

# Clinical outcome and patency rates of new generation venous stents

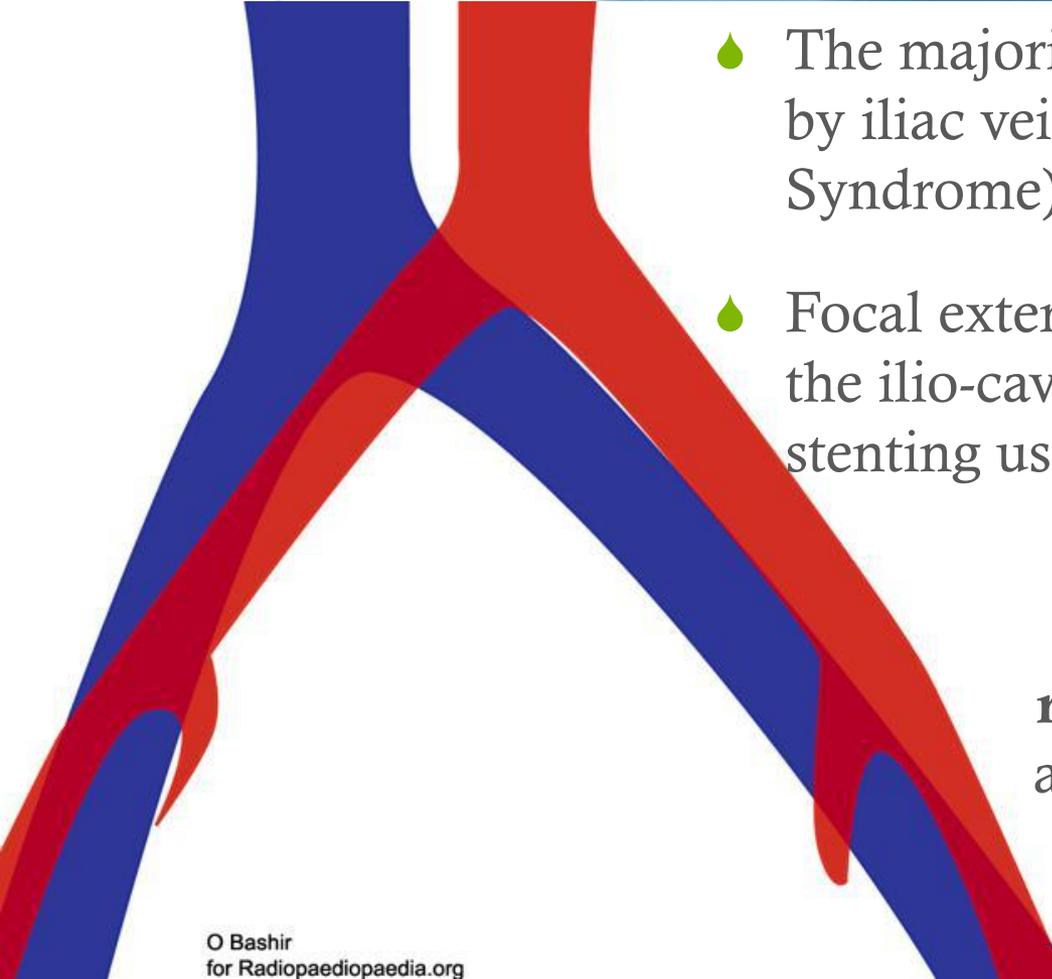
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# Background

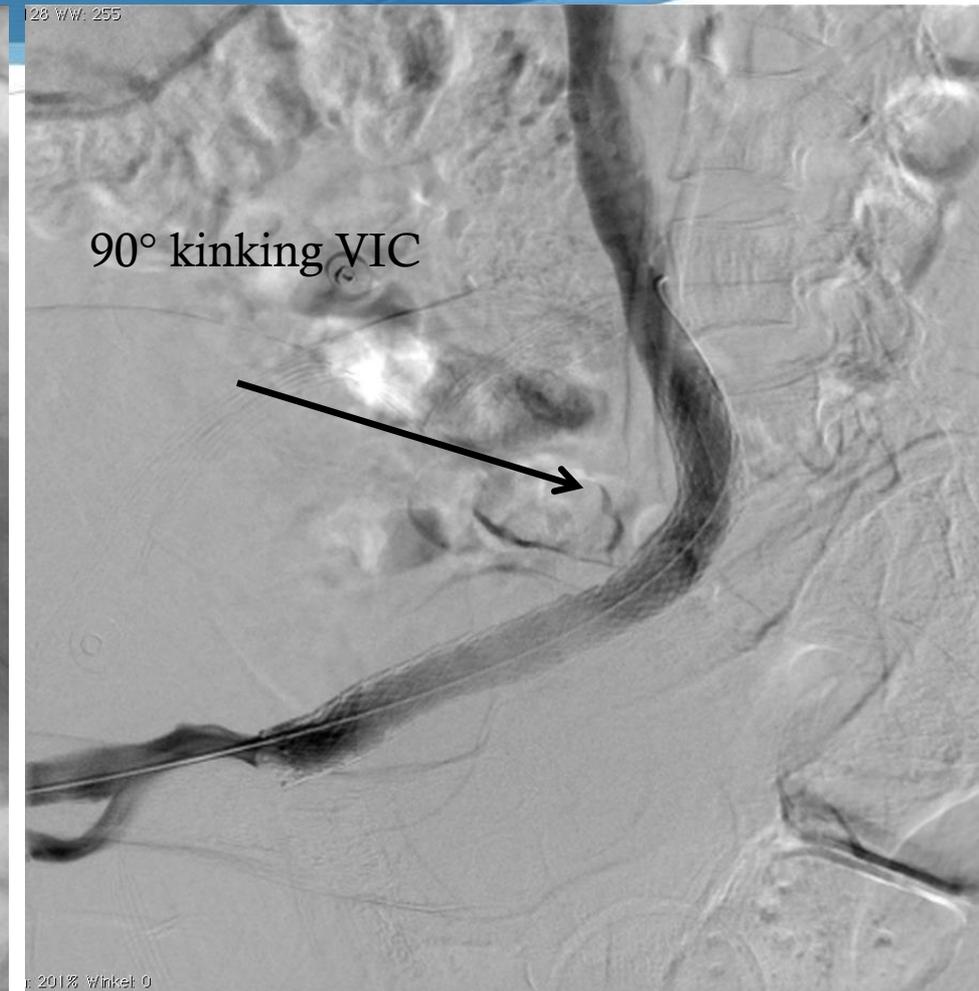
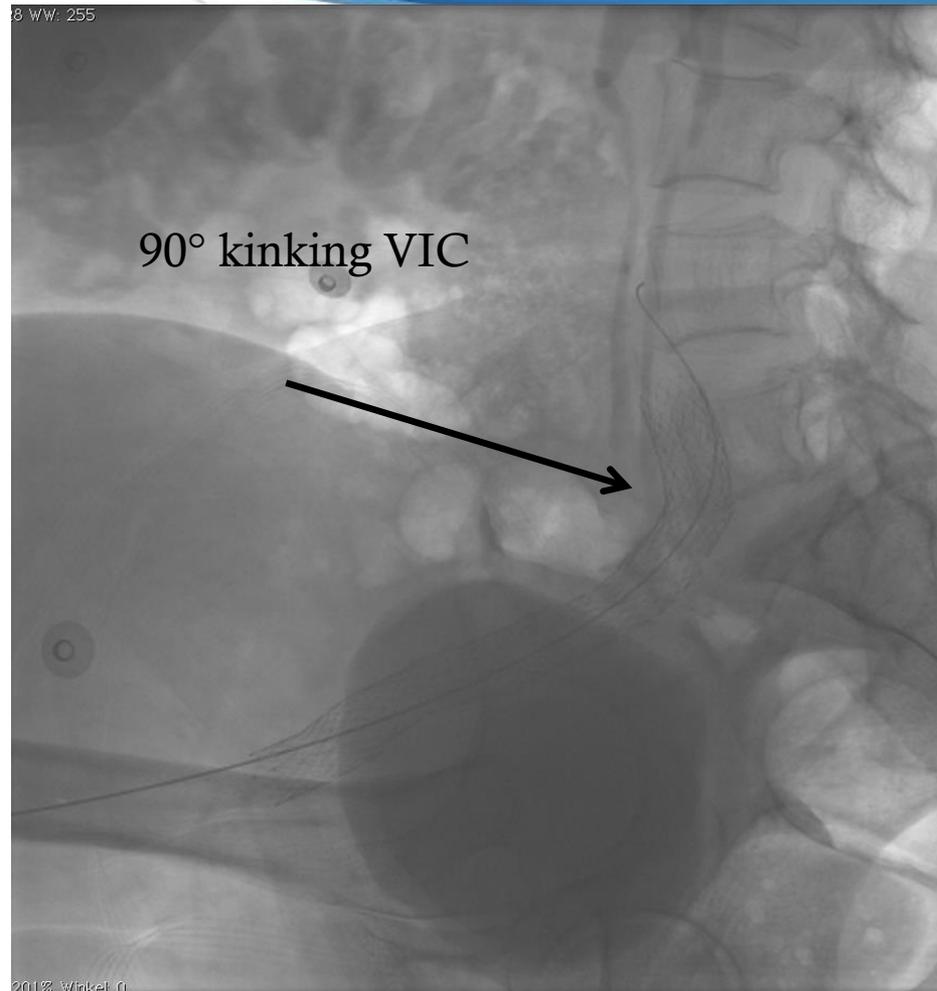
- ◆ Revascularization strategies have been developed aiming at restoring venous flow, thereby preventing the development of the postthrombotic syndrome (PTS).
- ◆ Catheter-directed thrombolysis followed by venous stenting has emerged as a promising revascularization strategy with venous patency rates of 70-90% and low complication rates.

# Challenge

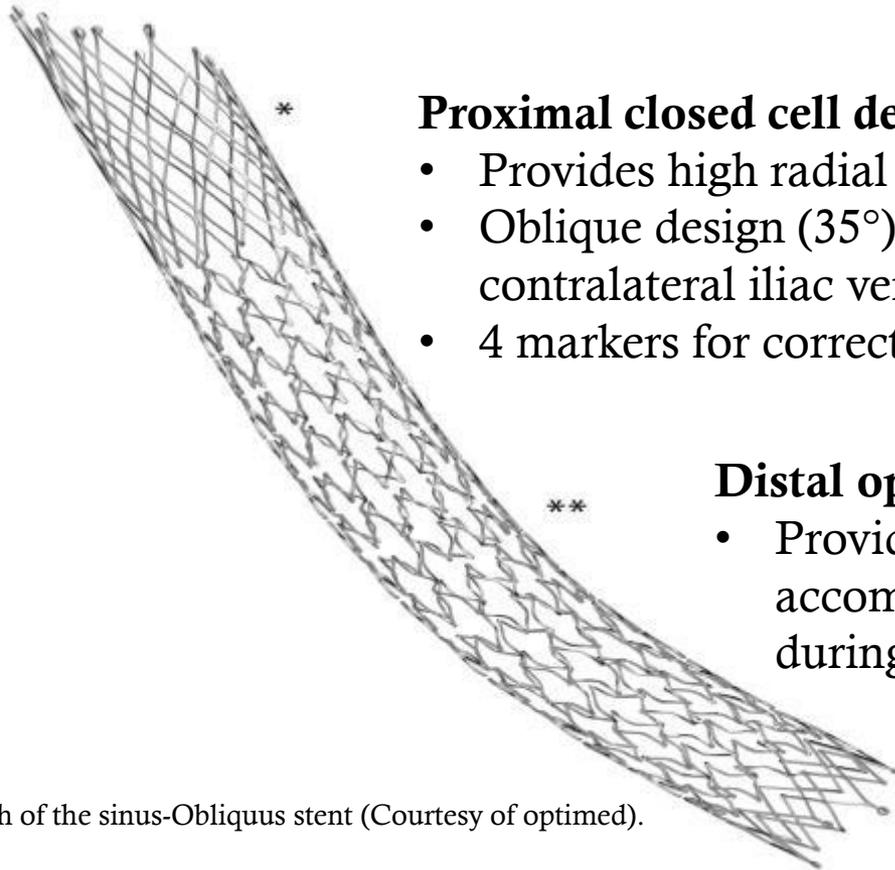
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- The majority of iliofemoral DVTs are caused by iliac vein compression (May-Thurner Syndrome)
  - Focal external compression and vicinity to the ilio-caval bifurcation hampers venous stenting using conventional stents.

**Ideal MT stent:**  
**radial force** at the compression site  
and **flexibility** to accommodate the  
anatomy of the curved iliac vein.

# Iliac vein anatomy: Lateral view 90 ° hip flexion



# sinus-Obliquus® stent



## **Proximal closed cell design:**

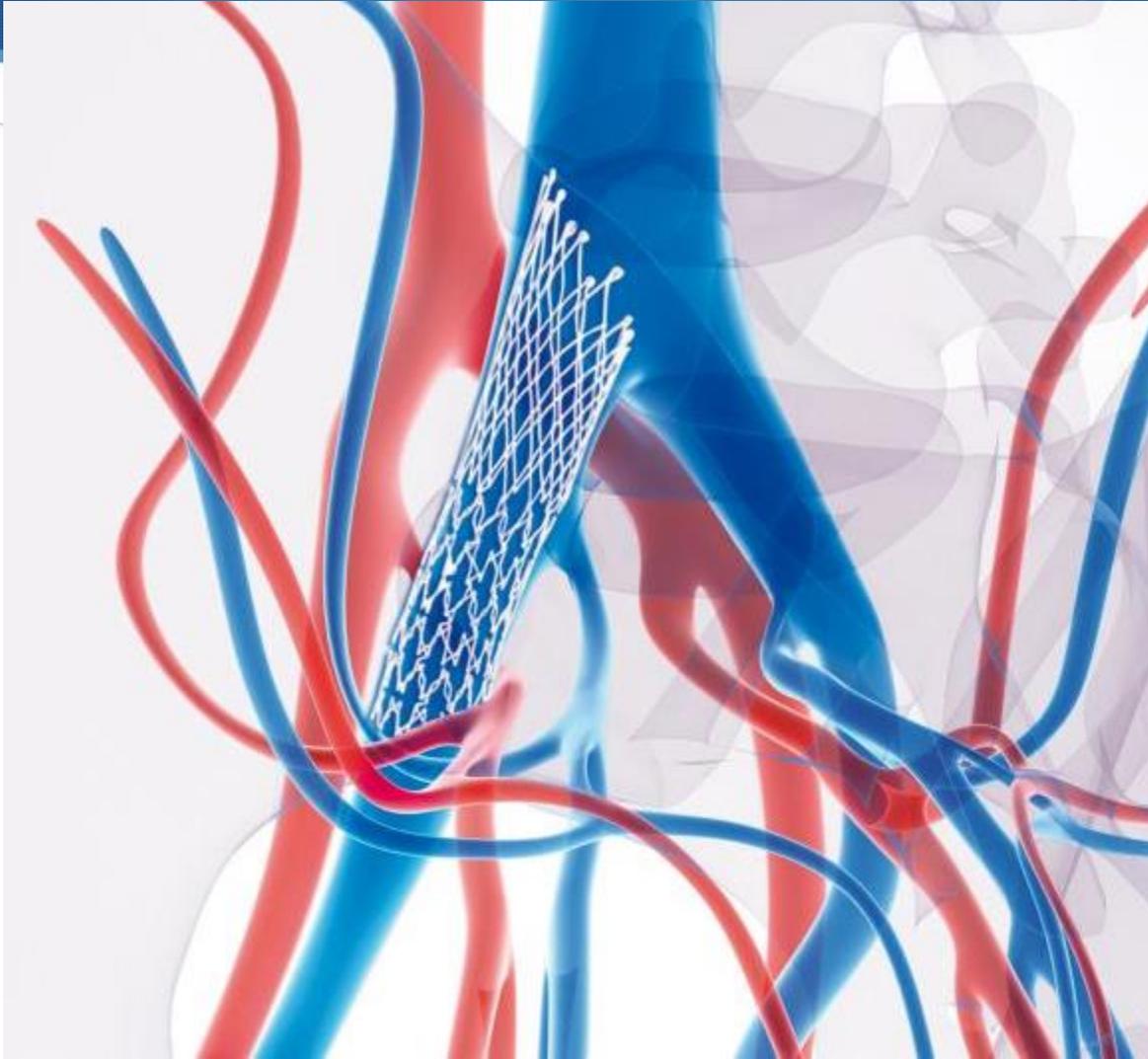
- Provides high radial force at compression site
- Oblique design (35°) prevents jailing off the contralateral iliac vein
- 4 markers for correct rotational positioning

## **Distal open cell design:**

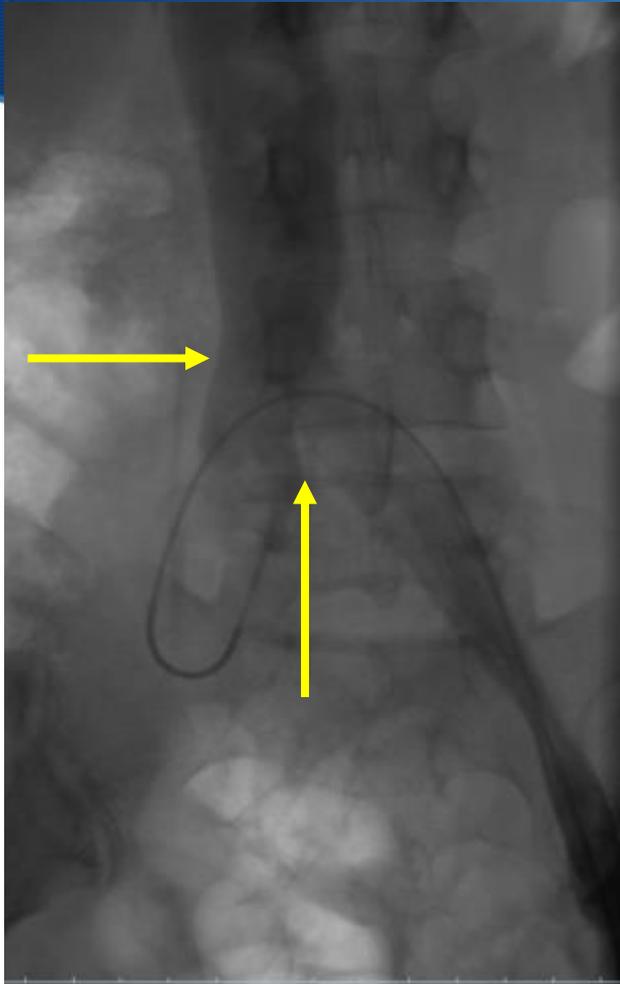
- Provides flexibility and less radial force for accomodating the curved anatomy of iliac veins during hip flexion

# sinus-Obliquus® stent

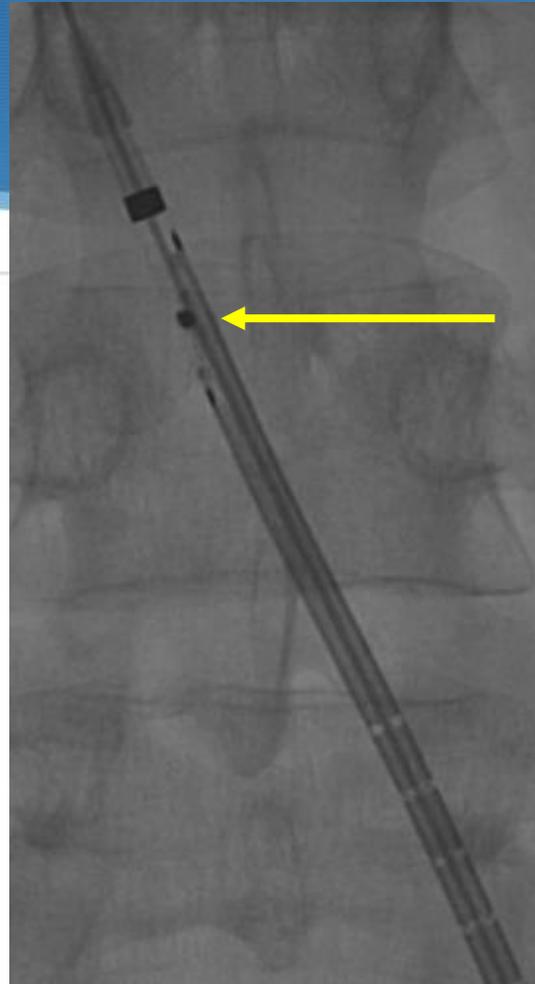
Visualized from behind



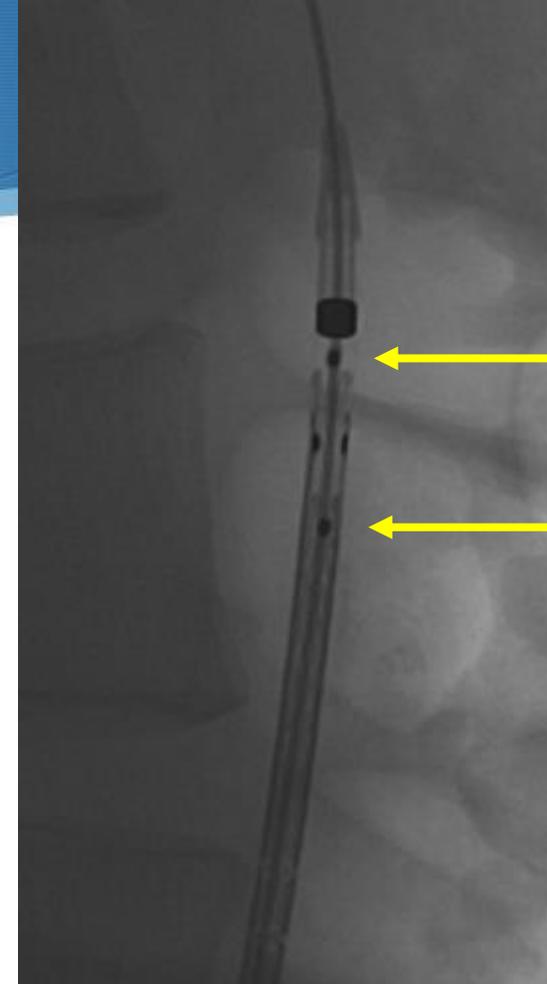
# Positioning of sinus-Obliquus® stent



**Contralateral injection:  
Identify IVC wall and carina**

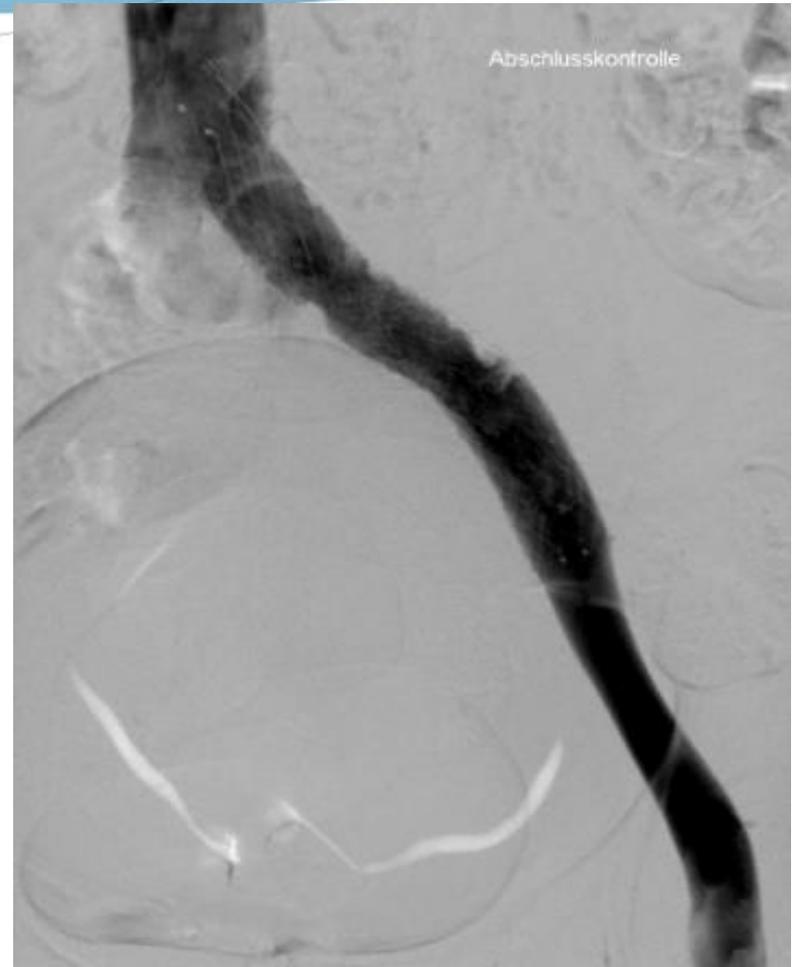
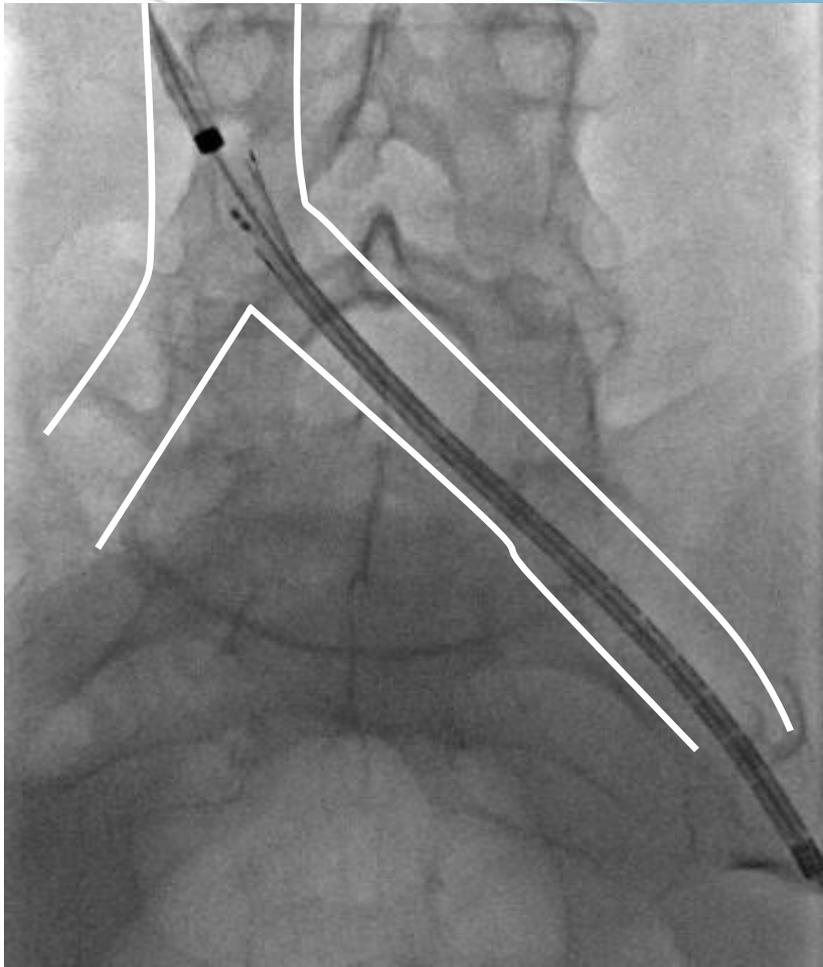


**AP view:  
two middle markers  
matching**



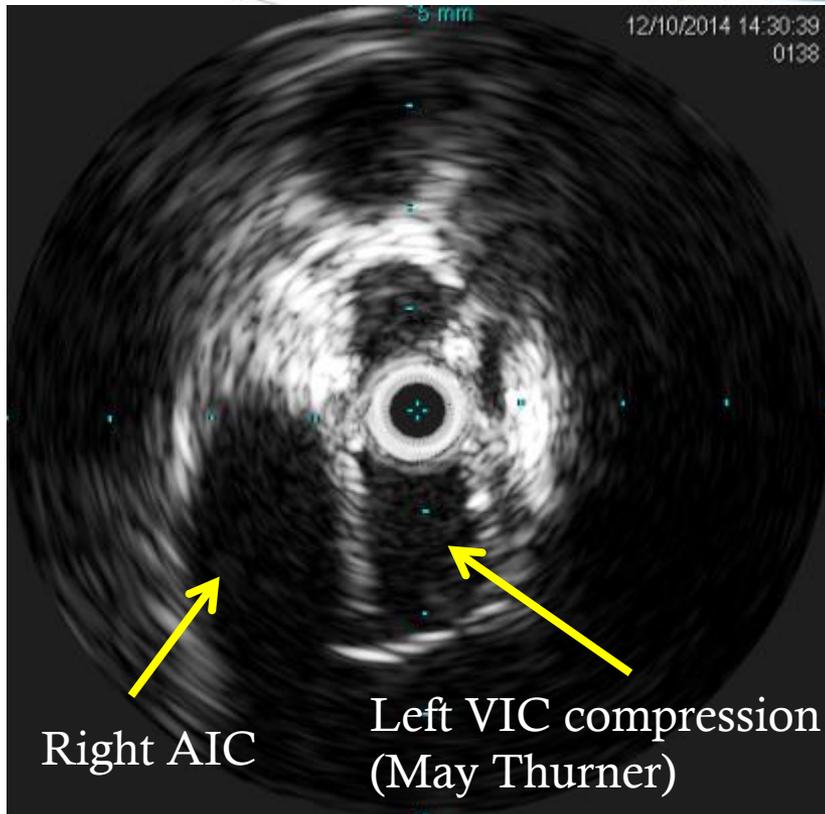
**Lateral view:  
Proximal and distal marker  
in line with wire**

# Implantation of sinus-Obliquus® stent

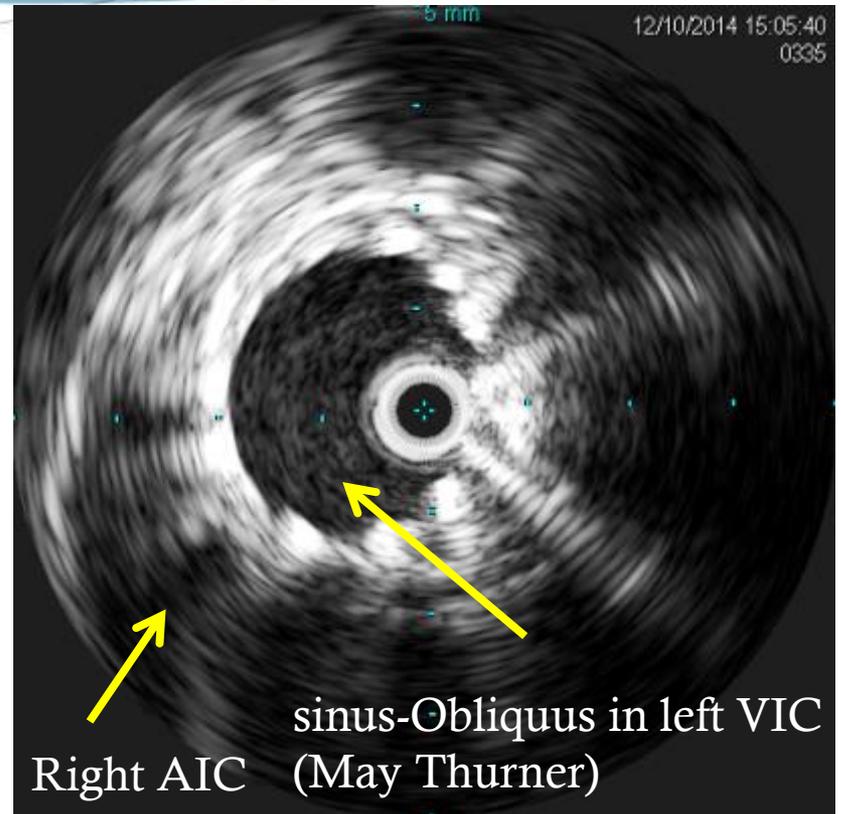


# IVUS

## pre and post sinus-Obliquus Stenting



Pre Stenting



Post Stenting

# Objective

- ◆ We investigated venous patency rates and clinical outcomes of patients with iliac vein compression treated with this novel venous self-expanding oblique hybrid nitinol stent (sinus-Obliquus®<sup>®</sup>, optimed, Germany)

# Bern Venous Stent Registry

- ◆ The Bern Venous Stent Registry is a prospective registry including all patients receiving venous stents at the University Clinic of Angiology in Bern, Switzerland
- ◆ Between December 2014 and July 2015  
23 patients with common iliac vein compression were treated with sinus-Obliquus stent:®
  - 9 patients with acute iliofemoral thrombosis after catheter-directed thrombolysis
  - 10 patients with postthrombotic syndrome (PTS)
  - 4 patients with non-thrombotic iliac vein compression.

# Results

- ◆ Total: 23 patients; 82% women, mean age  $38 \pm 4$  years
- ◆ 4 patients (17%) with a recurrent VTE event.
- ◆ 22 patients with stent implantation in left common iliac vein
- ◆ Mean time range between most recent DVT and intervention  
10.3 years in patients with PTS;  
7 days in patients with acute DVT

# Results:

## Outcomes at 3 months\*

- ◆ Primary patency rate: 100% (23/23)
- ◆ Clinical symptoms:  
completely resolved in 39%, improved in 52%, unchanged in 9%
- ◆ In patients with Postthrombotic Syndrome:  
Villalta score decreased by  $4.7 \pm 3.5$  points ( $P=0.002$ )  
Revised Venous Clinical Severity score (rVCSS) decreased  
by  $2.7 \pm 2.5$  points ( $P= .007$ )
- ◆ No procedural complication  
2 patients minor bleeding (popliteal hematoma, and  
hypermenorrhea)

\*Stuck AK, Kunz S, Baumgartner I, Kucher N.: Short-term Patency Rates and Clinical Outcomes of Patients with Common Iliac Vein Compression Treated with a Dedicated Venous Self-expanding Oblique Hybrid Nitinol Stent; submitted 2016.

# Discussion

- ◆ Our findings are consistent with prior studies of other dedicated venous stents, with good patency rates, low complication rates, and no mortality.
- ◆ **sinus-Venous® stent**  
de Wolf MA, de Graaf R, et al. Short-Term Clinical Experience with a Dedicated Venous Nitinol Stent: Initial Results with the Sinus-Venous Stent. *European journal of vascular and endovascular surgery : the official journal of the European Society for Vascular Surgery*. 2015;50(4):518-26.)
- ◆ **Zilver Vena® stent** (Cook, Bloomington, IN, USA):  
O'Sullivan GJ et al,. Iliofemoral venous stenting extending into the femoral region: initial clinical experience with the purpose-designed Zilver Vena stent. *J Cardiovasc Surg (Torino)*. 2013;54(2):255-61.)

# Discussion:

## Zilver Vena® stent\*

O'Sullivan GJ, et al.  
J Cardiovasc Surg 2013

- 20 patients  
(12 women; mean age 59)  
treated for iliofemoral vein  
obstruction
- Clinical patency rate: **85%**  
(17/20 patients),
- Clinical improvement was  
demonstrated by decreased leg  
swelling in these 17 patients

TABLE II.—*Baseline lesion characteristics.*

Characteristic	
Duration	
Acute ( $\leq 30$ days)	14 (70%)
Chronic ( $> 30$ days)	6 (30%)
Lesion characteristic	
Occlusive	10 (50%)
Non-occlusive	10 (50%)
Source of obstruction	
May-Thurner	5 (25%)
Malignant mass	3 (15%)
Other extrinsic compression	6 (30%)
Occlusive thrombus	4 (20%)
Non-occlusive thrombus	2 (10%)

\* Cook, Bloomington, IN, USA

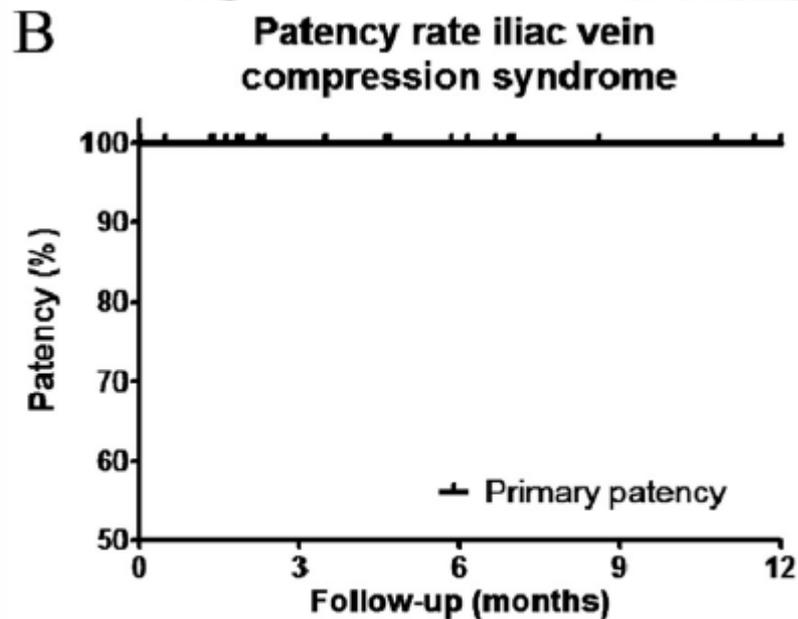
# Discussion: sinus-Venous® stent\*

de Wolf MA, de Graaf R, et al. European journal of vascular and endovascular surgery. 2015)

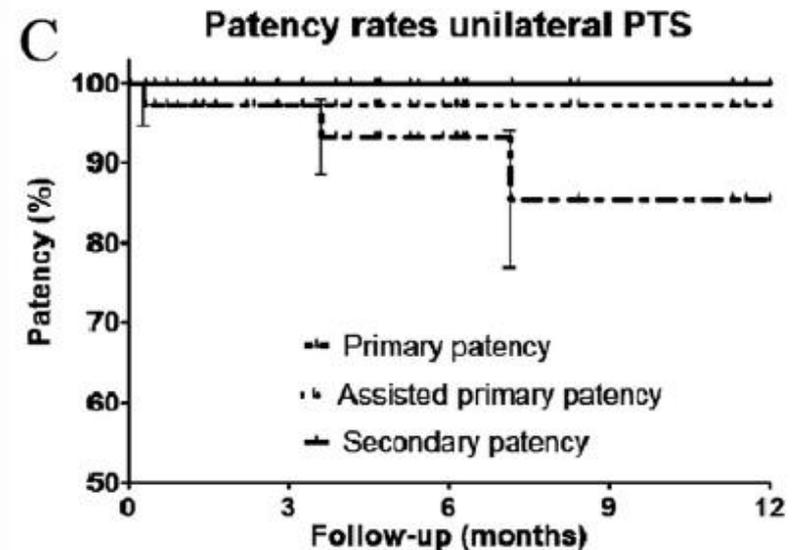
- ◆ The cumulative patency rates at 3, 6, and 12 months: 99%, 96%, and 92%, respectively.
- ◆ The cumulative assisted primary patency rates 99% at 3, 6, and 12 months. The cumulative secondary patency rate at 12 months: 100%.
- ◆ VCSS and Villalta score decreased significantly after stenting
- ◆ Morbidity was low without clinically relevant pulmonary embolism, and no mortality.

\* optimed, Ettlingen, Germany

# Discussion: sinus-Venous® stent



Subjects at risk	Baseline	3 months	6 months	9 months	12 months
Primary Patency	35	25	18	12	7



Subjects at risk	Baseline	3 months	6 months	9 months	12 months
Primary Patency	40	26	17	10	7
Assisted primary patency	40	25	17	10	7
Secondary patency	40	26	18	11	8

Differences exist in patency rate between non-thrombotic and post-thrombotic patients, (de Wolf MA, de Graaf R, et al. European journal of vascular and endovascular surgery. 2015)

# Conclusion

- ◆ In conclusion, patency rates and clinical outcomes at 3 months in patients with common iliac vein compression treated with the sinus-Obliquus stents were excellent.
- ◆ Further studies need to investigate the efficacy and safety of sinus-Obliquus stenting in a long-term perspective.

# Acknowledgments

Stuck AK, Kunz S, Baumgartner I, Kucher N.: Short-term Patency Rates and Clinical Outcomes of Patients with Common Iliac Vein Compression Treated with a Dedicated Venous Self-expanding Oblique Hybrid Nitinol Stent. Article under Review. 2016.

All collaborators of the Venous Stent Registry.

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