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The Chameleon® Technique: New Approaches to Access Maintenance

A discussion with Drs. Ari D. Kramer, Angela A. Kokkosis, and Mohamed A. Sheta on the characteristics that make the Chameleon® balloon dilatation catheter their device of choice for arteriovenous access care.



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he Chameleon® balloon dilatation catheter
(AV Medical Technologies Ltd) functions as a
high-pressure angioplasty balloon with the injection capability of a diagnostic catheter. It is indicated for percutaneous transluminal angioplasty (PTA) of
the peripheral vasculature, including the femoral, iliac, and
renal arteries, and for the treatment of obstructive lesions
of native or synthetic arteriovenous (AV) dialysis fistulas.
Chameleon® is also indicated for the injection of diagnostic or therapeutic fluids.

THE CHAMELEON® BALLOON DESIGN

The Chameleon® balloon catheter's proprietary SuperVision™ design incorporates a third port on the hub of the catheter (Figure 1). This luer lock injection port allows for connecting commonly used syringes containing the operator's choice of diagnostic (contrast media) or therapeutic fluids. The fluid travels the length of the Chameleon® catheter and exits through a side port just proximal to the balloon itself. The 0.035-inch over-the-wire platform allows for the injection of fluids, whether the balloon is inflated or deflated, while maintaining guidewire position. The Chameleon® has been cleared by the US Food and Drug Administration and has European CE Mark approval. It is currently in a limited market release at a select number of sites in the United States.

How would you describe your general perception of the Chameleon® balloon catheter?

Dr. Kramer: The Chameleon® is a quality high-pressure balloon. The unique side port feature is a real advantage in terms of delivering contrast or therapeutic agents during cases. The side port is what differentiates Chameleon® from other standard balloon designs. It is great to be able to deliver thrombolytics while maintaining wire position. Its overall performance is ideal for AV access procedures.

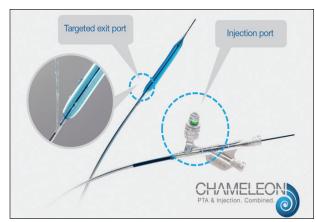


Figure 1. Chameleon® allows physicians to inject diagnostic or therapeutic fluids through the catheter at any time during the procedure, whether the balloon is inflated or deflated, all while maintaining wire position.

CHAMELEON® BALLOON DILATATION CATHETER

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Dr. Kokkosis: The Chameleon® has become an essential tool in my practice. I use it across a variety of different case scenarios. I like the flexibility of injecting contrast whether the balloon is inflated or deflated. I believe that it is one of the best modifications to the dialysis access work in my practice. Chameleon® reduces the amount of supplies and equipment that I need. It definitely cuts down the time on each procedure, as well as the amount of contrast and radiation that I use.

Dr. Sheta: There are a variety of applications where the side port proves beneficial, and the ability to maintain wire access while injecting contrast or medications is a real plus. Now that larger diameters are available, Chameleon® is becoming our go-to balloon for more central applications (Figure 2). The ability to deliver contrast right at the treatment area prior to angioplasty helps us verify the characteristics of the lesion, and we get instant feedback by injecting through the side port after angioplasty.

Could you expand and provide some specific situations in which you find Chameleon® to be helpful?

Dr. Kramer: I have integrated Chameleon® into all of my thrombectomy procedures. It's very efficient for delivering lytics prior to balloon maceration of the clot. As we begin the procedure, we administer 3,000 to 5,000 units of heparin. My technique is to gain antegrade access and advance the Chameleon® into the outflow side of the circuit. I then deliver 2.2 mg of tPA through the side port of the balloon to break up the clot burden. I follow this with a series of balloon inflations and maceration. Chameleon® also allows me to

inject contrast at any time during the procedure without having to remove the wire and without catheter exchanges. This is a real time saver during thrombectomy cases. I use the Chameleon® when working on both AV graft and fistula declotting procedures.

Dr. Kokkosis: Chameleon® has enabled me to streamline my access cases. After using Chameleon® a number of times with my traditional technique, I began to experiment using it without a sheath. I now perform a majority of my cases sheathless. I obtain a diagnostic image through my access kit, deliver a 0.035-inch wire beyond the treatment area, and then advance the Chameleon® over the wire without a sheath. I can obtain all of my intraoperative and final images by injecting contrast through the side port while maintaining wire access (Figure 3). I can also deliver sedation medications or lytics. Chameleon® is especially helpful when there is a short working distance between the access site and the treatment area. Adding a sheath in these cases can make it difficult to image and balloon the area. Going sheathless, I have full visualization of the fistula as soon as the Chameleon® is introduced. We actually collected data on a series of these sheathless cases and presented our findings at the recent VEITHsymposium and Charing Cross Symposium.^{1,2}

Dr. Sheta: When we review an image after any therapeutic intervention, there are three possible outcomes: (1) we have achieved the desired result, (2) there is no change, or (3) we have a complication and things are worse than when we started. Chameleon® provides real-time feedback on our results without the need for an exchange. We simply inject contrast through the side port and instantly see the

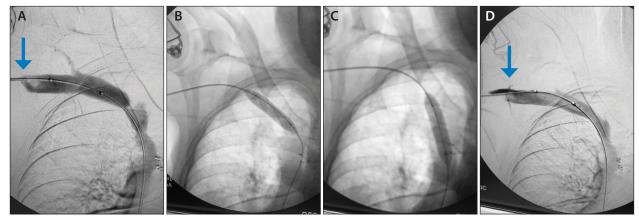
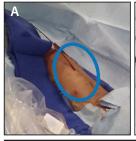
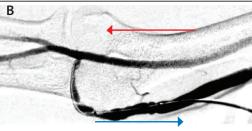


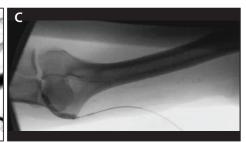
Figure 2. Brachiocephalic fistula with flow-limiting central venous stenosis as seen through hand injection of contrast using the side port of Chameleon® (A). PTA with a 10-mm Chameleon® (B). PTA with a 12-mm Chameleon® (C). Post-PTA imaging through the side port of Chameleon® (D).

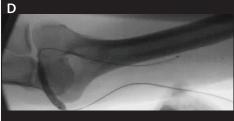
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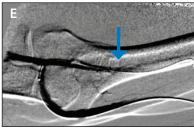


Figure 3. Retrograde sheathless access with Chameleon® over a 0.035-inch wire (A). Diagnostic image of the juxta-anastomotic segment of a radiocephalic fistula (B). Dilatation with a 6- X 40-mm Chameleon® (C, D). Chameleon® is deflated and advanced over the wire (E). Contrast is delivered through the side port for post-PTA imaging.

status postangioplasty. This is extremely efficient when working in a high-flow environment.

Those are terrific examples. Are there any other thoughts that you would like to add?

Dr. Sheta: There are several situations where we want the balloon to model the shape of the anatomy—a retrograde approach to juxta-anastomotic lesions comes to mind. Cephalic arch lesions are another situation in which the performance and capability of Chameleon® are of benefit. We are also using Chameleon® to perform angioplasty and imaging in conjunction with hemodialysis catheter exchanges where we suspect that a fibrin sheath may inhibit the functionality of the new catheter. After pulling back the existing catheter, we inject contrast through one of the lumens to look for evidence of a fibrin sheath. If there is clear evidence of a fibrin sheath, we remove the existing catheter and deliver a Chameleon® over the wire. We can now perform angioplasty and imaging through the side port to confirm disruption of the fibrin sheath. Chameleon® is then removed and we place the new catheter. This is all done without the need for a vascular sheath.

Dr. Kramer: I will add that the staff in the operating room really enjoys the simplicity that Chameleon® brings to our cases. We have streamlined our setup time and use of other equipment. We really appreciate the time savings and efficiency that the Chameleon® thrombectomy technique brings to our busy days of AV access maintenance. It is a great addition to our interventional toolbox.

Dr. Kokkosis: The recent launch of 10- and 12-mm diameters allows for use in the cephalic arch area and more central lesions. In addition, Chameleon® has successfully been used in deep vein thrombosis applications. My colleagues recently published their experience with Chameleon® in this setting.³ Chameleon® allows me to deliver any fluid I want, wherever I want (antegrade or retrograde), and whenever I want.

- 1. Kokkosis AA. Dialysis access intervention using a novel sheathless percutaneous balloon. Presented at the 2017 VEITHsymposium; November 16, 2017; New York, New York.
- 2. Kokkosis AA. Sheathless access using a novel balloon catheter. Presented at Charing Cross 2018; April 24, 2018; London, United Kingdom.
- 3. Garcia R, Gagne P, Elias S, et al. Single session venoplasty and targeted thrombolysis for chronic infrainguinal venous obstruction: a novel concept. VEIN Magazine. https://www.veindirectory.org/magazine/article/techniques-technology/single-session-venoplasty-and-targeted-thrombolysis-for-chronic-infrainguinal-venous-obstruction-a-novel-concept. Published March 1, 2018. Accessed May 24, 2018.

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