Clinical Analysis of

The PowerWire® Pro Radiofrequency Guidewire

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Executive Summary

Endovascular recanalization of central veins or central venous occlusions (CVOs) is a necessary procedure when patients experience symptoms related to vessel occlusions. These procedures have historically been performed using conventional recanalization methods, such as a guidewire, or angiographic catheter to mechanically push through an occlusion and prepare the vessel for ballooning, stenting, or a combination thereof. These conventional methods often fail, which prolongs and often worsens patient symptoms.

Baylis Medical Technologies Inc. has developed the PowerWire® Pro Radiofrequency (RF) guidewire to mitigate and improve outcomes in instances of recanalization failure. The PowerWire® Pro RF Guidewire is **FDA cleared for use in peripheral vessels 3mm or greater, including vessels with stents** and utilizes an atraumatic tip to deliver RF puncture energy to the occluded site. This enables traversal through a variety of lesions with great reliability, control, and efficacy.

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Background

Peripheral vascular disease (PVD) constitutes a significant vascular condition encompassing peripheral arterial disease (PAD) and chronic venous disease (CVD), primarily affecting vessels outside the heart and brain. An estimated 40-50% of PVD patients have Chronic Total Occlusions (CTOs) (Gutierrez et al., 2021). CTOs in PVD signify complete blockages within the peripheral vessels, often caused by a buildup of atherosclerotic plaque or fatty deposits. Severely restricted blood flow to the limbs can lead to drastic complications such as critical limb ischemia, gangrene, and risk of limb amputation (Tavallaei et al., 2018).

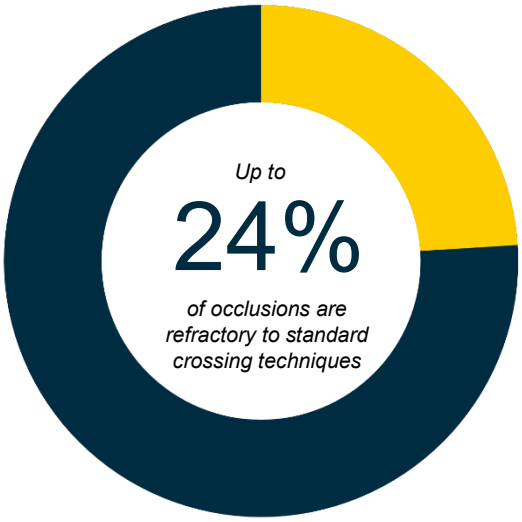
A CVO is a common complication in individuals with central venous catheters, such as those undergoing dialysis treatment for end-stage kidney disease with an incidence rate of up to 60% being reported (Tabriz et al., 2022). Treatment for such occlusions is necessary when a patient experiences:

- Edema (swelling of the face, chest, or peripheries)
- Pain
- Hemodialysis (HD) access malfunction

Endovascular Recanalization:

To restore blood flow in occluded vessels, various techniques can be employed. Traditional methods involve use of standard guidewires and angiographic catheters to mechanically traverse the lesion. In cases of challenging or complete occlusion, advanced approaches, such as utilizing a PowerWire® Pro RF Guidewire, can also be employed. After successfully crossing the lesion, the next step often involves percutaneous balloon angioplasty and stent deployment at the occlusion site to ensure vessel patency and restore blood flow.

Common Challenges:



During such procedures, crossing the lesion is often the most time-consuming and rate-limiting step of vessel recanalization. It has been reported that **up to 24% of occlusions cannot be crossed with conventional recanalization techniques** (Guimaraes et al., 2012), leading to either prolongation or worsening of patient symptoms (Iafrati et al., 2012; Keller et al., 2018; Kundu et al., 2012).

Reasons for failure may include:

- Hard lesion composition
- A difficult to traverse anatomical location of lesion (e.g., left brachiocephalic vein)
- A long-occluded segment

The Radiofrequency Solution:

Baylis Medical Technologies has developed the PowerWire® Pro RF Guidewire, which utilizes radiofrequency (RF) puncture technology to vaporize a channel through complete occlusions in native and stented peripheral vessels ≥ 3mm.

The PowerWire® Pro RF Guidewire features an atraumatic tip that delivers precise and controlled RF puncture technology to cross challenging occlusions and facilitate vascular recanalization. A radiopaque tip and distal marker bands allow for enhanced visibility under fluoroscopy.

The RF technology underpinning the PowerWire® Pro RF Guidewire allows for enhanced control during vascular recanalization procedures, which can be used in various lesion types found across diverse anatomies.

Benefits of RF Puncture for Crossing Vascular Occlusions

Clinical studies have highlighted the reliability and consistency provided by the PowerWire® Pro RF Guidewire, demonstrating:

- Reliable and reproducible recanalization of native and stented vessel occlusions unresponsive to traditional techniques.
- Effective recanalization in a variety of anatomies.
- The facilitation of hemodialysis access and alleviation of symptoms resulting from vessel occlusions.
- Crossing occlusive lesions with RF puncture requires less force compared to conventional techniques.

The following sections describe the evidence that supports the benefits of the PowerWire® Pro RF Guidewire in each of these categories. These benefits have been realized across all levels of physician expertise.

1

The PowerWire® Pro RF Guidewire enables reliable and repeatable vascular recanalization for both native and stented vessel occlusions unresponsive to traditional techniques.

(Clark et al., 2024; Foley et al., 2023; Guimaraes et al., 2012; Iafrati et al., 2012; Keller et al., 2018; Kundu et al., 2012; Patel et al., 2015; Salaskar et al., 2018; Sivananthan et al., 2015; Tapping et al., 2012; Tingerides et al., 2016; Yee N, 2014, Majdalany et al., 2019, Neidert et al., 2019, Shapiro et al., 2022)

The PowerWire® Pro RF Guidewire can successfully cross occlusions that have previously failed mechanical recanalization attempts in 125/149 (84%) of reported cases, 95/111 (86%) of native vessels, and 30/38 (79%) of stented vessels.

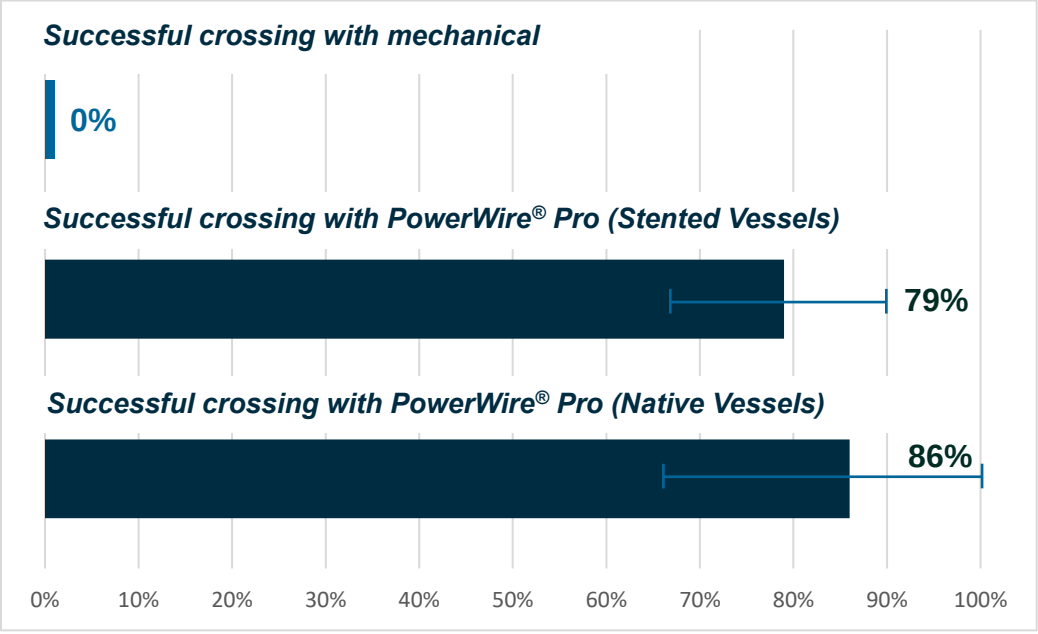


Table 1.

Study	*Study Design*	*Clinical Success*	*Success Rate*	*Locations of Venous/Arterial Occlusions*	*Failed Mechanical Recanalization (Y/N)*
[4] Guimaraes et al.	Retrospective Review	**n=35** The PowerWire® Pro RF Guidewire achieved a 100% success rate in patients where conventional recanalization had failed.	35/35 (100%)	CVO Locations: 6 subclavian vein, 29 brachiocephalic vein.	Y
[2] Clark et al.	Retrospective Review	**n=20** The PowerWire® Pro RF Guidewire achieved an 80% success rate crossing CVOs in patients where conventional catheter-based techniques had failed.	16/20 (80%)	CVO Locations: 7 brachiocephalic/ subclavian vein, 7 brachiocephalic vein, 1 subclavian/ axillary vein, 1 internal jugular/ brachiocephalic vein. (4 CVO locations of unsuccessful attempts not disclosed)	Y
[16] Majdalany et al.	Retrospective Review	**n=19** The PowerWire® Pro RF Guidewire successfully recanalized an occlusion in one patient that was repeatedly unable to be crossed with a hydrophilic guidewire.	17/19 (89%)	Chronically thrombosed venous stent locations: 3 left common iliac vein/ left external iliac vein/ left common femoral vein, 3 left common iliac vein/ left external iliac vein, 2 IVC/ left common iliac vein/ left external iliac vein, 2 IVC/ left common iliac vein/ left external iliac vein/ left common femoral vein, 2 right external iliac vein/ right common femoral vein, 2 IVC/ right common iliac vein/ right external iliac vein, 1 IVC/ left common iliac vein, 1 IVC/ left common iliac vein/ left external iliac vein, 1 brachiocephalic vein/ right subclavian vein/ right axillary vein, 1 right subclavian vein/ right axillary vein, 1 IVC/ right common iliac vein/ right external iliac vein/ right common femoral vein, 1 right subclavian vein/ right axillary vein.	Y

[17] Neidert et al.	Retrospective Review	**n=15** The PowerWire® Pro RF Guidewire successfully recanalized 10 stented iliac vein occlusions that were unable to be crossed with a conventional guidewire.	10/15 (67%)	15 stented iliac vein occlusions.	Y
[7] Keller et al.	Retrospective Review	**n=15** The PowerWire® Pro RF Guidewire achieved an 80% success rate of crossing occlusions in patients that were refractory to conventional recanalization.	12/15 (80%)	CVO Locations: 6 left common iliac veins, 1 left iliofemoral vein, 2 right iliofemoral veins, 3 right brachiocephalic veins, 2 left brachiocephalic veins, 1 Left axillary/ subclavian/ brachiocephalic vein.	Y
[11] Sivananthan et al.	Retrospective Review	**n=11** The PowerWire® Pro RF Guidewire successfully recanalized 73% of occlusions that were unable to be crossed with either angiographic catheters or hydrophilic guidewire.	8/11 (73%)	CVO locations: 1 right cephalic vein, 5 right brachiocephalic vein, 3 left brachiocephalic vein, 2 Inferior vena cava (IVC)/ iliac/ common femoral veins.	Y
[18] Shapiro et al.	Retrospective Review	**n=4** The PowerWire® Pro RF Guidewire successfully recanalized 3 chronic iliocaval venous occlusion after failing previous endovascular recanalization attempts.	Total: 6/10 (60%) In-stent: 3/4 (75%)	10 chronic iliocaval venous occlusions. 3 IVC/ left common iliac vein/ external iliac veins (stented), 1 IVC/ bilateral common iliac vein (stented), 1 IVC/ bilateral common iliac vein, 1 IVC/ bilateral common iliac vein/ external iliac vein, 1 right common iliac vein/ external iliac vein, 1 right external iliac vein/ common femoral vein, 1 bilateral femoral vein, 1 left common iliac vein/ external iliac vein (stented).	Y
[14] Tingerides et al.	Retrospective Review	**n=10** The PowerWire® Pro RF Guidewire successfully recanalized an occlusion in one patient that was unable	10/10 (100%)	Unilateral common iliac artery occlusions (9 left, 1 right).	Y

		to be crossed with a hydrophilic guidewire.			
[8] Kundu et al.	Retrospective Review	**n=6** The PowerWire® Pro RF Guidewire achieved 50% success rate in patients where conventional recanalization had failed.	3/6 (50%)	CVOs in brachiocephalic veins (1 left, 5 right).	Y
[6] Iafrati et al.	Case Series	**n=3** The PowerWire® Pro RF Guidewire achieved 100% success rate in patients where conventional recanalization had failed.	3/3 (100%)	CVOs in the brachiocephalic veins (2 left, 1 right).	Y
[9] Patel et al.	Case Report	**n=1** The PowerWire® Pro RF Guidewire successfully crosses an occlusion in one patient that was unable to be crossed with a conventional guidewire.	1/1 (100%)	Occlusion of the IVC, common iliac veins, and left external iliac vein.	Y
[10] Salaskar et al.	Case Report	**n=1** The PowerWire® Pro RF Guidewire successfully crosses an occlusion in one patient after multiple unsuccessful attempts with a conventional guidewire.	1/1 (100%)	Occlusion of the IVC.	Y
[12] Tapping et al.	Case Report	**n=1** The PowerWire® Pro RF Guidewire successfully recanalized an occlusion in one patient that was unable to be crossed with a hydrophilic guidewire.	1/1 (100%)	Isolated right common iliac artery occlusion.	Y
[15] Yee et al.	Case Report	**n=1** The PowerWire® Pro RF Guidewire successfully recanalized an occlusion in	1/1 (100%)	Chronic occlusion of the left brachiocephalic vein.	Y

		one patient that was repeatedly unable to be crossed with a hydrophilic guidewire.			
[3] Foley et al.	Case Report	**n=1** The PowerWire® Pro RF Guidewire successfully recanalized an occlusion in one patient that after attempts using hydrophilic guidewires and catheters and resulting in a contained dissection	1/1 (100%)	Chronic left subclavian vein occlusion.	Y
Total		**Total Vessels: 125/148 (84%)** **Native vessels: 95/110 (86%)** **Stented Vessels: 30/38 (79%)**		11 Arterial Occlusions, 100 Venous Occlusions, 38 Occluded Venous Stents	

2

The PowerWire® Pro RF Guidewire is capable of crossing lesions in a variety of anatomies.

(Clark et al., 2024; Foley et al., 2023; Guimaraes et al., 2012; Iafrati et al., 2012; Keller et al., 2018; Majdalany et al., 2019; Patel et al., 2021; Salaskar et al., 2018; Shapiro et al., 2022; Sivananthan et al., 2015; Tapping et al., 2012; Tingerides et al., 2016; Yee N, 2014)

The PowerWire® Pro RF Guidewire is a versatile tool that has been shown to effectively recanalize lesions found in several areas of the vasculature in both native and stented blood vessels. Investigators have successfully recanalized lesions of the left brachiocephalic vein, a notably difficult anatomy to traverse due to its tortuosity (Guimaraes et al., 2012).

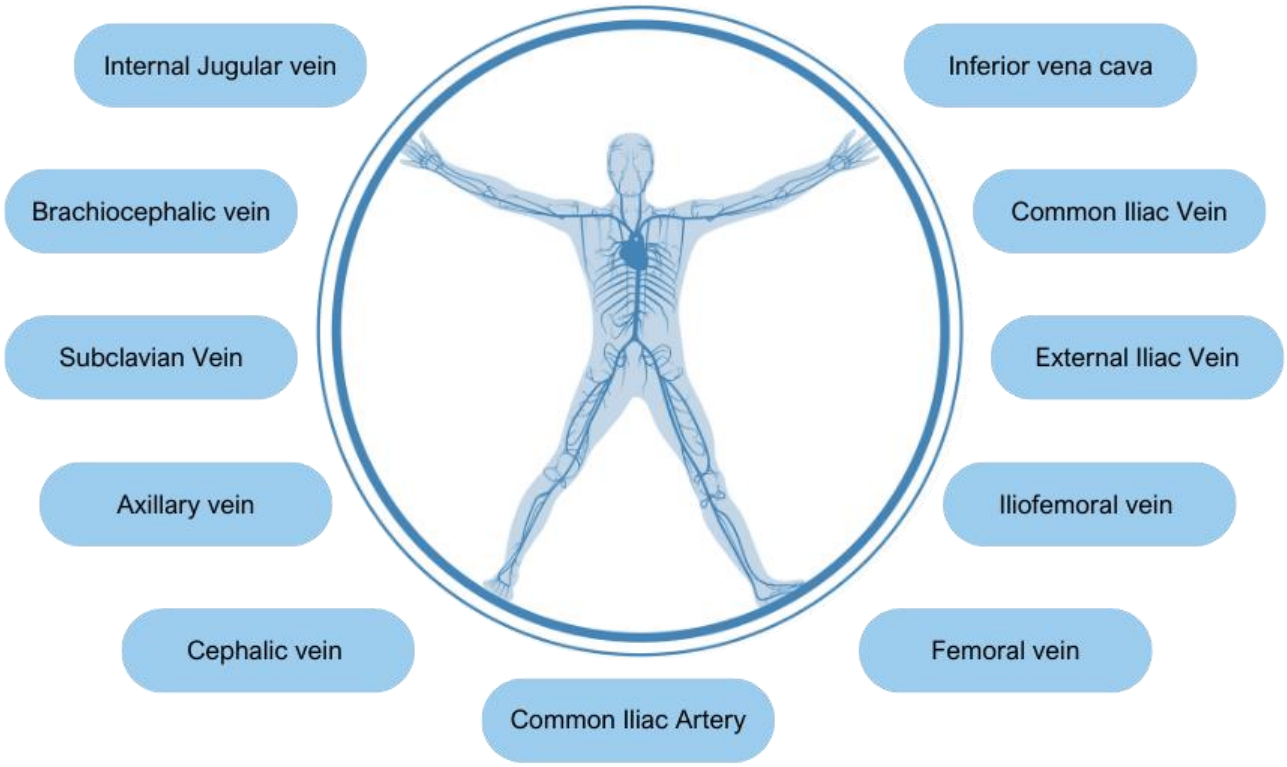


Table 2.

Reported Anatomical Locations Where PowerWire® Pro RF Guidewire use has been Successful	*Native or Stented Vessel*	*Number of successful cases*	*Article*
Brachiocephalic Vein	Native	54	[2] Clark et al. [4] Guimaraes et al. [6] Iafrati et al. [7] Keller er al. [8] Kundu et al. [11] Sivananthan et al. [15] Yee N.
Common Iliac Artery	Native	11	[12] Tapping et al. [14] Tingerides et al.
Brachiocephalic/Subclavian Vein	Native	7	[2] Clark et al.
Subclavian Vein	Native	7	[4] Guimaraes et al. [3] Foley et al.
IVC/ Common Iliac Vein/ External Iliac Vein	Stented	5	[16] Majdalany et al. [18] Shapiro et al.
Common Iliac Vein	Native	4	[7] Keller et al.
Common Iliac Vein/ External Iliac Vein/ Common Femoral Vein	Stented	3	[16] Majdalany et al.
Common Iliac Vein/ External Iliac Vein	Stented	3	[16] Majdalany et al.
IVC/ Common Iliac Vein/ External Iliac Vein/ Common Femoral Vein	Stented	2	[16] Majdalany et al.
Iliofemoral Vein	Native	2	[7] Keller et al.
External Iliac Vein/ Common Femoral Vein (Stented)	Stented	2	[16] Majdalany et al.
Subclavian Vein/ Axillary Vein	Stented	2	[16] Majdalany et al.
IVC/ Common Iliac Vein/ External iliac Vein	Native	1	[9] Patel et al.
IVC/ Common Iliac Vein	Stented	1	[16] Majdalany et al.
IVC/ Common Iliac Vein/ External Iliac Vein/ Common Femoral Vein	Native	1	[11] Sivananthan et al.

Inferior Vena Cava	Native	1	[10] Salaskar et al.
Common Iliac Vein/ External Iliac Vein (Stented)	Stented	1	[18] Shapiro et al.
Common Iliac Vein/ External Iliac Vein	Native	1	[18] Shapiro et al.
External Iliac Vein/ Common Femoral Vein	Native	1	[18] Shapiro et al.
Femoral Vein	Native	1	[18] Shapiro et al.
Brachiocephalic/ Subclavian/ Axillary Vein	Native	1	[7] Keller et al.
Brachiocephalic Vein/ Subclavian Vein/ Axillary Vein	Stented	1	[16] Majdalany et al.
Subclavian/ Axillary Vein	Native	1	[2] Clark et al.
Brachiocephalic/Internal Jugular Vein	Native	1	[2] Clark et al.
Cephalic Vein	Native	1	[11] Sivananthan et al.
Total Successes		**95 native vessel occlusions** **20 stented vessel occlusions**	

**Anatomical locations listed above with multiple vessels indicate that a single occlusion spans across multiple blood vessels.*

3

PowerWire® Pro RF Guidewire enables the restoration of hemodialysis access, which alleviates symptoms associated with vascular occlusions.

(Clark et al., 2024; Guimaraes et al., 2012; Iafrati et al., 2012; Keller et al., 2018; Kundu et al., 2012; Sivananthan et al., 2015; Tapping et al., 2012; Tingerides et al., 2016; Yee N, 2014)

Hemodialysis access was restored and symptoms such as swollen arms and superior vena cava syndrome were resolved in published cases where the PowerWire® Pro RF guidewire was used to recanalize the underlying lesion causing these symptoms.

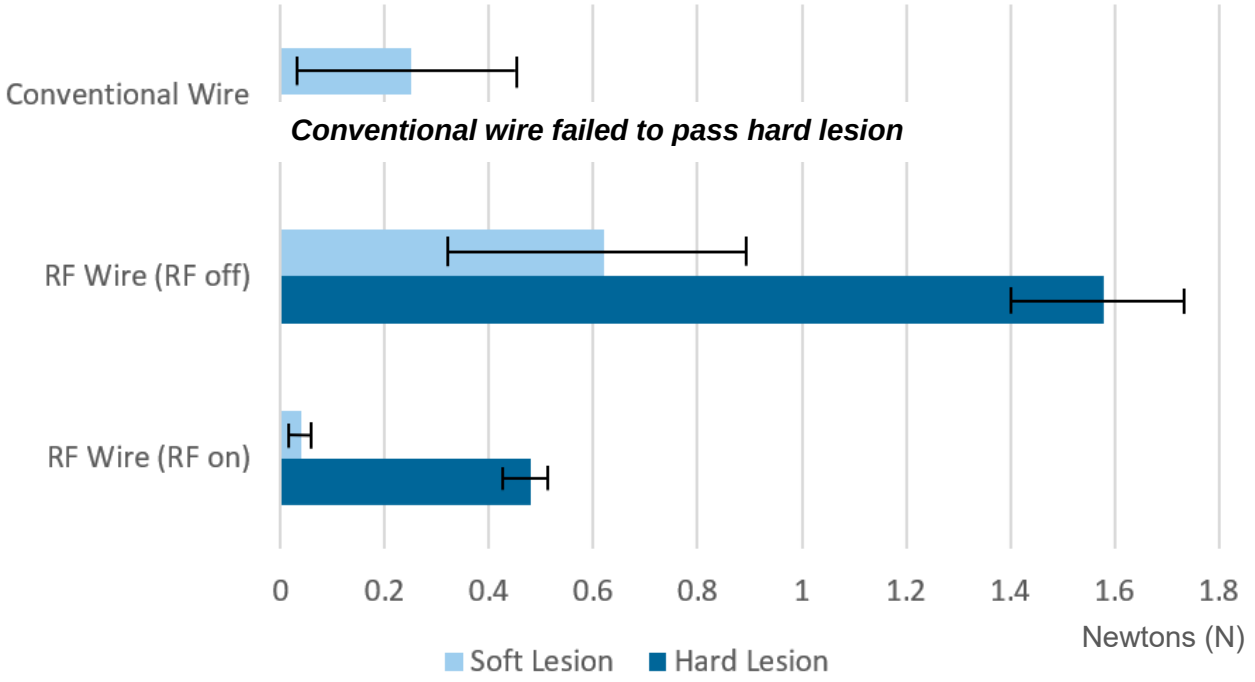
Table 3.

Reported Symptoms Resolved Following Successful Recanalization	*Article*
Pain and Swelling (arm, face, neck, axillary, extremities)	[4] Guimaraes et al. [2] Clark et al. [6] Iafrati et al. [8] Kundu et al. [7] Keller et al. [15] Yee et al.
Face, leg, and chest edema	[7] Keller et al. [11] Sivananthan et al.
Loss of dialysis access or access dysfunction with decreased access flows measuring less than 650 mL/min	[7] Keller et al. [8] Kundu et al.
Claudication symptoms	[14] Tingerides et al. [12] Tapping et al.
Headache	[6] Iafrati et al.

4

Use of the PowerWire® Pro RF Guidewire requires minimal force to cross an occlusive lesion when compared to use of a traditional guidewire.

Force required to cross occlusive lesion – in Newtons (N).



Adapted from Tavallaei et al (2018)

Tavallaei et al. [13] compared the performance of the PowerWire® Pro RF guidewire to hydrophilic guidewires in occlusive vascular lesions of various compositions. In the study, the performance of three different types of guidewires was evaluated: a conventional standard hydrophilic guidewire, a PowerWire® Pro RF guidewire with RF-power (ON), and the same RF guidewire without RF-power (OFF). *Ex vivo* lesion samples were harvested from cadaveric limbs from patients who had critical limb ischemia and subsequently characterized with a previously validated magnetic resonance imaging (MRI) and micro-computed tomography scanner technique to determine if the lesion was “soft” or “hard”. Soft lesions contained primarily lipids, smooth muscle, thrombus, micro-channels, loose fibrous tissue, and soft proteoglycan matrix. In contrast, hard lesions contained calcified nodules, speckled calcium, and dense fibrous tissue primarily made up of type I collagen. The force to cross the occlusions was generated by an electrical motor to ensure consistent force measurements.

Performance:

Soft lesion: Conventional guidewires penetrated with forces of 0.25 N ± 0.20 (n=5) and the RF wire (without RF energy) penetrated with forces of 0.62 N ± 0.28 (n = 5). In contrast, the RF wire (with RF energy) penetrated lesions with an average force of 0.04 N ± 0.03 (n = 5). There is a large significant difference between the force required to puncture using RF energy compared to conventional methods (one-way ANOVA; $p < 0.0002$).

Hard Lesion: Conventional guidewire failed to penetrate any of the hard lesions (n = 5) while the RF-wire (without RF energy) was able to penetrate the lesion with an average force of 1.58 N ± 0.18 (n = 5). The RF-wire (with RF energy) was able to puncture the hard lesion with a significantly lower average puncture force of 0.48 N ± 0.05 (n = 5; one-tailed t-test, $p < 0.002$).

Summaries

[2] Clark et al., 2024

In a retrospective study involving 20 patients with symptoms of arm and facial swelling due to end-stage renal disease (ESRD) and chronic central venous occlusions (CVOs), the PowerWire® Pro RF Guidewire facilitated recanalization procedures. Of the 20 attempts on 16 lesions, technical success was achieved in 80%. Using 1 or 2 second pulses of RF energy, the PowerWire® Pro RF Guidewire effectively crossed thoracic venous occlusions where conventional methods failed. Of the 16 successful recanalizations, stents were deployed in various anatomies including the brachiocephalic vein (6), border of the brachiocephalic and subclavian vein (6), border of the subclavian and axillary vein (1), a bifurcated stent construct between the right internal jugular vein, and right subclavian/ brachiocephalic veins (1), and a bifurcated stent construct between the right subclavian and bilateral brachiocephalic veins (1). Major complications occurred in 3 cases, including 2 hemothoraces and 1 hemopericardium. Despite challenges, the study reported a primary unassisted patency of 94% at 6 months and 85% at 12 months, indicating the effectiveness of the PowerWire® Pro RF Guidewire in resolving symptoms and maintaining venous patency in hemodialysis patients.

[3] Foley et al., 2023

In this case report, a 60-year-old patient with a chronic left subclavian vein occlusion required lead upgrade for cardiac resynchronization therapy. Conventional techniques using hydrophilic guidewires and catheters failed, resulting in a contained dissection. A PowerWire® Pro RF Guidewire was used to cross the occlusion with a 1-second burst of radiofrequency, successfully recanalizing the occluded vein. The occlusion was then dilated with angioplasty balloons, allowing lead implantation. The RF wire’s low-power radiofrequency effectively vaporized the occluding tissue without significant collateral damage. No major complications were reported during the procedure.

[4] Guimaraes et al. 2012

In this retrospective review, 34 patients experiencing symptoms such as swollen arms and superior vena cava syndrome due to CVOs, underwent recanalization with the PowerWire® Pro RF Guidewire. Recanalization attempts using conventional recanalization methods (hydrophilic

guidewires and semi-curved catheters) failed in all patients before successful recanalization with the PowerWire® Pro RF Guidewire. All 35 venous occlusions found in the subclavian (6), brachiocephalic (29), were successfully recanalized. 95.2% of patients remained patent at 6 and 9 months after treatment. In the context of on-label use, no major complications were reported.

[6] Iafrati et al. 2012

In this case series, Iafrati et al. reported on three patients experiencing CVOs. The first patient had superior vena-cava syndrome due to an occluded right brachiocephalic vein graft. After failing to traverse the lesion with conventional techniques, the lesion was successfully crossed with the PowerWire® Pro RF Guidewire with a 5F slip catheter. The second patient experienced an occlusion of the left brachiocephalic vein that prevented hemodialysis access. After failed attempts at traversing the lesion with conventional catheters and guidewires, the PowerWire® Pro RF Guidewire was used successfully to cross the occluded segment. The third patient had superior vena cava syndrome due to an occlusion in the brachiocephalic vein and experienced headache, as well as neck, facial, and axillary swelling. After an attempt at recanalization with conventional techniques had failed, the PowerWire® Pro RF Guidewire was used to successfully cross the occlusion, thereby resolving his symptoms.

[7] Keller et al. 2018

This retrospective review investigated the use of the PowerWire® Pro RF Guidewire to treat 15 symptomatic CVOs in 13 patients that were refractory to standard and advanced recanalization techniques. The patients in this study were experiencing symptoms such as pain, face, leg and chest edema, and loss of dialysis access. Venous occlusions were found in the left common iliac, iliofemoral, brachiocephalic, subclavian, and axillary veins. Technical success, defined as CVO traversal, venoplasty, symptom relief, and stent placement with resolution of the treated occlusion was achieved in 80% of CVOs. In the context of on-label use, no major complications were reported.

[8] Kundu et al. 2012

Kundu et al. conducted a retrospective review with 6 hemodialysis patients who had recanalization attempts with the PowerWire® Pro RF Guidewire to enable the treatment of symptomatic CVOs. Each patient had failed attempts at recanalizing these occlusions with conventional endovascular methods. Technical success, defined as a procedure with no significant residual stenosis, was achieved in 3/6 patients (50%). The length of the lesion in

successful cases averaged 6.5 cm, whereas the unsuccessful cases had longer lesions with an average of 8.1 cm. Overall, there were no complications in any of these cases.

[9] Patel et al. 2021

This case report characterized a patient with significant heaviness and swelling in both legs, debilitating dyspnea, and light-headedness with exertion likely due to occlusion-related decrease in venous return and subsequent reduction in cardiac output. Occlusion was present at the left external iliac vein, bilateral common iliac veins, and the IVC. The PowerWire® Pro RF Guidewire was successfully used for the traversal of the occluded caval segment after a prolonged attempt with a conventional guidewire was unsuccessful.

[10] Salaskar et al. 2018

In this case report, Salaskar et al. reported on a patient presenting recurrent massive hematemesis and the presence of systemic venous upper esophageal varices caused by the chronic occlusion of the IVC. The PowerWire® Pro RF Guidewire was successful in recanalizing the long segment of the IVC and improving the patient's symptoms after multiple attempts using traditional techniques were unsuccessful. After the recanalization procedure, post-procedure venography showed a patent stented IVC and a significant decrease in intra-abdominal-pelvic collaterals. The patient did not experience a recurrence of hematemesis and remained asymptomatic after 6 months, with a functioning right femoral arteriovenous hemodialysis graft.

[11] Sivananthan et al. 2015

This retrospective review evaluated the safety and efficacy of using the PowerWire® Pro RF Guidewire to treat CVOs in cases that have failed conventional techniques (angiographic catheters and hydrophilic guidewires). All cases were performed using a straight tip RF wire in conjunction with an angle-tipped diagnostic catheter with venous access from both sides of the occlusion. Of the six patients with extremity swelling due to a loss of dialysis access, four were successfully recanalized and had a complete resolution of symptoms. Overall, the PowerWire® Pro RF Guidewire successfully recanalized 8 of 11 vessels (73%). The successfully traversed vessels were found in the right brachiocephalic vein (5), left brachiocephalic vein (1), right cephalic vein (1), and IVC/ iliac/ common femoral veins (1). 1 major, and 4 minor complications occurred related to vascular perforation and resulting contrast extravasation. It was reported that the left brachiocephalic vein was more difficult to recanalize than the right due to its curvature as it crosses the mediastinum. Additionally,

longer occlusions were linked to lower rates of technical success.

[12] Tapping et al. 2012

This case report characterized a patient with an occlusion in the right common iliac artery with claudication symptoms persisting for 3 years. After several failed attempts to cross the occlusion with both normal and stiff Terumo® wires, the PowerWire® Pro RF Guidewire successfully passed through the occlusion. The patient experienced some discomfort due to the RF pulses. On follow up, 7 days after the procedure, the patient presented improvements in claudication symptoms with no complications.

[13] Tavallaei et al. 2018

This publication reported on a bench study conducted to compare the performance of the PowerWire® Pro RF Guidewire versus hydrophobic guidewires in occlusive vascular lesions of various compositions. The performance of three different types of guidewires was evaluated: a conventional standard hydrophilic guidewire vs. PowerWire® Pro RF Guidewire with RF-power (ON) vs. PowerWire® Pro RF Guidewire without RF-power (OFF). Conventional guidewires required forces averaging 0.25 N ± 0.20, while the RF wire, without RF energy, needed 0.62 N ± 0.28 for penetration. However, when the RF wire was used with RF energy, it required a significantly lower force of 0.04 N ± 0.03 for lesion penetration. This substantial difference in force was statistically significant ($p < 0.0002$, one-way ANOVA), indicating the effectiveness of RF energy in reducing the force required for puncturing soft lesions compared to conventional methods.

[14] Tingerides et al. 2016

This retrospective review studied 17 consecutive patients undergoing endovascular treatment for chronic occlusions of the common iliac artery. 10 patients that underwent conventional attempts at revascularization were included in the study and treated with the PowerWire® Pro RF Guidewire. Success, defined as passing the guidewire through the occlusion and into the true lumen with subsequent deployment of a bare metal stent and restoration of flow was achieved in all 10 patients (100%). All but one patient (lost to follow-up) reported resolution of claudication symptoms. One case was complicated by due contrast extravasation with no adverse sequelae after stent insertion.

[15] Yee et al. 2014

This case report investigated a patient experiencing recurrent swelling and pain in the left arm due to a chronic CVO in the left brachiocephalic vein. This patient previously

had 3 failed attempts to recanalize the occlusion before being treated with the PowerWire® Pro RF Guidewire on a subsequent visit. The segment was successfully traversed with vessels remaining patent at 1 and 5 month follow ups. At the 5 month follow up, the patient continued to have a resolution of symptoms.

[16] Majdalany et al., 2019

This retrospective review focusses on using the PowerWire® Pro RF Guidewire for recanalization in patients with chronically thrombosed venous stents that have failed previous attempts at recanalization with conventional and blunt techniques. The study found a 93% success rate in traversing occlusions and restoring anterograde flow, with 63% of procedures relying solely on RF wire recanalization. One procedure that was not initially technically successful was repeated by a more experienced operator successfully. The PowerWire® Pro RF Guidewire's ability to penetrate dense structures within stents is highlighted, although risks such as extraluminal passage exist. Radiofrequency wire recanalization is seen as an effective approach for managing challenging venous occlusions when standard techniques fail.

[17] Neidert et al., 2019

This retrospective study evaluated the effectiveness of the PowerWire® Pro RF Guidewire in recanalizing chronically occluded iliac venous stents. The PowerWire® Pro, delivering radiofrequency energy, was used after conventional guidewires failed. Out of 15 patients, recanalization was successful in 10, with a 62% 6-month and 43% 12-month patency rate. Two complications occurred, including transient footdrop and self-limited iliac artery perforation. The PowerWire® Pro RF Guidewire was deemed effective and relatively safe for recanalizing iliac venous stents.

[18] Shapiro et al., 2022

This retrospective study included 10 patients with symptomatic CICVO (chronic iliocaval venous occlusions) who had failed endovascular attempts at recanalization in both native and stented vessels. Technical success occurred in 60% of patients, and no complications or bleeding requiring blood transfusion were reported. This study suggests that the PowerWire® Pro RF Guidewire can safely and effectively be used in the recanalization and treatment of patients with both stented and native venous occlusions who had failed previous endovascular intervention.

Conclusion

The PowerWire® Pro RF guidewire demonstrates consistent efficacy in vascular recanalization of native and stented vessels, particularly in occlusions unresponsive to conventional techniques, proves effective across diverse anatomical conditions, enables restoration of hemodialysis access, alleviates symptoms arising from vessel occlusions, and requires less force for lesion crossing compared to conventional guidewires.

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