

## CASE REPORT

# Use of the NobleStitch™ EL for the treatment of patients with residual right-to-left shunt following device closure of PFO

Nadia Chaudhry-Waterman<sup>1</sup>  | Stephen Shapiro<sup>1</sup> | James Thompson<sup>1,2</sup>

<sup>1</sup>INOVA Children's Hospital, Falls Church, VA, USA

<sup>2</sup>Pediatric Medical Group, INOVA Children's Hospital, Falls Church, VA, USA

## Correspondence

Nadia Chaudhry-Waterman, 3300 Gallows Rd, Falls Church, VA 22042.

Email: nadiacwaterman91@gmail.com

## Abstract

The unique design of the NobleStitch™ EL allows it to be used to close residual defects following failed device PFO closure without impacting the integrity of previously placed double-disk Gore occluders.

## KEYWORDS

cryptogenic stroke, Heartstitch, patent foramen ovale, platypnea-orthodeoxia syndrome, residual shunt

## 1 | INTRODUCTION

NobleStitch™ EL was successfully used in two patients to close residual defects following failed transcatheter device closure of patent foramen ovale (PFO). Gore Helix and Gore CardioForm devices, respectively, had each been used in one patient.

The foramen ovale is a normal fetal interatrial communication.<sup>1,2</sup> In about 75 percent of the population, the opening closes in the first year of life by apposition and fusion of the atrial septum primum to the septum secundum.<sup>3</sup> However, in about 25 percent of the population, the foramen ovale remains patent or probe patent (PFO).<sup>2,4,5</sup>

Most people with PFO remain asymptomatic. However, there is a well-established association between PFO and the occurrence of cerebrovascular accidents, transient ischemic attacks, migraine headaches, and platypnea-orthodeoxia syndrome.<sup>2,5</sup>

Transthoracic echocardiography (TTE) and transesophageal echocardiography (TEE) are standard methods of PFO detection. In patients with PFO, contrast TTE (CTTE) during injection of agitated saline or echogenic contrast media, performed both at rest and during Valsalva maneuver, usually documents contrast in the left heart within 3-4 cardiac cycles.<sup>1,5</sup> Alternatively, transcranial Doppler interrogation of the middle cerebral artery following peripheral venous

echocontrast injection may be used to document and quantify the right-to-left atrial shunting.<sup>6</sup> Delayed appearance of contrast in the systemic circulation may be indicative of intrapulmonary right-to-left shunting.<sup>5</sup>

In symptomatic patients, PFO closure has been shown to eliminate or decrease symptoms associated with PFO. Transcatheter device closure is standard therapy. Most devices are of double-disk design, the disks connected by a short, narrower waist. One disk is deployed on each side of the atrial septum, functionally closing the hole. The device is usually endothelialized within six months, completing closure.<sup>2,5</sup>

Complications of device PFO closure are infrequent. However, thrombus formation on the device, device or thrombus embolization, arrhythmia, late atrial perforation with tamponade, device malposition, and residual shunting have been reported.<sup>7-9</sup> Nickel allergy may occur in patients receiving Nitinol-based occluders.<sup>10</sup>

In some studies, residual shunting has been noted in up to 10% of cases and may be associated with continued or recurrent symptoms.<sup>2</sup> Atrial septal aneurysm, use of larger defect sizing balloon, and choice of certain occluders are known associations with residual shunting.<sup>11,12</sup>

For patients with continued or recurrent symptoms following incomplete PFO device closure, closure of the residual defect is recommended. Various occluders have been used.

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## 2 | METHODS

We report the successful use of the NobleStitch™ EL to close residual defects in two patients who remained symptomatic after device partial PFO closure.

The NobleStitch™ EL system has had a CE mark in Europe for PFO closure for more than 8 years, typically used with the method described by Gasparдон, et al<sup>13</sup> The system has had a 510(k) clearance in the United States for intravascular and intracardiac shunting for over 3 years.

The NobleStitch™ EL system consists of three separate catheters. The two suture delivery catheters have arms on the distal ends which open up and allow for capturing the septum secundum and primum, respectively. An internal needle then pierces the septum and picks up the end of the 4-0 polypropylene suture. The suture ends are then loaded through the cylindrical KwiKnot, which is advanced via the third catheter to approximate the atrial septum, where the sutures are tightened to oppose the secundum and primum septa. The KwiKnot is locked in place, and the excess suture is cut and removed.<sup>13</sup>

A thorough literature search was conducted on PubMed, Ovid, and Google Scholar databases using keywords PFO, percutaneous closure, PFO device closure, and NobleStitch™ EL. We believe this is the first report of NobleStitch™ EL use for closure of residual PFO.

## 3 | CASE REPORT

### 3.1 | Case 1

A 66-year-old woman, with no significant medical history, initially presented at age 62 with complaints of chest pain and shortness of breath. Platypnea-orthodeoxia syndrome was diagnosed, and PFO closure was attempted with a Gore Helex occluder. Symptoms decreased initially, but later increased to baseline levels. Extensive pulmonary evaluation and chest CT scan were normal. CTTE showed early

left heart opacification following agitated saline injection. Transcranial Doppler evaluation showed grade 4 right-to-left shunting at rest, grade 5 out of 5 with Valsalva maneuver.

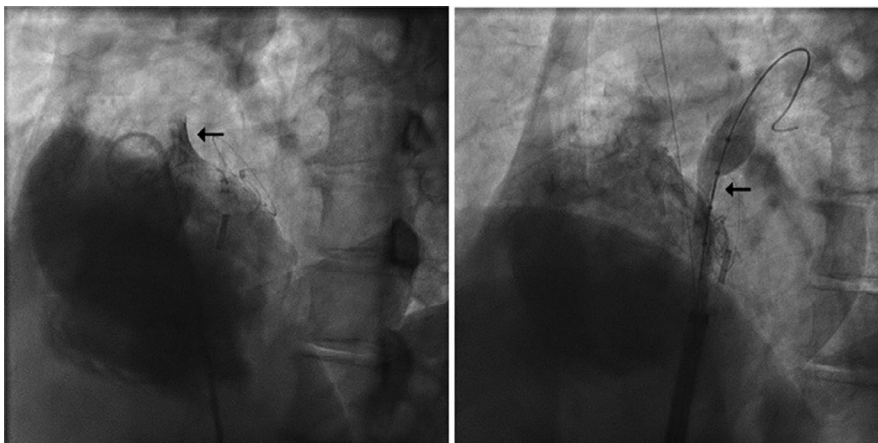
At cardiac catheterization, initial intracardiac echocardiography (ICE) showed the disks of the Helex occluder on appropriate sides of the atrial septum. However, the superior portion of the right atrial disk was not opposed to the atrial septum. The residual defect measured 4 mm as assessed by the sizing balloon. (Figure 1).

Rather than attempting to place an additional double-disk device, we used the NobleStitch™ EL system to close the residual defect. The secundum system was used to capture the superior margin of the secundum atrial septum. Next, the primum system of the device was used to capture the superior margin of the left atrial disk of the Helex device and oppose it to the secundum atrial septum. The NobleStitch™ EL KwiKnot was deployed, securing the sutures and closing the residual PFO. Angiography and contrast ICE during the procedure, performed both with and without simulated valsalva, and CTTE six months postprocedure demonstrated no residual shunt. (Figure 2).

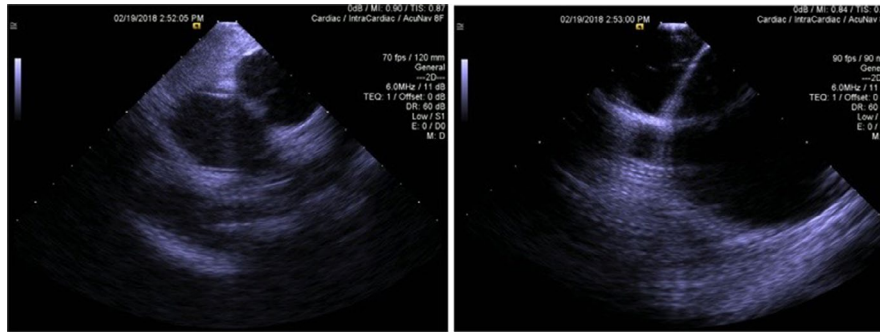
At the time of her six-month follow-up, the patient reported having experienced immediate resolution of symptoms and has since competed at a high level in masters swimming.

### 3.2 | Case 2

A 58-year-old man with Klinefelter's syndrome and a history of PFO closure with a Gore CardioForm device due to platypnea-orthodeoxia syndrome presented to the adult cardiology clinic. In the year since his PFO closure, he had developed supraventricular tachycardia (SVT) requiring ablation, atrial fibrillation requiring medical management with beta-blockers and anticoagulation, and he had continued to experience shortness of breath and had documented desaturations with minimal exercise. Right heart catheterization at an outside hospital showed he had developed

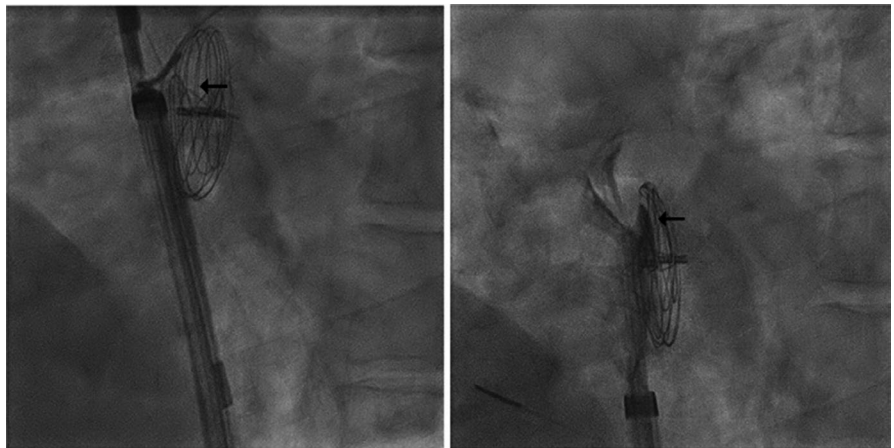


**FIGURE 1** Fluoroscopy during cardiac catheterization shows interatrial communication and residual shunt. Left: Residual shunting demonstrated by contrast-enhanced fluoroscopy showing contrast crossing over interatrial septum at the superior border of the previously placed double-disk device. Right: Sizing balloon positioned at the superior border of the previously placed double-disk device measured a 4 mm residual defect



**FIGURE 2** Intracardiac echocardiogram (ICE) displays interatrial septum before and after NobleStitch™ EL placement. Left: ICE from case 1 shows positive bubble study, with “snowstorm” appearance of the left atrium indicating the presence of a right-to-left shunt. Right: ICE from case 1 shows intact septum following NobleStitch™ EL placement. Negative bubble study performed at the time of this image showed complete resolution of left-to-right shunt

**FIGURE 3** Fluoroscopy during cardiac catheterization shows NobleStitch™ EL needle deployment and blind-ending tunnel following KwiKnot deployment. Left: Fluoroscopy during case shows needle of the NobleStitch™ EL system capturing the septum secundum. Right: After KwiKnot deployment, contrast-enhanced fluoroscopy shows blind-ending tunnel with complete closure



heart failure with preserved ejection fraction (HFpEF). TTE showed continued atrial right-to-left shunting.

At cardiac catheterization, initial ICE showed the device's left disk capturing the primum septum. However, the right disk was within the PFO tunnel and did not capture the secundum septum. In addition, an atrial septal aneurysm was present. As assessed by the sizing balloon, the residual PFO tunnel was 5 mm in diameter and 11 mm in length.

The secundum suture of the NobleStitch™ EL was used to capture the secundum atrial septum. Next, the primum suture was used to capture the superior margin of the CardioForm device, effectively serving as the primum septum. Following KwiKnot deployment, angiography showed a blind-ending tunnel. (Figure 3) By contrast ICE, there was a trivial residual shunt. At six-month follow-up, repeat CTTE both at rest and with valsalva showed no residual shunting.

The patient has now experienced complete resolution of symptoms. He continues on anticoagulation and beta-blockers for management of his underlying atrial fibrillation, but has not had any episodes of palpitations since prior to the procedure.

## 4 | DISCUSSION

For symptomatic patients, device PFO closure has become standard therapy. Residual shunting has been reported in up to 10–20 percent of patients.<sup>9,11</sup> It is thought that most residual shunts are insignificant; however, when a patient has continued or recurrent symptoms, closure of the residual interatrial communication is appropriate. Prior reported attempts have been with placement of a second double-disk device. Helex, CardioSeal, Amplatzer atrial septal occluder, Amplatzer cribriform, and StarFlex devices have been used.<sup>14</sup> In addition to the technical difficulty of deploying an additional double-disk occluder, this leaves a large mass of residual material in both atria and straddling the atrial septum.<sup>12</sup>

We report the first use of the suture-based NobleStitch™ EL system to close residual PFO. The NobleStitch™ EL system uses two polypropylene sutures, one to capture the secundum septum and the second to capture the primum septum. When the sutures are cinched together with the KwiKnot, the primum and secundum septae are sutured closed. No residual material remains in the left atrium, and the right atrial suture ends and KwiKnot occupy only 0.00074 cubic cm.

When used for initial PFO closure, the NobleStitch™ EL system eliminates or greatly diminishes the importance of confounding variables including width and length of the PFO tunnel, adequacy of septal rims, and tissue compliance. In addition, the risks of wire fracture and nickel reaction are eliminated. To our knowledge, the use of the NobleStitch™ EL system has not been associated with atrial fibrillation. As demonstrated by our cases, the suture-based PFO closure system also can be successfully used to close residual PFO using a low mass, Nitinol-free device.

## 5 | CONCLUSION

The NobleStitch™ EL system is a suture-based system for PFO closure, reducing most of the risks of double-disk PFO closure devices. It is widely used in Europe and is now being introduced in North America. Its unique design allows it to be used to close residual PFO without impacting the integrity of the previously placed double-disk Gore occluders.

### ACKNOWLEDGMENTS

Published with written consent of the patient.

### CONFLICT OF INTEREST

None declared.

### AUTHOR CONTRIBUTIONS

Nadia Chaudhry-Waterman, DO: is a primary author of case report, performed background literature search, and wrote all portions of the above case report. Stephen Shapiro, MD: provided expert advice during both implant procedures and served as primary editor of manuscript. James Thompson, MD: is a primary physician for both cases, one of the few physicians currently able to use this device in the United States, performed both implant procedures described above, and helped with manuscript production.

### ETHICAL APPROVAL

Consent was obtained from all subjects/patients at the time of the procedures.

### ORCID

Nadia Chaudhry-Waterman  <https://orcid.org/0000-0001-7047-3485>

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