

Mesh-covered (Roadsaver) stent as a new treatment modality for symptomatic or high-risk carotid stenosis

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Abstract

Introduction: Prevention of periprocedural stroke has a crucial role in carotid artery stenting (CAS) procedures.

Aim: To assess retrospectively 30-day safety and effectiveness of 41 procedures of internal and common carotid artery stenting using the Roadsaver double nitinol layer micromesh stent in 40 non-consecutive patients with symptomatic or high-risk carotid artery stenosis.

Material and methods: The patients were men ($n = 31$) and women ($n = 9$); mean age was 67.8 ± 7.9 years. Femoral access was used in 39 cases, whereas radial access was used in 2. Proximal ($n = 27$) or distal ($n = 14$) embolic neuroprotection was used.

Results: The Roadsaver stents (nominal diameter 7, 8 or 9 mm, length 25 or 30 mm) were implanted successfully in all cases. One minor stroke occurred after common carotid artery intubation with a guiding catheter (before stent deployment) and one transient postprocedural ischemic attack (TIA) of the ipsilateral cerebral hemisphere was observed. Internal/common carotid artery stenosis severity was evaluated by duplex Doppler. Maximal peak systolic velocity (PSV) before CAS was in the range: 2.0–7.0 m/s, mean: 3.9 ± 1.0 m/s, at 24–48 h after stenting mean PSV was 1.1 ± 0.4 m/s ($p < 0.05$), and at 30 days 1.1 ± 0.3 m/s ($p < 0.05$). Maximal end-diastolic velocity (EDV) was 0.85–3.5 m/s, mean 1.4 ± 0.5 m/s, at 24–48 h after stenting mean EDV was 0.3 ± 0.1 m/s ($p < 0.05$), and at 30 days 0.4 ± 0.1 m/s ($p < 0.05$). No restenosis or thrombosis was observed. Angiographic stenosis decreased from $82.9 \pm 9.1\%$ (range: 61–97%) to $19.3 \pm 7.3\%$ (range: 0–34%) ($p < 0.05$).

Conclusions: The CAS using the Roadsaver stent seems to be safe and effective. Further studies involving larger patient populations and longer follow-up are needed.

Key words: carotid artery stenting, Roadsaver stent, carotid artery disease, nitinol double-layer mesh stent.

Introduction

Carotid artery stenting (CAS) is an alternative to surgery, and prevention of embolization has a crucial role during the CAS procedure. The CREST (Carotid Revascularization Endarterectomy versus Stenting Trial) trial suggested a higher risk of ipsilateral strokes after CAS compared to carotid endarterectomy (CEA) by 30 days. In contrast, there was no significant difference in the incidence of ipsilateral major stroke related to CAS or CEA from 30 days until 4 years [1]. With conventional carotid stents, the risk of embolization as a result of plaque protrusion persists for 30 consecutive days until the stent is endothelialized [2]. The risk of emboli-

sation leading to adverse neurological events is particularly high after stent implantation, after postdilatation and after embolic protection device (EPD) removal. For this reason, it is necessary to refine the carotid stent design [2].

Use of closed-cell rather than open-cell design stents has been, in general, associated with a reduction of the number of periprocedural adverse neurologic events, particularly in symptomatic patients [3, 4]. Proper selection of patients, the most appropriate EPD and stent type (tailored CAS) is necessary to ensure periprocedural safety [5, 6].

One of the recently introduced new stent designs is the double nitinol layer micromesh self-expandable

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stent Roadsaver [1, 2, 7–10]. The stent has a double structure: external macromesh and internal micromesh. The smallest cell size is 375–500 μm . The external layer crushes the plaque, flattening it to the inner wall of the vessel. The internal layer protects against plaque protrusion and embolization thanks to the optimized micromesh density [1, 7].

Aim

We assessed the safety and effectiveness of percutaneous carotid stent implantation using the Roadsaver stent in the treatment of symptomatic or high-risk, extracranial carotid artery disease.

Material and methods

This is a retrospective analysis of 41 procedures using the Roadsaver stent in non-consecutive symptomatic cases ($n = 21$, 51.2%) and/or in patients with high-risk stenosis ($n = 20$, 48.7%). There were 31 men (age: 68.5 ± 8.2 range: 51–84 years) and 9 women (age: 59.6 ± 6.2 , range: 57–72) with significant ($> 50\%$ diameter stenosis,

DS) internal or common carotid artery (ICA or CCA) stenosis. One patient with severe, bilateral ICA stenosis underwent a sequential CAS procedure of both ICA. High-risk ICA stenoses were defined as lesions over 25 mm in length, containing aneurysm, thrombus or ulceration.

The patients suffered from hypertension ($n = 37$), hyperlipidemia ($n = 38$), diabetes ($n = 13$), and coronary artery disease ($n = 30$). Moreover, 10 patients had previous myocardial infarction, 8 patients had multivessel coronary artery disease, and 9 patients had previously undergone contralateral carotid artery stenting (Table I). Carotid stenosis grade was assessed on carotid Doppler duplex ultrasound and it was subsequently verified by quantitative carotid angiography (QCA) just before CAS. The mean DS was $82.9 \pm 9.1\%$ (range: 61–97%). The length of the stenotic segment was from 20 to 48 mm (mean: 27.2 ± 6.4 mm).

Each patient was on dual antiplatelet therapy (aspirin 75 mg and clopidogrel 75 mg daily for at least 3 days before the procedure or loading doses of 300 mg of aspirin and clopidogrel the day before the procedure). During CAS unfractionated heparin (100 IU/kg) was used.

We performed 15 procedures of right ICA stenting, 25 of left ICA stenting and one left common artery angioplasty. Proximal ($n = 27$) or distal ($n = 14$) embolic protection was applied. Guiding catheters 7 Fr ($n = 2$) for right radial access, 8 Fr ($n = 2$) or guiding sheaths 5 Fr ($n = 3$) or 6 Fr ($n = 7$) were used (Table II).

Table I. Baseline characteristics of patients

Parameter	Value
Number of patients	40
Age of all patients [years]	67.8 ± 7.9
Age of men [years]	68.5 ± 8.2
Age of women [years]	59.6 ± 6.2
Hypertension	38 (95%)
Hyperlipidemia	39 (97.5%)
Diabetes	13 (32.5%)
Active smokers	17 (42.5%)
Coronary artery disease	31 (77.5%)
Previous myocardial infarction	10 (25%)
Multivessel coronary artery disease	8 (20%)
Previous contralateral carotid artery stenting	9 (22.5%)
Previous percutaneous coronary artery intervention	14 (35%)
Restenosis after carotid endarterectomy	1 (2.5%)
Chronic renal failure	13 (32.5%)
Peripheral artery disease	9 (22.5%)
Transient ischemic attack of ipsilateral hemisphere in the last 6 months	1 (2.4%)
Stroke of ipsilateral hemisphere in the last 6 months	18 (44%)
Ipsilateral amaurosis fugax in the last 6 months	2 (4.8%)
High-risk lesion	20 (48.7%)

Table II. Devices used during carotid stenting with Roadsaver stents

Guiding catheters:	
– Softip XF 7 Fr ($n = 2$) for radial access	
– Mach Peripheral 8 Fr ($n = 1$)	
– HSII 8 Fr ($n = 1$)	
Guiding sheaths:	
– Terumo Destination 5 Fr ($n = 3$)	
– Terumo Destination 6 Fr ($n = 7$)	
Proximal embolic protection devices:	Distal embolic protection devices:
– MonoMo.Ma 8 Fr ($n = 1$)	– Wirion system ($n = 5$)
– Mo.Ma 8Fr ($n = 25$)	– Emboshield NAV ⁶ ($n = 3$)
– Mo.Ma 9 Fr ($n = 1$)	– Spider FX ($n = 5$)
	– Filter Wire EZ ($n = 1$)
Predilatation:	
Sizes of balloon catheter: 2.5–3.5 mm width diameter, mean: 2.9 ± 0.3 , 15–20 mm length diameter, mean: 18.1 ± 1.0 mm	
Inflation pressure: 10–16 atm, mean: 13.0 ± 1.5 atm	
Sizes of Roadsaver stents:	
– 7.0 mm width \times 25 mm length diameter ($n = 11$)	
– 8.0 mm width \times 25 mm length diameter ($n = 12$)	
– 8.0 mm width \times 30 mm length diameter ($n = 11$)	
– 9.0 mm width \times 30 mm length diameter ($n = 7$)	
Postdilatation:	
Sizes of balloon catheter: 4.5–6.5 mm width diameter, mean: 4.8 ± 0.3 mm, 20 mm length diameter	
Inflation pressure: 8–18 atm, mean: 13.07 ± 2.5 atm	

Direct stenting was performed in 24 (58.5%) cases, whereas in 17 (41.4%) cases predilatation with a small coronary balloon (2.5–3.5 mm) was required. In all cases postdilatation was performed using usually 4.5 to 5.5 mm diameter balloons (in one case 6.5 mm – during left common artery angioplasty) to optimize the angio-

graphic outcome (Figures 1, 2). In each patient angiography of intracranial arteries before and comparatively after the procedure was performed.

Patients were discharged 1–2 days after the procedure with the recommendation to take aspirin indefinitely and clopidogrel 75 mg for 3 months. In addition, in

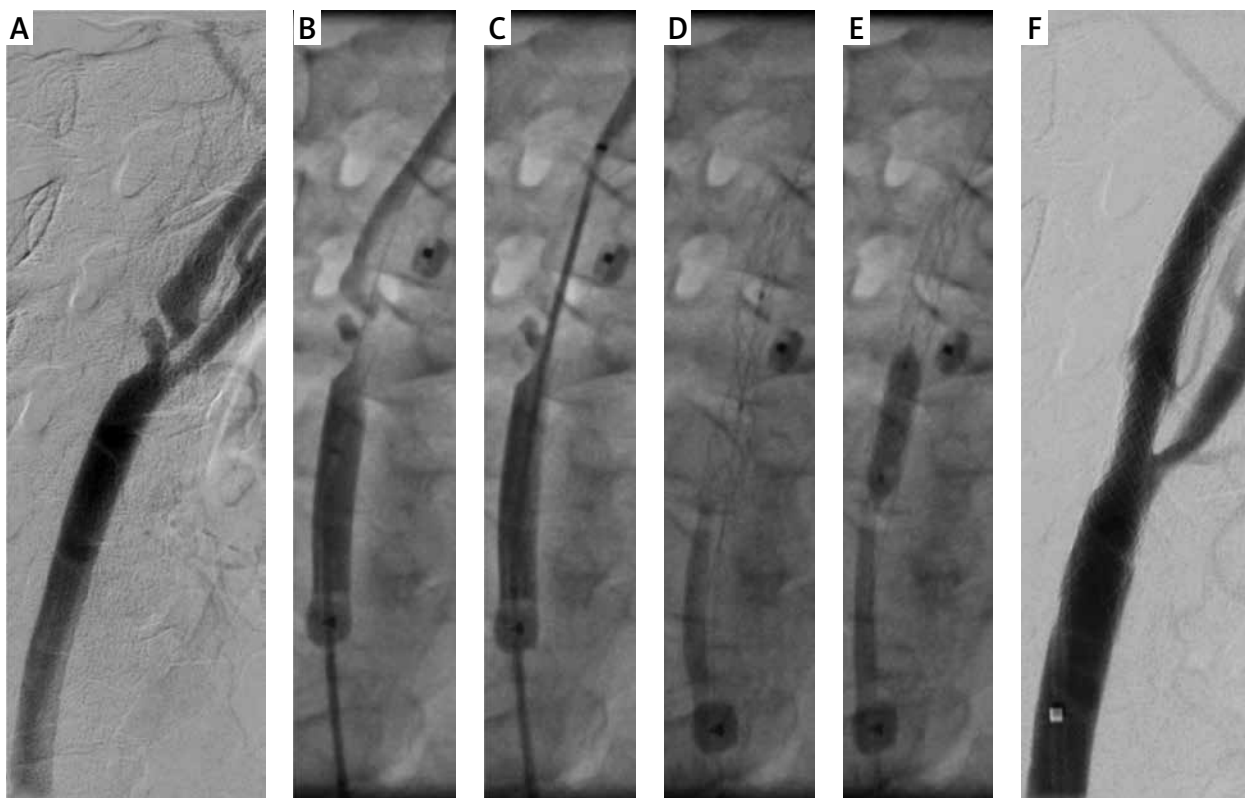


Figure 1. Severe, high-risk (aneurysm with thrombus) lesion of right ICA and the next steps of CAS using the Roadsaver stent and Mo.Ma EPD system: **A** – angiography, **B** – Mo.Ma balloons inflated in external and common carotid artery, **C** – stent placement, **D** – stent expanding – “direct stenting”, **E** – postdilatation, **F** – final angiography

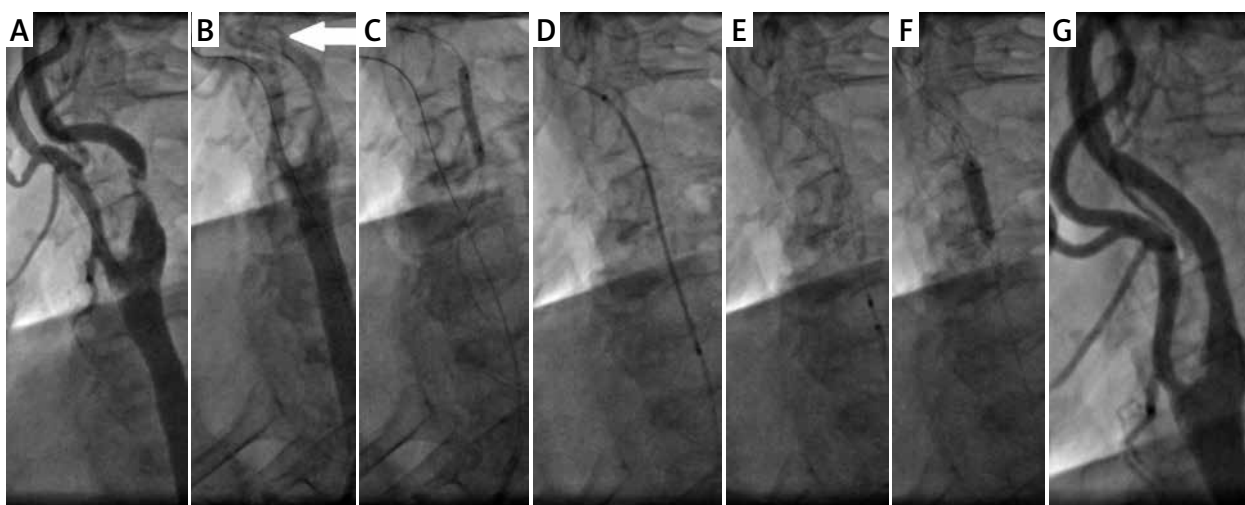


Figure 2. Severe symptomatic lesion of the left ICA and the next steps of CAS using the Roadsaver stent and distal EPD-Wirion: **A** – angiography, **B** – opening of the filter distal to the ICA stenosis (arrow), **C** – predilatation, **D** – stent placement, **E** – stent implantation, **F** – postdilatation, **G** – final angiography

4 patients with atrial fibrillation vitamin K antagonists were continued after CAS.

Statistical analysis

The data were analyzed using the Statistica 12.0 software suite (StatSoft). The Shapiro-Wilk W test and the Kolmogorov-Smirnov test with the Lilliefors correction were used to verify the normality of distribution of results. Depending on the result of the normality of distribution, the data were analyzed using parametric or non-parametric tests. The null hypothesis (H₀) was rejected at the established level α lower than 0.05.

Results

The Roadsaver stent was successfully delivered and expanded in all cases. One minor stroke occurred directly after common carotid artery intubation. In another patient transient ischemic attack (TIA) of the cerebral hemisphere ipsilateral to the ICA lesion was observed after the CAS procedure.

The postprocedural residual stenosis was 0–33% by in-house QCA (mean: $19.3 \pm 7.3\%$) vs. $82.9 \pm 9.1\%$ (range: 61–97%) before the procedure ($p < 0.05$). No stent thrombosis occurred by 30 days. The mean time of the procedure was 26 ± 6 (range: 18–32) min when proximal EPD was used, and for distal embolic protection the time of the procedure was 25 ± 2 (range: 17–30) min. Fluoroscopy time was 9.8 ± 1.1 (range: 8.1–11.7) min.

Postprocedural carotid Doppler duplex was performed at 24–48 h after CAS and showed that mean peak systolic velocity (PSV) decreased from 3.9 ± 1.0 m/s (range: 2.0–7.0 m/s) to 1.1 ± 0.4 m/s (range: 0.5–2.1 m/s) ($p < 0.05$) and at 30-day follow-up mean PSV was 1.1 ± 0.3 m/s (range: 0.7–2.7 m/s) ($p < 0.05$). Mean EDV at 24–48 h after CAS decreased from 1.4 ± 0.5 m/s (range: 0.85–3.5 m/s) to 0.3 ± 0.1 m/s (range: 0.17–0.6) ($p < 0.05$) and at 30-day follow-up mean end-diastolic velocity (EDV) was 0.4 ± 0.1 m/s (range: 0.2–0.6) ($p < 0.05$). No significant in-stent restenosis was observed up to 30 days.

Discussion

The micromesh double-layer self-expandable stent Roadsaver seems to be a significant step in the intra-procedural as well as postprocedural prevention of stroke. This particular type of stent is a part of new family of double-layered stents [1, 2, 7–10].

The Roadsaver stent combines the advantages of open-and closed-cell stents. Open-cell stents may cause fibrous cap rupture, plaque protrusion through the struts and higher risk of embolization, but they have better apposition to the vessel wall than the closed-cell stents. However, they have the advantage of good conformability in tortuous anatomies [2, 11, 12]. Although conventional carotid stents of closed-cell design may reduce the

risk of plaque protrusion-associated adverse neurological events [3, 4, 13], this risk is not totally eliminated as the free cell area is at least 1.08 mm^2 .

Schnaudigel *et al.* showed that significant, ipsilateral changes in diffusion-weighted magnetic resonance imaging of the brain are more frequent after CAS with open-cell stent than after closed-cell stent implantation ($p < 0.01$) [14]. Among currently available carotid stents, the closed-cell Carotid Wallstent has the smallest size of cells (it covers the plaque and decreases the risk of plaque protrusion through the struts). However, due to the low flexibility of this stent type, stent delivery in a tortuous vessel may be difficult [1, 2].

In the last few years, a new type of carotid stent, which combines optimal flexibility with embolic prevention, was developed. The dual-layer micromesh design and small cell size enable the plaque to be covered and possible debris to be “trapped” between the stent scaffold and the vessel wall. Another important feature of the Roadsaver stent is its flexibility, which makes the stent deliverable even in tortuous vessels, compared to the commonly used closed-cell stents such as the Carotid Wallstent or Xact [2, 12]. Recently published data on optical coherence tomography imaging of the Roadsaver stent showed good wall apposition without significant plaque protrusion through stent cells [1, 15].

The Roadsaver stent has other important aspects: it is fully re-sheathable and repositionable even after deploying 50% of the stent’s length, has a 5 Fr rapid exchange delivery system and a low profile, which enhances the crossability. One macro-mesh cell consists of 16 very small micromesh cells (size of 0.381 mm^2) [1]. The micromesh cells are expected to prevent plaque protrusion and embolization after stent implantation. The Roadsaver stent has the advantages of both open-cell (flexibility) and closed-cell (plaque coverage) stents. The stent is available from 5 to 10 mm width diameter and 22 to 47 mm overall stent length and can accommodate vessels 1 or 2 mm smaller in diameter than unconstrained conditions – maximal length 67 mm. In case of suboptimal stent deployment, repositioning is feasible.

Some authors believe that CAS using the Roadsaver stent could be performed without EPD [2, 3, 16]. This idea seems to be unreasonable, as periprocedural stroke can occur not only during stent implantation, but also at the level of introduction of the balloon catheter or stent in the unprotected diffusely diseased atherosclerotic artery. That might have been the possible cause of stroke in one of the patients in our study. Another important aspect of the micromesh double layer stent is the fact that, due to its specific design it can have an important role in the treatment of the extracranial carotid artery aneurysm or pseudoaneurysm. The unique features of micromesh can result in significant reduction of aneurysmal sac perfusion and later complete occlusion within

11–17 days only, while the time to full occlusion of the aneurysm using other carotid stents is significantly longer – at least 6 months [8].

The introduction of mesh-covered stents might lead to further reduction of the rate of periprocedural neurological complications of CAS procedures, which is now at the level of 2.38% (thirty-day complication rate) according to the ‘tailored-CAS’ registry [5, 6], performed in our high-volume center.

Another recently introduced micromesh design – the CGuard MicroNet-covered embolic prevention carotid stent system (MN-EPS) – gives similar favorable results within 30 days. Musialek *et al.* performed 101 CAS procedures in symptomatic (54.4%) or asymptomatic (45.6%) cases. Only 1 symptomatic patient (0.9%) suffered from minor ipsilateral stroke 24–48 h after CAS [17]. The registry of the CGuard stent by Shofer *et al.* revealed 30 CAS procedures. Possible neurological events were assessed not only by clinical symptoms (no complications were observed) but also on diffusion-weighted magnetic resonance imaging (DWI) at 48 h and 30 days after the procedure [10]. New ipsilateral minor ischemic lesions at 48 h occurred in 37% of patients (the average lesion volume was $0.39 \pm 0.08 \text{ cm}^3$). The 30-day DWI showed complete resolution of all but 1 periprocedural lesion and only 1 new minor lesion in relation to the 48-hour scan.

The recently published CLEAR-ROAD (CAS with the Roadsaver stent use) study, which included 100 patients, 31% symptomatic and EPD use was not mandatory (only 58% of patients underwent CAS with EPD), showed a low major periprocedural adverse event rate of 2.1% [16].

In our study patients were symptomatic or were at high risk of neurological embolic complications. Despite these unfavorable characteristics, a periprocedural event (minor stroke) occurred only in one patient during CAS, and it was not related to the Roadsaver because it occurred before stent deployment.

Conclusions

The CAS with the double-layer nitinol Roadsaver stent is effective and appears safe. Prospective studies involving larger numbers of consecutive patients are needed to fully demonstrate the benefit of Roadsaver in relation to conventional carotid stents.

Conflict of interest

Dr P. Pieniżek has received honoraria as a proctor from Terumo. Other authors declare no conflict of interest.

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