Objective(s): Objective measures of plaque area and tissue composition from DUS images may be useful for risk-stratification of patients with a higher likelihood of future adverse events (stroke, transient ischemic attacks or amaurosis fugax) and to assess the effect of vascular risk-factor modification strategies (by measuring change in overall plaque burden and/or individual plaque tissue constituents). Clinical assessment of carotid artery plaques is most commonly performed with two-dimensional duplex ultrasound (DUS) imaging. We therefore analyzed DUS images of CREST-2 participants at baseline and quantified the reliability of semi-automatic image processing to measure plaque area and tissue constituents.

Methods: CREST-2 consists of two multicenter, randomized trials in patients with asymptomatic ≥70% carotid stenosis. One trial compares Intensive Medical Management (IMM) plus endarterectomy to IMM alone, and the other compares IMM plus stenting to IMM alone. The composite primary outcome is stroke or death. Baseline B-mode DUS images from 408 patients underwent manual plaque outlining and automatic pixel brightness compositional assessment using a custom MATLAB-based program by a single observer. The observer repeated the analysis in 50 randomly selected studies 4 weeks later, while a second observer similarly analyzed 50 randomly selected studies. Gray Scale Median (GSM), plaque area (PA) and plaque tissue composition (areas of hemorrhage (HA), lipid (LA), fibrous (FA), muscle (MA) and calcified (CA) plaque regions) were the output parameters. Reliability of the technique was evaluated using intra- and inter-class correlation (ICC) and Bland-Altman (BA) plots. Geometric (shape) agreement was assessed using the Dice-Similarity-coefficient (DSC).

Results: The mean±SD of plaque measurements were: GSM (45.35±22.64), plaque area (62.51±37.04mm²), and tissue composition HA(5.66±9.11mm²), LA(9.47±8.84mm²), FA(10.17±10.12mm²), MA(16.04±11.22mm²) and CA(1.97±0.25mm²). These measurements were reproducible when performed by the same or a different observer. The intra- and inter class correlation coefficients confirmed that these measures were reliable. A DSC of 0.76±0.16 and 0.73±0.11, confirmed high reliability for intra and inter-rater reliability respectively for the plaque shapes outlined by observers.

Conclusions: In a randomized trial of asymptomatic patients with high-grade carotid stenosis, a semi-automatic protocol to measure plaque area, Gray Scale Median, and tissue composition from B-mode ultrasound images is feasible and reproducible.