Update on Clinical Results Using the Integrated Embolic Protection Platform

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Disclosure

Speaker name:

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I 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
Higher Minor Stroke During CAS vs CEA

Importance of Micro-Embolization

ACT 1  SAPPHIRE  CREST  EVA 3S

CAS (%)  CEA (%)

The first device that combines an embolic protection filter and balloon/stent
Platform designed for ease of use, enhanced safety and efficiency
Only filter that allows physicians to adjust filter size and optimize wall apposition
Patented filter design maximizes embolic capture and side branch protection
Reduces hospital inventory costs
Paladin System
Proven Superior Capture Efficiency

The Paladin System has the Highest Capture Efficiency of 4 Embolic Filters Tested

Paladin filter captured 100% of 75-90 µm embolic particles

Data on file at Contego Medical
Case Study: **Same** Patient Undergoing Bilateral Carotid Stenting

**Right Carotid Stent Procedure Done Without** Contego Technology:

2 cm Stroke on MRI at 48 hours post-procedure

**Left Carotid Stent Procedure Done With** Contego Technology:

No Stroke on MRI at 48 hours post-procedure
Diffusion-weighted lesions after carotid artery stenting are associated with cognitive impairment

Maggio, P.a, Altamura, C.a, Landi, D.a, Migliore, S.a, Lupoi, D.b, Moffa, F.c, Quintiliani, L.a, Vollaro, S.a, Palazzo, P.a, Altavilla, R.a, Pasqualetti, P.de, Errante,

CONCLUSIONS:

Our study showed that peri-procedural brain microembolic load impacts negatively on cognitive functions, independently from the influence of patients-related variables. © 2013 Elsevier B.V. 

Volume of subclinical embolic infarct correlates to long-term cognitive changes after carotid revascularization.


CONCLUSIONS:

Cognitive assessment of procedure-related subclinical microemboli is challenging. Volumes of embolic infarct correlate with long-term cognitive changes, suggesting that microembolization should be considered a surrogate measure for carotid disease management. 

Published by Elsevier Inc.
The PALADIN Study

Objective

– To evaluate the procedural safety and technical success of the Paladin System in subjects with carotid artery stenosis

• Co-Principle Investigators: Profs. Horst Sievert and Thomas Zeller

5 Sites in Germany

• Universitätsklinikum Leipzig, Leipzig, Prof. Dierk Scheinert
• Cardiovasculäres Centrum, Frankfurt, Prof. Horst Sievert
• Mathey Schofer Clinic, Cardiovascular Center Hamburg, Prof. Joachim Schofer
• Universitäts Herzzentrum-Bad Krozingen, Freiberg, Prof. Thomas Zeller
• Sankt Gertrauden-Krankenhaus, Berlin, Dr. Ralf Langhoff
PALADIN Study

Study Population

- Symptomatic subjects (history of ipsilateral TIA, stroke or amaurosis fugax within the past 6 months) with carotid stenosis ≥ 50% by angiography
- Asymptomatic subjects with carotid stenosis ≥ 70% by angiography

Primary Endpoints

- Acute Technical success
- 30 day (neurological death and stroke)
# Stents Used

<table>
<thead>
<tr>
<th>Stent Implanted</th>
<th>% (n = 106)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Roadsaver</td>
<td>43.4 (46)</td>
</tr>
<tr>
<td>Xact</td>
<td>31.1 (33)</td>
</tr>
<tr>
<td>Cristallo Ideale</td>
<td>17.0 (18)</td>
</tr>
<tr>
<td>Wallstent</td>
<td>4.7 (5)</td>
</tr>
<tr>
<td>Adapt</td>
<td>2.8 (3)</td>
</tr>
<tr>
<td>Precise</td>
<td>0.9 (1)</td>
</tr>
</tbody>
</table>
### 30 Day Clinical Results

<table>
<thead>
<tr>
<th>Event</th>
<th>Discharge (n=106)</th>
<th>30 Days (n=105*)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>MAE (death, stroke, MI)</strong></td>
<td>0.0 % (0)</td>
<td>0.95 % (1)*</td>
</tr>
<tr>
<td><strong>All Death</strong></td>
<td>0.0 % (0)</td>
<td>0.0 % (0)</td>
</tr>
<tr>
<td><strong>Stroke</strong></td>
<td>0.0 % (0)</td>
<td>0.95% (1)</td>
</tr>
<tr>
<td><strong>Myocardial Infarction</strong></td>
<td>0.0 % (0)</td>
<td>0.0 % (0)</td>
</tr>
</tbody>
</table>

- 1 patient withdrew consent and exited the study prior to the 30 day follow up.
- 1 patient was non-compliant with DAPT and developed stent thrombosis at day 12.
Sub-studies

- 30 Patients underwent DW-MRI pre-procedure and within 48 hours post-procedure at three sites

- 23 paired filters were sent for histological analysis to evaluate number and size of embolic particles
Results MRI Sub-study (n=30)

- New ischemic lesions were found in 11 subjects (36.7%)
- New ipsilateral lesions were seen in 8 subjects (27%)
- Average Number of New Lesions/Patient: 0.53
- Average lesion volume: 0.01 cm$^3$
- No new **ipsilateral** ischemic lesions were detected in any of the symptomatic patients
## MRI DATA

<table>
<thead>
<tr>
<th>Comparative DW-MRI Results</th>
<th>Paladin (n=30)</th>
<th>PROFI² Proximal group (n=31)</th>
<th>PROFI² Filter group (n=31)</th>
<th>ICSS³ Filter group (n=37)</th>
<th>CARENET¹ CGuard (n=26)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Incidence of New Lesions</td>
<td>36.7% (24% Ipsilateral)</td>
<td>45%</td>
<td>87%</td>
<td>73%</td>
<td>48%</td>
</tr>
<tr>
<td>Mean number of lesions per pt.</td>
<td>0.53</td>
<td>1.0 +/- 1.4</td>
<td>3.6 +/- 3.2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean Lesion Volume (cm³)</td>
<td>0.01</td>
<td>0.16</td>
<td>0.59</td>
<td>NA</td>
<td>0.05</td>
</tr>
</tbody>
</table>

23 filters collected for analysis of emboli count and size

Filter Histological Analysis: Particle Size

The majority of particles captured were less than 100 microns
Filter Histology in Patient Treated with Mo.MA and Paladin

Procedure performed in Leipzig, Germany with Medtronic Mo.MA proximal protection system

Courtesy: Dr. Andrej Schmidt

<table>
<thead>
<tr>
<th>Particle Size</th>
<th>40-99</th>
<th>199</th>
<th>299</th>
<th>&gt;300</th>
</tr>
</thead>
<tbody>
<tr>
<td>Particle Count</td>
<td>2599</td>
<td>136</td>
<td>299</td>
<td>7</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Particle Count</th>
<th>2599</th>
</tr>
</thead>
<tbody>
<tr>
<td>Procedure performed</td>
<td>Leipzig, Germany</td>
</tr>
<tr>
<td>Medtronic Mo.MA proximal protection system</td>
<td></td>
</tr>
</tbody>
</table>
The Paladin filter and Roadsaver captured

- 68% more particles by COUNT and
- 69% more particles between 40-10 microns than the primary filter the Roadsaver stent

\[ p=0.13 \text{ using the t-test} \]
### PALADIN Filter Analysis in Patients Receiving Mesh Covered Stents

#### Roadsaver + PALADIN

<table>
<thead>
<tr>
<th>Symptomatic CAS</th>
<th>25</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean # of particles/filter</td>
<td>3352</td>
</tr>
<tr>
<td>Mean # particles/filter 40-100µm</td>
<td>2499</td>
</tr>
<tr>
<td>Mean # particles/filter 100-200µm</td>
<td>267</td>
</tr>
<tr>
<td>Mean # particles/filter 200-400µm</td>
<td>48</td>
</tr>
</tbody>
</table>

Kedev, Vasilev, et al, 2018

#### C-Guard vs XACT Stent + PALADIN

<table>
<thead>
<tr>
<th></th>
<th>CGuard (n=5)</th>
<th>Xact Stent (n=8)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean particle count / Paladin filter, 40-100 µm</td>
<td>1310</td>
<td>1164</td>
</tr>
<tr>
<td>Mean particle count / Paladin filter</td>
<td>1379</td>
<td>1260</td>
</tr>
</tbody>
</table>

Petrov, et al, 2018
Summary

- The biggest risk of stroke is due to inadequate embolic protection during index procedure, especially during post-dilation.
- Micro embolization is important and causes minor stroke.
- The Paladin system allows capture of micro-embolic in an efficient and safe manner.
- >1000 cases now done with PALADIN with 184 patients included in clinical trials.
- No reported procedural strokes.
- Trans-femoral or trans-radial CAS with experienced operators using a double filtration with the PALADIN system appears to be a safe option. Further studies are on-going.
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