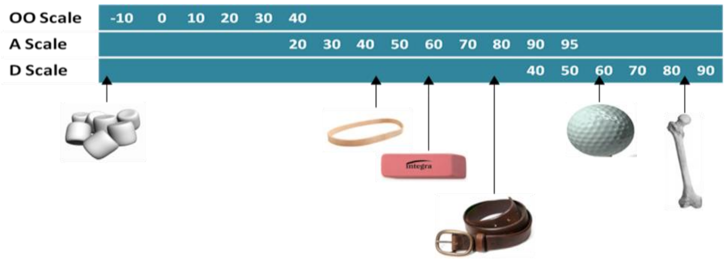
Polyimide Liners

For Cardiovascular Catheter Tubing

Percutaneous Transluminal Coronary Angioplasty (PTCA) is a technique used to dilate an area of arterial blockage with the help of a catheter that has an inflatable small balloon at its tip. Inflation is initially carried out at a pressure of 1 to 2 times that of the atmosphere and then sequential and gradually increased to 8 - 12 (118 – 176 psi) and sometimes as high as 20 atmospheres (294 psi), depending upon the type of balloon and/or stent that is used.[1]

The success of these minimally invasive procedures has accelerated the use of balloons and stents in a wide range of interventional radiology and cardiology applications. These new procedures often require reduced diameter tubes for smaller vascular openings, thinner tube walls to allow for larger lumen openings, and higher pressures for balloon and stent delivery. All of these place greater demands on the mechanical performance of the polymers used for construction. When designing these new devices, three important mechanical properties are important to consider: hardness, flexural modulus and tensile strength.

Hardness

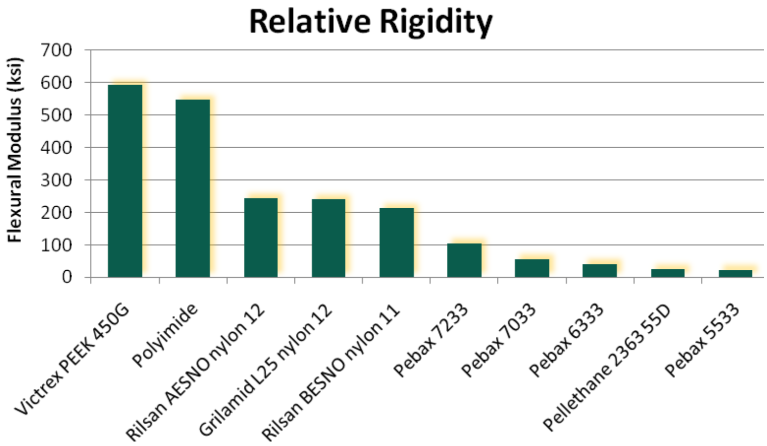


Hardness is perhaps the most common physical property used to define catheter materials. The common measure of hardness for polymers used in medical catheters is the Shore scale. Shore A is used to define softer polymers and D is used to define harder polymers.

Hardness, or more appropriately the inverse term softness, is an appropriate property for a material that must navigate vascular passageways without damaging tissue. Hardness is often used as a proxy to define the flexibility of the polymer. This characteristic is more accurately defined by flexural modulus.

Flexural Modulus

Flexural modulus is the measure of a material's bending stress relative to elongation under load. It provides a relative measure of a material's stiffness for a given test specimen. Mathematical relationships suggest the use of Shore hardness as a proxy for flexural modulus is reasonable (see sidebar) although actual studies indicate these formulas are not exact predictors in all materials. However, in general the higher the hardness value the stiffer the material.



Rigidity of a polymer tube, which is ultimately the property of concern in catheter design, is determined by the inherent stiffness of the material (modulus) and the cross sectional design of the catheter (defined by the moment of inertia of the cross section).

While the inherent non-linearity of polymers limits the use of standard rigidity equations as precise predictors, the relationship between radius and rigidity is important for catheter design. Changing the dimensions of the cross section of a tube can have a profound impact on rigidity (see sidebar where the radius is raised to the fourth power in the equation). For example, a smaller diameter with thinner walls is much less rigid than one of larger diameter and thicker walls.

Modulus = $\dfrac{0.098\,(56 + 7.66S_D)}{0.138\,(254 - 2.54S_D)}$

Where S_D = Shore D hardness

Tube Rigidity = $E*\pi/4*(r_o^4 - r_i^4)$

Where E = Modulus
r_o = outside radius
r_i = inside radius

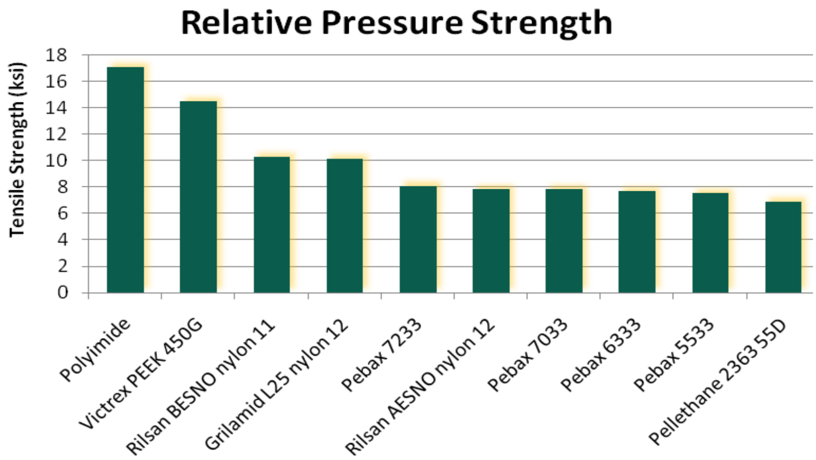
Burst Pressure = $\dfrac{2St(D_o - t)}{D_o^2 - 2D_o*t + 2t^2}$

Where S = tensile strength
D_o = outside diameter
t = wall thickness

Tensile Strength

When working with balloon and stent devices, the tube design and material of construction must be sufficient to resist burst pressure within a margin of safety. Simple equations have been developed to predict burst pressure (see sidebar - Lamé's equation); yet non-linear properties of polymers require use of finite element analysis for a more accurate prediction of performance.

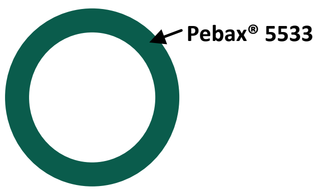
It is important to note in standard equations the direct relationship between burst pressure and tensile strength. Thus, for a catheter tube of a given cross section the relative burst pressure performance can be assessed by tensile strength of various materials. Materials such as Polyimide and PEEK have the highest burst pressure performance of materials commonly used in vascular catheters.



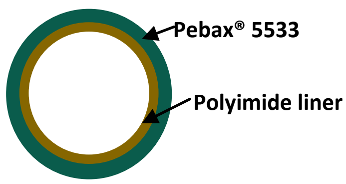
Polyimide Lined Catheters

Due to its high tensile properties, polyimide is an ideal material for catheter tubing that must resist high pressure. However, its high modulus suggests potential limitations for catheters that require flexibility. This potential limitation can be offset by using polyimide as an inner liner within a catheter whose outer liner is a softer, more flexibly material. With the higher modulus material closer to the center of the tube structure, the moment of inertia is greatly reduced resulting in reduced rigidity of the finished catheter tube.

Traditional Single Material Construction



Alternative High Pressure Liner



Due to the unique manufacturing process used to produce thermoset polyimide tubing, wall thickness can be very thin (as low as 0.0005 inches) and maintained with exceptional accuracy (+/- 0.0001 inches). Polyimide tubing must be pretreated on the outer surface to ensure a strong bond with the polymer extruded for the outer layer. The finished product is a catheter tube that has outstanding burst pressure resistance, good flexibility, and a soft outer surface when a low durometer is used as the outer layer.

Materials Commonly Used In Interventional Catheters

Polymer	Grades (Trade names)	Tensile Strength (psi)	Flexural Modulus (psi)	Shore Hardness
PEEK	450G (Victrex®)	14,500	595,000	87D
Polyimide	Putnam Plastics	17,100	548,000	87D
Nylon 11	BESNO (Rilsan®)	10,290	213,000	68D
Nylon 12	L25 (Grilamid®)	10,150	241,000	74D
	AESNO (Rilsan®)	7,832	245,000	70D
	LF2101F (Vestamid®)	6,525	203,000	74D
PEBA	7233 (Pebax®)	8,120	106,000	72D
	7033 (Pebax®)	7,830	56,600	69D
	6333 (Pebax®)	7,685	42,100	63D
	5533 (Pebax®)	7,540	23,200	55D
	4033 (Pebax®)	5,800	12,200	42D
	3533 (Pebax®)	5,650	3,630	33D
	2533 (Pebax®)	4,640	2,180	25D
TPU	EG 65D (Tecoflex®)	8,300	2,500	60D
	EG 72D (Tecoflex®)	8,100	3,400	67D
	EG 93A (Tecoflex®)	7,700	1,100	87A
	2363 55D (Pellethane®)	6,900	24,900	55D
	2363 65D (Pellethane®)	6,460	32,000	65D
	2363 75D (Pellethane®)	5,810	189,000	75D
HDPE	LR732 (Petrothene®)	4,000	181,000	67D
	4903 (Marlex®)	3,900	169,800	

About Putnam

For over two decades, Putnam Plastics has provided comprehensive extrusion technologies for medical catheters and minimally invasive devices. Technologies include thermoplastic and fluoropolymers extrusions, polyimide tubing, printing, and tipping and machining tubes. Putnam offers development through validated manufacturing services.

[1] www.heartsite.com - content by Abdulla M. Abdulla, M.D., F.A.C.P., F.A. C.C., Clinical Professor of Medicine and a prior Chief of Cardiology at the Medical College of Georgia.

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