

Resisting the Bioabsorbable Stent “Bandwagon”

A Healthy Dose of Skepticism

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Disclosures

Grant Support/Drugs

- Daiichi-Sankyo
- Janssen Pharmaceuticals
- Eli Lilly
- Astra-Zeneca

Grant Support/Devices

- Edwards Lifesciences
- Medtronic
- Biomet
- Abbott Vascular
- Boston Scientific
- Covidien

Consulting/Advisory Boards

- Medtronic
- Eli Lilly
- Boehringer-Ingelheim
- Astra-Zeneca

I will concede that...

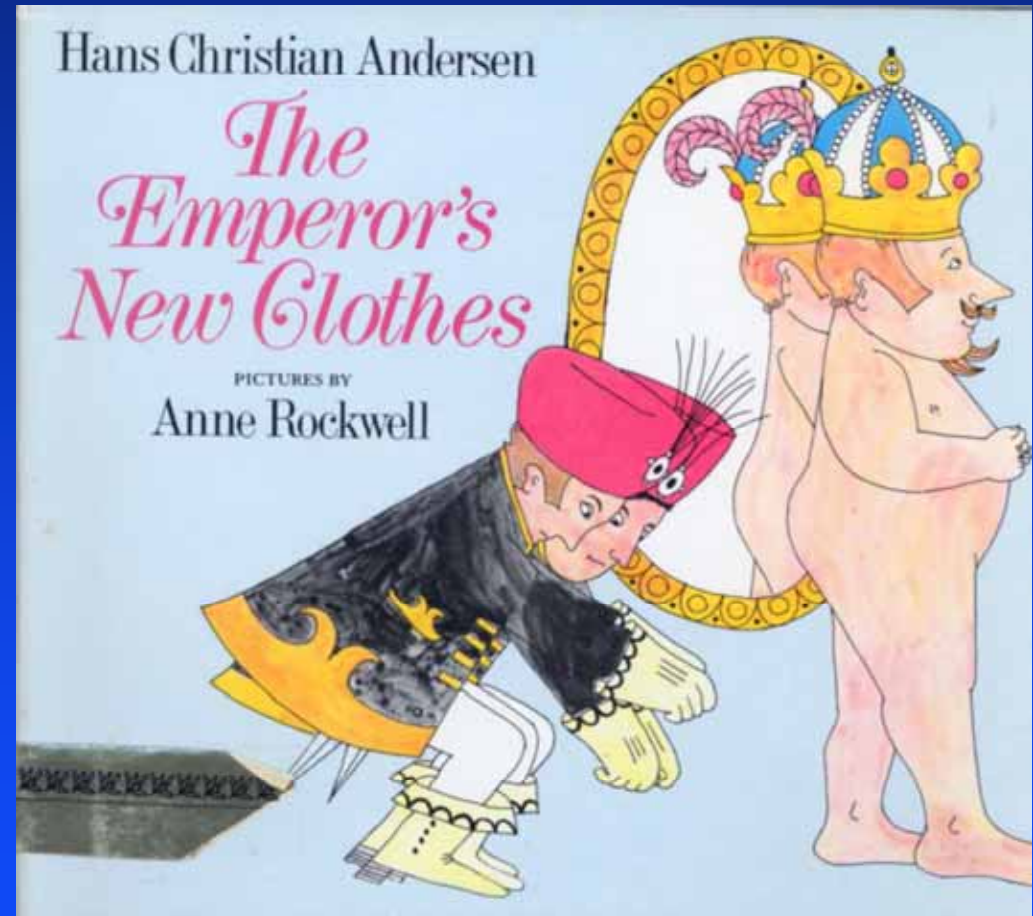
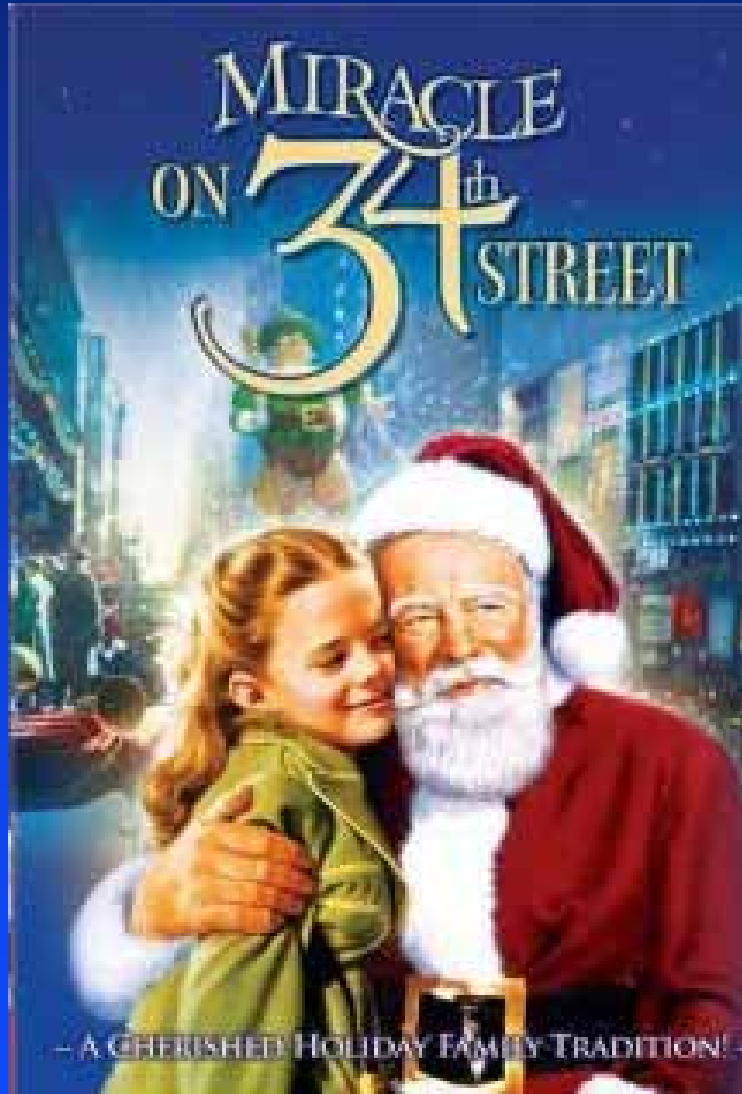
- I am a big fan of new technology
- DES are not perfect
- Early results with BVS have been very impressive and in many cases are comparable to the best current DES designs
- Patrick Serruys has rarely been wrong about important developments in interventional cardiology

Why we should be skeptical

The Annals of Anecdotal Mis-Information

- Positive inotropic agents in heart failure
- Lidocaine “prophylaxis” for acute MI
- Type I antiarrhythmic agents for patients with non-sustained VT
- Magnesium for acute MI
- Chelation therapy for vascular protection

Literary Analogies for BVS



Do BVS Overcome Current DES Limitations?

DES Limitation #1:
Long-term safety
(stent thrombosis)

The Facts

- Even BMS are not immune to late thrombosis
- Current generation DES are actually safer than BMS (recent meta-analyses)

Do BVS Overcome Current DES Limitations?

DES Limitation #2:
DAPT duration

The Facts

- All trials with BVS to date require at least 6 months of DAPT
- Emerging evidence to support early DAPT interruption with EES and ZES

Do BVS Overcome Current DES Limitations?

DES Limitation #3: *Late TLR*

The Facts

- Relatively minor problem with current generation DES (1%/yr)
- Possible advantage of BVS— will require very large trials

Do BVS Overcome Current DES Limitations?

DES Limitation #4:

*Long-term
consequences of
full-metal jacket
stenting*

The Facts

- How often is this really an issue in your practice (unless you are A. Colombo)?
- Most of these patients should probably get CABG anyway

Do BVS Overcome Current DES Limitations?

DES Limitation #5:
*Reduced
vasoreactivity*

The Facts

- BVS can definitely improve long-term epicardial vasoreactivity
- Is this really important, since most regulation of coronary blood flow occurs at the microvascular level?

Disadvantages of Current BVS

- More challenging to deliver and deploy than current advanced alloy DES designs
- Need for advanced imaging to ensure proper sizing
- Achieving good apposition with vessel tapering
- ↑ Cost— both due to the device, itself, and need for more complete lesion preparation

Fundamental Basis for Medical Intervention

Patient's Perspective

1. Live longer
2. Feel better
3. Prevent morbid events

Societal Perspective

1. Cost-effective (affordable)

At the present time, bioabsorbable vascular scaffolds have not demonstrated any one of these attributes

My Position on Bioabsorbable Scaffolds

I'm from Missouri...



... Show
me (the
data)!