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# The Roadsaver Stent to Treat Carotid Lesions

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Carotid Artery Stenting (CAS) is being widely performed in patients with symptomatic and asymptomatic carotid stenosis at high risk for carotid endarterectomy. The safety and efficacy of CAS has been well demonstrated in multiple trials and is accepted as an alternative therapy to the surgical approach in multidisciplinary guidelines. With the advances in CAS device technologies, a variety of products with different properties is available to contemporary CAS operators. The stent's scaffolding capacity plays a major role in preventing procedural events. To date, the ideal stent design has been discussed, yet remains unclear.

The RoadSaver™ carotid stent (Terumo Corp, Tokyo, Japan) is a novel self-expanding stent with a dual layer tubular nitinol mesh, designed to provide sustained embolic protection by extensive plaque coverage and prevention of plaque prolapse. This dual layer stent has a 450 µ lattice that makes it unique in comparison to the other commercially approved carotid stent devices. The implant is produced with various outer diameters ranging from 5 to 10 mm and with lengths of 20-40 mm.

Hopf-Jensen et al. investigated this RoadSaver stent in a small study with 7 patients. They concluded the RoadSaver stent seems to be safe and effective in the treatment of extracranial ICA stenosis and in the context of tandem lesions in ischemic stroke. Another study investigated the mechanical and implant behavior of the CASPER-RX stent in 12 patients. They concluded that this stent showed a safe implantation behavior without the occurrence of any ischemia. The structure of the new CASPER-RX stent creates an acceptable flexibility, low radial force and high collapse pressure. ASPER is another brand name for the dual-layer micromesh carotid stent (identical to the RoadSaver), used for commercialization within the Neuro-Radiology discipline.

The CLEAR-ROAD study is a prospective, multinational, single-arm study in high surgical risk patients with severe carotid stenosis. A total of 100 non-consecutive patients (31% symptomatic patients) were enrolled in nine clinical centers divided over Belgium, Germany and Italy. The CAS procedure (e.g. vascular access, the use and type of embolic protection devices) was performed according to the physician's standard of care and based on the instructions for use of the RoadSaver carotid stent system. An EPD was used in 58% of the cases.

Within the first 30 days of follow-up, one patient suffered a Myocardial Infarction (MI) which led to death. One patient suffered a minor ipsilateral stroke (14 days post procedure), due to an atrial fibrillation which was not adequately treated with warfarin medication. Freedom from MAE rate was therefore 97.9% within the first 30 days. While no statistical analysis could be performed, subgroup data suggested that there were no notable differences in the 30-day MAE rate between symptomatic & asymptomatic patients, or between EPD uses. At 6-month follow-up, freedom from MAE rate was 93.7%.

The 30-day and 6-month clinical outcome of 100 patients treated with the dual layer micromesh RoadSaver carotid stent shows promising results. The RoadSaver stent is a safe and effective device for endovascular treatment of subjects at high risk for carotid endarterectomy. The importance of the use of EPD's in combination with this new generation of carotid stent can be discussed, as several reports pointed out that EPD's do not completely eliminate the risk of cerebral embolization. Recent studies postulated that the stent design appears to have more important impact on the resulting complications in CAS, rather than in EPD's. Case examples are shown in **Figure 1.**

 


**Figure 1** A) Pre-op; B) Post-op; and C) RoadSaver™ carotid stent.