

Clinical Compendium

A collection of VasQ-related presentations
and publications.

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Comparative Studies

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1. Karydis et al (2020)

An Implanted Blood Vessel Support Device for Arteriovenous Fistulas: A Randomized Controlled Trial

Objectives: Reducing turbulent blood flow through dialysis arteriovenous fistulas (AVFs) and radial stretching of their venous wall may attenuate hyperplasia and stenosis and improve AVF outcomes in hemodialysis patients. The goal of this study was to evaluate the safety and efficacy of the VasQ implant, which intervenes on these mechanisms by physically supporting the surgical arteriovenous anastomosis.

Methods: A prospective, randomized, controlled, multicenter study enrolled 40 consecutive patients with kidney failure referred for creation of a brachiocephalic fistula in 4 vascular access centers in the United Kingdom and Israel. AVF surgical creation with placement of the VasQ implant (treatment) versus AVF placement without the implant (control). Safety assessed as percentage of severe device-related adverse events was the primary outcome. Secondary outcomes were efficacy assessments including: (1) AVF maturation at 3 months, defined as cephalic vein diameter ≥ 5 mm and flow ≥ 500 mL/min; (2) functional cumulative patency, defined as successful 2-needle cannulation for two-thirds or more of all dialysis runs for 1 month in study participants receiving dialysis; (3) cephalic vein diameter and blood flow; and (4) primary and cumulative patency at 6 months.

Results: No severe device-related adverse events were observed. There was no significant difference in maturation at 3 months or primary patency at 6 months between treatment and control (85% vs 80% and 80% vs 66%). Significantly larger vein luminal diameters were observed in the treatment group versus controls at 3 and 6 months (8.27 $\pm$ 2.2 vs 6.69 $\pm$ 1.8 mm [P = 0.03] and 9.6 $\pm$ 2.5 vs 7.56 $\pm$ 2.7 mm [P = 0.03]). Functional patency at 6 months was significantly greater in the treatment group (100% vs 56% [P = 0.01]).

Conclusions: No safety signals were detected for the VasQ external support of brachiocephalic AVFs. Higher functional patency and vein luminal diameters were achieved with the device at 3 and 6 months. VasQ may safely intervene on mechanisms associated with the disturbed hemodynamic profile in the juxta-anastomotic region.

2. Shahverdyan et al (2021)

Patency and functionality of radiocephalic arteriovenous fistulas with an external support device (VasQ™): Real-world single-center experience

Objectives: The VasQ™ device was designed to improve the outcome of arteriovenous fistulae by optimizing the hemodynamics of the flow in the juxta-anastomotic region of the arteriovenous fistulae through tailored external support. The aim of the study was to evaluate the impact of the VasQ on outcome of radiocephalic arteriovenous fistulae in a real-world setting.

Methods: This was a single-center, retrospective analysis of patients with either fistula creation before or after dialysis initiation with implantation of the VasQ device during creation of end-to-side radiocephalic arteriovenous fistulae between June 2018 and May 2019. The flow rate and vein diameter were evaluated intraoperatively, at discharge within 48 h post-procedure and at a follow-up of 1, 3, 6, 9, and 12 months.

Results: Thirty-three VasQ devices were implanted during 33 radiocephalic arteriovenous fistula procedures. The study population comprised mostly of men, with an average age of 66 years. Mean intraoperative flow was 428 ml/min (range: 130-945). All patients were discharged with patent arteriovenous fistulae and mean fistula flow of 740 ml/min (range: 230-1300 ml/min). The primary patency was 100% and 79% at 3 and 6 months, respectively. Cumulative/secondary patency was 100% and 90% at 3 and 6 months, respectively.

Conclusions: Data presented here suggest that the VasQ device has the potential to provide benefit to the functionality of radiocephalic arteriovenous fistulae.

3. Benedetto et al (2022)

Initial single-center experience with a new external support device for the creation of the forearm native arteriovenous fistula for hemodialysis

Objectives: To assess and compare the maturation rate of the native radiocephalic arteriovenous fistula (RC-AVF) created with and without a nitinol external support (VasQ™ Laminate Medical Technologies Ltd, Tel Aviv, Israel).

Methods: Data of all consecutive patients who underwent the creation of native RC-AVFs at our center between October 2018 and January 2020 was prospectively collected and retrospectively analyzed. Selected patients who had a suitable vein and a radial artery with triphasic flow at preoperative duplex ultrasound exam and were selected for the creation of a radiocephalic fistula were included. Exclusion criteria were: malignant tumors, acute renal failure, previous upper limb revascularization, and septic status. Patency and maturation, vein, and artery diameter and blood flow rate were assessed at the following intervals: post-operatively, 24 h post-operatively, 1 month, 3 months, and 6 months post-operatively.

Results: Forty-nine patients (31 males, mean age 65.7 years old) were included. Patients who received VasQ™ devices were 25 (VasQ group), the other 24 formed the control group. All patients underwent radio-cephalic AVF placement (21 on the wrist, 20 on the forearm, 8 on the proximal forearm). There were no perioperative complications and fatalities. At 1, 3, and 6 months, primary patency rates were 96 +/- 4%, 96 +/- 4%, 91 +/- 6% (VasQ group) versus 87 +/- 7%, 87 +/- 7%, 80 +/- 9% (control group, P 0.17), secondary patency rates were 96 +/- 4%, 96 +/- 4%, 91 +/- 6% (VasQ group) versus 95 +/- 4%, 90 +/- 7%, 90 +/- 7% (control group, P 0.79). A significantly larger vein diameter increase postoperatively (P 0.009) and a greater maturation rate (96% vs 74%, p 0.044) were found in the VasQ group compared to the control group.

Conclusions: The use of the VasQ™ device was associated with higher maturation rates and larger vein diameters postoperatively. The patency rates were slightly higher but not significantly. Further studies are needed to confirm these findings.

4. Palumbo et al (2022)

Hemodynamic impact of VASQ device in vascular access creation

Objectives: Native arteriovenous fistula is the preferred vascular access in term of functionality, efficiency and complication rate. Nevertheless, research continues to seek strategies to reduce the risk of neointimal hyperplasia and hemodynamic modification. The aim of the study was to evaluate the impact on hemodynamic of the VasQ device in arteriovenous fistulae creation.

Methods: The analysis included patients who underwent to fistula creation with or without implantation of the VasQ device between May and September 2019. The hemodynamic parameters were evaluated pre-operatively and at a follow-up of 1, 3, 6 months. The patency and complication rate were evaluated.

Results: Fifteen VasQ devices were implanted during 30 arteriovenous fistula surgeries. The baseline patient features were similar between groups (VasQ treated/control). At baseline, preoperative arterial flow was similar; radial artery diameter at surgical site was 3.4 +/- 0.8 mm in treated and 2.8 +/- 0.5 mm in the control group. The mean arterial flow at 1 month was 480 +/- 210 mL/min in treated and 561 +/- 27 mL/min in the control group. At 3 months the mean arterial flow in treated was 645 +/- 143 mL/min versus 824 +/- 211 mL/min ($p = 0.02$) in the control group; at 6 months the arterial flow was 714 +/- 146 mL/min versus 810 +/- 194 mL/min ($p = 0.05$) in control group. The cardiac output flow at 6 months in the treated group was 4458 +/- 928 mL/min versus 5599 +/- 1355 mL/min ($p = 0.05$) in the control group. At 6 months the primary patency was 73% and 80% and the secondary patency 80% and 86% in treated compared to the control group, respectively. No VASQ device complications were recorded.

Conclusions: The analysis of these data suggested that using VasQ device could be protective against the hemodynamic modification that occur during arteriovenous fistulae creation.

5. Lucas et al (2025)

Comparative Effectiveness of Arteriovenous Fistulas Created with a Nitinol External Vascular Support in Patients with Advanced Kidney Disease

Objectives: Use of a nitinol external vascular support implanted during AVF (arteriovenous fistula) creation has been gaining traction due to its potential to improve functional success and reduce interventions; however, comparative effectiveness data with traditional unsupported AVFs are lacking. The objective of this study was to compare outcomes of AVFs created with a vascular support device versus traditional unsupported AVFs in patients with advanced kidney disease.

Methods: This was a comparative effectiveness retrospective observational cohort study conducted using data from the prospective, multi-center, single-arm VasQ US Pivotal trial (external vascular support AVF group) matched with an unsupported AVF control group developed using Medicare claims data from the same surgeons that participated in the trial. Eligible control participants were Medicare fee-for-service beneficiaries who underwent AVF creation (2017-2019). Endpoints included 6-month primary patency, intervention rate, and functional success. Propensity score methods using inverse probability treatment weighting were used to examine the association between supported device use and outcomes.

Results: A total of 782 unsupported AVF patients were compared to the 144 supported AVF patients from the Pivotal study. Compared with unsupported AVFs, primary patency at 180 days was superior for supported AVFs (66% vs. 36% for control; OR, 3.27; 95% CI, 2.15–5.17; $P < 0.0001$). Intervention rate for supported AVFs (0.97 per patient-year; 95% CI, 0.71-1.28) was nearly half of unsupported AVFs (1.91 per patient-year; 1.58-2.07) ($P < 0.0001$). Functional success for supported AVF patients was significantly greater than unsupported AVFs at 90 days (43.4% versus 26.7%, respectively; $P = 0.005$) and 180 days (72.5% versus 53.7%, respectively; $P = 0.004$).

Conclusions: AVFs created with external vascular support maintained higher primary patency, improved functional success, and had less reinterventions than unsupported AVFs. More patients may begin using their AVF for dialysis sooner with a lower risk of requiring a maturation procedure if created with external vascular support.

Extravascular Supported Arteriovenous Fistulas Reduces Need for Interventions to Support Maturation and Time to Achieve Two-Needle Cannulation for End-Stage Kidney Disease Patients in a Multicenter U.S. Study

Objectives: This study sought to assess the functional outcomes of arteriovenous fistulas (AVFs) created with VasQ, a permanent, surgically-implanted extravascular scaffold made of nitinol, and compare it with outcomes of unsupported AVFs in patients with end-stage kidney disease (ESKD).

Methods: The VasQ U.S. Pivotal Study was a prospective, single-arm, multicenter study that enrolled patients eligible for radiocephalic and brachiocephalic AVF creation from 2018 through 2019 to evaluate the safety and efficacy of creating AVFs with VasQ support. For this study, VasQ trial sites were invited to participate in a retrospective chart review for comparative analysis with patients who underwent creation of unsupported AVFs. Control patients were identified from a time period immediately prior to study initiation, utilizing the same inclusion/exclusion criteria as the Pivotal study. Patient follow-up records were prohibited from review prior to inclusion into the control cohort to minimize ascertainment bias. Outcomes evaluated included functional AVF success, time to first use, and rate of fistula abandonment and interventions to support maturation prior to first use. A multivariate analysis was performed to compare outcomes between VasQ supported and unsupported (control) AVFs.

Results: Six VasQ U.S. Pivotal Study sites participated, which provided 104 ESKD patients; 52 VasQ AVFs and 52 controls. Groups were well matched in baseline parameters, including vessel diameter and AVF location. VasQ AVFs experienced a significant reduction in median time to first use (56 vs. 85 days, $p = .04$). Additionally, significantly fewer interventions to support maturation were needed in VasQ AVFs (0.25 vs. 0.63 per patient, $p = .002$). More VasQ AVFs achieved functional success without the assistance of interventions to support maturation at 3 months (46% vs. 23%, $p = .013$) and 6 months (65% vs. 45%, $p = .03$). Multivariate analysis demonstrated that implantation of VasQ was significantly associated with greater odds for 3- and 6-month unassisted functional success after AVF creation (adjusted odds ratio, 2.95 [95%-CI: 1.23-7.43] $p = .018$, and adjusted odds ratio, 2.44 [95%-CI: 1.09-5.61] $p = .031$, respectively), and lower odds for needing reinterventions (adjusted odds ratio, 0.40 [95%-CI: 0.16-0.96] $p = .045$).

Conclusions: Creation of VasQ AVFs was associated with more unassisted functional success, an overall lower maturation procedure rate, and shorter time to first use when compared to well matched control AVFs created by the same surgeons. Improvement in these key functional outcomes should translate directly into clinically meaningful benefits for ESKD patients.

Long-term outcomes of radiocephalic arteriovenous fistulas created in anatomical snuffbox or with VasQ external support device

Objectives: This study evaluates the long-term outcomes of radiocephalic arteriovenous fistulas (RCAVFs) created in the anatomical snuffbox (SB-AVF) or with the VasQ external support device (ES-RCAVF).

Methods: We conducted a single-center retrospective analysis including 394 primary AVFs created for hemodialysis access in patients with advanced kidney disease between November 2017 and October 2024. Outcomes examined included rates of access maturation, successful cannulation, patency (primary, assisted primary, and secondary), reintervention rates, and rates of juxta-anastomotic stenosis. Multivariate analyses were used to study the associations between baseline characteristics and clinical outcomes, aiming to identify variables that could inform algorithmic decision making for optimal distal RCAVF configuration selection.

Results: The cohort consisted of 148 SB-AVFs and 246 ES-RCAVFs. ES-RCAVFs had significantly higher rates of 4-week maturation (81.9% vs 69.7%; $P = .009$), successful cannulation (82.6% vs 71.6%; $P = .044$), and tunneled dialysis catheter (TDC) removal (62.9% vs 56.9%; $P = .28$) at 6 months as compared with SB-AVFs. There was no significant difference in juxta-anastomotic stenosis rates (34% in the SB-group and 32% in the ES-group; $P = .734$) or 5-year patency rates between the two groups (26.1% vs 26.6% for primary [$P = .531$]; 51.2% vs 52.4% for assisted primary [$P = .778$]; and 56.5% vs 57.8% for secondary [$P = .1278$] patency rates) for the SB-AVF vs ES-RCAVFs, respectively. The number of interventions per patient year was 0.46 for SB-AVFs and 0.57 for ES-RCAVFs ($P = .998$). In the multivariate analysis, the VasQ significantly ($P = .001$) increased the probability of maturation, and female gender ($P = .007$) and diabetes ($P = .026$) significantly reduced that probability at 4 weeks. The VasQ also significantly increased the probability of overall maturation ($P = .002$). Female gender ($P = .003$) and older age ($P = .028$) negatively contributed to the probability of overall maturation. Moreover, VasQ significantly increased the probability of cannulation success ($P = .034$) and was the only significant factor for increased likelihood of TDC removal by 6 months ($P = .031$). Female gender ($P = .002$) and older age ($P = .006$) were associated with a significantly decreased likelihood of TDC removal.

Conclusions: Our findings indicated that, although ES-RCAVFs achieve superior short-term and long-term outcomes, SB-AVFs remain a valuable option for select patients, particularly younger and nondiabetic individuals, to preserve distal access sites for future use.

Long-term Outcomes & Interventions

8. **Dillavou et al (2023)**

VasQ US Pivotal Study with 24-month follow-up

9. **Shahverdyan & Hentschel (2023)**

150 consecutive VasQ RCF with 36-month follow-up

VasQ U.S. pivotal study demonstrates the safety and effectiveness of an external vascular support for arteriovenous fistula creation

Objectives: Arteriovenous fistula (AVF) creation is a commonly performed vascular operation that reports 6-month functional success rates as low as 50%. Recently, a nitinol external vascular support device, VasQ, has shown potential in studies outside the United States (U.S.) to improve AVF outcomes when implanted at creation. Here, the pivotal study results of this novel technology in treating patients in the U.S. are described.

Methods: VasQ was implanted in 144 patients at 16 centers across the U.S. who were referred for creation of a new AVF and consented for enrollment in a 2-year, prospective, multicenter, single-arm, open-label study. Brachiocephalic (n ¼ 129) and Radiocephalic (n ¼ 15) AVFs were analyzed. The primary endpoint was primary patency at 6 months compared against a performance goal of 55% derived from a systematic literature search. Safety endpoints included device-related events, ischemic steal, infection, aneurysm, and seroma at up to 6 months. Minimum arterial size was 2.0 mm; target veins were required to measure 2.5 to 6mm. Key exclusion criteria were patients <18 or >80 years, those with known ipsilateral central venous occlusion, target cannulation zone venous depth greater than 8 mm, and New York Heart Association class 3 or 4.

Results: Patients were 61% male, 53% White, 35% African American, and 14% Hispanic. Mean age was 60 years, and median body mass index was 30.4. Of the patients, 69% were diabetic, 66% were on dialysis at the time of creation, and 70% had a prior access surgery. At 6 months, steal was observed in 2.1%, infection in 0.7%, and no aneurysms or seromas were seen. Primary patency at 6 months was 66% (P < .021 vs performance goal). Physiological maturation was achieved in 92.4% of patients. Successful two-needle cannulation for patients that entered the study on dialysis was achieved in 88% of VasQ AVFs at a median of 56 days. Pre-dialysis patients who initiated dialysis during the study achieved two needle cannulation in 81.6% VasQ AVFs. Interventions were required at a rate of 1.07 per patient year over the entire study period. Two-year cumulative patency was 76.6% (95% confidence interval, 67.9%-83.4%) with no statistical difference between patients requiring interventions and those that did not. No patency differences were observed between brachiocephalic and radiocephalic AVFs.

Conclusions: The U.S. pivotal study results demonstrated improved AVF outcomes and an excellent safety profile with VasQ use relative to traditional AVFs. Under the conditions of this trial, VasQ shows great promise in expeditiously and efficiently enhancing AVF functional success.

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

Objectives: 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.

Mechanism of Action

10. **Hentschel & Berger (2018)**

Poster – Original hemodynamic model informing VasQ design

11. **Bozzetto et al (2024)**

MRI-based CFD randomized-controlled study VasQ RCF

12. **Franchin et al (2024)**

VasQ improved hemodynamics for steal revision vs banding

A Computation Fluid Dynamics (CFD) Approach to Optimize Arterial-Venous Autogenous Access (AVF) Anastomotic Hemodynamics with an External Support Device (VasQ™)

Objectives: Although arterial-venous autogenous accesses (AVFs) are the preferred form of vascular access, the high rates of maturation failure are a heavy burden on the end stage renal disease population. Lack of function AVFs results in inferior dialysis access alternatives associated with higher long-term morbidity and mortality. A leading cause of AVF maturation failure is inward remodeling due to neointimal hyperplasia (NH) in the juxta-anastomotic region (JAR). NH develops in this segment as a consequence of low and oscillating wall shear stress (WSS), flow separation, complex geometry and multidirectional flow pattern. Using a computation fluid dynamics (CFD) model we characterized the ideal configuration of an external support device to minimize geometric drivers of NH formation. These findings served as the basis for designing the VasQ™ device.

Methods: An end-to-side AVF CFD model (ANSYS) was designed through a range of vessel diameters (2.9-8mm) and flow rates (265-1200 ml/min). A 3D rigid AVF model with fully developed, steady, laminar ($Re=150-1500$) and Newtonian flow was assumed. 2D velocity streamline patterns were analyzed. Geometric parameters controllable by an external scaffold were optimized for minimizing the segment length of flow separation along the venous wall (A1) and maximizing the distance of the flow separation point from the anastomosis (P1). Parameters included anastomotic angle (20° - 60° range), vein inflow parameters: cone diameter ratio ($CDR=PV/DV$) (1.2-2 range) and conical segment length (CSL) (15-25mm range). P1 and A1 were analyzed to qualitatively compare different models and forecast their success.

Results: Results from the CFD model were used to design an external support device, the VasQ, to optimize the geometrical configuration in the JAR. The VasQ consists of two Nitinol components: (1) a laser cut Brace which wraps the artery at the JAR regulating anastomotic angulation, and (2) an external mesh Braid, which determines cone length and cone diameter ratio shape of the juxta-anastomotic vein. The device is expected to decrease flow separation in the JAR, change WSS ($\sigma=PR/t$) and wall tension to favorably stabilize the inflow segment and limit progressive NH.

Conclusions: In a CFD Model, parameters of AVF anastomosis including angle, cone diameter ratio and cone segment length can be manipulated to create laminar flow patterns with increased distance of flow separation from the anastomosis, as well as minimize segment length of the flow separation. The CFD Model predicts most favorable distance to the point of flow separation and segment length of flow separation with an AVF anastomotic angle of 40° , A cone diameter ratio of 1.5 and a cone segment length of 25mm. This favorable effect on laminar flow patterns is preserved in the setting of access flows from 450 to 1200 ml/min, which corresponds to real world flow volumes found in newly created and mature upper arm brachiocephalic autogenous accesses. A nitinol external scaffold, the VasQ device, was created based on the CFA Model parameters. Initial clinical studies suggest favorable effects on maturation.

11. Bozzetto et al (2024)

Arteriovenous fistula creation with VasQ™ device: A feasibility study to reveal hemodynamic implications

Objectives: Arteriovenous fistula (AVF) is the preferred vascular access (VA) for hemodialysis, but it is still affected by high non-maturation and early failure rates due to stenosis development. Increasing evidence suggests that the presence of turbulent-like flow may play a key role, therefore, to stabilize the flow in the venous segment, an external support device (VasQ™) has been designed. The aim of this study was to provide preliminary evidence of VasQ's impact on AVF hemodynamics as compared to AVFs created with conventional surgery.

Methods: In this pilot single-center prospective randomized study six patients were enrolled, three in the VasQ group and three in the control group. Contrast-free magnetic resonance imaging (MRI) scans were acquired at 3 days, 3 months and 1 year after AVF surgery and were used to generate 3D patient-specific models. Computational fluid dynamic (CFD) simulations were performed using pimpleFoam, imposing patient-specific flow waveforms derived from ultrasound (US) examinations at the inlet of the proximal and distal artery, and a traction-free condition at the venous outflow. Morphologic and hemodynamic changes occurring over time were compared between VasQ and control AVFs.

Results: Our MRI protocol provided high-quality images suitable for reliable segmentation and reconstruction of patient-specific 3D models of AVFs at all three timepoints in four out of six patients. The VasQ™ device maintained the angle between the artery and the vein almost unchanged over time, with a more stable flow in the AVFs supported by the device. In contrast, one of the AVFs of the control group evolved to an extreme dilatation of the vein and highly disturbed flow, while the other developed a stenosis in the juxta-anastomotic region.

Conclusions: This study demonstrated the feasibility of characterizing the morphological and hemodynamic changes occurring over time in AVFs created using the VasQ™ device and provided preliminary evidence of the potential hemodynamic benefits of its use.

Implanted blood vessel external support device for the treatment of distal hypoperfusion ischemic syndrome in arteriovenous fistulas and high-frame-rate Vector Flow quality assessment

Objectives: Distal hypoperfusion ischemic syndrome (DHIS) is a complication occurring after arteriovenous fistula (AVF) creation. Different surgical alternatives have been proposed in case of severe DHIS. Aim of the present paper is to present a new technique for DHIS treatment.

Methods: Between the 1st of January 2021 and the 31st December 2021 all the patients referred to our center for DHIS grade 2-4 were treated with a new surgical technique. It consists of AVF remodeling using an external nitinol support (VasQ) to reduce the risk of outflow vein enlargement and DHIS recurrence. To better appreciate the hemodynamic effects of the surgery, a new ultrasound technique called high-frame-rate Vector Flow (HiFR-VF) was used.

Results: Seven patients (M:F 1:3; mean age 43 +/- 12 years, range 29-65) were included in this study. Central line was never necessary, and technical success was 100% at 12 months. The comparison with historical data demonstrated lower recurrence of symptoms in comparison to simple artery-to-vein redo ($P = 0.50$). The HiFR-VF showed flow with limited turbulent characteristics at the anastomosis site.

Conclusions: The new technique proposed demonstrated to be safe and effective for treatment of DHIS, preventing symptoms recurrence. Ultrasound examination and HiFR-VF can be considered a valuable method to evaluate complex flows at the levels of vascular anastomosis.

Single-Arm Studies

13. **Chemla et al (2016)**

First in human VasQ study

14. **Leonardi et al (2021)**

Single-Center Italian Study

15. **Shahverdyan et al (2022)**

Multinational BCF+RCF Study

16. **Hauguel et al (2024)**

Single-center French Study - Trainee Data

13. Chemla et al (2016)

Arteriovenous Fistula Construction with the VasQ™ External Support Device: A Pilot Study

Objectives: Arteriovenous fistulas (AVF) are currently the gold standard for access, exhibiting the best combination of a low complication profile with a long patency period and attractive pricing. Despite a steady increase in the use of autogenous AVF in recent years, there is still a high rate of non-maturation of native fistulas. VasQ™ (Laminate Medical Technologies, Israel) is an external support device for AVFs designed to improve flow and reduce neointimal hyperplasia at the anastomotic site. Preliminary data are presented of its use, assessing its safety and efficacy for brachiocephalic AVFs in haemodialysis patients.

Methods: A single institution study of VasQ™ use was conducted with placement of the device in patients undergoing a brachiocephalic fistula, followed for 6 months. The VasQ™ was available in three sizes and was deployed externally over the fistula. Patients were assessed for flow, maturation and patency at 1, 3 and 6 months by Doppler ultrasonography.

Results: Twenty patients were implanted. Mean venous flow at 1, 3 and 6 months was 1130, 1426 and 1304 mL/min, respectively. Primary patency rates for these time periods were 95%, 79% and 79%, respectively, with unassisted maturation rates of 80%, 79% and 74%, respectively. There were no device-related serious adverse events. At the end of the follow-up period, 14/15 patients requiring dialysis were able to use the AVF.

Conclusions: VasQ™ is safe with high unassisted maturation and patency rates. The device may prevent perianastomotic stenosis, the leading cause of AVF failure.

14. Leonardi et al (2021)

Implanted blood vessel external support device (VasQ™) for creation of hemodialysis arteriovenous fistula: A single-center experience

Objectives: the external support device VasQ is intended to promote arteriovenous fistula (AVF) maturation by maintaining the optimal anastomotic angle in order to minimize blood flow disturbances around the anastomotic area. The aim of the study is to assess efficacy and safety of the VasQ device both in brachiocephalic and radiocephalic fistulae.

Methods: a single institution prospective study was conducted with implantation of the VasQ device during AVF creation. Clinical and Doppler ultrasound evaluations were performed at day-1, 1, 6, and 12 months for assessment of device-related adverse events, AVF maturation and patency. Moreover, volume flow rate and diameter of outflow vein were measured. A total of 16 patients were enrolled. Ten brachiocephalic and 6 radiocephalic AVFs were created with VasQ. Preoperatively cephalic vein diameter was 3.6 ± 0.9 mm.

Results: our population included 13 male and 3 females patients, 9 end stage kidney disease in conservative therapy, 4 dialysis treated patients, and 3 transplanted patients; mean age was 74.0 ± 8.1 years; no severe device-related adverse events were observed. Primary patency at 1, 6, and 12 months was 100%, 87.5%, and 67.7%, respectively, while secondary patency was 100%, 100%, and 78.3%, respectively. Comparing brachiocephalic to radiocephalic AVFs no significant differences in patency rates were seen. Overall maturation rate was 94% (15/16). Mean vein diameter measured with Doppler ultrasound at postoperative day-1 and at 1, 6, and 12 months was 5.0 ± 1.0 , 5.9 ± 0.9 , 7.2 ± 1.6 , and 7.9 ± 1.4 mm, respectively, with a mean flow rate at the brachial artery of 841 ± 176 , 1052 ± 224 , 1261 ± 490 , and 1348 ± 477 ml/min, respectively.

Conclusions: in our limited experience VasQ was safe, with high maturation and patency rates. Positive results suggest a potential benefit for VasQ in AVF.

15. Shahverdyan et al (2022)

Multicenter European real-world utilization of VasQ anastomotic external support device for arteriovenous fistulae

Objectives: To evaluate the outcomes of arteriovenous fistulae (AVF), created with VasQ external support device under standard clinical practice across three vascular access clinics.

Methods: This multinational, retrospective study evaluated prospectively collected clinical outcomes of both forearm and upper arm brachiocephalic AVF (BCAVF) created using the VasQ device. Fifty-one AVF patients were pooled from three different vascular access centers in Germany, Italy, and Spain. Post-procedure outcomes were assessed by flow measurement with ultrasound examination in all centers. Primary failure, usability, patency, and intervention rates during the study period were evaluated.

Results: Fifty-one VasQ devices were implanted during 37 forearm (36 radiocephalic and 1 ulnar-basilic AVF) and 14 BCAVF procedures. The study population comprised mostly males (73%) and Caucasians (82%), with a mean age of 62.5 years (range, 38-84 years) and mean body mass index of 29.2. One patient died owing to access-unrelated reasons, and one patient was lost to follow-up without AVF assessment after its creation. From the remaining 49, 3 patients had a follow-up of less than 4 weeks and were excluded from maturation, primary failure, and dialysis initiation analysis (because those factors could not be evaluated yet), leaving 46 patients in this evaluation. Maturation was achieved in 91% of patients. The primary failure rate was 9%. A primary patency rate of 77% was observed at 6, 12, and 18 months. The secondary patency rate was 91% at 6 months, and 85% at 12 months and 18 months. Both primary patency and secondary patency did not differ statistically when comparing forearm AVF with BCAVF ($P > .25$). Successful cannulation was achieved in 86% of patients (32/37) requiring dialysis with a median time from creation to cannulation of 46 days. Of those patients, the functional patency rate was 94%. Five patients underwent seven interventions to maintain or restore patency or functionality, with an overall rate of 0.248 interventions per patient-year.

Conclusions: AVFs created with VasQ external support device demonstrated promising patency and functionality outcomes in multicentric real-world setting across the two most commonly used anatomic locations.

Safety and efficacy of an innovative external support device for de novo arterio-venous fistula creation: a French bicentric experience

Objectives: The aim of this study was to evaluate the safety and efficacy of VasQ™, a permanent extravascular nitinol vascular support device, implanted around the anastomosis of de novo arteriovenous fistulas (AVF), in consecutive patients.

Methods: This was a French prospective bicentric study. All patients with an indication for creation of a distal or proximal end to side AVF performed by supervised trainee were eligible. Follow-up was performed clinically and by Duplex scan at 6 weeks and 6 months post fistula creation. Primary endpoint was functional maturation at 6 weeks defined as successful use for dialysis via 2-needle cannulation in dialysis patients or a flow rate of ≥ 600 mL/min and a target vein diameter ≥ 6 mm for pre-dialysis patients. Overall functional success for dialysis patients was assessed as well.

Results: Between March and November 2022, 21 patients received the VasQ™ device and were followed for an average of 165 days. Median age was 61. Eleven patients (52%) were on dialysis at the time of implantation. AVFs were created with distal radial (N.=8), proximal radial (N =5), brachial cephalic (N.=4) or brachial basilic (N =4) arteries with 100% technical success . Functional maturation at 6-weeks was achieved in 81% (17/21). Functional success was 80% (12/15) with unassisted functional success of 67% (10/15) at 6 months for patients requiring dialysis at that time point. Two reoperations were performed within the device, one thrombectomy and one angioplasty, both were successful. Freedom from access-related interventions occurred in 71% (15/21) of the study population at 6-months.

Conclusions: This study demonstrates that the VasQ™ AVFs achieved high rates of maturation at 6-weeks, without the need to modify standards of care. VasQ™ can successfully assist in achieving excellent results at the introduction of the device to a new center.

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VasQ is intended for use as an external support for upper extremity arteriovenous fistulas created for vascular access by means of vascular surgery. Prior to use, please reference the Instructions for Use for more information on indications, contraindications, warnings, precautions and adverse events available at <https://laminatemedical.com/eIFU>.

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