ISSN: 3049-5849

Journal of Vascular Medicine & Surgeries

SCIENTIFIC Research and Community

Case Report

Open Access

Unconventional Use of the Merit Wrapsody® Cell-Impermeable Endoprosthesis for Complex Iliac Arterial Reconstruction: A Two-Case Series

Adalberto Pereira de Araujo[1,2*], Cristiane Ferreira de Araujo Gomes[2,3], Eduardo Loureiro de Araujo[4], Carlos Felipe da Silva Delgado[2], Monica Rochedo Mayall[2,3], Flavia Figueira Baltarejo Campanario[2] and Rafael de Athayde Soares[5]

[1]Federal University of Rio de Janeiro (UFRJ), Rio de Janeiro, Brazil

[2]Director of the Angio Cardiology Center - Rio de Janeiro, RJ, Brazil. Former Head of the Vascular Surgery Service at Marcílio Dias Naval Hospital, Rio de Janeiro, RJ, Brazil

[3]Head of the Vascular and Endovascular Surgery Service at Pedro Ernesto University Hospital (HUPE), Rio de Janeiro State University (UERJ), Rio de Janeiro, Brazil

[4]Eduardo Loureiro de Araújo - Vascular and Endovascular Surgeon at Santa Teresa Hospital – Petrópolis, Rio de Janeiro, Brazil

[5]Rafael de Athayde Soares - Institute of Medical Assistance to State Public Servants of São Paulo (IAMSPE), Brazil

ABSTRACT

Nonlinear systems with memory arise in learning algorithms, hereditary mechanics, biological regulation, combustion, and other processes whose present state depends on a distributed history of the unknown. This paper develops a compact mathematical and computational framework for regularized Urysohn operators acting on Banach spaces of continuous trajectories. We consider nonlinear integralmemory models of the form

***Corresponding author**

Adalberto Pereira de Araujo, Angio-Cardiological Center, Rua Vice-Governador Rubens Berardo, No. 125, Bldg. 2 / Apt. 101, Gávea, Rio de Janeiro, RJ, Zip Code 22451-070, Brazil.

Received: July 27, 2026; **Accepted:** August 04, 2026; **Published:** August 15, 2026

Keywords: Wrapsody, Covered Stent, Iliac Artery, Peripheral Arterial Disease, Arteriovenous Fistula, Endovascular, Off-label

Introduction

Peripheral arterial disease (PAD) affecting the aortoiliac segment remains a major source of morbidity worldwide, with manifestations ranging from limiting claudication to critical limb-threatening ischemia. Endovascular intervention encompassing balloon angioplasty, conventional bare-metal stenting, and covered stent implantation has largely supplanted open aortofemoral bypass surgery as the primary revascularization strategy for iliac occlusive disease, owing to lower perioperative risk, shorter hospital stays and acceptable medium-term patency in appropriately selected patients [1,2].

Covered stents, or vascular endoprostheses, offer a theoretical advantage over conventional alternatives by interposing a physical barrier between the arterial lumen and the vessel wall, thereby reducing restenosis driven by neointimal hyperplasia and inflammatory cell proliferation. Several systematic reviews and meta-analyses have confirmed that covered stents provide superior or equivalent patency to bare-metal stents for complex aortoiliac lesions, with particular benefit in TASC II C and D morphologies. Pooled primary patency rates for covered stents in the iliac territory at one and three years approximate 91% and 81%, respectively [3].

Beyond occlusive disease, covered stents have become the preferred endovascular solution for arteriovenous fistulae (AVF), pseudoaneurysms, and vascular perforations, providing immediate hemodynamic correction without open surgery.

The Merit Wrapsody® Cell-Impermeable Endoprosthesis (CIE; Merit Medical Systems, South Jordan, UT, USA) is a self-expanding covered stent composed of a nitinol scaffold encased by three distinct PTFE layers: an outer expansile ePTFE layer designed to promote tissue ingrowth and prevent device migration; an intermediate cell-impermeable layer designed to block transmural tissue migration and macrophage accumulation; and an inner luminal layer of a novel “spun” PTFE intended to reduce platelet adhesion and fibrin deposition. The nitinol framework provides substantial radial force and crush resistance,

conforming to vessel angulation, with softened, atraumatic ends to minimize wall injury. The device received US FDA approval in December 2024 for the treatment of stenoses in venous, prosthetic, or covered-stent hemodialysis arteriovenous access circuits. In the pivotal randomized WAVE trial, six-month target lesion primary patency reached 89.8% in patients with arteriovenous fistulae (AVF) and 82.0% in those with arteriovenous grafts (AVG) [4,5].

Despite its regulatory indication for dialysis access, the structural characteristics of the Wrapsody® - its flexibility, radial strength, availability in diameters from 6 to 16 mm and lengths up to 80 mm, and cell-impermeable anti-restenosis architecture render it an attractive option for peripheral arterial reconstruction [6]. A growing number of case series report its successful use in aortoiliac occlusive disease, popliteal artery aneurysms, subclavian artery pathology, and iatrogenic lesions [7-10]. Nonetheless, systematic experience in this context remains limited, and published evidence consists predominantly of small, single-center series. Herein we present two technically challenging cases in which the Wrapsody® CIE was employed as a key component of endovascular arterial reconstruction: one involving chronic occlusion of a long-segment Dacron graft with a concomitantly occluded drug-eluting stent in the iliac artery, and another involving definitive exclusion of a complex iatrogenic iliac arteriovenous fistula persisting for more than a decade. Both cases illustrate the device's versatility and the intraoperative decision-making required when standard device options prove anatomically inadequate.

Case Descriptions

Case 1: Chronic Iliac Graft and Drug-Eluting Stent Occlusion

A 48-year-old male physical education teacher was referred with a four-month history of progressive left lower limb claudication, paresthesia, and toe numbness, limiting ambulatory capacity to approximately 30 meters. His vascular history was notable for a left traumatic injury with external iliac artery rupture sustained in a motorcycle accident 19 years prior, treated with an 8-mm Dacron bypass graft from the common iliac artery to the proximal femoral artery. The reconstruction provided durable results for 14 years, after which graft thrombosis was managed with a hybrid approach consisting of mechanical thrombectomy and implantation of an 8 × 100 mm drug-eluting stent.

The patient remained asymptomatic for an additional seven years. He had no history of diabetes, hypertension, or tobacco use. Physical examination revealed absent left femoral, popliteal, and pedal pulses. Computed tomographic angiography (CTA) demonstrated complete occlusion of the Dacron graft and drug-eluting stent throughout their entire length, from the distal right common iliac artery to the distal left external iliac artery, with extensive collateral circulation formation (Figure 1). The native aorta and infrainguinal arterial tree were normal. Preoperative cardiovascular risk stratification indicated low surgical risk.

Figure 1: Computed Tomographic Angiography Demonstrating Complete Occlusion of the Dacron Graft and Drug-Eluting Stent throughout their Entire Length, from the Distal Common Iliac Artery to the Distal External Iliac Artery, with Extensive Collateral Circulation Formation

The procedure was performed under general anesthesia in a hybrid operating room using an endovascular approach. Surgical exposure of the proximal superficial femoral artery was obtained through the anterosuperior aspect of the thigh, above the anterior scar. Direct arterial puncture with placement of a 7F sheath and a hydrophilic guidewire following an H1 catheter successfully recanalized the occluded segment along the left iliac axis. After guidewire exchange for a 0.014" × 300 cm guidewire, a Jetstream mechanical thrombectomy device was advanced and six passes were performed (three with closed blades, three with expanded blades), achieving satisfactory thrombus volume reduction. Balloon angioplasty preceded sheath exchange to a 12F delivery system, and calibrated pigtail catheter angiography delineated a treatment segment of 100 mm in length (87 mm on CTA) (Figure 2).

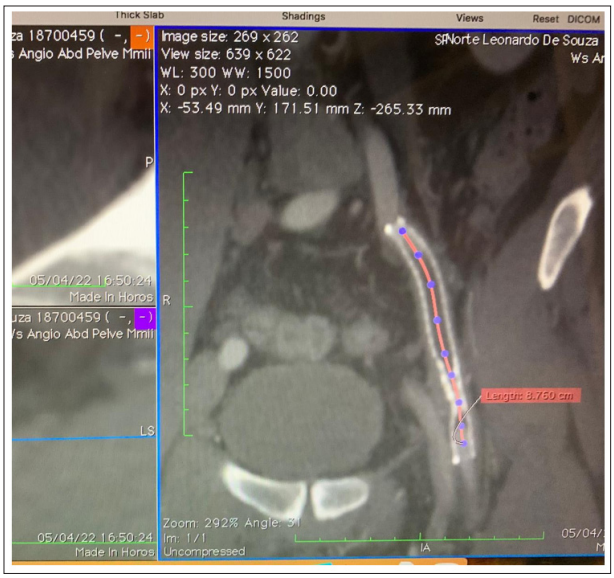

Figure 2: Computed Tomographic Angiography Demonstrating the Length of the Dacron and the Drug Eluting Stent Occlusion

The original strategy had anticipated implantation of a Medtronic Endurant iliac extension endoprosthesis; however, intraoperative angiography revealed that this device would exclude a large collateral network collaterals deemed critical in connecting the internal iliac artery to the common femoral artery to maintain limb viability in the event of future reclusion. Open aortofemoral bypass was similarly abandoned in favor of covered stent reconstruction, as a device of appropriate length could be deployed without excluding the aforementioned collateral circulation.

Two self-expanding Wrapsody® stents were implanted: a distal 9 × 75 mm stent positioned at the level of the epigastric artery, and a proximal 9 × 50 mm stent extending to the vicinity of the left internal iliac artery (Figure 3), covering the entire diseased segment while preserving the critical collaterals. Post-implantation angioplasty was subsequently performed with 7 × 40 mm and 8 × 40 mm balloons (Figure 3). Final angiography demonstrated excellent patency of both stents, with normal deep femoral artery patency and no residual obstruction (Figure 4). Arteriorraphy of the superficial femoral artery was performed with 6-0 Prolene suture. The patient was discharged on postoperative day 3. At first follow-up, femoral, popliteal, and posterior tibial pulses were symmetrically palpable. At 14-month follow-up (October 2023), the patient was asymptomatic, had returned to full activities, and the ankle-brachial index (ABI) was 1.19. At 3 years and 11 months, the patient remained asymptomatic with strong pulses to the feet, with ankle-brachial index = 1,09. Doppler ultrasound demonstrated normal stent patency, corroborated by computed tomographic angiography (Figure 5 and 6), confirming durable perfusion and Wrapsody® stent patency.

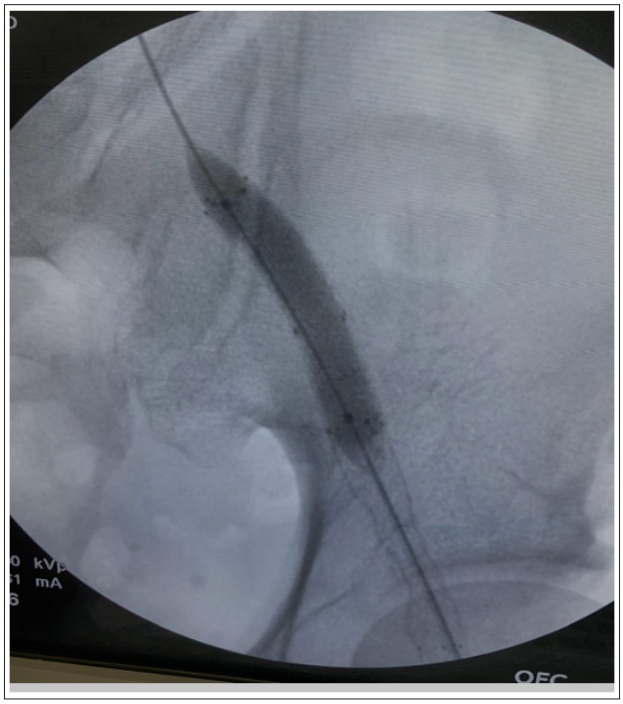

Figure 3: Post-Implantation Angioplasty was Subsequently Performed with 7 × 40 mm and 8 × 40 mm Balloons

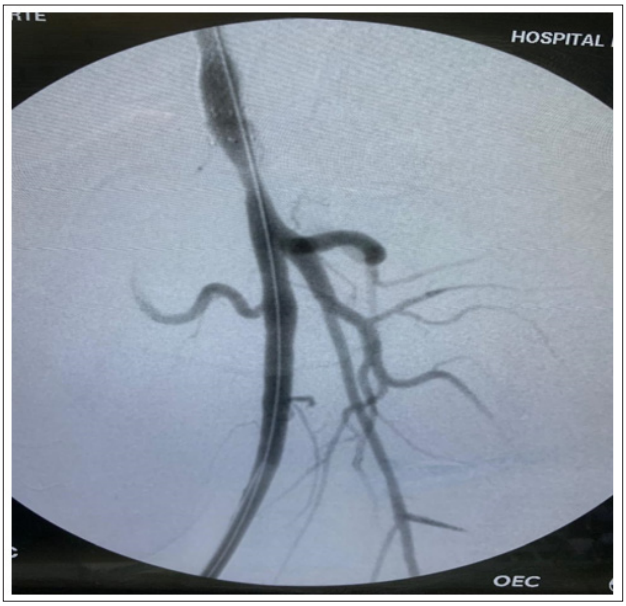

Figure 4: Final Angiography Demonstrated Excellent Patency of Both Stents, with Normal Deep Femoral Artery Patency and No Residual Obstruction

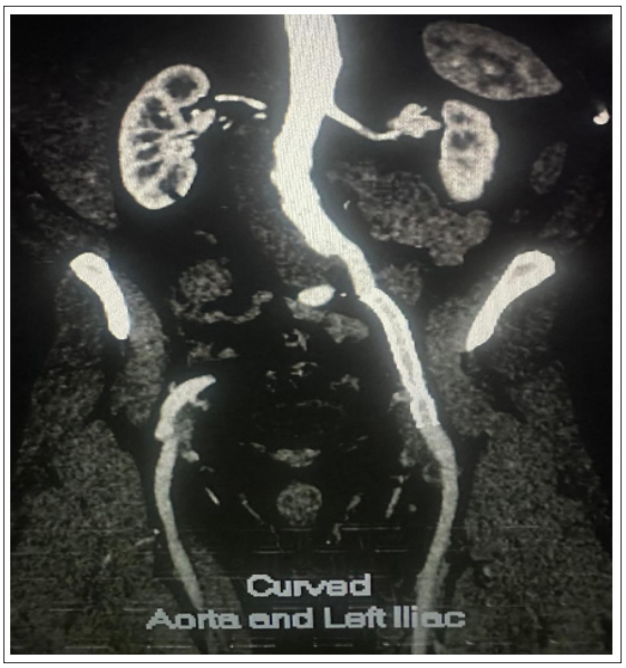

Figure 5: CT-SCAN After 3 Years and 11 Months Follow-Up Demonstrating Wrapsody Patency

Figure 6: CT-SCAN After 3 Years and 11 Months Follow-up Demonstrating Wrapsody Patency

Case 2: Chronic Iatrogenic Iliac Arteriovenous Fistula with Complex Aortic Anatomy

A 56-year-old woman presented with a longstanding iatrogenic arteriovenous fistula (AVF) of the left common iliac artery, resulting from inadvertent vascular injury during lumbar spinal prosthesis implantation performed in June 2012. The initial injury caused both arterial and venous perforation, leading to a three-month hospitalization and the subsequent development of massive left lower limb edema and severe venous hypertension, progressing to a variant of phlegmasia coerulea dolens. In 2013, the fistula was treated with an 8 × 39 mm Advanta covered stent in the left common iliac artery, with initial clinical improvement and AVF exclusion (Figure 7). The patient recovered satisfactorily, with resolution of pain, edema, and cyanosis; she was discharged three days later, with improvement of dyspnea, normalization of systemic arterial pressure, and heart rate.

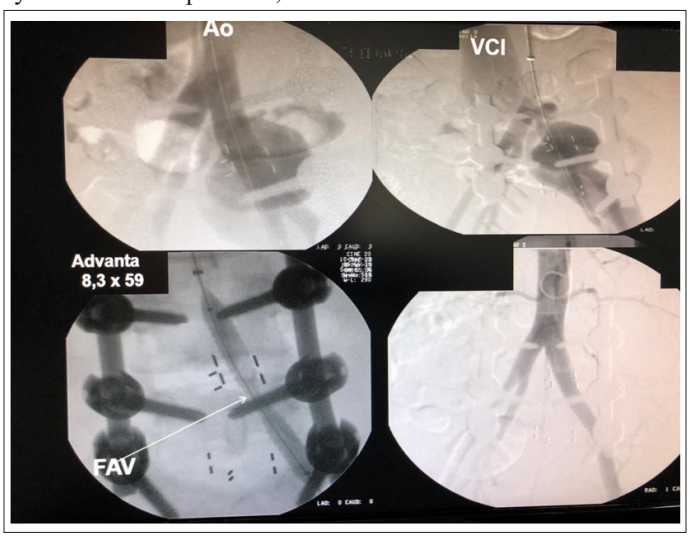

Figure 7: In 2013, the Fistula was Treated with an 8 × 39 mm Advanta Covered Stent in the Left Common Iliac Artery, with Initial Clinical Improvement and AVF Exclusion

Computed tomographic angiography performed on September 26, 2018 demonstrated 5 mm distal migration of the Advanta stent below the aortic bifurcation, with a persistent fistulous tract and exacerbated venous collateral circulation, further aggravated by occlusion of the proximal segment of the left common iliac vein. Due to the COVID-19 pandemic, the patient was lost to follow-up and returned to consultation on November 4, 2021, presenting with marked right-sided lower limb edema. Serial CTA showed stent patency but persistence of a high-flow AVF at the ostium of the left common iliac artery, with chronic venous occlusion and extensive pelvic venous collateral circulation.

Imaging also revealed exclusion of the left internal iliac artery by the previously implanted stent, an extremely short infrarenal aorta (76 mm), an aortic diameter of 16 mm, and a short right common iliac artery (30 mm), which precluded conventional sizing of bifurcated endografts. An extensive pre-procedural planning strategy was established, including contingency plans for conversion to an aorto-monoiliac configuration with crossover femoral bypass.

The procedure was performed on May 28, 2025 under general anesthesia in a hybrid operating room. Bilateral percutaneous common femoral artery access was obtained using a pre-closure technique. Intraoperative calibrated angiography confirmed the fistula location (Figure 8) and aortic measurements. Through an 18F introducer sheath, the shortest available Medtronic Endurant bifurcated endograft (23 × 70 mm) was implanted with a left iliac extension limb extending to the external iliac artery (Figure 9). A 14 × 50 mm Wrapsody® covered stent was implanted as the contralateral limb into the right common iliac artery, extending to the level of the right hypogastric artery (Figure 10). Molding was performed with a Reliant compliant balloon. Completion angiography demonstrated a stenosis in the left endograft limb, resolved with angioplasty using a 10 × 40 mm semi compliant balloon, and confirmed complete AVF exclusion, restoration of arterial flow (Figure 09), and preservation of pelvic circulation through the contralateral hypogastric artery. Bilateral percutaneous closure devices were deployed.

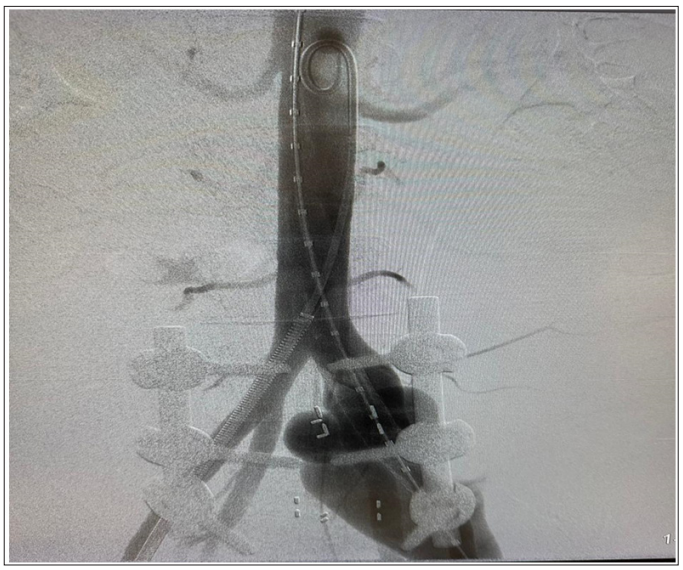

Figure 8: Intraoperative Calibrated Angiography Confirmed the Fistula Location

Figure 9: Medtronic Endurant Bifurcated Endograft (23 × 70 mm) was Implanted with a Left Iliac Extension Limb Extending to the External Iliac Artery

Figure 10: A 14 × 50 mm Wrapsody® Covered Stent was Implanted as the Contralateral Limb into the Right Common Iliac Artery, Extending to the Level of the Right Hypogastric Artery

The patient was extubated immediately and transferred to the intensive care unit. Within hours, the patient and her family noted marked reduction in venous congestion, improvement in limb coloration, disappearance of the suprapubic bruit, and visible skin wrinkling on the dorsum of the foot, indicating rapid venous decompression. She was transferred to the ward on postoperative day 2. At two-week follow-up, abdominal wall varices had disappeared, operative wounds were healed, no bruit was detectable, and lower limb pulses were palpable. Anticoagulation with rivaroxaban and clopidogrel was maintained. CTA at 6 months demonstrated patent endoprostheses (Figure 11).

Figure 11: At 6 Months, Angio-CT Showed Full Patency of the Endoprostheses

At 13-month follow-up (November 2025), CTA demonstrated occlusion of the left endograft limb; however, the Wrapsody® stent-maintained patency of the endograft body and right iliac axis (Figures 11 and 12). Although the left iliac limb occluded, definitive AVF exclusion was preserved. Perfusion of the left lower extremity was maintained via collateral vessels supplying the left femoral territory through the Wrapsody®-perfused internal iliac artery. Lower limb edema and venous congestion resolved. The patient reports non-disabling left calf claudication and loss of the left femoral pulse, without recurrence of venous hypertension. Conservative management with physiotherapy and antiplatelet therapy was recommended, with femorofemoral crossover bypass reserved for incapacitating symptoms.

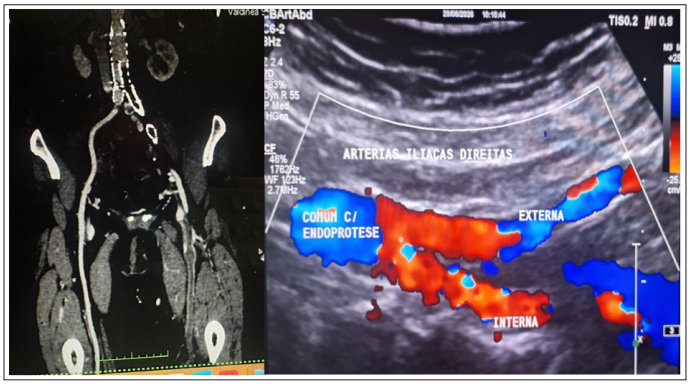

Figure 12: At 11-Month Follow-Up (March 2026), CTA Demonstrated Occlusion of the Left Endograft Limb; However, The Wrapsody® Stent Maintained Patency of the Endograft Body and Right Iliac Axis Demonstrated in Both CTA and Duplex Ultrasound

Discussion

These two cases illustrate the value of the Wrapsody® CIE as a versatile endovascular tool beyond its approved indication for dialysis access. The device's unique triple-layer PTFE architecture — combining an outer anti-migratory ePTFE layer, an intermediate cell-impermeable barrier, and an inner anti-thrombotic spun PTFE luminal surface addresses failure mechanisms affecting conventional covered stents, particularly neointimal hyperplasia driven by transmural cellular migration. These properties are directly relevant to arterial reconstruction, where in-stent restenosis and thrombosis remain the primary determinants of long-term patency.

Case 1: Recurrent Iliac Occlusion and the Role of Covered Stents

Recurrent occlusion of a pre-existing iliac stent whether covered or bare represents a technically and anatomically challenging reconstructive problem. The accumulation of thrombotic material within an aged scaffold, compounded by chronic inflammation and neointimal proliferation, creates a hostile environment for plain balloon angioplasty or uncovered re-stenting. The case reported here was particularly complex due to the composite nature of the target lesion: a 19-year-old Dacron graft in series with a 7-year-old drug-eluting stent, completely occluded over a length requiring approximately 100 mm of coverage.

Endovascular management with mechanical thrombectomy and covered stent reconstruction is well supported in the literature for complex iliac occlusive disease. Squizzato et al., in a multicenter study of 93 patients treated with self-expanding covered stents for external iliac artery obstructive disease, reported 100% technical success and favorable mid-term patency rates. A 2024 meta-analysis by Bontinis et al., published in the European Journal of Vascular and Endovascular Surgery, confirmed that covered stents outperform bare-metal stents for complex aortoiliac lesions in terms of patency and freedom from target lesion revascularization [2]. A systematic review and meta-analysis including 1,983 patients across 25 studies reported pooled primary patency rates of 91% at 12 months and 81% at 36 months for covered stents.

The intraoperative decision to abandon the originally planned Endurant iliac extension in favor of Wrapsody® stents warrants particular attention. The identification of a critical internal iliac-to-femoral collateral network recognizable on calibrated angiography precisely because of the intraoperative imaging capabilities inherent to hybrid procedures exemplifies how surgical judgment must adapt in real time to anatomical findings that preoperative imaging may not fully characterize. Preservation of these collaterals was deemed essential to maintain limb viability in the event of future reclusion. The flexible, self-expanding profile of the Wrapsody®, available in a 9-mm diameter matching the target vessel, permitted precise segmental coverage without excluding collateral ostia. The ABI of 1.19, Doppler imaging, and CTA at 39-month follow-up confirm the restoration of hemodynamically significant perfusion.

The cell-impermeable design of the Wrapsody® is mechanically relevant in this context. Prior publications on its off-label use in the aortoiliac territory by Bortoluzzi et al. and colleagues in Brazil documented satisfactory patency across a variety of aortoiliac conditions, attributing part of the benefit to the PTFE barrier against macrophage-mediated intimal hyperplasia [8]. In an ovine external iliac artery model, Dolmatch et al. demonstrated that the outer ePTFE layer promotes organized tissue ingrowth to anchor the device without transmural cellular migration a finding particularly relevant in the iliac segment, were radial forces and vessel motion challenge long-term stent integrity [7].

Case 2: Chronic Iatrogenic Arteriovenous Fistula A Decade-Long Challenge

Iatrogenic vascular injury during lumbar spine surgery, although uncommon, is a potentially devastating complication. Perforation of the major iliac vessels may result in massive hemorrhage, arteriovenous fistula formation, or both. When the arteriovenous communication persists, progressive venous hypertension, venous claudication, lower limb edema, and eventually high-output cardiac failure may develop [11]. The clinical evolution from phlegmasia alba dolens to the cerulean variant described in this patient illustrates the hemodynamic severity that a sustained high-flow AVF can impose on the peripheral venous system.

Endovascular exclusion with covered stents has become the treatment of choice for iliac AVFs, offering lower morbidity than open surgical repair in what is frequently a highly fibrotic operative field, particularly following prior spinal intervention. Tang et al. reported successful exclusion of an iatrogenic iliac AVF with a single stent after lumbar discectomy, with complete symptom resolution. Ji et al., in a 10-year single-center experience with iliac AVF management, confirmed the efficacy of endovascular approaches across multiple etiologies [11,12]. In the present case, the additional challenge was anatomical: an infrarenal aorta of only 76 mm in length with a diameter of 16 mm necessitated selection of the shortest available bifurcated endograft, while the short right common iliac artery imposed significant constraints on maintaining right internal iliac artery patency, particularly given that the left internal iliac artery had been excluded during the first intervention.

The use of a 14 × 50 mm Wrapsody® stent as the contralateral limb into the right common iliac artery was motivated by the need for a flexible, conformable device capable of adapting to the short right common iliac artery anatomy while providing reliable sealing against the persistent fistulous communication. The cell-impermeable architecture offered additional security against recurrence via any transmural route. The rapid and dramatic post-procedural improvement immediate disappearance of the bruit, limb color normalization, and visible venous decompression evidenced by skin wrinkling of the dorsum of the foot within hours confirms complete hemodynamic correction of the AVF [13].

The subsequent occlusion of the left endograft limb at 10 months, while representing a patency failure, did not result in recurrence of venous hypertension or AVF, underscoring that the primary objective of the reconstruction fistula exclusion was durably achieved. Occlusion of the left iliac axis in the context of chronic collateral circulation established by a long-standing AVF is often better tolerated with respect to limb ischemia, given well-developed pelvic and femoral collateral networks, as evidenced by the maintenance of limb viability in this patient with only intermittent claudication.

The late occlusion of the left endograft limb may reflect the anatomical challenges posed by a previously implanted stent, the narrow aortic bifurcation, the pre-existing hemodynamic disturbance induced by venous hypertension, or an in adequate anticoagulation response factors that collectively emphasize the importance of rigorous surveillance and the availability of secondary interventions such as crossover femoral bypass.

The Wrapsody® CIE as an Off-Label Arterial Device

The regulatory approval of the Wrapsody® is currently restricted to hemodialysis access circuits. Its use in peripheral arterial disease constitutes off-label practice. Nevertheless, a growing body of

evidence encompassing aortoiliac occlusive disease, popliteal artery aneurysmal disease, subclavian artery pathology, iatrogenic lesions, and aortic pathology demonstrates its technical feasibility and short- to medium-term safety across a spectrum of conditions. Mansano et al. and de Athayde Soares et al. published series demonstrating successful application of the device in the aortoiliac territory with satisfactory early patency, while our group has contributed experience with popliteal artery aneurysms [9,10].

The Wrapsody® Iliac Artery Trial (NCT03994185) was conceived as the first dedicated safety and efficacy study in the iliac artery, although enrollment ultimately did not proceed leaving an evidence gap that current off-label registries and case series are beginning to address. The device's profile compares favorably with established covered stents for arterial reconstruction. Relative to the GORE Viabahn the most extensively studied self-expanding covered stent in the peripheral arterial literature, with documented primary patency rates of approximately 73% to 86% at one year in the external iliac artery the Wrapsody® differs primarily in its triple-layer PTFE structure and the addition of the cell-impermeable anti-proliferative barrier, a design feature not present in conventional ePTFE-only covered stents [14-16].

Whether these differences translate into superior long-term patency in the peripheral arterial setting requires direct comparative evidence. Clinicians considering off-label use of the Wrapsody® for arterial reconstruction should be aware of several device-specific considerations. Available diameters (6–16 mm) and lengths (up to 80 mm in some configurations) encompass common and external iliac targets but may require tandem implantation for longer lesions, as in Case 1. The self-expanding nitinol framework requires precise sizing prior to implantation, as oversizing beyond 10–20% may compromise radial force and conformability. Delivery through a 12F sheath is compatible with most percutaneous femoral access systems. Finally, the device's inner spun PTFE surface, while anti-thrombogenic, does not eliminate the need for periprocedural anticoagulation and long-term antiplatelet therapy [16,17].

Conclusion

The two cases reported herein expand the evidence base for off-label use of the Merit Wrapsody® Cell-Impermeable Endoprosthesis in complex peripheral arterial reconstruction. In a patient with chronic composite iliac graft and drug-eluting stent occlusion, dual Wrapsody® implantation following mechanical thrombectomy achieved durable limb perfusion with an ABI of 1.19 at 39 months. In a patient with a decade-long iatrogenic iliac arteriovenous fistula complicated by an extremely short and narrow-caliber aorta, the Wrapsody® served as a key component of a hybrid aortoiliac reconstruction that definitively excluded the fistula with dramatic and sustained clinical improvement.

Both cases underscore the importance of intraoperative flexibility and the value of a covered stent with a distinct anti-restenotic architecture in scenarios where standard devices are anatomically inadequate or potentially harmful. The cell-impermeable design of the Wrapsody® offers a theoretically meaningful advantage over conventional covered stents in preventing neointimal hyperplasia; however, prospective comparative data and longer follow-up are required to confirm this benefit in the peripheral arterial context.

Registries and prospective studies specifically designed to evaluate the Wrapsody® in peripheral arterial indications are warranted. Until such data are available, carefully selected off-label use — guided by sound anatomical assessment, multidisciplinary discussion, and thorough patient counseling represents a reasonable approach in cases where conventional options are limited or inadequate.

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