1. SPECIFIC AIMS

We are proposing a pilot, pragmatic, and multicenter randomized trial, comparing the effectiveness of one-stage to two-stage surgical approach for the creation of an upper arm brachial-basilic arteriovenous fistula (BBAVF). The target population are patients on renal replacement therapy who are receiving hemodialysis (HD) with central venous catheters (CVCs) at the time of the surgery and are candidates for a new BBAVF.

A BBAVF is a reliable autogenous hemodialysis access in patients without suitable cephalic vein.[1, 2] It can be created in either one or two stages.[3] The advantage of the one-stage approach is a shorter time between access creation and the cannulation for HD. The disadvantage is the potential for a longer upper arm incision if the AVF fails to mature. Although the two-stage approach can circumvent a more extensive procedure if the AVF fails, the need for two separate operations usually leads to more extended CVC dependency and a higher risk of CVC-related bacteremia (CRB).

While literature confirms good results for BBAVFs, comparative studies of one-stage and two-stage methods are limited.[1] They rest on small case series and few have reported relevant clinical outcomes, including functional patency, duration of CVC dependency, and postoperative complications. In addition, an insufficient number of studies have used intention-to-treat analysis to account for the risk of primary fistula failure. The majority of these studies have concentrated on the fistula-related outcomes rather than patient-centric and patient-reported outcomes (PROs), including the quality of life (QOL) measure.[3]

There is a clinical equipoise in the surgical approach for the creation of a BBAVF and it is unclear whether patients prefer a one-stage or two-stage procedure.[1] Currently, the decision to use one-stage or two-stage approach varies widely among access surgeons and is based on factors such as the size of basilic vein and surgeon’s bias or preference. A patient-centered approach, incorporating a balance between population-based evidence and individual patient perspectives might be preferred. This pilot study will allow us to understand patient-centered outcomes and QOL measures regarding the respective BBAVF techniques. We will use the valuable results to design a Patient-Centered Outcomes Research Institute (PCORI)-sponsored pragmatic clinical trial to determine the optimal surgical procedure for a BBAVF and to understand the perspective of patients receiving a complex AVF.

Specific Aim 1: Compare patient-centered clinical outcomes of one-stage and two-stage BBAVF procedures. To compare the primary and secondary endpoint event rates in patients receiving HD with CVCs randomized to undergo one-stage or two-stage BBAVF surgical procedure. We will recruit 60 patients undergoing the creation of a new BBAVF (30 patients in each group and a minimum of 10 patients per center) at six high-volume centers and followed up for at least 12 months. Patients who are randomized to two-stage BBAVF will undergo a second procedure within eight weeks after the first procedure.

Primary endpoint is Primary Clinical Functional Patency, defined as the successful use of the index fistula with two dialysis needles for at least 75% of dialysis sessions within a 4-week period to achieve the prescribed dialysis. The primary endpoint will be compared between two techniques during available follow-up up to 12-months (from the index procedure in the one-stage approach and the first procedure for the two-stage approach).

Secondary endpoints will include 1) Fistula-related outcome: stenosis and thrombosis, wound infection, arm swelling, hand ischemia, and surgery or intervention; 2) CVC-related outcome: duration of catheter-dependency, infection, bacteremia, and additional CVC procedure (exchange, placement of new catheter); and 3) Composite outcomes of Primary Clinical Functional Patency or CVC-related bacteremia or death.

Specific Aim 2: Compare patient-reported outcomes of one-stage and two-stage BBAVFs. We will compare the PROs using the Patient-Reported Outcome Measurement Information System (PROMIS) Computerized Adaptive Testing (CAT) in the 60 randomized patients. Patients will be asked to complete the PROMIS CAT at the baseline, 6 months, and 12 months following the BBAVF creation (index procedure in the one-stage approach and first procedure in the two-stage approach). The analysis will be performed after excluding those who do not complete the two-stage procedure (only the first procedure for the two-stage approach). We will compare the score difference from baseline and among the two procedures.

Hypothesis: Primary Clinical Functional Patency will be superior following two-stage approach compared with the one-stage BBAVF approach. Patients who underwent the two-stage procedure will have higher risks of infectious complications due to a more extended CVC dependency. The PROs will be affected by the number of procedures (one vs. two), postoperative fistula-related or CVC-related complications, and the duration of CVC dependency.
2. RESEARCH STRATEGY

2.1. SIGNIFICANCE

2.1.a. The brachial basilic arteriovenous fistula (BBAVF) is a reliable tertiary vascular access. An autogenous arteriovenous fistula (AVF) is superior to an arteriovenous graft (AVG) or a central venous catheter (CVC) in terms of survival, patency, infective complications, and quality of life (QOL).[4] An upper arm BBAVF is the third hemodialysis (HD) access choice after radial-cephalic AVF and brachial-cephalic AVF.[2, 5] It is usually a more complex procedure to perform due to the need to transpose or elevate the deep basilic vein.[1] The patency rate of BBAVF is comparable to a brachial-cephalic AVF.[1] Importantly, a BBAVF has superior long-term patency and lower infectious complication compared to an AVG.[1, 6] It generally requires less intervention and is more cost-effective than an AVG.[1, 6] As a result, the BBAVF plays a major role in patients who have exhausted primary and secondary autogenous HD access options.[2, 5]

2.1.b. A BBAVF can be created with a one-stage or two-stage approach.[1] For the one-stage procedure, an incision is made in the antecubital fossa to the axilla to expose and mobilize the basilic vein. The vein is then transposed and anastomosed to the brachial artery. In the two-stage technique, a first operation is used to create the arteriovenous anastomosis through a small incision. A longer incision is needed for the second procedure 6-8 weeks later to elevate or transpose the arterialized vein. When both approaches are complete, the length of the incision is comparable. The advantage of the one-stage method is the shorter time between the procedure and cannulation. It does not require a second procedure and, hence, can be more cost effective. The disadvantage is a potential for the long incision if the AVF fails to mature. On the other hand, with the two-stage approach, complications after the first procedure such as venous stenosis or steal can be addressed prior to the second procedure. Nonetheless, even though this approach can circumvent a more extensive procedure if the AVF fails, it still requires two separate operations. A known drawback of the two-stage method is the risk of CVC-related bacteremia, which is estimated to be 9% per month of CVC dependency.[7]

2.1.c. Need for well-designed prospective trial. Comparative evidence about the one-stage and two-stage approaches, both considered to be standard of creating a BBAVF, is limited. Two small randomized control trials comparing the one-stage and two-stage BBAVF procedures found that early patency and maturation rates were superior with the two-stage approach.[8, 9] There are a few retrospective series and a recent meta-analysis that demonstrate better patency and maturation for the two-stage method, but it is at the expense of the increased time before cannulation.[7, 8, 10-12] Others have however found no significant difference in maturation and patency rates between the two techniques.[13, 14] Our recent study suggests comparable 12-month fistula patency for the one-stage and two-stage approaches.[3] Two other meta-analyses that included more than 800 patients suggested no statistical difference in maturation and patency rates between the surgical approaches.[15, 16] Clearly, the specific comparative evidence regarding the different approaches is limited by small sample sizes and inconsistent quality.[1, 11, 15, 16] The majority of these studies concentrated on fistula-related outcomes rather than patient-centered outcomes, such as QOL measures and CVC-related complications. For these reasons, a surgeon’s preference or bias, rather than a reliable, standardized criterion, is the common basis for determining how to create a BBAVF. There is a need for a prospective randomized trial with intention-to-treat design to understand the optimal surgical technique for BBAVF.

2.1.d. A patient’s perspective should be considered in the creation of vascular access.[17, 18] Vascular access is an important determinant of QOL in patients on renal replacement therapy. Physical complications such as pain, swelling, or bleeding and infectious complications are major source of dissatisfaction.[19] Studies on vascular access decision-making have found significant differences in the way that patients and their physicians perceive the different types of access.[20] The essence of patient-centered care is a shared decision-making process between the patient and physicians, and it should take the patient’s perspectives and preferences seriously.[21, 22] This, in turn, requires an understanding of the patients’ preference and perspective when comparing different surgical techniques.[23] Patient-reported outcome (PRO) and QOL survey comparing various surgical techniques can help the surgeons better understand and incorporate the perspective of the patients in complex access procedures.[18, 24]

2.2. INNOVATION

The absence of reliable data to establish the optimal surgical approach for creating a new BBAVF has resulted in high degree of treatment equipoise and the decision to use one-stage or two-stage approach is largely based on surgeon’s preference. The pilot trial will provide a framework for an evidence-based surgical approach to create a BBAVF for patients receiving renal replacement therapy. The pragmatic trial design will
allow the inclusion of different surgical techniques currently used by the access surgeons to create a new BBAVF. Subjects in whom randomly assigned approach (one-stage or two-stage) is not completed will be considered appropriately treated as intended to account for the risk of primary fistula failure. We will use the patient-centric clinical endpoints and PROs to incorporate the perspective of patients undergoing complex vascular access surgery.

In ESRD, the most widely used QOL measure is the Kidney Disease Study Short Form Survey Instrument (SF-12 or SF-36).[25-27] However, the SF-12 and SF-36 can be difficult to administer because of the length and complexity. Currently, no QOL tool that had been developed or verified in vascular access.[27] The NIH-sponsored Patient-Reported Outcome Measurement Information System (PROMIS) tool has been designed to measure health-related QOL efficiently but has not been tested in vascular access. We will demonstrate the feasibility of the novel use of the PROMIS tool in measuring health-related QOL in the patients receiving complex vascular access procedures.

The proposed study is significant, as it focuses on the traditionally understudied complex AVFs (tertiary AVF is excluded in the Hemodialysis Fistula Maturation (HFM) study and the Dialysis Access Consortium (DAC) AV fistula Trial).[28, 29] The proposed study is innovative in that it uses PROs to better understand the perspective of patients. The proposed study is both necessary and timely and reflects the core of the ASDIN Research in Vascular Access in patient-oriented clinical research and the application of quality-of-life in comparative effectiveness research.

2.3. APPROACH

2.3.1. SA 1. Compare patient-centered clinical outcomes of one-stage and two-stage BBAVF procedures

2.3.1.a. Trial Design

This is a pilot, pragmatic, multicenter randomized clinical trial of the one-stage or two-stage surgical approach in the creation of a new BBAVF, in a target population of subjects with ESRD, and are candidates for both one-stage and two-stage surgical approaches. The trial design is depicted in Figure 1. Patients will be randomized in a 1:1 ratio to one-stage or two-stage BBAVF surgical approaches balanced by each site. We plan to enroll 60 patients (n=30 in each group) with ESRD receiving hemodialysis with a CVC from 6 centers with busy vascular access practice (Table 1), including 2 centers who had participated in the recently completed NIH-supported HFM study (Boston University and University of Utah). All 6 centers participate and report their vascular access result in the Society of Vascular Surgeon Vascular Quality Initiative (VQI).

The randomization scheme will be set up at University of Arizona (UA) and participating sites will access the scheme by telephone. Within each cohort, the subjects will be randomized in a 1:1 ratio to one-stage and two-stage surgical approaches. The randomization scheme is as follow: For each center, envelopes indicating either one-stage or two-stage approach will be placed in a container in the blocks of 10. Each block of 10 envelopes will contain 5 representing one-stage and 5 for two-stage approach.

There is no masking of treatment group in this trial. Participants will be considered appropriately treated as intended (intension-to-treat analysis) if the randomly-assigned procedure (one-stage or two-stage) is attempted but not completed. Trial crossover is defined as completion of one-stage procedure when randomized to two-stage procedure, or completion of two-stage procedure when randomized to one-stage procedure. Loss to follow-up is defined as permanent loss to follow up due to refusal to continue study follow-up, withdrawal of consent, or because of non-traceable geographic move.

One-stage and two-stage approaches will be performed according to established techniques and left to the discretion of individual access surgeon to reflect real-world practice. For the one-stage approach, the arteriovenous anastomosis and superficialization or transposition of the basilic vein is performed during the index procedure. In the two-stage technique, the arteriovenous anastomosis is created in the first procedure and a second procedure to elevate or transpose the matured AVF is performed within 6-8 weeks after the first procedure (unless it is delayed by complications). All participants will undergo vein mapping with or without tourniquet (standard practice for all the participating sites) and have a basilic vein size of ≥ 3 mm.

<table>
<thead>
<tr>
<th>Table 1. Participating Sites</th>
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<tr>
<td><strong>Site</strong></td>
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<tr>
<td>Boston University</td>
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<tr>
<td>Louisiana State University</td>
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<tr>
<td>Health Sciences Center</td>
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For each center, envelopes indicating either one-stage or two-stage approach will be placed in a container in the blocks of 10. Each block of 10 envelopes will contain 5 representing one-stage and 5 for two-stage approach.
2.3.1.b. Trial Objectives and Outcomes

**Primary Aim:** To compare the primary endpoint event rates in patients with ESRD and candidates for a new BBAVF randomized to have one-stage or two-stage BBAVF procedure.

**Primary Endpoint:** Primary Clinical Functional Patency, defined as the successful use of the index BBAVF with two needles for \( \geq 75\% \) of dialysis sessions over a continuous 4-week period without any endovascular or surgical procedure on the fistula (modified from the HFM study).[28] Time to first occurrence of a qualifying clinical event will be compared utilizing follow-up at 6-month and 12-month after fistula creation (minimum of 12-month/subject).

**Secondary Aims:** To compare the secondary endpoints (Fistula-related, CVC-related, and composite clinical outcomes) of subjects randomizing to one-stage or two-stage BBAVF procedure. CVC-related events will be calculated from the index procedure in the one-stage approach and the first procedure for the two-stage BBAVF approach.

**Secondary Endpoints:** 1) Fistula-related outcome: stenosis and thrombosis, infection, arm swelling, hand ischemia, surgery or intervention, and hospitalization; 2) CVC-related outcome: duration of dependency, infection, bacteremia, and additional CVC procedure (exchange, placement of new CVC); and 3) Composite outcomes of Primary Clinical Functional Patency or CVC-related bacteremia or death.

**Hypothesis:** Primary Clinical Functional Patency will be superior following two-stage compared to one-stage BBAVF procedure. CVC-related complications will be higher following two-stage compared to one-stage BBAVF procedure.

2.3.1.c. Trial Timeline

The proposed trial timeline encompassing 24 months and three phases: Preparation and Start up; Accrual and Follow-up; Analysis and Reporting (Table 2).

<table>
<thead>
<tr>
<th>Table 2. Trial Timeline</th>
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<tr>
<td><strong>Phase I:</strong> Start-up (Month 0-2)</td>
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<tr>
<td>Protocol finalization</td>
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<tr>
<td>Central or site IRB application</td>
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<tr>
<td>Investigator meeting</td>
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<td>Site initiation</td>
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</table>

2.3.1.d. Trial Population

We will recruit 60 subjects aged 18 years or older with ESRD who will undergo a BBAVF. Thirty subjects will be randomized in the one-stage approach and 30 subjects in the two-stage approach. The expectation for enrollment is 1 subject/month/site, and the recruitment period will be for 12 months. This is a realistic goal as each of the participating centers performed 30-40 brachial-basilic fistulas every year. The distribution of patients undergoing one-stage and two-stage procedures were approximately 60% and 40% for each of the participating centers. We will provide each participant with a certificate of appreciation.

2.3.1.e. Trial Eligibility

**Inclusion criteria** (all must be present for inclusion): 1. Age \( \geq 18 \) years; 2. ESRD receiving hemodialysis (CVC) in need for new hemodialysis access; 3. Candidate for one-stage and two-stage BVT procedure as judged by the enrolling investigator; 4. Greater than 3 mm diameter of upper arm basilic vein on venous duplex scan; 5. Life expectancy \( \geq 12 \) months; 6. Anticipated ability to comply with study procedures; and 7. Agrees and signs consent to participate in the study

**Exclusion criteria** (none of these can be met for inclusion): 1. Life expectancy < 12 months; 2. Brachial artery stenosis or occlusion; 3. A documented hypercoagulable state (defined as a known blood disorder associated with venous or arterial thrombosis); 4. Current immunosuppressive medication, chemotherapy or radiation therapy; 5. Pregnancy or lactation; and 6. Inability or refusal to provide informed consent

2.3.1.f. Data Collection and Follow-up

Data collection is summarized in Table 3.

<table>
<thead>
<tr>
<th>Table 3. Data Collection and Study Follow-up</th>
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<tr>
<td><strong>Baseline</strong></td>
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</table>

- Stanford University
- Stanford, CA
- Manuel Garcia-Toca
- mgarciat@stanford.edu
- University of Arizona
- Tucson, AZ
- Tze-Woei Tan
- ttan@surgery.arizona.edu
- University of Utah
- Salt Lake City, UT
- Benjamin S. Brooke
- benjamin.brooke@hsc.utah.edu
2.3.1.g. Outcome Measurement
Primary Clinical Functional Patency will be as defined in Primary Endpoint (2.3.1.b). Fistula-related outcome including stenosis and thrombosis, infection, arm swelling, hand ischemia, surgery or intervention, and hospitalization will be classified (local access and remote complications), graded, and reported as per the recommended standards.[2, 30] Fistula-related outcomes and the rates of percutaneous procedure and open surgery are routinely collected in the VQI. Catheter-related outcome includes duration of dependency (from index procedure in one-stage approach and first procedure in two-stage approach), catheter-related sepsis (growth of organisms on the catheter tip and blood), catheter-related infection (exit site and tunnel infection without bacteremia), catheter malfunction, exchange, or removal.[31]

2.3.1.h. Data Analysis and Statistical Power
The primary analysis of the primary endpoint will be a comparison of the primary clinical functional patency by treatment approach, where the distributions are based on available follow up to 12 months. A log-rank test will be used to evaluate the null. The secondary analytic method of the secondary endpoints will utilize a Cox regression model to adjust for the subject factors in order to adjust for baseline imbalance such as vein size. Based on a recent publication utilizing primary patency rate as the main outcome, the reported rates of primary functional patency of one-stage BBAVF was 56% at 12-month follow-up and was 72% for the two-stage procedure.[12] Based on a two-sided Fisher’s exact test at significance level of 5%, a sample size of 153 per group is required to achieve a power of 80% to detect the percentage patency difference of 16% (56% vs. 72%). A sample size of 336 participants (168 per arm), with an estimated loss to follow-up rate of 10%, will be required to achieve a 5% significance level.

With the restraint of the time and resources of this ASDIN research grant, the pilot trial will be exploratory (60 participants) and will be used to demonstrate the feasibility of the research plan in a high-risk ESRD population and the recruitment target. We will use the preliminary data to verify the sample size calculation. The data will be stored within the RedCap and managed by the UA research team. The access to the database will be limited to the research team.

2.3.2. SA 2. Compare patient-reported outcomes of one-stage and two-stage BBAVFs

2.3.2.a. Overview of Research
The goal is to prospectively evaluate the impact of the one-stage and two-stage BBAVF approaches on qualitative quality of life (QOL) in order to address the knowledge gap within the existing literature on complex AVF procedures. We will use the NIH-sponsored Patient-Reported Outcome Measurement Information System (PROMIS) Computerized Adaptive Testing (CAT) tool to evaluate self-reported measures for functions, symptoms, behaviors, and feelings following the BBAVF procedure (www.healthmeasures.net) (Figure 2).

2.3.2.b. Study Design
We will ask trial participants (30 one-stage and 30 two-stage BBAVFs) to complete the QOL survey at the baseline, 6 months, and 12 months after the BBAVF creation. Participants will complete PROMIS CAT surveys in four domains of QOL, including 1) global health (physical function, mental function), 2) physical health (fatigue, pain intensity, pain interference, physical function, sleep disturbance, pain behavior, pain quality), 3) mental health (anxiety, depression), and 4) social health (ability to participate in social roles and activities) (Figure). Each participant will complete the CAT tool over the phone with a research associate. The CAT contains 4-12 tailored items, and each item is completed in under a minute. The CAT is tailored to each respondent and continues to administer items until specific level of measurement precision is reached (e.g., <3.0 on a T-score metric) or a specific number of items are administered (generally 12 measures). A higher T-score equal more of the concept being measured. A score of 60 is one standard deviation above the average normal population and could be a desirable (positively-worded measure such as physical function) or an undesirable outcome (negatively-worded measure such as fatigue). The data will be stored in RedCap from PROMIS and restricted to the research team.

2.3.2.c. Statistical Analysis
The changes in the individuals’ PROMIS domain scores and overall scores from the baseline will be compared between the patients who underwent a one-stage procedure and those who had a two-stage procedure. The analysis will be performed after excluding those who do not complete the two-stage procedure (only first procedure for two-stage approach). The impact of clinical events including infection and catheter-related complication on PROMIS domain scores will be evaluated using the student T-test.

2.3.3 Potential Problems and Alternative Approaches
Based on the VQI database, each center performs 30 to 40 BBAVFs annually, and approximately 60% of these are done via the two-stage method. In the event of low participant numbers or a higher numbers of attrition rate (>10% over 12 months), we will recruit participants from the Arizona Kidney Disease & Hypertension Centers (Dr. Ziggy Yang) and the Southwest Kidney Institute (Dr. Gabriel El-Kass), both based in Tucson, AZ and perform at least 20 BBAVFs annually. Drs. El-Kass and Yang have agreed to participate in the pilot trial if needed and our future BBAVF trial. Additionally, we will extend our recruitment period for an additional 6 months (to 18 months). The research team at the UA has extensive experience recruiting patients to participate in hemodialysis access-related clinical trials, which will facilitate enrollment.

2.3.4. Anticipated Results
We anticipate the two-stage BBAVFs have higher functional primary patency rates with significantly higher rates of CVC-related bacteremia and hospitalization. The PROMS-measured health-related QOL will be similar at baseline, more significant for positively-worded outcomes including physical function and ability to participate in social roles and activities after the one-stage procedure, but higher for negatively-worded outcomes such as fatigue and sleep disturbance after the two-stage BBAVF procedure. Surgical and catheter-related complications will negatively impact health-related QOL.

2.4. REFERENCES
RESOURCES AND FACILITIES

Banner University Medical Center (BUMC). BUMC Tucson and BUMC South are the main UA affiliated academic medical centers in Tucson, Arizona. Located on the UAHS campus in Tucson, BUMC Tucson is a 487-bed acute care hospital and Southern Arizona’s only Level 1 Trauma center. BUMC South is a 245-bed licensed bed hospital and is the main safety net hospitals for Southern Arizona. BUMC North is a 200,000 square feet multispecialty health center housing outpatient specialty clinics, imaging, lab, and pharmacy. The vascular surgery clinic at BUMC South and North see 20-30 patients for creation of a new HD access or the maintenance of pre-existing arteriovenous fistulas or arteriovenous grafts per month. The group performs 40 to 50 brachial basilic AVF every year and 50-60% are two-stage procedure. We are planning to recruit patients from the BUMC clinics and inpatient service.

Division of Vascular Surgery, University of Arizona (UA). The UA is the primary referral center for complex HD access in suburban and rural Arizona. Our clinical and research team has a long-standing relationship with the nephrology communities and a track record of accomplishment in recruiting patients to participate in clinical trials. As the primary research coordinator of the UA team, Marcy Watchman has been involved in recruitment, data collection, and data entry for clinical trials for more than 20 years. She is bi-lingual and is fluent in English and Spanish. Diane Bock is the full-time research coordinator at the UA team is familiar with various data storage software, including Microsoft Access and RedCap. Both research coordinators will be helping with the planned Aim 1a and 1b. The research funding will be used to support a research coordinator (part-time) for the qualitative aim 2.

Principal Investigator. The UA offices are connected to the secure campus network via Local Area Networks (LANs). These physical servers are backed up regularly and stored off-site for security. The UAWIFI is a secure wireless network covering more than seven million square feet. The University Information Technology Services (UITS) is available 24 hours to provide support to campus system and applications. They are also provide onsite support for computers and devices and has certified repair technicians on staff. The PI has an online secure online cloud storage (50 GB of storage) and collaboration tool (Box @UA) that is provided free to all current faculty, as well as full access to the secure RedCap database. The PI has access to several large conference rooms in the Department of Surgery and nearby College of Medicine which are fully equipped with modern audio-visual aids to conduct meetings, teleconferences, and presentations.

Collaborators. We will plan to recruit participants from the Boston Medical Center (BMC), the Pima Vascular Institute (Pima), the Louisiana State University Health Sciences Center (LSUHSC), the Stanford University, the University of Arizona (UA), and the University of Utah (UU). All six centers are tertiary referral centers for complex HD access in the respective region. We are participating in the Society of Vascular Surgery Vascular Quality Initiative (VQI) and routinely report the outcomes of HD access to the VQI registry. The pre-existing structure will facilitate the data collection for the Specific Aims. The collaborators, including Drs. Jeffrey Siracuse (BMC), Scott Berman (Pima), Chiranjiv Virk (LSUHSC), Manuel Garcia-Toca (Stanford), and Benjamin Brooke (UU) are faculty at the respective centers. As per the VQI, each center performs approximately 30 to 40 brachial basilic arteriovenous fistula (BBAVF) every year, and about 60% is the two-stage procedure. The research group has a track record of collaborating in clinical research projects which will facilitate the successful execution of the planned specific aims.

Budget

<table>
<thead>
<tr>
<th>Description</th>
<th>Cost</th>
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<tbody>
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<td>TBN, Research Associate</td>
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</tr>
<tr>
<td>IRB application</td>
<td>$ 5,000 ($1000 per center x 5 centers)</td>
</tr>
<tr>
<td>Statistical support</td>
<td>$ 1,000 ($120 per hour x 8 hours as per university-approved rate)</td>
</tr>
<tr>
<td>Total</td>
<td>$25,000</td>
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