2022 MID-ATLANTIC CONFERENCE

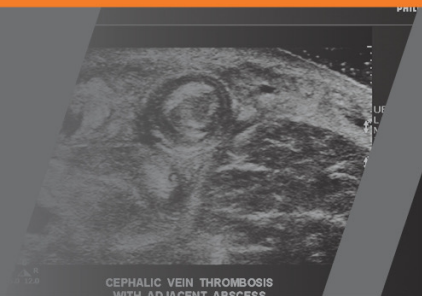
10th ANNUAL CURRENT CONCEPTS IN

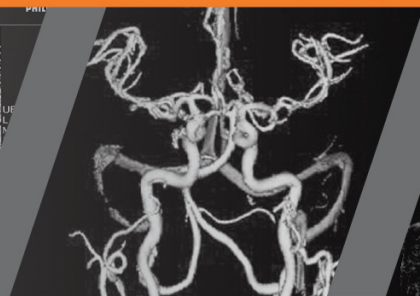
VASCULAR THERAPIES

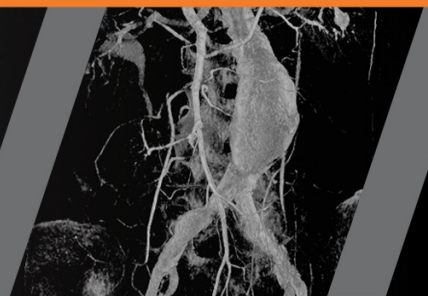
2022

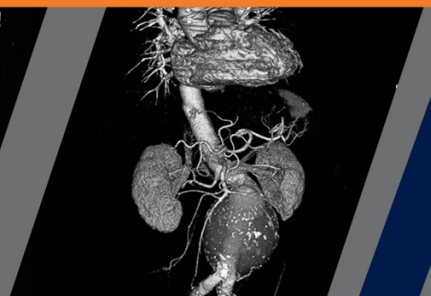
Hilton Virginia Beach Oceanfront
Virginia Beach, Virginia

APRIL 28-30









Sentara Vascular Specialists

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Bioabsorbable Stents

Christine Ou

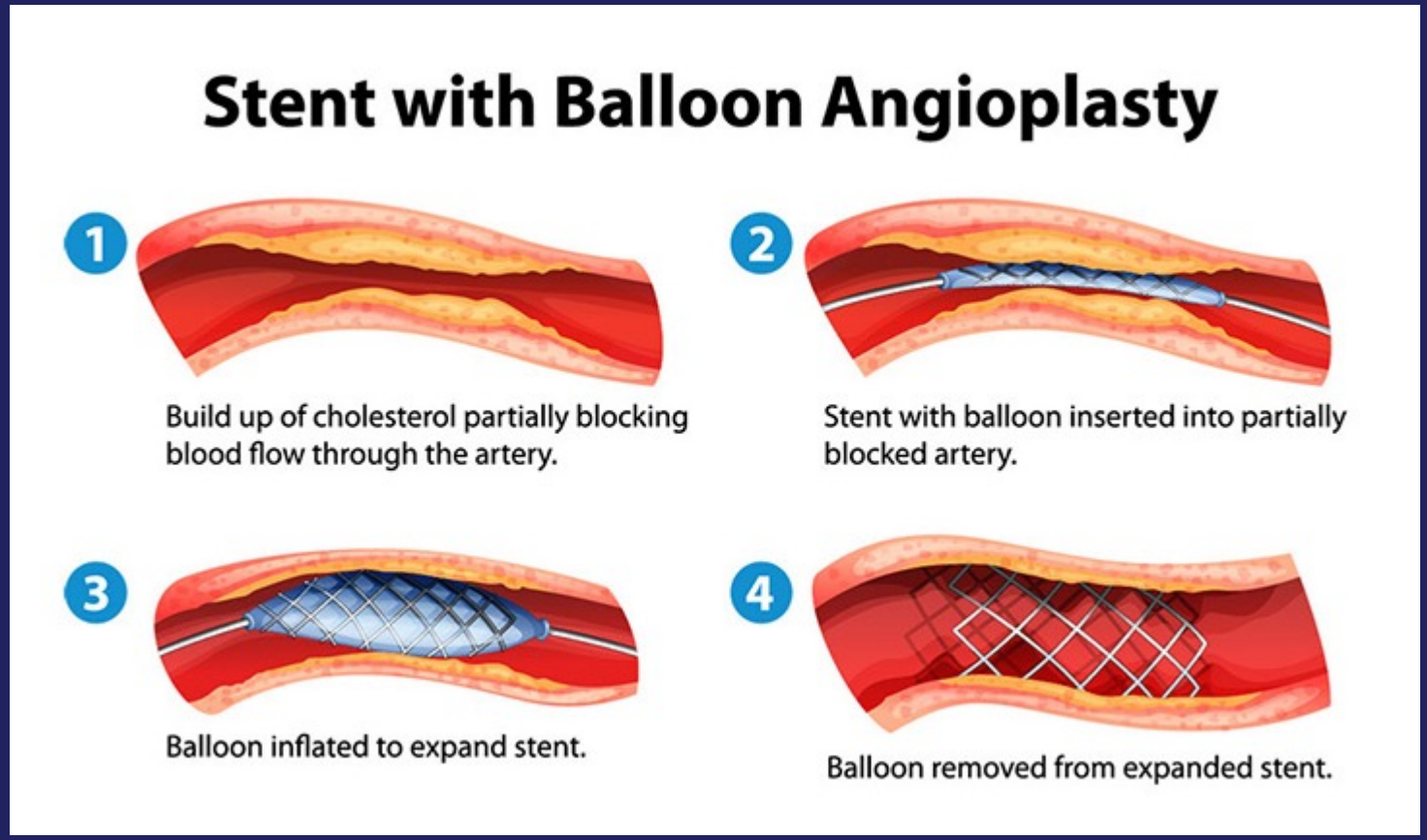
Sentara RMH

Overview

- Endovascular balloons vs stents
- History of bioabsorbable vascular stents (BVS)
- Benefits of BVS
- Various stent models
- Results of trials
- Future of BVS

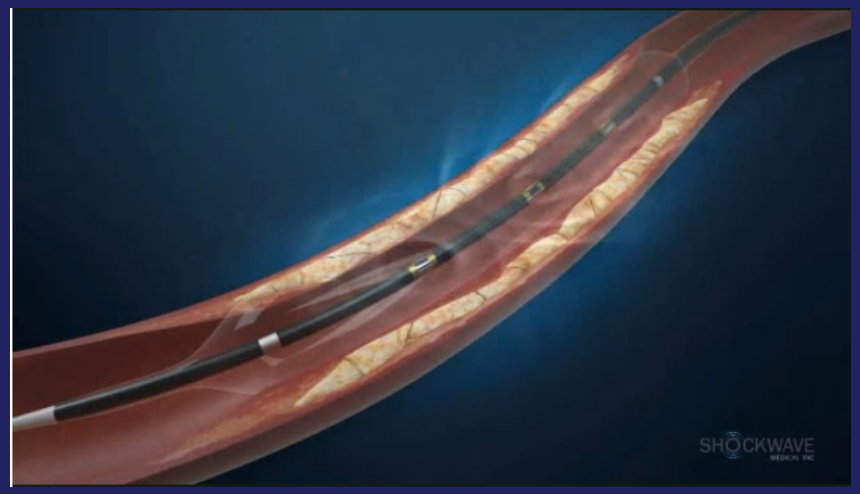
Endovascular Balloons

- Percutaneous transluminal angioplasty (PTA)
- ‘Plain old balloon angioplasty’ POBA
- Used to widen a narrowed or obstructed artery or vein
- Minimally invasive



Endovascular Balloons

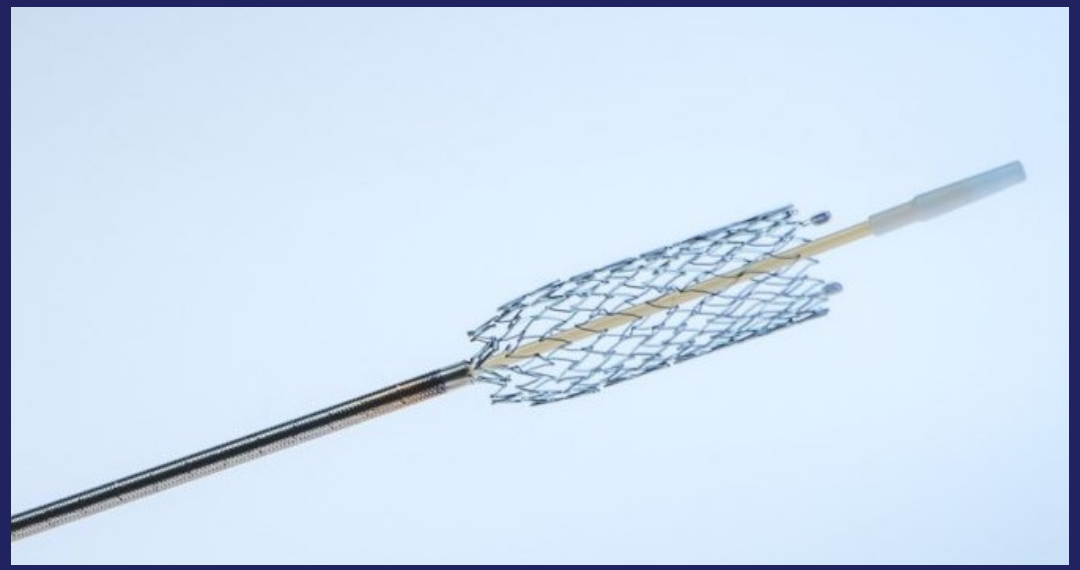
- Cutting, scoring
- Intravascular lithotripsy (IVL)
- Drug coated balloon (DCB)- antiproliferative drugs inhibits inflammatory process
- Limitations-recoil, dissections, stretch injuries, inflammatory changes



Endovascular Stents

- Insertion of a wire mesh stent into the artery
  - Metals such as stainless steel, nitinol, or metal alloy

- Self expanding
  - Pros-flexible, long lengths, radial force if oversized, crush resistant
  - Cons-low radial force, limited radiopacity



Endovascular Stents

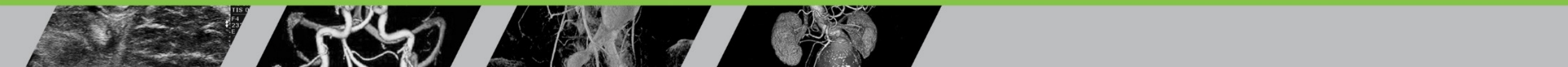
- Balloon expanding
  - Pros-high radial force, radiopaque
  - Cons-short lengths, prone to crushing

- Drug eluting stents (DES)-antiproliferative drugs inhibits inflammatory process

- Limitations-in stent restenosis/thrombosis, stent fractures, prevent future treatments

Goals of BVS

- Occlusion of the artery can be open with implantation
- Maintain vessel patency during the first 6-9 months as vessel is healing
- ‘Leave nothing behind’ concept
- Limit acute and subacute stent thrombosis
- Prevent recoil
- After the stent is absorbed, it restores the normal vasomotion and endothelial function of the vessel
- Prolong dual antiplatelet therapy might not be necessary



Timeline of Bioabsorbable Stents

- First developed in 1990s
- First coronary BVS was used in 2000
- First peripheral sent was used in 2009
- Vascular BVS was FDA approved in 2016

Polymeric Stent

- Poly-L-lactic acid (PLLA)
- Polyglycolic acid (PGA)
- Poly (D,L lactide/glycolide) co polymer (PDLA)
- Polycaprolactone (PCL)
- Long chains that are hydrolysed, phagocytosed, and degraded to lactic acid, carbon dioxide, and water, and eliminated via the kreb cycle
- Degradation time between 6-24 months

Metallic Stents

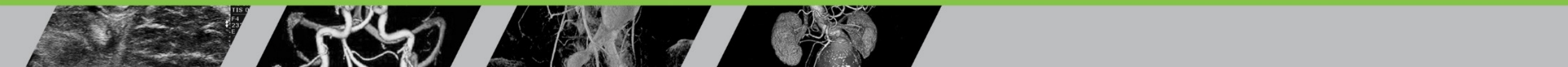
- Magnesium alloy
  - Tubular, slotted, balloon expandable bare metal stents sculpted by laser from biodegradable magnesium alloy
  - rare earth elements with radio opaque markers at the ends
- Low elastic recoil
- Large cells with open mesh design idea for side branch access
- Degradation ranges from 60-90 days with overall integrity at 28 days

Combination Stents

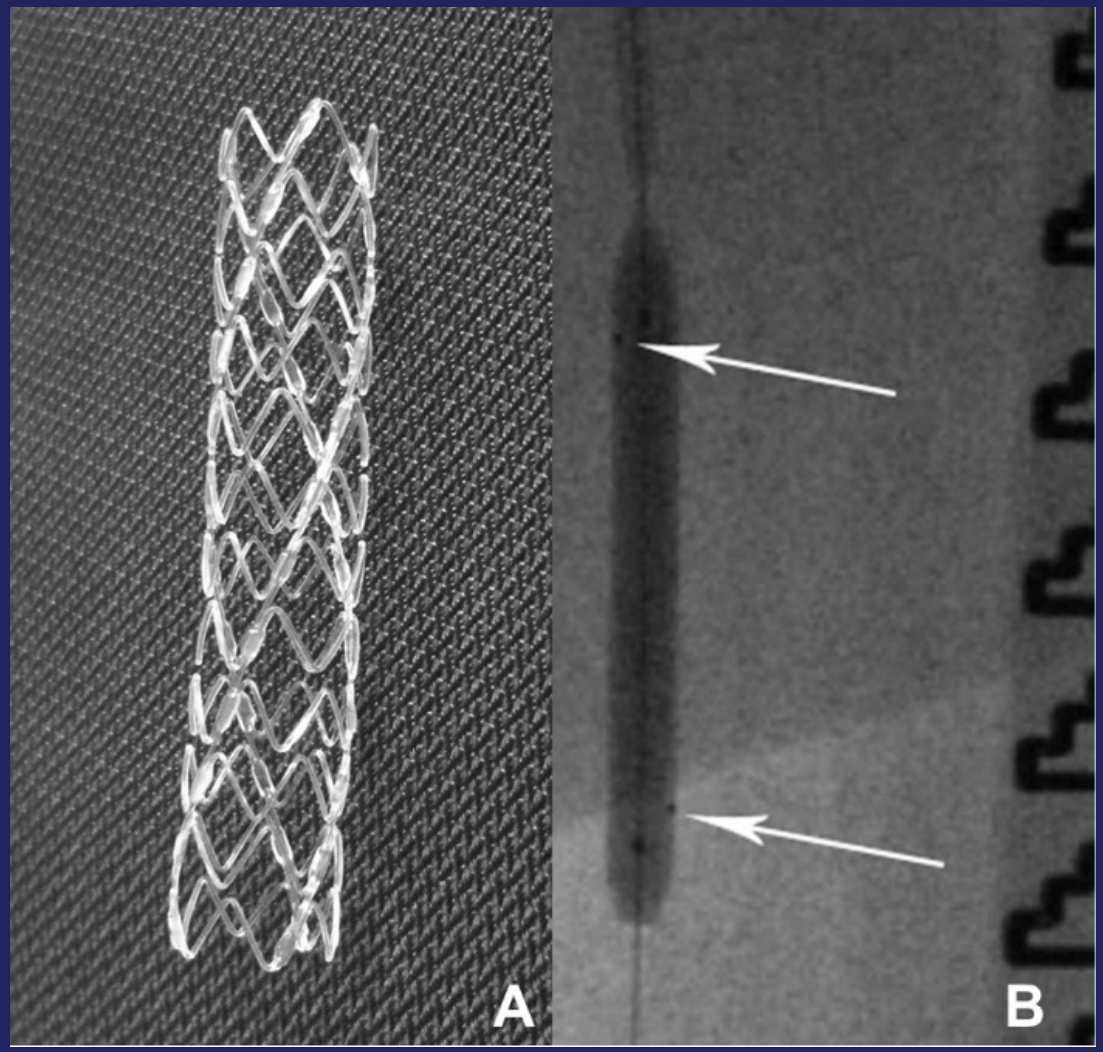
- Tacrolimus eluting cobalt chromium polymer stents
  - Thin, flexible cobalt chromium alloy coated with PDLA polymer incorporating tacrolimus
  - Degradation of matrix at 9 months
  - Early endothelialization and reduction of neointimal thickness up to 90 days after implant
- Everolimus eluting stents
- Paclitaxel BVS

Igaki Tamai Stent

- Self expanding with PLLA with radio opaque markers at the ends
- Developed in the late 1990s
- First fully bioresorbable peripheral stent
- GAIA study
  - First informative series testing device in 30 femoropopliteal lesions with a mean length of 5.9 cm
  - Initial results showed technical success with comparable metal stents
  - IVUS showed complete absorption of stents
  - Binary restenosis rates were 39.3% and 67.9% at 6 and 12 months respectively
  - Histopathology from specimens retrieved by atherectomy showed mixed hyperplastic tissue and remnants of stent struts, inflammatory cells, and thrombus



Igaki Tamai Stent



REMEDY Stent

- Follow up to the Igaki-Tamai stent
- Received Conformité Européene mark in 2009 for treatment of SFA lesions in Europe
- Made of semicrystalline PLLA
- Radial strength and flexibility maintained for 6-9 months after implantation
- Fully bioabsorbed in 2-3 years
- Primary patency at 6 months was 68% but dropped to 58% at 12 months
  - 1 in 3 patients needed TLR after 1 year follow up
- CFA vs endarterectomy –BVS did worst compared to open surgery

Stanza Stent

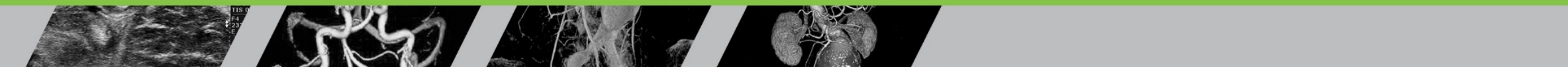
- Self expanding PDLA stent
- BVS with drug eluting resorbable scaffold-paclitaxel
- STANCE trial
- Stanza stent in treatment of PAD in SFA
  - Prospective, single arm, multicenter trial
  - Problems with late lumen loss due to vessel recoil and neointimal hyperplasia
- SPRINT trial was done after device modification

Absorb Stent

- Had been shown to be safe in coronary arteries
  - CE approval in 2010 and FDA approved in 2016
  - Great short term results but higher risk of target lesion failure compared to drug eluting stents (Xience)
- Balloon expandable, everolimus coated PLLA stent
- BVS in SFA or common/external iliac arteries
- Thick struts

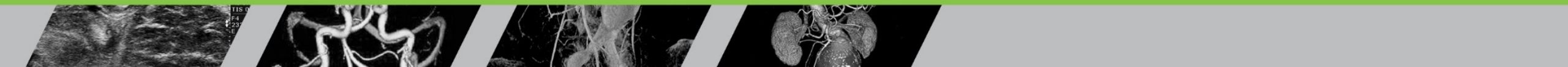
ESPRIT BTK

- Thin strutted scaffold
- Made from PLLA
  - Semi-crystalline bioresorbable polymer engineered to resist vessel recoil
- Scaffold is coated with PDLLA (allows controlled drug release) and everolimus



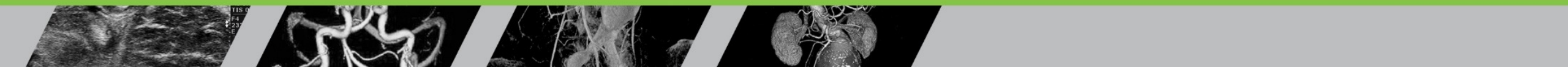
DISAPEAR Trial

- Absorb Stent
- Retrospective analysis in patients with Rutherford class 4-6 Chronic limb threatening ischemia (CLTI) with infrapopliteal lesions
- Primary patency at 6 and 12 months were 98% and 86% respectively
- Rates of freedom from clinical driven TLR was 98% and 93%
- Freedom from major amputation was 98% at both points
- Complete wound healing in 79.5% at the end of 12 months after index procedure



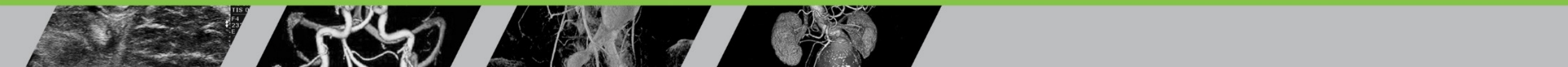
ABSORB BTK Trial

- Absorb stent
- Prospective, nonrandomized, single center study
- 55 limbs treated
- Implanted in arteries in the proximal calf
- Mean lesion length was 20.1 mm
- Closed due to poor enrollment



Set Backs

- Made of polymer used in dissolvable sutures
- Have heterogeneous (non uniform) inner structure
  - Allows certain locations to degrade faster-promoting large deformation
- Inflation causes internal layer to disrupt and rendered susceptible to structural failure
- Recoil might occur after placement
- Difficulty visualizing stent on fluoroscopy
- First commercial bioresorbable stent pulled off market in 2017 after ABSORB III trial

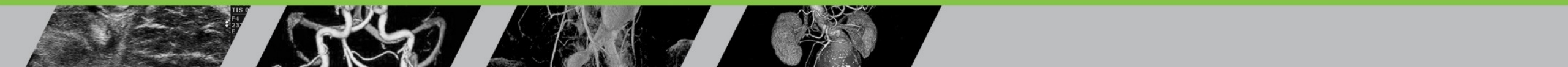


ABSORB BTK Trial

- Absorb stent
- Prospective, nonrandomized, single center study
- 55 limbs treated
  - 95% had clinical improvement
  - 90% rate for complete wound healing
  - 0% amputation rate
  - Primary patency were 89.2%, 80.3%, and 72.9% at 12, 36, and 60 months
  - Freedom from TLR were 97.2%, 90.7%, and 90.7%

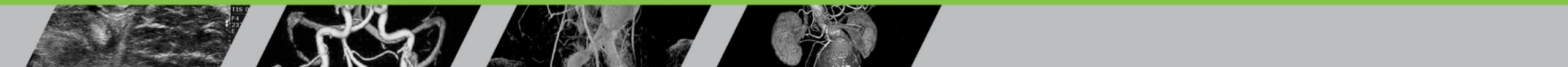
ESPRIT Trial

- ESPRIT I
  - Prospective, multicenter, single arm
  - 35 patients followed through for 3 years
  - Treatment of symptomatic claudication from occlusive vascular disease of the SFA, common, or external iliac artery
  - Lesion lengths of 35.5 mm
  - No related deaths or amputations to 3 years
  - Freedom from TLR at 12 and 24 months in 91.2% and 88.2%
  - Freedom from binary restenosis was 87.9% and 83.9%



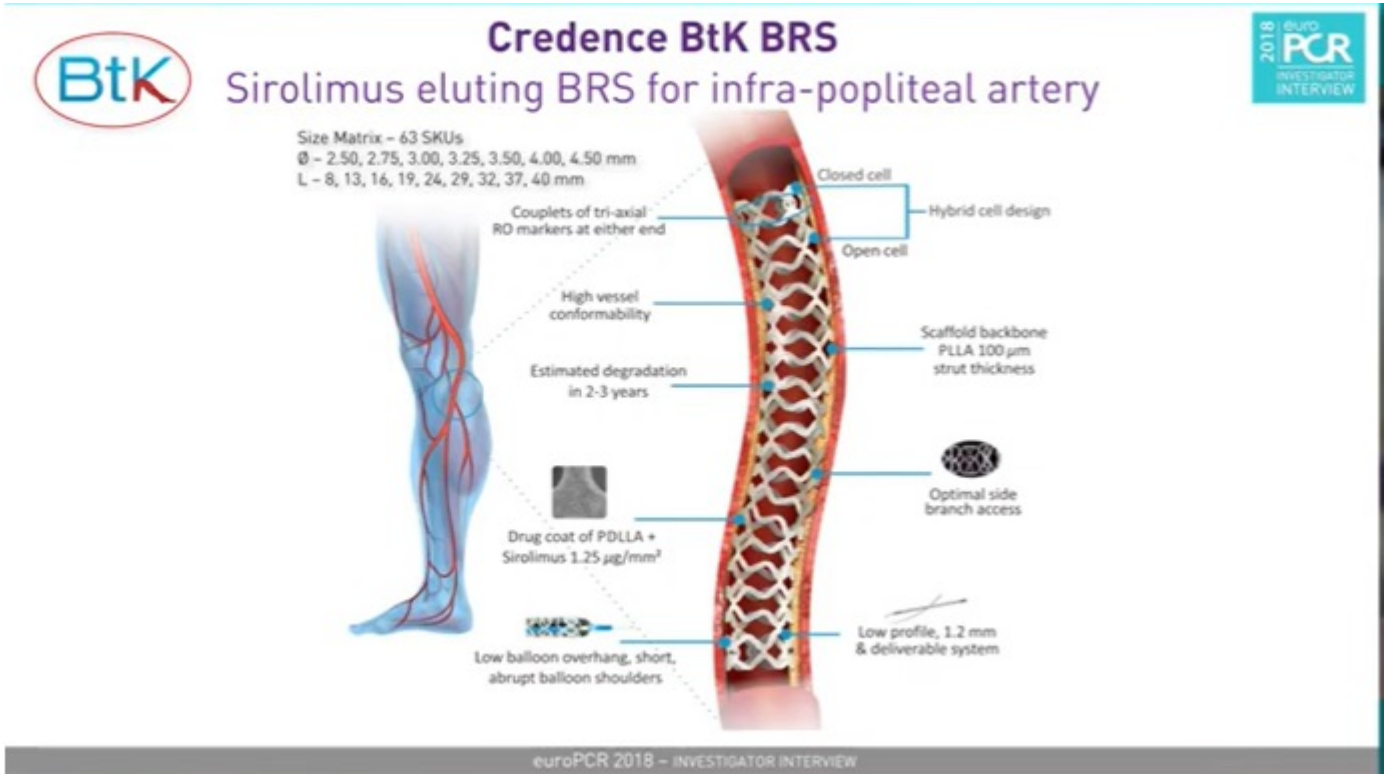
LIFE BTK Trial

- 2020-Abbott announced the start of the LIFE BTK trial to evaluate safety and effectiveness of the Esprit BTK Everolimus Eluting Resorbable Scaffold System
- Prospective, randomized controlled clinical trial
- Comparing Esprit BTK to PTA
- Currently no drug eluting stent, drug coated balloons, or bare metal stent approved for use below the knee in the US
- Co-Primary endpoint of composite of limb salvage and primary patency, and freedom from major adverse limb events and peri operative death



Closing

- Bioresorbable stents have the advantage of metallic stents and drug coated balloons
- Offers acute vessel support and limits neointimal hyperplasia and late lumen loss over time
- Ultimately disappears and allow for return of physiologic vasomotion
- Renewed interest with launch of LIFE BTK trial
- Promising future?



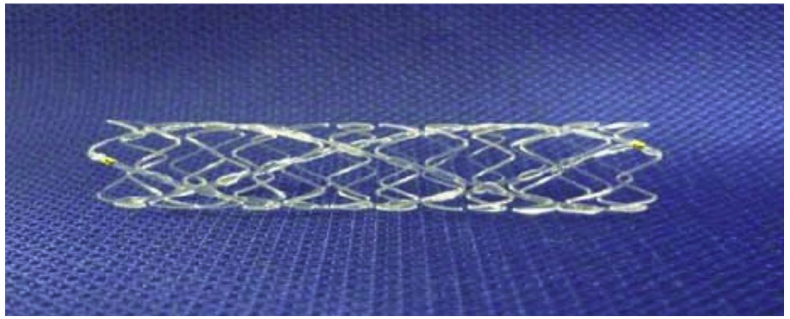


Fig 1. The REMEDY stent (Kyoto Medical Planning Co, Kyoto, Japan) is designed as a zig-zag helical coil. Its monofilament struts are 0.24 mm thick. The stent is thermal self-expanding but needs balloon dilatation for optimal wall apposition. Two gold markers are placed at 2.0 mm of each end.