MERIT WRAPSODY™ Cell-Impermeable Endoprosthesis

CLINICAL CASE REVIEW

Treatment of a cephalic arch stenosis with WRAPSODY™

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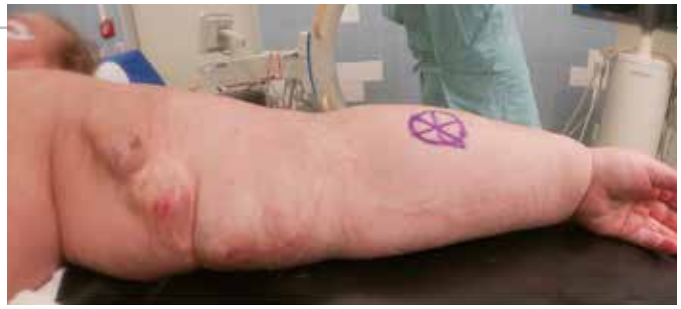
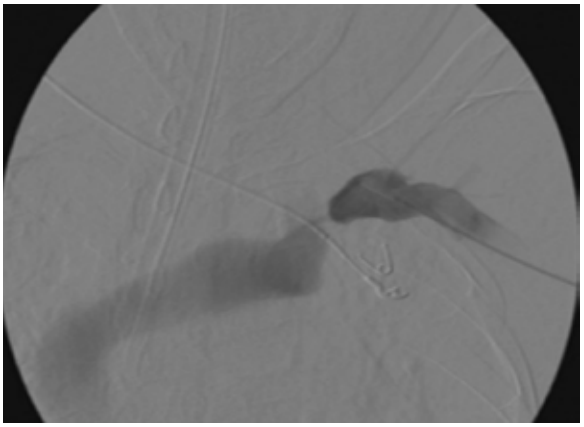


CLINICAL HISTORY

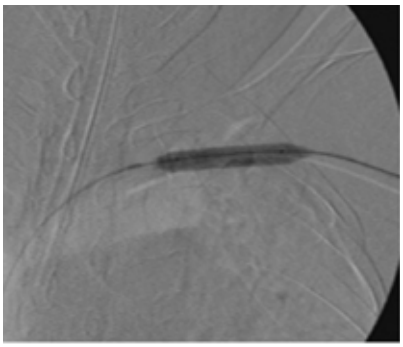
A 42-year-old female patient with ESRD with an history of multiple reinterventions due to recurrent central vein stenosis presented with a dysfunctional left basilic AV fistula with an increasing symptomatic arm swelling due to a subtotal stenosis of the subclavian vein at the junction of the brachiocephalic vein.

INTERVENTIONAL TREATMENT

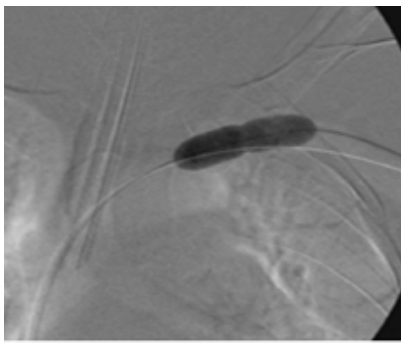
Initial access was gained with a 7Fr sheath using a standard puncture procedure and venography was performed to evaluate the venous vasculature within the dialysis outflow circuit. The image to the right shows a high-grade stenosis at the junction of the subclavian vein with the innominate vein on the left side.



The left central vein system was initially dilated with an 8mm x 40mm high-pressure balloon and then with a 12mm x 40mm high-pressure balloon.

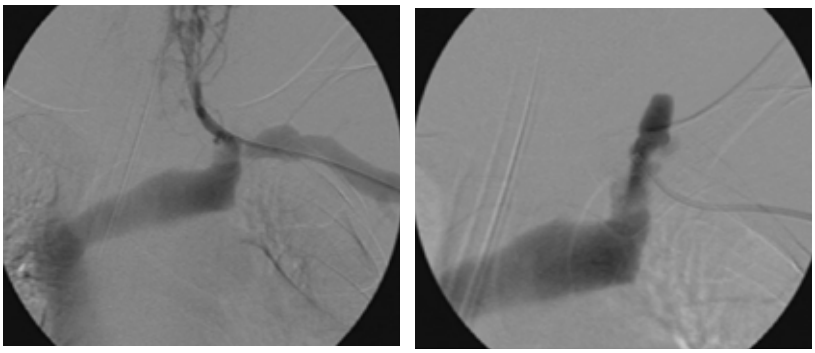


Percutaneous angioplasty with 8mm x 40mm balloon



Percutaneous angioplasty with 12mm x 40mm balloon

Because of the challenging location very close to the jugular vein and the vertebral vein, a selective venography was performed to determine the appropriate WRAPSODY Cell-Impermeable Endoprosthesis size which will not jail these veins.

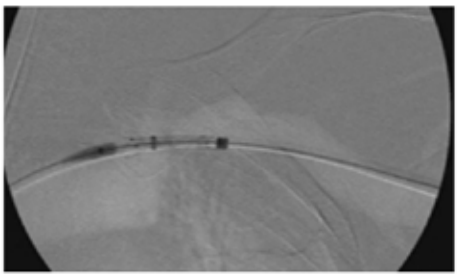


Identification of the jugular vein & the vertebral vein

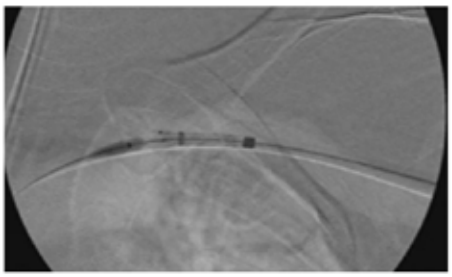
A **12mm x 30mm WRAPSODY Cell-Impermeable Endoprosthesis** was selected per the IFU and the access sheath in the arm was upsized to a 12Fr to accommodate the WRAPSODY delivery system.

CONTINUED

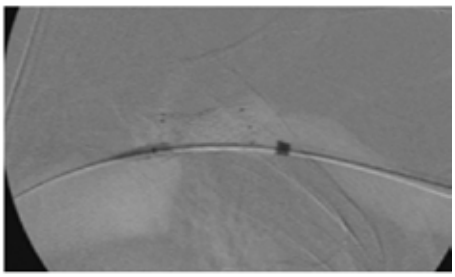
Then, a WRAPSODY Cell-impermeable Endoprosthesis (12mm x 30mm) was deployed row by row in a very controlled fashion. After priming the endoprosthesis a couple of millimeters beyond the lesion, the delivery system was readjusted on IFU to the desired landing zone and fully deployed.



Priming of WRAPSODY, beyond the desired landing zone

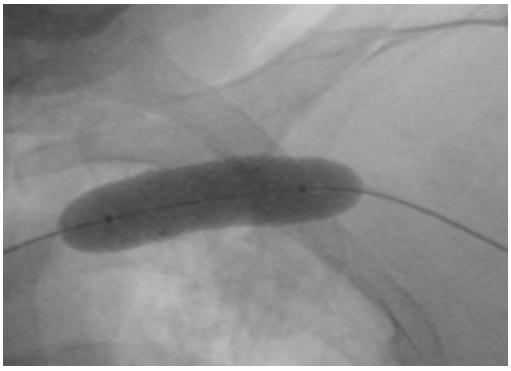


Readjustment of WRAPSODY, to the desired landing zone

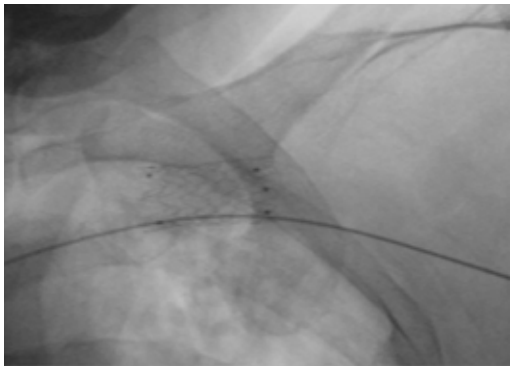


Full deployment of WRAPSODY

Post-deployment dilatation with a 12mm x 40mm balloon was performed within WRAPSODY.



Post-deployment dilatation



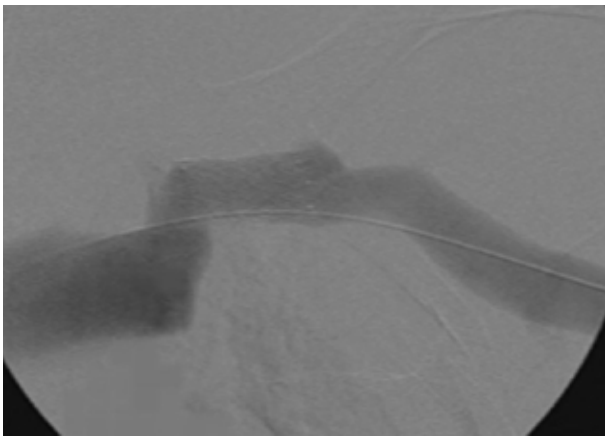
WRAPSODY implanted

CLINICAL RESULTS

The final venogram showed good angiographic result with no complication.

The sheath was removed, and hemostasis was achieved using a purse string suture.

Post operatively, the oedema in the patient's left arm reduced dramatically. The dialysis flow rates improved to enable effective treatment.



KEY TAKEAWAYS

The 12 mm x 30mm **WRAPSODY** is a **unique size option** for a cell-impermeable endoprosthesis or covered stent.

The "flare and pull-back technique" allows **very accurate positioning** of WRAPSODY, the ratchet handle provides **good control** when deploying WRAPSODY and allowed for a very **accurate deployment and positioning** of this short-length WRAPSODY.

The **patency of the central venous system** was reestablished. Function was returned to the failing fistula.

This product is intended for sale and/or use only in the European Union, for use in hemodialysis patients for the treatment of stenosis or occlusion within the dialysis outflow circuit of an arteriovenous (AV) fistula or AV graft. This product is not approved, cleared or available for sale or use in the United States, and may not be approved, cleared or available for sale or use in other countries. Before using any product, refer to the Instructions for Use (IFU) for indications, contraindications, warnings, precautions, and directions for use.

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