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ORIGINAL ARTICLE

Safety and efficacy of electrospun polycarbonate-urethane vascular graft for early hemodialysis access: first clinical results in man

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ABSTRACT

Objectives: **The purpose of this study was to assess the safety and efficacy of an electrospun multilayered, self-sealing polycarbonate-urethane graft for early hemodialysis access in patients.**

Method: **Seventeen eligible consenting patients had a polycarbonate-urethane graft (AVflo™) implanted and followed up prospectively for 12 months or to the end of secondary patency. Performance measures included graft patency, complications, time to first cannulation, and hemostasis times after needle withdrawal.**

Results: **All patients were of Asian origin (mean age 57 years, range 29-78). Diabetes mellitus was the most common cause of renal failure (52.9%). There were no systemic or local reactions to the graft. Five patients (29.4%) died due to medical complications unrelated to the device. There was 1 pseudoaneurysm, 3 infected grafts that subsequently thrombosed, and 1 primary thrombosis associated with thrombophilia. One venous stenosis needed balloon angioplasty. Primary and secondary patency rates at 6 months were 72.7% and 81.8%, and at 12 months, 54.5% and 72.7%, respectively. Postimplantation vascular access needs were met entirely by the graft in every instance and prevented the need for venous catheters. Fifty-six percent were accessed within 8 days, the earliest being 48 hours. Finally, all arterial punctures and 98% of venous punctures had sealed in less than 5 minutes, with two thirds sealing off within 3 minutes of needle withdrawal.**

Conclusion: **The electrospun polycarbonate-urethane graft is safe in humans, permits early access obviating the need for venous catheters, and has equivalent patency to other prosthetic grafts at 1 year.**

Key words: Hemodialysis, Early vascular access, Electrospun, Polyurethane

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INTRODUCTION

As life expectancy improves and the population with end-stage renal disease grows, the provision of reliable long-term hemodialysis vascular access (HVA) becomes a major challenge (1). Although an autogenous arteriovenous (AV) fistula is the first choice for HVA (2), there are numerous instances where a suitable vein is not available, and a synthetic AV graft becomes necessary. The main shortcoming of synthetic devices is their loss of patency over a short period of time and limited life-span, necessitating frequent reinterventions to recover and maintain patency or further surgery to create new access routes at new sites (3). An additional limitation with fistulas and AV grafts is that they both require weeks to months of maturation and incorporation time, prior to first use, because early cannulation has a high risk of thrombosis, infection, seroma, weeping, hematoma, conduit laceration, or bleeding into the tunnel (4). Current evidence (5) and practice recommendations (6) are that an AV fistula should not be accessed prior to 1 month, and polytetrafluoroethylene (PTFE) AV grafts should not be accessed prior to 14 days after placement (6, 7). However the majority of those with end-stage renal disease present late, needing early dialysis, and thus go on to dialysis via percutaneous central venous catheters (PCVCs) (4). PCVCs are prone to infection, thrombosis, dislodgement, and discomfort in the short term and venous stenosis in the long term (8). There is a need to develop an implantable self-sealing AV graft that permits early vascular access with acceptable patency, thereby decreasing the need for PCVCs. Recently several new products have been introduced that encourage early cannulation (9-13), but their patency and complication rates have been of concern. Thus the creation of an AV graft that permits early access for hemodialysis and has acceptable long-term performance continues to be an elusive goal.

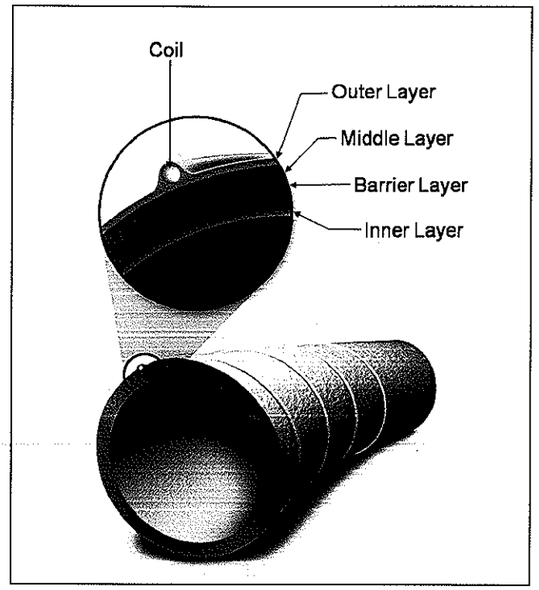

Fig. 1 - *The AVflo™ vascular access graft.*

A new AV graft using polycarbonate-urethane and silicone copolymers and electrospinning technology (AVflo™; Nicast Ltd, Israel) to produce ultrafine fibers in a nonwoven fashion (Fig. 1) was designed to spontaneously and rapidly seal punctures after needle withdrawal enabling early hemodialysis access. This graft was tested for the first time in humans as a self-sealing early access graft in end-stage renal failure. We report the 1-year graft performance (patency and complication rates) and dialysis outcomes in terms of time to first dialysis access and time for hemostasis after needle removal.

MATERIALS AND METHODS

All material components in the graft had been tested by their manufacturers and by Nicast, Israel, and found to be noncytotoxic and nonhemolytic (unpublished data). Electrospinning uses an electrostatic field and high voltage to create ultrathin polymer fibers. A polymer solution held by surface tension at the end of a capillary tube is subjected to an electrostatic field. Charge is induced on the liquid surface. Mutual charge repulsion creates a force directly opposed to the surface tension. As the intensity of the electrostatic field is increased, the hemispherical surface of the solution at the tip of the capillary tube elongates to form a cone. When the electrostatic field intensity reaches a critical value

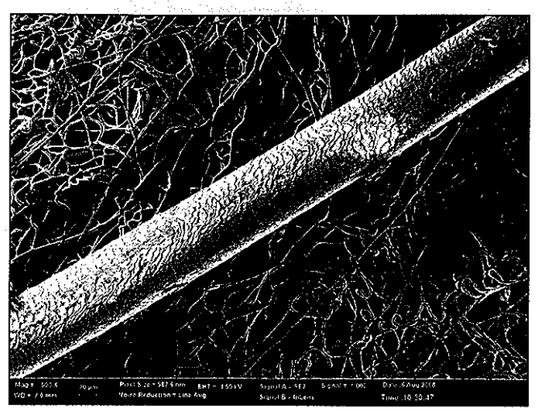

Fig. 2 - *A SEM image (500x) of electrospun fibers. A human hair is provided for comparison.*

where the repulsive electrical force overcomes the surface tension force, a charged jet of the solution is ejected from the cone tip. As the jet travels forward, the solvent evaporates, leaving behind a polymer fiber. The fibers are collected on an opposite-charged electrode in the form of a nonwoven fabric (Fig. 2). This process allows control of the size, density, diameter, and orientation of the fibers, giving the final product mechanical properties such as post-puncturing spontaneous sealing, flexibility, and radial pulsatility.

Structure

The graft features a self-bonded, 4-layer design (Fig. 1). As documented in prior in vivo experiments (unpublished data), the nanofiber blood-contacting inner layer was found to minimize platelet adhesion. The self-sealing middle layer is highly flexible and imparts elastic properties that mimic those of the natural blood vessel. A third layer serves as a barrier that prevents the diffusion of large molecules and provides strength and elasticity to the graft's structure. The nanofiber fourth outer layer adds on to the self-sealing properties of the device and permits ingrowth of surrounding tissue.

Patient enrollment

Seventeen patients needing implantation of a prosthetic graft for hemodialysis received the polycarbonate-urethane graft (AVflo™; Nicast, Israel). This study was conducted at the Colombo National Hospital in Sri Lanka. The Colombo University Faculty of Medicine Ethics Review Board granted approval, and the study was registered in the clinical trials registry of the Sri Lanka Medical Association.

Patient enrollment was according to predetermined

criteria (Tab. I) and not predicated on the need for early cannulation of the graft. However, information with regard to the need for urgent dialysis was obtained. Criteria for urgent dialysis involved electrolyte imbalance, uremia, and fluid overload. Baseline data on etiology, risk factors, demographics, and prior dialysis shunt placement were obtained before implantation.

Surgical procedure

Surgical implantation of the graft was performed according to current surgical practice. The brachial artery and axillary vein were accessed under 2% lignocaine infiltration anesthesia just above and below the cubital fossa and axilla, respectively. A 6-mm AVflo™ graft was laid subcutaneously in a straight configuration in the medial upper arm using a tunneler and anastomosed to the brachial artery just above the cubital fossa, and to the axillary vein just below the axilla in an end-to-side fashion using 7/0 polypropylene (Prolene™, Ethicon) sutures. A single intravenous bolus of cefuroxime 1.5 g and 5,000 U unfractionated heparin were given during implantation.

Postoperatively, hand exercises were encouraged, and graft flow was monitored clinically by palpating the thrill and auscultating a bruit. Postoperative follow-up information was obtained on all patients through review of the dialysis sheets from the dialysis units. All were followed up for 12 months or until the graft was explanted or thrombosed, or the patient died.

Efficacy

Three parameters were considered as end points for efficacy: (i) primary and secondary patency rates, (ii) time to first puncture, and (iii) hemostasis time. Primary and secondary patency rates for 6 months and 1 year were determined with Kaplan-Meier analysis from the date of implant. Primary patency rate was defined as the time point where physical intervention was required to allow continued use of the graft. Secondary patency rate was defined as the time point of the end of the functional patency. Time to first puncture was measured as the time elapsed between the graft implantation and first access puncture. Early access/cannulation was defined as use of the prosthetic graft ≤8 days postimplantation.

Finally hemostasis time was recorded for arterial and venous puncture sites. Fifteen-gauge needles were used for cannulation. Manual compression was performed in 1-minute increments to determine hemostasis at the puncture site. This data were compared with literature controls (14).

Statistical analysis

Study data were recorded on case report forms (CRFs). The CRF data was logged into a predefined database. Data integrity and completeness were checked and compared with the original CRFs. The data was then analyzed with

TABLE I - INCLUSION/EXCLUSION CRITERIA

Inclusion criteria
- Patients with chronic renal failure who require vascular access for hemodialysis. These are patients who, in accordance with the standard of care in the medical center, are not eligible for creation of native fistulas.
- The vascular access graft can be placed in the upper extremity (either above or below the elbow).
- Male or female patients 18 years or older, of any race.
- Patient is undergoing or will undergo hemodialysis at a hospital or hemodialysis center.
- Patient willing to participate, as evidenced by signing the informed consent form.

Exclusion criteria
- Any medical condition that in the investigator's opinion would expose the patient to increased risk from the investigational device or procedure.
- Patient is unable to comply with the study follow-up.
- Elevated white blood cell counts.
- Bilirubin levels >3mg/dl.
- Severe coagulation disorder.
- Patient has a previous vascular access graft implanted. It is not possible to place the study graft proximal to the existing device, and no other sites are available.
- Concurrent existence of another vascular access graft in the same limb.
- Impaired arterial or venous circulation in the upper extremity (as detected by angiography or duplex studies).
- Immunodeficiency syndrome.
- History of bacterial infection within 8 weeks prior to implantation of graft.
- Known hypersensitivity or allergy to polyurethane products, or any other contraindication to implantation of a polyurethane graft.
- Life expectancy less than 1 year.
- Female patient who is pregnant or lactating.
- Current participation in any other clinical study.
- Patient who has undergone mastectomy or any procedure that may affect the lymphatic drainage in the limb planned to host the graft.
- Patients in whom a non-planar implantation of the graft is anticipated (e.g., obese patients).

Statistical Analysis Software (SAS, version 9; SAS Inc, Cary, NC, USA). Survival analyses were conducted with the Kaplan-Meier product limit estimator. The frequencies of adverse events, complications, and deaths were tabulated by event.

RESULTS

Data sets analyzed and patient accountability

The intention-to-treat (ITT) analysis set included 17 consecutive patients (Tab. II) with a total follow-up of 3,822 days. Of the 17 patients enrolled in this study, 5 were not using the graft at 12 months, for the following reasons: 3 had had kidney transplants, 1 had developed a strong aversion to needle puncture and opted for a long-term venous catheter, and another had had significant recovery of renal function and did not need dialysis. All 5 had patent grafts on clinical examination, confirmed by color Doppler. A further 5 patients had died of medical causes unrelated to the device. All 5 were dialyzed with the graft until their death. Four grafts failed – 3 due to infection and 1 due to recurrent thrombosis secondary to thrombophilia.

TABLE II - OUTCOMES AFTER 12 MONTHS

	No. of patients
Total enrolled	17
Patients with graft implanted (ITT population)	17
Death – not device-related	5
Graft explantation	2
Patients who did not complete dialysis, but graft remains patent*	4
Patients who did not start dialysis†	1
Nonfunctional grafts	2
Number dialyzing via graft at 12 months	3

ITT = intention-to-treat.
*Three patients had a kidney transplant. One patient undergoing dialysis decided to convert to a neck line catheter at 3-month follow-up due to an aversion to needle puncturing.
†One patient did not dialyze through his patent graft over the 12 months, because his creatinine clearance improved after the implantation.

Patient demographics and baseline characteristics

Table III presents patient demographics based on the ITT population. Just over one half of the patients enrolled were male (52.9%). Their ages ranged from 29 to 78 years with a mean age of 57.1 (± 16.7) years. Their mean height and weight was 159 cm (± 9.6) and 58.9 kg (± 17.6), respectively. All subjects were of Asian/Oriental origin. Almost two thirds of the subjects (65%) had undergone a previous surgical vascular intervention, as detailed in Table IV. One third of the subjects (35%) had had a previous graft failure prior to implantation of the AVflo™. Diabetes mellitus was the most common cause (52.9%) of renal failure, as shown in Table V, with hypertensive nephrosclerosis as the second commonest cause (23.5%).

Complications

Five deaths were reported during the 12 months of the study. These deaths were due to myocardial infarctions in 3, stroke in 1, and pneumonia in another. None of the 5 deaths were due to inadequate dialysis or an access graft complication. There were no intraoperative problems related to handling and implantation of the device. Similarly there were no kinks that developed in these grafts. However, there was 1 instance of a puncture site pseudoaneurysm. At surgical exploration, a 3-mm laceration was observed at the puncture site and was successfully repaired by direct suture. Thereafter the graft continued to be used without similar complications. Three grafts were infected: 2 localized to puncture sites, while the other involved the entire graft and caused septic distal embolism. All 3 infected grafts were initially patent but thrombosed subsequently and were explanted. Finally, only 1 graft was complicated with primary thrombosis. Thrombosis was recurrent (2 and 8 weeks after implantation), and the patient was found to be strongly positive for lupus anticoagulant, and thus the graft was abandoned without further intervention.

Two patients had small wound hematomas, and 14 had arm swelling, with only 1 being severe. This was due to a proximal vein stenosis secondary to previous central vein catheter trauma and was successfully balloon dilated.

TABLE III - BASELINE PATIENT DEMOGRAPHICS

		AVflo™ patients (n=17)
Sex, no. (%)	Female	8 (47.1%)
	Male	9 (52.9%)
Age, years	Mean ± SD	57.1 ± 16.7
	Median (range)	61 (29-78)
Height, cm	Mean ± SD	159 ± 9.60
	Median (range)	159 (144-176)
Weight, kg	Mean ± SD	58.9 ± 17.65
	Median (range)	55 (33-96)
Previous surgical vascular intervention, no. (%)		6 (35.3%)
Previous minimally invasive intervention, no. (%)		9 (52.9%)
Previous graft failure intervention, no. (%)		7 (41.2%)

Efficacy

Primary and secondary patency rates

Primary and secondary patency rates at 6 months after implantation were 72.7% and 81.8%, respectively. The corresponding figures at 12 months after implantation were 54.5% and 72.7%, respectively (Fig. 3). These patency rates are compared with those for the polyetherurethane Vectra graft and ePTFE grafts from Glickman et al (14) in Table VI. Three instances of infection and 1 thrombophilia-induced thrombosis were the main causes of graft loss.

Time to first dialysis access

Fifty-six percent (n=9) of the grafts were cannulated in 8 days or less, with 1 graft being cannulated within 48 hours after implantation. Another graft was cannulated between day 8 and 14 after implantation, and the remaining 6 grafts (38%) were cannulated more than 2 weeks after implantation. Clinical need determined the time to cannulation. All those needing early postimplantation dialysis had access through the graft, and none needed a venous catheter.

Hemostasis time

The compression times until hemostasis for 1,092 punctures of the AVflo™ are shown in Table VII. All arterial punctures and 98% of venous punctures had sealed in less than 5 minutes, with almost two thirds sealing off within 3 minutes of needle withdrawal.

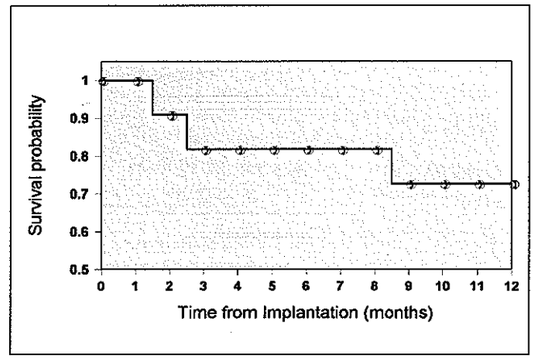

Fig. 3 - *Kaplan – Meier survival curve from implant to end of secondary patency.*

TABLE IV - DETAILS OF PREVIOUS VASCULAR PROCEDURES

	Number of patients	Frequency, %
Previous surgical vascular intervention		
None	11	64.7%
AV fistula	5	29.4%
Implantation of graft	1	5.9%
Previous graft failure		
None	11	64.7%
Anastomotic obstruction	2	11.8%
Thrombosis	2	11.8%
Unspecified	2	11.8%

AV = arteriovenous

TABLE V - UNDERLYING DISEASE

	AVflo™ patients (n=17)	
	Number of patients	Frequency, %
Diabetes mellitus	9	52.9%
Insulin dependent	3	33.3%
Non-insulin dependent	6	66.7%
Hypertensive nephrosclerosis	4	23.5%
Chronic glomerulonephritis	2	11.8%
Polycystic disease	0	0.0%
Interstitial nephritis	1	5.9%
Chronic pyelonephritis	2	11.8%
Other	2	11.8%

TABLE VI - COMPARISON OF GRAFT PATENCY RATES WITH LITERATURE CONTROLS

	% Primary patency			% Secondary patency		
	AVflo™	Vectra polyurethane*	ePTFE*	AVflo™	Vectra polyurethane*	ePTFE*
6 months	72.7	51	59	81.8	85	86
12 months	54.5	44	43	72.7	74	79

ePTFE = expanded polytetrafluoroethylene.
*Data from Glickman et al (14).

TABLE VII - TIME TO HEMOSTASIS AFTER DIALYSIS NEEDLE REMOVAL

Time to hemostasis (n=1,092 punctures)
One minute: Arterial 24%, venous 30%
Two minutes: Arterial 46%, venous 48%
Three minutes: Arterial 66%, venous 62%
Four minutes: Arterial 88%, venous 90%
Five minutes: Arterial 100%, venous 98%

DISCUSSION

This is the first report of an electrospun polycarbonate-urethane vascular access graft tested in human subjects, and the results confirm its safety, efficacy, and durability at 1 year. Although the number of subjects and grafts studied were only 17, this report analyzes 3,822 graft-days and 1,092 needle punctures.

AVflo™ safety

All 5 deaths (29.4%) during the study were due to underlying medical conditions and were neither due to the device nor to inadequate dialysis. The rate of patient deaths reported by Glickman et al (14) was 15.5% for the polyurethane group and 13% for the ePTFE group. The higher death rate among those in this study reflects the severity of the underlying cardiovascular disease and limited access to coronary and cerebral revascularization in a developing country.

Complications seen with the repeatedly punctured AVflo™ grafts were similar to those seen with other access grafts (9-14). Mild swelling overlying the implanted graft lasting a few days was frequent and was probably due to the tunneling process, and it was similar to that observed after any trauma. Furthermore, most patients had some amount of systemic fluid excess that would have amplified any swelling from local surgical trauma. However, the commonly observed mild transient swelling was not a hindrance to early vascular access, and this prevented many from needing venous catheters. The only instance of severe swelling was due to a central vein stenosis secondary to previous venous catheterization, and this resolved after balloon dilatation.

Other reported graft-related and technical complications include pseudoaneurysms and graft kinking. In the present study, there was 1 pseudoaneurysm and no kinked grafts after 1 year. The pseudoaneurysm was due to a laceration at a puncture site probably due to the flicking of the needle tearing the graft at the time of its withdrawal rather than to a material defect, as it did not happen again despite the continued use of the same graft. The incidence of pseudoaneurysms for ePTFE grafts varies from 1.4% at 12 months (13), to 2.4% at 24 months (12) and 3.5% after 36 months (13). Interestingly, graft elongation and kinking was a specific problem with a polyetherurethane graft, with an incidence of 8% (14). The straight configuration used for all grafts in this AVflo™ study may have prevented the graft elongation from significant kinking noted by Glickman et al (14).

Infection remains a common cause of synthetic graft loss. In the current study, 17.6% (3/17) of grafts were infected and accounted for 5.4% (3/55) of all adverse events during the 12-month follow-up period. The incidence of infection reported by Glickman et al (14) for both polyurethane and ePTFE was 5.6% for a 12-month follow-up period. Peng and Tan (13) reported 61.5% graft loss due to infection in polyurethane grafts after a median follow-up of 12 months.

Thrombosis is another common problem with prosthetic grafts. Primary thromboses, at 8 months and 2 weeks after implantation, occurred in 2 AVflo™ grafts (11.8% of grafts) during the 12 months of follow-up. Although both grafts were successfully thrombectomized initially, the early thrombosis recurred at 8 weeks, and the graft was abandoned when this patient was found to be strongly positive for lupus anticoagulant. The thrombosis rate for the AVflo™ graft compares well with ePTFE and polyurethane grafts, whose rates at 24 months are 26%-38% (3, 11, 12) and 32.7%-48% (13, 14), respectively.

Three grafts (17.6%) were lost during the study due to infection. Peng and Tan (13) reported 47.8% grafts lost during the 5-year follow-up. Although the need to be scrupulous about surgical asepsis and puncture technique is well known, further advances with antimicrobial drug incorporation into grafts need to be considered.

AVflo™ efficacy

Primary and secondary patency

Considering the difficulties of vascular surgery, the high cost of vein/artery loss due to graft and hemodialysis complications, as well as vascular grafts costs, preserving the implanted graft is vital for the patient's well-being. Primary and secondary patency rates 6 months after implantation were 72.7% and 81.8%, respectively, while at 12 months the corresponding figures were 54.5% and 72.7%, respectively. These results are comparable to those from the study of Glickman et al (Tab. V) comparing the polyetherurethane Vectra and ePTFE grafts (14). Similarly Salimi and Zafarghandi (15) reported a primary patency rate of 78%, and Modarai et al (16) of 66% at 6 months for ePTFE grafts. The better primary patency rates at both 6 and 12 months for the AVflo™ graft must be interpreted with caution considering the small sample in this study. Furthermore, it may be argued that AVflo™ patency was improved by the upper-arm location and nearly straight configuration of 96% of the grafts in the study. However, this was addressed by Glickman et al (14) in their comparative study of PTFE and polyurethane access grafts, where the majority of polyurethane grafts were placed in a similar fashion to those in the current AVflo™ study. Subgroup analysis established that there was no significant difference in patency rates in all groups determined by location and configuration of graft placement.

Time to first dialysis

In the current study, 56% (n=9) of the subjects were cannulated prior to 9 days postimplantation, while 1 was accessed at 48 hours without jeopardizing the graft. This reflects the urgency with which those being studied needed dialysis and the suitability of the AVflo™ graft to provide early access. What is important is that none of the patients studied needed an alternate access after the AVflo™ graft was implanted. Glickman et al (14) reported 53.9% access within 9 days after implantation of the polyurethane Vectra graft, similar to that in our series. Based on our study results, it would be safe to say that the AVflo™ graft can be punctured safely within a few days after implantation.

Time to hemostasis

Most patients undergo up to 3 hemodialysis sessions a week, each lasting several hours, and the time required for hemostasis after needle withdrawal can have a major impact on the overall session time. Considering the limited number of hemodialysis beds, minimizing session time by shortening hemostasis time becomes an important property of grafts. Nearly all AVflo™ graft punctures had sealed off within 5 minutes of direct moderate pressure, and nearly two thirds had done so in less than 3 minutes. These hemostasis times are better than those for other polyurethane grafts and clearly superior to those for ePTFE grafts (14).

The overall results of the study demonstrate that the new polycarbonate-urethane AVflo™ graft is safe with no unanticipated device-related complications. The incidence rates of most complications reported in this study are comparable to those reported for other prosthetic grafts. The results of this first study in humans demonstrate that this graft is at least equivalent to, if not better than, other prosthetic grafts with respect to patency, time to first dialysis, and time to hemostasis. Continued study of larger numbers would further strengthen our conclusions.

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Conflict of interest: None of the authors have any proprietary interest in Nicast, Israel.

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Informed consent: A statement on ethics approval and consent is included in the "Methods" section.

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