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

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Venous Stents Placed Below the Inguinal Ligament: No Worries

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Disclosure

Speaker name: Lowell S. Kabnick, MD, FACS, FACPh, RPhS

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I have the following potential conflicts of interest to report:

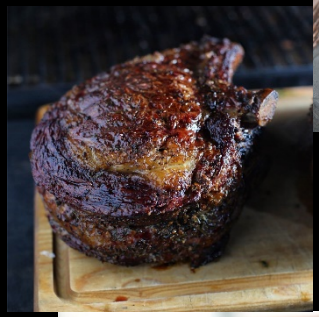
Consulting: AngioDynamics, Amsel, Bard

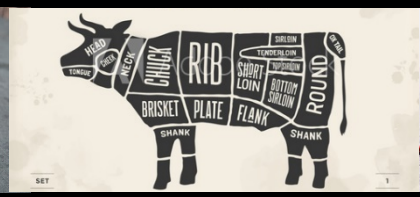
Scientific Advisory Board: Venclose

Speakers Bureau: Boston Scientific

Royalties: AngioDynamics

Disclosures

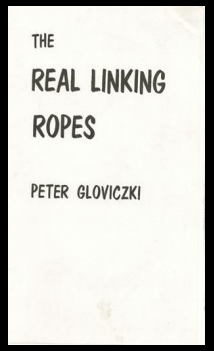




- I love steak
- I am not an engineer

Vs

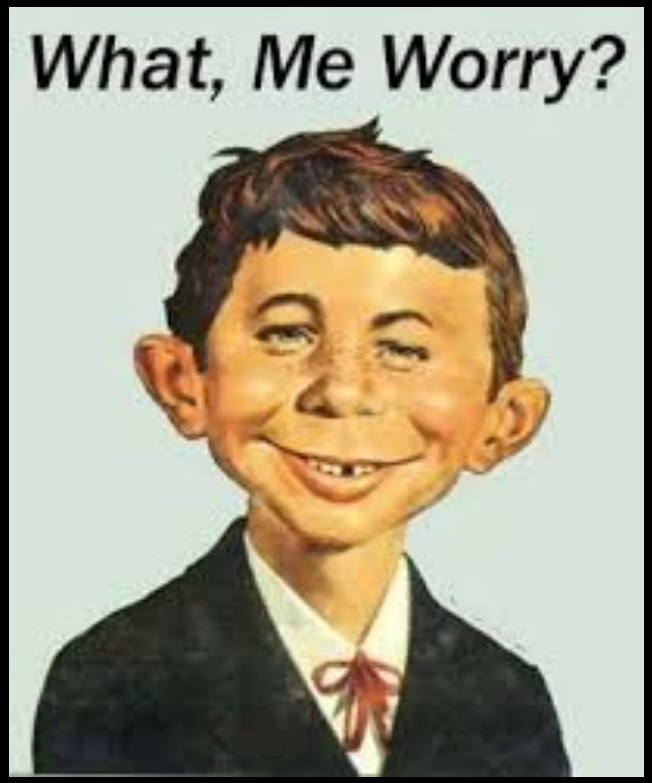
About My Opponent
Peter G The Master Magician



This is Not Magic or Illusions

Ladies and Gentleman

- *Stenting across the inguinal ligament should be avoided.”*

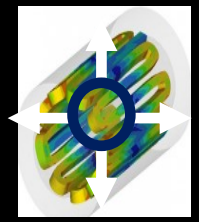

What, Me Worry?

Definition of the Word: Worry

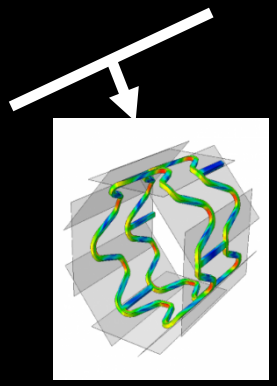
- mental distress or agitation resulting from concern usually for something impending or anticipated : anxiety.

Shifting Gears

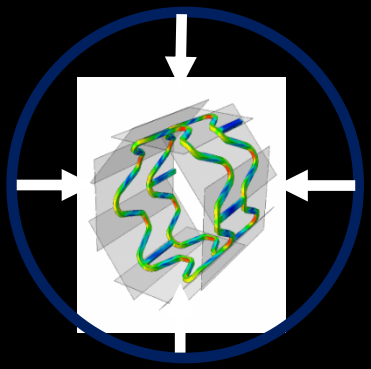
Stent Strength



Chronic Outward Force
Force stents exerts on vessel during expansion

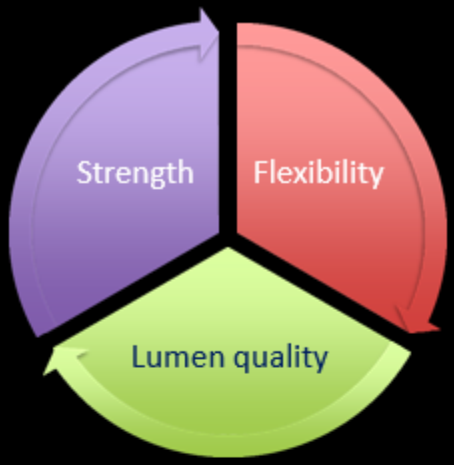


Crush Resistance Force
stent exerts as it resists external, focal or distributed loads



Radial Resistive Force (RRF) – Force stent exerts as it resists constriction

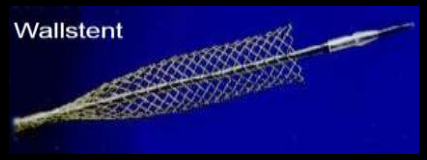
Venous Stent Attributes



- Self-expandable
- Crush resistant across length of stent
- Sufficient chronic outward force
- Sufficient wall coverage
- Flexibility sufficient to resist kink at physiological angles
- Durability allowing repeated shortening, twisting, and bending at the groin
- Minimal foreshortening

Venous Stent Options (CE)

Boston Wallstent



Optimed

Cook Zilver Vena

VIVO Trial

Veniti Vici

Optimed Sinus obliquus

Sinus Obliquus-01-NIS

Bard Venovo

VERNACULAR Trial

Medtronic ABRE

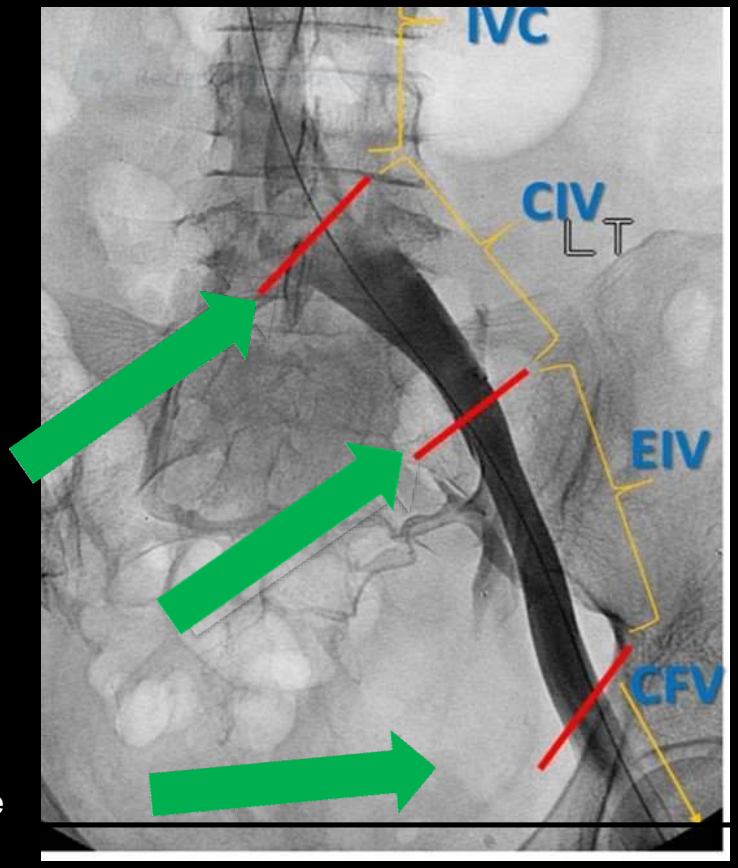
ABRE Clinical Study **ongoing**

Different venous stents for different locations

High radial force

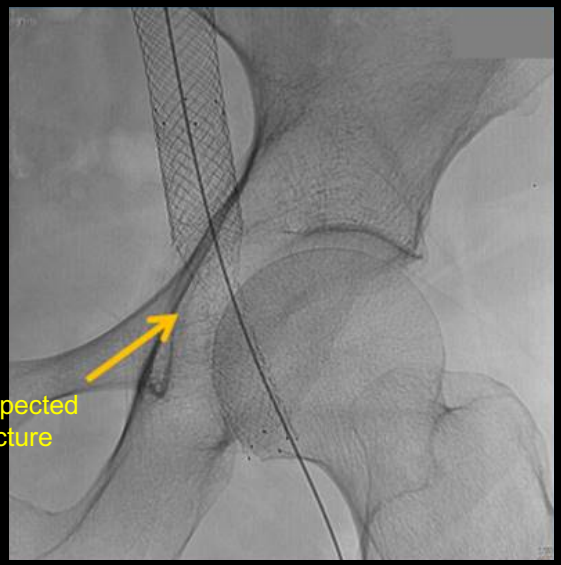
Radial force plus flexibility

non Flexibility, kink resistance, low fracture rate



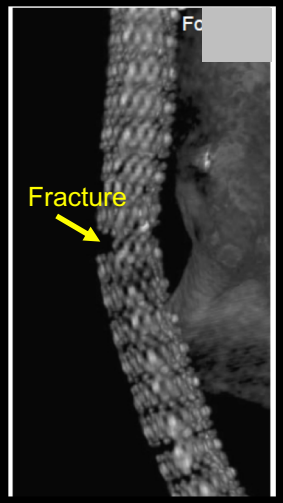
Venous Stent Fracture: Early Learnings

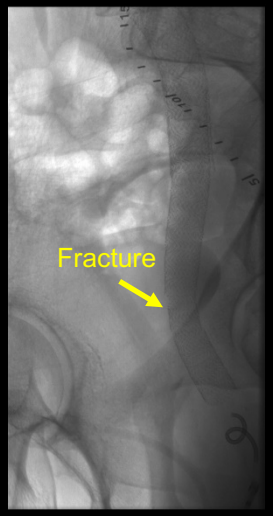
- Causes are multifactorial
- Occurs more high flexion /torsion areas versus deep pelvis
- May be asymptomatic,, likely undetected with DUS (standard of care) follow-up

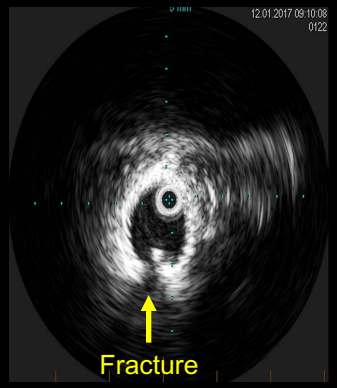


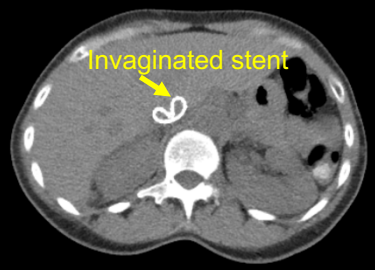
Unless there is sequelae, typical follow-up likely to miss

Observed Fractures in Various Stent Designs by Multiple Modalities



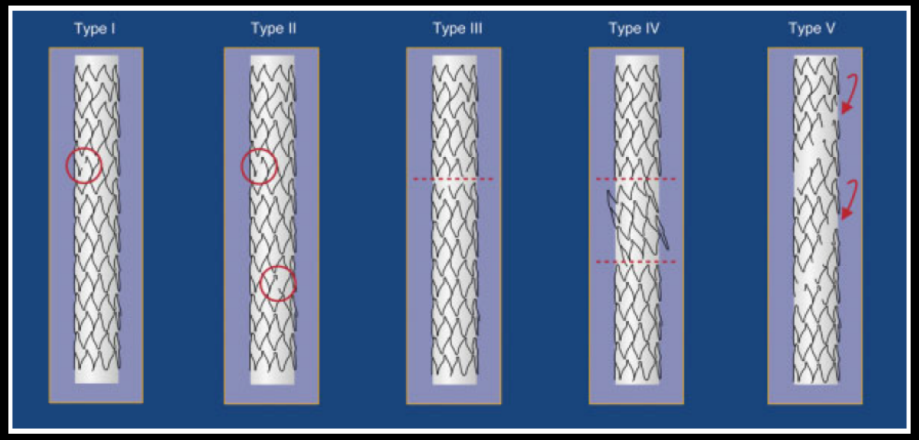






DUS only valuable if patency impacted!

Stent Fracture Classification (Types)

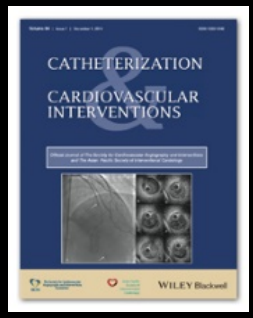


Non-coronary (arterial) types standardized 2007

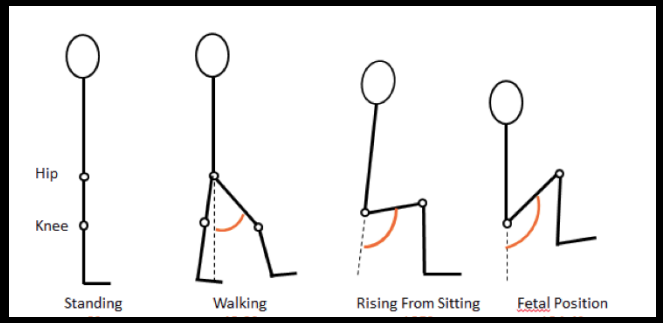
2007

- Sequalae vary by stent design & application

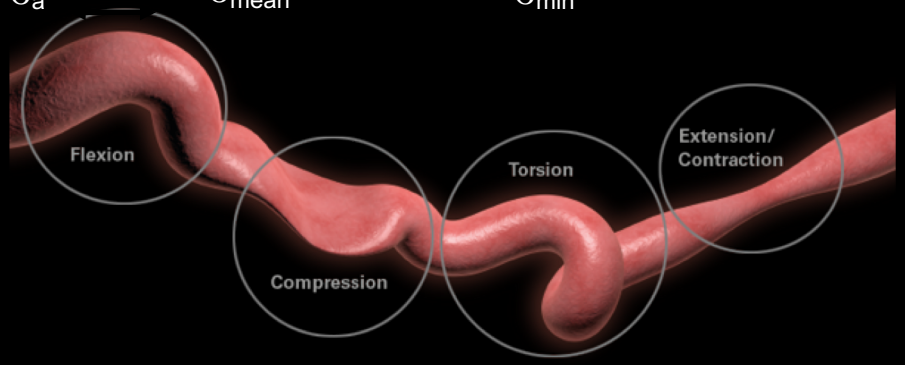
What does this classification system mean for venous fractures?



Fracture Occurs Most Often in Highly Mobile Locations

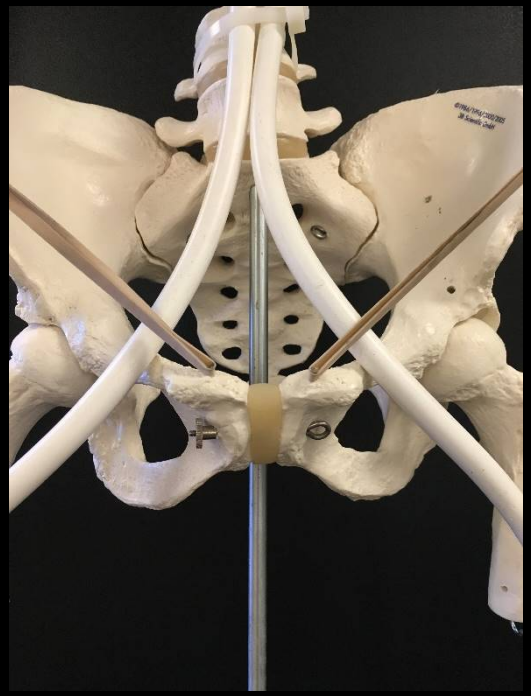


σ_a σ_{mean} σ_{min}



First highlighted in SFA stenting and has similarities to venous

Iliofemoral Vein Segment



Course of CIV to CFV under Inguinal Ligament/ over Superior Ramus

result in complex radii, curvatures, and biomechanical loads

Peripheral Stent Fracture *Well Described* in Scientific Literature, Little in Regards to Venous Stents

Fracture Contributors:

- Stent design/ materials
- Longer stents
- Stent overlap
- Areas of high motion

Detection/ Impact/ Rate of Fractures:

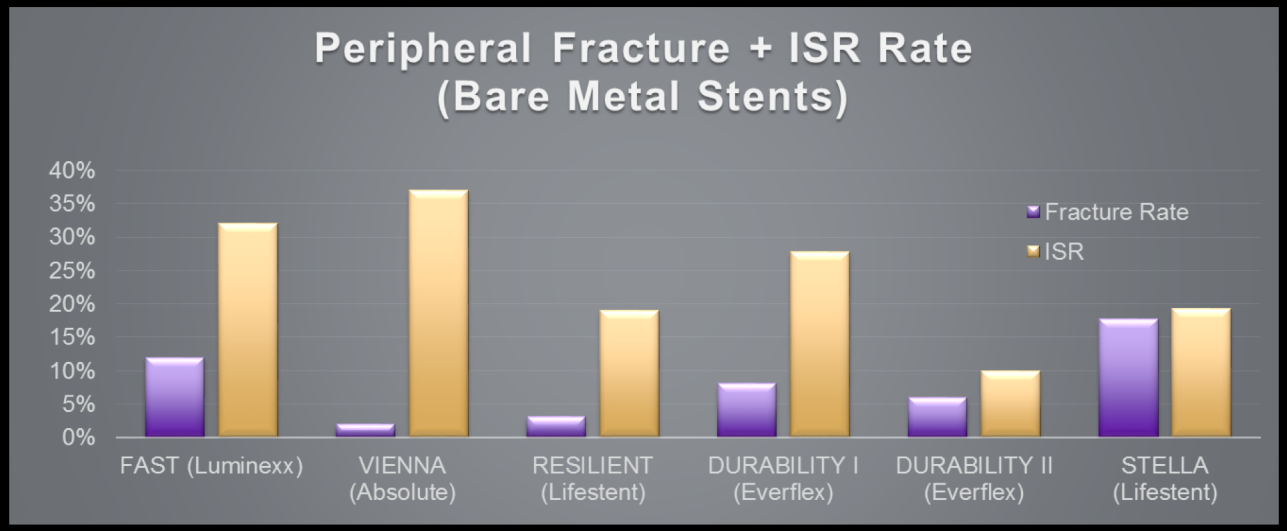
- Restenosis/patency rates differ by stent design
- Many Fx never detected (observed incidentally)
- Formal approval trials have lower rates
- Commercial real-world use report higher rates

						Follow-up		
No	Author/year	Vascular bed	No of Tx	No of #	CI of # (%)	Mean (m)	Total (pm)	IR (/1,000)
1	Scheinert D, 2005	FPA	121	45	37	11	1.295	35
2	Sabety S, 2005	FPA	53	8	15	8	424	19
3	Iida O, 2006	SFA	40	11	28	14	544	20
4	Duda SH, 2002	SFA	33	6	18	6	198	30
5	Duda SH, 2005	SFA	50	4	8	6	300	13
6	Duda SH, 2006	SFA	65	17	26	18	1.170	15
7	Schlager O, 2005	SFA	220	25	11	29	6.380	4
8	Allie DE, 2004	SFA	110	72	65	11	1.210	60
9	Ferreira M, 2007	SFA	59	1	2	29	1711	0.6
10	Schillinger M, 2006	SFA	51	2	4	12	612	3
11	Schilinger M, 2007	SFA	46	2	4	24	1104	2
12	Müller-Leisse C, 2001	IA	3	1	33	?	?	?
13	Thony F, 2005	RA	3	1	33	24	72	14
14	Tsutsumi M, 2006	VA	12	3	25	32	378	8
15	Weber W, 2005	VA	26	2	8	11	286	7

FPA = femoropopliteal artery, SFA = superficial femoral artery, IA = iliac artery, RA = renal artery, VA = vertebral artery, CI = cumulative incidence, IR = incidence rate, m = months, pm = person-months, Tx = treatment, # = fracture.

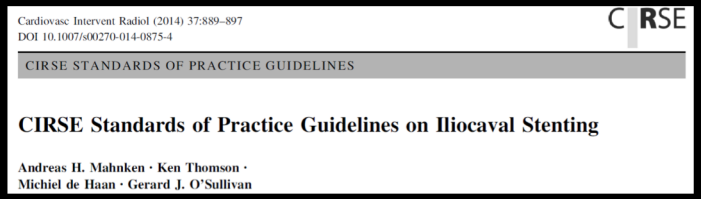
Fracture rates are from 1st and 2nd Gen SFA stents, contributors & impact trends similar

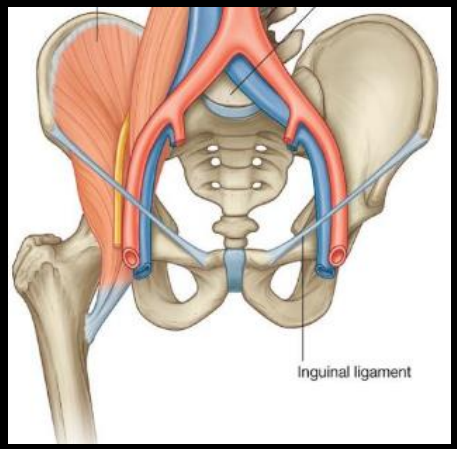
In SFA Arterial Stents, Fracture Rates and Resulting Clinical Impact vary by Design/Type & Use



Fractures alone do not predict in-stent restenosis
Initial venous stent experience indicate many symptom free, some impact patency

Special Consideration: Inguinal Ligament– A Concern?





Stenting across the inguinal ligament should be avoided."

- Guidelines present risk/benefits

Risks

- No data on venous stent fracture
- Increased risk of early in-stent stenosis

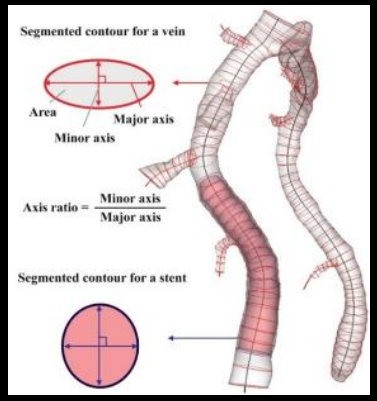
Benefits

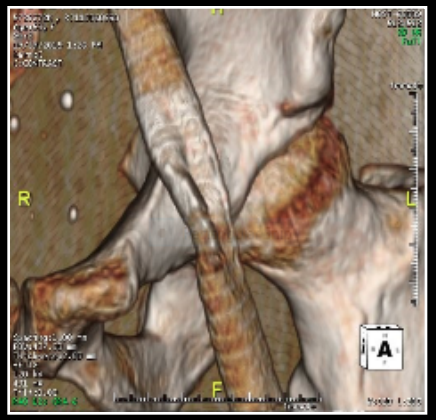
- "Stenting down to a normal flow segment is more important than avoiding crossing the inguinal ligament."

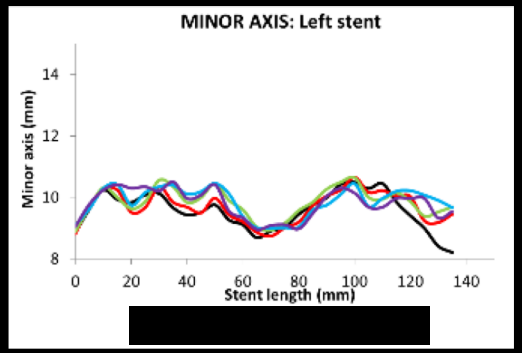
- Stents should not overlap at/near inguinal ligament.

Compression at the Inguinal Ligament: Biomechanical Loads likely more complex than Bending Alone

- Quantification of cross-sectional geometry metrics, including area, major axis, minor axis performed in cadaveric studies

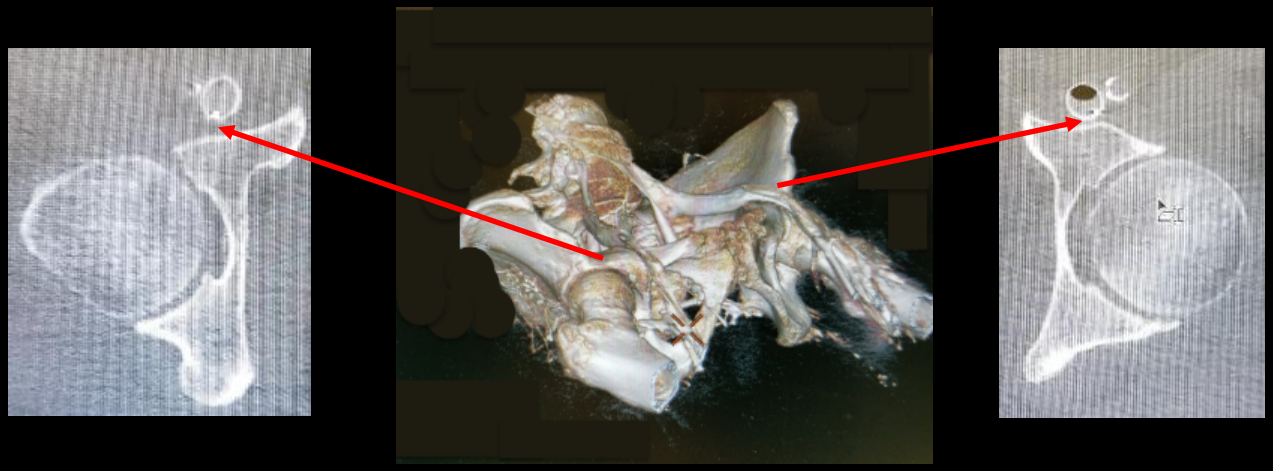






- At fetal position, minor axis drops to 0°, supporting the theory of compression at the inguinal ligament and pubis

Proximity of Vein to Superior Ramus: Could this be a Contributor to Fracture Risk in Certain Patients?



There is no conclusive data published to date, however this may be worth of further study to help predict patients at higher risk

If Luminal Diameter Is Maintained, Will Tissue Incorporation Minimize Clinical Sequelae?

Potential Risks Due to Fx?

- Lumen compromise/ patency
- Intimal vein/tissue trauma
- Damage to neighboring organs
- Embolism/ Fragments of stents
- Migration

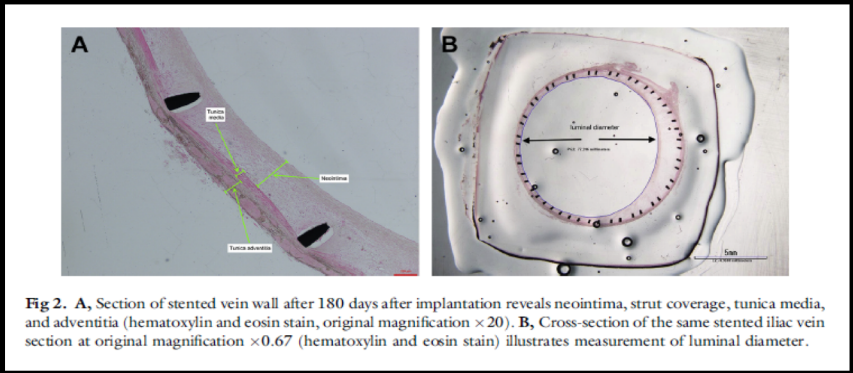
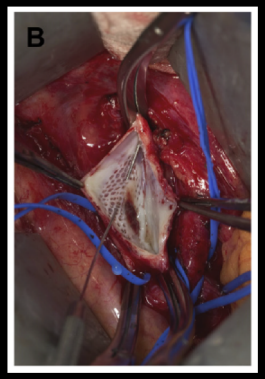


Fig 2. **A,** Section of stented vein wall after 180 days after implantation reveals neointima, strut coverage, tunica media, and adventitia (hematoxylin and eosin stain, original magnification ×20). **B,** Cross-section of the same stented iliac vein section at original magnification ×0.67 (hematoxylin and eosin stain) illustrates measurement of luminal diameter.

Marston et al, Journal of Vascular Surgery Venous and Lymphatic Disorders. 2015; Vol.4, Issue 1:73-79



Rathore et al, Journal Vascular Surgery Venous and Lymphatic Disorders. 2016; Vol.4, Issue 4:525-529

Does stent incorporation lead to reduced impact?

Venous stenting across the inguinal ligament.

Neglén P[1], Tackett TP Jr, Raju S.

⊕ Author information

Abstract

BACKGROUND: Arterial stenting across joints is not recommended because of increased risk of in-stent focal neointimal hyperplasia and compression or fracture of the stent by joint motion with decreased long-term patency. The aim of this study was to assess the risk of placing stents in the venous system across the inguinal ligament.

MATERIALS AND METHODS: From 1997 to 2006, 177 limbs with chronic non-malignant obstructive lesions had stents placed in the iliofemoral venous outflow across the inguinal ligament into the common femoral vein. Transfemoral venograms and duplex ultrasound scans to assess performed during foll it.

RESULTS caudad stent terminatio tic obstructio for stents terminatin CSP rates between li fference whether o 96% and 95%, P = ented cephalad of the inguinal lig ed.

CONCLU nal crease with no risk of stent fractures, narrowing due to external compression, focal development of severe in-stent restenosis, and no effect on long-term patency. The patency rate is not related to the length of stented area or the placement of the stent across the inguinal ligament, but is dependent upon the etiology and whether the treated postthrombotic obstruction is occlusive or non-occlusive.

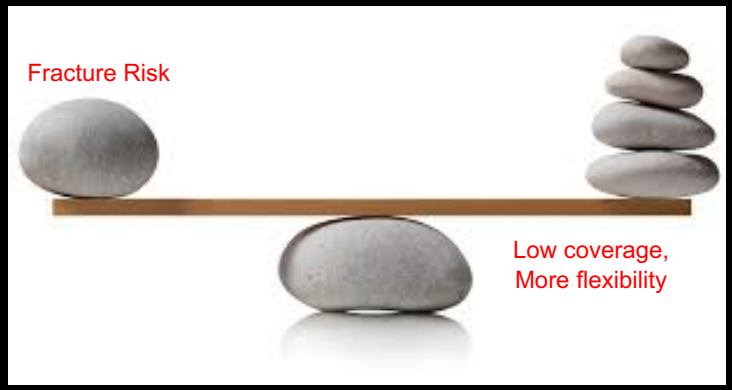
braided stainless stents can be safely placed in the venous system across the inguinal crease with no risk of:

- stent fractures
- narrowing due to external compression
- focal development of severe in-stent restenosis no effect on long-term patency

2008

Conclusions

- Venous stent fracture understanding in infancy
- Fractures occur in high flex areas vs. more stable pelvis
- FEW VENOUS STENT FRACTURES HAVE BEEN REPORTED



Physicians must consider disease coverage, placement in high risk areas, stent type selected and f/u surveillance

LADIES AND GENTLEMEN

- ARTERTIAL STENTS ARE NOT VENOUS STENTS
- ENGINEERING PROPERTIES ARE DIFFERENT
- NOT ALL VENOUS STENTS ARE THE SAME
- AT PRESENT THERE HAVE BEEN VENOUS STENT FRACTURES WITHOUT SEQUELLAE AS A RESULT OF THEIR ENGINEERING
- Physicians must consider disease coverage

YES, IT IS SAFE TO STENT UNDER THE LIGAMENT