



New Deep Valve Choices 2018: Do We Really Need This? The Holy Grail?

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Disclosures

- Medtronic Inc. – Scientific Advisory Board
- Vascular Insights – Scientific Advisory Board
- Le Maitre Inc. – Consultant
- Hancock-Jaffe Laboratories - Consultant



Holy Grail: Worth Seeking?

- Chretien de Troyes –Conte de Graal (Story of the Grail)
1180
- King Arthur – *Fisher King* needed Holy Grail to be healed
- C4 – C6 need a functioning deep valve to be healed
- Good enough for King Arthur, good enough for me

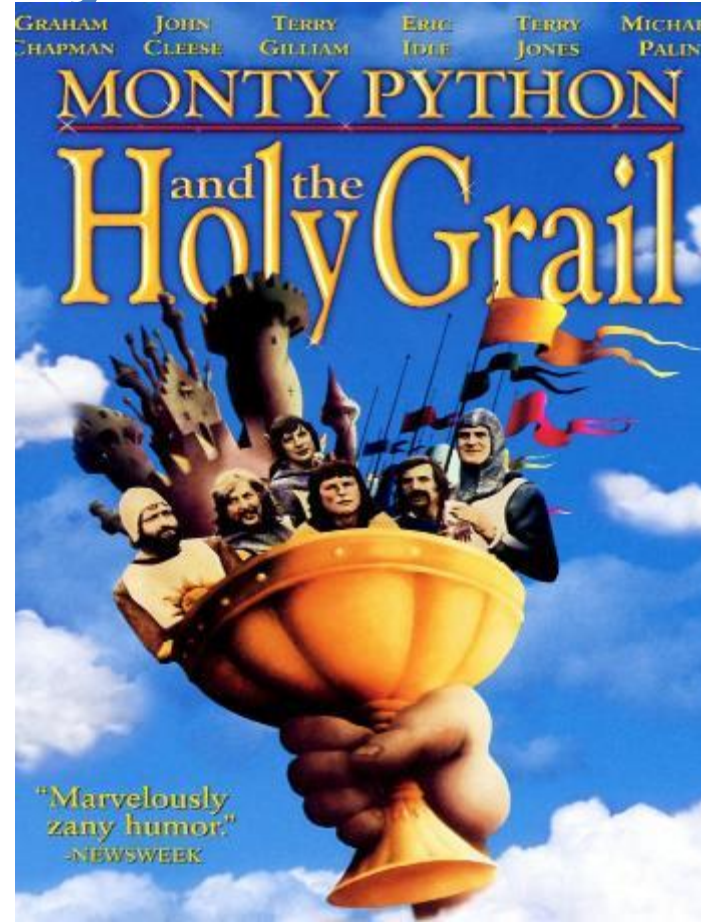


The Holy Grail: A Simple Vessel To Collect The Blood of Christ





Good Enough For These Guys: Monty Python and the Holy Grail





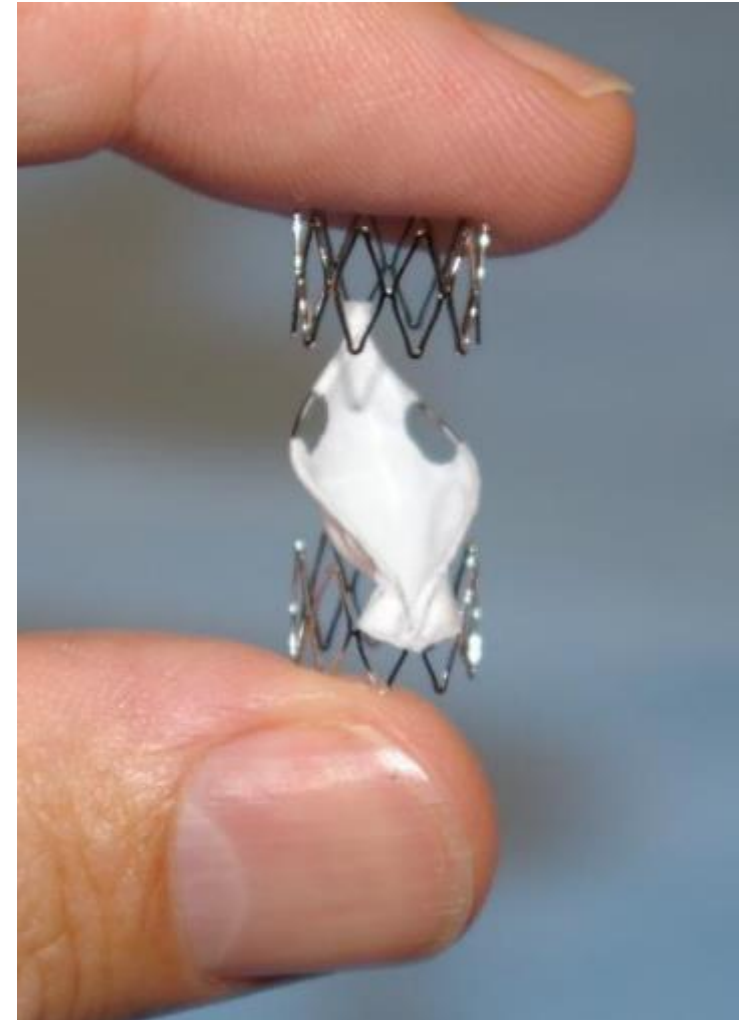
Valve Options 2018

| | INDICATION | VALVE TYPE | INSERTION |
|---------------------------|------------|-------------------------|-----------|
| VALVOPLASTY | PRIMARY | BICUSP | OPEN |
| VALVE TRANSPLANT | SECONDARY | BICUSP | OPEN |
| NEOVALVE | SECONDARY | MONOCUSP (BICUSPID) | OPEN |
| SAIL VALVE | SECONDARY | MONOCUSP (DIFFERENT) | PERC |
| BLUELEAF/INTERVENE | SECONDARY | MONOCUSP | PERC |
| VENOVALVE | SECONDARY | MONOCUSP | OPEN |



#1 - Sail Valve

- Percutaneous
- Monocusp – sort of
- PTFE
- Physiologic leak





Sail Valve Study

- Iliac veins – 10 pigs
- Femoral vein access – 6 Fr.
- Deployment 100% - expands to 10mm

Boersma DB et al. Proof of concept evolution of the Sail Valve self expanding deep venous valve system in a porcine model. J Endovascular Surg 2017.



Sail Valve – Results 4 weeks

- Ascending venogram – all patent
- Descending venogram 8 valves
 - 5 competent
 - 1 partial
 - 2 incompetent malposition/tilt
- Histology – no macroscopic thrombus on valve

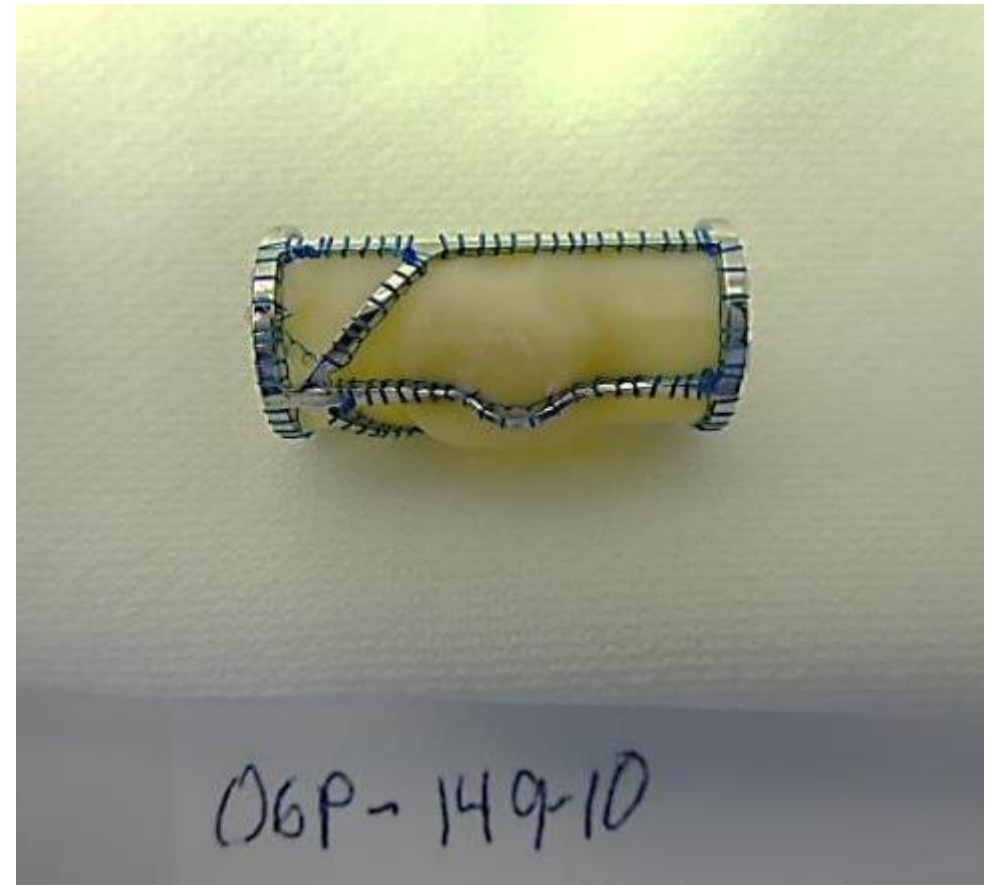


#2 - VenoValve

- Porcine derived **monocusp/open** from heart valve
- Hancock-Jaffe Labs – 20 yrs heart valves
- Can tailor inflow/outflow size mismatch*
- *Tien W-H et al. Role of vessel-to-prosthesis size mismatch in venous valve performance. JVS V&L 2017;5;105-113.

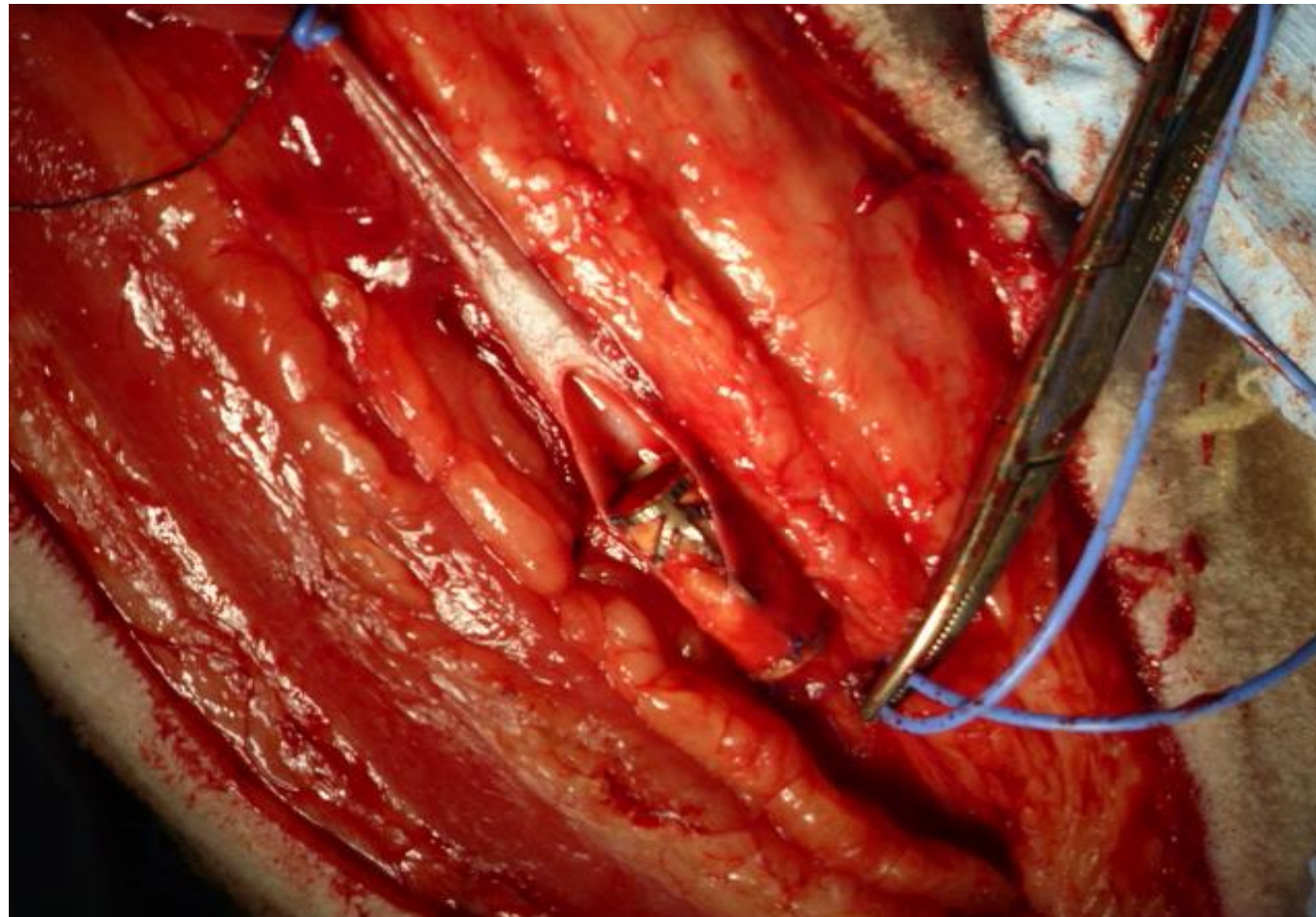


VenoValve: Percutaneous/Monocusp



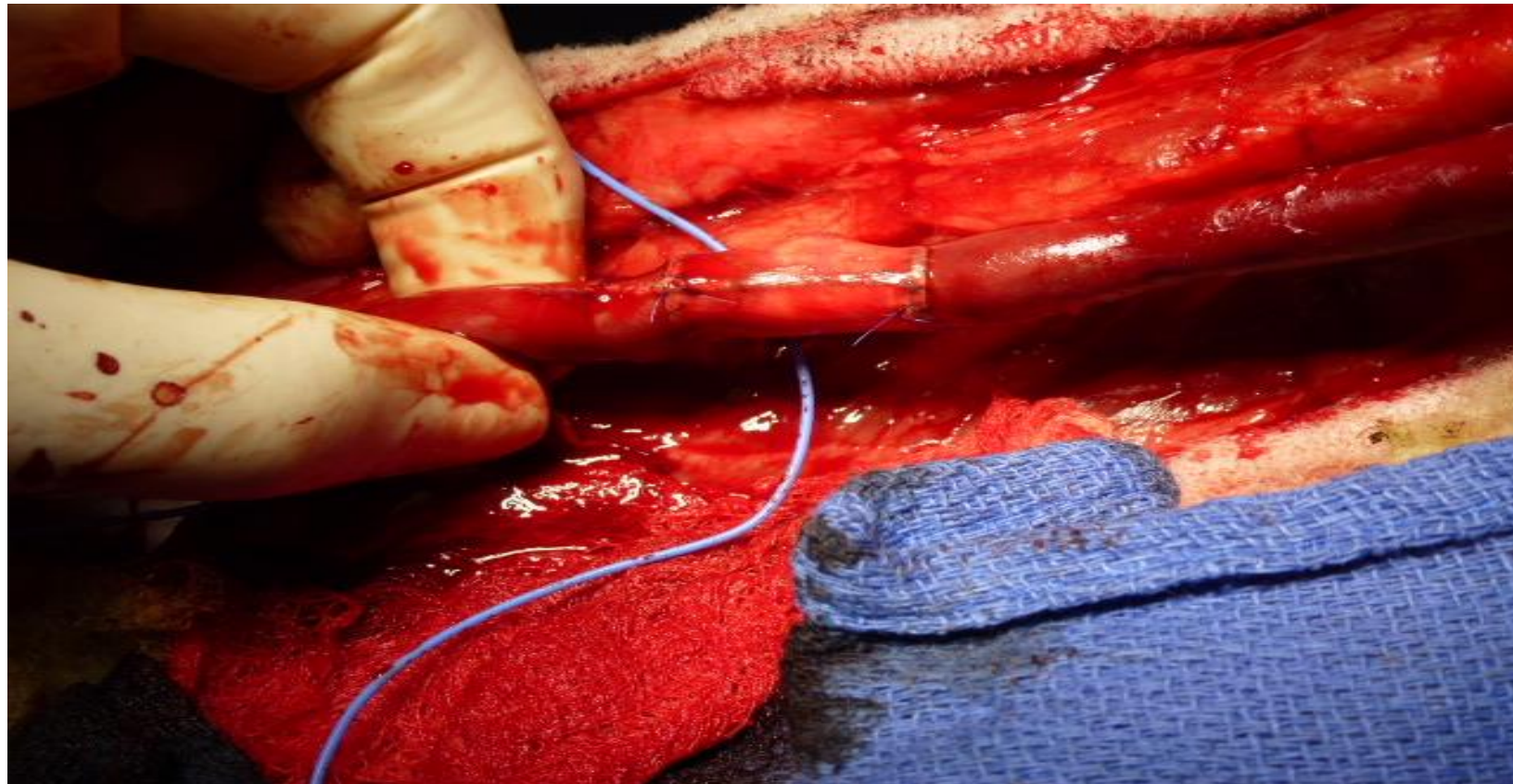


Valve implant and insertion: sheep EJV



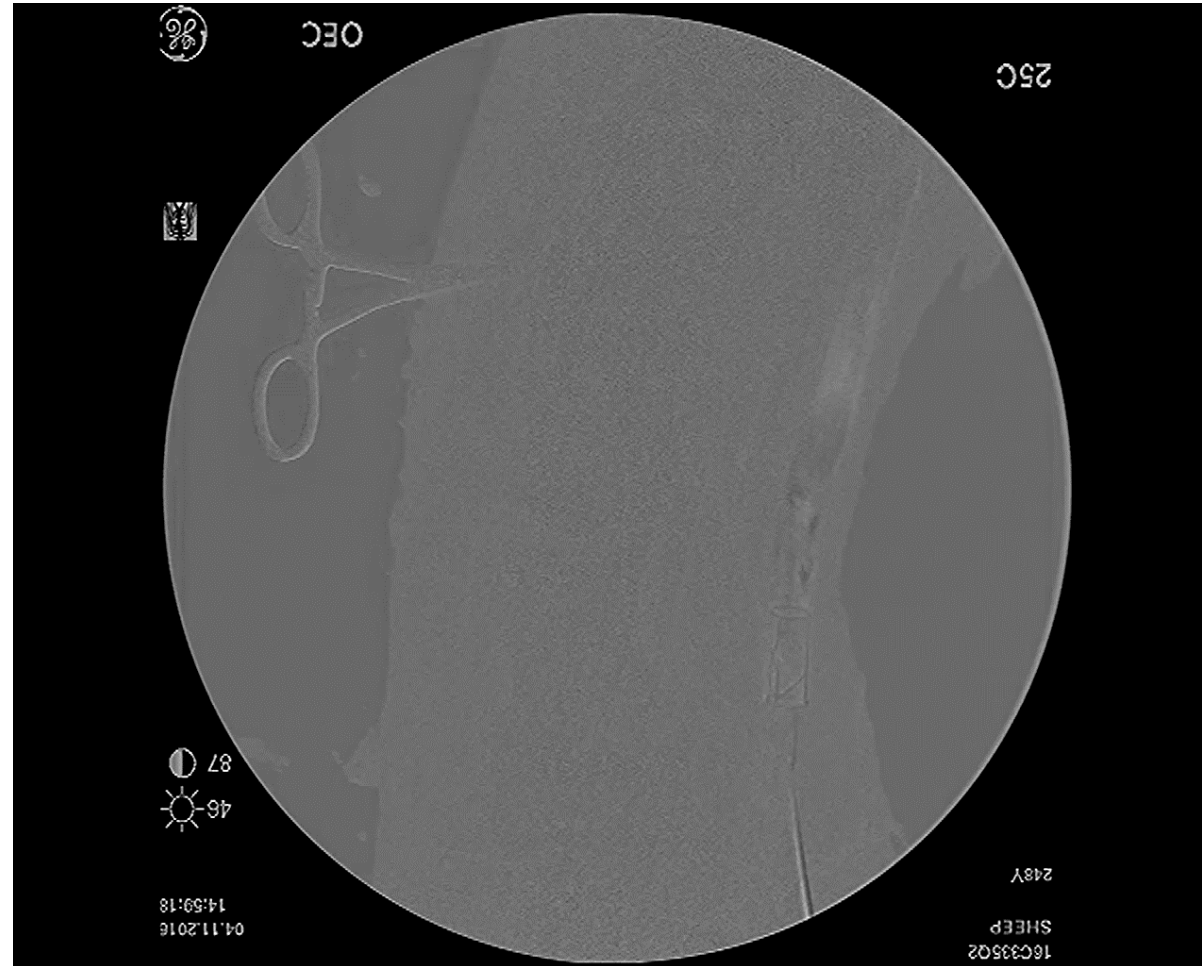


Venotomy closure and implant



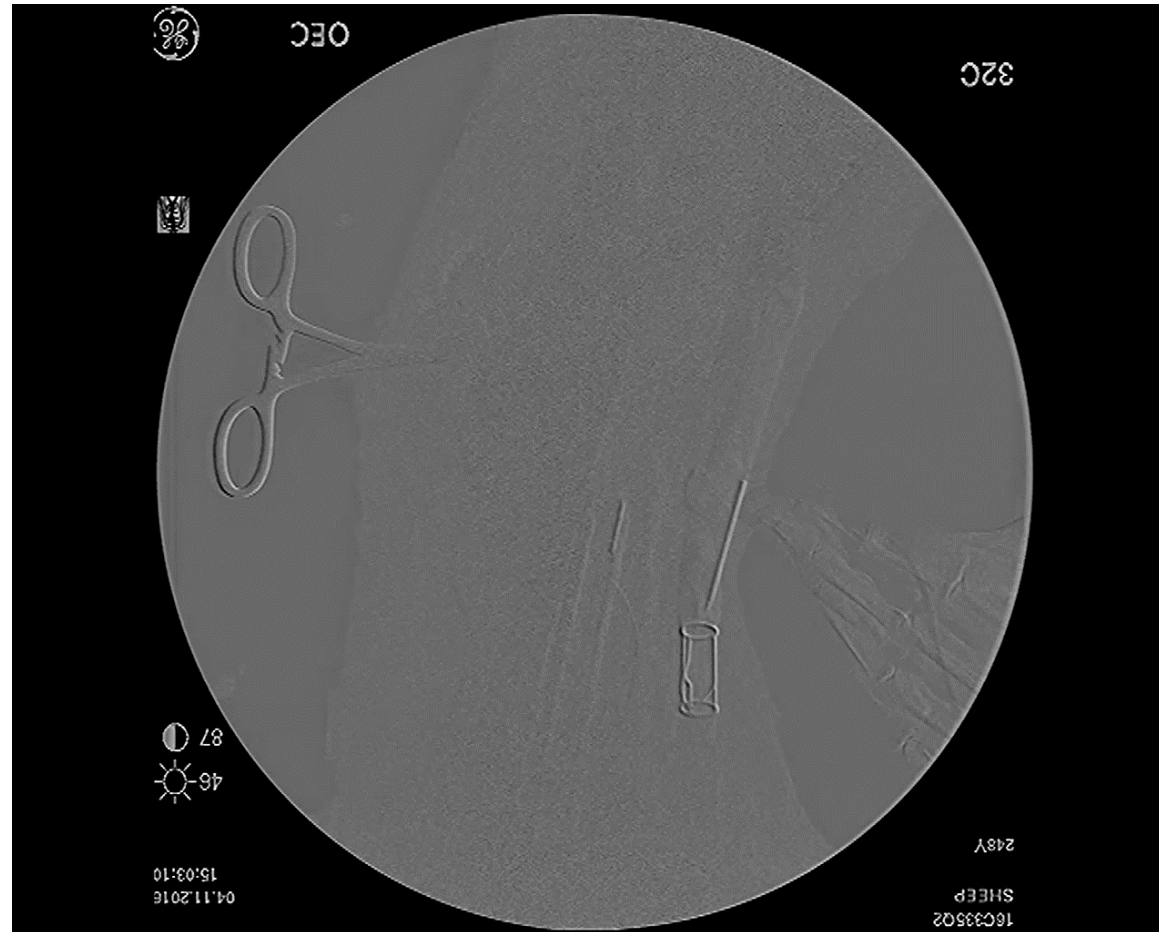


Ascending Venogram





Descending Venogram





VenoValve: Current Status

- FDA submittal – Early feasibility in man as per FDA
- FDA – sheep first 30 and 90 day results. Enoxaparin
- Feasibility trial in United States – Late 2018 C5/C6
Elias/Gasparis: Principal Investigators



Summary: VenoValve “Back to the future”

Axillary Valve Transplant – 36 years ago*

- **Monocusp** – probably better and simpler – mirrors Maleti
- **Open insertion** – allows exact placement and tailor inflow/outflow
- Better flow dynamics and less size mismatch



Challenges: Things To Think About

- Who needs this?
- Is this first line care or final line care?
- Location of placement or creation – pop, fem, or common fem? Profunda vein status?
- We've been at this for > 35 years – 1st year resident



Realistic Algorithm: C4 - C6 Patients

- Wound care and compression
- Superficial – axial/VV
- Deep – Occlusive: NIVL/TIVL (angioplasty/stent)
- Perforator – PAPS
- Deep – Reflux: Valve



Do We Really Need This?

- NO – if you don't care about a small minority
- YES – if you care about a small minority
- MAYBE – if you are a thoughtful person
- When all else has been done and still a problem



Rules To Live By

- Respect the elders
- Embrace the new
- Encourage the improbable and impractical
- Without bias
- So let's finally do this – we do need this



Good Enough For Them, Good Enough For The Right Patient



Monty Python and The Holy Grail