

Early Cannulation of A New Prosthetic Graft in AV Access

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Disclosures

- Consultant and speaker for Atrium Medical Corp.
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Vascular Access

- We are in favor of the Fistula First Initiative, but not all patients are candidates for AV fistulae
- It has been reported that 30-60% (JAMA) of AV fistulae never mature or are able to be cannulated
- For those patients who cannot have a fistula, we have a graft that is far superior to the alternative option: a double-lumen cuffed catheter

The Ideal Vascular Access Graft

- Never clots
- Never gets infected
- Easy to implant
- Easy to cannulate
- Does not bleed after cannulation
- Never forms pseudoaneurysms

It's nice to dream!!

The Attempt to Achieve an Ideal Graft

- There is a need for a graft that:
 - Decreases weeping
 - Has better incorporation
 - Can be cannulated within 24-72 hours
 - Has enhanced resistance to repeated needle sticks

What is Flixene?

- FLIXENE* is a next generation “composite graft.”
- This vascular graft has been engineered to overcome the major drawbacks of conventional grafts and is projected to become the new graft of choice.

Why Was Flixene Developed?

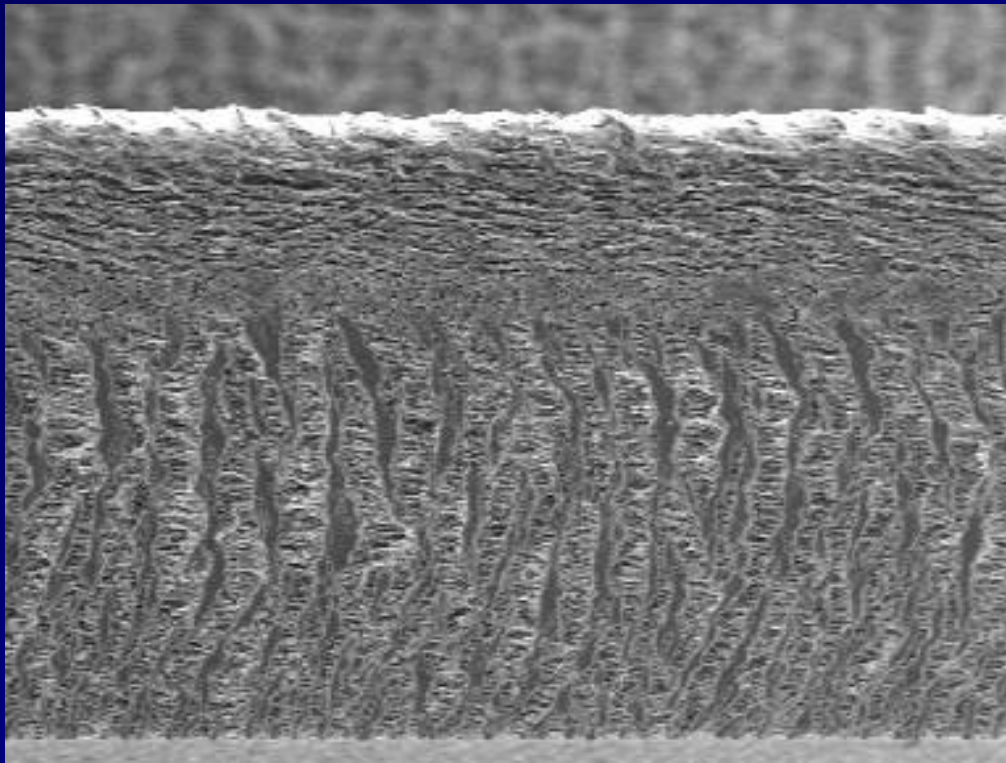
- Grafts are commonly placed in patients who have no veins available for an autologous fistula.
- Many have had multiple prior access procedures.
- Many have spent inordinate time with double lumen catheters.
- Flixene is designed specifically for these patients.

What's Unique About Flixene?

- FLIXENE is a state-of-the-art PTFE vascular graft composed of three distinct layers.
- A layered design maximizes handling, strength, and implantation properties of the Flixene graft.

What's Unique About Flixene?

A Trilaminar Structure



- Incorporation Zone
 - 60 microns
- Flixene Membrane
 - <5 microns
- Flow Interface Zone (Hybrid Structure)
 - 60/20 design
 - Promotes rapid tissue ingrowth

Flixene: Superior Resistance

■ Compression Resistance

- More resistant than any non-helixed grafts
- More resistant than thin-wall ringed grafts

■ Kink Resistance

- Better than any non-helixed product

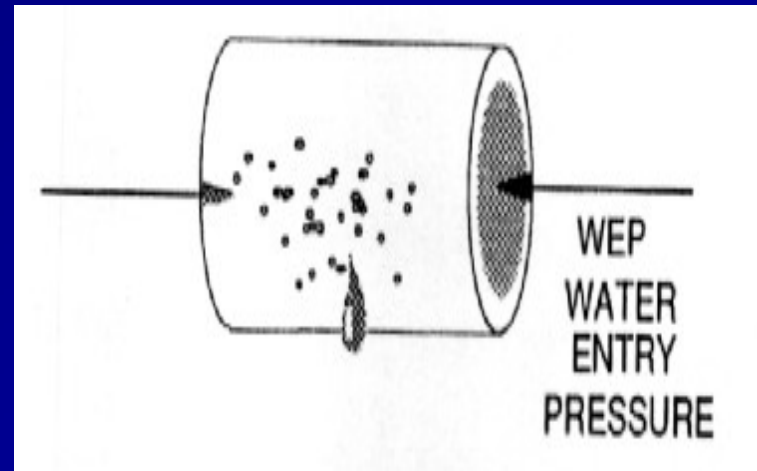
■ Torque Resistance

- Equal to the best in the industry



Flixene: Non-Weeping

- It has superior water entry pressure (WEP)
- This tends to eliminate blushing and weeping of the graft
- Benefit for Physician & Patient
 - Less likely to form seromas
 - Increases longevity of grafts and decreases need for further surgery



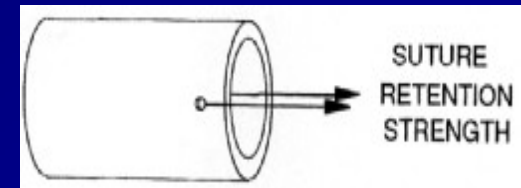
Flixene: Improved Strength

■ Extremely High Suture Retention

- 4 times greater than competition

■ Benefit For Physician

- Less suture hole elongation
- Less suture line bleeding = Less time in O.R.

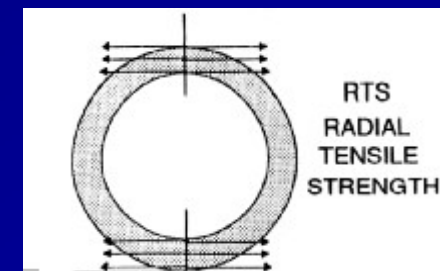


■ High Radial Tensile Strength

- Greater resistance to cannulation

■ Benefit For Physician & Patient

- Withstands repetitive cannulations
- Fewer revisions and less pseudoaneurysms



Features of Flixene

- The graft has the slider capability with a polyethylene clear, slide sheath that allows ease of tunneling
- It has a pre-attached tunneler tip that easily screws into most tunnelers
- There is also a polyethylene sheath that protects the graft from skin and other non-sterile objects (Blue Transfer Sleeve)



Flixene Study

- This was a two center study performed in Miami, FL and Portland, OR
- All grafts were cannulated within 24-72 hours
- Patients were followed for six months post-op
- All thirty-three patients successfully cannulated according to study protocol
 - 31 patients within 24 hours
 - 1 patient within 48 hours
 - 1 patient within 72 hours

Flixene Study: Protocol

- All patients:
 - 18 to 70 years old
 - Previous access failure
 - No veins available for AV fistula

In essence, the most challenging Access patients

Previous Access Type	Percentage
Central Venous Catheter	91% (30/33)
AVF	55% (18/33)
AVG	12% (4/33)

Patient Demographics

Race	Percentage of Total
African American	33% (11/33)
Caucasian	27% (9/33)
Latino	27% (9/33)
Other	12% (4/33)

Gender	Percentage of Total
Male	48% (16/33)
Female	52% (17/33)

Co-morbidities

Patient Co-morbidities	Percentage of Total
Hypertension	96% (32/33)
Diabetes	60% (20/33)
Hypertension and Diabetes	60% (20/33)
Neither	1% (1/33)

Graft Locations

■ Arteries

- Brachial - 30
- Radial - 1
- Axillary - 2

■ Veins

- Basilic - 15
- Cephalic - 9
- Axillary – 9

Complications

Complications	Percentage of Total
Thrombosis	8 (26%)
Hematoma	5 (16%)
Graft Infection	2 (6%)
Steal Syndrome	2 (6%)
Seroma	0 (0%)
Aneurysm	0 (0%)

Cause of Primary Failures

■ Infections	3
■ Occlusion/Thrombosis	11
■ Stenosis	3

Primary Patency Results

Interval Months	Number at Risk	Failed	Timed Out	Effective Sample Size	Interval Patency	Cummulative Patency
0-1 Month	33	3	1	32.5	91%	91% 1-month
1-3 Month	29	7	0	29	76%	69% 3-month
3-6 Month	22	6	3	20.5	71%	49% 6-month

■ Overall primary patency at six months was 49%

Primary Assisted Patency Results

Interval Months	Number at Risk	Failed	Not Yet Reached Follow-up Time Point	Effective Sample Size	Interval Patency	Cumulative Patency
0-1 Month	33	1	2	32	97%	97% 1-month
1-3 Month	30	1	0	30	97%	94% 3-month
3-6 Month	29	4	5	26.5	85%	80% 6-month

■ Overall primary-assisted patency at six months was 80%

Previous AV Graft Studies

- Current results in line with previous clinical trials.

Author	Patency Rate	Type	Time Period
Glickman et al, 2001	47%-55%	Primary	6-months
Didlake et al, 1994	60%	Primary	6-months
Katzman et al, 1999	58%-60%	Primary	6-months
Schild et al, 2004	42%-75%	Primary	6-months
Glickman, et al. 2001	87%-90%	Secondary	6-months
Katzman, et al. 1999	79%-81%	Secondary	6-months
Schild et al, 1996	88%-92%	Secondary	6-months

Grafts After Six Months



Summary

- Flixene was designed with the most complex and challenging dialysis patients in mind
- Its layered design helps to minimize weeping
- The graft also boasts excellent kink and compression resistance
- Early cannulation can successfully be achieved within 24-72 hours after access surgery

Summary:

- Decreased graft complications such as seromas and pseudoaneurysms
- Early cannulation is perhaps the greatest advantage for AV grafts
- This decreases the time and need for double-lumen cuffed catheter use and its associated complications

Conclusions

- 100% of Study patients were safely cannulated within 24-72 hours
- The majority of complications were typical of AV access and not attributable to the Flixene graft
- Flixene early cannulation graft is a better last-resort option for patients who cannot receive a fistula as compared to the double-lumen cuffed catheter

Thank You

