A new device developed at UW-Madison may lead to a safer, more effective treatment for aneurysms

By Victoria Yakovleva and Stephanie Dar

One morning, while making breakfast, you spill a little milk. To clean up the mess, you rip off tiny pieces of paper towel and place them on the puddle, one by one.

This inefficient process is similar to the current aneurysm treatment available for patients.

An aneurysm is a balloon-like dilatation in a blood vessel wall. This dilatation can form in any vessel throughout your body; however, Dr. Roham Moftakhar, chief resident in the UW-Madison neurological surgery department, is specifically concerned with cerebral aneurysms.

"These aneurysms take place because the [blood vessel] wall in your brain gets weakened, and it sort of blisters out, and when it blisters out there is a risk of rupture," Moftakhar says.

When an aneurysm ruptures, blood flows out into the area of the skull surrounding the brain. There’s often quick onset of a headache—the worst headache of a person’s life. Half the people with a ruptured aneurysm, Moftakhar says, never make it to the hospital—they die at home.

In the other half, the puncture is blocked off by clotted blood, thus containing the aneurysm. These patients can make it to the hospital in time for surgery.

However, the procedures that are currently used in the operating room, endovascular coiling and open surgery clipping, are often inefficient and unsafe.

Endovascular coiling involves “a bunch of wire [coils] that they just randomly shove into the aneurysm,” Wendy Crone, professor of engineering physics at UW-Madison who partnered up with Moftakhar, says.

A catheter is a thin, hollow, flexible tube that is inserted through a blood vessel in the groin and guided through the venous system, with the help of an imaging technique called fluoroscopy. Small metal coils are then deposited through the catheter into the aneurysm to block off blood flow. This process can take anywhere from two to eight hours.

According to Kristyn Masters, professor of biomedical engineering at UW-Madison who later joined Moftakhar’s team, the metal coils are about three times the diameter of a human hair. They are made out of Nitinol, a shape-memory alloy that can be treated to remember a specific shape. Even after being straightened for travel through the catheter, the coils return to the predetermined shape inside the aneurysm.

However, this procedure is relatively unsafe.

“Every time you introduce a new coil, it’s more risk of death—more risk of complications—because it’s essentially many procedures all in a row,” Masters says.

Another risk of endovascular coiling is coil compaction, the result of blood flow pressure pushing the coils deeper into the aneurysm. According to Masters, 30 percent of aneurysms treated with endovascular coiling undergo coil compaction, which may “lead to enlargement or rupture of the aneurysm.”

“The method is also] really imprecise in terms of they don’t even know how many coils they’re going to use [and] how long it’s going to take. It’s just shove coils in there until it’s full, and that’s not how engineers like to do things,” Masters says.

The other treatment available to block off blood flow to the aneurysm is open surgery clipping. This extravascular procedure in-
volves removing a piece of the patient’s skull, locating the aneurysm, then “clipping” it at the neck with a device similar to a metal clothespin. It takes about three to four hours to complete.

“When you have to approach from outside the blood vessel, especially somewhere as sensitive as your head, it’s going to be really hard to be digging around and finding the aneurysm,” Masters says.

Rather than resorting to the lesser of two evils, Moftakhari wanted to develop a less time-consuming and less hazardous treatment. Together with Crone and Masters, the team came up with the idea of a single coil opening up a polymer shell.

Consequently, clipping as an aneurysm treatment is being phased out.

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The Nitinol alloy is used to create a sturdy and compliant coil, which essentially inflates a balloon-like shell by aligning along its circumference.

The shell is composed of polyurethane, a biocompatible elastic material, and hyaluronic acid, a substance necessary for wound healing.

“People complain about their breast implants looking all funny and misshapen; it’s because the body essentially came in and performed what’s called a fibrotic response, which means it formed a scar around the implant. In that case, it was really bad; in this case, it’s what we’re trying to do. We want the body [to] form a scar around this [device] in order to wall off the aneurysm,” Masters says.

This copolymer shell combined with the Nitinol coil frame results in a device that, as Moftakhari puts it, “blocks the aneurysm in one step.”

It’s also a much safer treatment. Using one coil as opposed to multiple coils decreases the chance of puncture. The risk of compaction also drastically decreases because the polymer surface in contact with the blood is very elastic and tailored to withstand blood flow pressure.

Large-scale tests of the device were performed to simulate the conditions it would need to withstand inside a cerebral aneurysm. These tests showed no blood entering the aneurysm and no compaction.

Before the device will be available in the operating room it has to undergo further testing. The team still needs to ensure that the device will become integrally connected with the surrounding tissue, Crone says.

Finally, the device needs to get approval from the Food and Drug Administration (FDA), which can sometimes take as long as 12 years.

“It’s possible that some of the FDA hurdles will be overcome in that we’re not including anything new in our material,” Masters says.

The Nitinol coil is already an FDA approved material. The material for the shell, while newly developed in the laboratory, is a polymer of polyurethane and hyaluronic acid, both of which are approved.

When this device is fully approved, it will offer surgeons and patients a safer, more effective treatment option. Like the principle of Occam’s razor states: the simplest solution tends to be the right one.

Author bios: Victoria is a sophomore studying biomedical engineering and Stephanie is a sophomore majoring in journalism and mass communications.

![A close-up of the aneurysm occlusion device exhibits the internal coil structure that gives the polymer shell its shape.](Image)
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