CHAPTER 6

Step-by-Step on Lesion Preparation and Atherectomy

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Introduction

The American Heart Association (AHA) recommended classification of atherosclerotic lesions is a useful classification that aids the interventional cardiologist in considering the approach to lesion preparation. In general, most lesions reach clinical significance when they are either Type IV or greater.[1] Of these, the predominantly fibrotic (Type VIII) and the predominantly calcific (Type VII) lesions offer the greatest challenge.

Coronary calcification is present in approximately one third of all lesions using angiography alone and this increases to 74% when intravascular ultrasound (IVUS) assessment is added.[2] Percutaneous Coronary Intervention (PCI) of severely calcified vessels is technically challenging and is associated with worse clinical outcomes.[3,4] Severe calcification in the coronary arteries can result in extensive dissection during balloon angioplasty, and rotational atherectomy (RA) was initially developed as a standalone therapy in this scenario.

In the contemporary era, these severe calcifications can impede optimal stent expansion and prevent delivery of equipment including balloons and stents. Lack of optimal stent expansion is linked to higher incidence of stent thrombosis and in-stent restenosis. Stent malapposition may delay re-endothelization, and forceful advancement of equipment through calcified lesions can theoretically

damage the drug polymer and the stent platform. The primary goal of atherectomy today is plaque modification to facilitate stent delivery and optimal stent expansion in heavily calcified vessels.

Figure 1 shows the main strategies employed in lesion preparation based on plaque morphology.

Rotational Atherectomy (RA)

The Rotational atherectomy system (Boston Scientific, Marlborough, MA) has been in use for over 25 years. Its components are the Rotablator, the RotaWire (Rota Floppy and Rota Extra Support), compressible gas, console, foot pedal, and advancer. The most recent iteration of this technology is the Rotapro, which has removed the need for a foot pedal.

Rotational atherectomy utilizes a rotating nickel-plated brass elliptical burr coated on the leading surface with thousands of diamond chips that allow modification of calcified plaque; the trailing surface is a smooth surface with no diamond coating. It is powered pneumatically requiring compressible gas (typically nitrogen) with an adjustable dial (on a non-sterile console that requires additional personnel assistance) to set and adjust speed in rotations per minute (rpm). The burr is activated with a foot pedal with a side button that allows switching to “Dynaglide mode”, which facilitates burr exchange or removal. The burr advances over a 0.009 inch RotaWire using the advancer knob while activating the burr with the foot pedal. Simultaneous imaging acquisition is done by the same operator or a second operator. The wire has a 0.14” distal coil that prevents the burr from advancing beyond the tip of the wire. A lubricating solution is delivered through the shaft to minimize heating and friction between the burr and the wire; this Rota-flush solution contains heparin in normal saline.

The burr comes in several sizes depending on the size of the vessel (1.25 mm to 2.50 mm), thus creating a predictable lumen size. The size of the guide catheter needed depends on the size of burr that

is used and ranges from 6 to 10 Fr. The Rotablator system burr only has 1 axis of rotation on the RotaWire and ablates a fixed diameter as the concentrically mounted burr creates a lumen the size of the burr. This along with the diamond coating only on the distal end allows for the possibility of burr entrapment. Furthermore, due to the single axis of rotation and constant contact between the burr and plaque, there is a risk of thermal injury and platelet activation with RA.

Labeled contraindications to RA include occlusions through which a guidewire will not pass, last remaining vessel with compromised left ventricular function, saphenous vein grafts, angiographic evidence of thrombus or significant dissection. Relative contraindications to RA include patients who are not candidates for coronary artery bypass surgery, diffuse three-vessel disease, unprotected left main coronary artery disease, ejection fraction less than 30%, lesions longer than 25 mm, and angulated (≥ 45°) lesions.

The ROTAXUS trial randomized patients with severely calcified native coronary disease (n=240) to stenting with or without routine rotational atherectomy. RA did not improve clinical outcomes (MACE or TLR) compared with standard pre-dilation followed by drug eluting stent placement at 9 months or 2 year follow up.[5] At 9 months, the trial demonstrated 11.7% TLR in patients with moderate to severely calcified lesions. Safety outcomes at 2 years: MACE rate of 29.4% vs. 34.3% (p=0.47), TVR rate of 19.3% vs. 22.2% (p=0.62), TLR rate of 13.8% vs. 16.7% (p =0.58) with no difference between RA and standard groups respectively. However, there was a higher procedural success rate in the RA arm (92.5% vs. 83.3%, p = 0.03). The findings of this study as well as others including a large meta-analysis suggest that Balloon dilation with only provisional RA should remain the default strategy for complex calcified lesions where the goal is to facilitate stent implantation and optimize stent expansion.[6]

Orbital Atherectomy (OA)

The Diamondback 360® Coronary Orbital Atherectomy (OA) System (Cardiovascular Systems, Inc., St. Paul, MN) is a newer addition to the atherectomy armamentarium. The crown is 1.25 mm in diameter and is eccentrically mounted and coated with 30 µm diamond chips. It is advanced over a 0.014" ViperWire. As the crown rotates and orbit increases, the crown expands laterally with centrifugal force up to a maximum orbit diameter that depends on low (80,000 rpm) vs high (120,000 rpm) speed. This allows for bidirectional as well as differential sanding; the soft healthy vessel wall flexes away from the orbiting crown, thus minimizing trauma to healthy coronaries. The bidirectionality allows for reduced risk of crown entrapment when used appropriately. Only one size coronary crown is used for different size vessels and this allows reduction in guide catheter size; a 6 Fr Guide alone is sufficient. The OA System is electrically powered and does not require the use of compressed gas. Speed settings are on the orbital atherectomy device (OAD); there is no foot pedal as all controls including on and off buttons are on the hand-held OAD.

Labeled contraindications to OAS include inability to pass the ViperWire across the lesion, target lesion within a bypass graft, target lesion within a previously placed stent, target lesion within last patent vessel, angiographic evidence of thrombus or significant dissection. Furthermore, OAS is contraindicated when the patient is not an appropriate candidate for bypass surgery, as well as in pregnant women and children.

The Orbit II trial was a single-arm trial that enrolled 443 patients at 49 sites.[7] In this study, *de novo*, severely calcified coronary lesions were treated with OAS prior to stenting. The primary safety endpoint was 30-day MACE: the composite of cardiac death, MI, and TVR (inclusive of target lesion revascularization (TLR)). The primary efficacy endpoint was procedural success: stent delivery with a residual stenosis of <50% without the occurrence of in-hospital MACE. The overall cumulative 3-year MACE rate was 23.5%, including cardiac death (6.7%), MI (11.2%), and TVR (10.2%); the 3-year TLR rate was 7.8%. Orbital atherectomy of heavily calcified coronary lesions followed by stenting results in a low

rate of adverse ischemic events compared with historical controls; it represents a reasonable revascularization strategy for patients with severely calcified coronary lesions.

Excimer Laser Coronary Atherectomy (ELCA)

ELCA has been approved for coronary intervention for over 20 years ago, but its use has been largely limited after its initial negative trials. The CVX-300 system (Spectranetics, Colorado Springs, CO) uses xenon chloride and emits pulses of ultraviolet light at 308 nm wavelength, which has relatively limited tissue penetration and can thus cause plaque disintegration without injuring the deeper medial or adventitial layers. The most commonly used catheter in the coronary arteries is the 0.9 mm ELCA catheter. To minimize the risk of inadvertent dissections or perforations induced by microbubbles generated from particles within the blood, a continuous normal saline infusion (usually at 1-2 mL/s) during laser is recommended; exceptions to use of contrast instead of/in addition to saline are in the treatment of underexpanded stents.

Although the role of ELCA is limited in calcified lesions, it forms an important role in the management of in-stent restenosis and SVG lesions. In addition, other atherectomy techniques require the delivery of specialized guidewires into the distal coronary vessel. ELCA may be conducted over a standard workhorse wire, and therefore offers a role for “balloon or microcatheter-uncrossable lesions.” Initial ELCA may thus allow for exchange to a specialty guidewire via a microcatheter, followed then by an alternative atherectomy device. The combination of ELCA and RA is sometimes termed as the RASER technique.[8]

Specialty Balloon Angioplasty

Although plaque modification with atherectomy devices may be adequate to produce enough debulking and compliance modification, adjunctive balloon angioplasty may also facilitate successful case completion beyond standard semi-compliant and non-compliant balloons.

Cutting balloon

The Wolverine cutting balloon (Boston Scientific, Marlborough, MA) is the latest version of this device. It consists of a balloon that, when inflated, presses multiple atherotomes (up to 4) against the vessel wall, thus producing controlled longitudinal incisions. It has also been used successfully for in-stent restenosis.

Scoring balloon

The Angioscore scoring balloon (Philips, Andover, MA) consists of a balloon with a helical scoring element that is inflated against the vessel wall and produces helical plaque modification. It has been used for in-stent restenosis successfully as well.

Chocolate balloon

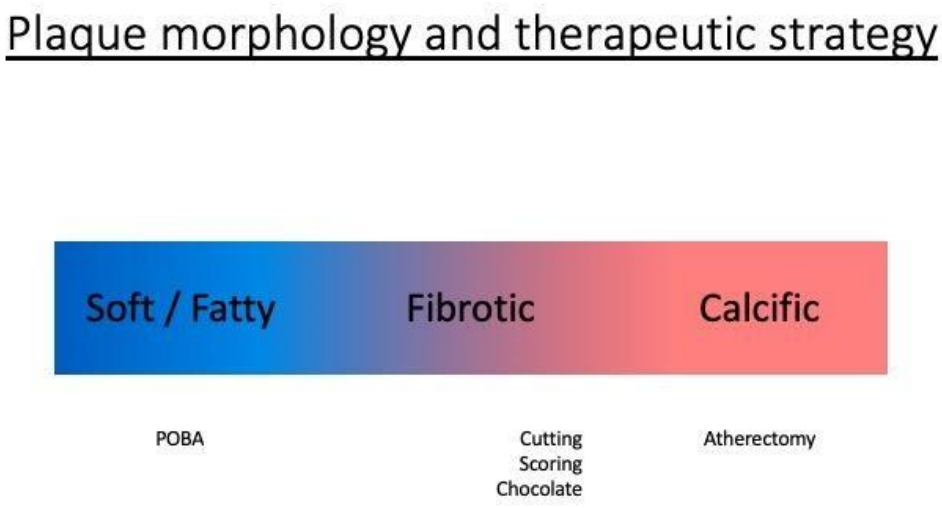
The Chocolate balloon (Teleflex Inc, Wayne, PA) consists of a semi-compliant balloon constrained within a restraining cage. When inflated, this results in the development of grooves along the cage structure and pillows where the balloon material extrudes.

Conclusion

In conclusion, there are multiple techniques in lesion preparation, which are based largely on the type and location of lesion. These can vary from conventional balloons to specialty balloons and various forms of atherectomy.

Chapter 6: Step-by-Step on Lesion Preparation and Atherectomy

Figure 1: The figure below shows the main strategies employed in lesion preparation based on plaque morphology.



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