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This is the first study evaluating a novel technology, Carotid Stenotic Scan (CSS), developed by the sponsor, CVR Global. The overall objectives of this study are to demonstrate that the CSS can accurately detect significant carotid artery stenosis, a known risk factor for stroke. A secondary objective is to relate changes in CSS signal to different degrees of stenosis. We obtain a "proof of concept" if the device correlates strongly with the established classification of atherosclerotic carotid disease derived various imaging modalities including magnetic resonance and computer tomographic angiography, conventional angiography, or carotid ultrasound.

Carotid duplex ultrasound uses B-mode ultrasound imaging and Doppler ultrasound to detect focal increases in blood flow velocity indicative of high grade carotid stenosis. It is noninvasive, safe, and relatively inexpensive. Compared with intra-arterial cerebral angiography for detecting a significant stenosis of the internal carotid artery, ultrasound has a sensitivity of 81 to 98 percent and a specificity of 82 to 89 percent.

The results presented here represent the first 109 carotid ultrasound subjects' testing results for the primary objective, to assess the association between carotid artery stenosis as measured by CSS and carotid ultrasound.

Table 1 reports the demographic characteristics for the first set of subjects, including the hospital-based location of the Radiology ultrasound testing.

Table 2 reports the Enrollment metrics to date.

Table 3 reports the measurement values for the Left and Right carotid arteries as reported by the CSS device and by radiology-reported clinical ultrasound exam.

Table 1 Characteristics of Subjects Consented for CSS / CVR Global Study (n=109)

Variable	n (%)
Female	51 (47)
BMI (m±SD)	28.1 ± 5.96
Age (m±SD)	67.2 ± 13.6
Race	
White	78 (71.56)
Black	28 (25.70)
Other	3 (2.75)
Medical History	
Ischemic Heart Disease	21 (19.27)
Myocardial Infarction	17 (15.60)
Heart Failure	6 (5.50)
Peripheral Arterial Disease	13 (11.93)
TIA	12 (11.01)
Stroke	15 (13.76)
Diabetes	25 (22.94)
Hypertension	70 (64.22)
Hyperlipidemia	60 (55.05)
COPD	10 (9.17)
Enrollment Location	
General Radiology	64 (58.72)
Vascular Radiology	34 (28.44)
Inpatient	14 (12.84)

Table 2 Enrollment Metrics

Milestone	Date
1st patient Enrolled	2/3/2017
Exclusion Criteria Revised to include Pre/Post-op Subjects	5/8/2017
Most Recent Patient Included in Analysis Enrolled	6/8/2017
Overall Enrollment Rate	6.06 pts per week
Enrollment Rate before Exclusion Criteria Change	4.84 pts per week
Enrollment Rate after Exclusion Criteria Change	9.94 pts per week

Table 3 CSS and Clinical Exam Reported Values

Left Carotid Results	
CSS Reported Result Left Carotid **(m±SD)**	30.30 ± 21.46
CSS Results Left Carotid (Categorical) <50% Stenosis 50-69% Stenosis 70-99% Stenosis	 87 (79.82) 17 (15.60) 5 (4.59)
Clinical Exam Results Left Carotid (Categorical) <50% Stenosis 50-69% Stenosis 70-99% Stenosis >99% Stenosis Not Reported	 93 (85.32) 8 (7.34) 4 (3.67) 2 (1.83) 2 (1.83)
Right Carotid Results	
CSS Reported Result Right Carotid **(m±SD)**	24.53 ± 17.95
CSS Results Right Carotid (Categorical) <50% Stenosis 50-69% Stenosis 70-99% Stenosis	 102 (93.58) 5 (4.59) 2 (1.83)
Clinical Exam Results Right Carotid (Categorical) <50% Stenosis 50-69% Stenosis 70-99% Stenosis >99% Stenosis Not Reported	 93 (85.32) 12 (11.01) 2 (1.83) 1 (0.92) 1 (0.92)