was significantly higher for the closed cell group than the open cell (98% vs. 89%, P=0.03).

**Conclusion:** There was no difference in neurological events between the two groups but the patency rates in the closed cell group were significantly higher than the open cell.

4:24 PM Abstract No. 41

Outflow vessel treatment during infrapopliteal endovascular procedures: Long-term outcome of below-the-ankle angioplasty and stenting

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**Purpose:** To present the long-term angiographic and clinical outcome of percutaneous angioplasty and optional bail-out stenting of the arteries below the level of the ankle for critical limb ischemia (CLI) treatment.

**Materials and Methods:** We retrospectively searched our department’s archives for patients who underwent infrapopliteal revascularization procedures including angioplasty and bail-out stenting of the dorsalis pedis and/or the plantar arteries. Primary endpoints included technical success, limb salvage and need for repeat target lesion recanalization (TLR) because of recurrent symptoms. Secondary endpoints included primary patency, binary restenosis and stent integrity (in cases that a stent was used).

**Results:** 17 patients (15 males, mean age 73±8 years) met the inclusion criteria and were included in the analysis. The majority of the patients were diabetics (82%). 20 lesions in 19 participants without known CVD history and/or diabetes was calculated for each participant. Risk was stratified into 3 FRS categories: low (0-0.90), intermediate (0.90-1.4), and high (>1.4). However, prevalence estimates of abnormal ABI among 822 participants, which was derived from previous carotid stenting trials. Secondary endpoints included device, technical, and procedural success.

**Results:** The 30-day MACCE rate was 2.7%, well beneath the performance goal of 13%. The major stroke rate through 30 days was less than 1%. Device success for the Mo.Ma device was 98.2%. Technical success was 94.6% and Procedural success was 93.2%. The access site complication rate was 3.1%.

**Conclusion:** The Mo.Ma™ proximal cerebral protection device used in combination with FDA approved carotid stents in high surgical risk subjects, resulted in excellent safety and effectiveness outcomes as compared to a performance goal derived from previous carotid stenting trials.

4:36 PM Abstract No. 42

**FEATURED ABSTRACT**

Use of the INVATEC Mo.Ma™ proximal cerebral protection device during carotid stenting (the ARMOUR trial)

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**Purpose:** The ARMOUR trial is a pivotal, prospective, multi-center, non-randomized trial to evaluate the safety and effectiveness of cerebral protection with the Mo.Ma device in high surgical risk subjects undergoing carotid artery stenting (CAS).

**Materials and Methods:** All subjects who provided informed consent and met inclusion/exclusion criteria underwent percutaneous revascularization of the carotid artery using the Mo.Ma device and a stent approved by the FDA for carotid artery stenting. Follow-up took place at pre-discharge and at 30 days post-procedure. A total of 262 subjects (225 ITT, 37 Roll-In) were enrolled at 25 investigational sites in the United States (20) and the European Union (5) between September 2007 and February 2009. For the ITT population, mean age was 74.7 years, 66.7% were male, 28.9% of the subjects were octogenarians and 15.1% of the subjects were symptomatic. The primary endpoint for this trial was major adverse cardiac and cerebrovascular events (MACCE) within 30 days of stent implantation. MACCE was defined as any myocardial infarction (MI), stroke, or death through 30 days post-procedure as adjudicated by a Clinical Events Committee (CEC). Results were compared to a performance goal of 13% for the 30-day MACCE composite rate, which was derived from previous carotid stenting trials. Secondary endpoints included device, technical, and procedural success.

**Results:** The 30-day MACCE rate was 2.7%, well beneath the performance goal of 13%. The major stroke rate through 30 days was less than 1%. Device success for the Mo.Ma device was 98.2%. Technical success was 94.6% and Procedural success was 93.2%. The access site complication rate was 3.1%.

**Conclusion:** The Mo.Ma™ proximal cerebral protection device used in combination with FDA approved carotid stents in high surgical risk subjects, resulted in excellent safety and effectiveness outcomes as compared to a performance goal derived from previous carotid stenting trials.

4:51 PM Abstract No. 43

Prevalence of abnormal ankle-brachial index among subjects with low-intermediate Framingham Risk Score

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**Purpose:** Traditional risk scoring algorithms, such as Framingham Risk Score (FRS), are known to have low sensitivity for predicting risk of fatal or non-fatal cardiovascular events. An abnormal ankle-brachial index (ABI) has been shown to be associated with a higher risk of cardiovascular disease (CVD), and is considered a coronary heart disease equivalent. However, prevalence estimates of abnormal ABI among subjects otherwise not considered at high risk based on FRS have not been reported.

**Materials and Methods:** We analyzed data from the PEDAL Study (Population-based examinations to determine ankle-brachial index) Study, 2007-2009), a multicenter cross-sectional study conducted in conjunction with Legs for Life®, a national free public screening program, for 822 participants (average age 64.3±11.6 years, 69.7% female, 89.7% non-Hispanic white) at 23 study sites, without known CVD or diabetes at baseline, who were screened for peripheral artery disease with an ABI, and for whom all the variables to compute FRS were available. The FRS to determine 10-years risk of CHD was calculated for each participant. Risk was stratified into 3 FRS categories: low (<6%), intermediate (6% to 19%) and high (≥20%). Abnormal ABI was defined as an ABI <0.90 and/or >1.4 in either leg.

**Results:** The prevalence of abnormal ABI among 822 participants without known CVD history and/or diabetes was...