Treatment Mode	N	TIMI 2-3 Post Penumbra/Indigo	TIMI 2-3 Post All Interventions
Penumbra/Indigo as initial therapy	39	79.5% (31/39)	94.9% (37/39)
tPA prior to Penumbra/Indigo	12	91.7% (11/12)	No Change
Mechanical thrombectomy prior to Penumbra/Indigo	15	92.9% (13/14)*	100% (15/15)
Both adjunctive tPA + mechanical therapies prior to Penumbra/Indigo	13	100% (13/13)	No Change
Total	79	87.2% (74/78)	96.2% (76/79)

CONCLUSION Thrombectomy using XTRACT was safe and effective as both primary and secondary intervention in patients with peripheral arterial occlusions.

CATEGORIES ENDOVASCULAR: Peripheral Vascular Disease and Intervention

TCT-364

Comparison between catheter guided and ultrasound accelerated thrombolysis for the treatment of DVT of lower extremities: A Meta-Analysis

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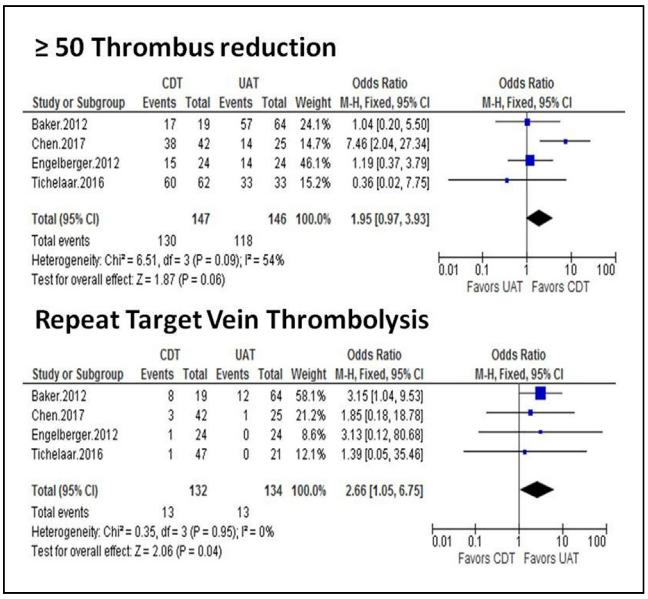
BACKGROUND Catheter direct thrombolysis (CDT) and ultrasound-facilitated thrombolysis (UAT) are newer techniques that facilitate to dissolve thrombus in patients with deep vein thrombosis (DVT). We aimed to do a meta-analysis comparing the clinical outcomes between them.

METHODS Pub Med, Cochrane and Embase were searched for all the clinical data that directly compared CDT and UAT for acute DVT of lower veins. Primary outcomes included ≥ 50 % thrombus reduction and repeat target vessel thrombolysis. Secondary outcomes included major and minor bleedings, additional angioplasty (PTA+ stent) and mean days of hospital stay. We used Fixed or Random Effect analysis using the Cochrane Handbook of Systematic Reviews and RevMan 5.2 for statistical analysis.

RESULTS A total of 4 clinical studies provided a total of 293 (CDT=147; UAT=146). There was a trend towards higher rates of ≥ 50 % thrombus reduction in the CDT group compared to UAT (88% vs. 80%; p=0.06) whereas there was a significant less recurrence thrombus in the UAT group compared to the CDT (9% vs. 10%, p=0.04). Secondary outcomes analysis showed significant less stents required after UAT compared to CDT (39% vs. 62%, p= 0.04). There was no difference between groups in terms of length of hospital stay, minor and major bleeding events.



CONCLUSION Out analysis suggested that UAT not only requires significant less angioplasty with stents but also might be associated with better re-stenosis rates whereas CDT significantly offered better thrombus burden reduction. Complication rates were similar between both groups. Further randomized trials should be pursued.

CATEGORIES ENDOVASCULAR: Peripheral Vascular Disease and Intervention

TCT-365

Feasibility and Safety of Atherectomy in Endovascular Treatment of Infrainguinal Peripheral Arterial Disease via Retrograde Transpedal Approach

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BACKGROUND Technological advances have made endovascular approach the treatment of choice for the management of symptomatic peripheral arterial disease (PAD). However, the presence of severe calcification, particularly in the infrainguinal vasculature, presents a significant procedural challenge. Plaque modification strategies by debulking using an atherectomy device has been used to reduce restenosis rate compared to angioplasty and stenting alone. Successful treatment via traditional transfemoral approach may be limited due to complications including thromboembolism, slow flow, acute vascular closure and vascular complication. Using a retrograde transpedal approach (TPA) may reduce these complications.

METHODS We analyzed prospectively collected data on patients with symptomatic PAD who underwent endovascular intervention with atherectomy using TPA, from 7/2015 - 1/2017. Primary endpoint was 1 year major adverse events (MAE) - death, amputation and target lesion revascularization (TLR). Secondary endpoint was peri-intervention thromboembolism, slow flow, acute closure, access site patency and access complication at 30 days. Follow up was censored at 1st MAE event or at 1 year follow up.

RESULTS A total of 743 patients (Age 75 years. Rutherford Class 3-5 100%) underwent endovascular intervention with atherectomy for 1254 lesions (**Table**). Procedural success rate was 99.4%. The 1 year MAE was 13.8%. There were no peri-intervention thromboembolism, slow flow or acute closure. At 30 days, access site pseudoaneurysm was 0.2%, AV fistula was 0.3% and access site occlusion was 0.08%.

Lesion	N=1254
SFA, %	5.1
SFA/Tibial, %	53.3
Tibial, %	41.6
Peripheral Run-off (mean ± SD)	2.0 ± 0.9
Procedural Details	
Orbital Atherectomy + Balloon Angioplasty, %	85
Directional Atherectomy + Balloon Angioplasty, %	15
Stent, %	5
Distal Protection, %	0

CONCLUSION Treatment of infrainguinal calcified lesions using atherectomy via TPA is safe and feasible and may reduce TFA associated complications.

CATEGORIES ENDOVASCULAR: Peripheral Vascular Disease and Intervention

TCT-366

The PRELUDE Study: PRospective Study for the TrEatment of Atherosclerotic Lesions in the Superficial Femoral and/or Popliteal Arteries Using the Serranator® DevicE

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BACKGROUND This first-in-human study evaluates serration angioplasty on the arterial surface to enhance lumen gain and to promote constructive use of angioplasty force. The PRELUDE study assessed preliminary safety and efficacy of the Serranator® Alto PTA Serration Balloon Catheter in subjects with atherosclerotic disease of the superficial femoral and popliteal arteries.

METHODS Study design is a single arm, prospective, multi-center feasibility study. Acute angiographic data comparing the pre-Serranator® inflation versus post inflation effects were evaluated by an independent core lab. Inclusion criteria were claudication or ischemic rest pain, and de novo or non-stented re-stenotic lesions. Subjects with stenosis > 70%, lesion length < 10 cm, with reference vessel diameters of 4. 0 mm to 6. 0 mm inclusive, were included. Occlusions were allowed up to 6 cm in length. The primary safety endpoint was a composite of Major Adverse Events (MAE) plus Peri-procedural Death (POD) at 30 days post procedure. The primary efficacy endpoint was defined by device success with a final diameter stenosis < 50%. A secondary objective was to confirm the presence of serrations across the lesions using Optical Coherence Tomography (OCT) and or Intravascular Ultrasound (IVUS) following treatment in a subset of 10 subjects. Follow-up after serration angioplasty is at 30 days and 6 months.

RESULTS Twenty-five subjects enrolled at 4 study centers. Moderate or severe calcification was present in 56% (n=14) of subjects. Thirty-two percent of subjects (n=8) had chronic total occlusions. The average pre-treatment stenosis was 88% with a post treatment stenosis of 23%. Only 1 stent was placed (4%) post-Serranator®. There were no MAEs or POD reported. Serrations were confirmed by an independent core lab in all OCT or IVUS images (n=10).

CONCLUSION This first-in-human study of serration angioplasty demonstrated safety and feasibility. Acute results suggest that the Serranator® can safely achieve low residual stenosis. The presence of serrations by OCT and IVUS in a wide variety of lesions demonstrates that serrations may play a role enhancing and improving the results of angioplasty. Final study results are pending, with 6-month follow up expected to be completed in 2017.

CATEGORIES ENDOVASCULAR: Peripheral Vascular Disease and Intervention

STUDIES WITH MAGNESIUM BRS

Abstract nos: 367 - 371

TCT-367

Mechanical properties of magnesium and polymeric bioresorbable scaffolds compared with durable metallic stents

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BACKGROUND Understanding the mechanical and structural properties of bioresorbable scaffolds (BRS) is crucial for appropriate implantation.

METHODS We compared the mechanical and physical properties of the magnesium BRS, Magmaris (Biotronik, Bülach, Switzerland) with the Absorb BRS (Abbott Vascular, Santa Clara, CA, USA) and the DESolve CX BRS (Elixir Medical Corp., Sunnyvale, CA, USA) and the permanent metallic drug-eluting stents (DES) Xience Xpedition (Abbott Vascular, USA) and the Promus Premier (Boston Scientific, Natick, USA). We measured crossing profile of 3.0 mm devices, recoil, radial strength and limit for post-dilatation before fracture, safety of side branch dilatation and mini-kissing balloon dilatation.

RESULTS The crossing profile (mm) for Magmaris BRS was numerically greater than for Absorb BRS (table 1) and these were greater than for the metallic DES Promus Element and Xience Xpedition. For a 3.0 mm Magmaris scaffold, no fractures were observed after main branch post-dilatation with 4.0 mm NC balloons for pressures up to 24 atm. For dilatation through stent cells, no fractures were observed with a 3.0 mm NC balloon up to nominal pressure. A single fracture in a connecter was observed after mini-kissing technique with two 3.0 NC balloons at 5 atm. All other fractures caused by mini-kissing balloons occurred at pressures above 17 atm. Crossing profile, radial strength, post-dilatation and side branch dilatation results are presented in table 1.

	Magmaris	Absorb	DESolve CX	Promus Element	Xience Xpedition
Crossing profile (mm)	1.48±0.01	1.43±0.02	1.41±0.02	1.10±0.01	1.14±0.01
Radial strength. Pressure (Bar) to reduce cross-sectional area by 10%	1.26±0.23	1.27±0.14		1.84±0.16	1.45±0.13
Radial strength. Pressure (Bar) to reduce cross-sectional area by 25%	1.8±0.08	1.37±0.18		1.97±0.12	1.6±0.10
Fractures after post-dilatation with 4 mm balloon	None	At 10 atm	None		None
Fractures after side-branch dilatation with 3.0 mm balloon	None	At 14 atm	None		None

CONCLUSION The Magmaris scaffold has a numerically larger crossing profile compared with Absorb BRS. It was more resistant to strut fracture with main branch post-dilatation, side-branch dilatation and mini-kissing post-dilatation, and had greater radial strength than Absorb.

CATEGORIES CORONARY: Stents: Bioresorbable Vascular Scaffolds

TCT-368

The Drug-eluting Absorbable Magnesium Vascular Scaffold in Complex Coronary Bifurcations: Insights from an In-Vivo Multimodality Imaging study

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BACKGROUND Metal absorbable scaffolds constitute a conceptually attractive alternative to metallic stents or polymeric scaffolds in complex bifurcation lesions. This acute animal study sought to provide insights regarding the feasibility of performing complex bifurcation stenting with Magmaris bioresorbable magnesium-alloy scaffold (Biotronik AG, Bülach, Switzerland).

METHODS Twenty-five New Zealand White rabbits underwent stenting of non-diseased aorto-iliac bifurcations with Magmaris using provisional (PS,n=5), culotte (n=6), modified-T (n=6), or T-and-protrusion (TAP,n=8) stenting techniques. Angiography, optical coherence tomography and micro-computed tomography were performed to assess the result.

RESULTS 45 Magmaris were successfully delivered and implanted in 25 rabbits without complication, and with procedural success of 100%. In all bifurcation procedures (n=25), the angiographic results were excellent. In 7/25 stenting procedures single strut fractures were identified, whilst following 2 procedures multiple strut fractures were identified. The majority of strut fractures occurred at the bifurcation affecting the main vessel scaffold (n=3), SB scaffold (n=3), or both (n=1) with connectors (n=4) and rings (n=4) equally affected. PS optimally opened the SB without scaffold compromise. Culotte resulted in complete bifurcation coverage and good scaffold expansion; single strut fractures were present in 3/6 and double fractures in 1/6 procedures. Mod-T and TAP resulted in complete bifurcation coverage, minimal neocarina double-strut layers and good expansion. In 2/6 Mod-T procedures single strut fractures were present with SB scaffold deformity present in additional 2/6 procedures. In 2/8 TAP procedures single strut fractures were present at the bifurcation without compromising overall scaffold integrity. This non-diseased model may not accurately predict scaffold behavior in humans and long-term outcomes following scaffold degradation are unknown.

CONCLUSION Bifurcation stenting using Magmaris appears feasible. PS with additional TAP if needed seems reasonable. When a 2-stent technique is required from outset, TAP appears favorable whilst Mod-T and culotte stenting should probably be avoided.