**CATEGORIES ENDOVASCULAR:** Peripheral Vascular Disease and Intervention

**KEYWORDS** Carotid artery stenting, Carotid endarterectomy, Metaanalysis

### TCT-794

# Lesion preparation with an orbital atherectomy system enhances paclitaxel deposition in calcified peripheral arteries

Abraham R. Tzafriri,<sup>1</sup> Brett Zani,<sup>1</sup> James Stanley,<sup>1</sup> Peter Markham,<sup>1</sup> Alexander Nikanorov,<sup>2</sup> Elazer R. Edelman<sup>3</sup>

<sup>1</sup>CBSET Inc., Lexington, MA; <sup>2</sup>Cardiovascular Systems, Inc, Saint Paul, MN; <sup>3</sup>Harvard-MIT Biomedical Engineering Center, Cambridge, MA

**BACKGROUND** It has been hypothesized that efficacy of DCB can be improved through treatment of calcified plaque with orbital atherectomy. We evaluated the effects of orbital atherectomy system (OAS) treatment on paclitaxel distribution in cadaveric samples of human peripheral arteries with substantial calcified plaque burdens.

METHODS Five fresh human lower limbs were obtained from a certified research institution and maintained on ice for further evaluation. Computed Tomography (CT) was performed on all limbs to identify distribution and severity of calcification in the peripheral vasculature. Intravascular sheaths were inserted proximally and distally to simulate the arterial flow. Under fluoroscopic guidance, a guide catheter was advanced through the sheath into designated peripheral arteries and angiographic images obtained with contrast media to identify locations for atherectomy. The superficial femoral, popliteal and tibial arteries were divided through angiographic measurements into approximately equal segments, and the proximal or distal segment of each artery treated using the DIAMONDBACK 360® OAS (Cardiovascular Systems, Inc., Saint Paul, MN). Arteries were explanted and cut in pairs of 3 cm in length along atherectomy-treated vs. non-treated demarcation lines, lumenally infused with a buffered solution (PBS/4% BSA) of radiolabeled (14C, 10 µM) or fluorescent (Oregon Green 488, 10  $\mu$ M) paclitaxel and incubated in shaking drugfree buffered solution for 1h at 37°C. At the end of 1h, incubated segments were rinsed and processed for scintillation counting or fluorescent microscopy.

**RESULTS** All arteries exhibited high levels of calcification in CT angiography. Quantification of 14C-labeled paclitaxel revealed a clear trend of increasing drug deposition in OAS treated tissue segments, ranging from 20% more in superficial femoral and popliteal arteries to more than 400% increase in tibial arteries. The average increase of drug deposit in OAS treated arteries was above 50% (N=10). Fluorescent microscopy revealed distribution patterns that declined with increasing distance from the lumenal surface and tended to be more diffuse and extended in OAS treated tissue segments, further supporting the tissue retention trends exhibited by radiolabeled paclitaxel.

**CONCLUSIONS** These data illustrate that controlled orbital atherectomy may modify calcified plaque barriers to intravascular drug delivery and improve drug distribution throughout the superficial femoral, popliteal and below the knee artery beds.

**CATEGORIES ENDOVASCULAR:** Peripheral Vascular Disease and Intervention

**KEYWORDS** Drug-eluting stent, paclitaxel, Paclitaxel-eluting balloon, Pre-clinical

#### TCT-795

## Technical success rates of endovascular treatment of femoropopliteal chronic total occlusions

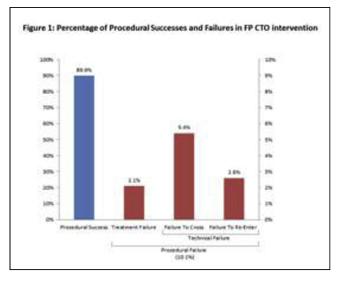
Thomas M. Das,<sup>1</sup> Kyle Planchard,<sup>2</sup> Denizen Kocak,<sup>3</sup> Atif Mohammad,<sup>4</sup> Ehrin J. Armstrong,<sup>5</sup> Nicolas W. Shammas,<sup>6</sup> Osvaldo Gigliotti,<sup>7</sup> Mazen Abu-Fadel,<sup>8</sup> Anand Prasad,<sup>9</sup> Andrew Klein,<sup>10</sup> Emmanouil Brilakis,<sup>11</sup> Subhash Banerjee<sup>12</sup>

<sup>1</sup>University of Texas Southwestern Medical Center, Dallas, TX; <sup>2</sup>UT Southwestern Medical Center, Dallas, TX; <sup>3</sup>UT Southwestern Medical School, Dallas, TX; <sup>4</sup>UT Southwestern Medical Center, Dallas, TX; <sup>5</sup>University of Colorado, Denver, CO; <sup>6</sup>Midwest Cardiovascular Research Foundation, Davenport, IA; <sup>7</sup>Seton Heart Institute, Austin, TX; <sup>8</sup>University of Oklahoma HSC, Oklahoma City, OK; <sup>9</sup>UTHSCSA, San Antonio, TX; <sup>10</sup>St. Louis VA Medical Center, St. Louis, United States; <sup>11</sup>VA North Texas Healthcare System and UT Southwestern Medical Center, Dallas, TX; <sup>12</sup>UT Southwestern Medical Center and VA North Texas Health Care System, Dallas, TX, Dallas, TX **BACKGROUND** There is limited data on immediate and longer-term outcomes of crossing femoropopliteal (FP) chronic total occlusions (CTO).

**METHODS** Consecutive patients between January 2006 and March 2015 undergoing endovascular revascularization for symptomatic peripheral artery disease with FP CTO were analyzed as part of the Excellence in Peripheral Artery Disease (XLPAD) registry (NCT01904851). Procedural success was defined as restoration of flow through the lesion with  $\leq$ 30% residual stenosis. Procedural failures included technical failures (defined as failure to cross the CTO or failure to renter the true lumen from the subintimal space) and treatment failures (defined as >30% residual stenosis after successful crossing). One year outcomes were analyzed.

**RESULTS** A total of 1100 CTO lesions from 948 patients were included in the analysis. Procedural success was achieved in 989 (89.9%) CTO, while procedural failure occurred in 111 (10.1%). Treatment failures comprised 23 (2.1%) and technical failures 88 (8.0%), with 59 (5.4%) intraluminal failures to cross and 29 (2.6%) failures to re-enter from subintimal space (Figure 1). There were significantly more surgical revascularizations following failed procedures compared to successful (13.5% vs. 3.9%;  $\bar{p}$ <0.0001), although with a lower need for repeat revascularization procedures (6.3% vs. 20.5%; p=0.0003). Need for amputations were similar for patients with failed or successful procedures (5.4% vs. 3.3%; p=.26). Univariate analysis indicated age (p=.0004), lesion length (p=.002), heavy calcification (p=.0001), and multilevel FP disease (p=.001) to be predictors of procedural failure; lesion calcification (p=.03) and multilevel FP disease (p=.03) were independent predictors in multivariable analysis.

**CONCLUSIONS** Advanced patient age, lesion length, heavy calcification, and multilevel FP disease are associated with higher procedural failure rates of crossing FP CTO. Patients experiencing procedural failures undergo significantly higher rates of surgical revascularization, albeit with lower need for repeat revascularization.



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#### TCT-796

Impact of Nitinol Self-Expanding Stent on the Patency of SubIntimal Angioplasty for Below-The-Knee Occlusions with Critical Limb Ischemia (NEXSIA-BTK): Multicenter, prospective registry

Jung-Hee Lee,<sup>1</sup> Jaewon Oh,<sup>2</sup> Young-Guk Ko,<sup>3</sup> Seung-Woon Rha,<sup>4</sup> Ki Chang Kim,<sup>5</sup> Sang-Ho Park,<sup>6</sup> Donghoon Choi<sup>7</sup>

<sup>1</sup>Severance Cardiovascular Hospital, Yonsei University College of Medicine, Seoul, Korea, Republic of; <sup>2</sup>Yonsei University College of Medicine, Seoul, Korea, Republic of; <sup>3</sup>Severance Hospital, Seoul, Korea, Republic of; <sup>4</sup>Korea University Guro Hospital, Seoul, Korea, Republic of; <sup>5</sup>Sarang Hospital, Incheon, AK; <sup>6</sup>Cardiology Department, Soonchunhyang University Cheonan Hospital, Cheonan, Chung-Nam; <sup>7</sup>Severance Hospital, Yonsei University, Seoul, Korea, Republic of