

## Original Article

**Effectiveness of MemoPart for Patent Foramen Ovale Closure in Real-World Patients**

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**Abstract**

**Aim:** Patent foramen ovale (PFO) is a common congenital heart defect associated with cryptogenic stroke, transient ischemic attacks (TIAs), and migraines. The Multifenestrated MemoPart device is specifically designed to address complex anatomical variations of PFO. This study evaluates the feasibility, safety, and effectiveness of MemoPart for PFO closure in a real-world setting.



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**Methods:** Consecutive patients undergoing PFO closure with the MemoPart device were included. Diagnosis was based on transthoracic echocardiography with bubble contrast and quantification of Valsalva maneuver intensity with the Valsalan approach. Procedural success, adverse events, residual shunts, and clinical outcomes were assessed at baseline and up to 3 months.

**Results:** A total of 60 patients were included in the overall analysis, with age  $51.6 \pm 12.6$  years, and 30 (50%) women. Most participants (46 [77%]) reported a history of stroke, and a Reduce PFO morphology was the most common (34 [57%]). Acutely complete closure was achieved in 59 (98% [91%-100%]) cases, whereas 3-month echocardiographic follow-up showed complete closure in all 60 (100% [94%-100%]). No major or other serious adverse events were reported, and bubble testing showed 0 MES in 49 (82% [70%-91%]) cases. Exploratory ordinal logistic regression suggested that MES were higher in those with complicated (OR=1.54 [0.04-3.04],  $p=0.044$ ) and Tunnel morphologies (OR=1.23 [0.01-2.45],  $p=0.048$ ), as well as with atrial septal aneurysm (OR=2.22 [0.54-3.91],  $p=0.010$ ).

**Conclusion:** MemoPart is a safe and effective option for PFO closure, in routine as well as anatomically complex cases. These findings support its routine use and encourage further long-term studies to confirm its clinical benefits.

**Keywords:** Patent foramen ovale, stroke, transient ischemic attack

## INTRODUCTION

Patent foramen ovale (PFO) is a common congenital heart defect found in approximately 25% of the general population.<sup>[1-3]</sup> While often asymptomatic, PFO has been implicated in cryptogenic stroke, transient ischemic attacks (TIAs), and migraine with aura, particularly in patients with high-risk anatomical features such as large shunts or atrial septal aneurysms.<sup>[4-6]</sup> Closure of PFO has become a pivotal strategy to mitigate

these risks, with percutaneous device-based interventions offering a less invasive alternative to traditional surgical methods.<sup>[7-11]</sup>

MemoPart (Lepu Medical Technology, Beijing, China) represents a novel device designed to address the unique anatomical complexities of PFO, particularly in patients with challenging multi-fenestrated septal defects. Its design features aim to enhance procedural safety, ensure effective closure, and minimize residual shunting while maintaining a favorable recovery profile.<sup>[12-13]</sup> Early clinical experience suggests high success rates with minimal complications, as demonstrated in case reports and small observational studies.<sup>[12]</sup>

We aimed at appraising the effectiveness of MemoPart in real-world clinical practice, capturing a diverse patient population with varied clinical presentations. The study integrates comprehensive procedural, echocardiographic, and follow-up data to provide robust insights into device performance, procedural outcomes, and long-term patient benefit. Key outcomes of interest include acute success rates, residual shunt prevalence, and adverse events

## **METHODS**

### **Design**

We conducted a retrospective observational study evaluating the feasibility, safety, and effectiveness of the MemoPart device in patients undergoing percutaneous closure of PFO at our Institution.

### **Patients**

Eligible patients were those diagnosed with PFO based on clinical presentation and imaging evidence, including stroke, TIA, or migraine. Key inclusion criteria, as per established clinical practice recommendations, included presence of PFO confirmed by transthoracic echocardiography with bubble contrast and quantification of Valsalva

maneuver intensity with the Valsalan approach, age  $\geq 18$  years, and indication for PFO closure per current guidelines.<sup>[2-3,14-15]</sup>

## Procedures

MemoPart was used for all procedures, with choice of device size at operator's discretion, but taking into account specific PFO morphology features.<sup>[12]</sup> In particular, on top PFO size, we explicitly appraised the presence of atrial septal aneurism and lipomatosis of the superior septum, as well as complicated, Cryb-Reduce, Cryb-Tunnel, Reduce, Reduce-Tunnel, and Tunnel patterns.<sup>[2-3,9-10,14,16-19]</sup>

Procedures were performed under fluoroscopic and echocardiographic guidance, employing always transesophageal echocardiography. Mild Sedation was always utilized based. All patients provided written informed consent for the procedure and data collection.

## Follow-up

Post-procedure, patients underwent follow-up echocardiography with bubble contrast at 3 months to assess for residual shunts or complications. Procedural success and adverse events, including major adverse events (MAE) and serious adverse events (SAE) were systematically collected. In addition, echocardiography with bubble contrast was regularly used during 3-month follow-up imaging control, with images acquired at rest and after Valsalva with homemade Valsalvometer (Valsalan).<sup>[20,21]</sup>

## Analysis

Continuous variables were summarized for descriptive purposes using mean $\pm$ standard deviation, while categorical variables were presented as frequencies and percentages. Exact 95% confidence intervals were generated for inferential purposes. In addition, an exploratory analysis for features associated with MES at follow-up echocardiography with bubble contrast was performed using ordinal logistic regression, reporting odds

ratios (OR), with accompanying 95% confidence intervals and p values. Computations were performed with Stata 18 (StataCorp, College Station, TX, USA). This registry was conducted in keeping with ethical regulations at our Institution, with ethical approval waived given the retrospective design.

## RESULTS

A total of 60 patients were included, with age of  $51.6 \pm 12.6$  years, and 30 (50%) women (Table 1; Table 2). The most common clinical presentation was stroke, which was reported by 46 (77%) participants. Anatomical features included atrial septal aneurysms in 4 (7%) and Reduce morphology in 34 (57%), with complex morphologies quite common, such as Tunnel in 25 (42%) and Cryb-Tunnel in 10 (17%).

**Table 1. Patient and procedural features in the overall sample.**

Feature	Mean $\pm$ SD or count (%)
Patients	60
Age (years)	51.6 $\pm$ 12.6
Female sex	30 (50%)
Clinical history	
Stroke	46 (77%)
Transient ischemic attack	34 (57%)
Migraine	35 (58%)
Patent foramen ovale features	
Atrial septal aneurism	4 (7%)
Complicated	7 (12%)
Cryb-Reduce	10 (17%)
Cryb-Tunnel	10 (17%)
Lipomatosis of the superior septum	7 (12)
Reduce	34 (57%)
Reduce-Tunnel	1 (2%)

Tunnel	25 (42%)
Device size	
24/24 (Hub)	44 (73%)
24/24 (No Hub)	6 (10%)
28/28 (Hub)	9 (15%)
28/28 (No Hub)	1 (2%)
Final result	
Mild residual shunt	1 (2%)
No residual shunt	59 (98%)
Echocardiographic result at 3 months	
No residual shunt	60 (100%)
Micro-embolic signals after contrast saline test at 3 months	
>5	2 (3%)
3-5	6 (10%)
2	1 (2%)
1	2 (3%)
None	49 (82%)
Mitral valve impairment at 3 months	0
Major adverse event	0
Serious adverse event	0

Device size was 24/24 with Hub design in 44 (73%), and all procedures were uneventful. Notably, no shunt was evident in 59 (point estimate of effect: 98% [95% confidence interval: 91%-100%]) of cases, with only 1 case (2% [0-9%]) of minimal shunt at repeat transthoracic echocardiography with bubble contrast.

**Table 2. Patient and procedural features in the quality appraisal sample.**  
PFO=patent foramen ovale.

Feature	Mean±SD or count (%)
Patients	17
Age (years)	55.2±8.0
Female sex	8 (47%)
Clinical history	
Stroke	7 (41%)
Transient ischemic attack	10 (59%)
Migraine	4 (24%)
Right-to-left shunt grading	
I	2 (12%)
II	3 (18%)
III	12 (71%)
Patent foramen ovale features	
Atrial septal aneurism	14 (82%)
Chiari network	0
Comp+licated	0
Cryb-Reduce	2 (12%)
Cryb-Tunnel	0
Lipomatosis of the superior septum	1 (6%)
Long Eustachian valve	1 (6%)
Reduce	12 (71%)
Reduce-Tunnel	0
Right-to-left shunt	9 (53%)
Tunnel	5 (29%)
Patent foramen ovale length (mm)	19.8±4.7
Patent foramen ovale diameter (mm)	4.3±2.3
Device size	
24/24 (Hub)	14 (82%)
28/28 (Hub)	3 (18%)

Technical success	17 (100%)
Final result	+
Mild residual shunt	1 (6%)
No residual shunt	16 (94%)
Echocardiographic result at 3 months	
No residual shunt	17 (100%)
Micro-embolic signals after contrast saline test at 3 months	
None	17 (100%)
Mitral valve impairment at 3 months	0
Major adverse event	0
Serious adverse event	0

At 3-month follow-up, no residual shunt was evident in all cases (100% [94%-100%]), whereas echocardiography with bubble contrast showed micro-embolic signals (MES) counts of >5, 3-5, 2-1, and 0 in, respectively, 2 (3% [0-12%]), 6 (10% [4%-21%]), 3 (5% [1%-14%]), and 49 (82% [70%-91%]). In terms of safety, no case of mitral valve impairment was evident, and no MAE or SAE were reported (0 [0-6%]).

Exploratory ordinal logistic regression showed that MES at 3-month follow-up with echocardiography with bubble contrast were significantly associated with complicated (OR=1.54 [0.04-3.04],  $p=0.044$ ) and Tunnel morphologies (OR=1.23 [0.01-2.45],  $p=0.048$ ), as well as with atrial septal aneurysm (OR=2.22 [0.54-3.91],  $p=0.010$ ).

## DISCUSSION

We hereby report on a real-world clinical experience with PFO closure using the MemoPart device in several challenging patients. Indeed, this study, despite being limited by its retrospective design and moderate sample, demonstrates the feasibility, safety, and effectiveness of MemoPart in this setting. In particular, the favorable



procedural and follow-up outcomes, as well as capability of MemoPart to be used in a variety of challenging anatomic settings, support a wider adoption of this device in routine clinical practice (Figure 1).

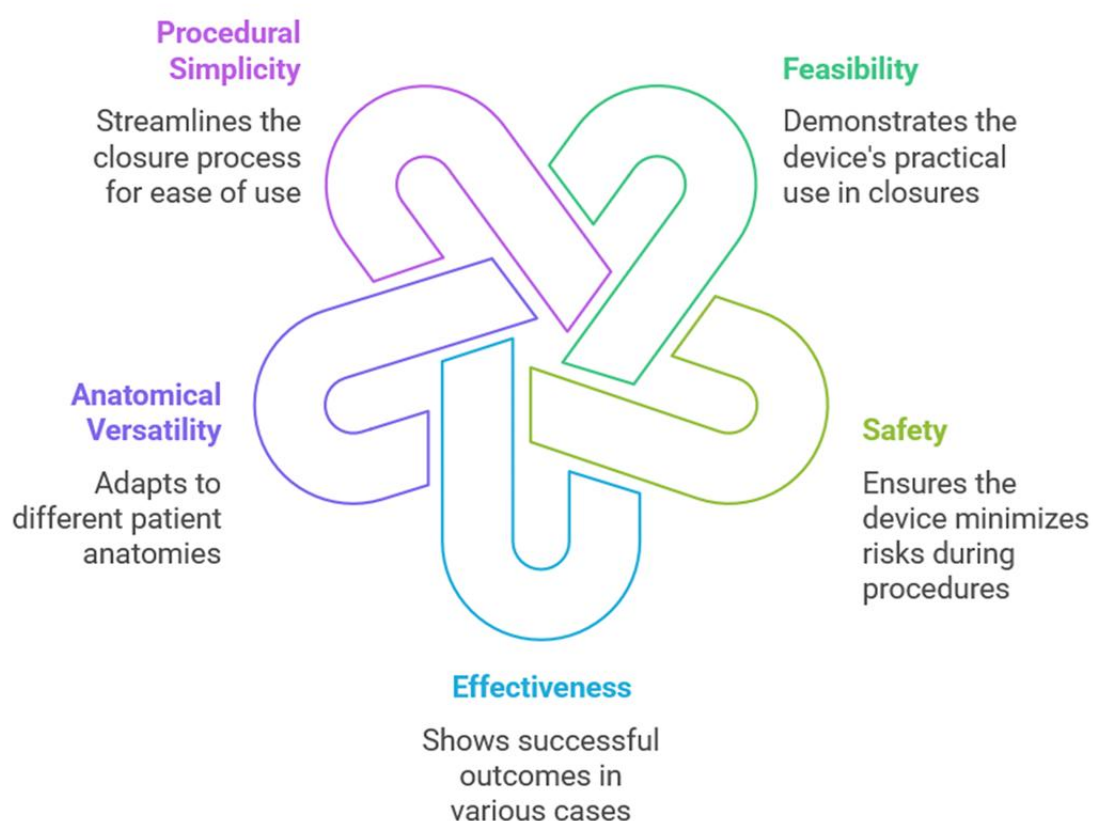
Clinical Case	Clinical features	Anatomic features	MemoPart Advantages
Young woman with migraine	32-year-old-woman with migraine with aura	Large shunt with atrial septal aneurysm	Effective closure of high-risk PFO; significant symptom improvement; durable results
Elderly man with TIA	72-year-old man with recurrent TIA and concomitant hypertension	Long-tunnel PFO with moderate shunting	Adaptability to complex anatomy; low procedural complication rate; effective PFO closure
Middle-aged woman with stroke	48-year-old woman with cryptogenic stroke, atrial septal aneurysm, and no other embolic sources	Multi-fenestrated PFO	High procedural success in complex anatomy; no residual shunt at follow-up; safety and reliability
Young man with migraine and TIA	26-year-old man with long-standing history of migraine and recent TIA	Large shunt with redundant septum	Immediate symptom resolution; effective closure with minimization of residual shunt; favorable recovery

**Figure 1.** Features and pros of the MemoPart patent foramen ovale occluder in real-world cases. PFO=patent foramen ovale; TIA=transient ischemic attack.

The management of clinically significant PFO is now strongly based on transcatheter closure. Indeed, PFO closure is beneficial in patients with stroke, TIA and migraine, as long as objective evidence of right-to-left shunt is accrued.<sup>[2-3,8,22-24]</sup> Over the last decades, several devices of PFO closure have been tested and adopted, and extensive evidence in favor of some, such as the Amplatzer (Abbott Vascular, Santa Clara, CA, USA), is already available.<sup>[15,21,23]</sup> Conversely, the evidence base for some newer devices is more limited, despite their appealing features. In particular, despite the rosy

design characteristics, limited clinical evidence is available on the MemoPart PFO closure devices.<sup>[12,23]</sup>

Our results thus support a broader use of MemoPart in patients with PFO, even when adverse anatomic features are present. Indeed, we can envision several factors contributing to favorable outcomes achieved by MemoPart (Figure 2). In particular, the self-expanding nitinol frame and polyester fabric ensure effective occlusion while minimizing the risk of residual shunts. The versatility of the device in accommodating diverse anatomical variations enhances its applicability across a wide range of patient profiles. Furthermore, its streamlined and stepwise procedural approach supports its use in high-volume centers, and this holds even truer given the user-friendliness of the release mechanism.



**Figure 2.** Key reasons to consider the MemoPart device for patent foramen ovale occlusion.

Focusing attentively on the study results, an exploratory analysis for predictors of MES at follow-up echocardiography with bubble contrast suggested that they were significantly associated with the presence of atrial septal aneurysm and a Tunnel or complicated morphology. While these findings confirm the established perspective that PFO closure is more challenging in the presence of adverse anatomic features, they should not be seen as an indication to avoid using MemoPart in similar cases. Conversely, even in such cases repeat transthoracic echocardiography with bubble contrast showed the absence of any clinically significant shunt, and in any case MES counts very were low even in such cases.

Our findings thus support a wider adoption of MemoPart, as well as the design and conduct of dedicated controlled trials, hopefully randomized, to compare this device to other devices for PFO closure. Indeed, this work is limited by its single center setting and retrospective design. Furthermore, while 60 cases represent a reasonably extensive experience with a unique PFO closure device, this sample is still limited for precise statistical effect estimation, and even more so for exploratory analyses for predictors of outcomes. Accordingly, the reader should peruse attentively and carefully the present findings, which remain descriptive and hypothesis-generating in scope.<sup>[25]</sup>

In conclusion, the MemoPart Occluder is a safe, effective, and versatile option for percutaneous PFO closure, particularly in complex cases. These findings support its incorporation into routine clinical practice and highlight the need for further research to validate its long-term benefits and broader applications.

## **DECLARATIONS**

### **Acknowledgments**

This manuscript was based on analyses conducted and was drafted with the assistance of artificial intelligence tools, including ChatGPT 4 (OpenAI, San Francisco, CA, USA)

and Napkin AI (Napkin AI, Palo Alto, CA, USA), in keeping with established best practices (Biondi-Zoccai G, editor. ChatGPT for Medical Research. Torino: Edizioni Minerva Medica; 2024). The final content, including all conclusions and opinions, has been thoroughly revised, edited, and approved by the authors. The authors take full responsibility for the integrity and accuracy of the work and retain full credit for all intellectual contributions. Compliance with ethical standards and guidelines for the use of artificial intelligence in research has been ensured.

### **Authors' contributions**

Dr. Lanzone designed the study, supervised data collection and analysis, and participated in manuscript drafting, eventually approving it.

### **Availability of data and materials**

Anonymized source data from this study can be provided upon request from the corresponding author.

### **Financial support and sponsorship**

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### **Conflicts of interest**

Giuseppe Biondi-Zoccai has consulted for Abiomed, Advanced Nanotherapies, Aleph, Amarin, AstraZeneca, Balmed, Cardionovum, Cepton, Cranmedical, Endocore Lab, Eukon, Guidotti, Innovheart, Meditrial, Menarini, Microport, Opsens Medical, Terumo, and Translumina, outside the present work. All other authors report no conflict of interest.

### **Ethical approval and consent to participate**

This registry was conducted in keeping with ethical regulations at our Institution, with ethical approval waived given the retrospective design. All patients provided written informed consent for the procedure and data collection.

### Consent for publication

Not applicable.

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