Is Transcarotid Artery Revascularization (TCAR) a Revolutionary Advance?

Yes, It Is a Game Changer for Both Outcomes and Adoption of Carotid 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.

<table>
<thead>
<tr>
<th>Affiliation/Financial Relationship</th>
<th>Company</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Grant/Research Support</td>
<td>• Abbott, Silk Road, WL Gore</td>
</tr>
<tr>
<td>• Consulting Fees/Honoraria</td>
<td>• Silk Road</td>
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<tr>
<td>• Major Stock Shareholder/Equity</td>
<td>• Company Names</td>
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<td>• Royalty Income</td>
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<tr>
<td>• Ownership/Founder</td>
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<tr>
<td>• Intellectual Property Rights</td>
<td>• Company Names</td>
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<tr>
<td>• Other Financial Benefit</td>
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</tbody>
</table>
There is a single, fundamental premise to treating carotid disease.

The intent of carotid revascularization is to prevent stroke.
Is TCAR a game changer for outcomes?

YES!
ROADSTER Study Outcomes in High Surgical Risk Patients
Intention to Treat & Per Protocol Groups

<table>
<thead>
<tr>
<th>High Surgical Risk</th>
<th>Pivotal Group, ITT (N=141)</th>
<th>Pivotal Group, PP (N=136)</th>
</tr>
</thead>
<tbody>
<tr>
<td>S/D/MI</td>
<td>5</td>
<td>4</td>
</tr>
<tr>
<td>Major Stroke</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Minor Stroke</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Death</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>MI</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Stroke &amp; Death</td>
<td>4</td>
<td>3</td>
</tr>
</tbody>
</table>

Per Protocol excludes major protocol deviations
All FDA-approved carotid stent systems were used per site preference (Acculink, Xact, Precise, Protégé, Wallstent)
## ROADSTER Study Outcomes
### Key Subgroups

<table>
<thead>
<tr>
<th>High Surgical Risk Pivotal ITT</th>
<th>Age ≥ 75</th>
<th>Symptomatic</th>
<th>Female</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>N=66 (47%)</td>
<td>N=36 (26%)</td>
<td>N=49 (35%)</td>
</tr>
<tr>
<td>S/D/MI</td>
<td>3 (4.5%)</td>
<td>1 (2.8%)</td>
<td>1 (2.0%)</td>
</tr>
<tr>
<td>Major Stroke</td>
<td>0%</td>
<td>0%</td>
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<td>2.8%</td>
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CREST 30-Day Results vs. ROADSTER

Standard Surgical Risk vs. High Surgical Risk

**CREST – 30-Day All Stroke Rates**

- **4.1%** for TF-CAS
- **2.3%** for CEA
- [VALUE] for TCAR

30-Day All Stroke (1)

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Is TCAR a game changer for adoption?

ABSOLUTELY!
After 20 years of evolution, CAS is stagnant

~112,500 carotid interventions (2013)*

59% of patients are HSR
AND
81% of HSR patients are treated with CEA**
An alternative to CEA remains an unmet need
More S/D is not the answer (TF-CAS)

30 Day Stroke and Death in the SVS Vascular Registry

<table>
<thead>
<tr>
<th></th>
<th>Symptomatic</th>
<th>Asymptomatic</th>
</tr>
</thead>
<tbody>
<tr>
<td>High Surgical Risk CEA</td>
<td>6.4%</td>
<td>3.7%</td>
</tr>
<tr>
<td>High Surgical Risk CAS</td>
<td>7.9%</td>
<td>4.8%</td>
</tr>
</tbody>
</table>

n=5,736
If you Solve the Stroke Problem
You Solve the Adoption Problem

CREST – 30-Day All Stroke Rates

- CREST CAS: 4.1%
- CREST CEA: 2.3%
- [VALUE]: [VALUE]

30-Day All Stroke (1)

Is TCAR too complex?

NO!
TCAR is a short and simple procedure

- **Mini-incision** (like EVAR, TEVAR and TAVR)
- **Local Anesthesia**
- **Direct carotid access** avoids arch navigation
TCAR is a short and simple procedure

- Dedicated TCAR tool set for direct CCA access
- No crossing lesion
- No filter - no balloons
- Short, direct path to lesion for accurate stent deployment
Procedure Times for TCAR in ROADSTER

Compared with TF-CAS and CEA procedure times in CREST*

*Stroke 2012;2408-2416.
Outcomes as a function of the number of patients per physician in CAPTURE 2

Regression equation: \( \log(y) = 4.71 - 0.85 \times \log(x) \)

- P-value of slope: <0.0001
- R-square: 0.81

TCAR SD Rate = 2.8%

CREST-2 Credentialing threshold
How was **1.4% stroke rate (0.7% PP)** achieved in ROADSTER?

- Gen 1 Device
- 29 operators
  - 4 operators with >5 TCAR procedures
  - 1 operator with 1-5 TCAR procedures
  - 24 operators with **NO PRIOR TCAR experience**
Summary:
TCAR is a game changer

- TCAR 30-day stroke rate of 1.4% (0.7% PP)
- TCAR delivers a minimally invasive alternative to CEA, benefits of proximal occlusion
- TCAR is simple and efficient, the benefits of CAS with a short learning curve