ANALYSIS OF CARDIOVASCULAR STENTS TECHNICAL DOCUMENTATION

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Involves: Organic Chemistry, Physics, Fluid Dynamics, 3D Modeling

Model Focus: Honeycomb Design

MOTIVATION

This project is largely inspired by the merging of my passions: Organic Chemistry, Physics, Biological Transport Phenomena, 3D Printing, current NASA internship and the desire to create something meaningful. It also gave me the exciting opportunity to translate engineering into medical practice.

The motivation behind the honeycomb design is NASA's utilization of this model in aerospace applications. The honeycomb pattern (my design focus), sandwiched between two thin panels of material, enables less material to be used than solid products while maintaining a good weight to strength ratio. Whether or not the honeycomb design was originally pioneered by the bees or by NASA is I guess a discussion that could be up for debate.

EXISTING PRODUCTS

WallStent (Boston Scientific): wire mesh stent, self-expanding

The Endeavor (MedTronic)

Cypher (Cordis Corporation/Johnson & Johnson): sirolimus eluting stent, sequential ring design, inert and non-erodible polymeric coating

Taxus (Boston Scientific): paclitaxel eluting stent, inert and non-erodible polymeric coating

XIENCE V: the only DES FDA approved,metallic stent, acrylic coating, drug and polymer are not exposed to flowing blood, eventual degradation of polymer

DESIGN CONSIDERATIONS

- flexibility
- trackable
- biocompatible
- expandable: balloon expandable or self expandable
- radial strength
- low surface area
- hydrodynamic compatible
- corrosion resistant
- long term safety
- patient affordability

Biological Concerns:

- Restenosis
- Thrombosis
- Drug toxicity
- stent causes local arterial tissue destruction

EXPANDABILITY

self-expanding:

manufactured in expanded shape and compressed in delivery system, upon release stent springs back to original shape

- low elastic modulus
- high yield stress

balloon expandable:

manufactured in small diameter and expands upon balloon inflation

- high elastic modulus (stiffer)
- low yield stress

elastic modulus = stress/strain

yield stress: amount of stress at which material becomes permanantly deformed

MATERIAL

How long does a stent need to remain in body to produce noticable results?

Approximately 3 years

What biocompatible (biodegradable?) material matches this lifespan?

DESIGN

There are many different designs possible for stent configuration but it is key to maintain sight of the ultimate goal: homogeneous drug delivery in uniform concentrations (Sangiorgi).

5 main categories of stent design:

- coil
- helical spiral
- woven
- individual rings
- sequential rings

Drugs with:

- wider toxic-to-therapeutic window: regularity of cell spacing is less important (eg: sirolimus)
- narrower toxic-to-therapeutic window: regularity of cell spacing is more important due to toxic doses possibly occurring where stent cells bunch together (eg: paclitaxel)

Therapeutic window: ratio of minimum effective concentration to minimum toxic concentration

Debate can persist of which design is particularly "best", but a possible solution could be utilization of a different stent type specific to the present lesion.

COATING

Gold: highly radiovisible and biocompatible

Silicon carbide: potentially less thrombogenic and more compatible than stainless steel

Phosphorylcholine:

Heparin:

Key Conclusion (Sangiorgi): As indicated from randomized trials, there was no clear clinical benefit of coated stents over bare metal stents.

COST

Stent implantation: 1 million Americans a year (John McPherson, a cardiologist at Vanderbilt University Medical Center in Nashville)

But because we like to think on a grand scale, let's move globally..

Annually: around 17.7 million people die from cardiovascular disease, coronary artery disease most common (Abbott)

Globally: around 8 million (possibly more) received XIENCE stent

Cost of Bare Metal Stent (BMS): $111.8 (NPPA cap)

Cost of Drug Eluting Stent (DES): $407 (NPPA cap)

Facility Fee of stent placement: $17,000-$53,000, US median: $21,000

DRUG DELIVERY

- bio-absorbable polymeric stent
- drug bound to surface or embedded in nano-pores
- stent is coated with outer layer of polymer that is drug loaded

REFERENCES

Sangiorgi et al. Engineering aspects of stents design and their translation into clinical practice. 2007.