Important Stent Design and Delivery System Issues Make All the Difference for Coronary Stents

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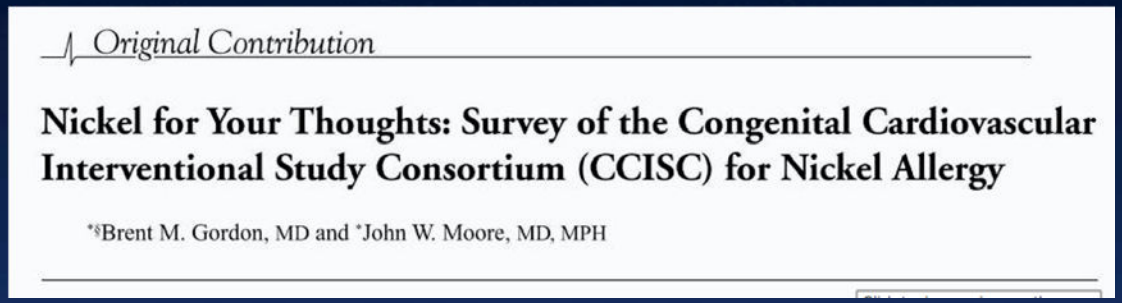
Disclosures

- Authors are employed by Nitinol Devices & Components, Inc (NDC)
- NDC is a supplier and/or development partner to many companies developing and commercializing Nitinol cardiovascular devices

Heard at TCT...

Nitinol and Nickel Allergy

Nickel Allergy
Reconciling myth and science



Original Contribution

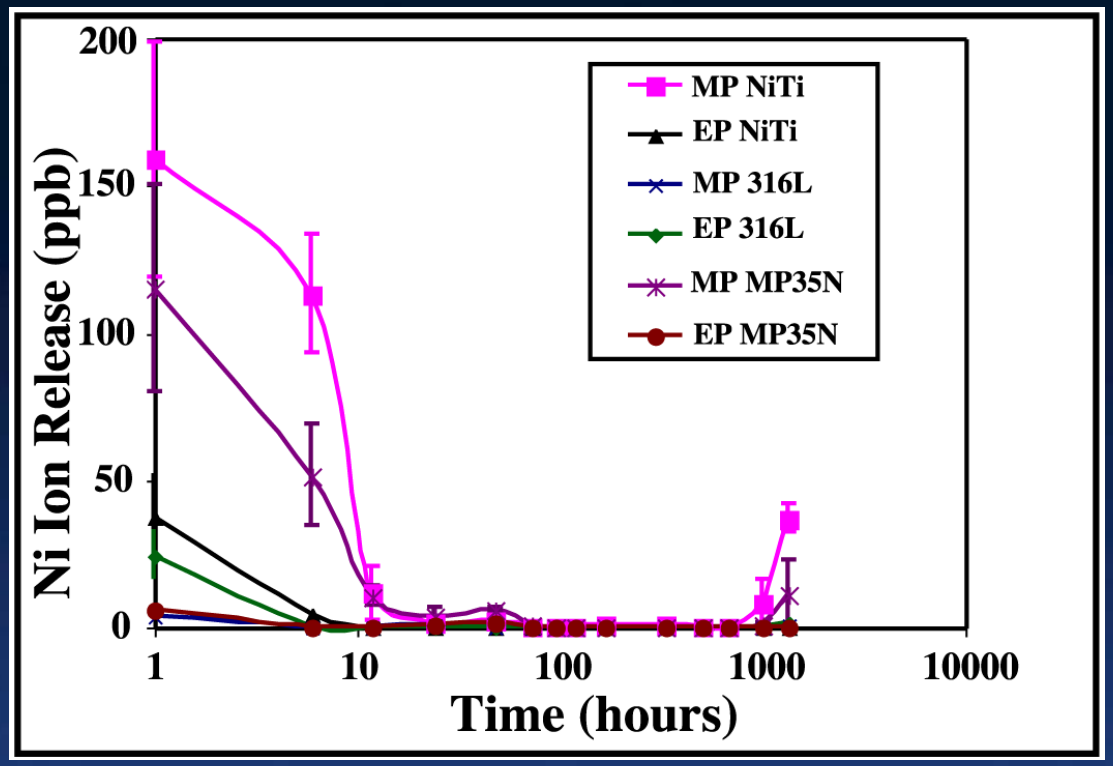
Nickel for Your Thoughts: Survey of the Congenital Cardiovascular Interventional Study Consortium (CCISC) for Nickel Allergy

*§Brent M. Gordon, MD and *John W. Moore, MD, MPH

J Invasive Cardiol. 2009 Jul;21(7):326-9.

Nickel Release

f (Material + Processing)



Different devices – different surfaces – different processes – different outcomes

Overview

- Nitinol Stents are Different
  - Delivery System Issues
  - Stent Strength Issues
  - ~~Profile Issues~~
  - ~~Scaffolding & Uniformity Issues~~
- Coronary Nitinol Stenting
  - ~~Advantages & Disadvantages of Nitinol~~
  - ~~Future Directions~~
  - Thought provoking questions:
    Relating ENGINEERING to Clinical OUTCOMES

Delivery Systems

Balloon Expandable

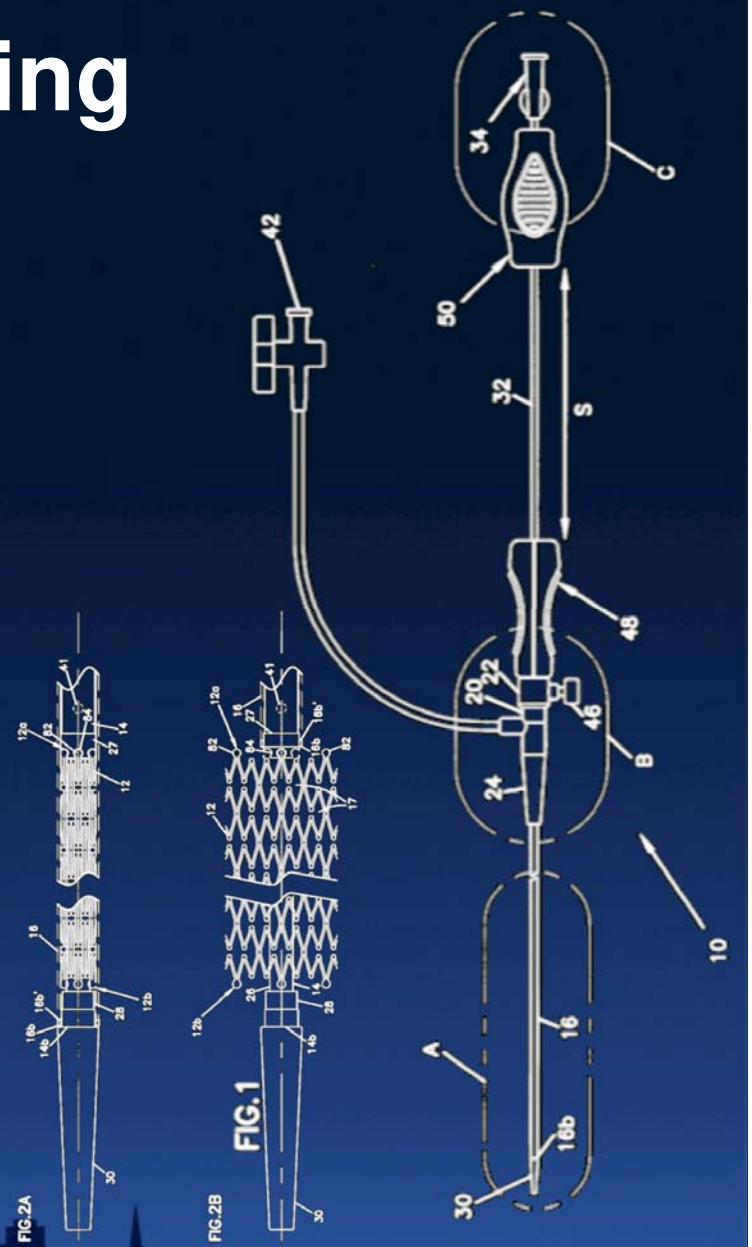
Fig-1

Fig-3

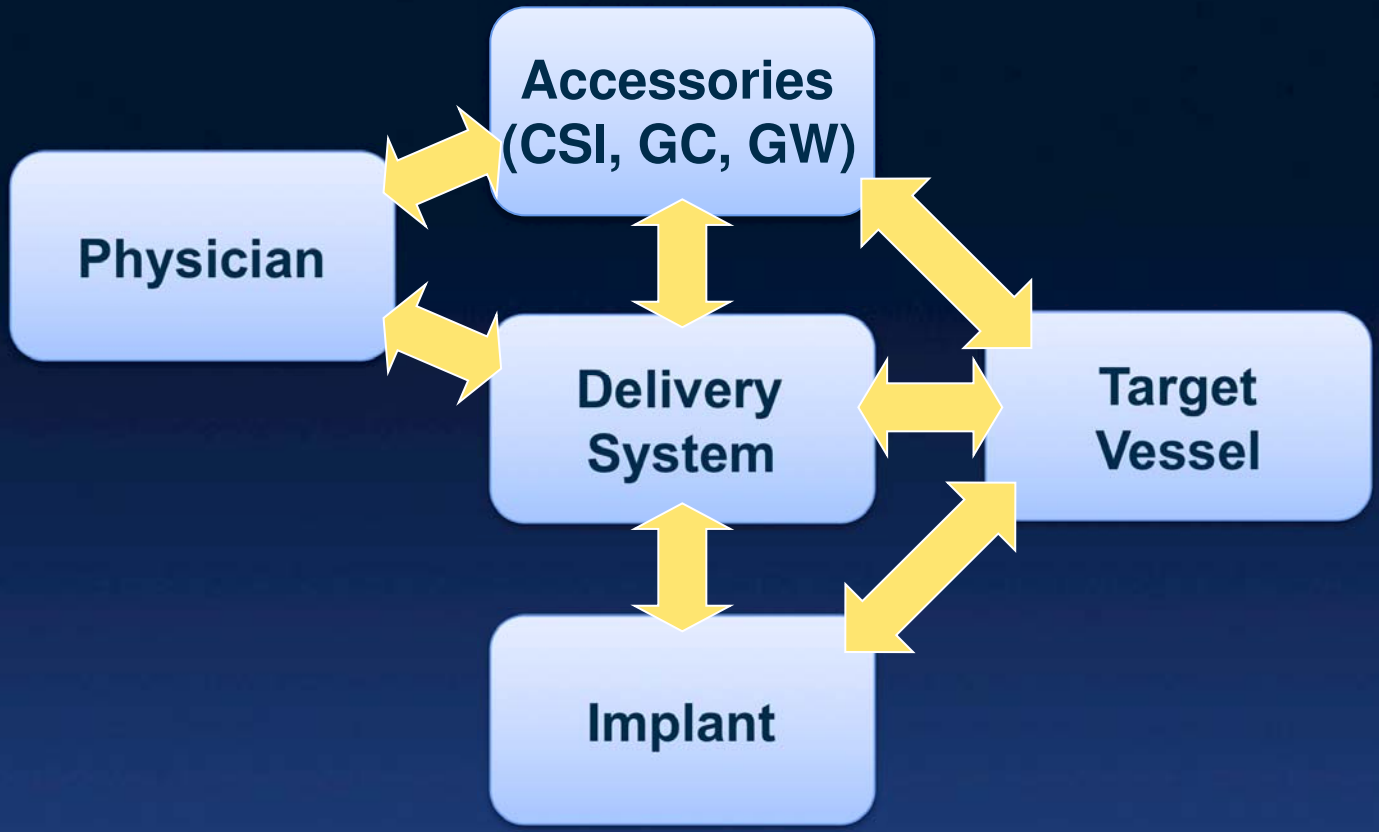
- Benefits
  - Familiar
  - Reliable
- Issues
  - Flexibility
  - Stent retention
  - Compliance
  - Profile

Self Expanding

- Benefits
  - Versatility
  - Profile: no balloon
- Issues
  - Less familiar
  - Relative motion
  - Axial energy
  - Friction



SX Delivery System Primer



The **INTERACTIONS** drive success or failure of design!

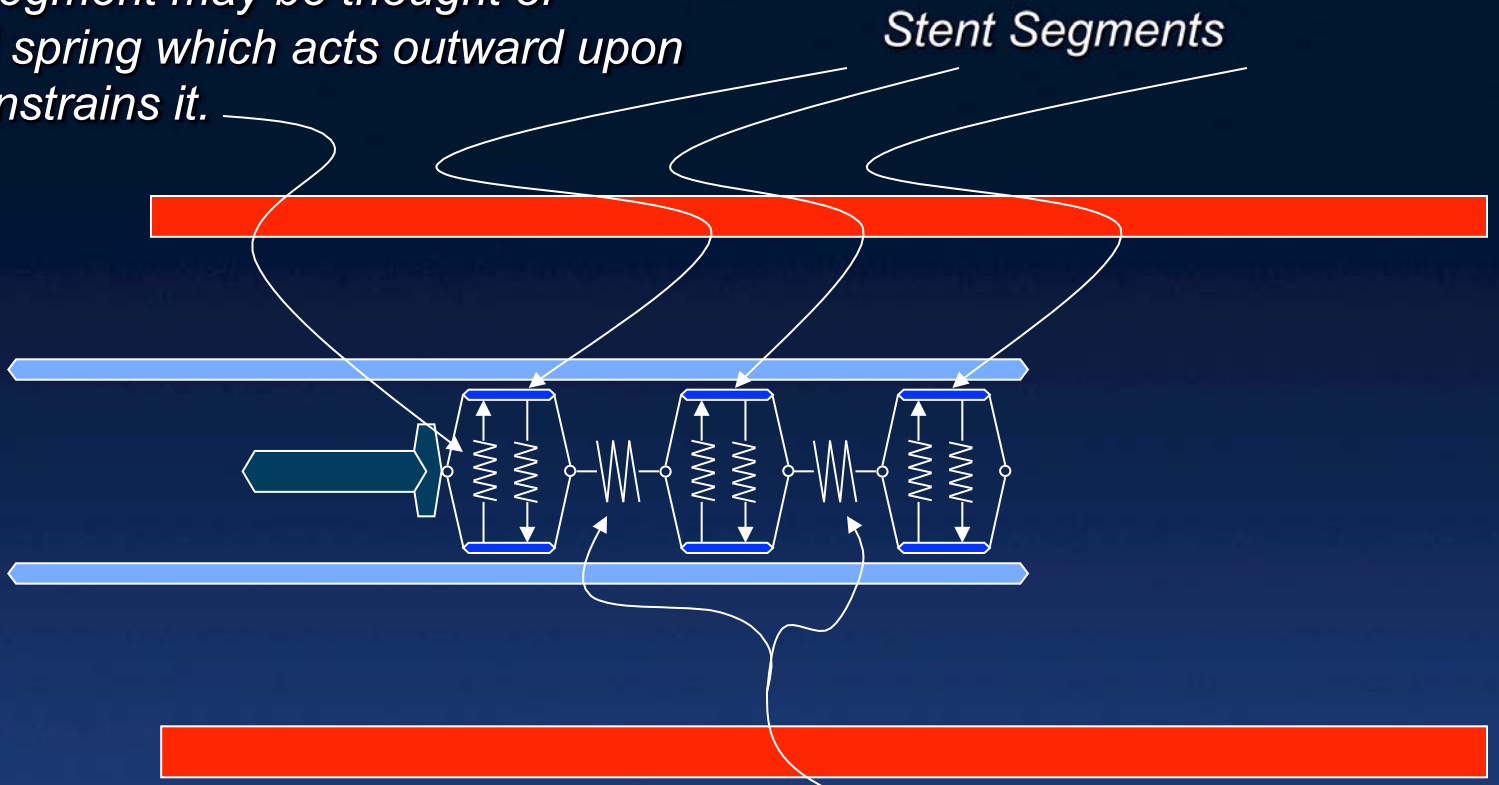
SX Delivery System Primer

SX Delivery System Primer

SX Delivery System Primer

SX Delivery System Primer

Each stent segment may be thought of as individual spring which acts outward upon whatever constrains it.

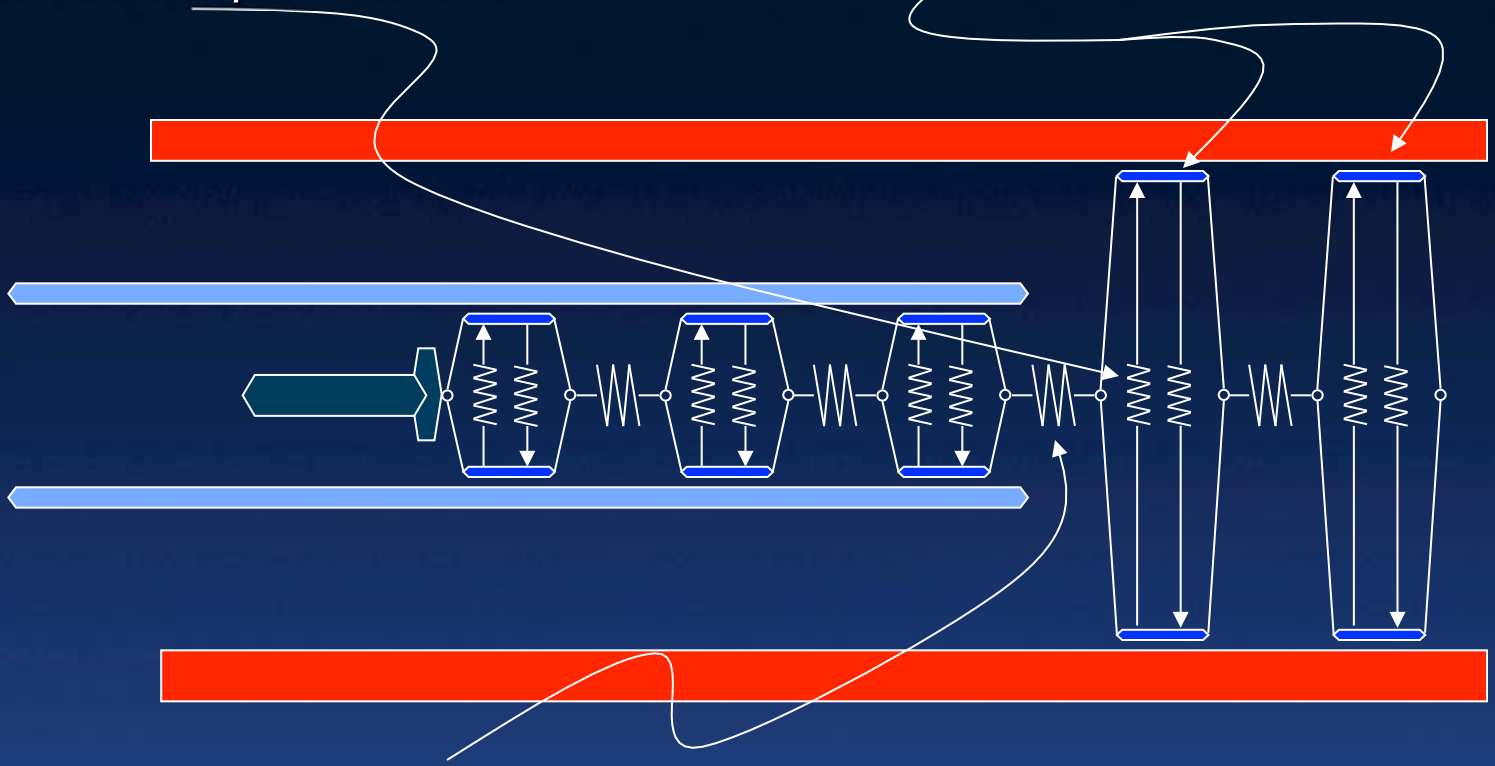


Adjacent stent segments are connected by bridges. One may consider each stent segment to have some axial elasticity represented by these springs. This spring constant is a function of stent diameter (constrained or expanded).

SX Delivery System Primer

These springs exert less outward force when in the expanded state.

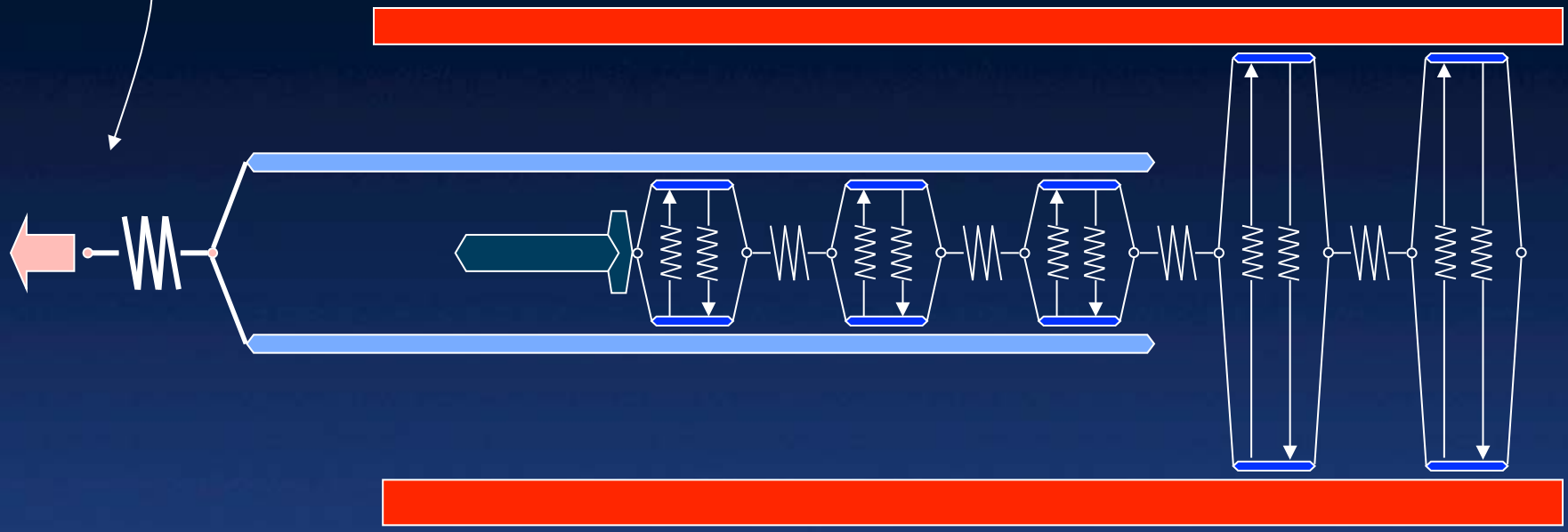
Expanded Stent Segments



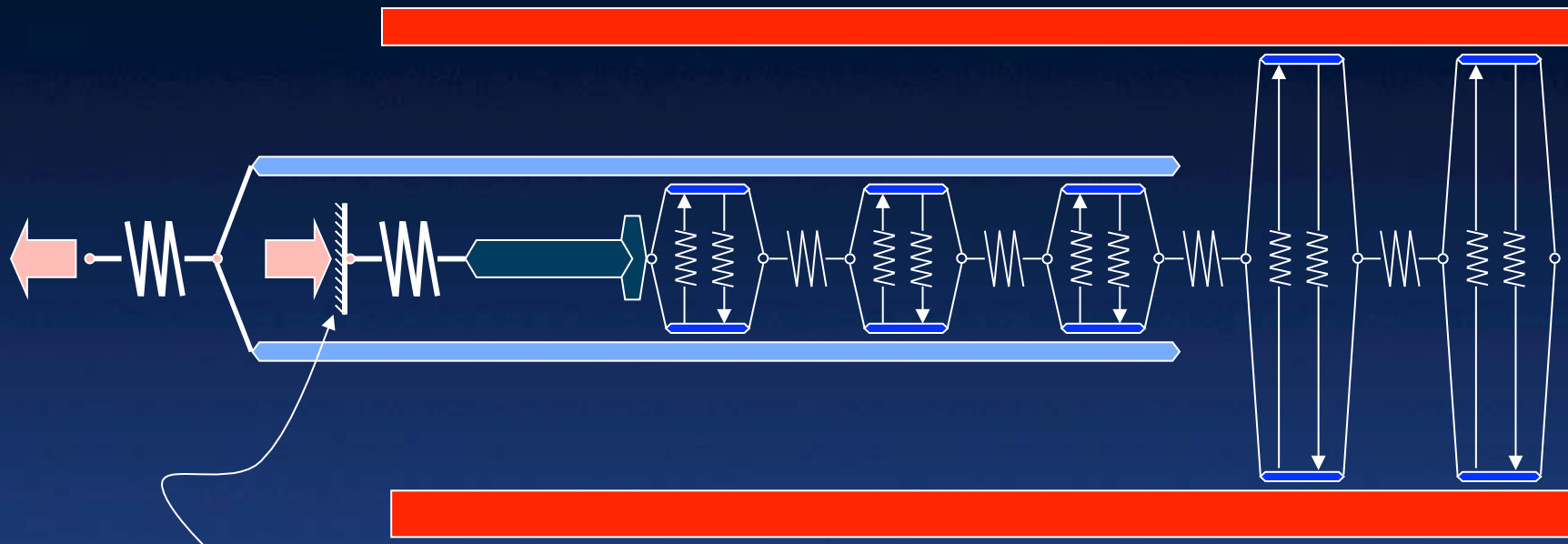
These springs become less stiff when the stent escapes its constrained state.

SX Delivery System Primer

The stent is deployed by pulling back on the outer member… But the outer member has an elasticity which is represented by its own spring.



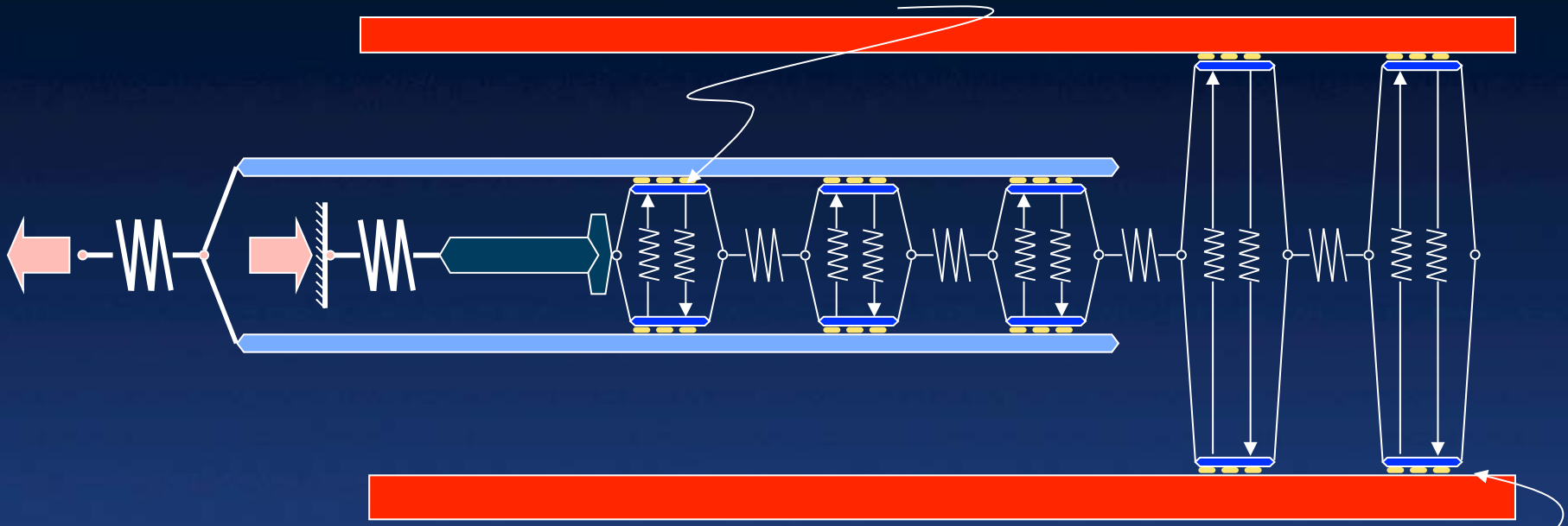
SX Delivery System Primer



The inner body must be constrained at the back end of the catheter. An opposite force must be exerted to enforce this constraint. But the inner body may also have an elasticity, represented by its spring.

SX Delivery System Primer

The constraining sheath and "pusher pin" forces are communicated through a frictional coupling. This is a function of the number of stent segments in contact within the catheter, the force exerted by those segments, and the static and/or dynamic coefficient of friction between these elements.

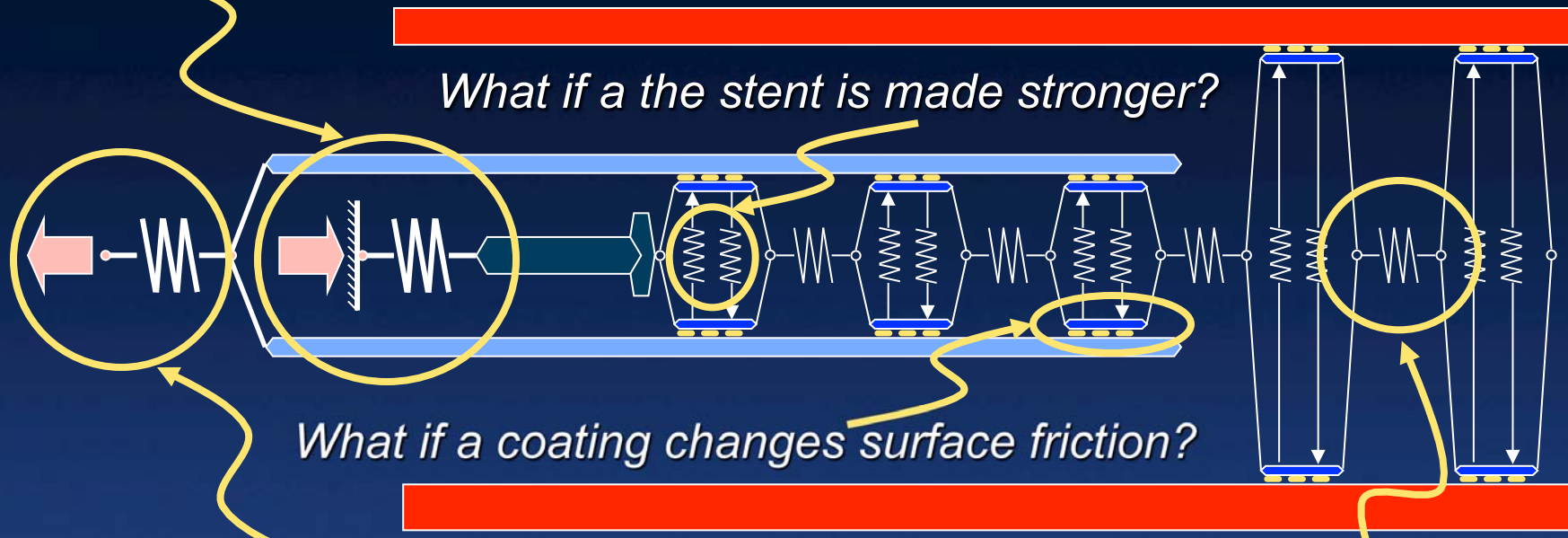


The expanded segments are held in place in the vessel by a similar frictional coupling. The outward force exerted by the stent is less here, so the coupling is not as strong.

Forces, Interactions, Consequences

What if the "pin" isn't held perfectly stable?

What is the "pin" is stable, but the inner shaft absorb energy (compresses)?



What if a the stent is made stronger?

What if a coating changes surface friction?

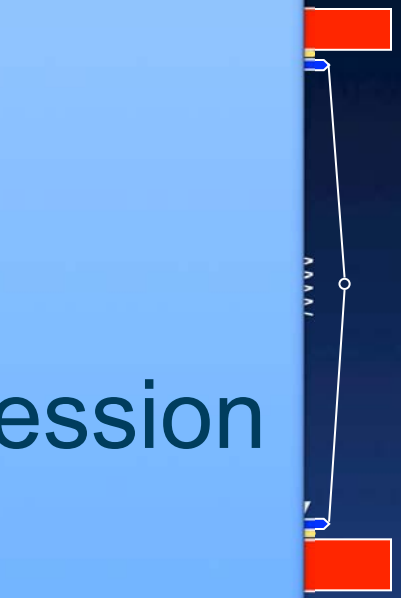
What if the outer sheath stretches?

What if the stent is more axially conformable, with "weak" intersegment links?

Forces, Interactions, Consequences

CONSEQUENCES

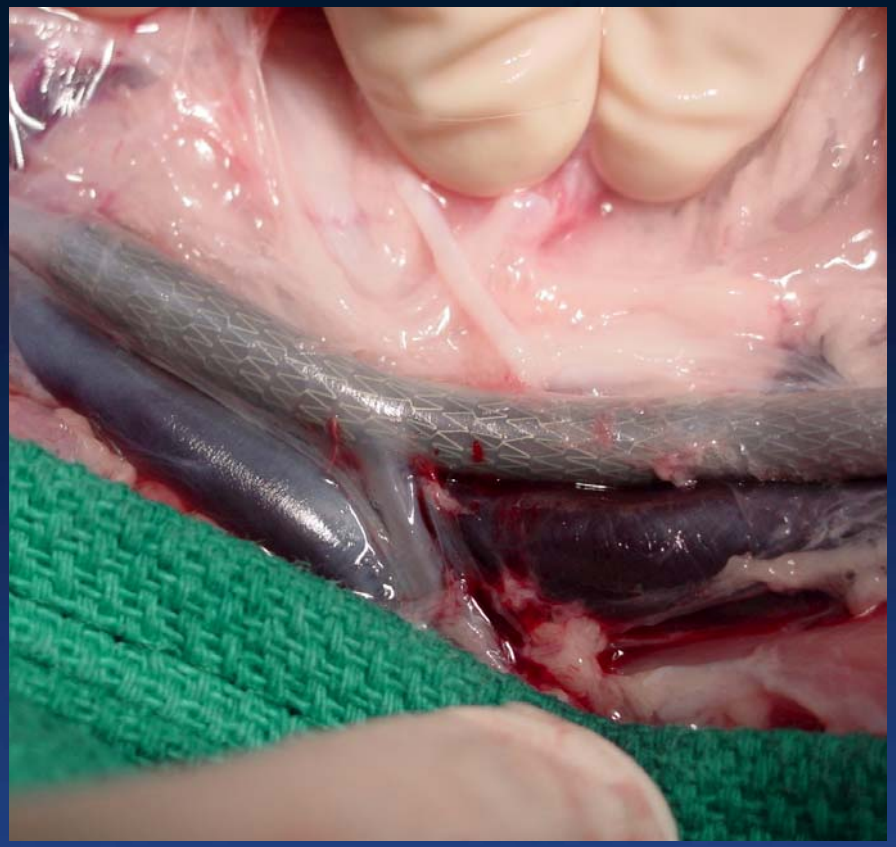
- “Stent Jumping”
- High deployment forces
- Placement Inaccuracy
- In-situ stretching or compression of stent



Desired Outcome

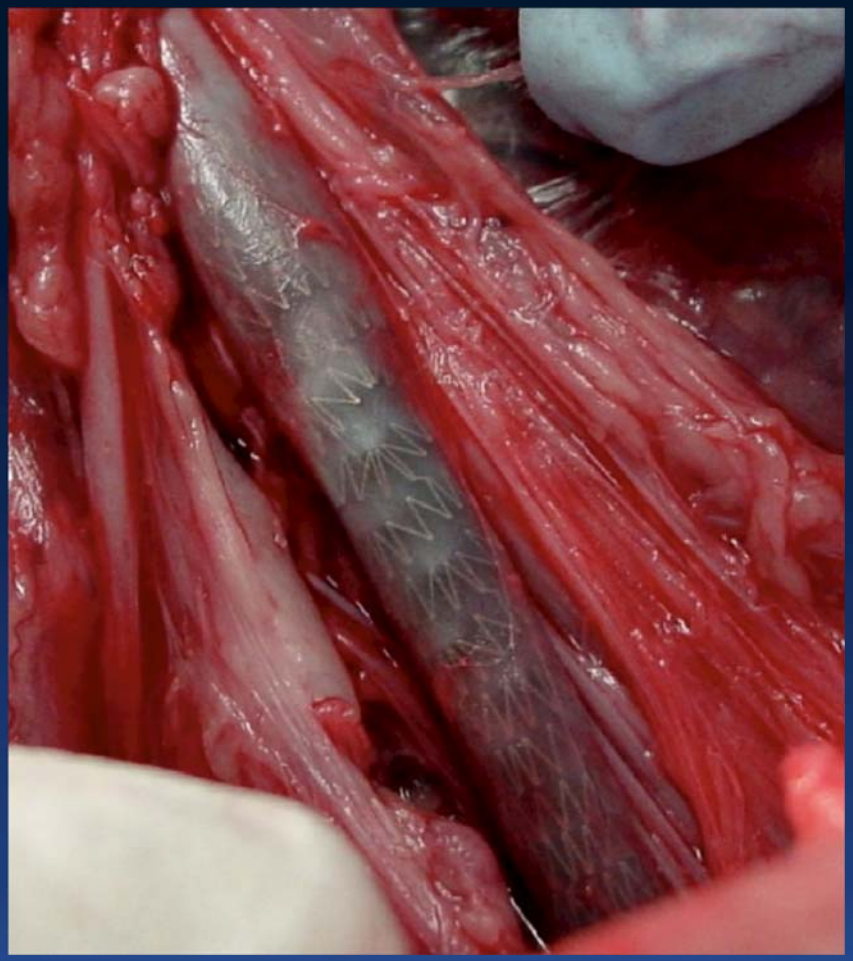
Commercially available stent placed in an exposed porcine artery

A perfect result…



Undesirable Outcome

Axially unstable prototype stretched during deployment in an exposed porcine artery.



Stent Strength

what does “strength” mean?

Ex Vivo Experiment

- 1 3oz can
  Potted Meat Food Product
  (no frills)
- 1 12oz can Corned Beef
  (with natural juices)
- 1 50oz can Whole Chicken
  (without giblets)
- 1 expanded SX stent in tube
- 1 expanded BX stent in tube

Step 1: Potted Meat Food Product

Step 1: Potted Meat Food Product

BX stent and SX stent withstand 3oz of P.M.F.P. without deformation

Step 2: Corned Beef

Step 2: Corned Beef

Step 2: Corned Beef

BX stent withstands 12oz of Corned Beef without deformation
SX stent flattens under Corned Beef load…

Step 2: Corned Beef

…When the Corned Beef is removed, the SX stent resumes its original shape.

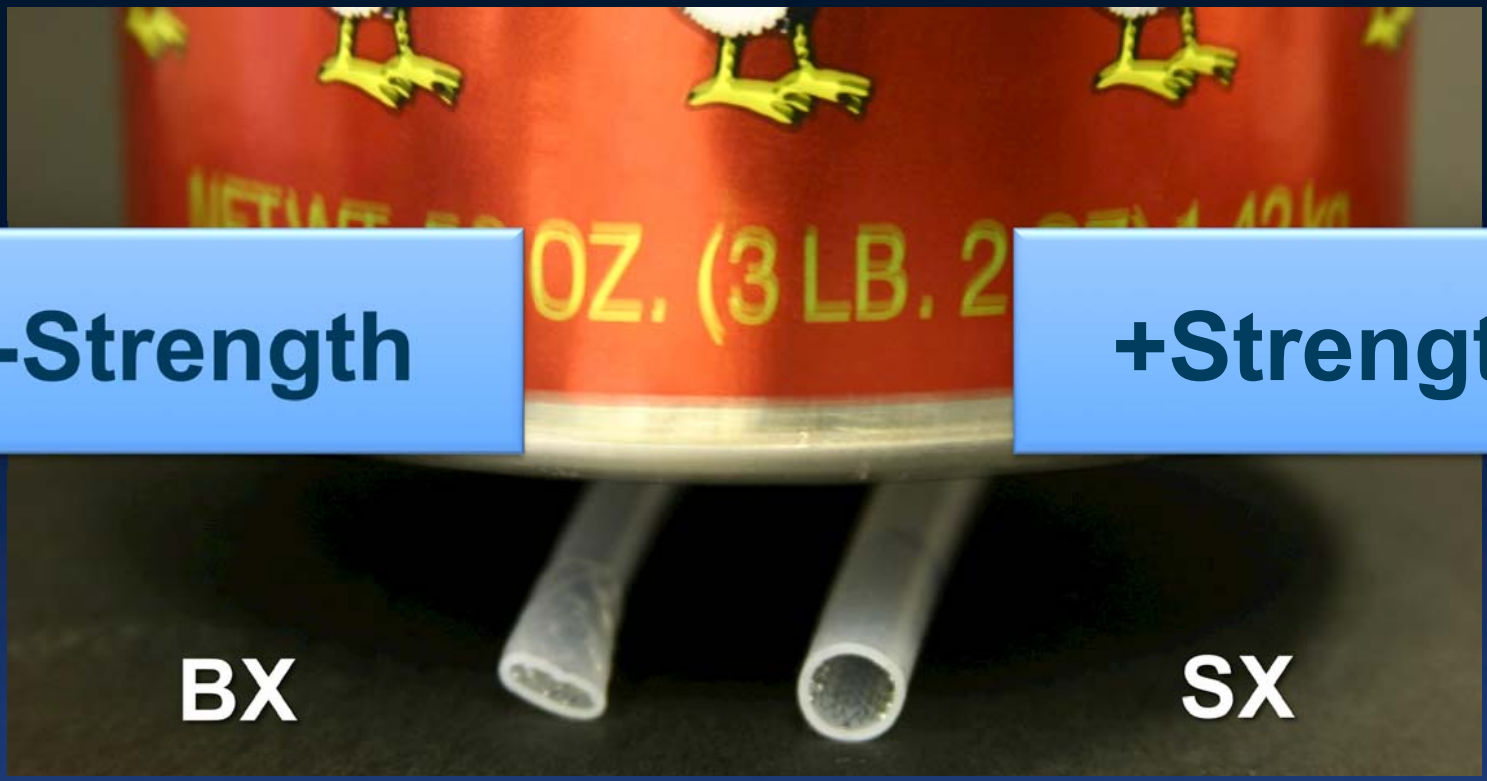
Step 3: Whole Chicken in a Can

Step 3: Whole Chicken in a Can

Step 3: Whole Chicken in a Can

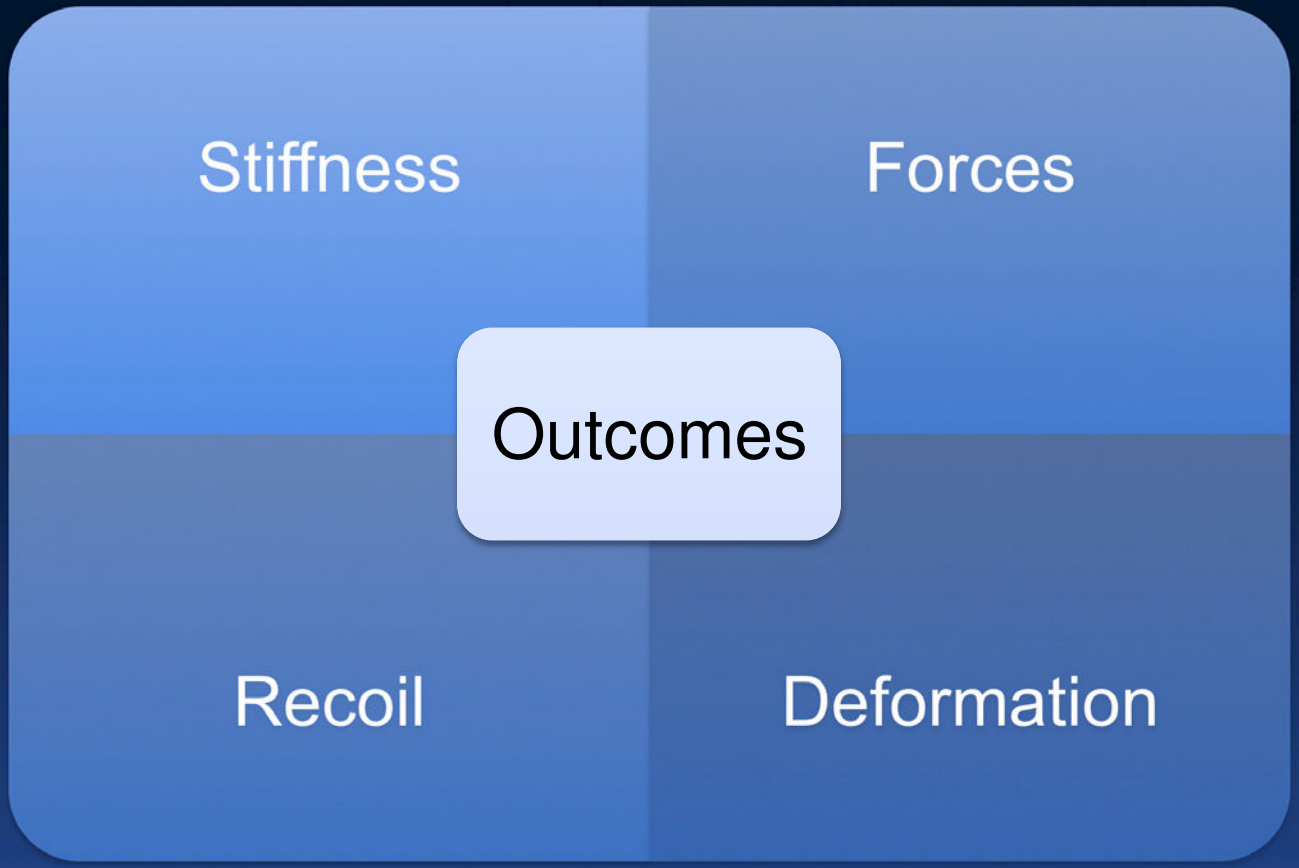
BX and SX stents both flatten under load of One Whole Chicken

Step 3: Whole Chicken in a Can

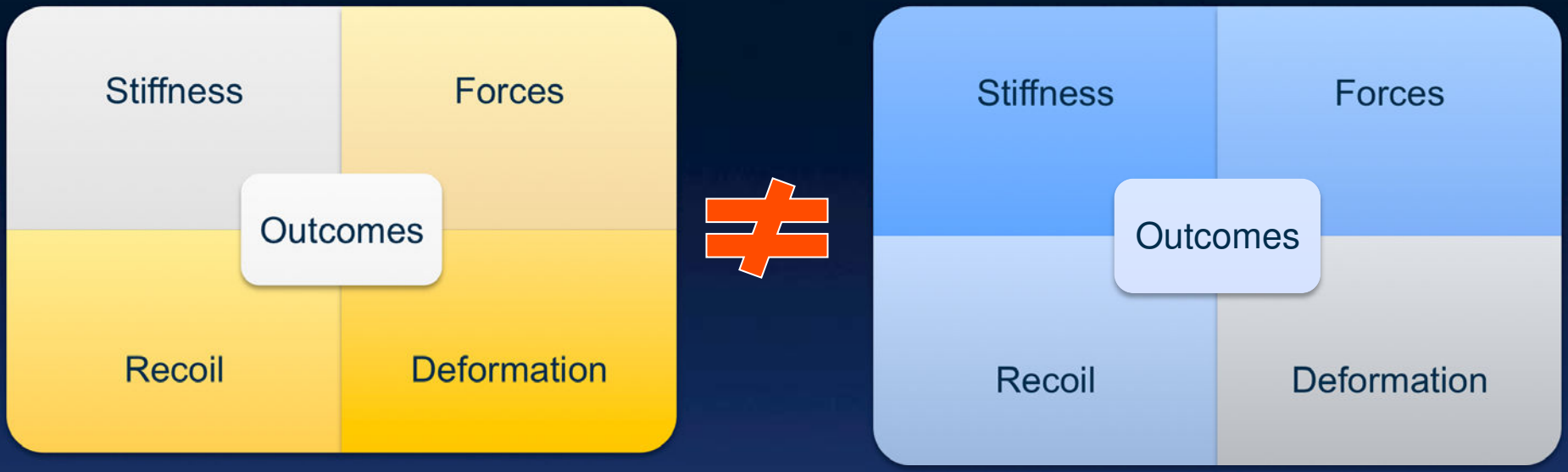


Removing the load of One Whole Chicken, BX stent remains permanently deformed, while SX stent resumes its original shape

Stent Structural Relationships



Stent Structural Relationships



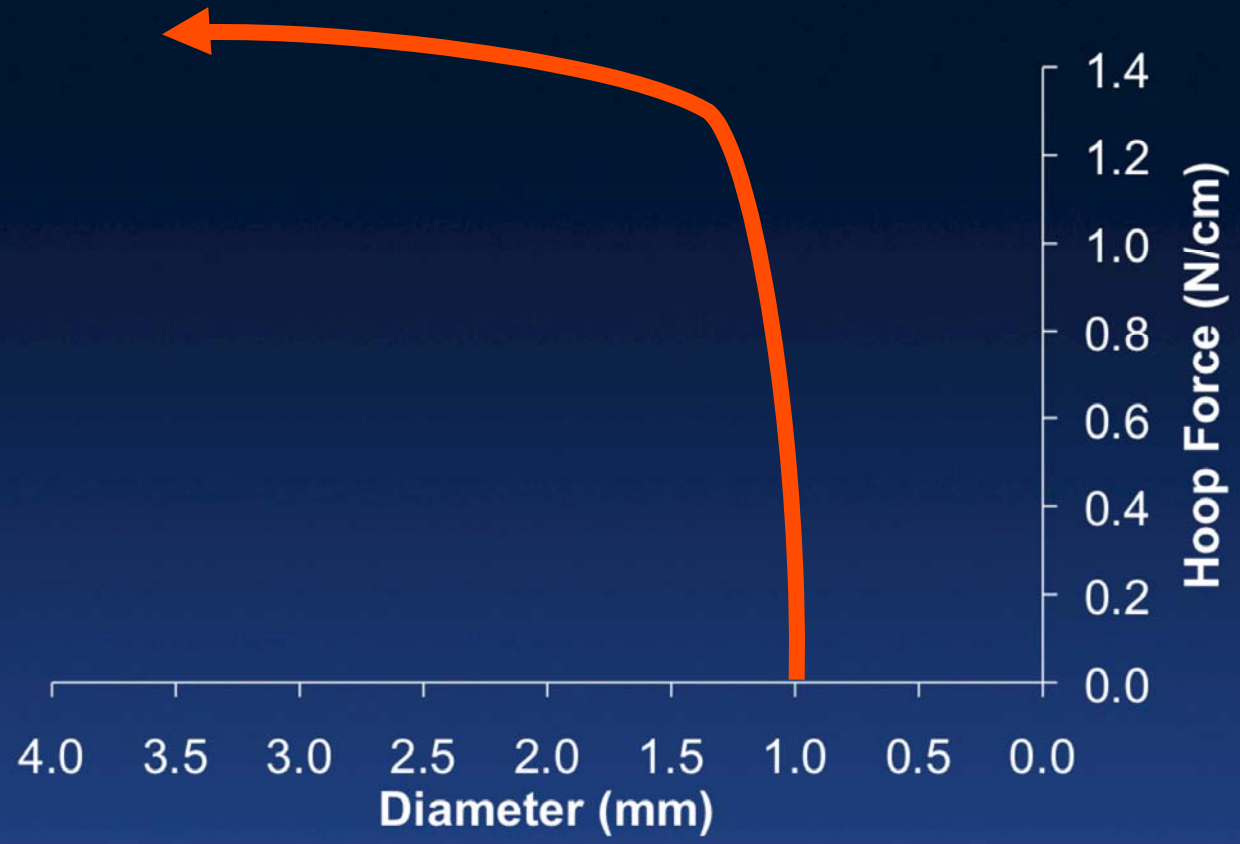
Balloon Expandable
Stainless Steel; Cobalt Alloys

Self Expanding
Nitinol

Balloon Expandable

forces and deformations
during stent deployment & service

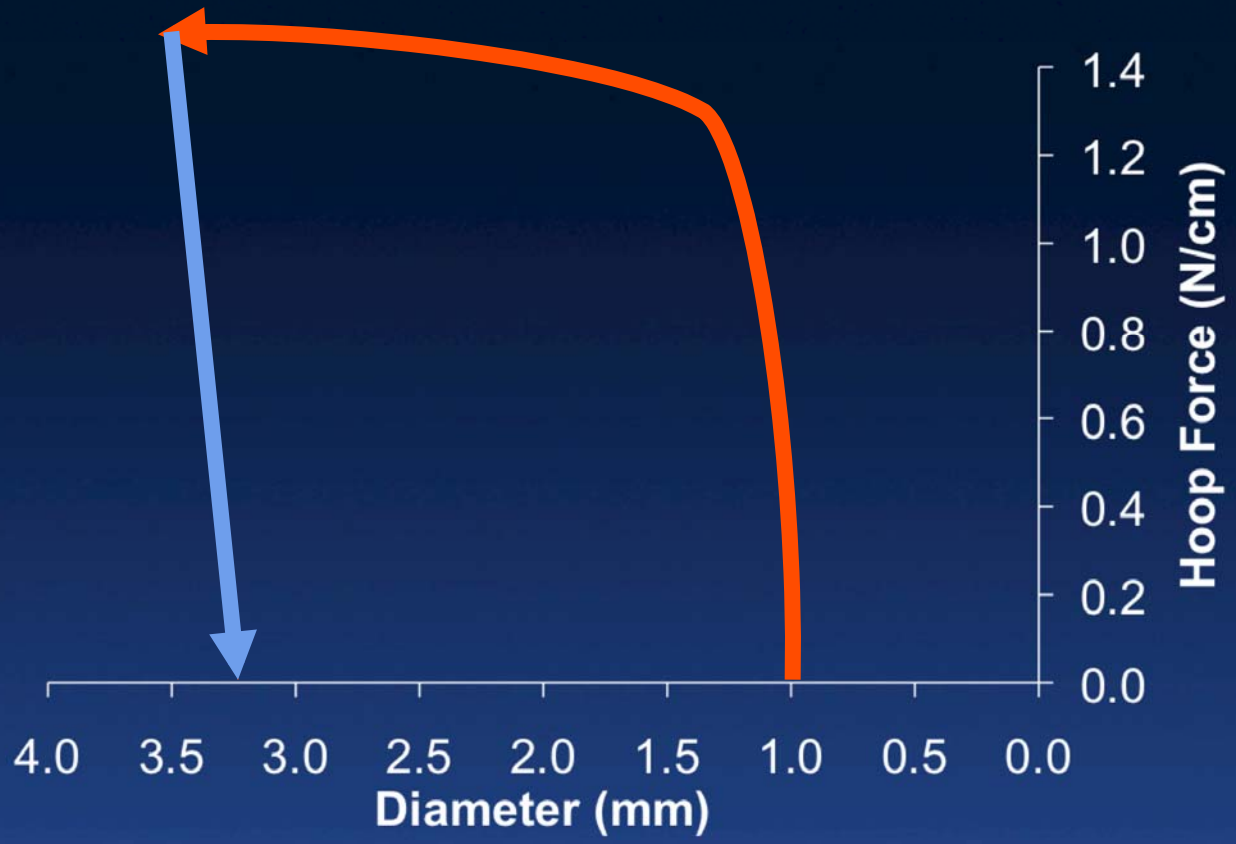
Balloon expansion



expand
with
balloon

Balloon Expandable

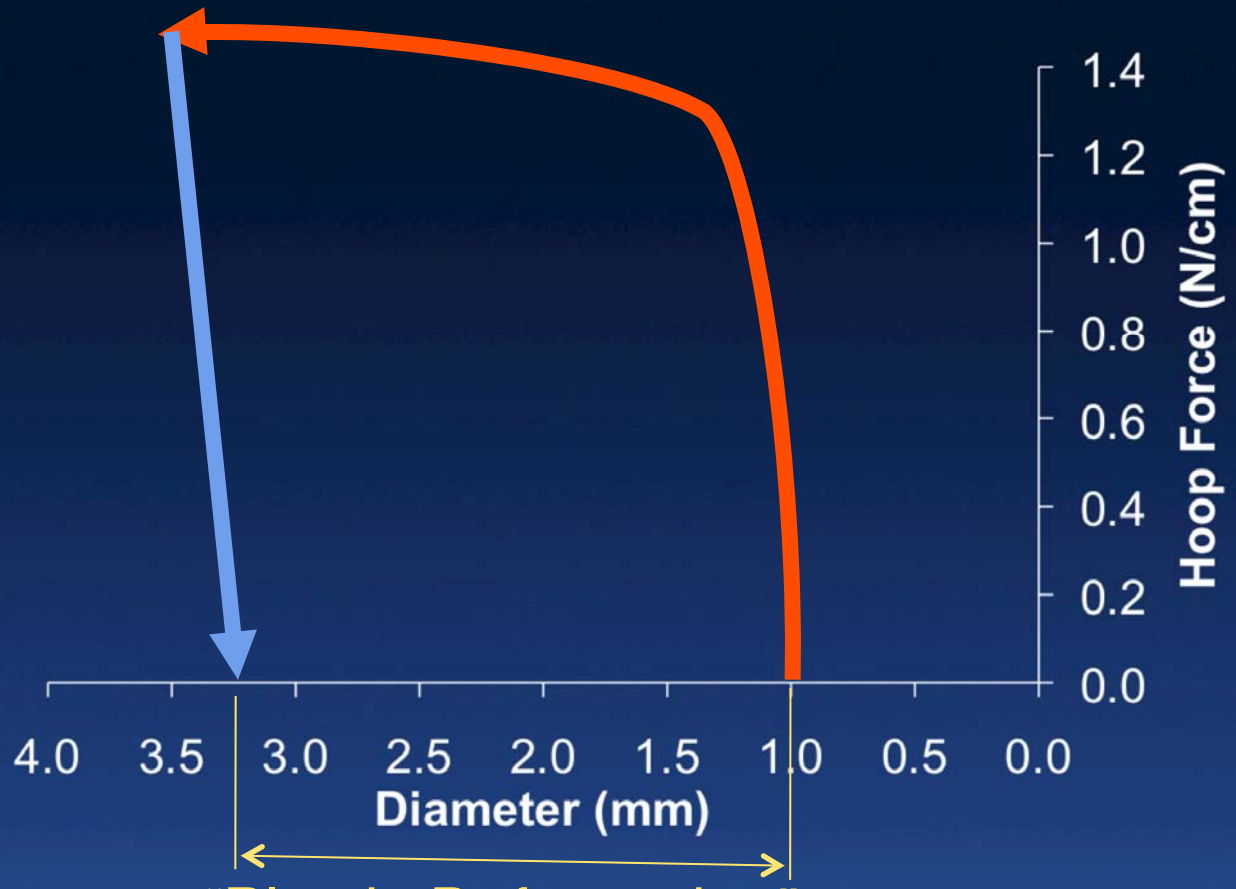
Load vs. Deformation



Release balloon pressure (not in vessel)

Balloon Expandable

Load vs. Deformation

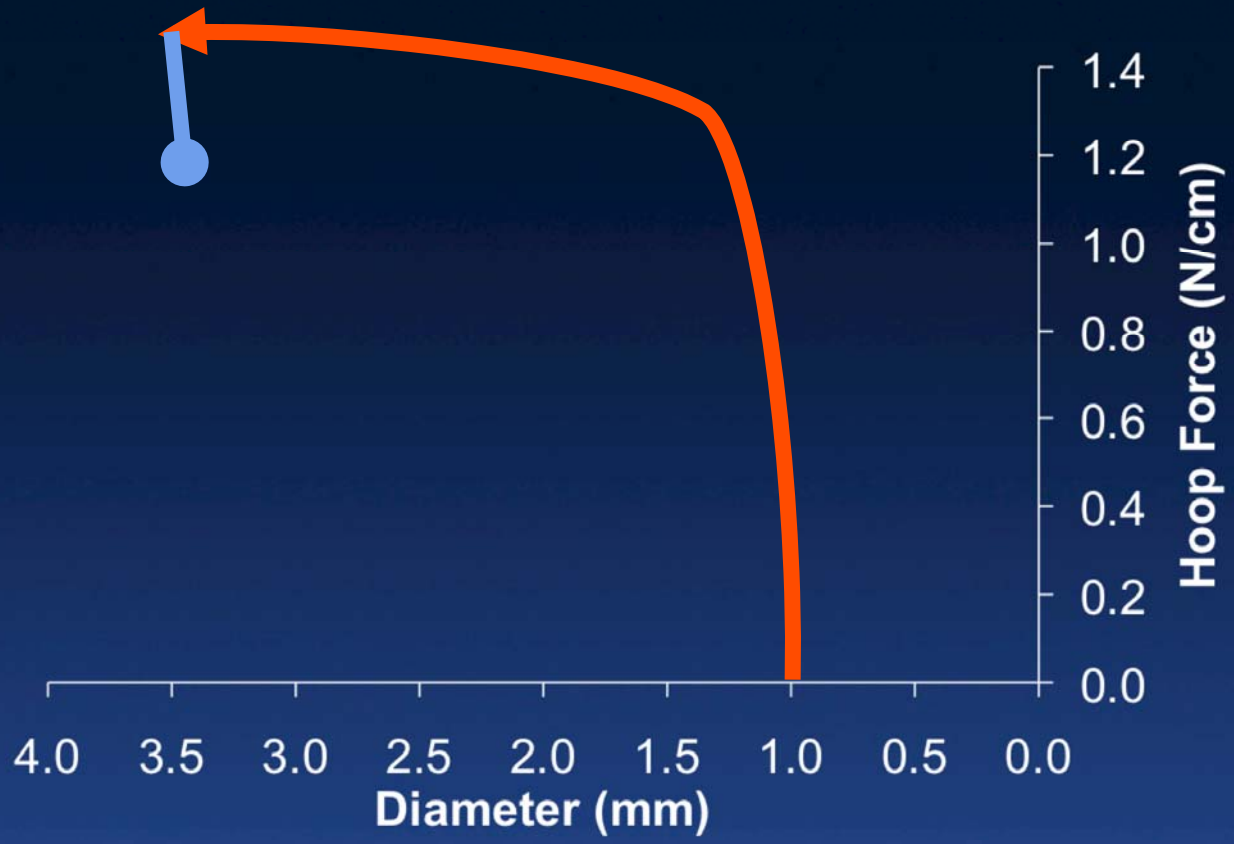


"Plastic Deformation"

Release balloon pressure (not in vessel)

Balloon Expandable

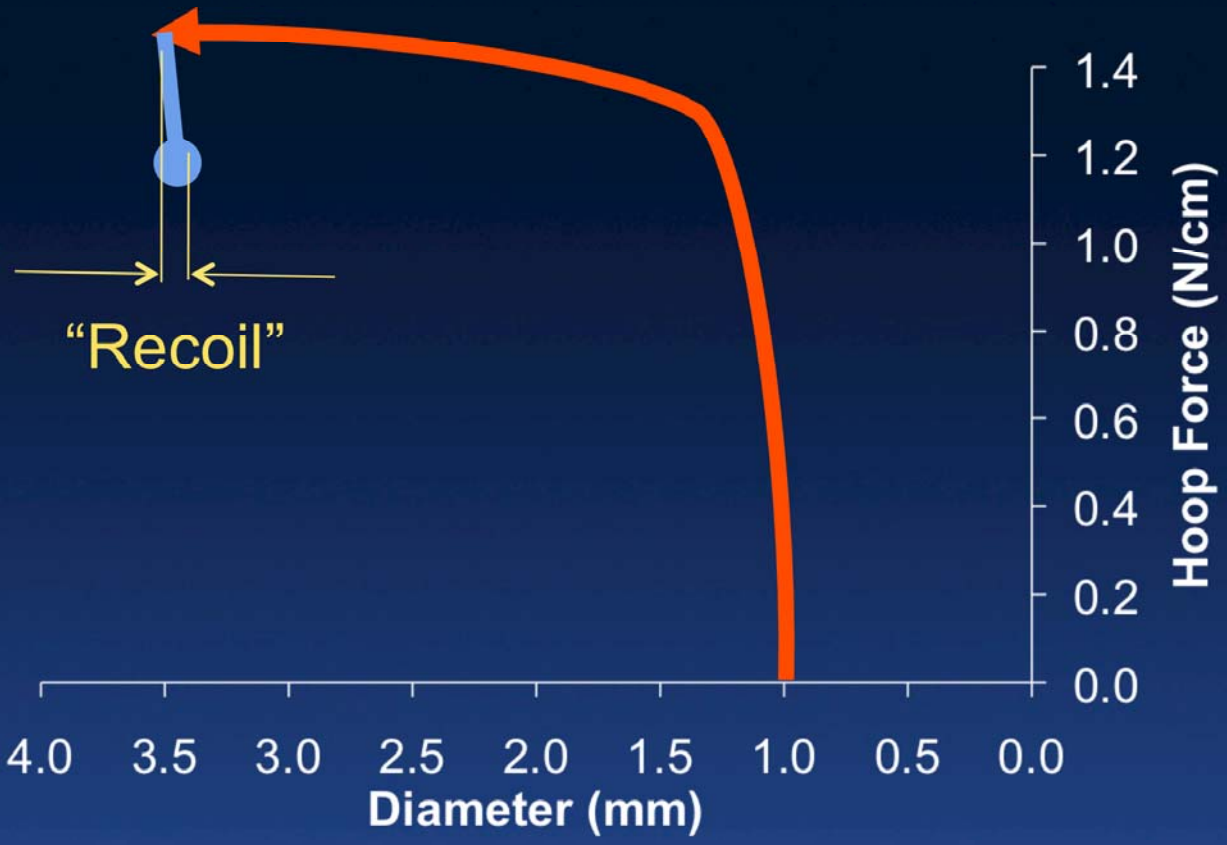
Balance with vessel



Release balloon pressure, balance with vessel

Pulsatile Loading

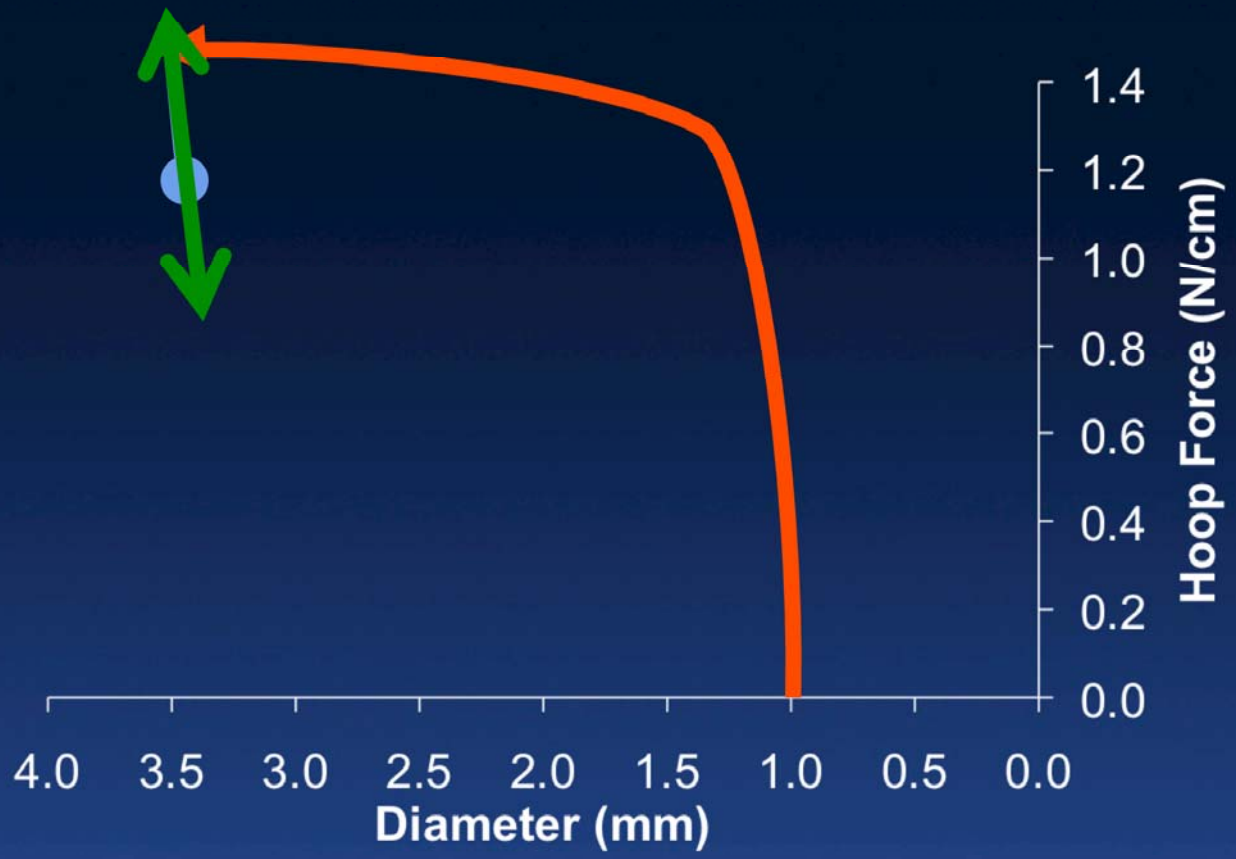
Low "Recoil"



Release balloon pressure, balance with vessel

Pulsatile Loading

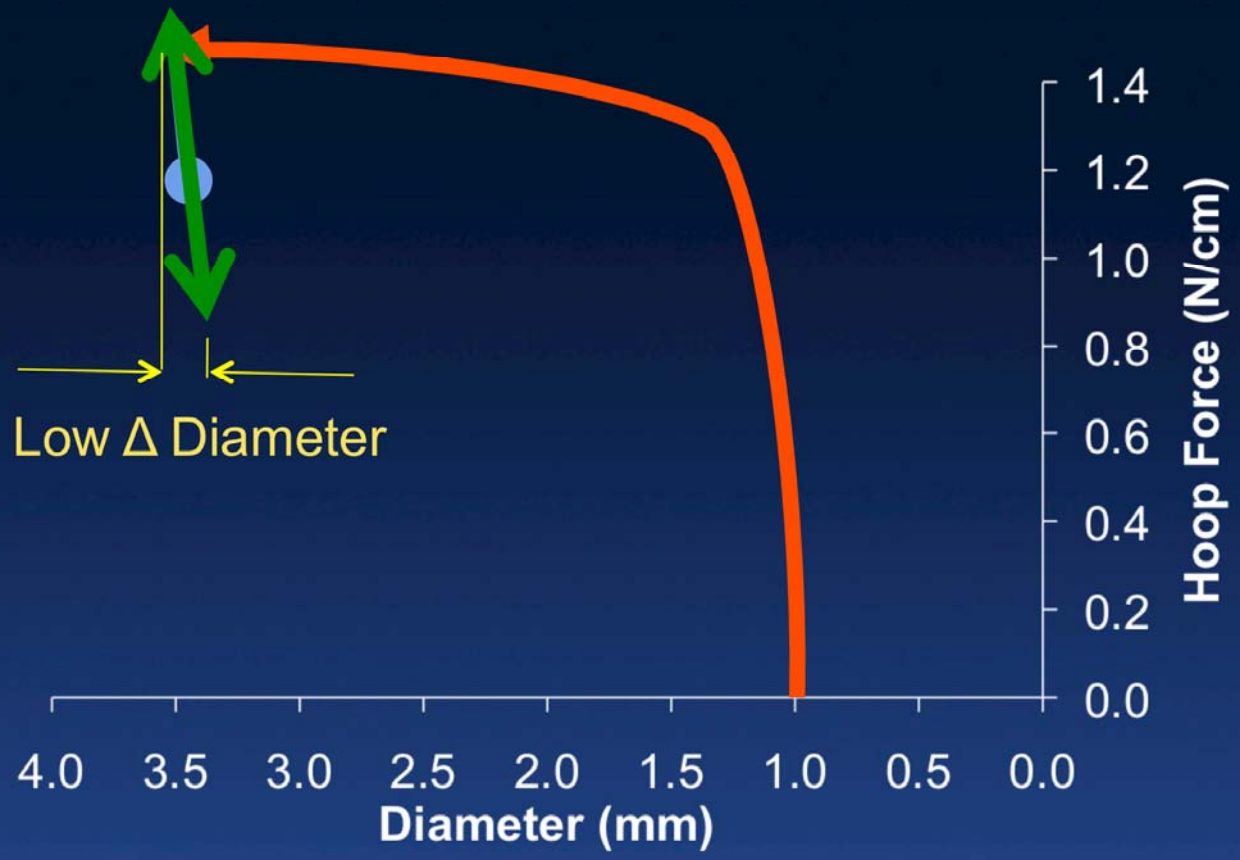
Balloon Expandable: Rigid during pulsing



cycle

Pulsatile Loading

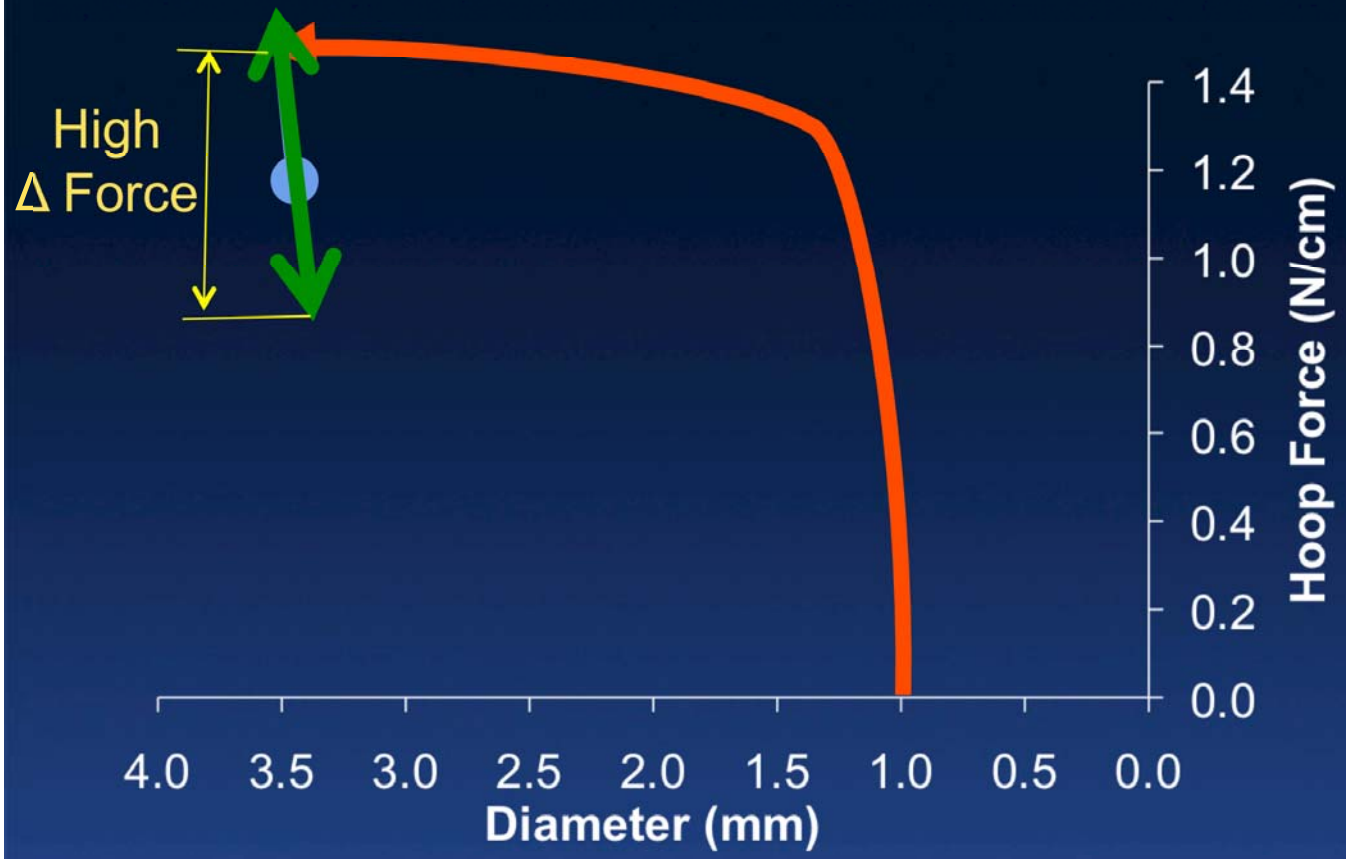
Balloon Expandable: Low cyclic DEFORMATION



cycle

Pulsatile Loading

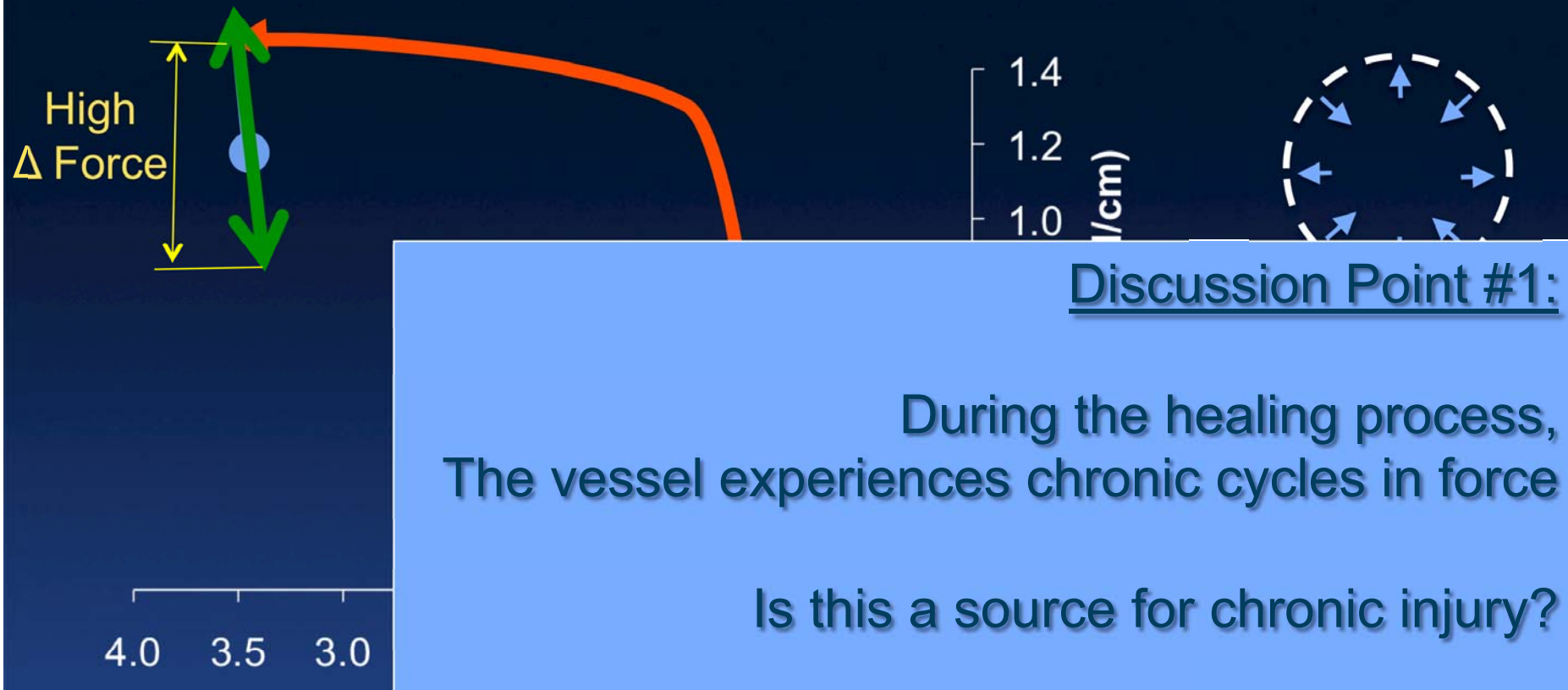
Balloon Expandable: High Cyclic FORCE



cycle

Pulsatile Loading

Balloon Expandable: High Cyclic FORCE



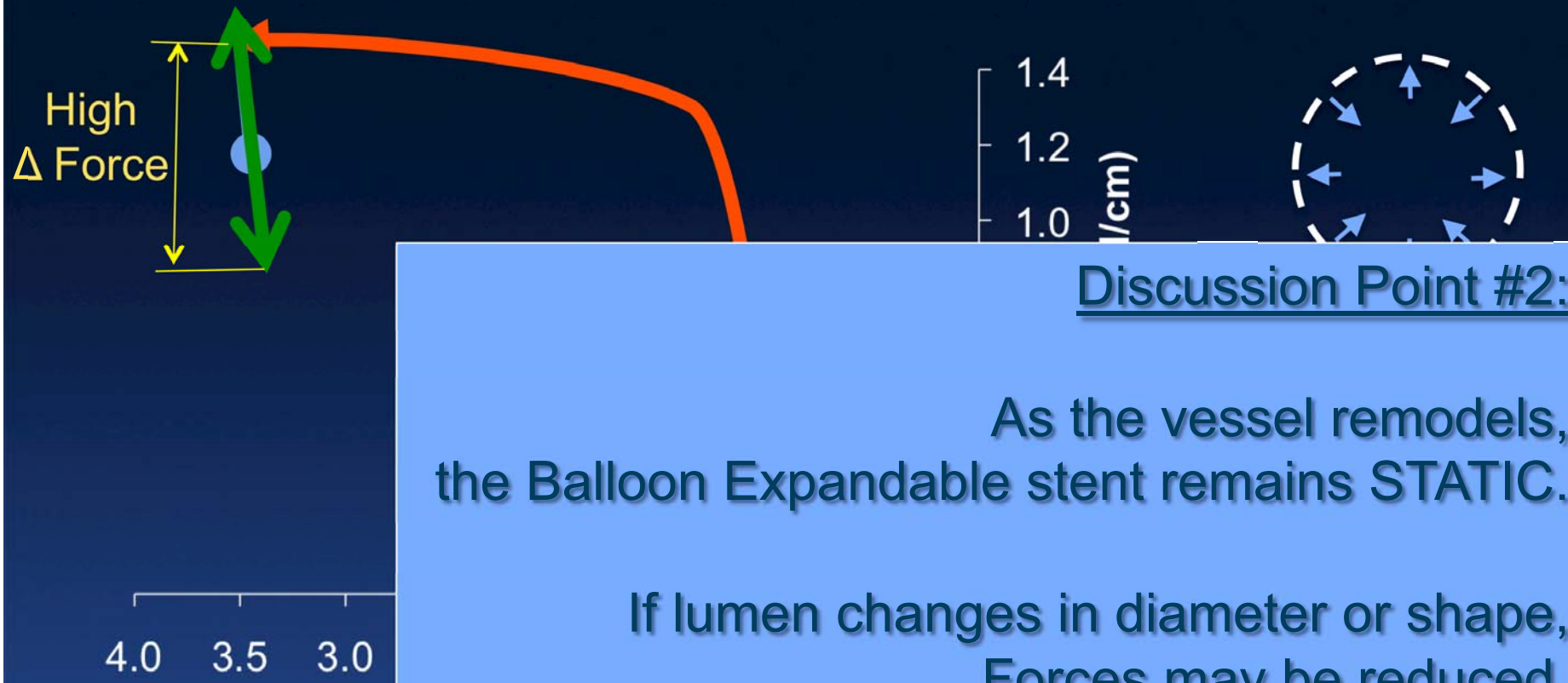
Discussion Point #1:

During the healing process,
The vessel experiences chronic cycles in force

Is this a source for chronic injury?

Pulsatile Loading

Balloon Expandable: High Cyclic FORCE



Discussion Point #2:

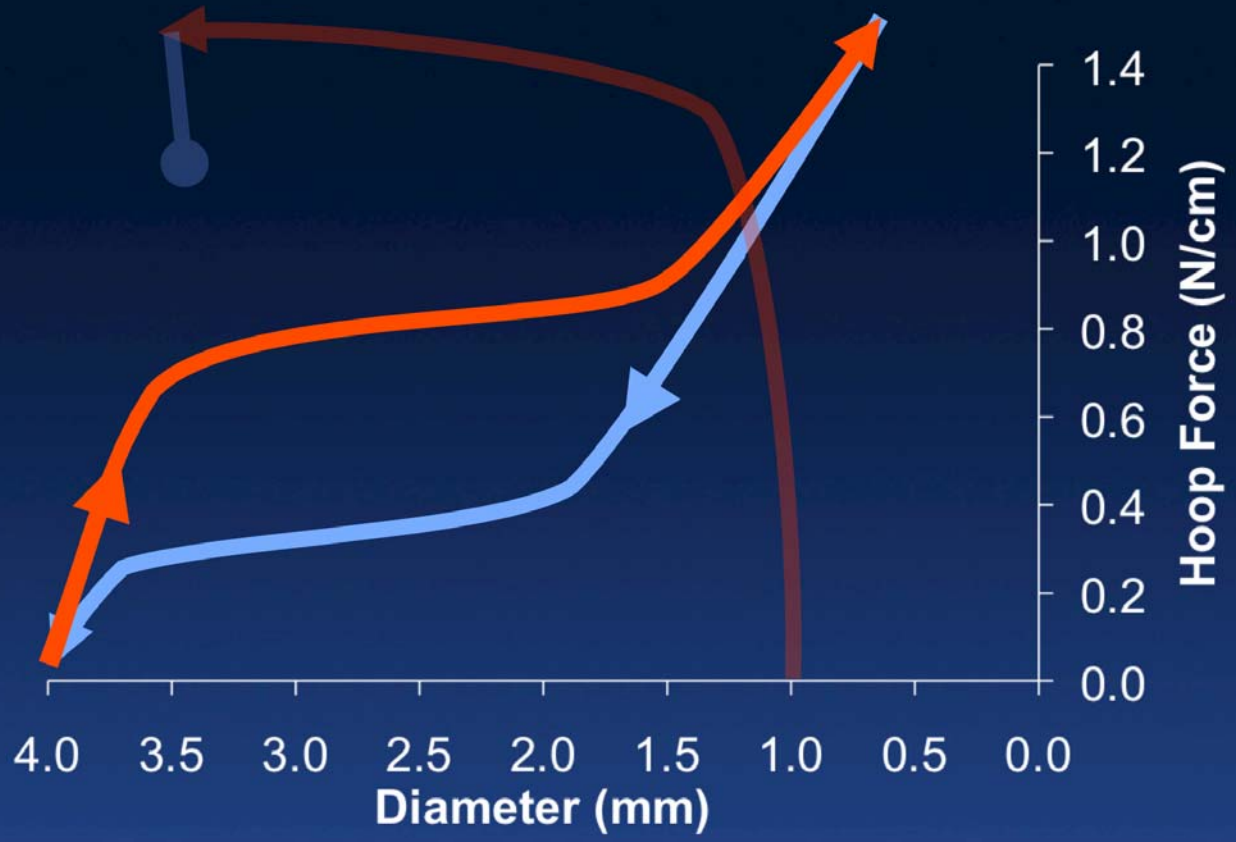
As the vessel remodels,
the Balloon Expandable stent remains STATIC.

If lumen changes in diameter or shape,
Forces may be reduced,
Apposition may be compromised…

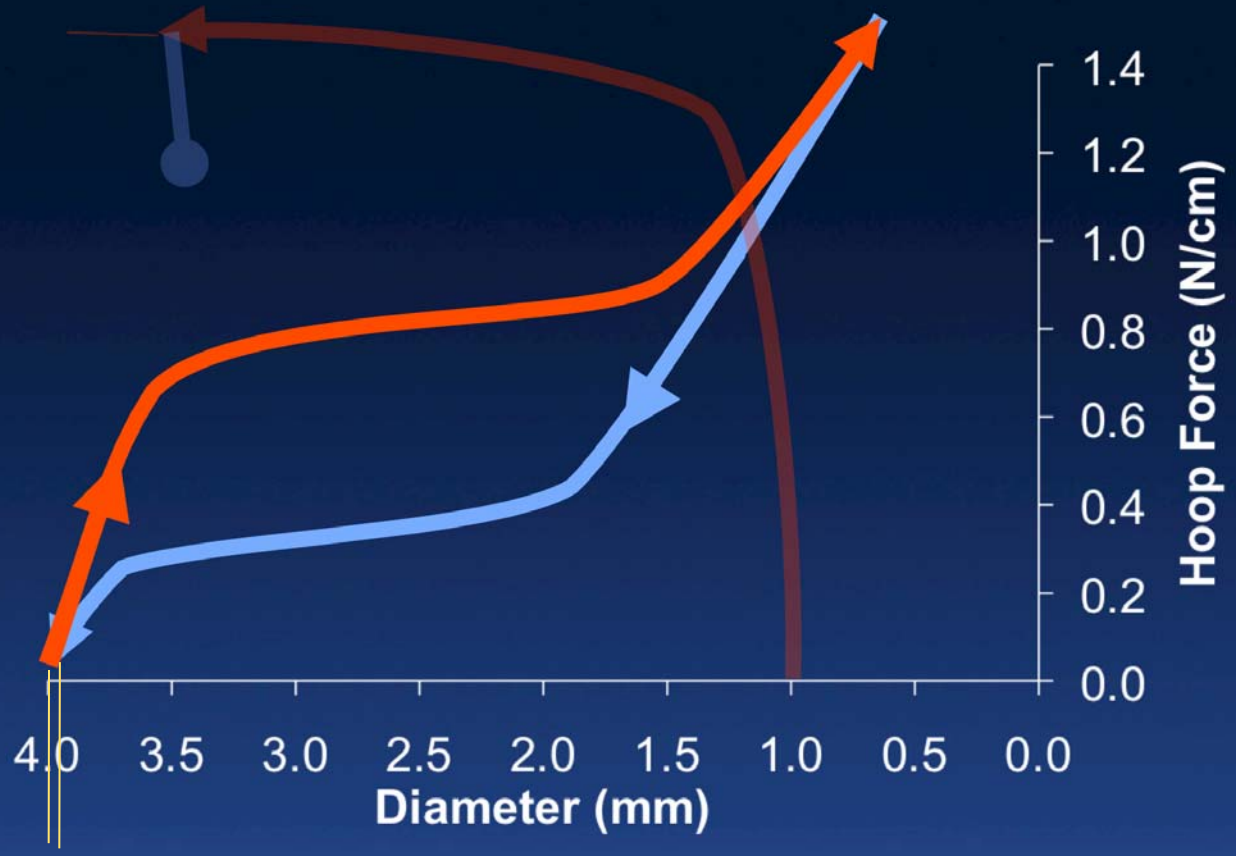
Self Expanding

forces and deformations
during stent deployment & service

Self Expanding
Load vs. Deformation

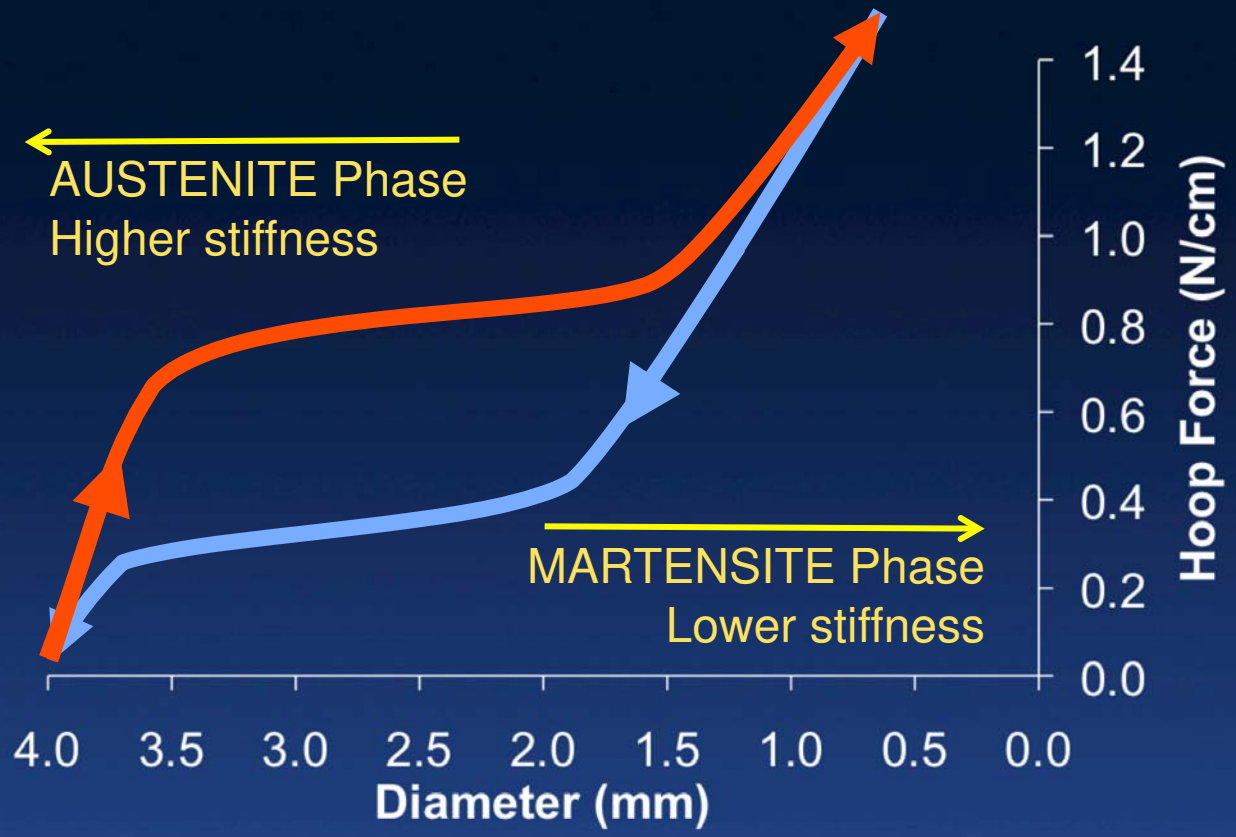


Self Expanding
Load vs. Deformation



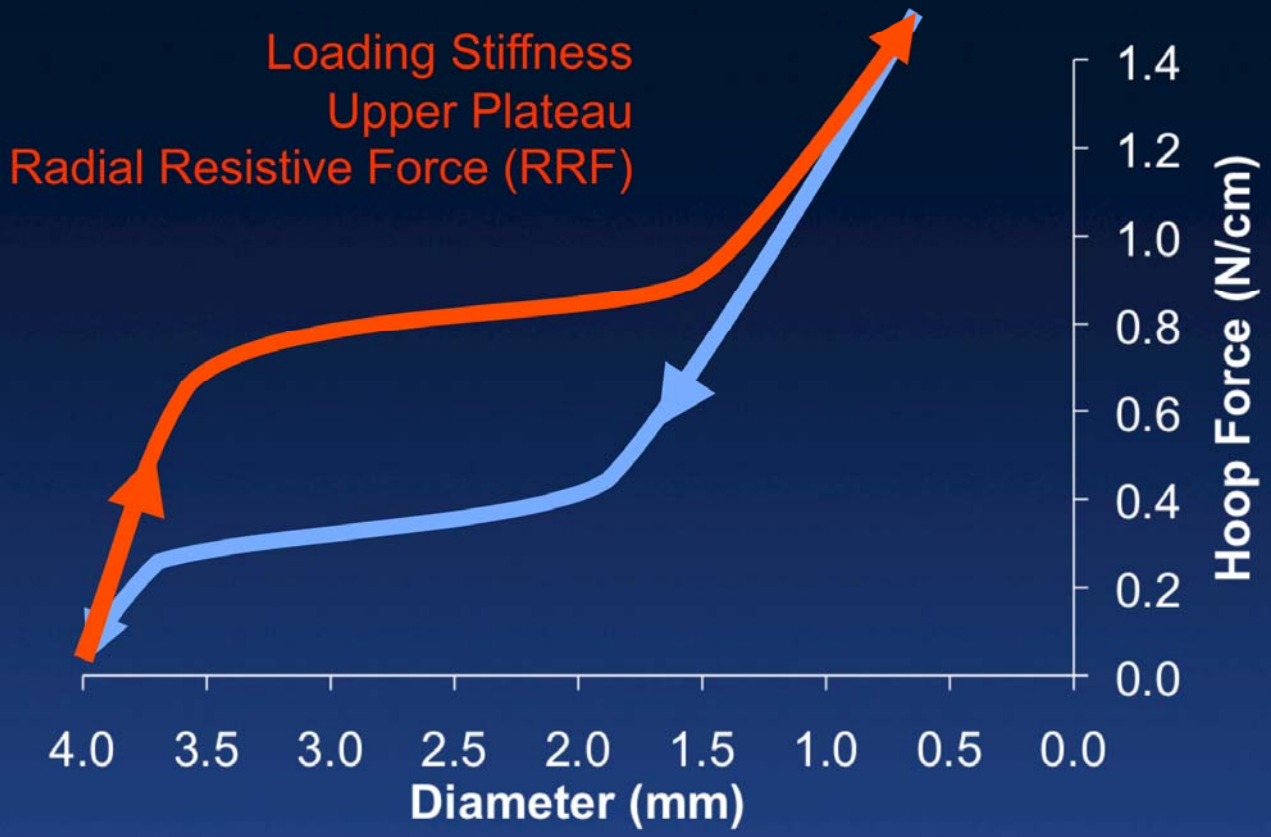
No “Plastic Deformation” or “Permanent Set”

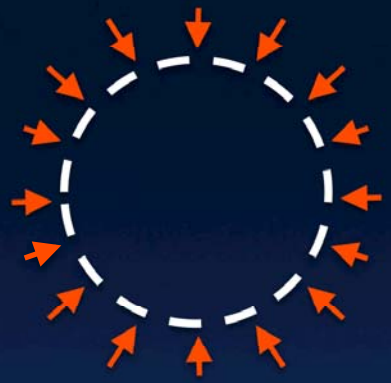
Self Expanding
Nitinol Phase Transformation



Self Expanding

Biased Stiffness of Nitinol: LOADING



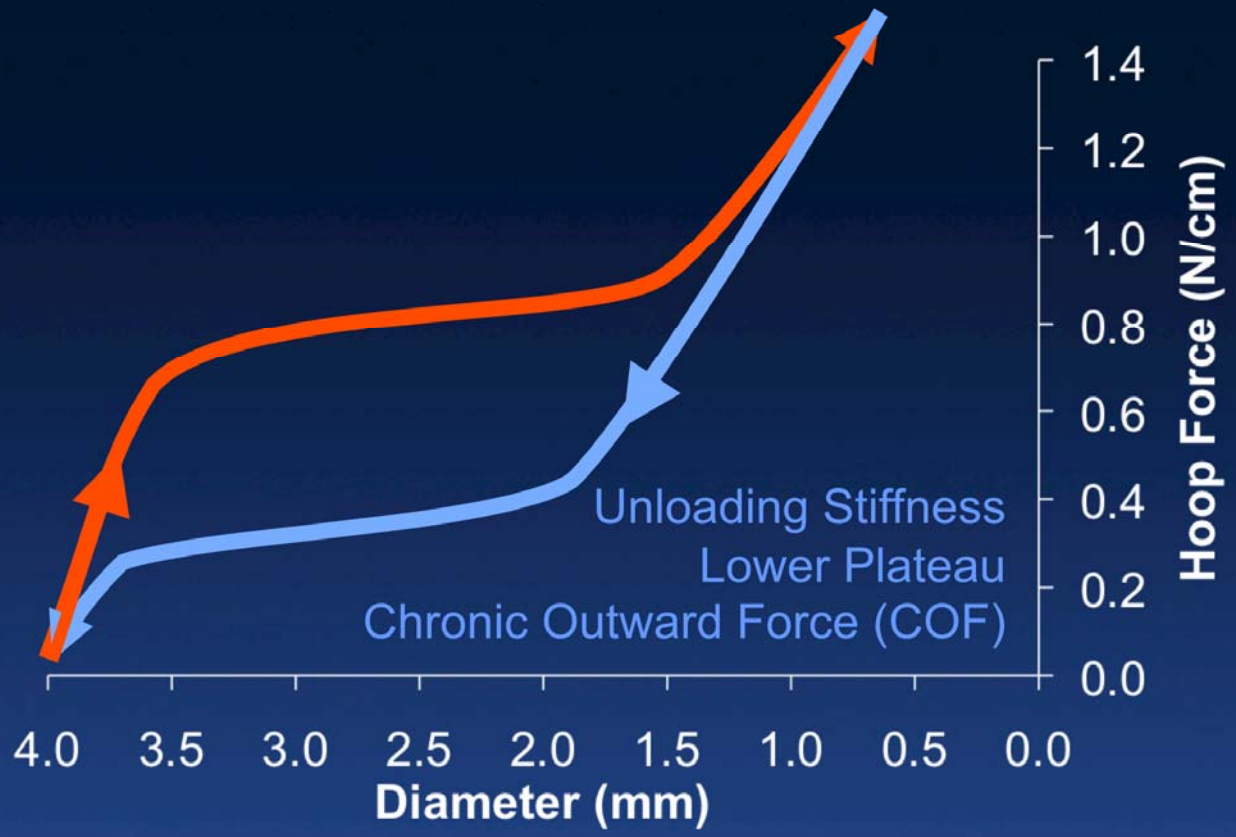


External Compression

Vessel Recoil

Self Expanding

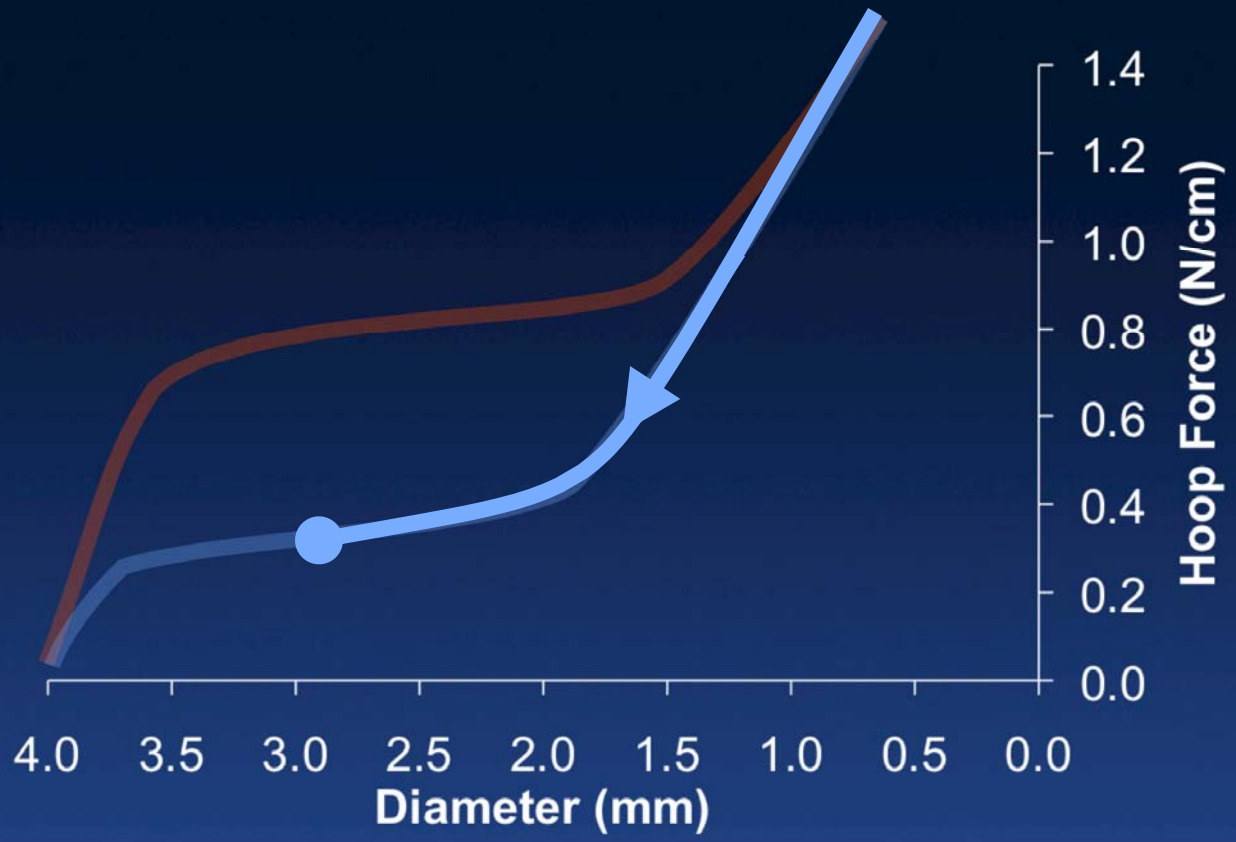
Biased Stiffness of Nitinol: UNLOADING



release
from
catheter

Self Expanding

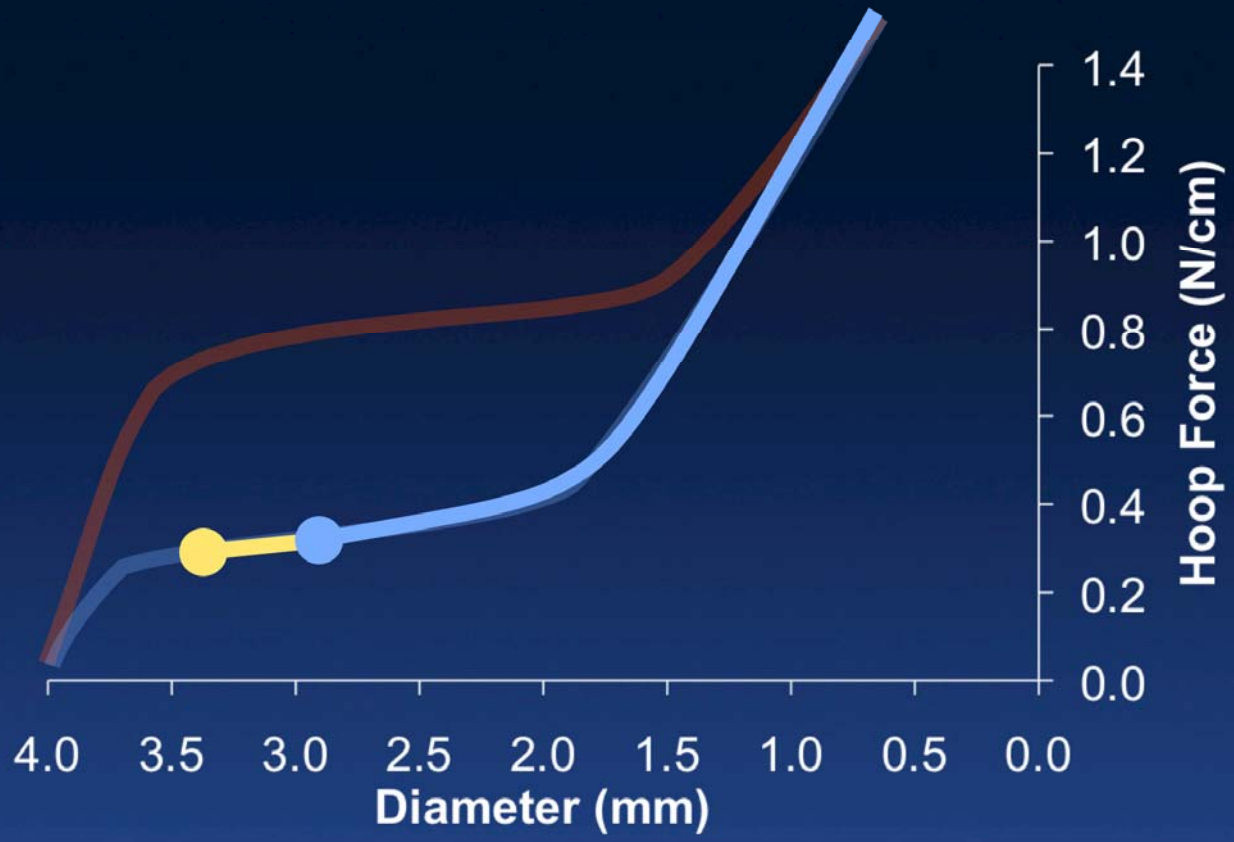
Release to vessel



release from catheter

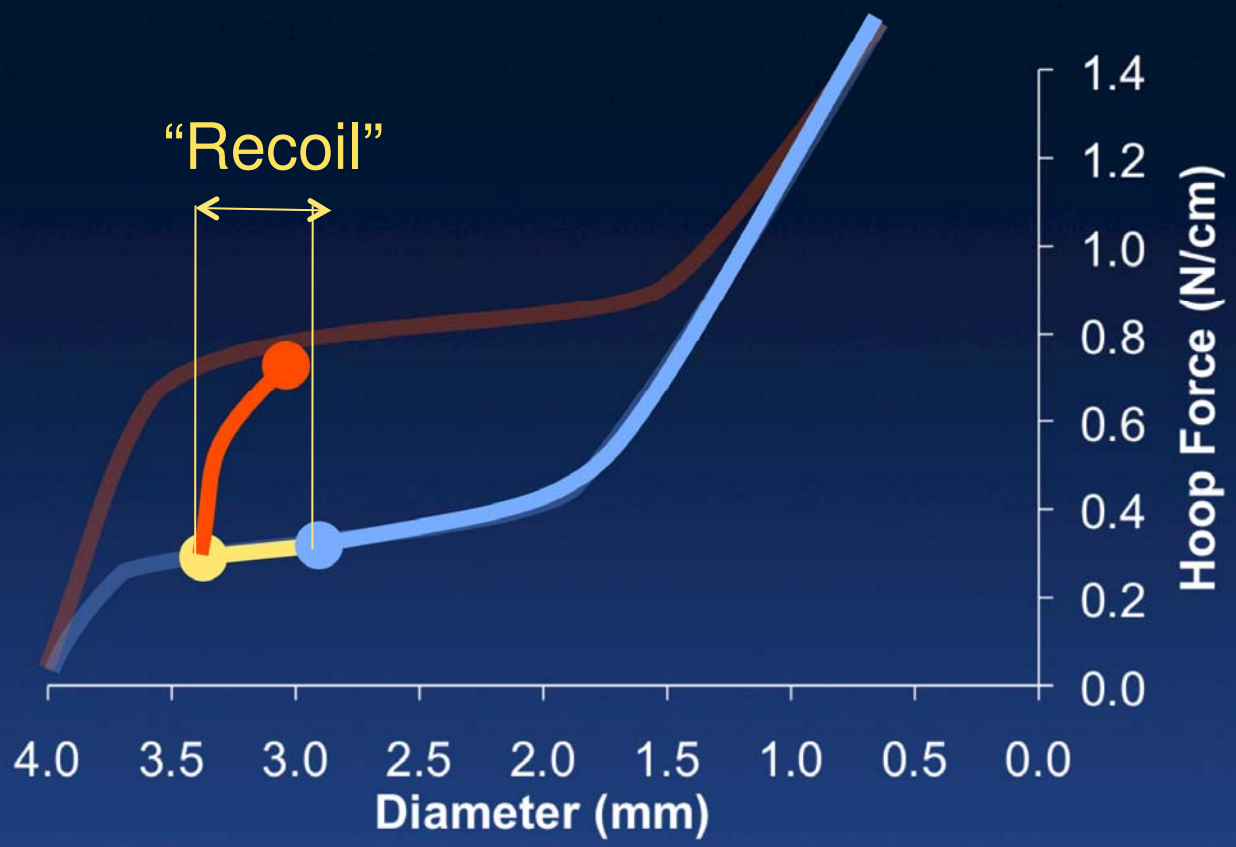
Self Expanding

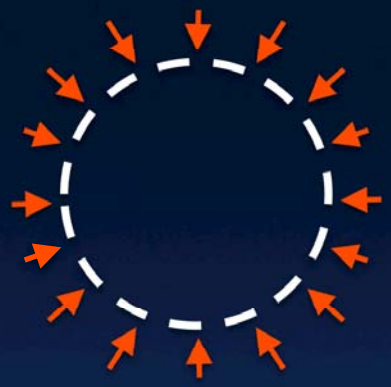
Post-Dilate with Balloon



post dilate with balloon

Self Expanding
Post-Dilate with Balloon



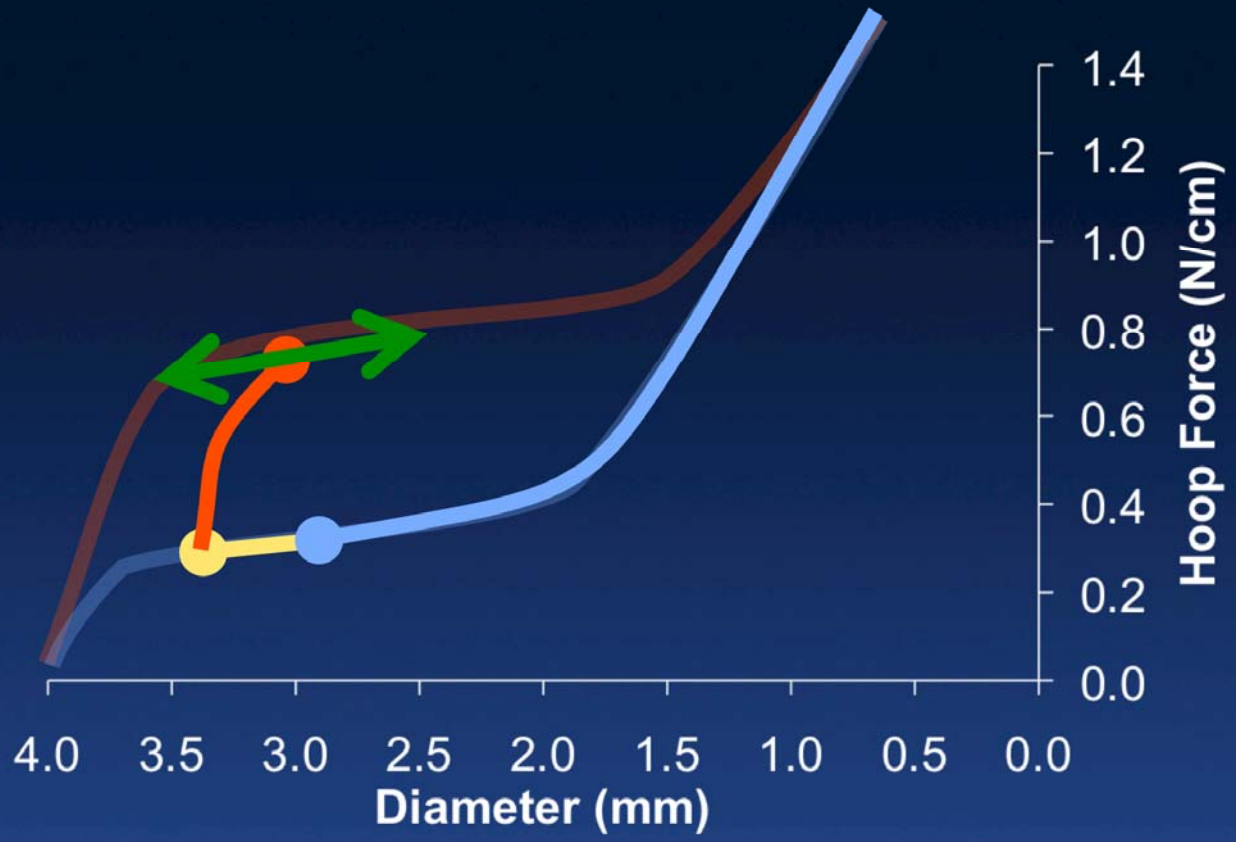


Release balloon pressure

Vessel Recoil

Pulsatile Loading

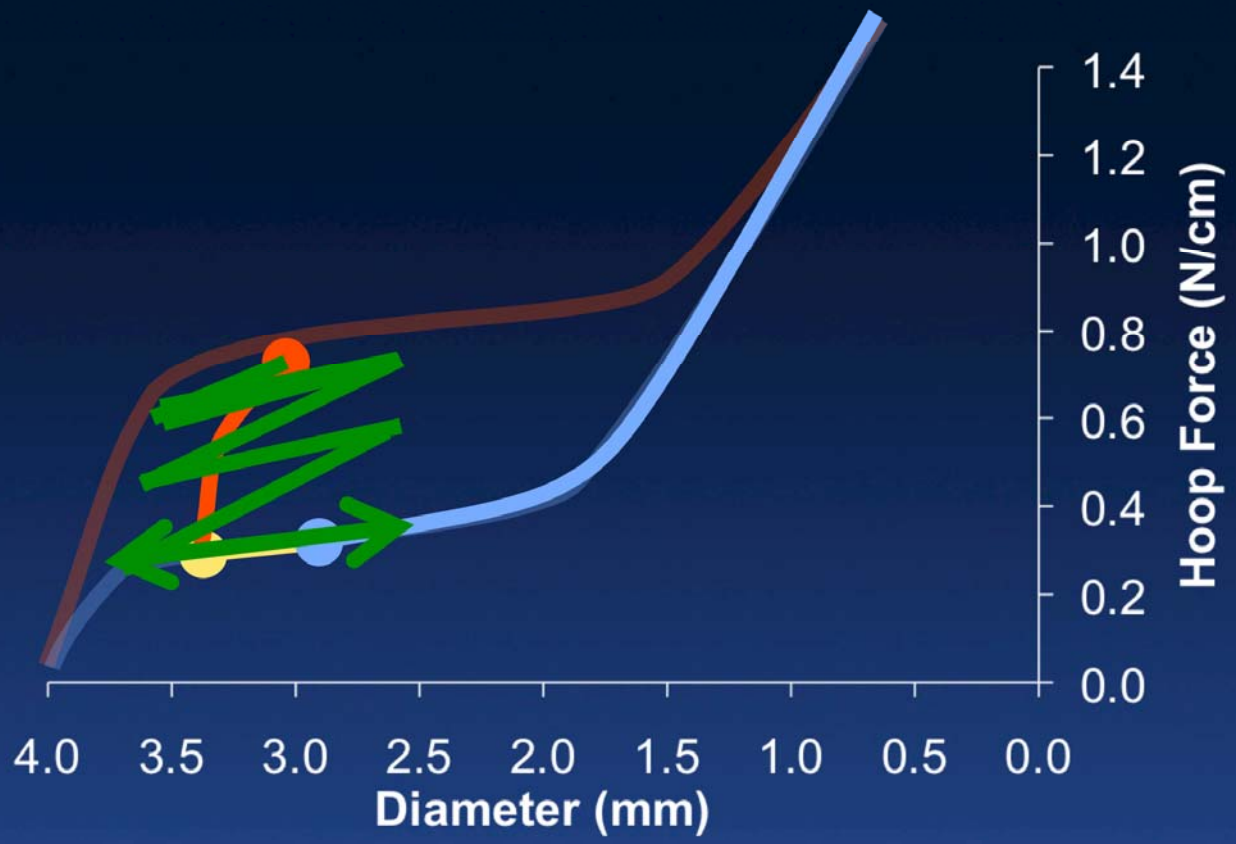
Self Expanding: “Breathes” during pulsing



cycle

Pulsatile Loading

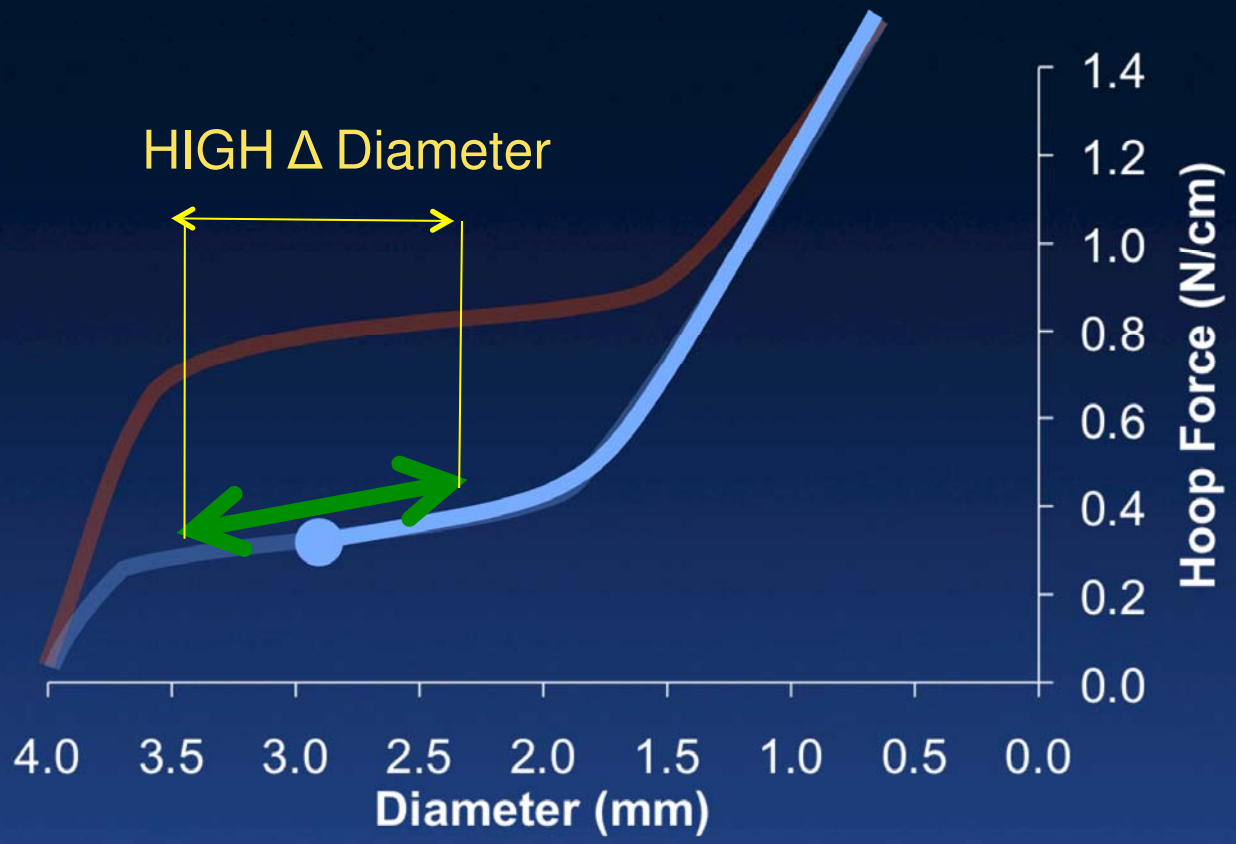
Self Expanding: “Breathes” during pulsing



cycle

Pulsatile Loading

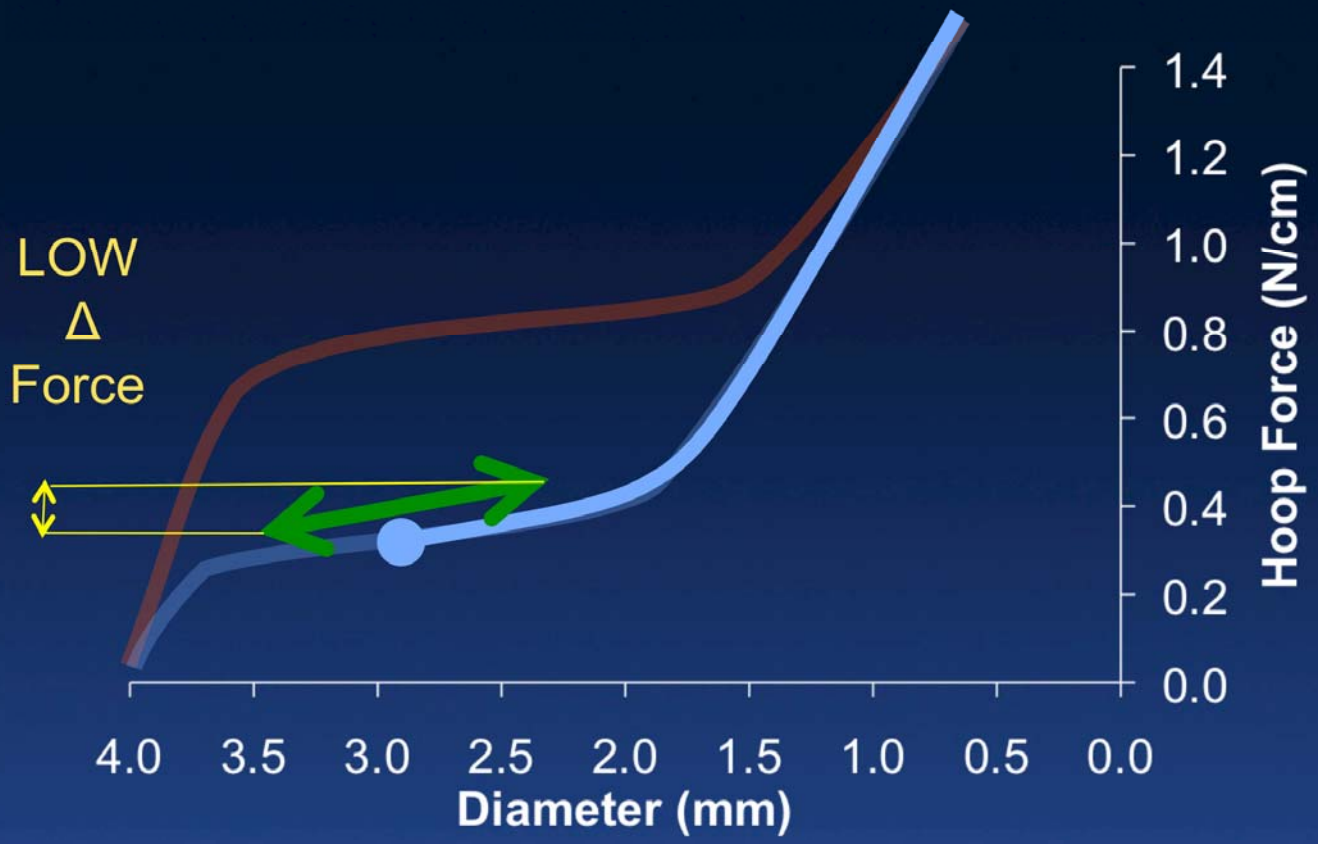
Self Expanding opposite BX: High cyclic deformation



cycle

Pulsatile Loading

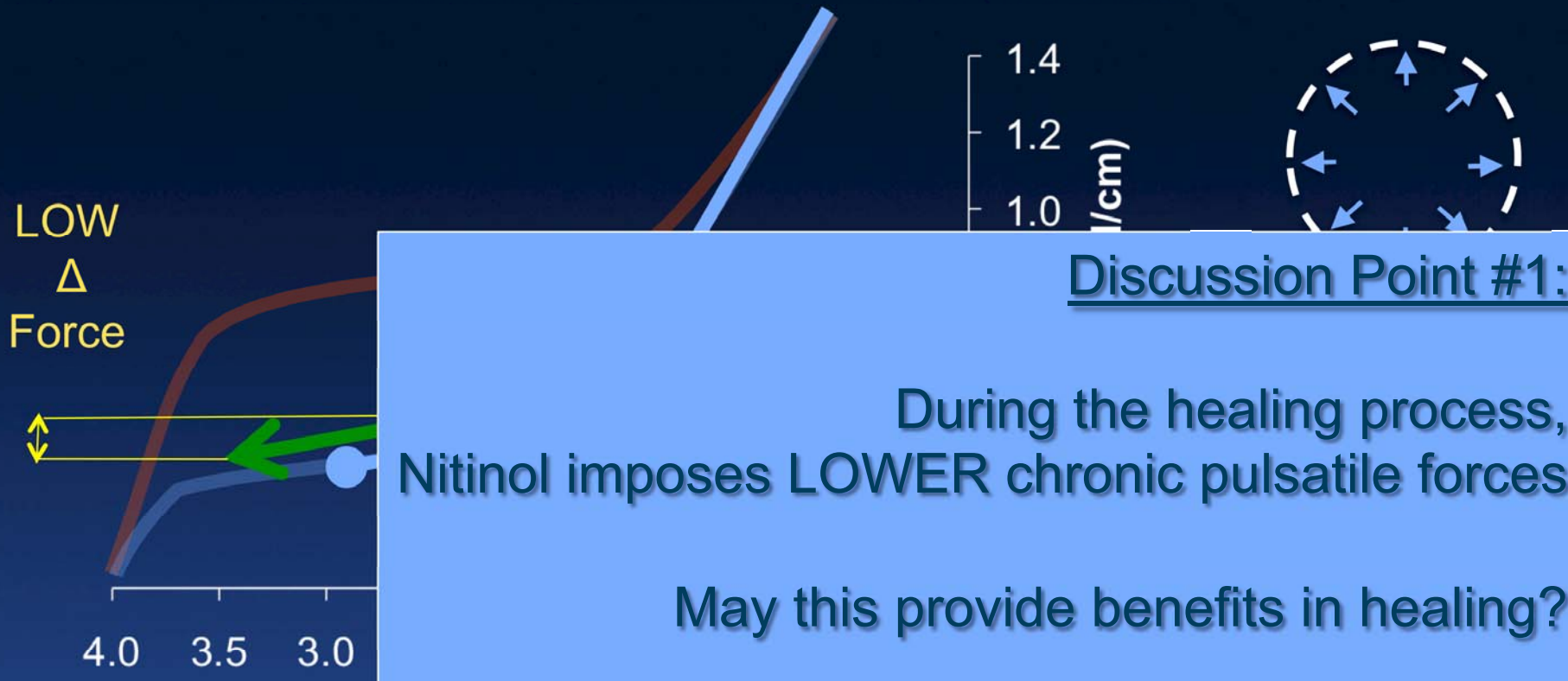
Self Expanding opposite BX: Low cyclic forces



cycle

Pulsatile Loading

Self Expanding opposite BX: Low cyclic forces



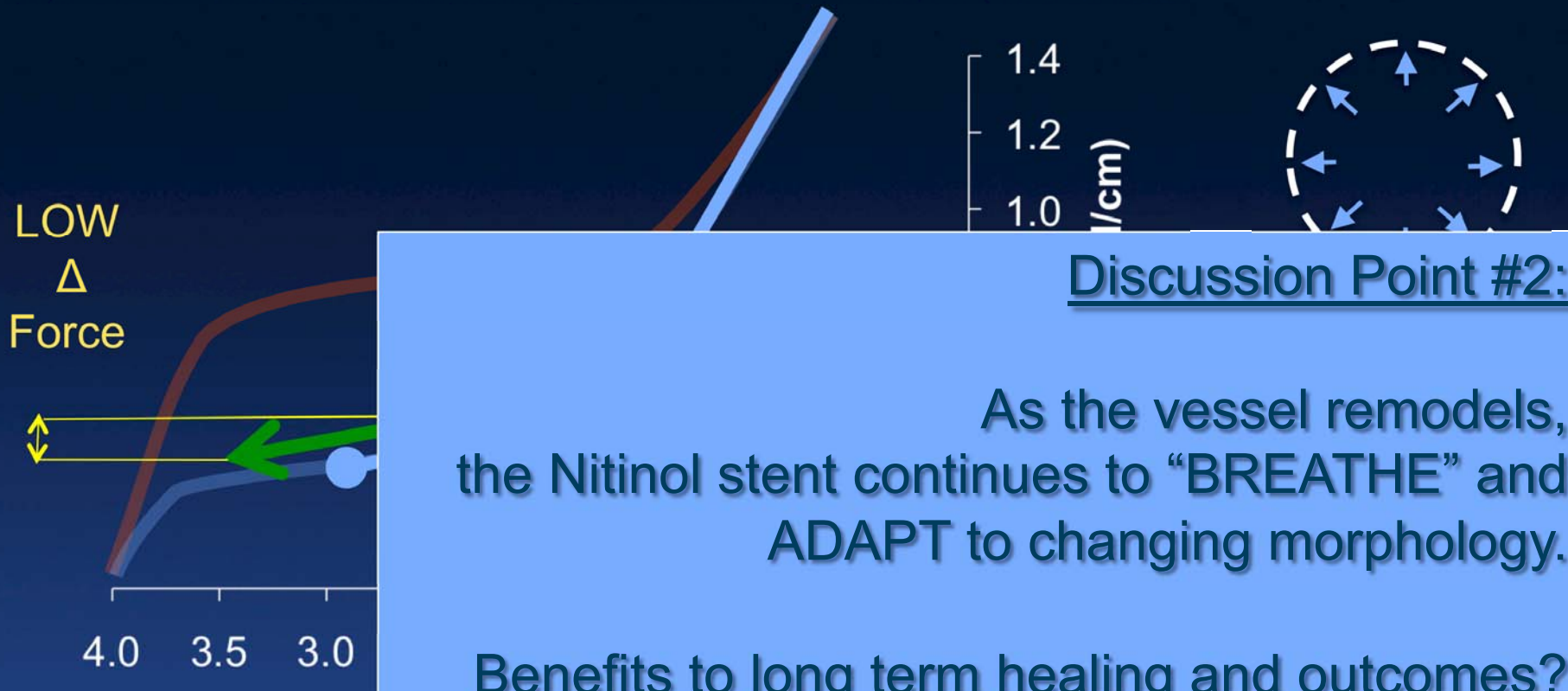
Discussion Point #1:

During the healing process,
Nitinol imposes LOWER chronic pulsatile forces

May this provide benefits in healing?

Pulsatile Loading

Self Expanding opposite BX: Low cyclic forces



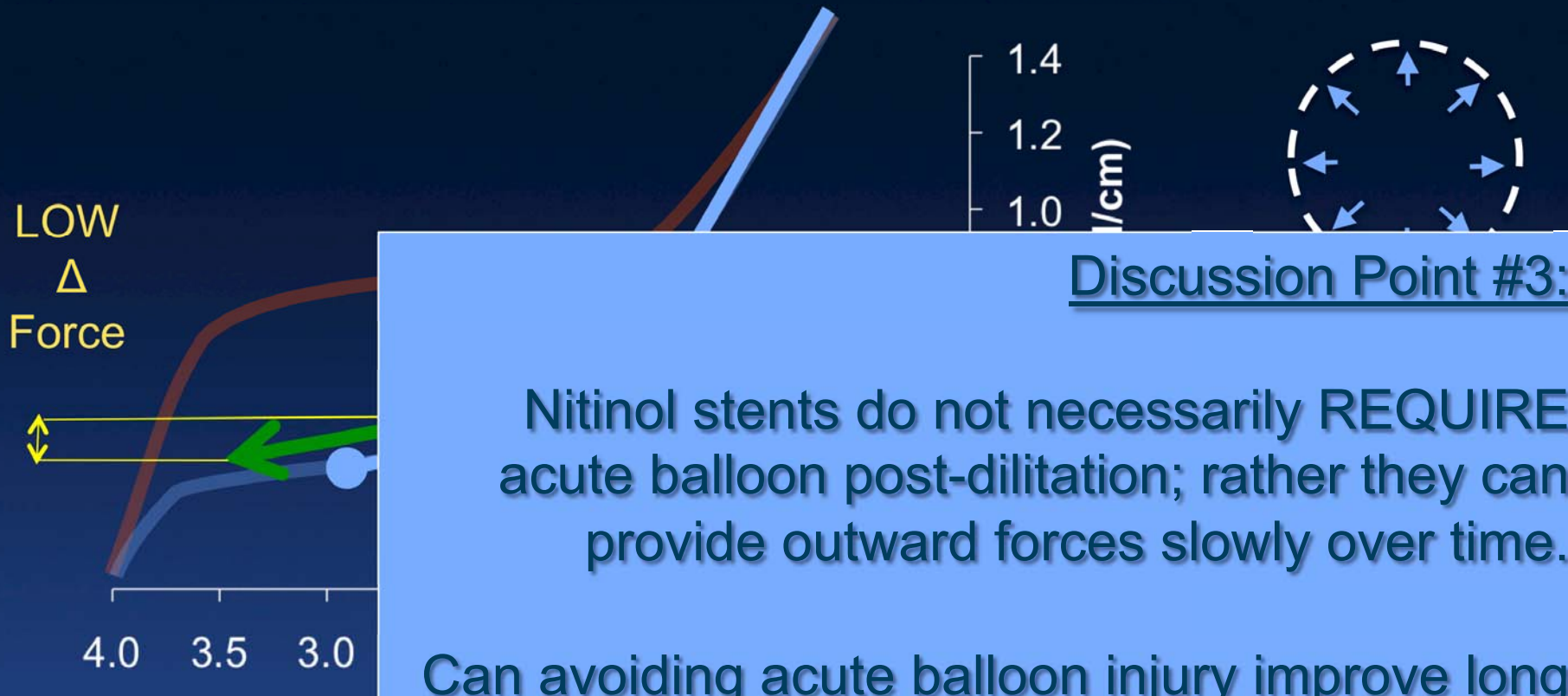
Discussion Point #2:

As the vessel remodels, the Nitinol stent continues to "BREATHE" and ADAPT to changing morphology.

Benefits to long term healing and outcomes?

Pulsatile Loading

Self Expanding opposite BX: Low cyclic forces



Discussion Point #3:

Nitinol stents do not necessarily REQUIRE acute balloon post-dilitation; rather they can provide outward forces slowly over time.

Can avoiding acute balloon injury improve long term outcomes?

A new toolbox for coronary stenting

- Adaptive and programmable forces & deflections
- Dynamic apposition
- Highly engineered scaffolding
- Conformability in complex geometries
- Radically different injury profile