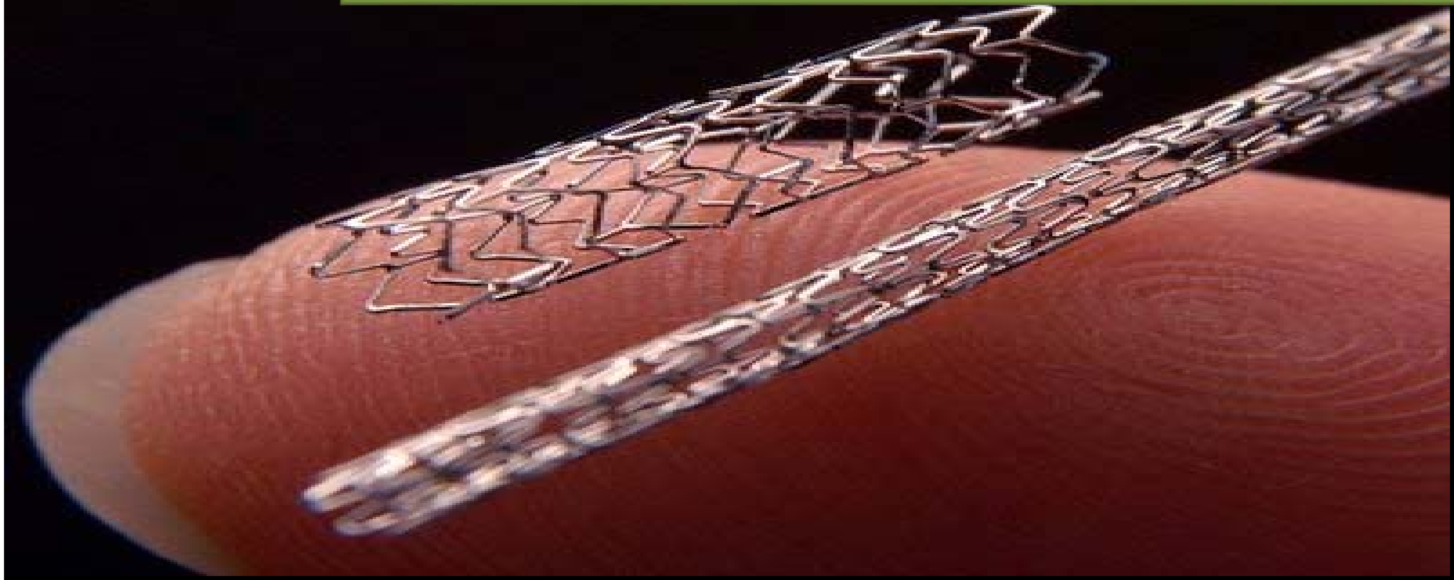
Computational Analysis on Commercially Available Stent Designs



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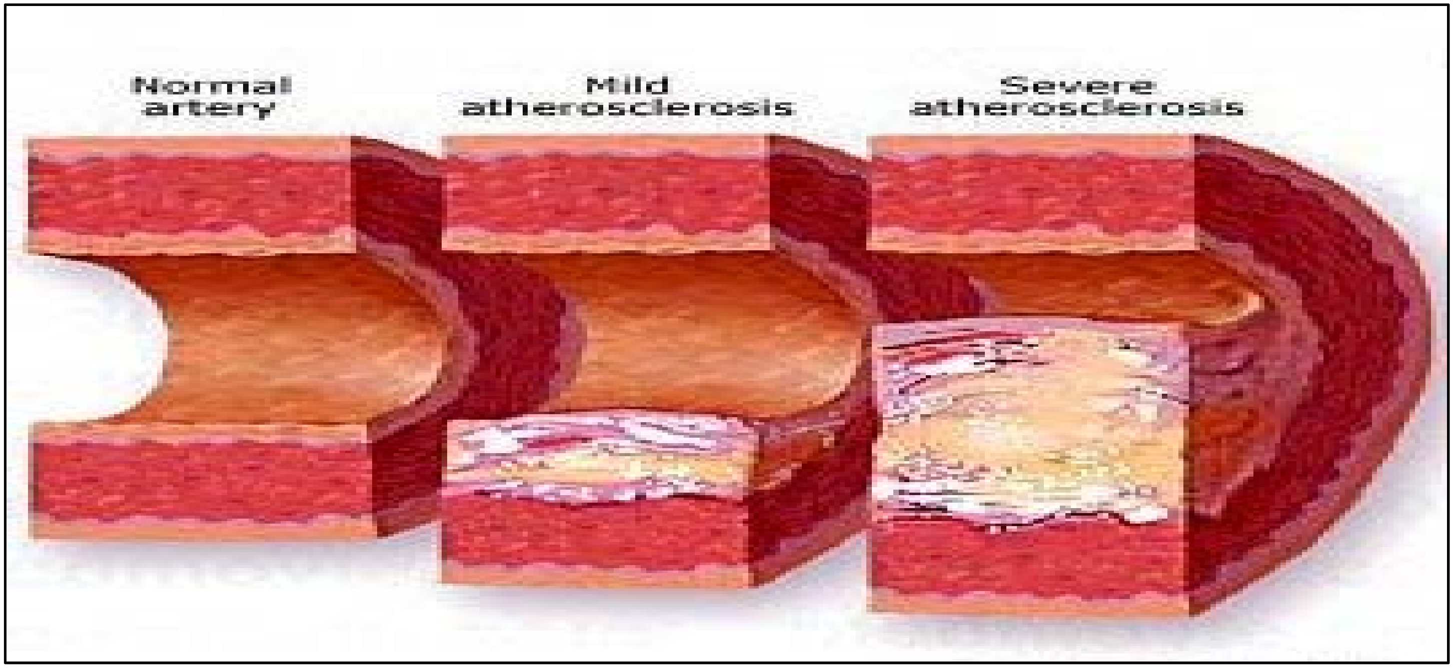
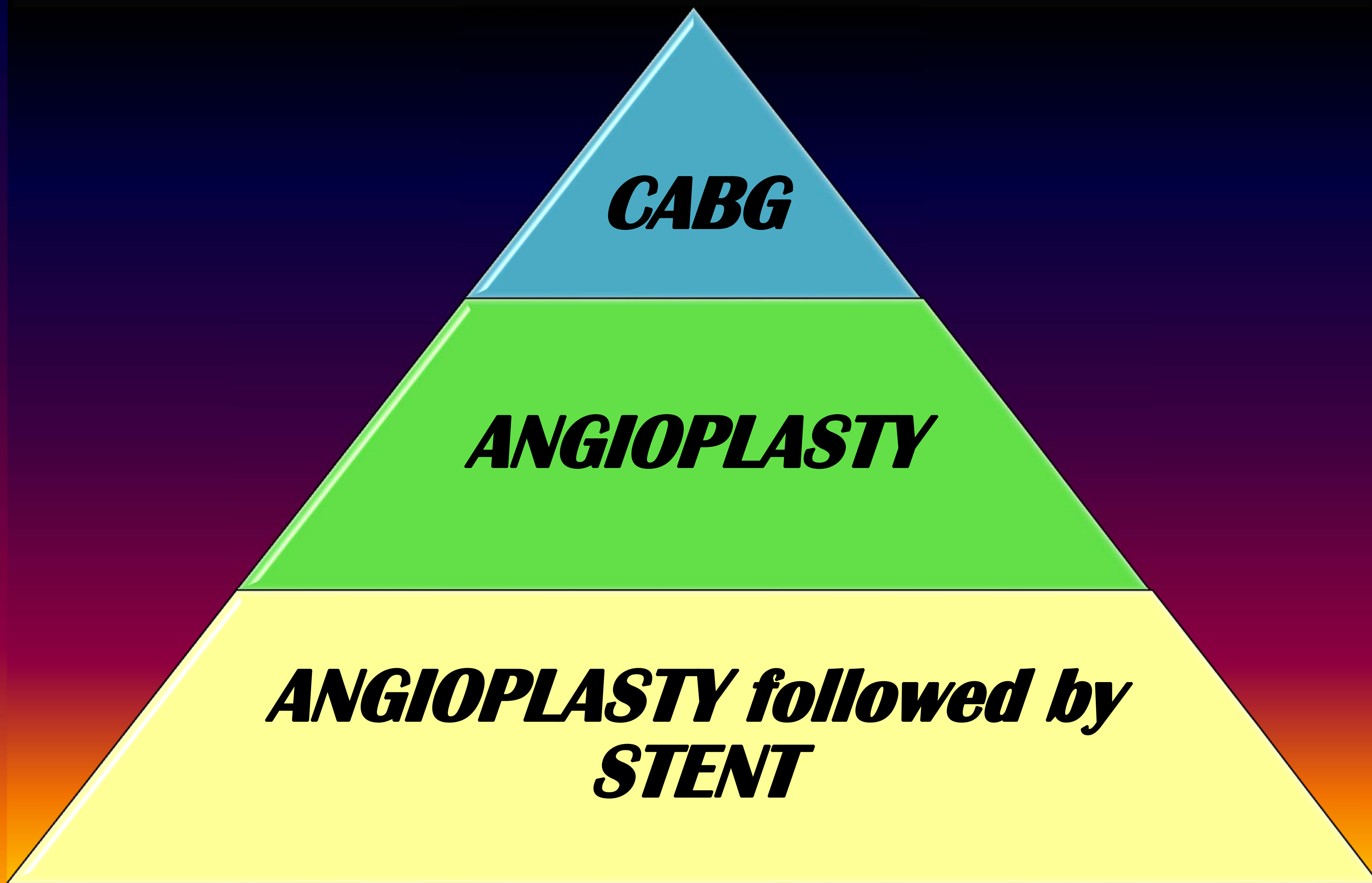
ATHEROSCLEROSIS- the problem



THE TREATMENT



WHAT IS A STENT ?

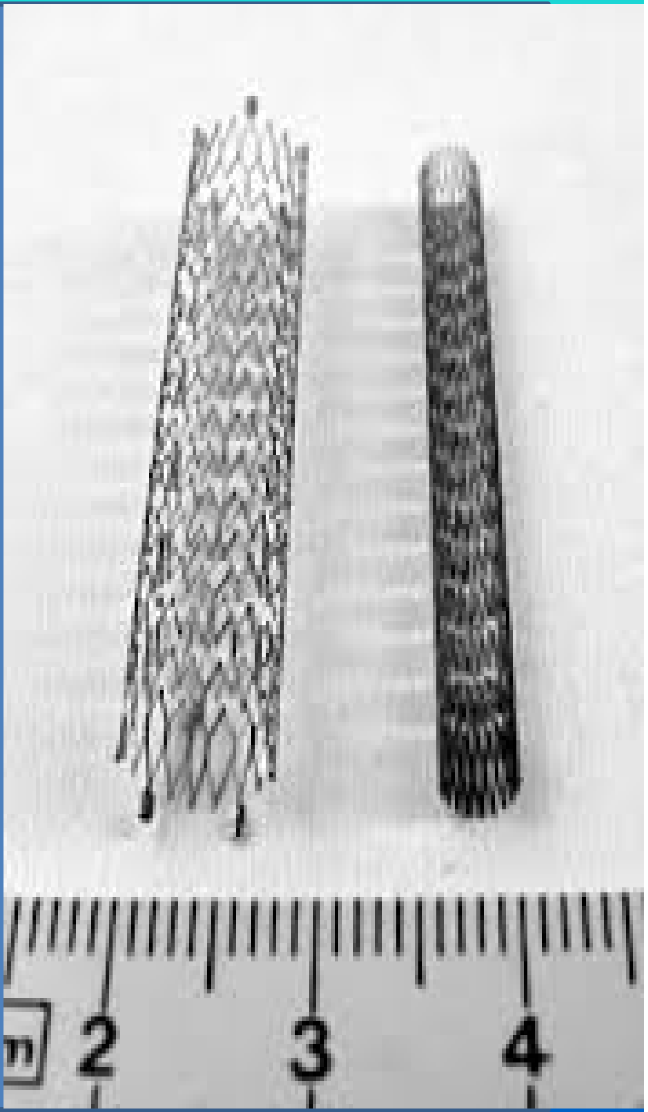
*A **stent** is an artificial 'tube' inserted into a natural passage/conduit in the body to prevent, or counteract, a disease-induced, localized flow constriction. The term may also refer to a tube used to temporarily hold such a natural conduit open to allow access for surgery.*

Material requirements of stents

- ✓ *Radiopacity*
- ✓ *Biocompatibility*
- ✓ *Haemocompatibility*
- ✓ *Corrosion-resistance*
- ✓ *Good fatigue properties*

Design Requirements of Stents

- High Radial Strength
- Low Elastic Radial Recoil
- Good Flexibility
- Low Stent Profile
- Good Trackability
- Minimal Foreshortening
- Minimal Elastic Longitudinal Recoil
- Optimum Scaffolding



Restenosis : A MAJOR CONCERN

- ***Result of arterial damage with subsequent neo-intimal tissue proliferation***
- ***Binary angiographic restenosis is defined as >= 50% luminal narrowing at follow up angiography***

- ***20% restenosis rate in 12 months***
- ***restenosis occurring in 20-50% of vessels stented with bare-metal stents***
- ***3%-20% restenosis rate in DES***
- ***<u>DES have reduced restenosis rates significantly However, stent design is a still a major determinant of in-stent restenosis</u>***

Restenosis: CAUSES

- Procedural Errors
- Drug/ Material Toxicity
- Stent Design Implications

How Do We Stop RESTENOSIS

STATE OF ART

Methodology of the Study (1)

Analysis of Clinical Data

Determination of cases where stent implantation is considered

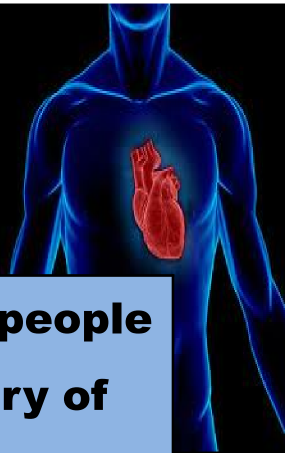
↓

Identification of various materials and designs used in commercially used stents

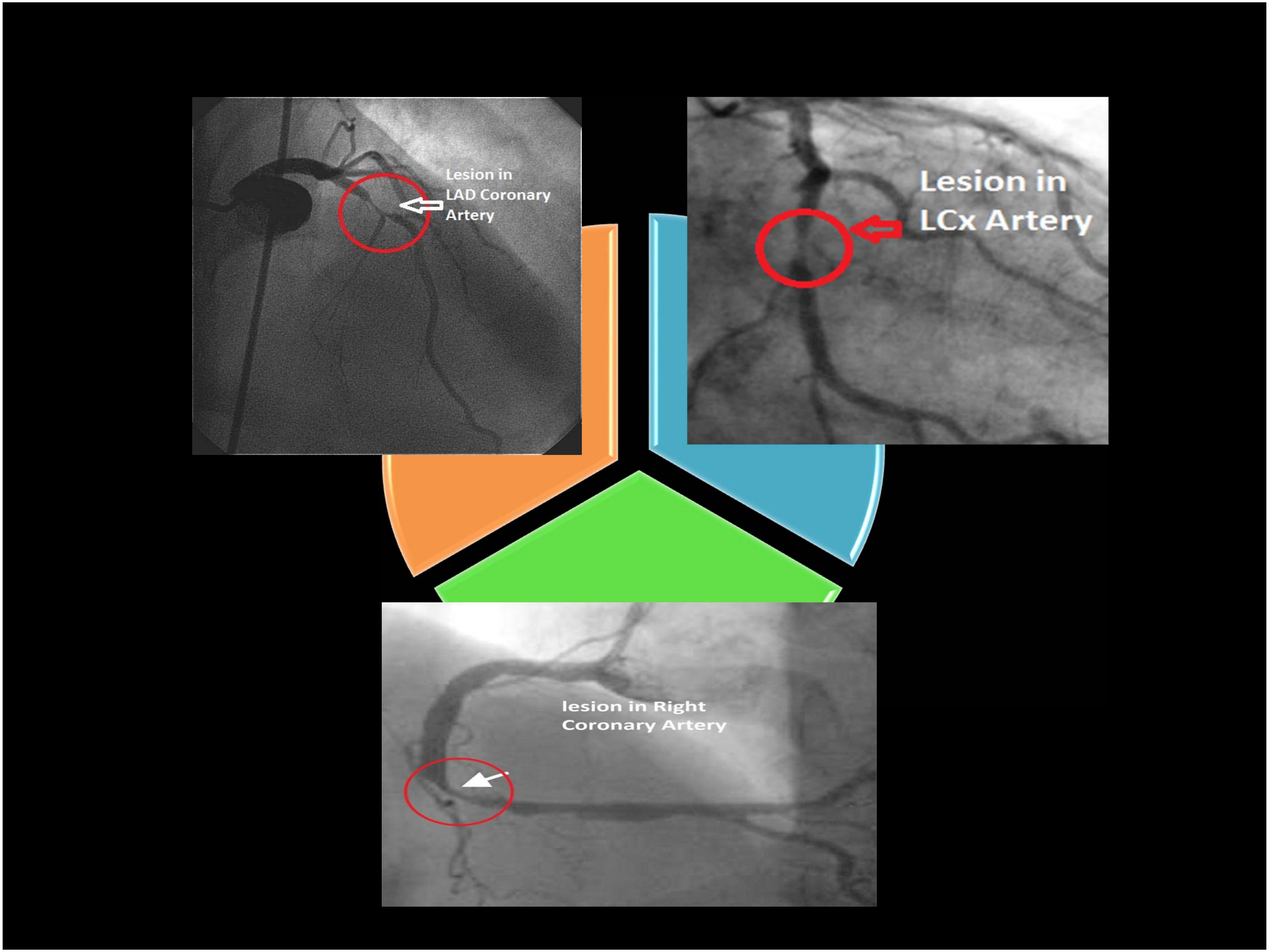
↓

Identification of the stent deployment pressures by which a stent is inflated

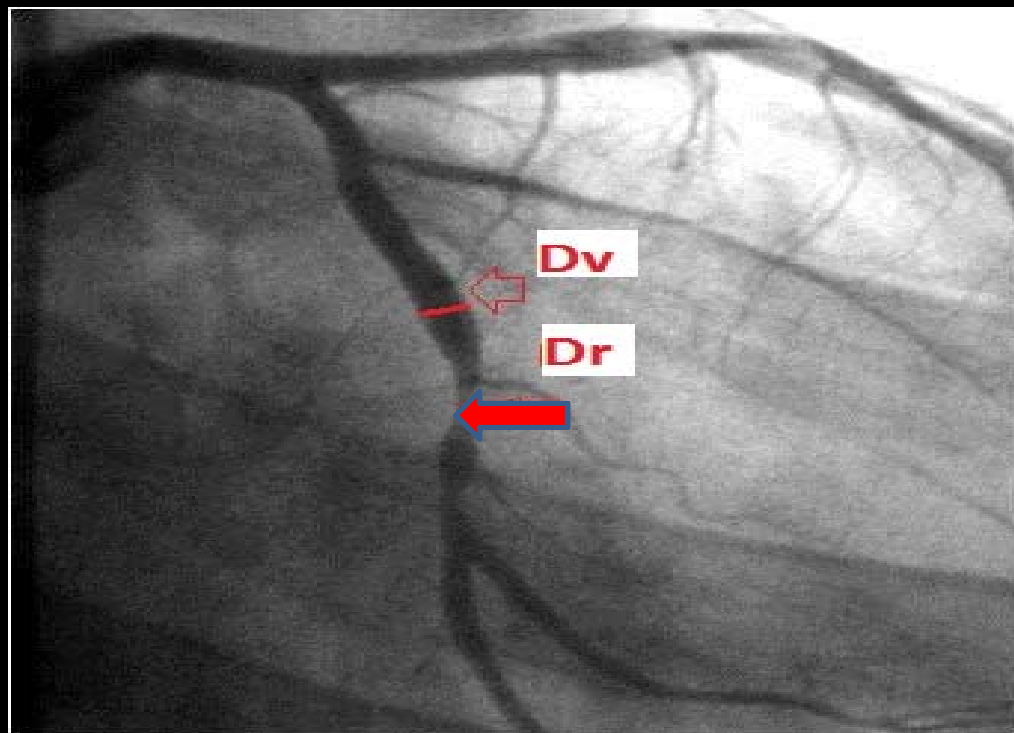
Patient Profile



Percentage Stenosis	Coronary Artery			Total number of people in each category of stenosis
	LAD	LCA	RCA	
≤ 50 %	2	0	0	2
50- 60%	4	3	4	11
60- 70%	2	3	6	11
70- 80%	0	2	3	5
80- 90%	6	4	2	12
90- 100%	4	3	8	15
Total number of people with stenosis in each artery	18	15	23	GRAND TOTAL 56


Lesion in
LAD Coronary
Artery
Lesion in
LCx Artery
lesion in Right
Coronary Artery

Measurement of Stenosis



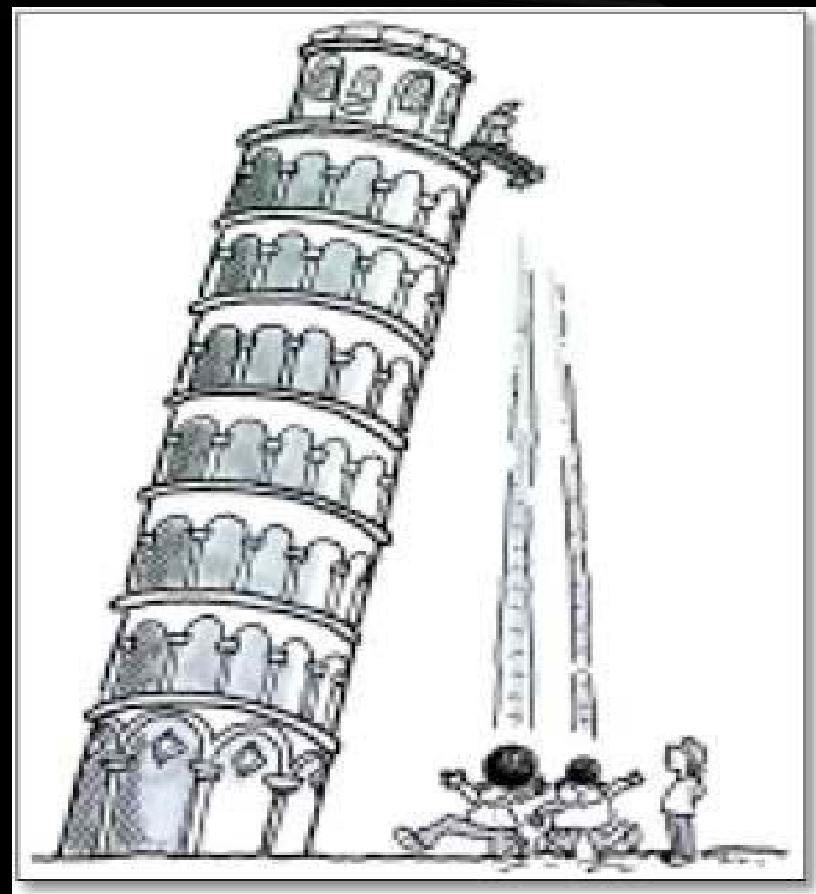
$$Do = Dv - Dr$$

$$\% \; Stenosis = \frac{Dv - Dr}{Dv} X \; 100$$

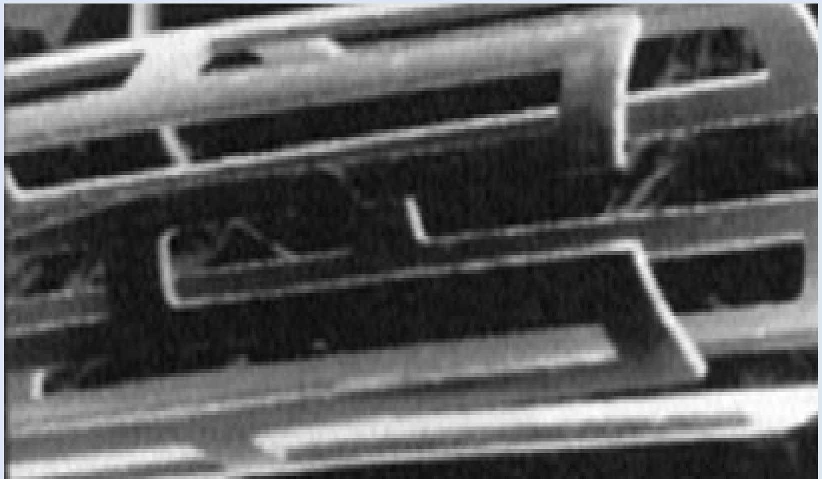
Why COMPUTATIONAL MODELING?

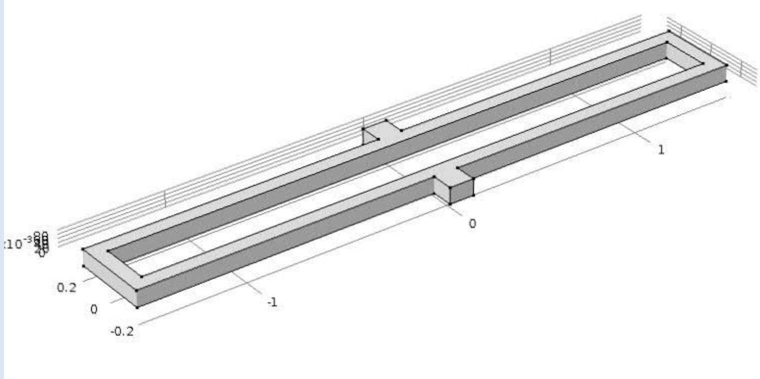
Q: In a free fall, how long would it take for an object to reach the ground from the Leaning Tower of Pisa?

Ans: I have never performed this experiment.

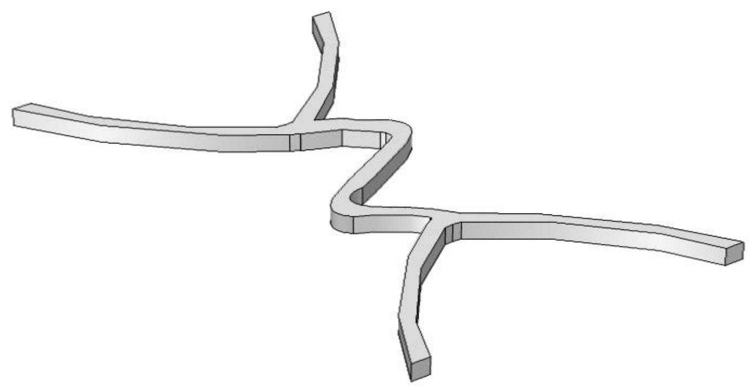


Stationary Analysis of Stent expansion:





PS Stent



Bx Velocity Stent

Stationary Analysis of Stent expansion:

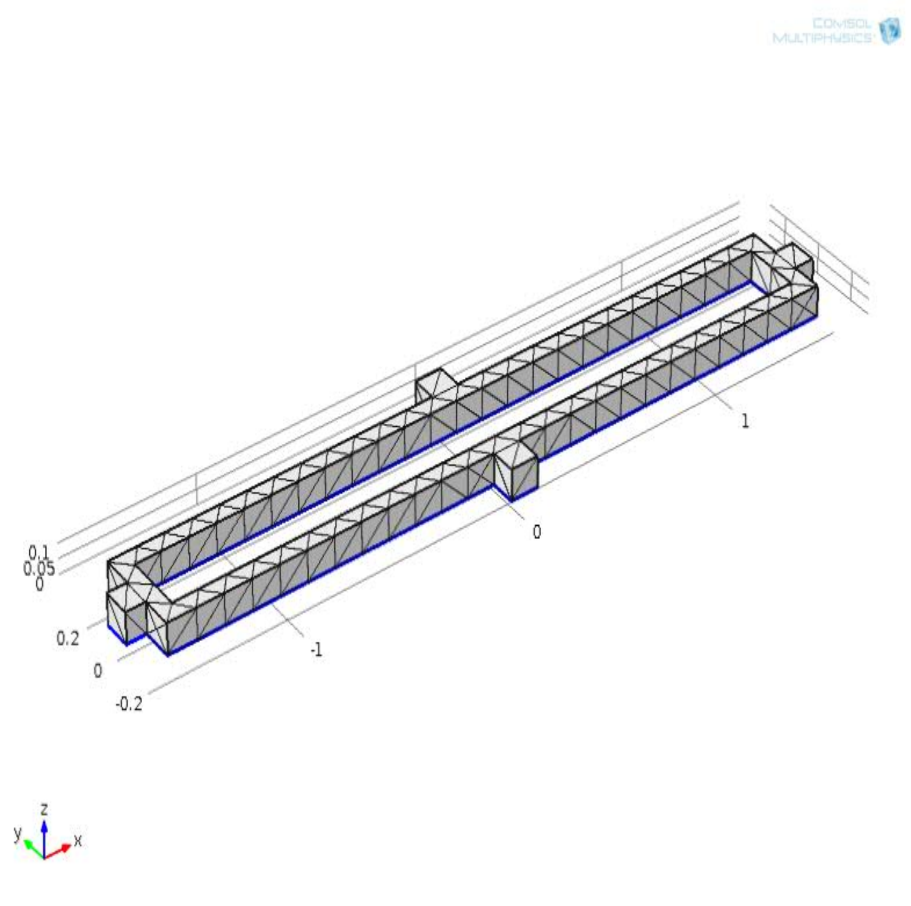
1. *COMSOL Multiphysics® v4.3A*
2. *Structural Mechanics Module*
3. *Symmetry applied in all its arms (struts)*
4. *Boundary conditions:*
   - *Deployment pressure of 14 atm, 15 atm and 16 atm applied at the inner wall of the stent*
   - *A pressure of 780 KPa applied in the outer wall of the stent by atherosclerotic plaque build up*

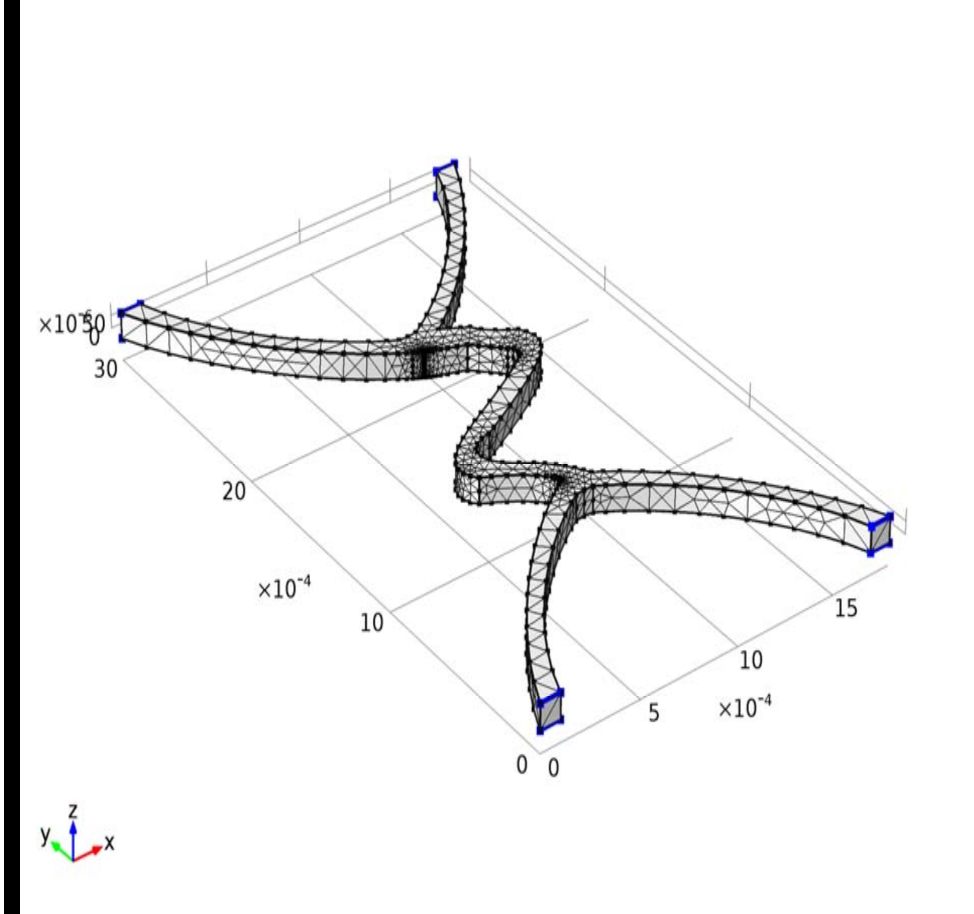
Stationary Analysis of Stent expansion:

Material properties of stent materials:

S. No.	Material	Density (kg/m^3)	Modulus of Elasticity (GPa)	Poisson's Ratio	UTS of material (MPa)
1.	316L SS	7850	193	0.226	595
2.	L 605 Co-Cr	9100	243	0.3	1020
3.	Pt- Cr	9900	203	0.3	834
4.	Ni- Ti	6478	83	0.3	1100-1200
5.	Tantalum	1669	185	0.35	285

Meshing



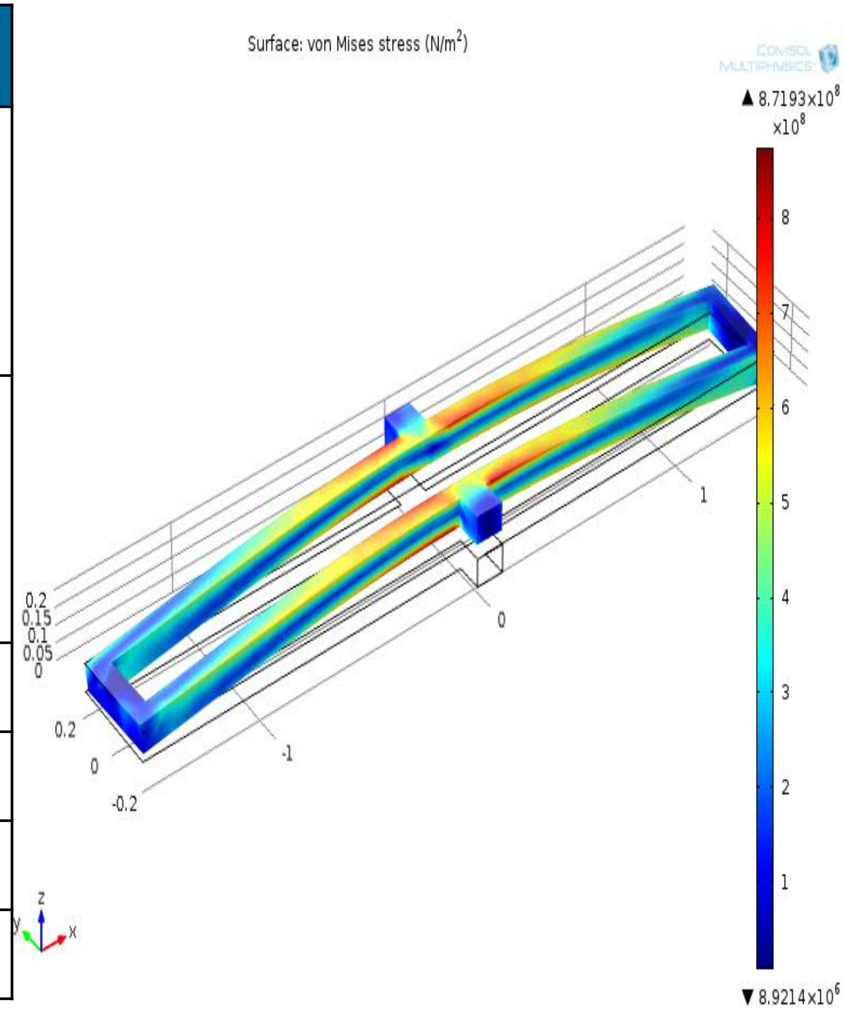


PS Stent

Bx Velocity Stent

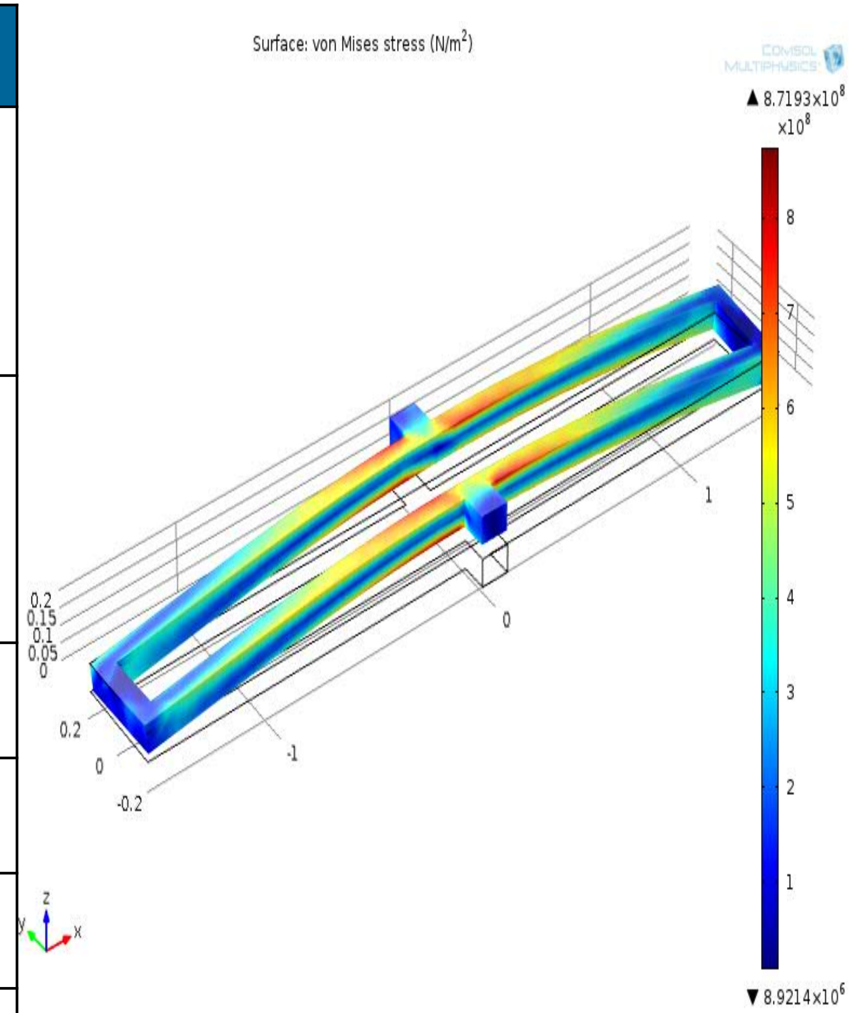
PS STENT Expansion

S. No.	Material	Von Mises Stress (MPa)		
		at 14 atm pressure	at 15 atm pressure	at 16 atm pressure
1.	316L Stainless Steel	878.53	1020.3	1162
2.	L 605 Co-Cr	558.96	649.15	739.35
3.	Pt- Cr	*599.56*	*696.22*	*792.88*
4.	Nitinol	871.93	1012.60	1153.3
5.	Tantalum	866.85	1006.7	1146.6



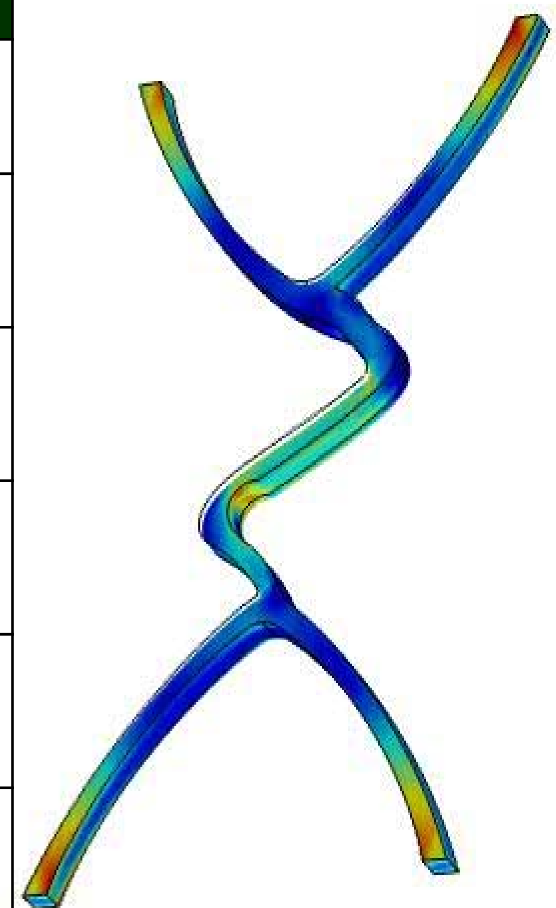
PS STENT
FAILURE AND SUCCESS

S. No.	Material	Will FAILURE occur?		
		at 14 atm pressure	at 15 atm pressure	at 16 atm pressur e
1.	316L Stainless Steel	YES	YES	YES
2.	L 605 Co-Cr	NO	NO	NO
3.	Pt- Cr	NO	NO	NO
4.	Nitinol	NO	NO	NO
5.	Tantalum	YES	YES	YES



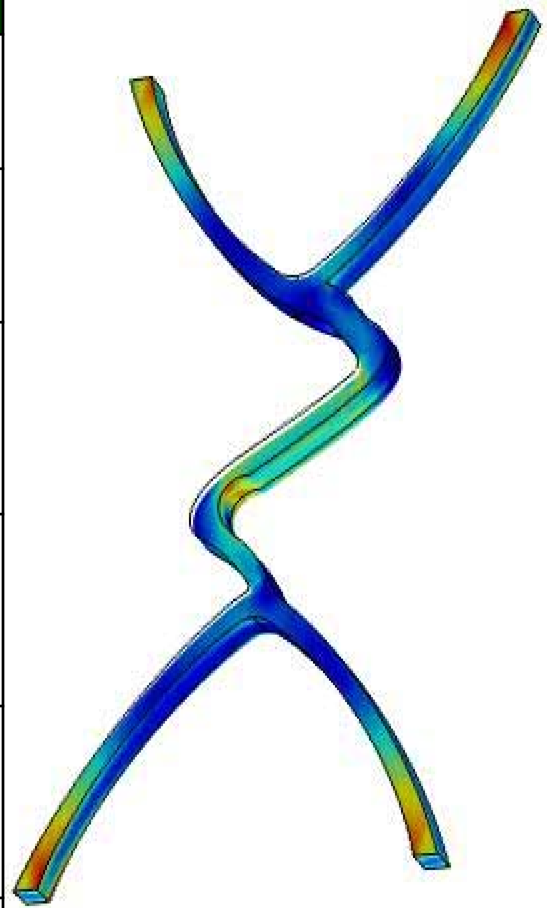
Bx VELOCITY Stent Expansion

S. No.	Material	Von Mises Stress (MPa)		
		At 14 atm pressure	At 15 atm pressure	At 16 atm pressure
1.	316L Stainless Steel	475.59	552.28	628.96
2.	L 605 Co-Cr	470.66	546.56	622.45
3.	Pt- Cr	*469.0*	*544.88*	620.66
4.	Nitinol	470.62	546.51	622.39
5.	Tantalum	466.79	542.06	617.32



Bx VELOCITY Stent Expansion

S. No.	Material	Will Fracture Occur?		
		At 14 atm pressure	At 15 atm pressure	At 16 atm pressure
1.	316L Stainless Steel	NO	NO	YES
2.	L 605 Co-Cr	NO	NO	NO
3.	Pt- Cr	NO	NO	NO
4.	Nitinol	NO	NO	NO
5.	Tantalum	YES	YES	YES



Conclusion (1)

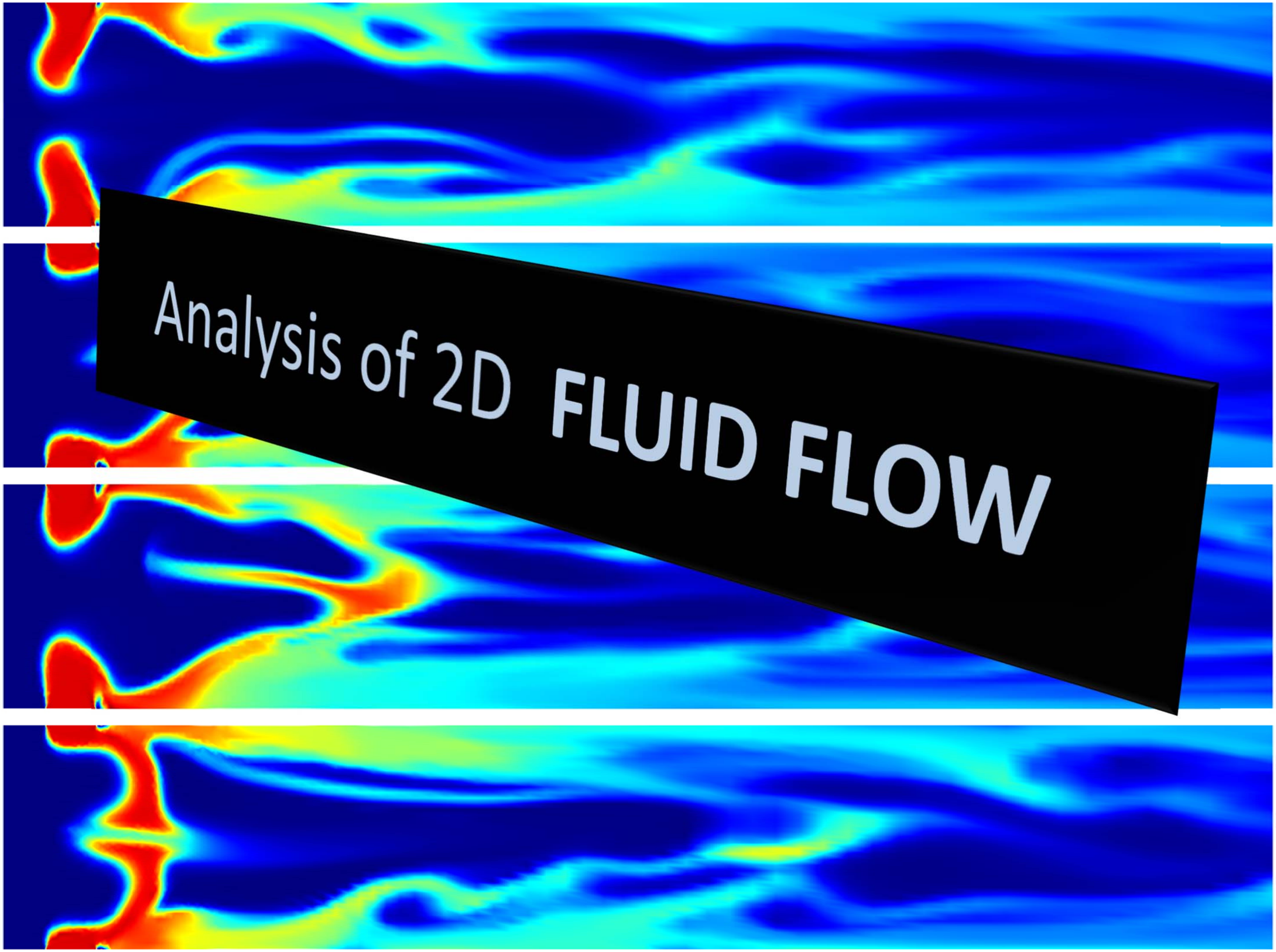
1. *Stent deployment technique was an important factor that determined the success or failure of stents.*
2. *Stainless Steel stents might experience Mechanical failure under high deployment pressure.*
3. *L 605 Cobalt Chromium Alloy is highly acceptable biomaterial.*
4. *Platinum Chromium alloy also makes a very good metallic alloy for coronary stent design.*
5. *Nitinol can also be considered as a good biomaterial provided other aspects of the material like nickel release and corrosion gives satisfactory results.*
6. *Tantalum should be avoided when considering stent designs*

Conclusion (contd.)

- *The high values of Von Mises Stress in the stents lead to arterial injury which leads to neo intimal hyperplasia resulting in Restenosis.*

- *Even if the stresses exceed the UTS of the material, it doesn't necessarily lead to immediate breakage of the metallic stents.*

But as a result of this phenomenon micro cracks are likely to develop in the body of the stents which due to fatigue loading over time ultimately contributes to mechanical failure of the stents.


Analysis of 2D FLUID FLOW

1. Laminar Flow module of COMSOL Multiphysics
2. Time dependant Analysis
3. Pulsatile flow employed.

$$f(t) = \begin{cases} \sin \pi t & 0 \le t \le 0.5s \\ 1.5 - 0.5\cos(2\pi(t - 0.5)) & 0.5 < t \le 1.5s \end{cases}$$

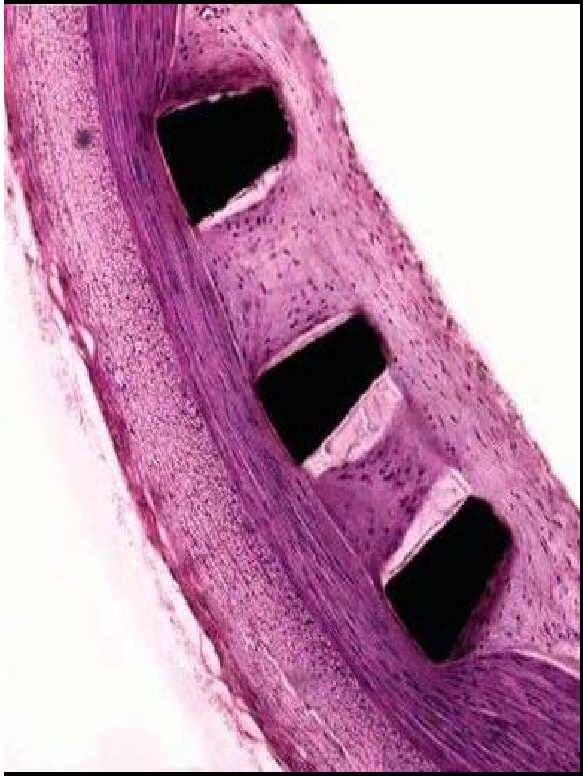
4. Blood density: 1060 kg/m3
5. Newtonian and non Newtonian models used.
   - For Newtonian: viscosity is *0.004* Pa.S
   - For Non Newtonian: Power law Model is utilized.

   Here *m= 1.029*

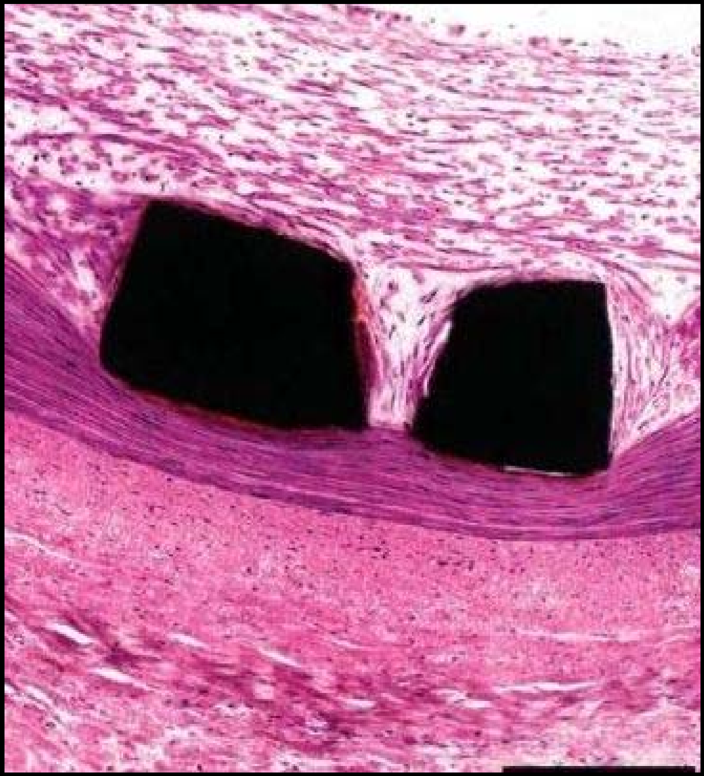
   n= 0.703

$$\mu = m\left(\frac{\partial \gamma}{\partial t}\right)^{n-1}$$

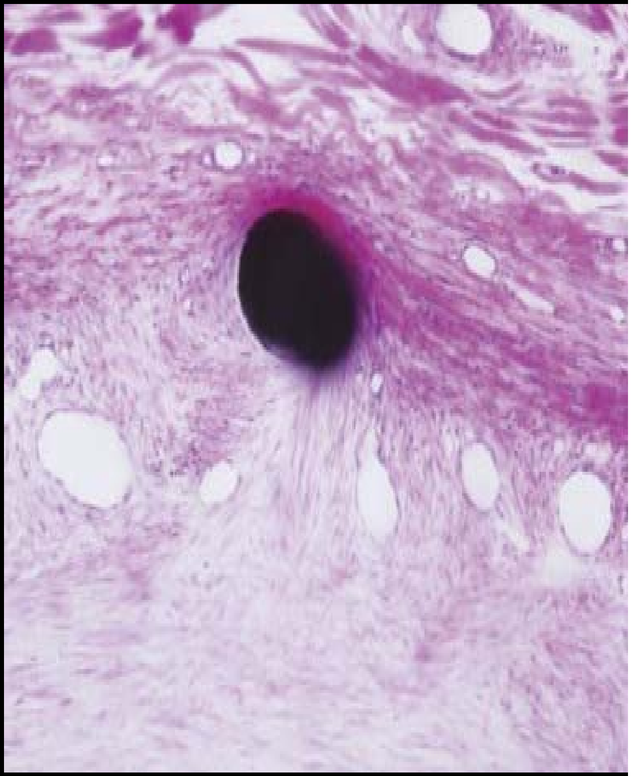
STRUT DESIGNS…



Rectangular struts

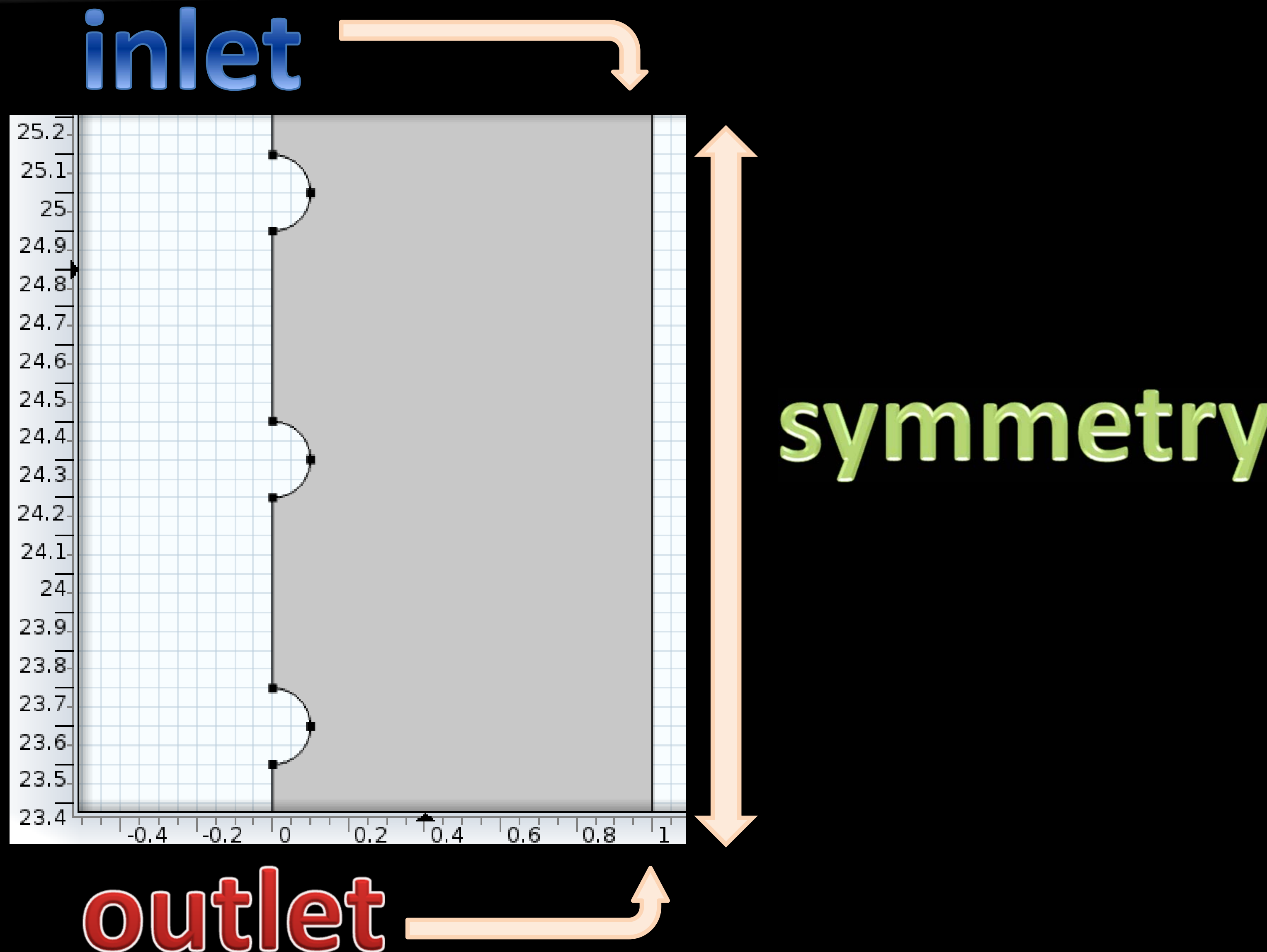


Square struts

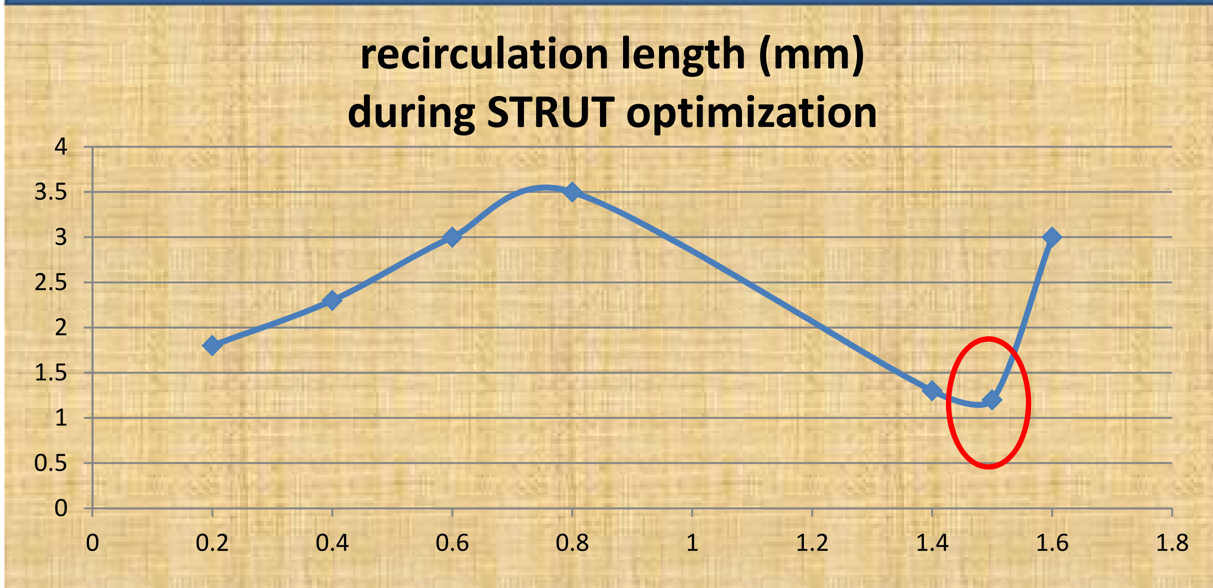


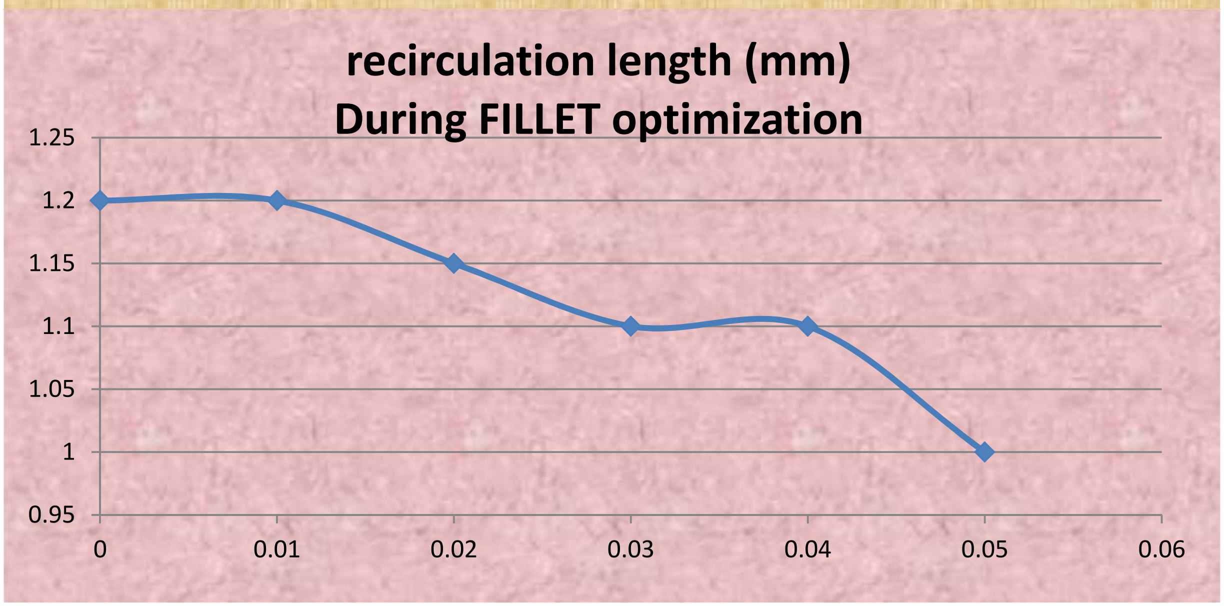
Circular struts

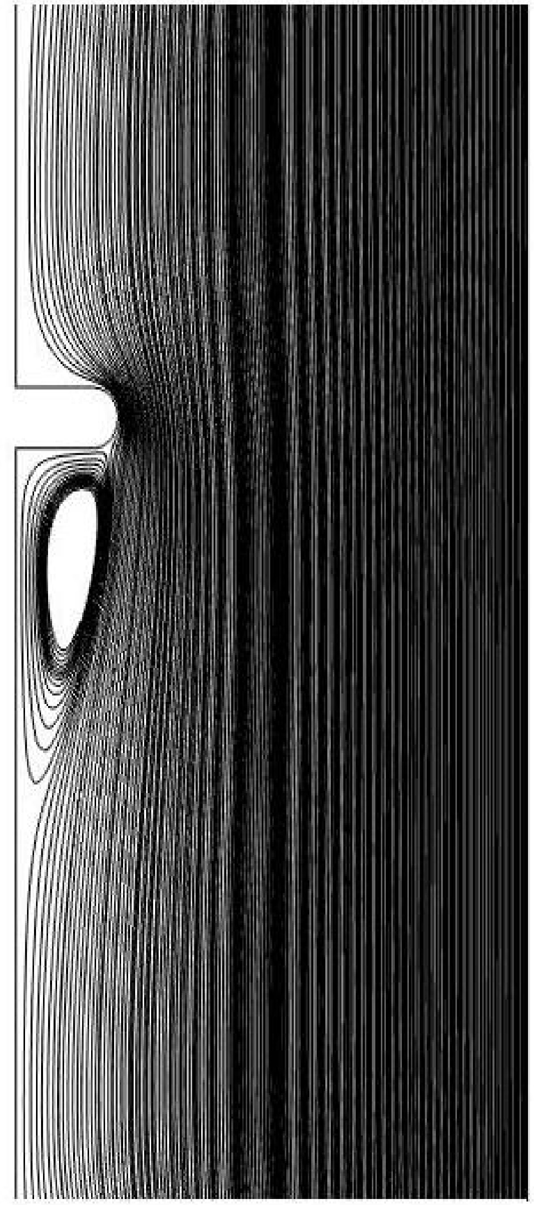
Boundary assumptions



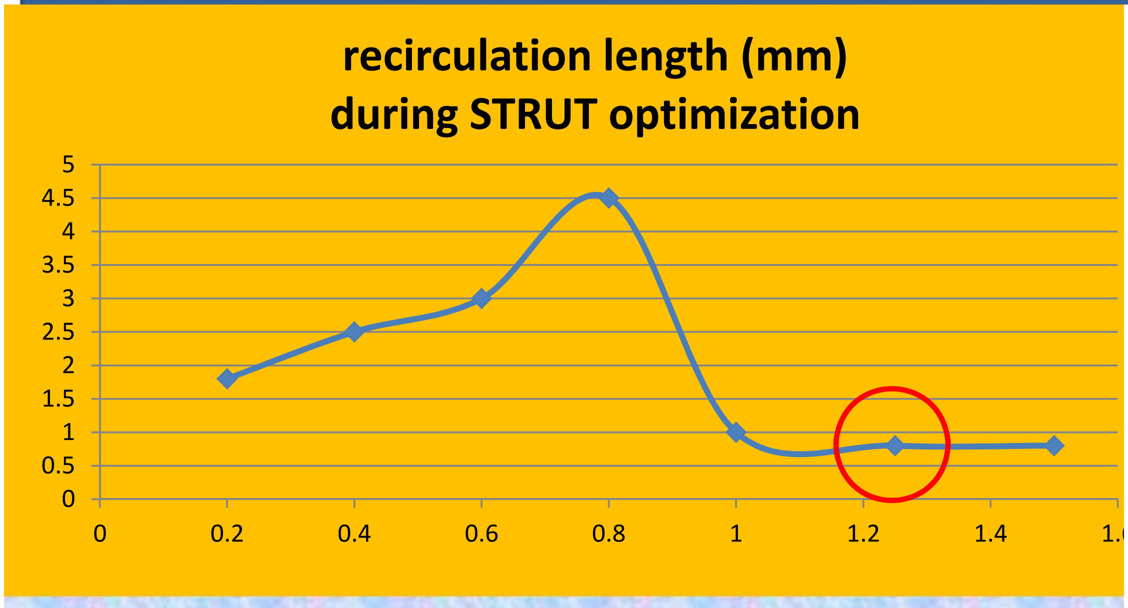
Behavior of Rectangular struts (0.2mm X 0.1mm) in Newtonian Fluid Model

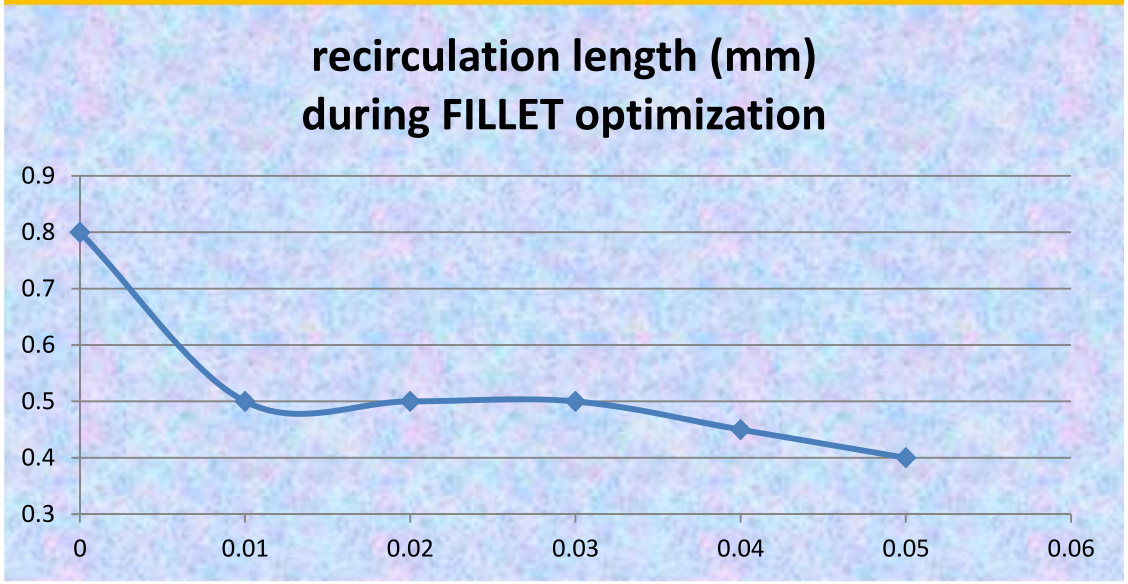


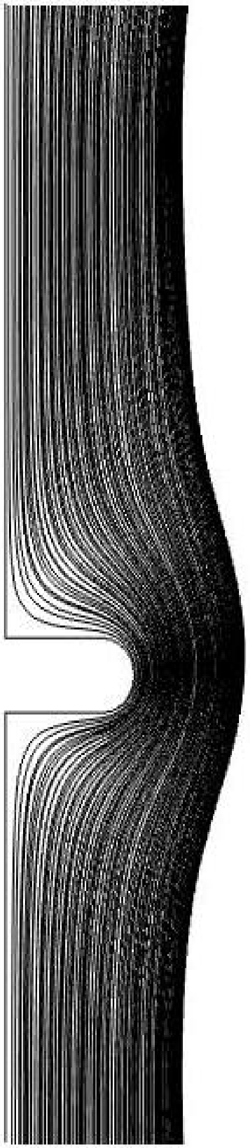


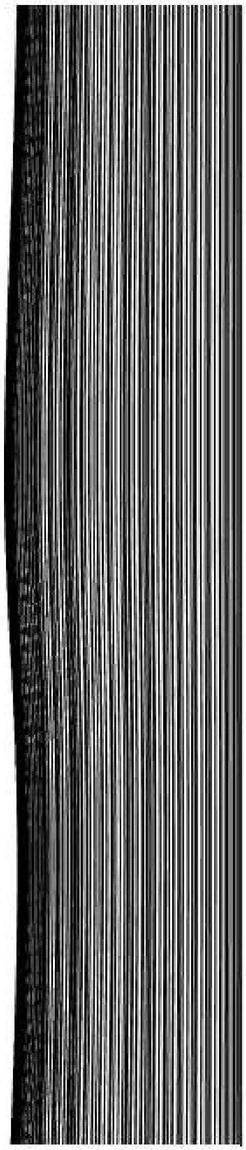


Behavior of Rectangular struts (0.2 X 0.1mm) in Non Newtonian Fluid Model

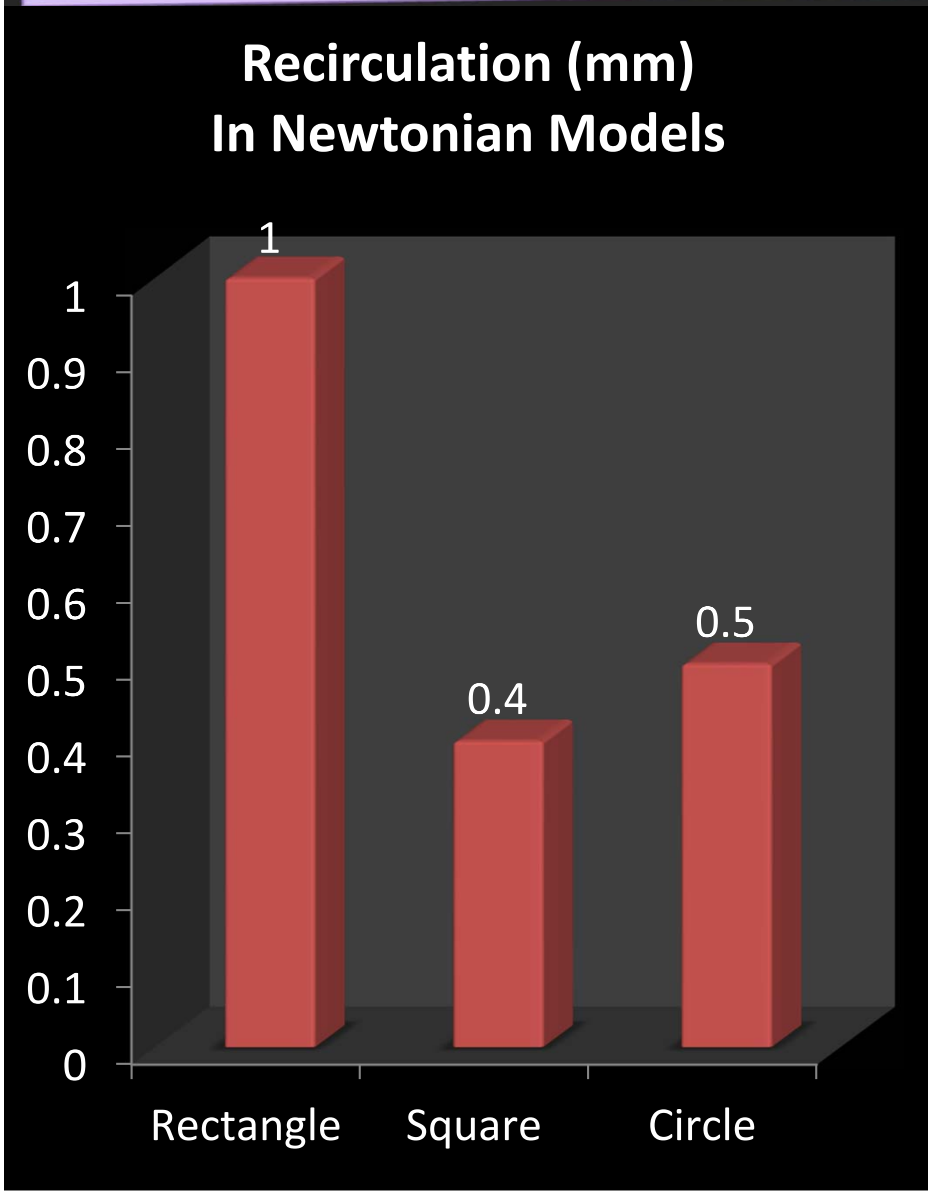


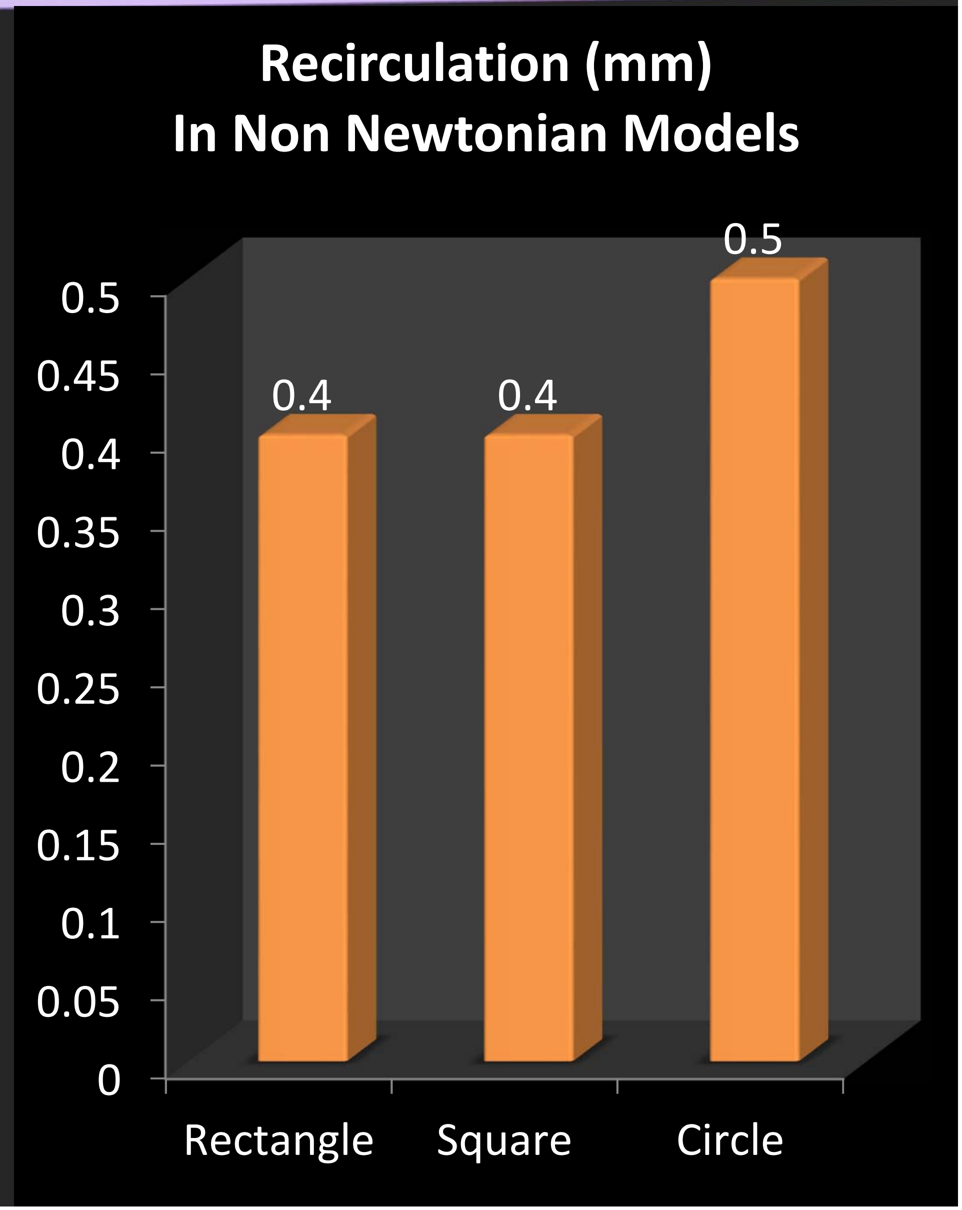






Recirculation – the Culprit





Conclusion (2)

1. *In rectangular struts best results achieved when struts are placed at a distance of 1.5mm apart (Newtonian model) and 1.25mm apart (Non Newtonian Model).*
2. *Square and Circular struts delivered best results in terms of achieving minimum recirculation length if they were placed 0.7mm apart regardless of the Newtonian/ non Newtonian blood behavior*
3. *Presence of rectangular struts initiated larger recirculation lengths when compared with square or circular struts.*
4. *The rectangular struts initiated large vortex formations in the central region of fluid flow*
5. *The square shaped struts of stents gave the best results in our study. The recirculation lengths were found to be least in the case of square shaped struts*

FUTURE SCOPE OF STUDY

More clinical data analysis (n≥ 500) required to find the exact trends in coronary artery disease where stent angioplasty is incorporated

Intra Vascular Ultrasound images in this kind of clinical study would greatly enhance in finding the nature of stenosis and the exact three dimensional nature of atherosclerotic plaque

radial design of the stents should be simulated so as to achieve exact mechanical behavioral patterns

Radial displacement of stents due to expansion

Detailed analysis of various factors counteracting the stent expansion

Inlet flow pressure of coronary artery, Reynold's number or vorticity indices should be included

FUTURE SCOPE OF STUDY

For a complete analysis of stents behavior, the research should be carried out under the following three radiuses:

- ***Extensive Clinical Analysis***
- ***Complete Computational Analysis of stents incorporating all factors of structural mechanics and fluid dynamics***
- ***Experimental analysis of various designs and fluid dynamics***

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THANK YOU


Questions, Questions..