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A Mechanically Detachable Coil for the Treatment of Aneurysms and Occlusion of Blood Vessels

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PURPOSE: To evaluate mechanically detachable coil designs capable of controlled and instantaneous release within an aneurysm or vascular space. **METHODS:** Three mechanically detachable coil designs, clamped ball, looped ribbon, and interlocking cylinder, were evaluated using in vitro and in vivo testing to study reliability of coil release, retractability, and coil behavior in a microcatheter. In vitro tests were performed using a glass side-wall aneurysm model and conventional microcatheters. In vivo experiments in rabbits included aneurysm models (side-wall and bifurcation) and arterial occlusions (carotid and renal). **RESULTS:** All three designs deployed coils easily and were able to retract coils after partial deployment. Motion was seen in previously released coils and in the catheter when using the clamped ball and looped ribbon designs. The interlocking cylinder design did not cause similar motion. When compared with the other two designs, the interlocking cylinder had significantly greater separation forces between coil pusher and coil while in the catheter. Frictional forces within the catheter were lower for the interlocking cylinder mechanically detachable coil design than for a commercially available conventional coil and coil pusher system. During in vivo testing, the mechanically detachable coil design operated smoothly in the catheter, providing good release and retraction in aneurysms and straight vessels. **CONCLUSION:** The interlocking cylinder mechanically detachable coil design is superior to the other two tested designs. The mechanically detachable coil was reliably delivered and detached in in vivo testing for the treatment of aneurysms and for the occlusion of blood vessels.

Index terms: Interventional instrumentation, coils; Interventional neuroradiology, models; Anyeurism, therapeutic blockade; Arteries, therapeutic blockade; Animal studies

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Conventional coils have been used in a variety of clinical settings to achieve thrombosis of a blood vessel or a vascular space with an endovascular approach. Vascular lesions that have been treated with conventional coils include aneurysms, arteriovenous malformations, and arteriovenous fistulas (1–6). Conventional coils are not directly attached to the coil pusher, so there are inherent risks with their placement. The coil cannot be retrieved once it is released into an aneurysm or blood vessel. Therefore, the released coil may protrude into a parent vessel when placed in an aneurysm (6). In addition, if an incorrect coil size is chosen to perform an embolization procedure, the coil cannot be retracted once partially ejected. Similarly, if a particular coil proves unstable in a blood vessel or other area of high flow, it cannot be repositioned or retracted (7). For these reasons, coil embolization procedures would be improved if coils could be modified to allow for their retraction. One recently described modification has been the development of retractable coils that are electrolytically detached from the coil pusher (8). We report the development of a mechanically detachable coil, which allows for instantaneous release of the coil from the coil pusher mechanism as the last portion of the coil leaves the catheter, and the results of testing it in vitro and in an animal model.

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Materials and Methods

In Vitro Testing

Initial in vitro testing was done with three different detachment mechanism designs (Fig 1). Two designs hold the coil with a coil pusher that has swinging arms. These

arms are radially compressed while within the diameter of the catheter, allowing the coil pusher to grasp the coil. Once the coil and the coil pusher protrude from the distal portion of the catheter, the arms assume an open configuration, releasing the coil from the pusher. These two designs were the clamped ball and looped ribbon. A third design, interlocking cylinders, uses a radial enlargement of the distal end of the coil pusher and proximal end of the coil. These two ends of the device are opposed in the catheter so that the cylinder attached to the coil cannot travel beyond the coil pusher until fully ejected (Fig 1).

The distal portion of the mechanically detachable coil beyond the detachment mechanism on all three mechanically detachable coil designs is similar to other commercially available platinum coils with a diameter of 0.015 inches and a three-dimensional shape memory. While within the catheter, the coil assumes a straight shape that allows it to be pushed through the length of the catheter. Outside the catheter it assumes a complex three-dimensional shape. Coil shapes used with the clamped ball and looped ribbon designs included a hypocycloidal or pretzel shape and a simple helical design. These shapes were used because prior experience indicated they were efficacious in the occlusion of vascular spaces (1, 2, 6, 8). The interlocking cylinder design was tested with the simple helical design shape. Variable shapes were used in this experiment to evaluate the behavior of the release mechanism in the catheter at the time of deployment. Variable coil shapes would not affect an evaluation of the release mechanism itself.

The sizes of the hypocycloidal-shaped coils used were 3 mm × 6.0 cm, 4 mm × 6.0 cm, and 5 mm × 5.0 cm (diameter of one turn of the coil times total length of the coil). The simple helical shapes used were 4 mm × 6.0 cm and 8 mm × 40 cm in diameter. All coils were constructed from 0.003-in-diameter platinum wire provided by the same source (Target Therapeutics). This wire stock is

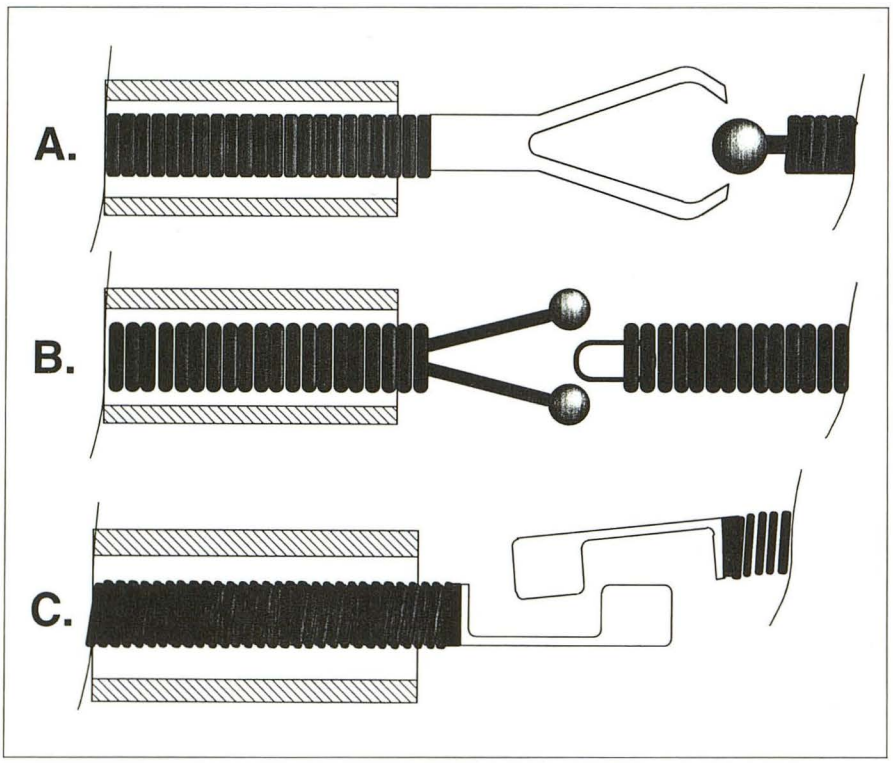

Fig. 1. The three coil-release mechanisms used in the mechanically detachable coil. The coil pusher is shown to the *left* as it is leaving the catheter with separation between the distal end of the coil pusher and the proximal end of the coil shown to the *right* in each of the three designs.

A, Clamped ball design. The proximal end of the coil has a small ball attached to it, which is kept in place by the swinging arms of the distal end of the coil pusher while within the catheter. The arms widen after leaving the distal end of the catheter and release the coil from the coil pusher.

B, Looped ribbon design. The proximal end of the coil with this design is modified by attaching a strip of metal ribbon. This is shown from above in the diagram. While within the catheter the two smaller balls at the end of the coil pusher are compressed and sit within the open center of the looped ribbon. As the coil pusher is pushed beyond the length of the catheter, the arms widen on the coil pusher and release the coil.

C, Interlocking cylinder design. The coil and coil pusher are interposed while within the catheter so that the cylinder attached to the coil is not capable of traveling or escaping beyond the cylinder attached to the coil pusher until the device is pushed out of the catheter, effecting separation.

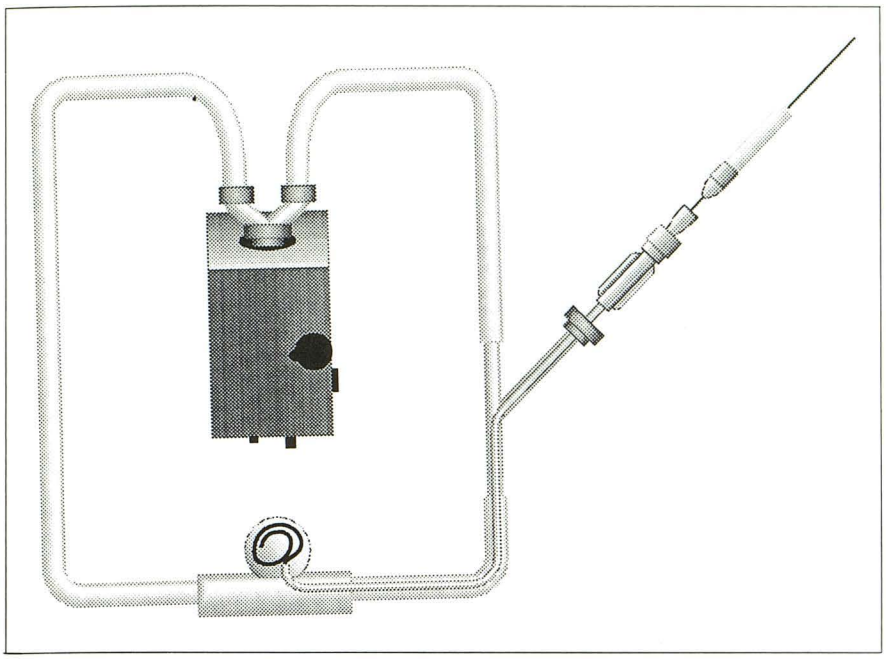

Fig. 2. Pulsatile flow system used to test coil placement in a glass model of aneurysms. A Tracker 18 catheter is introduced via a Y connector into the glass aneurysm after steaming a small curve into the distal end.

wound into a primary coil measuring 0.015 inches in diameter.

Coil designs were evaluated in three stages. In the initial stage the three coil designs (clamped ball, looped ribbon, and interlocking cylinder) were tested in a glass model of aneurysms. Diameters of glass aneurysms were 5 mm, 8 mm, and 1.0 cm. Each aneurysm size was evaluated with two to four trials of coil placements. The aneurysms were connected via 5-mm-diameter tubing to a pulsatile pump set at 70 beats per minute, 5 mL per beat (model 1421, Harvard Apparatus, South Natick, Mass). This yielded a flow rate of 350 mL/min, similar to measured flow rates in the carotid artery (9). A 2.2-F Tracker 18 microcatheter (Target Therapeutics) was introduced into the glass aneurysm (Fig 2). The mechanically detachable coils were then inserted into the glass aneurysm. The 5-mm aneurysm was tested with 3 mm × 6.0 cm and 4 mm × 6.0 cm hypocycloidal coils and 4 mm × 6.0 cm simple helical coils. The 8-mm aneurysm was tested with 4 mm × 6.0 cm and 5 mm × 5.0 cm hypocycloidal coils and 4 mm × 6.0 cm simple helical coils. The 1.0 cm aneurysm was tested with 5 mm × 5.0 cm hypocycloidal coils and 8 mm × 40 cm simple helical coils. The following performance characteristics were evaluated: ability to fully eject coils, ability to retract coils after partial ejection, catheter motion at the time of ejection, and coil motion at the time of ejection.

In the second stage of evaluation, the static release forces of the three coil designs were tested with the coils inside the microcatheter using an Instron tensile tester (model 4201, Instron, Boston, Mass). The release force measurements were made in the distal clear section of a Tracker 18 catheter and represented the force required to separate the coil from the coil pusher after the coil had been partially ejected and was being retracted.

The coil release mechanism judged to have the best performance characteristics during stages 1 and 2 was then evaluated for pushability, or frictional resistance, while within the microcatheter system during the third stage of in vitro evaluation. In this stage of the testing, the mechanically detachable coil design was placed in a catheter aligned in a tight figure-eight test path, and the force required to advance the coil and pusher 50 cm was measured with an Instron tensile tester. The mechanically detachable coil was compared with a conventional coil and coil pusher assembly in the same test path (Fibered coils, Target Therapeutics). A conventional coil and pusher assembly were chosen for comparison with the mechanically detachable coil design to allow a reference to a widely available and commonly used coil system. Mechanically detachable coils tested were simple helical coils sized 2 mm × 4 cm and 8 mm × 40 cm. The conventional coils tested were fibered coils 2 mm × 1.0 cm and 20 mm × 10 cm (vein of Galen aneurysm coil). Release forces and push forces were evaluated statistically using analysis of variance.

In Vivo Testing

New Zealand white rabbits weighing 3.5 to 5.0 kg were used for in vivo testing of coil release with an arterial bifurcation aneurysm model (10) or a side-wall aneurysm model. The protocol for animal testing was approved by the Stanford University Animal Panel for Laboratory Animal Care. In both models intramuscular xylazine (5 mg/kg) and Ketamine (35–50 mg/kg) were administered before surgery. Rabbits were then intubated, and anesthesia was maintained with 2% to 3% halothane throughout the procedure. A midline incision was made in the rabbit's neck from the sternum to the angle of the jaw in order to create both aneurysm types. A small segment of the left external jugular vein was isolated to be used in both models as the vein pouch for the surgically created aneurysm. Bifurcation

aneurysms were made using a previously described model to ligate the left common carotid artery and anastomose it to the right common carotid artery (end-to-side anastomosis). The jugular vein segment was then placed into the surgically created bifurcation (10). Side-wall aneurysms were produced by exposing the right common carotid artery where an elliptical arteriotomy was made. A vein pouch was created in the same way as was done for the bifurcation aneurysm model, and this was then sewn into the elliptical arteriotomy site. Interrupted 10–0 monofilament nylon sutures were used for all anastomosis sites.

The animals were allowed to recover. Carotid angiography was then performed 2 to 6 weeks later via a femoral artery cut down. Animals were sedated with a mixed solution of Ketamine (50 mg/kg), xylazine (5 mg/kg), and acepromazine maleate (1 mg/kg) given intramuscularly before starting the procedure. A Tracker 18 catheter was introduced into the right carotid artery, and an angiogram was obtained to determine whether the aneurysm remained patent. Then the Tracker microcatheter was placed into the aneurysm using a Taper 14 flexible tip guide wire (Target Therapeutics). Coils were then placed into the aneurysm to achieve thrombosis or significant slowing of flow of contrast into and out of the aneurysm. Coil diameters were chosen to match the measured diameters of the aneurysm as determined from the angiogram. Aneurysms varied in size from 4 × 6 mm to 7 × 15 mm. Coils varied from 2 mm × 1 cm to 8 mm × 20 cm. The in vivo tests used hypocycloidal and simple helical shapes for clamped ball and looped ribbon designs; the interlocking cylinder design was tested with the simple helical shape.

As with the in vitro testing, the following performance characteristics were evaluated: ability to retract coils after partial release, ability to eject coils fully, catheter motion, and coil motion at the time of release. When the surgically created aneurysm was found to have been occluded, a carotid or renal artery was catheterized with the microcatheter, and coil behavior in the vessel lumen was evaluated, again testing for releasability, retractability, and coil or catheter motion.

Results

In Vitro Studies

All three release mechanisms were able to retract the coil after nearly full ejection when evaluated in the glass model of aneurysms. All released the coil easily. When multiple coils were introduced, the arms of the coil pushers of the clamped ball and looped ribbon designs were observed to occasionally grab or grasp a coil segment within the arms of the coil pusher as the coil pusher was retracted into the catheter after ejecting a coil. This intermittent occurrence resulted in movement of the nest of coils. The interlocking cylinder design showed no propensity to grab or move coils previously placed into the glass model. In addition, the clamped ball and looped ribbon designs were observed to move the catheter tip slightly at the time of disengagement. However, this did not displace the catheter tip from the aneurysm. The interlocking cylinder design was smooth at the time of release, and no catheter movement was observed.

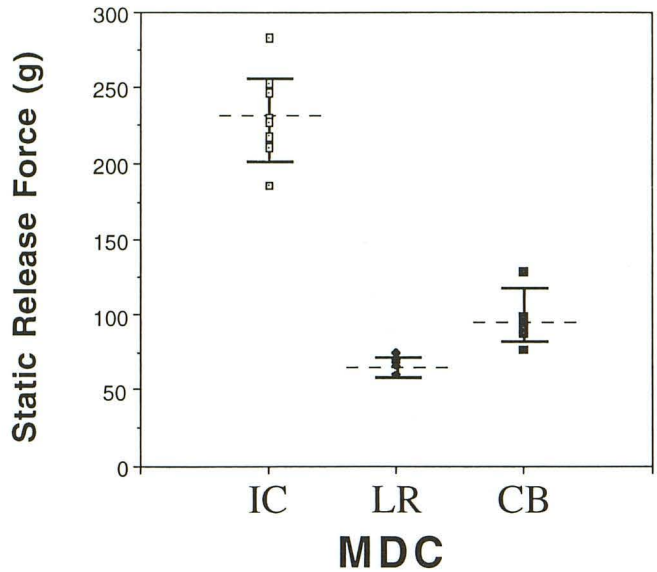

Fig. 3. Static release force in grams for the three coil designs: interlocking cylinder (IC), looped ribbon (LR), and clamped ball (CB). Ten measurements were made for the interlocking cylinder design, nine for the clamped ball design, and five for the looped ribbon design. The *dashed line* indicates the mean. For the interlocking cylinder the mean was 228 ± 27, for the looped ribbon 68 ± 4, and for the clamped ball 97 ± 20.

Figure 3 shows the static release force necessary to cause separation of the coil from the coil pusher while within the most pliable distal clear section of a Tracker 18 catheter. All three designs demonstrated consistent release forces with multiple trials. However, the interlocking cylinder design had significantly greater release forces ($P = .0001$) than the other two designs. The clamped ball and looped ribbon designs released before the coil itself became distorted by the applied release force. The interlocking cylinder mechanically detachable coil required a static release force (mean, 228 g) that distorted and unraveled the coil before separating the junction between the coil pusher and the coil.

On the basis of the results obtained in the first two stages of testing, the interlocking cylinder design was chosen for push-force testing. Table 1 shows the push forces (in grams) required to move the interlocking cylinder design 50 cm through the catheter with 2 mm × 4 cm and 8 mm × 40 cm simple helical coils. These forces

TABLE 1: Push forces for mechanically detachable coil and conventional coil

Coil Type	Push Force (g)[a]
Fibered coil (2 mm × 1 cm)	81 ± 14
Fibered coil (20 mm × 10 cm)	113 ± 17
Mechanically detachable coil[b] (2 mm × 4 cm)	15 ± 2
Mechanically detachable coil[b] (8 mm × 40 cm)	15 ± 3

[a] Force required to advance coil/coil pusher 50 cm in Tracker 18 (see text). Numbers represent mean (for five separate measurements with each coil) ± SD.

[b] Interlocking cylinder design.

were compared with conventional fibered coils (2 mm × 10 mm and 20 mm × 10 cm), with a hypocycloidal shape. Conventional coils may require greater push force because of the fiber and/or their different geometric shapes. However this comparison between mechanically detachable coils and conventional coils was made to use a standard reference of commercially available coils. The mechanically detachable coils were found to require significantly lower push strengths ($P = .0001$) than conventional designs.

In Vivo Evaluation

Table 2 shows the aneurysms or blood vessels treated with the various coil release mechanisms. A total of 20 rabbits that underwent surgery for aneurysm creation were studied by angiography. Four animals had side-wall aneurysms treated with mechanically detachable coils, and four had bifurcation aneurysms treated with mechanically detachable coils (Fig 4). In animals with thrombosed aneurysms, seven carotid arteries and five renal arteries (Fig 5) were also evaluated with mechanically detachable coils.

The release mechanism for the clamped ball and looped ribbon designs showed reliable separation between the coil and coil pusher after full ejection. The coils could be ejected and retracted using these designs. However, after coil release the jaws of the coil pusher would sometimes grasp a portion of the released coil as the coil pusher retracted into the catheter, causing the displacement of previously inserted coils. As with the in vitro experiments, the catheter was observed to move or jump slightly at final release of the coil using either design. This movement of the catheter did not, however, cause significant displacement of the catheter while within either an aneurysm or blood vessel.

The interlocking cylinder design reliably released the coil at full ejection. It was easily retracted, and no separations were observed between the coil and coil pusher while within the catheter. This proved true in both the aneurysm and blood vessel evaluations. Multiple interlocking-cylinder mechanically detachable coils effectively treated both the side-wall aneurysm and the bifurcation aneurysm (Fig 4). No significant movement of the catheter was observed at separation.

Discussion

All three detachment mechanism designs for the mechanically detachable coil proved capable of retracting and releasing coils in a conventional microcatheter system at the time of in vitro and in vivo testing. However, the interlocking cylinder coil design demonstrated advantages over the two designs that used swinging arms. The swinging arms proved in both in vitro and in vivo testing to be capable of grasping or grabbing portions of the coil, thus causing displacement of a coil or nest of coils after correct placement. In addition, as the swinging arms left the catheter tip and expanded their radial diameters, there was a slight movement in the catheter. Although this did not cause any catheter displacement during the in vivo testing, it could possibly cause a catheter to change position after coil placement, thus requiring repositioning and manipulation of the catheter. No motion in previously released coils or in the catheter was seen with the interlocking cylinder design. In addition, the interlocking cylinder device also demonstrated significantly greater separation strengths while within the catheter than the other two designs. This separation strength proved greater than the force required to distort or unravel the coil itself, making premature separation of the device unlikely if retraction of the mechanically detachable coil is required. The mechanically detachable coil design

TABLE 2: Aneurysms and arteries treated with the mechanically detachable coil

	Coil Type			Total
	Clamped Ball	Looped Ribbon	Interlocking Cylinder	
Side-wall aneurysm	0	0	4	4
Bifurcation aneurysm	3	0	1	4
Carotid artery	1	3	3	7
Renal artery	0	3	2	5
Total	4	6	10	20

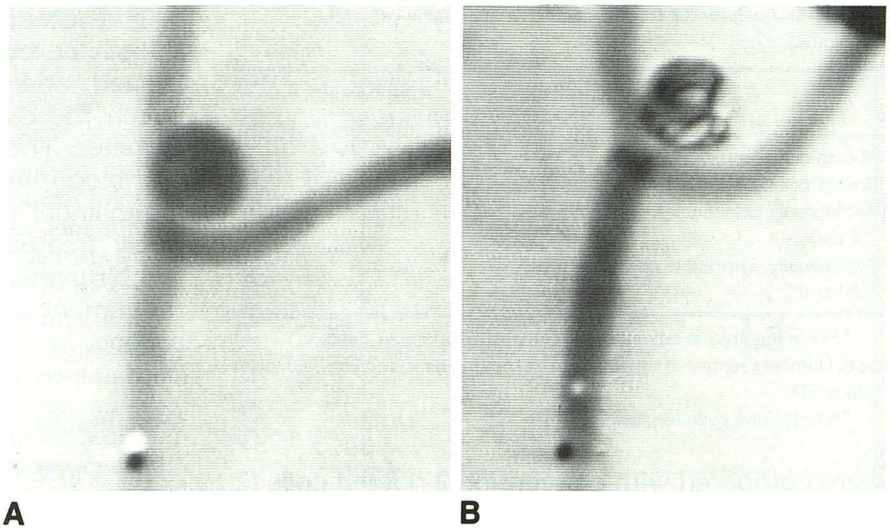

Fig. 4. Bifurcation aneurysm measuring 6 mm × 6 mm.

A, Angiogram from the right carotid artery shows the surgically created anastomosis between the left and right carotid artery and the aneurysm at the bifurcation of this anastomosis.

B, Angiogram from the right carotid artery obtained after coiling. Two mechanically detachable coils were used with the interlocking cylinder design, 4 mm × 10 cm and 4 mm × 6 cm. Contrast was noted in some areas of the aneurysm; however, the flow of contrast was observed fluoroscopically to be significantly slower.

with interlocking cylinders also showed significantly lower frictional push forces than commercially available conventional fibered coils. Conventional coils of shorter lengths with fiber were used in this experiment to provide a standard of comparison with commonly used, commercially available coils. Despite the use of conventional coils of shorter lengths, the frictional push forces needed to advance the larger mechanically detachable coils were lower. This difference relates to the fiber present and also may be affected by the geometric differences in shape between the two coil types.

The controlled release mechanism of the mechanically detachable coil allows for a margin of safety not previously available with conventional coil systems in that the coil can be retracted and repositioned even after nearly complete ejection. If coil positioning, stability, or size are not judged adequate, this can be corrected. Another retractable coil design, the Guglielmi detachable coil design, has recently been reported in an animal model (8) and has shown great promise in the treatment of a series of patients with aneurysms (11). The Guglielmi detachable coil design makes use of electrolysis to dissolve an uninsulated portion of stainless steel core wire and effect separation of the coil from the coil-pusher segment. Electrolysis takes 4 to 12 minutes to separate the coil and coil-pusher segments, with longer times required as more coils are placed (11). The mechanically detachable coil design achieves separation immediately with full ejection. The Guglielmi detachable coil creates a positive charge at the time of electric current application, which attracts negatively charged blood particles causing electrothrombosis (8). It is not clear how much of the observed thrombosis is the result of electrothrombosis or vascular stasis from packing of coils into a vascular space. It has

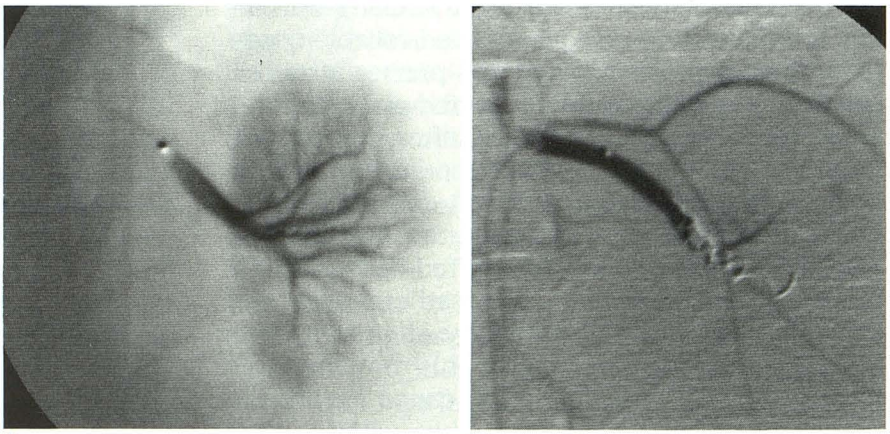

Fig. 5. *A,* Left renal artery angiogram before coiling.

B, Left renal artery angiogram after coiling demonstrating occlusion of the distal main renal artery. One interlocking-cylinder 5 mm × 20 cm mechanically detachable coil was placed.

been observed that intraaneurysmal thrombosis progresses after detachment using this coil system (11). Endovascular coil procedures are generally performed using systemic heparinization to impede blood clot formation at the time of placement; it is not clear whether there is an advantage to having thrombus form at the time of each coil placement. More clinical and experimental investigation is required to determine the best timing for thrombosis and the need to enhance thrombosis with electric current, alteration in the coil skeletal material, or coating of coils.

Conventional coils have been used in a variety of endovascular settings, including the treatment of aneurysms (1, 2, 6). Before the treatment of aneurysms with coils, balloon embolization had been the only endovascular treatment available (12–14). Several risks have been associated with balloon embolization. These include rupture of the balloon, inability to navigate the balloon into a stable location, migration of the balloon after placement into aneurysmal clot, and rupture of the aneurysm after balloon embolization (2, 13–15). Some researchers believe that platinum coils are less traumatic to the aneurysm during endovascular treatment than balloons (11). Platinum was chosen for the mechanically detachable coils because it proved to be a softer pliable metal with some degree of thrombogenicity (5, 8).

In conclusion, a mechanically detachable coil system that provides instantaneous coil release at the time of coil placement has been developed. The mechanically detachable coil design with interlocking cylinders has separation strengths that make premature release while within the catheter highly unlikely. The mechanically detachable coil requires very low frictional push forces compared with conventional coils. In addition, coils may be retrieved or repositioned at the time of placement. Finally, the mechanically detachable coil design has been shown to work well in a rabbit model of aneurysms and straight vessels.

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