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

Craig Bonsignore
Tom Duerig, Ph.D.
Alan R Pelton, Ph.D.
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

Nickel Release
\( f (\text{Material + Processing}) \)

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

- **Benefits**
  - Familiar
  - Reliable

- **Issues**
  - Flexibility
  - Stent retention
  - Compliance
  - Profile
Self Expanding

• Benefits
  - Versatility
  - Profile: no balloon

• Issues
  - Less familiar
  - Relative motion
  - Axial energy
  - Friction
The INTERACTIONS drive success or failure of design!
SX Delivery System Primer

Target vessel

[Image of a cityscape with the Bay Bridge and the word TCT2009]
SX Delivery System Primer

Constraining Sheath
SX Delivery System Primer

“Pusher” or “Pin”
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.

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

Stiffness

Forces

Recoil

Deformation

Balloon Expandable
Stainless Steel; Cobalt Alloys

Self Expanding
Nitinol
Balloon Expandable forces and deformations during stent deployment & service
Balloon expansion

Diameter (mm)

Hoop Force (N/cm)

expand with balloon
Balloon Expandable

Load vs. Deformation

Release balloon pressure (not in vessel)
Balloon Expandable
Load vs. Deformation

Release balloon pressure (not in vessel)

“Plastic Deformation”
Balloon Expandable
Balance with vessel

Release balloon pressure, balance with vessel
Pulsatile Loading

Low “Recoil”

“Recoil”

Release balloon pressure, balance with vessel

Diameter (mm)

Hoop Force (N/cm)
Pulsatile Loading
Balloon Expandable: Rigid during pulsing

Diagram showing the relationship between diameter and hoop force over a pulsing cycle.
Pulsatile Loading
Balloon Expandable: Low cyclic DEFORMATION

Low Δ Diameter

Diameter (mm)

Hoop Force (N/cm)

cycle

TCT2009
Pulsatile Loading
Balloon Expandable: High Cyclic FORCE

**High Δ Force**

![Graph showing the relationship between hoop force and diameter over a cycle.](image)
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

No “Plastic Deformation” or “Permanent Set”
Self Expanding Nitinol Phase Transformation

AUSTENITE Phase
Higher stiffness

MARTENSITE Phase
Lower stiffness

Diameter (mm)

Hoop Force (N/cm)

4.0 3.5 3.0 2.5 2.0 1.5 1.0 0.5 0.0
Self Expanding Biased Stiffness of Nitinol: LOADING

Loading Stiffness
Upper Plateau
Radial Resistive Force (RRF)

Hoop Force (N/cm)

Diameter (mm)
Self Expanding
Biased Stiffness of Nitinol: UNLOADING

Unloading Stiffness
Lower Plateau
Chronic Outward Force (COF)

Diameter (mm)

Hoop Force (N/cm)

release from catheter
Self Expanding
Release to vessel
Self Expanding
Post-Dilate with Balloon

![Graph showing post-dilatation with balloon effect on hoop force and diameter.]

Diameter (mm)

Hoop Force (N/cm)

post dilate with balloon
Self Expanding
Post-Dilate with Balloon

"Recoil"

Diameter (mm)

Hoop Force (N/cm)

4.0 3.5 3.0 2.5 2.0 1.5 1.0 0.5 0.0

Release balloon pressure
Vessel Recoil
Pulsatile Loading
Self Expanding: “Breathes” during pulsing
Pulsatile Loading
Self Expanding: “Breathes” during pulsing

![Graph showing pulsatile loading with self-expanding properties.](image-url)

- Diameter (mm) on the x-axis
- Hoop Force (N/cm) on the y-axis
- Cycle illustration

TCT 2009
Pulsatile Loading
Self Expanding opposite BX: High cyclic deformation
Pulsatile Loading

Self Expanding opposite BX: Low cyclic forces

LOW Δ Force

Diameter (mm)

Hoop Force (N/cm)

cycle

TCT2009
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-dilation; 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