Traditional and Novel Metal Alloys: Advantages, Disadvantages and Trends

Juan F. Granada, MD

Executive Director and Chief Scientific Officer
Skirball Center for Cardiovascular Research
Cardiovascular Research Foundation
Columbia University Medical Center

Common Metallic Materials Used in Stent Development & Manufacturing

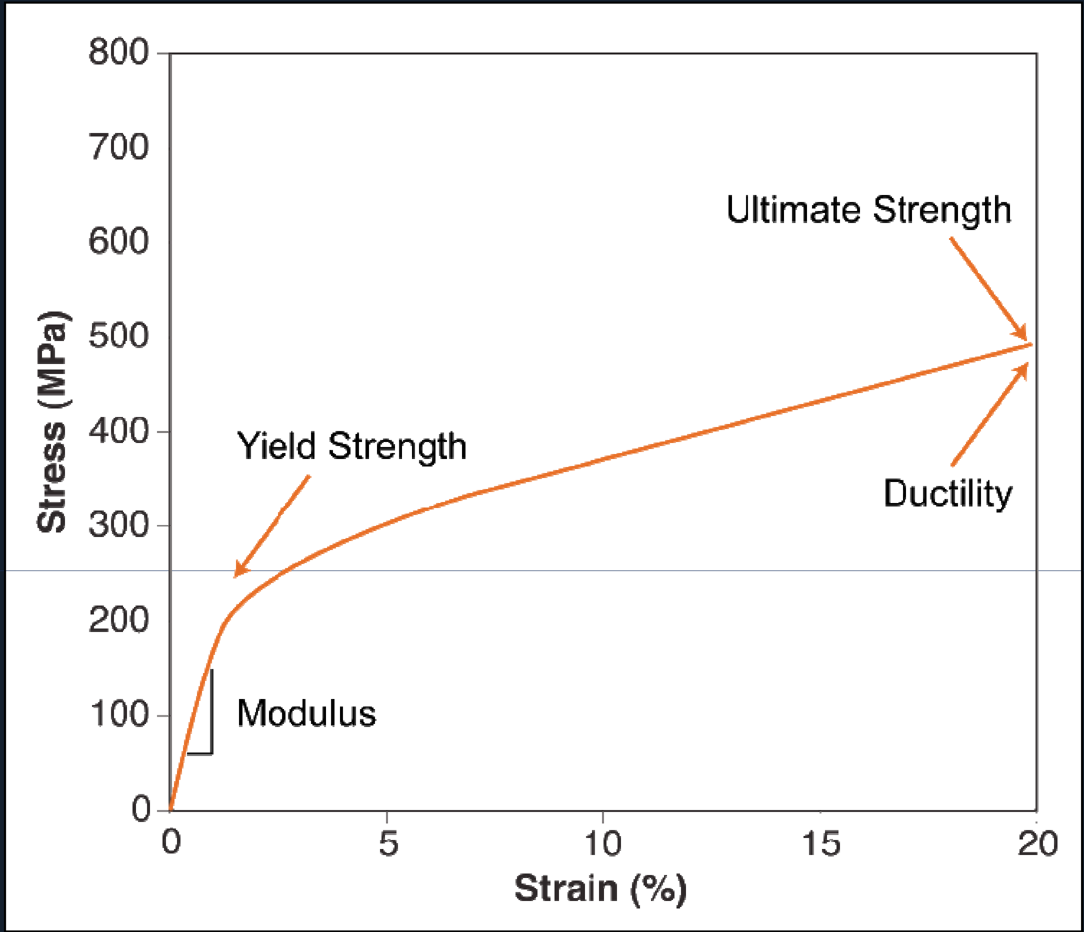
Key Element	Stainless Steel (316L)	Cobalt Chrome (Elgiloy, MP35N,L-605)	Titanium (CP, Ti-6-4)	Nitinol
Iron	63%	1-15%		
Titanium			90-100%	45%
Nickel	14%	15-35%		55%
Chromium	18%	20%		
Cobalt		40-50%		
Other	Mo, Mn	Mo, Mn, W	Al, V	

Slide courtesy (adapted) from Tom Duerig, Ph.D, NDC.

Definition of Metal Strength

"Ability of the material to withstand an applied stress without failure"

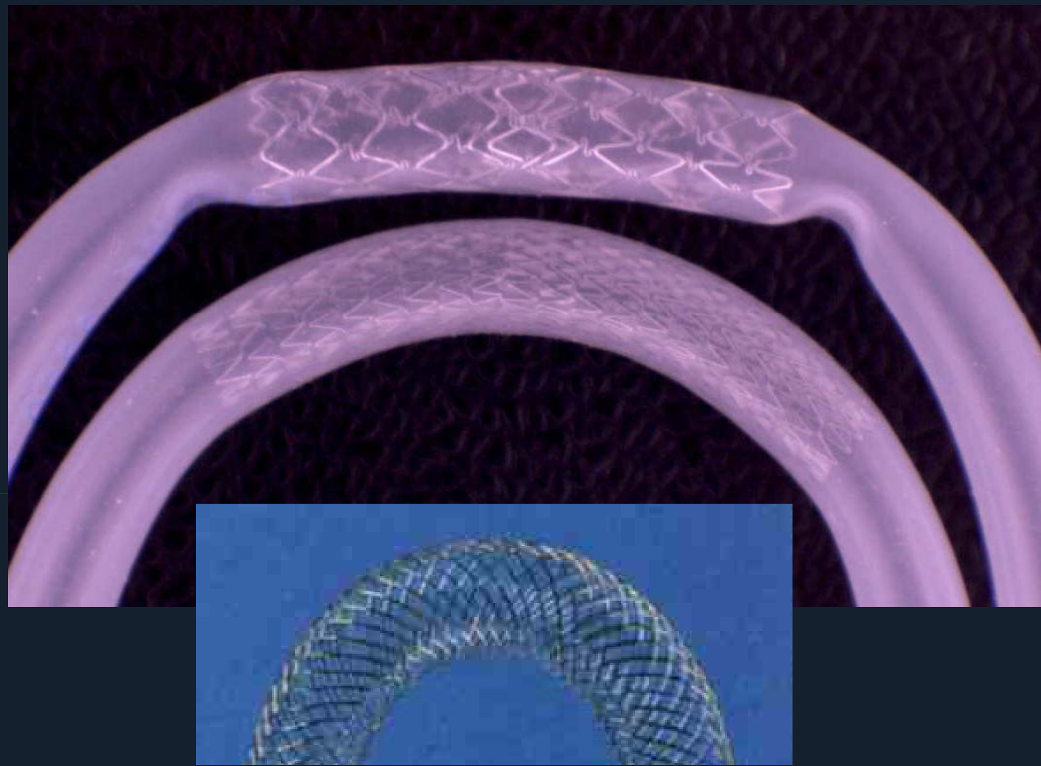
Material	Strength
Stainless Steel	Medium 300/560 MPa
Cobalt-Chrome	High 600/1140 MPa
Titanium	High 880/950 MPa
Nitinol	High 500/1400 MPa



Metal Stiffness: What is it?

"Resistance of an elastic material to deformation by an applied force"

Material	Stiffness
Stainless Steel	High 200 GPa
Cobalt-Chrome	High 200 GPa
Titanium	Moderate 90 GPa
Nitinol	Very Low ~25 GPa

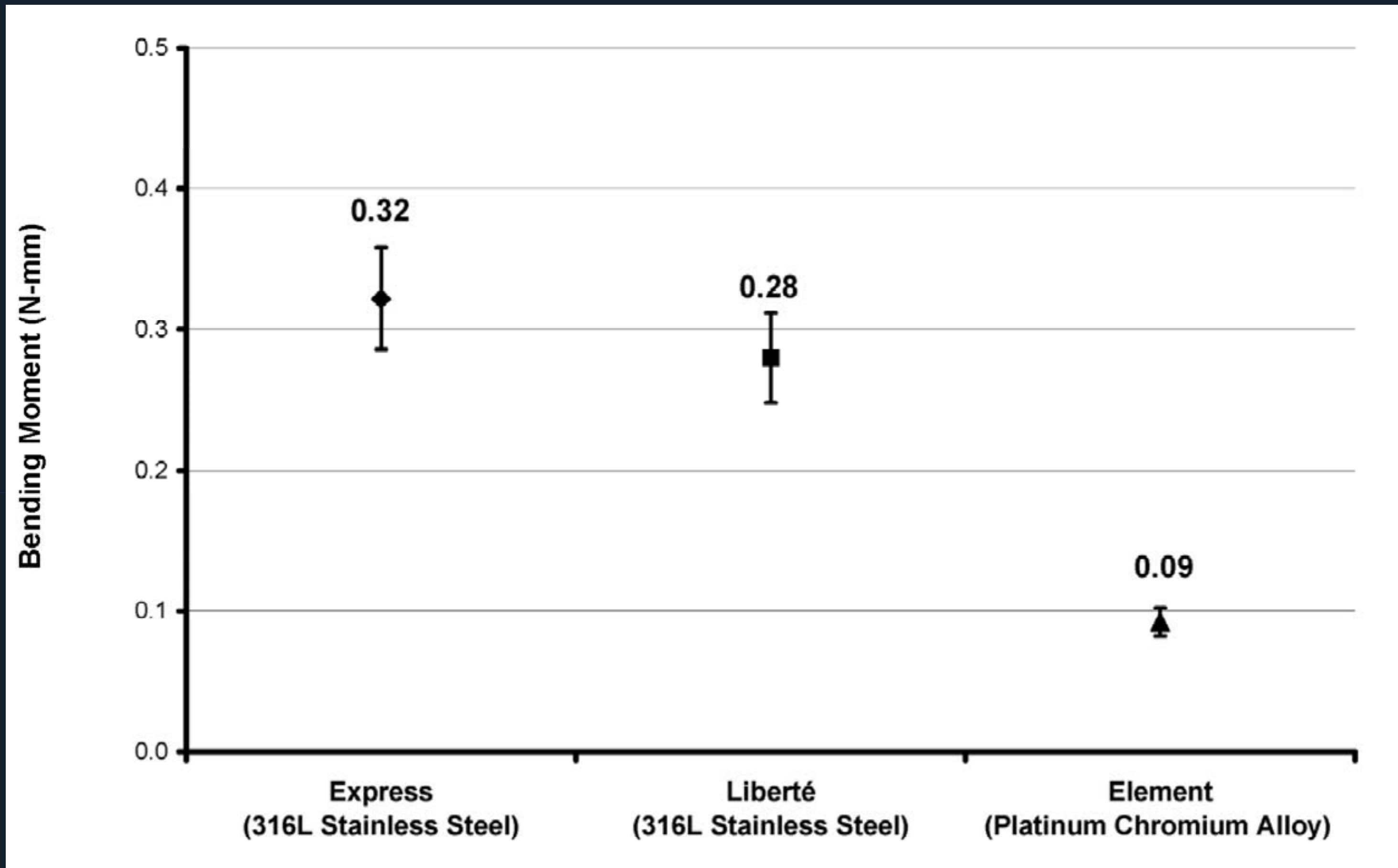


Nitinol

Slide courtesy (adapted) from Tom Duerig, Ph.D, NDC.

Conformability in Different Stent Materials

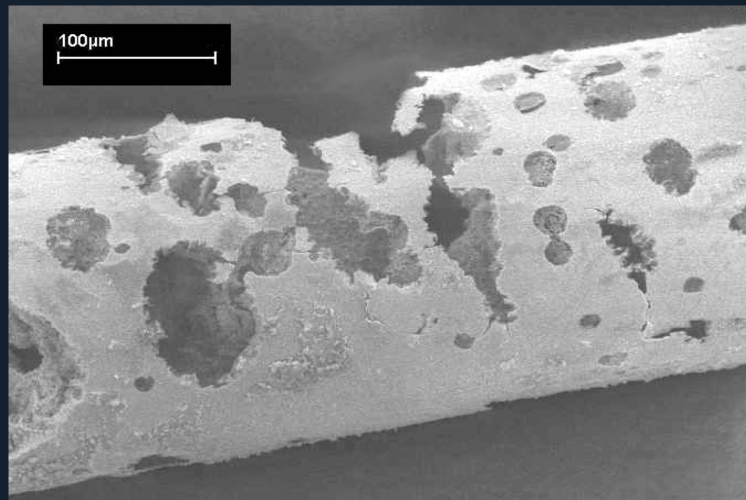
A measure of the torque required to bend the stent to a specific curvature, which is directly related to the flexibility of the stent. A lower required bending moment indicates increased flexibility. N=15 for each stent type.



Allocco et al. Trials 2010;11:1.

Corrosion Resistance

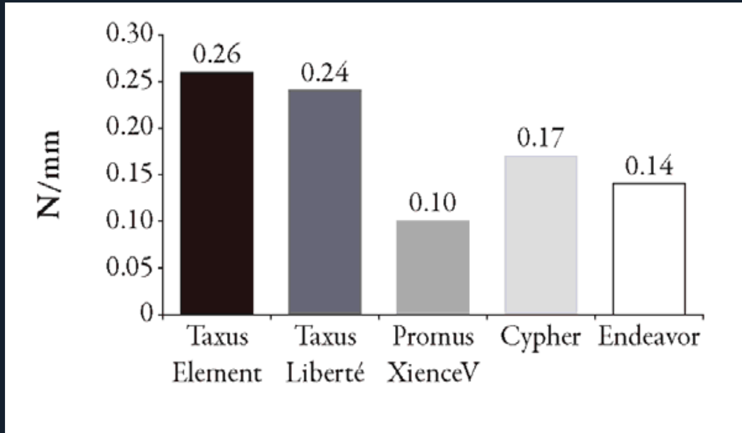
Material	Corrosion
Stainless Steel	Good – Cr_2O_3 (500 mV)
Cobalt-Chrome	Good – Cr_2O_3 (500 mV)
Titanium	Excellent – TiO_2 (800 mV)
Nitinol	Excellent – TiO_2 (800 mV)



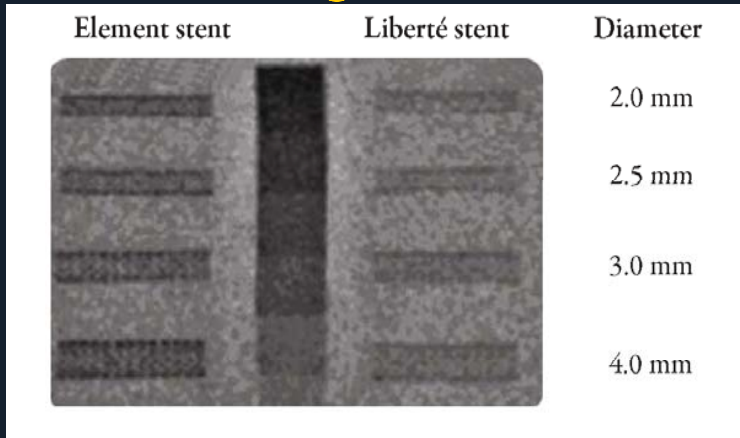
Slide courtesy (adapted) from Tom Duerig, Ph.D, NDC.

Impact of Metal Properties on Stent Performance

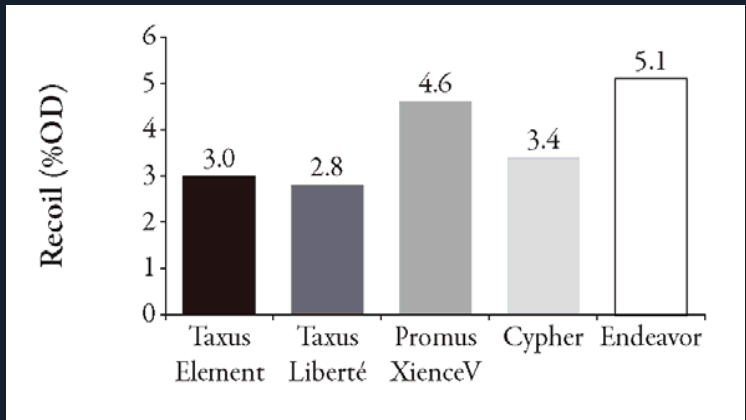
Radiopacity



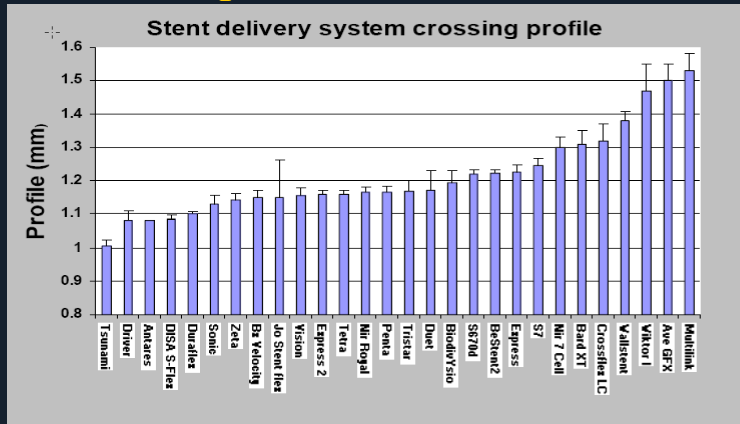
Radial Strength



Stent Recoil



Crossing Profile

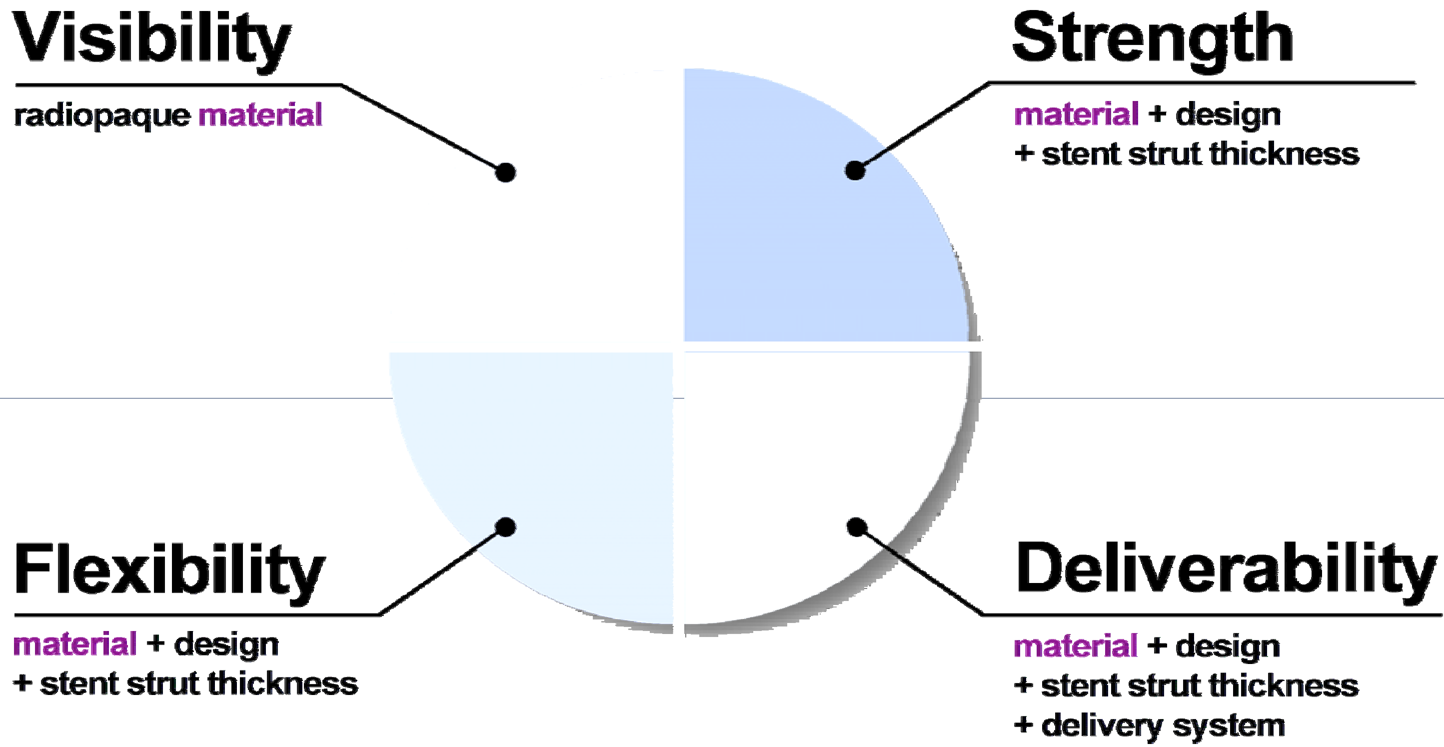


Menown et al. Adv Ther 2010;27:129-141

Material +Structure + Design

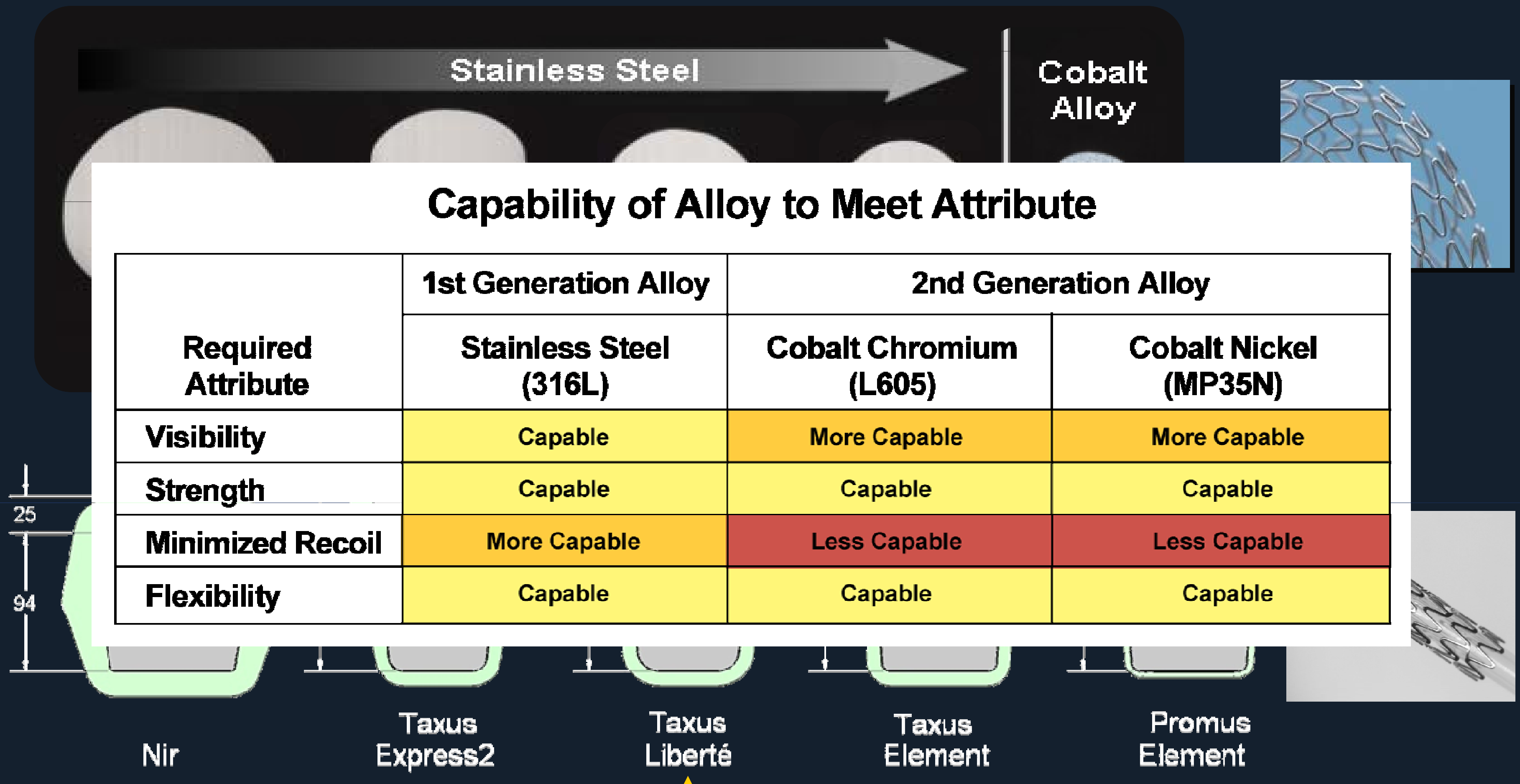
Stent Design Performance

How Do you Increase Stent Deliverability Maintaining Visibility and Strength?



Evolution of Stent Technology

Reduced Strut Thickness= Increase Deliverability

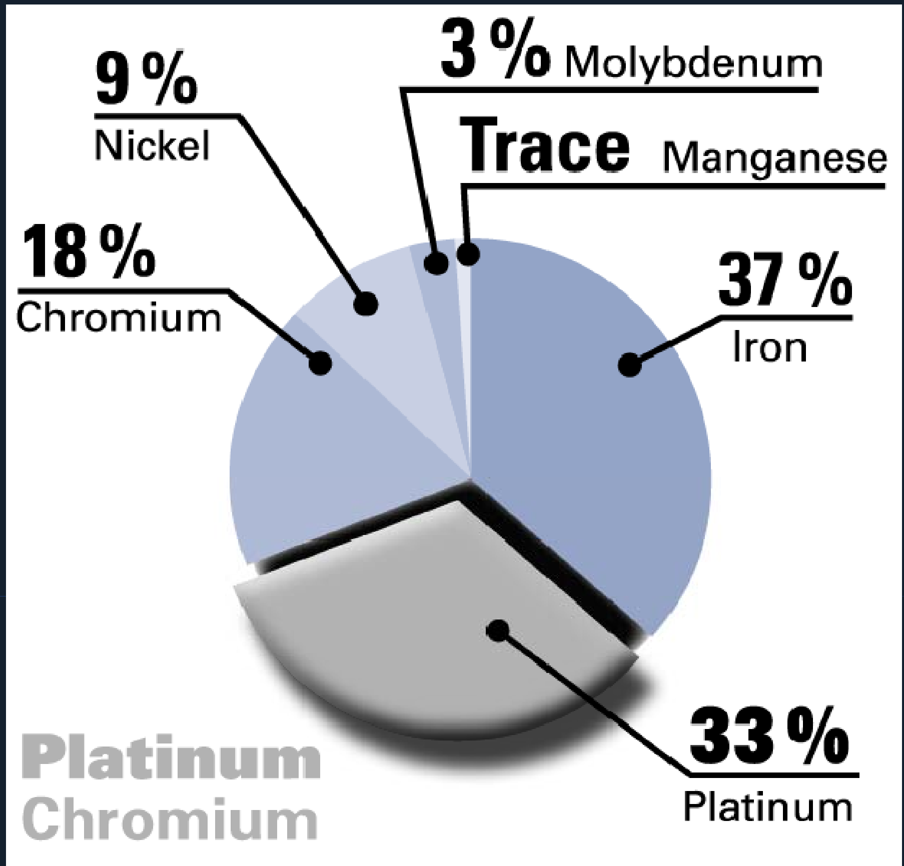


Capability of Alloy to Meet Attribute

Required Attribute	1st Generation Alloy	2nd Generation Alloy	
	Stainless Steel (316L)	Cobalt Chromium (L605)	Cobalt Nickel (MP35N)
Visibility	Capable	More Capable	More Capable
Strength	Capable	Capable	Capable
Minimized Recoil	More Capable	Less Capable	Less Capable
Flexibility	Capable	Capable	Capable

Platinum Chromium

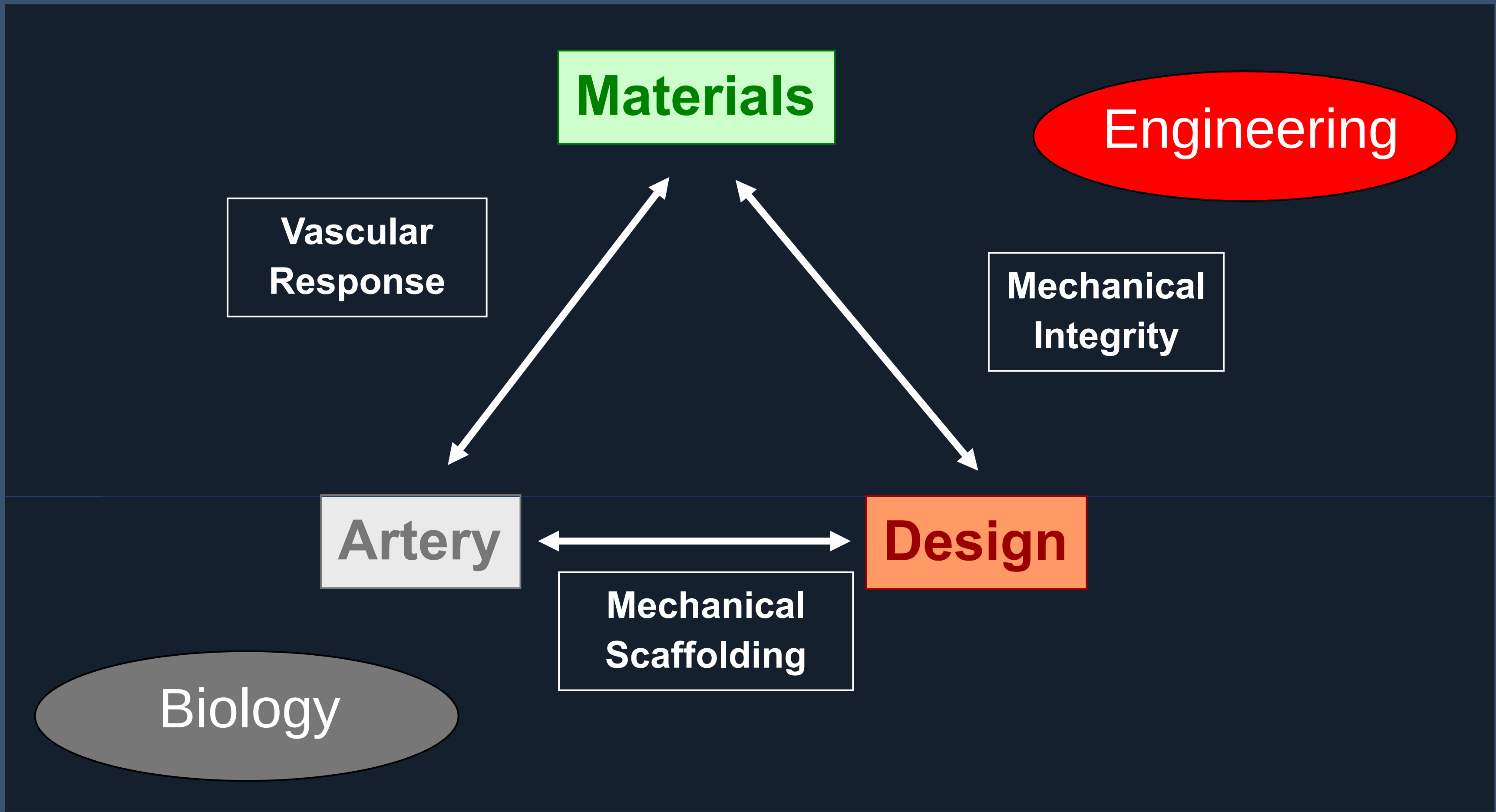
Elemental Composition



- **Platinum has over 2x the density of iron or cobalt (superior radiopacity).**
- **Platinum is distributed evenly throughout the alloy to provide the appropriate level of visibility.**
- **Platinum increases strength when alloyed with 316L stainless steel.**
- **Platinum chromium has the lowest nickel content (9%) compared to**
  - **316L Stainless Steel: 14% (TAXUS® Liberté Stent®)**
  - **L605 Cobalt Chromium: 10% (XIENCE V® Stent)**
  - **MP35N Cobalt Nickel: 35% (Endeavor® Stent)**

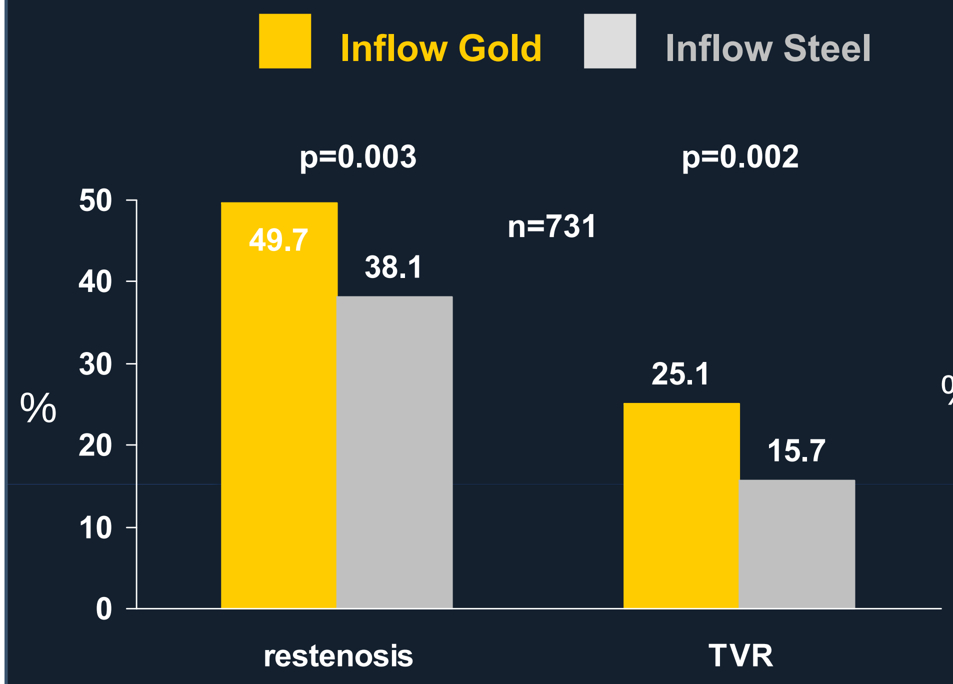
Steiner R: ASM Handbook Volume 1: Properties and Selection: Irons, Steels, and High-Performance Alloys. 10th ed. Materials Park, OH: ASM International; 1990. Bench test results may not necessarily be indicative of clinical performance. Data on file at BSC. MP35N is a trademark of SPS TECHNOLOGIES, LLC.

Restenosis is the Result of the Interaction of Several Related Factors

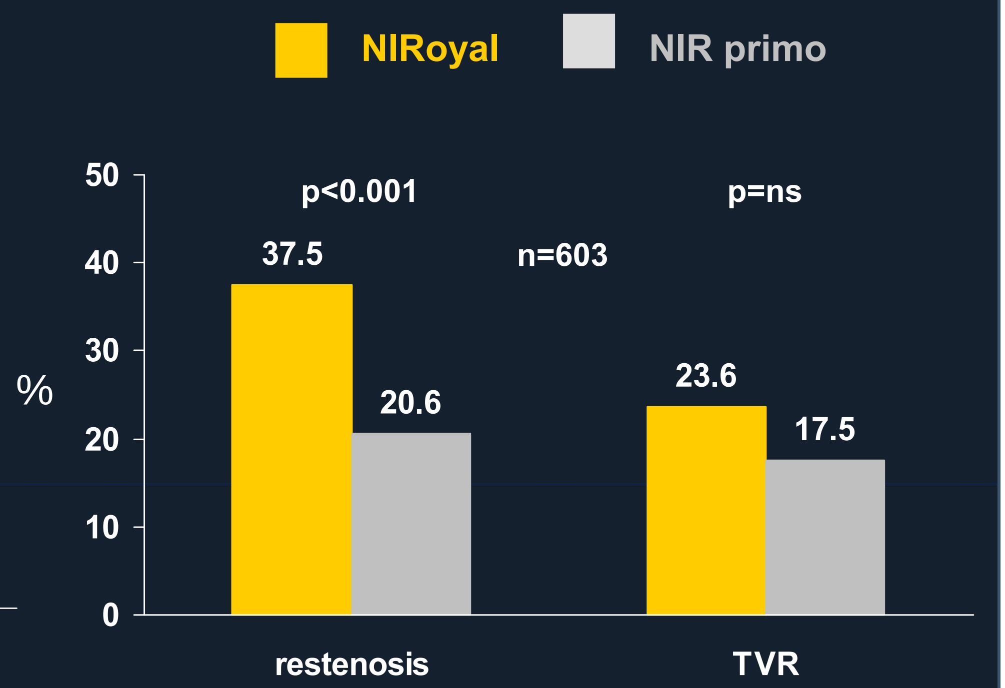


Strut Surface/Material and Restenosis

Impact of Surface Material on Restenosis



Kastrati et al., Circulation. 2000;102(21):2593-8



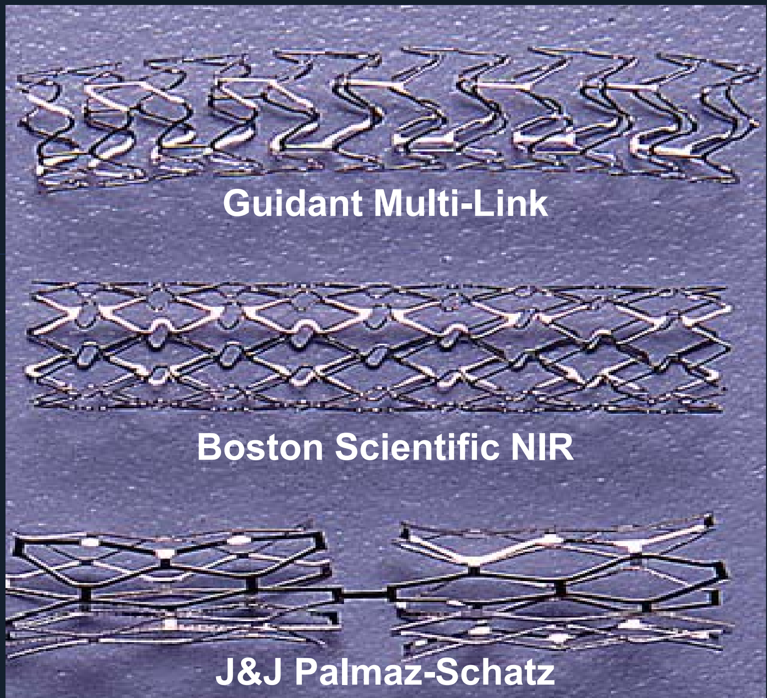
Reifart et al., Cathet Cardiov Interv. 2004;62(1):18-25

Evolution of Early Stent Technology

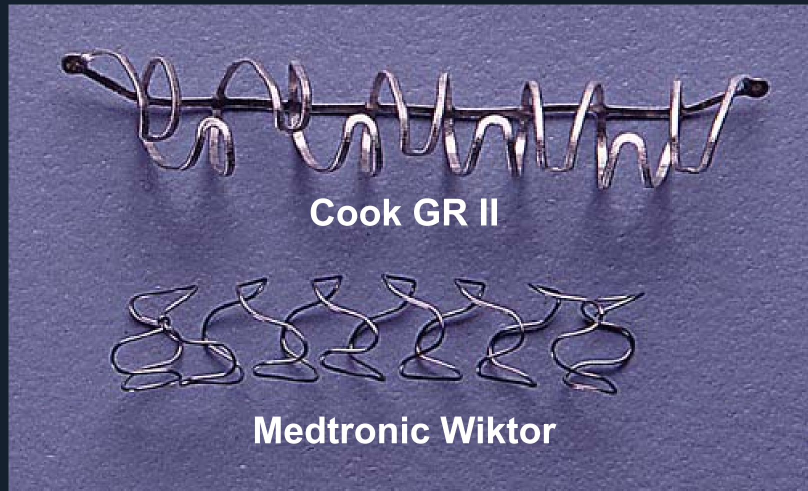
The Evolution of Stent Designs

Wire Mesh Stent

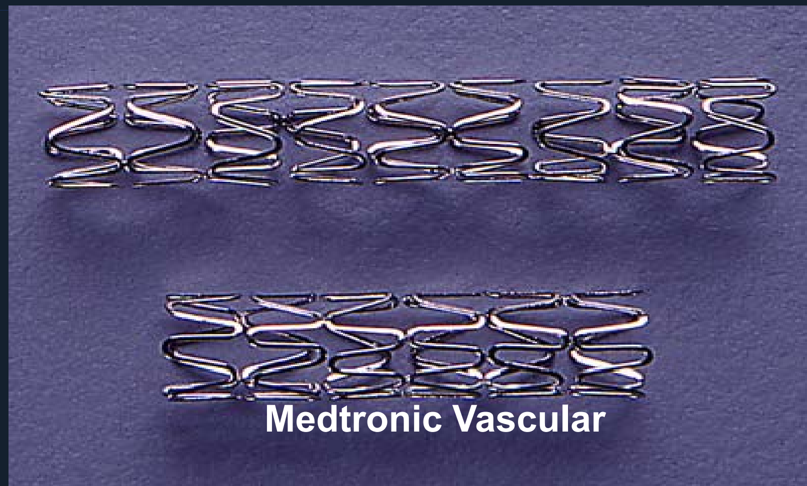
Tubular Slotted Stents



Wire Coil Stents

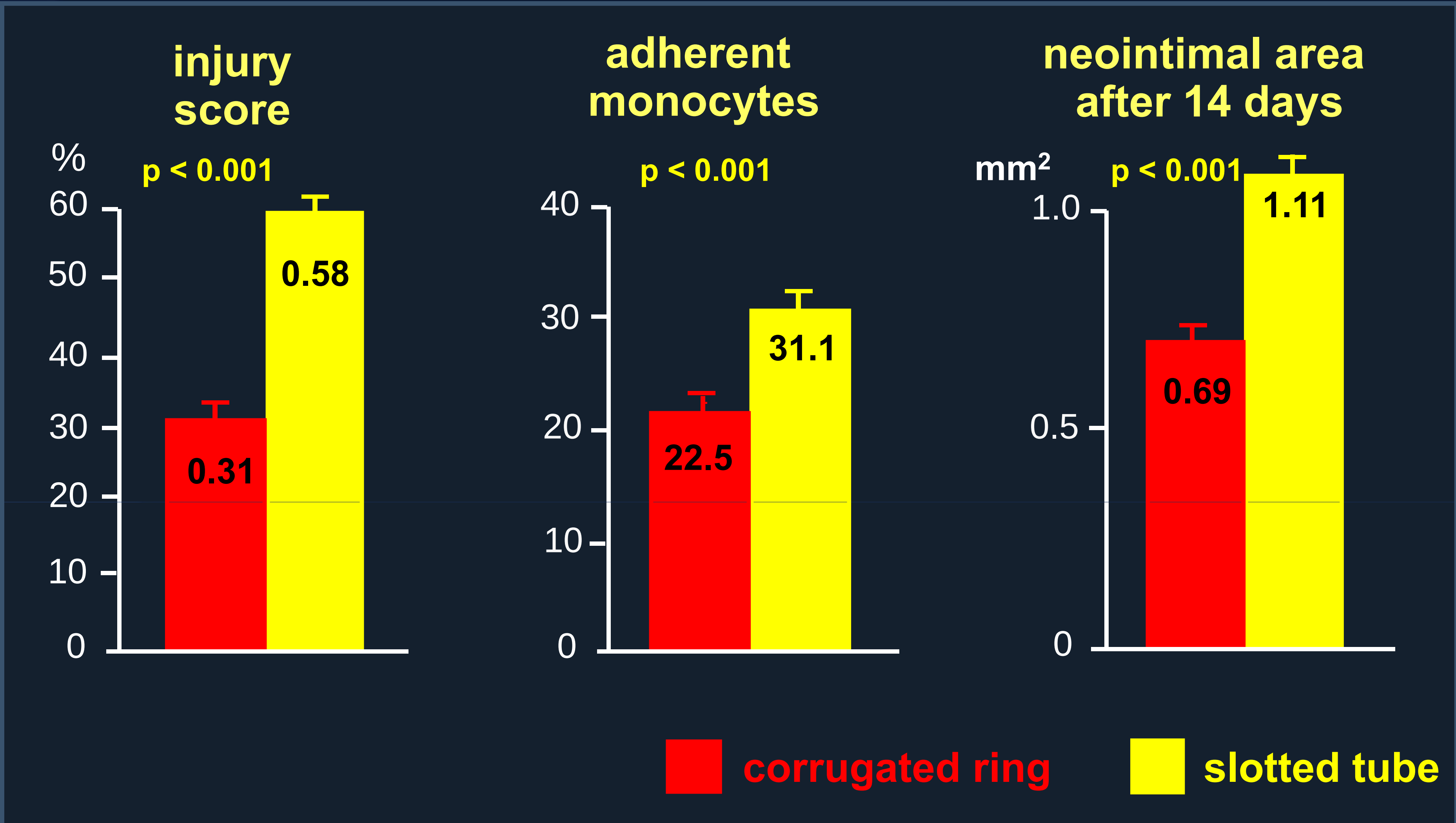


Modular Stents



Stent Design, Vessel Injury and Restenosis

Experimental Data



Rogers et al., Cir Res 1999

Randomized Trial With 5 Different Stents

1147 Patients

n= 231

Inflow
Inflow Dynamics

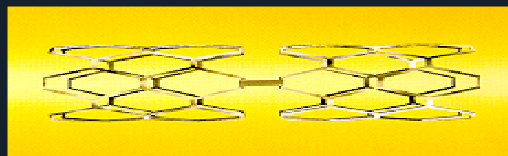
n= 227

MULTI-LINK
ACS Guidant

n= 229

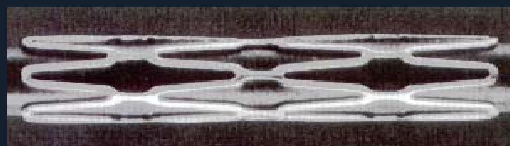
NIR
Boston Scientific

n= 233



Palmaz-Schatz (PS)
Johnson & Johnson

n= 227



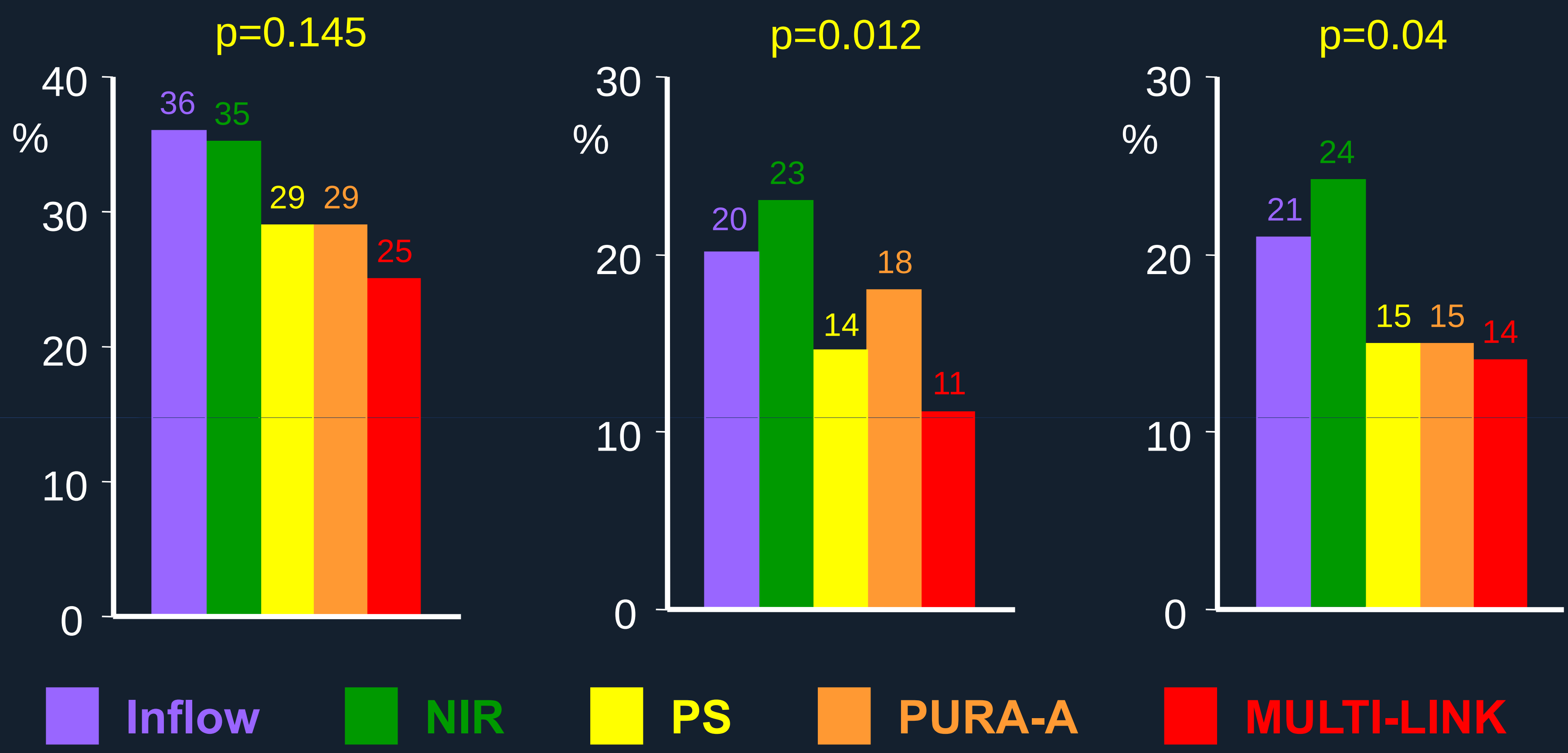
PURA-A
Devon Medical

Kastrati et al., Cathet Cardiovasc Interv 2000 Jul;50(3):290-7

Randomized Trial With 5 Different Stents

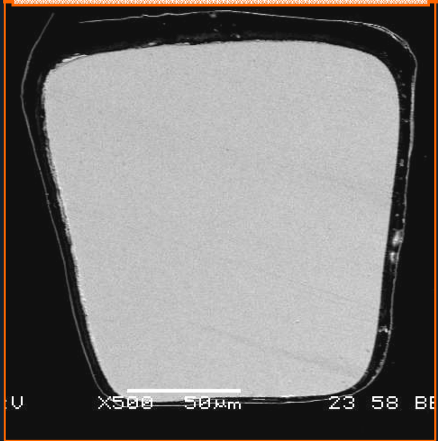
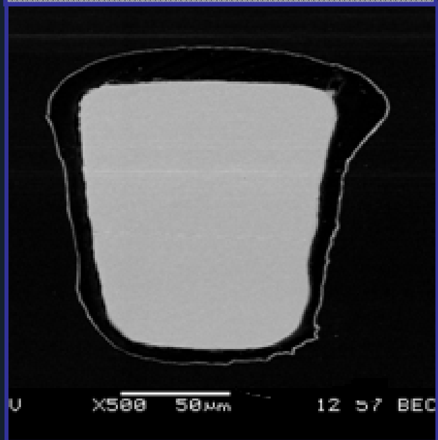
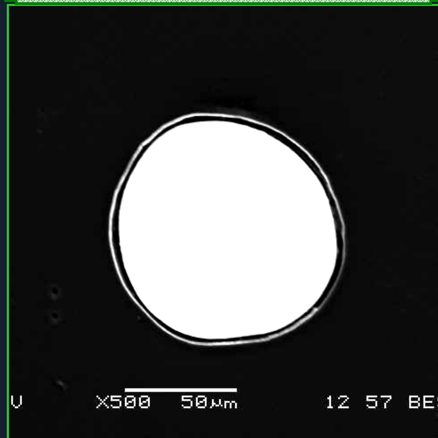
6-Month Results

Restenosis (≥50%) **Restenosis (≥ 75%)** **TVR**



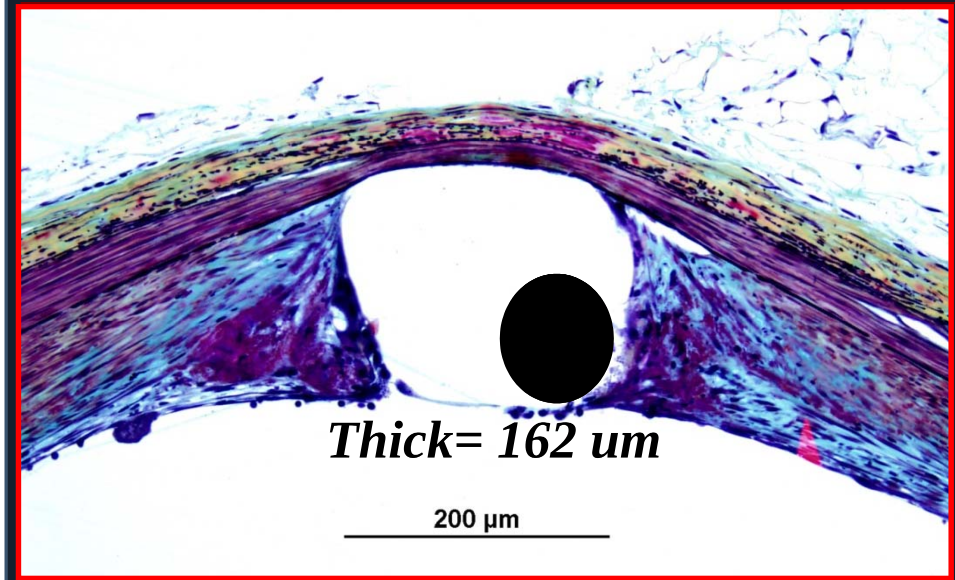
Kastrati et al., Cathet Cardiovasc Interv 2000 Jul;50(3):290-7

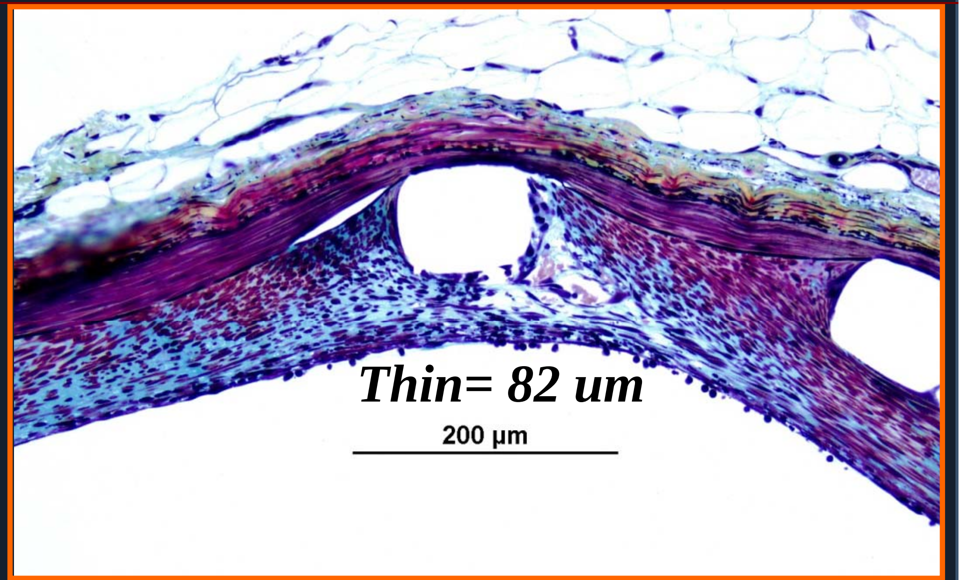
Stent Strut Design and Thickness in Currently FDA Approved Drug Eluting Stents

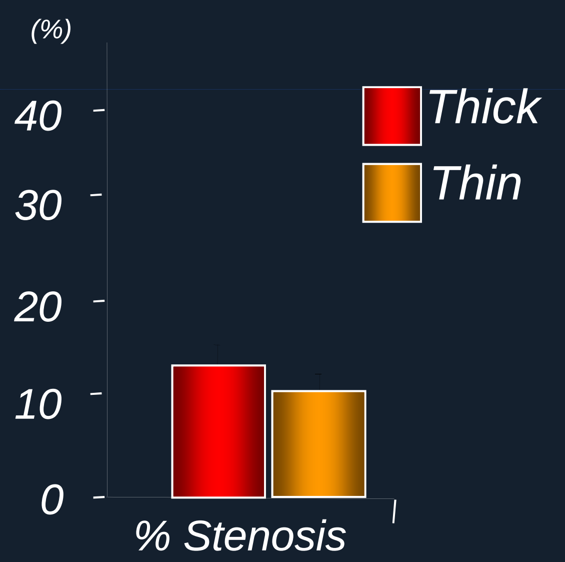
CYPHER®	***TAXUS® Express***	***ENDEAVOR™***	***XIENCE V™***
			
Strut Thickness:	**Strut Thickness:**	**Strut Thickness:**	**Strut Thickness:**
140 μm	**132 μm**	**91 μm**	**81 μm**
Coating Thickness:	**Coating Thickness:**	**Coating Thickness:**	**Coating Thickness:**
12.6 μm	**19.6 μm**	**4.8 μm**	**7.8 μm**

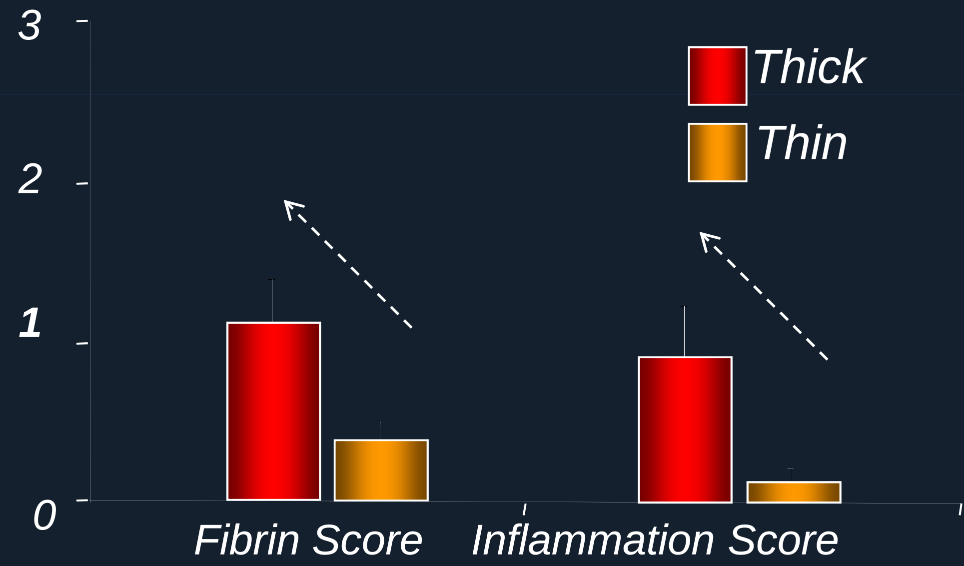
Abluminal coating thickness represented, 3.0x18mm stent, 500X magnfication

Optimization of Strut Thickness Leads to Reduction of Inflammation (14 Day Rabbit Iliac Arteries)







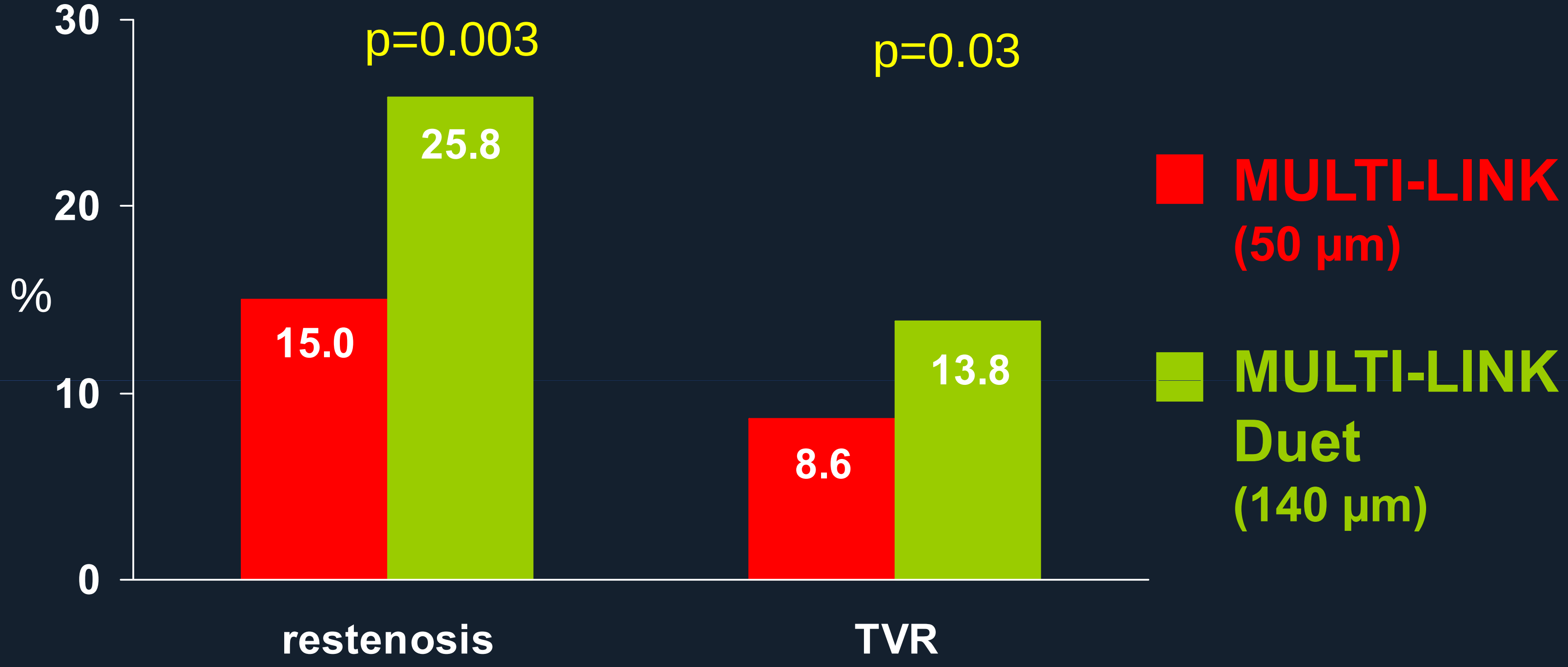


Slide courtesy (adapted) of Renu Virmani

Strut Thickness and Restenosis

Vascular Injury versus Rapid Endothelialization?

ISAR-STEREO-1

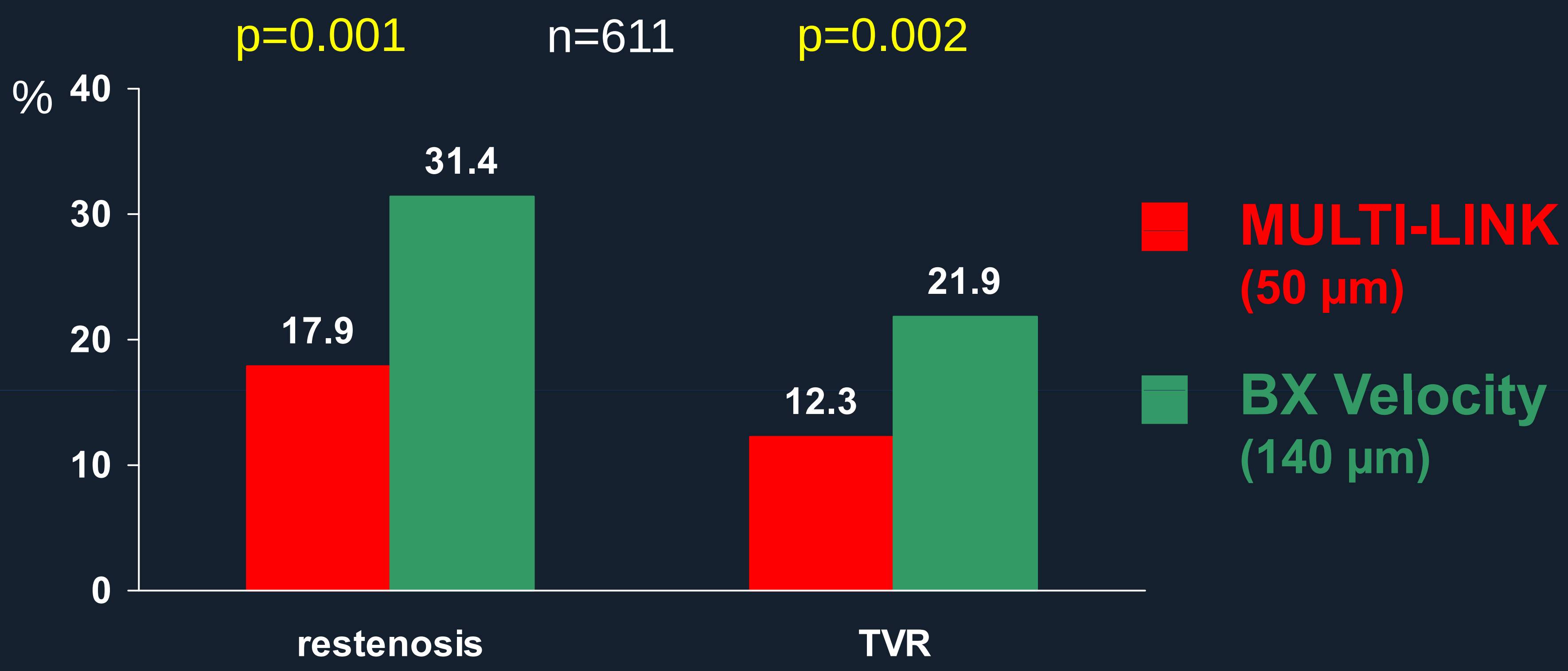


Kastrati A. Circulation. 2001 Jun 12;103(23):2816-21.

Strut Thickness and Restenosis

Vascular Injury versus Rapid Endothelialization?

ISAR-STEREO-2



Pache J. JACC. 2003 Apr 16;41(8):1283-8.

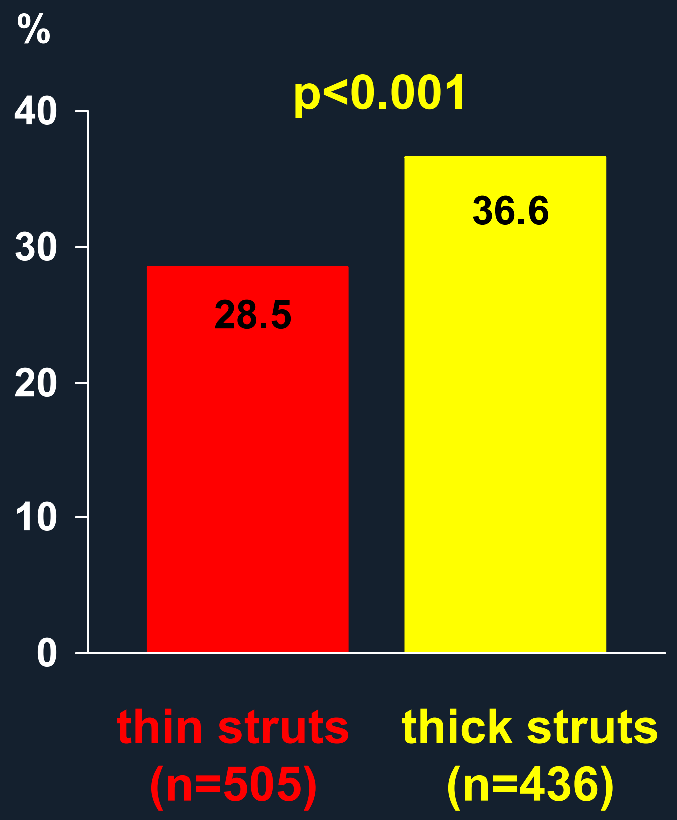
Strut Thickness and Angiographic Restenosis in Small Coronary Arteries

Retrospective Analysis of 941 Patients

Thin Struts (<100 μm):
- Palmaz-Schatz
- ACS MULTI-LINK
- BiodivYsio
- BeStent
- JOSTENT Flex
- Diamond (Phytis)
- V-Flex (Global Therapeutic)
- Sorin Carbostent

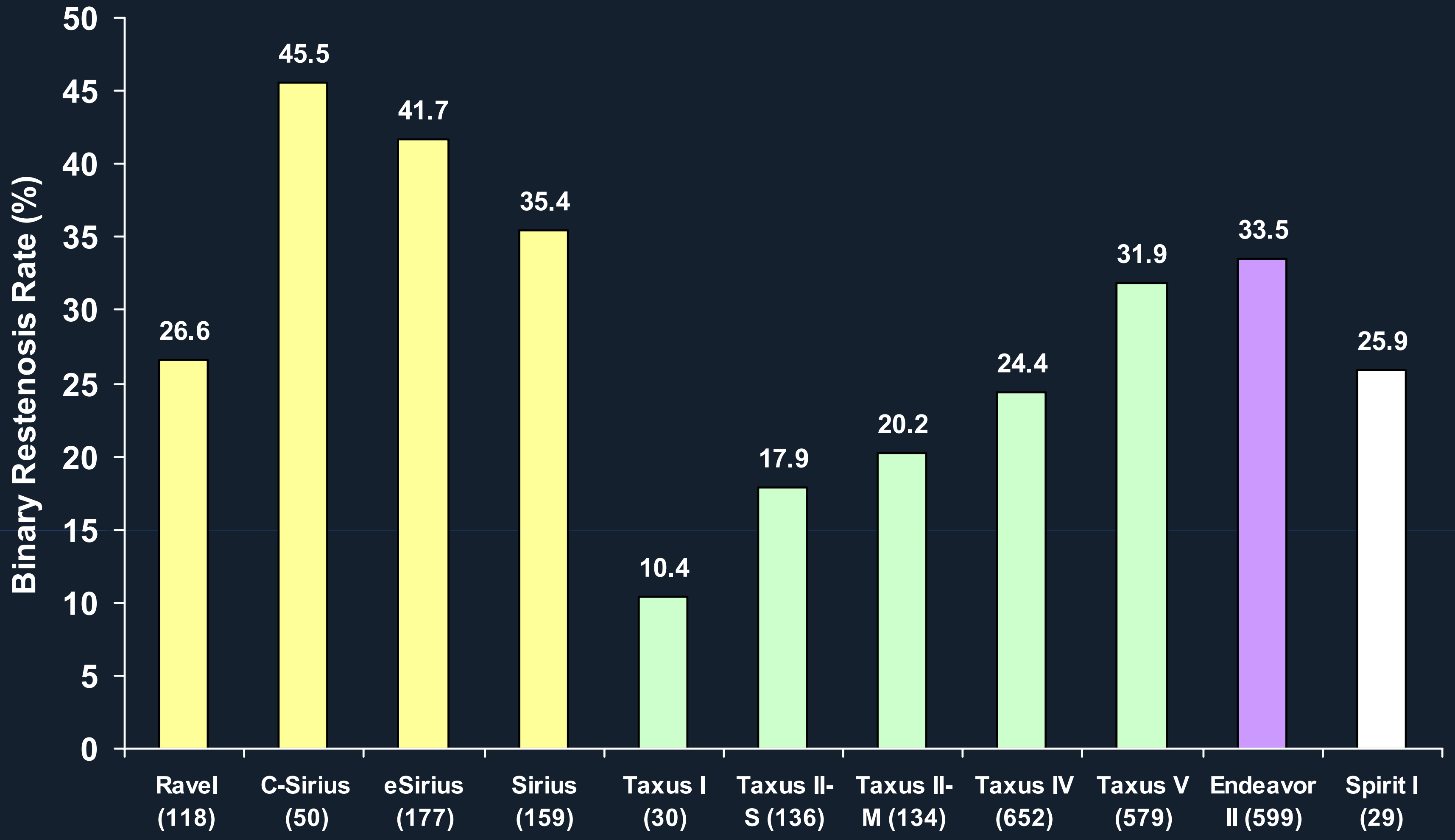
Thick Struts (≥100μm):
- NIR
- ACS Duet
- BX Velocity
- AVE-II
- Cordis Crossflex LC
- Bard XT

Restenosis Rates



Briguori C. JACC. 2002 Aug 7;40(3):403-9.

Binary Restenosis Rate in the BMS Arms of Randomized Trials of DES



Data Obtained from JACC, Aug 31,2010;Vol56, No10 (Suppl S)

Conclusions

- **Stent material science is still evolving and aims to find the perfect balance between acute device performance and clinical outcomes.**
- **New stent materials have permitted the development of thinner stent struts, but still maintaining similar mechanical properties compared to previous generation stents.**
- **Other factors (i.e., surface characteristics) may equally impact the overall long term performance of the device.**
- **Therefore, the "ideal" stent design has to achieve a perfect balance between material selection, design and strut thickness.**
- **Still, despite the fact that BMS platforms have plateau in their restenosis rate, they have become superior delivery platforms for DES technologies.**