Mechanical Properties of the Magmaris (magnesium) Bioresorbable Scaffold

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7.24-7.32
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Background

- **The Absorb polymeric BRS had increased scaffold thrombosis**
- **Magnesium has mechanical properties somewhat better than polymers and is anti-thrombotic**

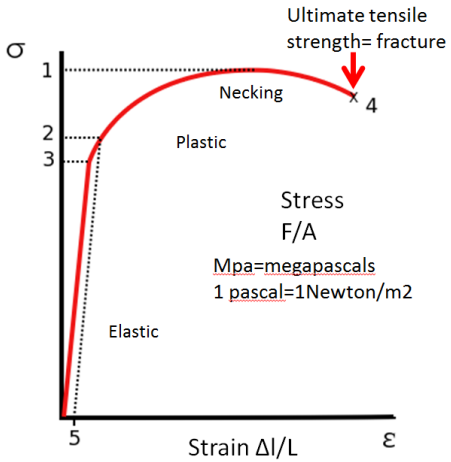
Waksman Circ Cardiovasc Interv 2017
Onuma Circ Cardiovasc Interv 2017
Rukshin Circulation 2002
Shechter Am J Cardiol 1999
Dong Thromb Haemost
Huntsman J Clin Path 1960
Huntsman Nature 1960

- **This study compared mechanical properties of the Magmaris (magnesium) scaffold with polymeric scaffolds and a metallic stent**

Magnesium has better qualities than PLLA but not as good as CoCr

	Young's Modulus, Gpa	Ultimate tensile strength, Mpa	Elongation to break, %
PLLA Absorb	3.1-3.7	60-70	2-6
Magnesium alloy*	40-45	220-330	2-20
Cobalt Chromium Xience	210-235	1449	≈40

Sotomi Circ Research 2017



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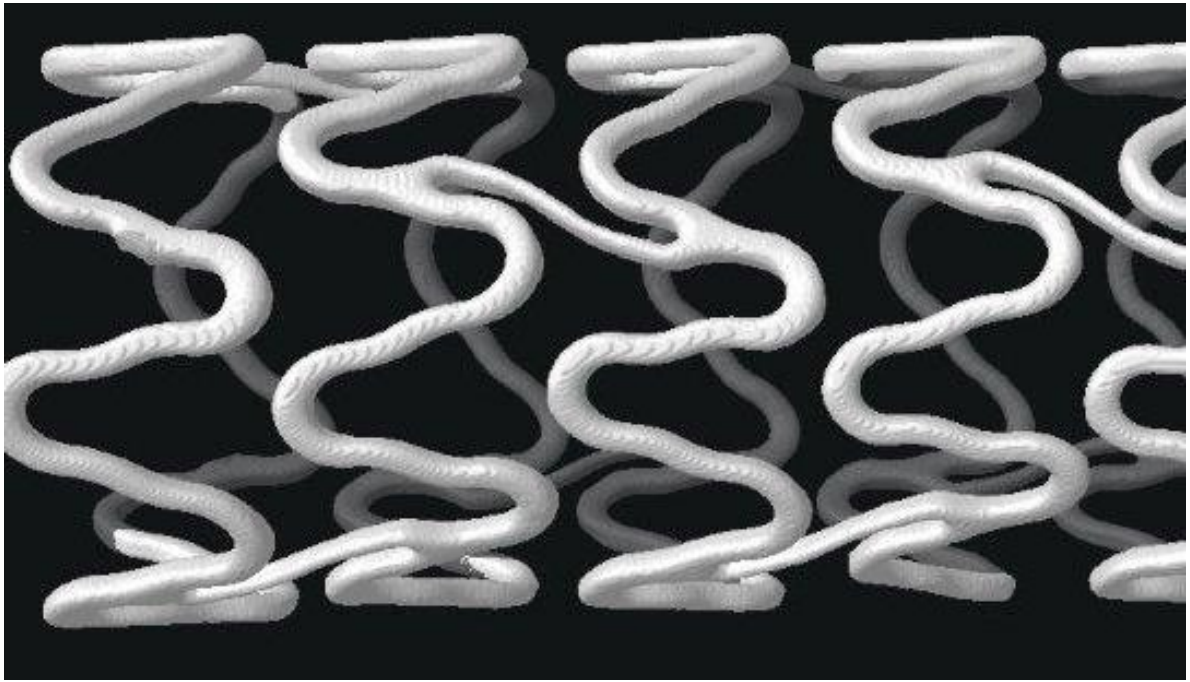
Magmaris design is in-phase sinusoidal hoops linked by 2 connectors that join the hoops midway between peaks and troughs

Strut edges are rounded



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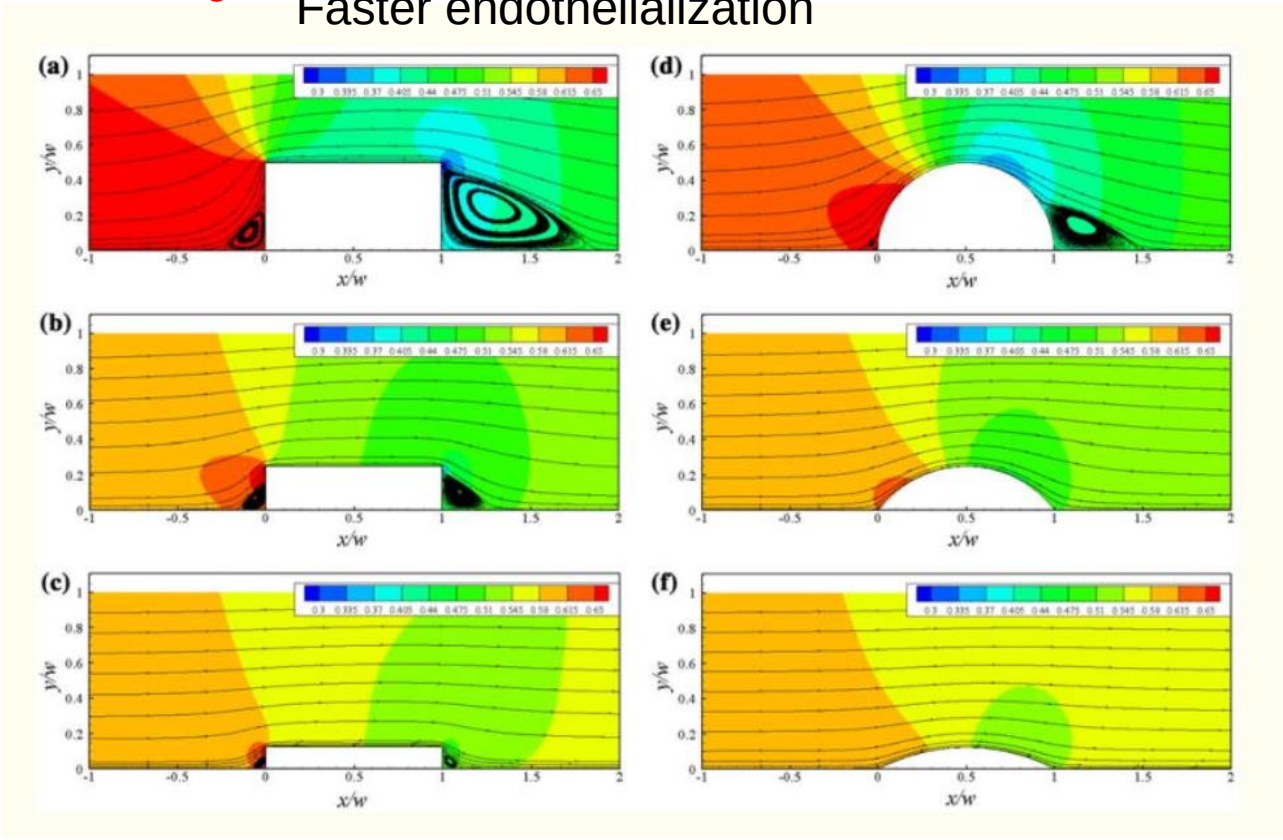
Strut rounded edges vs square

- Less flow disturbance
- Easier to deliver
- Faster endothelialization



Strut dimensions and vessel coverage for Magmaris, polymeric BRS and durable DES (3.0mm devices)

	DES	Polymeric BRS			Mg BRS
					
	ML8/Xience Expedition	Absorb	DESolve	DESolve Cx	Magmaris
Strut thickness	89µm	157µm	150µm	120µm	150µm
Strut width	89-112µm	Hoop 191µm Connector 140µm	Hoop 165µm Connector 100µm	Hoop 165µm Connector 100µm	Hoop 150µm Connector 80-100µm
Strut/vessel coverage (Footprint)	13%	27%	30%	30%	20% *Ormiston*

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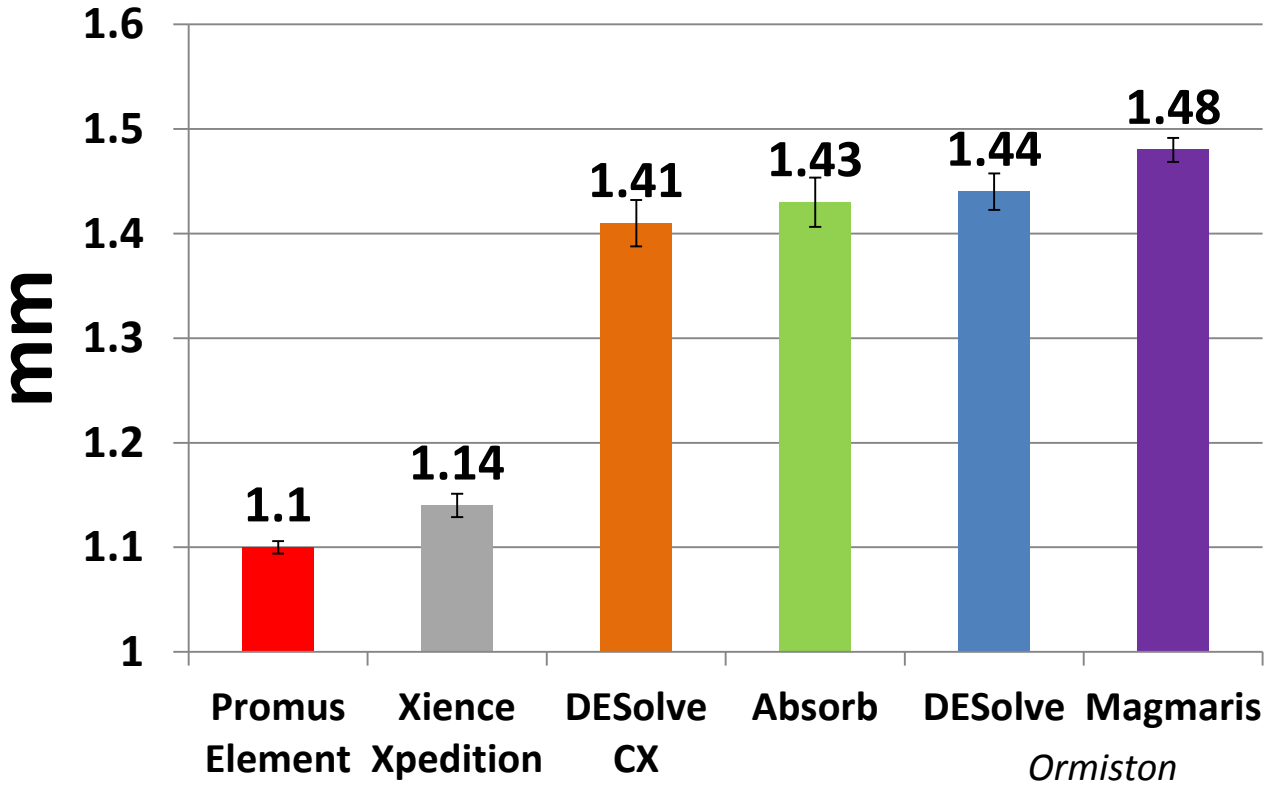
3.0 mm Device Crossing Profile

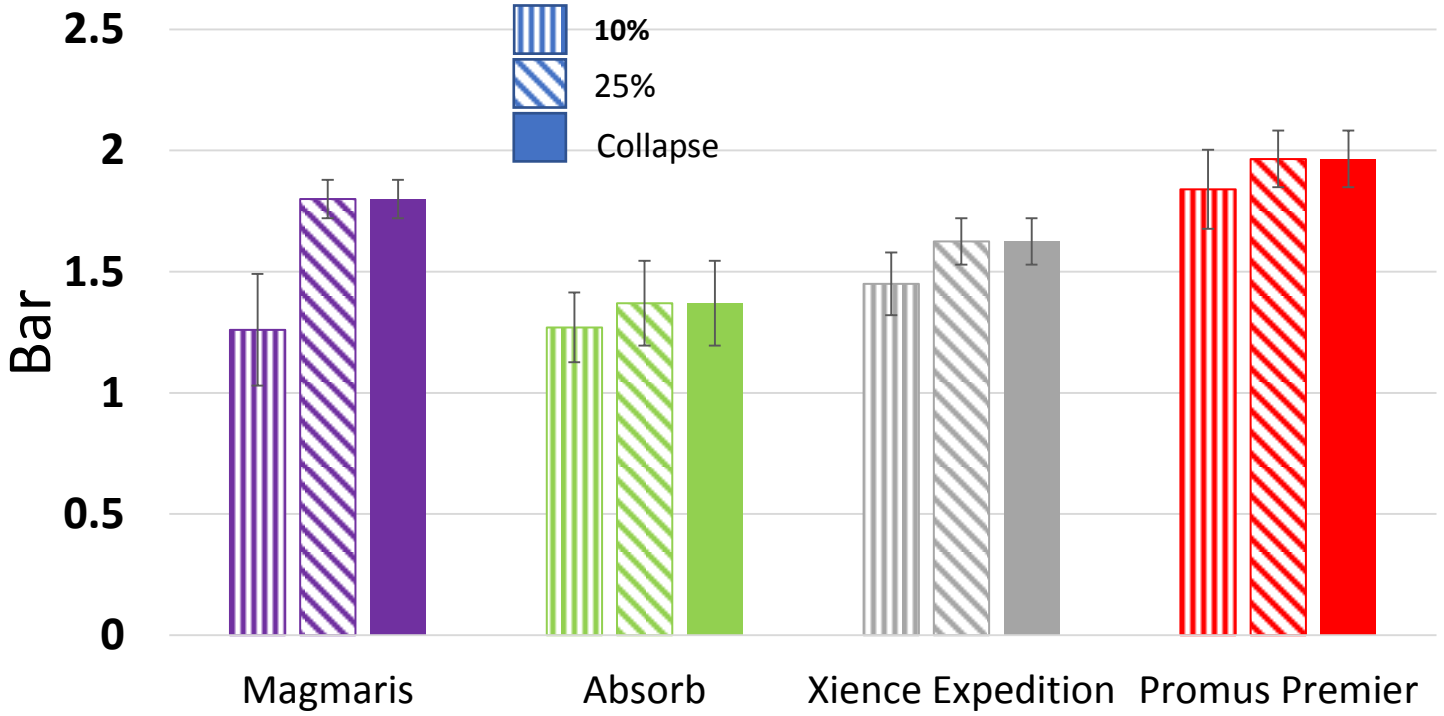
The Magmaris has a large crossing profile

Large profile makes delivery more difficult



Radial Strength at implantation

Pressure and Cross-sectional Area Reduction



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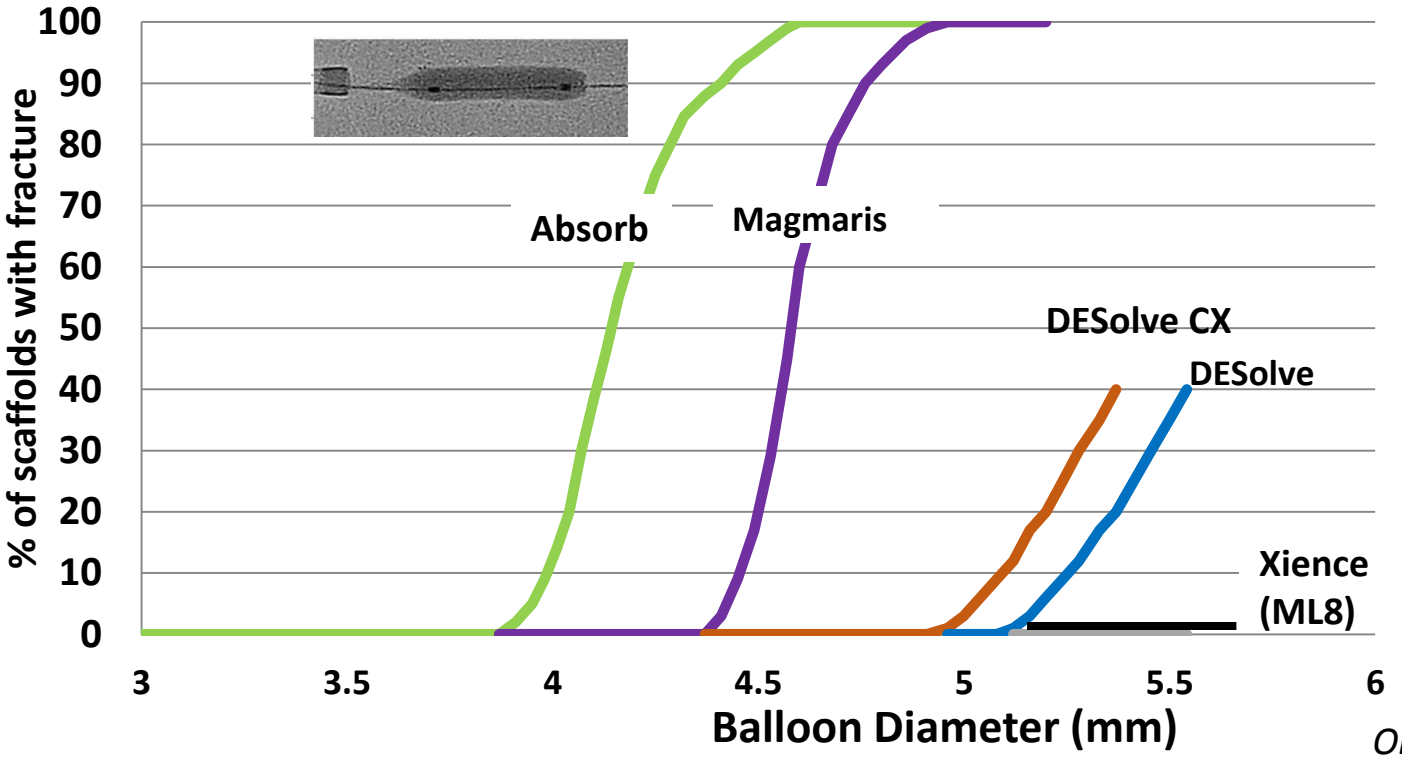
Risk of 3.0 mm Scaffold Fracture with Increasing Main Branch Balloon Diameter
Magmaris is less likely to fracture than Absorb



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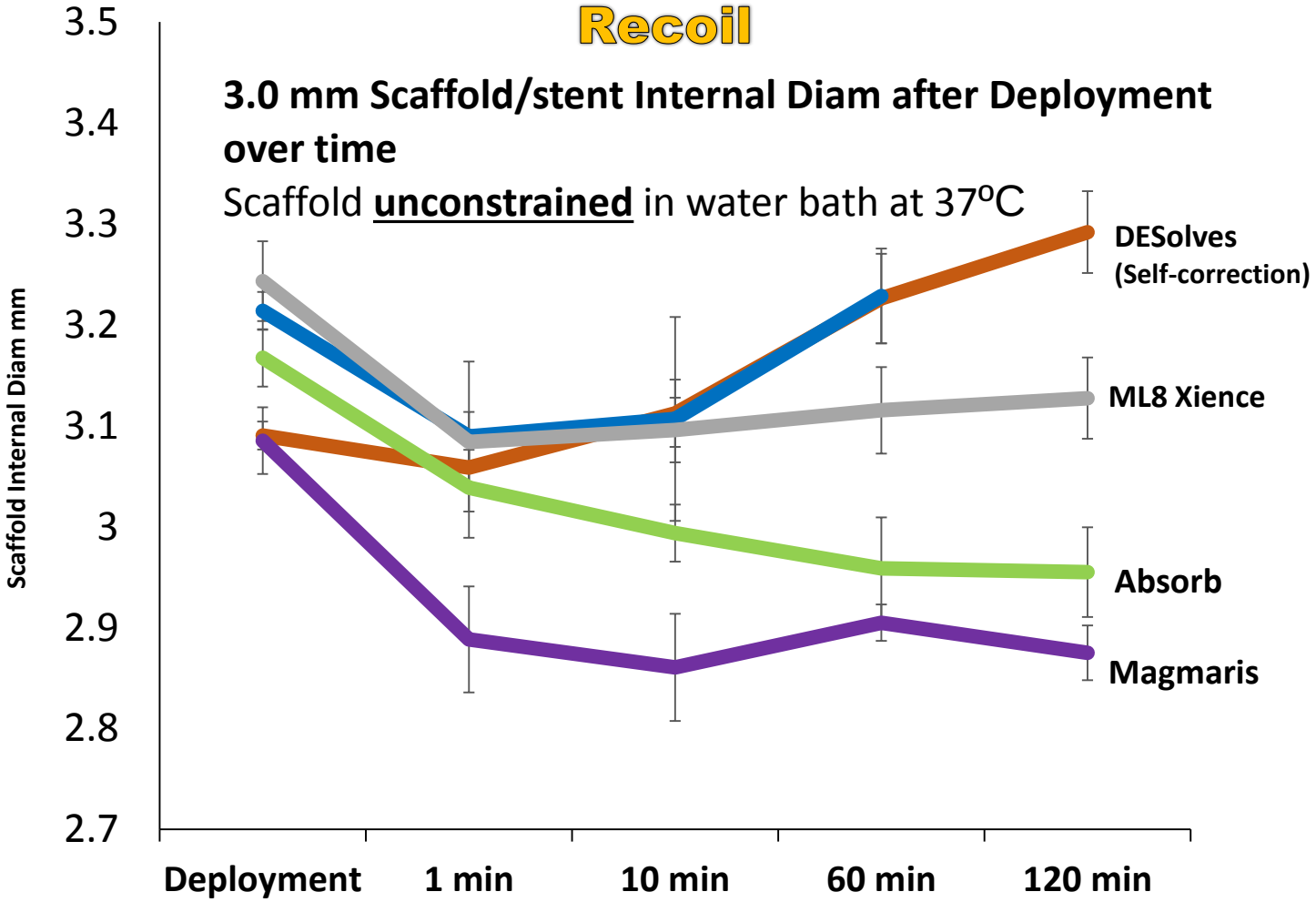
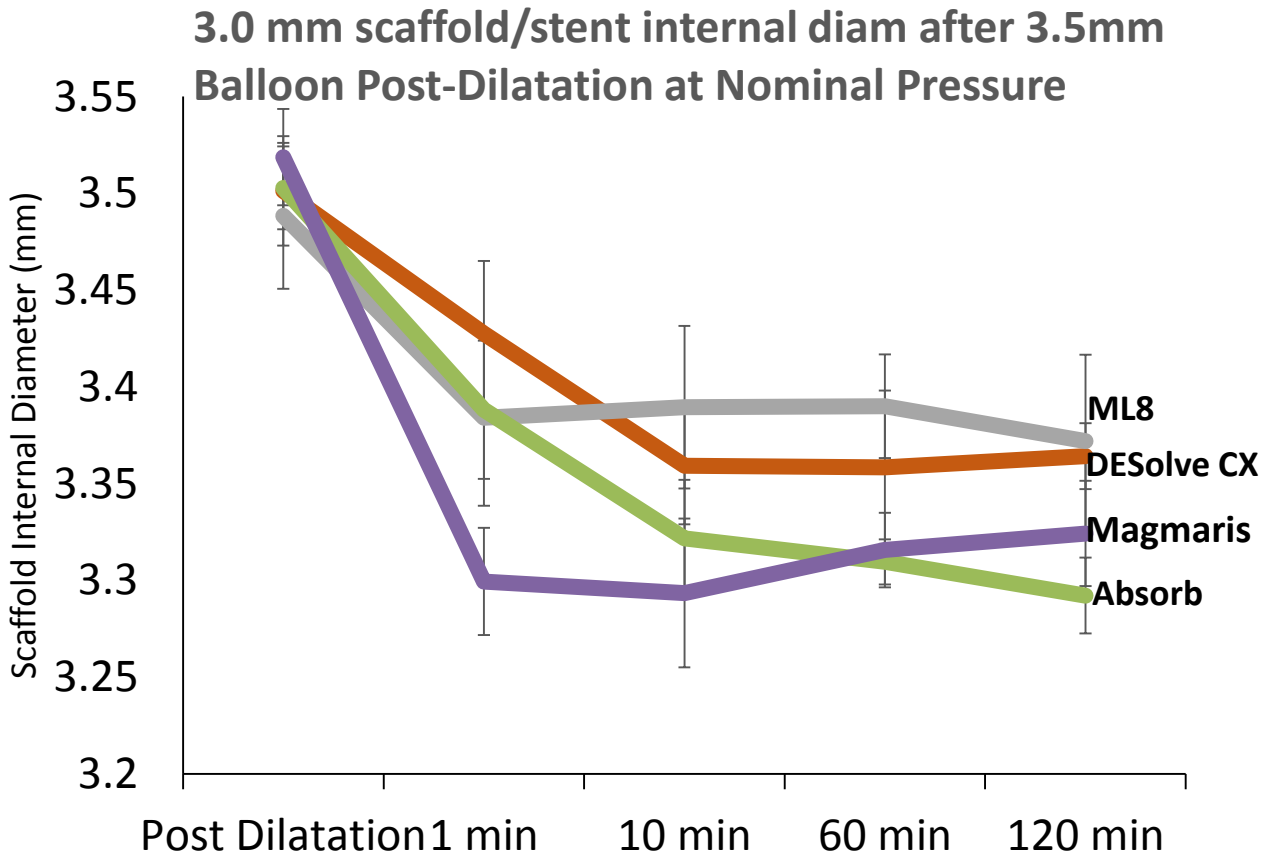
Recoil


3.0 mm Scaffold/stent Internal Diam after Deployment over time
Scaffold unconstrained in water bath at 37ºC
Scaffold Internal Diam mm
3.5
3.4
3.3
3.2
3.1
3
2.9
2.8
2.7
Deployment
1 min
10 min
60 min
120 min
DESolves (Self-correction)
ML8 Xience
Absorb
Magmaris

3.5mm post-dilatation improves diams after recoil



Timing of freedom from "caging"

If too early, the negative remodelling is not opposed-> Restenosis

Device	Timing	Evidence for timing
Magnesium	<<<6 months	*Haude Lancet 2013*
Absorb	1 year	*Ormiston Circ Int 2012*
ReZolve REVA	?6 months	*Strandberg Circ Int 2012 (preclinical)*
DESolve Elixir	6 months	*Verheye TCT 2012 Sirhan CRT 2013,*
ART	3 months	*Lafont, Virmani Fajadet TCT 12*
		Ormiston

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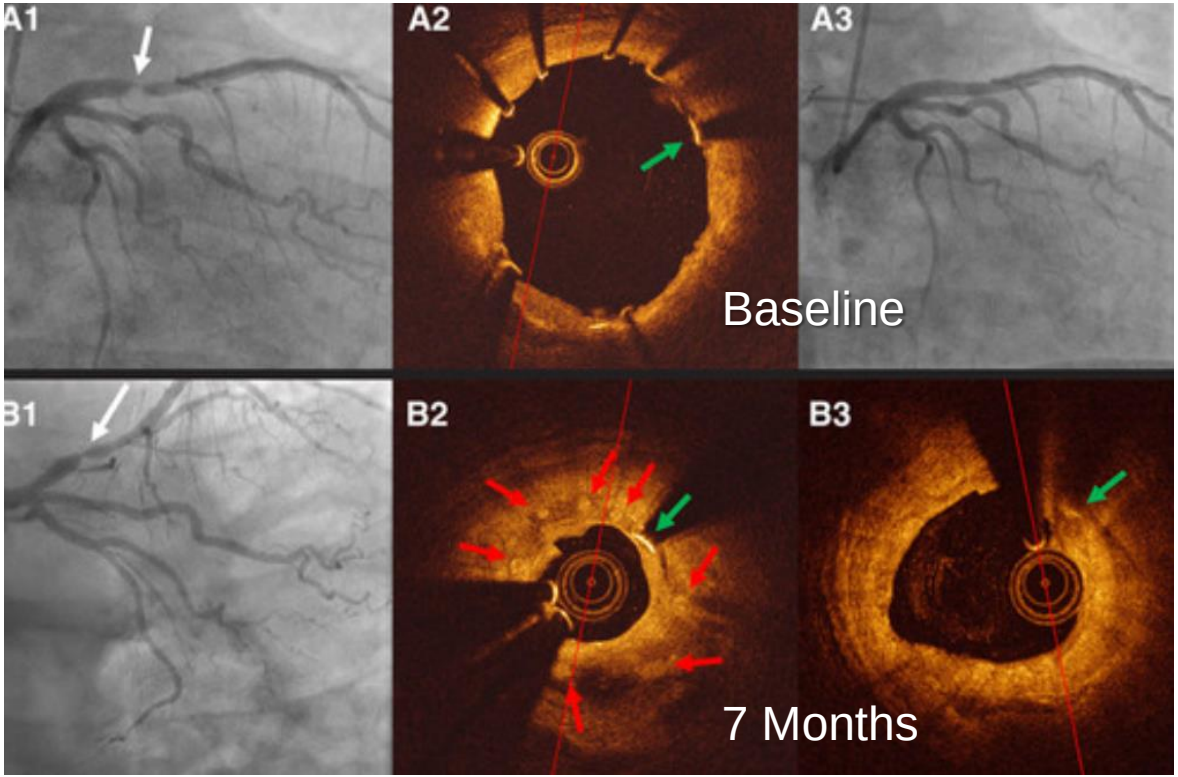
Restenosis in a Collapsed Magnesium Bioresorbable Scaffold (Rare)

Resorption too early to counter negative remodelling of PCI?

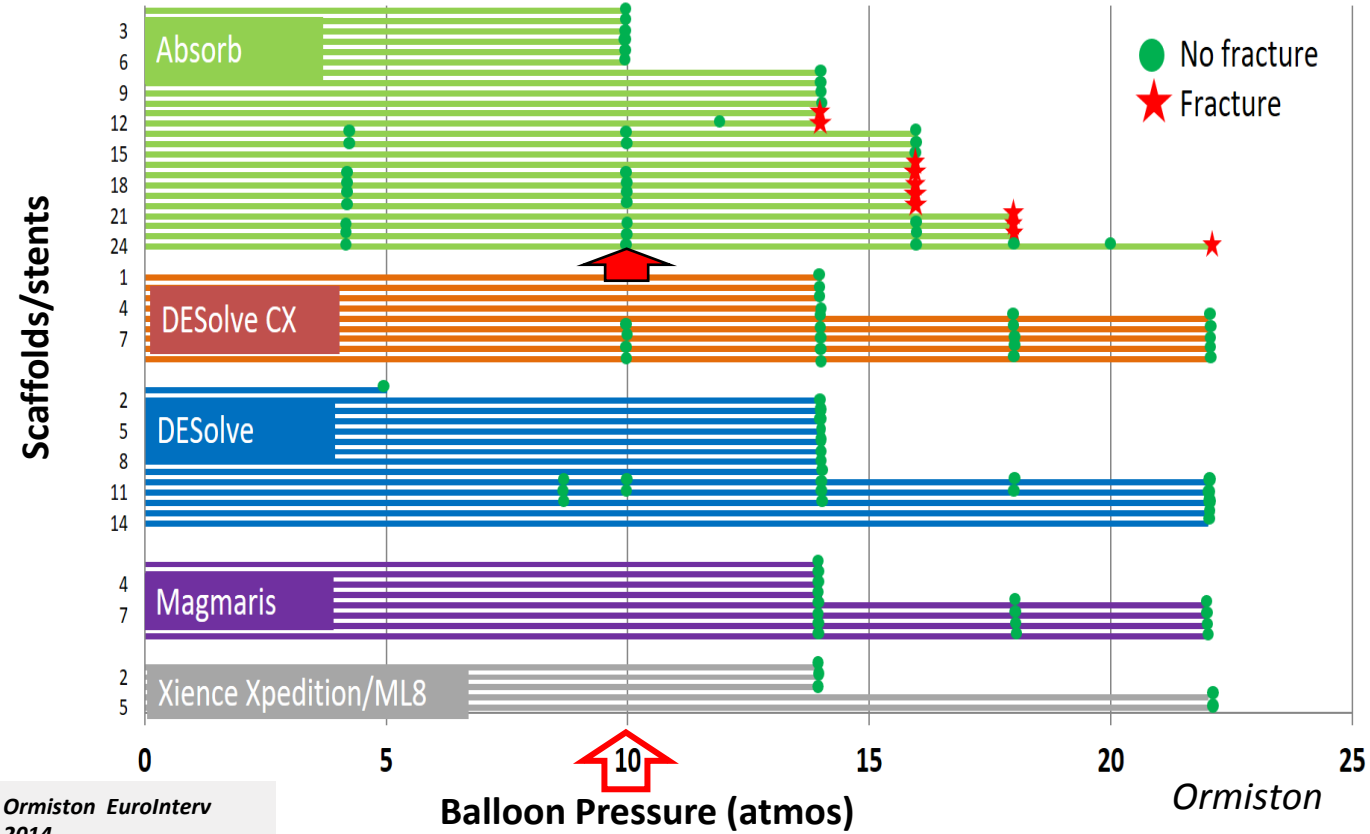


Barkholt Circ Cardiovasc Int 2017

Also
Marynissen CCVI 2018
Yang JACC Interv 2018

3.0mm Side-branch balloon dilatation pressure and strut fracture in 3.0mm scaffolds/stents

10 atm is a safe threshold for Absorb. Others did not fracture



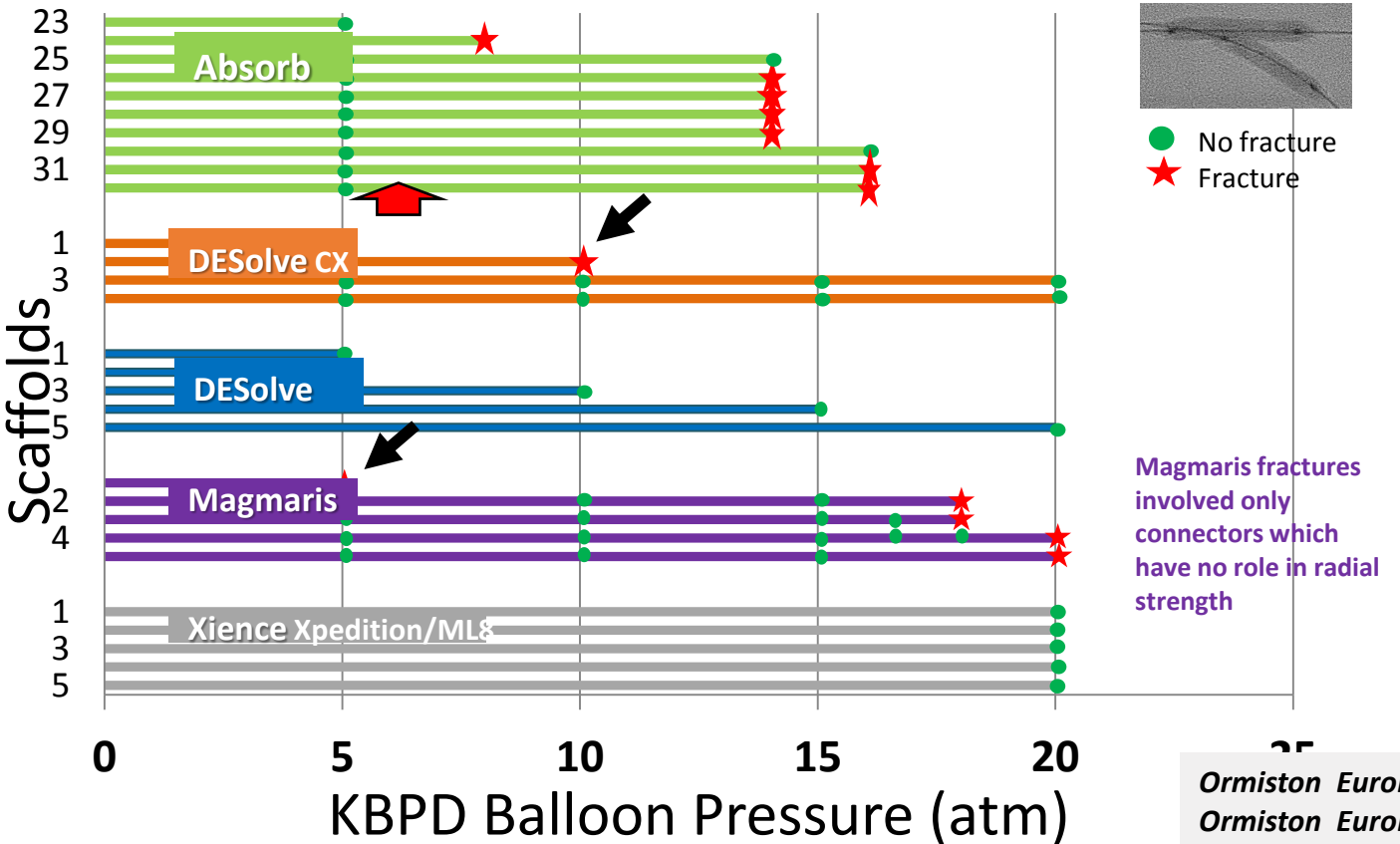
Ormiston EuroInterv 2014

Scaffold fractures during mini-kissing balloon post-dilatation

(30 degree SB angle phantom)

5 atm is the safe threshold for 3.0mm Absorb and two 3.0mm NC balloons

The low pressure fractures for DESolve Cx and Magmaris are “outliers”.



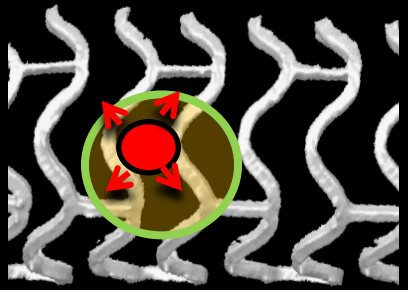
Ormiston EuroInterv 2014

Ormiston EuroInterv 2015

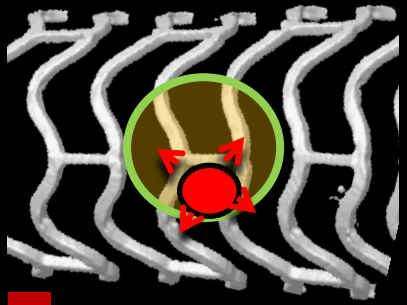
Strut damage is not always predictable

Struts are more fixed in B, scaffold expansion
→ potential for strut rupture

One reason a 2.5mm balloon may sometimes cause strut fracture even in 3.5mm scaffold



A **Strut fracture less likely**



B **Strut fracture more likely**

=Side branch ostium

=Balloon uninflated

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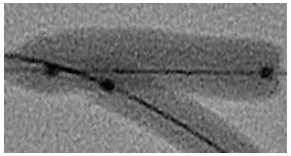
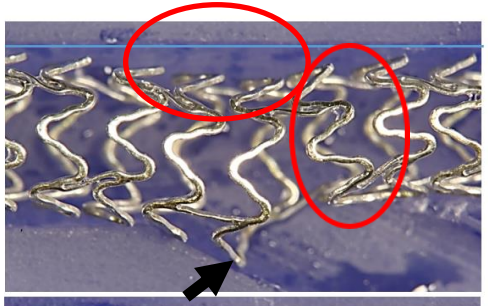
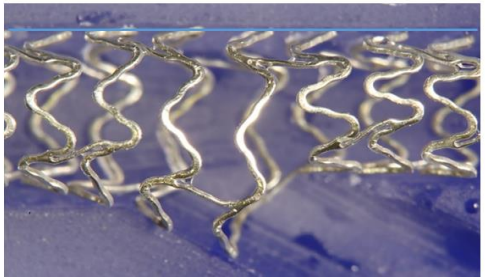
Typical distortion after SB dilation is corrected by mini-kissing balloon post-dilatation





Mini-Kissing Balloon
Post-dilatation at 5 atmos

Mini-Kissing Balloon
Post-dilatation at 10 atmos



Mini-Kissing Balloon
Post-dilatation at 15 atmos

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Summary

- Magnesium has mechanical properties better than polymers and is anti-thrombotic compared with Absorb
- The Magmaris has thinner, narrower and more rounded struts than Absorb and wall coverage (footprint) is less
- With post-dilatation, Magmaris is more resistant to fracture than Absorb but less resistant than DESolve and metallic durable DES
- The Magmaris crossing profile is similar to Absorb but larger than metallic durable DES

Magmaris may be a new hope for BRS