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Anatomical predictors for suture-based closure of the patent foramen ovale: A multicenter experience

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Abstract

Background: NobleStitch EL is a novel suture-based technique used for patent foramen ovale (PFO) closure and an alternative to traditional double-disc devices without the need for antithrombotic therapy. However, successful closure rates are still unknown, and certain anatomies may be unfavorable for successful closure.

Aims: We assessed the efficacy of the NobleStitch EL and sought to identify patient-related anatomical features associated with successful suture-based closure.

Methods: We included 55 patients who underwent PFO closure with the NobleStitch EL in The Netherlands and Switzerland. Successful closure was defined as residual right-to-left shunt grade ≤1 with Valsalva maneuver at a cardiac ultrasound. Predefined possible anatomical determinants for effective closure included PFO length, atrial septal aneurysm, PFO entry- and exit diameter.

Results: Successful closure was achieved in 33 patients (60%). The PFO length was shorter in patients with successful closure compared to unsuccessful closure with a median length of 9.6 mm (IQR 8.0–15.0) versus 13.3 mm (IQR 11.4–18.6) on preprocedural ultrasound ($p = 0.041$) and 9.9 mm (IQR 8.0–13.1) versus 12.5 mm (IQR 9.7–15.4) on angiography ($p = 0.049$). Additionally, the PFO exit diameter and PFO volume were smaller in patients with successful closure than unsuccessful closure, with a mean diameter of 7.0 ± 3.1 mm versus 9.5 ± 3.8 mm ($p = 0.015$) and a median volume of 381 mm^3 (IQR 286–894) versus 985 mm^3 (IQR 572–1550) ($p = 0.016$).

Conclusion: In our study cohort, the successful PFO closure rate using NobleStitch EL was relatively low (60%). With this alternative procedure, patients with a small PFO driven by a short PFO tunnel length and small exit diameter seem to be eligible for successful suture-based closure.

Abbreviations: ICE, intracardiac echocardiography; IQR, interquartile range; PFO, patent foramen ovale; RLS, right-to-left shunt.

Lars S. Witte and Mick P. L. Renkens contributed equally to this study.

KEYWORDS
cryptogenic stroke, heartstitch, NobleStitch EL procedure, patent foramen ovale, PFO closure

1 | INTRODUCTION

Patent foramen ovale (PFO) device closure has proven its superiority over medical therapy alone for secondary prevention in selected cryptogenic stroke patients.[1–5] NobleStitch EL is a novel suture-based technique used for PFO closure and an alternative to traditional closure devices.[6] The use of NobleStitch EL may overcome early and late device-related risks, including arrhythmia, device embolization, thrombus formation, and erosion.[7] Above all, the absence of bi-atrial foreign material may omit the need for continued antiplatelet therapy with inherent bleeding risks. Furthermore the possibility of future interventions requiring an interatrial septal puncture (e.g., pulmonary vein ablation or transcatheter mitral valve repair) remains preserved.[7,8] Therefore, this novel closure technique without a permanent device is promising for the relatively young patient population with PFO and cryptogenic stroke. However, overall closure rates are still unknown, and certain anatomies may be unfavorable for successful closure. In this retrospective observational study, we assessed the efficacy and safety of the NobleStitch EL. Second, we sought to identify characteristics associated with successful suture-based PFO closure. Previous studies only reported two-dimensional echo measurements of PFO tunnel length and width. In this study, we correlated angiographic and balloon sizing measurements with closure success.[6,9–11]

2 | METHODS

2.1 | Study population

In this multicenter retrospective observational study, we analyzed 55 patients, who underwent PFO closure with the NobleStitch EL (Heartstitch, Inc) in The Netherlands (24 patients, UMC Utrecht) and Switzerland (31 patients, Cantonal Hospital Baselland) between 2017 and 2021. All patients considered for PFO closure were asked if they wanted to receive a NobleStitch instead of a traditional closure device (Amplatzer PFO occluder). The patients that agreed were included, there were no selection or exclusion criteria. Right-to-left shunting (RLS) was assessed with transthoracic (TTE) or transesophageal echocardiogram (TEE) by contrast bubble study and Valsalva maneuver in all patients. Shunt size was evaluated as the amount of microbubbles passing through the atrial septum within three heart cycles and graded in four groups: grade 0 (no bubbles), grade 1 (<10 bubbles), grade 2 (10–20 bubbles), and grade 3 (>20 bubbles).[12]

2.2 | Closure procedure

Patients were planned and prepared similarly as for PFO-closure with traditional double-disc devices. One 14 Fr catheter provided venous femoral access to the right atrium. A PTS 20 mm sizing balloon was introduced with simultaneous contrast injection into the right atrium to assess the size and anatomical properties of the PFO. Subsequently, two dedicated 4–0 polypropylene suture delivery systems (NobleStitch S and NobleStitch P) were used to close the PFO. Two guidewires were used to position both delivery systems, one guidewire extending in the superior vena cava (SVC) for correct positioning of the NobleStitch S system and one guidewire crossing the PFO to position the NobleStitch P system.

The procedure was performed as follows (Figure 1). First, the septum secundum is targeted by the NobleStitch S delivery system. The internal suture-carrying arm can be opened once the NobleStitch S system is correctly positioned over the SVC guidewire. Then, the

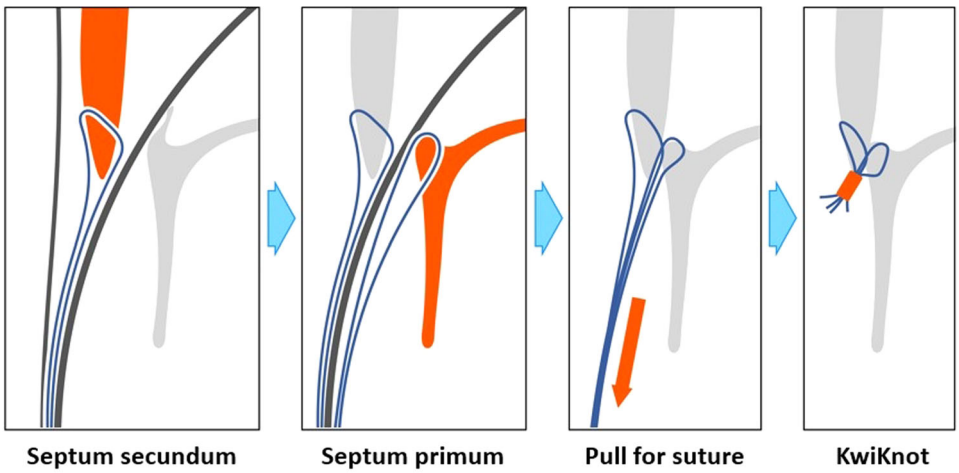

FIGURE 1 Suture based PFO closure. Schematic display of the NobleStitch procedure. The first suture is placed in the septum secundum, the second suture in the septum primum. Finally the KwikNot is placed to secure the sutures. [Color figure can be viewed at wileyonlinelibrary.com]

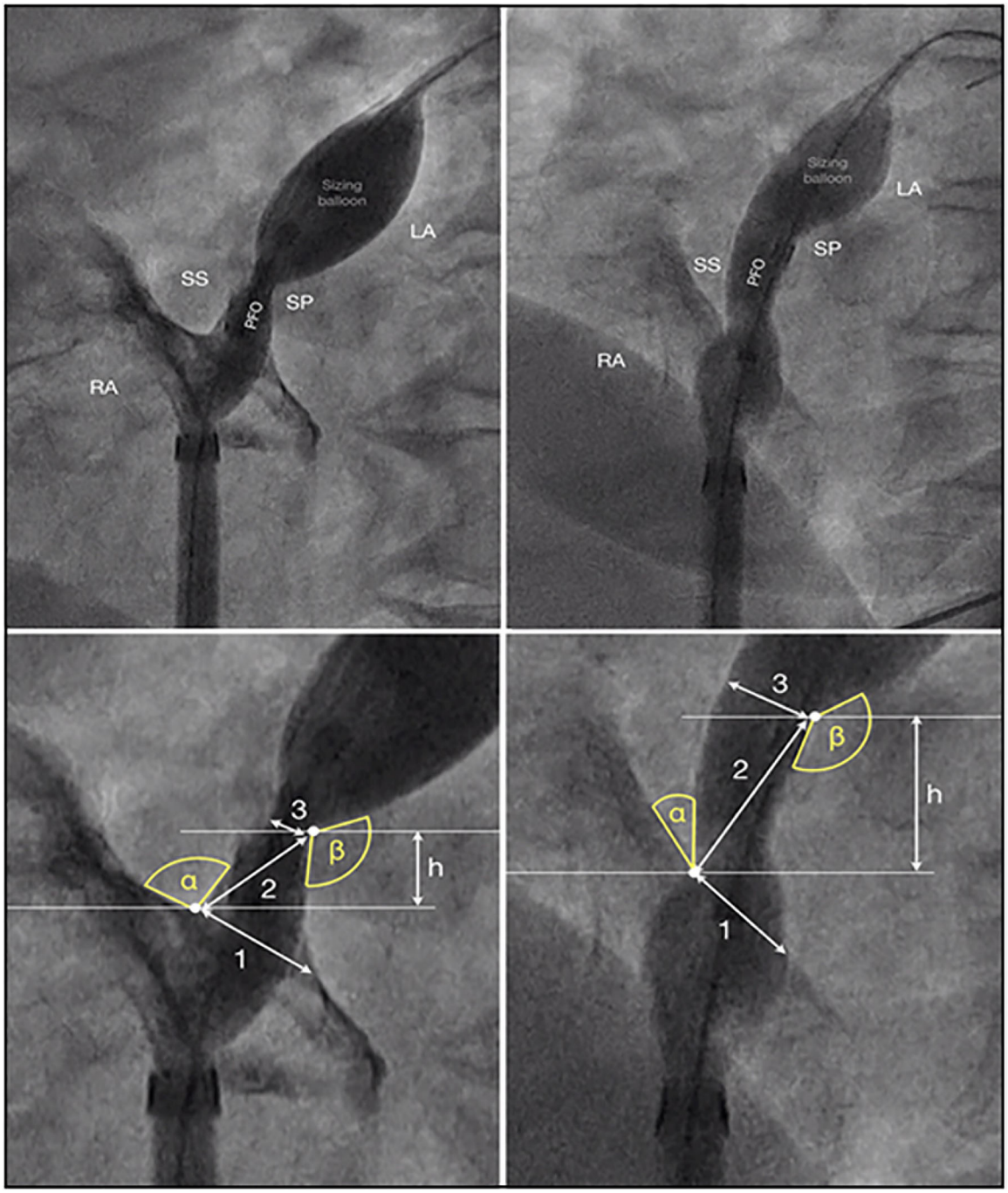

FIGURE 2 Angiographic measurements of the PFO with a sizing balloon. Example of the angiographic measurements of the PFO with a sizing balloon placed through the defect in two patients. 1: PFO entry diameter, 2: PFO tunnel length, 3: PFO exit diameter, h: vertical height of the angle point, *α*: angle at the tip of septum secundum, *β*: angle at the shoulder of the septum primum. LA, left atrium; PFO, patent foramen ovale; RA, right atrium; SP, septum primum; SS, septum secundum. [Color figure can be viewed at wileyonlinelibrary.com]

PFO crossing guidewire is used to guide the movement of the suture-carrying arm toward the PFO and pierce the tissue of the septum secundum. During the piercing process, the suture is released from the suture-carrying component and picked up by the distal segment of the delivery system situated in the right atrium. The entire NobleStitch S delivery system is then retracted together with the SVC guidewire.

Second, the septum primum is targeted by the NobleStitch P delivery system and positioned correctly across the PFO using the PFO guidewire. The suture-carrying arm of the NobleStitch P delivery system can be opened in the left atrium. Once opened, the delivery device can be retracted, and the primum tissue can be pierced with the suture. After piercing, the suture is collected by the proximal part of the delivery system, and the entire system is retracted together

TABLE 1 Baseline characteristics of all patients.

	Overall (*N* = 55)
Indication for closure	
Cryptogenic stroke	49 (89.1%)
Decompression illness	4 (7.3%)
Vestibular migraine	2 (3.6%)
Age (years)–mean (SD)	49.6 (±11.4)
Gender–male	37 (67.3%)
Height (m)–mean (SD)	1.78 (±0.1)
Current or prior smoker	14 (25.5%)
History of hypertension	17 (30.9%)
Blood pressure–mean (SD)	
Systolic (mmHg)	128 (±15.3)
Diastolic (mmHg)	79 (±9.6)
History of diabetes	1 (1.8%)
History of hypercholesterolemia	11 (20.0%)
Family history of CVD	11 (20.0%)
History of ischemic heart disease	3 (5.5%)
Previous myocardial infarction	2 (3.6%)
Previous PCI	1 (1.8%)
History of congestive heart disease	3 (5.5%)
History of valvular dysfunction	2 (3.6%)
Previous TIA or ischemic stroke	20 (36.4%)
Cortical infarction on imaging	29 (52.7%)
Presence of arrhythmia	1 (1.8%)
RoPE-score–median [IQR]	6 [5, 7]

Note: Data are presented as number of patients with percentage, mean with standard deviation or median with interquartile range.

Abbreviations: CVD, cardiovascular diseases; PCI, percutaneous coronary intervention; RoPE, risk of paradoxical embolism; TIA, transient ischemic attack.

TABLE 2 Preprocedural ultrasound measurements.

	Unsuccessful (*N* = 22)	Successful (*N* = 33)	*p* Value
RLS grade			
1	2 (9.1%)	3 (9.1%)	0.491
2	3 (13.6%)	9 (27.3%)	
3	16 (72.7%)	20 (60.6%)	
Unknown	1 (4.5%)	1 (3.0%)	
ASA (>10 mm excursion)			
Yes	6 (27.3%)	10 (30.3%)	0.946
Floppy septum ("jump-rope like")			
Yes	7 (31.8%)	12 (36.4%)	0.889
Left atrium volume index (mL/m^2)			
Mean (SD)	42.6 (±6.2)	41.8 (±9.9)	0.669
Atrial septum thickness (mm)			
Median [IQR]	2.7 [2.2, 4.0]	3.0 [1.9, 5.0]	1
PFO tunnel length (mm)			
Median [IQR]	13.3 [11.4, 18.6]	9.6 [8.0, 15.0]	0.041
Patient height (m)			
Mean (SD)	1.82 (± 0.1)	1.75 (± 0.1)	0.012

Note: Preprocedural ultrasound measurements in patients with unsuccessful (*n* = 22) and successful (*n* = 33) closure. Patients with successful closure had a significantly shorter PFO tunnel length compared to patients with unsuccessful closure. Data are presented as number of patients with percentage, mean with standard deviation or median with interquartile range. Normally distributed variables were compared using the *t* test and non-normally distributed variables using the Mann–Whitney *U* test. A $p < 0.05$ was considered statistically significant.

Abbreviations: ASA, atrial septal aneurysm; IQR, interquartile range; PFO, patent foramen ovale; RLS, right-to-left shunt; SD, standard deviation.

with the guidewire crossing the PFO. This results in two polypropylene loops extending from the interatrial septum to the femoral access.

Finally, a third catheter (KwiKnot™) is advanced over these polypropylene loops and enables PFO closure by releasing a radiopaque polypropylene knot on the right side of the interatrial septum and to cut the proximal sutures and trimming the excess suture material.

All closure procedures were performed under local anesthesia with fluoroscopic guidance. Additional intracardiac echocardiography (ICE) guidance was used during all procedures in the UMC Utrecht (*n* = 24). For ICE, the right and left femoral veins were punctured to introduce a 14- and 10-Fr delivery sheath after which the ACUSON X300 (Siemens Medical Solution) and a 10 Fr AcuNav V catheter (Siemens-Acuson, Inc) were used. The ICE catheter was positioned in the RA through the sheath and was maneuvered for optimal visualization of the PFO.

At the end of the procedure, the final result of the suture-based closure was evaluated using ICE and intraprocedural contrast bubble study with agitated saline during the Valsalva maneuver in all patients treated in the UMC Utrecht.

All patients were pretreated with 100 mg of aspirin and prophylactic antibiotics. At the beginning of the procedure, all patients received 70 IU/kg of heparin, followed by additional boluses depending on the activated clotting time (>250 s). Since there are no official recommendations, postprocedural antiplatelet therapy was left to the discretion of the attending physician. The standard protocol was aspirin 100 mg daily for 1 month unless the patient was already on antiplatelet therapy for another indication. Antibiotic prophylaxis was advised for 5 days after the procedure.

TABLE 3 Angiographic measurements.

	Unsuccessful (*N* = 22)	Successful (*N* = 33)	*p* Value
LAO angulation c-arm (degrees)			
Mean (SD)	56.2 (±4.3)	55.0 (±5.1)	0.403
CAU/CRA angulation c-arm (degrees)			
Mean (SD)	0.4 (±1.0)	1.2 (±1.8)	0.119
PFO entry diameter (mm)			
Mean (SD)	10.2 (±4.0)	10.0 (±4.6)	0.827
PFO exit diameter (mm)			
Mean (SD)	9.5 (±3.8)	7.0 (±3.1)	0.015
PFO tunnel length (mm)			
Median [IQR]	12.5 [9.7, 15.4]	9.9 [8.0, 13.1]	0.049
PFO calculated volume (mm^3)			
Median [IQR]	985 [572, 1550]	381 [286, 894]	0.016
Angle at tip of septum secundum (α) (°)			
Mean (SD)	73.2 (±21.0)	67.4 (±23.8)	0.338
Angle at shoulder of the septum primum (ß) (°)			
Mean (SD)	109.4 (±25.2)	120 (±28.2)	0.154
Vertical height of Angle point (h) (mm)			
Median [IQR]	3.6 [1.9, 9.0]	4.1 [3.1, 5.5]	0.495

Note: Angiographic measurements in patients with unsuccessful ($n = 22$) and successful ($n = 33$) closure. Patients with successful closure had a significantly smaller exit diameter, shorter tunnel length and smaller volume compared to patients with unsuccessful closure. Data are presented as mean with standard deviation or median with interquartile range. Normally distributed variables were compared using the *t* test and non-normally distributed variables using the Mann–Whitney *U* test. A $p < 0.05$ was considered statistically significant.

Abbreviations: CAU, caudal; CRA, cranial; LAO, left anterior oblique; PFO, patent foramen ovale.

2.3 | Outcomes and follow-up evaluation

Primary outcomes for efficacy and safety were defined as residual RLS grade ≤1 with Valsalva maneuver within 3 months after the procedure and device- and intervention-related mortality, respectively. After 3 months, follow-up echocardiography with contrast bubble study and Valsalva maneuver was performed to evaluate procedural success. In case of unsuccessful PFO closure with the NobleStitch EL, a traditional double-disc device was implanted to obtain PFO closure. Secondary outcomes were shunt grading and procedural major and minor adverse events. Preprocedural echocardiography and peri-procedural angiography determinants for effective closure included PFO tunnel length, atrial septal aneurysm (>10 mm excursion of the septum), floppy (hypermobile, "jump-rope like") septum, PFO entry- and exit diameter, angulation of the c-arm, angle at the tip of the septum secundum, and the angle at the shoulder of the septum primum (Figure 2). The PFO volume was calculated as a cylinder (volume = $\pi \times r^2 \times$ height), where "r" is the half of the mean diameter ((entry diameter + exit diameter)/2) and "height" is the PFO tunnel length.

2.4 | Statistical analysis

Data were summarized as a number of patients (%) for categorical variables; mean (±standard deviation) for normally distributed continuous variables, and median (interquartile ranges) for non-normally distributed continuous variables. Categorical variables were compared using the χ^2 test. Continuous variables were compared using the *t* test or Mann–Whitney *U* test according to the distribution of the variable. Statistical analyses were performed with RStudio V.1.4.1717 (RStudio Team, Boston, USA) using R-version 3.6.1 (R Core Team, Vienna, Austria). A $p < 0.05$ was considered statistically significant.

3 | RESULTS

The mean age of the patients was 49.6 ± 11.4 years, and 37 patients (67%) were male. Indication for PFO closure was mostly the cryptogenic stroke (89%). Other indications were decompression illness (7%) and vestibular migraine (4%). The median Risk of Paradoxical Embolism (RoPE) score was 6 (IQR 5–7). Other relevant baseline characteristics are shown in Table 1.

Successful closure of the PFO was achieved in 33 of the 55 patients (60%). Peri-procedural complications occurred in one patient, who suffered from pericardial effusion without compression of the right atrium several hours postprocedure, paroxysmal atrial fibrillation after 1 day and pericarditis after 14 days, which all resolved without permanent sequelae. Only one patient with an initial RoPE-score of 3 (>70-year-old with hypertension and diabetes mellitus) suffered from a recurrent stroke during follow-up. In 8 of the 22 patients (36.4%) of the unsuccessful closure group a traditional double-disc device was implanted during the initial NobleStitch EL procedure (direct) and in 14 patients (63.6%) during a second closure procedure (staged) 3 to 6 months after the initial NobleStitch EL procedure.

The median PFO tunnel length, measured on preprocedural TTE was 9.6 mm (IQR 8.0–15.0) and 13.3 mm (IQR 11.4–18.6), ($p = 0.041$). Additionally, the median PFO tunnel length, measured on peri-procedural angiography, was 9.9 mm (IQR 8.0–13.1) versus 12.5 mm (IQR 9.7–15.4), ($p = 0.049$). The mean entry and exit diameters were 10.2 ± 4.0 mm versus 10.0 ± 4.6 mm, ($p = 0.827$) and 9.5 ± 3.8 mm versus 7.0 ± 3.1 mm, ($p = 0.015$), respectively. The median calculated volume of the PFO 985 mm^3 (IQR 572–1550) versus 381 mm^3 (IQR 286–894), ($p = 0.016$). See Tables 2 and 3 for detailed PFO characteristics. Figure 3 graphically visualizes the association between the PFO tunnel length and exit diameter. When looking at only small PFOs (tunnel length <10 mm), the success rate increased to 74% (Figure 4).

The median follow-up time was 3 months (IQR 3–6). At 3 months follow-up, all patients underwent TTE with shunt assessment. No residual RLS (grade 0) was seen in 28 patients (50.9%), RLS grade 1 in 5 patients (9.1%), RLS grade 2 in 6 patients (10.9%) and RLS grade 3 in 8 patients (14.5%). In eight patients (14.5%) a substantial RLS was observed during the initial NobleStitch procedure.

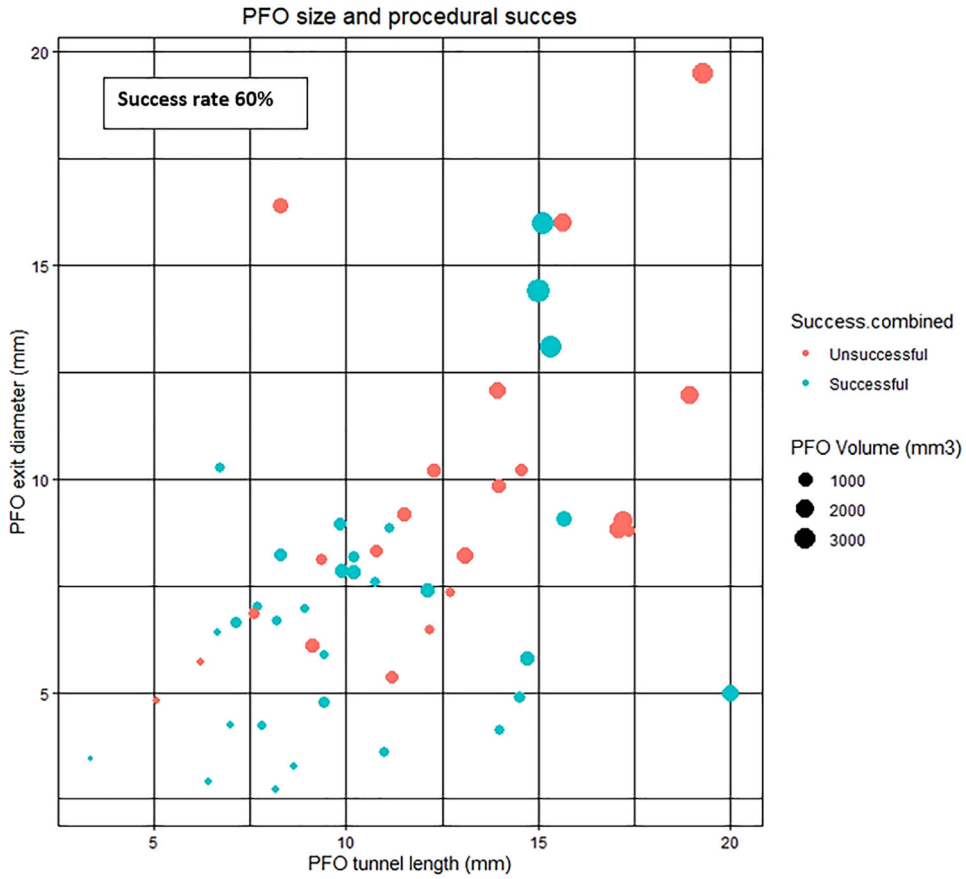

FIGURE 3 PFO size and procedural success. PFO size and procedural success. Visualization of the PFO volume for different PFO sizes with procedural success. The success rate was 60% (22 unsuccessful vs. 33 successful). Two patients of the successful closure group are not visualized because the PFO volume could not be calculated. PFO, patent foramen ovale. [Color figure can be viewed at wileyonlinelibrary.com]

4 | DISCUSSION

The findings of our study indicate that suture-based PFO closure is safe and successful in selected patients with small PFO determined by PFO tunnel length and PFO exit diameter assessed by balloon sizing. We achieved successful closure in 60% of the patients, which is lower compared to previous reports (Table 4).[6,9–11] This contradiction might be partly explained by a difference in study populations and follow-up echocardiographic protocols. In our study, the median PFO tunnel length was significantly shorter on 2D-ultrasound (9.6 mm vs. 13.3 mm, $p = 0.041$) and procedural angiography (9.9 mm vs. 12.5 mm, $p = 0.049$) in patients with successful closure. The median PFO exit diameter was significantly smaller in patients with successful PFO closure compared to patients with unsuccessful PFO closure (7.0 mm vs. 9.5 mm, $p = 0.015$), which is in accordance with Gaspardone et al.[13] where a smaller tunnel width of ≤5 mm was predictive of success.

In our cohort, peri-procedural complications occurred in one patient (2%), and one recurrent stroke occurred during follow-up, in a patient with unsuccessful closure after implantation of a double-disc device. These rates are lower but cannot be compared with double-disc device studies due to sample sizes.[2–5,12,14,15] Importantly, no persistent arrhythmias occurred in our study, compared to the occurrence of atrial fibrillation between 2.7% and 6.6% in the double-disc device studies.[2–5,12,14,15]

Another pertinent point is the importance of procedural evaluation directly after the procedure or during follow-up with echocardiography when assessing successful suture-based closure. Procedural evaluation was performed at the end of all procedures in the UMC Utrecht with contrast bubble study with agitated saline and Valsalva maneuver. In all unsuccessful procedures a double-disc device could be implanted during the same procedure preventing the need for a second closure procedure. In one patient only, significant residual shunt was observed at 3 months follow-up, for which a double-disc device was implanted in a second procedure. In contrast, nine patients in Cantonal Hospital Baselland had a significant residual shunt at 3 months follow-up and needed a second procedure to implant a double-disc device. This emphasizes the importance of image guided procedural evaluation to have the possibility to escalate to double-disc device closure during the initial procedure and thus preventing the need for a second closure procedure.

In total, 14 patients (25.5%) had residual shunt after 3 months and a second closure procedure was scheduled to implant a double-disc device to close the PFO. Without follow-up echocardiography with contrast bubble testing and Valsalva maneuver, these patients would

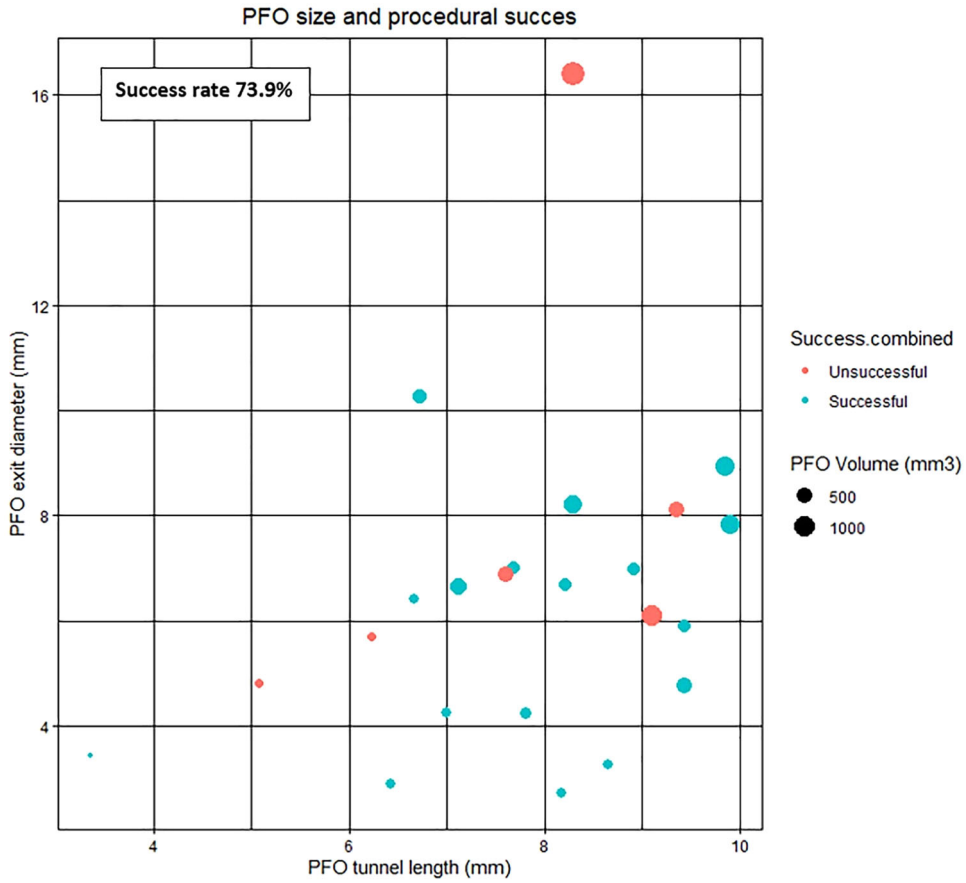

FIGURE 4 Small PFO size and procedural success. Small PFO size and procedural success. Visualization of the PFO volume for small PFOs (tunnel length <10 mm) with procedural success. The success rate increased to 73.9% (6 unsuccessful vs. 17 successful) for this subgroup of patients. PFO, patent foramen ovale. [Color figure can be viewed at wileyonlinelibrary.com]

TABLE 4 Closure rate of NobleStitch EL reported in different studies.

Study	NobleStitch EL closure rate
Gaspardone et al.[6,a]	89% (166/186)
Beneduce et al.[9,a]	82% (53/65)
Zannoni et al.[10,a]	80.2% (93/116)
Neto et al.[11,b]	100% (23/23)

[a]Successful closure was defined as residual right-to-left shunt ≤1 (0–9 bubbles) during follow-up.

[b]Successful closure was defined as no residual right-to-left shunt at the end of the closure procedure.

still have a patent shunt and are still at risk for PFO attributable stroke recurrence. This percentage is comparable to the 18.5% and 19.8% of patients with RLS ≥ 2 at 3–6 months follow-up reported in previous studies.[9,10] Zannoni and colleagues demonstrated multiple mechanisms for ineffective PFO closure exist (e.g., stitch failure, KwiKnot embolization or atrial septal tear) in patients who were initially successfully treated with NobleStitch EL. In comparison, moderate or large residual shunt was present between 4.1% and 13.9% of the patients after PFO closure with traditional double-disc devices at 6–12 months follow-up.[2,4,5,12,14,15] Any residual shunt grade was present in up to 27.3% of the patients.[4,12,16,17]

In a large Italian registry of 200 patients by Gaspardone and colleagues the efficacy of suture-based PFO closure was assessed prospectively. Successful closure was achieved in 186 (96%) patients. However, median PFO diameter and PFO length observed in this registry were 6.0 mm (IQR 4.0–7.3) and 6.7 mm (IQR 4.1–9.0).[6] Furthermore, Beneduce et al.[9] conducted a prospective cohort study in 80 consecutive PFO patients and determined cut-off values for successful closure; a PFO width >4 mm and a PFO length <10 mm, measured as septal overlap on TEE, were considered to be associated with unsuccessful closure. Altogether, wide PFO seems to be unfavorable for suture-based closure.

PFO size is assessed on cardiac ultrasound or on angiography with sizing balloon in a 2-dimensional view. Traditional closure with double-disc device might mitigate the limitations of the 3-dimensional PFO geometrics present in suture-based closure. We found PFO volumes to be smaller in patients with successful suture-based closure 353 mm^3 (IQR 285–833) versus 884 mm^3 (IQR 532–1580), $p = 0.016$. A potential mechanism of stitch failure in large PFO might be the deformation of the PFO as achieving septal alignment with merely one stitch is challenging in these cases: where to put the stitch?

Interestingly, in female patients the success rate was significantly higher compared to male patients, 83.3% (15/18) versus 48.6% (18/37) respectively, ($p = 0.03$). Of note, female patients showed a tendency toward smaller PFOs however statistical differences in PFO characteristics were not observed in our cohort.

The success rate of suture-based PFO closure might be improved with procedural guidance with high quality peri-procedural imaging. TEE enables the operators to visualize the PFO in a 3-dimensional view, which can be used to guide stitch positions in the septum primum. Furthermore, this could stimulate the operators' learning curve with a novel closure device.

In conclusion, suture-based PFO closure (such as NobleStitch EL) is not suited for all patients. As demonstrated in our study and with the current limited available evidence from registry data, case reports, and cohort studies large PFO (defined by PFO length and diameter) show a tendency to be unfavorable for this suture-based closure. Therefore, preassessment with TEE, ICE, and/or balloon sizing might be essential to select patients suitable for suture-based closure, to increase the success rate of this technique. Last but not least, a suture-based closure ensures the possibility for potential future transseptal access and may omit the need for antithrombotic therapy, compared to a device-based closure possibly inducing atrial fibrillation in young patients with PFO and cryptogenic stroke.

5 | LIMITATIONS

Our study was a multicenter study. However, the sample size was small, with 55 included patients. Furthermore, the total follow-up period was short, therefore long-term effectiveness of suture-based PFO closure is unknown and late residual shunt opening cannot be excluded.

6 | CONCLUSION

In our study cohort, the successful PFO closure rate using NobleStitch EL was relatively low (60%). With this alternative procedure, patients with a small PFO driven by a short PFO tunnel length and small exit diameter seem to be eligible for successful suture-based closure. Our findings emphasize the importance of detailed echocardiographic and fluoroscopic assessment of the PFO when considering suture-based closure.

7 | IMPACT ON DAILY PRACTICE

Suture-based percutaneous PFO closure is effective in 60% of the patients. Short PFO length and small PFO exit diameter seem favorable characteristics for successful suture-based closure.

CONFLICT OF INTEREST STATEMENT

The authors declare no conflict of interest.

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