



## Ekos, Swedish Aim to Shake Up Stroke Treatment with Ultrasound Brain Clot Buster

Luke Timmerman 3/5/10

Innovation stories don't get more local than this. A local medical device company provides an innovative tool to a local doctor, who gets money from local taxpayers to test the idea. And, before you dismiss this as some irrelevant insider-y project, an independent expert from Boston has said publicly that this Seattle collaboration may transform the way doctors treat a common type of stroke.

This new technology for the treatment of [hemorrhagic stroke](#) is the product of a partnership between Bothell, WA-based Ekos, neurosurgeon [David Newell](#) of the Swedish Neuroscience Institute in Seattle, and a \$170,000 [grant](#) from Washington state taxpayers via the Life Sciences Discovery Fund.

The idea is to treat burgeoning clots in the brain sort of like how clots are treated in other parts of the body. [Ekos is known for having developed a miniature ultrasound probe](#) that slithers inside blood vessels, and gently amplifies clot-dissolving drugs. The hope is to get rid of clots faster, which ought to help people live healthier lives after they get out of the hospital. The company markets this tool for people with clots in the legs, known as deep vein thrombosis, and it is trying to expand into a broader patient population of [people with dangerous clots in the lungs, known as pulmonary embolisms](#).



But Newell, and Ekos, saw another group of gravely ill patients who might benefit—those who suffer from hemorrhagic strokes. This is what happens when a blood vessel ruptures in the brain (usually from uncontrolled high blood pressure), which creates dangerous swelling and clots. About 100,000 patients in the U.S.—one-fifth of all stroke patients—are diagnosed with this form of stroke every year. While doctors sometimes try to surgically remove the squishy new clot, the disease is fatal about half of all cases, Newell says.

[David Newell](#)

There is no effective treatment for hemorrhagic stroke, although some evidence has emerged lately to suggest that clot-dissolving drugs like Roche's genetically engineered tissue plasminogen activator (t-PA) can be effective. That made Newell and his colleagues wonder: What if you added the gentle pulsating waves of the Ekos ultrasound probe to loosen up the clot, and help t-PA do a better job? Could that save lives, and precious time to help survivors avoid disabling brain damage?

No one had ever tried to combine ultrasound inside the brain with clot-busters before, but the [results](#) opened the eyes of a number of physicians last month at the American Heart Association's International Stroke Conference in San Antonio, TX.

“We got a very enthusiastic response,” Newell says. The moderator of the session, [Lee Schwamm](#), the vice chairman of neurology at Massachusetts General Hospital, said to the audience after Newell’s talk that the Ekos system is a potential “paradigm shift.”

It must be stated that this is all very preliminary. And before diving into the [details](#) that caught Schwamm’s eye, I should be clear about who stands to gain here and who doesn’t. About 80 percent of all strokes in the U.S. every year are what are known as [ischemic strokes](#)—which is totally different from the hemorrhagic variety. Ischemic strokes arise when a piece of plaque buildup breaks off from a blood vessel wall, and causes a blockage that cuts off oxygen to the brain. Those patients get clot-busting drugs like t-PA as well, but they need to get the drug in a matter of a few hours to restore blood flow to the brain. Clot-busters have traditionally been avoided in hemorrhagic patients, Newell says, because of the fear it would accelerate the dangerous bleeding. A new school of thought has emerged which says that hemorrhagic patients can become stable enough after a few days to actually benefit from the clot-buster, Newell says.

So here’s what Newell did in his clinical trial at Swedish. A total of nine patients agreed to have the experimental procedure done. They had a burr hole drilled in their skull, and doctors used a GPS-style system to precisely locate the best place to thread the probes into the brain’s blood clot. Then they combined an early-generation model of a thin Ekos ultrasound-emitting catheter alongside another catheter that was supposed to drain the blood. The ultrasound waves did their thing, while the patient received a steady dose of t-PA clot-buster for 24 hours.

The results were striking. Eight of the nine patients were alive after 30 days, even though the death rate for people with their prognosis is around 50 percent, Newell says. Importantly, there were no cases of increased bleeding episodes, no treatment-related deaths, and no infections that can sometimes crop up with invasive procedures. The ultrasound appeared to make the t-PA work in one day, instead of two or three days that doctors might expect when the clot-buster is given alone, Newell says. CT image scans showed that patients with intracerebral hemorrhages had their clots shrink by 59 percent, while those with a different form of hemorrhage saw 45 percent shrinkage. Seven of the nine patients reported improvements in quality of life, as measured by the National Institutes of Health Stroke Score.

One individual, Port of Seattle police officer Ray Blackwell, recovered well enough to go back to work after getting this treatment. It’s an anecdote that [Gov. Chris Gregoire has started talking about publicly](#) when she tries to persuade citizens and lawmakers to support her Life Sciences Discovery Fund.

Of course, Newell is the first to admit it is way too early to start talking about miracle cures. This study enrolled a small number of patients, was primarily designed to assess safety, and didn’t have a control group to see if the Ekos treatment is truly any better than t-PA on its own.

That’s where the next steps get interesting. Bob Hubert, the CEO of Ekos, told me he’s in active talks with big corporate partners who have the resources to run the rigorous kind of trials that could prove this idea works, and lay the groundwork for FDA approval. Ekos’ R&D team is working to develop a new ultrasound probe that incorporates some of its latest technology, and shortens the probe so it’s designed to work in the short anatomical distance the probe needs to travel in the brain—as opposed to the longer probes that Ekos currently makes to travel in leg arteries.

There's no lack of interest among partners, Hubert says. Hemorrhagic stroke has all the hallmarks of a lucrative medical device opportunity—a big patient population that's terminally ill, with no other legitimate treatment options, and no real competition in clinical trials. Ekos figures about three-fourths of all hemorrhagic stroke patients in the U.S., Europe, and Japan—150,000 people each year—could be candidates for this kind of therapy. At \$6,000 to \$10,000 per patient for the ultrasound procedure, sales could add up in a hurry. (Hubert didn't offer a market size figure, but my math says if you assume Ekos captures 10 percent of the patients Ekos says are out there, and sets a price in the middle of this range, it would generate \$120 million a year in annual sales).

All those business calculations are probably years away from becoming reality, if ever. A rigorous clinical trial that's designed to compare how well patients perform after the treatment is the next step, Newell says. He sounds very hopeful that trial will get done, and deliver a promising answer.

"If this approach is successful, it will have worldwide impact," Newell says.

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