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ORIGINAL RESEARCH

Proximal protection devices for carotid artery stenting - A benchtop assessment of flow reversal performance

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ABSTRACT

BACKGROUND AND PURPOSE: Proximal protection devices, such as TransCarotid Artery Revascularization (TCAR, SilkRoad Medical, Sunnyvale), aim to yield better outcomes in carotid artery stenting (CAS) than distal protection devices by preventing plaque embolization to the brain. However, transfemoral catheters may not fully reverse flow from the external carotid artery (ECA) to the internal carotid artery (ICA). We assess a new balloon-sheath device, Femoral Flow Reversal Access for Carotid Artery Stenting (FFRACAS), for this purpose.

MATERIALS AND METHODS: The FFRACAS prototype (ID = 0.117"; L=80cm) was compared to TCAR (ID=0.104", L=30cm) and MoMa (Medtronic, Minneapolis; ID=0.083", L=90cm) in a pulsatile flow model with blood simulant at 800mL/min. MoMa was used according to labeled instructions, with both CCA and ECA balloon inflation, without CCA-femoral vein shunt placement, and in an off-label fashion with single balloon occlusion in the CCA and shunt. Flow rates of the ICA, ECA, and shunt, when applicable, were monitored during CAS stages: CCA flow arrest, shunt activation, and stent delivery. Experiments were conducted under two ECA inflow conditions (-10 and -20 mL/min). Statistical comparison of ICA flow rates was conducted using ANOVA and Tukey's post-hoc tests.

RESULTS: MoMa's on-label use maintained retrograde ICA flow (-0.3 mL/min) throughout CAS. Upon shunt activation, TCAR and FFRACAS reversed ICA flow similarly under low ECA inflow (ICA=-5.10 mL/min vs. -4.83 mL/min; p=0.349), but neither achieved ICA flow reversal under high ECA inflow or during stent delivery. MoMa off-label use failed to reverse ICA flow.

CONCLUSIONS: FFRACAS presents a potential alternative to TCAR, achieving similar degrees of flow reversal from a transfemoral approach to that achieved with the transcarotid approach. The MoMa system reliably prevents anterograde flow in ICA during CAS.

ABBREVIATIONS: CAS = Carotid Artery Stenting; TCAR = Transcarotid Arterial Revascularization; CCA = Common Carotid Artery; ICA = Internal Carotid Artery; ECA = External Carotid Artery; VA = Vertebral Artery; FFRACAS = Femoral Flow Reversal Access for Carotid Artery Stenting; ID = Inner Diameter; OD = Outer Diameter.

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SUMMARY SECTION

PREVIOUS LITERATURE: Flow reversal is a promising approach to prevent plaque embolization distally during carotid artery stenting.

KEY FINDINGS: The MoMa flow reversal system reliably prevented the anterograde flow in our benchtop setup. The FFRACAS represents a promising device for achieving flow reversal through transfemoral access.

KNOWLEDGE ADVANCEMENT: This study provides a quantitative analysis of the flow reversal efficacy exhibited by the TransCarotid Artery Revascularization (TCAR) system, the transfemoral double-balloon MoMa system, and a prototype of a novel transfemoral flow reversal device (FFRACAS), designed for CAS.

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INTRODUCTION

Major advances in minimally invasive therapies for carotid artery disease have focused on preventing distal emboli during carotid artery stenting (CAS). Currently, distal filter devices are the most widely used protection devices during transfemoral CAS. However, distal protection devices must be navigated through the plaque prior to deployment, exposing patients to embolic risk[1,2]. Proximal protection devices with flow reversal aim to reduce complications that may arise from plaque manipulation during carotid artery stenting[3].

The transcarotid arterial revascularization (TCAR) approach (Silk Road Medical)[4], consisting of surgical exposure of the common carotid artery (CCA), placement of the access sheath, and temporary surgical occlusion of the CCA, followed by the creation of an arteriovenous shunt (CCA-femoral vein) with resultant flow reversal, protects against distal emboli throughout CAS prior to the plaque being manipulated. However, approximately 29% of patients undergoing CAS do not meet the eligibility criteria for TCAR based on anatomical considerations. Among these patients, 74% were identified as normal risk candidates for transfemoral CAS[5].

To date, no commercially available single-balloon transfemoral flow reversal system exists. Simple proximal occlusion of the CCA fails to stop antegrade flow to the brain through the internal carotid artery (ICA) because of the brain's high demand for blood; specifically, CCA occlusion leads to retrograde flow through the external carotid artery (ECA) from the contralateral ECA and ipsilateral vertebral artery (VA) that then flows antegrade to the brain[6]. Thus, any flow reversal system must account for the potential of retrograde ECA inflow. The MoMa system (Medtronic)[7] is placed via the femoral artery and consists of a proximal occlusion balloon placed in the CCA and a second balloon in the ECA, the latter of which occludes potential retrograde ECA flow.

In this study, we propose a balloon-sheath device, Femoral Flow Reversal Access for Carotid Artery Stenting (FFRACAS), aimed at enabling flow reversal without the need for ECA occlusion. We provide a quantitative comparison of its flow reversal performance throughout CAS with TCAR and MoMa systems.

MATERIALS AND METHODS

Proximal Protection Devices

The comparative references for this study include the commercially available MoMa system (ID=0.083", L=90cm, arteriotomy size=0.147") and a TCAR system analog (ID=0.104", L=30cm). The TCAR analog includes a sheath designed to match the dimensional specifications of the original TCAR arterial sheath and the ENROUTE Transcarotid Stent System (Silk Road Medical, OD=0.065", L=57cm). Notably, MoMa is distinguished by its utilization of a double-balloon system to concurrently halt flow in the CCA and ECA. The FFRACAS device (**Figure 1**) was designed for direct access with a damage-resistant balloon, eliminating the need for a separate access sheath, which typically adds approximately 2 French (0.026") to the arteriotomy size. This design maximizes the ID of the system, thus enhancing flow reversal capabilities. The FFRACAS prototype tested in the current work features a 0.117" ID, 0.140" OD, and an 80cm length. Incorporating a dual braid/coil reinforcement, the prototype is designed to enhance kink resistance, pushability, and torqueability[8]. The balloon material selected for this prototype is pellethane 80AE, chosen for its high compliance and resistance to plastic deformation. The OD was chosen to mimic that of a standard 9F short arterial sheath. The FFRACAS device is designed to serve as both a sheath and balloon, similar to the BOSS balloon system[9], obviating the need for a separate short arterial access sheath.

To emulate the typical stent delivery systems used clinically, an analog was constructed, consisting of a 0.035" guidewire with a 6F distal end (2cm) followed by a 5F segment (20cm). The length of this stent delivery system analog was 135 cm and it was used with MoMa and FFRACAS.

For comparison purposes, MoMa will be employed in two modes: (1) MoMa on-label, adhering to the manufacturer's recommendations, and (2) MoMa off-label, akin to the approach of TCAR and FFRACAS systems, by solely employing the proximal CCA occlusion balloon followed by the shunt placement.

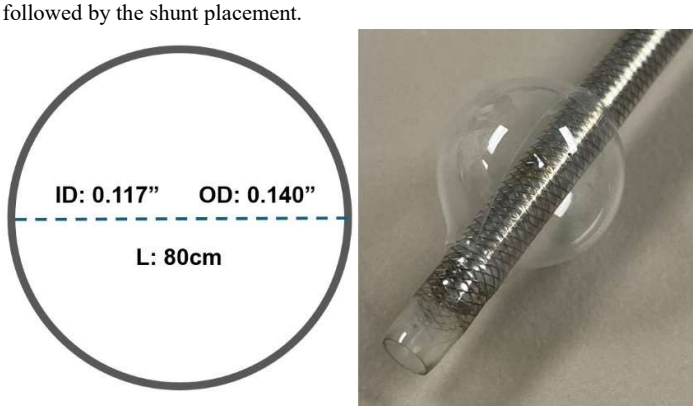

FIGURE 1. Illustration of the Femoral Flow Reversal Access for Carotid Artery Stenting (FFRACAS) balloon sheath

Experimental Setup

The flow-loop system is illustrated in **Figure 2**. The arterial system consisted of a 3D-printed neurovascular model with 70% stenosis (1.5 mm) in the right ICA, reflecting the clinical indication for carotid revascularization at this level of stenosis, even in the absence of symptoms.[10,11] The setup included a blood-mimicking fluid reservoir maintained at 37°C, with a roller pump circulating a blood simulant (60:40 water:glycerol, 0.01%w/v xanthan gum[12]) at 800mL/min[13]. Valves were used to regulate the system at a mean pressure of 90 [60, 120] mmHg in the arterial system, and the system pressure was continuously monitored with a blood pressure transducer through the side port of the femoral sheath. In addition, we included a side port in the right CCA, through which we simulated the transcarotid access. The

venous system included an elevated saline reservoir pressurized at 10mmHg. The arteriovenous shunt comprised 70cm of 0.25" ID tubing with a one-way stopcock connecting the catheter and venous system. In-line flow sensors (Sensirion AG, Switzerland) were placed post-stenosis in the right ICA, ipsilateral ECA, and arteriovenous shunt. At baseline, both ICA and ECA flows were 100-110 mL/min anterograde[14].

In each experiment, proximal protection devices were navigated to the right CCA via transfemoral (MoMa on and off-label and FFRACAS) or transcarotid access (TCAR). After device insertion, the pressure at the CCA bifurcation was reassessed to ensure a consistent mean pressure of 90 mmHg throughout the experiments. For FFRACAS and MoMa off-label, the balloon was inflated to arrest the flow in CCA. In the case of TCAR, CCA flow arrest was achieved by clamping the vessel. In the instance of MoMa on-label, in addition to inflating its proximal balloon to arrest the CCA flow, its distal balloon was placed in the ECA and dilated to arrest the retrograde flow in the ECA.

Two ipsilateral ECA retrograde (-) flow conditions were pre-established by adjusting the resistance in the contralateral ECA and ipsilateral VA: low flow (-10mL/min) and high flow (-20mL/min). In the case of MoMa on-label, confirmation of the absence of ECA inflow preceded stent delivery. Upon confirming the initial ECA retrograde flow conditions for MoMa off-label, TCAR, and FFRACAS, the arteriovenous shunt was activated, allowing the pressure gradient between CCA and femoral vein to reverse the flow. MoMa, as per its label, did not utilize the arteriovenous shunt; instead, ICA flow reversal during the opening of the rotating hemostatic valve to insert the stent delivery system was recorded for comparison with the other experimental arms.

Subsequently, the stent delivery system was advanced within the catheter until the distal 0.5cm extended beyond the catheter tip. Flow rate alterations were continuously monitored throughout the entire experiment. Five repetitions were conducted for each device configuration (MoMa on-label, MoMa off-label, TCAR, and FFRACAS) and initial ECA retrograde flow condition, resulting in a total of 40 experiments. At each stage of the simulated CAS, namely flow arrest, shunt, and stent delivery, five readings were taken to compute statistics.

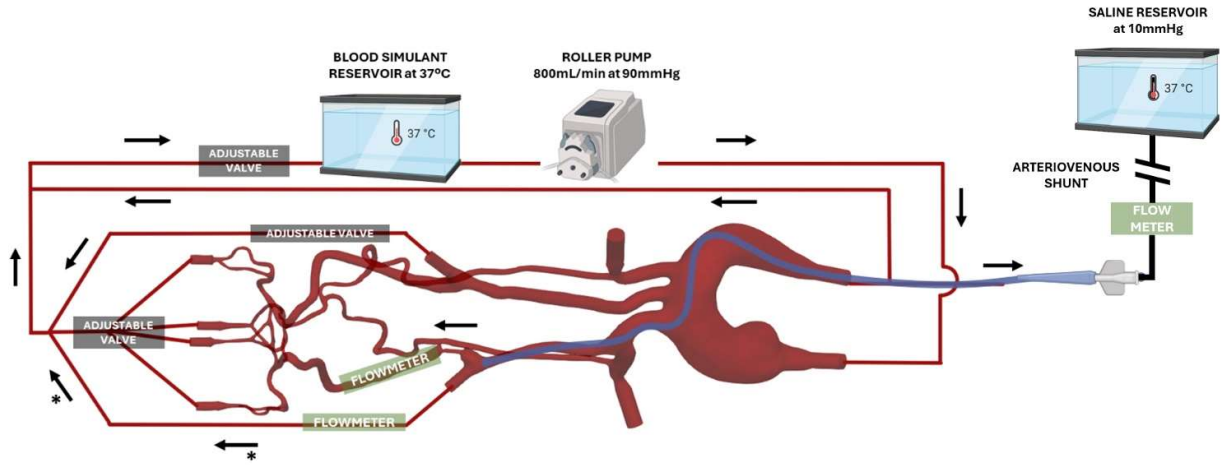

FIGURE 2. The 3D-printed benchtop setup for the experiments

Statistics

After confirming normality through the Shapiro-Wilk test and ensuring equal variances using Levene's test, an analysis of variance (ANOVA) followed by post-hoc Tukey's tests were conducted to assess the differences in ICA flow reversal performance among the devices. Statistical significance was established at a p-value<0.05. The data were analyzed using the SPSS software (IBM). Flow rates are expressed as the mean ± standard deviation.

RESULTS

Flow rate changes are summarized in **Table 1** and **Figure 3**.

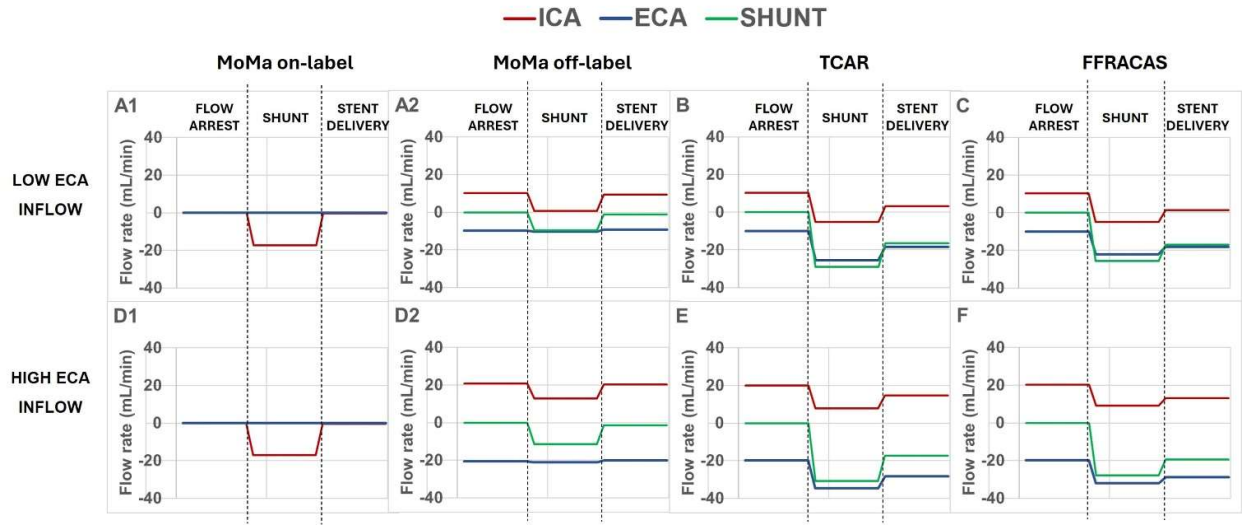

FIGURE 3. The flow rate changes during the carotid artery stenting procedure with different devices

Upon activation of the arteriovenous shunt, a pressure gradient between the catheterized CCA and the contralateral femoral vein induced increased retrograde ECA flow in TCAR and FFRACAS experiments. However, in MoMa off-label use, the shunt activation did not yield a significant difference from the baseline retrograde ECA flow. In MoMa on-label use, where arteriovenous shunt was not employed, the ECA balloon effectively suppressed the ECA inflow.

Low ECA retrograde flow conditions

Upon activating the shunt, TCAR achieved a shunt flow rate of -29.08 ± 0.84 mL/min, significantly higher than FFRACAS (-25.61 ± 0.38 mL/min), with both devices surpassing MoMa off-label (-9.68 ± 0.62 mL/min), $p<0.001$. As a result of the shunt activation, all systems successfully reversed ICA flow, except for MoMa off-label (ICA=0.64 ± 0.45 mL/min). MoMa on-label (ICA=-17.26 ± 0.40 mL/min) significantly outperformed FFRACAS (ICA=-4.83 ± 0.46 mL/min) and TCAR (ICA=-5.10 ± 0.96 mL/min), $p<0.001$. Notably, no significant differences in ICA flow reversal were found between FFRACAS and TCAR ($p=0.349$).

During stent delivery, shunt flow rates were as follows: MoMa off-label, -1.22 ± 0.36 mL/min; TCAR, -16.46 ± 0.60 mL/min; and FFRACAS, -17.05 ± 0.55 mL/min ($p<0.001$). Consequently, in terms of ICA flow rate, TCAR (ICA=3.10 ± 0.40 mL/min), FFRACAS (ICA=1.38 ± 0.49 mL/min), and MoMa off-label (ICA=9.51 ± 0.54 mL/min) failed to reverse ICA flow, while MoMa on-label achieved -0.29 ± 0.23 mL/min. All pairwise comparisons demonstrated statistical significance ($p<0.001$).

High ECA retrograde flow conditions

Upon activating the shunt, TCAR achieved a shunt flow rate of -30.83 ± 1.13 mL/min, higher than FFRACAS (-27.77 ± 0.80 mL/min), with both systems surpassing MoMa off-label (-11.58 ± 1.65 mL/min), $p<0.001$. In this setting, only MoMa on-label successfully reversed ICA flow (ICA=-17.08 ± 0.61 mL/min), while FFRACAS (9.21 ± 0.76 mL/min), TCAR (7.74 ± 0.69 mL/min), and MoMa off-label (12.79 ± 0.66 mL/min) maintained anterograde ICA flow, despite significant differences among them ($p<0.001$).

During stent delivery, shunt flow rates were -1.09 ± 0.23 mL/min for MoMa off-label, -17.22 ± 1.00 mL/min for TCAR, and -19.46 ± 0.65 mL/min for FFRACAS, $p<0.001$. Thus, in terms of ICA flow rate, TCAR (ICA=14.65 ± 0.64 mL/min), FFRACAS (13.15 ± 0.70 mL/min), and MoMa off-label (20.40 ± 0.36 mL/min) failed to reverse ICA flow, while MoMa on-label achieved -0.30 ± 0.22 mL/min. All pairwise comparisons were statistically significant ($p<0.001$).

Table 1. ICA, ECA, and arteriovenous flow rate changes during CAS with different proximal protection devices. Different superscript letters indicate significantly different levels with >99% confidence interval.

			MoMa on-label Flow rate (mL/min)	MoMa off-label Flow rate (mL/min)	TCAR Flow rate (mL/min)	FFRACAS Flow rate (mL/min)
Low ECA retrograde flow (10mL/min)	Flow arrest	ECA	-	-9.98 ± 0.20	-10.14 ± 0.45	-10.12 ± 0.41
		ICA	-	10.09 ± 0.24	10.20 ± 0.48	10.22 ± 0.34
		Shunt	-	-	-	-
	Shunt / HRV opening	ECA	-	-10.25 ± 0.21 [a]	-25.47 ± 0.91 [b]	-22.18 ± 0.49 [c]
		ICA	-17.26 ± 0.40 [a]	0.64 ± 0.45 [b]	-5.10 ± 0.96 [c]	-4.83 ± 0.46 [c]
		Shunt	*NA*	-9.68 ± 0.62 [a]	-29.08 ± 0.84 [b]	-25.61 ± 0.38 [c]
	Stent delivery	ECA	-	-9.36 ± 0.32 [a]	-18.48 ± 0.41 [b]	-18.10 ± 0.40 [c]
		ICA	-0.29 ± 0.23 [a]	9.51 ± 0.54 [a]	3.10 ± 0.40 [b]	1.38 ± 0.49 [c]
		Shunt	*NA*	-1.22 ± 0.36 [a]	-16.46 ± 0.60 [b]	-17.05 ± 0.55 [c]
High ECA retrograde flow (20mL/min)	Flow arrest	ECA	-	-20.04 ± 0.20	-19.90 ± 0.84	-19.90 ± 0.80
		ICA	-	20.28 ± 0.21	20.09 ± 0.84	20.12 ± 0.71
		Shunt	*NA*	-	-	-
	Shunt / HRV opening	ECA	-	-21.15 ± 0.35 [a]	-34.53 ± 0.83 [b]	-31.99 ± 0.91 [c]
		ICA	-17.08 ± 0.61 [a]	12.79 ± 0.66 [b]	7.74 ± 0.69 [c]	9.21 ± 0.76 [d]
		Shunt	*NA*	-11.58 ± 1.65 [a]	-30.83 ± 1.13 [b]	-27.77 ± 0.80 [c]
	Stent delivery	ECA	-	-20.05 ± 0.25 [a]	-28.30 ± 0.65 [b]	-28.86 ± 0.65 [c]
		ICA	-0.30 ± 0.22 [a]	20.40 ± 0.36 [b]	14.65 ± 0.64 [c]	13.15 ± 0.70 [d]
		Shunt	*NA*	-1.33 ± 0.27 [a]	-17.22 ± 1.00 [b]	-19.46 ± 0.65 [c]

Note. Different superscript letters (a, b, c, d) indicate statistically significant differences between the corresponding measurements.

DISCUSSION

The MoMa double-balloon system emerged as the most effective proximal protection device, consistently maintaining retrograde ICA flow across all phases of CAS, irrespective of ECA inflow level. This study underscores the promising performance of the proposed 0.117" ID FFRACAS device, showcasing its capability to achieve flow reversal comparable to the commercially available TCAR system, while offering the advantage of being easier to use than both MoMa and TCAR. Some clinical scenarios might benefit from using FFRACAS if they were originally intended for TCAR. Unlike TCAR, FFRACAS eliminates the need for CCA exposure, reducing the risk of complications associated with surgical procedures and vascular access in the CCA. The surgical approach of TCAR also restricts patient selection due to specific anatomical criteria, including a CCA diameter >6 mm, a clavicle-to-CCA bifurcation distance >5 cm, an ICA diameter of 4–9 mm, and minimal to no plaque at the puncture site.5 In addition, navigating the FFRACAS to the right CCA was uncomplicated in our 3D-printed benchtop setup. Additionally, FFRACAS requires the same arteriotomy size as MoMa, further enhancing its practicality and ease of implementation. Notably, while FFRACAS demonstrates equivalence to TCAR in efficacy under low ECA flow, neither TCAR nor FFRACAS matches MoMA's performance under high ECA flow conditions.

MoMa has demonstrated remarkable reliability in ensuring the absence of anterograde ICA flow, implying enhanced protection against the embolization of plaque fragments into distal vessels. In this study, we deviated from the conventional clinical practice by shunting the MoMa device to the venous system following the occlusion of the CCA with its proximal balloon. Our results indicate that the distal ECA balloon is vital to MoMa´s performance. This distal balloon is necessary because the flow reversal achieved by a long (90cm), relatively small inner diameter (ID=0.083") device was insufficient to overcome the inflow of ECA blood.

Another flow reversal device similar to MoMa is the GORE Flow Reversal System, which consists of a balloon sheath (placed in the CCA), a balloon wire (placed in the ECA), and an arteriovenous shunt, similar to the TCAR and FFRACAS devices. The EMPiRE study

reported a stroke and/or death rate of 2.9% in patients using this system.[15] Due to discouraging financial projections, the GORE Flow Reversal System was later discontinued, and as a result, we did not include it in our experiment.[16]

According to Hagen-Poiseuille's law, the sheaths of TCAR and FFRACAS, being shorter and larger than the MoMa´s, have lower resistance, allowing these devices to achieve sufficient flow reversal to diminish ICA anterograde flow. The shunt flow rate data obtained from MoMa off-label use indicates that other commercially available balloon guide catheters used for proximal flow control during CAS, with inner diameters ranging from 0.084 to 0.087" and lengths between 85-95cm[17,18], may not generate adequate flow reversal through a passive arteriovenous shunt to prevent microemboli effectively. Active reversal, employing an aspiration pump, and the concomitant use of distal protection filters become necessary in these instances.

Our results indicate that FFRACAS presents a promising standalone or complementary alternative to current practices. By augmenting its ID, we hypothesize that there is a potential for achieving ICA flow reversal during stent delivery, particularly under conditions of low ECA retrograde flow. Considering the current prototype's OD is 0.140" and the maximum tolerable arteriotomy size is 0.149", there is room to increase the FFRACAS ID up to 0.126". This adjustment could potentially enhance the device's flow reversal performance.

Limitations

This study is subject to certain limitations. Firstly, the two pre-established conditions of initial ECA retrograde flow rates were determined due to the absence of available literature reporting ECA retrograde inflow to ipsilateral stenotic ICA when the CCA is occluded. Consequently, the reported data should be considered for comparative purposes, and any translation to clinical settings should be approached with care. Secondly, despite our efforts to simulate hemodynamically accurate conditions on our benchtop setup, the manual adjustment of initial flow rates introduces a limitation. The autoregulation of collateral flows, present in physiological conditions, is not replicated in our system, potentially leading to exaggerated retrograde flow from ECA during shunt activation. Thirdly, we did not assess flow rate changes during angioplasty or stent deployment. We prioritize investigating the most critical stage—navigating the stent delivery system—where carotid plaque can fracture and embolize. In addition, our ICA stenosis analog is solely a geometrical replica and cannot undergo fracture. Consequently, the quantification of emboli during CAS using different devices was not feasible. Future research should explore replicating the mechanical behavior of carotid plaques and quantifying fragments migrating downstream. Lastly, the impact of flow reversal in improving the outcomes in carotid artery stenting has not yet been proven to be superior to distal filtering. A randomized controlled trial with a total of 40 patients (21 for flow reversal and 19 for distal filter interventions) has shown that the flow reversal with the GORE flow-reversal system had more incidences of new ischemic brain lesions after the procedures compared with distal filtering. The ROADSTER-2 study reported very low rates of stroke (1.9% in intention-to-treat analysis vs. 0.6% in per-protocol analysis) and death (0.4% in intention-to-treat analysis vs. 0.2% in per-protocol analysis) in patients followed for 30 days.[4] The ROADSTER-2 study with a 1-year follow-up has reported a 0% rate of stroke and a death rate of 2.6%.[19] However, the study's single-arm design lacked a comparison with distal protection strategies. Liang et al. have shown that patients who underwent TCAR with flow reversal had lower stroke or death rates compared to transfemoral carotid artery stenting with proximal balloon occlusion (0.8% vs. 3.1%; p=0.03). Larger randomized controlled trials are needed to prove the superiority of proximal protection strategies.

CONCLUSIONS

The MoMa system reliably prevents anterograde flow in ICA during CAS. This work demonstrates the feasibility of achieving transfemoral flow reversal for CAS using the FFRACAS device in an experimental setting. Further adjustments of the device dimensions and geometry may be needed to match or exceed the performance of the MoMa system in reversing ICA flow during stent delivery. With further optimization, FFRACAS may provide an effective transfemoral alternative to TCAR.

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