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BRS Mechanical Properties: From Bench to Bedsides

April 26 9:40-9:50 AM

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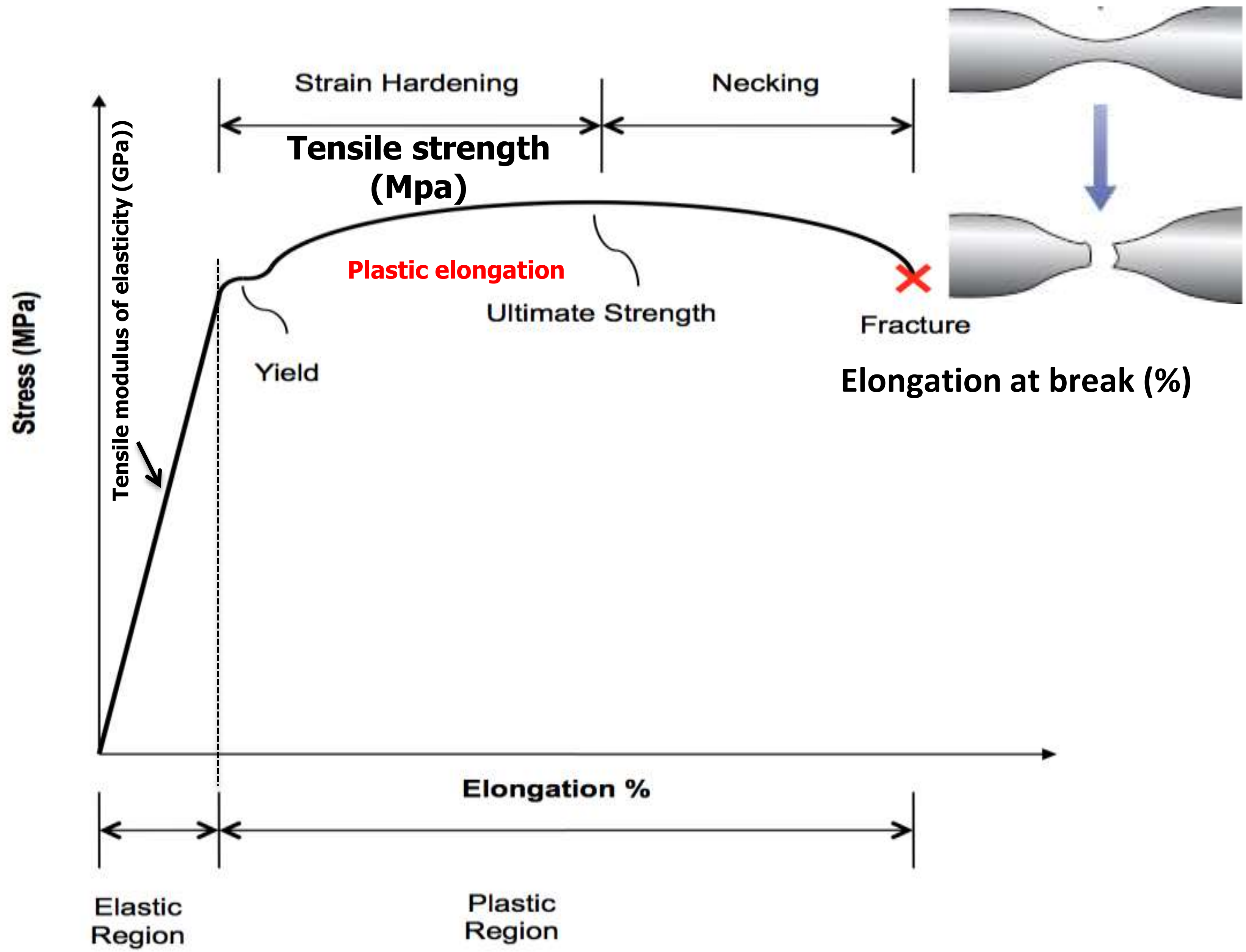
Current limitation of BRS

If a bioresorbable scaffold is ultimately expected to have the same range of applicability as a durable metal stent, the gap in mechanical properties must be reduced.

Currently, three primary limitations exist:

- **Low tensile strength and stiffness which require thick struts to prevent acute recoil**
- **Insufficient ductility which impacts scaffold retention on balloon catheter and limits the range of scaffold expansion during deployment**
- **Instability of mechanical properties during vessel remodeling if bioresorption is too fast**

Let’s take a “crash course” of material science



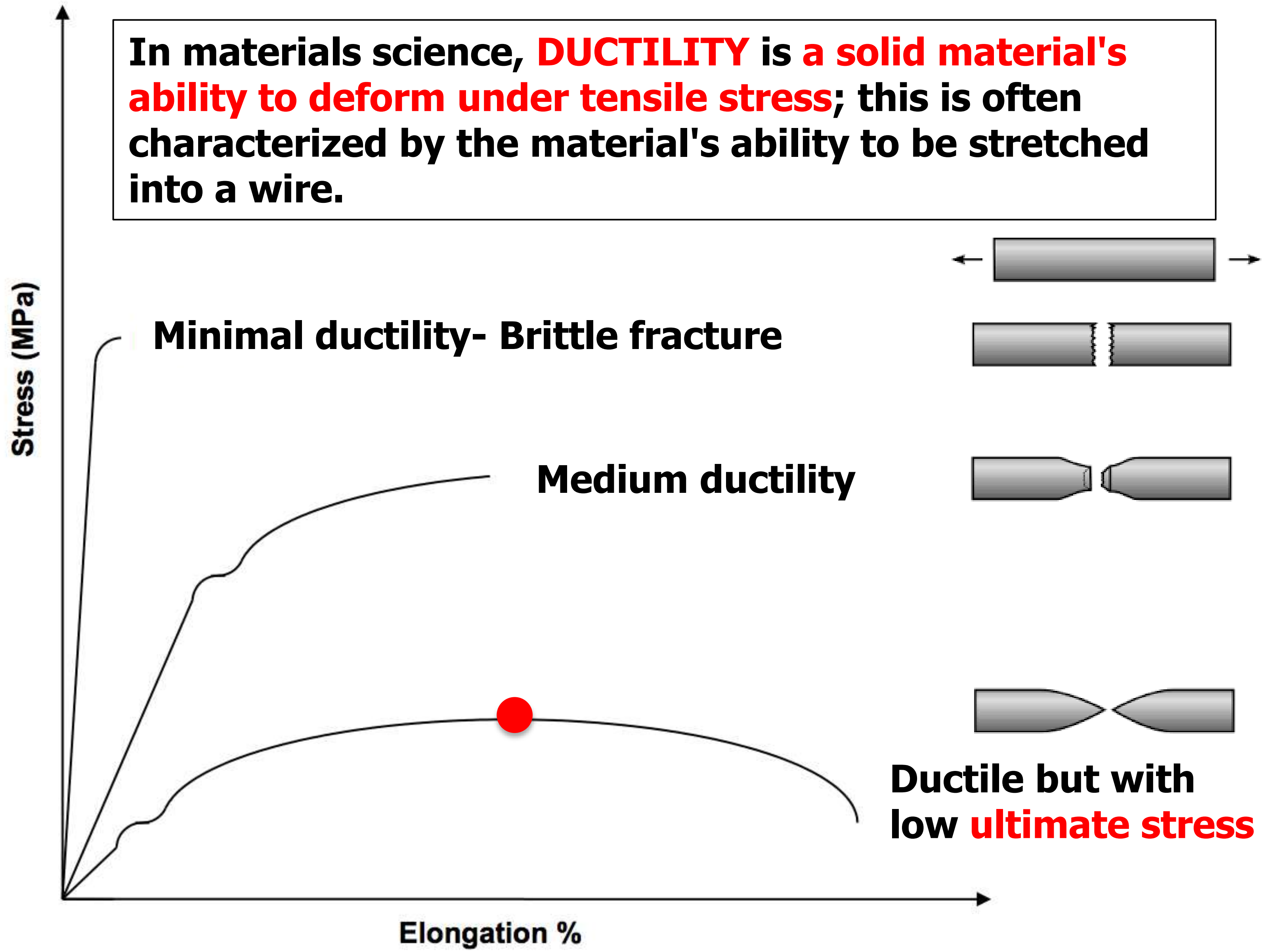
Mechanical properties of metal vs. PLLA

Polymer/ metal	Tensile modulus of elasticity (Gpa)	Tensile strength (Mpa)	Elongation at break (%)
Poly(L-lactide)	3.1-3.7	60-70	2-6
Poly (DL-lactide)	3.1-3.7	45-55	2-6
Cobalt chromium	210-235	1449	~40
Magnesium alloy	40-45	220-330	2-20

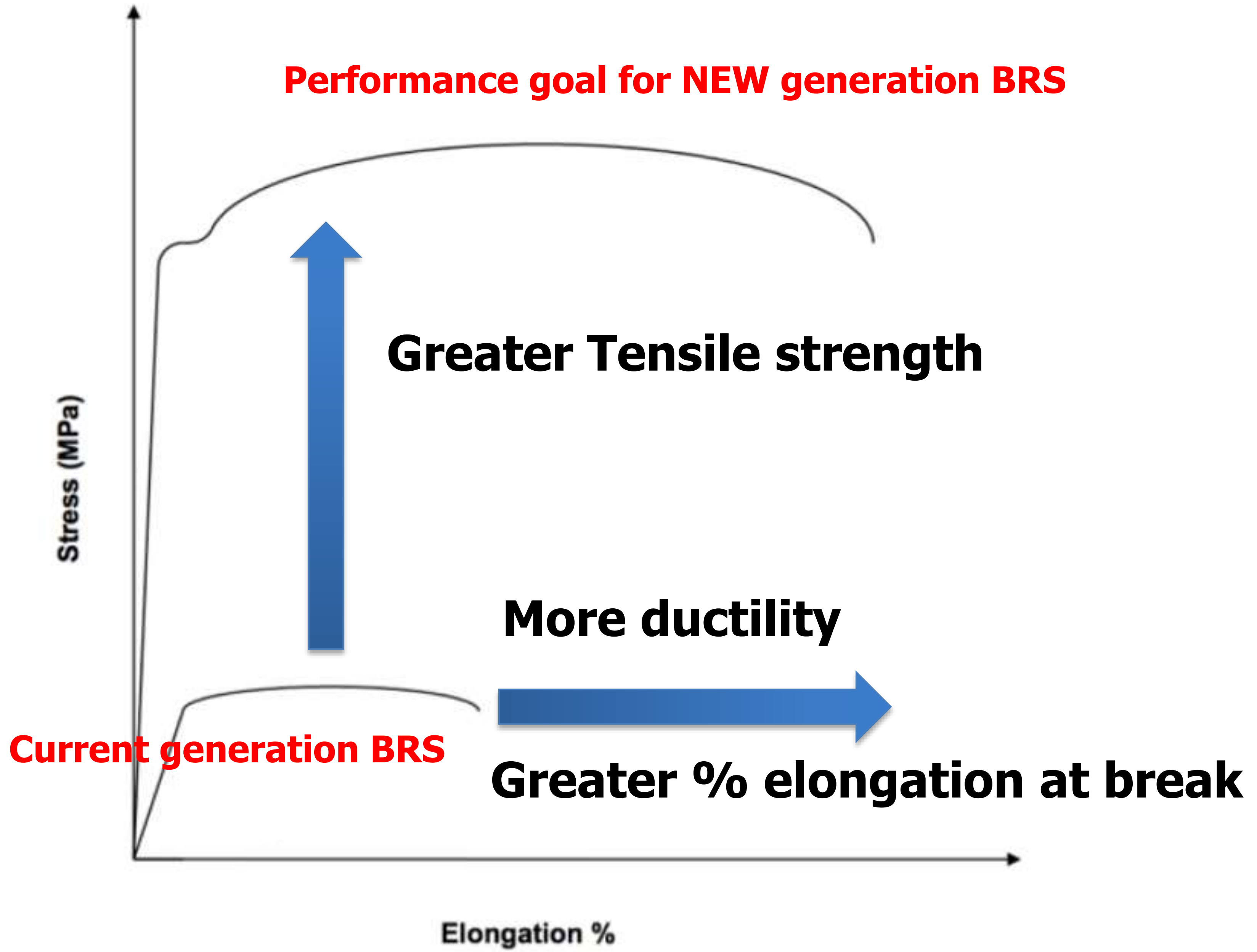
Onuma, Serruys Circulation 2011

Insufficient ductility impacts scaffold retention on balloon catheter and limits the range of scaffold expansion during deployment

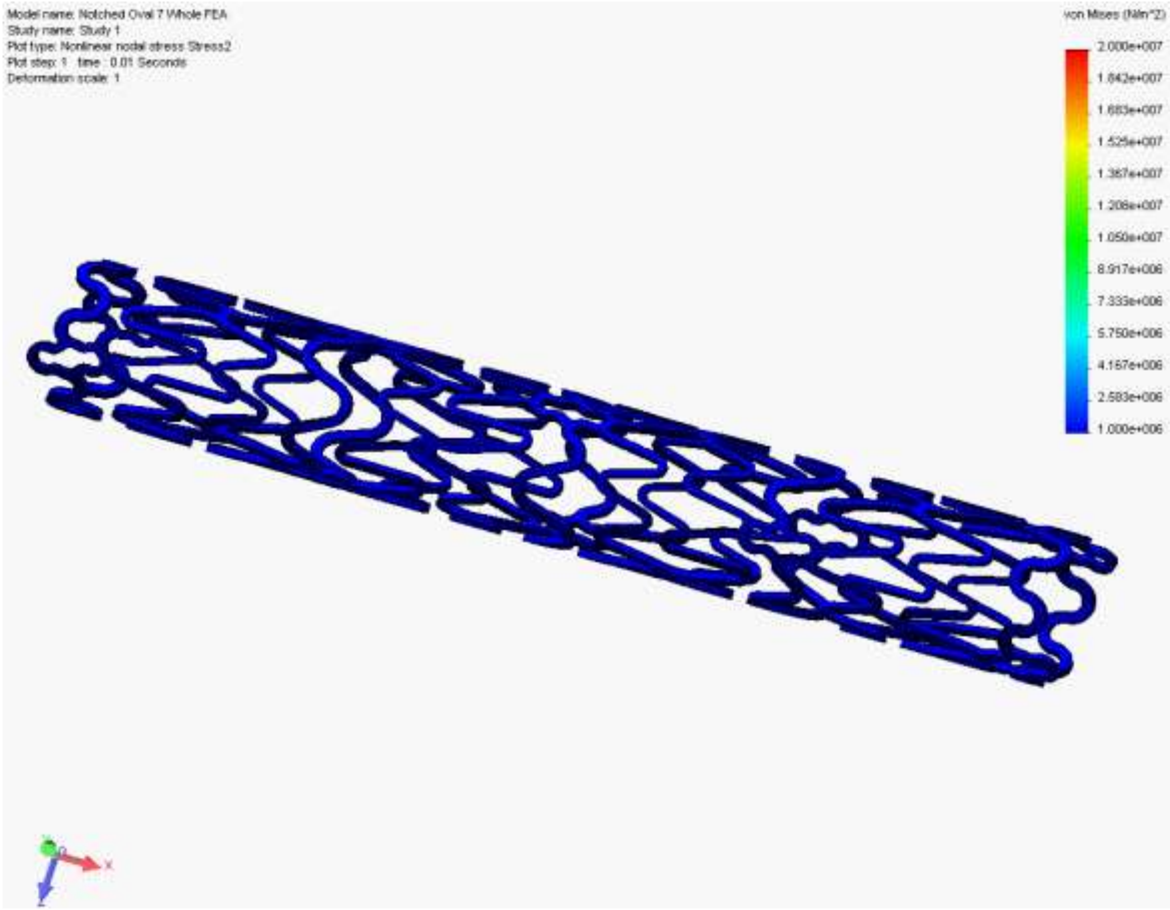
In materials science, DUCTILITY is a solid material's ability to deform under tensile stress; this is often characterized by the material's ability to be stretched into a wire.



Performance goal and mechanical dilemma



From a single wire to a coronary scaffold/stent
Strain of scaffold during crimping and implantation



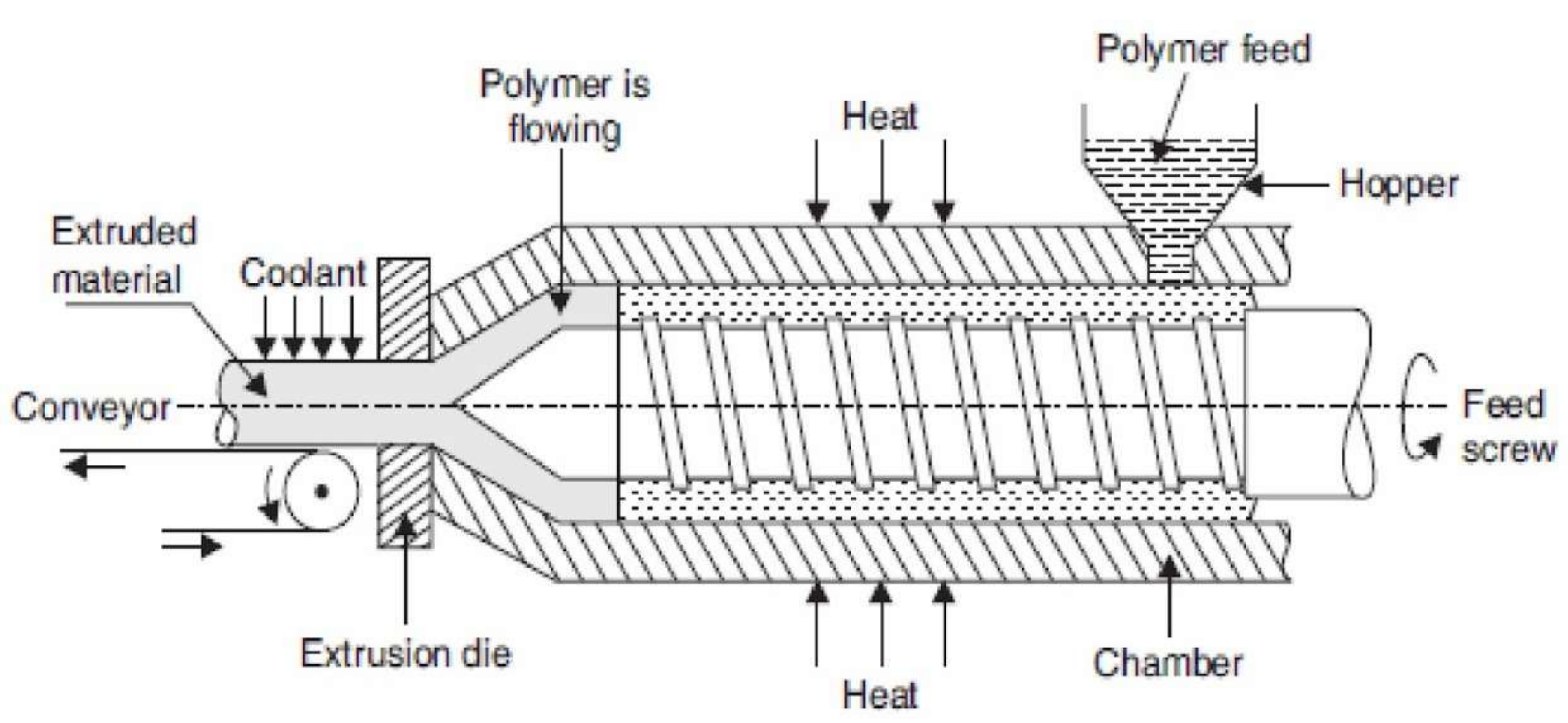
Processing methods of PLLA

	Processing method	Materials form
Zeus Inc	Extrusion tubing	PLLA
Arterius	Solid orientation by die-drawing of extruded tubing	PLLA
Abbott Vascular	Blow-moulding of extruded tubing	PLLA
Elixir	Spraying PLLAD dissolved in a solvent onto a mandrel to form a tube. The tube has to be subjected to **annealing** process up to 72 hrs. The device might also require **heat annealing**	PLLA (dissolved in an organic solvent)
ART	**Annealing** of the scaffold made from a tube	PLLA (specifically synthesised)

Annealing is a heating of a polymeric part to below it's glass transition temperature in order to relieve the internal stresses introduced into the part during its fabrication (molding, cooling after molding, machining, welding)

Extrusion

Extrusion

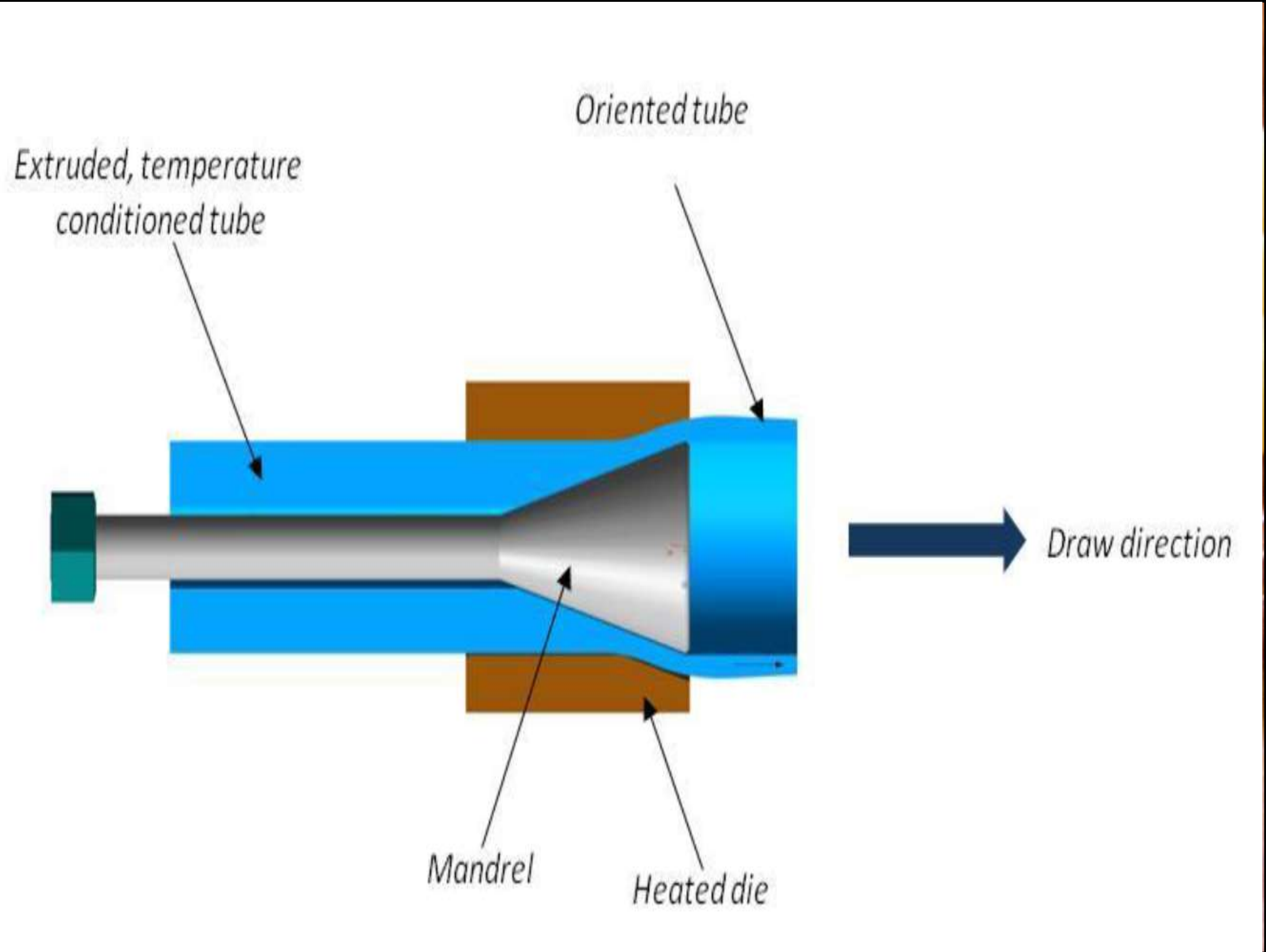


- **Melt polymer resin and shape it into a tubular geometry.**
- **Select a screw based upon the material of interest.**
- **Select process conditions leading to:**

  Predictable and acceptable decrease in polymer molecular weight.

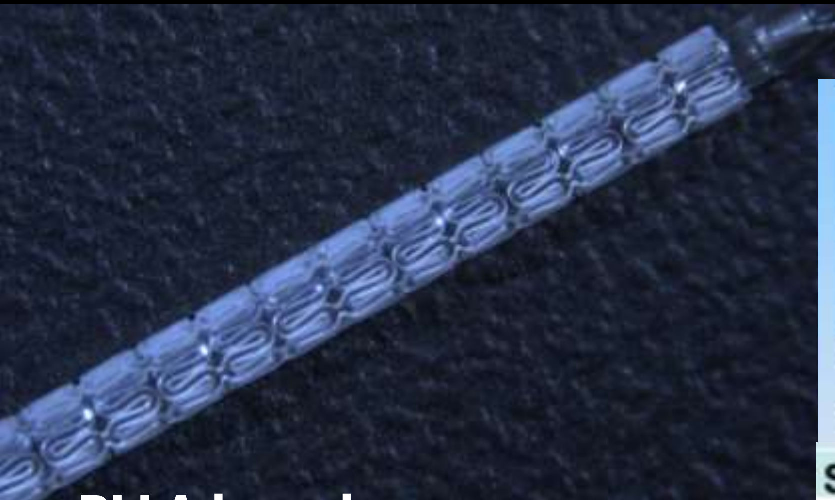
  High concentricity and tight dimensional control.

Extrusion

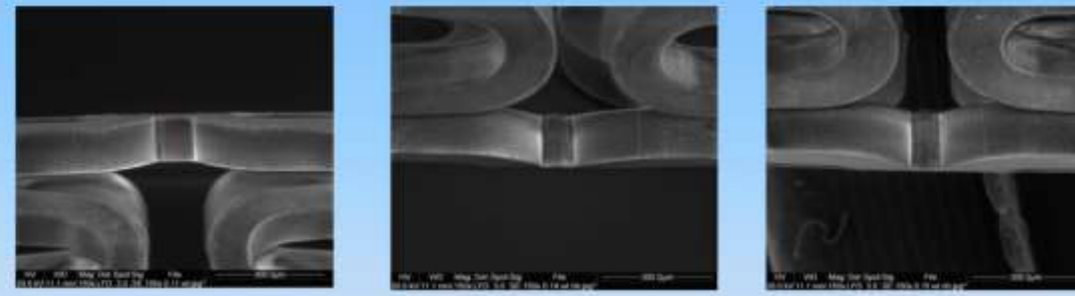


Oriented tube
Extruded, temperature conditioned tube
Draw direction
Mandrel
Heated die

ARTERIUS: ArterioSorb scaffold

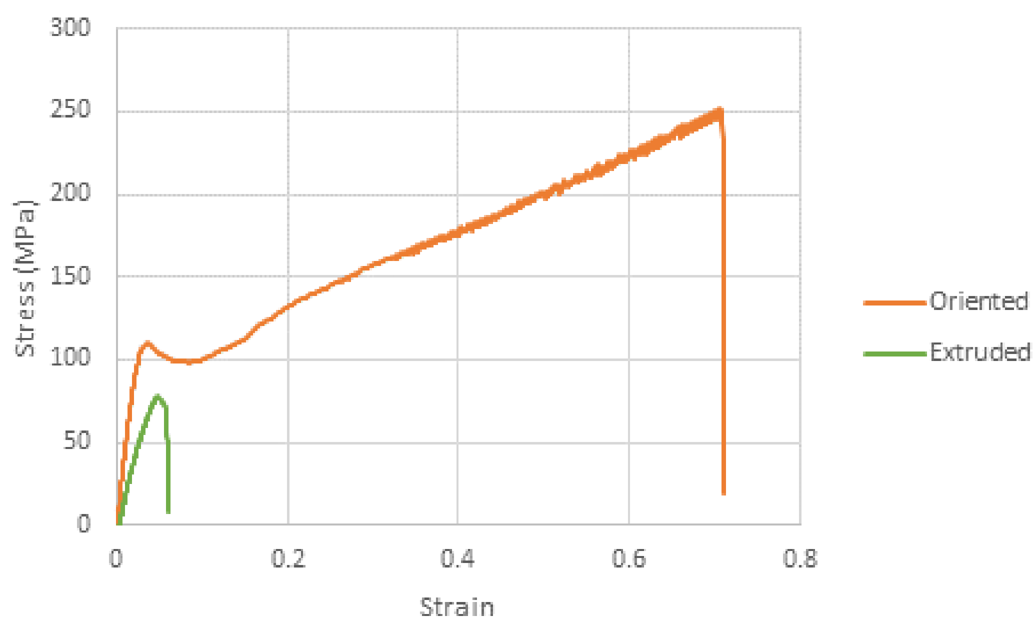


- **PLLA based**
- **Melt processing (EXTRUSION) and DIE-DRAWING (solid phase orientation)**
- **Solid-Phase Oriented tube with very high mechanical properties**
- **Thinner strut (≤ 150μm wall thickness, including 140μm and 110μm) to be manufactured with enhanced physical performance similar to that of metal alloy stents.**



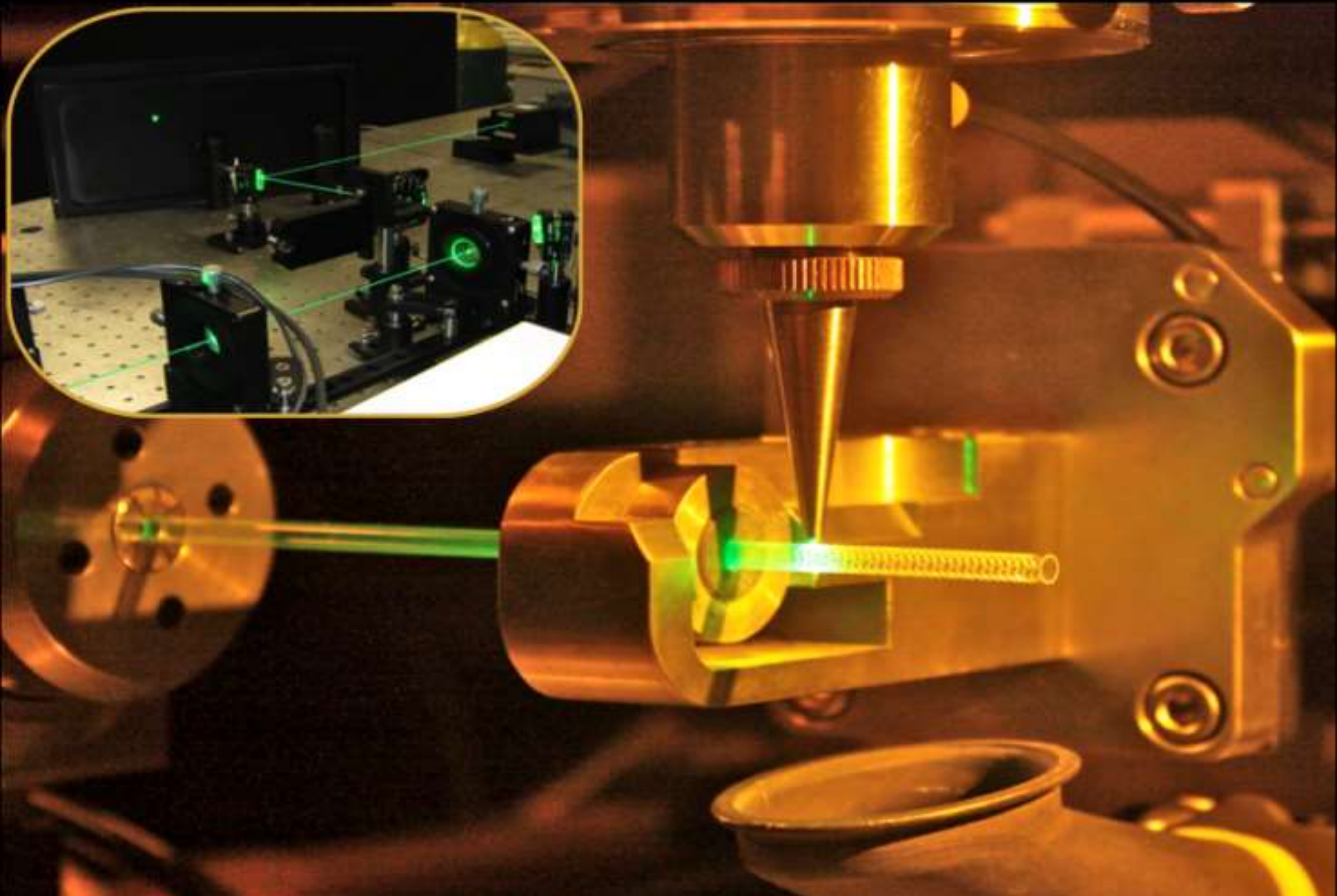
(a) Wall thickness = 110micron (b) Wall thickness = 140micron (c) Wall thickness = 150micron

Strut wall thickness (micron)	Target size (mm)
110	2.5 - 3.00
140	3.00 – 3.50
150	3.5 – 4.00

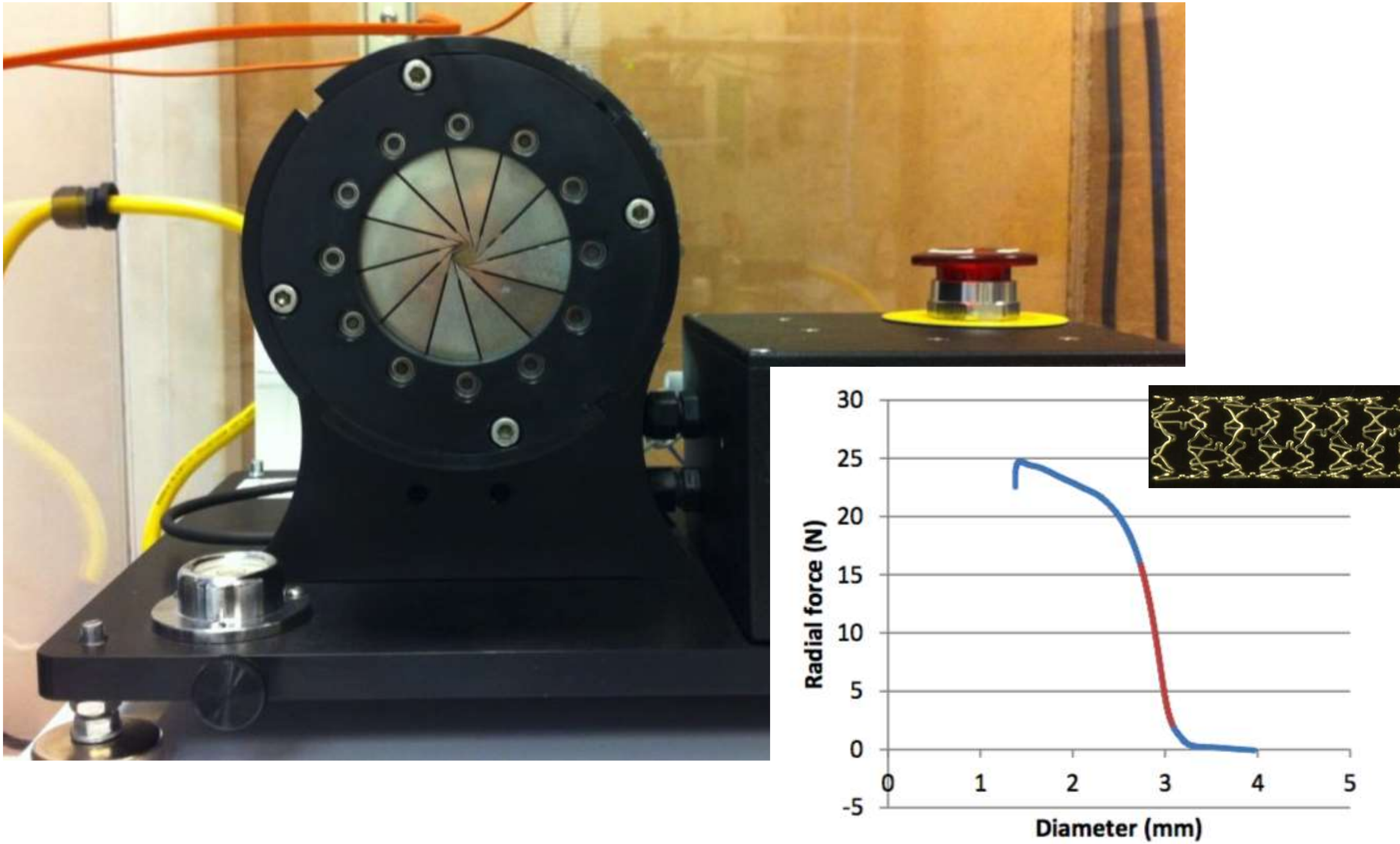


Extrusion

Cutting

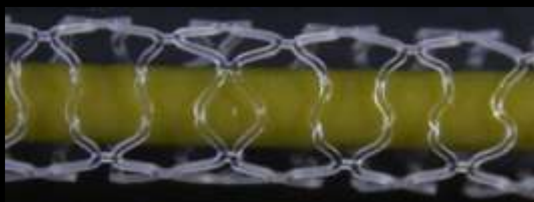


Crush resistance test



Impact of platform and polymer on radial force compared to metallic stents

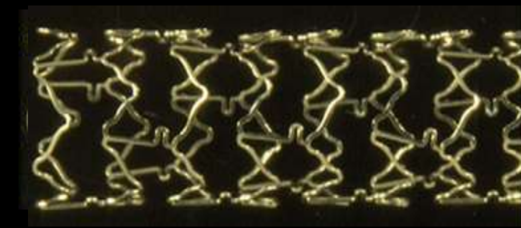
Platform 1

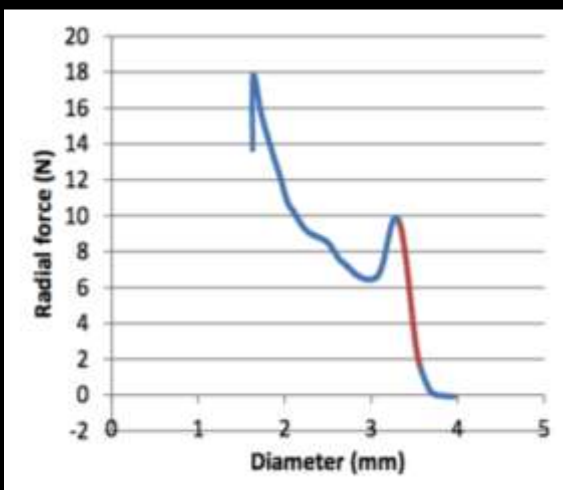


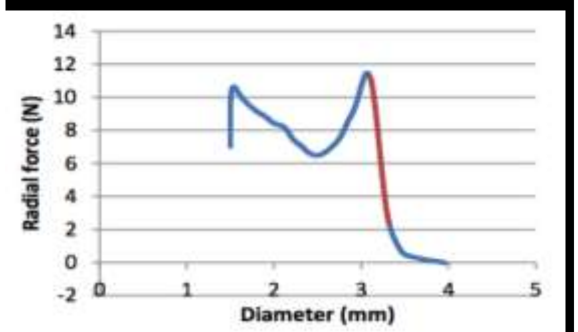
Platform 2

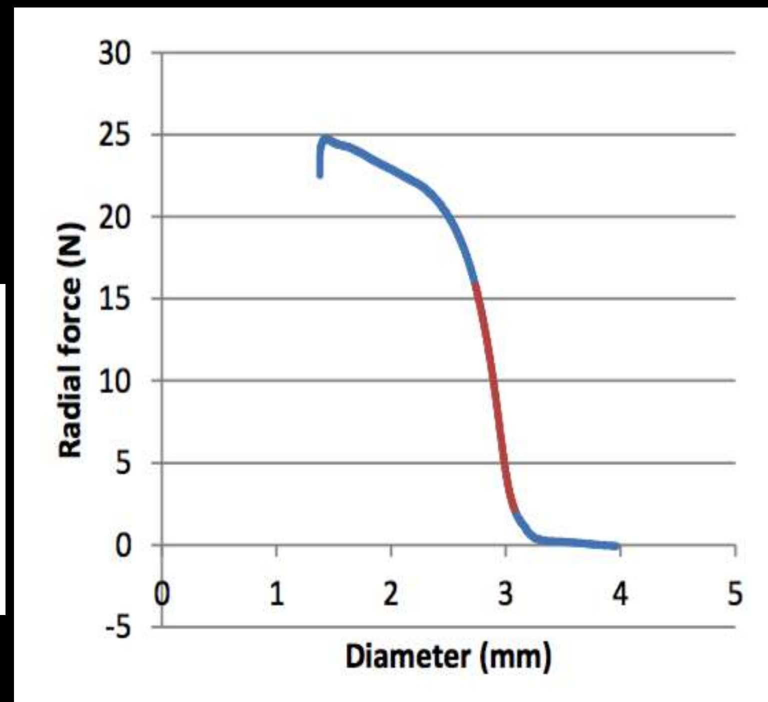
Same polymer

Metallic stent









Radial force at inflexion point

9.5 N **11.2 N** **15.8 N**

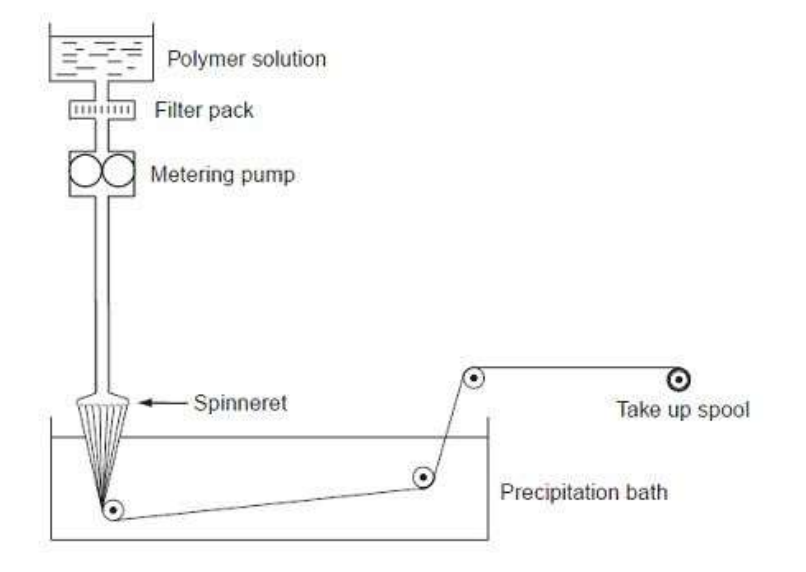
Spinning

- **Solution spinning vs. Melt spinning**

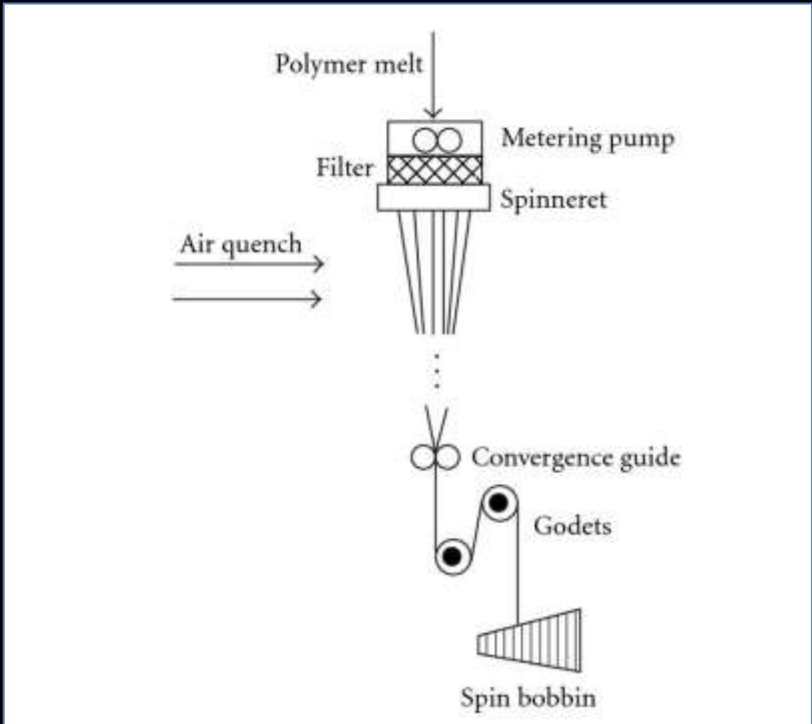
- **In solution spinning, the polymer is dissolved in a solvent whereas in melt spinning the material is melted to form the liquid prior to fiber formation.**

- **Fibers prepared by solution spinning are generally superior to melt spun fibers with respect to mechanical properties** (higher drawability, less thermal degradation, less mechanical degradation, and less hydrolytic degradation)

Solution spinning



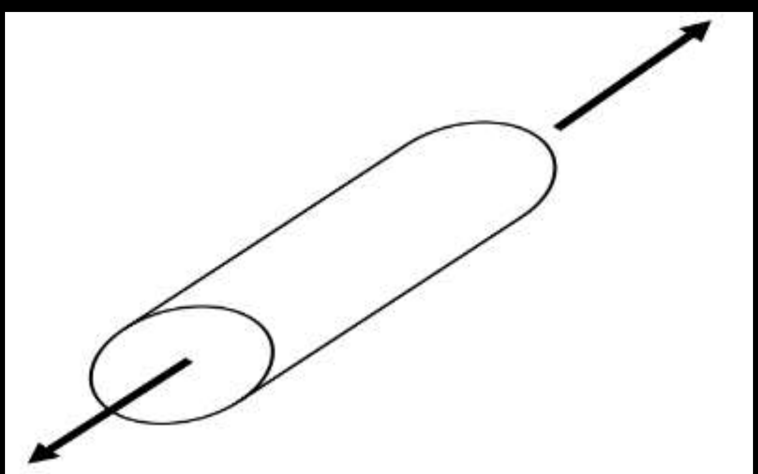
Melt spinning



Stretching/Spinning/MicroBraiding

- Stretching the fibers extends the molecular chains to increase the strength of the fibers from 70 to 620 Mpa (reference: strength of stainless steel 316L = 500MPa)

- A bioresorbable scaffold comprised of fibers is strengthened by stretching or drawing the fibers.



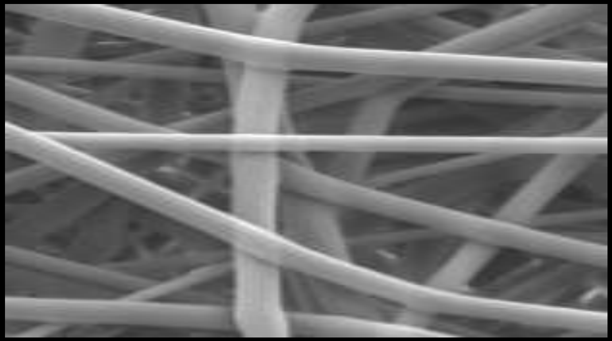
Example PLLA	As-polymerized Material [1]	Fiber
Tensile Strength*	60-70 MPa	<2.3 GPa[2]- Solution <0.6 GPa[2]- Melt
Elongation to break*	2-6%	<25%[3]
Modulus*	3.1-3.7 MPa	4-10 GPa[2]

Forming Interconnected fibrous network

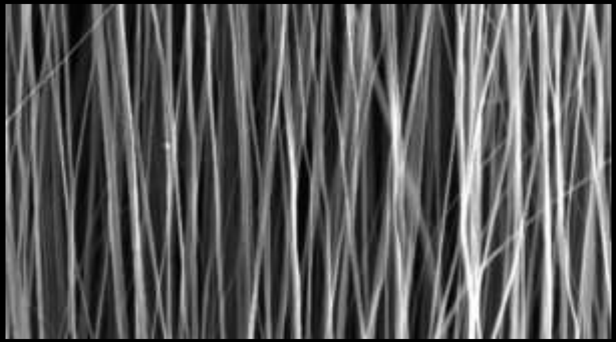
Fiber by itself is useless.

Forming an interconnected fibrous network is critical:

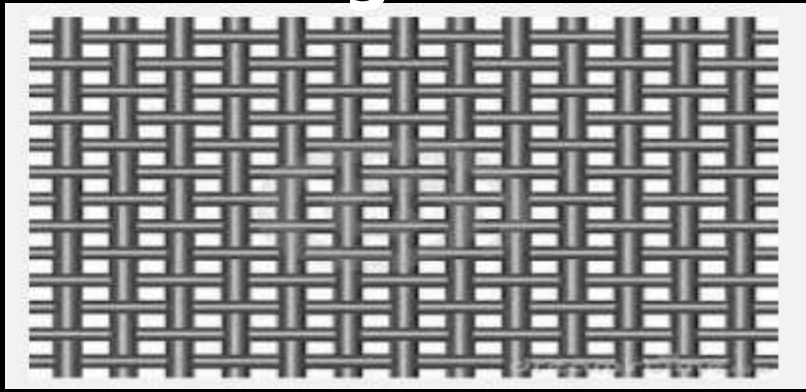
- **Fiber-to-fiber junctions**
- **Fiber alignment**
- **Consolidation vs. porosity**
- **Polymer morphology**



Random



Aligned

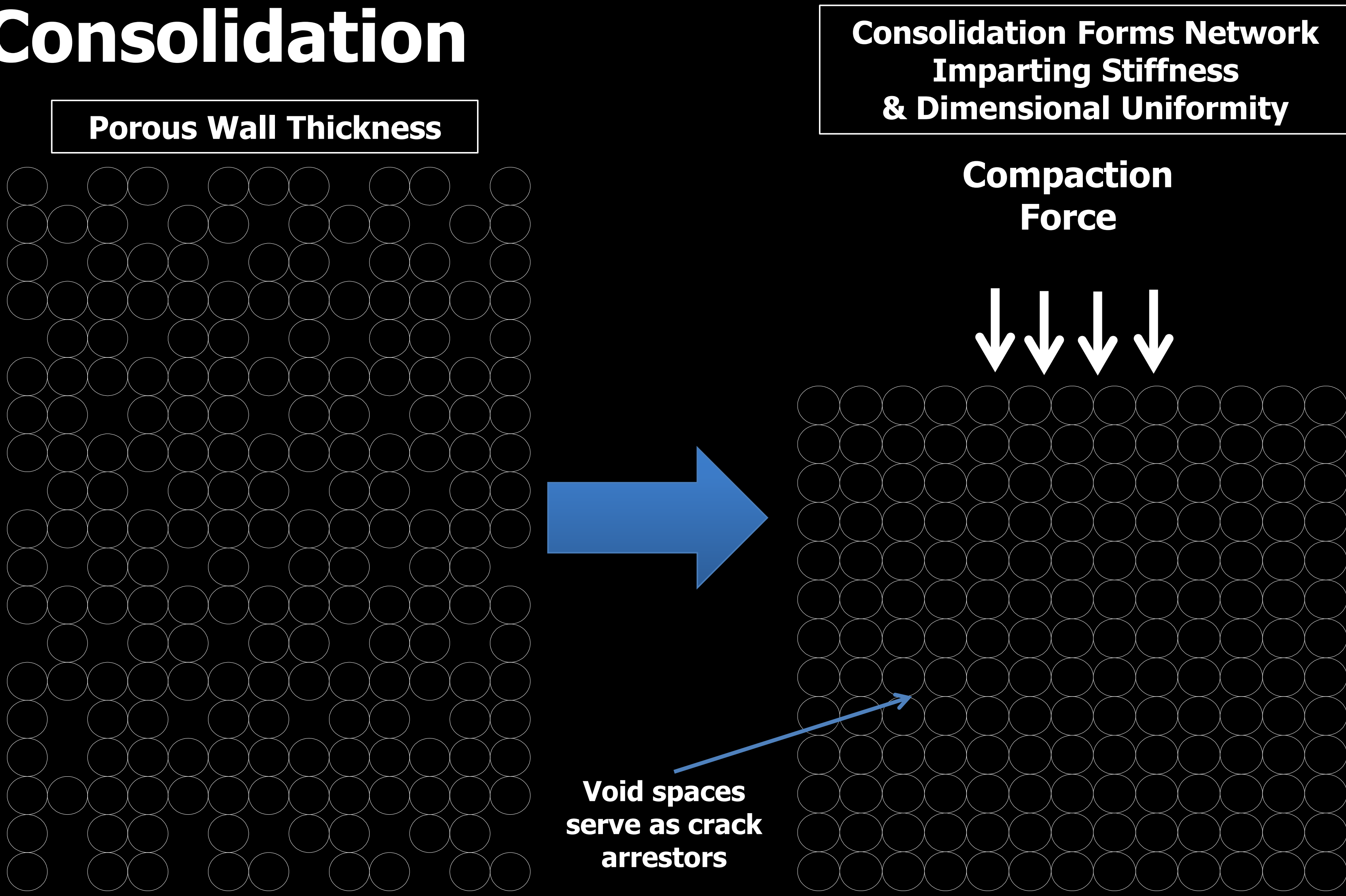


Woven

In collaboration with Jack Scanlon (Heartlon)

Forming Interconnected fibrous network

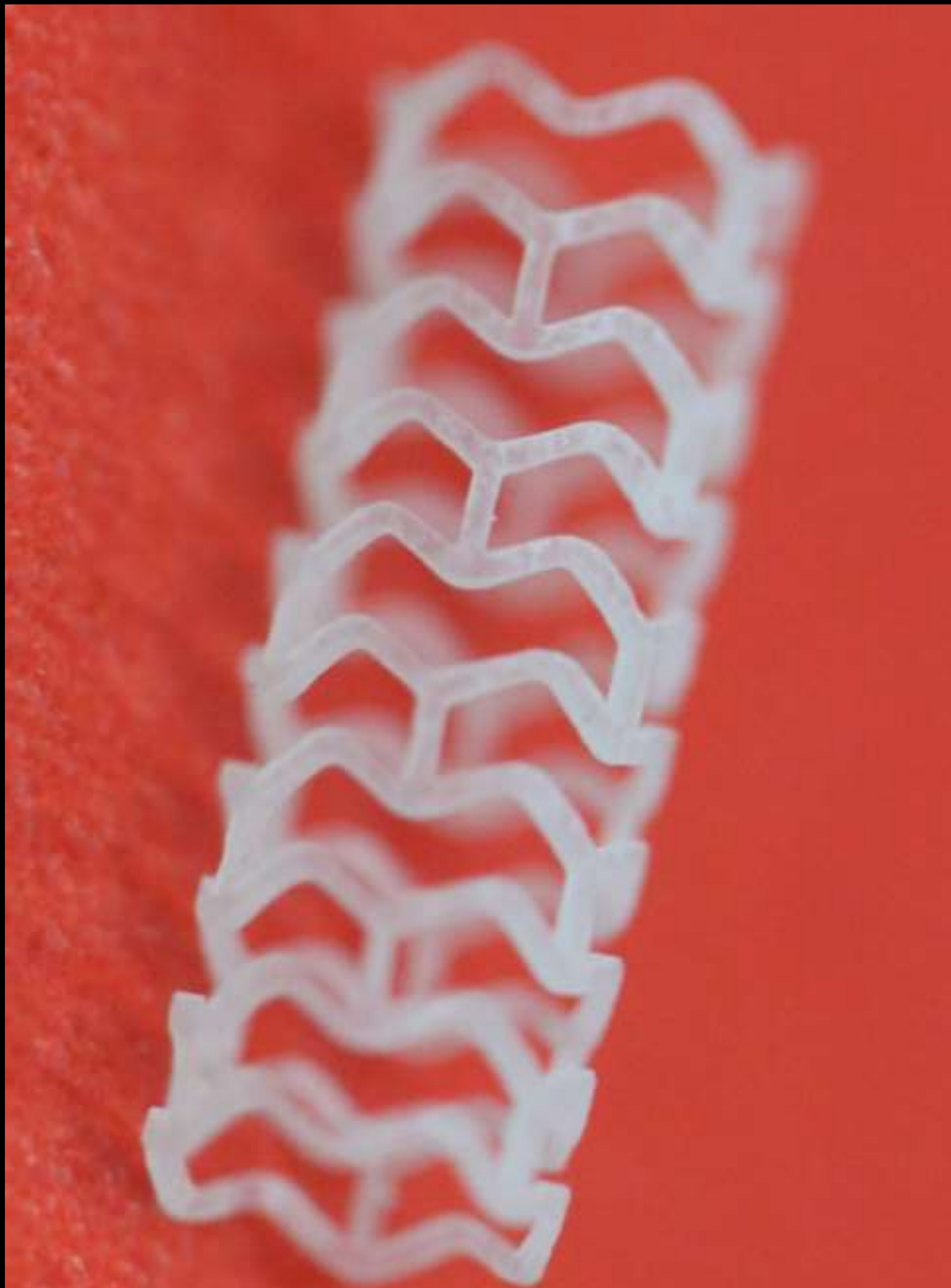
Consolidation

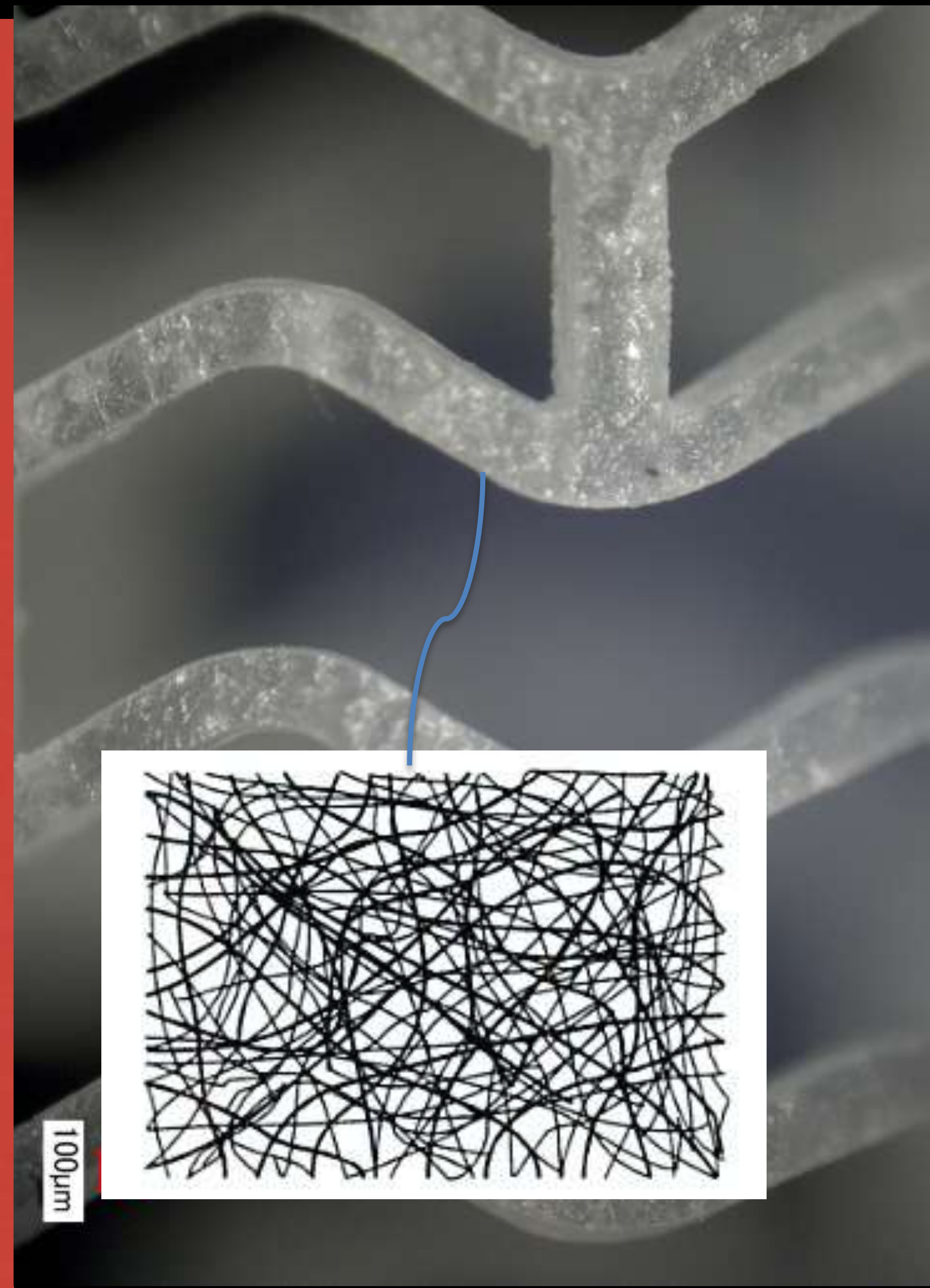


In collaboration with Jack Scanlon (Heartlon)

Microbraiding

In collaboration with Jack Scanlon (Hartlon)





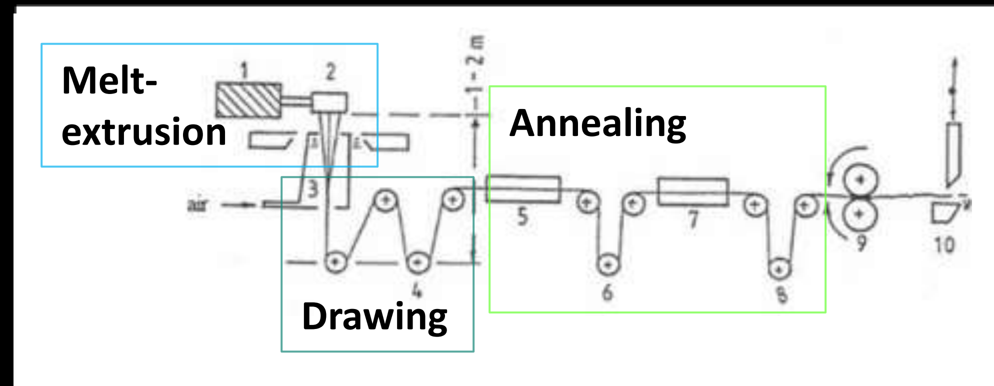
Manli Cardiology's Microfiber Technology

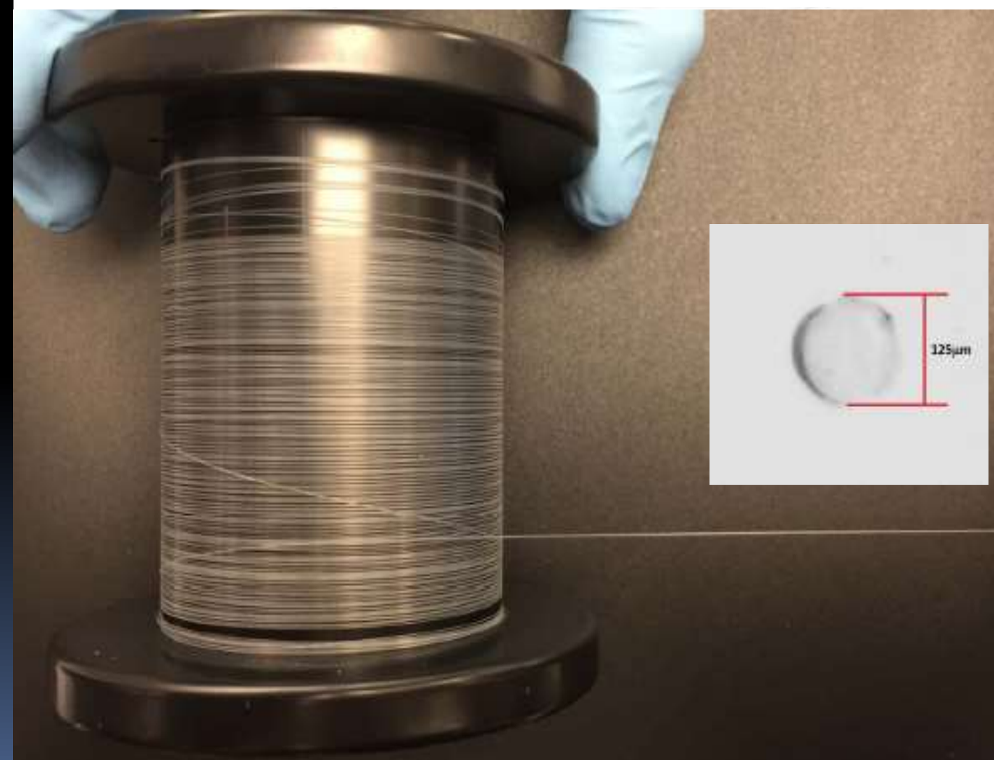
1. **Highly oriented polylactide constituting a circular monofilament with preferred directional mechanical properties.**

2. **Convert monofilament's directional mechanical properties into scaffold's radial mechanical properties.**

3. **Transform circular monofilament into a scaffold with circular strut geometry.**

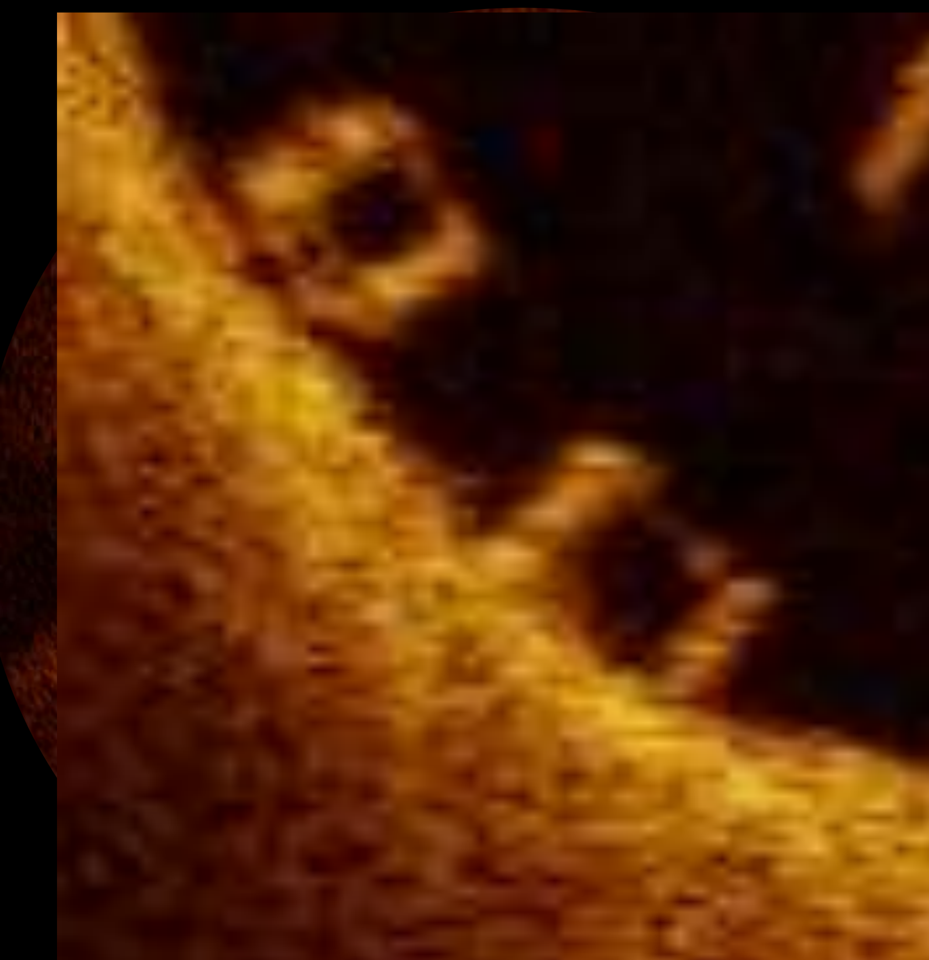
Amorphous Polymer   Oriented Polymer Chain



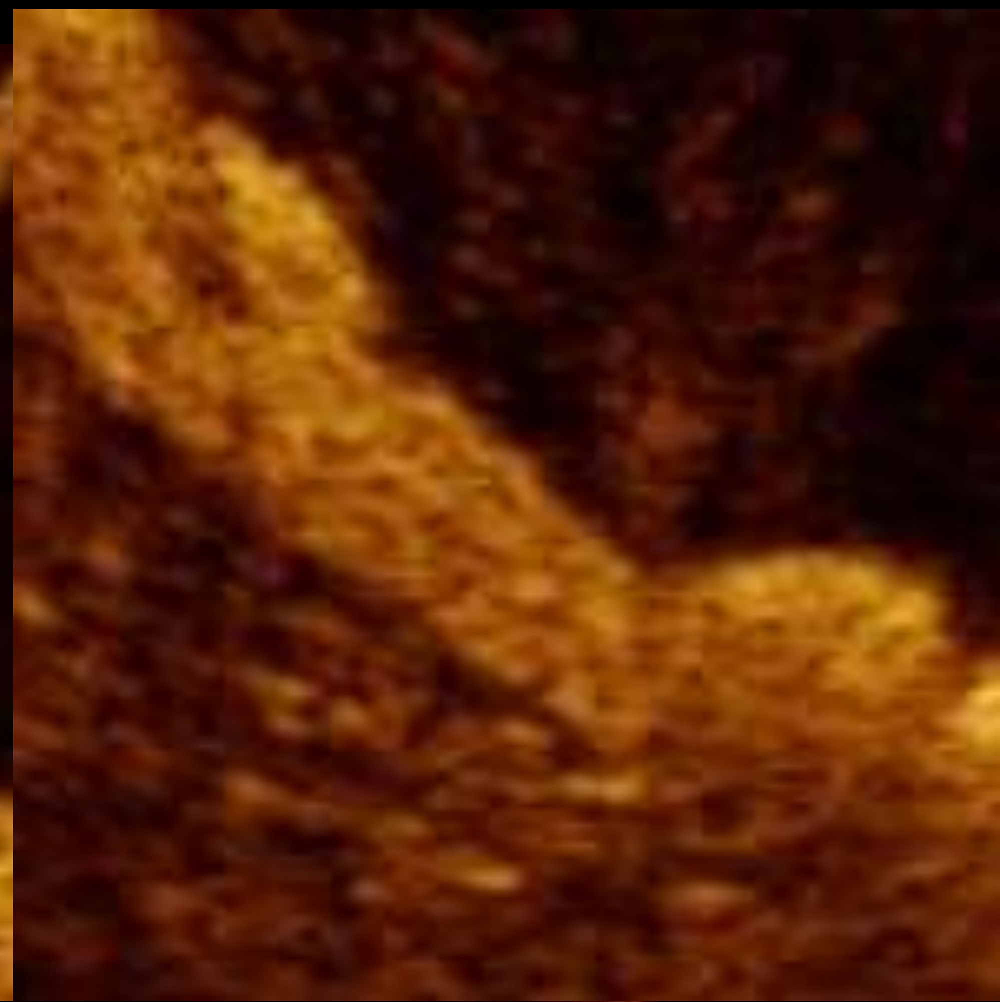


From the rectangular shape of the struts into the ovoid shape

Absorb

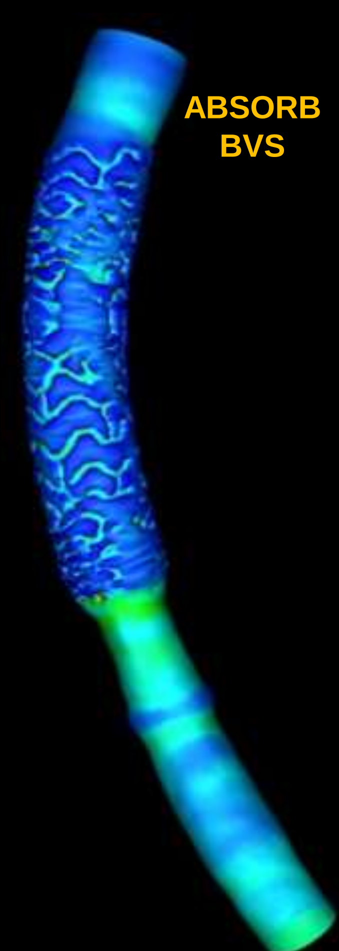


Mirage

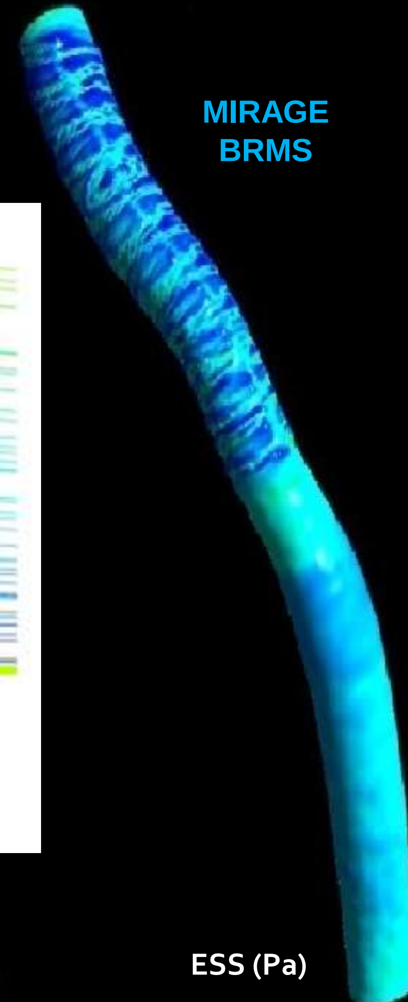


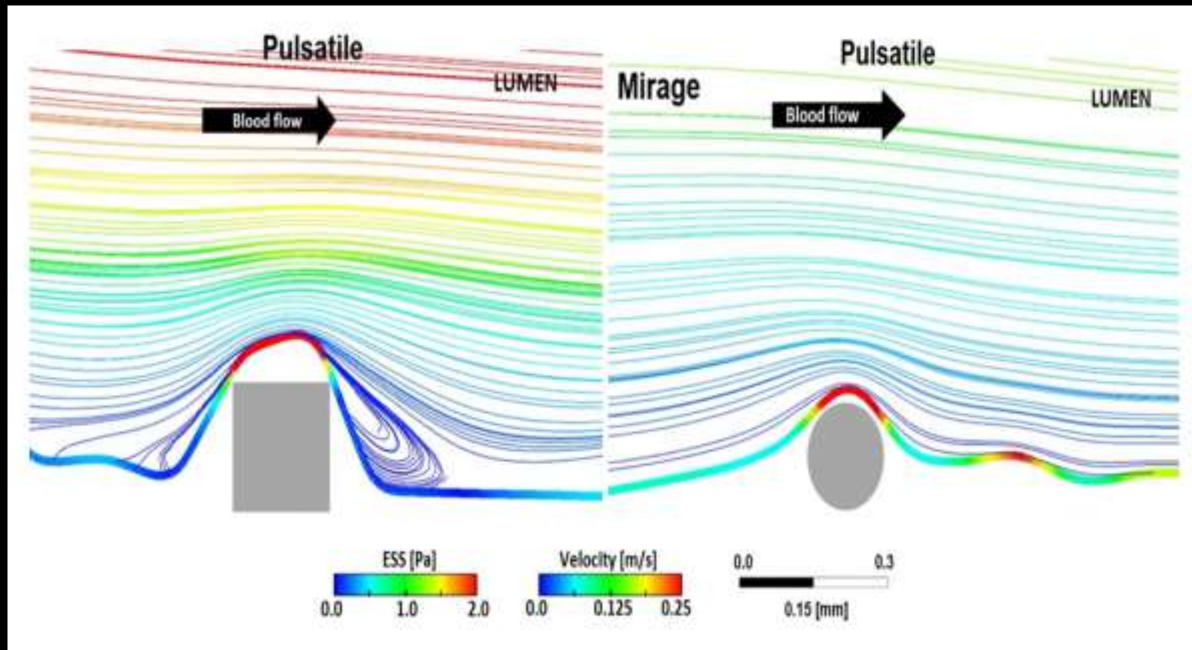
Shear stress and flow analysis in ABSORB and MIRAGE

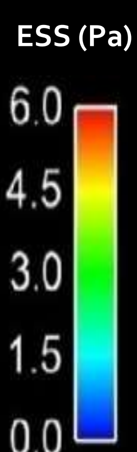
ABSORB BVS

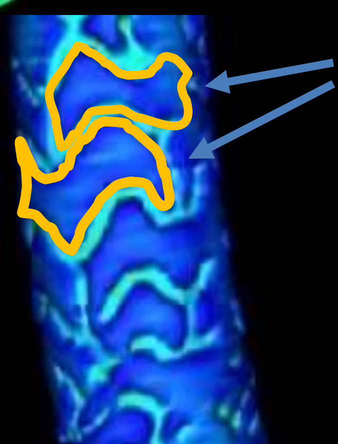


MIRAGE BRMS

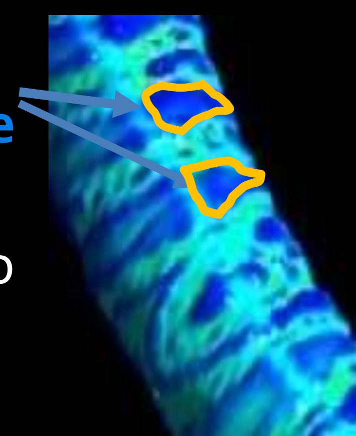




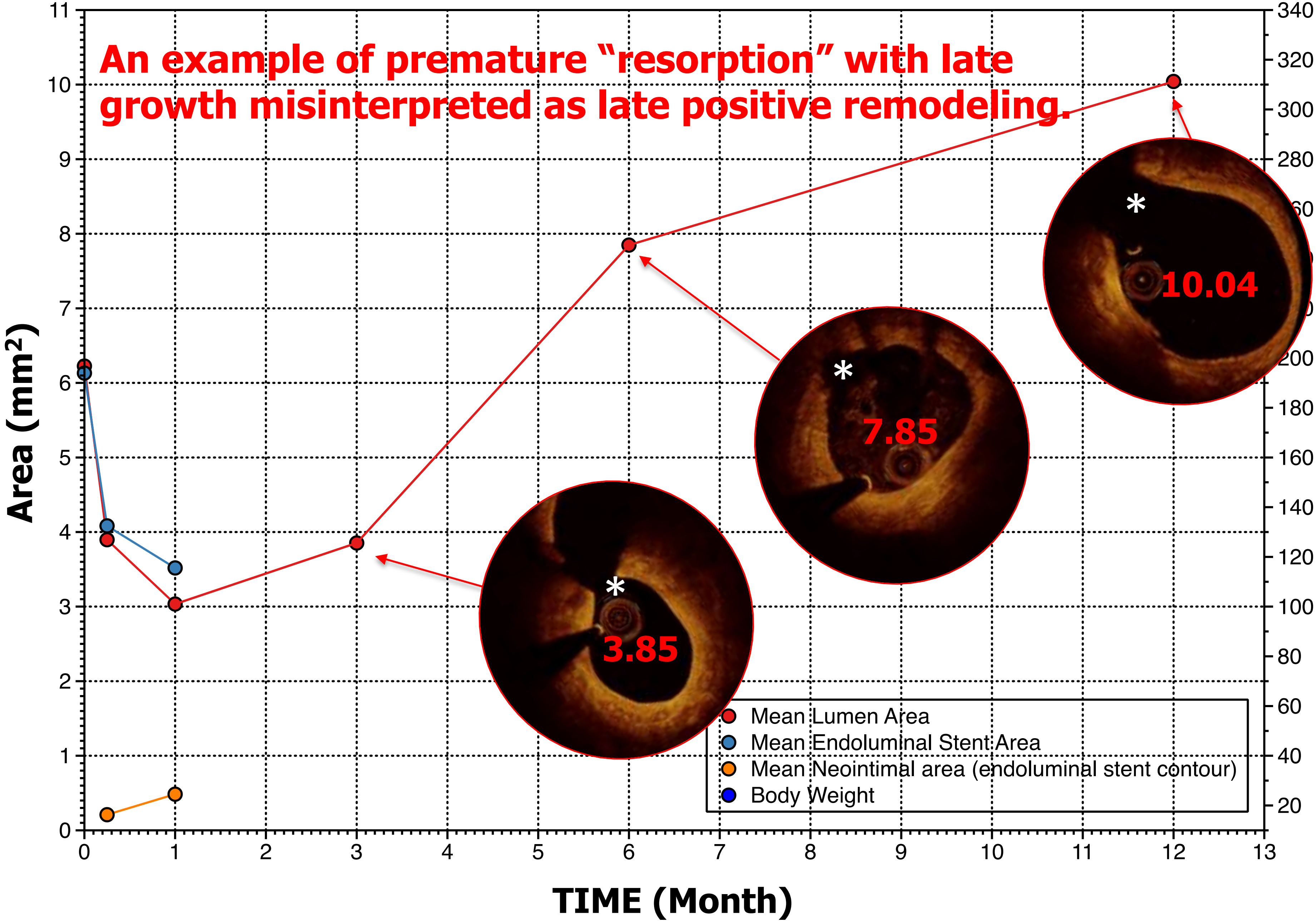




The lower ESS (**dark blue area**) had a wider distribution in the Absorb BVS compared to the Mirage BRMS



Pre-clinical study has to respect some basic rules…



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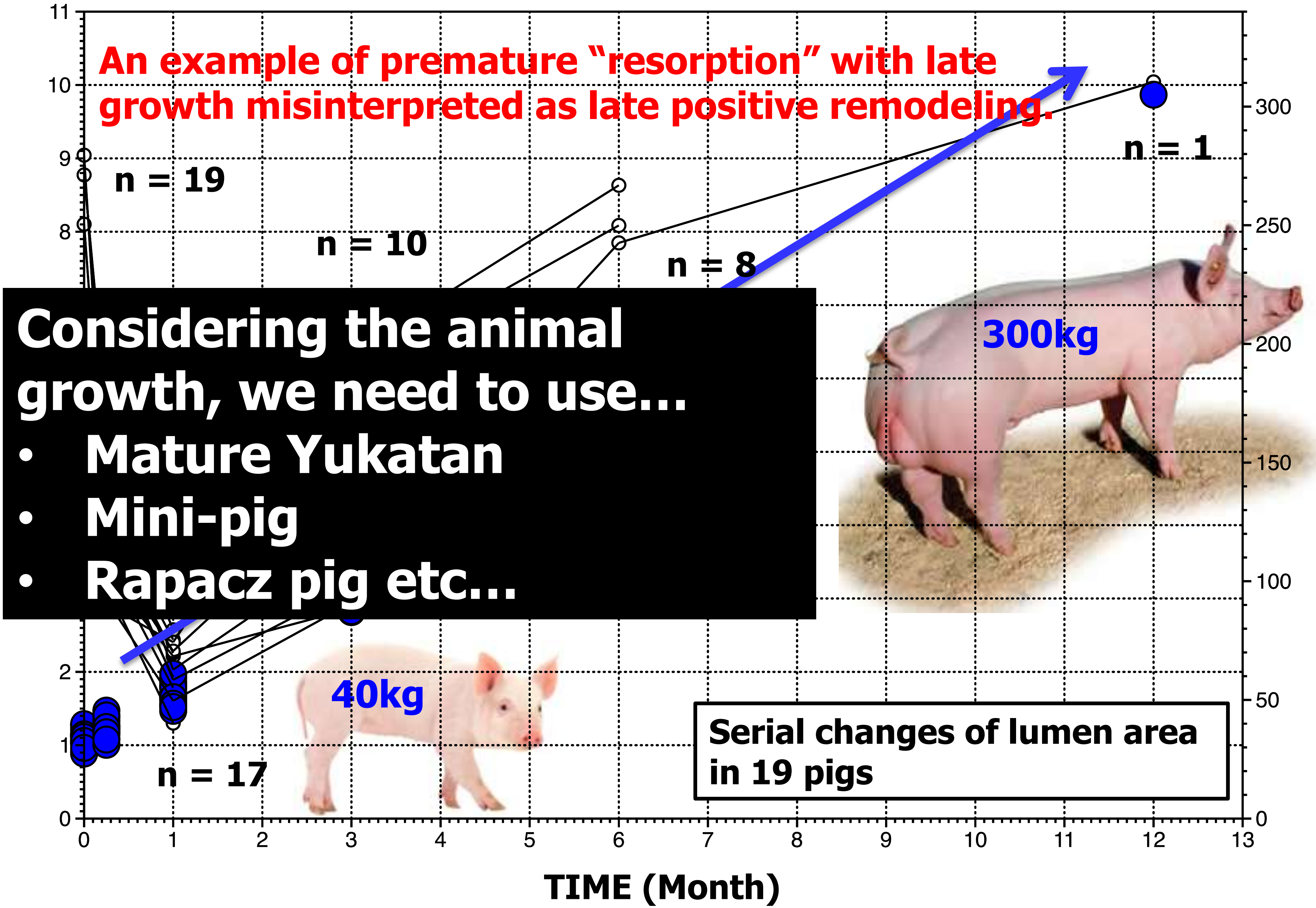

Conclusions

Future struts of BRS are to be:

- **Stronger and ductile**
- **Thinner and round**
- **Potentially quickly resorbable but without inducing inflammatory reaction**

… Yes, we can!

Thank You!

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EDITORIAL

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