History Of Transcervical Carotid Artery Stenting

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Disclosure Statement of Financial Interest

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

Affiliation/Financial Relationship Company
Consultant / Equity holder Silk Road Medical

Retrograde Carotid Flow was first utilized for Cerebral Protection during Cardiopulmonary bypass with Retrograde Cerebral Perfusion and Hypothermic Arrest

First report of the Transfemoral Parodi Antiembolic System Using Carotid Flow Reversal (PAES Catheter)

Potential of Transcervical CAS 2001-2002

- Eliminate the complications and risk of the transfemoral approach
- Avoid the limitations and cost of DPDs
- Incorporate the advantages of carotid flow reversal for cerebral protection
A new approach to carotid angioplasty and stenting with transcervical occlusion and protective shunting: Why it may be a better carotid artery intervention

David K. Chang, MD; France L. Schobben, MD; P. Weiss; Frank J. Vukic, MD; and Christopher K. Tariot, MD

J Vasc Surg. May 2004

Carotid angioplasty with internal carotid artery flow reversal is well tolerated in the awake patient*

Edward C. Smith, Jr., MD; Robert Bilchick, MD; and Roy L. Rana

Transcervical carotid stenting with internal carotid artery flow reversal: Feasibility and preliminary results

Eantiago Criado, MD; Manuel Delbaere, MD; Jean-Marc Rivaud, MD; and Anatole Opie, MD


Transcervical carotid stenting with carotid artery flow reversal: 3-year follow-up of 103 stents

Eantiago Criado, MD; Jean-Marc Rivaud, MD; Anatole Opie, MD; Manuel Delbaere, MD; and Edouard Chevalier, MD


Flow Controller
Large Bore Arteriovenous Shunt Circuit
Transcervical Arterial Sheath (8F)
Venous Return Sheath (8F)

In April 2007 Silk Road Medical was born

MICHI™ Neuroprotection System, Silk Road Medical

Flow Controller

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MICHI™ Neuroprotection System, Silk Road Medical

Flow Controller

Safety and feasibility of a novel transcervical access neuroprotection system for carotid artery stenting in the PROOF Study

Latino Pera, MD; Rinat Bivins, MD; Christopher Levis, MD; Emanuelle Couv, MD; Joan Robles, MD; Gregory T. King, MD; and Ralph B. Scheld, MD

JVS 2011:54:1317

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Transcervical CAS with Flow Reversal: Cumulative MAE’s = 0.7%

STUDY |
| Total |
| # Deaths (30 d) | # Major strokes (30 d) | # Minor strokes (30 d) | Patency |
|---|---|---|---|---|
| Chang 2004 | 21 | 0 | 0 | 0 | 100% 6 m |
| Lin 2005 | 31 | 0 | 0 | 0 | 100% 8 m |
| Alvarez 2012 | 218 | 3 | 0 | 0 | 100% 36 m |
| Criado 2007 | 103 | 0 | 0 | 2 | 97% 40 m |
| Faraghi 2008 | 52 | 0 | 1 | 1 | 100% 8 m |
| Leal 2010 | 35 | 0 | 0 | 1 | 100% 3 m |
| Kolvenbach 2011 | 75 | 0 | 0 | 1 | 100% 3 m |

TOTAL | 553 | (0.2%) | (0.7%) | (1%) |

# of Patients (n=65)

<table>
<thead>
<tr>
<th># of Patients (n=65)</th>
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<tbody>
<tr>
<td>30 day major stroke, MI and death</td>
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<tr>
<td>Minor contralat. stroke at 30 d</td>
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<tr>
<td>Cranial Nerve Injury</td>
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This led to product approval in the European Union
2012 The ROADSTER TRIAL (FDA/USA)
Prospective, single-arm, multi-center clinical trial of the
ENROUTE NPS in high surgical risk patients.

September 2016 Medicare Expands
Reimbursement for Asymptomatic Carotid
Stenosis using TCAR with EnRoute NPS

The Story of Transcervical Carotid Stenting
From an Idea…
to an Approved Device…
to a Reimbursed Procedure…