The INVOS™ Cerebral/Somatic Oximeter Monitors Cerebral Perfusion in:

Carotid Endarterectomy (CEA)

Common methods of monitoring the adequacy of bilateral perfusion and identifying the need for shunting during CEA under general anesthesia are electroencephalogram (EEG), stump pressure (SP), or transcranial Doppler (TCD) monitoring. EEG monitoring requires specialized staff, SP monitoring is not continuous, and some patients have an insufficient temporal bone window for TCD monitoring. Near infrared spectroscopy (NIRS) can be a practical, continuous method to monitor perfusion.

The INVOS™ Cerebral/Somatic Oximeter is NIRS-based technology that can be used to monitor cerebral perfusion during CEA and help clinicians identify patients who may benefit from shunting. In a retrospective study of 594 CEA patients, INVOS™ monitoring technology was moderately sensitive and specific for identifying patients who would experience a postoperative neurologic deficit after intraoperative cerebral desaturation. In two prospective, observational studies in 100 or more CEA patients, INVOS™ monitoring technology was 76-100% predictive of the need for shunting compared to EEG. When paired with an interventional algorithm for responding to cerebral desaturation, a multicenter, randomized controlled trial in 253 patients demonstrated that INVOS™ monitoring technology could assist clinicians in selecting appropriate patients for shunting, significantly reducing the number of patients shunted compared to unmonitored patients with no increase in the incidence of neurological deficits.
INVOS™ monitoring technology can be used to identify patients at risk for cerebral ischemia during CEA


<table>
<thead>
<tr>
<th>Study design</th>
<th>Single center, retrospective study (Italy)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arms</td>
<td>Single arm: INVOS™ monitoring</td>
</tr>
<tr>
<td>Objective</td>
<td>Identify the relative change from baseline rSO₂ values 2 minutes after clamping that is predictive of impending cerebral ischemia</td>
</tr>
<tr>
<td>N</td>
<td>594</td>
</tr>
<tr>
<td>Population</td>
<td>CEA under general anesthesia</td>
</tr>
<tr>
<td>Threshold for intervention</td>
<td>No interventions were described and no shunts were placed</td>
</tr>
</tbody>
</table>

**Results**

- 20/594 patients (3.4%) presented with neurological complications
- 16/594 patients (2.7%) showed an early decrease in rSO₂ >20% from baseline
  - 6/16 patients (37.5%) showing an early decrease in rSO₂ >20% from baseline also presented with neurological complications
  - 14/578 patients (2%) showing a decrease in rSO₂ <20% from baseline presented with neurological complications (p=0.0001)
- An rSO₂ decrease of 11.7% from baseline at 2 minutes post-clamping was identified as the optimal threshold to identify patients with a neurological complication
  - Positive predictive value (PPV) = 10%
  - Negative predictive value (NPV) = 99%
  - Sensitivity = 75%
  - Specificity = 77%
- A threshold of 20% was associated with lower sensitivity (30%), higher specificity (98%), and with a PPV and NPV of 37% and 98%, respectively, for identifying patients with neurological complications

**Conclusions**

NIRS monitoring technology is a useful method to detect cerebral ischemia during CEA
Monitoring with INVOS™ technology can be considered as a sensitive, specific, and practical method compared to EEG to predict cerebral ischemia during CEA


<table>
<thead>
<tr>
<th>Study design</th>
<th>Single center, prospective observational study (South Africa)</th>
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<tbody>
<tr>
<td>Arms</td>
<td>Single arm: concomitant INVOS™, electroencephalogram (EEG), and stump pressure (SP) monitoring</td>
</tr>
<tr>
<td>Objective</td>
<td>Compare the ability of INVOS™ monitoring technology to SP and EEG in detecting the need for shunting</td>
</tr>
<tr>
<td>N</td>
<td>100</td>
</tr>
<tr>
<td>Population</td>
<td>CEA under general anesthesia</td>
</tr>
<tr>
<td>Definition of desaturation</td>
<td>rSO₂ &gt;20% from baseline value</td>
</tr>
<tr>
<td>Threshold for intervention</td>
<td>Shunt was placed when EEG detected an attenuation or loss of higher-frequency background activity and appearance or increase of regional delta activity</td>
</tr>
</tbody>
</table>

- **Results**
  - 6/100 (6%) of patients were shunted based on EEG changes
  - In 6/6 cases, rSO₂ also dropped to >20% from baseline values
  - In 12/94 of the remaining patients not shunted, rSO₂ dropped to >20% from baseline values without EEG changes, although a change in blood pressure was observed
  - 82 patients showed no change in EEG or rSO₂ drop of >20% from baseline
  - Compared to EEG, rSO₂ demonstrated the following with respect to indications for shunting
    - Sensitivity = 100%
    - Specificity = 87.2%
    - PPV = 33.3%
    - NPV = 100%
    - False positives = 66.6%
    - False negatives = 0%
  - SP showed a PPV of 12% and NPV of 97% compared to EEG

- **Conclusions**
  - NIRS monitoring technology can be considered as a practical and non-invasive method to monitor ischemia, with the added benefit of providing an early warning for changes in blood pressure.
## Monitoring with INVOS™ technology can be considered as a sensitive, specific, and practical method compared to EEG to predict cerebral ischemia during CEA

**INVOS™ technology paired with an interventional algorithm can inform the need for shunt placement during CEA.**


<table>
<thead>
<tr>
<th>Study design</th>
<th>Single center, prospective observational study (The Netherlands)</th>
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<tr>
<td>Arms</td>
<td>Single arm: concomitant INVOS™, EEG, and transcranial Doppler (TCD) monitoring</td>
</tr>
<tr>
<td>Objective</td>
<td>Compare the ability of INVOS™ monitoring technology and TCD to EEG in detecting cerebral ischemia and determining the need for shunting</td>
</tr>
<tr>
<td><strong>N</strong></td>
<td>151</td>
</tr>
<tr>
<td><strong>Population</strong></td>
<td>CEA under general anesthesia in patients with a sufficient TCD window</td>
</tr>
<tr>
<td><strong>Definition of desaturation</strong></td>
<td>rSO₂ ≥16% from baseline value</td>
</tr>
<tr>
<td><strong>Threshold for intervention</strong></td>
<td>Shunt was placed when EEG detected the occurrence of new delta or theta activity</td>
</tr>
</tbody>
</table>
| **Results**        | • 17/151 (11%) of patients were shunted based on EEG changes  
• In 16/17 cases, rSO₂ also dropped to ≥16% from baseline value  
• In 5/134 of the remaining patients not shunted, rSO₂ dropped to ≥16% from baseline value without EEG changes  
• 129 patients showed no change in EEG or rSO₂, drop of ≥16% from baseline value  
• Compared to EEG, rSO₂ demonstrated the following with respect to indications for shunting  
  – PPV = 76%  
  – NPV = 99%  
  – Sensitivity = 94%  
  – Specificity = 96%  
• Similar results were seen with TCD, although the PPV and specificity were lower at 53% and 90%, respectively  
• Trend towards higher incidence of stroke in shunted patients was seen (11.8% vs 1.5%; p=0.06) |
| **Conclusions**    | NIRS monitoring technology may be effective for shunt selection, and the optimal threshold for shunt selection requires further study |
INVOS™ monitoring technology paired with an interventional algorithm can inform the need for shunt placement during CEA


<table>
<thead>
<tr>
<th>Study design</th>
<th>Multicenter, prospective, randomized controlled trial (Greece)</th>
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</table>
| Arms         | **Group A:** INVOS™ monitoring and use of an interventional protocol to restore rSO₂  
**Group B:** INVOS™ monitoring without the use of an interventional protocol  
**Group C:** Control, no INVOS™ monitoring used |
| Objective    | Examine the effect of using NIRS monitoring with an interventional protocol on the decision to place a shunt |
| N            | 253                                                          |
| Population   | CEA under general anesthesia                                  |
| Threshold for intervention | rSO₂ >20% of baseline value prompts employment of interventional protocol, including consideration to place a shunt |

**Results**
- The incidences of shunt placement were significantly different between groups (p<0.001):
  - Group A= 27.7%
  - Group B = 59.5%
  - Group C= 100%
- Compared to Group A, patients in Groups B and C had a 3.7 times and 70.6 times greater likelihood of receiving a shunt, respectively
- Compared to Group B, Group C had a 19.4 times greater likelihood of receiving a shunt
- No difference in neurologic deficits was observed between the three groups

**Conclusions**
NIRS monitoring technology paired with the use of a specific treatment algorithm may aid in the selective shunting of patients undergoing CEA
A selection of clinical studies using INVOS™ technology intraoperatively in carotid endarterectomy surgery


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INVOSTM monitoring technology may be an effective monitoring method compared to EEG to predict cerebral ischemia during CEA.

Monitoring with INVOSTM technology can be considered as a sensitive, specific, and practical method compared to EEG to inform shunt selection during CEA.

INVOSTM technology may be a sensitive monitoring method compared to EEG to inform shunt selection during CEA.

INVOSTM monitoring technology paired with an interventional algorithm can inform the need for shunt placement during CEA.

A selection of clinical studies using INVOSTM technology intraoperatively in carotid endarterectomy surgery.

Now That You’ve Read the Evidence

Consider using INVOSTM monitoring in all Carotid Endarterectomy (CEA) Surgeries

For more information, contact your Covidien representative or visit covidien.com/rms/products/cerebral-somatic-oximetry