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Introduction

Atherosclerotic carotid artery disease remains a significant cause of ischemic stroke worldwide. Surgical options like carotid endarterectomy (CEA) and carotid artery stenting (CAS) reduce stroke risk, but patients remain vulnerable to procedure-related events, confounding clinical data regarding procedural benefit in overall risk reduction. Innovations in CAS have focused on minimizing these risks, including improvements to procedural embolic protection and alternative approaches such as transcarotid artery revascularization (TCAR). While these innovations were not studied in the recently completed CREST-2 study, ongoing clinical research and shared decision-making will continue to advance a patient-centered approach. First introduced in 2004,[1,2] TCAR combines surgical and endovascular techniques to minimize embolic risk during stent delivery. The technique utilizes direct transcervical carotid artery access to avoid the embolic risk associated with endovascular navigation of the aortic arch and high-risk carotid anatomy. Flow reversal for distal embolic protection via common carotid artery (CCA) control reduces the likelihood that embolic material produced during the crossing or treatment of pathology will enter the cerebral circulation. Clinical outcomes data from the ROADSTER trials have demonstrated 30-day stroke rates as low as 1.4% with TCAR.[3] Consequently, TCAR has rapidly gained adoption, with more than 100,000 procedures performed to date.[4]

After more than a decade of clinical experience, opportunities for modification in TCAR are becoming evident. Flow reversal alone has certainly advanced stroke protection, but limited progress in access sheath and stent design have left lingering concerns around vessel injury and long-term patency. Recent evidence also underscores that CCA clamping with flow reversal reduces—but does not completely eliminate—the risk of cerebral microembolization.[5]

A novel dual-neuroprotection strategy, TCAR-IEP (Transcarotid Artery Revascularization with Integrated Embolic Protection), has been developed to enhance neuroprotection by combining flow reversal with a 40-µm integrated embolic protection (IEP) filter. This approach was evaluated in the PERFORMANCE III trial, which has completed enrollment and is currently under FDA review.

The trial assessed the 70 cm Neuroguard IEP System (Contego Medical, Inc.) for the treatment of bifurcation carotid artery disease via direct carotid access. This investigational stent uses the same design and integrated filter technology as the FDA-approved 140 cm Neuroguard IEP System, which is indicated for transfemoral (TF) and transradial access and was previously studied in the PERFORMANCE II trial.

The Neuroguard IEP System is an innovative 3-in-1 device that incorporates a purpose-built stent, a post-dilation balloon, and an integrated filter, reducing the need for multiple catheter exchanges. While the 70 cm Neuroguard IEP System, designed for use via a transcarotid approach, remains investigational and restricted by Federal law to investigational use, results from the PERFORMANCE III trial have been accepted for presentation at the upcoming VIVA and VEITH 2025 annual meetings.

This roundtable brings together leading experts in carotid artery disease to share their perspectives on the next chapter of TCAR. The discussion will highlight lessons learned and areas for improvement from the past decade of TCAR experience, review results from a transcranial Doppler (TCD) study characterizing internal carotid artery (ICA) flow during CCA clamping with flow reversal, and summarize key findings from PERFORMANCE II, the pivotal trial of the Neuroguard IEP System. Particular attention will be given to the design features of TCAR-IEP and the recently completed PERFORMANCE III trial. The supplement concludes with a forward-looking perspective on the future of carotid artery revascularization. ■

Steven Abramowitz, MD

Caution: The Neuroguard IEP® 3-in-1 Carotid Stent and Post-Dilation Balloon System with Integrated Embolic Protection, 70 cm (Neuroguard IEP® System, 70 cm), the Neuroguard IEP® Embolic Protection System, and the Neuroguard IEP® Microintroducer Kit are investigational devices and limited to Federal (or United States) law to investigational use.

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MODERATOR

Steven Abramowitz, MD
Executive Director
MedStar Vascular Surgery Program
Chair, Department of Vascular Surgery
MedStar Washington Hospital Center
Associate Professor of Surgery
Georgetown University
Washington, DC

PANELISTS

Gregg S. Landis, MD, FACS
System Chief of Vascular Surgery
Vice Chairman of Surgery
Northwell Health
Associate Professor of Surgery
Zucker School of Medicine at Hofstra/Northwell
Hempstead, New York

Alexandros Mallios, MD
Department of Vascular and Endovascular Surgery
Groupe Hospitalier Paris Saint Joseph
Paris, France
Department of Surgery
Centre Hospitalier de Chartres
Chartres, France

Syed Bokhari, MBBS
PGY3
UT Southwestern Medical Center
Dallas, Texas

Michael C. Siah, MD
Assistant Professor
Department of Surgery
Director of Limb Salvage
UT Southwestern Medical Center
Dallas, Texas

Sean P. Lyden, MD
Professor and Chairman
Department of Vascular Surgery
Cleveland Clinic
Cleveland, Ohio

Nicolas J. Mouawad, MD, MPH, MBA, DFSVS, FACS, FRCS, RPVI
Chief and Medical Director, Vascular & Endovascular Surgery
McLaren Health System–Bay Region
Associate Clinical Professor of Surgery
Michigan State University
Central Michigan University
Bay City, Michigan