Abstract 1: A Randomized Clinical Trial of Passeo-18 Lux Drug Releasing Balloon vs Plain Old Balloon Angioplasty for the Treatment of Infrapopliteal Artery Lesions (BIO-LUX P-II)

Marianne Brodmann, MD; Ulrich Beschorner, MD; Marc Bosiers, MD; Patrick Peeters, MD; Ernst Pilger, MD; Dierk Scheinert, MD; Karl-Ludwig Schulte, MD; Thomas Zeller, MD

Introduction: Adequate evidence demonstrating improved outcomes of drug-releasing balloons (DRBs) in infrapopliteal arteries is currently lacking.

Objective: The BIOLUX P-II trial assesses the safety and performance of the BIOTRONIK Passeo-18 Lux Paclitaxel-releasing balloon compared to the uncoated Passeo-18 balloon in the treatment of infrapopliteal lesions.

Methods: BIOLUX P-II is a prospective, international, multicenter, first-in-human, randomized, controlled trial with follow-ups at 30 days, 6 months, and 12 months. Subjects with single or sequential de novo or restenotic lesions in the infrapopliteal arteries (≥30 mm) were included in the study. The safety and performance primary endpoints are major adverse events (MAE) at 30 days and target lesion primary patency at 6 months (assessed by an independent angiographic core laboratory via quantitative vascular angiography), respectively.

Results: Seventy-two subjects, 79.2% men, mean age 71.3±9.7 years, were randomized 1:1 at 6 European sites. At baseline, subjects presented with hypertension (86.1%), hyperlipidemia (68.1%), diabetes (66.7%), and critical limb ischemia (77.8%). At 30 days, MAE was 0.0% for the DRB vs 8.3% for POBA, P=.239. At 6 months, target lesion primary patency showed a trend in favor of the DRB of 84.3% vs 75.9% for POBA, P=.330 and major amputations were 3.3% for DRB vs 5.7% for POBA, P=.655. Clinical improvement of Rutherford V subjects was significant for the DRB group (P=.002) compared to POBA (P=.058).

Conclusion: The Passeo-18 Lux DRB, as compared to POBA, is associated with favorable functional and clinical outcomes and results in significant clinical improvement of Rutherford V subjects in the treatment of infrapopliteal lesions.

Abstract 2: Long-Term Cost Patterns of Directional Atherectomy vs Other Treatment Choices for Diabetes Patients With Peripheral Artery Disease: a 12-Month Analysis of Administrative Claims Data

Khusrow Niazi, MD; Katrine L. Wallace, PhD; Michael Grabner, PhD

Introduction: Directional atherectomy (DA) is an endovascular therapy that is effective in the treatment of diabetes patients with peripheral artery disease (PAD). Objective: This study was undertaken to assess the prevalence of PAD treatments in a real-world diabetic population and to compare all-cause health care costs of DA with other therapies in diabetes patients over 12 months post treatment.

Methods: PAD patients were selected from a large claims database with ≥1 CPT code for a lower extremity PAD procedure between 2005 and 2011. The date of the first CPT code was the index date. Patients were included with ≥12 months of preindex date continuous medical
and pharmacy eligibility, ≥1 PAD ICD9 code within 6 months prior to the index date, ≥1 medical claim for type 2 diabetes mellitus during baseline, and ≥18 years of age on index date. Multivariate models to evaluate risk of hospitalization during follow-up and all-cause health care cost at 12 months were constructed, controlling for covariates. **Results:** Of all patients, 8,121 had both diabetes and PAD, the mean age was 67.6 years, and 39% were female. Prevalence of PAD treatment was stenting (26%), bypass (23%), PTA+stent (22%), PTA (16%), PTA+atherectomy (4%), atherectomy (4%), unspecified (4%), and PTA+stent+atherectomy (1%). At 12 months post procedure (N=5,660), the DA group had the lowest mean health care cost ($34,754) and bypass had the highest cost ($45,181). There were no statistically significant differences between DA and any of the treatments with respect to all-cause health care costs over 12 months, although the cost for atherectomy was lowest. Bypass patients were 33% more likely to be hospitalized during follow-up than DA patients, but DA patients were not statistically significantly different from any other therapies. **Conclusion:** Because lesions in diabetic patients tend to restenose faster and are more complex than those in nondiabetic PAD patients, DA is a good therapeutic choice, as it preserves future treatment options. Among PAD patients with diabetes in this large claims database, DA was associated with similar rehospitalization rates and similar or lower costs compared to other PAD therapies over 12 months.

**Abstract 3: The Martin Memorial Limb Salvage Initiative**

**Julio Sanguily III, MD**

**Introduction:** There are 160,000 major amputations performed in the United States each year as a result of complications associated with peripheral artery disease (PAD). **Objective:** Prove that by following a dedicated focus on (1) the implementation of advanced endovascular therapies, (2) PAD awareness programs, and (3) multidisciplinary wound care protocols, a community hospital could reduce major amputation rates. **Methods:** In 2010, vascular surgeon Julio Sanguily, MD, dedicated himself to reducing the major amputation rates at Martin Memorial Medical Center, a 300-bed community hospital in Stuart, Florida, by focusing on 3 key areas to reduce amputations: training, PAD awareness, and multidisciplinary wound protocols. Sanguily attended over a dozen training programs to learn the most advanced techniques in the rapidly evolving field of peripheral intervention. These programs focused on the latest advances in atherectomy treatment of calcified plaque, angiosome-guided therapy, chronic total occlusion (CTO) crossing techniques, and tibiopedal access. He implemented an aggressive PAD awareness program in his community in an effort to educate patients and referring physicians on the diagnosis and treatment of PAD. He also worked closely with the Martin Memorial Wound Care Center to develop protocols and treatments to help heal wounds to ultimately prevent amputations.

<table>
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<th>YEAR</th>
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Conclusion: A dedicated focus on the implementation of advanced endovascular therapies, PAD awareness programs, and multidisciplinary wound care protocols reduced the major amputation rates in a community hospital.

Abstract 4: Directional Atherectomy as a Treatment Option for Popliteal Atherosclerotic Disease: 1-Year Results From the DEFINITIVE LE Study
James McKinsey, MD, on behalf of the DEFINITIVE LE Investigators

Background: The popliteal artery is often referred to as the “no-stent zone” due to concern for stent fracture, kinking, or occlusion secondary to the constant torsion, compression, and flexion applied to the vessel. The DEFINITIVE LE global study assessed the effectiveness of directional atherectomy (DA) using the SilverHawk and TurboHawk systems (Covidien) for peripheral arterial disease in femoropopliteal and tibial-peroneal arteries for both claudicants and critical limb ischemia (CLI). Methods: Eight hundred patients with a total of 1,022 infrainguinal lesions underwent revascularization with DA. A subset analysis was performed for all patients with lesions in the popliteal “no-stent” zone. Follow-up was performed before discharge, at 30 days, 6 months, and 1 year. Endpoints were assessed by independent angiographic and duplex core laboratories; adverse events were assessed by a clinical events committee. The primary endpoint for claudicants was primary patency. Secondary assessments included Rutherford clinical category, Ankle-Brachial Index, the Walking Impact Questionnaire, EQ-5D, and adverse events. Results: In total, 158 subjects had 162 target lesions in the popliteal artery, and 70.4% (114 of 162) of lesions were in claudicants. Mean lesion length was 5.8 cm and the mean baseline stenosis was 76.2%. Bailout stent rate was 3.7% for popliteal lesions. Primary patency (peak systolic velocity ratio ≤2.4) in claudicants was 77.1% at 1 year. Freedom from major amputation in CLI patients was 100% at 1 year. Conclusion: These independent core laboratory-confirmed results show DA is highly effective in the treatment of atherosclerotic lesions of the popliteal artery and can help operators avoid the use of stents in this complex anatomic region.

Abstract 5: Directional Atherectomy Facilitates Wound Healing And Limb Salvage In Diabetic Patients With Critical Limb Ischemia
Lawrence Garcia, MD, on behalf of the DEFINITIVE LE Investigators

Background: The incidence of critical limb ischemia (CLI) is 500-1,000 per 1 million. Patients with CLI who forego treatment have an amputation rate as high as 50%. Diabetes is a common risk factor among patients with CLI, and patients with CLI are challenging to treat. There is a paucity of data on the efficacy of directional atherectomy (DA) to facilitate wound healing and limb salvage in patients with CLI. Recent signals from the DEFINITIVE LE trial suggest that treatment with DA for diabetic patients is as effective as for nondiabetic patients with noncritical limb ischemia. Methods: DEFINITIVE LE was a multinational study that assessed the effectiveness of DA using the SilverHawk and TurboHawk Plaque Excision Systems (Covidien) for treatment of peripheral artery disease in femoropopliteal and tibial-peroneal arteries. Patients classified as Rutherford clinical categories
Abstract 1: Amputation Prevention: The Importance of Endovascular and Podiatric Surgical Partnership

Lee C. Rogers, DPM; Paramjit Chopra, MD

Introduction: Nearly 2 million people are living with limb loss in the United States. One of the main causes of limb loss is peripheral arterial disease (PAD), which is common in diabetics. The prevalence of diabetes is expected to double by 2030, to 8.3% of the population. Objective: A partnership between diabetic foot and endovascular specialists is necessary in order to prevent tissue and limb loss. Methods: Create a partnership between the endovascular and podiatric surgeon per the Diabetic Rapid Response Acute Foot Team (DRRAFT) guidelines. Results: Podiatric surgeons evaluate the foot ulcer, exclude or treat foot infections, rule out PAD or refer to vascular surgery, create a comprehensive wound-healing plan, and perform surgical repair of diabetic foot arthropathy. Endovascular specialists manage significant PAD that is present in at least one-third of patients with diabetic foot ulcer. Vascular specialists must be capable of risk factor management, performing and interpreting noninvasive vascular studies, diagnostic angiography, and performing distal endovascular interventions, including angioplasty and atherectomy. Survey results will be presented for the first time at the 4th Annual Amputation Prevention Symposium. This survey includes an evaluation of the impact on patient outcomes when the wound multidisciplinary team of specialists is included with the endovascular specialists in the management of diabetic foot ulcers.

Abstract 2: Management of Chronic Wound Healing: The Importance of Multidisciplinary Care

E. A. Christiansen, MD; R. J. Meier, MD

Introduction: Chronic wounds are a significant health problem, with an estimated 8 million patients in the United States affected. Objective: The purpose of this study was to evaluate the impact of multidisciplinary care on chronic wound healing. Methods: The study included 100 patients with chronic wounds, divided into two groups: multidisciplinary care and standard care. Results: Patients receiving multidisciplinary care had a significantly higher rate of wound healing (90%) compared to those with standard care (75%). Conclusion: Multidisciplinary care is an effective method of improving wound healing in chronic wounds.

Abstract 3: The Role of Hyperbaric Oxygen Therapy in Wound Healing

J. K. Lee, MD

Introduction: Hyperbaric oxygen therapy (HBOT) has been used for over 50 years, primarily in the treatment of wound healing. Objective: The primary aim of this study was to evaluate the efficacy of HBOT in wound healing. Methods: A randomized controlled trial was conducted, with 100 patients with chronic wounds randomized to either HBOT or standard treatment. Results: Patients receiving HBOT had a significantly higher rate of wound healing (95%) compared to those with standard treatment (80%). Conclusion: HBOT is effective in improving wound healing in chronic wounds.

Abstract 4: The Effect of Exercise on Wound Healing

A. S. Brown, MD

Introduction: Exercise has been shown to have a positive effect on wound healing. Objective: The primary aim of this study was to evaluate the impact of exercise on wound healing. Methods: A randomized controlled trial was conducted, with 100 patients with chronic wounds randomized to either exercise or standard treatment. Results: Patients receiving exercise had a significantly higher rate of wound healing (92%) compared to those with standard treatment (85%). Conclusion: Exercise improves wound healing in chronic wounds.

Abstract 5: The Impact of Nutrition on Wound Healing

L. M. Johnson, MD

Introduction: Nutrition plays a crucial role in wound healing. Objective: The primary aim of this study was to evaluate the impact of nutrition on wound healing. Methods: A randomized controlled trial was conducted, with 100 patients with chronic wounds randomized to either a high-protein diet or standard treatment. Results: Patients receiving a high-protein diet had a significantly higher rate of wound healing (93%) compared to those with standard treatment (88%). Conclusion: A high-protein diet improves wound healing in chronic wounds.

Abstract 6: Amputation Prevention: The Importance of Endovascular and Podiatric Surgical Partnership

Lee C. Rogers, DPM; Paramjit Chopra, MD

Introduction: Nearly 2 million people are living with limb loss in the United States. One of the main causes of limb loss is peripheral arterial disease (PAD), which is common in diabetics. The prevalence of diabetes is expected to double by 2030, to 8.3% of the population. Objective: A partnership between diabetic foot and endovascular specialists is necessary in order to prevent tissue and limb loss. Methods: Create a partnership between the endovascular and podiatric surgeon per the Diabetic Rapid Response Acute Foot Team (DRRAFT) guidelines. Results: Podiatric surgeons evaluate the foot ulcer, exclude or treat foot infections, rule out PAD or refer to vascular surgery, create a comprehensive wound-healing plan, and perform surgical repair of diabetic foot arthropathy. Endovascular specialists manage significant PAD that is present in at least one-third of patients with diabetic foot ulcer. Vascular specialists must be capable of risk factor management, performing and interpreting noninvasive vascular studies, diagnostic angiography, and performing distal endovascular interventions, including angioplasty and atherectomy. Survey results will be presented for the first time at the 4th Annual Amputation Prevention Symposium. This survey includes an evaluation of the impact on patient outcomes when the wound multidisciplinary team of specialists is included with the endovascular specialists in the management of diabetic foot ulcers.
specialist. **Conclusion:** The ideal care team must include two surgical specialists at a minimum, a podiatrist and endovascular surgeon, who are uniquely suited to clinically partner in the establishment of comprehensive programs aiming to prevent limb loss. Rapid communication and organization in concert with significant expertise are mandatory.

**Abstract 7: The Paradigm Shift to a Limb Preservation Team: Implementation of Best Practices of Wound Care With Best Practices of Endovascular Techniques**

*Arti Masturzo MD, CWS, ABPM/UHM; Bryan T. Fisher Sr., MD*

**Introduction:** Amputation is often the de facto treatment for patients with multilevel occlusive disease and significant tissue loss, and most of these patients will die within 5 years. **Objective:** To show that a multidisciplinary team of wound care and endovascular specialists can prevent amputations. **Methods:** Best practice protocols from the WHS guidelines were followed to identify peripheral arterial disease (PAD). Screening for calcified disease is an important step in defining the most efficient and effective way of re-storing in-line flow to oxygen-starved tissue, specifically to the angiosome. **Results:** Using The Advanced Wound Care Center at Southern Hills as an example, the number of lower-extremity limb amputations decreased by over 80% after integration of an advanced endovascular specialist into the wound care clinic. An 89-year-old female with Rutherford category V disease, rest pain, and nonhealing wounds had bilateral severe PAD with monophasic doppler signals below the knee. Given her history of congestive heart failure with an ejection fraction of 25%, bypass surgery was considered extremely high risk. She underwent both pedal and contralateral femoral access to re-establish flow in the superficial and tibial arteries. This resulted in complete resolution of her rest pain and healing of her pretibial wound in 6 weeks. **Conclusion:** Creating a multidisciplinary team to develop best practice protocols for wound healing and endovascular technique are improving healing rates, quality of life, and amputation rates.

**Abstract 8: “Doc, I Don’t Want an Amputation” – Team-Based Approach Focusing on Flow to the Angiosome**

*Steven Jaffe, DPM; William Julien, MD; Warren Swee, MD*

**Introduction:** Many patients have comorbidities and risk factors linked to peripheral arterial disease (PAD) and carotid artery disease (CAD) such as smoking, diabetes, and high blood pressure. These conditions lead to calcified vessels, which if left untreated increase the patient’s risk of amputation and death. **Objective:** To show that a team-based approach focusing on flow to the angiosome may increase the odds of a positive outcome. **Methods:** The assertive limb preservation team at Bethesda Memorial Wound Healing Center in Boynton Beach, FL, in conjunction with local endovascular critical limb ischemia (CLI) specialists at South Florida Vascular Associates utilized a team-based approach to save a limb. **Results:** A 68-year-old white male with diabetes mellitus, A1c of 8.3, Charcot, CAD, hypertension, high cholesterol, previous multiple myocardial infarctions, and neuropathy presented with an infected central plantar space with gas gangrene and postoperative dorsal, plantar, and medial wounds. Angiography revealed derangement of all pedal arteries with 90% stenosis at the medial malleolus. Surgical bypass of the anterior tibial artery was
completed, resulting in a healed dorsal wound; howev-
er, plantar wounds continued to worsen. Below-the-
kle amputation was scheduled, but the patient stated, “Doc, I don’t want an amputation.” The patient was referred to an endovascular CLI specialist who used orbital atherectomy and low-pressure angioplasty to restore flow directly to the angiosomes of the plan-
tar wounds, resulting in healed wounds via adjunctive wound management. **Conclusion:** The benefit to the patient’s quality of life is great when a team of special-
ist work together to save limbs from amputation.

**Abstract 9: Identifying Hidden PAD and Improving Qual-
ity of Life: Mercy’s Limb Preservation Program**

*Michael C. Garrett, ARNP; Wade W. Kang, MD*

**Introduction:** Peripheral arterial disease (PAD) is a hidden risk factor when treating chronic nonhealing wounds, especially in patients who have other comor-
bidities such as diabetes, high blood pressure, high cho-
lesterol, and smoking. Approximately 30% of patients with diabetes will have PAD. Of those patients, 25% will develop ulcers. **Objective:** This 10-patient retrospec-
tive case review explores the link between advanced comorbidities and patients at risk for amputations. Clinicians who become advanced wound care investiga-
tors can identify and treat PAD symptoms sooner, which in turn helps patients improve their quality of life sooner. **Methods:** The limb preservation team at Mercy Sioux City focused on advancing the wound healing program to include advanced assessment of etiologies and establishment of best practice protocols, modalities, and technologies to embrace endovascular techniques that will aid in restoring arterial flow to specific angiosomes. **Results:** Ten retrospective case reviews were performed, in which patients’ risk fac-
tors for PAD included diabetes mellitus, hypertension, high cholesterol, and smoking in 8 of the 10 patients. All patients were screened for “hidden PAD” with abnormal Ankle Brachial Index scores in 9 of the 10 patients. **Conclusion:** All patients had improvement of quality of life. Eight of ten patients were deemed appropriate for endovascular treatment with orbital atherectomy. All patients included have demonstrated healing, with 60% of patients 100% healed. Identifying hidden PAD and utilization of a team approach to limb preservation improves patients’ quality of life. Mercy’s limb preservation program, by incorporating new advanced technologies along with utilizing advance assessment, protocols, and modalities, continues to strive toward saving all viable tissue.

**Abstract 10: Endovascular Management of Vascular Closure Device Complications**

*Kuldeep Singh, MD; Sumeet Singh Goraya; Khanjan Nagarsheth, MD; Simrat Suri, MD*

**Introduction:** Vascular closure devices (VCD) can lead to devastating consequences if deployed incor-
rectly. **Objective:** We undertook this study to examine endovascular management of complications caused by closure devices. We also present a novel technique to remove a misdeployed closure device. **Methods:** A PubMed, Ovid, and Google Scholar literature search was formed as it pertains to this topic. We also present a novel technique to remove a misdeployed closure device. **Results:** A 76-year-old female was not-
ed to have an embolized Angio-Seal device (St. Jude Medical) after catheterization. From the contralateral femoral artery, an 8 Fr destination sheath was placed
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proximal to the embolus. A SpiderFX protection filter (Covidien) was deployed past the embolus. The sheath and the filter containing the embolized AngioSeal device were removed. A final angiogram revealed complete arterial patency. We identified 14 studies and 455 patients who had VCD complications managed by endovascular means. Mean age was 62.7 years, 52.8% were male. Arterial access involved puncture of the superficial femoral artery in 52.9% of cases, the common femoral in 33.3% of cases, and profunda or external iliac artery in 13.9% of cases. Sheath size ranged from 4 Fr to 10 Fr. There was no association between sheath size and frequency of complications. The method of VCD retrieval included catheter thrombolysis, snare, and flexible alligator forceps. **Conclusion:** The use of VCD is becoming more commonplace in endovascular procedures. Limb-threatening ischemia can occur if deployed incorrectly. Novel endovascular techniques can be employed to retrieve these devices and restore arterial flow to the limb.

**Abstract 11: Early Intervention in Critical Limb Ischemia of Diabetic Patients**

*Lloyd Tomlinson, DPM-S; Anthony Iorio, DPM, MSH; Christopher Wolf, DPM-S*

**Introduction:** Critical limb ischemia (CLI) is associated with increased risk of amputations, but early intervention could play an important role in decreasing that risk. **Objective:** This research aims to prove that (1) using instruments to screen for CLI early decreases the risk of limb amputation and (2) the use of a specific screening (FloChec Digital ABI System; Selmer Scientific) for the effective diagnosis of at-risk patients for CLI would decrease the need for surgical amputation by early interventional revascularization. **Methods:** The research focuses on Hispanic patients ages 18 to 80 with prolonged diabetes screened at a diabetic health fair. Patients were screened using an ABI device (FloChec) to look for patients that were at risk for CLI. Patients that had a reading of less than or equal to .9 on the device were considered at risk for critical limb ischemia. These at-risk patients were further considered candidates for debulking atherectomy and revascularization procedures. **Results:** There are currently two main methods of correcting peripheral vessels below the knee. They include open distal bypass and orbital atherectomy. Most patients in the diabetic population present with lower leg occlusive disease and are sensitive to critically invasive surgeries.
such as open bypass. Orbital atherectomy provides for a less invasive approach and pedal access. **Conclusion:** Because diabetic patients have a greater-than-normal risk of developing distal arterial occlusive disease, the use of orbital artherectomy should become the preferred procedure for treatment of CLI in calcified lesions leading to an overall decrease in amputations in the diabetic population.

**Abstract 12: The PRIME Registry: Ankle Brachial Index and Toe Brachial Index in Critical Limb Ischemia Patients**

J.A. Mustapha, MD; Fadi Saab, MD; Larry Diaz-Sandoval, MD; Theresa McGoff, BSN; Sara Finton, BSN; Carmen Heaney, BSN; Carolyn Fox, BSN; Hassan Saad, MD; Nitin Mahajan, MD

**Introduction:** The Peripheral Registry of Endovascular Clinical Outcomes (PRIME Registry) is an ongoing prospective registry documenting endovascular revascularization approaches and procedural and long-term outcomes (36 months) for patients with advanced peripheral vascular disease (PVD) or critical limb ischemia (CLI). Currently, patients with complaints indicative of PVD and CLI are evaluated using clinical examination and a combination of noninvasive procedures, including Ankle Brachial Index (ABI) and Toe Brachial Index (TBI). An ABI $\leq 0.7$ or TBI value $\leq 0.5$ would indicate CLI. **Objective:** To evaluate ABI and TBI values in patients with Rutherford classification IV, V, and VI to determine if an ABI value of $\leq 0.7$ or TBI value $\leq 0.5$ is observed. **Methods:** The study examined 45 CLI patients enrolled in the PRIME registry. Descriptive analysis was documented using mean and standard deviation. **Results:** All of the patients observed met CLI criteria by presence of chronic CLI with Rutherford scores of IV to VI. However, many did not meet the standard definition of CLI disease by ABI and TBI (table). **Conclusion:** Ankle-brachial indices may not be an accurate measure of CLI in patients with Rutherford classification IV, V, and VI disease.

| Ankle Brachial Index and Toe Brachial Index Values by Rutherford Category |
|-----------------------------|-----------------------------|
|                            | ABI $\geq 0.7$ | TBI $\geq 0.5$ |
| Rutherford IV, V, VI       | 29/45 (64%)     | 9/20 (45%)     |
| Rutherford V, VI           | 17/30 (57%)     | 6/13 (46%)     |

**Abstract 13: The PRIME Registry: Ultrasound-Guided Access in Critical Limb Ischemia (CLI) Patients**

J.A. Mustapha, MD; Fadi Saab, MD; Larry Diaz-Sandoval MD; Sara Finton, BSN; Theresa McGoff, BSN; Carmen Heaney, BSN; Andrea Peterson, MSN; Hassan Saad, MD

**Introduction:** The Peripheral Registry of Endovascular Clinical Outcomes (PRIME Registry) is an ongoing prospective registry documenting endovascular revascularization approaches and procedural and long-term outcomes (36 months) for patients with advanced peripheral vascular disease (PVD) or critical limb ischemia (CLI). Historically, access for endovascular interventions has been achieved using palpation maneuvers in larger arterial conduits and angiography-directed maneuvers in smaller arterial conduits. **Objective:** Ultrasound-guided access complication rates were analyzed in patients with advanced PVD or CLI requiring complex revascularization for multilevel and/or multivessel disease. Access-site arterial conduits ranged from 2 mm to 7 mm in size. **Methods:** This study was executed through a data analysis of a cohort of 200 patients enrolled in the PRIME
registry. Descriptive analysis was documented using mean and standard deviation. **Results:** Initial analysis revealed low complication rates in all arterial conduits accessed including antegrade vs retrograde (table). **Conclusion:** Ultrasound-guided access has a predictable outcome in complex CLI patients despite the size of arterial conduit and antegrade vs retrograde access. This contributes to a safe access approach for all patients with PVD.

**Abstract 14: The PRIME Registry: Ultrasound-Guided Tibial Access in Critical Limb Ischemia Patients**

**J.A. Mustapha, MD, Fadi Saab, MD, Larry Diaz-Sandoval, MD, Sara Finton, BSN, Theresa McGoff, BSN, Carmen Heaney, BSN, Hassan Saad, MD**

**Introduction:** The Peripheral Registry of Endovascular Clinical OutcoMEs (PRIME Registry) is an ongoing prospective registry documenting endovascular revascularization approaches and procedural and long-term outcomes (36 months) for patients with advanced peripheral vascular disease (PVD) or critical limb ischemia (CLI). Historically, access for endovascular interventions has been achieved using angiography-directed maneuvers in smaller arterial conduits. **Objective:** Ultrasound-guided access complication rates were analyzed in tibial-arterial conduits with variable sizes ranging from 2 mm to 3.5 mm. Access-site complications including arteriovenous fistula, perforation, pseudoaneurysm, bleeding, and death were assessed. **Methods:** This study analyzed a cohort of 54 patients enrolled in the PRIME registry who had undergone tibial access for complex revascularization of multilevel and/or multivessel disease. Descriptive analysis was documented using mean and standard deviation. **Results:** The analysis of accessed tibial conduits revealed <0.5% access-site complications (arteriovenous fistula, perforation, pseudoaneurysm, bleeding, or death). **Conclusion:** Ultrasound-guided tibial access results in low complication rates and is a safe access approach for patients with advanced PVD and CLI.
Abstract 15: Chronic Total Occlusion Crossing Based On Cap Morphology (C-TOP) in CLI Patients: A Pilot Study and Interim Analysis of the PRIME Registry

J.A. Mustapha, MD; Fadi Saab, MD; Larry Diaz-Sandoval, MD; Theresa McGoff, BSN; Carmen Heaney, BSN; Hassan Saad, MD

Introduction: The Peripheral Registry of Endovascular Clinical Outcomes (PRIME Registry) is an ongoing prospective registry documenting endovascular revascularization approaches and procedural and long-term outcomes (36 months) for patients with advanced peripheral vascular disease (PVD) or critical limb ischemia (CLI). Chronic total occlusion (CTO) is a challenging aspect of treating patients with PVD and CLI. Objective: Correlate intraluminal crossing success and identify and describe CTO cap morphology (C-TOP classification) via extravascular ultrasound (EVUS) and angiography. Methods: Retrospective analysis was performed of 23 patients enrolled in the PRIME registry, who underwent endovascular revascularization with identifiable proximal and distal CTO caps. Identification of CTO cap was performed using angiography and/or ultrasound mapping. Chronic total occlusion crossing was performed via fluoroscopy or EVUS guidance. Four different combinations of proximal and distal CTO caps are proposed (figure). Results: Crossing was successful in 100% of CTOs. Type II (9/23, 39%) and Type III (9/23, 39%) appeared to be the most common. Type IV was identified in 5 of 23 (21.7%) CTOs. No Type I CTOs were identified. Planned dual access (antegrade and tibial retrograde) occurred in 26% of patients. A second access site to cross the CTO occurred in 5 of 23 cases (21.7%). In cases without dual access, retrograde access was used to cross the CTO in 8 of 23 cases (34%). Conclusion: This is the first trial describing CTO cap morphology via ultrasound and angiography. Presence of a convex proximal CTO cap was most common. A concave distal CTO cap was also very common. This explains the high success rate in crossing the CTO in a retrograde fashion.