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ORIGINAL STUDIES

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EDITORIAL COMMENT: Expert Article Analysis for:
Comparative effectiveness research applied to medical devices: Which PFO closure device is the best?

Comparison of residual shunt rate and complications across 6 different closure devices for patent foramen ovale

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Abstract

Objectives: To compare residual shunt rate and complications associated with six different devices used for PFO closure.

Background: Transcutaneous PFO closure is an effective treatment for preventing recurrent stroke in patients with a history of cryptogenic stroke. The rate of residual shunt is one metric by which the technical success of PFO closure can be measured.

Methods: Patients who underwent PFO closure at a single center between February 2001 and July 2019 were retrospectively enrolled in the study. Right-to-left shunt at baseline and during follow-up was assessed using transcranial Doppler (TCD) or transthoracic echocardiography (TTE). Periprocedural and device-related complications, including atrial fibrillation, were also assessed.

Results: Of 467 PFO closures performed during this period, 320 patients received quantitative assessment of right-to-left shunting both before and after percutaneous closure. The highest effective closure was achieved with the Cardioform device (100%, *n* = 104), followed by the Amplatzer Cribriform (93%, *n* = 14), Helex (90%, *n* = 137), Amplatzer ASO (88%, *n* = 17), CardioSEAL (86%, *n* = 14), and Amplatzer PFO (85%, *n* = 33) devices. The most common significant adverse event was atrial fibrillation, which was more common with the Cardioform device (13%) than the Helex (4%) or the Amplatzer PFO (4%) devices.

Conclusions: The Gore Cardioform Septal Occluder provides more robust closure of a PFO when compared to other devices but its effectiveness is offset by the higher prevalence of transient atrial fibrillation.

KEYWORDS

complications, patent foramen ovale, patent foramen ovale closure, PFO closure device, residual shunt rate

1 | INTRODUCTION

The foramen ovale is a vestigial structure of fetal cardiac embryology present in mammals.[1,2] It usually closes within the first year after birth but remains patent in 20–25% of adults and permits intermittent right-to-left shunting between the right and left atria.[3,4] A patent foramen ovale (PFO) has been implicated in numerous medical conditions, including cryptogenic stroke, migraine with aura, decompression illness, high

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altitude pulmonary edema, acute mountain sickness, and platypnea-orthodeoxia syndrome.[5–9] Transcatheter PFO closure is an effective means of preventing recurrent stroke in patients with a history of cryptogenic stroke, and is superior to medical therapy alone.[10–12]

In this retrospective study, the efficacy of six different PFO closure devices used in the United States (Amplatzer ASO, Amplatzer PFO, Amplatzer Cribriform, Gore Helex, Gore Cardioform, and NMT CardioSEAL) over an 18-year period, was assessed by measuring the degree of residual shunt after implantation. In addition, the safety of PFO closure was assessed for serious procedure- and device-related adverse events.

2 | METHODS

From February 2001 to July 2019, a total of 467 patients with right-to-left shunt underwent PFO closure. Technical success of the procedure was defined as successful delivery and implantation of the PFO closure device, followed by effective resolution of the right-to-left shunt as measured by transcranial Doppler (TCD) or transthoracic echocardiogram (TTE).

2.1 | Transcranial Doppler

The baseline right-to-left shunt was evaluated using TCD with agitated saline (Terumo 150 PMD, Power M-Mode). Bilateral ultrasound probes were mounted on a headband and placed around the patient's forehead. The right and left middle cerebral arteries were insonated through temporal acoustic windows. An agitated saline mixture containing 8 ml of normal saline, 1 ml of blood, and 0.5 ml of air was intravenously injected using a 20-gauge Angiocath via right antecubital fossa access at rest. The injection was repeated after the patient was instructed to perform a Valsalva maneuver (induced by forced expiration into a tube connected to a manometer, with gauge target pressure of 40 mmHg for 8–10 s). TCD results were categorized using the Spencer Logarithmic Scale (Table 1).[13,14] TCD studies were performed at baseline and after device placement, with post-PFO closure studies occurring every 3 months until either effective closure was achieved or 12 months of follow-up had elapsed, whichever occurred first. Effective closure was defined as Spencer grade ≤ 2 following Valsalva maneuver. Residual shunting was defined as the presence of Spencer grade ≥ 3 at 12 months after device placement.

Of note, TCD follow-up studies were delayed in the CardioSEAL device group and some of the Amplatzer device recipients as the routine use of this study only became available after 2009, by which time the 12-month postdevice implantation mark for these patients had passed.

TABLE 1 Spencer Logarithmic Scale

Spencer grade	# of microbubbles
Grade 0	None
Grade 1	1–10
Grade 2	11–30
Grade 3	31–100
Grade 4	101–300
Grade 5	>300

2.2 | Transthoracic echocardiogram

A TTE with bubble study (similar method as with TCD) was performed when TCD was unavailable. Residual shunting was defined as the presence of ≥1 air bubble in the left atrium within the first five cardiac cycles after the agitated saline injection, at the 12-month mark after the PFO closure procedure.

2.3 | Patent foramen ovale anatomy

The PFO length, defined as the length of overlap of the septum primum with the septum secundum, was determined using transesophageal echocardiography (TEE). The PFO width, defined as the balloon waist diameter in the right anterior oblique angiographic projection, was determined using a 24-mm Amplatzer sizing balloon at the time of PFO closure. Following the PFO closure procedure, two individuals independently reviewed the TEE and sizing balloon images to make the required measurements.

2.4 | Follow-up

Patients were seen either 1–3 months following PFO closure for a routine follow-up visit or sooner if they had any complaints. Of note, extended electrocardiogram monitoring was not performed unless the patient complained of recurrent symptomatic palpitations.

2.5 | Statistical analysis

Categorical variables were compared with either chi-squared analysis or Fisher's exact test (if the frequency was <5). Data were checked for homogeneity using Levene's test. Continuous variables were compared using one-way Analysis of Variance (ANOVA) with post hoc testing. Bonferroni correction was applied to adjust the p-value for multiple comparisons. The Games-Howell test was used when the assumption of the homogeneity of variance among the compared groups was violated. The Kruskal–Wallis test was used to compare the medians among the groups. Pearson correlation coefficient and Bland–Altman analysis were utilized to measure the interobserver variability of the balloon measurements. Median and interquartile ranges were used to describe the resolution of the shunt over time. Kaplan–Meier analysis was used to compare the effective closure rates among the devices within the first year. A value of $p \leq .05$ was considered statistically significant. All analyses were performed with SPSS version 24 (IBM corporation, Armonk, New York).

3 | RESULTS

The study population was drawn from the pool of patients who were evaluated by the UCLA Interventional Cardiology Program between

February 2001 and July 2019. Of the 1,034 patients that were evaluated for PFO-related conditions, 467 patients (45.1%) elected to have their PFO closed.

PFO closure was performed using the Amplatzer ASO, Amplatzer PFO, Amplatzer Cribriform, Gore Helex, Gore Cardioform, or NMT CardioSEAL devices. The Helex and CardioSEAL devices are no longer manufactured, but their data are presented to permit comparison of PFO closure effectiveness over a longer period of time. Of the 467 patients who underwent PFO closure, 320 (68.5%) had adequate baseline and follow-up assessments and were included in this study. Of these 320 patients, 304 (95%) had a TCD assessment and the remaining 16 (5%) had a TTE assessment. Table 2 lists the baseline characteristics of patients who participated in the study. Table 3 lists the PFO length and width for patients who had these data available and the frequency of each of the six different PFO closure devices used. The Amplatzer ASO group had a wider PFO canal compared to the other groups because in the early experience, an ASO device was chosen to treat larger PFOs. The length of the PFO was similar across all device groups except for the Cardioform group. The CardioSEAL was implanted in 14 (4.4%), Amplatzer ASO in 17 (5.3%), Amplatzer PFO in 33 (10.3%), Amplatzer Cribriform in 14 (4.4%), Gore Helex in 137 (42.8%), and Cardioform in 105 (32.8%).

One patient in the Cardioform group had pulmonary arteriovenous malformations in addition to a PFO and was excluded from the final analysis due to an inability to close all of the pulmonary shunts.

TABLE 2 Baseline characteristics of the study participants

Variable		*N* (%) or Mean ± *SD*
Total # of patients		320
Male		152 (47.5%)
Age at procedure		52.9 ± 14.5
Hypertension		65 (20.3%)
Hyperlipidemia		88 (27.5%)
Diabetes		20 (6.2%)
Reason for referral	CVA	245 (76.6%)
	Migraine headaches	175 (54.7%)
	TIA versus complex migraine	63 (19.7%)
	MI	9 (2.8%)
	Orthodeoxia	42 (13.1%)
	≥ 1 diagnosis	267 (83.4%)
Device	CardioSEAL	14 (4.4%)
	Amplatzer Cribriform	14 (4.4%)
	Amplatzer PFO	33 (10.3%)
	Amplatzer ASO	17 (5.3%)
	Helex	137 (42.8%)
	Cardioform	105 (32.8%)
First follow-up visit (in months)[a]		8.2 ± 16.3
TCD done on follow-up		304 (94.8%)
Baseline RLS (at rest)		3.0 ± 1.6[b]
Baseline RLS (with Valsalva)		4.2 ± 1.0[b]
First TCD post-PFO closure (at rest)		0.7 ± 1.2[b]
First TCD post-PFO closure (with Valsalva)		1.4 ± 1.5[b]

Abbreviations: ASO, atrial septal occlude; CVA, cerebrovascular accident; MI, myocardial ischemia; PFO, patent foramen ovale; RLS, right-to-left shunt; TCD, transcranial Doppler; TIA, transient ischemic attack.
[a]Includes delayed follow-up for CardioSEAL and Amplatzer PFO groups.
[b]Spencer logarithmic scale.

3.1 | PFO closure assessment

TCD assessment at baseline demonstrated a mean Spencer grade of 3.0 ± 1.6 at rest and 4.2 ± 1.0 with Valsalva. The mean time to first follow-up TCD post-PFO closure was 8.2 months. There was significant variability in follow-up time with the different devices because TCD was not routinely used until 2009, and this was more than 12 months after the CardioSEAL and some of the Amplatzer devices were implanted. In the CardioSEAL group, the mean for the first post-PFO closure TCD study was 72.5 ± 30.9 months. Similarly, in the Amplatzer PFO group, the mean for the first post-PFO closure TCD study was 41.5 ± 31.5 months.

In the Cardioform group, the follow-up protocol was modified over time such that the first TCD study was done 1 month after device implantation and if necessary, again at months 2, 3, 6, and 12 because of the observation that the baseline RLS in most of the patients was resolved by 3 months.

For the 16 patients who had follow-up visits at outside hospitals, TTE, which occurred 5.4 ± 4.0 months following PFO closure device placement, was used to assess for residual RLS. Of these 16 patients, two demonstrated persistent shunt around the PFO device (one in the Helex group and one in the Amplatzer PFO group).

Table 4 compares patient groups stratified by device type. The highest effective closure was achieved in the Cardioform group (100%) followed by the Amplatzer Cribriform group (93%) (Figure 1). The time elapsed from device placement to effective closure of the shunt was significantly shorter in the Cardioform group relative to the Helex and Amplatzer ASO recipients. Among the patients who received the Amplatzer devices, the highest proportion of residual shunting was noted with the Amplatzer PFO device (15%).

Based on the Kaplan–Meier analysis, which estimated time to effective PFO closure using data from device groups that had TCD assessment within the first 3 months of PFO closure (i.e., Amplatzer ASO, Cardioform, and Helex), recipients of the Cardioform device achieved the highest effective closure rate and reached this endpoint the quickest (Figure 2).

When stratified by PFO closure device size, only 3/11 (27%) who received the 30 mm Helex device had no evidence of residual shunt at the 1-year mark. In contrast, 49/49 (100%) patients who received the 30 mm Cardioform device had no evidence of residual shunt by 2.2 ± 2.0 months after device implantation ($p < .0001$).

The anatomical parameters of the PFO canal were similar between the Gore Helex 30 mm and Gore Cardioform 30 mm groups: 12.4 ± 2.9 mm versus 11.7 ± 3.4 mm for width ($p = .53$) and 16.6 ± 5.9 mm versus 13.1 ± 2.0 mm for length ($p = .10$).

TABLE 3 Anatomical characteristics of PFO (stratified by descending PFO width)

Device	*N*	PFO length[a] (mean ± *SD*, mm)	*N*	PFO width[b] (mean ± *SD*, mm)
Amplatzer Cribriform	3	10.1 ± 9.5	2	13.9 ± 0.4
Amplatzer ASO	17	9.4 ± 3.0	17	13.0 ± 2.8[d]
Cardioform	43	16.8 ± 4.4[c]	44	10.4 ± 3.6
Amplatzer PFO	9	10.1 ± 3.5	4	8.3 ± 3.9
Helex	69	10.6 ± 4.7	61	8.3 ± 3.3
CardioSEAL	9	10.4 ± 4.3	1	6.4 ± 0.4
p-value		<.0001		<.0001

Abbreviations: ASO, atrial septal occlude; PFO, patent foramen ovale.
[a]Measured from ICE or TEE images.
[b]Measured from sizing balloon images.
[c]PFO canal in the Cardioform group was longer compared to that in the Amplatzer ASO group ($p < .0001$), Amplatzer PFO group ($p = .0058$), and Helex group ($p < .0001$).
[d]PFO canal in the Amplatzer ASO group was wider compared to the Cardioform group ($p = .0096$) and Helex group ($p = .0001$).

TABLE 4 Comparison of effective closure rate and TCD grade at rest and follow-up among the study groups by descending frequency of complete closure

	Device						
Variable	Cardioform	Amplatzer Cribriform	Helex	Amplatzer ASO	CardioSEAL	Amplatzer PFO	*p*-value
# of patients	104	14	137	17	14	33	N/A
Age at procedure (years ± *SD*)	55.0 + 14.7	53.2 ± 12.8	52.6 ± 14.9	51.6 ± 14.6	49.7 ± 12.1	47.9 ± 12.2	NS
Time elapsed from device placement to first TCD assessment (months)	1.9 ± 1.5	11.5 ± 6.3	3.9 ± 1.8	3.3 ± 0.7	72.5 ± 30.9	41.5 ± 31.4	.0001[a] .0035[b]
Spencer grade with Valsalva at baseline	4.6 ± 0.8	4.5 ± 1.0	4.1 ± 1.1	4.0 ± 1.4	Not performed	4.2 ± 1.0	NS
Spencer grade with Valsalva at last follow-up post-PFO closure	0.5 ± 0.7	1.1 ± 1.6	1.4 ± 1.5	0.9 ± 1.0	1.2 ± 1.4	1.0 ± 1.6	<.0001[a]
Effective closure time (months)	2.3 ± 1.7	12.7 ± 6.5	5.7 ± 7.2	3.0 ± 3.4	N/A due to delayed follow-up	N/A due to delayed follow-up	<.0001
Effective closure rate	100% (104/104)	93% (13/14)	90% (123/137)	88% (15/17)	86% (12/14)	85% (28/33)	.0004[a] .0007[c]

Abbreviations: ASO, atrial septal occluder; PFO, patent foramen ovale; TCD, transcranial Doppler.
[a]Cardioform versus Helex group.
[b]Cardioform versus Amplatzer ASO.
[c]Cardioform versus Amplatzer PFO.

3.2 | Adverse events

Table 5 lists the incidence of adverse events based on device type. All device groups had patients who experienced mild chest pain (average = 13.3%). All device groups except for the Amplatzer Cribriform group had patients who complained of episodic palpitations. Unique adverse events include prompt surgical extraction of the PFO closure device due to a wire frame fracture causing cardiac tamponade ($n = 1$, Cardioform group) (submitted for publication), device embolization requiring endovascular removal and percutaneous placement of a new device ($n = 1$, Helex group),[15] and thrombus formation on the device ($n = 3$, CardioSEAL group).[16]

Over the span of this study, there were four MRI-proven recurrent strokes, three in the Helex group and one in the Cardioform group. A retrospective review of these cases revealed three to have clear causes (atrial fibrillation [$n = 1$], carotid web [$n = 1$], small vessel disease [$n = 1$]), and one to have an unclear cause in the absence of a residual RLS.

A subgroup analysis of patients within the Gore Helex and Gore Cardioform groups revealed that the incidence of atrial fibrillation following PFO closure was significantly different: 4% (5/137) in the Helex group versus 13% (11/85) in the Cardioform group ($p < .01$) (Figure 3). Data from the RESPECT and REDUCE trials are included to compare the results of this study with those observed in multicenter trials.

4 | DISCUSSION

PFO closure is currently FDA-approved for prevention of recurrent stroke in patients without an alternative etiology for their initial

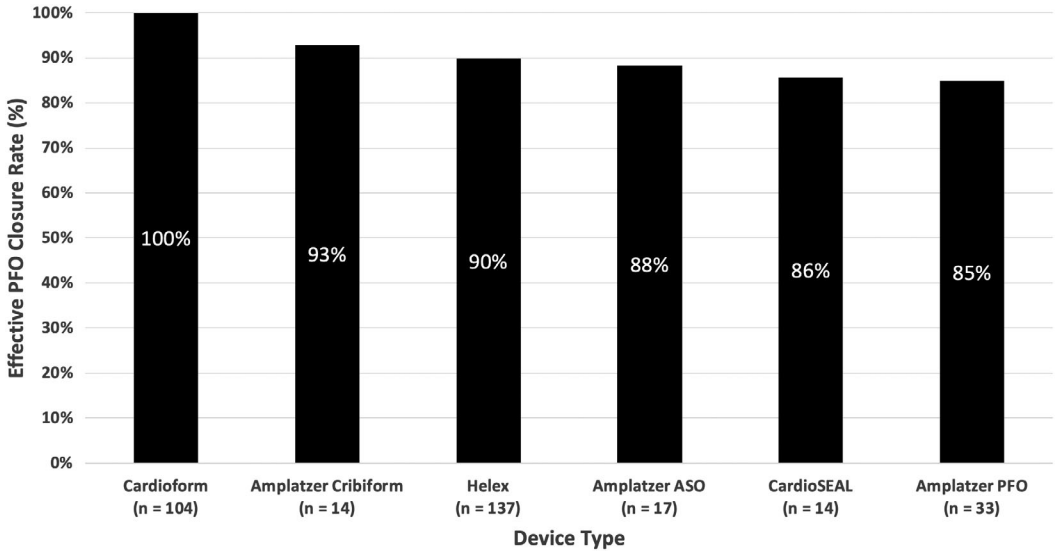

FIGURE 1 Effective PFO closure rate by device type. ASO = atrial septal occluder; PFO = patent foramen ovale; RLS = right-to-left shunt

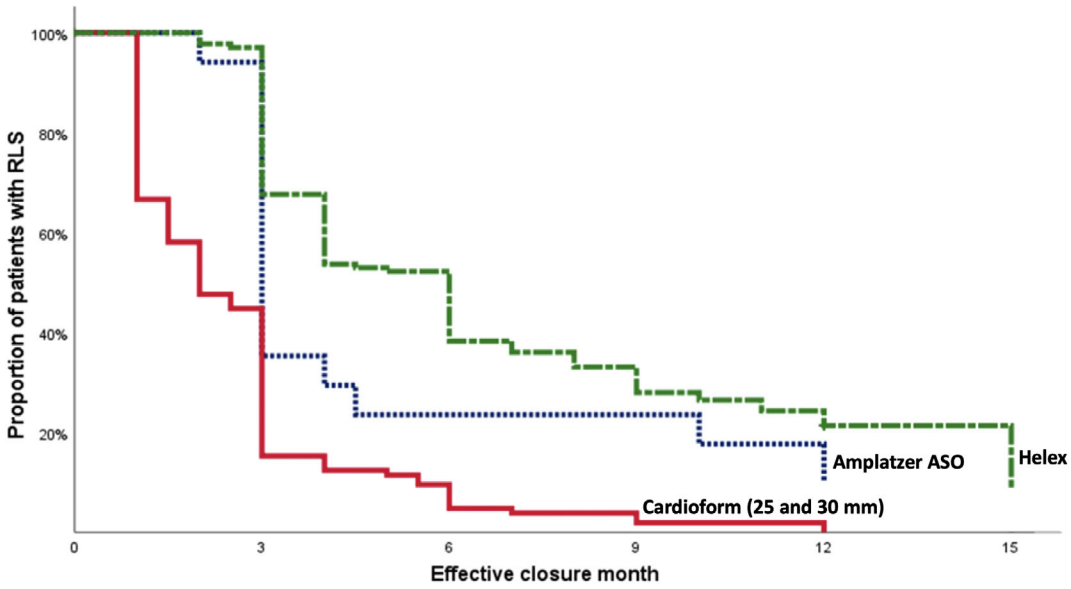

FIGURE 2 Kaplan–Meier analysis demonstrating proportion of patients with residual RLS as a function of time. At month 12, the Cardioform device had the lowest proportion of patients with residual RLS shunt, followed by the Amplatzer ASO and Helex devices. ASO = atrial septal occluder; RLS = right-to-left [Color figure can be viewed at wileyonlinelibrary.com]

stroke. Complete resolution of right-to-left shunt is an important determinant of a technically successful PFO closure. This study demonstrates that, among six different PFO occluders used across 320 subjects, the Cardioform device achieved the highest effective closure rate but at the expense of a higher frequency of atrial fibrillation. These two observations are presumably related by the stronger force between the two disks used in this device compared with the previous Helex model. The stronger attractive force provides more effective closure but may produce more irritation.

Conformation of the PFO closure device to the PFO and septal anatomy are important determinants of an effective PFO closure procedure. Unlike atrial septal defects that have an oval-shaped hole, the PFO often has a horseshoe shape with a windsock-like tunnel resulting from the failed fusion between the septum primum and septum secundum. To promote adequate endothelization, the PFO closure device has to approximate the ends of both septa and mechanically hold them together.

A large PFO with an atrial septal aneurysm, lipomatous septum secundum, prominent Eustachian valve, Chiari network, and other associated congenital malformations introduce technical difficulties at the time of the procedure and device deployment that may hinder effective closure.[17–19] In this study, the highest frequency of residual shunting was noted with some of the larger non-self-centered devices (8/11 [73%] 30 mm Helex devices and 2/6 [33%] 35 mm Amplatzer PFO devices vs. 0/6 [0%] 35 mm Amplatzer Cribriform device, $p = .009$).

TABLE 5 Adverse events based on device type

Device type	Adverse event type	*n*	%
CardioSEAL (*n* = 14)	Atrial fibrillation	1	7.1
	Chest pain	1	7.1
	Thrombus formation on device	3	21.4
Amplatzer ASO (*n* = 17)	Access site hematoma	1	5.9
	Chest pain	2	11.8
	Dyspnea	3	17.6
	Palpitations	2	11.8
Amplatzer PFO (*n* = 33)	Chest pain	2	6.1
	Bleeding	1	3.0
	Palpitations	4	12.1
Amplatzer Cribriform (*n* = 14)	Access site hematoma	1	7.1
	Chest pain	5	35.7
	DVT	1	7.1
	Hematuria	1	7.1
Helex (*n* = 137)	Chest pain	18	13.1
	Device embolization	1	0.7
	Palpitations	16	11.7
	Atrial fibrillation	6	4.4
	Atrial flutter	1	0.7
	Bigeminy	1	0.7
	Multifocal PVCs	1	0.7
	Recurrent stroke	3	2.2
	Known etiology	2	1.5
	Unknown etiology	1	0.7
Cardioform (*n* = 105)	Access site hematoma	1	1.0
	Bacteremia	1	1.0
	Cardiac tamponade	1	1.0
	Chest pain	6	5.7
	Palpitations	19	18.1
	Atrial fibrillation[a]	9	8.6
	Supraventricular tachycardia	1	1.0
	Surgical extraction of device	1	1.0

Abbreviations: DVT, deep vein thrombosis; PVCs, premature ventricular contractions; TIA, transient ischemic attack.
[a]One patient had an ischemic stroke thought to be related to atrial fibrillation.

In the RESPECT study, shunt resolution after placement of the Amplatzer PFO device was significantly higher than that observed in our study (458/462 [99%] in RESPECT vs. 28/33 [85%] in this study).[12] This large difference may be due to the protocol of RESPECT using TEE, which is less sensitive compared to TCD in the evaluation of shunts, and sample size.[20]

Large PFO defects present challenges for the central pin devices as distinguished from the self-centering ASD occluders because the pin could rest against the perimeter of the defect and permit the edge of the device to fall under the septum secundum, through the PFO tunnel, and into the left atrium. When deployed, the pin devices tend to lodge asymmetrically onto the lateral sides of the PFO. Furthermore, generation of inadequate closing force by the Helex device introduces risk for device slippage and embolization postdeployment.[21] Inability of the Helex device to hold itself against the septal wall may be responsible for the increased incidence of residual shunting observed in the 30 mm Helex device compared to the other 25 mm devices, consistent with findings by Matsumura et al.[22] To compensate for the inadequate clamping force associated with the earlier devices (prior to the release of the Cardioform device), interventionalists often chose the Amplatzer ASO device if balloon sizing yielded a PFO width > 12 mm. Both the Amplatzer PFO and Amplatzer ASO devices provide sufficient closing force, but given the stiffness associated with the nitinol mesh disks and the possibility of a nickel allergy, these devices have been shown to be associated with higher prevalence of chest pain, excessive scarring, and device erosion.[23] On the contrary, among the non-self-centered devices, the Cribriform device, due to its larger left atrial disk diameter and stiffness, accommodates atrial septal aneurysms better. This was described in a study by Rigatelli et al, who showed a lower incidence of residual shunting with the Amplatzer Cribriform device compared to the Gore Helex device.[24]

In REDUCE, where 61% of the PFO closure devices used were Cardioform and the remaining 39% were Helex,[25] the effective closure rate was 98.8%, similar to our observations with the Cardioform device. The structure of the Cardioform device is similar to the Helex device (both have a thin nitinol wire that supports expanded polytetrafluoroethylene [ePTFE]-covered disks) but the Cardioform device has greater opposing strength. An alteration over the previous Helex device design, the right and left disks of the Cardioform are split into five petals circumscribed with a single nitinol wire that extends to the perimeter of each petal. This design generates a higher amount of closing force, allowing the device to have a better grip on the surrounding septum and subsequently decreasing the risk of device slippage and embolization. Furthermore, the Cardioform device can be successfully utilized with different variations of fossa ovalis anatomy. Given these advantages, after the Cardioform device became available, the use of the Amplatzer ASO device for larger PFOs declined.

This study had to modify the follow-up timeline for assessment of residual right-to-left shunt in the Cardioform group because of the observation that patients who had their PFO closed with the Cardioform device had no evidence of residual shunt at the 3-month mark. The resulting nonuniform TCD measurement protocols across the different device groups introduced a bias when analyzing time to effective closure, but not the primary measure of effective closure.

The incidence of atrial fibrillation was higher with the Cardioform device (13%) than with the Helex device (4%) ($p < .01$). In the RESPECT trial, which used the Amplatzer PFO occluder, the incidence of atrial fibrillation was 4% (20/499) at a median follow-up of 5.9 years. In the REDUCE trial, which used the Cardioform device in 61% (*n* = 269) of patients in the PFO closure group, the incidence of atrial fibrillation was 7% (20/269), compared to 5% (9/172) in the remaining 39% (*n* = 172) who had the Helex device. Although the Cardioform device yields a lower residual shunt rate, it places patients at a

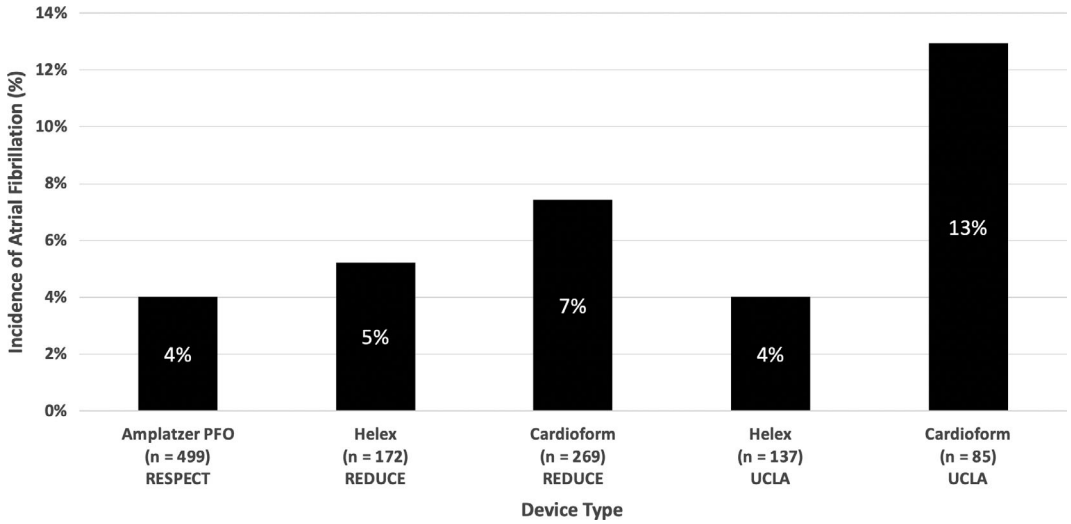

FIGURE 3 Incidence of atrial fibrillation with different PFO closure devices. The UCLA Cardioform subgroup had a higher incidence of atrial fibrillation compared to RESPECT, REDUCE, and the UCLA Helex subgroup. PFO = patent foramen ovale; REDUCE = Patent Foramen Ovale Closure or Antiplatelet Therapy for Cryptogenic Stroke; RESPECT = Randomized Evaluation of Recurrent Stroke Comparing PFO Closure to Established Current Standard of Care Treatment; UCLA = University of California, Los Angeles

higher risk of developing transient atrial fibrillation, thereby emphasizing the need to balance risks and benefits when choosing which device to use when closing a PFO. All of the clinical trials that looked at PFO closure as a means of preventing recurrent cryptogenic stroke, as well as this study, likely underestimate the true incidence of atrial fibrillation because consistent ECG monitoring was not performed following the procedure. ECG monitoring with an implantable monitor is superior to conventional follow-up for detecting this arrhythmia after cryptogenic stroke.[26]

5 | LIMITATIONS

This study was limited by a relatively small sample size in the Amplatzer and CardioSEAL groups compared to the Helex and Cardioform groups. However, the numbers reflect the frequency at which each device was used in the involved center and opens the pathway for other centers to publish their experiences to enable broader comparisons. Second, based on device availability over the time course of this study, the Amplatzer Cribriform and Amplatzer ASO devices were implanted in patients with wider and shorter PFO canals compared to the Cardioform device. Third, since this study did not enroll the CardioSEAL and some of the Amplatzer subjects prospectively, there was a significant delay in their post-PFO closure TCD assessment, which would affect the time from implantation to complete closure, but not the effectiveness of closure or the residual shunt size. Prospective ECG monitoring was not performed unless the patient complained of palpitations, which could underestimate the frequency of atrial fibrillation.

6 | CONCLUSIONS

This study assessed the degree of residual right-to-left shunt with six different devices used to close a PFO over an 18-year period at one institution with the same operators. Although the Cardioform device demonstrated an effective PFO closure rate of 100%, this occurred at the expense of a higher risk (13%) of developing transient atrial fibrillation.

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