







PARIS, FRANCE

| DIS | sciosure |
|-----|---|
| Sp | eaker name: Miltos Lazarides, Univ. of Cyprus |
| | |
| | |
| | I have the following potential conflicts of interest to report: |
| | Consulting |
| | Employment in industry |
| | Shareholder in a healthcare company |
| | Owner of a healthcare company |
| | Other(s) |
| | I do not have any potential conflict of interest |



Chronic Hemodialysis Using Venipuncture and a Surgically Created Arteriovenous Fistula

Michael J. Brescia, M.D.[†], James E. Cimino, M.D.[‡], Kenneth Appel, M.D.[§], and Baruch J. Hurwich, M.D. N Engl J Med 1966; 275:1089-1092 November 17, 1966 DOI: 10.1056/NEJM196611172752002

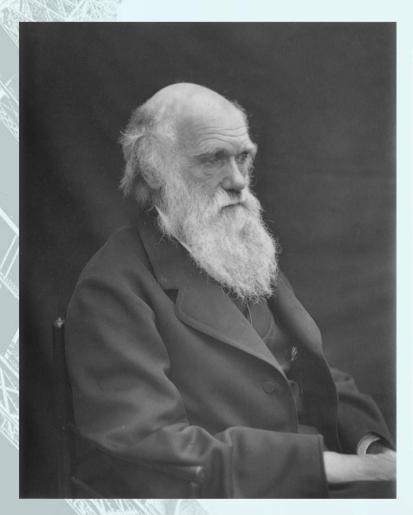


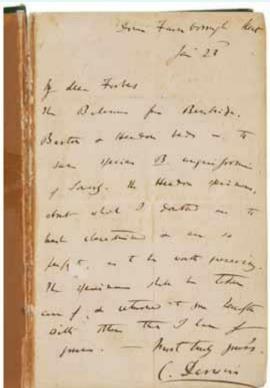


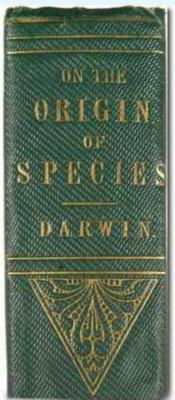


Charles Darwin (1808-1896)











Have access surgeons to change or risk becoming extinct?







The era of "minimal invasive" interventions



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Predicted percentage of vascular lesions that will be treated endovascularly by 2026



| centage |
|---------|
| 0-95 |
| 0-95 |
| 5-85 |
| 0-95 |
| 0-95 |
| 5-90 |
| 5-90 |
| 5-90 |
| 5-90 |
| 5-90 |
| 0-90 |
| 5-95 |
| |

Veith FJ, J Vasc Surg 2016



Lesions currently best treated by open surgery



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Thoracic outlet and entrapments

Some ascending aorta and arch lesions

A few unusual aneurysms

Some Takayasu lesions

Some congenital, genetic aortic, and renal artery lesions

Some infected arteries and grafts

Some recurrent or complex lower extremity lesions

Some carotid lesions

Some failed endovascular treatments

AV Fistula creation

Veith FJ, J Vasc Surg 2016



Drs. Jeffrey E. Hull and Dheerai K. Raian discuss technical concepts and ongoing research in this emerging option for hemodialysis access.



Jeffrey E. Hull, MD Radiology Associates of Richmond

Director of Richmond Vascular Center North Chesterfield, Virginia Dr. Hull has disclosed that he is Founder of and stockholder in Avenu Medical.



Dheeraj K. Rajan, MD

Head and Associate Professor Division of Vascular & Interventional Radiology Department of Medical Imaging University of Toronto, Toronto, Canada

Dr. Rajan has disclosed that he is a paid consultant and shareholder to TVA Medical. sure with fewer interventions. We are further evaluating if fistulas created using our minimally invasive technique result in a more reproducible access with improved clinical outcomes. This may translate into better quality of life for patients and may potentially reduce hemodialysis access maintenance costs.

Dr. Hull: In the United States and around the world. there is a shortage of dedicated access surgeons to create AV fistulas. The Ellipsys system (Avenu Medical) could increase the number and types of physicians capable of creating reliable fistulas to include endovascular surgeons, interventional radiologists, and interventional nephrologists. In addition to this, important goals are to improve patient care by creating and maturing fistulas quickly to reduce the time from request for fistula to usable access for dialysis, thereby reducing morbidity associated with temporary catheter access.

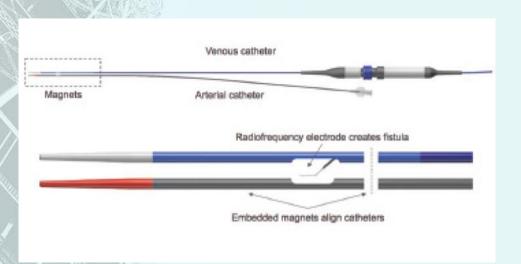


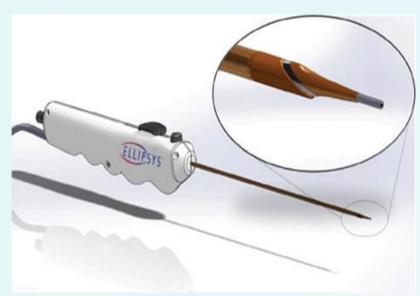






Endovascular AV Fistula





EVERLINQ SYSTEM

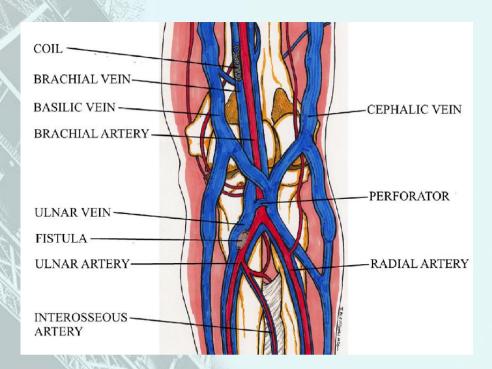
ELLIPSYS SYSTEM



Percutaneous Creation of an Arteriovenous Fistula for Hemodialysis Access

Dheeraj K. Rajan, MD, Adrian Ebner, MD, Sudhen B. Desai, MD, Jesus M. Rios, and William E. Cohn, MD





n=33
Technical success=97%
Maturation rate=96%
6mo patency rate=96%

J Vasc Interv Radiol 2015



Novel Endovascular Access Trial (NEAT)



NEAT trial shows six times fewer post-creation interventions with endovascular than with traditional surgical arteriovenous fistulae

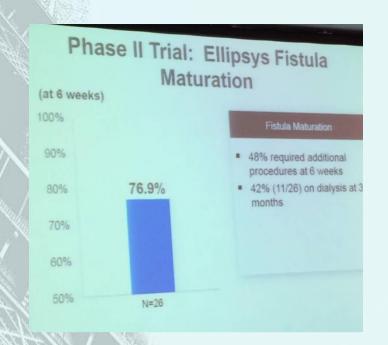


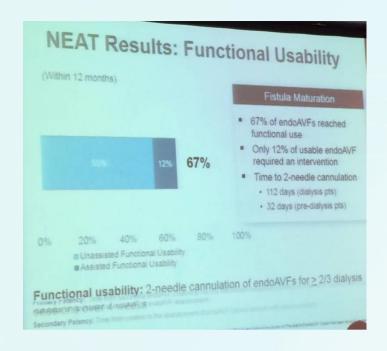
- n=80
- Technical success=99%
- At 4 weeks, the rate of thrombosis was 3.75%



Accumulating data, the results are coming down to earth







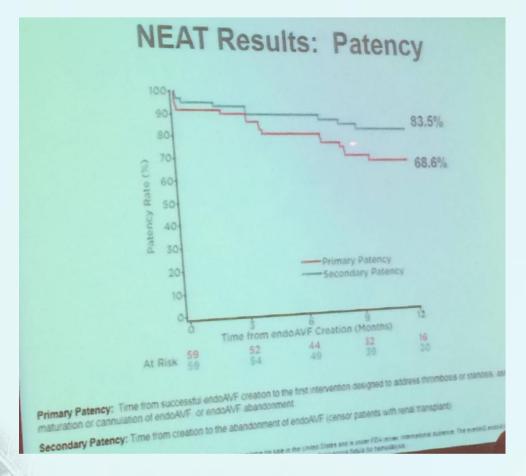
Taken from a recent presentation of Marc Glickman







Accumulating data, the results are coming down to earth



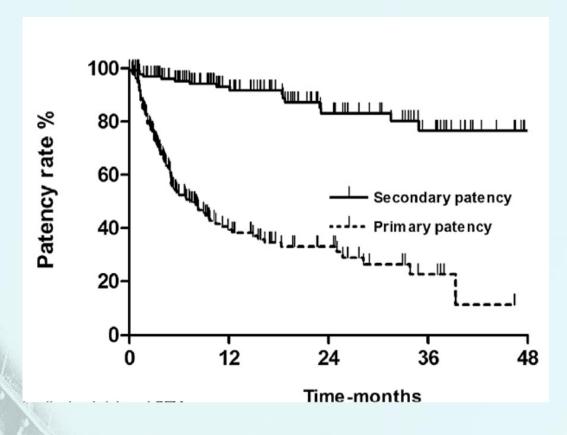
Taken from a recent presentation of Marc Glickman





Patency of surgically created AVFs

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Olsha O et al, J Vasc Surg 2015



The prerequisites of a successful innovation









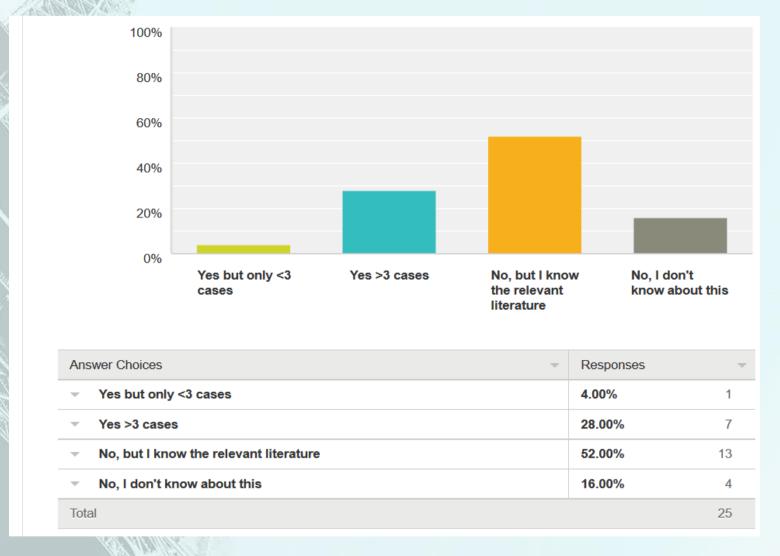
What is the view of experts?

65 members of the EB of J Vasc Access were contacted by e-mail (using the software SURVEYMONKEY ®)



CONTROVERSIES & UPDATES IN VASCULAR SURGERY

Do you have personal experience in creating/maintaining an endovascular AVF? ANUARY CARRIED TRAVESCULAR AVF

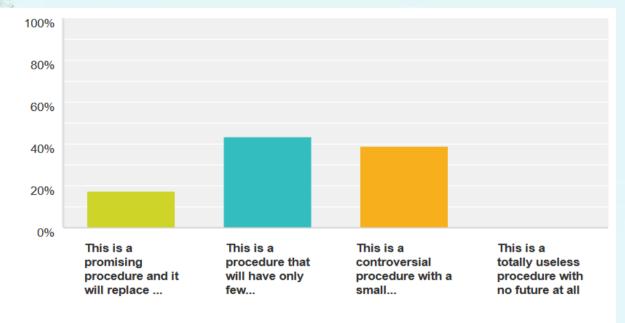




CONTROVERSES ET ACTUALITES EN CHIRURGIE VASCULAIRE CONTROVERSIES & UPDATES IN VASCULAR SURGERY

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What is your view about the endovascular AV Fistula creation?



| Ans | swer Choices | Respons | es ¬ |
|-------|--|---------|------|
| • | This is a promising procedure and it will replace in the future the open surgical AV Fistula | 17.39% | 4 |
| _ | This is a procedure that will have only few indicationsand will partially replace the open AV Fistula | 43.48% | 10 |
| • | This is a controversial procedure with a small possibility to replace in the future the open surgical AV Fistula | 39.13% | 9 |
| • | This is a totally useless procedure with no future at all | 0.00% | 0 |
| Total | | | 23 |



The view of those having personal experience with endo-AVF



What is your view about the endovascular AV Fistula creation?

Answered: 8 Skipped: 0

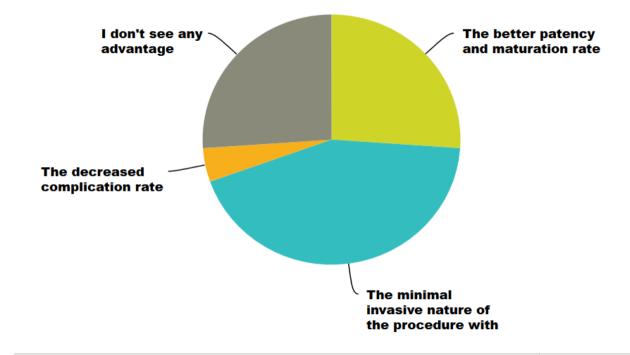




CONTROVERSES ET ACTUALITÉS EN CHIRURGIE VASCULAIRE
CONTROVERSIES & UPDATES
IN VASCULAR SURGERY

What will be in your view the main advantage of the endovascular AV Fistula?

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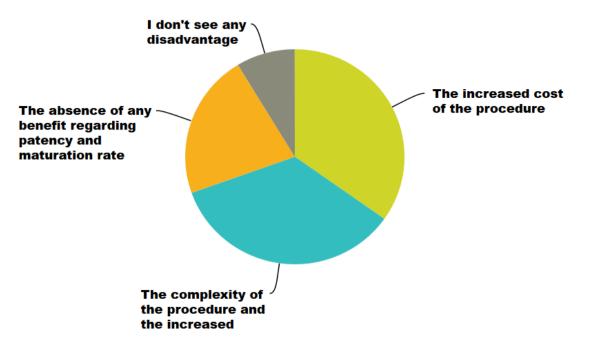
| Answer Choices | | es · |
|--|--------|------|
| The better patency and maturation rate | 26.09% | 6 |
| The minimal invasive nature of the procedure with no incisions and scars | 43.48% | 10 |
| The decreased complication rate | 4.35% | 1 |
| ▼ I don't see any advantage | 26.09% | 6 |
| Total | | 23 |



CONTROVERSIES & UPDATES IN VASCULAR SURGERY

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What will be in your view the main disadvantage of the endovascular AVF?



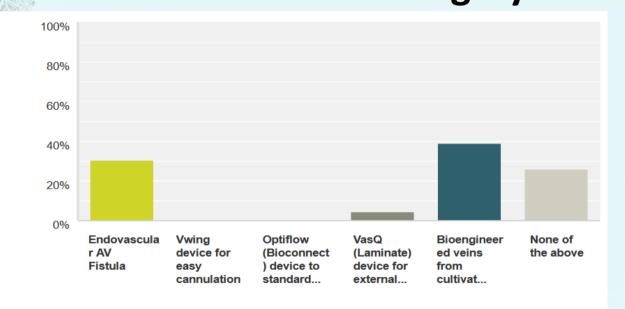
| Answer Choices | | es 🔻 |
|---|--------|------|
| The increased cost of the procedure | 34.78% | 8 |
| The complexity of the procedure and the increased learning curve needed | 34.78% | 8 |
| The absence of any benefit regarding patency and maturation rate | 21.74% | 5 |
| ▼ I don't see any disadvantage | 8.70% | 2 |
| Total | | 23 |



CONTROVERSES ET ACTUALITES EN CHIRURGIE VASCULAIRE
CONTROVERSIES & UPDATES
IN VASCULAR SURGERY



What is in your view the most promising new innovation in access surgery?

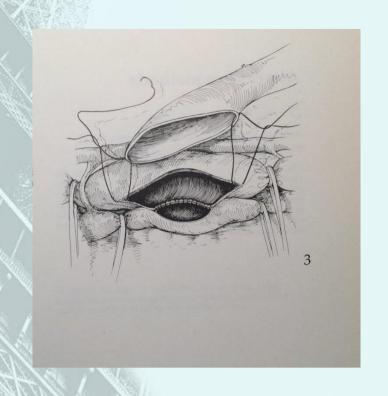


| Answer Choices | | Responses | s • |
|----------------|--|-----------|-----|
| _ | Endovascular AV Fistula | 30.43% | 7 |
| • | Vwing device for easy cannulation | 0.00% | 0 |
| ~ | Optiflow (Bioconnect) device to standardize the surgical AVF anastomosis | 0.00% | 0 |
| • | VasQ (Laminate) device for external support of the anastomosis | 4.35% | 1 |
| ~ | Bioengineered veins from cultivated human cells | 39.13% | 9 |
| ~ | None of the above | 26.09% | 6 |
| Total | | | 23 |



Adjuvant AV fistula at the distal anastomosis of a fem-pop bypass graft









If you have a hammer everything looks like a nail









Conclusions:

- Endovascular AV Fistulas <u>will not</u> replace the surgically created AVFs
- Endovascular AV Fistulas are here to stay and they will have indication in subgroups of ESRD patients
- Endovascular AV Fistulas will find application and in other areas of vascular surgery







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