

## Original Studies

# Use of Balloon Pull-Through Technique to Assist in CardioSEAL Device Closure of Patent Foramen Ovale

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CardioSEAL device closure of patent foramen ovale (PFO) has been advocated for the treatment of patients with cryptogenic stroke. Using the standard delivery technique, partial deployment of the CardioSEAL device can occur, especially in patients with a thick septum secundum and/or long PFO tunnel. We hypothesized that using a left atrial-to-right atrial balloon pull-through to make the septum primum incompetent would result in improved final device position regardless of septal thickness or tunnel length. Catheterization reports, cineangiograms, and transesophageal echocardiograms of 51 patients who underwent CardioSEAL device closure of PFO between March 2000 and August 2002 were retrospectively reviewed. Group 1 (n = 21) included patients with CardioSEAL placement using the standard technique and group 2 (n = 30) included patients with CardioSEAL placement using the balloon pull-through technique. There were no differences between the groups in terms of age (43.6 vs. 45.3 years; *P* = NS), weight (83.3 vs. 89.9 kg; *P* = NS), septum secundum thickness (6.4 vs. 7.0 mm; *P* = NS), PFO tunnel length (15.5 vs. 13.1 mm; *P* = NS), or device size. In group 1, 4/21 (19%) had partial deployment of the CardioSEAL device, while in group 2, no partial CardioSEAL deployment (0/30) was observed. No complications were associated with the balloon pull-through technique. We conclude that the left atrial-to-right atrial balloon pull-through technique is safe and may allow for better final position of the CardioSEAL device during PFO closure. *Catheter Cardiovasc Interv* 2003;60:101–106. © 2003 Wiley-Liss, Inc.

**Key words:** heart defects; congenital; cerebrovascular accident; catheterization

## INTRODUCTION

Patent foramen ovale (PFO) diagnosed by transesophageal echocardiography (TEE) is present in approximately 10% of a controlled population [1] and in 30% of patients with cerebrovascular accident or transient ischemic attacks [2]. Until the last decade, surgical PFO closure or anticoagulation therapy was used in patients presumed to have paradoxical embolus as the etiology of their stroke [3,4]. Recently, transcatheter PFO closure using various devices has become increasingly popular, with a few small studies suggesting reduction in stroke recurrence during a short-term follow-up [5–7], with several other large-scale prospective randomized trials being in place. The CardioSEAL device (Nitinol Medical Technologies, Boston, MA) is a non-self-centering device approved for use in the United States under a Humanitarian Device Exemption (HDE) protocol since February 2000.

Certain anatomical characteristics of septum primum and septum secundum may preclude optimal CardioSEAL de-

vice positioning during closure of PFO. Improper final device position may be related to a long PFO tunnel length and/or a thick septum secundum. When the degree of overlap between septum primum and septum secundum is large, the long PFO tunnel that has to be traversed may potentially cause deformity of the left atrial umbrella before complete deployment of the right atrial side when using the standard

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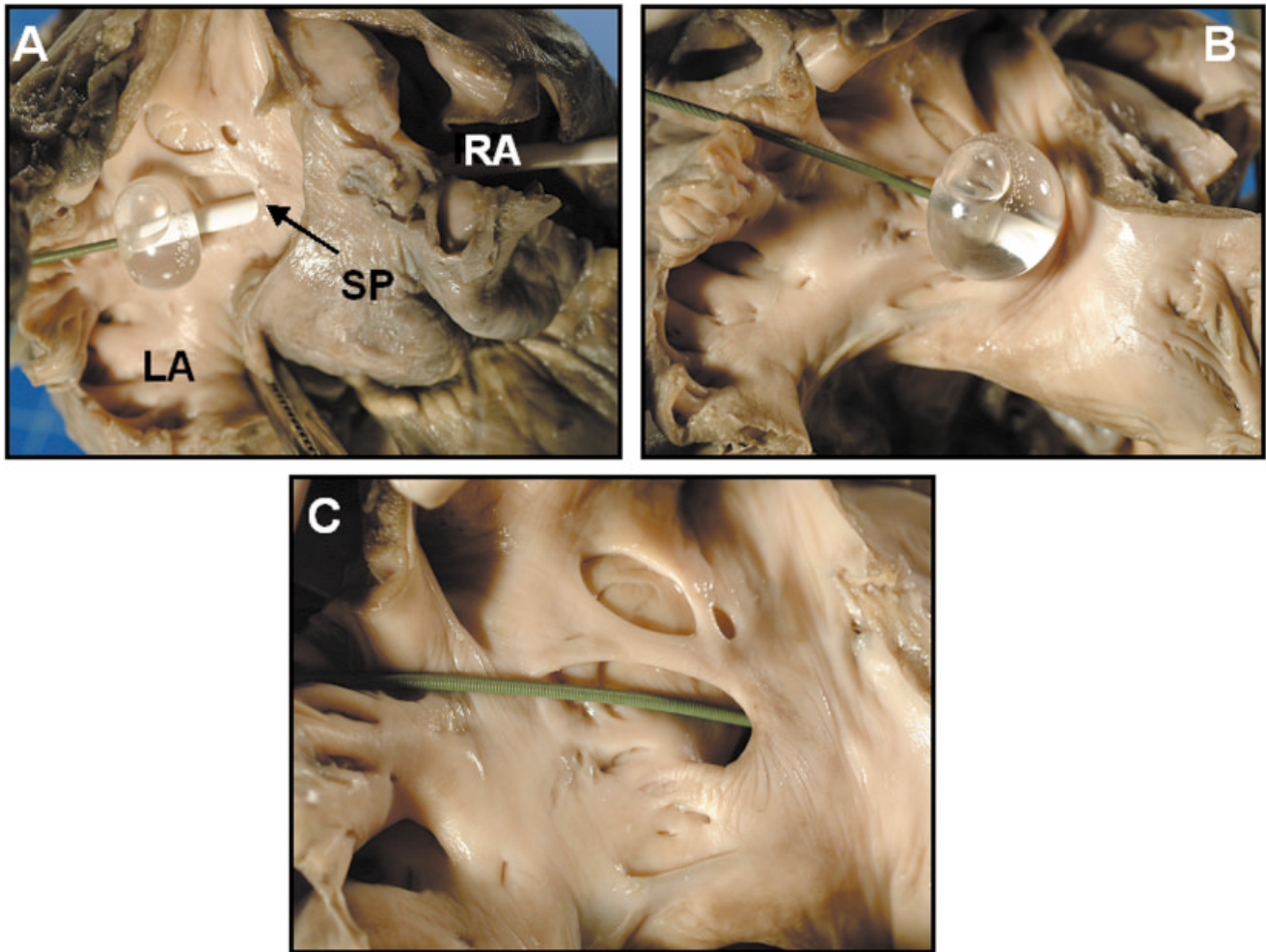
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**Fig. 1.** Pathologic reproduction of the balloon pull-through technique. The pictures were taken from the posterior aspect of the specimen. A shows the balloon catheter crossing the PFO from the right atrium (RA) to the left atrium (LA). Septum primum (SP) overlaps septum secundum to form the PFO tunnel. B depicts the inflated balloon being pulled through the PFO, everting septum primum. C demonstrates a compliant septum primum and a shorter PFO tunnel length. [Color figure can be viewed in the online issue, which is available at [www.interscience.wiley.com](http://www.interscience.wiley.com)].

technique. One or both umbrellas may become trapped within the PFO tunnel. A thick septum secundum may also preclude proper device position by preventing the right atrial umbrella from lying flush against the septum. These difficulties have prompted some to use transseptal technique to position the CardioSEAL device properly [8]. This article describes a new technique that involves a left atrial-to-right atrial balloon pull-through to help achieve proper CardioSEAL device position during transcatheter closure of PFO.

## MATERIALS AND METHODS

### Study Population

The study population included 51 patients who underwent transcatheter closure of PFO using the CardioSEAL

device at our institution between March 2000 and August 2002. The indication for PFO closure was single cerebrovascular accident in 33 patients, multiple cerebrovascular accidents in 7 patients, multiple transient ischemic attacks in 4 patients, cerebrovascular accident and transient ischemic attack in 4 patients, and platypnea-orthodeoxia syndrome in 3 patients. Three patients had a hypercoagulable state secondary to malignancy and three patients had history of migraine headaches. Each cerebrovascular accident was cryptogenic in nature. The diagnosis of PFO was made by TEE with or without the use of agitated saline contrast. The anticoagulation regimen prior to device closure consisted of coumadin in about half the patients, aspirin in a quarter, and clopidogrel (Plavix) or a combination of antiplatelet and anticoagu-

lant medications in the other quarter of patients as determined appropriate by their neurologist. Patients were divided into two groups based on the technique used to place the CardioSEAL device.

### Catheterization Procedure: Standard Technique

Written informed consent was obtained from all patients. The procedure was performed using general anesthesia with TEE guidance or under conscious sedation with fluoroscopic guidance. All patients received systemic heparin during the procedure to maintain an activated clotting time of more than 275 sec.

Right heart catheterization was performed and hemodynamic data were derived. Angiograms were performed in the right atrium or within the PFO tunnel to delineate the anatomy. A long sheath was advanced over a wire to the inferior vena caval/right atrial junction. The dilator was removed and the sheath was cleared of air and flushed with heparinized saline before it was advanced over the wire to the left upper pulmonary vein. The CardioSEAL device attached to a delivery system was advanced to the tip of the sheath. The left atrial umbrella was deployed and the device was pulled back so that the center pin was within the PFO tunnel. After angiography through the sheath documented satisfactory device position, the right atrial umbrella was delivered by withdrawing the sheath. After device release, an angiogram was performed in the right atrium.

### Balloon Pull-Through Technique

After crossing the PFO and positioning a wire in the left upper pulmonary vein, a 7 Fr balloon wedge catheter was advanced over the wire to the left atrium. The wedge balloon was inflated with 2 cc of diluted contrast and the catheter was pulled back over the wire through the PFO to the right atrium (Fig. 1). This maneuver was performed two to three times in an attempt to evert or increase the compliance of septum primum. This was followed by device delivery as described above.

### Angiographic Measurements and Device Position

Angiographic measurements included PFO tunnel length, defined as the degree of overlap between the septum primum and septum secundum, and thickness of the septum secundum, which was measured at the midpoint of the tunnel (Fig. 2). Fluoroscopic images were reviewed to determine final device position. Satisfactory device position was achieved when each side of the device remained in contact with the atrial septum (Fig. 3). Poorly positioned devices included those where the right or left atrial umbrellas were flexed away from the atrial septum (Fig. 4).

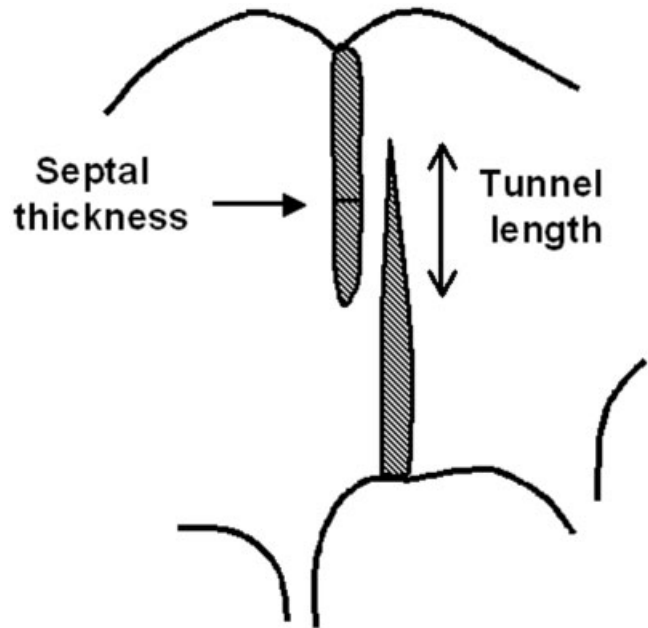


Fig. 2. PFO tunnel length measured as the degree of overlap between septum primum and septum secundum. Septum secundum thickness measured at the midpoint of the PFO tunnel.

### Follow-Up

Those patients who were on coumadin (or clopidogrel) prior to the procedure were placed on a regimen of coumadin (or clopidogrel) and aspirin for 2 months and aspirin alone for the following 4 months. Patients who took aspirin prior to device placement were continued on the same medication for at least 6 months and subsequent need for anticoagulation was decided by the neurologist. All patients had chest X-ray, electrocardiogram, and transthoracic echocardiography performed prior to discharge to confirm device position and to assess for the presence of any residual shunting. Follow-up consisted of clinical assessment, chest X-ray, and a transthoracic echocardiogram (without bubble study).

### Statistical Analysis

The nonpaired Student's *t*-test was used to evaluate differences in dependant variables between the two groups. Chi-square analysis was used for comparison of final device position.

## RESULTS

### Demographics

A total of 51 patients aged 16 to 83 years were included in the study. Group 1 ( $n = 21$ ) consisted of patients who had CardioSEAL placement using the standard technique and group 2 ( $n = 30$ ) consisted of patients

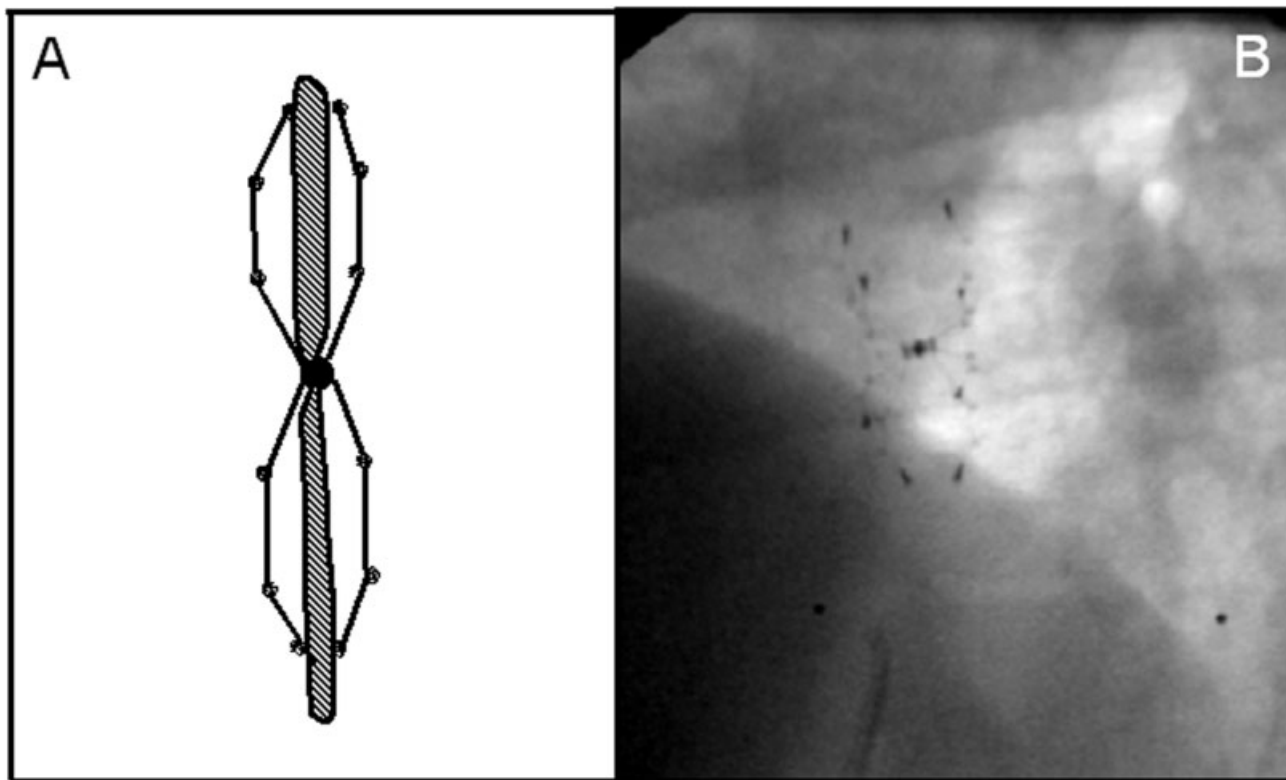


Fig. 3. Diagrammatic (A) and angiographic (left anterior oblique projection; B) representation of a CardioSEAL device in satisfactory position with each arm well flexed against the atrial septum.

who had CardioSEAL placement after the balloon pull-through technique. There were no significant differences in patient demographics, PFO anatomy, or device size between the groups (Table I). There were no procedural complications in either group.

#### Device Position

In group 1, 4/21 patients (19%) had poor device position as defined above. No patient in group 2 (0/30) had a poorly positioned device (Table II;  $P = 0.01$ ). Patients in group 1 with poorly positioned devices using the standard technique had PFO tunnel lengths  $> 15$  mm (Table III). All patients in group 2 with similar PFO tunnel lengths had satisfactory device position with use of the balloon pull-through technique.

#### Follow-Up Events

None of the patients had embolization of the device. During a median follow-up of 17.5 months (range, 1–30 months), two patients in group 1 had recurrence of neurological events. The first patient had a hypercoagulable state secondary to ovarian carcinoma and developed a stroke the evening of the device placement. She subsequently died 2 months later of advanced metastatic can-

cer. The second patient with no known identifiable risk factors had a transient ischemic attack 3 months after device placement, with no recurrent events at 18-month follow-up. Both these patients had good device position and absence of residual shunt at discharge.

#### Follow-Up Echocardiography

Echocardiographic evaluation with color Doppler at discharge revealed the presence of trivial to small shunts in 11 patients (6 in group 1 and 5 in group 2). Follow-up echocardiography at a median of 9 months (range, 1–30 months) showed resolution of these residual shunts in all except two patients (one from each group), where they persisted to be small in size. Both these patients remain free of recurrent neurological events. Among the four patients in group 1 that had a poorly positioned device, only one had residual shunt at follow-up.

#### DISCUSSION

Successful device closure of PFO in patients with cryptogenic stroke should interrupt the presumed pathway of paradoxical embolus by effective anatomic approximation of septum primum and septum secundum

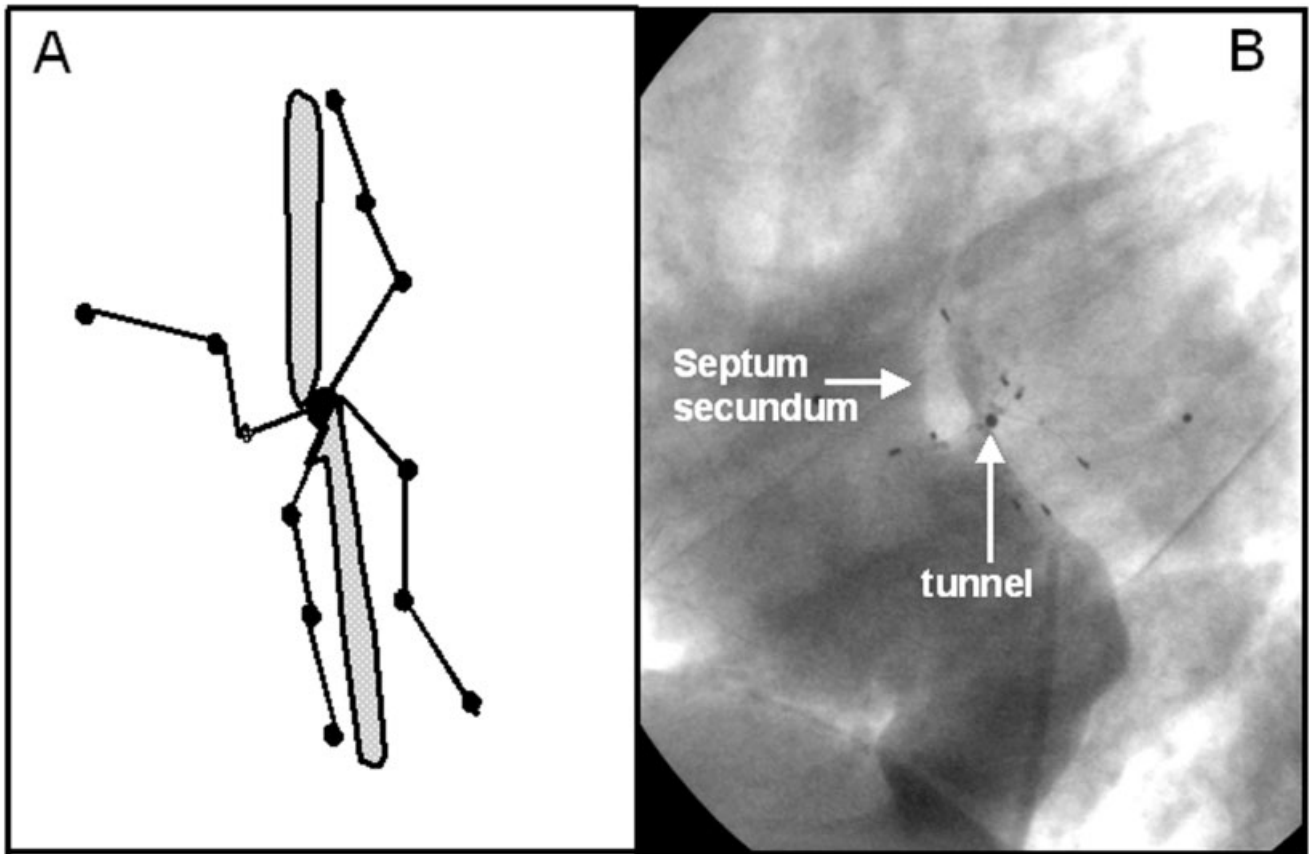


Fig. 4. Diagrammatic (A) and angiographic (left anterior oblique projection; B) representation of a poorly positioned CardioSEAL device with its arms flexed away from the atrial septum.

TABLE I. Comparison of Demographic Variables and PFO Anatomy\*

	Standard technique (group 1; n = 21)	Balloon pull-through technique (group 2; n = 30)	P
Age (years)	43.6 ± 15.5	45.3 ± 15.1	0.7
Weight (kg)	83.3 ± 16.6	89.9 ± 39.2	0.4
Tunnel length (mm)	15.5 ± 4.9	13.6 ± 4.5	0.07
Septal thickness (mm)	6.4 ± 1.9	7.0 ± 1.9	0.3

\*Values are mean ± SD.

and by rapid and complete endothelialization of the device. A device that is in an optimal position with each arm well apposed to the atrial septa facilitates this process. An improperly positioned device may result in device embolization, delayed or incomplete endothelialization, thrombus formation, or an increased likelihood of residual shunting through the PFO. The latter has been shown to predispose to recurrent cerebrovascular accidents after PFO device closure [9].

The CardioSEAL device has been used extensively for transcatheter closure of PFO in patients with cryptogenic stroke. Poor device position may occasionally occur us-

TABLE II. Device Position in Relation to Technique Used

Technique (group)	n	Satisfactory position (%)	Poor position (%) <sup>a</sup>
Standard (1)	21	17 (81)	4 (19)
Balloon pull-through (2)	30	30 (100)	0 (0)

<sup>a</sup>P = 0.013.

ing the standard delivery technique and is more likely to happen in patients with unfavorable PFO anatomy, which includes a long PFO tunnel and a thick septum secundum. In order to achieve satisfactory device position, some investigators have advocated the use of transeptal technique [8]. We hypothesized that optimal device position may also be achieved by the use of a simple balloon pull-through technique.

It has been shown that PFO tunnel length shortens or disappears completely by inferior displacement of septum primum after placement of a non-self-centering device [10]. The balloon pull-through technique as described in this study facilitates the process of shortening PFO tunnel length either by everting or folding the sep-

**TABLE III. Characteristics of Patients With Poor Device Position**

	Tunnel length (mm)	Septum secundum thickness (mm)	Device size (mm)	Side involved
1	15.8	9.9	33	Right atrial
2	19.9	6.9	33	Right atrial
3	15.4	6.9	33	Right atrial, left atrial
4	23.0	4.6	28	Right atrial

tum primum or by increasing its compliance prior to device placement. In this study, all patients who underwent the balloon pull-through technique had satisfactory final device position as compared to only 17 out of 21 patients where the device was delivered using standard technique.

We have noted in our study that each of the four patients who had poorly positioned devices after standard delivery technique had PFO tunnel lengths of 15 mm or more. Conversely, it may be said that satisfactory device position may be achieved in patients with shorter PFO tunnel lengths irrespective of the technique used. The difference in outcome (device position) between the two techniques was most significant at tunnel lengths of  $\geq 14$  mm. We therefore suggest that while the balloon pull-through technique may be employed safely in all patients, it is especially useful in patients with PFO tunnel lengths  $\geq 14$  mm.

The simple, quick, and uncomplicated nature of this balloon pull-through technique makes it an attractive method for optimal device placement and may obviate the need for transseptal procedure during CardioSEAL placement. Additional studies are needed, however, to compare the efficacy and safety of these two techniques.

Our study is aimed at evaluation of catheter techniques that improve final device position so that optimal endothelialization of the device is achieved. Even though one patient out of the four with poor device position had a residual shunt in our study, the small number of patients and the short duration of follow-up preclude us to draw meaningful conclusions regarding the effect of device position on residual shunt. Moreover, the recurrence of neurological events in the absence of residual shunt in the

two patients outlines the difficulty in predicting recurrent stroke risk in individual patients after device closure of PFO. Large-scale randomized controlled trials are necessary to address these issues.

In conclusion use of a simple balloon pull-through technique to assist in transcatheter CardioSEAL device closure of PFO in patients with cryptogenic stroke resulted in improved final device position compared to using the standard delivery technique. This procedure is especially useful in patients who have long PFO tunnel lengths.

## REFERENCES

1. Fisher DC, Fisher EA, Budd JH, Rosen SE, Goldman ME. The incidence of patent foramen ovale in 1000 consecutive patients. *Chest* 1995;107:1504–1509.
2. Lechat P, Mas JL, Lascault G, Loron P, Theard M, Klimczak M, Drobinski G, Thomas D, Grosgeat Y. Prevalence of patent foramen ovale in patients with stroke. *N Engl J Med* 1988;318:1148–1152.
3. Homma S, Sacco RL, Di Tullio MR, Sciaccia RR, Mohr JP, PFO in Cryptogenic Stroke Study (PICSS) investigators. Effect of medical treatment in stroke patients with patent foramen ovale: patent foramen ovale in cryptogenic stroke study. *Circulation* 2002;105:2625–2631.
4. Ruchat P, Bogousslavsky J, Hurni M, Fischer AP, Jeanrenand X, Von Segesser CK. Systematic surgical closure of patent foramen ovale in selected patients with cerebrovascular events due to paradoxical embolism: early results of a preliminary study. *Eur J Cardiothor Surg* 1997;11:824–827.
5. Butera G, Bini MR, Chessa M, Bedogni F, Onofri M, Carminati M. Transcatheter closure of patent foramen ovale in patients with cryptogenic stroke. *Ital Heart J* 2001;2:115–118.
6. Sievert H, Babic UU, Hausdork G, et al. Transcatheter closure of atrial septal defect and patent foramen ovale with ASDOS device. *Am J Cardiol* 1998;82:1405–1413.
7. Bridges ND, Hellenbrand WE, Latson L, Filiano J, Newburger JW, Lock JE. Transcatheter closure of patent foramen ovale after presumed paradoxical embolism. *Circulation* 1992;86:1902–1908.
8. Ruiz CE, Alboliras ET, Pophal SG. The puncture technique: a new method for transcatheter closure of patent foramen ovale. *Catheter Cardiovasc Interv* 2001;53:369–372.
9. Windecker S, Wahl A, Chatterjee T, Garachemani A, Eberli FR, Seiler C, Meier B. Percutaneous closure of patent foramen ovale in patients with paradoxical embolism: long-term risk of recurrent thromboembolic events. *Circulation* 2000;101:893–898.
10. Marshall AC, Lock JE. Structural and compliant anatomy of the patent foramen ovale in patients undergoing transcatheter closure. *Am Heart J* 2000;140:303–307.