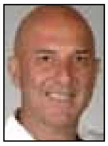
Ruby Detachable Coils

Case reports illustrating the utility of this novel technology.

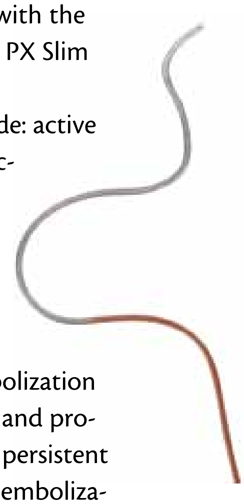


In 1960, Alfred J. Luessenhop and William T. Spence published the first article on embolization entitled "Artificial Embolization of Cerebral Arteries" in the *Journal of the American Medical Association*.[1] It included a detailed case report of a young patient with a cerebral arteriovenous malformation that was treated by artificial embolization using "an embolus of predetermined size and configuration," which was introduced far proximal to the malformation. This described one of the first embolization agents and techniques.

The development and improvement of materials and techniques in recent years has led to a wide spectrum of embolization innovations. Advances in agents for embolization and in catheter and guidewire technology have increased the capability in treating a variety of pathologic conditions that were traditionally treated by surgery. One of the leaders in detachable coil technology, Penumbra, Inc. (Alameda, CA), has released the new Ruby line of detachable coils that are specially designed for peripheral applications.

The peripheral Ruby coils have a controlled mechanical detachment mechanism, which permits the operator to deliver and reposition the coil until the final satisfactory position is reached before detachment. These coils are available in multiple levels of softness, allowing for tight packing without catheter "kick out." Ruby coils have diameters similar to 0.035-inch macrocoils but can be delivered through high-flow microcatheters.[2] In addition, the coil is available in up to 60-cm lengths, reducing the number of devices needed

per case. This allows a high-volume coil to be delivered virtually anywhere, especially when paired with the company's extremely flexible and trackable PX Slim microcatheter.



The main indications for these coils include: active extravasations in patients with trauma, selective embolization in patients with visceral aneurysms (renal, splenic, etc.), exclusion of branches prior to chemoembolization and radioembolization (gastroduodenal and cystic arteries), embolization in patients with gastrointestinal bleeding, embolization of branches prior to stent graft procedures, and procedures after stent grafting in patients with persistent type II endoleaks and sac enlargement. Coil embolization is also used to treat patients with varicocele and pelvic congestion syndrome. Case-based examples of these indications are presented in the following sections of the article.

More than 50 years after the first reported embolization case, we have access to this technology for use in peripheral indications now that it has been perfected in the challenging field of neurovascular interventions.

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1. Luessenhop AJ, Spence WT. Artificial embolization of cerebral arteries. Report of use in a case of arteriovenous malformation. J Am Med Assoc. 1960;172:1153-1155.
2. Data on file at Penumbra.

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The goal of new technology is to positively impact the way we practice intervention and outcomes for the patient. Penumbra's new Ruby coil is the most unique embolization system on the market. The ability to deploy such a large-volume coil through a microcatheter allows for embolization with fewer coils, even in difficult and tortuous anatomy. Unlike other detachable coils, Ruby is compatible with high-flow microcatheters, allowing for better imaging. Also, having the option of switching to softer coils eliminates the problem of catheter kick out.

CASE REPORT

The patient presented with a hepatic artery aneurysm on CT imaging. Angiography revealed a large 3.8-cm aneurysm (Figure 1). To preserve the hepatic artery, we decided to coil the outflow and sac. Nine 60-cm Ruby coils were placed in the aneurysm in < 30 minutes (Figure 2). The long lengths and large diameters (up to 32 mm) held the coils in place against high flow. The large volume and thrombogenic nature of platinum eliminated the need for fibers, as we saw angiographic stasis after the final coil was placed (Figure 3).

The patient was discharged the next day, and follow-up CT scans show the aneurysm to be excluded. He is asymptomatic.

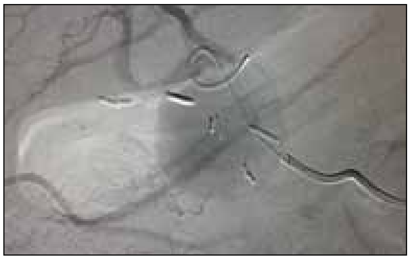

Figure 1. Angiogram showing a large hepatic artery aneurysm.

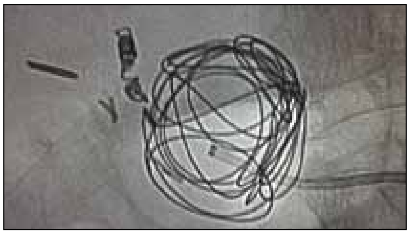

Figure 2. Small coils are in the left hepatic artery distal to the aneurysm. This prevents backflow into the aneurysm. The large coils are Penumbra coils in the aneurysm sac.

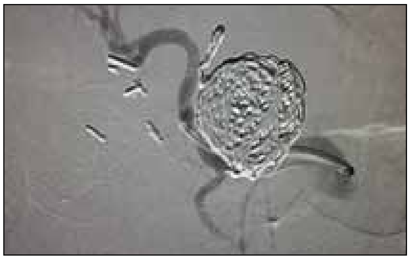

Figure 3. The aneurysm is now completely packed with excellent flow distal to the aneurysm in the right hepatic artery.

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The need to reduce procedure times and improve efficiency within operating rooms and vascular labs has become more important than ever before. This improvement in efficiency is coupled with maintaining excellent clinical outcomes. In order to accomplish this, we need to utilize the proper tools. With regard to coil embolization, Penumbra's new Ruby coil is valuable in this regard. It is the largest-volume coil available, while maintaining excellent deliverability. Ruby can be used in a variety of vascular beds because it can be delivered through high-flow microcatheters. The coil is easily deployed in even severely tortuous anatomy. The large volume, lengths, and controlled detachment have allowed for faster and more efficient embolizations. Most recently, I used them in an emergent case described here.

CASE REPORT

An 82-year-old man with chronic kidney disease had a hypotensive episode while traveling from New York to South

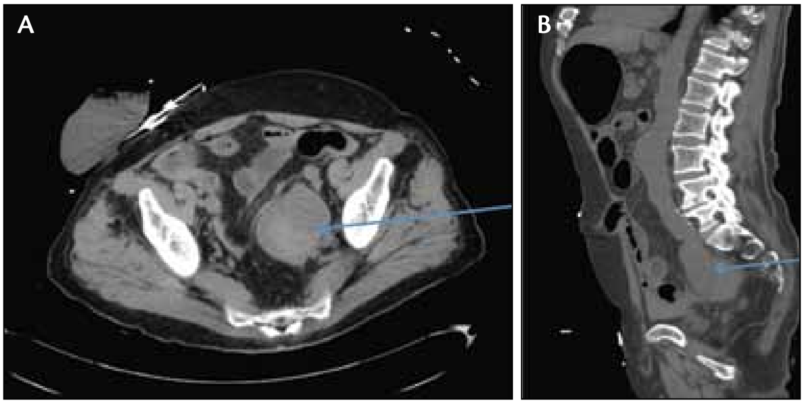

Figure 1. Contrast CT imaging before repair (A) and sagittal view (B).

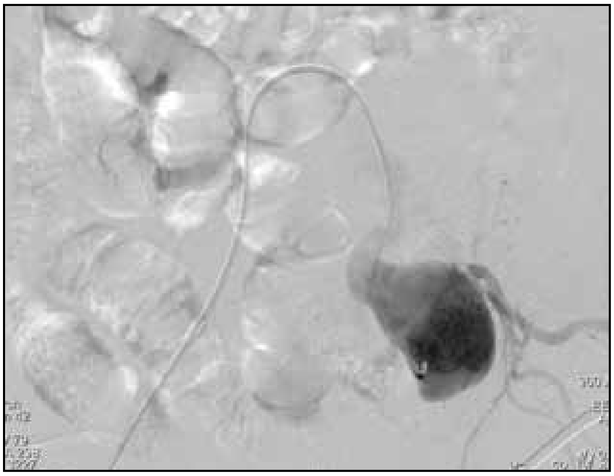

Figure 2. Angiography before repair.

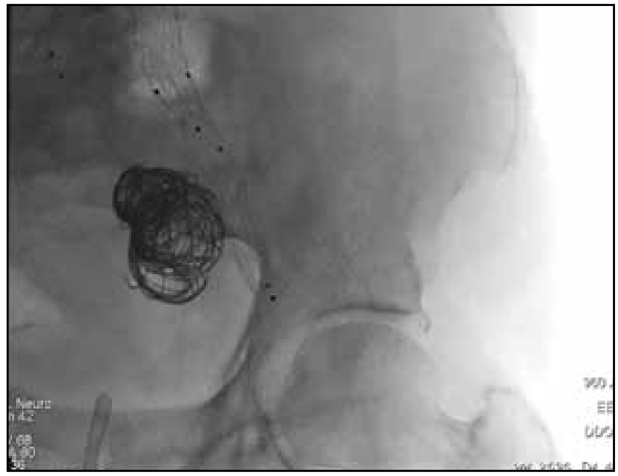

Figure 3. Angiography after repair.

Carolina and was hospitalized in a small South Carolina hospital while on anticoagulation. Noncontrast CT was performed, and he was told that he had some internal bleeding. The patient was managed nonoperatively and remained on warfarin. He was discharged from the hospital 5 days later after feeling slightly better. While in the process of flying back to New York, he lost consciousness at the airport. He was then transported emergently to Carolinas Medical Center.

The patient presented with hypotension, a creatinine value of 5 mg/dL, and contrast CT showing a large left pelvic hematoma associated with a 6-cm ruptured internal iliac aneurysm (Figure 1). Utilizing a C2 Glide catheter (Terumo Interventional Systems, Inc., Somerset, NJ) with the Penumbra's PX Slim microcatheter (Figure 2), the left internal iliac artery was rapidly cannulated. The aneurysm was treated emergently with six Ruby coils measuring 24 mm X 57 cm (two coils), 20 mm X 60 cm (two coils), and 18 mm X 57 cm (two coils).

I was able to deliver 348 cm of coil in < 10 minutes (Figure 3). The orifice of the internal iliac was covered with an Endurant stent graft (Medtronic, Inc., Minneapolis, MN). The patient did well, slowly recovered from his acute kidney injury, remained off of dialysis, and was discharged home 8 days later. Follow-up CT showed that the hematoma had resolved, and the aneurysm was decreasing in size (Figure 4).

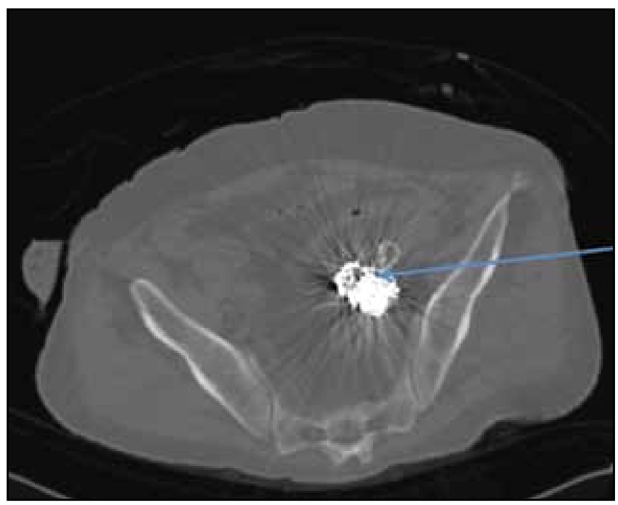

Figure 4. CT imaging after repair.

For my practice, this coil system will be useful in treating visceral aneurysms, type 2 endoleaks, and coiling hypogastric or inferior mesenteric arteries pre-EVAR.

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A great deal of evidence has been reported on the success of densely packing cerebral aneurysms with coils.[1] The debate of how to treat visceral aneurysms and pseudoaneurysms is ongoing. Although packing density is one of the most important metrics when coiling cerebral aneurysms, detailed attention to the percentage of packing has not been given the same importance when treating visceral aneurysms. Occluding the inflow and outflow of pseudoaneurysms may be enough, but true aneurysms need to be fully embolized. I believe Penumbra's new Ruby coil gives the operator the right tool to efficiently and effectively embolize aneurysms. The extremely long lengths and large diameters allow for higher packing densities with fewer coils. Additionally, because of their extreme softness when compared to other peripheral detachable coils, catheter kick out is not an issue. Both of these benefits are demonstrated in the following case.

Figure 1. CT showing a 2.4-cm aneurysm.

Figure 2. Visualization of the aneurysm via the PX Slim microcatheter.

CASE REPORT

A 2.4-cm aneurysm was observed via CT (Figure 1). The celiac artery was selected using a Simmons-shape diagnostic catheter over a 0.035-inch guidewire. A PX Slim microcatheter was then tracked over a 0.016-inch wire to the aneurysm. The 0.025-inch lumen of the PX Slim device allows for good visualization of the artery and aneurysm (Figure 2). The splenic artery aneurysm had a wide neck, and we would have typically stented across it. By deploying and withdrawing the first two coils multiple times, the coils were placed well within the aneurysm with multiple loops covering the neck, and the use of a stent was avoided. With a total of six coils, a 42% packing density was achieved (Figure 3).

In addition to the new line of Ruby coils, Penumbra has already added some new unique configurations. The new 8-mm X 60-cm soft coil has allowed for very efficient and tight packing in a range of vessels. I think new tools like these will make embolization procedures much more efficient. To prove this hypothesis, Penumbra is also conducting the Aneurysm Coiling Efficiency (ACE) trial. Beyond clinical outcomes, the trial will study the number of coils and fluoroscopy time for cerebral and visceral embolizations.

Figure 3. After six coils were placed, a 42% packing density was achieved.

1. Molyneux AJ, Kerr RSC, Yu LM, et al; for the International Subarachnoid Aneurysm Trial (ISAT) Collaborative Group. International subarachnoid aneurysm trial (ISAT) of neurosurgical clipping versus endovascular coiling in 2,143 patients with ruptured intracranial aneurysms: a randomised comparison of effects on survival, dependency, seizures, rebleeding, subgroups, and aneurysm occlusion. Lancet. 2005;366:809-817.

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The Penumbra Ruby coil system offers unique benefits for vessel sacrifice situations. The softness profile allows the coil to fall into side branches, occluding them, but also anchoring the coil in place. The operator can then ride the microcatheter over the coil into those side branches for further occlusion. Having standard and soft coil options also allows the operator to tailor the packing density. By placing forward pressure on the microcatheter, the operator can achieve a denser pack, whereas pulling back will allow a looser pack over a longer length of vessel. Oversizing in arteries is not necessary because standard coils in long lengths create enough friction for the coil to stay in place. For veins, I recommend using coils equal to twice the diameter of the vessel. After the first coil is in place, I use 60-cm-long coils, regardless of diameter, to efficiently embolize the vein. If you do not have stable microcatheter position, I suggest using the soft coils to eliminate catheter kick out.

CASE 1

Ovarian Vein Embolization

A 48-year-old woman presented with a 2-year history of chronic pelvic pain. She was evaluated by her gynecologist and a vascular surgeon and was diagnosed with pelvic congestion syndrome.

A CT scan demonstrated a dilated left ovarian vein and left-sided pelvic varices (Figure 1). Traditionally, these veins are embolized with conventional "pushable" coils. However, this procedure can be time-consuming, and there is not always an optimal ability to control the placement of conventional embolization coils. Therefore, detachable Penumbra coils were used (Figure 2). The large diameter and lengths of these coils allowed faster and more accurate embolization. The softness profile also gives the coil excellent packing characteristics. The Penumbra catheter maintained its position and responsiveness throughout the procedure.

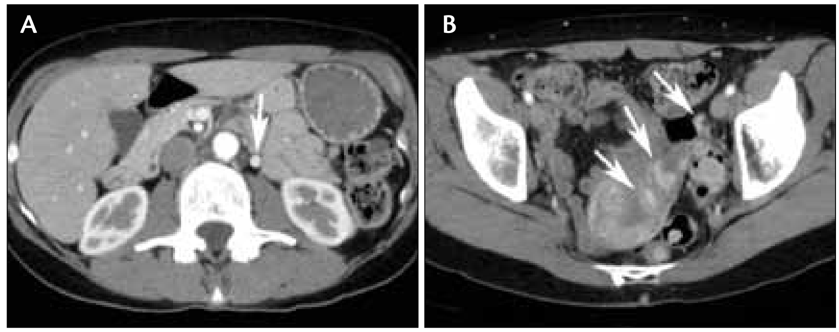

Figure 1. Left ovarian varices. Preprocedural axial-enhanced CT image through the abdomen demonstrates a dilated left ovarian vein (arrow, A). CT through the pelvis delineates the left pelvic varices (arrows, B).

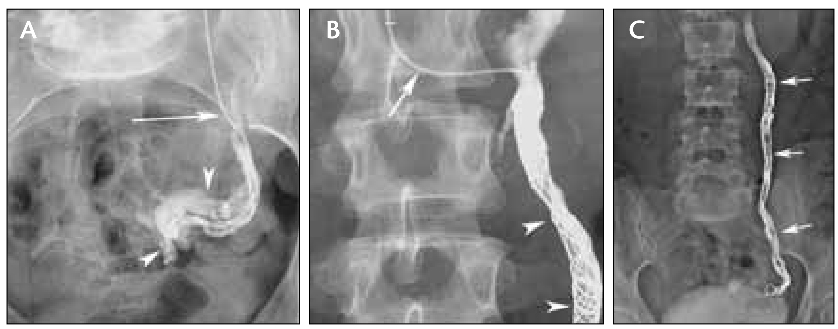

Figure 2. Ovarian vein embolization with Penumbra coils. (Angiographic image obtained with the Neuron 053 (arrow) deep in the left ovarian vein in the region of pelvic varices (arrowheads) (A). A PX400 microcatheter (Penumbra, Inc.) (arrow) was used to deploy Penumbra coils (arrowheads) (B). Postprocedural image delineates Penumbra coils (arrows) along the length of the left ovarian vein (C).

CASE 2

Embolization of an Accessory GDA Vessel Before Treatment of Hepatic Cellular Carcinoma

In this case, the Penumbra Neuron 053 guide catheter was utilized to gain stable access while coiling the gastroduodenal artery (GDA) (Figure 3). After selectively cannulating the celiac artery, the Neuron 053 was advanced over a standard 0.035-inch guidewire. The GDA was selected with a guidewire and the Penumbra microcatheter, and the vessel was occluded instantaneously with three coils. Again, we were able to create a tight pack of coils because of the softness and accuracy of the Penumbra coil and stable catheter position of the Neuron guide catheter. Due to its compatibility with high-flow microcatheters, I was able to obtain a high-quality angiogram and deliver coils through one catheter. With the new longer Ruby coils, we are able to embolize the GDA with a single coil (4 mm X 35 cm). ■

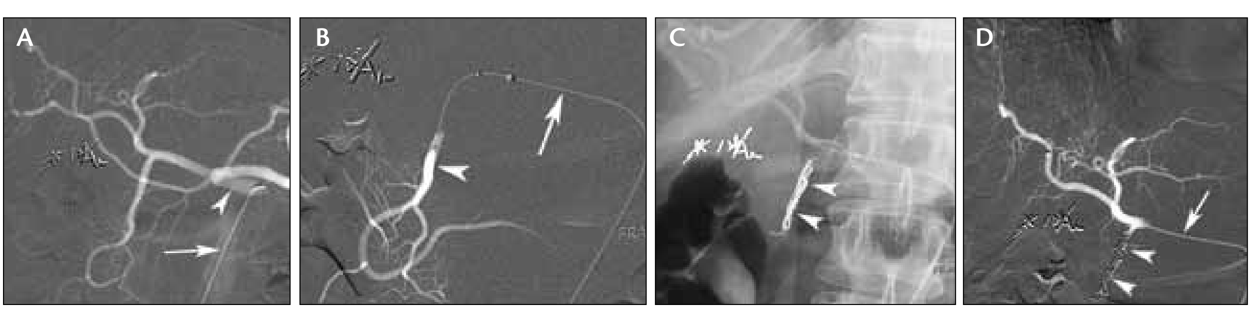

Figure 3. GDA embolization utilizing Penumbra coils. Celiac artery (arrowhead) is selected using the Neuron 053 and 0.035-inch guidewire (arrow) (A). The GDA (arrowhead) is selected using the Penumbra microcatheter and a 0.016-inch guidewire (arrow) (B). Three Penumbra coils (arrowheads) embolize the GDA prior to chemotherapy delivery (C, D).