Use of the Flixene vascular access graft as an early cannulation solution

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Objective: **The primary end points of this study were safety and efficacy of early cannulation of the Flixene graft (Maquet-Atrium Medical, Hudson, NH). Secondary end points were complications and patency.**
Methods: **This is a prospective single-center nonrandomized study. Study data included patient characteristics; history of vascular access; operative technique; interval between implantation and initial cannulation; complications; and patency at 1 month, 3 months, and every 6 months. Patency rates were estimated by the Kaplan-Meier method.**
Results: **Between January 2011 and September 2013, a total of 46 Flixene grafts were implanted in 44 patients (27 men) with a mean age of 63 years. The implantation site was the upper arm in 67% of cases, the forearm in 11%, and the thigh in 22%. Seven grafts were never cannulated during the study period. Of the remaining 39 grafts, 32 (82%) were successfully cannulated within the first week after implantation, including 16 (41%) on the first day. The median interval from implantation to initial cannulation was 2 days (interquartile range, 1-3 days). The median follow-up was 223.5 days (interquartile range, 97-600 days). Five hematomas occurred, but only one required surgical revision. Primary assisted and secondary patency rates were 65% and 86%, respectively, at 6 months and 56% and 86%, respectively, at 1 year.**
Conclusions: **This study suggests that cannulation of the Flixene graft within 1 week after implantation is safe and effective. Early cannulation avoids or shortens the need for a temporary catheter. One-year patency rates appeared to be comparable to those achieved with conventional grafts, but long-term follow-up and randomized controlled studies will be needed to confirm this finding. (J Vasc Surg 2015;62:128-34.)**

Achieving a reliable and durable vascular access[1,2] is essential for hemodialysis, which is the mainstay replacement therapy for patients with end-stage renal insufficiency. A particularly challenging aspect of this issue involves the growing number of elderly[3] and other patients requiring an immediately usable vascular access. In this regard, it should be underlined that complications associated with use of central line catheters as a temporary conduit are major causes of hospitalization and death.[4] A number of early stick graft devices have been proposed as a permanent solution to obtain access within less than a week. However, initial results[5-13] have been mixed, with many nephrologists and nurses being reluctant to perform early puncture even though these grafts were designed for that purpose. The purpose of this study using the Flixene early cannulation prosthetic graft (Maquet-Atrium Medical, Hudson, NH) was threefold: to evaluate the safety of early cannulation, to assess implementation in a dialysis center, and to report midterm patency and complication rates.

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Author conflict of interest: In May 2014, X.B. received a travel grant from Maquet to make an oral presentation of some of the results from this study at the European Vascular Access Course in Maastricht, The Netherlands.

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METHODS

Study design and end points. Patient recruitment for this prospective single-center single-arm study began in January 2011 and ended in September 2013. During this period, our vascular surgery department performed 412 procedures involving 261 creations (82% arteriovenous fistulas [AVFs] and 18% synthetic grafts) and 151 revisions of a vascular access site. Demographic data, surgical techniques, and follow-up findings for all patients who underwent initial implantation of an early cannulation Flixene graft were prospectively recorded in a computer database. The primary end point of this study was to evaluate the safety and effectiveness of cannulation during the first week after graft implantation. Secondary end points included complication and patency rates at 1 month, 6 months, and 12 months after implantation. Informed consent was obtained from all patients. The study has been approved by the Ethics Committee of Bordeaux University Hospital.

Graft description. The Flixene vascular graft is an expanded polytetrafluoroethylene (ePTFE) graft with a trilaminate composite structure. A hydrostatic protection membrane designed to minimize weeping and suture hole bleeding is interposed between a smooth inner blood-contacting surface designed to minimize platelet aggregation and a microporous outer anchoring surface designed to promote tissue adherence. Flixene grafts are

available with either an enlarged tapered hood or graduated wall thickness. Implantation is performed using the Slider Graft Deployment System (Maquet-Atrium Medical) featuring a preattached tunneler tip (available in various sizes) and a clear, flexible polyethylene sheath that facilitates pulling through subcutaneous tissue and minimizes risk of contamination.

Patient selection. Graft implantation was performed instead of AVF only in patients with poor veins unsuitable for native AVF creation. The early cannulation Flixene graft was implanted in patients in whom a central line catheter was used to start dialysis, previous vascular access failed with no catheter in place, or creation of a native AVF failed during the predialysis period.

Preoperative workup. All patients were referred to our department by a nephrologist. In all cases, duplex ultrasound examination was performed to determine the feasibility of AVF by measuring the diameter and depth of arteries and veins in both upper and lower limbs. When the thigh was chosen as the implantation site, ankle-brachial index was calculated to determine the best-perfused limb. Clinical examination of superficial veins and arteries, including an Allen test to determine the vessel supplying the most flow to the hand, was carried out in all cases.

Procedures. All procedures were performed at our institution by board-certified and dialysis-experienced surgeons. Upper limb implantation was carried out under general or local anesthesia; lower limb implantation was always carried out under general anesthesia. All patients received 1 g of cefuroxime and 0.5 mg/kg heparin intravenously during anesthetic induction. The vein and artery were dissected by the same or a separate 5- to 7-cm incision. Superficial femoral vessels were exposed by a single incision at least 15 cm from the genital organs. Venous anastomosis was performed first by a continuous running suture of Prolene polypropylene 6-0 (Ethicon, San Angelo, Tex) to preserve the two soft ePTFE layers of the graft. After completion of the suture, subcutaneous tunneling was performed using the plastic sheath (Slider Graft Deployment System). Adapting a curved tunneler to the end of the graft allows safe, clean pulling with little risk of kinking or twisting. Arterial anastomosis was then performed generally on a rigid part of the graft because graft length is always too long to have two soft segments. Before closing of the incision, a drain was inserted and left in place for 2 days to avoid lymph and hematoma collection. At the end of the procedure, thrill was assessed by manual palpation and by listening with a stethoscope at the anastomosis sites. The graft location and flow direction were drawn with a waterproof pen directly on the skin of the patient (Fig 1) to assist nurses in selecting the cannulation site. Patients with thigh grafts were not allowed to stand until postoperative day 2.

Statistical analysis. Statistical analysis was performed with Prism V (GraphPad Software, Inc, La Jolla, Calif). Nominal variables were expressed as number and percentage of patients. Continuous variables were expressed as means and standard deviation or medians and interquartile range, depending on distribution. The Kaplan-Meier life-table method was used to calculate the patency curves. Primary patency was defined as the time interval between implantation and any intervention (surgical or endovascular) to maintain or to re-establish patency. Primary assisted patency was defined as the interval from the time of access placement until access thrombosis including intervention (surgical or endovascular) to maintain functionality of a patent access. Secondary patency was defined as the time interval between implantation and abandonment of the graft.

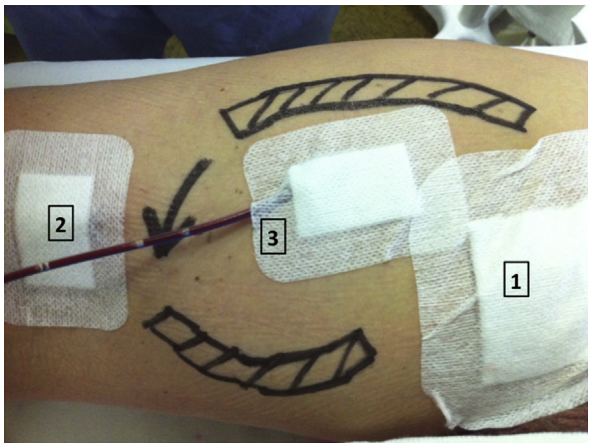

Fig 1. Graft freshly implanted in thigh with drawings showing potential cannulation sites (*hatched*) and flow direction (*arrow*). Dressings cover the cutdown for the femoral vessel approach (*1*), cutdown for loop tunnelization (*2*), and suction drain (*3*).

RESULTS

Patients and grafts. During the study period, 46 Flixene grafts were implanted in 44 patients (27 men) with a mean age of 63 ± 3.2 years. Patient characteristics are summarized in Table I. Two patients had undergone previous implantation with Flixene grafts. The first patient experienced early occlusion at day 4 because of the small size of forearm vessels and was treated the same day with another Flixene graft. In the second patient, graft removal was performed at 2 months because of upper arm swelling with suspicion of infection. Two months later, another Flixene graft was placed in the thigh. All bacteriologic test results on the explanted graft including analysis of fluid obtained after sonication were negative.

Indications for early cannulation of the graft and graft locations and configurations are given in Table II. The four cases involving acute failure of vascular access in patients with no prior catheter included the first patient described in the preceding paragraph and three patients who developed false aneurysm and occlusion of previous grafts. Median procedural duration was 95 minutes (interquartile range, 80-110 minutes). At the beginning of our experience, catheters were removed after 2 weeks of successful cannulation. For the last cases of this series, they were