

Melissa I



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Melissa I

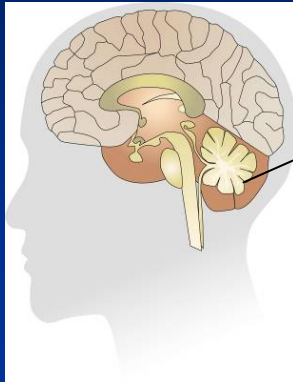
Melatonin Eluting Layers,

An Investigative Study for Safety and
Accuracy

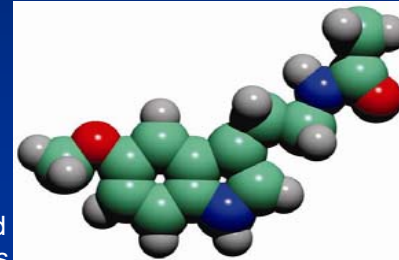


Melatonin

(N-acetyl-5-methoxytryptamine)



Pineal gland



Stimulates
antioxidative
enzymes

Wide intracellular
distribution

Inhibits
pro-oxidative
enzyme

Reduces
NF-KB binding
to DNA

Detoxifies oxygen-based
radicals/reactive species

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Reduces
pro-inflammatory
cytokines
Reduces adhesion
molecules

Crosses all
morphophysiological
barriers

Stabilizes cellular
membranes

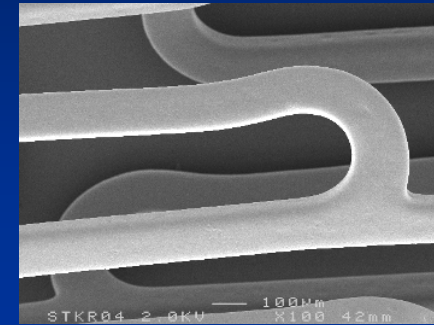
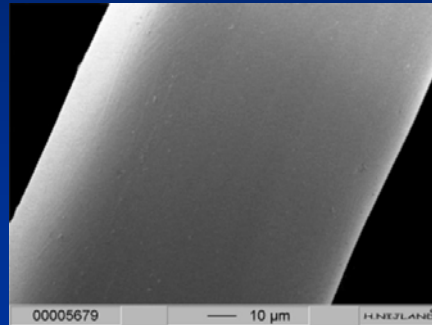
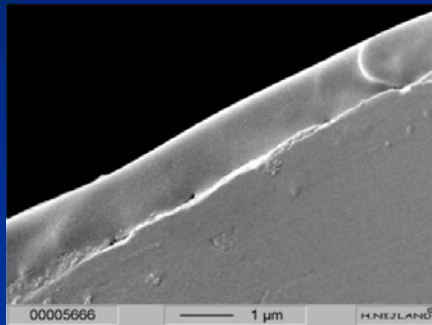
Increases efficiency of
oxidative phosphorylation

- A human hormone produced in the pineal gland, mainly to control the biological clock and 24h rhythm
- Known for several beneficial effects on cardiovascular disease
- Extensive animal and cell biology data prove **strong reduction** of proliferation **without any cell death**

- Bio-compatible
- No toxic dose
- Anti-cancer effect
- Strong antioxidant
- Inhibition of NO tolerance
- Cardio protective
- Suppresses formation of cholesterol
- Reduces blood pressure



PEA bio-degradable coating



- PEA is based on natural amino- and fatty acids, which means it is fully biocompatible and non-toxic and **non-inflammatory**. Therefore it is not necessary to overcome toxicity and inflammatory responses of the coating.
- The active compounds are released through the bio-absorption of the delivery layers ensuring all drugs and coating is gone after 60 days; **NO LATE THROMBOSIS RISK FACTORS.**
- Human data of the coating (Noblesse Study) indicated efficacy and safety (late loss at 24months FU: 0.69)

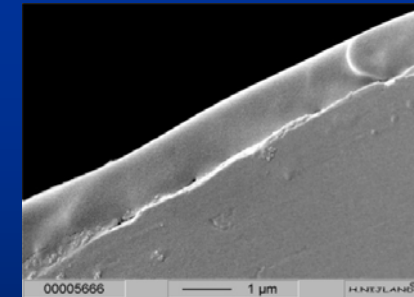
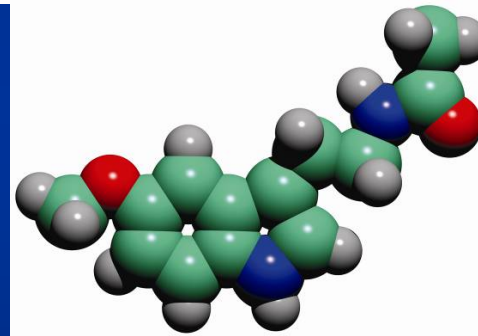


MELISSA

Non-Toxic and safe next generation through vessel healing



- **Drug: Melatonin**
 - Nitric Oxide preserving
 - Anti-inflammatory
 - Strong anti-oxidant
- **Drug carrier: PEA**
 - Fully bio-degradable and bio-absorbable coating
- **Platform:**
 - Blue Medical XTRM FIT Coronary Stent System



Primary Endpoint

- Six-month follow-up in-stent restenosis and late loss determined by QCA and IVUS



Secondary Endpoints

- MACE at 30,60 days and 12 months
- Binary restenosis rate at 6 months
- Acute, subacute, late stent thrombosis
- Functional class



Melissa I

- Baseline Patient Demographics
- Number 13
- Female 7.7%



Melissa I

- Baseline Lesion Characteristics, N=13
- Lesion RCA 31%, RDA 69%
- Type A 7.7%, B 92.3%
- Tortuosity: none 84.6%, moderate 15.4%
- Calcification: none 84.6, moderate 15.4%



Melissa I

- Procedural, N=13
- Pre/post dilatation: 23.1%/15.4%
- Stent length (mm): 14 (38.5%), 18 (61.5%)
- Stent diameter (mm): 3.0 (46.2%), 3.5 (53.8%)



Melissa I

- In-hospital events:
- Days from procedure-discharge: 0.85
- No complications



Melissa I

- 1 month:
- No angina: 76.9%
- CCS class I-II-III: each 7.7%



Melissa I

- 6 month:
- No angina: 76.9%
- CCS II: 23.1%
- No stent thrombosis, MI 7.7%, no death
- Additional PCI's: 23.1% (TLR), 7.7% (TVR)



Melissa I

- Angiographic data:
- Pre PCI: Ref \emptyset 2.75, length 13.43
- Post PCI: MLD 2.61
- 6 month: MLD 1.56



Melissa I

- IVUS:
- MLD: 2.66, 6 month: MLD 2.15
- Stent volume: 110.6, 6 month: 106.8



Melissa I

- Conclusion:
- In the first 13 pt
- recurrent angina pectoris: +/- 23% (CCS II)
- re-PCI (TLR): 23%



Melissa I

- Conclusion:
- Concept is proven feasible and save. Next phase improvement will be tested in further clinical trials

