

Procedure Overview

Chameleon™ PTA Balloon Catheter



Retrograde Approach to Fistula

Overview

For stenoses close to the fistula's anastomosis, retrograde access from the venous side is required and work is performed "against the flow." In other words, the wire and catheter are working away from the shoulder and toward the hand. With blood flowing in the opposite direction, the source of contrast media must be beyond the treatment site to image the treatment area. Trying to inject contrast media in a standard way will result in its dilution and in poor imaging. Therefore, the PTA catheter is removed and a diagnostic catheter is placed for a precise injection of contrast and imaging. This technique requires a number of exchanges to perform angioplasty, visualize, angioplasty again if needed, and final imaging.

The Chameleon™ PTA Balloon Catheter and the retrograde technique

The Chameleon™ PTA balloon catheter provides a simpler, more intuitive solution by combining angioplasty and imaging in one device — resulting in a more efficient procedure:

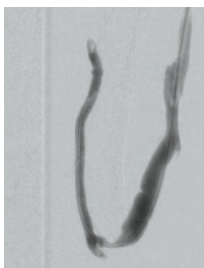
1. Once access is achieved, the Chameleon™ PTA balloon catheter is advanced to the treatment site and angioplasty is performed.
2. Then, the device is deflated and advanced to the arterial side.
3. Finally, contrast is injected directly through the Chameleon™ PTA balloon catheter, enabling the assessment of angioplasty results.

The Chameleon™ PTA balloon catheter eliminates the need for several device exchanges during the angioplasty procedure.¹ This includes removing the standard PTA balloon catheter and guidewire, as well as advancing a diagnostic catheter.

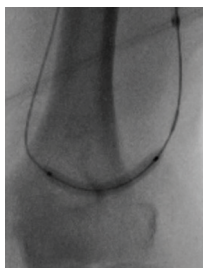
Once these steps are performed, contrast can be delivered.

Advantages of the Chameleon™ PTA Balloon Catheter

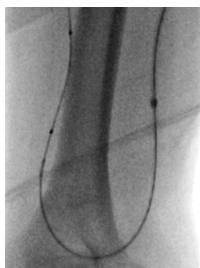
The Chameleon™ PTA balloon catheter reduces the post-angioplasty exchanges and potentially provides time savings, lower fluoroscopy time, and reduced radiation dose to the operator, staff, and patient.^{1,2}



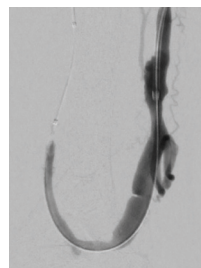
Tight stenosis near anastomosis



Balloon inflation at AV anastomosis



Post-inflation, deflate and advance balloon over the wire beyond anastomosis



Maintaining wire position, inject contrast to visualize area post treatment

Retrograde Technique

Dr. Hyeon Yu, Carolina Vascular Access, Chapel Hill, NC
Chameleon™ PTA balloon catheter, Fistula procedure 8x40 mm

Procedure Overview

Reflux Angiography of AV Grafts

Overview

Synthetic AV grafts connect arteries to veins. Unlike fistulas, grafts have two connections — a venous anastomosis (VA) and an arterial anastomosis (AA). Both of these connections need to be visualized to complete the procedure.

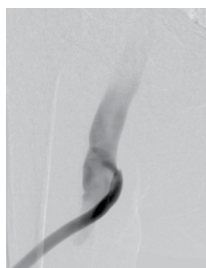
The Chameleon™ PTA Balloon Catheter and the reflux technique

Current standard procedures enable final visualization of both anastomoses by injecting contrast through the sheath while performing manual occlusion (fingers, clamp). This method exposes the operator to direct radiation.

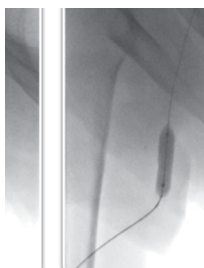
An alternative technique is to use a standard balloon to occlude the outflow vein. Both of these techniques involve injecting contrast through the sheath, which is at the midpoint of the graft. This can result in a diluted image of the circuit.

Advantages of the Chameleon™ PTA Balloon Catheter

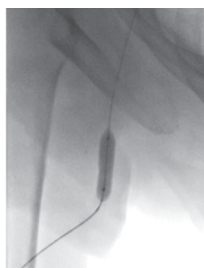
With the Chameleon™ PTA balloon catheter, contrast media can be injected while the balloon is inflated — enabling the visualization of the entire circuit. Occlusion and injection of contrast are combined in one device, resulting in improved imaging while enhancing operator safety.²



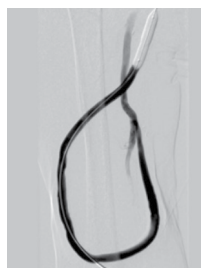
Diagnostic angiogram



Balloon inflation



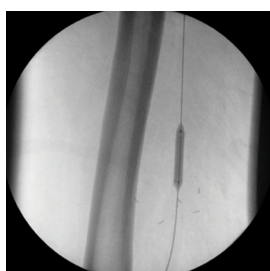
Full dilatation



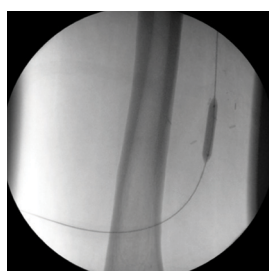
Reflux angiography

Reflux Technique

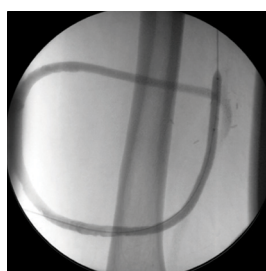
Dr. Anthony Verstandig,
Shaare Zedek, Jerusalem, Israel
Chameleon™ PTA balloon catheter,
AV graft with venous anastomotic
stenosis, 8×40 mm



Balloon inflation



Balloon inflation



Hands-free reflux angioplasty
through inflated Chameleon™
PTA balloon catheter

Reflux Technique

Dr. Hyeon Yu, Carolina Vascular
Access, Chapel Hill, NC
Chameleon™ PTA balloon catheter,
leg graft, 8×40 mm

Procedure Overview

Declot Procedure

Overview

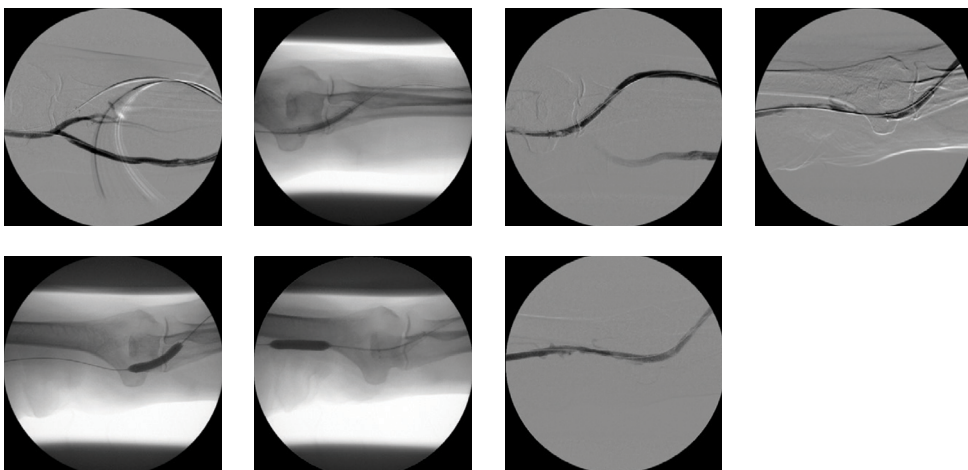
With little to no blood flow, declot cases are typically long and require multiple device exchanges to assess progress. These cases are performed “in the dark” as visualization cannot be completed without flow. The standard approach is to have access in both directions, with sheaths overlapping each other. Current standard PTA balloons must be exchanged for diagnostic catheters, or the guidewire is removed to image through the balloon catheter. Losing wire access goes against best practice for interventional techniques.

The Chameleon™ PTA Balloon Catheter and the declot technique

Through precise injection of contrast into the site, the Chameleon™ PTA balloon catheter offers real-time feedback while maintaining wire access and reducing device exchanges.¹ The device (optional sheathless) provides access in both directions and enables repeated angioplasty and imaging whenever needed.

Advantages of the Chameleon™ PTA Balloon Catheter

The Chameleon™ PTA balloon catheter enables an efficient procedure with potentially shorter procedure times vs. standard PTA.²

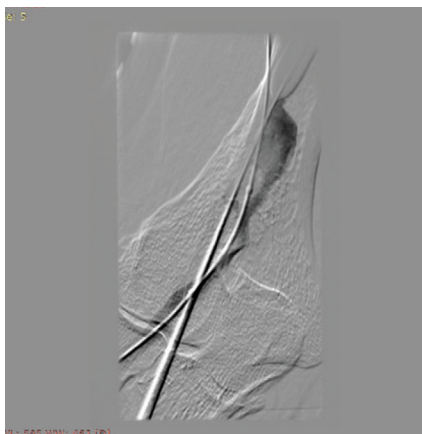


Declot Technique

Dr. Jeffrey Hoggard, Carolina Vascular Access Chapel Hill, NC
Chameleon™ PTA balloon catheter, loop AV graft, brachi-basilic, 6×40 mm



Injection while balloon is inflated-arterial



Both sides - visualization without exchanges

Declot Technique

Dr. Michael Tal, Assuta Medical Center, Tel Aviv, Israel
Chameleon™ PTA balloon catheter, brachiocephalic fistula, 6×40 mm

Efficient procedure with reduced steps and catheter exchanges
— vein and arterial sides in parallel

Procedure Overview

Fibrin Sheath Disruption Procedure

Overview

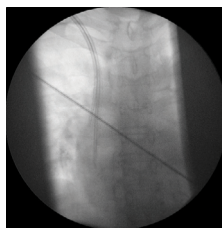
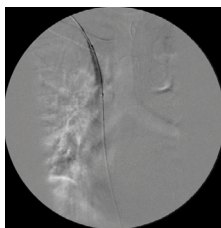
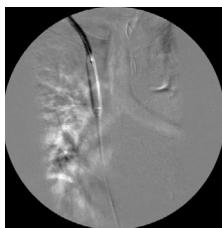
Fibrin sheaths can develop around the distal portion of the dialysis catheter and require balloon angioplasty prior to placing the new catheter. These cases are often performed sheathless. The original catheter is pulled back over a wire and contrast is delivered to identify a fibrin sheath. After the original catheter is removed, a standard PTA balloon is then delivered over the wire for angioplasty. Angioplasty results can't be visualized and verified due to the procedure being performed sheathless.

The Chameleon™ PTA Balloon Catheter and the fibrin sheath technique

The Chameleon™ PTA balloon catheter visualizes the fibrin sheath during and after the angioplasty procedure by injecting contrast media through the catheter without using a sheath.

Advantages of the Chameleon™ PTA Balloon Catheter

The Chameleon™ PTA balloon catheter allows efficient verification of procedure status.²

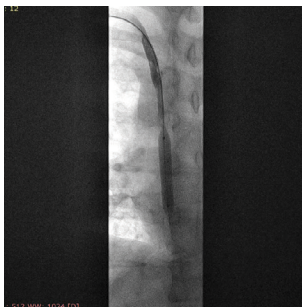
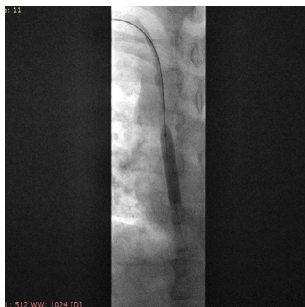


Fibrin Sheath Technique

Dr. Jeffrey Hoggard, Carolina Vascular Access Chapel Hill, NC

Chameleon™ PTA balloon catheter, AV graft with venous anastomotic stenosis, 8×40 mm

Sheathless, maintaining wire access



Fibrin Sheath Technique

Dr. Michael Tal, Assuta Medical Center, Tel Aviv, Israel

Chameleon™ PTA balloon catheter, 6×40 mm, 8×40 mm

Simple visualization of fibrin sheath

Simultaneous angioplasty and imaging

1. Crawford, J., Kokkosis, A., Kim, P., et al. Fistuloplasty using a radiation-and-time saving sheathless balloon catheter. J Vasc Access 2019;20(3): 276–2802.
2. Crawford J, Gasparis A, Kim P, Jotwani M, Banerjee S, Labropoulos N. Procedural comparison of a standard PTA balloon for fistula and graft maintenance procedures with the novel Chameleon™ PTA balloon catheter. J Vasc Access. 2020.

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