Technical Characteristics of coronary prostheses(stents)

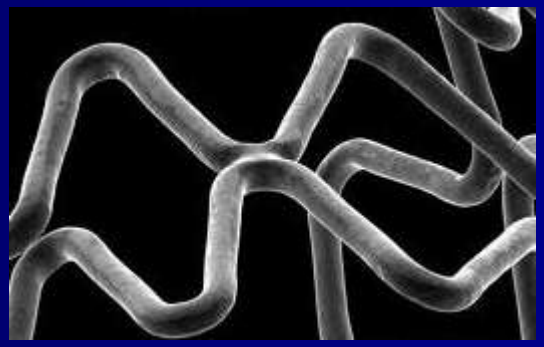

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Fig. 1. Charles Stent, 1807-1885.

The word "stent" is attributed to Charles R. Stent, a nineteenth century English dentist, and was originally used to describe a mold for keeping a skin graft in place

Coronary stents/coronary prostheses

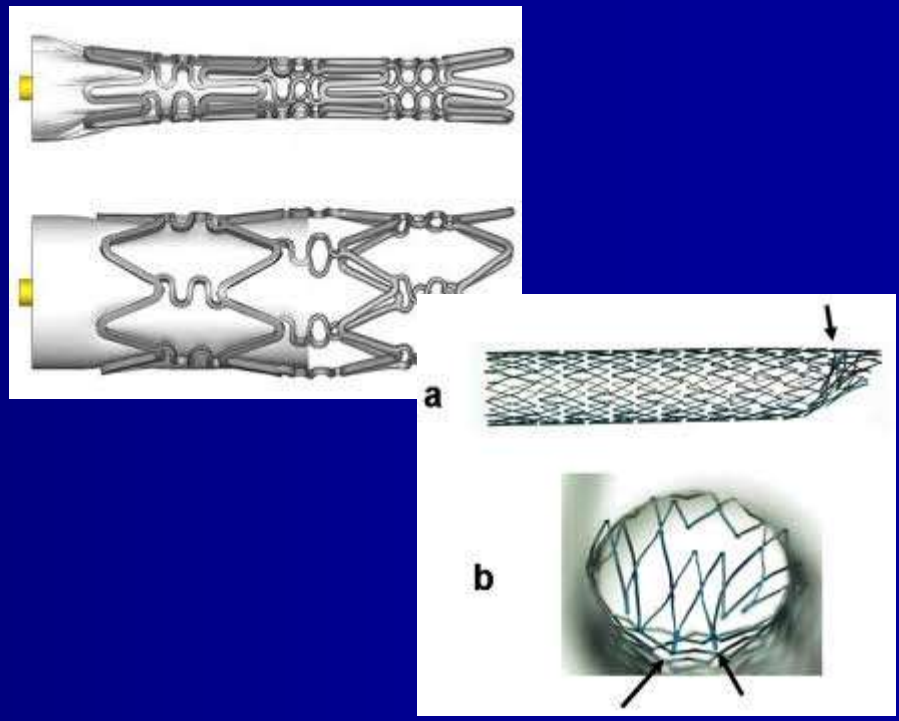
Coronary stents are scaffolds permanently deployed within diseased segments of coronary arteries to restore and maintain luminal vessel patency.

Changes in Luminal Dimension Over Time After Coronary Intervention

Classification according to the mode of expansion

- Balloon-expandable stents
  (more than 98% currently used)

- Self-expanding stents



Balloon-expandable stents

- Mounted on a delivery balloon in a collapsed state
- Inflation of the balloon expands and imbeds the stent into the arterial wall
- A stent diameter with a ratio of 1.0-1.1 to the reference vessel diameter is chosen with an adequate length for complete lesion coverage starting 2mm before and after the lesion shoulder
- Implanted at ≥12-15 atm. and if it is necessary higher pressure noncompliant and/or larger postdilatation balloon is used for achievement of the lowest possible residual stenosis which is close to 0%
- Finally the stent delivery system is removed

Self-expanding stents

- Are mounted onto the delivery system in a collapsed state and constraint by a restraining membrane or a sheath with an unconstraint diameter 0.5-1.0 mm greater than reference vessel diameter
- The extreme flexibility and the reduced friction in fibrocalcific vessels was initially hoped to reduce vessel trauma and restenosis but it was not shown in controlled clinical trials.
- Difficulties in precise placement, sizing and a longer learning curve, render them unsuitable especially in ostial or adjacent to side branches lesions.
- Supplanted almost totally in coronary arteries and grafts by balloon-expandable stents.

Classification of coronary stents based on their composition

- Metallic
- Polymeric

Metallic coronary stents

- The most widely used metal is 316L stainless steel which is biologically inert but contains also about 5% nickel ,allergy to which may be linked to increased risk of restenosis.
- Metallic alloys of tantalum, cobalt/platinum, cobalt/chromium , allow construction of thinner stent struts without effects on strength or radiopacity.
- A surface layer of chromium oxide may reduce biological activity while gold surface coatings increase restenosis compared to stainless steel.
- Biodegradable/ bioabsorbable metals.

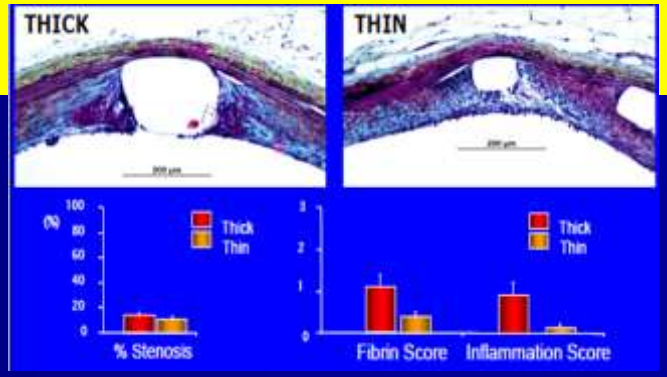
THIN STRUT vs. THICK STRUT

VS.

The Value of Thin Stent Struts

- **PreClinical Models have demonstrated**

- **Reduced acute injury**
- **Reduced inflammation**
- **Rapid incorporation of struts within neointima**
- **Rapid re-endothelialization**



Classification of stents based on their configuration-design(1)

- Slotted tube: are laser cut slotted tube stents, with fenestrations according to their design.
- Laser cutting produces minimal mechanical and thermal damage.

- Also laser cutting is high quality with precision in the micrometer level.

Classification of stents based on their configuration-design(1a)

- Corrugated, modular or hybrid stents:

  created by flexibly joining multiple repeating modules to each other.

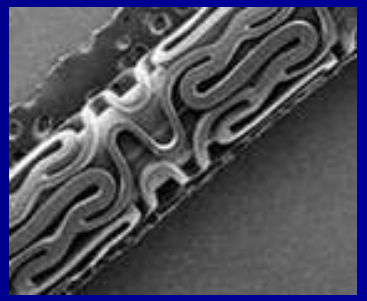
- Coiled wire:

  is a monofilamentous interdigitating coil-like structure mounted on a balloon catheter.

Classification of stents based on their configuration-design(2)

- **Open cell designs**:

  varying cell sizes and shapes providing increase flexibility, deliverability and side branch access conforming better on bends but may open excessively on the outer curve.

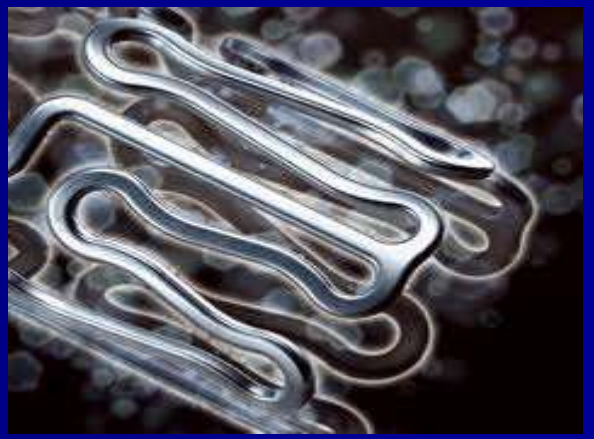


- **Closed cell designs**:

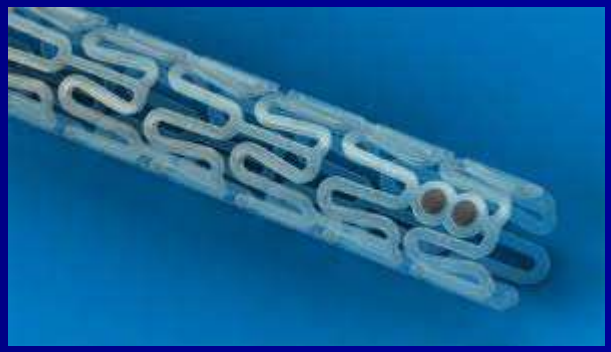
  repeating unicellular elements providing more uniform coverage at the expense of reduced flexibility and side branch access and also a tendency to straighten vessel bends more than open cell configurations.

Classification of stents based on bioabsorption

- Inert-biostable

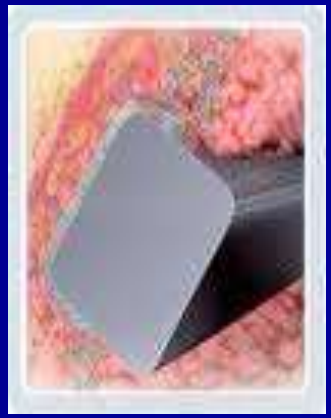


- Degradable-bioabsorbable



Classification of stents based on their coating

- None
- Passive: PTFE, micro porous membrane, covalent heparin e.t.c.
- Bioactive: drug eluting e.t.c.



Classification of coronary stents based on every day clinical practice

Coronary stents

- - BMS
- - DES
- Bioabsorbable or Biodegradable stents(Bare or Eluting)

- Covered stents: PTFE, Vein, Other.
- Genetically engineered etc.
- Dedicated stents

Stent Delivery System(SDS) –Mechanical Performance

- PUSHABILITY: is defined as the ability of the SDS to transfer the proximal exerted force (F prox) by the operator to the distal tip (F dist) of the system.
- Essentially: the amount of force lost in the system.
- Both forces can be measured in vitro in vessel models derived from typical vessel anatomy and pushability can be calculated as: (Fdist /Fprox) x 100%

Stent Delivery System(SDS) –Mechanical Performance

- TRACKABILITY: the ability of the SDS to track or move easily through a curved vascular pathway.
- Essentially: a measure of the resistance against the SDS moving through a curved vessel pathway.
- The lower the proximal push forces, the better the trackability.

Stent Delivery System(SDS) –Mechanical Performance

- CROSSABILITY: is considered as the ability of the SDS to pass through the target lesion.

- Crossability is influenced by distal reactive forces developed during crossing the lesion.

Stent Delivery System(SDS) –Mechanical Performance

- BENDING STIFFNESS of the crimped stent: is a measure of the structure's resistance to bending deformation and is the reciprocal of flexibility.
- It is a function of the ratio of the bending force and the deflection of the SDS due to this force.
- The larger the ratio, the higher the bending stiffness.

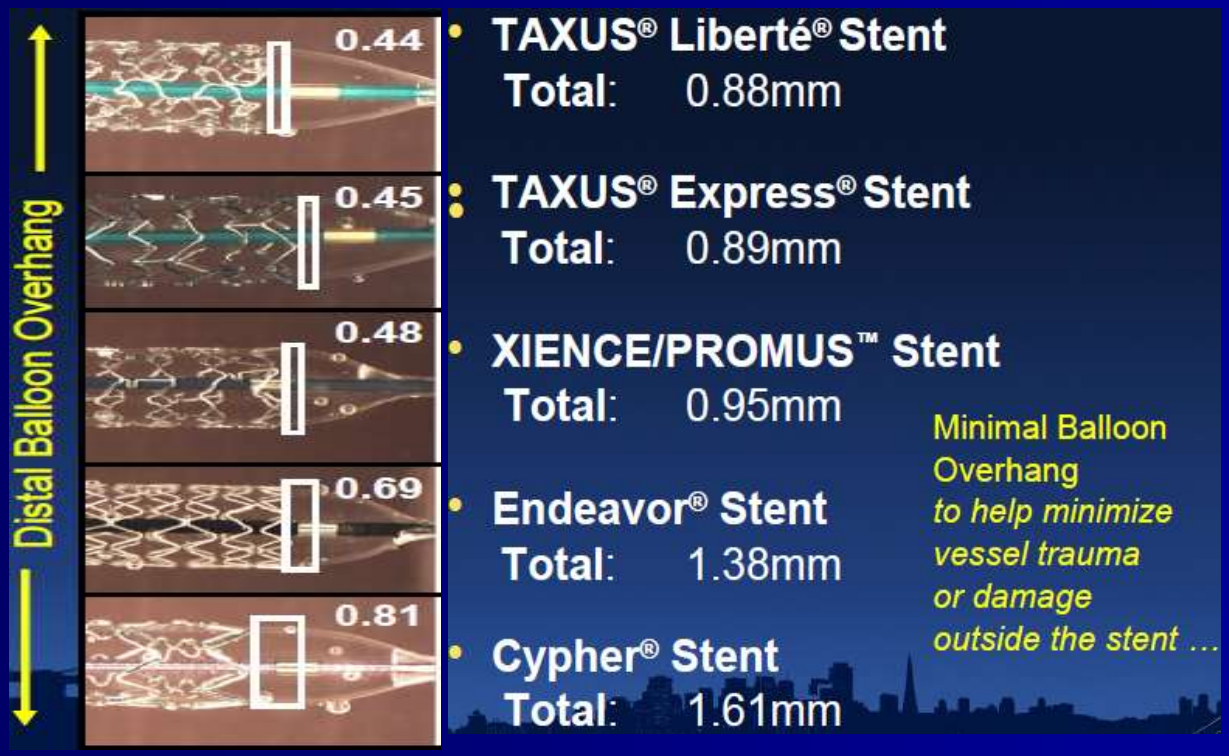
Stent Delivery System(SDS) – Mechanical Performance

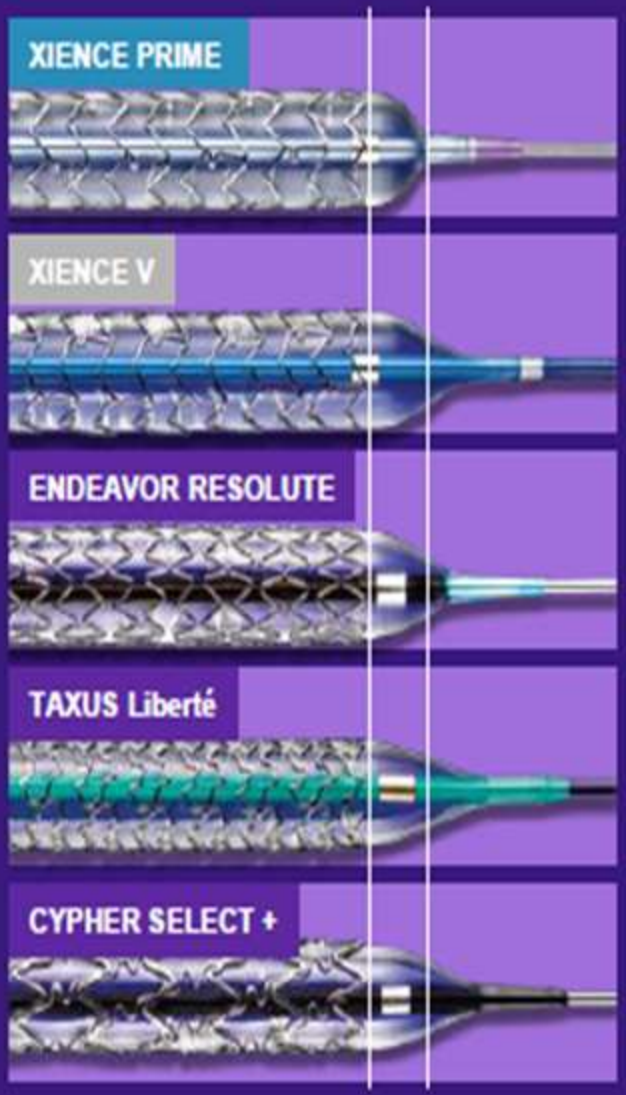
- CONFORMABILITY: The flexibility of the stent to conform to the vessel.
- FLEXIBILITY refers to the stent system as a whole.

Stent Delivery System(SDS) –Mechanical Performance

- STENT PROFILE: is defined as the outside diameter of the stent-carrying SDS segment with the stent crimped on the balloon catheter.

Stent profile-balloon profile hang over





Device	RBP (atm)	Balloon Outside Stent (mm)
XIENCE PRIME	18	2.10
XIENCE V	16	3.41
ENDEAVOR RESOLUTE	16	3.30
TAXUS Liberté	18	4.07
CYPHER SELECT +	16	3.93

38% Reduction Compared to XIENCE V

Minimal balloon outside of stent reduces potential for peri-stent injury[1]

STRUT APPOSITION AND DELIVERABILITY

- GOOD STRUT APPOSITION: The ability of the stent to sufficiently expand so that its struts abut against the vessel wall.

- DELIVERABILITY: The general term physicians use to indicate the overall ease with which a stent system can be "delivered" to the lesion site.

STENT SHORTENING

- Transition from the crimped state to expanded state causes a small shortening along its long axis.

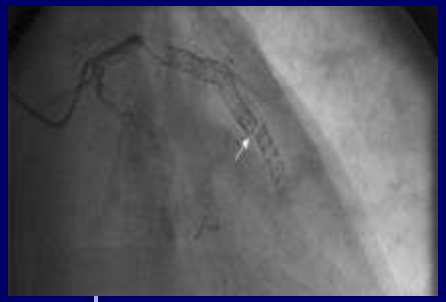
- This may be crucial when treating ostial lesions.

SURFACE AREA COVERAGE

- Refers to the ability to cover the lesion and is measured as the percentage of vessel wall surface covered by the expanded stent.
- The amount of metal surface area maybe related to a tendency towards thrombus formation.
- Inadequate metal surface area may be unable to withstand the elastic recoil and provide adequate scaffolding of severe dissections thus facilitating thrombus formation and/or restenosis.

STENT RECOIL

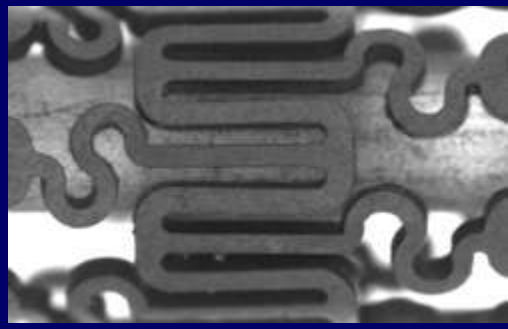
- Stents are expected to exhibit sufficient radial strength and minimum radial recoil.
- This means that expanded stents must resist to crushing-deformation of their geometry and diameter.
- There are numerous in vitro methods for evaluation of radial strength and radial force.



VISIBILITY

- VISIBILITY: the ability to visualize the stent by fouoroscopy.
- Necessary for optimal stent placement.
- It is not sufficient to rely on balloon markers since this relationship may change slightly during advancement through the guiding catheter.

STENT BIOCOMPATIBILITY



- Refers to the ability of stent material to resist to thrombosis, corrosion and not to cause allergic reactions or toxic effects.
- Minimization of tendency to thrombosis can be achieved by highly polished, ultra-pure grades of stainless steel and by minimizing the metal surface area.
- A surface layer of chromium oxide may reduce biological activity.

Stent Properties

What influences design modifications?

- Scaffolding
- Visibility
- Deliverability
  - Flexibility
  - Trackability
  - Profile
  - Smoothness
- Conformability
- Securement

- Radial strength
- Recoil
- High pressure balloon
- Non -compliant balloon
- Size and length
- Monorail
- 6 fr compatible
- Side branch access
- Pushability

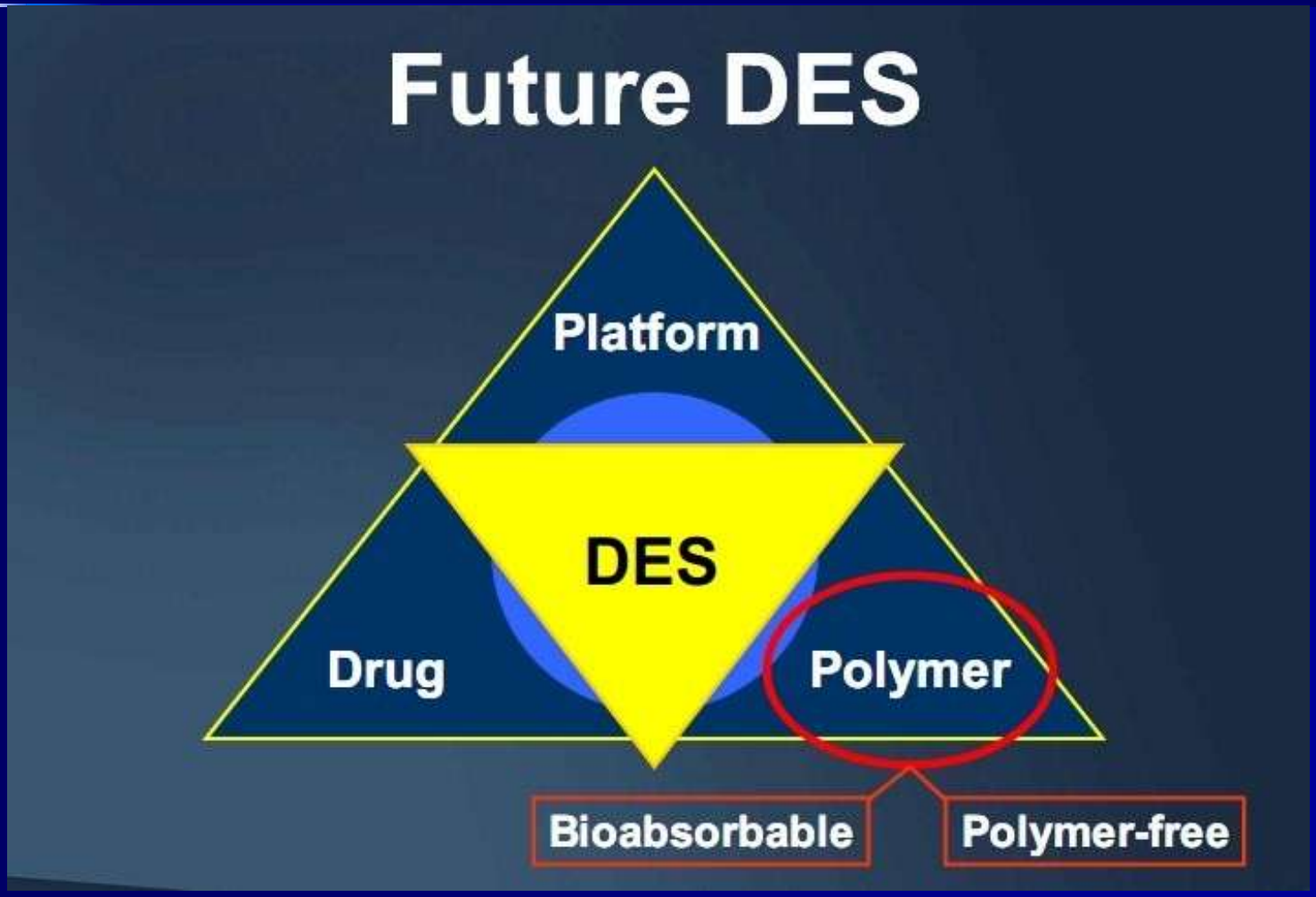
DRUG ELUTING STENTS

The combination of stent properties to inhibit recoil and negative remodeling with drugs that inhibit neointimal proliferation, utilizing the stent as a local delivery platform, have emerged as a highly promising alternative to reduce instent restenosis.

DES STRUCTURE

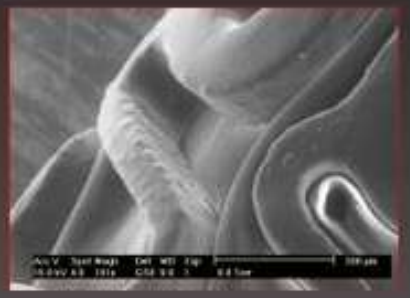
- Backbone
- Polymer or other system (laser cut holes in the backbone e.t.c.
- Drug
- Delivery system

An important factor of uncertainty about the efficacy of drug-eluting stents is the use of polymers

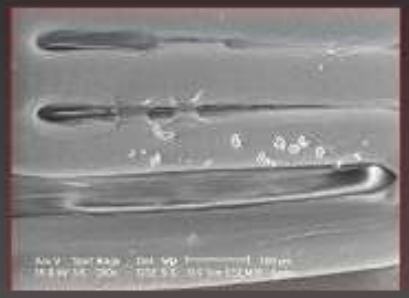


Current Problems with Polymers

Shortcomings often associated with polymers during stent delivery



Non uniform polymer coating



"Webbed" polymer surface leading to stent expansion issues"

Polymer delamination

- Durable Coatings-Potential for:
  - Continuing source of inflammation
  - Poor healing/thrombosis risk

Preferred Combined DES properties

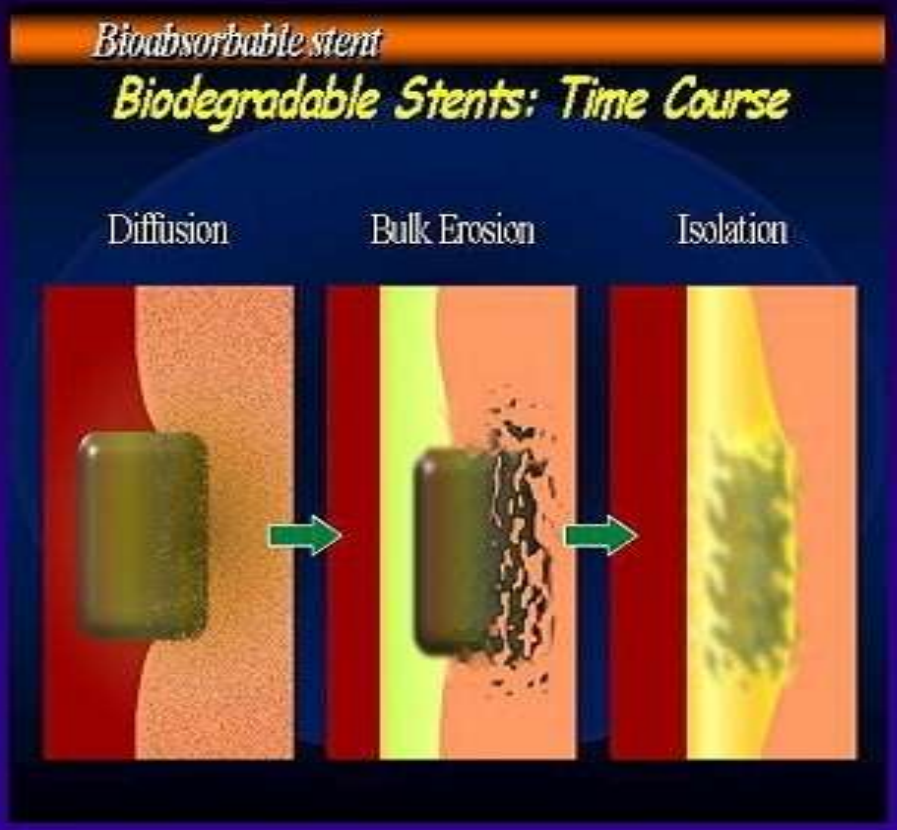
- Safety
- Efficacy
- Deliverability
- Durability

BIOABSORBABLE STENT STRUCTURE

- Polymer-based bioabsorbable stents
  - -Non drug eluting
  - -Drug eluting

- Non polymer-based bioabsorbable stents
  - -Non drug eluting
  - -Drug eluting

Biodegradable stents

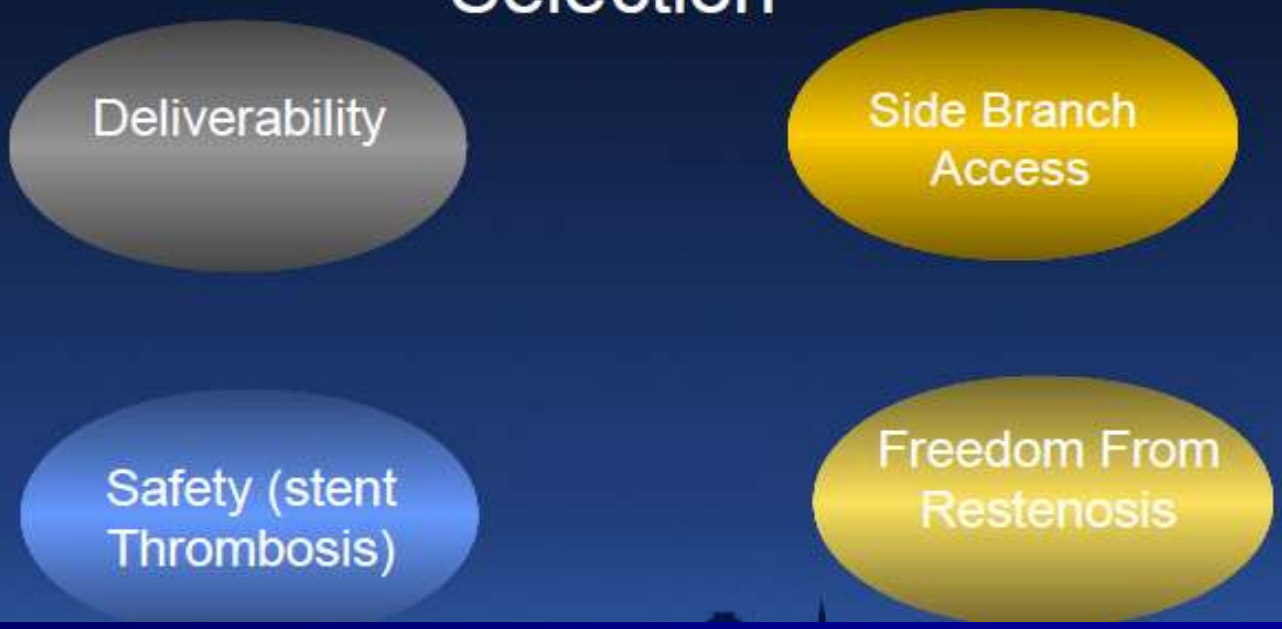


CLINICAL UTILITY OF BIOABSORBABLE STENTS

- Leave no permanent implant, so repeat PCI or CABG maybe accomplished easily if needed at a later time.
- Tissue response issues have been solved with newer designs.
- Are compatible with MRI and CT- angio.
- Likely useful in younger patients and promising in the field of pediatric cardiology.
- May provide temporary scaffolding of vulnerable plaques and prevent their rupture.

Stent Selection

- Key Factors that Influence Stent Selection



STRIVE FOR AN OPTIMAL ANGIOGRAPHIC STENT RESULT

- A residual stenosis <10%.
- No edge dissection greater than NHLBI type A.
- TIMI grade 3 flow.
- Patency of all side branches ≥2.0mm in diameter.
- Absence of distal thromboemboli, perforation or other angiographic complications with associated chest pain, electrocardiographic changes, or hemodynamic instability.

Predilatation vs. direct stenting

- DIRECT STENTING may be considered with bare metal or drug-eluting stents when guide catheter support is good to excellent. Lesions generally not amenable to direct stenting include those with excessive vessel or lesion tortuosity or calcification, diffuse disease or subtotal stenoses, bifurcations, acute myocardial infarction or chronic total occlusions.

- If direct stenting is not feasible, PREDILATION should be performes with balloons undersized to the reference diameter by 0.5mm, and with length shorter than the lesion so as to not extend the length of stenosis requiring stenting.If this degree of predilatation does not allow stent passage, larger and /or higher-pressure balloon inflations may be required.

OPTIMAL STENT SELECTION AND IMPLANTATION

Choose the optimal stent length

- Ensure adequate lesion coverage while avoiding excessively long stents, as stent length is a risk factor for periprocedural myonecrosis, stent thrombosis,and restenosis.
- Implant the stent from normal reference to normal reference if possible (starting 2 mm before and after the lesion shoulder),which will avoid edge dissections. An edge dissection, unless mild, should be treated with an additional short(8-10mm) overlapping stent.
- In diffusely diseased vessels, a normal reference segment can not be identified. The most severe atherosclerotic segments should be stented so that there are no major inflow or outflow lesions lesions to any stenosis.Spot stenting may be preferable to the "full metal jacket" with bare metal stents.
- For long lesions, use one long stent if possible. If multiple stents are required, they should overlap by ~3mm to ensure complete coverage, a technique that does not increase restenosis.
- Modification for drug eluting stents: Stent and lesion length are not so critical for restenosis, so more liberal use of long stents is favored.Use 3-4mm edge margins.

OPTIMAL STENT SELECTION AND IMPLANTATION

Choose the optimal stent diameter

- Size the stent diameter with a ratio of 1.0-1.1:1.0 to the distal reference diameter.
- If the vessel is tapering, a larger noncompliant balloon can then be used to more fully expand the proximal stent segments.
- Be aware that in the same stent line, different-sized stents exist for different-dimeter vessels (e.g.the six-cell Cypher for 2.5-3.0-mm vessels, and the seven-cell Cypher for3.5-4.0mm vessels;)Oversizing stents designed for small vessels will lead to inadequate scaffolding and possibly strut fracture.

OPTIMAL STENT SELECTION AND IMPLANTATION

Implant the stent at adequate pressure

- Most stents should be implanted at≥12 atm.
- Higher routine implantation pressures(16-18atm or greater) are preferred by many to optimize stent expansion and are required in fibrocalcific lesions.
- In diffusely diseased vessels, consider implanting the stent at 12-14 atm to avoid edge dissections, and then post-dilate the stent at higher pressures using a short noncompliant balloon positioned within the stent margins.

Stent Development

FUTURE Stent Technology may include:

- Different drugs on stents to combat restenosis
- Different drugs on stents to increase endothelial healing
- Combination of drugs on stents
- Bioabsorbable stents
- Stents with progenitor cells (stem cells)
- Gene therapy stents

THANK YOU FOR YOUR UNDEVIDED ATTENTION!