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Dr. Amir Malik is an Interventional Cardiologist who trained at SUNY– Stonybrook in Long Island, New York. He has been in private practice in Fort Worth, Texas since 1998 and is the Director of the Peripheral Interventions program at Plaza Medical Center of Fort Worth. Dr. Malik is the principal investigator on the majority of the cardiovascular research performed at Plaza Medical Center.

PATIENT HISTORY:

The patient is an 80 year old female with a history of peripheral vascular disease, including leg pain at rest and the presence of ulcerations on the toes of both feet. The patient also has a history of CHF, dialysis dependent renal failure, hypertension, hypercholesterolemia, and is bedridden due to prior CVAs. Angiography demonstrated the presence of multiple diffuse 90-95% stenoses in the patient's left anterior tibial artery (Figure 1) and a 99% stenosis of the left dorsalis pedis artery.

PROCEDURE:

A 6F femoral arterial sheath was placed in antegrade fashion using the modified Seldinger technique. A 2.5 x 20 mm AngioSculpt Scoring Balloon Catheter was advanced to the left anterior tibial artery over a 0.014" Choice PT Extra Support guide wire (Boston Scientific Corporation). The AngioSculpt Scoring Balloon Catheter was inflated sequentially throughout the vessel to a maximum of 16 atm in order to treat the diffuse disease in the left anterior tibial artery (Figure 2). A 2.0 x 20 mm AngioSculpt balloon was then used to treat the dorsalis pedis artery. Several inflations were performed to a maximum of 10 atm.



Figure 1. Pre-procedure angiogram demonstrating diffuse 90-95% stenosis in the left anterior tibial artery.

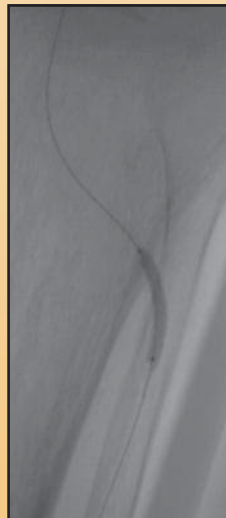


Figure 2. AngioSculpt Scoring Balloon Catheter (2.5 x 20 mm) inflated in the proximal anterior tibial artery.

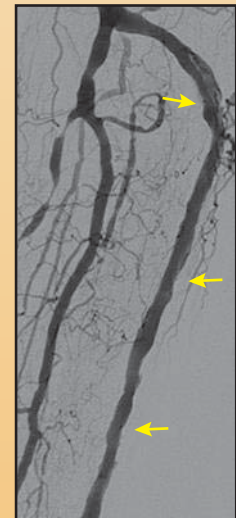


Figure 3. Post-procedure angiogram demonstrating no residual stenosis in the left anterior tibial artery.

RESULTS:

There was no significant residual stenosis in any of the lesions treated with the AngioSculpt Scoring Balloon Catheter (Figure 3). There was two vessel runoff to the foot. No other devices were used to treat the left anterior tibial or dorsalis pedis artery. The total fluoroscopic time was approximately 15 minutes.

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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