

Nation's first cardiac ablation with mapping system recently cleared by the FDA performed at Penn Medicine

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After eight years of failed treatment for persistent atrial fibrillation (AF), Janet Szilagyi, 78 of Clayton, New Jersey, became the first patient in the United States to undergo cardiac ablation—a procedure in which an electrophysiologist will scar or destroy tissue in the heart that's allowing incorrect electrical signals to cause an abnormal heart rhythm—using an intraoperative imaging and mapping system recently cleared by the Food and Drug Administration (FDA).

Szilagyi is one of the more than three million individuals in the United States who experience AF, a quivering or irregular heartbeat that can lead to a host of dangerous complications and everyday symptoms like shortness of breath, chest pains, and lightheadedness. Szilagyi had undergone several <u>cardiac procedures</u> and tried different medications to treat and/or control her AF, before coming to Penn Medicine in December 2017 to explore other interventions.

"When I was in <u>atrial fibrillation</u>, it was hard to breathe, and I couldn't walk from here to there without getting tired," said Szilagyi. "I'm usually pretty active; I try to walk every day, but I wasn't able to do that when I was feeling bad. I really wasn't myself." Szilagyi, about six weeks postop, is home recovering, hoping to get back to her normal activities in the coming months.

"There were many areas of Janet's <u>heart</u> that required ablation, and



having access to this new technology allowed us to see more of these regions that we would not have normally been able to, so we could fully address the areas of concerns," said Pasquale Santangeli, MD, an assistant professor of Cardiovascular Medicine, who performed the <u>procedure</u>. "Janet's procedure went well, and she is recovering nicely. I expect that with standard follow-up she will be able to return to normal life without severe threat of AF recurrence."

In October 2017, the system, AcQMap High Resolution Imaging and Mapping System and the 3-D Imaging and Mapping Catheter, received FDA clearance for <u>patients</u> with complex arrhythmias who may need a more extensive cardiac ablation procedure in order to treat the irregularities, based on successful European studies.

Santangeli along with David Callans, MD, associate director of Electrophysiology at Penn Medicine, who performed the country's second procedure with this new system just days later, said the new equipment has the potential to greatly improve treatment accuracy. "Preliminary data from European studies suggests that the success rates of ablation for patients with persistent AF have potential to climb by more than twenty-five percent, and even higher for paroxysmal (sporadic AF) patients," said Callans. "We see these as incredibly promising increases, as these are patients who often still experience symptoms of AF even after they've undergone similar cardiac procedures."

Current data shows that ablation procures are successful for patients with persistent AF about 50 to 55 percent of the time, and about 70 to 75 percent of the time in patients with paroxysmal AF. Researchers believe these numbers could increase to 75 percent and upwards of 85 percent, respectively, if the regions responsible for AF maintenance are adequately addressed with this new system.

Previous systems had only allowed physicians to see certain areas or



angles of the heart, which proved challenging when trying to treat more complex cases of AF which require more sites to be ablated. With the new system, higher resolution mapping of the heart is available as it combines ultrasound technology with an ability to map every heartbeat to help pinpoint the cause and placement of each complex arrhythmia. Once an ablation treatment occurs in a specific area, physicians are then able to re-map the heart in seconds to see the effects of each single ablation in real-time. When repeated throughout the entirety of the <u>ablation</u> procedure, physicians can eliminate the arrhythmia-causing areas throughout the heart.

"As a next step, Penn Medicine researchers are exploring clinical trial possibilities, and hope to launch our own trials to evaluate the effectiveness of using this <u>system</u> for patients with complex arrhythmias here in the United States," said Callans.

Provided by Perelman School of Medicine at the University of Pennsylvania

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