

CARESS Phase I Trial: One Year Results in Treating the Asymptomatic Patient

CAROTID REVASCULARIZATION WITH ENDARTERECTOMY OR STENTING SYSTEMS (CARESS) Phase I: One-Year Results

Sponsor



**INTERNATIONAL SOCIETY OF
ENDOVASCULAR SPECIALISTS®**



OBJECTIVE

To assess the equivalence of CSS to CEA in treating both high-risk (symptomatic $\geq 50\%$ stenosis) and low risk (asymptomatic $\geq 75\%$ stenosis) populations consistent with current clinical practice for the broadest possible indication in labeling any future device approval.



METHODS

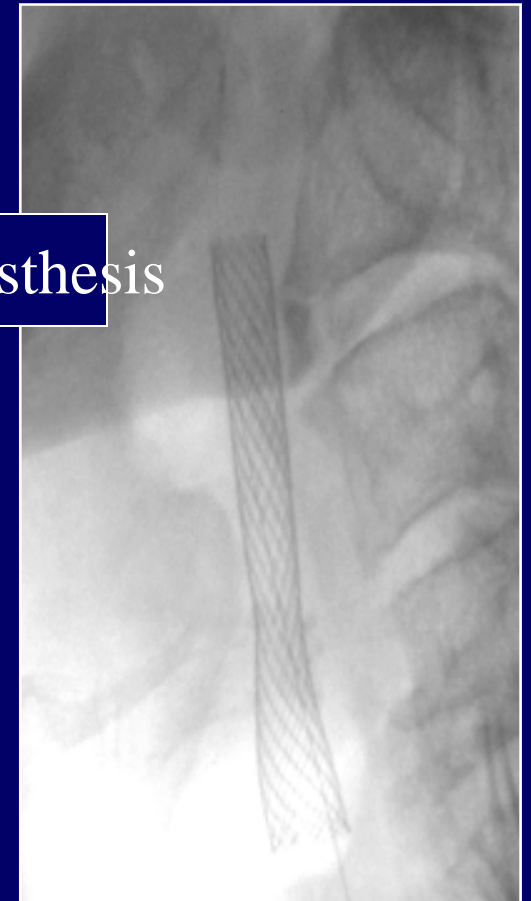
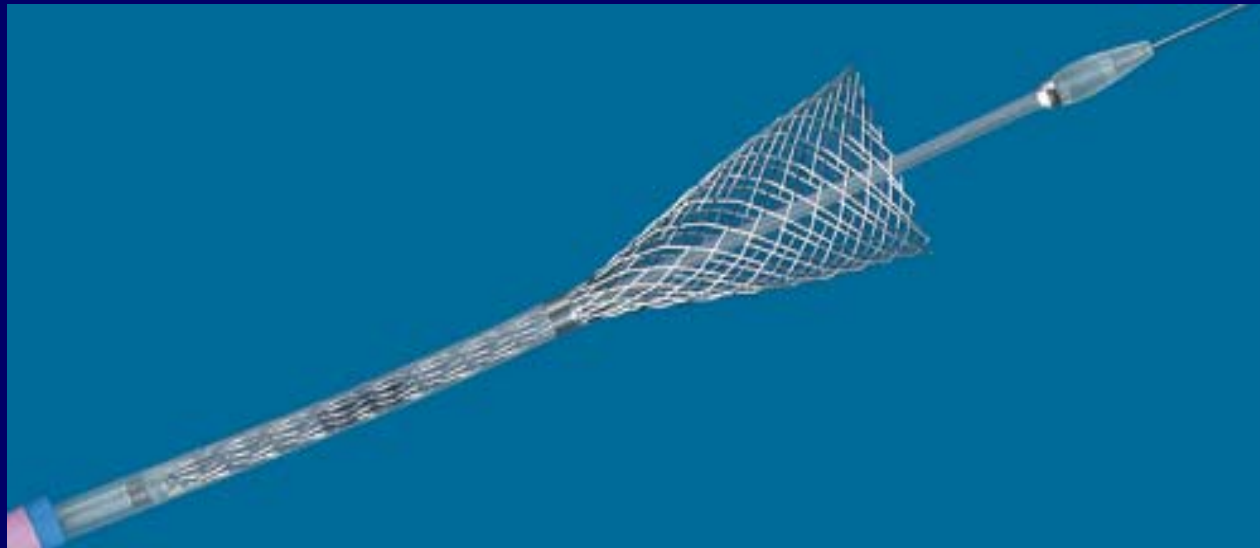
- Non-randomized, prospective, cohort study
 - Standard (CEA) vs. Investigational (CSS)
 - 2:1 ratio (2-CEA: 1-CSS)
 - 450 subjects (300-CEA, 150-CSS)
- Primary Endpoints
 - All cause mortality at 30-Days
 - Non-fatal stroke at 30-Days
- Carotid Stent System
 - Stent: Monorail Wallstent (Boston Scientific, Natick, MA)
 - Embolic protection: Guardwire Plus (Medtronic AVE, Santa Rosa, CA)





Percusurg Guardwire Plus
Protection Device

Carotid Wallstent Monorail Endoprosthesis



PHASE 1 STUDY

- Purpose is to determine CEA 30-Day primary endpoint event rates for pivotal study design
- 450 patients (300 CEA, 150 CSS)



RESULTS - Investigative Sites

- 14 Clinical Centers
- Enrollment 4/27/01 – 12/31/02 (20 mo.)
 - 397 subjects (254 CEA 143 CSS)
 - Enrollment rate of 3 per month per clinic



Carotid Stenting

Treatment by Specialty

- Total 143 patients
 - Vascular surgery 65 (45%)
 - Interventional cardiology 63 (44%)
 - Neurosurgery 9 (6%)
 - Interventional Radiology 6 (4%)



RESULTS - Medical History

	Treatment Arm	
	CEA	CSS
History of TIA or CVA	37.2%	37.5%
CEA Prior to study*	11.5%	37.5%
Carotid stent prior to study*	0.0%	5.6%
Prior PTA	0.4%	2.1%
Contralateral stenosis >50%	39.8%	34.7%
CAD or previous MI	60.9%	36.1%
CHF	16.6%	13.9%
Hypertension	81.4%	81.2%
Hypercholesterolemia	69.6%	63.2%
Diabetes	24.1%	29.2%
PVD	39.9%	45.1%



*Statistically significant

RESULTS - Demographics

	Treatment Arm			
	CEA (254)		CSS (143)	
Age	71.4 ± 8.8		71.2 ± 9.6	
Male	161 (63.4%)		86 (60.1%)	
Caucasian	236 (92.9%)		133 (93.0%)	
Symptomatic	83 (32.7%)		44 (30.8%)	
	Asympt	Sympt	Asympt	Sympt
50-75%	6 (2.4%)	26 (10%)	1 (0.7%)	8 (5.6%)
>75%	164 (65%)	57 (22%)	98 (69%)	37 (26%)



Overall 68% asymptomatic (67% CEA and 69% CSS)

RESULTS (30-Days)

Primary/Secondary Endpoints

	Primary Endpoint		Secondary Endpoint	
	CEA	CSS	CEA	CSS
# at risk	254	143	254	143
# events	6	3	8	3
# censored	35	9	35	9
KM estimate	0.0230	0.0214	0.0309	0.0214
Std Error	0.0093	0.0122	0.0108	0.0122
P-value	0.8741		0.5494	



2% Event Rate for both CEA and CSS
 No statistical significant difference between groups

RESULTS (1-Year)

Primary/Secondary Endpoints

	Primary Endpoint		Secondary Endpoint	
	CEA	CSS	CEA	CSS
# at risk	254	143	254	143
# events	30	13	32	14
# censored	98	47	98	47
KM estimate	0.8643	0.8998	0.8568	0.8910
Std Error	0.0233	0.0265	0.237	0.277
EVENT RATE	13.6%	10.0%	14.3%	10.9%
P-value	0.302		0.288	



No statistically significant difference between groups

RESULTS (1-Year)

Secondary Outcome Measures

	CEA (N=192)	CSS (N=112)	P-value
Residual Stenosis	0 (0%)	1 (0.9%)	0.366
Restenosis	7 (3.6%)	7 (6.3%)	0.296
Carotid Revasc	2 (1.0%)	2 (1.8%)	0.627
Repeat Angio	4 (2.1%)	4 (3.6%)	0.472



1-Year Compliance

	CEA	CSS
Completed	192 (75.6%)	113 (79.0%)
Died	14 (5.5%)	8 (5.6%)
Missed (in study)	10 (4.0%)	8 (5.6%)
Refused (Early Termination)	38 (14.9%)	14 (9.8)
Total	254 (100%)	143 (100%)



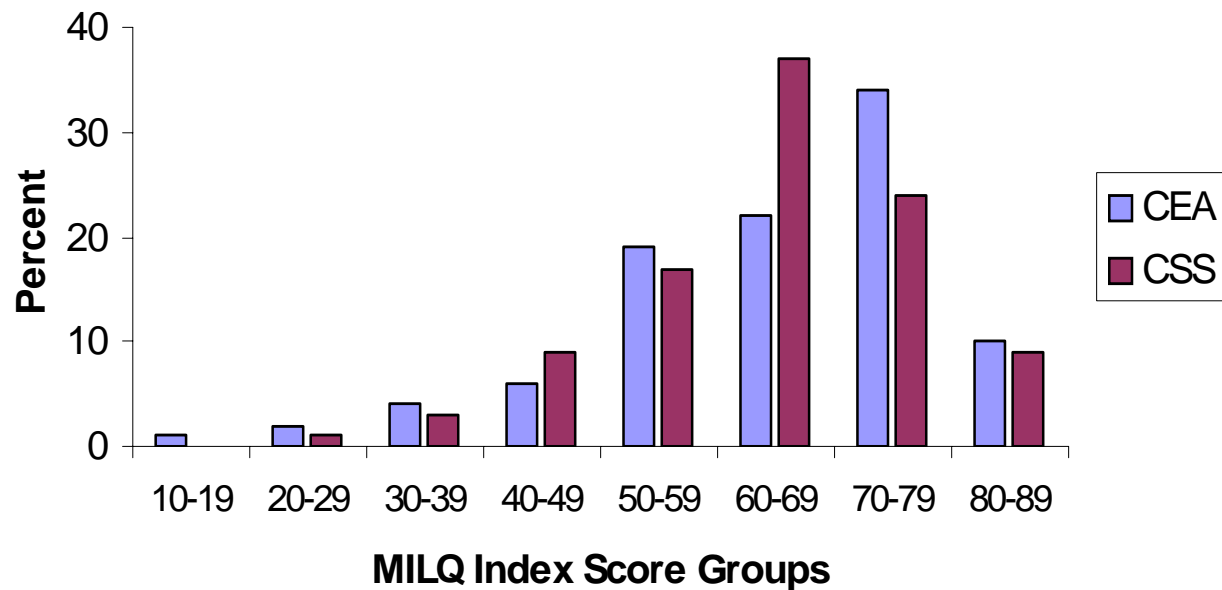
Quality of Life

	CEA			CSS		
	N	Base	1-Yr	N	Base	1-Yr
Both	119	66.5	64.9	72	64.1	59.9
Baseline	69	60.4	--	45	64.9	--
1-Year	28	--	55.2	12	--	61.2
Neither	38	--	--	14	--	--



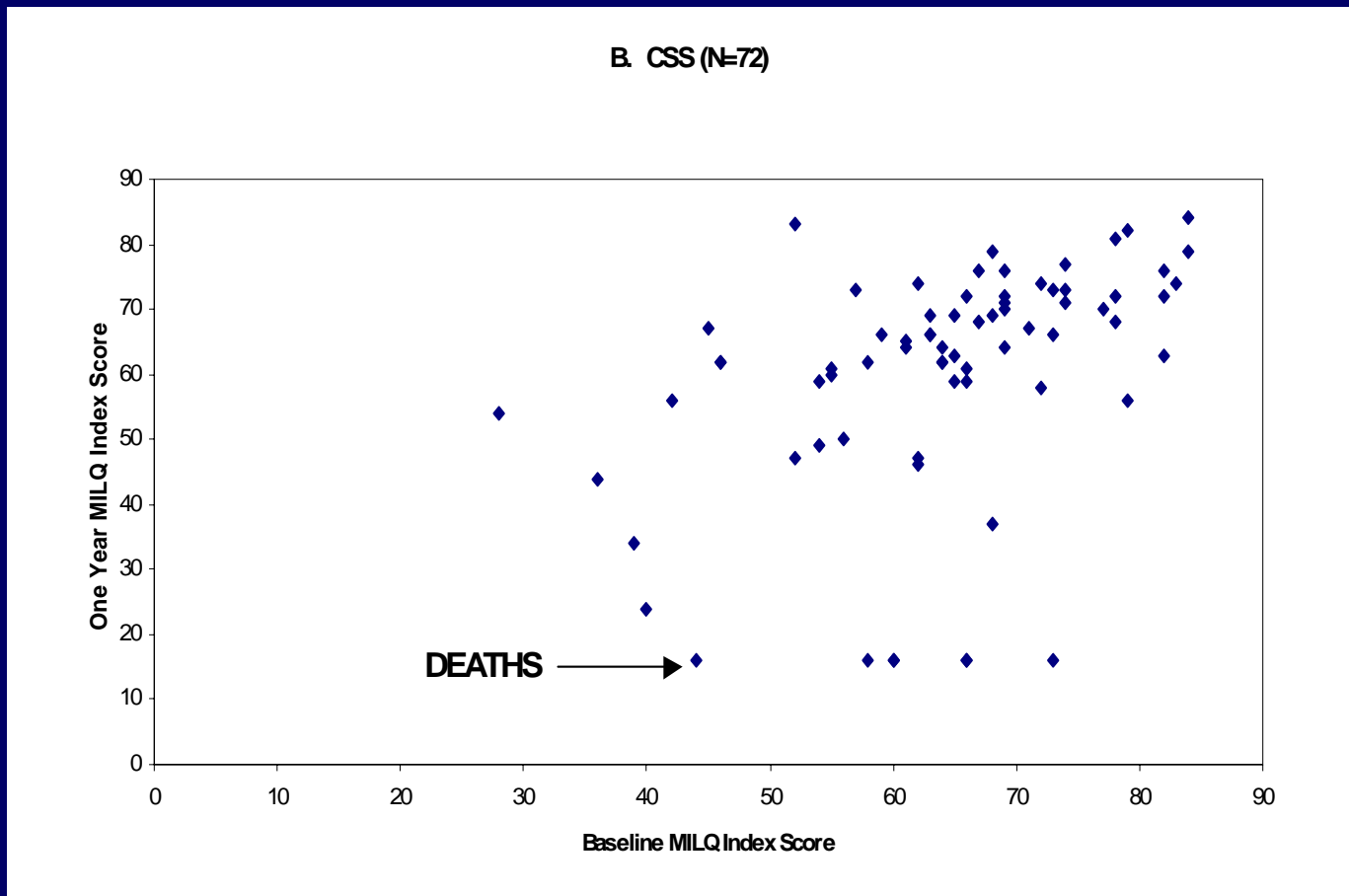
Quality of Life Baseline Distribution

Figure 1. Baseline Distribution (Percent) of MILQ Index Scores, by Treatment Group (CEA vs CSS): CARESS PHASE 1 (July 2001-December 2002)



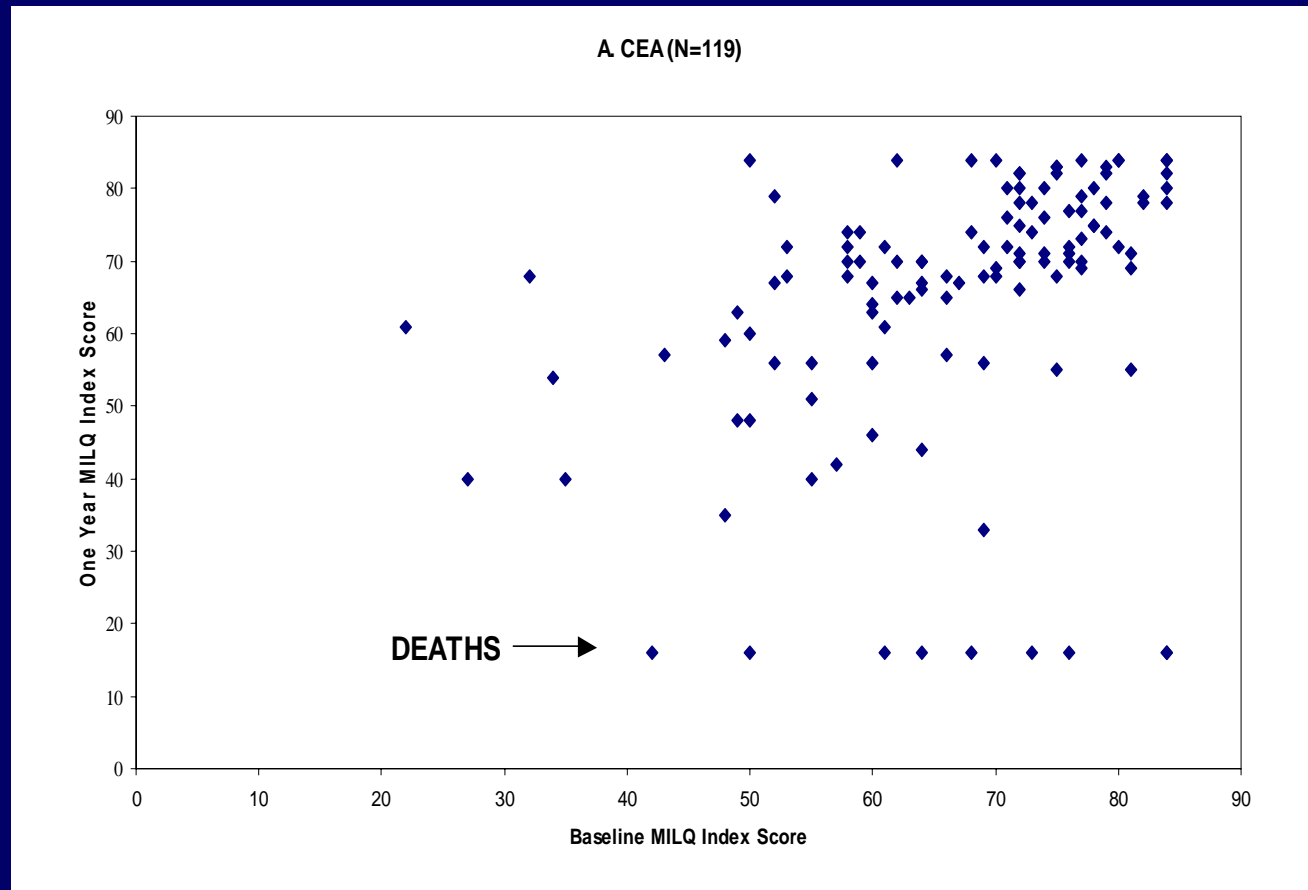
Quality of Life

CSS - 1 Year Comparison



Quality of Life

CEA - 1 Year Comparison



Phase 2 Study

- FDA final approval on July 11, 2003
- At least 30 Clinical Centers in U.S.
- 3,000 Patients
 - 1,000 CEA
 - 2,000 CSS (667 for each CSS)
- Up to 6 carotid stent systems
 - CSS arm will be randomized

