



Published in final edited form as:

*J Vasc Surg.* 2009 March ; 49(3): 602–606. doi:10.1016/j.jvs.2008.10.016.

## Open-cell vs. Closed-cell Stent Design Differences in Blood Flow Velocities after Carotid Stenting

Damon S. Pierce, MD, Eric B Rosero, MD, J Gregory Modrall, MD, Beverley Adams-Huet, MS, R James Valentine, MD, G Patrick Clagett, MD, and Carlos H Timaran, MD

From the Division of Vascular and Endovascular Surgery, Department of Surgery, Veterans Affairs North Texas Health Care System and the University of Texas Southwestern Medical Center, Dallas, Texas

### Abstract

**Objective**—The differential effect of stent design, i.e. open-cell vs. closed-cell configuration, on carotid velocities detected by duplex ultrasonography (DUS) has not been established. To identify possible stent design differences in carotid velocities, we analyzed our experience with DUS obtained before and immediately after CAS.

**Methods**—In a series of 141 CAS procedures performed over a 3 year period, data from the first postinterventional DUS and carotid angiograms were evaluated for each patient. Peak systolic velocities (PSV), end-diastolic velocities (EDV), and internal carotid artery-to-common carotid artery (ICA-CCA) PSV ratios were compared according to stent design. Differences in carotid velocities were analyzed using nonparametric statistical tests.

**Results**—Completion angiogram revealed successful revascularization and less than 30% residual stenosis in each case. The 30-day stroke-death rate in this series was 1.6% and was unrelated to stent type. Postintervention DUS was obtained a median of 5 days after CAS (interquartile range [IQR], 1–25 days). Closed-cell stents were used in 41 cases (29%) and open-cell stents in 100 cases (71%). The median PSV was significantly higher for closed-cell stents (122cm/s; IQR, 89–143cm/s) than for open-cell stents (95.9cm/s; IQR, 77.–123) ( $P=.007$ ). Median EDV (36 vs. 29 cm/s;  $P=.006$ ) and median ICA-CCA PSV ratio (1.6 vs. 1.1;  $P=.017$ ) were also significantly higher for closed-cell stents. 45% of closed-cell stents had carotid velocities that exceeded the threshold of 50% stenosis by DUS criteria for a nonstented artery compared to 26% of open-cell stents ( $P=.04$ ). In fact, closed cell-stents had a 2.2-fold increased risk of yielding abnormally elevated carotid velocities after CAS compared with open-cell stents (odds ratio, 2.2; 95% confidence interval, 1.02–4.9).

**Conclusions**—Carotid velocities are disproportionately elevated after CAS with closed-cell stents compared with open-cell stents, which suggests that velocity criteria for quantifying stenosis may require modification according to stent design. The importance of these differences in carotid velocities related to stent design and the potential relationship with recurrent stenosis remains to be established.

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Carotid artery stenting (CAS) with cerebral protection is an effective alternative for the treatment of carotid stenosis in select patients, particularly those with significant comorbidities

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CORRESPONDENCE: Carlos H. Timaran, MD, University of Texas Southwestern Medical Center, 5909 Harry Hines Blvd, Dallas, TX 75390-9157, Phone: (214) 857-1808. Fax: (214) 857-1840, E-mail: carlos.timaran@utsouthwestern.edu.

Presented at the 2008 Vascular Annual Meeting, San Diego, California, June 5–8, 2008.

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or a hostile neck from previous surgical procedures or radiation.<sup>1–3</sup> Carotid stents of different design and configuration are available. Depending on the density of struts, stents can be classified into stents with a closed-cell or an open-cell configuration.<sup>4</sup> Closed-cell stents are characterized by small free cell areas between struts, whereas open-cell stents have larger gaps uncovered (Table I).<sup>5</sup>

Because of the possibility of restenosis and unknown long-term durability of the procedure, strict follow-up and surveillance are imperative after CAS.<sup>6,7</sup> Duplex ultrasonography (DUS) is the diagnostic modality of choice in the follow-up of patients who undergo carotid revascularization for carotid artery disease.<sup>6</sup> Stented carotid arteries have, however, shown artificially elevated blood flow velocities on postinterventional duplex.<sup>8</sup> Several published reports thus suggest ultrasound criteria for surveillance need to be modified to define clinically significant in-stent restenosis (ISR) after CAS.<sup>7,9,10</sup> The effects of stent design and other vessel characteristics on carotid velocities after CAS remain to be established and quantified.

We analyzed our experience with DUS obtained immediately after CAS to assess stent design differences in carotid velocities that could alter baseline velocity criteria for surveillance according to stent design.

## METHODS

Over a 3-year period, 141 patients underwent CAS procedures under cerebral embolic protection. Indications included moderate (50% or greater) symptomatic carotid stenosis or severe (80% or greater) asymptomatic carotid stenosis determined with DUS. All CAS procedures were performed under local anesthesia and IV sedation through retrograde access from the common femoral artery. All patients received dual antiplatelet therapy with aspirin and a thienopyridine prior to the procedure and perioperatively. Completion carotid angiograms and postoperative DUS were obtained in all patients after CAS and data derived from these tests were used for the analysis in this study. Baseline and postoperative angiograms after CAS procedures were performed with an OEC/GE Model 9800 mobile C-arm (OEC, Salt Lake City, Utah) or fixed angiographic units (AXIOM Artis dTA, Siemens, Malvern, Pa or Allura Xper FD10, Philips, Bothell, Wash). Angiographic projections that demonstrated the most severe degree of stenosis were selected and used to assess the degree of residual carotid in-stent stenosis according to the North American Symptomatic Carotid Endarterectomy (NASCET) criteria.<sup>11</sup> Carotid tortuosity was graded according to the vascular angulation from the proximal center line flow (absent, 0°; mild, <30°; moderate, 30°–60°; severe, >60°).<sup>12,13</sup>

Procedural details and CAS protocols at our institution followed techniques described in detail before.<sup>14</sup> Briefly, several types and models of cerebral protection devices were used to prevent distal embolization: Abbott AccUNET filter (ACCULINK System, Abbott Vascular, Santa Clara, CA), FilterWire EZ system (Boston Scientific, Natick, MA), and Angioguard Filter (Cordis, Warren, NJ). The following stents were available: Abbott Acculink carotid stent (ACCULINK System, Abbott Vascular, Santa Clara, CA), Carotid Wallstent (Boston Scientific Corp, Natick, MA), PRECISE carotid stent (Cordis, Warren, NJ), Xact Carotid stent, (Abbott Vascular, Santa Clara, CA), Protégé Carotid Stent (Cordis, Warren, NJ), and the NEXSTENT carotid stent (Boston Scientific Corp, Natick, MA). Carotid stent design choice was left to the discretion of the operating surgeon and there was equal availability of all stent designs.

Duplex ultrasound scanning was performed using Phillips ATL HDL 5000 SonoCT or Phillips IU 22 DU imaging systems (Bothell, WA) in two laboratories accredited by the Intersocietal Commission for the Accreditation of Vascular Laboratories (ICAVL). All studies were performed with the patients lying supine on the examining table with their necks extended 45 degrees toward the head of the table and rotated 45 degrees away from the examiner. Velocity

measurements were made at 60° insonation angles and were estimated using the software included with the individual duplex scanner. The degree of carotid stenosis was measured using velocities as well as the location of the carotid bifurcation, the distal extent of plaque, the diameter, and presence of redundancy or kinking of the internal carotid artery. Carotid bifurcations were imaged in transverse and longitudinal views. Linear transducers in the 5-MHz to 10-MHz range were used to measure blood flow velocities at the proximal, middle, and distal common carotid arteries (CCAs) and the proximal external carotid artery (ECA). Velocities in the proximal CCA and internal carotid artery (ICA) at proximal, middle and distal portions of the stent were carefully assessed and recorded. Lower frequency probes were used as needed to evaluate the distal ICA or deep lying vessels. ICA velocity was measured, if present, at the site of maximum residual in-stent stenosis. For the purposes of our study, results obtained with DUS were interpreted as abnormal when carotid velocities met the University of Washington modified previously validated criteria for nonstented carotid arteries that use digital subtraction angiography as the reference standard, which consider ICA stenosis as moderate to severe when peak systolic velocity (PSV) is greater than 125 cm/s and internal carotid artery-to-common carotid artery (ICA/CCA) PSV ratio is greater than 2.0.<sup>10,15</sup>

Descriptive statistics for categorical variables are presented as relative frequencies and compared using Chi-square contingency table analysis. Continuous variables were expressed as medians and interquartile ranges (IQR) and means  $\pm$  standard deviation (SD). Data was then compared with regard to stent-cell design using non-parametric statistical tests due to the skewed distribution of the variables. Blood flow velocities were compared according to stent design and type as independent samples using the Mann-Whitney U test. Mantel-Haenszel common odds ratio (OR) estimates are reported with 95% confidence intervals (95% CI). The SAS 9.1 (SAS Institute, Cary, NC) and MedCalc 9.5.1.0 (MedCalc Software, Mariakerke, Belgium) software programs were used for data analyses.

## RESULTS

Carotid DUS and angiographic imaging data for CAS procedures performed in 141 patients (121 men and 18 women) were analyzed. Sixty-four patients (45%) were treated for symptomatic carotid artery stenosis and 77 patients (55%) were asymptomatic. Indications for CAS included high surgical risk due to severe comorbidities (45%), hostile neck (previous CEA, radical neck dissection, radiation, permanent tracheostomy; 22%), high or low primary or concomitant lesion (lesion above C2 or below the clavicle; 19%) and contralateral ICA occlusion (14%). Successful revascularization (<30% residual stenosis) was achieved in all cases. Closed cell stents were used in 41 (29%) CAS procedures and open-cell stents in 100 (71%). There were no significant differences in symptomatic status, indications for CAS, carotid tortuosity and residual stenosis according to stent design. Acculink was the most commonly used open-cell stent and was used in 77 patients (57%) (Table II). Wallstent was the most commonly used closed-cell stent and was used in 39 patients (28%). The proportion of stents used related to stent design are outlined in Table II. Post-intervention DUS was obtained in all patients within a median of 5 days (IQR, 1–25 days) after CAS. The 30-day stroke-death rate in this series was 1.6% and was unrelated to stent type.

PSV was significantly higher after CAS with closed-cell stents (median, 122 cm/s; IQR, 89–143; mean  $\pm$  SD, 132 $\pm$ 57) compared with open-cell stents (95.9 cm/s; IQR, 77–123; mean  $\pm$  SD, 103 $\pm$ 37) ( $P = .007$ ). EDV was also significantly higher for closed-cell stents than for open-cell stents (median, 36 cm/s [IQR, 28–56] vs. 29 cm/s [IQR, 23–38];  $P = .006$ ) (means  $\pm$  SD, 41 $\pm$ 17 vs. 32 $\pm$ 15). ICA/CCA PSV ratios were also significantly higher for closed-cell stents than for open-cell stents (means  $\pm$  SD, 2.1 $\pm$ 3.1 vs. 1.3 $\pm$ 0.5, respectively). The median ICA/CCA PSV ratios were 1.6 (IQR, 1.2–2.1) and 1.2 (IQR, 0.9–1.5) for closed-cell and open-cell stents, respectively ( $P = .017$ ). Analysis confined to Wallstents vs. Acculink, the most

commonly used closed and open-cell stent types respectively, also yielded significantly higher median PSV (122 cm/s [IQR, 89–146] vs. 95 cm/s [IQR, 78–119]), EDV (36 cm/s [IQR, 27–54] vs. 30 cm/s [IQR, 24–38]), and ICA/CCA PSV ratio (1.6 [IQR, 1.1–2.20 vs. 1.1 [IQR, 0.8–1.5]) ( $P < .05$ ).

According to modified University of Washington duplex velocity criteria, 45% of closed-cell stents had carotid velocities that exceeded the threshold for moderate to severe (50% or greater) stenosis for a nonstented artery compared with 26% of open-cell stents ( $P = .04$ ) (Table III). Moreover, closed-cell stents demonstrated a 2.26 fold increased risk (OR, 2.26; 95% CI, 1.02–4.9) of having an abnormal duplex after CAS compared to open-cell stents. With respect to the two extremes of stent design related to free cell area, the Wallstent (smallest open free cell area) demonstrated 2.63 fold increased odds of yielding an abnormal duplex after CAS compared with the Acculink stent (largest open free cell area).

## DISCUSSION

The results of our study indicate that significant stent design differences in duplex velocities occur after CAS. Carotid blood flow velocities are, in fact, significantly higher after CAS with closed-cell stents compared with open-cell stents. Moreover, our data reveal that carotid blood flow velocities after CAS using closed cell stents can more frequently be considered abnormal according to established criteria for nonstented carotid arteries compared with open-cell stents. It remains unknown to what extent such stent design differences in carotid velocities may influence duplex criteria for restenosis and the incidence of ISR during follow-up.

CAS has emerged as an alternative in the treatment of carotid artery stenosis in select populations.<sup>1,16</sup> Despite some early promising results, the long-term durability of this treatment modality still remains in question.<sup>17</sup> Although DUS is the most frequent imaging technique used in the follow-up and surveillance of patients undergoing CAS, the application of current duplex criteria for nonstented carotid arteries is unreliable.<sup>6,9,10</sup> 18–20 Despite the reported relatively low incidence of ISR after CAS, select patients have a higher risk of recurrent disease, particularly those with a history of previous endarterectomy or neck radiation.<sup>21</sup> Therefore, it remains extremely important to identify patients at risk for clinically significant ISR as well as duplex criteria to detect it. Current studies have focused on identifying velocity criteria for stented carotid arteries that better predict ISR. To our knowledge, however, the effects of stent design on duplex flow velocities and ISR have not been explored.

Flexibility and scaffolding are key characteristics derived from stent design.<sup>4</sup> Closed-cell stents are less flexible and may develop kinks and incomplete expansion. Conversely, stents with an open-cell configuration conform best to angulated vessels or tortuous anatomy. In fact, the differences in the functional properties of stent subgroups are specifically related to the amount of free cell area between scaffolding components.<sup>4</sup> Scaffolding refers to the amount of support given to the vessel wall by a stent, which may hypothetically be important in the case of vulnerable plaques, where insufficient scaffolding may cause distal embolization and stroke if plaque material is squeezed through the struts of the stent. Closed-cell stents could potentially offer maximal scaffolding to the vessel wall. In approximately 75% of all CAS procedures, either open-or closed-cell stents may be used indiscriminately.<sup>22</sup> For the remaining fraction, careful preoperative screening is recommended. In addition to eventual access issues, the choice of the optimal carotid stent depends mainly on arterial anatomic characteristics and, to a lesser extent, lesion morphology. When treating an angulated vessels or tortuous anatomy, stents with a flexible and conformable open-cell configuration are preferred. Lesions with suspected high embolic potential could be primarily treated with stents with a closed-cell configuration. Unfortunately, optimal clinical evaluation of carotid plaque composition and the embolic potential of certain lesions are still not available. The potential hemodynamic

effects of stent design on carotid velocities and the subsequent risk of ISR remain unknown and could also potentially influence the choice of stent for CAS.

The importance of stent design has centered on the periprocedural outcomes of CAS. Although direct comparisons of open- vs. closed-cell stents have not been performed, two observational studies from the same institution suggest that stents with closed-cell design result in a significant decrease in periprocedural neurologic events after CAS.<sup>5,23</sup> However, no significant differences in major adverse events, including stroke-death rates, have been reported in recent observational studies, registries and postmarketing studies of carotid stents efficacy among different stent designs.<sup>24–26</sup> Prospective randomized clinical trials comparing different free cell areas and stent designs are necessary to further investigate their influence on CAS outcomes and durability. Moreover, clear demonstration of the efficacy and durability of closed-cell stents in preventing cerebral embolization and adverse neurologic events would be very important before adopting their widespread use as this would come at the cost of more kinks, incomplete deployment higher blood flow velocities and turbulence, all of which may occur more frequently with these more rigid stents.

CAS clearly changes the vascular wall mechanical characteristics of the carotid artery as stenting make it less compliant and more rigid.<sup>6,8,27,28</sup> In fact, a 2/3 reduction in compliance of the carotid artery after CAS has been demonstrated.<sup>6</sup> This alteration in compliance may be a contributing factor to the elevated velocities seen after CAS. Stent design further plays a pivotal role in changing the compliance of the carotid artery after CAS.<sup>22</sup> Open-cell and closed-cell stent design differ in how they alter the carotid wall mechanics and such differences are mainly derived from the stent architecture as mentioned above. As a result, closed-cell stents may yield vessels even less compliant and more rigid than open-cell stents because of less free cell area.

The differences in carotid blood flow velocities related to stent design are intuitive, as principles of fluid mechanics demonstrate that ventricular contraction would be converted to an elevation in velocity in a less distensible conduit rather than in increased arterial volume. Although our data reveal that the absolute median peak systolic velocities are not exceptionally elevated, the comparative elevation of velocities seen with closed-cell stents versus open-cell stents is significant. Admittedly, a limitation of our study is that the elevation in velocities in our study were only demonstrated in duplex scans obtained immediately after CAS, and it is unknown if these elevations or the differential effect of velocities related to stent design will persist in longer follow-up. Clearly, this will warrant longer follow-up to delineate. Additionally, our data suggest that the type of stent used (open vs. closed cell) and its effect on vessel compliance may have a critical role in developing duplex criteria for ISR. Defining accurate duplex criteria for ISR according to stent design will also help avoid the unnecessary risks of angiography-related morbidity in these patients.

Although the present study includes a considerable number of carotid interventions, important limitations should be acknowledged. First, our study is an observational study and therefore non-randomized. Second, stent type choice was at the discretion of the interventionalist, a source of possible selection bias. Third, stent type distribution was highly unbalanced with only one predominant stent type in each stent design group. In conclusion, DUS obtained immediately after CAS reveals disproportionately elevated carotid velocities that are to some extent related to stent-design. The importance of these differences in carotid velocities and their potential relationship to recurrent stenosis remains to be established. Further investigation and additional evaluation are warranted to better define duplex criteria for restenosis and long-term durability of CAS according to stent design.

## Acknowledgments

This study was in part supported by CTSA NIH Grant UL1-RR024982.

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**Table I**

Stent types, design and free cell area used for carotid stenting\*

Stent Type	Stent Design	Free Cell Area (mm <sup>2</sup> )
Wallstent	Closed-cell	1.08
Xact	Closed-cell	2.74
Nexstent	Closed-cell	4.7
Precise	Open-cell	5.89
Protégé	Open-cell	10.71
Acculink	Open-cell	11.48

\* As reported by Bosiers et al (Eur J Vasc Endovasc Surg 2007;33:35–141).



**Table II**  
Stent design and types used for carotid artery stenting

Stent design and type	No. (%)
Closed-cell Stents	
Wallstent	39 (28)
Xact	1 (0.8)
Nexstent	1 (0.8)
Open-cell Stents	
Acculink	77 (55)
Precise	22 (15)
Protégé	1 (0.8)

**Table III**

Stent design duplex ultrasound results obtained immediately after CAS to detect moderate to severe (50% or greater) stenosis using validated criteria for nonstented carotid arteries <sup>\*†</sup>

Duplex Ultrasound	Stent Design		Total
	Closed-cell (%)	Open-cell (%)	
Positive for 50% or greater stenosis	17 (42)	24 (24)	41
Negative for 50% or greater stenosis	24 (58)	76 (76)	100
Total	41 (100)	100 (100)	141

\* Ultrasound criteria for nonstented carotid arteries defined 50% or greater carotid stenosis according to modified University of Washington criteria (peak systolic velocity [PSV] greater than 125 cm/s and internal carotid artery-to-common carotid artery [ICA/CCA] PSV ratio greater than 2.0).

† Completion angiogram revealed successful revascularization in each case and none had >30% residual stenosis.