Challenges in treating mixed morphology SFA lesions
–my strategy for success

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The clinicians have been compensated by Becton, Dickinson and Company to participate in this presentation.
Disclosures

I have the following potential conflicts of interest to report:

- Bayer
- BMS Pfizer
- BD
- BIOTRONIK

- Boston Scientific
- Terumo
- M.A. Med Alliance SA
- PMI
Treatment of symptomatic PAD
Biomechanics in femoro-popopliteal segment

Implants reduce vascular compliance and flexibility

- Torsion
- Compression: Longitudinal and lateral
- Flexion/bending
- Extension / Contraction
- Pulsatile Distension
Lesion length correlates to stent length

- **PTA**
- **DES**
- **Stents**
- **Woven nitinol**

12-month Primary Patency vs. Lesion Length (cm)

Stent length correlates to decreased patency

- Stent length and 1-year primary patency are inversely related.
- As total stent length increases, the 1-year primary patency decreases.

**Table: 1-year primary patency (%) for different stent lengths**

<table>
<thead>
<tr>
<th>Total stent length (mm)</th>
<th>50</th>
<th>100</th>
<th>150</th>
<th>200</th>
<th>250</th>
<th>300</th>
<th>350</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-y-pp %</td>
<td>88.1</td>
<td>84.1</td>
<td>79.8</td>
<td>75.8</td>
<td>72.0</td>
<td>68.7</td>
<td>66.2</td>
</tr>
<tr>
<td>Lower CL %</td>
<td>84.9</td>
<td>81.4</td>
<td>76.7</td>
<td>72.3</td>
<td>68.2</td>
<td>63.7</td>
<td>58.0</td>
</tr>
<tr>
<td>Upper CL, %</td>
<td>90.7</td>
<td>86.5</td>
<td>82.6</td>
<td>79.0</td>
<td>75.5</td>
<td>73.4</td>
<td>73.5</td>
</tr>
</tbody>
</table>

**Graph:**
- The graph shows a trend line indicating the decrease in 1-year primary patency with increasing stent length.
- At 275 mm stent length, the primary patency is around 66%.
Debulking & Lesion preparation

Mechanical Atherothrombectomy  Directional Atherectomy  Scoring Balloon
Scoring Balloon Angioplasty

Standard PTA Balloon

Vessel wall

Lesion

Force is distributed along entire surface area of lesion

Standard PTA
Scoring Balloon Angioplasty

Standard PTA Balloon
Vessel wall
Lesion

Standard PTA

How UltraScore™ Focused Force PTA Balloon Works

Wire
UltraScore™ Balloon
Vessel wall
Lesion

Force is focused where the wire contacts the lesion
Scoring Balloon Angioplasty

How UltraScore® Focused Force PTA Balloon Works

- Longitudinally fracture plaque at low inflation pressures
- More controlled plaque fracture and less vessel recoil, even in calcified lesions
- Provides approximately 24 times the concentrated force than standard balloons
Atherothrombectomy and Drug-Coated Balloon Angioplasty

1. Atherectomy removes atherosclerotic/calcific tissue, similar to open surgical techniques, resulting in lumen gain without barotrauma
**Lutonix Global SFA Registry**

**Primary Patency rate at 12 and 24 months**

### Primary Endpoints

<table>
<thead>
<tr>
<th>Endpoint Description</th>
<th>Success</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Safety</strong>: freedom from TVR, major amputation, device-and procedure-related death within 30 days</td>
<td>99.4 (681/685)</td>
<td>98.5-99.8</td>
</tr>
<tr>
<td><strong>Efficacy</strong>: freedom from TLR at 12 months</td>
<td>93.4 (605/648)</td>
<td>91.2-95.2</td>
</tr>
<tr>
<td>freedom from TLR at 24 months</td>
<td>89.3 (526/589)</td>
<td>86.5-91.7</td>
</tr>
</tbody>
</table>

### Long Lesion Subgroup

<table>
<thead>
<tr>
<th>Endpoint Description</th>
<th>Success</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Safety</strong>: freedom from TVR, major amputation, device-and procedure-related death within 30 days</td>
<td>99.3 (138/139)</td>
<td>961-100.0</td>
</tr>
<tr>
<td><strong>Efficacy</strong>: freedom from TLR at 12 months</td>
<td>93.2 (123/132)</td>
<td>87.5 - 968</td>
</tr>
<tr>
<td>freedom from TLR at 24 months</td>
<td>88.2 (105/119)</td>
<td>81.0-93.4</td>
</tr>
</tbody>
</table>
Less is more!

"As Less As Reasonably Achievable Stenting"

ALARAS
Clinical case presentation
Patient History

63 year old male
- Intermittent Claudication
- Rutherford Category 3
- Prior STEMI one month ago
- Hypertension
- Hyperlipidaemia
- Current Smoker

Treatment:
- Thrombotic and Calcified Subtotal Stenosis of the Right Superficial Femoral Artery
  - Rotarex™
  - Ultrascore™
  - Lutonix™
Rotarex™ S Catheter

Indications
Rotarex™ catheters in combination with the Straub Medical Drive System (REF SRS-Set/B0300) are intended for the percutaneous transluminal removal of thrombotic, thromboembolic and atherothrombotic material from fresh, subacute and chronic occlusions of blood vessels outside the cardiopulmonary, coronary and cerebral circulations; Indicated for Native blood vessels or vessels fitted with stents, stent grafts or native or artificial bypasses outside the cardiopulmonary, coronary and cerebral circulations.

Contraindications

Patients not suitable for thrombectomy. Vessels of the cardiopulmonary, coronary or cerebral circulations; undersized or oversized vessel diameters; subintimal position of the guidewire – even if only in short segments; use in stents, stent grafts, or venous caval filters if the guidewire has become threaded at any point in the wire mesh / construction of stent, stent graft or the lining of the stent graft; if the introducer sheath, the guide catheter, the guidewire or the Rotarex™ catheter sustains any damage, especially kinking; in the fracture areas of broken stents; if used inside or via narrow vessel radii or in tortuous vessel courses (radius of curvature < 2 cm); in severely calcified vessel segments; in aneurysmatically altered vessel segments; in veins; if it is impossible to achieve sufficient anticoagulation and platelet aggregation inhibition.

Warnings

Before using the Straub Endovascular System and its components, the user must be entirely familiar with the user manuals and the Introduction of the Straub Medical Drive System and Straub rotational catheters; Only use sheaths that are highly resistant to kinking. If used incorrectly, Rotarex™ catheters and/or the guidewire used can cause vessel perforation. Insert and operate the catheter over the supplied guidewire of the appropriate length only. During the procedure, unforeseen complications of technical or medical origin may make it necessary to carry out unplanned, emergency additional measures, such as, but not limited to, administration of thrombolytic agents or surgical intervention; The products are for single use and must not be resterilized; Do not use the products after the expiration date; Appropriate testing of the patient's coagulation status is mandatory. Rotarex™ catheters may only be used in the indicated diameters of target vessels. The catheter must always be guided via the guidewire, which has been correctly positioned according to the instructions for use. Make sure that the flexible tip of the guidewire is placed as distal as possible to the occluded segment to prevent the flexible tip from being aspirated into the catheter head. The guidewire must lie inside the lumen throughout its course from the introducing sheath to its flexible tip. Do not use the catheter if the guidewire has become threaded in the wire mesh of stent or stent graft or the lining of the stent graft. Do not operate the catheter in the fracture areas of broken stents or stent grafts, despite correct positioning of the guidewire. Monitor the correct position of the guidewire throughout the entire process of catheter use. The catheter must never be kinked at any stage. At no point should the catheter ever be exposed to pressure that is sufficient to compress the tube so that it is pressed against the rotating helix. The catheter lumen must be filled with liquid (heparinised isotonic saline or blood) at all times throughout catheter use in the patient. If resistance is experienced, pull the catheter back a little way into the open(ed) segment with the motor continuing to run so that the ablated material can be processed and carried away. Advancing the catheter too quickly increases the risk of this advancement mobilising more material than can be aspirated and carried away, which can cause distal embolisation; Maneuvering the catheter through areas with very hard, especially heavily calcified plaques, requires special care.

The internal lumen of the introducer sheath must at least correspond to the external diameter of the catheter. At all times monitor the natural flow of blood transported into the collecting bag. Effective anticoagulants at a suitable dose have to be administered before the patient is treated with the Straub Endovascular System in order to achieve an activated clotting time (ACT) > 250 seconds or equivalent values according to other measuring techniques, throughout use of the catheter. If used correctly, embolizations caused by material detached by the catheter head are very rare. Ensure that the catheter lumen is completely filled with solution when the motor is running. The wire adapter must be in the working position (knob pulled out) during use of the catheter; If there is unlikely to be enough natural flow of blood to the catheter head, the supply of liquid to the catheter head can be guaranteed by providing additional appropriate liquid, such as isotonic saline, via a suitable access, such as the side-port of the introducer sheath being used. If the LEDs go out or the alarm is audible, safe functioning of the catheter is no longer guaranteed. If the activated motor is not kept at the same height as the introducer sheath, or if the section of the catheter located outside the patient's body is not completely straightened at all times, or if the outlet tube does not run vertically and completely stretched from the catheter into the collecting bag, technical problems such as blockage of the catheter, helix fracture or guidewire fracture may occur; Blood and thrombus fragments in the catheter lumen might clot if the helix has stopped. Therefore, if catheter use is interrupted, the catheter must be rinsed immediately in heparinised isotonic saline.

Precautions

The catheter sets do not contain any parts that need to be maintained or serviced by the end-user. Do not repair or change the configuration of the product. An annual service is recommended for the Straub Medical Drive System (see Straub Medical Drive System user manual).

Potential Adverse Events

Embolioms, especially distal thromboembolisms; pulmonary embolisms of all degrees of severity; thromboses, especially recurrent thromboses; re-occlusion; vessel wall injury or valve damage; vessel dissection / perforation / rupture; perforation as a result of mural calcium being torn out of the vessel wall; arteriovenous fistula / pseudo-aneurysm; haemotoma, bleeding, haemorrhage; organ perforation; implants such as stents / stent grafts / bypass grafts getting damaged, caught or dislodged; disruption of the catheter and/or guidewire: debris remaining in the body; allergic reactions to catheter material; death; infections or necrosis at the puncture site; allergic reactions; catheter-induced sepsis.

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Lutonix™ 035 Drug Coated Balloon PTA Catheter

INDICATIONS FOR USE:
The Lutonix® 035 Drug Coated Balloon Catheter is intended for Percutaneous Transluminal Angioplasty (PTA) in the peripheral vasculature and for the treatment of obstructive lesions and decreasing the incidence of restenosis. In addition, the Lutonix® 035 Drug Coated Balloon Catheter is intended for PTA of native dialysis fistulae or synthetic grafts, opening narrowing and immature fistulae, to improve blood flow, and decreasing the incidence of restenosis.

CONTRAINDICATIONS:
The Lutonix® Catheter is contraindicated for use in 1) Patients who cannot receive recommended anti-platelet and/or anticoagulant therapy. 2) Women who are breastfeeding, pregnant or are intending to become pregnant or men intending to father children. It is unknown whether paclitaxel will be excreted in human milk and there is a potential for adverse reaction in nursing infants from paclitaxel exposure. 3) Pediatric patients. The safety and effectiveness of the Lutonix® Catheter in pediatric patients has not been established 4) Patients judged to have a lesion that prevents complete inflation of an angioplasty balloon or proper placement of the delivery system. 5) This product should not be used in patients with known hypersensitivity to paclitaxel or structurally related compounds.

WARNINGS:
1) Contents supplied STERILE using ethylene oxide (EO) process. Do not use if sterile barrier is damaged or opened prior to intended use. 2) Do not use if product damage is evident. 3) Do not use after the “Use By” date. 4) The Lutonix® Catheter is for use in one patient only; do not reuse in another patient, reprocess or resterilize. Risks of reuse in another patient, reprocessing, or resterilization include Compromising the structural integrity of the device and/or device failure which, in turn, may result in patient injury, illness or death. Creating a risk of device contamination and/or patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to patient injury, illness or death. 5) Do not exceed the Rated Burst Pressure (RBP) recommended for this device. Balloon rupture may occur if the RBP rating is exceeded. To prevent over-pressurization, use of a pressure monitoring device is recommended. 6) Use the recommended balloon inflation medium of contrast and sterile saline (≤50% contrast). Never use air or any gaseous medium to inflate the balloon. 7) The safety and effectiveness of the Lutonix® Catheter have not been established for treatment in cerebral, carotid, coronary, renal vasculature or mesenteric arteries.

Post-Procedure Antiplatelet Regimen
If applicable, dual antiplatelet therapy should be administered according to current medical standards pre-procedure and for a minimum of 4 weeks after the intervention. Prolonged antiplatelet therapy can be given at the discretion of the physician. Post-Procedure Antiplatelet Regimen

Pre- and Post-Procedure Antiplatelet Regimen
If applicable, dual antiplatelet therapy should be administered according to current medical standards pre-procedure and for a minimum of 4 weeks after the intervention. Prolonged antiplatelet therapy can be given at the discretion of the physician. Please consult product labels and instructions for use for indications, contraindications, hazards, warnings, and precautions. © 2023 BD, BD logo, and Lutonix are trademarks of Becton, Dickinson and Company or an affiliates. All Rights Reserved. BD Switzerland, Park – A4, Sänter Tre Bonne, Route de Crassier 17, 1262 Eysins, Switzerland. BD-87791
ULTRASCORE™ Focused Force PTA Balloon

The ULTRASCORE™ Focused Force PTA Balloon is intended to dilate stenoses in the iliac, femoral, ilio-femoral, popliteal, infra-popliteal and renal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. This device is also recommended for post dilatation of balloon expandable stents, self-expanding stents, and stents in the peripheral vasculature.

Contraindications

1. Carefully inspect the catheter prior to use to verify that catheter has not been damaged during shipment and that its size, shape and condition are suitable for the procedure for which it is to be used. Do not use if product damage is evident. 2. The ULTRASCORE™ Focused Force PTA Balloon should only be used by physicians experienced in the performance of percutaneous transluminal angioplasty. 3. It is recommended to consider the use of anti-coagulants, anti-platelet agents, and/ or vasodilators in conformance with the accepted standard of practice or institutional guidelines surrounding peripheral endovascular procedures. 4. For ULTRASCORE™ .014 guidewire sizes only, in order to activate the hydrophilic coating, wet the ULTRASCORE™ balloon and catheter with sterile saline or wipe the balloon catheter with sterile saline saturated gauze immediately prior to its insertion in the body. Do not excessively wipe the coated portions of the device, or wipe with dry gauze, as this may damage the hydrophilic coating. 5. ULTRASCORE™ .014 guidewire sizes are coated with a hydrophilic coating at the distal segment of the shaft and balloon. Please refer to the Directions for Use section for further information on how to prepare and use this device to ensure it performs as intended. Failure to abide by the warnings in this labeling might result in damage to the hydrophilic coating, which may require intervention or result in serious adverse events. 6. The minimal acceptable sheath French size is printed on the package label. Do not attempt to pass the PTA catheter through a smaller size introducer sheath than indicated on the label. 7. Use the recommended balloon inflation medium (25% contrast medium/75% sterile saline solution). Never use air or other gaseous medium to inflate the balloon. 8. The ULTRASCORE™ Focused Force PTA Balloon should be used with caution for procedures involving calcified lesions, stents or synthetic vascular grafts due to the abrasive nature of these lesions. 9. Fully evacuate the balloon prior to withdrawing the system. Larger sizes of ULTRASCORE™ Focused Force PTA Balloons may exhibit slower deflation times. 10. If resistance is felt during post procedure withdrawal of the catheter through the introducer sheath, determine if contrast medium is trapped in the balloon. 11. If resistance is still felt during post procedure withdrawal of the catheter, it is recommended to remove the balloon catheter and guidewire introducer sheath as a single unit, and replace the previously used balloon catheter with a new balloon. 12. Do not continue to use the balloon catheter if the shaft has been bent or kinked. Do not excessively bend, twist, or alter the shape of the device as it may compromise the integrity of the hydrophilic coating. 13. For ULTRASCORE™ .014 guidewire sizes only, prior to re-insertion through the introducer sheath, re-activate the hydrophilic coating, and clean the balloon catheter by wiping the balloon catheter with sterile saline saturated gauze and rinsing with sterile saline. Using different media other than the recommended solution could affect the hydrophilic coating and its performance. 14. GEOALIGN introducer sheath, re-activate the hydrophilic coating, and clean the balloon catheter by wiping the balloon catheter with sterile saline saturated gauze and rinsing with sterile saline. Using different media other than the recommended solution could affect the hydrophilic coating and its performance. 15. Avoid using alcohol, antiseptic, or any type of cleaning or disinfectant agents because this may cause unpredictable changes in the coating which could affect the device safety and performance. 16. Avoid pre-soaking devices for extended periods, as this may impact the coating performance.

Potential Adverse Reactions

The complications that may result from a peripheral balloon dilatation procedure include: • Additional invasive surgery • Additional non-invasive surgery • Air embolism • Aneurysm • Pseudoaneurysm • Arterio-thrombosis • Excessive or uncontrollable amount of bleeding due to vessel injury or trauma • Foreign body embolism • Hematoma • Hemorrhage or bleeding • Hemothorax • High blood pressure • Hypertension • Hypersensitivity, allergic reaction • Infection • Inflammation • Low blood pressure • Hypotension • Pain • Perforation of vessel • Peripheral arterial ischemia • Peripheral arterial occlusion - renal or limb • Peripheral arterial thrombosis - renal or limb • Pneumothorax • Prolonged surgery • Shock • Stroke • Vessel dissection • Vessel spasm

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