

Early Cannulation

Being able to cannulate a PTFE graft for hemodialysis access in less than 2 weeks is extremely desirable in patients where insertion of a temporary catheter may be of clinical concern. Temporary dialysis catheters can be associated with a high rate of infection and complication. The ability to cannulate Atrium's Advanta™ PTFE vascular grafts in 3 to 5 days can help reduce

the dependence on temporary catheter placement. Lessening this dependence long term can help improve the quality of life for the dialysis patient. APHECS has demonstrated that the unique structure of Atrium's Advanta PTFE™ graft can be cannulated in 3 to 5 days with no loss of long term performance vs. the standard 14 day waiting period.

APHECS was completed by A. Frederick Schild, M.D., F.A.C.S. at the University of Miami Medical School at Jackson Memorial Hospital in Miami, FL.

Mission Statement:

APHECS (Atrium Prospective Hemodialysis Early Cannulation Study) is a randomized prospective study designed to demonstrate that it is safe and effective to cannulate Atrium's Advanta™ PTFE vascular graft in 3 to 5 days versus the standard 14 day waiting period.



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APHECS

APHECS is a randomized prospective study designed to demonstrate the safety and efficacy of cannulating Atrium's Advanta™ PTFE vascular graft for hemodialysis access within 3 to 5 days versus the standard 14 day waiting period.

APHECS

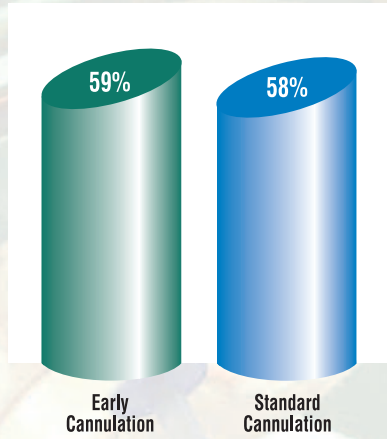


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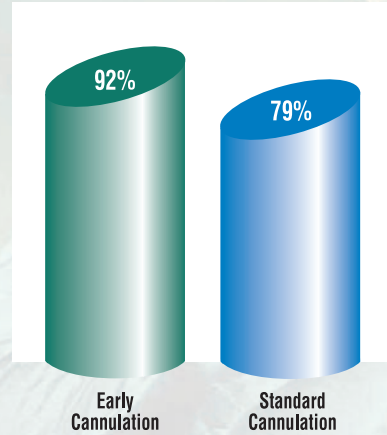
APHECS
Atrium Prospective
Hemodialysis Early
Cannulation Study

APHECS is a single-center prospective randomized study. Each patient enrolled into the study had an Atrium graft implanted for hemodialysis. The patients were randomized to either an early cannulation group or a standard cannulation group. The early cannulation group includes those patients that were cannulated in 3 to 5 days, while those patients in the standard cannulation group were cannulated in 10 to 14 days.

Primary Patency* at 12 months



Secondary Patency* at 12 months

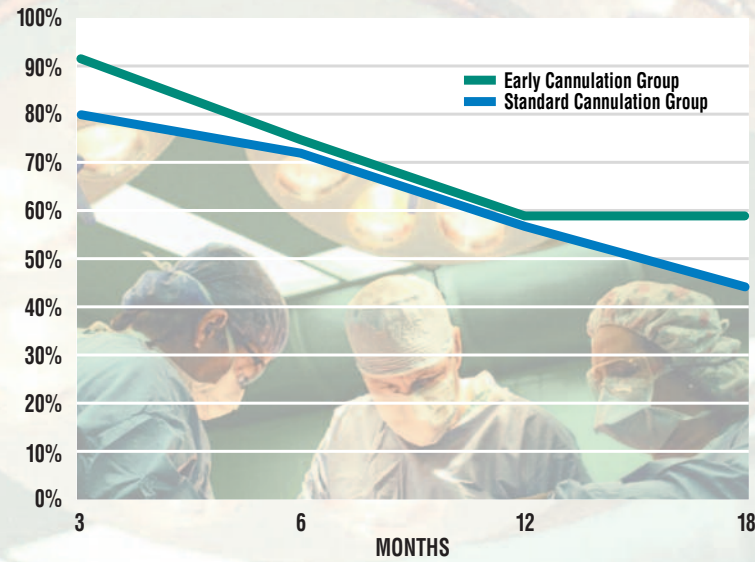


Life-Table Results

APHECS demonstrates that there was no statistical difference in access performance of the Atrium Advanta™ PTFE vascular graft, when cannulated within 3 to 5 days of implantation compared to the standard 14 day cannulation group. At 12 months the secondary patency rate for the early cannulation group was 92%, while the standard cannulation group was 79%. These results demonstrate that early cannulation of Atrium Advanta™ PTFE vascular graft can be performed in patients requiring early dialysis access.

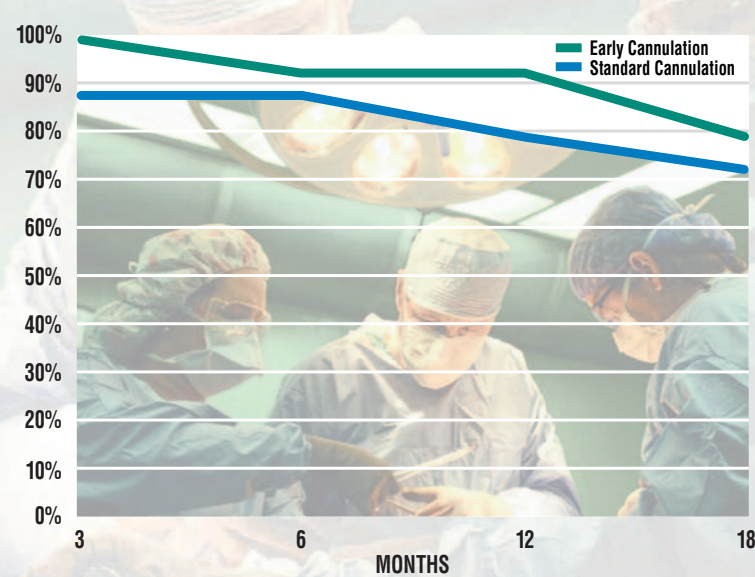
Primary Patency*

18 Month AV Access Graft Life-Table Results



Secondary Patency*

18 Month AV Access Graft Life-Table Results



Primary Patency*

Life-Table Data at 18 Months

Month	Early Cannulation Group (n=13)	Standard Cannulation Group (n=25)
3	92%	80%
6	75%	72%
12	59%	58%
18	59%	44%

p-value=.74

Secondary Patency*

Life-Table Data at 18 Months

Month	Early Cannulation Group (n=13)	Standard Cannulation Group (n=25)
3	100%	88%
6	92%	88%
12	92%	79%
18	79%	72%

p-value=.56

* Reference Robert B. Rutherford, MD, J. Dennis Baker, MD, Calvin Ernst, MD, K. Wayne Johnston, MD, John M. Porter, MD, Sam Ahn, MD, and Darrell N. Jones, PhD. Recommended standards for reports dealing with lower extremity ischemia: Revised version. (J Vasc Surg 1997;26:517-38.)



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