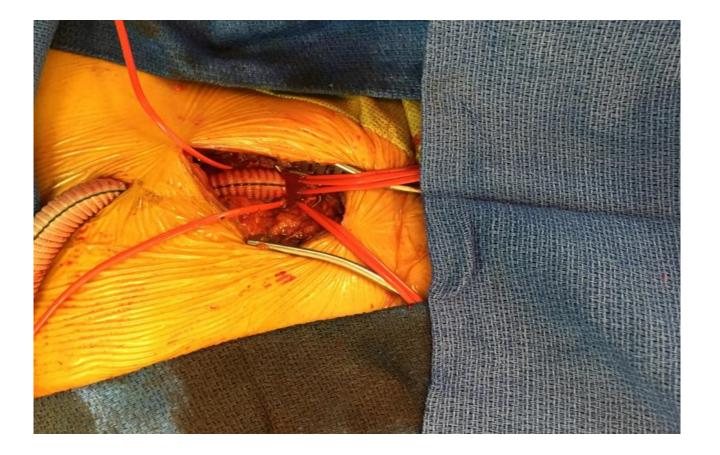


"End to Side" Anastomosis



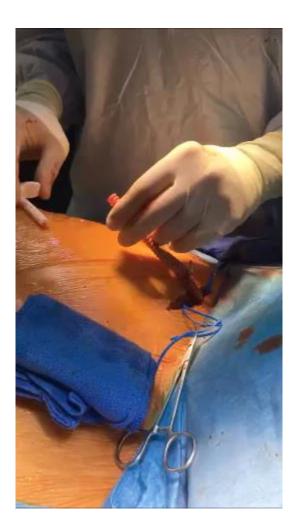


Short Lateral Tunnel



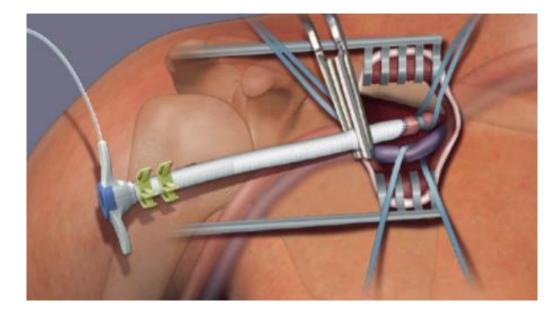


INSERTION OF THE 23FR AXILLARY SHEATH



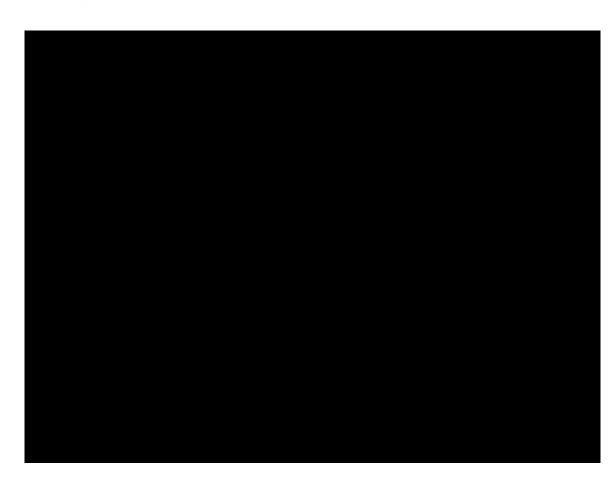


Insertion of the 23Fr Axillary Sheath





Insertion of the Impella 5.5° with Fluoroscopic Control

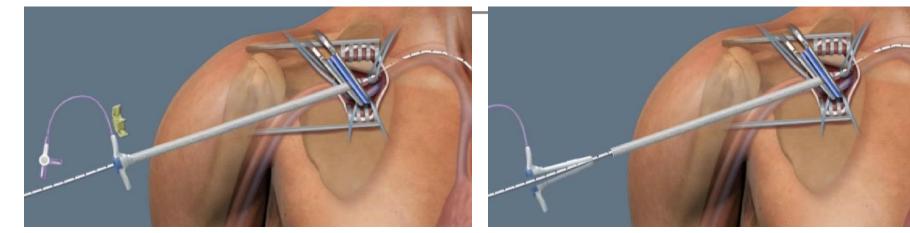


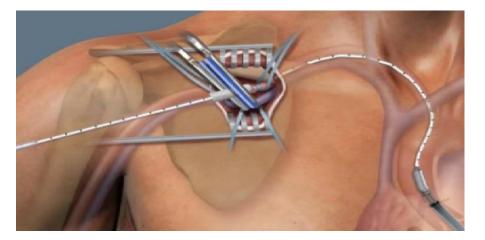


Note the use of a vascular clamp on the graft above the anastomosis during insertion through the valve to eliminate bleeding



Trimming the Graft







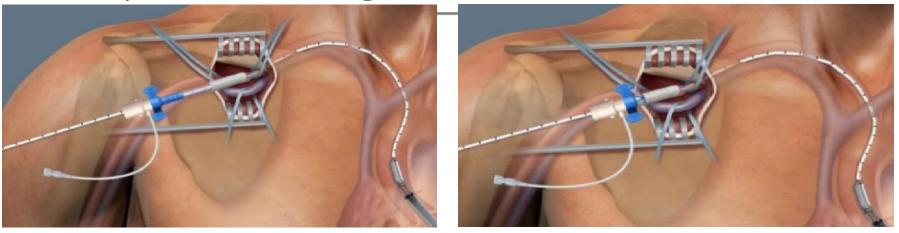
TRIMMING THE GRAFT



- "Potts Ties" on the vessel loops are tightened with excellent hemostasis
- The peel away sheath is removed after releasing the clamps
- The graft is trimmed to approximately 4cm
- Note that the assistant is providing digital control but the hemostasis is excellent with the vessel loops



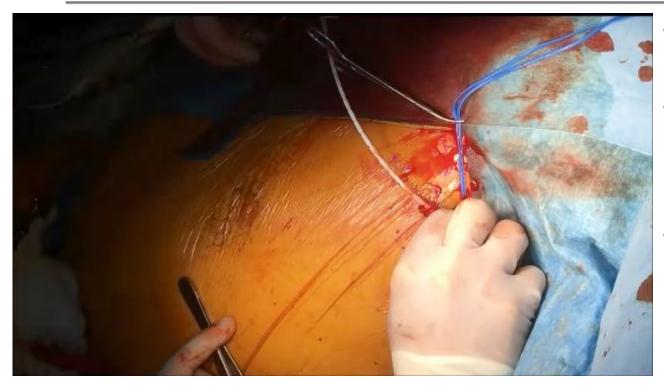
Repositioning Sheath







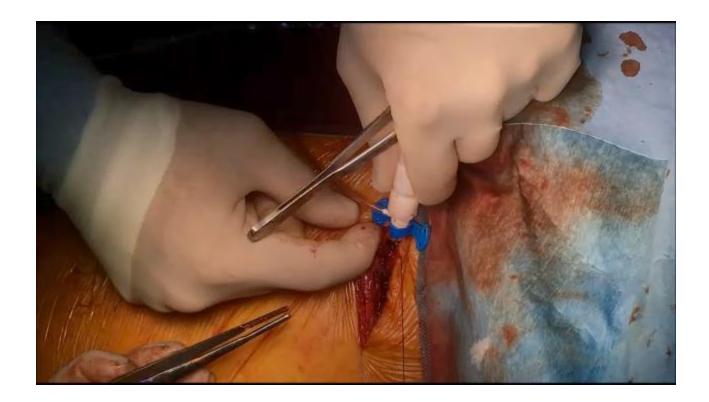
REPOSITIONING SHEATH



- The repositioning sheath
 is carefully advanced into
 the axillary artery
- Care is taken to assure that no movement is applied to the Impella[®] catheter using fluoroscopic control
- The end of the graft is secured to the suture rib on the blue butterfly hub with two heavy silk ties



INCISION CLOSURE



Note the care taken to remove excessive graft material avoiding any exposed graft



Final Incision Closure



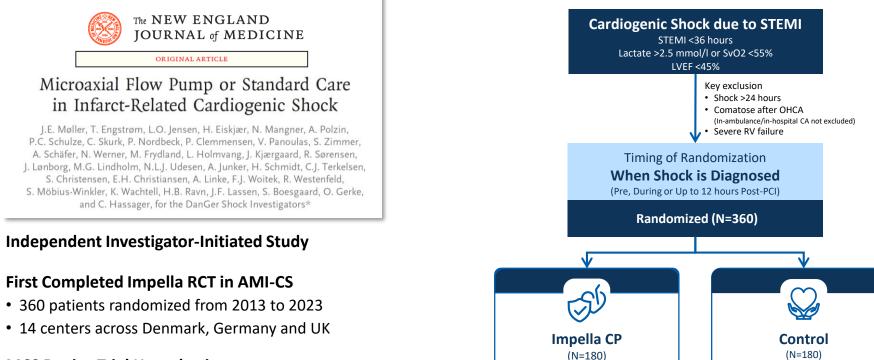
Future role for ECMO and Cardiac Surgeon in Impella Era

OBECOBECOBECCEEEE



DanGer Shock

DanGer Shock RCT



MCS Device Trial Hypothesis

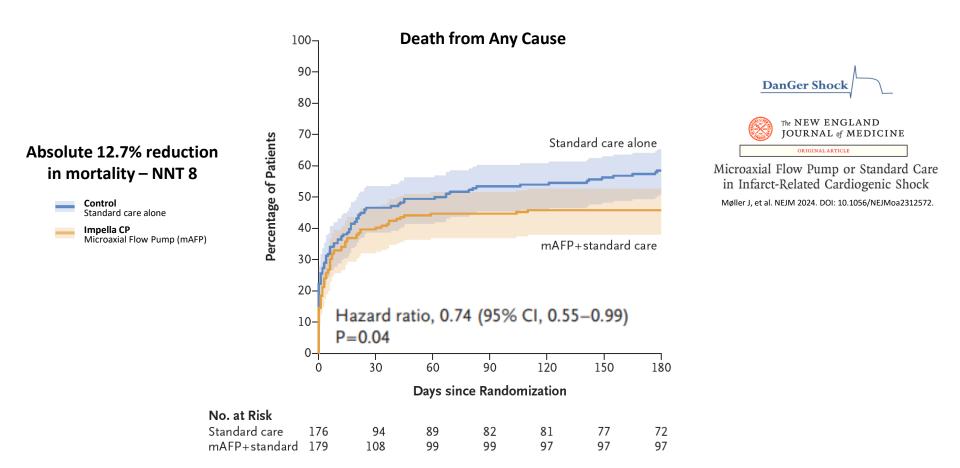
Routine Impella CP use reduces mortality in AMI-CS due to STEMI



Møller J, et al. Microaxial Flow Pump or Standard Care in Infarct-Related CS. N Engl J Med 2024. DOI: 10.1056/NEJMoa2312572.



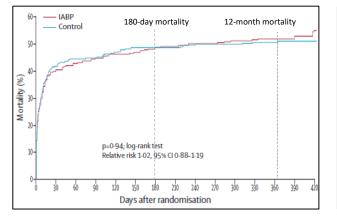
Routine Use of Impella Reduces All-Cause Mortality at 180 Days in AMI Cardiogenic Shock due to STEMI Compared to Standard Care Alone





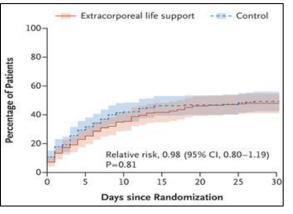
Impella is The Only MCS Shown to Improve Survival in MCS Device Trials in AMI Cardiogenic Shock Patients

IABP Shock II^{1,2}



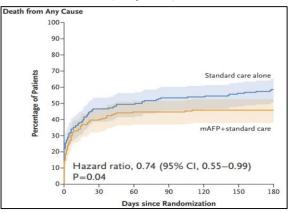
No Difference in 30-Day Mortality (p=0.69) **No Difference** in 1-Year Mortality (p=0.91)

ECLS Shock (ECMO)³



No Difference in 30-Day Mortality (p=0.81)

DanGer Shock (Impella)⁴



12.7% Absolute Reduction in 180-Day Mortality (p=0.04)

DanGer Shock

Data presented on this slide to put results from various MSC studies into perspective, and are not intended to imply a direct comparison among the studies.

- 1. Thiele H, et al. Intraaortic Balloon Support for Myocardial Infarction with Cardiogenic Shock. N Engl J Med 2012. DOI: 10.1056/NEJMoa1208410.
 - 2. Thiele H, et al. IABP-SHOCK II final 12 month results. Lancet 2013. DOI: 10.1016/S0140-6736(13)61783-3.

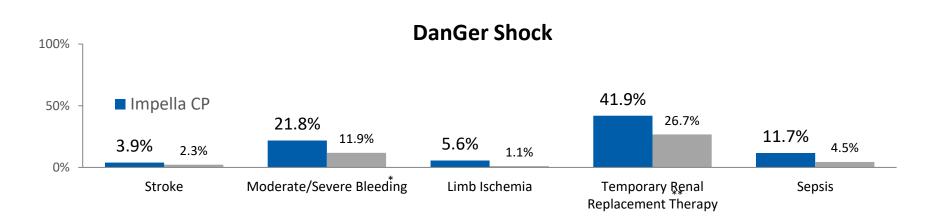
3. Thiele H, et al. Extracorporeal life support in infarct-related cardiogenic shock. N Engl J Med 2023. DOI: 10.1056/NEJMoa2307227.

4. Møller J, et al. Microaxial Flow Pump or Standard Care in Infarct-Related CS. N Engl J Med 2024. DOI: 10.1056/NEJMoa2312572.



DanGer Shock

Adverse Events Do Not Overshadow the Significant Reduced Mortality benefit in AMI Cardiogenic Shock Patients



Use of best practices including vascular and anticoagulation management could further optimize outcomes

- * Bleeding Rates: Control NO ECMO (3.5%), Control WITH ECMO (48.5%), Impella NO ECMO (15.8%), Impella WITH ECMO (67%).
- ** RRT: Only 3 (1.7%) patients remained in dialysis at >90 days in the Impella group and 1 (0.6%) in the control group.

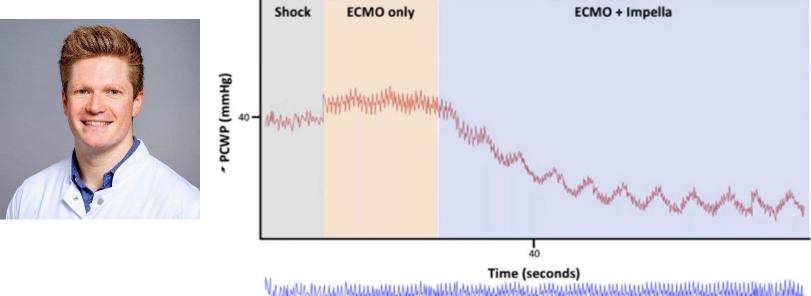
Møller J, et al. Microaxial Flow Pump or Standard Care in Infarct-Related CS. N Engl J Med 2024. DOI: 10.1056/NEJMoa2312572. * Data on file. ** CRT Virtual Spring 2024 April 14.

Unloading of the Left Ventricle During Venoarterial Extracorporeal Membrane Oxygenation Therapy in Cardiogenic Shock



LV unloading - Percutaneous

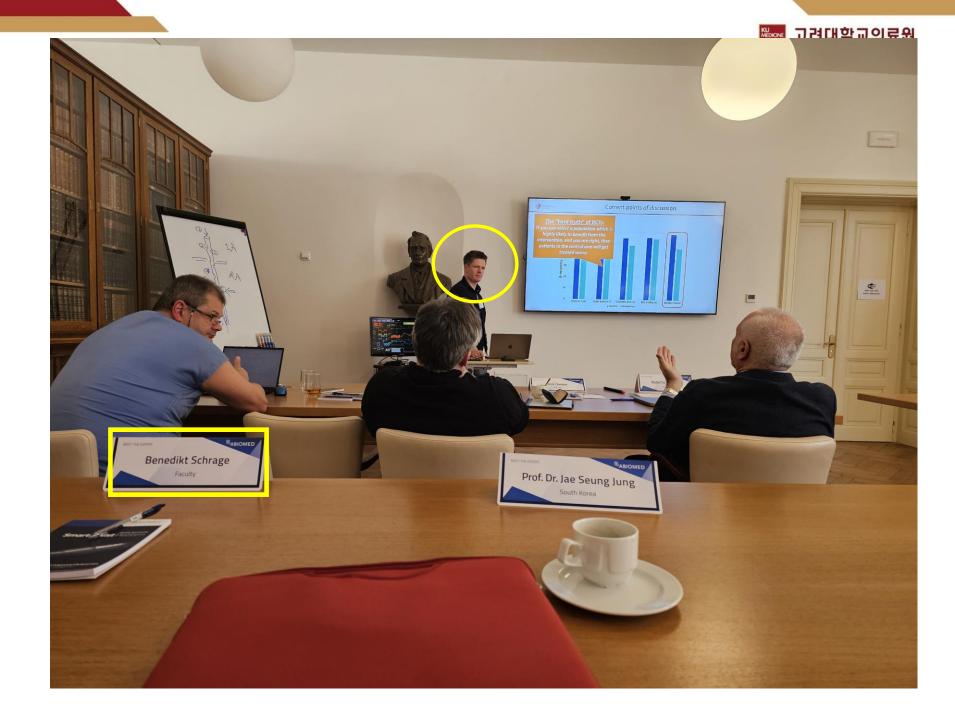
Benedikt Schrage, MD,^{a,b} Daniel Burkhoff, MD, PHD,^c Nicole Rübsamen, PHD,^a Peter Moritz Becher, MD,^a Michael Schwarzl, MD, PHD,^{a,b} Alexander Bernhardt, MD,^d Hanno Grahn, MD,^a Edith Lubos, MD,^a Gerold Söffker, MD,^e Peter Clemmensen, MD,^a Hermann Reichenspurner, MD, PHD,^d Stefan Blankenberg, MD, PHD,^{a,b} Dirk Westermann, MD, PHD^{a,b}



"ECPELLA" in the US and "ECMELLA" in Europe



Recovering hearts. Saving lives.





Universitäres Herz- und Gefäßzentrum UKE Hamburg

Unloading with Impella – Evolving evidence

Unloading in Cardiogenic Shock Masterclass | 23.04.2024 Benedikt Schrage, MD, PhD, FESC

Universitätsklinikum Hamburg-Eppendorf

Rationale of the DanGer-SHOCK trial

DanGer Shock

A summittee

Danish German Cardiogenic Shock trial

Randomized trial of Impella vs. SOC in STEMI-CS with reduced EF

Strict enrollment criteria (no prolonged cardiac arrest)

Strict SOPs for implementation and weaning of MCS (...maybe not so strict...)

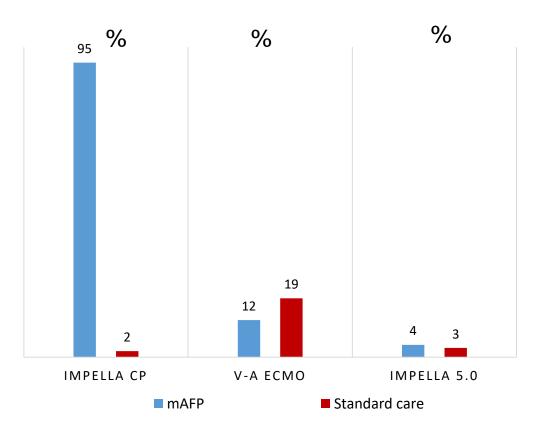


Table 3. End Points and Adverse Events in the Intention-to-Treat Population.*			
Event	Microaxial Flow Pump plus Standard Care (N = 179)	Standard Care Alone (N=176)	Effect Size (95% CI)†
Primary end point: death from any cause at 180 days — no. (%)	82 (45.8)	103 (58.5)	0.74 (0.55 to 0.99)‡
Secondary end point			
Composite cardiac end point — no. (%)§	94 (52.5)	112 (63.6)	0.72 (0.55 to 0.95)
No. of days alive and out of the hospital (range)¶	82 (0 to 177)	73 (0 to 179)	8 (-8 to 25)
Adverse events			
Composite safety end point — no. (%)	43 (24.0)	11 (6.2)	4.74 (2.36 to 9.55)
Moderate or severe bleeding — no. (%)**	39 (21.8)	21 (11.9)	2.06 (1.15 to 3.66)
Limb ischemia — no. (%)	10 (5.6)	2 (1.1)	5.15 (1.11 to 23.84)
Renal-replacement therapy — no. (%)	75 (41.9)	47 (26.7)	1.98 (1.27 to 3.09)
Stroke — no. (%)	7 (3.9)	4 (2.3)	1.75 (0.50 to 6.01)
Cardioversion after ventricular tachycardia or fibrillation — no. (%)	59 (33.0)	52 (29.5)	1.17 (0.75 to 1.83)
Sepsis with positive blood culture†† — no. (%)	21 (11.7)	8 (4.5)	2.79 (1.20 to 6.48)



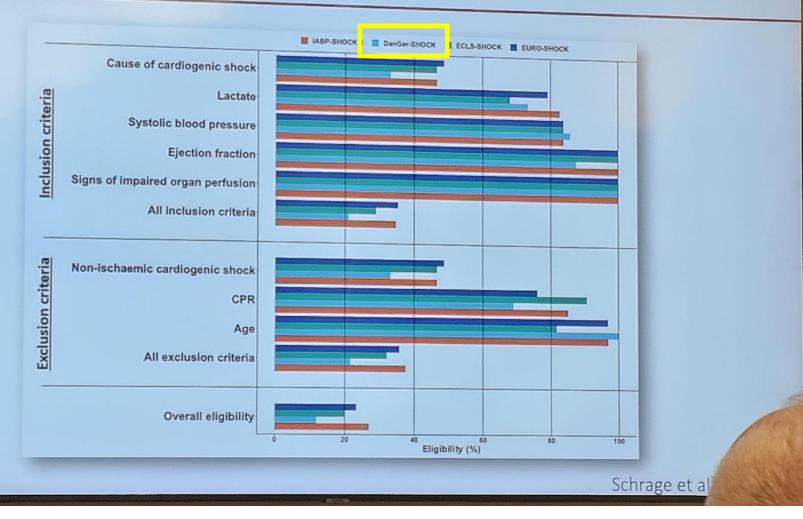








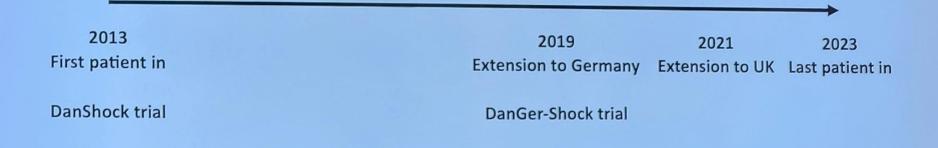
Generalization is the limitation of the DanGer-SHOCK trial





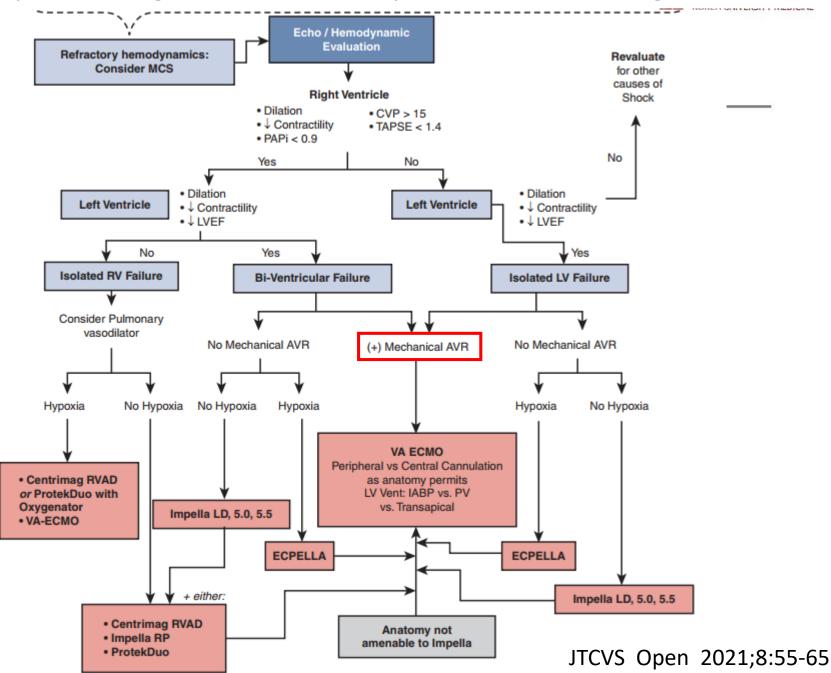
Universitäres Herz- und Gefäßzent UKE Hamburg

36 patients per year ~2 per center per year





Intraoperative algorithm of MCS in patients with cardiogenic shock





Summary

- Impella는 일단 희소의료기기로 심인성 쇼크의 적응증에 한해서 도 입될 가능성이 높다
- CP가 먼저 도입될 예정이고 5.5가 이어서 도입예정이나 가격이 관건
- CP는 hemolysis에 의해 합병증 발생 위험성이 높아 궁극적인 심장 보 조를 위해서는 cardiac surgeon에 의해 삽입되는 5.5가 필요하게 될 것으로 예상, 특히 postcardiotomy syndrome에서는 향후 ECMO보다 는 Impella 5.5가 더 많이 쓰이게 될 가능성이 높아보임
- ECPELLA를 비롯한 다양한 조합의 temporary MCS 구비하게 됨으로써 치료 선택의 폭이 높아지지 않을 까 하는 기대가 있다



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SmartAssist Platform

The latest innovation on the Impella platform integrates the trusted performance of the Impella heart pump with state-of-the-art SmartAssist technology. This next generation heart pump is designed to improve patient outcomes by using real-time intelligence to optimize positioning, managing and weaning of the Impella device for better patient care.



Impella 5.5° Heart Pump

Greater hemodynamic support and ease of use. New sensor technology allows for repositioning in the ICU without the need for imaging.*

Advanced Pump Metrics Intelligent nump metrics on the

Intelligent pump metrics on the Automated Impella Controller™ assist in positioning, managing and weaning the Impella device.

Impella Connect[®]

Cloud-based mobile view of the Impella device status for remote patient monitoring and collaborative patient management to optimize patient outcomes.

Thank you for your attention