Heavily Calcified SFA Lesions: Treatment Strategies to Consider. Case Examples.

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Vascular Calcification

- The bane of endovascular therapy – particularly an issue for the superficial femoral artery

- Age, smoking, diabetes, and chronic kidney disease are all risk factors.

Calcification starts early in CKD: prevalence and progression increases with declining GFR
Vascular Calcification can be either medial, intimal or both

Medial Calcification
Vascular Calcification can be either medial, intimal or both.
Vascular Calcification is an Active Process Like Bone!

Bony Trabeculae

Bone marrow elements

Janzen and Vuong. Z. Kardiol 90: 6-11, 2001
Limitations of balloon angioplasty for calcified SFA disease.

67 year old male with DM, CKD, Rutherford 3 claudication.

Left SFA calcified lesion.
Limitations of balloon angioplasty for calcified SFA disease.
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Limitations of balloon angioplasty for calcified SFA disease.
Calcium poses a mechanical problem and so needs a mechanical solution...

<table>
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<tr>
<th>Device</th>
<th>Indication</th>
<th>Mechanism</th>
<th>Comments</th>
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<tr>
<td>Cutting or scoring balloon</td>
<td>Fibrotic lesions [Coronary or Peripheral]</td>
<td>Scores or cuts into fibrotic plaque to induce controlled dissections</td>
<td>Limited ability to cut calcium, can be helpful for fibrocalcific lesions</td>
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<td>Laser (Spectranetics)</td>
<td>Thrombotic lesions, mild calcium [Coronary or Peripheral]</td>
<td>Photo-acoustic energy breaks molecular bonds</td>
<td>Limited role in heavy calcium</td>
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<td>Rotablator (Boston, Sci)</td>
<td>Calcified lesions [Coronary or Peripheral]</td>
<td>Differential ablation of plaque into microparticles</td>
<td>Established therapy in the coronaries, recent re-use in peripheral cases</td>
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<td>JetStream (Boston, Sci)</td>
<td>Calcified lesions [Peripheral]</td>
<td>Rotational atherectomy with or without blades, active suction</td>
<td>Utility is greatest in femoral lesions</td>
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<td>TurboHawk (Medtronic)</td>
<td>Fibrotic lesions and moderate to severe calcium [Peripheral]</td>
<td>Directional cutting blade</td>
<td>Can be challenging to deliver in very severe diffuse calcium, able to remove plaque, large luminal gain</td>
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<td>CSI Orbital Atherectomy (CSI)</td>
<td>Fibrotic and calcified lesions [Peripheral and Coronary]</td>
<td>Orbital motion of a diamond tipped crown</td>
<td>Limited luminal gain but deliverable and improves vessel compliance as adjunct to PTA/stenting</td>
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<td>Pantheris (Avinger)</td>
<td>Fibrotic and calcified lesions [Peripheral]</td>
<td>OCT guided directional atherectomy</td>
<td>Allows visualization of plaque in real time</td>
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Illustrative Case: Typical Role of Atherectomy

- Heavy calcium in R SFA
- Unlikely to get acceptable result with PTA alone.
JETSTREAM AHERECTOMY

PTA

Overlapping Self Expanding Stents

Final after post dilation
Atherectomy has a price to pay....
Emerging technology: Shockwave Intravascular Lithotripsy

Sonic Pressure Waves Crack Calcium Inside Artery Wall

After inflating the integrated balloon to 4-atm, a small spark at the emitters vaporizes the saline-contrast solution and creates a bubble which rapidly expands and collapses within the balloon; this expanding and collapsing bubble creates a short burst of sonic pressure waves.

The sonic pressure waves travel through the vessel tissue, while reflecting off and cracking calcium with an effective pressure of ~50 atm. The emitters along the length of the device create a localized field effect within the vessel to fracture both intimal and medial calcium.

The integrated balloon plays a unique role; its apposition to the vessel wall facilitates efficient energy transfer during IVL, after which, it is used to dilate the lesion to maximize lumen gain.
OCT demonstrated calcium disruption leading to **acute luminal gain and alteration in vessel compliance** in both peripheral and coronary arteries.
Disrupt PAD III Study: Combination Therapy

Next Steps in Clinical Development

Study Design: Randomized study of the Shockwave Medical Peripheral Intravascular Lithotripsy (IVL) System with DCB versus standard balloon angioplasty with DCB to treat moderate and severely calcified femoropopliteal arteries (Disrupt PAD III).

Objective: The objective is to assess the optimal therapy to dilate heavily calcified lesions with IVL versus traditional angioplasty, in achieving less than 30% stenosis without the need for a stent. In addition, all patients who do not receive a stent will be treated with a drug-coated balloon.
Take home points...

- Calcified lesions are common in older patients, those with diabetes, and in patients with CKD.

- Vascular calcium is associated with reduced acute procedural success and increased complications.

- Atherectomy is often a necessary step to get adequate vessel expansion...but has a risk of embolization.

- Intravascular lithotripsy is an emerging technology which may help with vessel expansion without overt debulking.