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Achieving high maturation and cannulation rates of radial-cephalic arteriovenous fistulas with VasQ™ device

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Abstract

Background: Hemodialysis is the predominant treatment modality for chronic kidney disease, with arteriovenous fistula (AVF) being considered to be the preferred type of long-term vascular access. Implantation of the external anastomotic VasQ™ support device during AVF creation has been suggested to improve the functional outcomes of AVFs. In the current study, we report the clinical outcomes when using the device with radial-cephalic AVF (RCAVF) creation in a large cohort over 3 years.

Methods: One hundred fifty RCAVFs were created between June 2018 and August 2021 with implantation of VasQ™. Time to maturation, cannulation characteristics, and assisted (AP) and secondary patency (SP) rates were analyzed.

Results: In this predominantly male (68%), median 64 years old cohort, 150 VasQ™ devices were implanted. Physiological maturation was achieved in 142/150 (95%) and was unassisted in 133/150 (89%). Of those, 129 matured within 1 month and four additional AVFs within 165 days. Eight AVFs achieved maturation following percutaneous transluminal angioplasty, and one required surgical patch angioplasty. The median time from creation to first successful cannulation in dialysis patients was 41 days. AP at 6, 12, 18, 24, and 30 months was 89%, 81%, 78%, 73%, and 73%, and SP was 94%, 87%, 86%, 84%, and 84%, respectively.

Conclusions: Consistent use of the VasQ™ device in RCAVF creation demonstrates excellent AVF maturation and patency rates with very low frequency of assisted maturation and interventions for maintenance. The VasQ™ device appears a suitable aid in increasing the creation of functional RCAVFs.

1 | INTRODUCTION

Efficient hemodialysis (HD) is dependent on a reliable and long-lasting vascular access, and autogenous arterial–venous access (arteriovenous fistula [AVF]) is considered the preferred type of access.[1–3] There are many well-established benefits to using AVFs over other types of vascular access, such as grafts and dialysis catheters, including longer usability, fewer complications, lower patient mortality, and higher patency rates.[4–6] However, AVFs, and in particular forearm radial-cephalic AVFs (RCAVF), have reported high failure rate to mature, significant early thrombosis, and often require several months before cannulations can be attempted.[7–13] This prolongs dialysis catheter times with increased risk of infection, need for secondary fistula creation or revisions, and potentially leads to overall higher costs.

In recent years, we have adopted the routine use of the external support device VasQ™ (Laminate Medical Technologies Ltd., Tel-Aviv, Israel) in the creation of AVFs based on published studies.[13–15] The device is implanted externally at the juxta-anastomotic region (JAR) of the AVF and designed to optimize the JAR geometry for more uniform wall sheer stress and to provide structural support to reduce wall tension.[16] Previously, the use of the VasQ™ device demonstrated reduced rates of stenosis, larger vein diameters, and improved functional patency for upper arm brachial-cephalic AVFs (BCAVF).[13] In addition, it was not associated with surgical complications or increase in length of surgery. A retrospective study performed at our center compared outcomes of 33 forearm RCAVFs created with the device with 17 forearm RCAVFs created without the device: The use of the device was associated with higher secondary patency at 180 days (90% vs. 76%) and a higher maturation rates without need for intervention (79% vs. 53%).[14,15] Additionally, AVFs created with the device required fewer interventions per patient-year, compared to standard surgical procedure.

In view of these results, we expanded the use of the VasQ™ external support device for all forearm RCAVFs and present here outcomes for this patient cohort with up to 36 months follow-up.

2 | METHODS

2.1 | Patients and setting

This was a retrospective evaluation of prospectively collected medical records of patients who underwent RCAVF creation with the VasQ™ device at a dedicated vascular access center between June 2018 and September 2021. The collected data included patient demographics, medical history (especially diabetes status), and dialysis status. Importantly, information was also collected reporting any secondary interventions, access-related complications, time to AVF maturation, cannulation start date in dialysis patients, and assisted primary and secondary patency rates.

The device was implanted consecutively in all but one RCAVF creation since June 2018 (the exception was one at the beginning of our experience due to the very close distance between the artery and vein and hence expected angulation <40°: less than the VasQ device supports) in patients with preoperative forearm cephalic vein diameter of 2–6 mm (measured while using a tourniquet, as the device only allows for vein diameter up to 6 mm, and an internal vein diameter ≥2 mm is recommended by the European Society of Vascular Surgery [ESVS] guidelines).[17] For the radial artery, inner diameter of ≥1.6 mm was accepted for RCAVF creation. No patients were excluded due to known allergy to nitinol (nickel–titanium alloy). The procedure of AVF creation and implantation of VasQ™ has been previously described in detail and does not differ from standard AVF creation.[13,16] Due to its retrospective anonymized nature, the Ethics Committee of Hamburg ruled that an approval of the study is not required.

2.2 | Definitions

Physiological maturation (referred to as "maturation" throughout the manuscript) was defined as an access suitable for two-needle cannulation with minimal brachial artery flow (Qa) of 500 ml/min and minimum target vein inner diameter of 5 mm. Maturation was considered assisted when either a percutaneous or surgical interventions were performed before the access matured or was successfully used for dialysis.[18] Routine measurement of Qa was performed at the end of every procedure using ultrasound in the brachial artery and transit time flow measurement (TTFM) (Medistim, Oslo, Norway) around the juxta-anastomotic cephalic vein, as well as 2 days later, 4 weeks after date of surgery, and every 3–6 months using ultrasound—either in the brachial artery or in the axillary artery for patients with high axillary bifurcation. Secondary patency (SP) was defined as the time from AVF creation until either its abandonment or reaching a censored event including end of study, death, loss to follow-up, transfer to peritoneal dialysis (PD), or kidney transplantation.[17] Assisted patency (AP) was defined as the time from AVF creation until an AVF occlusion, which was successfully restored.[19] Any unplanned surgical or endovascular procedure performed to maintain or reestablish patency was counted as an intervention.

2.3 | Statistical analysis

Time-related outcomes such as AP and SP are presented as observed patency and are analyzed using survival analysis (Kaplan–Meier curve). Only observed data were analyzed, no imputations were performed for missing data. Descriptive analyses were carried out on the entire study population using JMP 15.1 software (SAS, Cary, North Carolina, USA) and Excel (2007, Microsoft Corporation, Redmond, Washington, USA). Continuous variables were presented as mean ± standard deviation or median (interquartile range). Categorical variables were presented as numbers (percentage).

3 | RESULTS

3.1 | Study cohort

VasQ™ device was used to create 150 RCAVFs in 148 patients between June 2018 and August 2021. Two VasQ-patients underwent proximalization of RCAVFs using a new VasQ™ device after the primary AVF failed (3 months and 1.5 years later).

The demographic and clinical baseline characteristics of the study cohort are provided in Table 1. The study cohort was predominantly male (68%), with a median age of 64 years (range: 28–87). The most prevalent comorbidities in the cohort included arterial hypertension (72%) and diabetes (45%). Median body mass index (BMI) was 28 (18–59) with 37% of the patients having a BMI > 30. Fifty-eight percent (87/150) were on dialysis due to end-stage renal disease (ESRD) at the time of access creation, of which 79% (69/87)

TABLE 1 Demographics and baseline preoperative characteristics

	Proportion ($N = 150$)
Characteristics	
Age, years (median, range)	64 (28–87)
Gender (female/male), *n*/*N* (%)	48/102 (32%/68%)
Comorbidities	
Hyperlipoproteinemia	3/150 (2%)
Diabetes	67/150 (45%)
Hypertension	108/150 (72%)
Cardiac disease	45/150 (30%)
COPD	8/150 (5%)
Peripheral arterial disease (PAD)	12/150 (8%)
BMI (median, range)	28 (18–59)
Obese (BMI > 30)	55/150 (37%)
Dialysis status	
Predialysis	63/150 (42%)
Active dialysis (ESRD)	87/150 (58%)
TDC	69/87 (79%)
Previous AVF	27/87 (31%)
Peritoneal dialysis	4/87 (5%)
Previous AV graft	1/87 (1%)

Abbreviations: AVF, arteriovenous fistula; BMI, body mass index; COPD, chronic obstructive pulmonary disease; ESRD, end-stage renal disease; TDC, tunneled dialysis catheter.

were using a tunneled dialysis catheter (TDC), whereas 5% (4/87) were on PD. Three patients required AVF creation for apheresis due to hyperlipoproteinemia. Moreover, 18% (27/150) had a previous failed AVF, of which nine required a TDC until maturation of the new RCAVF. Additionally, one patient had a previously failed arteriovenous graft.

3.2 | Physiological maturation

Physiological AVF maturation was achieved in 142/150 (95%) (Table 2). The remaining 8/150 (5%) failed before maturation and were abandoned. Seven of those were converted to another access (one proximal RCAVF with VasQ™, one BCAVF, two Gracz-type AVFs, and three percutaneous AVFs), and one patient died prior to planned AVG creation. Unassisted maturation was observed in 89% (133/150) of all cases, with 86% (129/150) achieving maturation 4 weeks after access creation (Table 2). From the remaining nine primarily nonmatured AVFs, eight patients achieved successful balloon-assisted maturation within 165 days, and one patient underwent successful surgical thrombectomy and patch angioplasty of the forearm cephalic vein due to occlusion at 22 days after creation.

The median intraoperative Qa measured in the brachial artery was 382 ml/min (IQR: 240–470 ml/min). At 24–48 h post creation, Qa in the brachial artery was measured as 784 ml/min (IQR: 550–1000 ml/min), reaching a median of 922 ml/min (IQR: 605–1100 min) at 4 weeks (Figure 1).

TABLE 2 Maturation, cannulation

Maturation (Qa > 500 ml/min, vein diameter ≥5 mm)	95%	142/150
Unassisted maturation	89%	133/150
Unassisted maturation within 4 weeks	86%	129/150
Successful cannulations in HD patients	90%	109/121[a]
Time to first successful cannulation for patients on active HD prior to AVF creation (median, IQR)	41 days IQR (29–60), $N = 74/87$	
Time from AVF creation to TDC removal (median, IQR)	105 days IQR (72–167), $N = 45$	

[a]29/150 patients not included since 28 did not yet transition to ESRD and 1 remains on peritoneal dialysis.

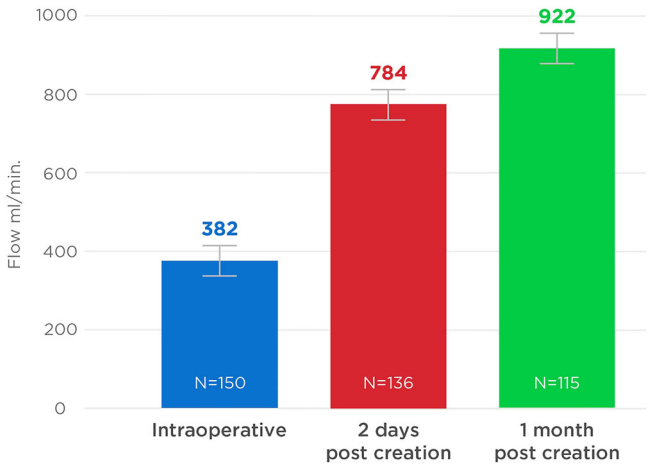

FIGURE 1 Intraoperative, 2 days postoperative, and 4 weeks postoperative volume flows [Color figure can be viewed at wileyonlinelibrary.com]

3.3 | AVF cannulation

Number of accesses reaching a dialysis status or starting apheresis at the end of the retrospective review window was 81.3% (122/150). One patient continued PD despite having a matured RCAVF (personal decision), leaving 121 cases with active dialysis access use. Two-needle cannulation was achieved in 90% (109/121) (Table 2). Of those remaining 121 patients, RCAVF failure occurred in eight (6.6%), leading to functional patency of 93.4%. Moreover, one patient with a failing yet functional contralateral AVF continued cannulations at the contralateral side at the time of the study endpoint.

The median time to first successful cannulation for 74/87 patients, who were on active HD prior to AVF creation, was 41 days (IQR: 29.0–60). Prematured veins due to previously failed ipsilateral access were present in 13 patients, and all were able to be cannulated

on Day 1 (11), Day 2 (1), and Day 4 (1) after new VasQ-RCAVF creation (Figure 2).

3.4 | Patency rates

At 6, 12, 18, 24, and 30 months, AP was 89%, 81%, 78%, 73%, and 73%, and SP was 94%, 87%, 86%, 84%, and 84%, respectively. The Kaplan–Meier plot presenting the dynamics of SP and AP is presented in Figure 3.

3.5 | Interventions

The majority of AVFs (94/150 [63%]) were free from interventions. A total of 56/150 (37%) patients underwent 102 interventions throughout the study period (Table 3). The number of interventions per patient-year was 0.55. Of those, 32 patients underwent one intervention, and 24 patients had two or more interventions. The mean time from AVF creation to intervention was 183 days (±23 days). Ninety-eight percent of all interventions were successful (100/102): The interventions that failed were initially successful with good outcome at the end of procedure, but AVF occluded shortly afterwards; thus, it was considered a failure. The main interventions were performed by using percutaneous transluminal balloon angioplasty (PTA) in 97% (99/102): either strictly endovascularly in 84% (86/102) or as hybrid procedure during open thrombectomy in 13% (13/102), including two cases of covered stent placement due to a perforation after PTA, and one bare-metal stent in the JAR, placed at an outside facility. If possible (distal radial artery patent with diameter ≥1.5 mm), a retrograde transradial approach for interventions was preferred (Table 3 and Figure 4), which resulted in high technical success and only one postprocedural asymptomatic distal radial artery occlusion.

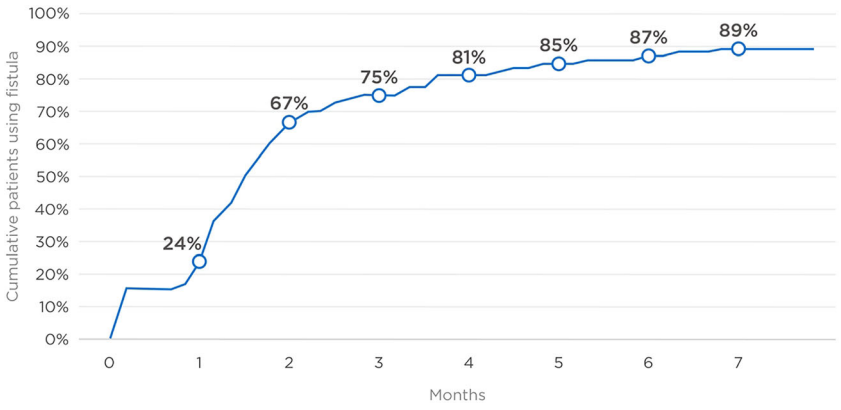

FIGURE 2 Time to successful first cannulation after access creation [Color figure can be viewed at wileyonlinelibrary.com]

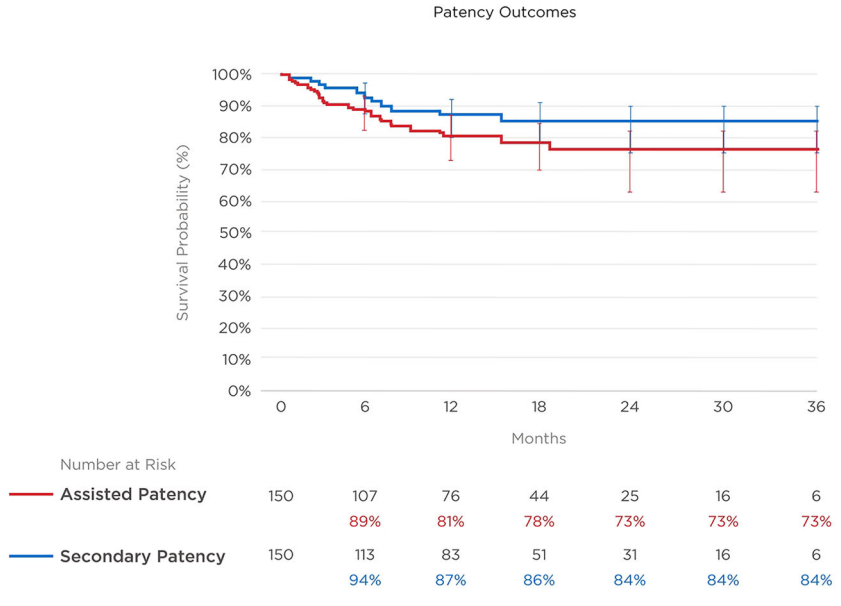

FIGURE 3 Kaplan–Meier analysis of primary assisted and secondary patency rates for up to 36 months [Color figure can be viewed at wileyonlinelibrary.com]

TABLE 3 Secondary intervention type and success rate

Intervention		Success rate (postintervention patency ≥48 h)
Number of patients free from interventions *n*/*N* (%)	94/150 (63%)	
Time to first intervention to maintain patency, mean ± standard error	183 days ± 23 days	
Interventions per patient-years	102/185 patient-years (0.55)	
Total number of interventions	102	100/102 (98%)
1 intervention/patient	32/150 (21%)	30/32 (94%)
2 or more interventions/patient	24/150 (16%)	24/24 (100%)
Percutaneous angioplasty *n*/*N* (%)	86/102 (84%)	84/86 (98%)
Stent graft	2/86 (2%)	2/2 (100%)
Bare-metal stent	1/86 (1%)	1/1 (100%)
Hybrid (open thrombectomy and balloon angioplasty) *n*/*N* (%)	13/102 (13%)	13/13 (100%)
Open thrombectomy and patch angioplasty	3/102 (3%)	3/3 (100%)

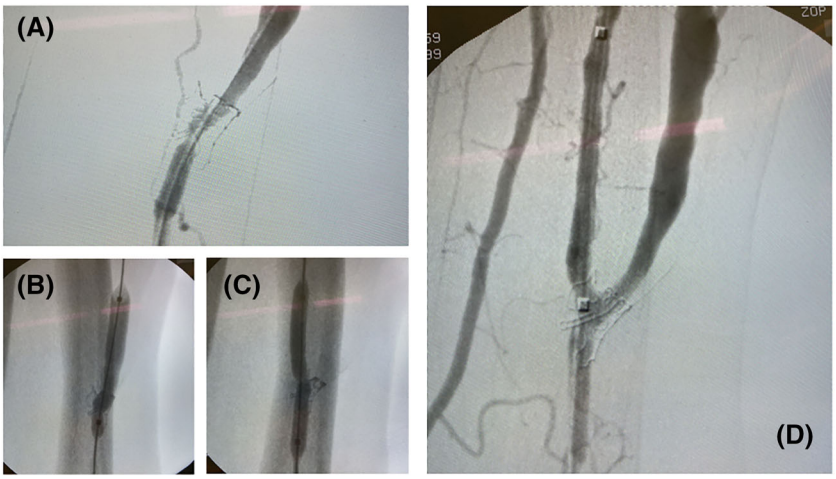

FIGURE 4 Secondary interventions: (A) retrograde transradial approach and angiogram with juxta-anastomotic stenosis, (B) percutaneous balloon angioplasty of juxta-anastomotic region, (C) inflow radial artery, and (D) completion angiogram [Color figure can be viewed at wileyonlinelibrary.com]

3.6 | Safety

The study achieved 100% technical success on device implantation as planned, and no device-related events were recorded (e.g., allergic reaction, infection, discomfort, or local pain). No patients developed symptomatic HD access-induced distal ischemia (HAIDI) or high-flow AVFs (Qa ≥ 2 L/min) during the study period.

4 | DISCUSSION

The routine use of the VasQ™ external support for forearm RCAVF creation resulted in high unassisted maturation rates with long-term durability of the access. It has resulted in a 95% success rate of physiologic AVF maturation, with 86% of unassisted maturation after 4 weeks and SP rates of forearm VasQ™ RCAVFs of 84% at 36 months. These outcomes compare very favorably to previously published studies reporting outcomes of forearm AVFs and are similar in SP to recent reports from dedicated centers but with lower rates of intervention to achieve maturation.[11,20–22]

The decision to use the VasQ™ for forearm RCAVF creation was initially made based on the 6-month randomized controlled trial data for BCAVFs, which was published prior to validation by our own initial comparative analysis.[13,15] Karydis et al. demonstrated that the use of the VasQ™ device for BCAVFs significantly improved the rate of two-needle cannulation with reduced rate of juxta-anastomotic stenosis.[13] Subsequently, a comparison of VasQ™ RCAVFs with historical controls suggested clinical benefit for use of the VasQ™ device also for RCAVFs.[15] A significantly reduced rate of primary failure and improvement of patency rates leading to a high rate of cannulation

was observed, which aligned with the expectations from the randomized controlled trial for upper arm accesses. The procedural impact of the device in terms of length of procedure is in our experience marginal, supported by a lack of statistically significant difference in mean skin-to-skin surgical time previously reported (data not shown). We have also observed that vascular footprint of the device in the JAR does not impact the available length of the cannulation zone and the presence of the device was not noticeable to the patient. Notably, no infection of the device was observed. The confirmation of clinical benefit during the first 6-months in our own hands and lack of disruption to our current process of care has led to the continuing of use of VasQ™ as our standard for forearm RCAVF creation.

The high rate of primary failure within the first 6 months has been the Achilles heel of AVFs, particularly forearm RCAVFs. Lok et al. demonstrated that primary failures within the first 6 months accounted for a reduction in the 18-month SP from 71% to 40% in 602 forearm AVF patients.[22] This is in stark contrast to the current study of VasQ™ forearm RCAVFs which reports a 6% early failure rate and 84% SP at 36 months using the device.

Historically, RCAVF outcomes for traditional creation surgery have been poor in major prospective studies over the years, which highlights the need for an improvement in creation methodology. The DAC study was one of the first major prospective studies to highlight not only the high failure rate of AVFs to be used for dialysis at 60% but also the increase risk of early thrombosis of forearm versus upper arm AVFs.[11] More recently published PATENCY-1 and PATENCY-2 studies demonstrated better yet still overall poor outcomes for RCAVF usability at 44% and 65%, respectively, as compared to the 90% of VasQ AVFs in this study used for dialysis in active HD patients.[23,24] Both PATENCY studies reported 43% of their AVFs used for dialysis required assistance of maturation procedures as opposed to the 14% from all VasQ AVFs in this study. Longer term outcomes have also been reported as relatively low for these large, prospective studies with 1-year SP of 61% and 76% for PATENCY-1 and PATENCY-2, respectively. Past 1 year, SP has been reported to be at 59.6% for RCAVFs at 18 months for a similar prospective study as PATENCY.[25] One criticism of comparing our results in Germany versus the results of these major US studies is the assumption that the differing demographics and practice patterns of the United States might have led to lower patency outcomes. However, a multinational meta-analysis has shown similar SP for the United States and Europe and has reported SP of 68% for forearm fistulas.[26] Another recent meta-analysis demonstrated that while the United States tends to perform more interventions, there is no difference in SP outcomes between the United States and other countries.[27] That study reported a SP of 71% for forearm AVFs at 1 year, again lower than 87% SP at 1 year in our study. The higher usability rates, particularly with assistance from maturation procedures, and long-term SP for VasQ™ RCAVFs compared to the consistently reported poor results for traditional RCAVF creation suggest that a shift towards the use of the external support device as standard of care could be warranted.

A concern with any use of an implanted device is the downstream effects of managing potential complications and failures. The location of the device around the vein prevents direct blood contact and reduces risk of (especially bloodstream) infection, compared to an intravascular device. To date, no increase in infection risk has been reported for VasQ™ in this or other studies.

Stenosis in VasQ™ AVFs has been a rare occurrence as reported previously, and intervention rates are generally low in those short-term studies.[13,15] Moreover, current study demonstrates that, if secondary interventions are necessary, 98% of the performed interventions were technically successful, indicating a high salvage rate of the AVFs. This shows that the presence of the device does not interfere with interventions, including PTA. One of the concerns with VasQ™ device is whether secondary interventions (especially percutaneous endovascular procedures) are compromised by the device. Our practice demonstrates that all patients requiring secondary interventions were able to undergo one. Typically, we recommend a retrograde transradial approach, which enables to easily access not only the juxta-anastomotic vein segment but also the radial artery, if an intervention is necessary (ultrasound guided and/or using fluoroscopy) (Figure 4). Usually, a 5-mm balloon is sufficient for a successful dilation of an "in-VasQ-stenosis," sometimes followed by 6-mm drug-coated balloon angioplasty (depending on the operator's preference). Using that technique, we were able to successfully treat 100% of patients. In rare cases, a surgical revision of JAR is necessary. Due to the soft struts of the device, it is easy to cut through the device for surgical patch angioplasty (one case). If a revision is either impossible, or deemed unsuccessful, proximalization of the AV anastomosis can still be performed with ease. In our cohort, two patients underwent successful (one early and one late) proximalization with a new VasQ device about 5 cm proximal to the initial AV anastomosis after failure of the first access. It is important to note that of the 19 abandoned (failed) RCAVFs, one patient lost the access during a COVID-19-associated sepsis with multiorgan failure, which was not revised, and another patient with bare-metal stent, placed at an outside facility along the JAR, could not be salvaged when the stent compressed and occluded the vein 10 days after placement. Moreover, four patients had a preoperative small radial artery and failed due to insufficient inflow of AVF.

Functional forearm AVFs provide dialysis access with reduced complications of steal and with overall lower access flows add less cardiovascular burden for ESRD patients. Since the fistula first initiative there has been a trend in the United States to AVF placement in the upper arm. This is apparent when comparing fistula distribution in forearm and upper arm between the DAC study and the HFM study.[11,21] The current study demonstrates a sustained decrease in primary failure rates of forearm RCAVFs confirming the benefit observed in a smaller earlier study. The single-center single-surgeon design of the study actually removes many covariants in the process of care that otherwise limit the strength of association between the device used and the outcomes that are observed. The low intervention rate needed to preserve primary patency is an additional advantage of using the VasQ™ device during forearm RCAVF creation: To avoid use of tunneled catheters for dialysis initiation given their

association with central venous stenosis and infection, there is a strong push to create AVFs in the pre-ESRD period. However, at the time of recommended eGFR for access creation, it is still not clear how many years a patient may actually have before reaching the need for HD. Especially, since accesses in the upper arm often require interventions of predefined segments prone to stenosis (cephalic arch, basilic swing point). The site of recurrent interventions for forearm RCAVFs is the juxta-anastomotic segment, but with the use of the VasQ™ device, the need for intervention is markedly reduced, making this a very favorable access to be created in the pre-ESRD period.

4.1 | Limitations

This study used a retrospective design and presented follow-up data limited to 3 years. To assure completeness of follow-up, direct contact with the dialysis units was established, and all clinical data were verified by study personnel. Despite earnest efforts, unrecorded event incidences cannot be excluded.

4.2 | Conclusions

Routine use of the VasQ™ external support device during forearm RCAVF creation is associated with low primary failure rate, high and early physiological maturation, and low rate of intervention to achieve physiological maturation and usability.

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None.

CONFLICT OF INTEREST

DMH is a consultant for Becton Dickinson/C.R. BARD, Bluegrass Vascular, Avenu Medical, Laminate Medical Inc., Medtronic, and Merit Medical. RS is a consultant for Avenu Medical, Becton Dickinson/C.R. BARD, and Medtronic and a speaker for Laminate Medical Inc.

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