Large Bore Percutaneous Arterial Closure: The Manta Closure Device

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Veith Symposium 2024

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Disclosures

- None

Percutaneous Large Bore Access Benefits

Mid-term follow-up of percutaneous access for standard and complex EVAR using the ProGlide device

N.A. Bradley [a,*], P. Orosvier [a], R. Bhat [b], S. Pal [a], S.A. Suttie [a], M.M. Flett [a], G.J.K. Guthrie [a]
[a] Department of Vascular Surgery, Ninewells Hospital, Dundee, UK
[b] Department of Interventional Radiology, Ninewells Hospital, Dundee, UK

Outcomes of total percutaneous endovascular aortic repair for thoracic, fenestrated, and branched endografts

Leonardo R. de Souza, MD,[a] Gustavo S. Oderich, MD,[a] Peter Y. Banga, MD,[a] Janet M. Hofer, BSN,[a] Jean R. Wigham, RN,[a] Stephen Cha, MS,[a] and Peter Gloviczki, MD,[a] *Rochester, Minn; Porto Alegre, Rio Grande do Sul, Brazil; and Budapest, Hungary*

A multicenter, randomized, controlled trial of totally percutaneous access versus open femoral exposure for endovascular aortic aneurysm repair (the PEVAR trial)

Peter R. Nelson, MD, MS,[a] Zvonimir Krajcer, MD,[b] Nikhil Kansal, MD,[c] Vikram Rao, MD,[d] Christian Bianchi, MD,[e] Homayoun Hashemi, MD,[f] Paul Jones, MD,[g] and J. Michael Bacharach, MD,[h] *Tampa, Fla; Houston, Tex; San Diego, Calif; Pittsburgh, Ohio; Loma Linda, Calif; Fall Church, Va; Chicago, Ill; and Sioux Falls, SDak*

- **Less invasive approach**
- **Shorter OR time**
- Earlier ambulation
- **Reduced EBL** and pain
- Improved QOL
- **Few access complications**
- **Non-inferiority to open exposure**

Bradley NA, Surgeon RCS 2021, de Souza JVS 2015, Nelson JVS 2014 3 UPMC

Practice Patterns of Percutaneous EVAR After Reimbursement Reform

Adam Tanious,[1] Laura T. Boitano,[1] Srihari K. Lella,[1] Mark F. Conrad,[1] Carlin Williams,[2] Margaret Tracci,[2] Matthew J. Eagleton,[1] W. Darrin Clouse[1] [1]Massachusetts General Hospital, Boston, Mass; [2]University of Virginia Health System, Charlottesville, Va; [3]University of Virginia, Charlottesville, Va

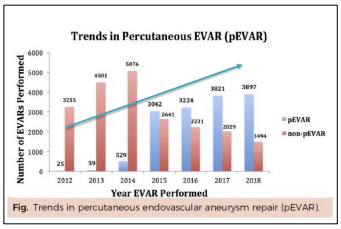


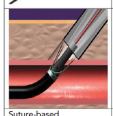
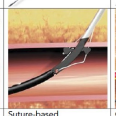
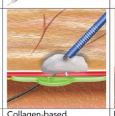
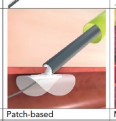
Fig. Trends in percutaneous endovascular aneurysm repair (pEVAR).

2018-Present

Open CFA exposure
- **RVU 4.13 (6.74)**

Perc access >12F (CPT 34713)
- U/S included
- **RVU 2.50 (mod -50)**

Tanious A. JVS 2020 4 UPMC

Prostar® XL	ProGlide®	MANTA™	PerQseal®	InSeal
				
				
Suture-based	Suture-based	Collagen-based	Patch-based	Membrane-based
8.5–10 Fr (off-label use > 10 Fr)	5–8 Fr (off-label use > 8 Fr)	10–14 Fr (14 Fr system) 14–22 Fr (18 Fr system)	< 24 Fr	14–21 Fr
CE mark	CE mark	CE mark	CE mark	CE mark

Source: Abbott Vascular, Essential Medical, InSeal Medical and Vivasure Medical.

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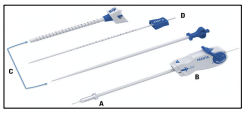

Teleflex Inc.
- **14F Manta (10-14F)**
  - OD 14-18F
- **18F Manta (15-22F)**
  - OD 18-25F
- 8F depth locator
- Extravascular collagen plug, intraluminal polymer anchor, radiopaque lock

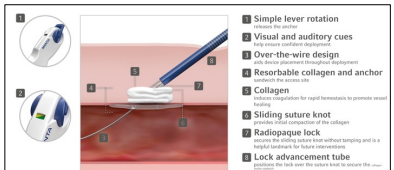

Fig 2. Features of the MANTA vascular closure device (VCD). Image courtesy of Teleflex Incorporated. © [2023] Teleflex Incorporated. All rights reserved.

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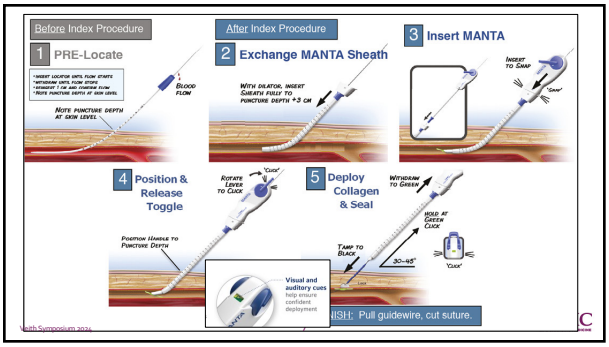
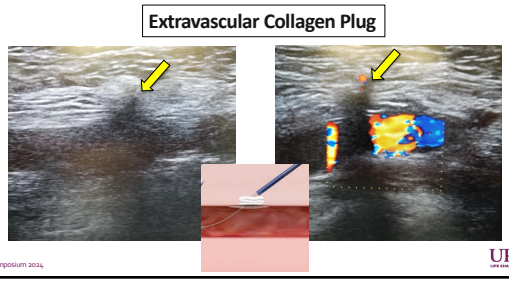
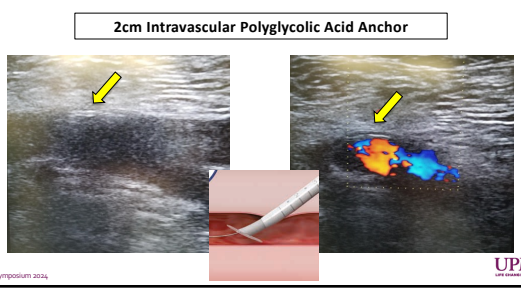


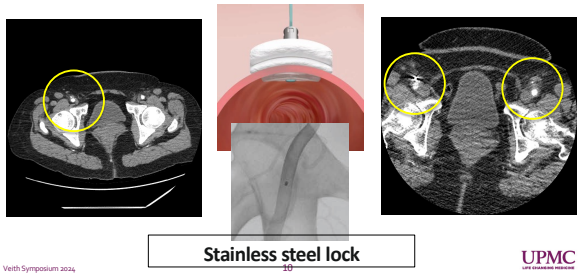
Manta Post Deployment Duplex Scan



Manta Post Deployment Duplex Scan



Manta CTA images (30 days)



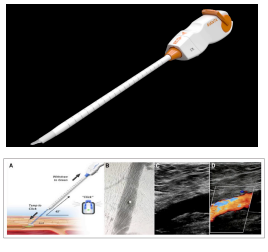
Circulation: Cardiovascular Interventions

ORIGINAL ARTICLE

Pivotal Clinical Study to Evaluate the Safety and Effectiveness of the MANTA Percutaneous Vascular Closure Device

The SAFE MANTA Study

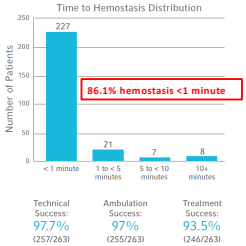
- US prospective multi-center study
  - **20 sites**, single arm
  - **263 enrolled (TAVR, EVAR, TEVAR)**
  - Follow-up at 30, 60-days
  - **Primary endpoint- time to hemostasis**
  - **Secondary- tech success**, ambulation, procedure time



SAFE Manta IDE Study

- Primary endpoint- time to hemostasis
  - **97.7% technical success**
  - Deployment to hemostasis:
    - **24 sec median**
    - Perclose 9.8 +/- 17.9 minutes
  - 5.3% 30-day major complication (14/263)
    - **2.3% major bleeding (n=6)**
    - 2.7% minor complication
    - 1.1% pseudoaneurysm (n=3)
  - 4.2% VARC-2 major vascular complication (11/263)
    - rate lower than suture mediated closure

➢ **Demonstrated safety and effectiveness, shorter time to hemostasis, few complications**



Comparison Manta vs. Suture Mediated Devices

Medranda GA, Case BC, Zhang C, Rappaport H:
Propensity matched comparison of large bore access closure in TAVR using Manta versus Perclose: A real world experience

Biancari F, Romppanen H, Savontaus M:
Manta versus Proglide vascular closure devices in transfemoral TAVR

Postaolia A:
MANTA versus Perclose for large-bore vessel closure: The evidence continues to grow

MANTA versus ProGlide patients:

- Pooled data
- Technical success 95.2% v. 96.4%
- No difference in access site hematoma or vascular complications
- Access site arterial occlusion was more frequent with Manta (n=2)
- Most Perclose cases required 6F Angioseal and 2 Perclose devices

Conclusion: similar rates of effectiveness, MANTA has a shorter time to hemostasis and fewer bleeding complications

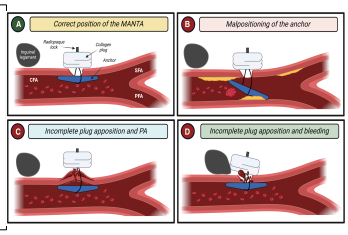
Medranda Cath Cardiovasc Interv 2021
Biancari Int J Cardiol 2018
Postaolia Cath Cardiovasc Interv 2021

Manta Failure Mechanisms

Anatomy:
- CFA <8mm diameter
- CFA >50% calcific plaque
- Obesity- incorrect depth

Device:
- Stiff wire- incorrect deployment angle
- Excessive outward force

Procedure:
- Access site hematomas



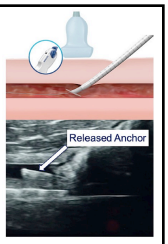
All You Need to Know for MANTA Closure Without Premeasurement of the Depth

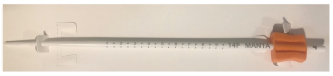
Itsik Ben-Dor *

Section of Interventional Cardiology, MedStar Washington Hospital Center, Washington, DC, United States of America

* *MedStar Washington Hospital Center, 110 Irving St., NW, Suite 4B-1, Washington, DC 20010, United States of America.*
E-mail address: Itsik.Ben-Dor@medstar.net.

1) **Novel fluoroscopic DOT technique**:
   - U/S imaging for placement of the Manta device
   - Radiopaque marker dot 25mm proximal to sheath tip
   - Locate arteriotomy access site (U/S or fluoroscopic)
   - Deploy with DOT technique, sheath is 25 mm inside the artery
2) **14F large bore depth locator**
3) **U/S guided deployment**



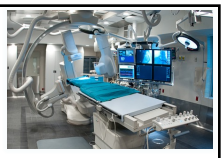


Cardiovasc Revasc Medicine 2023
Miyashita et al. Am J Cardiol 2022

Large Bore Access Closure: Mission vs. Margin

Type	Time to Hemostasis	IFU Access Approval	Product	Cost/unit
SiteSeal	compression	5-21F	5/box	
Angioseal	immediate	6F	10/box	$190
Angioseal	immediate	8F	10/box	$190
Perclose Proglide Abbott	**4-8 minutes**	**5-21F arterial 5-24F venous**	**10/box**	**$175**
Perclose Prostyle Abbott	**6 minutes**	**5-21F arterial 5-24F venous**	**10/box**	**$195**
Prostar XL Abbott	**3-5 minutes**	**8.5-10F**	**10/box**	**$275**
Manta Teleflex	**immediate**	**12-25F**	**5/box**	**$695**

Cost of an OR Minute



- Operating room (OR) is the largest revenue and cost generating department
- Significant impact on hospital's financial success
- **$62/minute OR time**
  - Calculations include cost of procedure equipment, disposables, circulating nurse, and scrub tech
  - Does not include wages/salary of surgeons, anesthesia, blood products, and medications
- Cost per closure procedure:
  - **Manta x 2 = $1,390**
  - **Perclose Prostyle x 4 = $780**
  - **OR time 12min x $62 = $744 (bilateral)**
  - **Perclose Prostyle Total = $1,524**

Cheng H et al. (2018 April) Prolonged Operative Duration Is Associated with Complications: A Systematic Review and Meta-Analysis. Journal of Surgical Research
Healy MA et al. (2016 September) Hospital and Payer Costs Associated with Surgical Complications. Journal of American Medical Association Surgery. (9):823-30. doi: 10.1001/jamasurg.2016.0773

Summary

- Percutaneous large bore femoral access is an integral component of EVAR and TEVAR procedures
- Current percutaneous closure devices demonstrate favorable outcomes and are comparable
- Manta is safe, effective, and a reliable for large bore access closure
- Manta obtains immediate hemostasis in nearly 90% of patients using a simple deployment mechanism

UPMC Vascular Manta Experience 2020-24

14F device:

- **100% technical success**
- 126/126- **no access site complications**
  - **98% immediate hemostasis**

18F device:

- **96.6% technical success**
- **5/148- access site complications**
- **94% immediate hemostasis**
  - Case #3- excessive force => device pulled out
  - Case #9- CFA plaque, focal dissection 20F sheath
  - Case #57- 12 cm inguinal hernia, hematoma
  - Case #98- obese, foot plate outside vessel
  - Case #117- obese, foot plate outside vessel

Systematic review and meta-analysis comparing Manta device and Perclose device for closure of large bore arterial access

The Journal of Vascular Access
1–7
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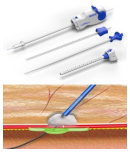
Tayyab Cheema[1], Carmelo Venero Jr[2], Shivam Champaneria[2], Sundas Younas[3], Muhammad Adil Hadeed Khan[4], Ibrar Anjum[3], Unaiza Ijaz[3], Sajjad Haider[2], Muhammad Shoaib Akbar[2], Mohammad Abdul-Waheed[1] and Sameer Saleem[2]



- Comparison of 2 devices in large >14F arteriotomy closure post TAVR
- Data analyzed using random effect model
- **12 studies (2 RCT, 10 observational)- 2,339 patients**
  - Odds of major/minor vascular complications, major/minor bleed, device failure, vessel injury and short-term mortality were similar
- **Manta device has similar efficacy and safety profile compared to Perclose device**

Comparison Manta vs. Suture Mediated Devices

Safety and Effectiveness of MANTA Vascular Closure Device After Large-Bore Mechanical Circulatory Support: Real-World Experience

Ankur Gupta, Lina Fouad, Mir Basir, Saroj Neupane, Mohammad Zaidan, Gerald Koenig, Mohammad Alqarqaz, Pedro A. Villablanca, William W. O'Neill, Khaldoon Alaswad

Percutaneous Plug-Based Arteriotomy Closure Device for Large-Bore Access

A Multicenter Prospective Study

Nicolas M. Van Mieghem, MD, PhD, Azeem Latib, MD, Jan van der Heyden, MD, PhD, Lennart van Gils, MD, Joost Daemen, MD, PhD, Todd Sorensen, Jurgen Ligthart, BT, Koen Wilbring, CCRN, Thom de Kroon, MD, Nathaniel Moes, Antonio Mangieri, MD, Matteo Montorfano, MD, Peter P. de Jaegere, MD, PhD, Antonio Colombo, MD, Gary Roubin, MD, PhD

INTERVENTIONS FOR VALVULAR DISEASE AND HEART FAILURE

Propensity-matched comparison of vascular closure devices after transcatheter aortic valve replacement using MANTA versus ProGlide

MANTA versus ProGlide patients:

- All-cause mortality (0% vs. 4%, p=0.02)
- Vascular complications (14% vs. 21%, p=0.21)
- Bleeding complications (18% vs. 33%, p=0.01)
- Access-site vascular injury was less frequent (8% vs. 17%, p=0.04)
- MANTA shorter hospital stay (3.3 vs. 5.8 days, p=0.02)
- **Significant decrease of all endpoints seen in the MANTA group**

Conclusion: MANTA resulted in shorter time to hemostasis and lower complication rates, especially for bleeding

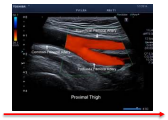
Gupta A Cardiovasc Revasc Med 2020
Van Mieghem JACC 2017
Moriyama N Eurointervention 2019

Reimbursement for Percutaneous Large Bore Access

Prior to 2018

Open CFA exposure (CPT 34812)
- **RVU 6.74**

Perc access: RVU 0.00
- U/S guided (76947)
- **RVU 0.41**



2018-Present

Open CFA exposure
- **RVU 4.13**

Perc access >12F (CPT 34713)
- U/S included
- **RVU 2.50 (mod -50)**

Clinical outcomes of MANTA closure device in percutaneous endovascular aortic aneurysm repair

Maxim Peeters, MD,[1] Rens Oosterveld, MD,[1,2] Gilles Decraemer, MD,[1] ChunYu Wong, MD, PhD,[1] Pieter Salemans, MD,[1] Ruben Nouwens, BSc,[1] Lee Bouwman, MD, PhD,[1,2] and Ozan Yazar, MD,[1] *Heerlan and Maastricht, The Netherlands*

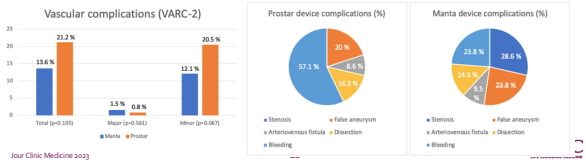
- Single center retrospective review, 4 years (2018-2022)
- 152 consecutive EVAR cases, 291 closure procedures
- CTA: mean CFA diameter 10.5mm, 52.6% cases no calcification
- 18F-169 implants and 14F-122 implants
- Combined technical success: 96.6%
- Access site vascular complications: 4.5%
- **Vascular closure method was NOT associated with increased risk for major bleeding, early mortality or LOS**

Technical success	96.6%
Major vascular complication	4.5%
Failure to close	2.7%
Occlusion	0.3%
Stenosis	0.7%
Hemorrhage/PA	0.7%

Vascular Complications Following Transcatheter Aortic Valve Implantation, Using MANTA (Collagen Plug-Based) versus PROSTAR (Suture-Based), from a French Single-Center Retrospective Registry

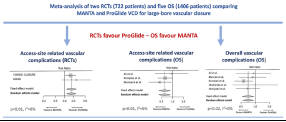
Clément Benic [1,*], Pierre Philippe Nicol [1], Sinda Hannachi [1], Martine Gilard [1], Romain Didier [1] and Bahaa Nasr [2]

- 264 TAVI patients, no significant difference in vascular complication rates (P=0.105)
- **Tendency to have fewer minor events in Manta Group (12% vs. 20.5%, P=0.067)**
- **Manta had fewer minor bleeding events (3.8% vs. 15.2%, P=0.002) and closure failures (4.5% vs. 13.6%, P=0.01)**



Comparison of plug-based versus suture-based vascular closure for large-bore arterial access: a collaborative meta-analysis of observational and randomized studies

Oliver Dumpies[1] · Alexander Jobs[1,2] · Danilo Obradović[1] · Maarten van Wiechen[3] · Philipp Hartung[1] · Johannes Rotta detto Loria[1] · Johannes Wilde[1] · Nicolas Majunke[1] · Philipp Kiefer[4] · Thilo Noack[4] · Holger Thiele[1] · Nicolas van Mieghem[3] · Steffen Desch[1,2] · Mohamed Abdel-Wahab[1]



- OS showed access site complications were less frequent with Manta closure
  - (RR 0.61 [95%CI 0.43-0.89],p=0.01, I^2=0%)
- RCT showed increased access site complications due to Manta device failure
  - (RR 1.7 [95%CI 1.16-2.51],p=0.01, I^2=0%)
- **Both data sets showed no difference in overall bleeding events (p=0.06)**

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