6-month results in 100 patients treated with the RoadSaver stent the CLEAR-ROAD study

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Conflict of interest

☐ have the following potential conflicts of interest to report:
  ☐ Consulting
  ☐ Employment in industry
  ☐ Stockholder of a healthcare company
  ☐ Owner of a healthcare company
  ☐ Other(s)

☒ I do not have any potential conflict of interest
results from EVA-3S and SPACE trial

- **EVA-3S**
  - CEA: 3.9% @ 30 days
  - CAS: 6.2% @ 4 yrs
  - 30-day stroke / death: 6.2% @ 4 yrs
  - 30-day stroke / death + ipsilateral ischemic stroke as from day 31: 6.2% @ 4 yrs

- **SPACE**
  - CEA: 6.34% @ 30 days
  - CAS: 9.2% @ 2 yrs
  - 30-day stroke / death: 9.2% @ 2 yrs
  - 30-day stroke / death + ipsilateral ischemic stroke as from day 31: 9.2% @ 2 yrs

EuroPCR, Paris 2010
Time frame: procedure \rightarrow discharge (24hrs)

Timing of complication occurrence

- 50% of procedure-related strokes occur immediately after procedure, before discharge.
- Less than 25% of procedure-related strokes occur during procedure.

\[55\% \text{!!} \]

⇒ We need better embolic protection AFTER the procedure.

Courtesy of MH Wholey
We need better protection against emboli

Protrusion of material through the stent
Free cell area based analysis shows us better results with closed cell designs and the smaller free cell area.
Room for **peri-procedural** improvement: D0→D31

Besides:
- Operator experience
- Patient selection
- Lesion selection

...we need a new kind of **Scaffolding Stent** to provide better protection against embolisation **peri-procedural** and direct post-procedural
Is there an ideal stent?
RoadSaver stent

TERUMO® Roadsaver

A novel design
- Closed cell structure (450 µ lattice)
- Double layer micromesh design
  Chronic embolic protection
- Flexible weave

Excellent wall apposition

CAUTION: Investigational Device. Limited by United States Law to Investigational Use only.
## Free cell area

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>ACCULINK® RX DEVICE</th>
<th>XACT® DEVICE</th>
<th>WALLSTENT® MONORAIL® DEVICE</th>
<th>PROTÉGÉ RX® DEVICE</th>
<th>PRECISE® DEVICE</th>
<th>CRISTALLO IDEALE DEVICE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Terumo &amp; Gore</td>
<td>Abbott Laboratories</td>
<td>Abbott Laboratories</td>
<td>Boston Scientific Corporation</td>
<td>ev3 Inc./ Covidien</td>
<td>Cordis Corporation</td>
<td>Medtronic, Inc./ Invatec</td>
</tr>
</tbody>
</table>
CLEAR-ROAD study

Primary Endpoint
30-day rate of Major Adverse Events (MAE), defined as the cumulative incidence of any peri-procedural death, stroke or myocardial infarction (≤30 days post-procedure)

Secondary Endpoints
• Late ipsilateral stroke (D31 – D365)
• Technical success rate & device malfunctions
• MAE by sub-group symptomatic/asymptomatic
• TLR – ISR
• Serious Device/Procedure Related Adverse Events (SAE)
CLEAR-ROAD study

Participating centers

- 3 Belgian centers
- 5 German centers
- 1 Italian center
Inclusion / Exclusion criteria

**Inclusion Criteria**

- High risk for carotid endarterectomy due to anatomical or co-morbid conditions
- Symptomatic + ≥50% stenosis, or asymptomatic and ≥80% stenosis (QVA)
- Arterial diameter 4-9 mm
- Age ≥ 18 years
- Life expectancy > 12 months post-procedure

**Exclusion Criteria**

- Contraindication for CAS
- Severe vascular tortuosity or anatomy
- Ostial CCA lesions
- Carotid occlusion
- Intraluminal thrombus
- Previous CAS
- Evolving stroke or intracranial haemorrhage
Study Timeline

Patient informed consent
In- & exclusion criteria check
Medical & clinical history
Medication
Physical examination
Angiography
Duplex Ultrasound
Device functionality
Adverse Events
Done by neurologist or a NIHSS certified person
<table>
<thead>
<tr>
<th></th>
<th>N=100</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male (%)</td>
<td>70 (70.0%)</td>
</tr>
<tr>
<td>Age (min – max; ±SD)</td>
<td>73.44 (47.78 – 89.12 ±9.55)</td>
</tr>
<tr>
<td>Neurological Status:</td>
<td></td>
</tr>
<tr>
<td>- Symptomatic (%)</td>
<td>31 (31.0%)</td>
</tr>
<tr>
<td>- Asymptomatic (%)</td>
<td>69 (69.0%)</td>
</tr>
<tr>
<td>Nicotine abuse* (%)</td>
<td>67 (67.0%)</td>
</tr>
<tr>
<td>Hypertension (%)</td>
<td>80 (80.0%)</td>
</tr>
<tr>
<td>Diabetes mellitus (%)</td>
<td>31 (31.0%)</td>
</tr>
<tr>
<td>Hypercholesterolemia (%)</td>
<td>74 (74.0%)</td>
</tr>
<tr>
<td>Obesity (%)</td>
<td>28 (28.0%)</td>
</tr>
<tr>
<td>Cerebrovascular disease (%)</td>
<td>24 (24.0%)</td>
</tr>
<tr>
<td>Characteristic</td>
<td>Value</td>
</tr>
<tr>
<td>----------------------------------------</td>
<td>--------------------------------------------</td>
</tr>
<tr>
<td>N=100</td>
<td></td>
</tr>
<tr>
<td>Left/Right (%)</td>
<td>49 (49.0%) / 51 (51.0%)</td>
</tr>
<tr>
<td>Lesion length (min – max; ±SD)</td>
<td>19.14 mm (2.0 – 50.0; ±8.20)</td>
</tr>
<tr>
<td>Reference vessel diameter (min – max; ±SD)</td>
<td>6.88 mm (4.0 – 9.0; ±1.36)</td>
</tr>
<tr>
<td>Mean lumen diameter (min – max; ±SD)</td>
<td>1.29 mm (0.08 – 4.05; ±0.77)</td>
</tr>
<tr>
<td>Degree of stenosis (min – max; ±SD)</td>
<td>85.30% (55 – 99 ; ±8.02)</td>
</tr>
</tbody>
</table>
With or without Embolic Protection Device

<table>
<thead>
<tr>
<th>Symptomatic (N=31)</th>
<th>Asymptomatic (N=69)</th>
</tr>
</thead>
<tbody>
<tr>
<td>18 without an EPD</td>
<td>24 without an EPD</td>
</tr>
<tr>
<td>13 with an EPD</td>
<td>45 with an EPD</td>
</tr>
</tbody>
</table>
Results – 30 days

Primary Endpoint: 30-day rate of Major Adverse Events (MAE), defined as the cumulative incidence of any peri-procedural death, stroke* or myocardial infarction (≤30 days post-procedure)

*Stroke is defined as an acute neurologic event with local symptoms and signs lasting more than 24 hours consistent with focal cerebral ischemia.
## MAE’s – 30 days

<table>
<thead>
<tr>
<th>All Death, Stroke, or MI</th>
<th>2,10%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death</td>
<td>1,0%</td>
</tr>
<tr>
<td>MI</td>
<td>1,0%</td>
</tr>
<tr>
<td>Stroke</td>
<td></td>
</tr>
<tr>
<td>Major</td>
<td>0%</td>
</tr>
<tr>
<td>Minor</td>
<td>1,0%</td>
</tr>
</tbody>
</table>

Day 4: 1 patient suffered from a myocardial infarction which led to death within the first 30-days after procedure.

Day 12: 1 patient experienced a stroke because of VKF and inadequately anticoagulantia medication.
Results neurological status

<table>
<thead>
<tr>
<th>Time</th>
<th>Baseline</th>
<th>30 days</th>
<th>Significant</th>
</tr>
</thead>
<tbody>
<tr>
<td>Symptomatic</td>
<td>at risk 31</td>
<td>30</td>
<td>96.8 %</td>
</tr>
<tr>
<td></td>
<td>% 100</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Asymptomatic</td>
<td>at risk 69</td>
<td>63</td>
<td>98.5</td>
</tr>
<tr>
<td></td>
<td>% 100</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
MAE’s no differents with or without EPB

<table>
<thead>
<tr>
<th>Time (days)</th>
<th>Cumulative Freedom from MAE (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 - 30</td>
<td>100</td>
</tr>
</tbody>
</table>

**Freedom from MAE - EPD used**

<table>
<thead>
<tr>
<th>Time (days)</th>
<th>Cumulative Freedom from MAE (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 - 30</td>
<td>100</td>
</tr>
</tbody>
</table>

**With Embolic Protection Device**
- at risk: 58
- %: 100
- 30 days: 52
- P = 0.842

**Without Embolic Protection Device**
- at risk: 42
- %: 100
- 30 days: 41
- 97.6 %
MAE’s D31 - 6months

MAE’s - full cohort 6MFU

Cumulative freedom from MAEs (%) vs. Time (days)

Number at risk

<table>
<thead>
<tr>
<th>Time (days)</th>
<th>Number at risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>100</td>
</tr>
<tr>
<td>30</td>
<td>96</td>
</tr>
<tr>
<td>60</td>
<td>90</td>
</tr>
<tr>
<td>90</td>
<td>89</td>
</tr>
<tr>
<td>120</td>
<td>87</td>
</tr>
<tr>
<td>150</td>
<td>87</td>
</tr>
<tr>
<td>180</td>
<td>87</td>
</tr>
<tr>
<td>210</td>
<td>58</td>
</tr>
</tbody>
</table>

93.7%
Day 66: 1 patient suffered from a stroke after planned contralateral carotid procedure

Day 101: 1 patient suffered from a myocardial infarction which led to death

Day 119: 1 patient suffered from cerebral infarction: paresthesia ipsilateral right arm & leg

Day 191: patient suffered from cerebral bleeding after revascularizing the study lesion, which led to death
Results – 6 months

Primary Patency - full cohort 6M

Cumulative Primary Patency Rate (%)

Time (days)

Number at risk

100 97 91 91 89 89 88 60

95.7%

Freedom from TLR - full cohort 6M

Cumulative freedom from TLR (%)

Time (days)

Number at risk

100 97 92 92 90 90 90 61

96.9%
Discussion

• Peroperative until 24 hours post op
  Excellent scaffolding reduce the amount of MAE’s.
  No embolic events

• 0-30 days
  Only two events. These events were not study stent related.

• 31 days until 6 moths
  Events which were expected and related to the disease
The RoadSaver Stent seems to be a valid, safe and effective treatment option to treat carotid lesions in symptomatic & asymptomatic patients. Even without the use of an embolic protection device
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