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Upper Extremity Access Has Worse Outcomes in F/BEVAR Using the VQI Dataset

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Background: Physician-modified endografts and custom-manufactured devices use branched and fenestrated techniques (F/BEVAR) to repair complex aneurysms. Traditionally, many of these are deployed through a combination of upper and lower extremity access. However, with newer steerable sheaths, you can now simulate upper extremity (UEM) access from a transfemoral approach. Single-institution studies have demonstrated increased risks of access site complications and stroke when UEM access is used. This study compares outcomes after F/BEVAR in a national database between total transfemoral (TTF) access and mixed UEM access.

Methods: This study is an analysis of the Vascular Quality Initiative for all patients who underwent F/BEVAR from 2014 to 2021. Patients were stratified based on a TTF delivery of all devices versus any UEM access for deployment of target vessel stents. Primary outcomes included stroke, myocardial infarction (MI), and perioperative death. Secondary outcomes included access site hematoma, occlusion or embolization, operative time, fluoroscopy time, and technical success. Multivariable linear and logistic regression analyses were performed.

Results: Three thousand one hundred forty six patients underwent an F/BEVAR: 2,309 (73.4%) TTF and 837 (26.6%) UEM. Logistic regression analysis indicated a two-fold increased risk of death and MI and a three-fold increased risk of stroke in the UEM group. Furthermore, there is decreased operative time (221 vs. 297 min, P < 0.001) and fluoroscopy time (62 vs. 80 min, P < 0.001) in the TTF group and no difference in technical success between groups (96% vs. 97%, P = 0.159). Finally, there was a decrease in access site hematoma 2.54% vs. 4.31% (P = 0.013), access site occlusion 0.61% vs. 1.91% (P = 0.001), and extremity embolization 2.17% vs. 3.58% (P = 0.026) in the TTF versus UEM group.

Conclusions: This study using Vascular Quality Initiative data demonstrates that patients who undergo an F/BEVAR using UEM access have an increased risk of perioperative MI, death, and stroke compared to TTF access.

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INTRODUCTION

For the last 3 decades, endovascular approaches have become the mainstay therapy for aortic aneurysmal disease.¹ The treatment of complex aneurysms including juxtarenal, pararenal, and thoracoabdominal aneurysms is slowly following the same trend.^{2,3} Despite a lack of level I evidence, fenestrated and branched endovascular repair (F/BEVAR) has been shown to be a viable, minimally invasive alternative to open surgery due to studies demonstrating reduced morbidity and mortality, technical feasibility, and good outcomes.^{4,5} First described in the late 1990s, the technique details the use of fenestrations and/or branches to preserve flow to the renal and visceral arteries.^{6,7}

F/BEVAR tools have evolved from both physician-modified endografts (PMEGs) and company-manufactured devices (CMDs).⁸ Whether due to regulatory issues or device availability, vascular surgeons have adapted different approaches to treating complex aortic aneurysms. One of the most noticeable variations is the selection of upper extremity (UEM) versus a total transfemoral (TTF) access for target vessel stent deployment in the visceral and renal arteries. This physician preference for UEM versus TTF approach to target vessel stenting may be due to physician comfort with anatomic characteristics such as target vessel angle/direction, ostial stenosis, the use of directional branches versus fenestrations, and access tortuosity or order of deployment of the aortic and target vessel components. With the advent of strong steerable/morphable sheaths, it is now possible to simulate UEM using a TTF approach minimizing manipulation of the arch vessels, improving the ergonomics of a case, and minimizing access points and risk to the patient (Fig 1). Despite literature demonstrating an increased risk for cerebrovascular events, UEM access is still commonly used currently and future device designs still depend on UEM access due to convenient visceral cannulation and ability to perform through-and-through brachio/ axillary-femoral wire access.9-11

In an era of constant innovation, patient safety and quality improvement are at the forefront of vascular surgery. The Vascular Quality Initiative (VQI) is a national cooperative designed to evaluate processes of care and outcomes in vascular surgery.¹² Using the VQI database, we aim to compare outcomes between lower extremity versus mixed UEM access for F/BEVAR of complex aortic aneurysms. This study would represent the first of its kind using large-volume multicenter data in the VQI to compare outcomes between types of extremity access.



Fig. 1. Example of simulated UEM from TTF access using steerable sheath demonstrating catheterization of a downward going renal artery **(A)** and stenting **(B)**.

METHODS

Dataset

This study was performed using the VQI dataset; a national, multicenter deidentified prospectively collected registry that contains more than 200 variables on preoperative, intraoperative, and postoperative data including 1-year follow-up on 1,000 centers in the United States and Canada.¹² The VQI Research Advisory Committee approved this project (Protocol #4688) and we were given access to the thoracic and complex endovascular aortic aneurysm repair dataset. Given the deidentified nature of this dataset, individual consent was not required and this study was approved locally by our Institutional Review Board. Additionally, our manuscript is compliant with both REporting of studies Conducted using Observational Routinely collected Health Data statement and the Journal of American Medical Association-Surgical Section (JAMA-Surgery) checklist.¹³

Population

We performed a retrospective analysis of all patients who underwent F/BEVAR between 2014 and 2021. Patients with missing data regarding arm or neck access were excluded. The final cohort was split in 2 groups: F/BEVAR patients with wire access from an UEM arm or neck access combined with

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Table I. Baseline characteristics

Variable	Total transfemoral access (TTF) 2,309 (73.4)	Upper extremity mixed access (UEM) 837 (26.6)	P value
Age (years)	73.2 ± 8.3	71.6 ± 10.0	< 0.0001
Male	1,738 (75.3)	595 (71.1)	0.018
Race (White)	1,992 (86.3)	635 (75.9)	< 0.0001
Current Smoker	762 (33.0)	269 (32.1)	0.649
Hypertension	2,026 (88.1)	7×55 (90.4)	0.064
Type 2 Diabetes	430 (18.6)	142 (17.0)	0.287
Coronary Artery Disease	1,011 (43.8)	311 (37.2)	0.001
Coronary artery bypass graft or percutaneous coronary intervention	832 (36.1)	255 (30.5)	0.004
Congestive Heart Failure	329 (14.3)	126 (15.1)	0.570
Chronic Obstructive Pulmonary Disease	884 (38.3)	308 (36.8)	0.447
History of Cerebrovascular Disease	248 (10.8)	105 (12.5)	0.158
Current Dialysis	34 (1.5)	17 (2.0)	0.273
Prior Carotid Endarterectomy or Carotid Artery Stent	93 (4.0)	33 (3.9)	0.914
History of Prior Aortic Surgery	342 (14.8)	272 (32.5)	< 0.0001
Maximum AAA Diameter Prior to Surgery	61.2 ± 10.6	64.2 ± 13.4	< 0.0001
Preop Aspirin Use	1,589 (68.9)	508 (60.1)	< 0.0001
Preop P2Y12 Inhibitor Use	387 (16.8)	119 (14.2)	0.086
Preop Statin Use	1,757 (76.1)	586 (70.0)	0.001
Number of Fenestrations			< 0.0001
0	26 (1.2)	96 (11.6)	
1	12 (0.5)	11 (1.3)	
2	375 (16.7)	52 (5.1)	
3	934 (41.7)	97 (11.7)	
4	893 (39.9)	585 (70.4)	

transfemoral approach compared to those patients without arm or neck access using TTF access.

Variables

Baseline characteristics included demographics (age, sex, race, and body mass index), comorbidities (diabetes, hypertension, congestive heart failure, coronary artery disease [CAD], history of cerebrovascular disease, and chronic obstructive pulmonary disease), previous history of aortic surgery, size of aortic aneurysm prior to surgery, number of fenestrations, smoking history, and preoperative medications (aspirin, P2Y12 inhibitor, and statin).

Outcomes

Primary outcomes included major perioperative events. These were defined as cerebrovascular accident (CVA), myocardial infarction (MI), and perioperative mortality. Secondary outcomes included access site complications including access site hematoma, occlusion or embolization, and intraoperative factors such as operative time, fluoroscopy time, and technical success defined by the VQI as accurate deployment and patency of the graft at time of deployment, absence of device deformation or inadvertent covering of branch vessels, and successful withdrawal of the delivery system.

Statistical Analysis

Continuous and binary variables were analyzed using Student's t-test and Pearson's chi-squared test, respectively. Univariate and multivariate logistic regression models were used to analyze outcomes of interest. Final models included statistically and clinically relevant variables which were chosen based on a stepwise backward selection. All models were clustered by center ID to account for intragroup correlation. Hosmer-Lemeshow goodnessof-fit test and area under the receiver operator curve were used to assess model fit and accuracy, respectively. Additionally, we performed a subanalysis to stratify UEM by laterality (right versus left UEM). A *P* value <0.05 was considered statistically significant. All analyses were performed using Stata 16.1 (StataCorp, College Station, Texas).

Primary outcome	Total transfemoral access (TTF) 2,309 (73.4)	Upper extremity mixed access (UEM) 837 (26.6)	P value
Postoperative Cerebrovascular Accident	18 (0.8)	24 (2.9)	< 0.0001
Postoperative Myocardial Infarction	47 (2.0)	33 (3.9)	0.003
Perioperative Mortality	79 (3.4)	57 (6.8)	< 0.0001

Table II. Univariate analysis of primary outcomes

RESULTS

Baseline Characteristics

Our final cohort consisted of 3,146 [1,969 (62.6%) had CMD and 1,177 (37.4%) had PMEG] patients who underwent an F/BEVAR in the VQI registry. When divided by extremity access, we found that 2,309 (73.4%) individuals had a TTF approach for device delivery, branch/fenestration treatment, or femoral-brachial wire. In contrast, 837 (26.6%) had a UEM approach for device delivery, target vessel stenting, or femoral-brachial wire. Of the UEM group, 711 patients or 85% had UEM access for branch treatment.

In terms of demographic variables, the TTF was significantly older (73.2 years vs. 71.6 years, P < 0.0001), had a greater proportion of White patients (86.3% vs. 75.9%, P < 0.0001), and men (75.3% vs. 71.1%, P = 0.018) than the UEM group. Additionally, the TTF had a greater proportion of individuals with CAD and a history of coronary artery bypass graft or percutaneous coronary intervention (CABG/PCI), while the UEM group had a higher proportion of patients with a previous aortic surgery and a larger aortic aneurysm size prior to surgery. Finally, TTF had a greater proportion of individuals with 2 or 3 fenestrations, 16.7% vs. 5.1% and 41.7% vs. 11.7%, respectively, while UEM had a greater proportion of individuals with 4 fenestrations, 70.4% vs. 39.9% (Table I).

Primary Outcomes–Perioperative Events

Table II demonstrates that the UEM group had a significantly greater proportion of postoperative CVA (2.9% vs. 0.8%, P < 0.0001), MI (3.9% vs. 2.0%, P = 0.003) and mortality (6.8% versus 3.4%, P < 0.0001).

Secondary Outcomes

On univariate analysis we found that the UEM group had significantly longer operative time (297.8 vs. 221.8 min, P < 0.0001) and fluoroscopy time (80.2 min vs. 62.3 min, P < 0.0001) compared to the TTF group. Additionally, the UEM group had

a greater amount of contrast used, estimated blood loss, and number of packed red blood cells transfused intraoperatively (Table III). However, there was no difference in technical success or branch/ fenestration leak on completion angiogram between UEM and TTF. Additionally, the UEM group had a significantly greater amount of access site complications (29.4% vs. 15.9%, P < 0.0001) compared to the TTF group and this was maintained even when broken down by subtype—hematoma, occlusion, or distal embolization (Table III). Of note, there was no difference in lower extremity compartment syndrome (1.1% in TTF and 1.7% in UEM, P = 0.187).

Multivariate Models

Table IV demonstrates that the UEM group has a 3.8-fold increase in CVA, two-fold increase risk of MI, and two-fold increase in mortality when compared to the TTF group. This maintained even after adjusting for age, gender, race, CAD, history of CABG/PCI, size of aneurysms, number of fenestrations, and history of aortic surgery. After adjustment, the UEM group had an increased risk of CVA (adjusted odds ratio [aOR] = 3.1, 95% confidence interval [CI] 1.4–6.7, P = 0.005), MI (aOR = 1.8, 95% CI 1.1–2.9, P = 0.012), and mortality (aOR = 1.8, 95% CI 1.2–2.9, P = 0.010) compared to the TTF group.

Similarly, after adjusting for the same factors, the UEM group maintained a significantly longer operative time, fluoroscopy time and greater amount of contrast used, estimated blood loss, and number of packed red cells transfused compared to the TTF group (Table V).

Subanalysis

On subanalysis, we looked at laterality for UEM access and our primary outcomes. We found that within the UEM group, 185 (22.9%) patients had a surgery with right UEM access (RUEM) using the right arm, right axillary, or right carotid, while 623 (77.1%) had a left UEM access (LUEM) using left arm, left axillary, or left carotid. We found no significant differences in terms of operative time,

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Secondary outcome	Total transfemoral access (TTF) 2,309 (73.4)	Upper extremity mixed access (UEM) 837 (26.6)	P value
Access Site Complication	366 (15.9)	246 (29.4)	< 0.0001
Hematoma	49 (2.5)	36 (4.3)	0.013
Occlusion	14 (0.6)	16 (1.9)	0.001
Embolization	50 (2.2)	30 (3.6)	0.026
Operative Time (min)	221.8 ± 104.5	297.8 ± 133.6	< 0.0001
Fluoroscopy Time (min)	62.3 ± 35.2	80.2 ± 58.2	< 0.0001
Contrast (cc)	117.7 ± 74.9	139.1 ± 78.1	< 0.0001
Estimated Blood Loss (cc)	355.1 ± 502.3	550.9 ± 819.2	< 0.0001
Packed Red Blood Cells Transfused Intraoperative	0.5 ± 4.6	1.1 ± 2.2	< 0.0001
Leak on Completion Angiogram at Branch or Fenestration	29 (1.3)	9 (1.3)	0.920
Technical Success	2,097 (96.2)	742 (97.3)	0.159

Table III.	Univariate	analysis	of	secondary	v outcomes
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fluoroscopy time, contrast volume used, estimated blood loss, technical success, branch/fenestration leak, or access site complications. There was a significantly greater proportion of MI from RUEM versus LUEM access (6.5% vs. 3.1%, P = 0.033) but no difference in stroke (3.8% vs. 2.4%, *P* = 0.313) or mortality (7.6% vs. 6.4%, P = 0.583). After adjusting for age, gender, race, CAD, history of CABG/PCI, size of aneurysms, number of fenestrations, and history of aortic surgery, there was no significant difference in postoperative CVA (0.5, 95% CI 0.1–1.9, P = 0.283) and mortality (aOR = 1.0, 95% CI 0.6-1.8, P = 0.990) [reference RUEM]. However, there was 50% reduction in MI in the LUEM compared to the RUEM group (aOR = 0.5, 95% CI 0.3-0.8, P = 0.005) (Supplemental Table I).

DISCUSSION

Using the VQI, we found that UEM access for F/ BEVAR is associated with worse outcomes than TTF access. UEM access was associated with higher odds of CVA, MI, mortality, and access site complications. To our knowledge, this is the largest study comparing F/BEVAR outcomes between partial upper access and total lower extremity access.

Over the past several years, there have been an increasing number of F/BEVAR cases being performed. Devices and techniques have progressed, improving the ability to complete these tasks with improved speed, safety, and in patients with more complex anatomy such as severe tortuosity, poor access, and vessel stenosis. Steerable sheaths have also aided in transfemoral access being able to deliver stiff wires and stents through antegrade branches or fenestrations simulating UEM access from a TTF approach. $^{\rm 14}$

In our cohort, patients in the UEM group were more than 3 times likely to suffer from CVA events than the TTF group. Chamseddin et al. compared UEM versus transfemoral access outcomes in an F/ BEVAR database collected from 9 physiciansponsored investigation device exemption protocols.¹¹ This Aortic Research Consortium found a CVA rate of 2.8% for UEM versus 1.3% for TTF access group.¹¹ Prior studies comparing both groups in simple EVARs or BEVAR have also found a similar association between UEM access and risk of stroke.^{9,10} This is likely due to crossing the aortic arch which imposes an increased risk of plaque disruption with subsequent embolization to the cerebral vasculature. Additionally, thrombus formation around the access sheath may also play a role. Larger sheaths can also cover the origins of vessels causing ischemia, especially the vertebral artery ipsilateral to UEM access. Regardless of the specific cause, lower extremity access seems to diminish the risk of cerebral embolic events by minimizing manipulation of the aortic arch. Finally, in a systematic review of 5 manuscripts, Malgor et al. found that percutaneous UEM access resulted in higher likelihood of complications than open UE access; however, unlike our study, this was not compared to a TTF approach.¹⁵

Placing endovascular instruments in the aortic arch might not only affect the circulation to the central nervous system but also the myocardium as well. Plotkin et al. found an MI rate of 4.4% for their UEM/neck access group versus 2.2% for femoral/iliac access (P < 0.0001).⁹ This was also reproduced in our population, with comparable rates that were significantly different between the 2 groups (3.9%)

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Primary outcomes	Unadjusted odds ratio	95% confidence interval	P value	Adjusted odds ratio ^a	95% confidence interval	P value
Cerebrovascular Accident	3.8	2.0-6.9	<0.0001	3.1	1.4-6.7	0.005
Myocardial Infarction	2.0	1.3-3.1	0.003	1.8	1.1-2.9	

Table IV. Unadjusted and adjusted multivariate analysis for primary outcomes

Reference Group: Total Transfemoral Access (TTF).

^aAdjusted for age, gender, race, hypertension, coronary artery disease, history of coronary artery bypass graft, maximum size of AAA prior to surgery, number of fenestrations, and history of previous aortic surgery.

Table `	V.	Adjusted	multivariate	analysis	for	secondary	outcomes
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Secondary outcome	Intercept	95% confidence interval	P value	
Operative Time (min)	73.0	62.9-83.2	< 0.0001	
Fluoroscopy Time (min)	18.6	14.1-23.1	< 0.0001	
Contrast (cc)	23.9	17.0-30.7	< 0.0001	
Estimated Blood Loss (cc)	178.8	117.3-240.4	< 0.0001	
Packed Red Blood Cells (units)	0.5	0.3-0.7	< 0.0001	

Adjusted for age, gender, race, hypertension, coronary artery disease, history of coronary artery bypass graft, maximum size of AAA prior to surgery, number of fenestrations, and history of previous aortic surgery.

Reference Group: Total Transfemoral Access (TTF).

vs. 2%; P < 0.003). Literature addressing the etiology is scarce, although it may respond to the same previously explained principle; risk is higher in patients with extensive atherosclerotic plaque in the aorta and aortic arch with increased manipulation and potential contribution from left internal mammary graft occlusion in patients with a prior CABG.¹⁶

Various studies have also compared outcomes between left and RUEM access in EVAR repairs.^{9,17} The assumption is that left-sided access avoids part of the aortic arch thus reducing the risk of plaque disruption. In our analysis, we did not find statistically significant differences for stroke, although left-sided access was associated with a lower risk for MI. Our findings could be due to type I error for the outcome of MI, lack of power, or type II error for the stroke outcome, closer manipulation of wires or sheaths near the cardiac ostium, or that this represents longer cases because most surgeons are more comfortable using their right hand and standing above the RUEM. Previous investigations have reported mixed results, ranging from higher incidence of stroke for right-sided access to no differences based on UEM laterality.^{16,18} Although results vary and studies are not prospective, it is important to note that data tend to still favor left-sided access if UEM access is needed.

Mortality was another major primary outcome which showed statistically significant lower rates for the TTF group. Patients who had UEM access were approximately twice as likely to have died within 30 days (6.8% vs. 3.4%; OR 2.1 P < 0.0001). Our results are consistent with those published by Plotkin et al. which showed the UEM/neck access group had an in-house mortality rate of 7.1%, while femoral/iliac access mortality rate was 4.1% (P < 0.0001).⁹ Van Calster et al. reported F/BEVAR prospective data with a 30-day mortality of 4.9%, which is similar to our overall rate combining both groups (4.3%).¹⁹ Although they did not analyze outcomes by access type, they found chronic kidney disease, procedure time, and aneurysm diameter as predictors of early mortality.19

Differences in primary outcomes, although compelling and endorsed by prior research, might be explained by the need for UEM access in more complex cases. Patients in the UEM group had statistically significant greater maximum aortic diameter, higher rates of prior aortic interventions, and greater number of patients with 4 vessel fenestrations; however, these factors were adjusted for in our final models. Longer operative and fluoroscopy times could also be seen as reflections of greater case difficulty. Nonetheless, we analyzed a very large, real-world population who had undergone a wide spectrum of F/BEVAR techniques for a wide variety of aneurysm types, from initial PMEG experience requiring brachial access to newer CMDs and steerable sheaths allowing an exclusive transfemoral approach.^{20,21} Additionally, analysis of baseline characteristics showed similar rates for most major comorbidities including smoking, hypertension, diabetes, congestive heart failure, chronic obstructive pulmonary disease, and history of cerebrovascular disease. We did find a higher rate of aspirin/ statin use in the transfemoral group, although the retrospective nature of our study precludes us from making conclusions about their potential cardioprotective effect. Overall, there are many other measures of case complexity that are not being captured in the VQI and therefore unable to be accounted for or adjusted for in our models.

Analysis of VQI data on local access site complications resulted in a higher percentage than previously reported in the literature. Both of our groups demonstrated elevated rates, 15.9% for the TTF group and 29.4% for the UEM group. Knowles et al. reported an UEM access—related complication of 4%; retrospective studies with prospective data collection have also indicated rates in the single digits, ranging from 3 to 6.5%.^{11,18,22} Such variations are likely due to discrepancies in data reporting. In fact, when observing our incidence for specific access sites complications (i.e., hematoma, occlusion), the percentages correlate with prior published data.

Limitations

Our study has several limitations, mostly due to the retrospective design of the VQI dataset. First, there could be selection and treatment bias; the data sharing is voluntary and self-reported, potentially affecting its integrity. Second, retrospective analyses give room to confounding factors and limit our ability to draw conclusions about casualty. Similarly, as a retrospective study, we do not have important surgical information on percutaneous versus open cutdown for UEM access and are unable to perform any subset analysis on access type. Third, surgeon experience might play a critical role in the outcomes, especially at the time of placing large sheaths in smaller caliber vessels such as the brachial artery. Fourth, we categorized types of aneurysm based on proximal and distal zones; however, less than 50% of our cohort contained these data and we were therefore unable to account for this in our analysis. Other limitations from this dataset include lack of F/BEVAR-related complex anatomic factors including target vessel ostial stenosis, directional nature of the target vessels, and aortic characteristics including tortuosity index or tight flow lumen. We did control for 3 surrogates of aneurysm complexity-aneurysm size, previous repair, and number of fenestrations which were notably different between

the 2 groups. Specifics regarding the use of parallel stent grafts are not contained in the VQI and therefore these cases were unable to be excluded. Additionally, less than 1% of our population contained UEM access via the carotid artery and these patients were not excluded. Finally, this study assesses all F/ BEVARs in the VQI which includes both custommodified and physician-modified devices which are not equally comparable to standard off-theshelf devices. Despite these limitations, we present the largest study comparing F/BEVAR outcomes between UEM and TTF access.

CONCLUSION

Our study is the largest multicenter analysis comparing mixed UEM access to a TTF approach for F/BEVARs. This analysis found that UEM access regardless of laterality is associated with an increased risk of perioperative stroke, MI, and death compared to total lower extremity access. The decision for UEM access in this dataset could be due to physician preference or anatomic characteristics not captured and controlled for. Experience at our institution demonstrated that steerable sheaths have been able to simulate UEM access while keeping a TTF approach. If anatomically and technically feasible with currently available accessories, our study shows F/BEVARs from a TTF approach decrease the morbidity and mortality that can be associated with UEM access. Additional studies are needed to further confirm these findings and delineate other factors that may be contributing to these differences such as anatomic complexity, inherent dataset limitations, and institutional volume. Another study we plan on pursuing is an overall cost analysis of steerable sheaths as they are expensive. Overall, these data support previous publications demonstrating that approaches for F/BEVARs should evolve to adapt a TTF approach when possible minimizing access sites and arch manipulation.

SUPPLEMENTARY DATA

Supplementary data related to this article can be found at https://doi.org/10.1016/j.avsg.2023.08. 002.

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