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Background: Carotid endarterectomy (CEA) remains the gold-standard treatment for high-grade carotid artery stenosis. While patch angioplasty reduces perioperative complications and restenosis risk compared to primary closure, the optimal patch material remains debated. This study evaluates the long-term safety and effectiveness of CEA with Dacron patch closure regarding overall survival, stroke prevention, and restenosis rates.

Methods: A retrospective analysis was performed on 200 patients who met the inclusion criteria of either symptomatic carotid stenosis of any degree according to the North American Symptomatic Carotid Endarterectomy Trial (NASCET) criteria, or asymptomatic stenosis with a NASCET grade $\geq$70%. All patients underwent CEA with standardized Dacron patch closure. Symptomatic stenosis was defined as ipsilateral transient ischemic attack or stroke within 6 months preoperatively. Perioperative data, survival, stroke-free survival, and freedom from restenosis ($\geq$70% restenosis) were assessed through structured clinical follow-up and serial duplex ultrasound over 5 years. Kaplan–Meier estimates and subgroup analyses were performed according to symptomatic status, baseline stenosis severity, and sex. Log-Rank and/or Wilcoxon Tests were applied to analyze differences between the subgroups.

Results: Among 200 patients, 26 adverse events (12.9%) were observed, with bleeding events exclusively associated with significantly prolonged clamping times ($P = 0.0221$ and twice $P < 0.0001$). Most complications (8.0%) occurred during follow-up, and no deaths were linked to stroke or restenosis. At 5 years, overall survival was 93.7%, freedom from stroke was 97.6%, and freedom from restenosis was 97.5%. Symptomatic patients showed slightly lower survival (91.8% vs. 95.7%) and stroke-free survival (96.2% vs. 99.0%) compared to asymptomatic patients, reflecting higher baseline vascular risk. No significant differences in outcome were observed across different NASCET stenosis subgroups. However, a significant sex difference was found in restenosis rates: 5-year freedom from restenosis was lower in women (88.4%) than in men (98.0%; $P = 0.017$). Stroke rates remained low and similar between sexes.

Conclusion: CEA with Dacron patch closure provides durable long-term stroke protection and patency, with perioperative and late complication rates at the lower end of reported ranges. All bleeding events linked to significantly prolonged clamping times, suggesting intraoperative

clamping duration may serve as an early indicator for postoperative bleeding risk. Our data advocate for a potentially increased risk of restenosis in females, which may warrant heightened vigilance and closer duplex ultrasound surveillance during follow-up. These results of this study support the continued use of Dacron patches as a safe and effective option for carotid reconstruction.

INTRODUCTION

Ischemic strokes represent approximately 80–87% of all stroke cases, with extracranial carotid artery stenosis contributing to 15–30% of these events,[1] underscoring its critical role in cerebrovascular events. The pathophysiology of stroke in the context of carotid artery disease involves 2 primary mechanisms: hemodynamic compromise and thromboembolism. Thromboembolism is regarded as the predominant mechanism of ischemic stroke in patients with carotid stenosis, whereas hemodynamic impairment plays a comparatively minor role.[2] A significant stenosis can lead to reduced cerebral perfusion, resulting in hypoxia and potential infarction. Additionally, unstable atherosclerotic plaques may rupture, leading to thromboembolic events that obstruct cerebral arteries. Timely and effective intervention is crucial to prevent stroke and its associated complications.[2,3] Carotid endarterectomy (CEA) has been established as a standard surgical procedure for the revascularization of significant carotid artery stenosis. Randomized clinical trials have demonstrated the efficacy of CEA in reducing the risk of stroke in both symptomatic and asymptomatic patients.[4] While the surgery is generally safe, it carries some risks, including stroke, bleeding, infection, and nerve damage. One of the most common complications after CEA with patch closure is stroke, which can occur either during or after the procedure. The incidence of stroke after CEA is typically between 1 and 5%,[5–7] depending on the patient's underlying risk factors. Additionally, bleeding and infection at the surgical site can occur, usually related to insufficient wound healing or inadequate postoperative care. Restenosis is another significant concern following CEA. The use of patch angioplasty has significantly reduced the risk of restenosis compared to primary closure of the artery.[8] The choice of patch material in CEA can impact surgical outcomes. Various materials, including synthetic options like polytetrafluoroethylene (PTFE) and Dacron, as well as biological materials like bovine pericardium, have been utilized. Comparative studies have indicated that the type of patch material may affect postoperative complications.[8–13] Dacron patches are favored for their strength, durability, and availability in standardized sizes. They offer a low risk of aneurysmal degeneration. Several studies have demonstrated the safety and efficacy of Dacron patches in CEA.[14,15] However, other studies have reported an association between the use of Dacron patches and an increased risk of perioperative complications such as recurrent stenosis and stroke when compared to other patch materials.[15,16] Understanding the durability and safety profile of Dacron closure over extended follow-up is crucial to refine patient selection and optimize perioperative management.

This study therefore aimed to evaluate the long-term survival, stroke, and restenosis outcomes of CEA with Dacron (Uni-Graft®, Aesculap AG, Germany) patch closure. We further explored subgroup outcomes based on symptomatic status, stenosis severity, and sex to identify potential contributing factors for restenosis and adverse events (AEs).

MATERIALS AND METHODS

Study Design and Patient Population

This retrospective cohort study evaluated the long-term outcomes of CEA with Dacron patch closure in patients with high-grade carotid artery stenosis. Patients were consecutively enrolled based on standardized inclusion criteria: symptomatic carotid stenosis of any degree or asymptomatic stenosis with a North American Symptomatic Carotid Endarterectomy Trial (NASCET) grade ≥70%, as determined by duplex ultrasonography and computed tomography angiography, following the NASCET criteria.[17] Both symptomatic and asymptomatic patients were included. Symptomatic stenosis was defined as any ipsilateral transient ischemic attack or ischemic stroke within 6 months prior to surgery. Exclusion criteria included prior ipsilateral CEA, concomitant carotid artery stenting, or incomplete follow-up data. Follow-up assessments were conducted according to a standardized surveillance protocol.

A total of 200 patients were analyzed. Demographic variables (age, sex), vascular risk factors (arterial hypertension (aHT), active or past smoking), prior or postinterventional stroke and major comorbidities (coronary artery disease, chronic obstructive pulmonary disease (COPD), malignancy) were

Table I. Demographic data of the study population total (top) and subgroups according to gender and actively consented versus deceased before consent subgroups

Patient (sub-) cohort	Gender	Variable	N	Mean	Std Dev	Median	Minimum	Maximum
All	All	Age at operation	200	71.4	9.0	74.0	50.0	90.0
		Height	197	171.6	8.6	172.0	150.0	190.0
		Weight	197	78.6	14.6	78.0	42.0	123.0
		NASCET preoperative	200	83.7	8.4	80.0	50.0	99.0
Actively consented	Male	Age at operation	88	68.1	8.6	69.0	50.0	83.0
		Height	88	175.7	7.5	176.0	152.0	190.0
		Weight	88	82.9	12.5	84.0	54.0	123.0
		NASCET preoperative	88	82.9	9.3	80.0	50.0	99.0
	Female	Age at operation	55	71.1	8.1	74.0	53.0	85.0
		Height	53	164.4	5.4	165.0	150.0	176.0
		Weight	53	71.2	15.3	67.0	50.0	118.0
		NASCET preoperative	55	83.9	8.4	90.0	60.0	99.0
Enrolled after death	Male	Age at operation	43	76.8	7.8	78.0	53.0	88.0
		Height	43	175.1	6.5	175.0	160.0	188.0
		Weight	43	82.7	13.2	80.0	58.0	109.0
		NASCET preoperative	43	84.4	7.0	90.0	60.0	90.0
	Female	Age at operation	14	76.8	8.0	78.0	58.0	90.0
		Height	13	161.5	5.3	163.0	153.0	170.0
		Weight	13	66.4	11.9	65.0	42.0	86.0
		NASCET preoperative	14	85.7	6.5	90.0	70.0	90.0

systematically collected. Preoperative carotid stenosis severity was assessed bilaterally by vascular ultrasound and classified according to the NASCET criteria.

The registered study was approved by the Ethic Committee of the Medical Faculty at the Heinrich-Heine-University Düsseldorf, Germany (ID: 2021−1636, Clinical Trials Gov ID: NCT05117515)

Surgical Procedure

All surgical interventions were performed under standardized conditions by experienced vascular surgeons. CEA was conducted under general anesthesia and intraoperative neuromonitoring with routine intraluminal shunting, which was applied in 191 cases, explicitly noted in 4 cases as not performed, and not mentioned in 5 cases. After plaque removal, arteriotomy closure was achieved using a Dacron patch (Uni-Graft®, Aesculap AG), ensuring vessel lumen restoration. The operating time and arterial cross-clamp time were documented. Clamping times were defined in 2 distinct phases.

- The first clamping time was measured from the moment of initial arterial clamping until the insertion of the temporary intraluminal shunt.
- The second clamping time covered the period from shunt removal until completion of the patch suture and final arterial closure.

Both intervals were recorded in minutes and analyzed regarding their potential association with intraoperative and postoperative complications.

Perioperative management followed institutional protocols, including standardized antiplatelet therapy.

The patch type (Dacron, Uni-Graft®, Aesculap AG) represents the standard of care for carotid patch angioplasty at our center.

Follow-up and Outcome Measures

Patients were followed postoperatively through scheduled clinical visits and serial duplex ultrasonography at 3, 6, and 12 months, and annually thereafter up to 5 years. The primary outcomes defined were as follows:

1. Overall survival, defined as time from surgery to death from any cause.
2. Freedom from stroke, defined as time from surgery to any ipsilateral or contralateral ischemic cerebrovascular event.
3. Freedom from restenosis, defined as freedom from recurrent carotid artery stenosis during follow-up (any restenosis ≥40% according to NASCET criteria, severe restenosis ≥70% according to NASCET criteria)

Table II. Comorbidities/Risk factors of the total study population and subgroups of actively consented versus enrolled-after-death

Patient (sub-) cohort	N	Any comorbidity	Hypertension	Smoking	CAD	COPD	Stroke	Cancer
All	200	19, 96.5%	165, 82.5%	65, 32.5%	84, 42.5%	17, 8.5%	80, 40.0%	18, 9.0%
Actively consented	143	138, 96.5%	116, 81.1%	51, 35.7%	56, 39.1%	10, 7.0%	57, 39.8%	11, 7.7%
Enrolled-after-death	57	55, 96.5%	49, 86.0%	14, 24.6%	28, 49.1%	7, 12.3%	23, 40.4%	7, 12.3%

Percentages refer to the total of the corresponding group.
CAD, coronary artery disease.

Secondary analyses included subgroup comparisons by symptomatic status, stenosis severity strata ($\leq$70%, >70–$\leq$80%, >80– $\leq$90%, >90%), and sex.

Statistical Analysis

Continuous variables were expressed as mean ± standard deviation or median (interquartile range) as appropriate. Categorical variables were presented as absolute numbers and percentages.

Survival, freedom from stroke, and freedom from restenosis analyses were conducted using Kaplan–Meier product-limit estimates up to 5 years of follow-up. Group comparisons were performed using the Log-rank test and Wilcoxon (Breslow) test to assess potential differences between subgroups. Hazard ratios with 95% confidence intervals (CIs) were calculated where appropriate. A 2-sided *P* value <0.05 was considered statistically significant.

All statistical analyses were conducted using SAS® software (SAS Institute Inc., Cary, NC, USA) and graphical visualizations were generated for survival estimates, including 95% CI shading and censoring tick marks.

RESULTS

Patient Characteristics

The mean age of the study cohort was 71.4 ± 9.0 years. The cohort consisted predominantly of men 131 (65.5%). The mean NASCET stenosis grade was (83.7 ± 8.4)%. The detailed patient characteristics can be found in Table I. The majority of patients suffered from at least 1 comorbidity (96.5%). Of those, 165 patients suffered from aHT (82.5%), while we observed COPD in 17 patients (8.5%). The detailed comorbidities within the study cohort can be found in Table II.

Surgical Data

All surgical procedures were performed by consultants for vascular surgery in the Department of

Table III. AEs and SAEs after CEA with Dacron patch closure, including timing and event type

Category	n (%)
Patients with at least 1 AE/ SAE	24 (12.0%)
Non-SAE	10 (5.0%)
SAE	15 (7.5%)
Timing of Complications	
During operation	3 (1.5%)
Until discharge	7 (3.5%)
During follow-up	16 (8.0%)
Type of Complication	
Bleeding	3 (1.5%)
Occlusion	4 (2.0%)
Infection	0 (0.0%)
Restenosis	5 (2.5%)
Ipsilateral stroke	5 (2.5%)
Contralateral stroke	0 (0.0%)
Other	9 (4.5%)
Total number of events	26 (13.0%)

The table summarizes the overall incidence of postoperative complications in 200 patients. Percentages refer to the proportion of affected patients relative to the total study cohort. AEs and Complications.

Vascular and Endovascular Surgery at the University Hospital Düsseldorf, Germany. The mean operating time was 123.1 ± 30.1 min, while the mean first clamping time was 7.8 ± 9.9 min and the mean secondary clamping time as 4.2 ± 2.1 min shunting was documented in 191 cases, explicitly noted in 4 cases as not performed (2%).

AEs and Complications

Among 26 total AEs, the most common were restenosis (19.2%), occlusion (15.4%), and bleeding (11.5%). Serious AEs (SAEs) accounted for 16 of these cases (61.5%) and were more frequently associated with bleeding (12.5%), occlusion (6.3%), and ipsilateral stroke (31.3%). Non-SAEs ($n = 10$) were most often related to restenosis (40%) and categorized under "other" (40%). Causality assessments revealed that 88.5% of AEs were deemed not

Table IV. Classification of AEs by type and severity

Patient (sub-) cohort	Total	Restenosis	Bleeding	Occlusion	Infection	Stroke ipsilateral	Stroke contralateral	Other
All AEs	26	5	3	4	0	5	0	9
		19.2%	11.5%	15.4%	0.0%	19.2%	0.0%	34.6%
SAE	16	1	2	1	0	5	0	7
		6.3%	12.5%	6.3%	0.0%	31.3%	0.0%	43.8%
Non-SAE	10	4	1	3	0	0	0	2
		40.0%	10.0%	30.0%	0.0%	0.0%	0.0%	20.0%

Classification of AEs, including the serious and nonserious subgroups.

Table V. Classification of AEs by assessment of their causal relationship to the investigated product and the surgical procedure

	Is there a causal relationship to the investigated product?			
Patient (sub-) cohort	Not	Possible	Probably	Causal
All AEs	23, 88.5%	3, 11.5%	0	0
SAE	14, 87.5%	2, 12.5%	0	0
Non-SAE	9, 90.0%	1, 10.0%	0	0
	Is there a causal relationship to the surgical procedure?			
	Not	Possible	Probably	Causal
All AEs	7, 27.0%	13, 50.0%	0	6, 23.1%
SAE	7, 43.8%	4, 25.0%	0	5, 31.3%
Non-SAE	0	9, 90.0%	0	1, 10.0%

Relationship between AEs and the investigated product (top) and surgical procedure (bottom).

related to the investigated product, with 11.5% classified as "possibly related." No events were rated as probably or definitely product-related. In contrast, 73.0% of events were considered not or only possibly related to the surgical procedure, while 23.1% were judged to be causally related to the surgery itself. Notably, 31.3% of SAEs were assessed as causally related to the surgical intervention, underlining the relevance of intraoperative and procedural factors in adverse outcome development (Tables III-V).

We overserved complications during follow-up in 16 patients (8.0%), while 10 patients (5%) experienced a complication during the inhospital stay. Of those, 3 patients (1.5%) experienced a complication during surgery and 7 patients (3.5%) postsurgery and prior to discharge. The overall mean duration of surgery across all 200 patients was 123.1 ± 30.3 min, with a median of 118.5 min. The average time for the first clamping was 7.8 ± 9.9 min, and for the second clamping 4.2 ± 2.1 min. Notably, the subgroup presenting with intraoperative complications ($n = 3$) had a markedly prolonged mean surgery time of 150.3 ± 30.0 min and exhibited a prolonged second clamp time of 10 ± 7.5 min and versus 4.1 ± 1.8 min,

whereas the inverse pattern was observed for the initial clamping time (Table VI).

Among the 3 patients with bleeding-related AEs 2 patients had markedly prolonged second clamping times (9 and 18 min), and 1 had a highly elevated first clamping time (65 min). A second clamping time of 9 min was associated with a statistically significant deviation ($P = 0.0221$), while the extreme value of 18 min for the same procedure showed a highly significant deviation ($P < 0.0001$). Additionally, a prolonged first clamping time of 65 min was also statistically highly significant ($P < 0.0001$). These results suggest that unusually long clamping durations may serve as intraoperative warning signs, potentially indicating an elevated risk of postoperative complications such as bleeding.

In terms of event type, the most frequently documented complications were restenosis and ipsilateral stroke, each occurring in 5 patients (2.5%). Occlusion was observed in 4 patients (2.0%), while bleeding occurred in 3 patients (1.5%). No infections or contralateral strokes were reported. Additional miscellaneous complications categorized as "other" were noted in 9 patients (4.5%), including 6 cases of death due to cardiogenic shock, syncopal events, pulmonary embolism, colon carcinoma,

Table VI. Descriptive statistics of surgery duration and clamping times (in minutes) for all patients, and subgroups with and without intraoperative complications (comp.)

Patient (sub-) cohort	Variable	Unit	N	Mean	Std Dev	Median	Minimum	Maximum
All	Surgery Duration	Min	200	123.1	30.3	118.5	56.0	236.0
	Time of first Clamping	Min	190	7.8	9.9	5.0	1.0	92.0
	Time second Clamping	Min	186	4.2	2.1	4.0	1.0	18.0
No comp.	Surgery Duration	Min	197	122.7	30.2	118.0	56.0	236.0
	Time of first Clamping	Min	187	7.9	10.0	5.0	1.0	92.0
	Time second Clamping	Min	183	4.1	1.8	4.0	1.0	15.0
With comp.	**Surgery Duration**	**Min**	**3**	**150.3**	**30.0**	**149.0**	**121.0**	**181.0**
	Time of first Clamping	**Min**	**3**	**3.7**	**1.5**	**4.0**	**2.0**	**5.0**
	Time second Clamping	**Min**	**3**	**10.0**	**7.5**	**9.0**	**3.0**	**18.0**

In the light of the limited number of interventions with complications (3 out of 200), the difference in distribution of surgery duration are not-significantly different (t-test for means: $P = 0.117$, F-test for variances $P = 1.00$). Distributions for first | second clamping times show a difference in variance (F-test $P\_1st = 0.0465$ | $P\_2nd < 0.001$), notable in different directions i.e. less variance in first clamping, more variance in second clamping. The Mean of the first clamping is significantly lower ($P = 0.0116$) compared to the non-complication group. The mean of the second clamping does not show a significant difference ($P = 0.308$). In all cases, the reliability of the testing method is limited by the low number of cases and should not be over interpreted.

brain metastasis and death after hospitalization after presentation with progressive reduced vigilance of unclear etiology. Of note, none of the death cases were associated with stroke or restenosis. The total number of recorded complication events was 26 (12.9%), reflecting that some patients experienced more than 1 event.

Survival

The Kaplan−Meier estimator analysis revealed a high overall survival during the observation period. None of the deaths was associated with stroke or restenosis. At 1 year, survival was $(97.0 \pm 1.5)\%$ At 2- and 5-year follow-up, overall survival was $(96.1 \pm 1.7)\%$ and $(93.7 \pm 2.9)\%$, respectively (Fig. 1A). Considering subgroup-specific survival, asymptomatic patients at the time of surgery showed a 1 year and 2-year follow-up survival of 100%. At 5-year follow-up survival was $(95.7 \pm 4.3)\%$ In contrast, the similarly sized subgroup of symptomatic patients at the time of surgery, showed a higher mortality. Survival rates at 1 year, 2-year at 5-year follow-up were $(93.7 \pm 3.1)\%$, $(91.8 \pm 3.6)\%$ and $(91.9 \pm 3.6)\%$, respectively (Log rank test $P = 0.068$, Wilcoxon test $P = 0.058$) (Fig. 1B). While the Wilcoxon test is more appropriate in this comparison due to the violation of the proportional hazards assumption underlying the log-rank test, likely caused by differing baseline risk profiles between groups—both tests may overestimate sensitivity when event counts are low. Survival probabilities remained high across all NASCET stenosis subgroups ($\leq 70\%$, $>70-\leq 80\%$, $>80-\leq 90\%$, $>90\%$),

with only minimal variation over time. The survival rates at 5-year follow-up for these subgroups were as follows: $\leq 70\%$: 100%, $>70-\leq 80\%$: $(94.1 \pm 3.3)\%$, $>80-\leq 90\%$: $(91.7 \pm 5.4)\%$, and $>90\%$: 100%) (Log-rank test $P = 0.85$; Wilcoxon test $P = 0.83$) (Fig. 1C). Patient survival remained high in both males and females, with only small differences between groups. Survival rates for females were $(97.8 \pm 2.2)\%$ at 1-, 2-, and 5-year follow-up. Survival rates for males was $(96.6 \pm 2.0)\%$ at 1-year follow-up, $(95.2 \pm 2.4)\%$ at 2-year follow-up, and $(91.4 \pm 4.4)\%$ at 5-year follow-up (Log-rank test $P = 0.38$; Wilcoxon test $P = 0.55$) (Fig. 1D).

Stroke

Overall freedom from stroke remained consistently high throughout the observation period. We observed 4 stroke events, of which 3 occurred during the in hospital-stay either during surgery or prior to discharge. That being said, the freedom from stroke rate was $(97.6 \pm 1.2)\%$ at 1-year, 2-year, and 5-year follow-up (Fig. 2A). In asymptomatic patients at the time of surgery, freedom from stroke $(99.0 \pm 0.9)\%$ at 1-, 2-, and 5-year follow-up, while we report a freedom from stroke rate for symptomatic patients of $(96.2 \pm 2.3)\%$ for the same follow-up time points (Log-rank test $P = 0.174$; Wilcoxon test $P = 0.346$) (Fig. 2B).

We observed a consistently high freedom from stroke rate across all NASCET stenosis subgroups ($\leq 70\%$, $>70-\leq 80\%$, $>80-\leq 90\%$, $>90\%$), with only minor variations. At 5-year follow-up the freedom from stroke for these subgroups was as follows: $\leq 70\%$: 100%, $>70-\leq 80\%$: $(98.8 \pm 1.2)\%$,
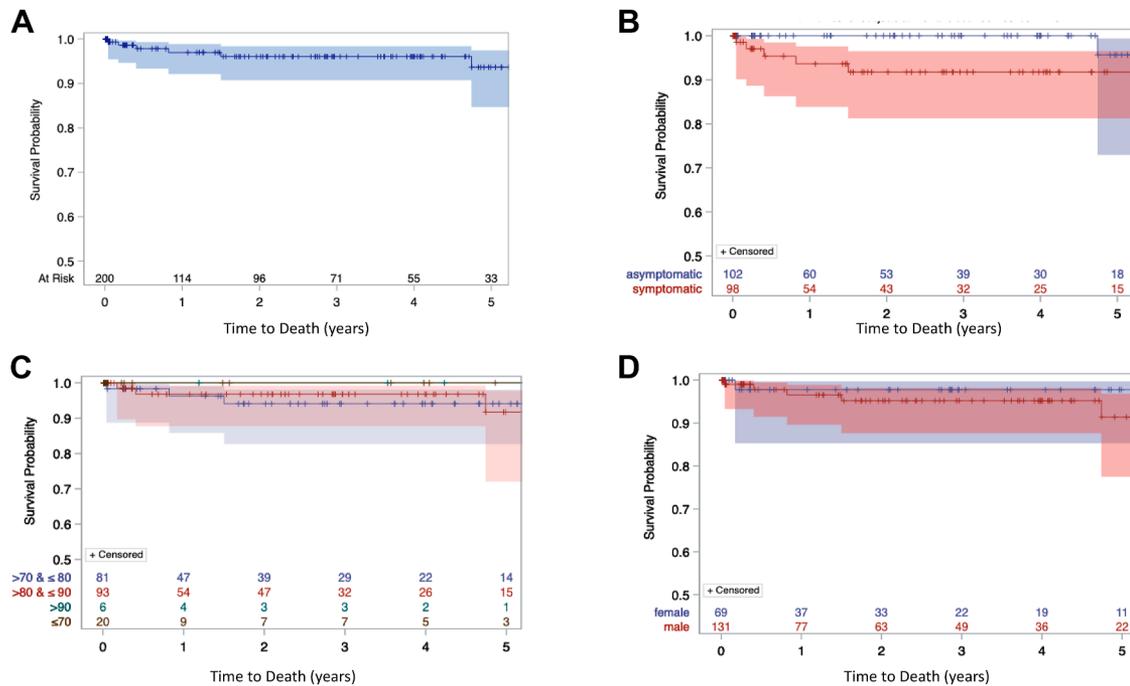
Fig. 1. (A) Kaplan–Meier estimator for patient survival for time to death starting with day of surgery. Overall survival remained high with a slight early decline. **(B)** Kaplan–Meier estimator for asymptomatic (blue) versus symptomatic (red) patient survival. Patient survival was superior for asymptomatic patients at the time of surgery versus symptomatic patients. **(C)** Kaplan–Meier estimator for patient survival stratified by NASCET stenosis severity (≤70%, >70–≤80%, >80–≤90%, >90%). No significant difference between subgroups was observed. **(D)** Kaplan–Meier estimator for patient survival stratified by gender. No significant difference in survival between males and females was observed. Tick marks indicate censored observations, and shaded areas represent the 95% CIs.

>80–≤90%: $(96 ± 2.35)$%, and >90%: 100% (Log-rank test $P = 0.56$; Wilcoxon test $P = 0.73$) (Fig. 2C). Freedom from stroke was comparably high across both sexes, exhibiting only marginal differences over the follow-up period. In detail, females showed a stable freedom from stroke of $(97.1 ± 2.0)$% over the entire observation period, while males revealed a freedom from stroke of $(97.95 ± 1.5)$% after 1 and 5 years (Log-rank test $P = 0.86$; Wilcoxon test $P = 0.37$) (Fig. 2D).

Recurrence Stenosis

The Kaplan–Meier estimator for freedom of any restenosis according to NASCET criteria found a rate of $(98 ± 2)$% at 1 year, $(97 ± 1.5)$% at 2-year, and $(95 ± 2)$% at 5-year follow-up. Of interest, we observed 5 restenosis events among the 200 patients, of which only one case presented with a restenosis rate of ≥70% (severe restenosis) according to NASCET criteria. From the distribution profile of restenosis cases, a continuous decline in freedom from restenosis can be inferred during the first

4 years, whereas no late occurrences of restenosis were observed. (Fig. 3A). Both asymptomatic and symptomatic patients maintained high freedom from restenosis rates over time. In asymptomatic patients at the time of surgery, freedom from restenosis was $(98.4 ± 1.6)$% at 1 year, $(96.6 ± 2.3)$% at 2-year, and $(96.6 ± 2.3)$% at 5-year follow-up. Notably, 2 restenosis events were observed. In contrast, symptomatic patients at the time of surgery revealed a freedom from restenosis of $(98.2 ± 1.8)$% at 1-year, $(98.2 ± 1.8)$% at 2-year, and $(92.4 ± 4.3)$% at 5-year follow-up (Log-rank test $P = 0.56$; Wilcoxon test $P = 0.76$) (Fig. 3B). Similarly, freedom from restenosis was high across all NASCET stenosis severity groups (≤70%, >70–≤80%, >80–≤90%, >90%). At 5-year follow-up the freedom from stroke for these subgroups was as follows: ≤70%: 85.7% ± 13.2, >70–≤80%: 97.9% ± 2.1, >80–≤90%: 93.1% ± 4.0, and >90%: 100% (Log-rank test $P = 0.617$; Wilcoxon test $P = 0.729$) (Fig. 3C). In summary, our data suggest no immediately apparent correlation between the preoperative NASCET criteria stenosis grade
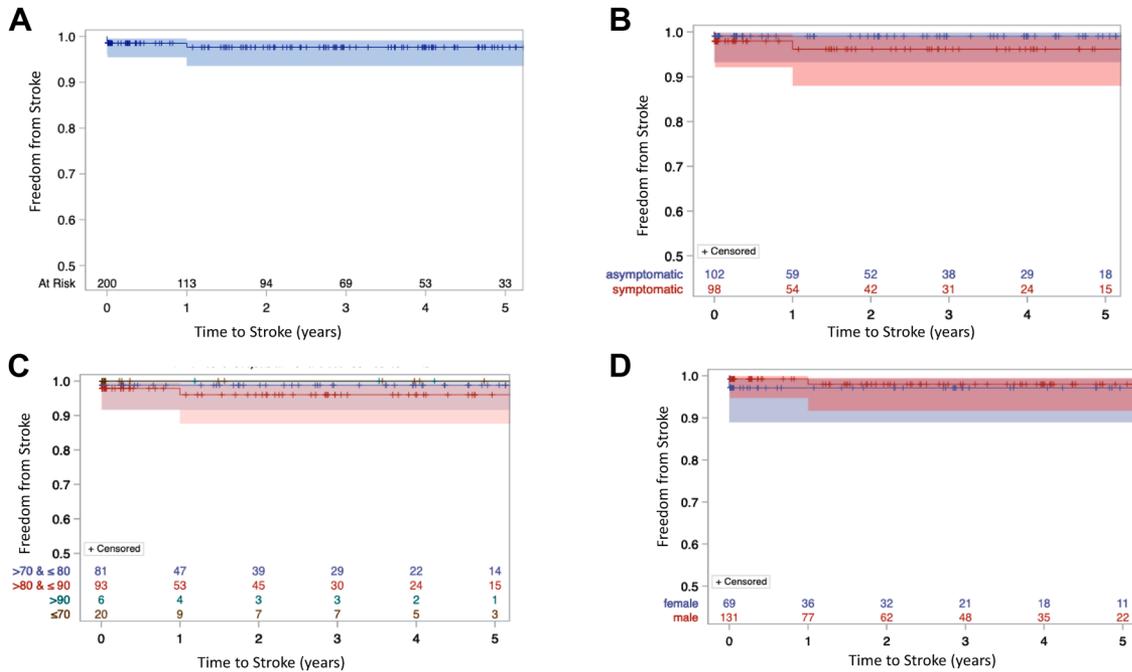
Fig. 2. (A) Kaplan−Meier estimator for freedom from stroke for time to death starting with day of surgery. Freedom from stroke remained high with only a marginal decline, reaching (97.6 ± 1.2)% at 1-, 2-, and 5-year follow-up with 4 recorded events. **(B)** Kaplan−Meier estimator for asymptomatic (blue) versus symptomatic (red) freedom from stroke rates. Asymptomatic patients maintained a (99.0 ± 0.9) % freedom from stroke rate throughout a 5-year follow-up with only 1 event, whereas symptomatic patients showed lower freedom from stroke rates of (96.2 ± 2.3)% at 1 and 5 years follow-up. **(C)** Kaplan−Meier estimator for freedom from stroke stratified by NASCET stenosis severity (≤70%, >70−≤80%, >80−≤90%, >90%). Freedom from stroke remained high across all subgroups with no events in the ≤70% and >90% categories. **(D)** Kaplan−Meier estimator for freedom from stroke stratified by gender. Both females (blue) and males (red) maintained high freedom from stroke rates throughout the follow-up. Tick marks indicate censored observations, and shaded areas represent the 95% CIs.

and the occurrence of a restenosis in the follow-up using Dacron patch closure. Considering the freedom of restenosis in males and females, our data revealed high rates in both subgroups. In females, the freedom from restenosis was (94.6 ± 3.7) % at 1-year, (91.8 ± 4.5) % at 2-year, and (88.4 ± 5.5)% at 5-year follow-up. Overall, 5 cases of restenosis occurred. In contrast, the freedom from restenosis in males was 100% at 1-and 2-year follow-up and declined to (98.0 ± 2.0)% at 5-year follow-up. Interestingly our data suggest a higher restenosis rate in females compared to males using Dacron patch closure (Log-rank test $P = 0.017$; Wilcoxon test $P = 0.0089$) (Fig. 3D).

DISCUSSION

In this cohort of 200 patients undergoing CEA with Dacron (Uni-Graft®, Aesculap AG) patch closure, long-term outcomes were excellent, with a 5-year overall survival of 93.7%, freedom from stroke of 97.6%, and freedom from restenosis exceeding 99% for high-grade recurrent stenosis. Subgroup analyses revealed consistent effectiveness across symptomatic status, NASCET stenosis severity strata, and sex, with the only significant subgroup difference being a higher 5-year restenosis rate in women compared to men (84.8% vs. 96.9%, $P = 0.017$).

Twenty-four patients (11.9%) experienced at least 1 AE, meaning that 88% of patients remained complication-free, demonstrating a favorable safety profile. Among those affected, 15 patients (7.5%) experienced SAEs, while 10 patients (5.0%) had non-SAEs, indicating that complications were more often of a serious nature. Most complications were identified during postdischarge follow-up (16 patients, 8.0%), while fewer occurred intraoperatively (3 patients, 1.5%) or before discharge (7 patients, 3.5%). This distribution underscores the importance of structured long-term follow-up and
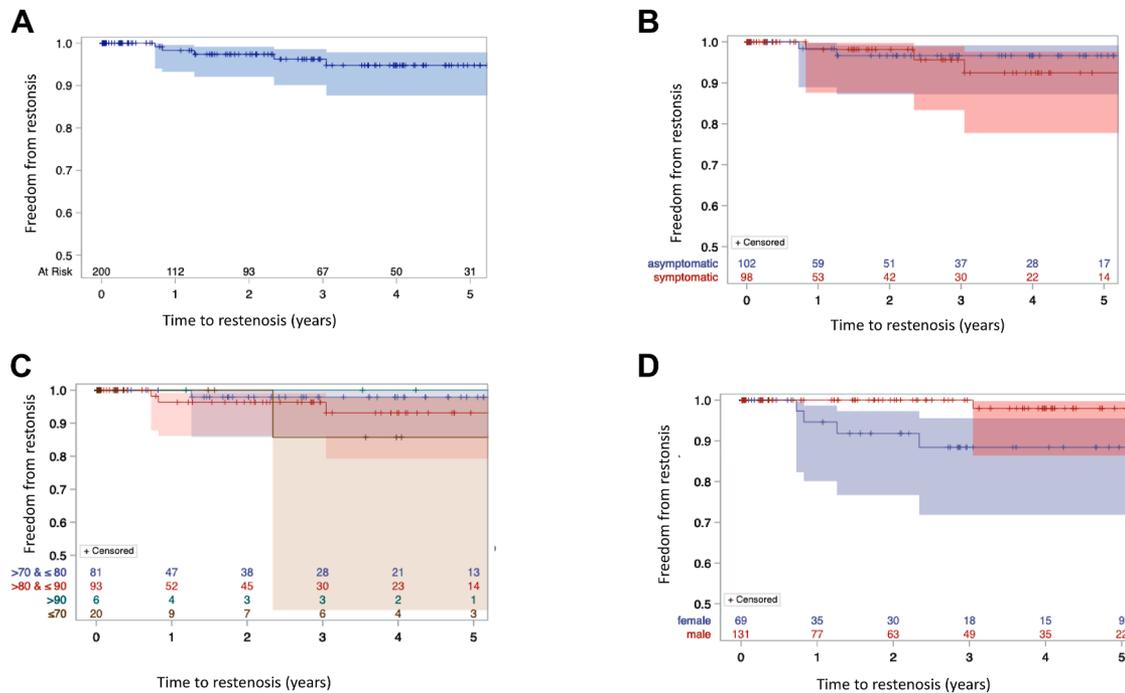
Fig. 3. (A) Kaplan−Meier estimator for freedom from restenosis for time to death starting with day of surgery. Freedom from any restenosis remained high during the follow-up period. **(B)** Kaplan−Meier estimator for asymptomatic (blue) versus symptomatic (red) freedom from restenosis rates. Freedom from restenosis was inferior for symptomatic patients at 5-year follow-up. **(C)** Kaplan−Meier estimator for freedom from restenosis stratified by NASCET stenosis severity (≤70%, >70− 80%, >80−90%, >90%). Freedom from restenosis remained high across all subgroups, with no restenosis events in the ≤70% and >90% categories. **(D)** Kaplan−Meier estimator for freedom from restenosis stratified by gender. Females (blue) revealed a greater decline in freedom from restenosis with a rate of 84.8% at 5-year follow-up versus 96.9% in males (red) at the same follow-up time point. Tick marks indicate censored observations, and shaded areas represent the 95% CIs.

surveillance, as the majority of issues arose beyond the immediate perioperative period.

The most frequent complications observed were carotid restenosis and ipsilateral stroke, each occurring in 5 patients (2.5%). An ipsilateral stroke rate of 2.5% in this cohort falls well within acceptable ranges for CEA—current guidelines consider a 30-day stroke/death risk below 3−6% as acceptable for asymptomatic and symptomatic patient.[18] The 2.5% incidence of restenosis is likewise in line with other reports; for example, large studies have found around ∼2% 5-year restenosis with patch closure and therefor significantly lower rates when compared to primary closure.[11] Occlusion of the operated carotid occurred in 4 patients (2.0%), and major bleeding complications in 3 patients (1.5%), which are relatively infrequent events. Importantly, there were no reported patch infections or contralateral strokes in this series. Dacron patch infection is a rare complication (estimated in only 0.25−0.5% of cases),[19] so its absence here is reassuring.

The total count of complication events (26 events in 24 patients) indicates that a few patients experienced multiple complications. In summary, the AE profile for CEA with Dacron patch in this group appears acceptable and comparable to literature benchmarks. The low stroke rate and lack of infections underscore the procedure's safety, while the occurrence of restenosis and other events during follow-up emphasizes the need for ongoing monitoring and secondary prevention strategies for affected patients.

Specifically, 88.5% of AEs were considered not related to the investigated product, and none were rated as probably or definitely product related. This aligns with previous findings that synthetic patches like Dacron are generally biocompatible and rarely implicated in device-related complications.[9] In contrast, nearly a quarter (23.1%) of all AEs was deemed causally related to the surgical procedure. This proportion increased to 31.3% when focusing specifically on SAEs, suggesting that

procedural factors play a critical role in more severe complications. Events such as bleeding, occlusion, and stroke—especially in the immediate perioperative phase—are likely influenced by technical aspects of the operation, including vessel handling, clamping technique, and shunt usage.

In our cohort, all bleeding events were associated with clamping times suggesting a statistically significant signal for elevated risk. Evidence from multiple studies indicates that prolonged carotid clamp time (or overall operative time) is associated with higher risks of perioperative complications after CEA. These complications include neurologic events (stroke or transient ischemic attack), cranial nerve injuries, neck hematomas, and even higher early restenosis rates.[20−22] Patients with extended occlusion times may benefit from intensified early postoperative monitoring, including more rigorous blood pressure control, lower thresholds for reimaging, and possibly prolonged inpatient observation. This aligns with recommendations from the European Society for Vascular Surgery (ESVS), which emphasize the importance of tailored surveillance strategies based on procedural and patient-specific risk factors.[18]

CEA remains the gold standard surgical treatment for high-grade carotid artery stenosis, effectively reducing the risk of ipsilateral ischemic stroke in both symptomatic and selected asymptomatic patients. Landmark trials such as the NASCET and the European Carotid Surgery Trial showed substantial stroke risk reduction in symptomatic patients with ≥70% stenosis.[23] Contemporary perioperative stroke rates range between 1 and 5% depending on patient comorbidities,[6] and long-term ipsilateral stroke rates are generally under 10% over 5 years following successful CEA.[24] Our data align with, and likely surpass these benchmarks, with only 4 strokes (≈2%) over 5 years, indicating particularly favorable outcomes and reflecting both procedural safety and durable efficacy. Symptomatic patients in our series had slightly lower overall survival (91.8% vs. 95.7%) and freedom from stroke (96.2% vs. 99%) after 5 years compared to asymptomatic patients, although freedom from stroke remained >90% in both groups. This is consistent with prior evidence showing that symptomatic patients have higher baseline cardiovascular risk but derive greater absolute benefit from surgery. These findings support current vascular surgery guidelines that recommend CEA for symptomatic stenosis ≥50% when perioperative stroke and mortality risk can be maintained below 3%.[9]

Furthermore, the ESVS 2023 Guidelines reaffirm these thresholds and add contemporary considerations, such as plaque imaging biomarkers and patient frailty, into decision-making for asymptomatic patients.[18] Our findings of very low perioperative stroke rates (<2%) are well within the safety limits defined by these guidelines, suggesting that Dacron patch closure remains compatible with modern standards of care.

Importantly, no significant differences in survival or freedom from stroke were observed across NASCET stenosis severity categories. This supports prior registry data suggesting that once high-grade stenosis is corrected, prognosis is more influenced by systemic comorbidities such as coronary artery disease and diabetes than by the initial degree of luminal narrowing. Thus, CEA serves primarily as a risk-modifying intervention for cerebrovascular events rather than a determinant of overall cardiovascular mortality.

Patch angioplasty is well established to improve perioperative outcomes and long-term patency compared to primary closure. A Cochrane review of 11 randomized trials involving approximately 2,100 CEAs demonstrated that patch closure significantly reduces perioperative arterial occlusion (odds ratio 0.17) and 1-year restenosis rates (odds ratio 0.24) compared to primary closure.[8] Patch closure also reduces early postoperative stroke rates by maintaining a wider lumen, reducing local turbulence, and minimizing thrombogenic flow disturbances.

However, the optimal patch material remains debated. Synthetic materials such as Dacron and PTFE and biological materials such as autologous vein or bovine pericardium have all been studied. Evidence comparing Dacron and PTFE patches is mixed. A randomized trial of 200 CEAs found higher perioperative stroke and transient ischemic attack rates with Dacron (7% vs. 0%; $P = 0.02$) and a higher rate of early (>50%) restenosis at 1 year (12% vs. 2%; $P = 0.013$).[24] Similarly, AbuRahma et al. reported inferior 3-year freedom from ≥70% restenosis with Dacron (78%) compared with PTFE (100%) and a higher ipsilateral stroke risk (8% vs. 0%).[10] In contrast, a meta-analysis of 16 studies including around 2,500 procedures reported no significant differences in perioperative stroke or mortality between Dacron and PTFE patches, although PTFE showed a modest advantage in late restenosis rates.[9]

Despite these mixed findings, our cohort using exclusively Dacron patches achieved <4% restenosis over 5 years, substantially better than earlier randomized trial data. These findings highlight the durability of CEA with patch angioplasty and

demonstrate that in experienced surgical hands, Dacron patches can achieve excellent long-term vessel patency.

This suggests that contemporary surgical techniques, improved perioperative care, and structured duplex surveillance can mitigate differences previously attributed to patch type.

A notable and clinically relevant finding in our study was the significantly higher 5-year restenosis rate in women compared to men. Female sex has been identified in multiple studies as an independent predictor of restenosis after CEA. A meta-analysis by Texakalidis et al. spanning 18 studies and over 17,000 patients found female sex associated with an increased risk of restenosis (hazard ratio 1.67; 95% CI 1.14−2.44) after CEA.[25] Similarly, pooled registry data reported higher 1-year restenosis rates in women (10.8% vs. 3.2% in men, odds ratio 3.71; $P = 0.005$).[26]

The most plausible explanation for this sex-specific disparity is anatomical. Women generally have smaller carotid artery diameters, which lead to several adverse hemodynamic and technical effects. Smaller luminal diameters increase flow resistance and alter wall shear stress at the artery−patch interface, creating disturbed flow patterns that promote endothelial dysfunction and neointimal hyperplasia, the primary driver of restenosis. In addition, smaller vessels are technically more challenging to patch, especially with Dacron, which is relatively stiff and less compliant than native tissue, resulting in greater compliance mismatch and local turbulence. PTFE and bovine pericardium patches, by contrast, are more flexible and conform better to native vessel anatomy, potentially reducing this mismatch.

Beyond anatomy, biological differences may also contribute. Postmenopausal estrogen deficiency alters vascular remodeling, promoting a more proliferative neointimal response after endothelial injury. Hormonal influences may also modulate inflammatory pathways involved in restenosis. Furthermore, women tend to have higher rates of connective tissue fragility, which can impair long-term arterial wall adaptation to synthetic materials.

Despite higher restenosis rates, our female patients did not experience higher stroke rates, likely due to structured postoperative duplex surveillance and timely management of restenosis before it became symptomatic. This highlights the importance of proactive follow-up in high-risk subgroups.

For female patients and others with small-caliber carotid arteries, alternative patch materials may help reduce restenosis risk. PTFE patches have a smoother surface and lower porosity than Dacron, inducing less inflammatory response and hyperplasia, as demonstrated in randomized trials.[10] Bovine pericardium patches are more compliant and better conform to native vessel curvature, minimizing compliance mismatch. Autologous vein patches provide the best physiological compliance but require additional operative steps and may degenerate over time.

Given these considerations, patch material selection should be individualized, particularly for women and patients with small vessels. However, meticulous surgical technique, proper patch sizing, and intensive duplex follow-up remain critical to mitigate restenosis risk regardless of patch type.

The strengths of this study include a well-characterized cohort, a uniform surgical technique performed by experienced vascular surgeons, and long-term follow-up with consistent duplex surveillance. However, its single-center retrospective design may limit generalizability. Patch material was not randomized, as all patients received Dacron, which precludes direct comparison with PTFE or biological patches. Furthermore, vessel diameters were not systematically recorded, which would have enabled more precise correlation between lumen size and restenosis risk.

Future research should include randomized trials comparing Dacron, PTFE, and bovine pericardium patches specifically in female and small-vessel patients. Mechanistic studies investigating sex-specific vascular healing responses, particularly hormonal and genetic determinants of neointimal hyperplasia, would also be valuable. Finally, development of compliance-matched hybrid or drug-eluting patches designed to inhibit hyperplasia may further reduce restenosis.

CONCLUSION

CEA with Dacron patch closure offers excellent long-term results with high overall survival and freedom from stroke and restenosis at 5 years underscoring the procedural efficacy and durability of Dacron-based reconstruction. Importantly, all perioperative bleeding events were associated with significantly prolonged clamping times, suggesting that extended intraoperative arterial occlusion may serve as an early warning marker for postoperative hemorrhagic complications. This highlights the value of careful intraoperative time monitoring and postoperative vigilance in patients with unusually prolonged clamp durations. Additionally, our findings revealed a significantly higher rate of

restenosis among female patients, despite similar stroke rates between sexes. The 5-year freedom from restenosis was notably lower in women (88.4%) compared to men (98.0%), emphasizing the importance of sex-specific risk assessment and the potential benefit of intensified duplex ultrasound surveillance in women following CEA.

Overall, the data from our study support the continued use of Dacron patches as a safe and effective method for carotid reconstruction. The integration of intraoperative parameters such as clamping time and sex-specific risk profiling into perioperative care protocols may further improve long-term outcomes and patient safety.

LIMITATIONS

Strengths of our study include a standardized technique (all surgeries with Dacron patch by experienced surgeons), systematic duplex ultrasound follow-up, and inclusion of both symptomatic and asymptomatic patients with meaningful subgroup analyses. Key limitations are its retrospective single-center design and lack of randomized comparison groups. Event rates for restenosis and subgroup analyses were relatively low, limiting statistical power.

CREDIT AUTHORSHIP CONTRIBUTION STATEMENT

Waseem Garabet: Writing − review & editing, Writing − original draft, Visualization, Methodology, Investigation, Data curation, Conceptualization. **Joscha Mulorz:** Writing − review & editing, Investigation. **Agnesa Mazrekaj:** Investigation. **Polina Shabes:** Investigation. **Julian-Dario Rembe:** Writing − review & editing, Investigation. **Amir Arnautovic:** Investigation. **Artis Knapsis:** Writing − review & editing, Investigation. **Fabian Kuger:** Writing − review & editing, Visualization, Formal analysis. **Hubert Schelzig:** Supervision, Resources. **Markus Udo Wagenhäuser:** Writing − review & editing, Validation, Supervision, Project administration, Methodology, Conceptualization.

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