Impact of Location and Geometry on Patency and Reintervention of Upper Extremity Arteriovenous Hemodialysis Grafts

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(Article begins on next page)
8mm non-tapered (NT) or 4-7 mm tapered (T) were placed during this period. U-grafts had greater cumulative patency as compared to F-grafts [Hazard Ratio (HR): 0.55, p=0.01]. Nontapered grafts had less cumulative patency compared to tapered grafts [HR: 1.827, p=0.055]. When we divided grafts into four subgroups (U-NT, U-T, F-NT, and F-T) there were significant differences in cumulative patency between groups [p=0.031]: F-NT had the lowest patency [990.1±151.3 days]. In addition, we discovered that F-T grafts had the highest rate of reinterventions within a year for pseudoaneurysms.

Conclusions: Location and geometry are important factors in determining cumulative patency and reinterventions of AVG. When planning to place an AVG, this information should be strongly considered.
**Table of Contents:**

Title Page and Abstract  1-2  
Table of Contents  3  
Glossary of Abbreviations  4  
Authors and Respective Contributions  5  
Section 1: Introduction  5-7  
Section 2: Materials and Methods  7-9  
Section 3: Results  9-12  
Section 4: Discussion & Conclusions  12-16  
References  17-19  
Table 1  20-21  
Table 2  22  
Figure 1  23
**Glossary of abbreviations:**

- Analysis of variance (ANOVA)
- Arteriovenous fistula (AVF)
- Arteriovenous grafts (AVG)
- Central venous catheters (CVC)
- Chronic kidney disease (CKD)
- Confidence intervals (CI)
- Coronary artery disease (CAD)
- End stage renal disease (ESRD)
- Forearm (F)
- Hemodialysis (HD)
- Hemodialysis Reliable Outflow (HeRO)
- IBM Statistical Package for Social Sciences (SPSS)
- Non-tapered (NT)
- Polytetrafluoroethylene (PTFE)
- Tapered (T)
- The National Kidney Foundation’s Dialysis Outcome Quality Initiative (NKF-KDOQI)
- Upper arm (U)
- Upper Arm Salvage AVF (SAVF)
Authors and respective contributions:
Michael Losak: Contributor to project conception/idea; all data collection and analysis; table and figure creation; bulk of writing; first author of first through final drafts
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Ioannis Konstantinidis: minor revisions, assistant to Girish
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Harry Schanzer: Suggestions on standards of practice and data presentation; minor revisions
Victoria Teodorescu: Contributor to project conception/idea; mentor throughout data collection; project oversight and guidance; substantive revisions

All writing and data analysis in this document was accomplished through collaboration among Michael Losak, Girish Nadkarni, and Victoria Teodorescu

Section 1: Introduction
End stage renal disease (ESRD) requiring hemodialysis is one of the largest problems facing our healthcare system today. As of 2011, there were 615,899 ESRD patients in America of which only 30% had a functioning renal transplant. Of the remainder, nearly 400,000 patients were on hemodialysis (HD) [2]. Hemodialysis patients are especially vulnerable due to an increased incidence of both cardiovascular and all-cause mortality [2]. But, appropriately delivered hemodialysis has been shown to reduce mortality: longer duration sessions are linked to lower mortality [3]. Thus, the delivery of optimal hemodialysis treatments is of crucial importance. Since vascular
access is a prime determinant of adequate, successful, and reproducible treatments, understanding the factors affecting access is imperative [4].

The National Kidney Foundation’s Dialysis Outcome Quality Initiative (NKF-KDOQI) clinical practice guidelines support the choice of arteriovenous fistula (AVF) as the optimal access for chronic HD [5]. The reasons for this recommendation are the reported lower thrombosis and infection rates, decreased all-cause mortality, reduced need for re-interventions to maintain patency, greater cumulative patency, and decreased cost of AVF when compared to arteriovenous grafts (AVG) and central venous catheters (CVC) [6-11]. This in turn has led to the “Fistula First” initiative as the general recommendation for all HD patients [12,13].

The benefits proposed by “Fistula First” have been questioned by many experts because AVF do not always mature. Immature fistulas necessitate the use of bridging CVC with its attendant complications; initiating dialysis with a CVC is associated with delays in establishing a permanent vascular access and risk of patient refusal [14]. Additionally, there is concern that patients with shorter life expectancy may not survive long enough to benefit from having a fistula [15]. This is an especially important consideration in older patients, who are already at increased risk for failed fistula maturation [16,17].

As the incident HD population is aging, the issue of vascular access in these patients is one of growing concern. In one study, 43% of elderly patients who had an AVF placed as their first predialysis access initiated dialysis with a CVC compared with 25% of patients who had an AVG placed as their first access [18]. In addition, recent studies have demonstrated that there is no mortality difference in elderly hemodialysis patients initiating HD with AVG vs. AVF [19]. These data suggest that the approach to placement of a vascular access for incident HD patients should be individualized in older adults [20,21] with choice of initial access a shared decision between the patient, the nephrologist, and the vascular surgeon.

Thus, a better understanding of factors affecting AVG patency amongst the dialysis care community is required to guide decision-making. Past studies on AVG often focus on the effects of tapering and differ in their conclusions as to whether tapering is or is not an important factor in graft performance [22-24]. Additionally,
heparin bonding has been studied and shown to have little effect on graft cumulative patency [25]. However, there are limited data on relative impact of patient and graft factors on cumulative AVG patency and reintervention rates.

We sought to compare AVG characteristics, identify factors that contribute to primary and cumulative graft patency, investigate relative rates of re-interventions between different AVG types that remained patent for at least a year, and examine the frequency of conversion to secondary upper arm AVF following access failure in a large tertiary care center.

Section 2: Material and Methods

2.1 Data Collection and Cohort:

The Institutional Review Board at The Mount Sinai Medical Center, New York approved this study. We obtained retrospective information from the medical record and operative report for all patients receiving an upper extremity polytetrafluoroethylene (PTFE) graft between March 31st, 2007 and January 1st, 2012. We included patients that received an AVG based on the axillary or brachial arteries. No ulnar artery inflow grafts were placed during the study period. We excluded two patients who had an AVG that utilized the subclavian vein as the outflow tract, four patients who had accesses that were based on the radial artery and all patients who had received Hemodialysis Reliable Outflow (HeRO) grafts based on the brachial artery. We extracted demographic information and comorbidities including hypertension, diabetes mellitus, and coronary artery disease (CAD) by physician review from patient charts.

The procedures were performed by a total of twelve board-certified vascular surgeons. Diameter, configuration (looped versus straight), manufacturer, and geometry (tapered versus non-tapered) information on the graft as well as the arterial and venous connections were available for every procedure. Choice of graft diameter, material, and location was determined by surgeon preference at the time of the procedure. Forearm accesses based on the brachial artery and connected to the antecubital, cephalic, brachial, or basilic vein and upper-arm accesses based on the axillary artery and connected to the axillary vein were considered looped. Brachial
artery to axillary vein accesses were classified as straight. The National Security Death Index was used to query death dates for deceased patients.

2.2 Outcome Measurements and definitions:

The primary outcome measures of this study included primary patency, cumulative patency, re-intervention rates, and proximal AVF (outflow AVG vein) created secondary to forearm graft failure. Primary patency is the number of days between the initial operation and time to first intervention or failure and cumulative patency the time between the initial operation and permanent failure, the point beyond which the graft was no longer used. We considered grafts to have permanently failed when they were excised, when there was an irreversible graft occlusion, or when there was placement of a new HD access site, including catheter exchanges with no subsequent attempts to salvage the graft. We monitored patency until July 27th, 2012 (the last day of data collection). Re-interventions included pseudoaneurysm repairs, thrombectomies, surgical revisions, stentings, and angioplasties.

2.3 Statistical Analyses:

Location, geometry, configuration, manufacturer, sex, and diabetes were considered categorical variables and age was considered a continuous variable. Cox proportional hazard modeling was used to determine if any of these variables was independently associated with primary or cumulative patency of the grafts. Backward conditional stepwise selection ($P_{in}=0.05$, $P_{out}=0.10$) was used for model selection in both analyses. Hazard ratios and 95% confidence intervals (CI) were then calculated. Kaplan-Meier analysis was used to estimate the survival functions of the four graft subgroups. The Breslow test was used to compare differences between these subgroups. For comparison of characteristics between subgroups, we employed the chi-square test for categorical and analysis of variance (ANOVA) for continuous variables. Hypertension, coronary artery disease, and patients lost to follow up were considered categorical in this analysis. We also used ANOVA to compare differences between subgroups in the number of re-interventions performed in the first year of use for grafts that remained patent for at least one year. Post-hoc Tukey HSD analysis was
used to determine which graft subgroups differed for a given re-intervention when ANOVA testing was statistically significant. A two-tailed p-value of <0.05 was considered statistically significant. We used IBM Statistical Package for Social Sciences (SPSS) Statistics Desktop (version 21.0.0, Armonk, NY) for statistical analysis.

**Section 3: Results**

3.1 *Patient Population:*

During the study duration, two hundred seventy-one procedures were performed on 257 unique patients. Table I details the characteristics of these procedures both by total cohort and broken out by subgroup. Of the 271 graft accesses assessed in this study, at the time of initial surgery the mean age was 62.8 years; 112 of the procedures (41%) were performed on males; 144 (53%) on known diabetics; 199 (73%) on known hypertensives; 69 (25%) on patients with known CAD; 211 of the accesses (78%) were created in the upper arm; tapered grafts were used in 50 of the 271 procedures (18%); 72 of the grafts (27%) were placed in a looped configuration; 20 grafts (7%) were lost to institutional follow-up; and, 86 grafts (32%), with no significant differences between subgroups, were placed in patients with known previous access in the ipsilateral arm (graft or fistula).

3.2 *Subgroup Populations:*

Table I details the characteristics of the four subgroups [upper arm non-tapered (U-NT); upper arm tapered (U-T); forearm non-tapered (F-NT), and forearm tapered (F-T)]. There were no significant differences between subgroups with respect to the average age of the patients, diabetic, hypertensive or CAD status of the patients, or grafts lost to institutional follow-up. However, there was a significant difference between subgroups relative to the sex distribution of patients. F-NT grafts had a significantly higher proportion of male patients than U-NT, U-T, and F-T (p=0.0035, 0.0010, & 0.011, respectively).

3.3 *Primary and Cumulative Patency:*
We considered seven variables for their impact on primary and cumulative patency: patient’s age, sex, and diabetic status at time of initial operation as well as location in the upper or fore- arm, tapering (geometry), manufacturer, and configuration. Backward stepwise conditional selection indicated that none of the considered variables was significantly associated with primary patency of the HD access. When we evaluated these variables for their association with cumulative patency, backward stepwise conditional selection with the same inclusion and exclusion criteria yielded a model with three parameters: sex, location and diameter. Of these, only location had a significant association with cumulative patency. Upper arm grafts had longer cumulative patency than forearm grafts (1,324.6±63.9 days vs. 1,152.8±121.1 days, respectively) [HR: 0.55; 95% CI: 0.34 to 0.89, p=0.015]. The use of tapered grafts trended towards significance in its correlation with cumulative patency. Non-tapered grafts had fewer cumulative days of patency than tapered grafts (1,257.5±63.7 days vs. 1,430.4±122.5 days, respectively) [HR; 1.83, 95% CI: 0.99 to 3.38, p=0.055]. Male sex was associated with greater cumulative graft patency; however, the correlation was not significant [HR: 0.69; 95% CI: 0.45 to 1.07, p=0.09]. Thus, sex was excluded from future analyses of graft survival. Location and geometry were used to divide grafts into four subgroups [U-NT, U-T, F-NT, and F-T].

3.4 Subgroup Survival Analysis:

Of the 271 total procedures, U-NT represented 183 (68%), U-T 28 (10%), F-NT 38 (14%), and F-T 22 (8%). The mean duration of primary patency, mean survival times, and mean number of pseudoaneurysm repairs within the first year are presented by subgroup in Table II. There were no significant differences in primary patency between subgroups. The mean survival time for U-NT was 1,305.7 days, for U-T 1,412.4 days, for F-NT 990.2 days, and for F-T 1,428.1 days. Figure 1 shows cumulative patency by Kaplan-Meier survival analysis for the four subgroups of grafts: U-NT, U-T, F-NT, and F-T. Cumulative patency differed significantly between these subgroups (p=0.03). However, F-NT diverged from the other subgroups almost immediately and had the most precipitous loss of cumulative patency among the subgroups over the first year following access placement. The other three subgroups
(U-NT, U-T, and F-T) had similar rates of decline in the first year following the initial operation. Whereas survival in the U-T and F-T subgroups plateaued after approximately 500 days, a slow but steady failure of U-NT grafts continued beyond this time point. Over the study period, 92 of the total 271 grafts (34%) permanently failed. A significantly higher proportion of grafts in the F-NT group failed as compared to the two upper arm subgroups: U-NT & U-T (p=0.017 & p=0.024, respectively). There was no significant difference in prevalence of permanent graft failures between the two forearm groups.

3.5 Reintervention Differences:

We then considered differences in reintervention rates by subgroups in all grafts that remained patent for at least a year (n=158). This included 113 U-NT, 16 U-T, 17 F-NT, and 12 F-T grafts. We excluded grafts that permanently failed within the first year of use, those that had been placed less than a year from the end of data collection, and those whose recipient expired within a year of placement.

There were no significant differences between subgroups in the prevalence of thrombectomies, surgical revisions, stentings, or angioplasties over a one-year period. However, there were significant differences between subgroups in the prevalence of pseudoaneurysm repairs in the first year of use (p=0.03). U-T and F-NT grafts had no pseudoaneurysm repairs performed. However, the mean number of pseudoaneurysm repairs per U-NT vs F-T grafts were significantly different 0.03 (SEM: 0.015) vs. 0.17 (SEM: 0.11) (p=0.041), respectively.

3.6 Upper Arm Salvage AVF (SAVF) Placement:

Of the total 60 forearm grafts followed in this study, 26 grafts were known to have permanently failed on or before the last day of data collection. The other 34 grafts were either still in use at the time of the patients’ death or on the last day of data collection. Of the 26 failed grafts, 8 were followed by tunneled central venous catheter placement, 7 by brachial artery-axillary vein PTFE grafts, 3 by brachial artery-basilic vein PTFE grafts, and one each by brachial artery-brachial vein PTFE graft, HeRO graft, radiocephalic fistula, brachiobasilic fistula, and brachiocephalic fistula; three patients
lacked information about subsequent access history in their charts following forearm graft failure.

Further investigation of these patients’ medical records was undertaken to clarify the management of these failed forearm grafts. Only two forearm grafts (8%) were converted to upper arm SAVF after permanent forearm graft failure, and review of these patients’ charts indicated that both of these fistulas were placed on the contralateral side from the original forearm graft access. Thus, in none of the patients was a mature outflow vein from a forearm graft used to create an ipsilateral SAVF. Vein mapping was recorded for 24 of these 26 patients (92%). At the time of subsequent surgery, placement of an ipsilateral SAVF was deemed not feasible by vein mapping for these patients because there was central venous stenosis or because the outflow veins were either too small to be used, thrombosed, or not visualized.

Section 4: Discussion & Conclusions

In 2010, Medicare spent $41 billion caring for patients with chronic kidney disease (CKD), nearly three quarters of which was spent on patients with end-stage renal disease (ESRD) [2]. Given that access issues comprise a sizable part of this large expenditure, robust data regarding factors affecting patency and intervention rates are needed. AVG have been increasingly used as the primary access of choice in the aging HD population [19]. Though currently the strongest data are for patients >80 years of age, patients >60 years of age may still benefit from an AVG over an AVF, especially if complicated by certain comorbid conditions [26]. The reasons for this include delayed maturation of AVF in the elderly, increased conversion to catheters for initiating HD, and the competing risk of death which may negate the long-term benefits of AVF over AVG [19]. There are limited studies on what factors influence patency and reintervention rates in grafts and data is needed to inform the discussion about both placement and surveillance of AVG [4].

Currently, many treatment decisions concerning what type of graft to use or where to place an AVG are based on clinical opinion alone; NKF-KDOQI guidelines suggest placement of a forearm AVG before placement of an upper arm AVG, partly due to the traditional wisdom of protecting more proximal access sites for later use.
Nevertheless, data from this study show that location is a significant determinant of cumulative patency for AVG with upper arm AVG having greater cumulative patency than those in the forearm.

When looking at location of the grafts, upper arm AVG outlasted forearm grafts on average by only 172 days. When the grafts were considered in four subgroups based on location and geometry, the best performing subgroups (U-T & F-T) outlasted the subgroup with the lowest cumulative patency (F-NT) on average by more than 400 days. While this survival difference could seem relatively inconsequential, it may represent a substantial fraction of the total time spent on HD considering both the average time spent on HD and life expectancy of these patients.

Another reason commonly cited for utilizing more distal sites prior to more proximal ones is the idea that failed forearm grafts can be converted to upper arm fistulas for immediate use by leveraging the mature graft outflow vein in the new fistula. However, not once in our study population was an upper arm AVF created from the outflow vein of a failed forearm graft. Review of these patients’ charts indicated that vein mapping data at the time of subsequent access creation precluded the possibility of AVF conversion due to central or peripheral venous problems.

Furthermore, these results indicated that while most subgroups were statistically indistinguishable in terms of the number of various reinterventions in the first year of use, F-T had significantly more pseudoaneurysm repairs in the first year than U-NT grafts. It is difficult to determine whether location, tapering, or some combination of these properties was associated with the observed difference. Increased difficulty in cannulating the F-T grafts as compared to U-NT, either because of their variable width and/or their variable course in a looped configuration, could explain the increased incidence of pseudoaneurysm repairs in the F-T population. These pseudoaneurysms, while not always direct determinants of patency, indicate damage to the graft material. As such damage can lead to graft ligation, these reinterventions were considered in our analysis of graft patency.

In summary, this study shows, in our experience 1. That all forearm, and especially F-NT, grafts on average have less cumulative patency than upper arm grafts; 2. That failed forearm grafts in this cohort were never converted to upper arm SAVF
using the original outflow vein despite aggressively exploring this possibility with vein mapping; and, 3. That F-T grafts have more pseudoaneurysm repairs than any other subgroup analyzed. Thus, more distal access sites might not be as advantageous as originally thought. The decision to privilege distal sites over more proximal ones must be carefully considered in the context of balancing access longevity and reintervention rates with life expectancy and the number of subsequently accessible HD sites. In long-term planning for a patient’s dialysis if no appropriate veins are found for arteriovenous fistula creation and the patient has suitable life expectancy, the best strategy may be to preserve proximal access sites and place a tapered graft in the forearm given its superiority to F-NT in terms of mean survival. Patients with a shorter life expectancy may be better served by placement of an upper arm access given the superior cumulative patency.

The limitations of these data stem largely from the retrospective manner in which they were collected and the sample size analyzed. Though these data are consistent with reported standards for graft patency [2, 27-30], they are most likely an optimistic analysis both of cumulative patency and reintervention rates because any access replacements or reinterventions performed outside of The Mount Sinai Medical Center system would not have been captured in these data. However, only a small percentage (7%) of our graft population was lost to institutional follow-up, which mitigates this potential source of error. Furthermore, there were no significant differences between subgroups in the proportion of grafts lost to follow-up. In other words, no single subgroup of graft is preferentially subject to these errors over any other subgroup studied; thus, the differences between subgroups in cumulative patency and reintervention rates, the primary focus of this paper, should remain relatively constant even if the absolute figures are subject to the errors discussed.

If the sample size had been larger, it might have been possible to further resolve not only the significance of subgroup on pseudoaneurysm reintervention rate but also the significance of tapering on AVG cumulative patency. The latter relationship trended towards but was not ultimately statistically significant; therefore, it is possible that a slightly larger study population could elucidate more clearly the relationships these variables have on the outcomes studied. A larger sample size or even a prospective
study would also allow generally for more precise graft optimization, especially for those parameters that appear more rarely in AVG creation surgeries.

Finally, it should be acknowledged that just under a third (32%) of this study population represented patients who had received a previous ipsilateral access, either fistula or graft, before the time of graft creation. Rather than artificially separate these procedures out from the larger cohort, we chose to include them in our data set in hopes of providing practitioners a representative, comprehensive analysis of this complex population for immediate, practical application.

Conclusions:

The results of this study shed light on factors affecting the primary and cumulative patency of AVG as well as the relative differences in reintervention rates between graft subgroups in the first year of use. Both location in the upper arm and tapering of the graft had positive associations with cumulative patency. These data show that while forearm AVG are preferred in the current NKF-KDOQI guidelines for access placement, they are associated with significantly lower cumulative patency when compared with upper arm AVG; F-T grafts had significantly more pseudoaneurysm repairs in the first year of use than a subpopulation of upper arm AVG; and, none of the forearm grafts followed in this study were converted to upper arm AVF. The study suggests that if the forearm is to be chosen as an access site, then using a tapered graft could mitigate the observed patency disadvantage while theoretically protecting more proximal sites.

This study highlights the discrepancy between evidence, guidelines, and clinical practice and provides the groundwork for further research into this area. An individualized decision-making process that takes into account unique patient characteristics is warranted when deciding about the optimal type and location of vascular access, with these data being particularly relevant to the ongoing discussion surrounding access placement in the elderly. Such an approach would have the potential to significantly improve patient care and reduce cost. A prospective, randomized controlled trial would aid in providing further evidence for an optimal
approach as well as further elucidating some of the observed factors affecting AVG patency.
References:


Table I. Procedure Characteristics: Overall and by Subgroup

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<tr>
<th>Characteristic</th>
<th>Total Cohort</th>
<th>Upper Arm Non-Tapered (U-NT)</th>
<th>Upper Arm Tapered (U-T)</th>
<th>Forearm Non-Tapered (F-NT)</th>
<th>Forearm Tapered (F-T)</th>
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<tr>
<td>Average Age Mean (SD)</td>
<td>62.8 (14.6)</td>
<td>63.6 (14.0)</td>
<td>60.9 (13.9)</td>
<td>61.2 (18.2)</td>
<td>61.3 (13.9)</td>
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<td>Male n (%)</td>
<td>112 (41)</td>
<td>73 (40)</td>
<td>7 (25)</td>
<td>25* (65)</td>
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<td>Diabetes Mellitus n (%)</td>
<td>144 (53)</td>
<td>101 (55)</td>
<td>16 (57)</td>
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<td>Hypertension n (%)</td>
<td>199 (73)</td>
<td>133 (73)</td>
<td>23 (82)</td>
<td>26 (68)</td>
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<td>69 (25)</td>
<td>47 (26)</td>
<td>8 (29)</td>
<td>7 (18)</td>
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<td>Gore® n (%)</td>
<td>172 (63)</td>
<td>117 (64)</td>
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<td>Tapered n (%)</td>
<td>50 (18)</td>
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<td>Upper Arm n (%)</td>
<td>211 (78)</td>
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<td>Looped n (%)</td>
<td>72 (27)</td>
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<td>38 (100)</td>
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<td>Lost to Follow-Up n (%)</td>
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<td>Permanently Failed n (%)</td>
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<td>59 (32)</td>
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<td>Number of Procedures</td>
<td>271</td>
<td>183</td>
<td>28</td>
<td>38</td>
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*F-NT contained a significantly higher proportion of male patients than Groups U-NT, U-T, & F-T (P=0.0035, 0.0010, & 0.011, respectively); it also contained a significantly higher proportion of Gore® grafts than groups U-T & F-T (P=0.014 & 0.020, respectively); and, it had a significantly higher prevalence of permanent graft failures over the study period as compared to the upper arm grafts (P=0.017 for U-NT; P=0.024 for U-T).

Otherwise, no significant differences between groups existed with respect to average age, proportion of diabetic patients, proportion of hypertensive patients, proportion of patients with coronary artery disease, usage of Gore® vs. Boston Scientific Gore® grafts, proportion of patients lost to follow up, or prevalence of permanent graft failures.
Table II. Subgroup Patency & Reintervention Analysis

<table>
<thead>
<tr>
<th></th>
<th>U-NT (n=183)</th>
<th>U-T (n=28)</th>
<th>F-NT (n=38)</th>
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<td>Mean (SEM)</td>
<td>Mean (SEM)</td>
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<td>699.1 (66.0)</td>
<td>675.1 (162.9)</td>
<td>577.4 (132.7)</td>
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<td><strong>Graft Survival</strong></td>
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<tr>
<td>in Days</td>
<td>Mean (SEM)</td>
<td>Mean (SEM)</td>
<td>Mean (SEM)</td>
<td>Mean (SEM)</td>
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<tr>
<td></td>
<td>1,305.7 (69.1)</td>
<td>1,412.4 (164.7)</td>
<td>990.1 (151.3)</td>
<td>1,428.1 (180.8)</td>
<td>0.031</td>
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<td><strong>Number of</strong></td>
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<td>Repairs in 1st year</td>
<td>0.03 (0.015)</td>
<td>0.00 (0.00)</td>
<td>0.00 (0.00)</td>
<td>0.17 (0.11)</td>
<td>0.041</td>
</tr>
</tbody>
</table>

Primary and cumulative patency data as well as pseudoaneurysm reintervention analysis for all graft subgroups (U-NT, U-T, F-NT, and F-T).
Figure 1. Kaplan-Meier cumulative patency survival curves broken out by graft subgroup (U-T, U-NT, F-T, F-NT).