



# Using the Casper Stent in Carotid Angioplasty: A Single Center Experience

## *O uso do stent casper na angioplastia carotídea: Experiência de único centro*

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### Abstract

**Objectives** To establish the success rate in endovascular internal carotid artery (ICA) stenosis recanalization using the double-layer stent Casper-RX (Microvention, Inc 35 Enterprise, Aliso Viejo, California, United States of America) and to identify the main comorbidities in individuals with ICA stenosis, morphological characteristics of the stenosis, diagnostic methods, intraoperative complications, as well as morbidity and mortality within 30 days of the surgical procedure.

**Materials and Methods** Retrospective analysis of 116 patients undergoing ICA angioplasty with a degree of stenosis  $\geq 70\%$  using Casper-RX stenting who underwent this procedure from April 2015 to December 2019.

**Results** Technical success was achieved in 99.1% of the patients. Three of them had postprocedural complications: one transient ischemic attack (TIA) and two puncture site hematomas. A cerebral protection filter was not used in only two procedures, as these consisted of dissection of the carotid. There was satisfactory recanalization and adequate accommodation of the stents in the previously stenosed arteries, with no restenosis in 99.4% of the cases.

**Conclusion** The endovascular treatment of extracranial carotid stenoses using the Casper-RX stent showed good applicability and efficacy. Although only two cases of thromboembolic complications occurred during the procedure, further investigation and studies on the effectiveness of this new device are needed.

### Keywords

- casper stent
- double-layer stent
- carotid stenosis
- angioplasty
- stroke

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## Resumo

### Palavras-chave

- stent casper
- stent de dupla camada
- estenose carotídea
- angioplastia
- AVC

**Objetivos** Identificar a taxa de sucesso na recanalização de estenose da artéria carótida interna (ACI) obtida por método endovascular quando utilizado o stent de dupla camada Casper-RX (Microvention, Inc 35 Enterprise, Aliso Viejo, California, United States of America) e identificar as principais comorbidades apresentadas pelos indivíduos com estenose de ACI, características morfológicas das estenoses, métodos utilizados para diagnósticos, ocorrência de complicações transoperatórias e a morbimortalidade nos 30 dias posteriores ao procedimento cirúrgico.

**Materiais e métodos** Análise retrospectiva de 116 pacientes submetidos a procedimento de angioplastia da ACI com grau de estenose  $\geq 70\%$ , com a utilização de stent Casper-RX, durante o período de abril de 2015 a dezembro de 2019.

**Resultados** O sucesso técnico foi alcançado em 99,1% dos indivíduos. Três pacientes apresentaram complicações pós procedimento, sendo um acidente encefálico transitório (AIT) e dois hematomas de sítio de punção. Em apenas dois procedimentos não se utilizou filtro de proteção cerebral devido tratar-se de dissecação carotídea. Houve satisfatória recanalização e acomodação adequada dos stents nas artérias previamente estenosadas, não havendo reestenose em 99,4% dos casos.

**Conclusão** O tratamento endovascular das estenoses carotídeas extracranianas com uso do stent Casper-RX demonstrou boa aplicabilidade e eficácia. Apesar de ter apresentado apenas dois casos de complicações tromboembólicas durante o procedimento, são necessárias maiores investigações e estudos sobre a eficácia deste novo dispositivo.

## Introduction

Extracranial stenosis of the internal carotid artery (ICA) accounts for between  $\sim 10$  and 15% of ischemic strokes, which is one of the main causes of death and disability in the world.<sup>1</sup> The advent of vascular microsurgery brought stent angioplasty as a promising alternative to ICA endarterectomy, especially for patients whose comorbidities increase their surgical risk, in cases of restenosis after procedures, and in those with previous radiation therapy of the cervical region.<sup>2</sup>

Stenting of the carotid artery is associated with long-term lower rates of stroke after elective treatment of individuals with significant extracranial ICA stenosis.<sup>3</sup> However, this technique poses a risk of intraoperative cerebral embolism due to mobilization of atherothrombotic materials after manipulation of the lesion, as well as to plaque protrusion through the expanded stent struts. For this reason, special attention has been paid to the design, material, and shape of the chosen stent.<sup>4</sup>

To reduce the embolic risk of the procedure, a dual-layer carotid stent model has been introduced. In addition to the self-expanding nitinol outer layer that provides support, its second micro mesh layer provides better plaque coverage while remaining flexible.<sup>5</sup> Short-term outcomes following the use of these devices in elective environments have proven to be promising.<sup>6</sup>

The Casper-RX carotid stent has the smallest area between closed cells of all carotid stents on the market. Double-layer devices have delivered greater benefits regarding atheroma plaque coverage and decreased likelihood of infarction due to the embolization of atheroma plaques.<sup>7</sup>

Thus, the purpose of the present article is to study carotid artery stenosis recanalization using a new model of double-layer stent, the Casper-RX, as well as to evaluate its clinical behavior in a reference center for endovascular neurosurgery in Brazil.

## Methodology

### Design and Sample

Retrospective study of the medical records of 116 patients undergoing angioplasty of the extracranial segment of the ICA using the Casper-RX stent from April 2015 to December 2019 in a reference center service for endovascular neurosurgery in the city of Blumenau, state of Santa Catarina, Brazil.

### Inclusion and Exclusion Criteria

Symptomatic and asymptomatic patients who underwent endovascular treatment of stenosis of at least 70% of the ICA with Casper-RX stent implantation from April 2015 to December 2019 were included. Insufficient data – such as segment loss within 30 days and absence of radiological reports – were considered exclusion criteria.

### Data Analysis

Categorical variables were expressed as absolute values (percentages), and quantitative variables, as means  $\pm$  standard deviation (SD) or medians (interquartile range [IQR]) as appropriate. Analyses were tabulated in Microsoft Excel 2020 (Microsoft Corporation, Redmond, WA, USA) and analyzed using the SPSS Statistics for Windows version 17.0 (SPSS Inc., Chicago, IL, USA). Device safety and therapeutic success were evaluated, as well as the rate of complications and restenosis, compared with literature data.

## Variables

Epidemiological variables such as gender, age, and pre-existing comorbidities – diabetes mellitus, hypertension, dyslipidemia, smoking, and heart disease were collected. Pretreatment symptoms included headache, dizziness, ischemic stroke, and transient ischemic attack (TIA). Regarding the carotid lesion, the degree of stenosis on the affected side, laterality, treated bilaterality, presence of dissection, ulcerated plaque, and contralateral occlusion were analyzed.

Regarding the surgical procedure, the access type (femoral or axillary), immediate therapeutic success, intra- and post-operative events – from 90 days up to 6 months –, use of a cerebral protection filter, and stent diameter were studied. The overall neurological outcome of the individuals was evaluated using the 90-day modified Rankin Scale (mRS). Technical success was evaluated by carotid Doppler ultrasonography (USG) at least 6 months after the endovascular intervention. According to the degree of stenosis, patients were divided into “absent stenosis” if < 30%, “residual stenosis” if the persistence was between 30 and 40%, and “late stenosis” if they presented a higher degree with onset after 6 months of follow-up. Stent occlusion was also analyzed.

The noninvasive preprocedural diagnostic methods used include magnetic resonance imaging (MRI), computed tomography (CT), magnetic resonance angiography, angiotomography, and carotid Doppler test. Regarding the invasive test, cerebral arteriography was used in all procedures during angioplasty.

## Procedure

Patients undergoing endovascular intervention had atherosclerotic disease in the extracranial portion of the internal carotid artery, with a degree of stenosis between 70 and 99%, were symptomatic, or had been incidentally diagnosed. They were first put under sedation and total heparinization 10,000 UI, with femoral intra-arterial instillation of low osmolarity nonionic contrast through a guide catheter. Then, cerebral angiographies were performed to identify the precise site of stenosis and its degree. Brain protection filters, such as Spider FX (Medtronic, 710 Medtronic Parkway, Minneapolis, MN, United States of America), AngioGuard (Cordis 5452 Betsy Ross Dr, Santa Clara, CA, United States of America), and EmPro (Microvention, Inc 35 Enterprise, Aliso Viejo, CA, United States of America) were inserted. The filter passed through the stenosis and was then deployed. The Casper-RX stents with diameters of between 7 and 9 mm adapted to the wall, which allowed total correction of the affected arteries. After mapping and real-time radioscopy, the stents were detached. The cerebral protection filters were removed, and postoperative angiographies were performed, showing full coverage of the plaques and correct device patency. The primary endpoint was achieved with the successful placement of the device.

## Antiplatelet Therapy

Double antiplatelet therapy was administered with aspirin 200 mg and clopidogrel 75 mg to all patients, from 7 days before the procedure up to 3 months after the angioplasty.

## Results

### Epidemiological Variables, Symptoms, and Comorbidities

The mean age of the patients was 73 (66 to 79) years old; 79% were ≥ 68 years old. Of the total sample, 61.2% were male. Regarding the clinical presentation, 111 (96%) were symptomatic, mainly with dizziness (59.5% of the cases), ischemic stroke (33.6%) and TIA (17.2%). The most prevalent comorbidities were arterial hypertension (90.5%), and dyslipidemia (94%) (– **Table 1**).

**Table 1** Epidemiological and clinical characteristics

Characteristic	All cases n = 116
Age (years old) (mean [IQR])	73 (66–79)
≥ 68 years old (n [%])	79 (68.1)
Gender (n [%])	
Male	71 (61.2)
Female	45 (38.8)
Clinically documented symptoms (n [%])	
Dizziness	69 (59.5)
Headache	7 (6)
Ischemic stroke	39 (33.6)
Transient ischemic attack	20 (17.2)
Comorbidities (n [%])	
Arterial hypertension	105 (90.5)
Diabetes mellitus	43 (37.1)
Current smoker	29 (25)
Dyslipidemia	109 (94)
Cardiopathy	29 (25)
Stenosis in arteriography/Doppler	
Degree (%), mean (IQR)	80 (70–92.5)
Ulceration (n [%])	112 (96.5)
Carotid dissection (n [%])	4 (3.4)
Side of occlusion (n [%])	
Left	62 (53.5)
Right	54 (46.5)
Contralateral internal carotid artery (n [%])	
Occlusion	10 (8.6)
Previous treatment	10 (8.6)
Neuroimaging before procedure (n [%])	
MRI	21 (18.1)
CT scan	27 (23.3)
Arteriography	116 (100)
AngioMRI	11 (9.4)
Angiotomography	50 (43.1)
Carotid Doppler	75 (64.6)

Abbreviations: CT, computed tomography; IQR, interquartile range; MRI, magnetic resonance imaging.

### Preprocedural Stenosis Characteristics

Arteriography was the neuroimaging test of choice in all patients, allowing preoperative assessment of the degree of stenosis, of the presence of ulcerated plaque, and of dissecting pseudoaneurysm in the carotid arteries. Carotid Doppler test was performed in 75 individuals (64.6%). Other imaging tests used are described in ►Table 1. The average duration of the procedure was ~ 30 minutes.

### Technical Success and Intraoperative Complications

The average diameter of the implanted devices was 8.0 mm, with no need for additional stenting for complete coverage of the plaque. The surgical access was through the femoral artery in all patients. In 114 patients (98.3%), a cerebral protection filter was used during the procedure, mostly AngioGuard (81%), EmPro (13.8%), and Spider (2.6%). There were neither intra- nor postoperative complications in the two cases performed without a cerebral protection filter; therapeutic success was achieved, as these were dissection cases.

In 113 patients (97.4%), Casper stents were successfully placed in the carotid artery. During the procedure, 1 patient (0.8%) underwent a dissection of the internal iliac artery. One patient (0.8%) had encephalic thromboembolic complications, which were promptly identified and treated with stenting and recanalization of the affected arterial segment. Another patient (0.8%), who had a critical stenosis of 99%, with calcified plaque and a kinking of the left internal carotid artery, had a rupture of the artery in the distal portion of the stent during balloon angioplasty; this was the only case of death during the procedure.

### Postoperative Complications

In 97.4% of the cases, there were no complications after the surgical procedure (113/116). Among the events observed, 1 patient had TIA (0.8%) and 2 had a hematoma at the puncture site (1.6%), both treated conservatively.

There were 3 deaths, at 12, 18, and 19 days after the procedure. There was no causal relationship between these late deaths and the endovascular intervention. This outcome is attributed to the intrinsic complications of the initial ischemic stroke – infectious disorders such as aspiration pneumonia and evolution toward multiple organ failure.

### Restenosis Control Follow-up and Modified Rankin Scale

Throughout the clinical follow-up, a total of 115 patients (99.1%) remained stenosis-free (< 30%) on imaging, whereas 1 patient (0.8%) had residual stenosis (between 30 and 40%). Up to the last evaluations, no patient developed carotid restenosis or device occlusion after implantation of the Casper stent.

►Table 2 shows the mRS after 90 days of follow-up. The mean mRS value after angioplasty was 0.38, which points to the existence of reduced deficits in the functional evolution of the studied individuals.

**Table 2** Outcomes and neuroimaging

Characteristic	All cases n = 116
Immediate procedure success (n [%])	115 (99.1)
Transprocedural events (n [%])	
None	113 (97.4)
Dissection of the internal iliac artery	1 (0.8)
Thromboembolic complication	1 (0.8)
Vascular rupture and death	1 (0.8)
Technical success (n [%])	
No stenosis (< 30%)	115 (99.1)
Residual stenosis (30-40%)	1 (0.8)
Late restenosis	0 (0)
Stent occlusion (n [%])	0 (0)
Post procedural events (n [%])	
None	113 (97.4)
Minor stroke	1 (0.8)
Groin hematoma at the puncture site	2 (1.6)
mRS after 3 months (mean ± SD)	0.38 ± 1.23
0 (n [%])	105 (90.5)
1 (n [%])	0 (0)
2 (n [%])	2 (1.7)
4 (n [%])	6 (5.2)
5 (n [%])	2 (1.7)
6 (n [%])	1 (0.8)
Late death (n [%])	3 ( )

Abbreviations: mRS, modified Rankin scale; SD, Standard deviation.

### Discussion

Advances in neurointerventional techniques and the emergence of new endovascular materials have made stent angioplasty a safe and effective alternative for the treatment of carotid stenosis. Factors contributing to this evolution range from greater operator experience and selection of candidates for intervention to better device design.<sup>2</sup> The present study reports the outcome of a case series performed in a reference center including 116 patients with asymptomatic (4%) and symptomatic (96%) carotid stenosis to evaluate the performance of the Casper-RX stent. As a primary endpoint, device placement was successfully completed in 97.4% of the cases, with no immediate intercurrents.

For a long time, arterial endarterectomy (AE) was the recommended therapy for carotid artery stenosis.<sup>8</sup> Currently, carotid angioplasty is increasingly indicated. Both methods achieve the same revascularization success rates, a similar incidence of complications and of stroke in the short- and long-term.<sup>9</sup> Patients < 70 years old, as well as the symptomatic ones with severe stenosis and comorbidities that put them at high surgical risk, seem to benefit from angioplasty treatment.<sup>10,11</sup> The current literature still favors

endarterectomy as being overall safer and more effective.<sup>12</sup> However, there is still much to learn about the feasibility and safety of stent systems used today.

A growing number of studies regarding this device supports its good performance and promising results in selected individuals. Mutzenbach et al.,<sup>13</sup> in a study of 138 patients who underwent angioplasty with Casper stenting, achieved full success in all cases, with no intraoperative technical failure or adverse neurological events reported within 90 days. Only 14.5% of the cases had residual stenosis (between 30 and 40%) after the procedure. In the present study, were also found a high rate of surgical success and few intraoperative complications when using Casper stents. After 90 days of follow-up, the neurological and functional outcome was favorable in most cases, with no deficits in 93.1% of the individuals assessed using the mRS scale. The rate of residual stenosis in the study population was even lower (0.8%), and no cases of late restenosis or stent occlusion were recorded, which speaks in favor of the efficacy of the implanted device. The contribution of brain protection filters and of antiplatelet therapy for these outcomes should be considered.

In another study, in a sample of 110 severe carotid stenosis patients, the implantation of Casper stents combined with a distal embolic protection device was shown to be safe and to lead to a lower rate of ischemic lesions on diffusion-weighted MRI when compared with other stents, especially the conventional single-layer ones.<sup>14</sup> Similarly, a reduced number of thromboembolic complications was observed in this study. During stent implantation, there was only one thromboembolic event, which was promptly reversed and did not cause any permanent neurological deficits. Throughout the follow-up of up to 6 months after the procedure, there was one case of TIA. Such an outcome may be attributed to the double nitinol layer and micro mesh, as well as to the closed-cell design, of the Casper stent.<sup>4</sup> The other complications – late deaths, vascular rupture, internal iliac artery dissection, and puncture site hematoma – were not related to the device itself, but rather to the inherent risk of the procedure and to the underlying diseases of the patient.

In a study with a smaller sample size, Ozpeynirci et al.<sup>15</sup> analyzed 29 patients who underwent ICA angioplasty using a Casper-RX stent, of whom 78.6% were male with a mean age was 71.7 years old. The authors report 6 adverse events in the perioperative period, including 1 stent occlusion (3.4%), 2 patients with type 2 parenchymal hematoma (6.8%), and 3 other patients (10.3%) with a massive cerebral infarction area not related to a worse prognosis or to stent occlusion. No thromboembolic events were observed intraoperatively.

## Conclusion

The outcomes achieved in the present study corroborate the efficacy and safety of the use of Casper-RX stents to treat ICA stenosis, as previously demonstrated in the literature. In this series, technical success was achieved, with good clinical

repercussion and a low complication rate, considering the sample size. However, long-term follow-up is needed to better evaluate this new device, as well as comparative studies with other closed-cell stents.

## Ethics

The present study was conducted according to the Standard Item Protocol: Recommendations for Interventions (SPIRIT) and was approved by the local ethics committee under CAEE 31685320.0.0000.5370. The Informed Consent Form (ICF) was presented and made available to all individuals in the study.

## Conflict of Interests

The authors have no conflict of interests to declare.

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