What exactly is a Bio Active Stent (B.A.S) ?

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Potential conflicts of interest

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I have the following potential conflicts of interest to report:

Consulting: InspireMD
Speakers bureau: Medtronic Vascular, Cordis Corporation, Hexacath
What is exactly a Bio Active Stent?

**Introduction:**

- A Bio Active Stent (B.A.S) is a stent which substitutes a biologically active coating to the pharmacological substance found in DES.
What is exactly a Bio Active Stent?

Titanium-Nitride-Oxide Biological Activity

I - The Fundamental Evidence
Titanium reduces inflammation (1)

Titanium-Nitride-Oxide Biological Activity

CORROSION RESISTANCE

10,000

2000

1

TOXICITY

SEQUESTRATION

INERTNESS

Cobalt

316L

CoCr

TITANIUM

+400%

Steinemann et al, Injury 1996
Titanium Oxide unlike other biocompatible materials has unique biological properties that reduce platelet aggregation & fibrinogen binding.

The formation of a thrombus on an artificial material is correlated with charge transfer from the inactive state of fibrinogen to the surface of the material.

Titanium Oxides have the potential to inhibit the electron transfer from fibrinogen to the coating surface thus minimizing the thrombus formation:

Zhang et al, Surface & Coatings Technology 1996
Titanium-Nitride-Oxide Biological Activity

Titanium-Nitride-Oxide further reduces thrombogenicity (4)

- Titanium-Nitride-Oxide is Active reducing platelet adhesion and fibrinogen adsorption vs. Titanium:

Tzyganov et al, NIMB Beam Interactions with Materials & Atoms 2007
Titanium-Nitride-Oxide promotes Endothelialisation (5)

- Titanium-Nitride-Oxide is Active in promoting endothelial cells growth vs. Stainless Steel:
Conclusions:

Thus, the four mechanisms of action of Titanium-Nitride-Oxide have each important impacts on:

- Reduction of Inflammation,
- Inhibition of Platelet Aggregation
- Minimizing Thrombogenicity
- Promoting Endothelial Cells Growth.

These encouraging scientific findings need to be confirmed by Animal & Clinical data.
What is exactly a Bio Active Stent?

Titanium-Nitride-Oxide Biological Activity

II - The Clinical Evidence
BAS versus DES

In the Animal Model
Titanium-Nitride-Oxide Biological Activity

BAS versus DES in the Animal Model

BAS PORCINE MODEL STUDY

DES PORCINE MODEL STUDY

Windecker et al, Circulation 2001

Suzuki et al, Circulation 2001
BAS versus DES

In Human
Titanium-Nitride-Oxide Biological Activity

BAS versus DES in Human

BAS RANDOMIZED TRIAL vs. BMS: TINOX STUDY

TITANIUM-NITRIDE-OXIDE PROVEN EFFICACY IN HUMAN VS. BMS

p<0.03
0.55±0.63 TiNOX
0.90±0.76 Control

Late Loss (mm)

% Patients

0
5
10
15
20
25
30

DES RANDOMIZED TRIAL vs. BMS: RAVEL STUDY

Sirolimus-eluting stents and Bare stents

number of lesions

late loss (mm)

0
10
20
30
40
50
60
70

SIROLIMUS PROVEN EFFICACY IN HUMAN VS. BMS

Windecker et al, Circulation 2005

Moric et al, NEJM 2001
BAS versus DES

In Randomized Trials
@ Long term Follow up
Titanium-Nitride-Oxide Biological Activity

BAS vs. DES in Randomized Trials

**BAS: TINOX 5-YEAR FOLLOW UP**

- BAS: has shown No Late Catch Up
- No Late/Very Late stent thrombosis
- No long term dual antiplatelet required

**SES: RAVEL 5-YEAR FOLLOW UP**

- SES have shown Late Catch Up
- Issue with Late & Very Late stent thrombosis
- Long term dual antiplatelet treatment required

The TINOX Trial
**MACE @ 5 years**

- TiNOX BAS
- Control BMS

What does RAVEL Reveal?

- Sodium
d- Bare metal stent
- Sirolimus

The early angiographic end-point clouds
the interpretation of the late follow-up
What is exactly a Bio Active Stent?

Conclusions
Basic and Clinical Studies have validated the biological properties of the Titanium-Nitride-Oxide coated stent from Hexacath: the first Bio Active Stent (BAS).

BAS like DES is a new category of stents reducing restenosis but is **not** associated with:

- Late Catch Up,
- Late & Very late Stent thrombosis,
- The need for long term dual antiplatelet treatment.

BAS should be considered as a true alternative in PCI along with DES or BMS.
What is exactly a Bio Active Stent?