

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

JANUARY 19-21 2017

MARRIOTT RIVE GAUCHE & CONFERENCE CENTER

PARIS, FRANCE



The HeRO Device: Benefits, but complications

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Disclosure

Speaker name:

Mr. James Gilbert

☒ I have the following potential conflicts of interest to report:

☒ Consulting

☐ Employment in industry

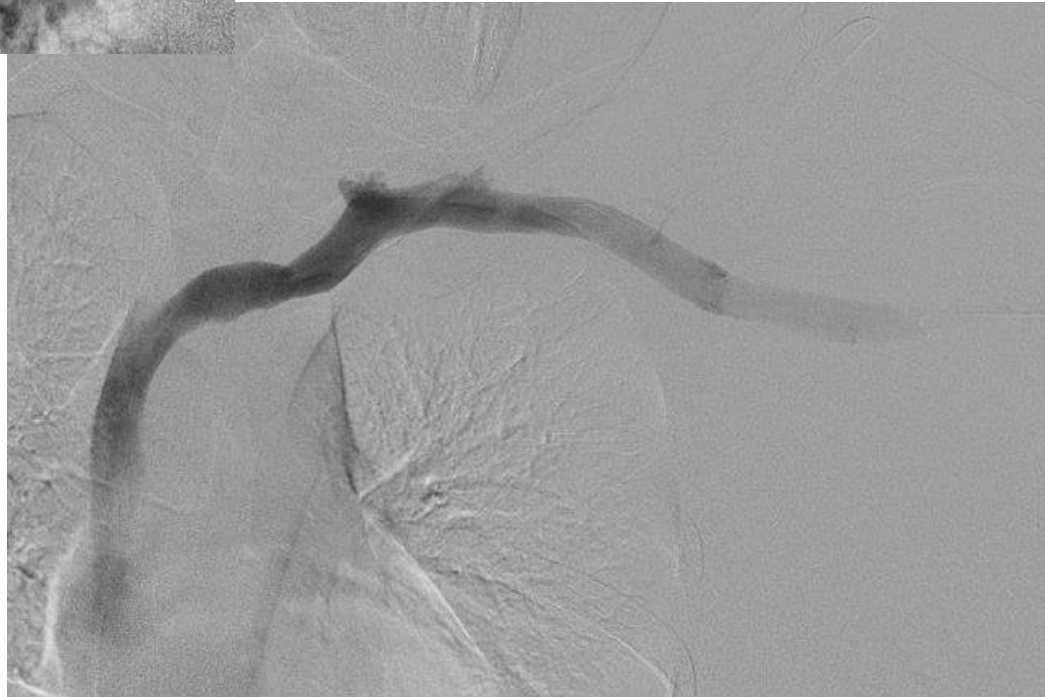
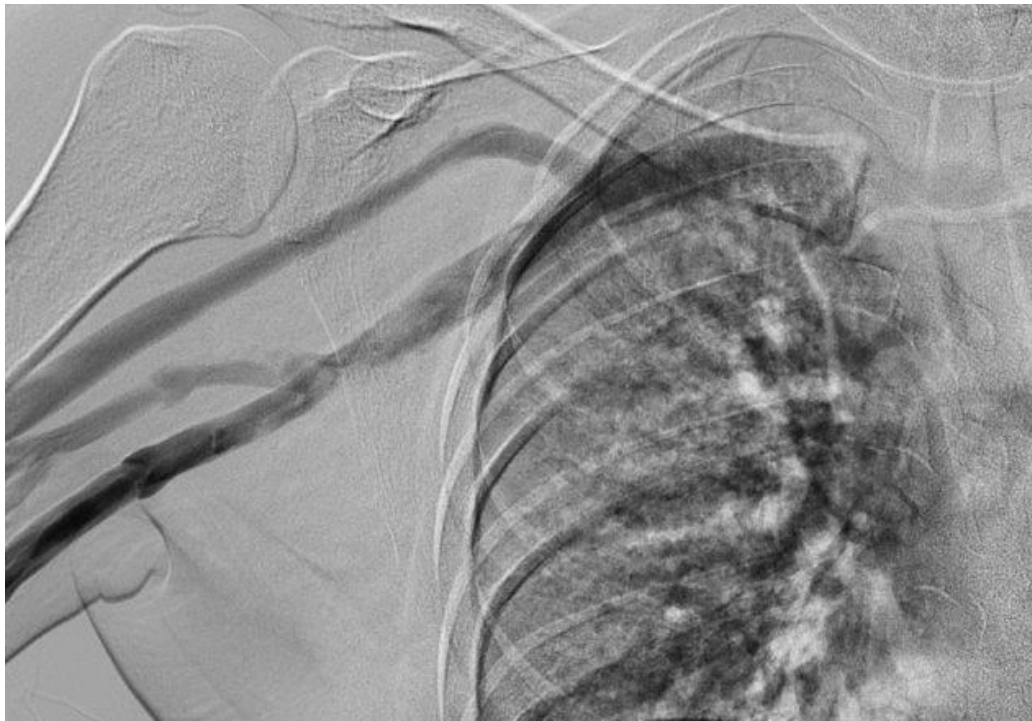
☐ Shareholder in a healthcare company

☐ Owner of a healthcare company

☐ Other(s)

☐ I do not have any potential conflict of interest

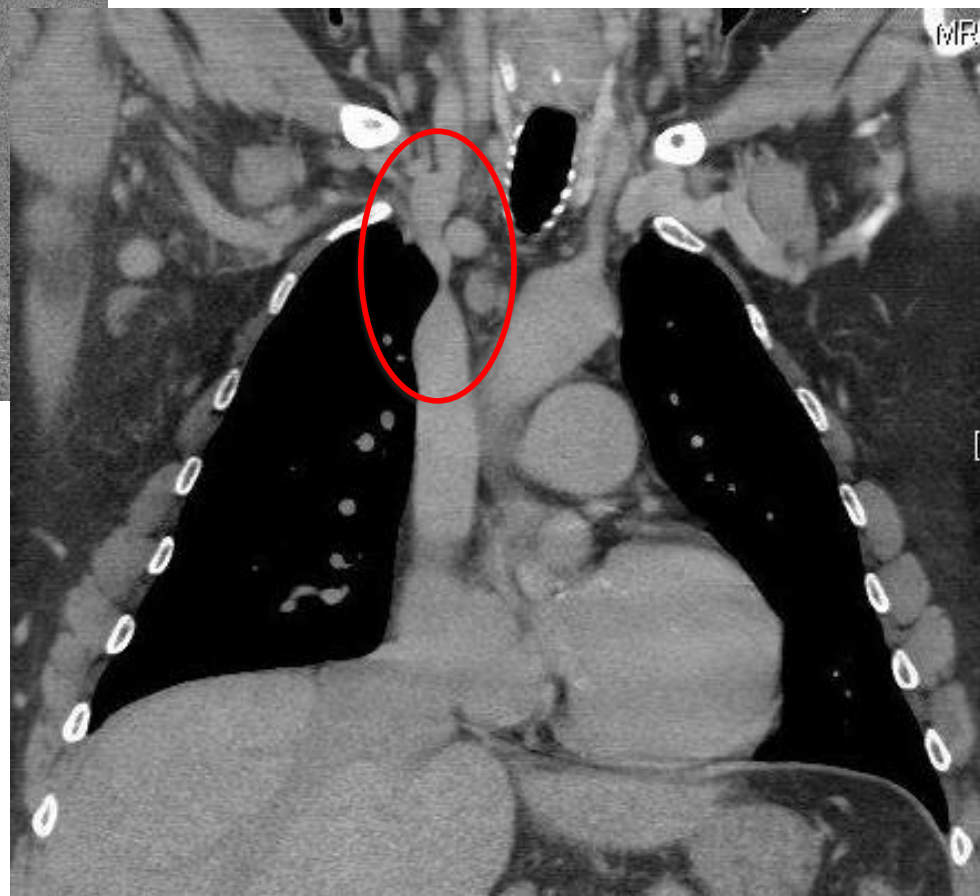
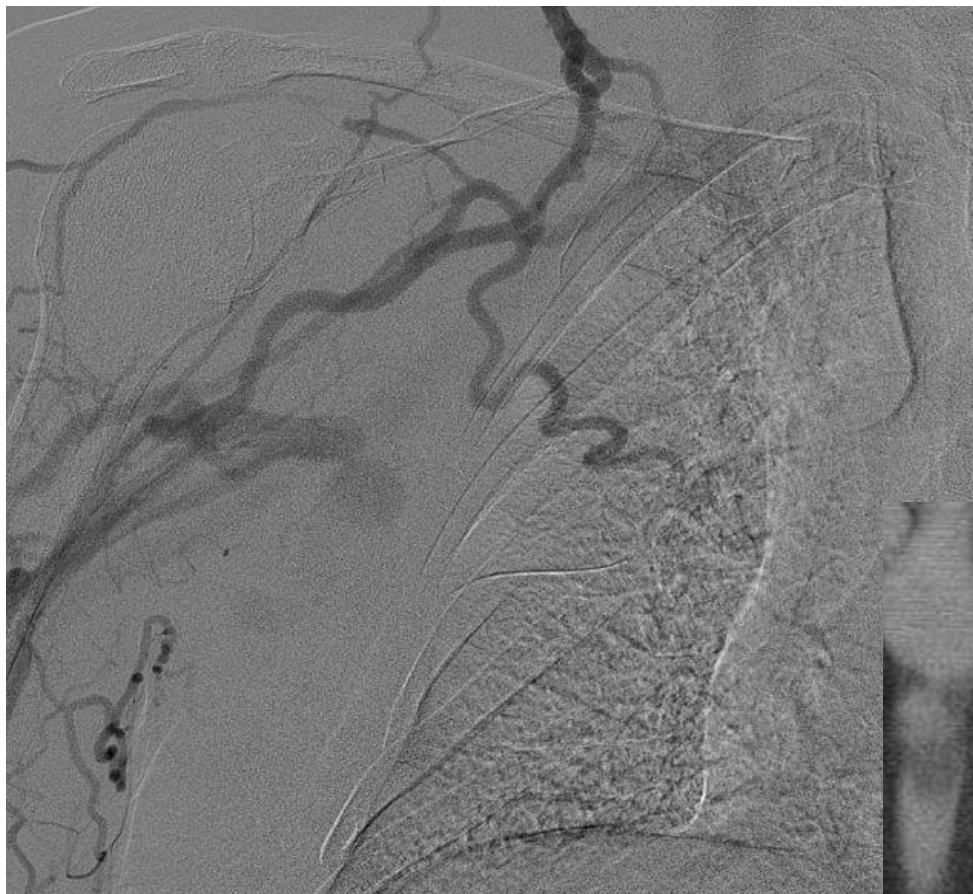




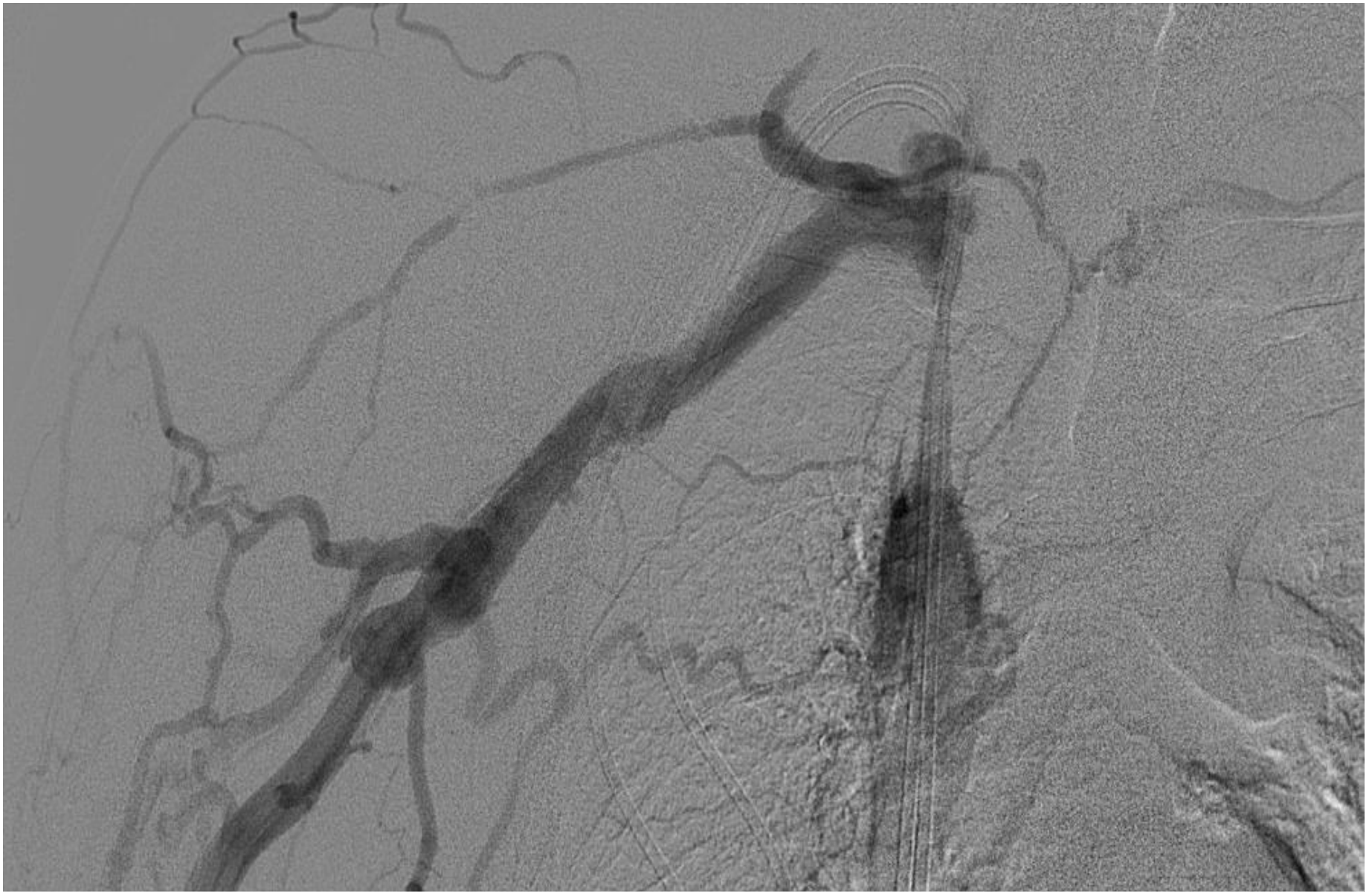


Consuming the 'real estate'

- Renal Replacement Therapy journey
 - 2 or more lines (tunneled)
 - 3 or more fistulae
 - 1-2 AV Graft(s)
 - 1-2 Transplants
- An increasing access challenge
- Especially if CVP!







15% to 25% of patients with dialysis access failure have CVS as the only identifiable hemodynamic cause *Kerlan RK, 2012*



Venous Hypertension



What could we do?

- Leave them on a line (wherever we can place one)
- Consider a ‘Heroic Intervention’

Any procedure or intervention that seeks to treat or bypass

Central Venous Pathology (CVP) to enable:

- Autologous access or grafts to function
- Treatment / prevention of venous hypertension
- Avoidance of TCC's

Heroic Options:

- Use of Lower Limbs
- Angioplasty / Stenting CVS
- Atypical / Exotic access / bypass procedures
- HeRO graft Insertion

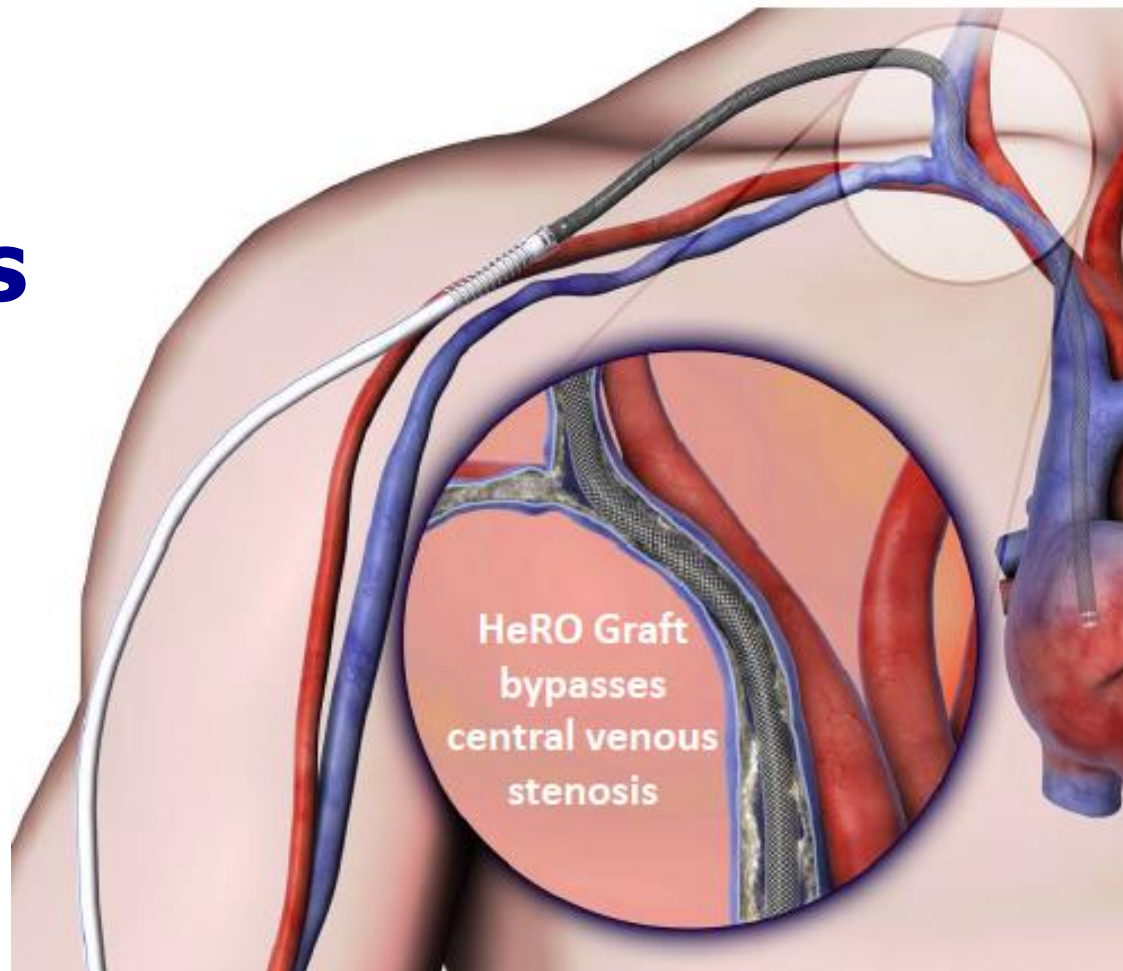




Hemodialysis

Reliable

Outflow

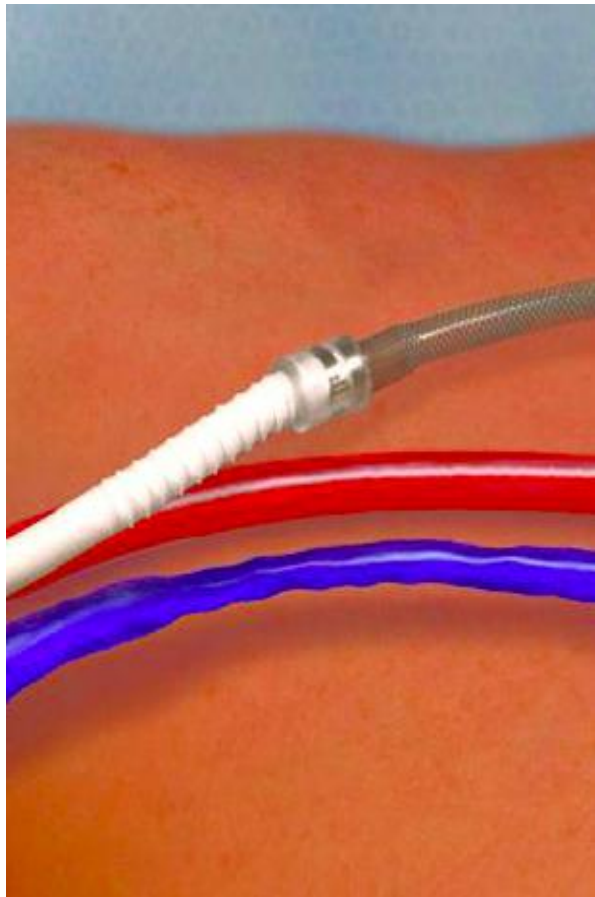
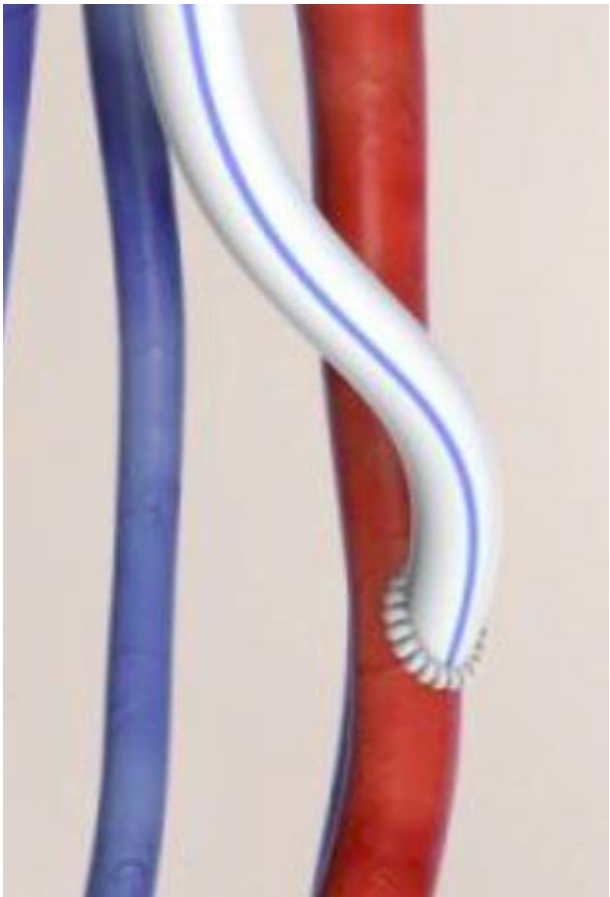


**Arterial Graft
Component**
6mm (ID) x 50cm



**Titanium
Connector**
6mm - 5mm (ID),
2.5° taper

Venous Outflow Component
5mm (ID), 6.3mm (OD), 19F (OD) x 40cm
(customizable length)



Oxford HeRO Experience

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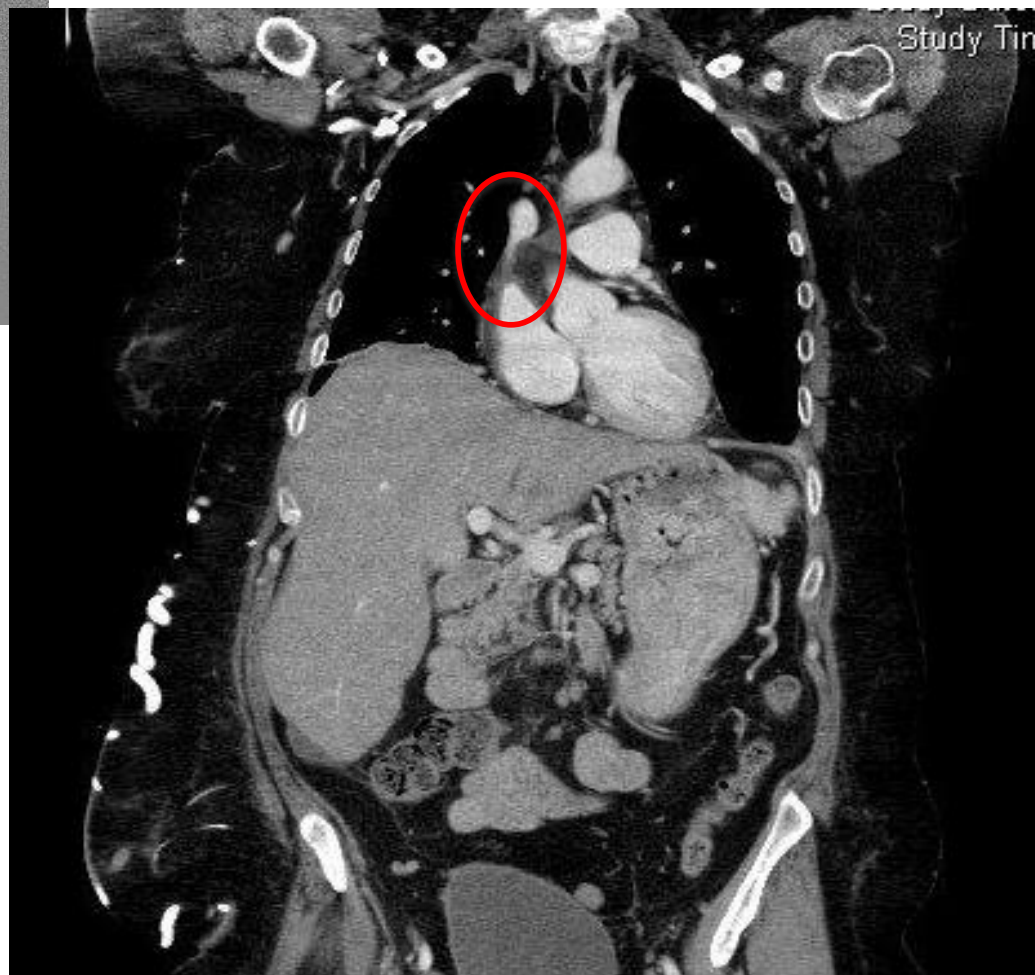
- First UK implantation July 2013
- 25 implantations to date
- FLIXENE graft used in 16 cases to enable CVC removal
- 8 cases onto existing AVF / AVG
- 1 patient with bridging PD catheter
- Bilateral venograms and CTV in all to plan atrial access
- 12 Right sided and 12 left sided implantations
- 1 left groin implantation

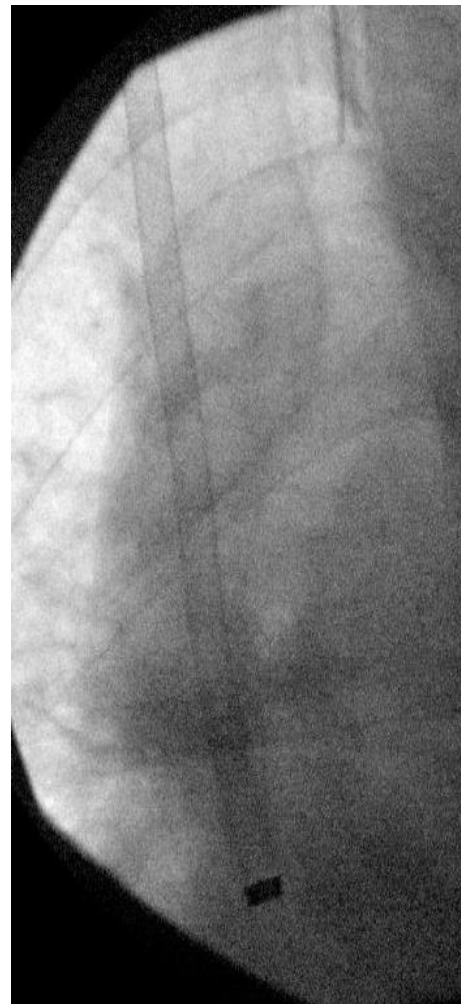
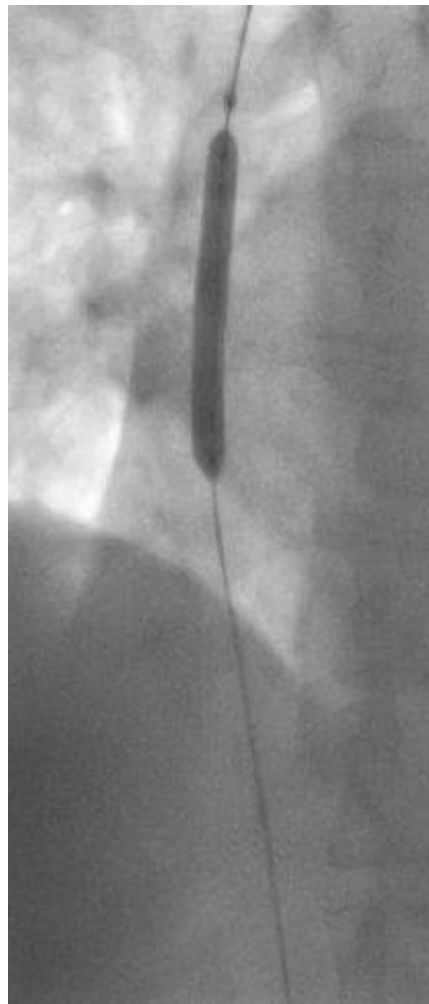


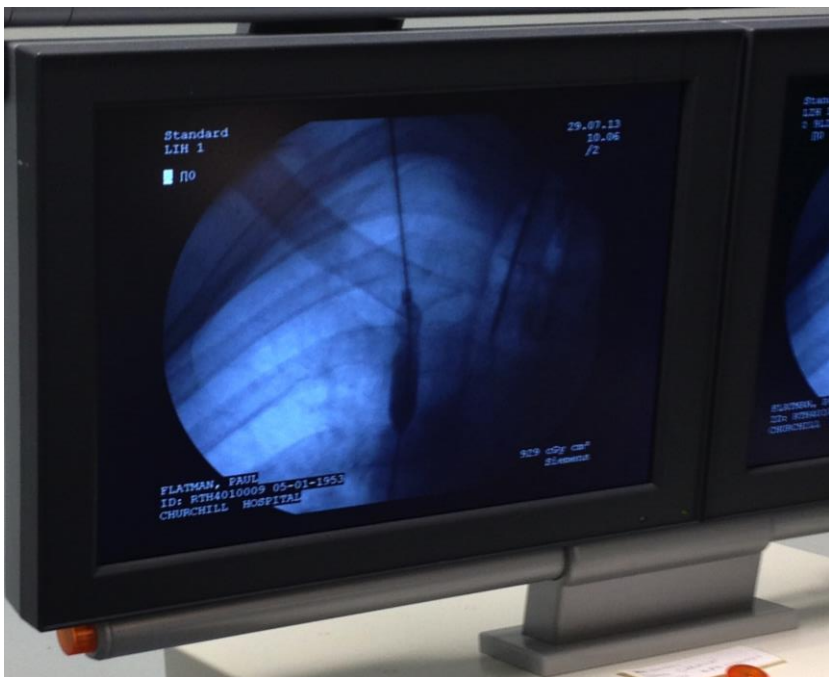
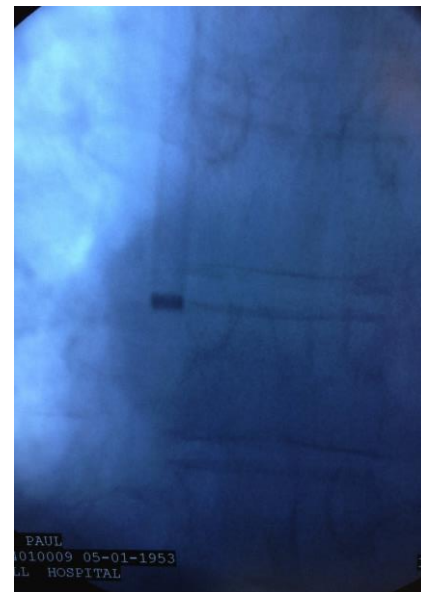
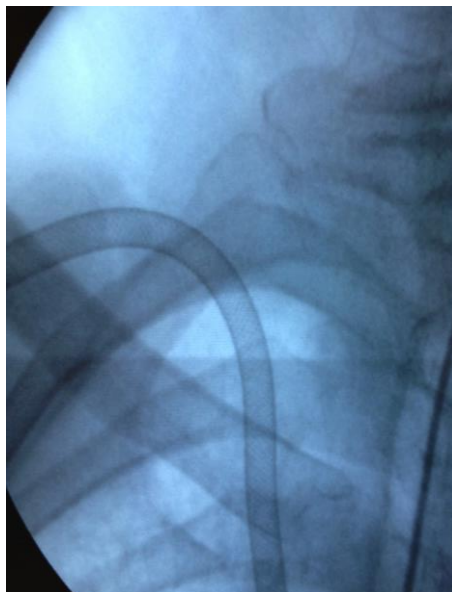
Oxford HeRO Experience

- 1 SVC recannalisation and 18 plasty to place outflow
- Teicoplanin 800mg on induction
- 20 patients beyond 6 months 14 patients beyond 1 year
- 3 patients DWFG in first year (due to other causes)
- Censored 1 year primary patency 54%
- Censored 1 year secondary patency 91%
- 1.2 interventions per patient in first year
- 1 needle site abscess but No bacteraemia













But what are the benefits and complications?

Clinical Outcomes (US data)

Clinical Outcomes	HeRO Graft Gage, et al ³	HeRO Graft Nassar, et al ²	HeRO Graft Katzman, et al ¹	Catheter Literature ¹	ePTFE Graft Literature
Bacteremia Rates (Device/Implant related Infections/1,000 days)	0.14	0.13	0.70	2.3	0.11 ⁵
Adequacy of Dialysis (mean Kt/V) [§]	Not Reported	1.6	1.7	1.18–1.46	1.37–1.62 ¹
Cumulative Patency (at 1 year)	91%	68%	72% [‡]	37%	65% ¹
Intervention Rate (per year)	1.5	2.2	2.5	5.8	1.6–2.4 ¹

[§] Note: Every 0.1 decrease in Kt/V is estimated to increase the mortality rate by 7%⁶ and is significantly ($P < 0.05$) and independently associated with 11% more hospitalisations and 12% more hospital days.⁷

[‡] 8.6 months

References

- 1) Katzman et al., J Vasc Surg 2009.
- 2) Nassar et al., Semin Dial 2014.
- 3) Gage et al., EJVES 2012.
- 4) Dageforde et al., JSR 2012.
- 5) Hajjar et al., Nephrologie 2004.

Multi-center Experience of 164 Consecutive Hemodialysis Reliable Outflow [HeRO] Graft Implants for Hemodialysis Treatment[☆]

S.M. Gage^{a,*}, H.E. Katzman^b, J.R. Ross^c, S.E. Hohmann^d, C.A. Sharpe^e, D.W. Butterly^f, J.H. Lawson^{a,g}

- Data collected from 4 large volume centres
- 2092 HeRO Months
- Mean follow up 12.2 months (0.07 -32.9 months)
- 29 Deaths during follow up period

	12 Months	24 months
Primary Patency	48.8 % (39.9 -57)	42.9% (33.3 – 52)
Secondary Patency	90.8% (84.9 – 94.4)	86.7% (78.9 -91.8)
Intervention Rates	1.5 per year (1.3 -1.67)	
Bacteraemia	0.14/1000 implant days v 2.3/1000 catheter days	

A Review on the Hemodialysis Reliable Outflow (HeRO) Graft for Haemodialysis Vascular Access

J. Al Shakarchi ^{a,b,*}, J.G. Houston ^{b,c}, R.G. Jones ^d, N. Inston ^{a,b}

esvs
European Journal of
Vascular & Endovascular Surgery

- 8 RCT's / Observational studies of 409 patients reviewed
- Primary End Point - 1 year primary & secondary patency
- Secondary End Points
 - Early Failure, Steal, Bacteraemia, Interventions

Table 2. Summary table for demographic of patients of included studies.

First author (reference)	Number of HeRO	Age	African American (%)	Male sex (%)	Diabetes (%)	Previous central catheter use (%)	Mean number of previous accesses	BMI
Katzman ⁵	38	62.7	37	50	68	100	5.4	29
Gage ⁶	164	55.9	78	49	46	NS	NS	NS
Steerman ⁷	60	58.2	88	49	61	100	3.1	32
Kokkosis ⁸	12	52	73	92	46	NS	NS	NS
Wallace ⁹	21	54.8	58	47	53	NS	2	NS
Nassar ¹⁰	52	62.9	46	46	65	NS	NS	28.9
Kudlaty ¹¹	20	57.1	91	45	60	NS	NS	29.2
Torrent ¹²	41	55	88	34	55	NS	NS	NS

NS = not specified.

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Vascular & Endovascular Surgery

esvs
Journal

- Mean Patency Rates across the 8 studies
 - Primary 21.9% (9.6 – 37.2%)
 - Secondary 59.4% (39.4 – 78%)
- Early Failure rates 9.2% (1.9 – 19.9%)
- Pooled Dialysis Access Associated Steal 6.3%
- 0.14 – 0.7 Bacteraemia / 1000 days
- 1.5 – 3 interventions per patient per year



UK & Ireland HeRO Outcomes

- Retrospective review of 52 HeRO graft placements across 9 centres from first insertion in 2013 to early 2016
- All 52 HeRO placements analysed
- Outcomes reviewed:
 - Primary and Secondary Patency
 - Infections
 - Interventions
 - HeRO Days (implant to graft loss or abandonment)



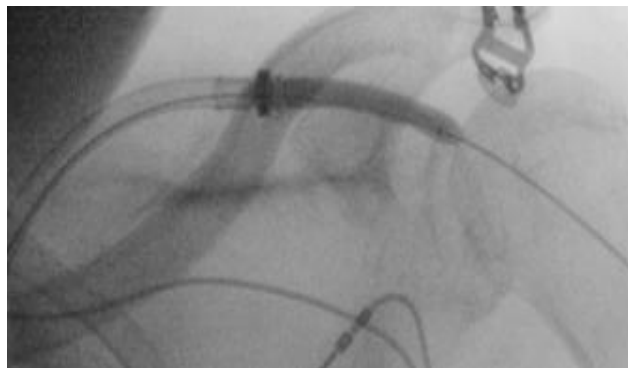
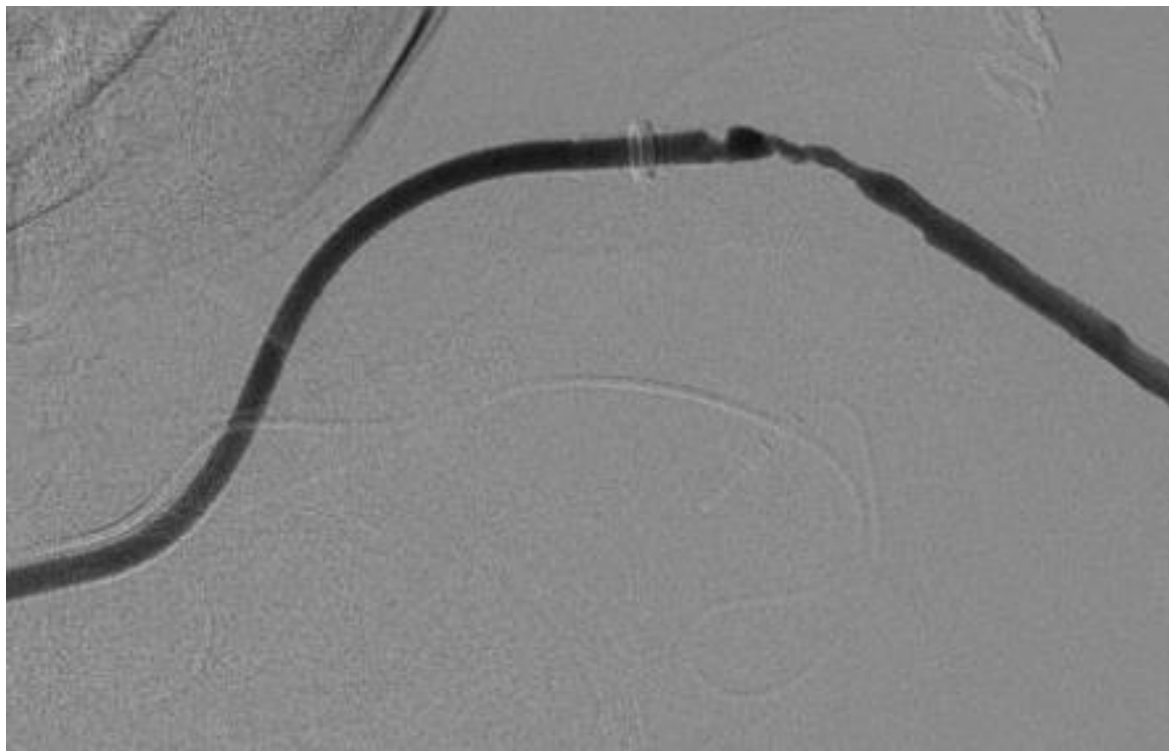
UK & Ireland HeRO Outcomes

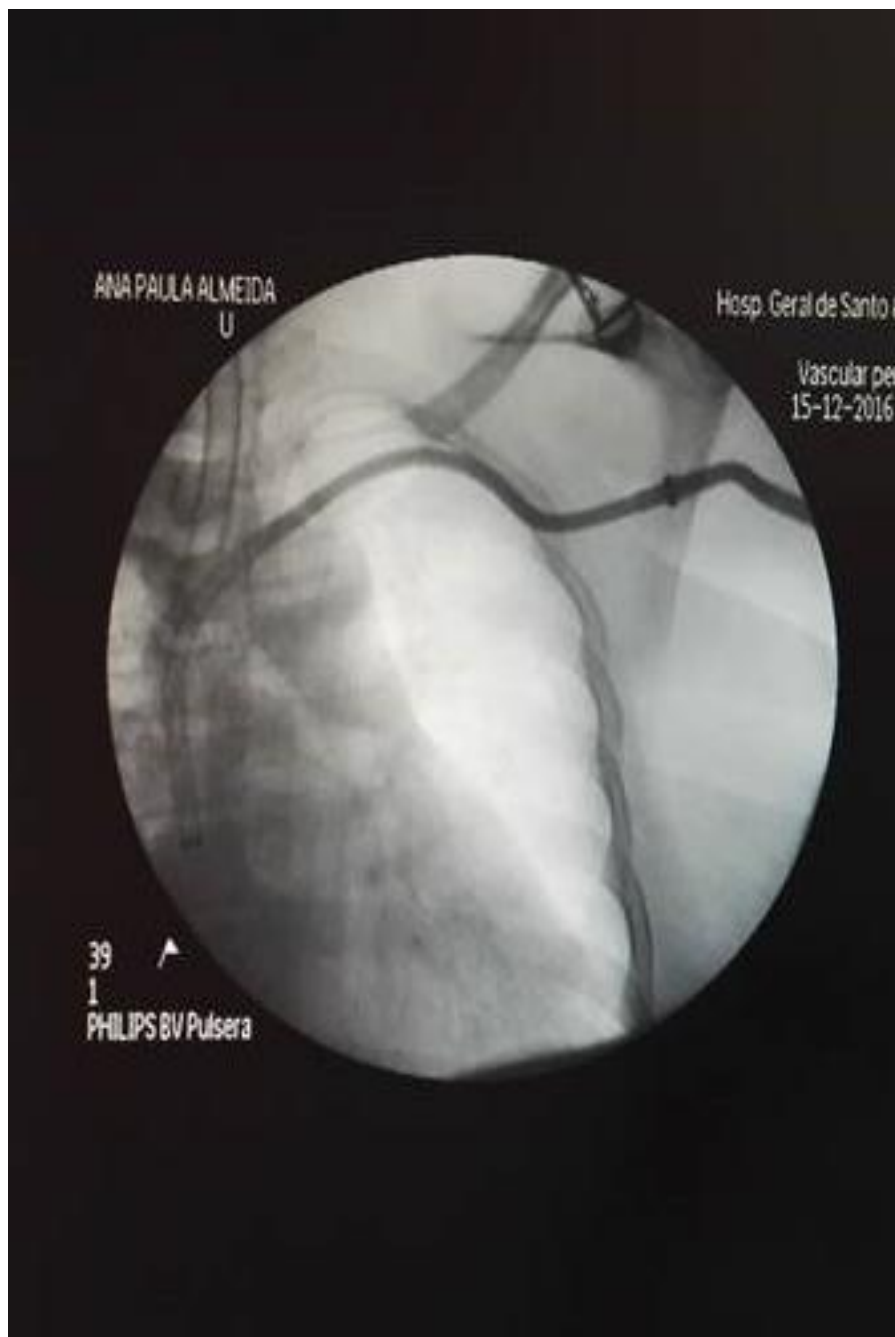
- Median follow-up 290 days (range 10-966 days)
- 622 HeRO months follow-up,
- 17,988 HeRO days
- 11 patients died with functioning graft (21%)
- Primary patency 51.2 % at 6/12 and 40.9% at 1 year
- Secondary patency 84.8% at 6/12 and **76.5% at 1 year**
- 4 infections after 30 days (2 grafts removed)
- 114 interventions to retain patency (2.2 per graft)



(Case) Reported Complications

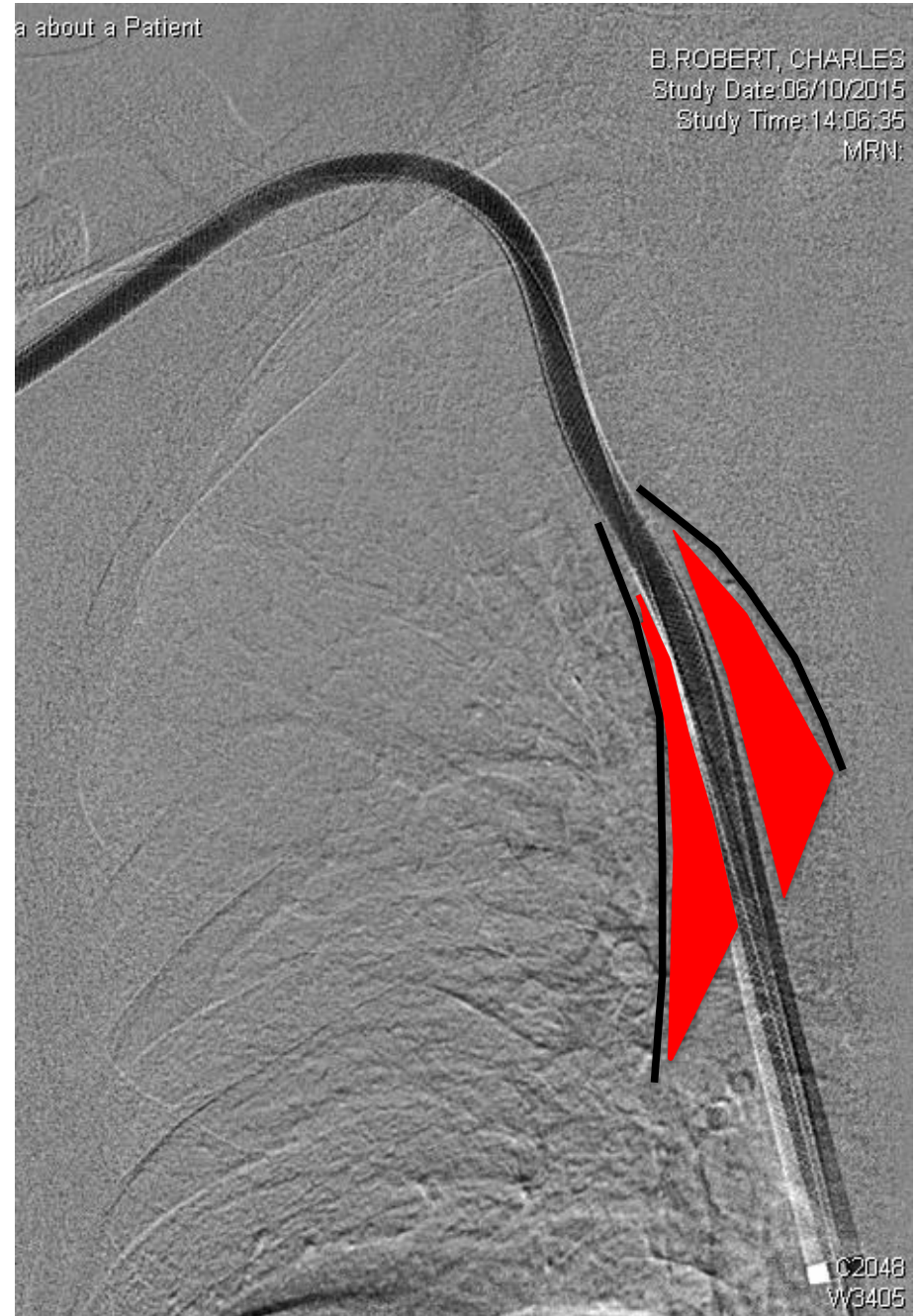
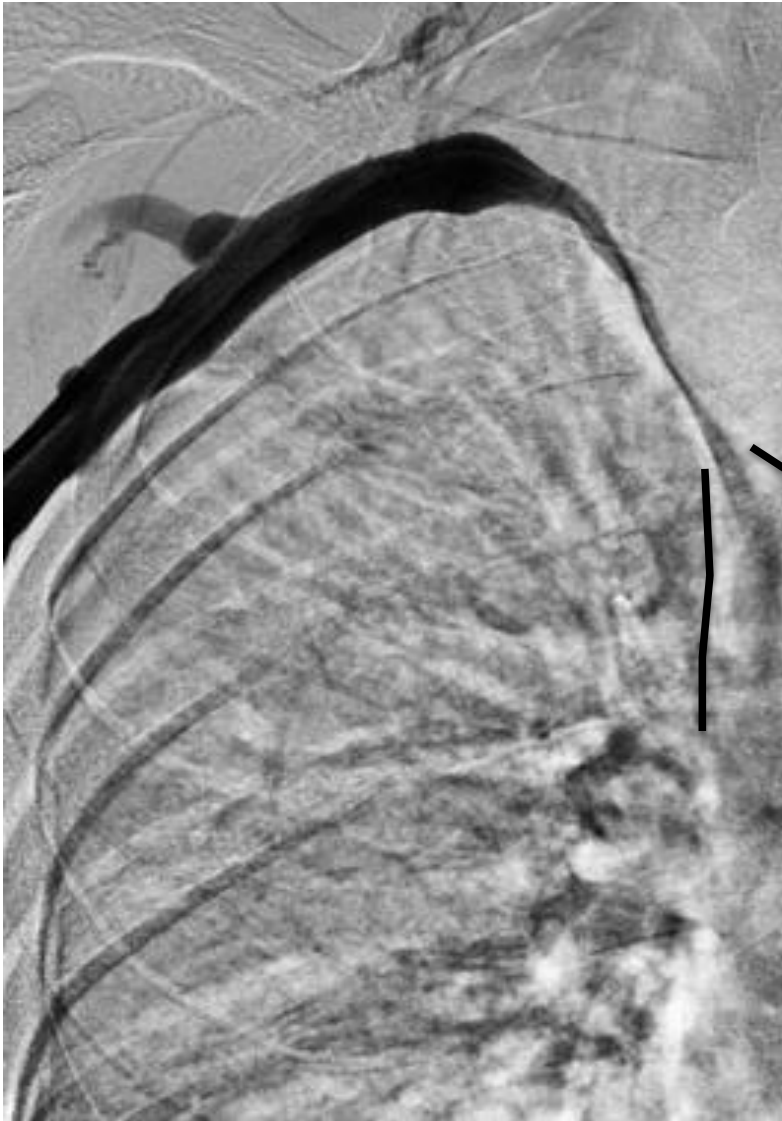
Intraoperative	Early Post Operative (<30 Days)	Long Term (>30 Days)
Central Vein Rupture	Bleeding	Thrombosis
Pneumothroax	Seroma / Haematoma	DASS
Air Embolus	Thrombosis	Infection
Wrong site Placement of Outflow component	DASS	Outflow Stent Migration (inwards and outwards)
Bleeding	Infection	Stenosis (inflow / connector)
Death		Fibrin Sheath
		Pulmonary Emboli
		Arrhythmia / Syncope





a about a Patient

B. ROBERT, CHARLES
Study Date: 08/10/2015
Study Time: 14:06:35
MRN:



102048
W3405

Not Quite a Hero (Hemodialysis Reliable Outflow Graft): A Rare Cause of Dyspnea and Positional Syncope in End Stage Renal Disease (ESRD)

Mariam Anis, MD; David Harris, MD; Jean Elwing, MD

- 43 year old male, ESRF and newly diagnosed PE
- Presented with worsening SOB and positional syncope
- Outflow component prolapsed through Tricuspid Valve into Right Ventricle
- Intermittent prolapsing as arm elevated causing syncope
- Echo = severe TR and dilated RV
- Instantaneous clinical and echo improvement after HeRO removed



Key Benefits

- Only fully subcutaneous AV device for CVP
- Increased needling surface area c/w AVF / standard AVG
- Reliable venous outflow as central and no anastomosis
- Excellent secondary patency rates
- Good dialysis adequacy data
- Cost saving compared with radiology plasty / CVC
- Improved quality of life for patients





Financial Benefits

Patient 1 – (New AVF previous line Hx & CVS)

Details	Pounds
3 x plasty of central stenosis in one year	£5220
HeRO graft	£2400
AVG Creation	£1494
Overnight Stay Post surgery	£500
Implantation Total Cost	£4394
Profit margin	£826
Additional income from dialysis on AVG for year	£4836
Total Profit	£5662

Financial Benefits



Patient 2 - Dialysis via a line

Details	Pounds
2 x plasty and stenting of central stenosis in a year	£5980
Radiological Line Placement	£500
HeRO graft	£2400
AVG Creation	£1494
Overnight Stay Post surgery	£500
Implantation Total Cost	£4394
Profit margin	£2086
Additional income from dialysis on AVG for year	£4836
3 x declotting of HeRO and bed stays in first year	£4500
Total Profit	£2422

What about this cost?



Approx. £15k per stay!

The 'priceless' patient views

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“It has made my life better”

“It generally makes me feel better about myself”

“Much easier to maintain good personal hygiene”

“It is very good. I was often in hospital with my line but not now that I have HeRO”

“I had many problems with lines, the HeRO graft is so much better and has made a real difference”

Closing Remarks



HeRO:

- The only fully subcutaneous AV option that offers long term access in CVS
- High maintenance but excellent secondary patency rates
- Low bacteremia rates c/w CVC
- A cost saving c/w CVC / Radiological interventions
- Does carry PE / Cardiac risk but case numbers small
- Improves quality of life for patients on dialysis

