

Autogenous Brachial-Brachial Fistula for Vein Access: One Year Clinical Outcome and Comparison with Arteriovenous Grafts

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Two-stage autogenous brachial vein-brachial artery access (ABBA) has been proposed as an option in the absence of superficial vein suitable for the creation of conventional haemodialysis fistulae.

We report our experience with the use of ABBA in a consecutive series of patients treated in a single centre and compare this with our contemporaneous experience of prosthetic arteriovenous grafts (AVGs).

Methods: Between May 2007 and December 2008, 48 consecutive patients presented for access procedures, but found to lack adequate superficial arm vein for the creation of standard fistulae. Seventeen had a brachial vein of diameter >2.5 mm and underwent ABBA. Thirty-one with poor brachial veins were scheduled for AVGs.

❖ ABBA fistulae were performed as a two stage procedure. The ABBA fistulae were assessed for suitability for transposition six weeks after the first stage procedure according to ultrasonic criteria.

❖ All patients having prosthetic procedures described in this study received *Flixene grafts* (Atrium Medical Corporation, Hudson, NH). This is a composite vascular graft, with a trilaminar structure made from expanded polytetrafluoroethylene (ePTFE). A significant advantage of this graft is that it can be used immediately after implantation.

Results: Of the 17 ABBA patients, 12 (71%) experienced at least one complication (Table I). One (6%) had a wound infection and ten (59%) developed moderate to severe fistula-related stenoses (Table II). Thirteen (42%) of the 31 AVGs patients experienced at least one complication (Table I), of which four (13%) had a wound infection and 14 (45%) developed moderate to severe graft-related stenoses (Table II).

❖ The median time to cannulation of the fistulae was 8 weeks following ABBA and 4 weeks after AVG. Twelve of the 31 patients (39%) had their grafts successfully cannulated during the first week

❖ The functional patency rate was 47.1% at twelve months in the ABBA group and 64.5% in the AVGs group (log rank test, $p=.222$).

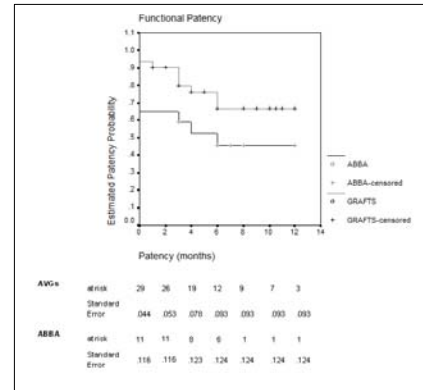


Fig. 1: One year functional patency rates of the AVGs and ABBA fistulae.

Complication	AVGs (n=31)	ABBA (n=17)	P
thrombosis	7 (23%)	6 (35.3%)	.543
haematoma	1(3%)	3 (17.6%)	.237
forearm oedema	7 (22.6%)	3 (17.6%)	.975
lymphorrhea	0	2 (11.7%)	.232
seroma	0	0	
wound infection	4 (13%)	1(5.9%)	.816
aneurysm	0	1(5.9%)	.758
steal syndrome	0	1(5.9%)	.758

Table I: Distribution of postoperative complications in ABBA and AVGs.

Interventions	AVGs (n=31)	ABBA (n=17)	P
PTA	12	8	.798
surgical thrombectomy	3	-	.483
surgical revision	1	-	.758
mechanical percutaneous thrombectomy	3	2	.789
Total interventions	19	10	.887

Table II: Interventions in AVGs vs. ABBA fistulae group.

Conclusions

❖ ABBA was characterized by a high incidence of complications and a long maturation period.

❖ Despite close monitoring and a high rate of secondary interventions, the functional patency was not significantly better than the AVGs.

❖ On the basis of these data and pending results from randomized trials, we suggest that in patients lacking superficial veins suitable for conventional AVF, a brachio-axillary prosthetic AV graft is the technique of choice. This allows early dialysis and an satisfactory functional patency, without increasing the number of interventions needed to prevent graft failure.

APHECS II Trial

Atrium's Prospective Hemodialysis Early Cannulation Trial with the FLIXENE™ Vascular Graft

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Introduction

The use of a native fistula as the primary conduit for vascular access is well accepted. When a fistula matures, fistulas have shown superior patency rates to other forms of access due to their low complication rates, low infection rates, and increased patency.^{1,2,3}

Often in patients where fistulas fail or fistulas fail to mature, there is an urgent need for dialysis. These patients often lead to prolonged usage of dialysis catheters.⁴ It has been well published that catheters are associated with an increased risk of complications, infections, and overall mortality. In these difficult to treat patients consideration of a vascular graft that can be used for early cannulation may be appropriate to reduce the dependence upon temporary catheters.

The APHECS II study is a prospective multi-center study to determine if the FLIXENE™ vascular graft can be safely cannulated within 72 hours. The FLIXENE™ vascular graft (Atrium Medical Corporation, Hudson, NH, USA) is a proprietary trilaminar composite ePTFE vascular graft specifically engineered to provide increased strength and durability even after repeated needle sticks. The product has a unique construction with a 60µ outer porosity designed to promote fast tissue ingrowth. The three-layer construction allows for smaller needle holes when cannulated and virtually eliminates weeping. The product comes with a proprietary deployment system (Slider™ GDS) which allows the graft to be tunneled with minimal graft and tissue disruption.

The primary objective of this trial is to assess graft patency and complications in patients who are implanted with the FLIXENE™ vascular graft in the upper extremity and are cannulated within 72 hours.

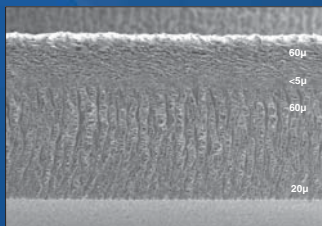
Methods

This is a multicenter prospective trial. A total of 31 patients were enrolled where it was determined they required a synthetic graft for vascular access.

Inclusion criteria consisted of Male or Female ages 18-80, required vascular access surgery with a new synthetic graft in the upper extremity, patients deemed eligible by the study physician for dialysis graft access within 72 hours, written informed consent, and willing and able to adhere to follow up visit schedule.

Exclusion criteria consisted of intravenous drug abuse, history of AIDS or HIV positive, pregnant women or nursing mothers, life expectancy of less than one year, documented hypercoagulable state, serious collagen disease, considered an inappropriate participant for this study by the study physician.

Patients will be followed at first dialysis session post surgery (within 72 hours), 1 month, 3 months, and 6 months post surgery. The study endpoints included successful cannulation of the FLIXENE™ vascular graft within 72 hours post operatively, graft patency at 6 months, and assessment of complications at 6 months.



- Incorporation Zone**
 60 microns
 Facilitates tissue attachment and healing
- FLIXENE™ Membrane**
 < 5 microns
 Prevents weeping, increases strength, and reduces needle-hole elongation
- Flow Interface Zone**
 60/20 design
 Offers incredible strength characteristics (ex. torque, kink and compression resistance)



Results

Table 1: Patient Demographics

Number of Patients	31
Gender	
Male	14 (45%)
Female	17 (55%)
Ethnicity	
African American	10 (32%)
Caucasian	9 (29%)
Latino	8 (26%)
Other	4 (13%)
Comorbidities	
Hypertension only	12 (38%)
Diabetes only	0
Hypertension and Diabetes	18 (58%)
Neither	1 (3%)
Cannulation Time Frame	
<24 hours	29 (94%)
24-48 hours	1 (3%)
48-72 hours	1 (3%)

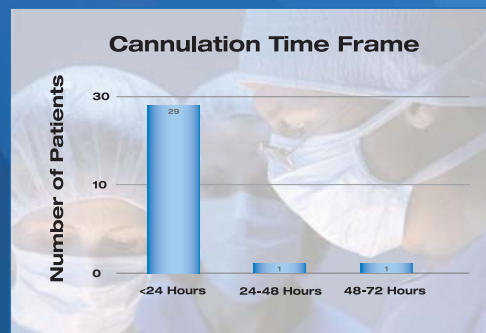
The demographic data was reflective of the American dialysis population.

Table 2: Complications

Complication	# of Patients (%)
Thrombosis	6 (19%)
Hematoma	5 (16%)
Graft Infection	2 (6%)
Steal Syndrome	2 (6%)

Complications were typical of AV access and not specific to the FLIXENE™ graft.

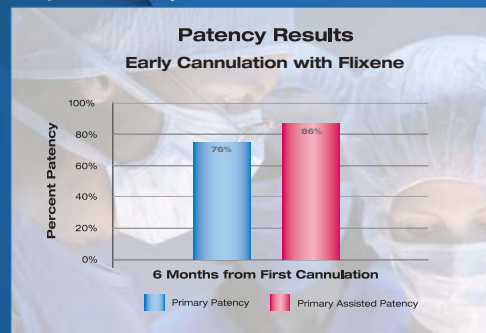
Graph 1: Early Cannulation Timeframe



There were no complications due to cannulation of the FLIXENE™ grafts within the 72 hour time frame.

- 94% of the patients were cannulated within 24 hours.
- 3% were cannulated within 24-48 hours
- 3% were cannulated within 48-72 hours.

Graph 2: Patency Results



The 6 month patency of 76% and primary assisted patency of 86% is in line or higher than historical patency rates of previous vascular access studies.^{5,6,7}

Conclusion

The ability to cannulate a graft for hemodialysis access within 72 hours is extremely desirable in patients where insertion of a temporary catheter may be of clinical concern. Temporary dialysis catheters are associated with a high rate of infection and complications.⁴ The ability to cannulate Atrium's FLIXENE™ vascular graft within 72 hours can help reduce the dependence on temporary catheter placement. Lessening this catheter dependence long term can help reduce the associated infections, stenoses, mortality rates, healthcare costs, and improve the overall quality of life for the dialysis patient. **The results from APHECS II strongly suggests that the unique structure of Atrium's FLIXENE™ vascular graft can be safely cannulated within 72 hours.**

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