

Two year follow –up results for Spiral Flow Grafts in AV Access

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Disclosure

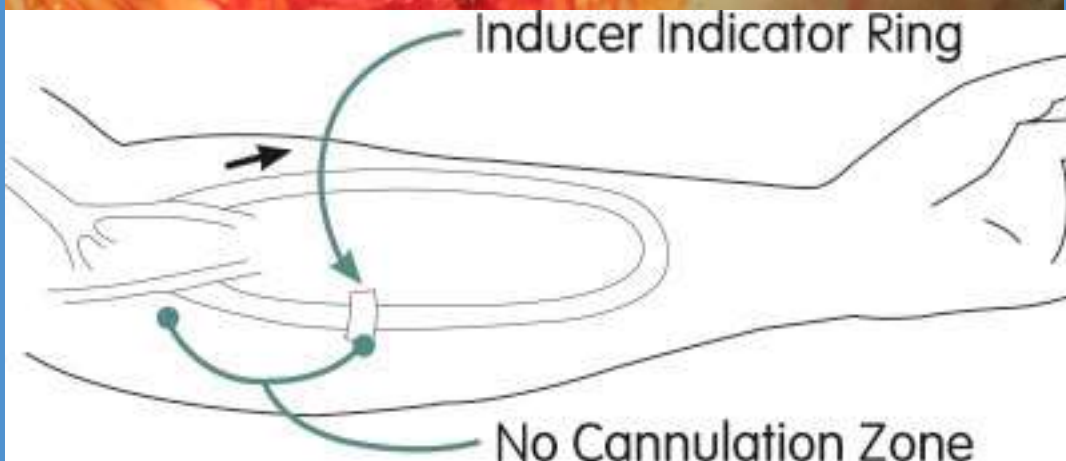
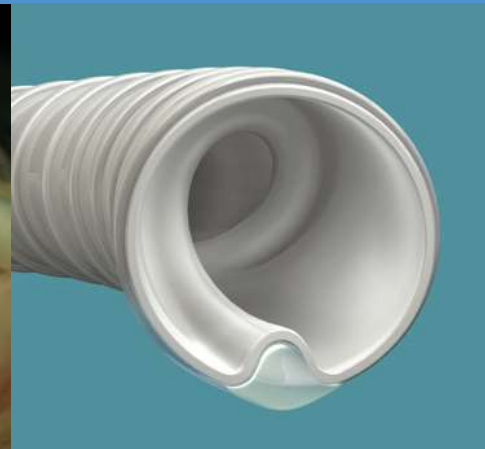
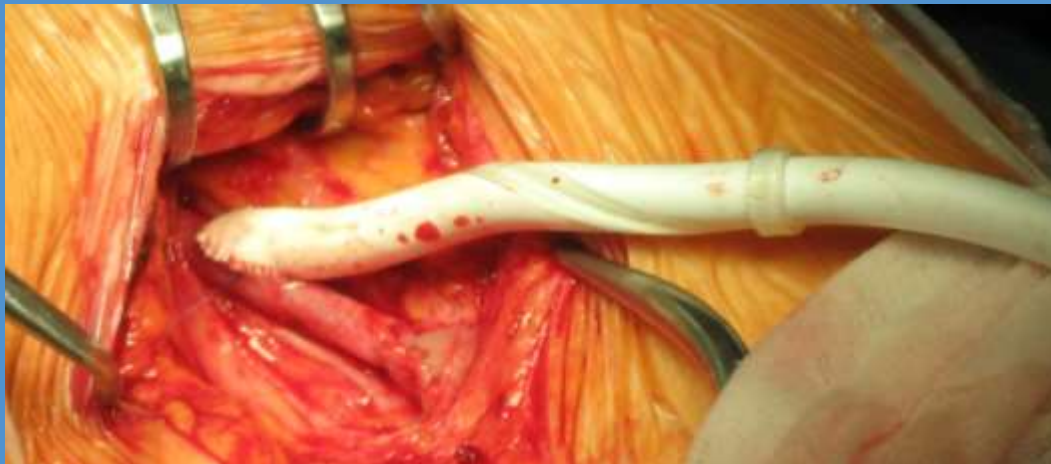
Speaker name: W J Hofmann

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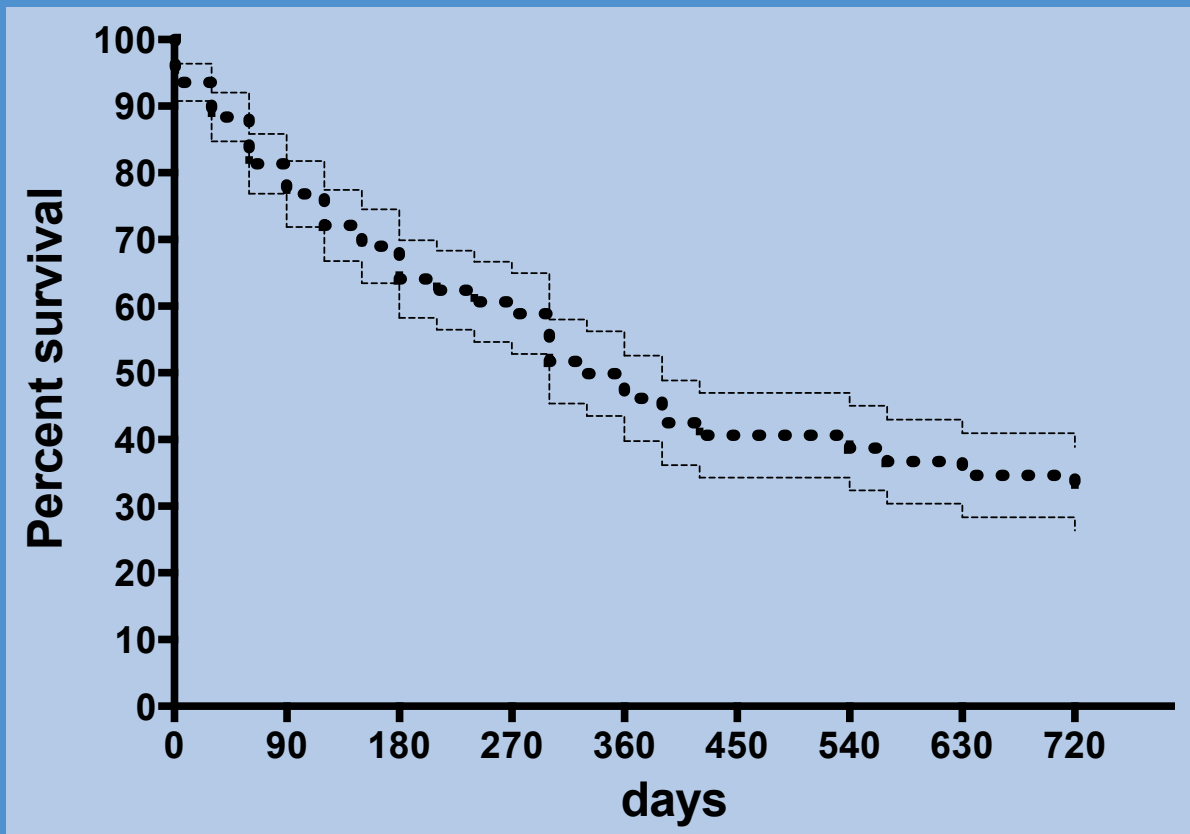
- I have the following potential conflicts of interest to report:
- Consulting for Vascular Flow Technologies
- Employment in industry
- Shareholder in a healthcare company
- Owner of a healthcare company
- Other(s)
- I do not have any potential conflict of interest

Spiral Flow AV Graft

First Implant in Europe 9/2010



Primary Conventional PTFE AV Grafts 1/2005 to 12/2009 n = 79



CHANGE IN AV ACCESS STRATEGY

Duplex Mapping of the Upper Extremity

Cimino Brescia Fistula

Cubital Fistula

Ulnar Artery – Basilic Vein Shunt

Transposition and Shunting of the Basilic Vein

**AV GRAFT ONLY IN PATIENTS NOT SUITABLE FOR
A NATIVE FISTULA**

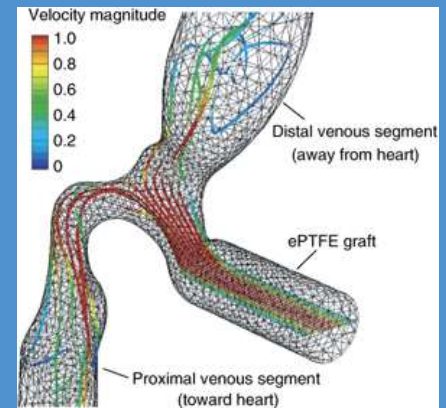
Prevention / Therapy of AV Graft Stenoses

Configuration of the Anastomosis (Venaflo[®])

Extern Beam Radiation

Patchplasty

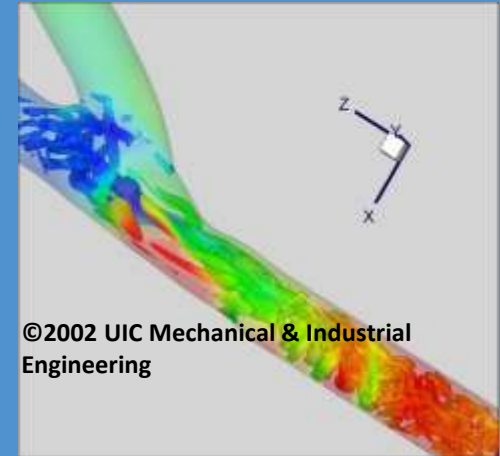
(repetitive) PTA



Bloodflow at the Anastomotic site !!!

Intimal Hyperplasia

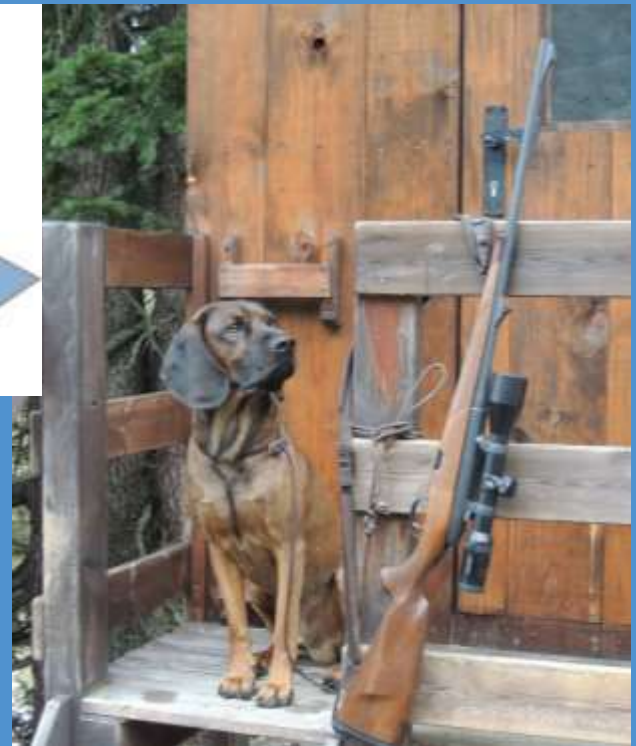
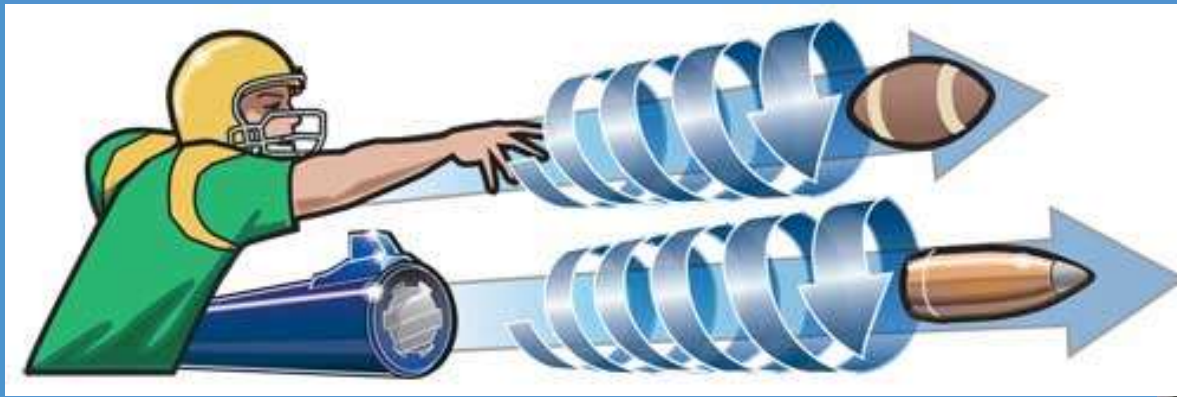
Prosthetic graft failure represents a normal tissue response to an abnormal flow environment



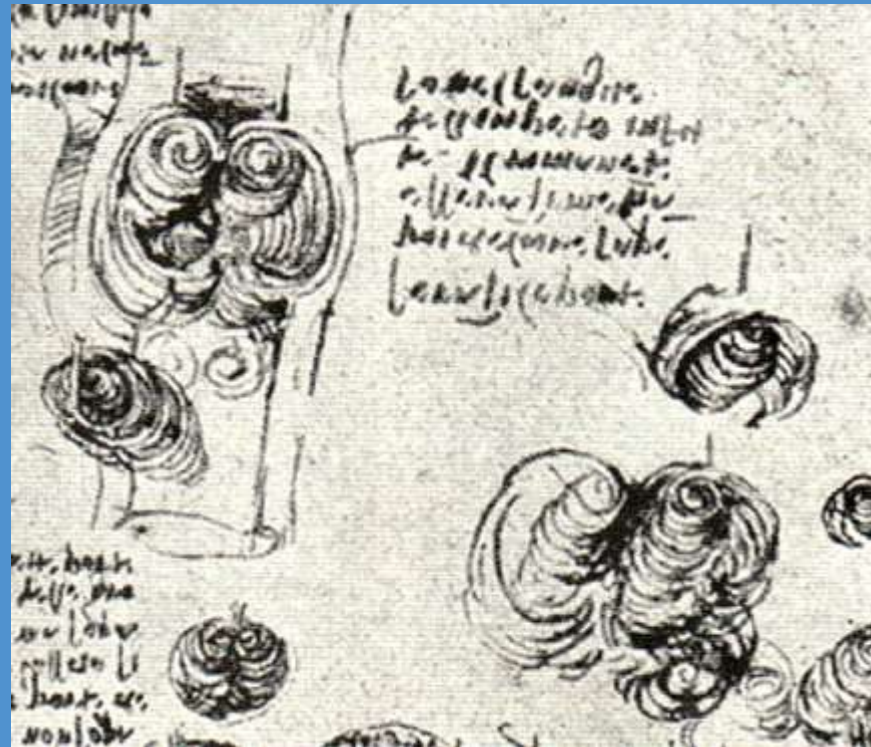
Endothelial cells at the venous anastomosis are sensitive to non laminar, turbulent flow

They react to turbulent flow by sending flow mediated signals which produces neo-intimal hyperplasia

Spiral motion is beneficial !!

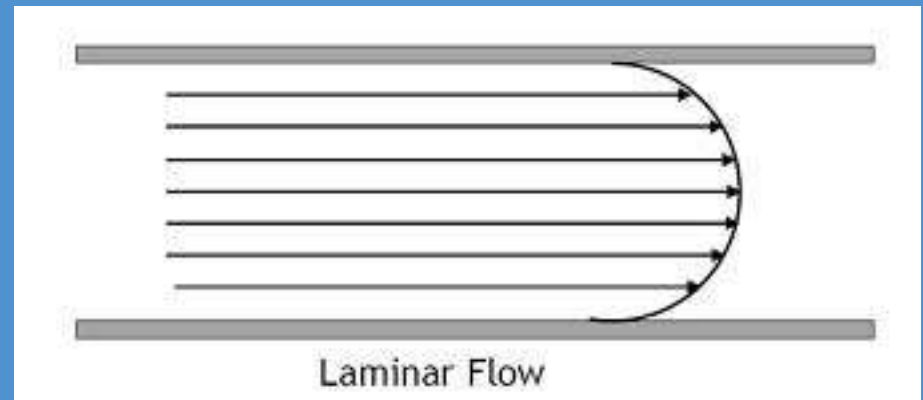


Rifling – the process of making helical grooves in the barrel of a firearm which imparts a spin to the projectile around its longitudinal axis, stabilizing the projectile and improving its aerodynamic stability



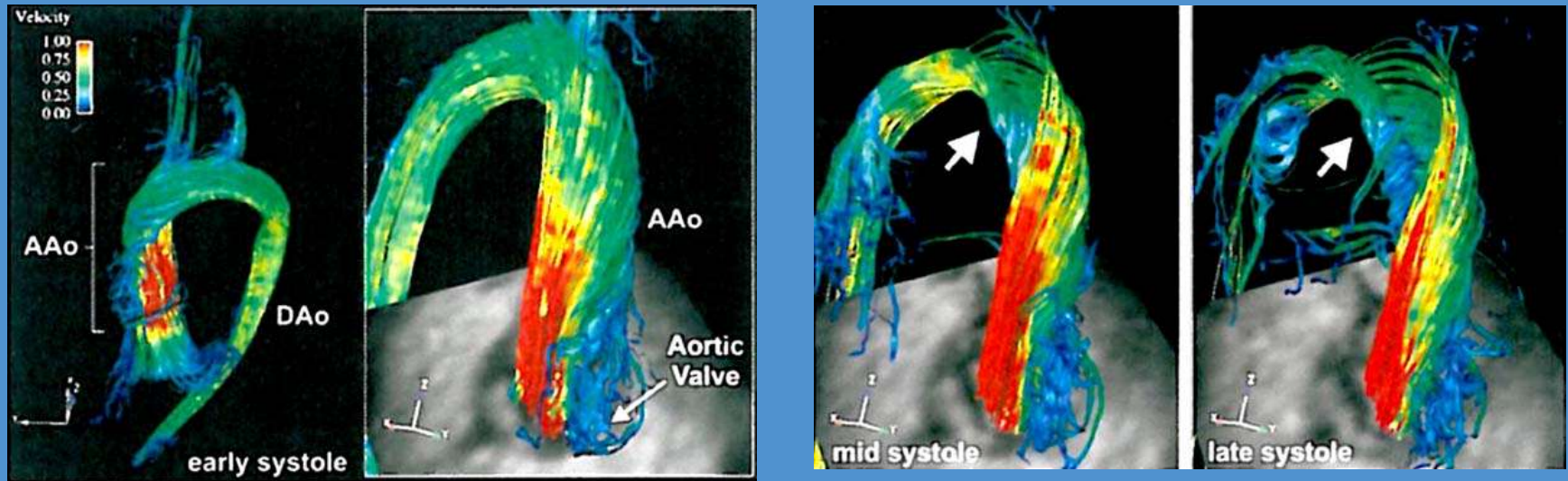
Spirals in art: the drawings of Leonardo da Vinci from Vindzone Library showing spiral flows in the heart cavity.

Natural Blood Flow is laminar - spiral



Stonebridge P *Lancet*. 1991;338:1360-1.

Natural blood flow is laminar spiral



Right-handed helical flow in the ascending aorta and arch during mid and late systole.

Markl M, Draney MT, Miller DC, et al. J Thorac Cardiovasc Surg 2005;130:456-63



C. Coghlan et al. European Journal Cardio-thoracic Surgery 2006;295:S4-S17

Published Characteristics of Spiral Laminar Flow

Laminar stability

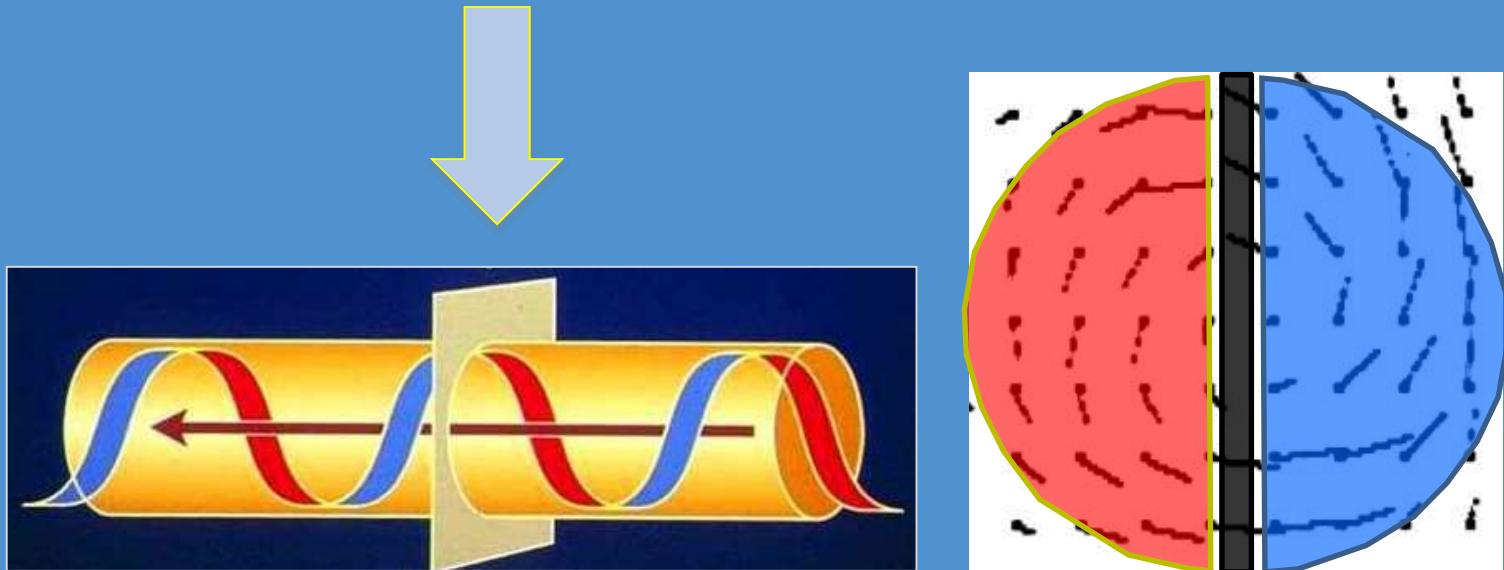
Reduced laterally directed forces

Reduced near-wall turbulences

No increase in platelet activation

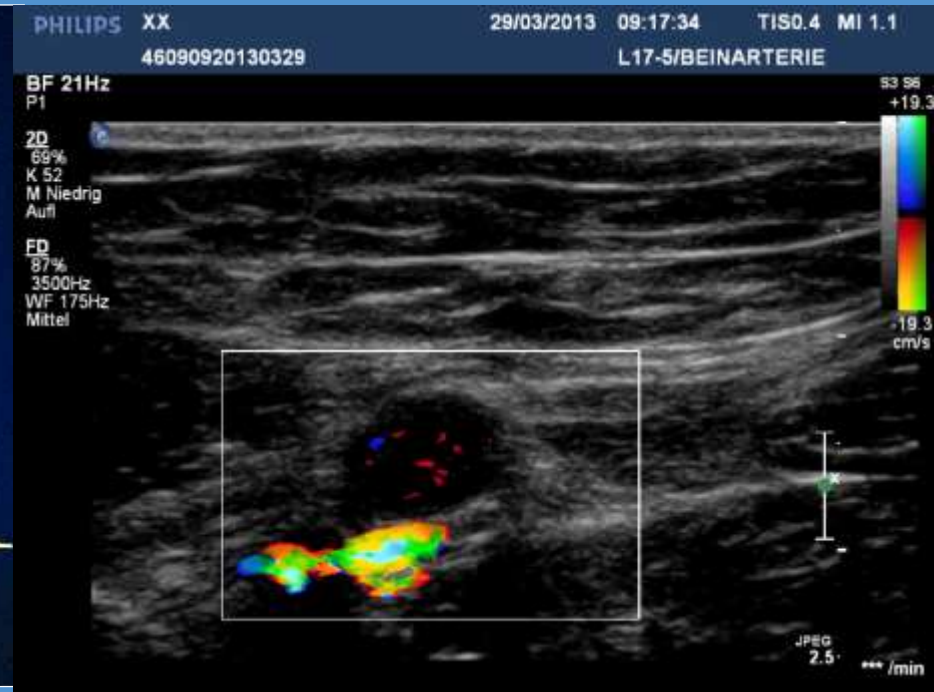
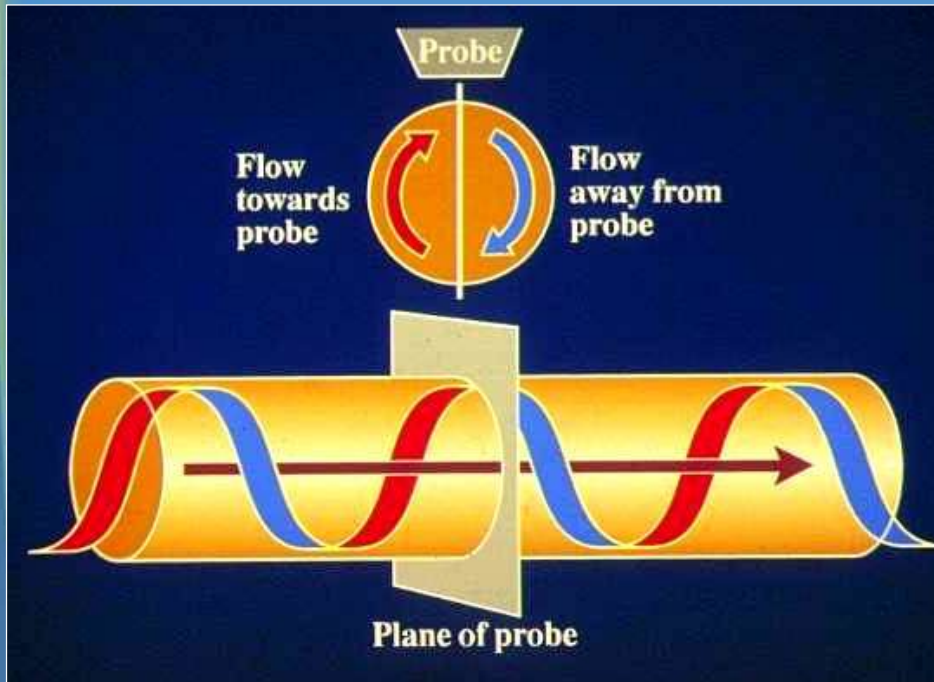
Lowers oscillatory shear stress

Spiral flow demonstrated in 12 individuals by means of Duplex scan

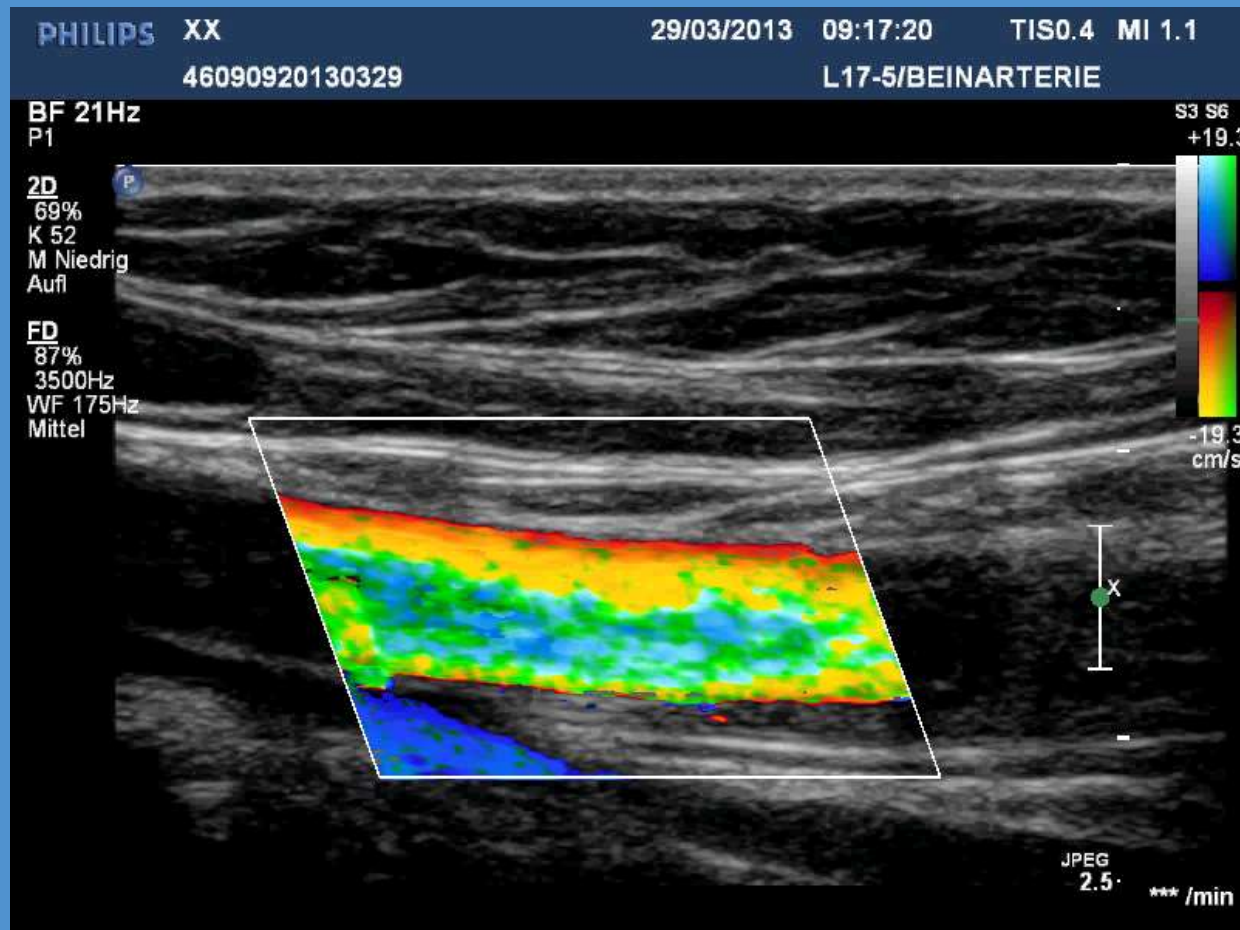


Spiral laminar flow in vivo Stonebridge PA et al
Clinical Science 1996 : 91;17 - 21

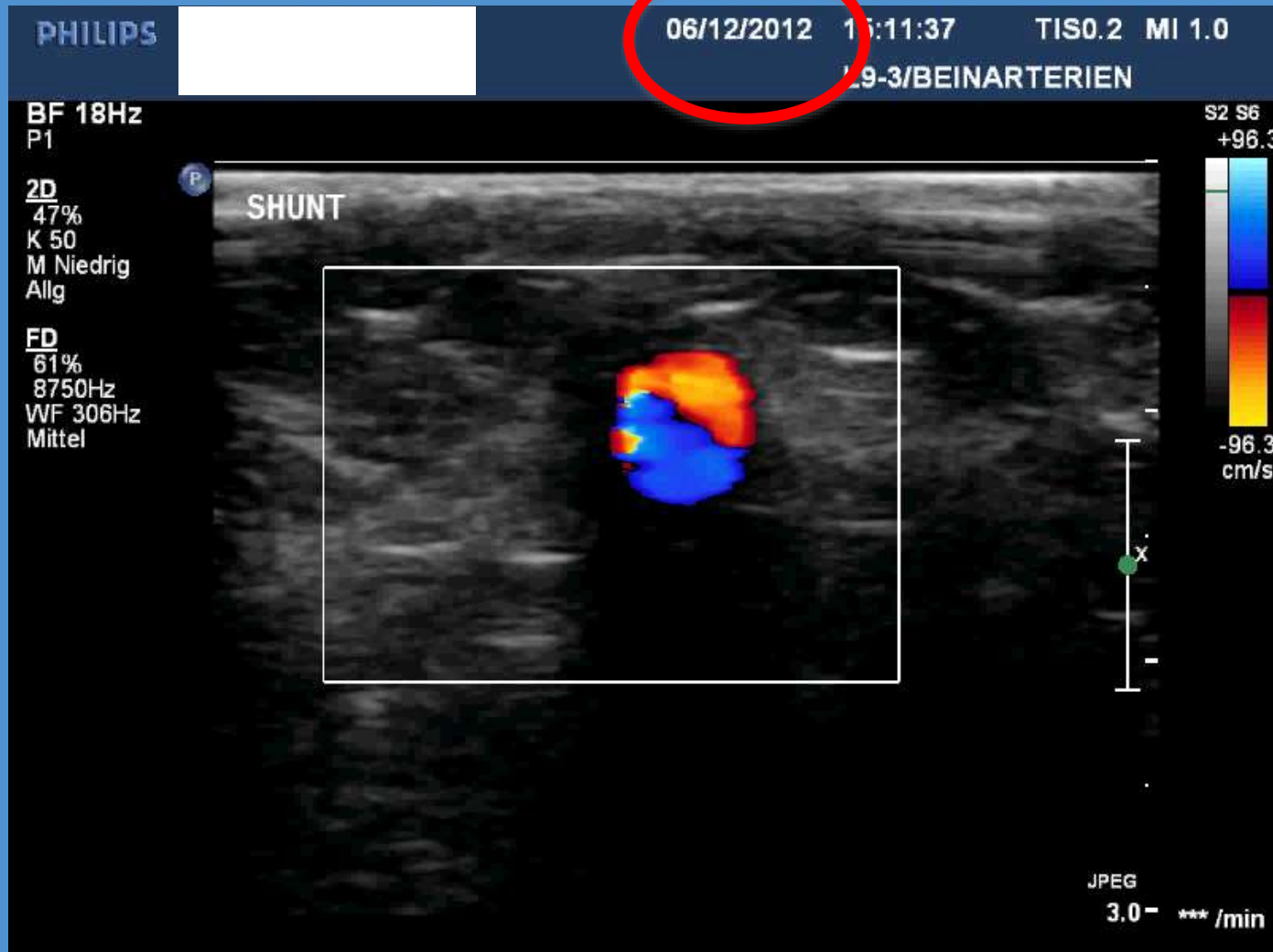
Spiral Laminar Flow / the Red : Blue Split



Spiral Laminar Flow / the Red : Blue Split



Spiral Laminar Flow at the Anastomotic site



SLF Grafts since 9/2010

Pat.	Op Date	no. prev. Proced	age	Diabetes	
WG	14.9.2010	3	63	yes	
MK	12.4.2012	3	69	no	
MH	11.9.2012	1	71	no	
ZJ	30.10.2012	8	60	yes	
ZC	7.12.2012	2	69	no	
RU	23.10.2012	2	46	no	
RU	16.1.2012	4	46	no	
VZ	5.3.2013	11	41	no	
PM	12.3.2013	3	58	yes	
MN	20.3.2013	1	68	no	
CO	24.4.2013	0	88	no	
NB	28.5.2013	0	30	no	HIV
AW	19.6.2013	1	71	yes	
ES	11.7.2013	0	68	yes	
UB	19.7.2013	6	74	yes	
TM	13.8.2013	24	34	no	

16 SLF Grafts since 9/2010

11 loop forearm

2 loop upper arm

2 straight upper arm

1 loop thigh

Follow Up

Duplex Scan every three months

Additional scan during interval if suspicion of shunt failure

Median Follow up 22 months

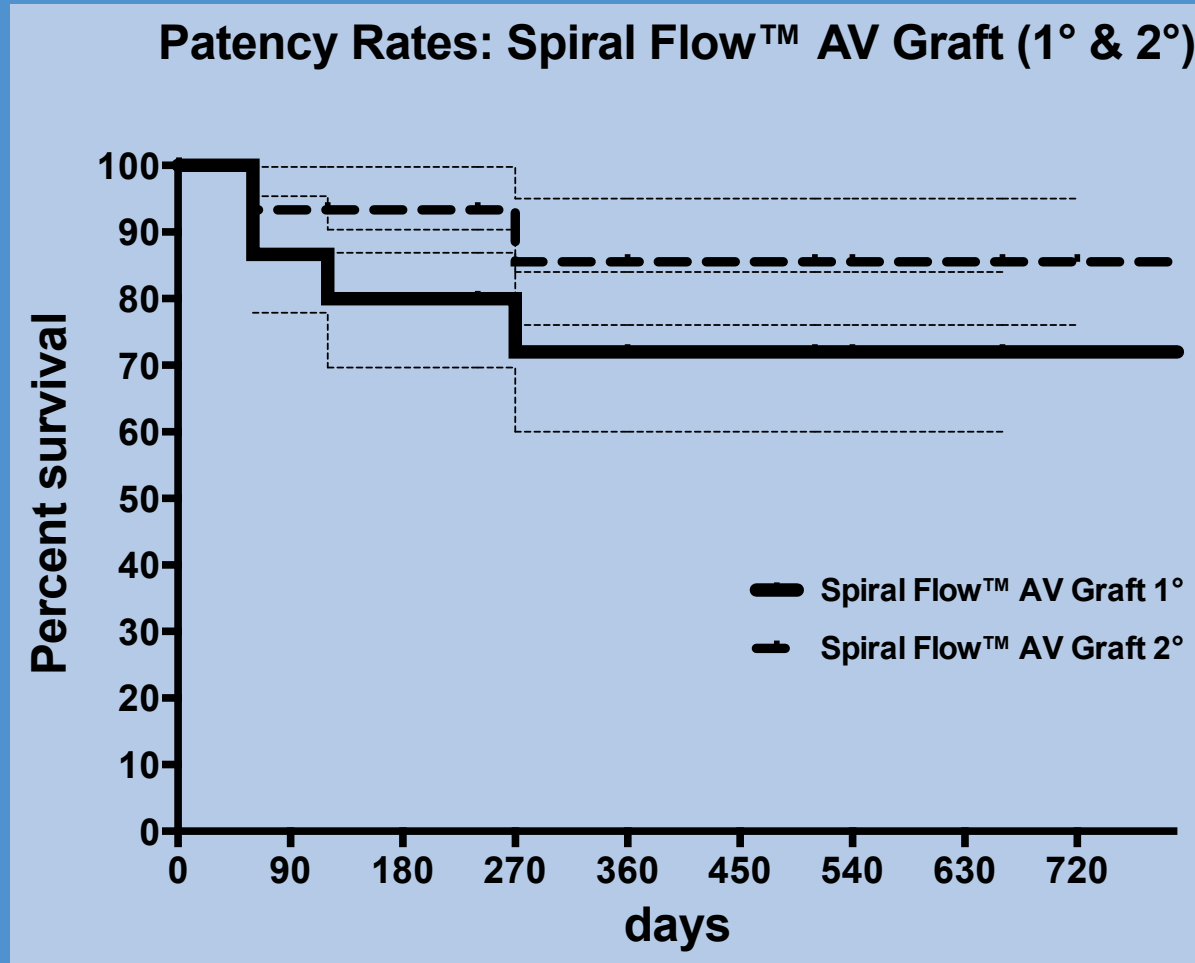
Follow Up

4 Graft occlusions

2 Successful graft thrombectomies

4 Graft explants (2 due to steal, 2 due to infection)

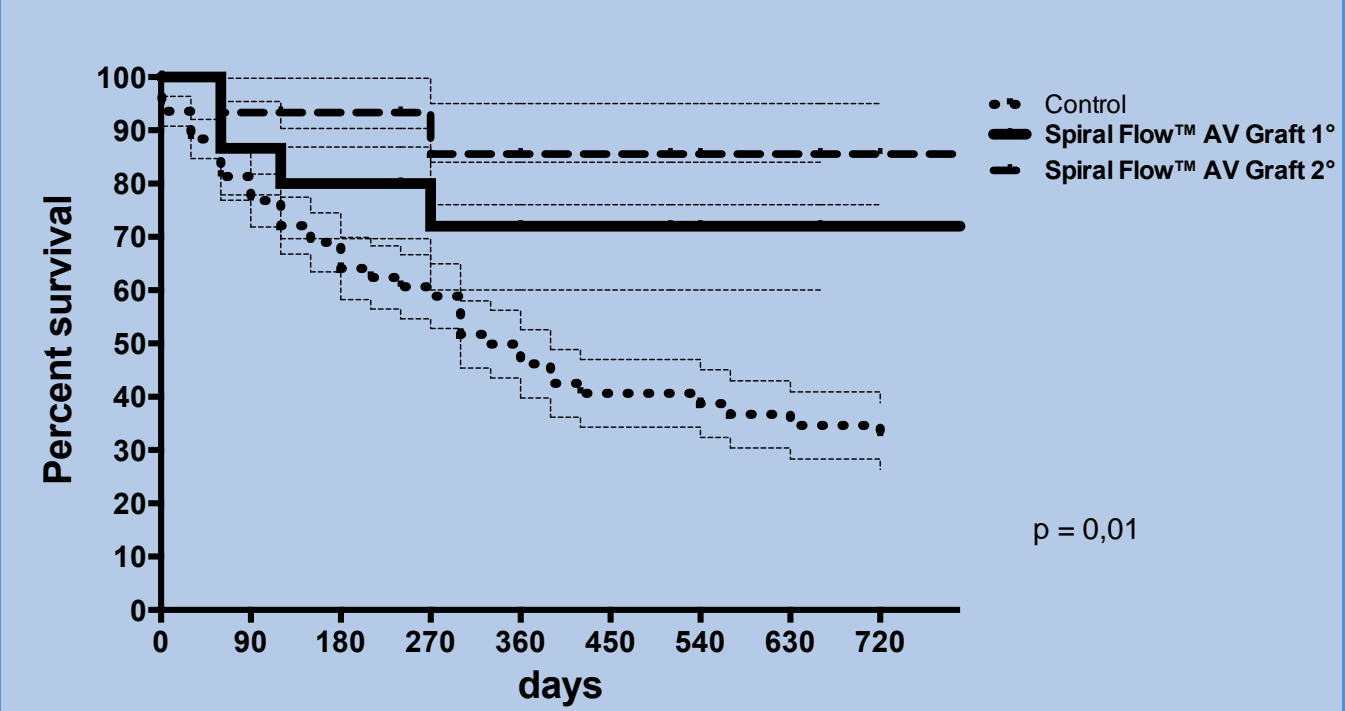
16 SLF Grafts since 9/2010



Primary Patency at 22 months 72%

16 SLF Grafts vs. 79 conventional PTFE Grafts

Patency Rates: Spiral Flow™ AV Graft (1° & 2°) vs Control (1°)



Primary Patency at 18 months 72% vs 36.7%

Conclusion

Changing the flow pattern at the venous anastomosis of AV grafts using the Spiral Flow Technology seems to be a simple but valuable tool in order to improve patency rates of PTFE AV grafts