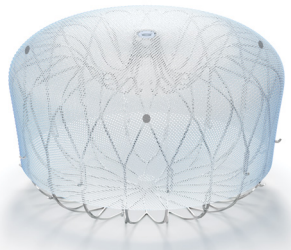
WATCHMAN™
INTEGRATED LAAC SOLUTIONS

Boston Scientific
Advancing science for life™

SIMPLAAFY: A potential next chapter in post-WATCHMAN care

Both reduced-dose NOAC and aspirin monotherapy were non-inferior to DAPT

WATCHMAN FLX™ Pro
LEFT ATRIAL APPENDAGE CLOSURE DEVICE



Featuring
HEMOCOAT™ Technology

SIMPLAAFY[1] studied two less aggressive monotherapy regimens for post-implant treatment after WATCHMAN FLX Pro

1,857
patients randomized 1:1:1
CHA_2DS_2-VASc: **4.2±1.3**
HAS-BLED: **2.7±1.1**

Post-implant drug regimens	3 mo	6 mo
DAPT (control) n=624	Clopidogrel + aspirin	
Reduced-dose NOAC n=620	½ Dose NOAC	Aspirin
Aspirin n=613	Aspirin Only	

Following implant with WATCHMAN FLX Pro both monotherapy regimens met non-inferiority

(Vs. DAPT Control Arm; p-value<0.0001)

5.1% Reduced-dose NOAC — vs — **6.9%** DAPT (Control) — vs — **3.3%** Aspirin

Primary composite endpoint at 6 months*
Death, stroke, systemic embolism, or major bleeding

Key clinical outcomes	Reduced-dose NOAC	vs	DAPT (Control)	vs	Aspirin
Ischemic stroke (6-month rate)	0.7%		0.7%		0.7%
Major bleeding (6-month rate)	2.7%		4.5%		1.7%
45-day DRT	0.9%		3.4%		2.7%

Patient characteristics	DAPT N=624	Reduced-dose NOAC N=620	Aspirin N=613
Age, mean (SD), years	76.3 (7.4)	76.1 (7.7)	76.0 (7.7)
Female sex	257 (41.2)	270 (43.5)	270 (44.0)
CHA2DS2-VASc, mean (SD)	4.2 (1.3)	4.2 (1.3)	4.2 (1.2)
HAS-BLED, mean (SD)	2.7 (1.1)	2.6 (1.1)	2.6 (1.1)
Congestive heart failure	196 (31.4)	212 (34.2)	195 (31.8)
Vascular disease	282 (45.9)	277 (45.2)	286 (47.0)
Diabetes	188 (30.1)	183 (29.5)	171 (27.9)
Hypertension	561 (89.9)	552 (89.0)	539 (87.9)
Abnormal renal function	101 (16.2)	104 (16.8)	97 (15.8)
Prior stroke or TIA	136 (21.8)	133 (21.5)	115 (18.8)
Prior major bleeding	130 (20.8)	134 (21.6)	125 (20.4)

Patient characteristics were well balanced. There were no significant differences between arms

45-day imaging outcomes	DAPT	Reduced-dose NOAC	Aspirin
Peri-device Leak			
Complete seal (Leak = 0 mm)	439 (78.4)	432 (78.8)	436 (78.7)
>0-3 mm	80 (14.3)	83 (15.1)	87 (15.7)
>3-5 mm	31 (5.5)	26 (4.7)	24 (4.3)
>5 mm	4 (0.7)	1 (0.2)	1 (0.2)
Device-related thrombus			
DRT (Grade 2 or 3 echodensity/HAT)[a]	20 (3.4)	5 (0.9)	16 (2.7)
Detected and treated by site	16 (2.7)	1 (0.2)	10 (1.7)

Values are % (# of patients); Core laboratory-assessed

a: Echodensity and HAT was characterized according to Kramer, et al. 2023 Eur Heart J Cardiovasc Imaging

6-month outcomes	DAPT N=624	Reduced-dose NOAC N=620	NOAC vs. DAPT Relative Risk [95% confidence interval]	Aspirin N=613	Aspirin vs. DAPT Relative Risk [95% confidence interval]
Primary composite (Death, stroke, systemic embolism, or major bleeding)*	41 (6.9)	31 (5.1)	0.75 [0.48, 1.18]	20 (3.3)	0.49 [0.29, 0.82]
Death	13 (2.2)	13 (2.2)	0.99 [0.46, 2.11]	8 (1.3)	0.61 [0.26, 1.47]
Cardiovascular	3 (0.5)	5 (0.8)	1.65 [0.40, 6.86]	3 (0.5)	1.00 [0.20, 4.92]
Non-cardiovascular	6 (1.0)	6 (1.0)	0.99 [0.32, 3.05]	3 (0.5)	0.50 [0.13, 1.98]
Unknown	4 (0.7)	2 (0.3)	0.49 [0.09, 2.69]	2 (0.3)	0.50 [0.09, 2.71]
Stroke	6 (1.0)	4 (0.7)	0.66 [0.19, 2.32]	4 (0.7)	0.66 [0.19, 2.34]
Ischemic	4 (0.7)	4 (0.7)	0.99 [0.25, 3.93]	4 (0.7)	1.00 [0.25, 3.97]
Hemorrhagic	2 (0.3)	0 (0.0)	–	0 (0.0)	–
Systemic embolism	0 (0.0)	0 (0.0)	–	0 (0.0)	–
All ISTH Bleeding	76 (12.8)	44 (7.3)	0.57 [0.40, 0.81]	33 (5.5)	0.43 [0.29, 0.64]
Major bleeding	27 (4.5)	16 (2.7)	0.59 [0.32, 1.08]	10 (1.7)	0.37 [0.18, 0.76]
Clinically relevant non-major bleeding	52 (8.7)	29 (4.8)	0.55 [0.36, 0.86]	23 (3.8)	0.44 [0.27, 0.71]

CEC-adjudicated. Binary event rates. Number of subjects included is based on subjects with sufficient follow-up and/or subjects who experienced an event.
ISTH (International Society on Thrombosis and Haemostasis).

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* DAPT served as the control arm. Reduced dose NOAC and Aspirin arms were not statistically compared.

1. Kar S, et al. Antithrombotic Monotherapy After Left Atrial Appendage Occlusion: Primary Results of the SIMPLAAFY Randomized Trial. Late-breaking clinical trial TCT 2026.
2. Saliba WI, et al. Enhanced Thromboresistance and Endothelialization of a Novel Fluoropolymer-Coated Left Atrial Appendage Closure Device. JACC EP 2023. (Results from a preclinical model)

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