Stent Conformability is most important in achieving good stent outcomes

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Engineering Requirements

- Crush Resistance
- Flexibility
- Radial Strength
- Deployment
- Scaffolding (Coverage)
- Diameters & Lengths
- NOT UNERPINNED BY DATA

"The ideal stent would be **flexible** with moderate **radial force**, no foreshortening, and allow for very precise and **accurate placement**." - Brooke Spencer, MD, FSIR

"The ideal stent has to be reasonably **long** and **flexible**, yet provide adequate **radial strength** to withstand opposing forces at the choke points." - Seshadri Raju, MD, FACS

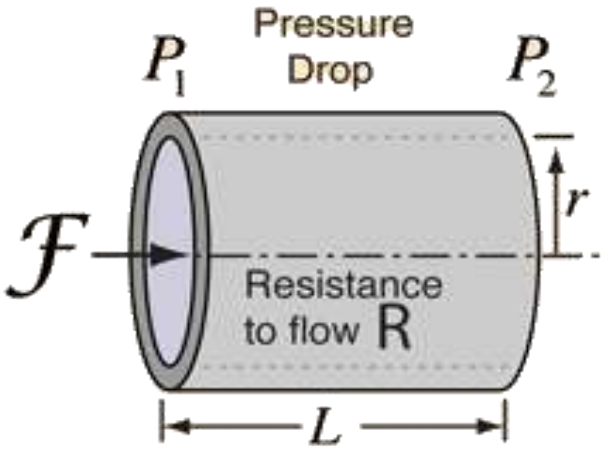
"Some desirable features are common to all stents, not just venous devices, and include **precise deployment**, good visibility, and **flexibility** of both a low profile delivery catheter and the deployed stent. However, certain attributes are more suited for venous applications, such as **larger diameters** (≥14 mm) and appropriate levels of **radial force and crush resistance**." - Mahmood K. Razavi, MD, FSIR

Venous Stenting: Expectations and Reservations; Raju S, Razavi MK, Spencer B, Williams DM, Endovascular Today, July 2013

Engineering Conflicts and Optimization

- Design Conflicts
  - Strength vs Flexibility vs Foreshortening
  - Scaffolding/Coverage vs Flexibility
  - Crush Resistance and Radial Strength vs Deployment
- Each requirement is a “lever” that can be moved, however, it may affect and move other levers
- Optimization of a design is based on how all the levers are prioritized

Why is Radius Important



Suppose the original flowrate is 100 cm^3/sec. The effect of changes in the parameters is as follows:

* Double length	⇒	50	cm^3/sec
Double viscosity	⇒	50	cm^3/sec
Double pressure	⇒	200	cm^3/sec
Double radius	➡	1600	cm^3/sec

$$\mathcal{R} = \frac{8\eta L}{\pi r^4}$$ where η = viscosity

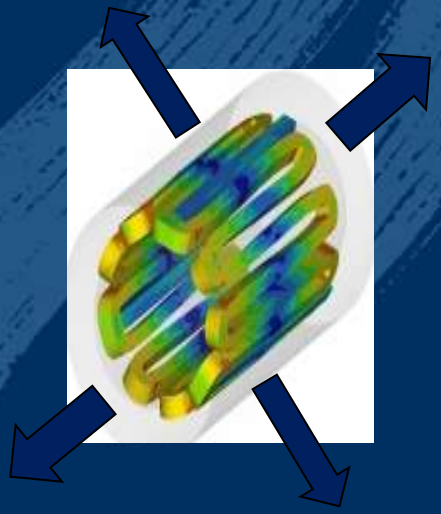
* With other parameters held at original values

$$\text{Volume Flowrate} = \mathcal{F} = \frac{P_1 - P_2}{\mathcal{R}} = \frac{\pi(\text{Pressure difference})(\text{radius})^4}{8(\text{viscosity})(\text{length})}$$

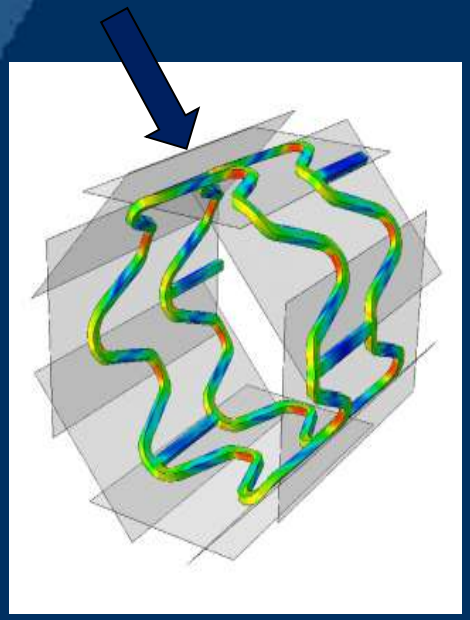
A 19% increase in radius will double the volume flowrate!

However bigger brings challenges

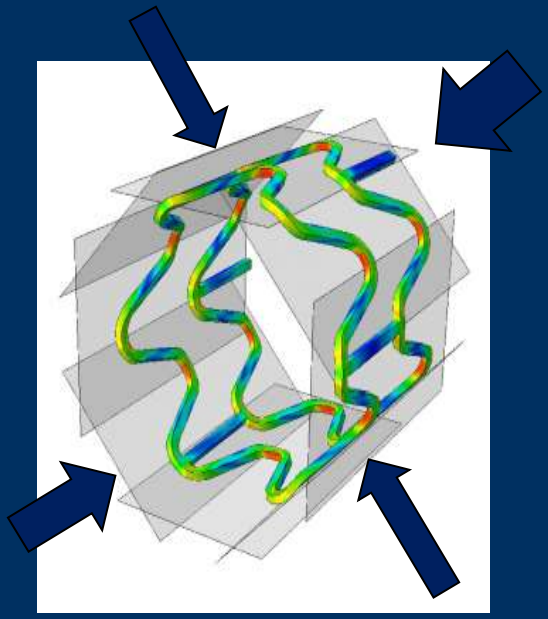
Stent Strength



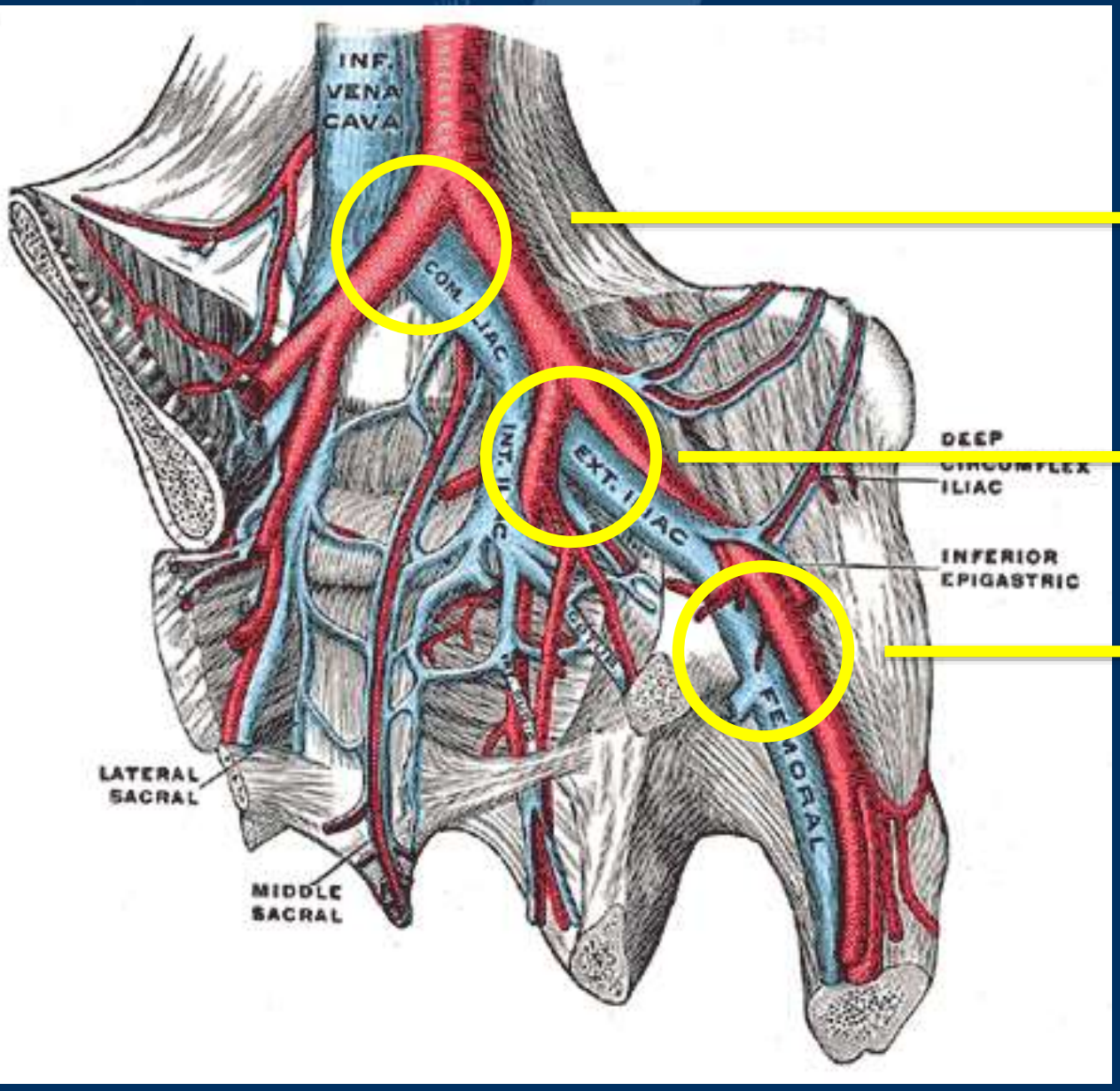
Chronic Outward Force:
How much the stent pushes outward. Often called Radial Force.



Crush Resistance:
How much the stent can resist a single load



Radial Resistive Force:
How much circumferential load a stent can resist



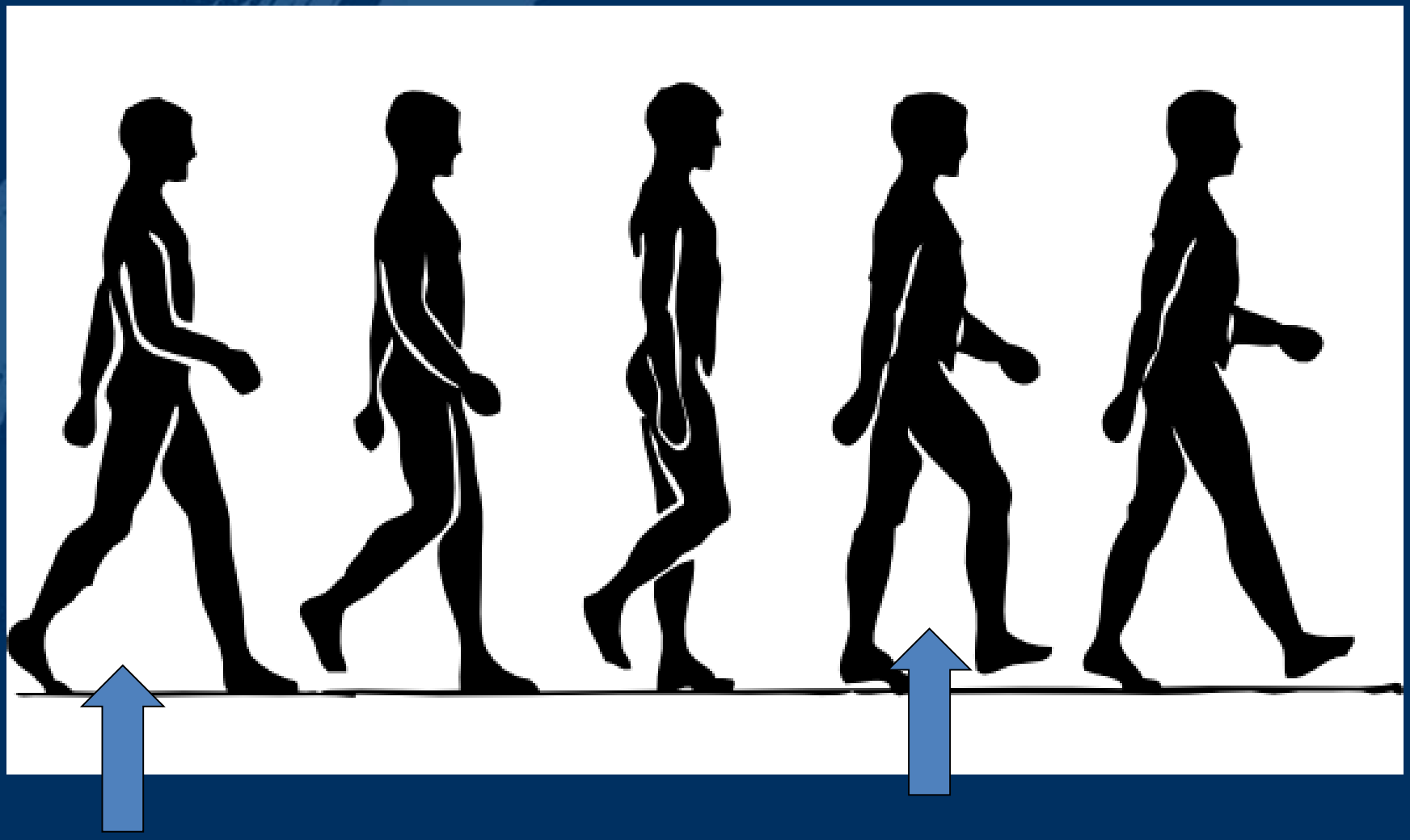
More strength
How much?

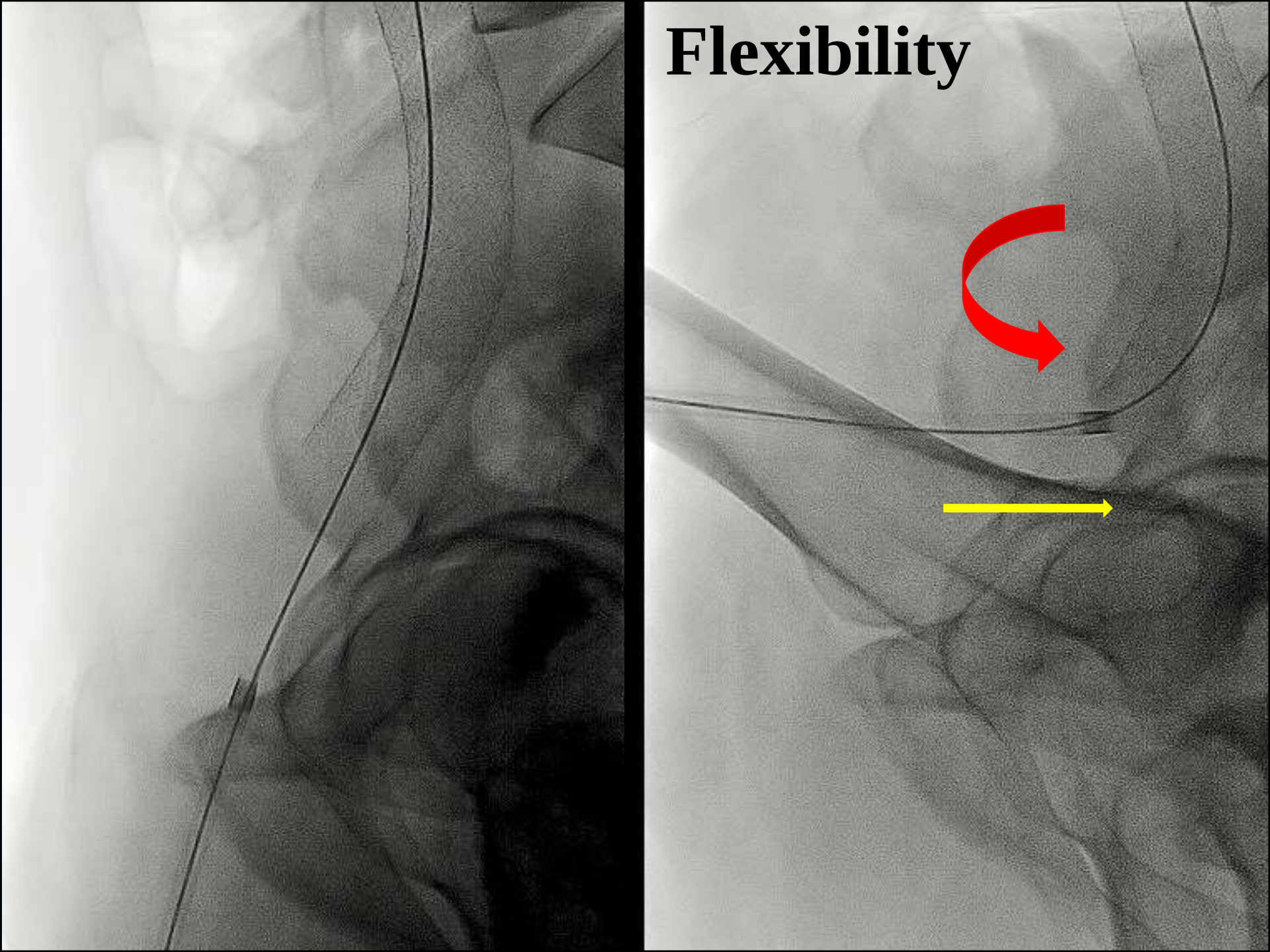
More flexible
How much?

Everything?
How much?

How strong is strong enough and how flexible is flexible enough?

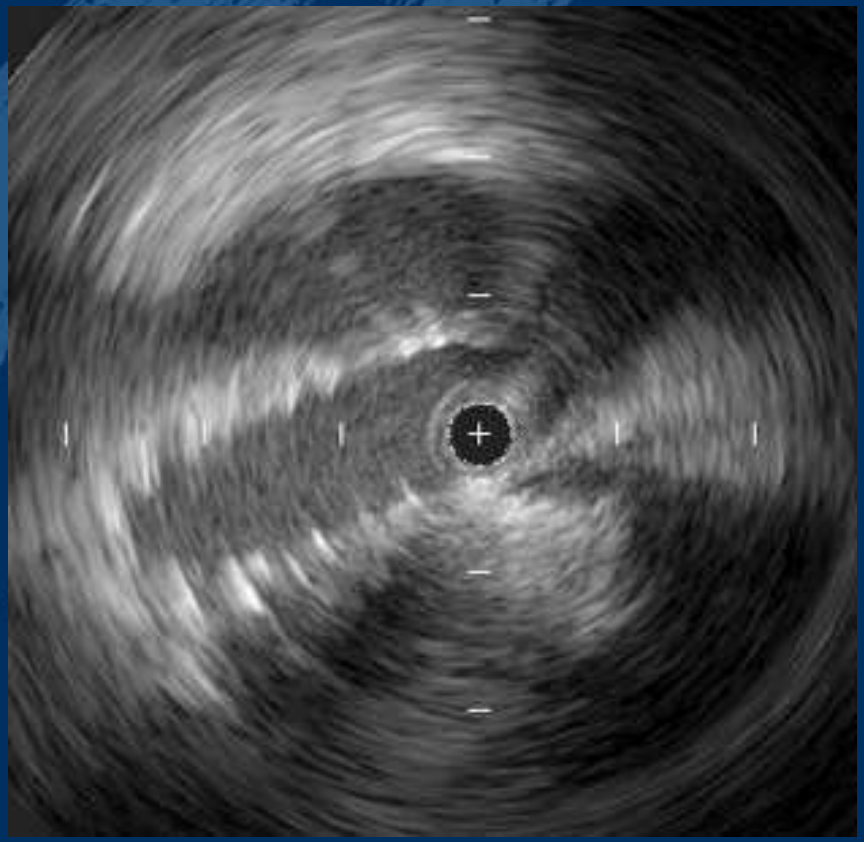
What happens when we walk?



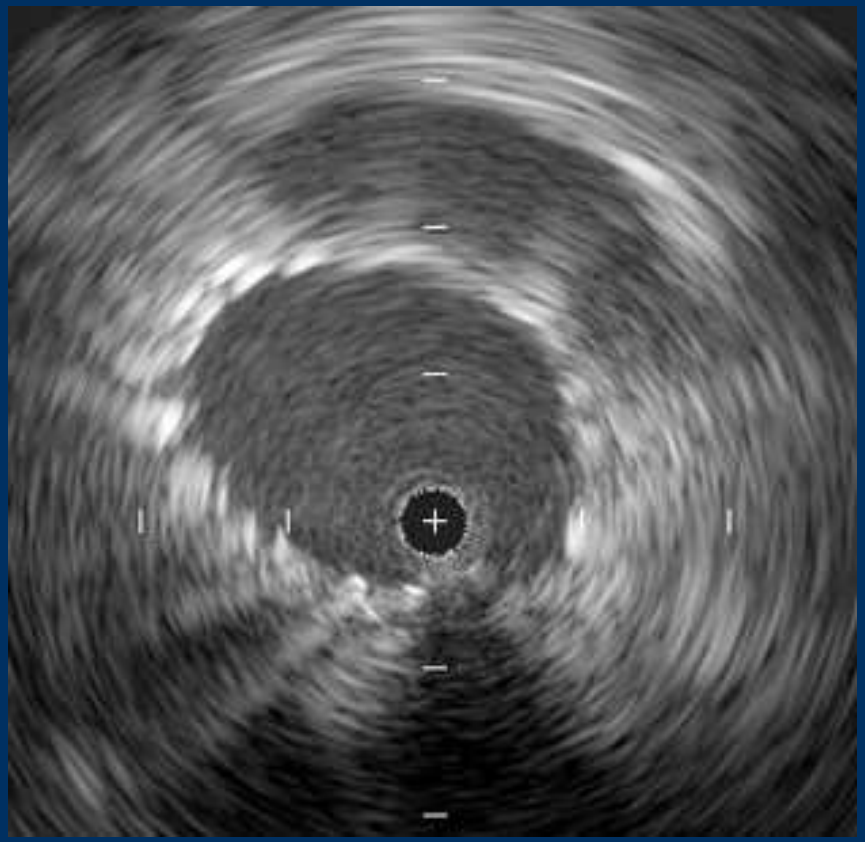

Flexibility

Strength or Rigidity

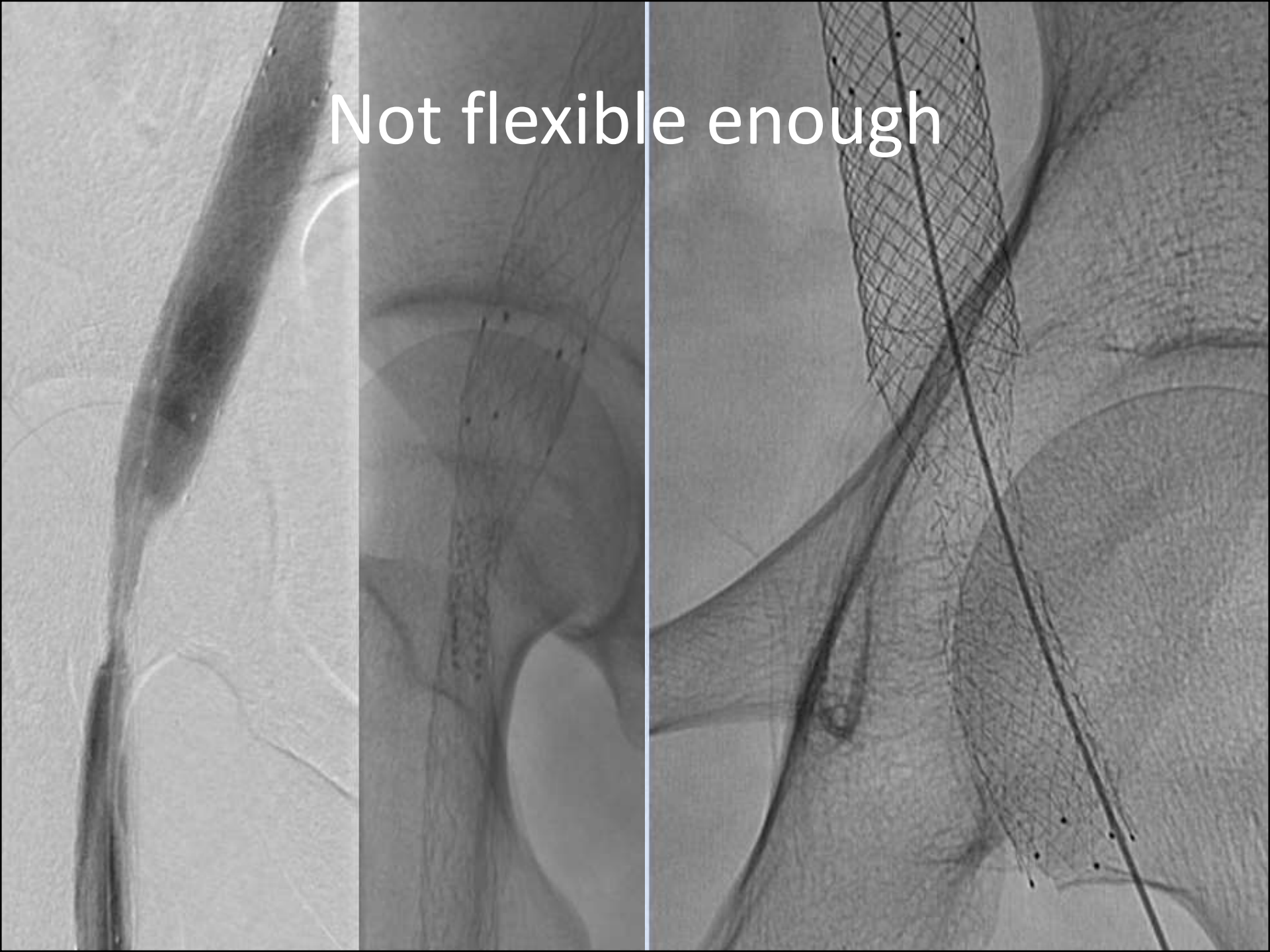
Collapse



Rigid



Aspect Ratio – what data do we have?


Not flexible enough

DATA?

SUBSCRIPTIONS

Changes to lumen shape may be more important than area in venous stenting patient outcomes

1st June 2018 3257

Lowell Kabnick on the podium at CX

Data presented at the Charing Cross Symposium (24–27 April, London, UK) indicate that a rounder post-stent lumen shape has a positive correlation to 12-month patient

Aspect Ration

- Same stent
- Not published

Original Article

Phlebology

Relevance of flexibility versus radial force in rigid versus more flexible venous stents?

Phlebology
2019, Vol. 34(7) 459–465

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Timme MAJ van Vuuren[1,2], Mark AF de Wolf[1,2,3] and Cees HA Wittens[1,2,4]

What is the definition for flexible vs rigid?

"There are known knowns. These are things we know that we know. There are known unknowns. That is to say, there are things that we know we don't know. But there are also unknown unknowns. There are things we don't know we don't know."

Donald Rumsfeld

What don’t we know

What are our expectations

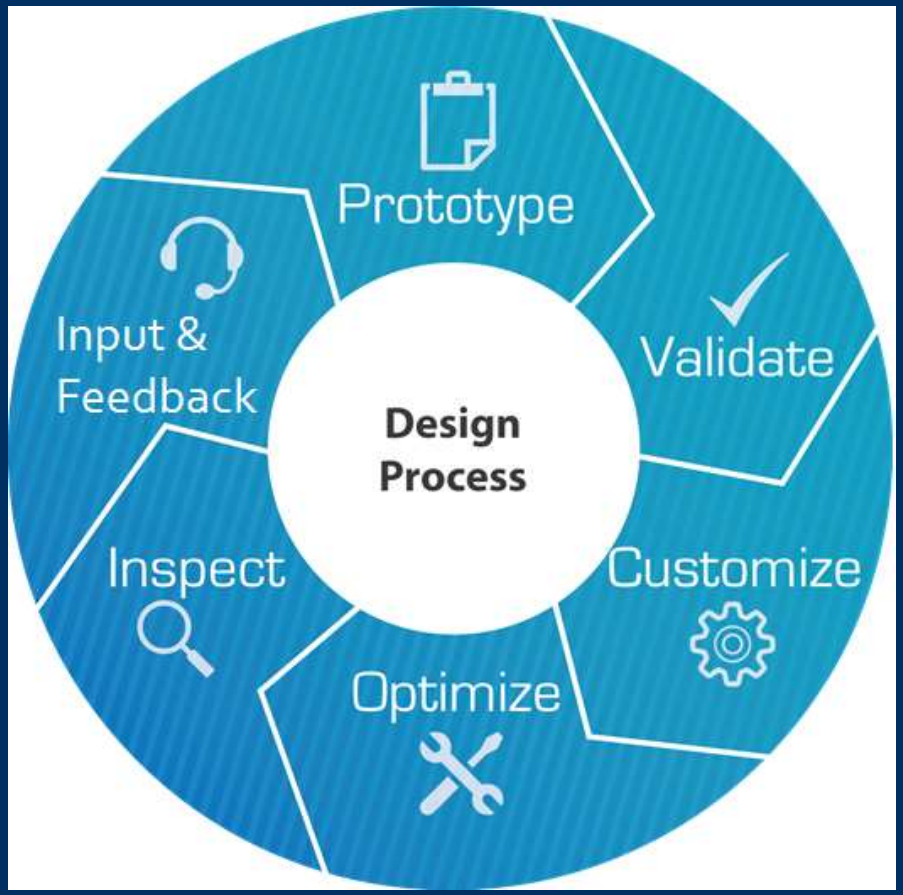
Arterial Patients

Venous Patients

Testing bench marks started the same as they were for arterial

Designing is Cyclic and Iterative

- Design inputs, i.e. Clinical requirements drive the design and development process
- Feedback repeats the design process
- We as users need to provide feedback
- WE NEED PROPER DATA



Conclusions

- Know each device and technical issues
- Be honest in feedback to patients and companies
- We need better data on what we are designing toward
- We need long term patient outcome data to support use
- One size may not fit all

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