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Joseph A. R. Cardenas is a board certified interventional cardiologist and a fellow of the American College of Physicians and American College of Cardiology. He also serves as a proctor to train physicians in the areas of interventional cardiology and peripheral endovascular surgery. Dr. Cardenas has written numerous articles, and abstracts, and is involved in several ongoing research studies.

PATIENT HISTORY:

A 57 year old male presented with severe lifestyle limiting claudication. The patient has a history of insulin dependent diabetes mellitus, prior smoking, and recently underwent triple coronary artery bypass graft surgery. A diagnostic angiogram revealed severe distal right SFA disease and a 6 cm total occlusion of the right popliteal artery with reconstitution of the anterior tibial artery and tibio-peroneal trunk resulting in 1-2 vessel runoff to the ankle (Figure 1).

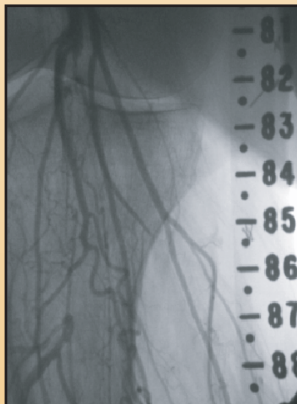


Figure 1.
Pre-procedure angiogram demonstrating 100% occlusion of the popliteal artery.

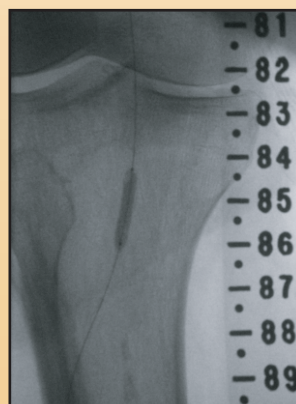


Figure 2.
AngioSculpt catheter (3.5 mm) inflated in the popliteal artery.

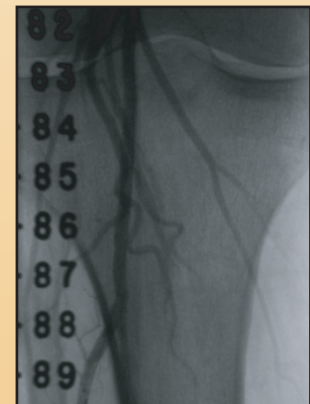


Figure 3.
Post-AngioSculpt angiogram demonstrating a residual diameter stenosis of <20% in the popliteal artery and no significant dissections.

PROCEDURE RESULTS:

A 6F sheath was placed in the right common femoral artery in antegrade fashion. Utilizing various support catheters and guide wires, a platinum plus guide wire was successfully passed through the popliteal artery occlusion to the distal anterior tibial artery. The AngioSculpt Scoring Balloon Catheter (2.0x20, 3.0x20, 3.5x20 mm devices) was utilized to treat the popliteal artery, and ostium of the anterior tibial artery (Figure 2). No other devices were used to treat these lesions. Angiographic results are shown in Figure 3.

SAFETY SUMMARY

INDICATIONS

The AngioSculpt PTA Scoring Balloon Catheter is intended for balloon dilatation of lesions in infrapopliteal arteries. Not for use in the coronary or neuro-vasculature.

CONTRAINDICATIONS

None known for Percutaneous Transluminal Angioplasty (PTA) procedures.

WARNINGS

This device is intended for single (one) use only. Do not resterilize and/or reuse, as this can potentially result in compromised device performance and increased risk of inappropriate resterilization and cross contamination.

The inflated diameter of the balloon should approximate the diameter of the vessel just proximal and distal to the stenosis, in order to reduce potential vessel damage.

When the catheter is exposed to the vascular system, it should be manipulated while under high quality fluoroscopic observation.

Do not advance or retract the catheter unless the balloon is fully deflated under vacuum. If resistance is met during manipulation, determine the cause of the resistance before proceeding.

Balloon pressure should not exceed the rated burst pressure (RBP). Refer to product label for device specific information. The RBP is based on results of in-vitro testing. At least 99.9% of the balloons (with a 95% confidence level) will not burst at or below their RBP. Use of a pressure monitoring device is recommended to prevent over-pressurization.

Use only the recommended balloon inflation medium. Never use air or any gaseous medium to inflate the balloon.

Proceed cautiously when using the AngioSculpt catheter in a freshly deployed bare metal or drug eluting stent. The AngioSculpt catheter has not been tested for post-dilation of stents or in lesions distal to freshly deployed stents in clinical studies. Bench testing has shown no additional risk when inserting or withdrawing the AngioSculpt catheter through stents (no interference with stent struts, no retention of or damage to the AngioSculpt catheter).

Use the catheter prior to the "Use Before" (expiration) date specified on the package.

PRECAUTIONS

A thorough understanding of the principles, clinical applications and risks associated with PTA is necessary before using this product. Any use for procedures other than those indicated in these instructions is not recommended. The device is not recommended for use in lesions which may require inflation pressures higher than those recommended for this catheter.

Do not use if package is opened or damaged.

Prior to angioplasty, the catheter should be examined to verify functionality, device integrity and to ensure that its size and length are suitable for the specific procedure for which it is to be used.

During and after the procedure, appropriate anti-coagulants, anti-platelet agents and vasodilators should be administered to the patient according to institutional practice for peripheral angioplasty of similar arteries.

Only pass the AngioSculpt catheter through a $\geq 6F$ guiding catheter or $\geq 5F$ introducer sheath.

POSSIBLE ADVERSE EFFECTS

Total occlusion of the treated artery, arterial dissection or perforation, arterial spasm, pseudo-aneurysm, restenosis of the dilated artery, embolism, thrombus, retained device components, hemorrhage or hematoma, arteriovenous fistula.

CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a physician.



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