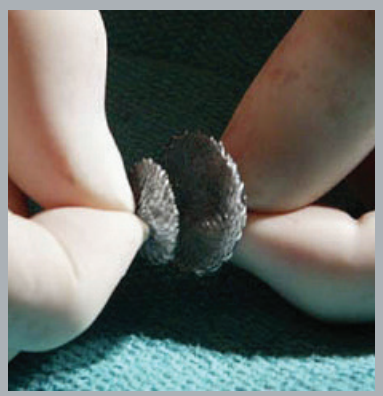
Key Points

- Transcatheter closure of patent foramen ovale (PFO) in patients with cryptogenic stroke has been shown to reduce stroke risk by 45 percent.
- PFO closure is now an FDA-approved therapy.
- Most patients who undergo transcatheter PFO closure at Mount Sinai are done under conscious sedation using intracardiac echo imaging and go home the same day.



Proven Risk Reduction with Patent Foramen Ovale (PFO) Closure in Cryptogenic Stroke

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It has been known for decades that patients with cryptogenic stroke are more likely to have a PFO (approximately 50 percent) than patients who have never experienced a stroke (20 to 30 percent). It is postulated that the mechanism of these strokes is due to paradoxical embolization of venous debris. Patients who have experienced a stroke and have a PFO are more likely to have recurrent stroke, and the best treatment strategy—medical therapy versus transcatheter closure of the PFO—has been a matter of debate. In November 2016, the follow-up results of the RESPECT trial, which randomized over 900 patients with cryptogenic stroke and a PFO to either medical therapy or PFO closure with the Amplatzer PFO occlude, were presented. Over a mean 5.6 years of follow-up, there was a 45 percent risk reduction (p=0.046) in the number of strokes in the device arm compared with the medically treated group. Based on this data, the FDA approved the Amplazter PFO Occluder for treatment of patients with cryptogenic stroke and PFO. The FDA approval is worded as follows:

The AMPLATZER™ PFO Occluder is indicated for percutaneous transcatheter closure of a patent foramen ovale (PFO) to reduce the risk of recurrent ischemic stroke in patients, predominantly between the ages of 18 and 60 years, who have had a cryptogenic stroke due to a presumed paradoxical embolism, as determined by a neurologist and cardiologist following an evaluation to exclude known causes of ischemic stroke.

On November 7, 2016, Barry A. Love, MD at The Mount Sinai Hospital performed the first-in-the-nation FDA approved PFO closure on a 46-year-old woman who had suffered a cryptogenic stroke. The 20-minute procedure is performed under light sedation and local anesthesia using a combination of fluoroscopy and intracardiac echocardiography to guide the placement of the occluder. Patients are usually discharged the same or next day on a single antiplatelet agent. Mount Sinai Heart continues to see an increasing number of patient referrals for PFO closure now that the procedure is FDA approved.

References:

1. Long-term comparison of patent foramen ovale (PFO) closure versus medical therapy after cryptogenic stroke: final results of the RESPECT trial, presented at TCT 2016, Washington, D.C.
2. PFO: "Please figure out" or now 'potentially figured out?" *J Am Coll Cardiol*. 2016 Mar 1;67(8):918-20