Absorbable Metal Stents

Making use of Biocorrosion

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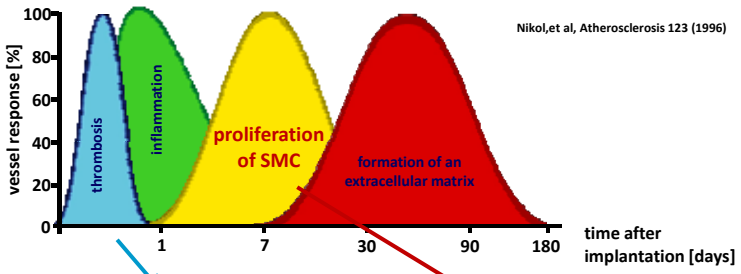
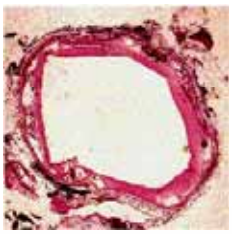
Stents - Host response



Nikol,et al, Atherosclerosis 123 (1996)



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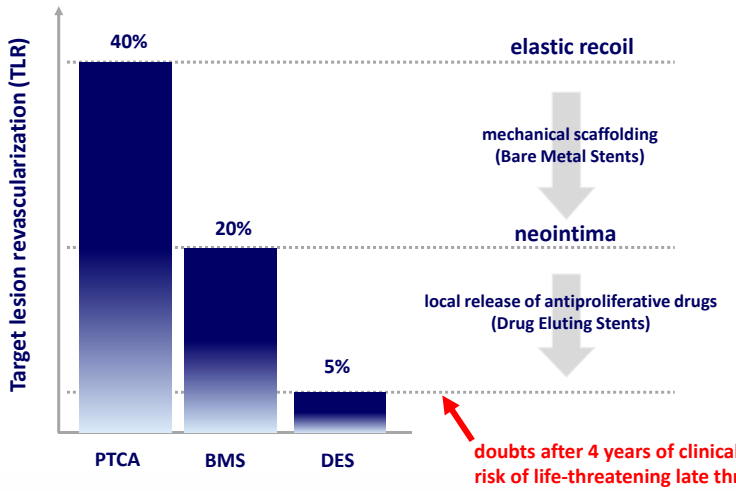
Drug Eluting Stents – overall complication rate (1 year)



Why do we develop a "3rd generation" of bioabsorbable stents?

- In-stent restenosis
- Arterial remodelling
- Long-term endothelial dysfunction
- Constricted vasomotion
- Limitations in surgical revascularization
- Inability to adapt to growth
- Late thrombosis
- Late inflammatory reactions

Bioabsorbable stents would eliminate most disadvantages of permanent stents

Bioabsorbable materials — A promising approach

Only a temporal scaffolding of the vessel is necessary for the treatment of a stenosis …

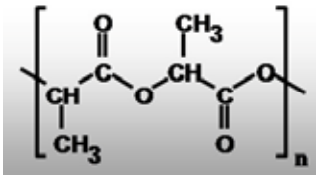
why then using permanent materials for stents?

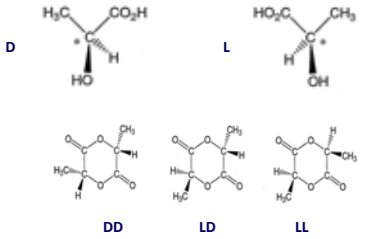
Requirements for bioabsorbable stents

Ideal biodegradable stent:

- Short-term need for vessel scaffolding (3 - 6 months)
- Mechanical stability of the stent structure
- Biocompatibility of all degradation products
- No significant inflammatory response

Biodegradable Polymers: Polylactic acid (PLA)

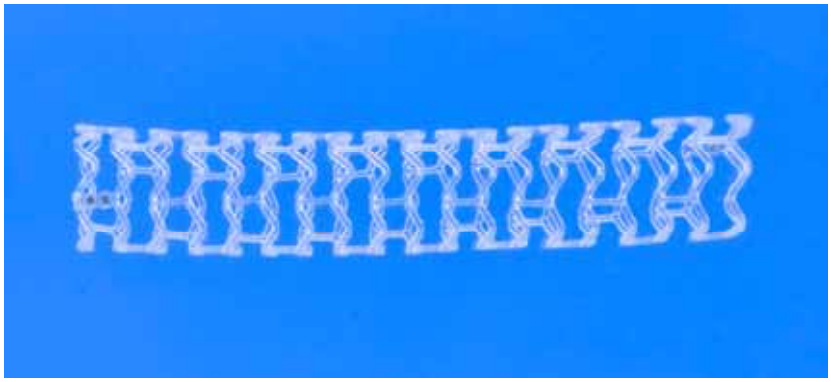




Igaki-Tamai biodegradable peripheral PLLA-based stent

Igaki-Tamai biodegradable coronary PLLA-based stent

Polymer stents in clinical studies



Abbott everolimus-eluting polymer stent (PLA)

Polymer Stent – The Absorb trial

Abbott

Abbott
A Promise for Life

Press Release

New Data Shows Abbott's Bioabsorbable Drug Eluting Stent Is Absorbed Within Two Years – Leaving Behind Functioning Blood Vessels

Data Indicate Bioabsorbable Stent Platform Has Potential to Become the Next Major Breakthrough in Interventional Treatment

October 13, 2008

Washington — Abbott (NYSE: ABT) today announced two-year data from 30 patients in its ABSORB clinical trial, demonstrating that its bioabsorbable drug eluting stent successfully treated coronary artery disease and was absorbed into the walls of treated arteries within two years, leaving behind blood vessels that appeared to move and function similar to unstented arteries. Patients who received Abbott's bioabsorbable drug eluting coronary stent and were followed out to two years experienced no stent thrombosis out to two years and no new major adverse cardiac events (MACE) between six months and two years. These results confirmed earlier positive one-year clinical results with Abbott's bioabsorbable drug eluting stent. The results were presented today at the Cardiovascular Research Foundation's 20th annual Transcatheter Cardiovascular Therapeutics (TCT) scientific symposium.

"Now you see it, now you don't – for the first time, we have data in patients showing that Abbott's bioabsorbable drug eluting stent does its job treating diseased coronary arteries and that it is absorbed by two years," said John Ormiston, M.D., principal investigator in the ABSORB trial and medical director at Mercy Angiography in Auckland, New Zealand. "Clinical safety and effectiveness were sustained at two years, and the previously stented portion of arteries demonstrated the

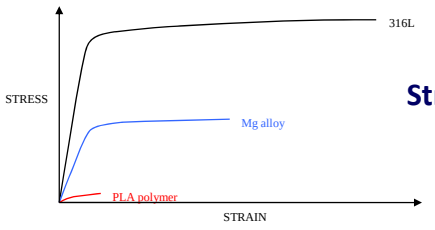
Learn more about Abbott's efforts to develop a fully bioabsorbable stent.

Windows Media

- Abbott PLA everolimus eluting coronary stent
- First in-human clinical trial for biodegradable coronary DES

Evaluation of polymer stents

The mechanical properties of polymers are a serious drawback:



Stress-strain diagramm

Strut section to obtain similar mechanical results:

The Absorbable Metal Stent (AMS)

The “Magic”
Absorbable Metal Stent

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Workshop Biocorrosion of Metals

Christina Engelhard / Flavius Deleanu / Kathrin Lorenz

- Corrosion of metals in the biological environment
- Metals used for biomedical implants
- Absorbable Metal Stents: Iron and Magnesium

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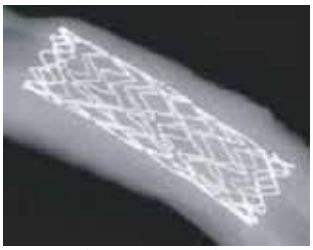
Porcine coronary arteries study

Magic (Mg) Stent
3rd day

Magic (Mg) Stent
28th day



Stainless steel stent
28th day

Reduced
neointima

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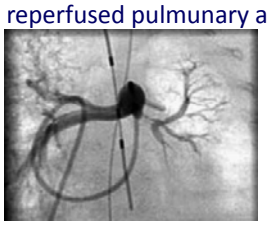
Clinical research applications

2005:
First Successful Implantation of a Biodegradable Magnesium Stent into the left pulmonary artery of a preterm baby

During intervention, partially reperfused pulmunary arterie



1 week after intervention, completely reperfused pulmunary arterie

Utilized stent:
AMS, Biotronik,
Bülach, Switzerland,
diameter 3mm, length 10 mm

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Absorbable stents - Outlook

Comparison aspect	Bioabsorbable Metal Stent	Bioabsorbable Polymer Stent
Advantages (especially in contrast to other group)	Vasodilating properties Beneficial effects Hypothrombogenicity Intrinsic mechanical properties	Combination with drug elution Experiance High flexibility
Results	Fast degradation Successful implantations	Appears safe and effective Thick struts cause problems

Open race between bioabsorbable metal and polymer stent:

- Intrinsic mechanical properties might decide
- Magnesium alloy stent appears more promising