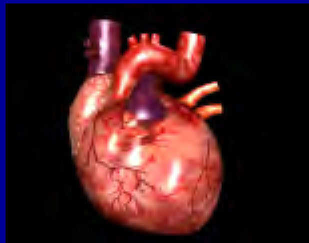


NUMERICAL STUDY ON MECHANICAL PROPERTIES OF STENTS

WITH DIFFERENT MATERIALS DURING STENT DEPLOYMENT WITH BALLOON EXPANSION

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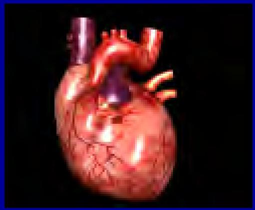
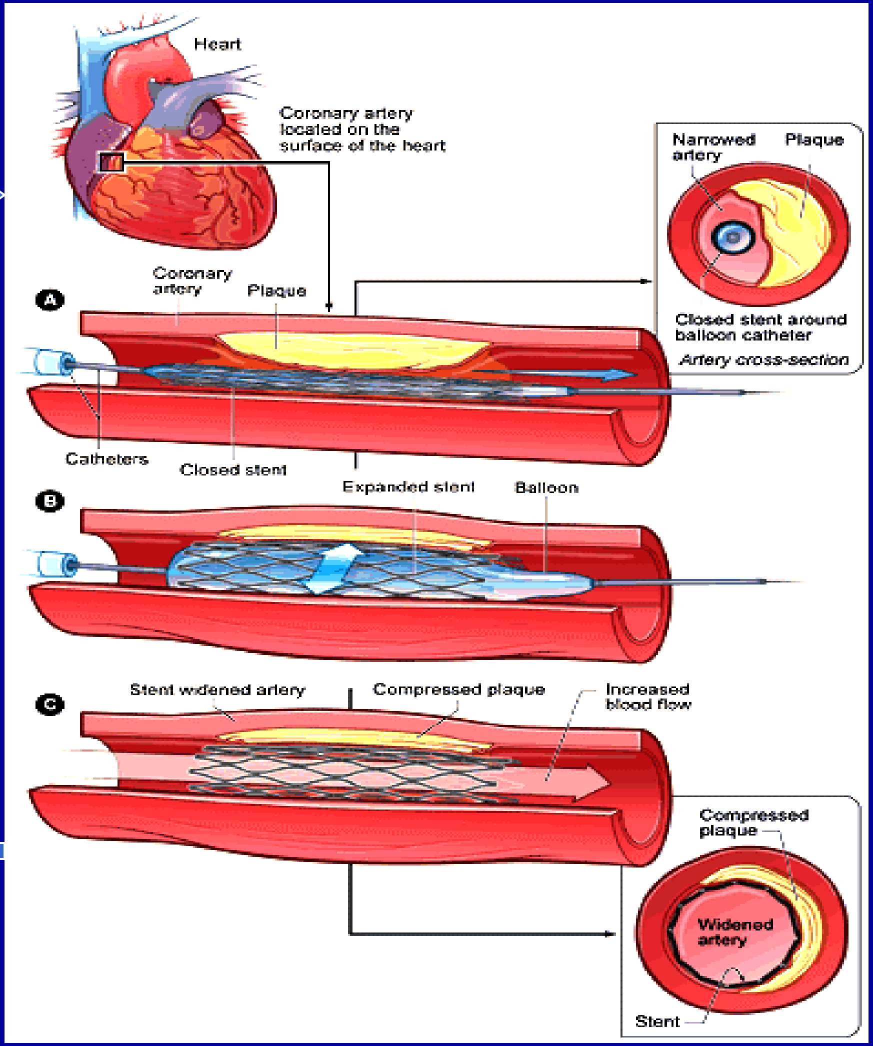
Excerpt from the Proceedings of the 2011 COMSOL Conference in Bangalore

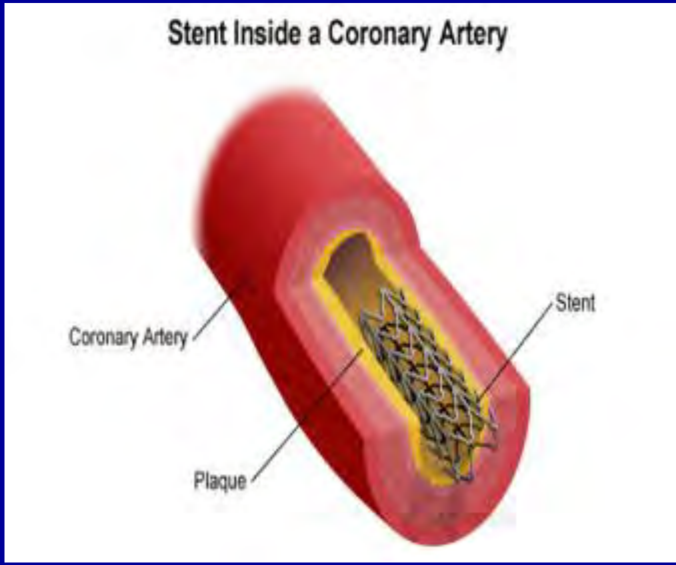


Balloon Expandable Stent

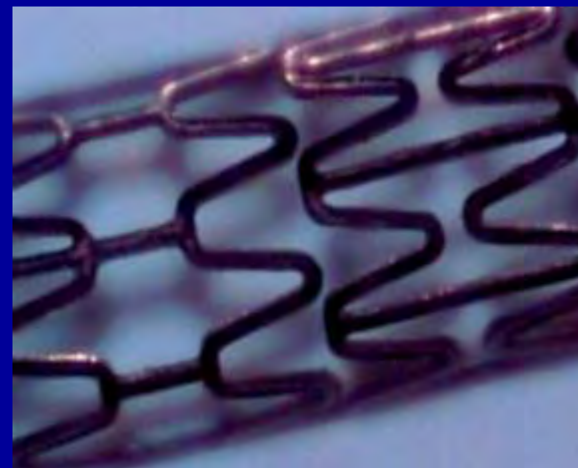
- Percutaneous transluminal coronary angioplasty (PTCA) is a wide spread method for treatment of coronary artery disease
- Balloon expandable stents are preferable in treatment of coronary artery stenosis
- Coronary stents are smooth metallic mesh like structures
- Stents can be either in tubular or in coil shape
- Stents are deployed inside arteries with balloon expander
- Balloon is inflated to expand the stent till it reaches to artery wall
- Finally, balloon is removed, and expanded stent continues to provide mechanical support to the artery wall

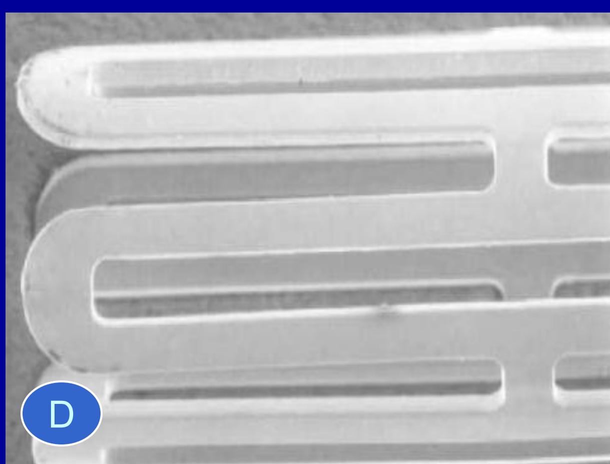
Coronary Stents

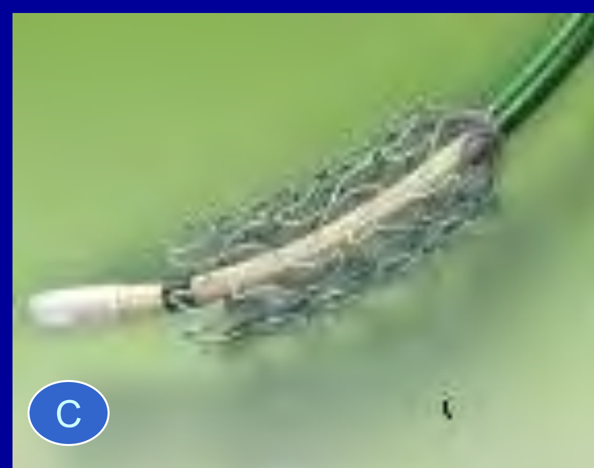




Different Types of Stents







Clockwise from Top Left:

A. Tubular Mesh

B. Tubular wire

C. Coil

D. Hollow slotted tube with open and closed struts

Stent Materials Used in the Model

- 4 sample stents with different materials are used
- All stents have same geometrical properties
- Same initial deployment pressure applied to all stent
- Materials are chosen which are commonly used in today's stent manufacturing.
- stent materials :

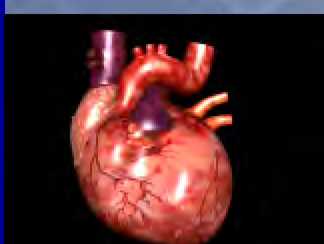
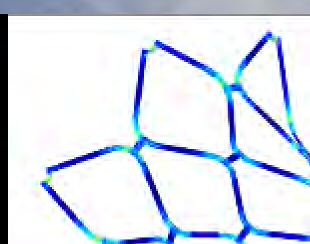
1. Stainless steel 316 L Annealed
2. Nitinol (austenite) – (55% nickel, 45% titanium)
3. Elgiloy (heat treated at 525 c) – 15.5Ni, 2Mn, 1Be, 0.15C, balance Fe
4. Tantalum (Pure)


Stent Materials Properties

Metal	Composition, wt%	Elastic modulus, GPa (Msi)	Tensile strength σε, MPa (ksi)	Ultimate tensile strength συλτ, MPa (ksi)	Elongation, %	Poisson's ratio	Yield Strength (Mpa)	Isentropic hardness modulus (GPA)	Density (kg/m-3)
316 L Stainless Steel, Annealed	17Cr, 12Ni, 2.5 Mo, <0.03C, balance Fe	193 (28)	260 (38)	550 (80)	50	0.3	300	2	7850
Nitinol (Austenite)	55 Ni - 45 Ti	83 (12),	195 to 690 (28 to 100)	960	25 to 50	0.3	560	1	6478
Tantalum	Pure	185 (27)	165 (24)	205 (30)	40	0.35	170		1669
Co-Cr-Mo Alloy (Elgiloy) Heat treated at 525 c for 5 hours	40Co, 20 Cr, 7Mo, 15.5Ni, 2Mn, 1Be, 0.15C, balance Fe	190 (28)	690 (100)	1020 (148)	38	0.226	520		8300

MODELLING USING COMSOL

- VERSION: COMSOL 3.5a
- STRUCTURAL MECHANICS MODULE
- Solid Stress-Strain
- Static analysis, elasto-plastic material model

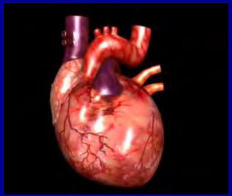




COMSOL MULTIPHYSICS

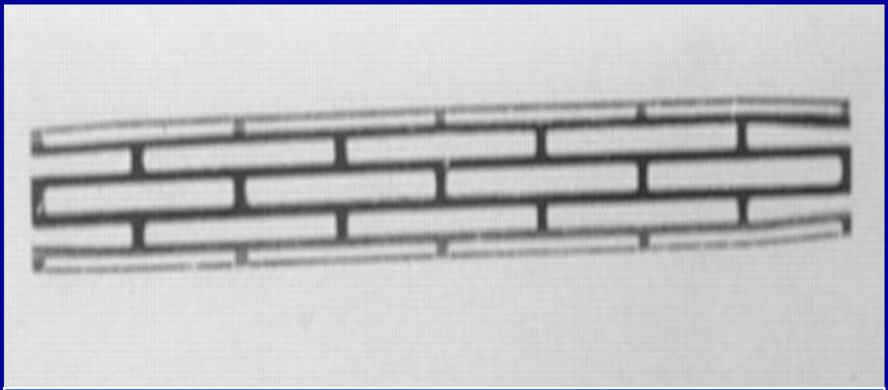
Theoretical Background

- The Structural Mechanics model
  - Current model uses Solid Stress Strain application mode
  - it aims to solve for displacement, strain and stress in 3D
- Fundamental Relationships
  - Strain Displacement Relationship
  - Stress Strain Relationaship
- Implementation and Analysis
  - Implementation based on weak formulation of the equilibrium equations of stresses

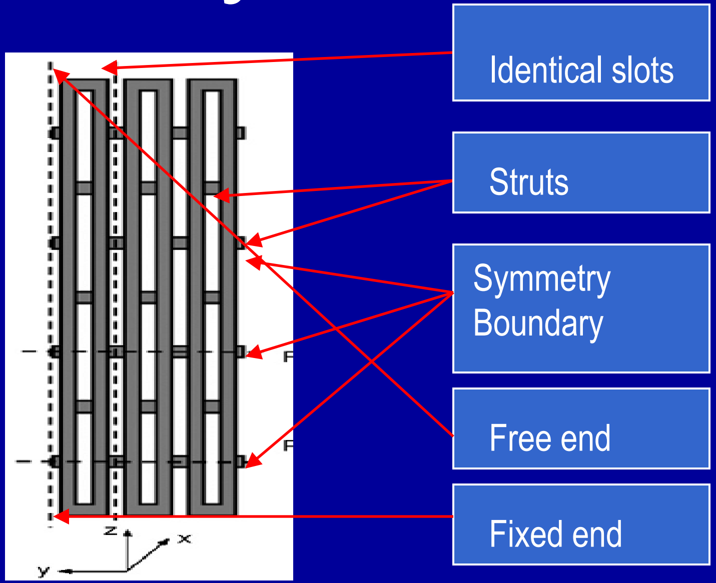
    $-\nabla \cdot \sigma = \mathbf{F}$ (where σ is the stress tensor)
  - Substituting with the fundamental relationships, Naviers' displacement equation is obtained
  - Analysis types
    - Static
    - Eigenfrequency
    - Transient
- Current model uses static analysis. Solver has been selected accordingly.



Model Geometry



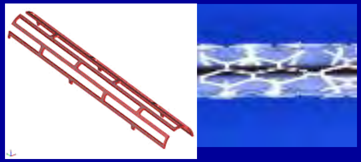
Palmaz-Schatz stent: Before deployment



Palmaz-Schatz stent: After deployment

(Fully expanded)

- Stent Type: Palmaz Schatz (J&J Cordis ®)
- Shape: Hollow slotted tube
- Length: 8 mm
- Diameter: 1.37mm
- Thickness: 0.1mm
- 6 Identical units are linked with struts

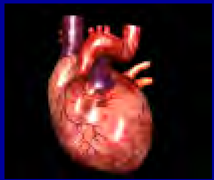


Modeling Parameters

Stent Type	Young modulus	Poisson’s Ratio	Ultimate Tensile Strength	Yield Strength	Density	Length	Diameter (Mounted)
Stainless Steel	193	0.3	550	300	7850	8	3.681
Nitinol	83	0.3	960	560	6478	8	1.568
Elgiloy	190	0.226	1020	520	8300	8	1.483
Tantalum	185	0.35	205	170	1669	8	3.681

Constant Definition: Young modulus, poisson’s ratio, Yield Strength, Isentropic Hardness ratio have been given for different

Sub-domain setting: Load, Density have been set up in physics mode, sub-domain setting



GOVERNING EQUATIONS

Governing Equations

A normal load applied acting radially outward on stent wall

Equation for load:

Load_max*((para<=1)*para+(para>1)*(2-para)).

Navier's displacement equation: $-\nabla \cdot (c\nabla \mathbf{u}) = \mathbf{F}$

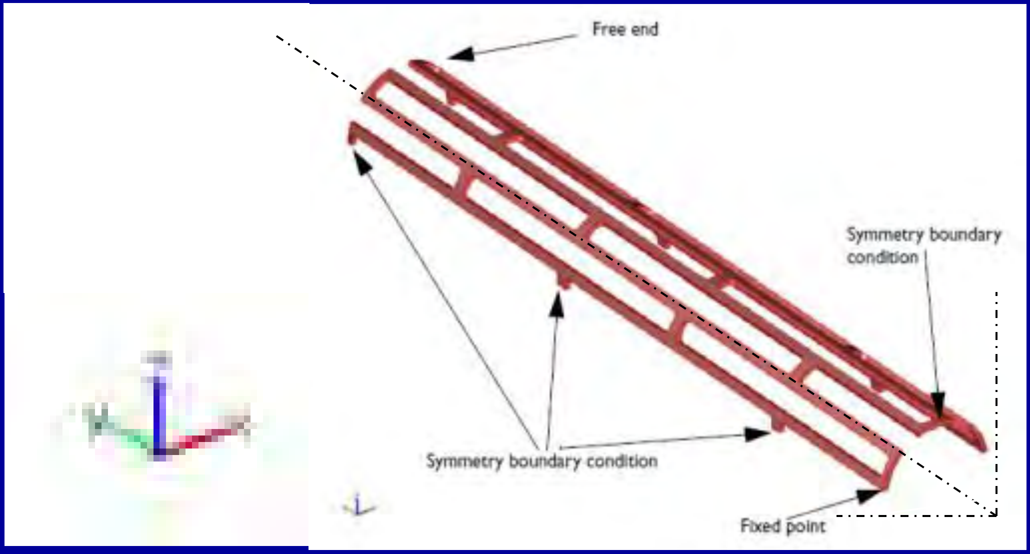
Load

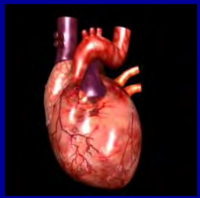
- From clinical study, it is found that standard 0.3 MPa or 2 atm pressure is applied to inflate the balloon.
- In the study, a radially outward pressure is applied on the inner surface of the stent.
- During loading, pressure is increased with the parametric solver to a maximum value of p_{max} = 0.3 MPa.
- Followed by decreasing the load to zero to obtain the final shape of the deformed stent

BOUNDARY CONDITIONS

Boundary Condition

- Symmetry boundary conditions
- Prevents rigid body translation along y and z direction
- Prevents rotation around all axes
- A point constraint along x direction to prevent rigid body translation along x





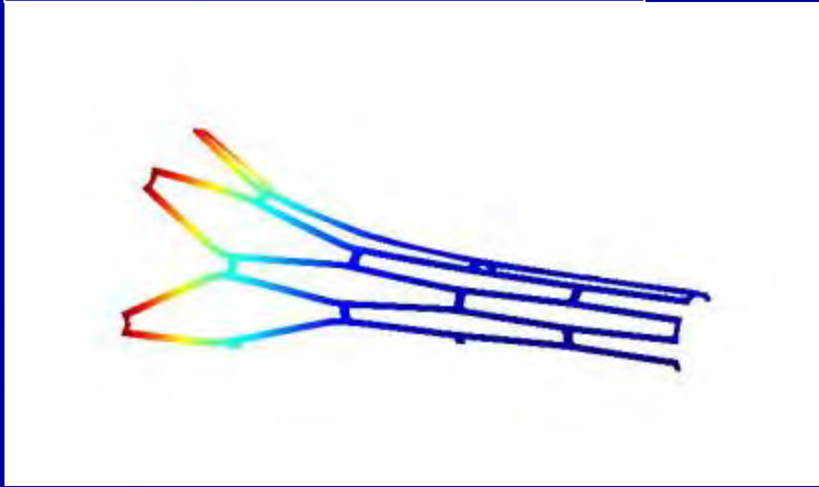
MESH GENERATION

- Predefined fine mesh size has been chosen in Free mesher parameter
- Tetrahedral elements (Lagrangian-Quadratic)
- Approximately 7300 elements generated

Results

- Outputs
  - Von Mises Stress
  - Diameter deformation in all directions(u,v,w)
  - Integral volumetric deformation (u,v,w)

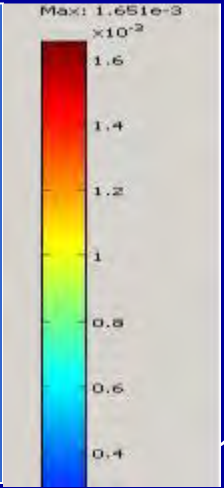
A Sample Output of Model



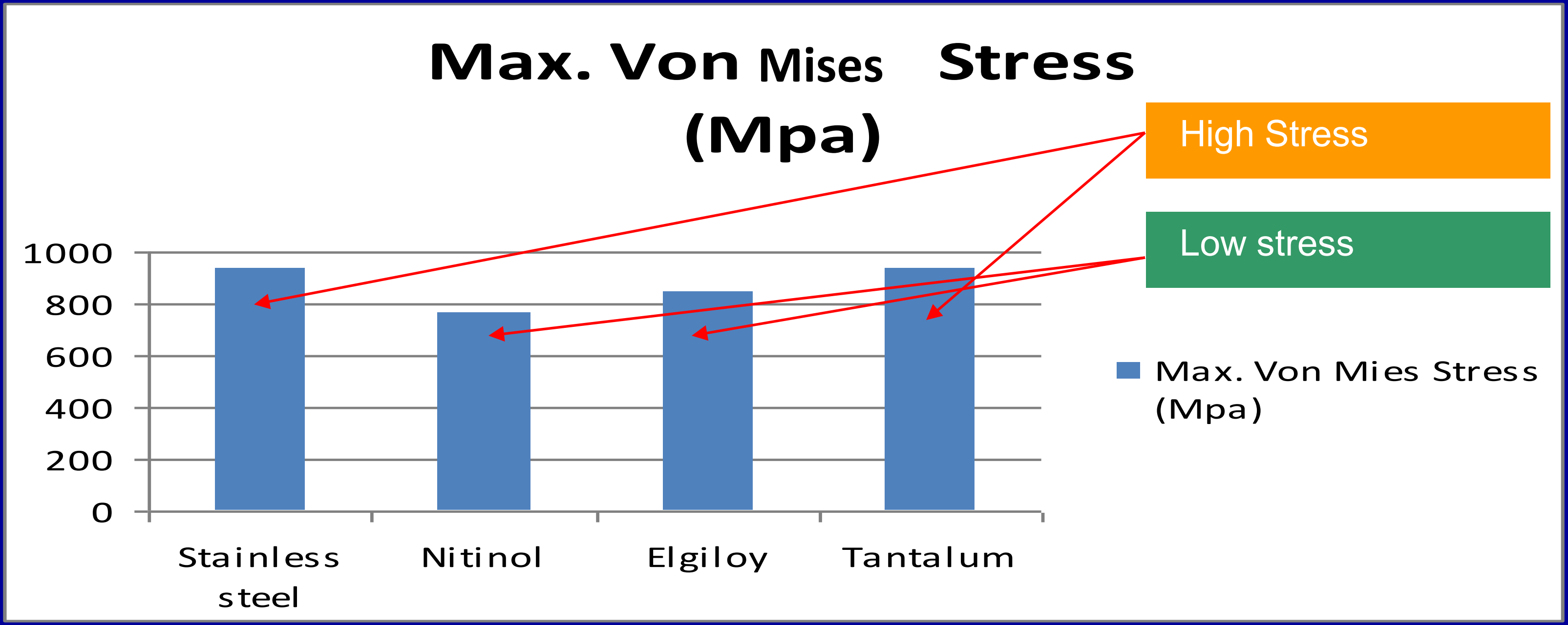
- Fully deformed stent after expansion

(nitinol material)

- Measure: Boundary deformation (Displacement (m))
- Color legend shown at right

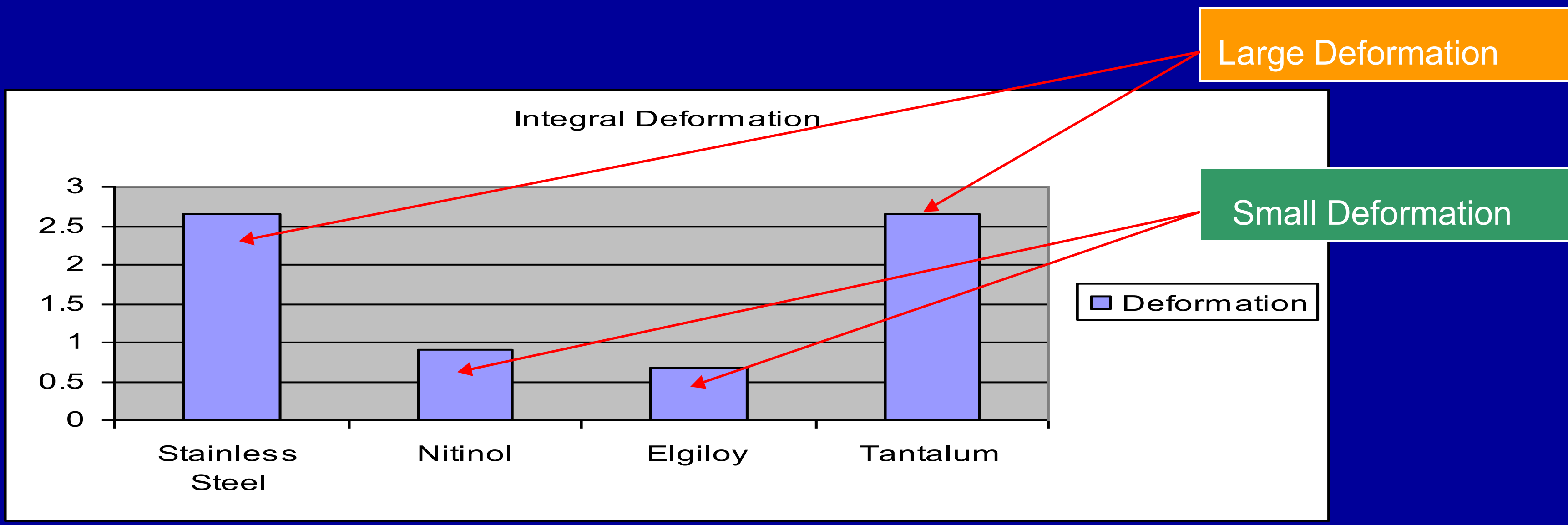


Comparison of Stress Developed



Sl. No.	Materials	Max. Von Mises Stress (Mpa)	Maximum Displacement (mm)
1	Stainless steel	939.1	3.681
2	Nitinol	762	1.568
3	Elgiloy	847.3	1.483
4	Tantalum	939.1	3.681

Comparison of Volume Deformation

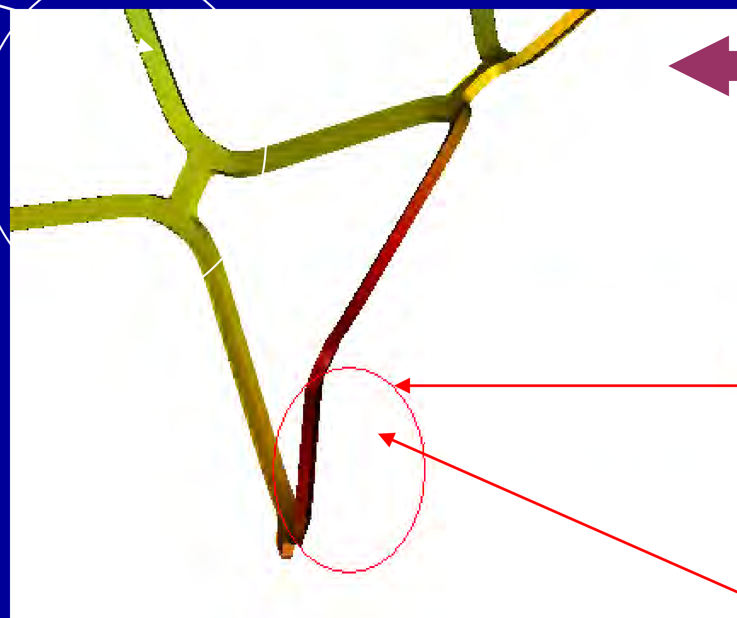


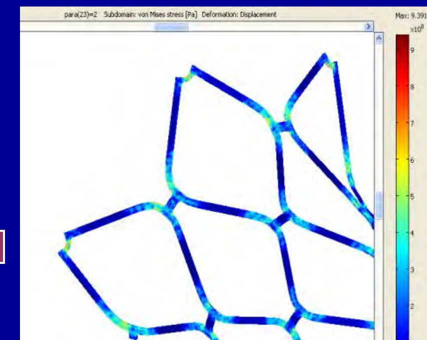
Stent	Stainless Steel	Nitinol	Elgiloy	Tantalum
Deformation	2.64	0.9	0.67	2.64

Stress and Deformation in Stainless Steel

Minimum Deformation

Low Stress Concentration Region



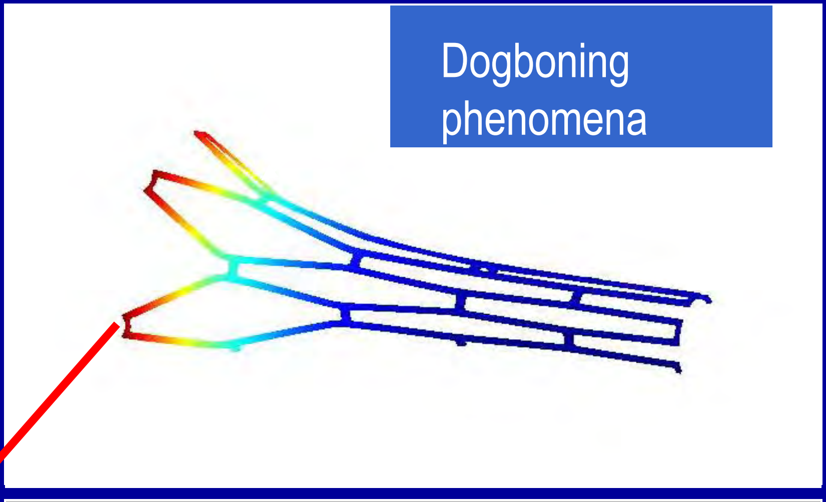


High Stress Concentration Region

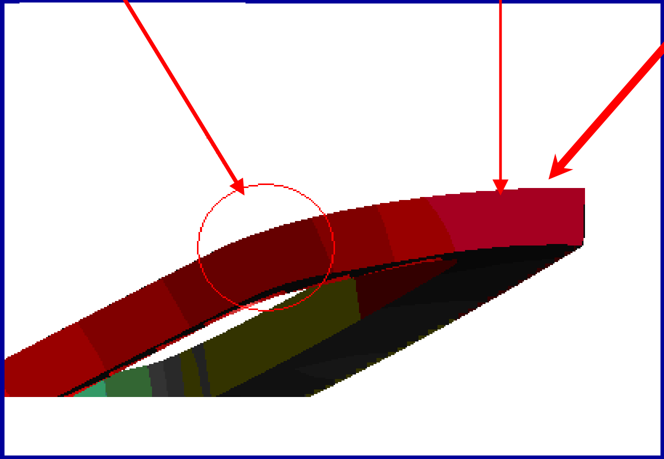
Maximum Deformation

Fracture will initiate as stress exceeds the ultimate tensile strength

Stress and Deformation in Nitinol

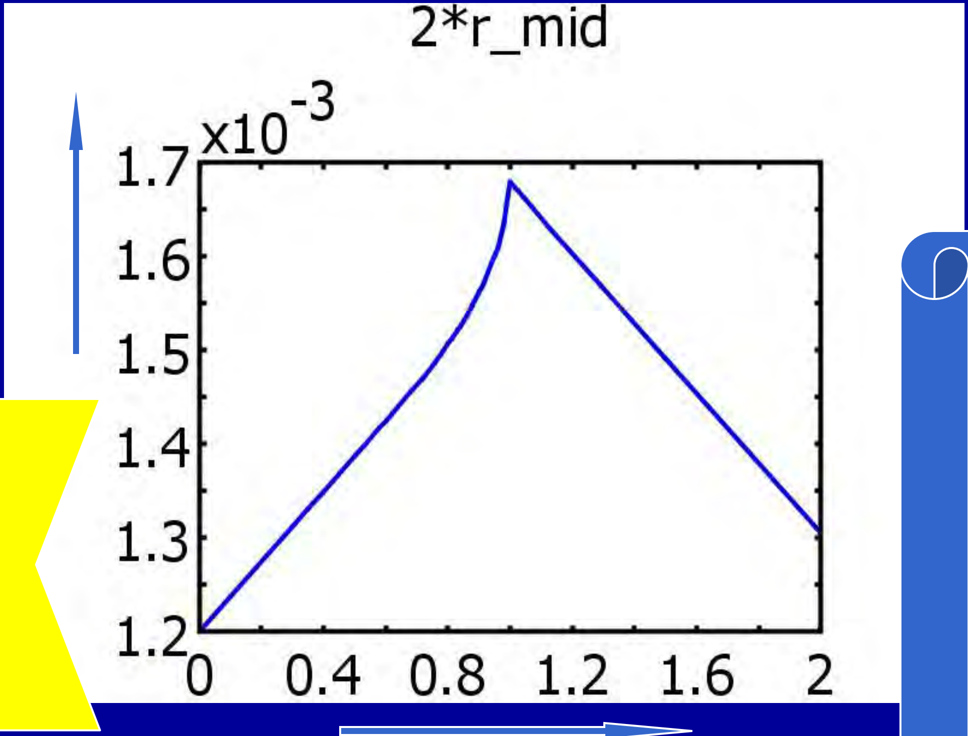


Fully expanded Nitinol Stent



Fracture will not initiate as stress does not exceed the ultimate tensile strength

Deformation Process Monitoring



Diameter Deformation

Load Parameter

The plot shows a standard characteristic of mechanical behavior of shape memory alloy Nitinol

Nitinol is preferable as it remain the shape as predefined

(1.3 mm diameter approx. in this case)

Plot of load parameter vs. radial deformation

Detailed Deformation Study of Different Stent

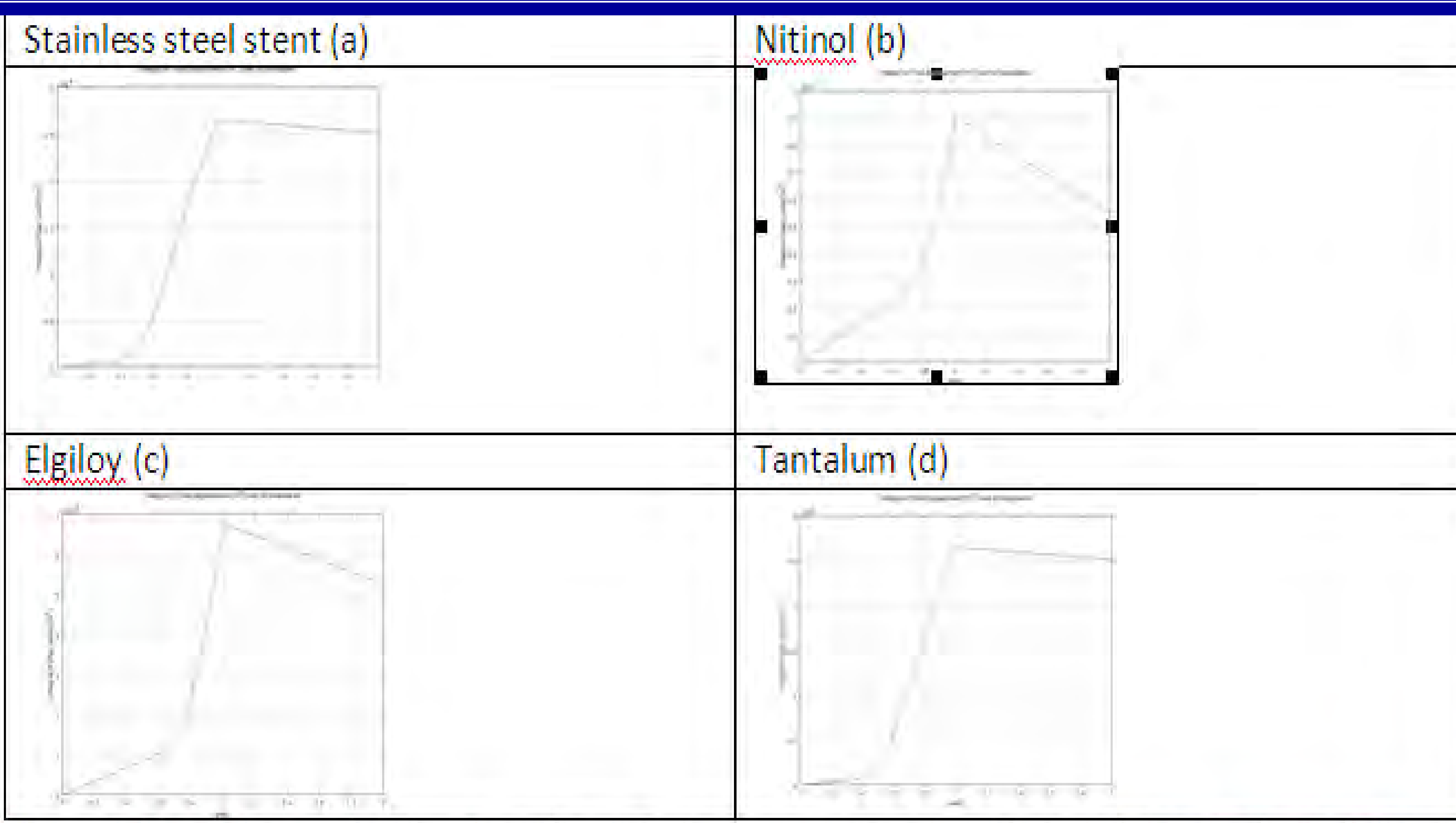


Figure 3: Plot of integrated deformation of stents against parameters – (a) stainless steel, (b) nitinol, (c) elgiloy, (d) tantalum

Study of Stress developed and Fractures

Stent Materials	Ultimate Tensile Strength (MPa)	Max. Von Mises stress (MPa)	Will fracture occur?
Stainless steel	550	939.1	Yes
Nitinol	960	762	No
Elgiloy	1020	847.3	No
Tantalum	205	939.1	Yes

- Above comparison shows that fracture risk is there in case of Stainless steel and Tantalum stents.
- In case of nitinol and elgiloy, fracture will not occur as their ultimate tensile stresses are higher than the maximum von Mies stress developed.
- Here, the load on stents and stent geometries are kept constant

Conclusions

- The study of deformation and stress development during the stent deployment process are important for determining the stent efficacy
- Comparison of different stent materials' mechanical properties during the expansion process is important to decide the preferred material to choose
- The comparison of stress developed during the stent expansion process determines the risk factors of developing fractures inside stents
- The current model results shows that, with constant pressure load on stent wall and constant stent geometry, fracture development risks in nitinol and elgiloy stents are less and that in stainless steel and tantalum are more

Acknowledgement

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