

The issue of distal embolization

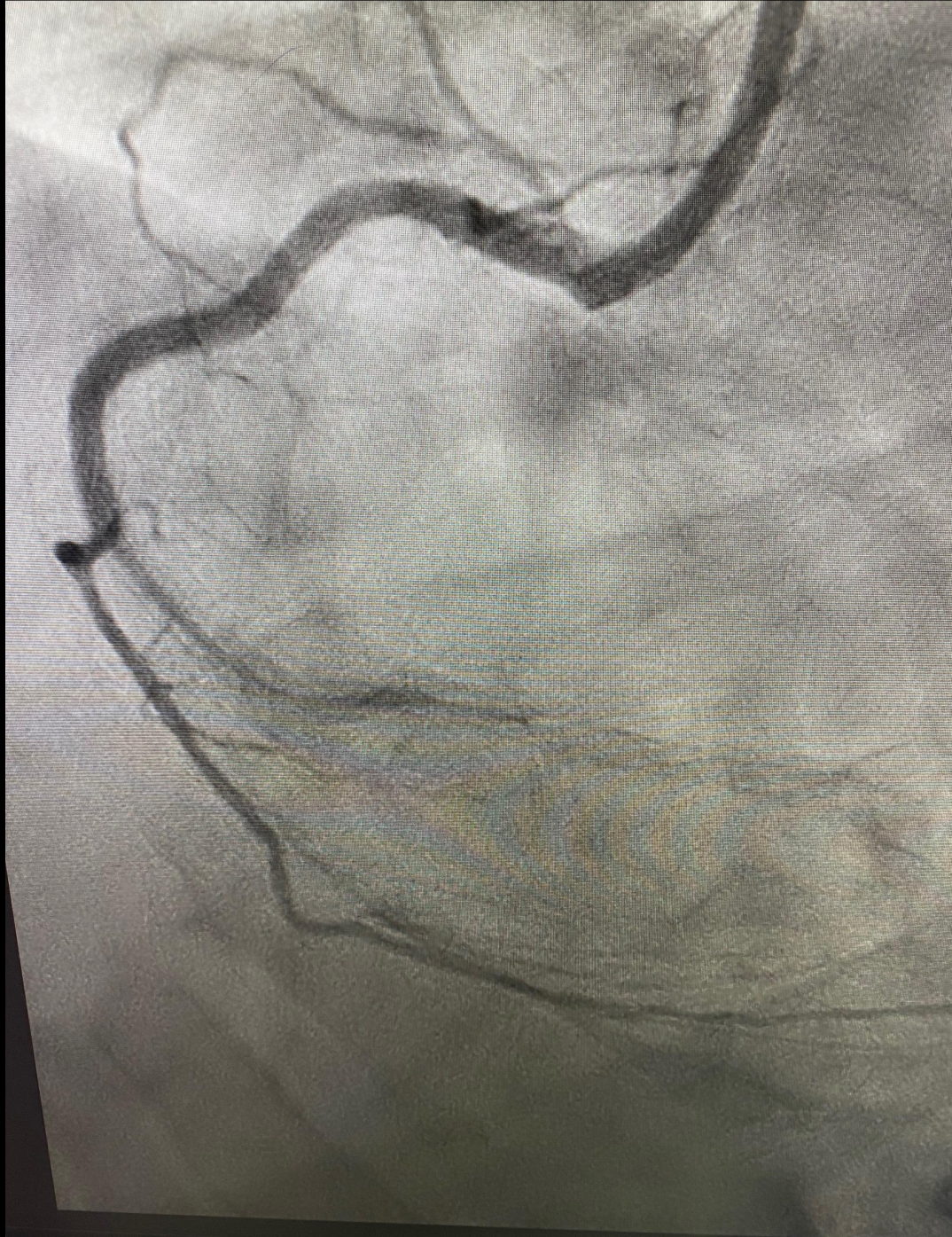
Antonio Colombo

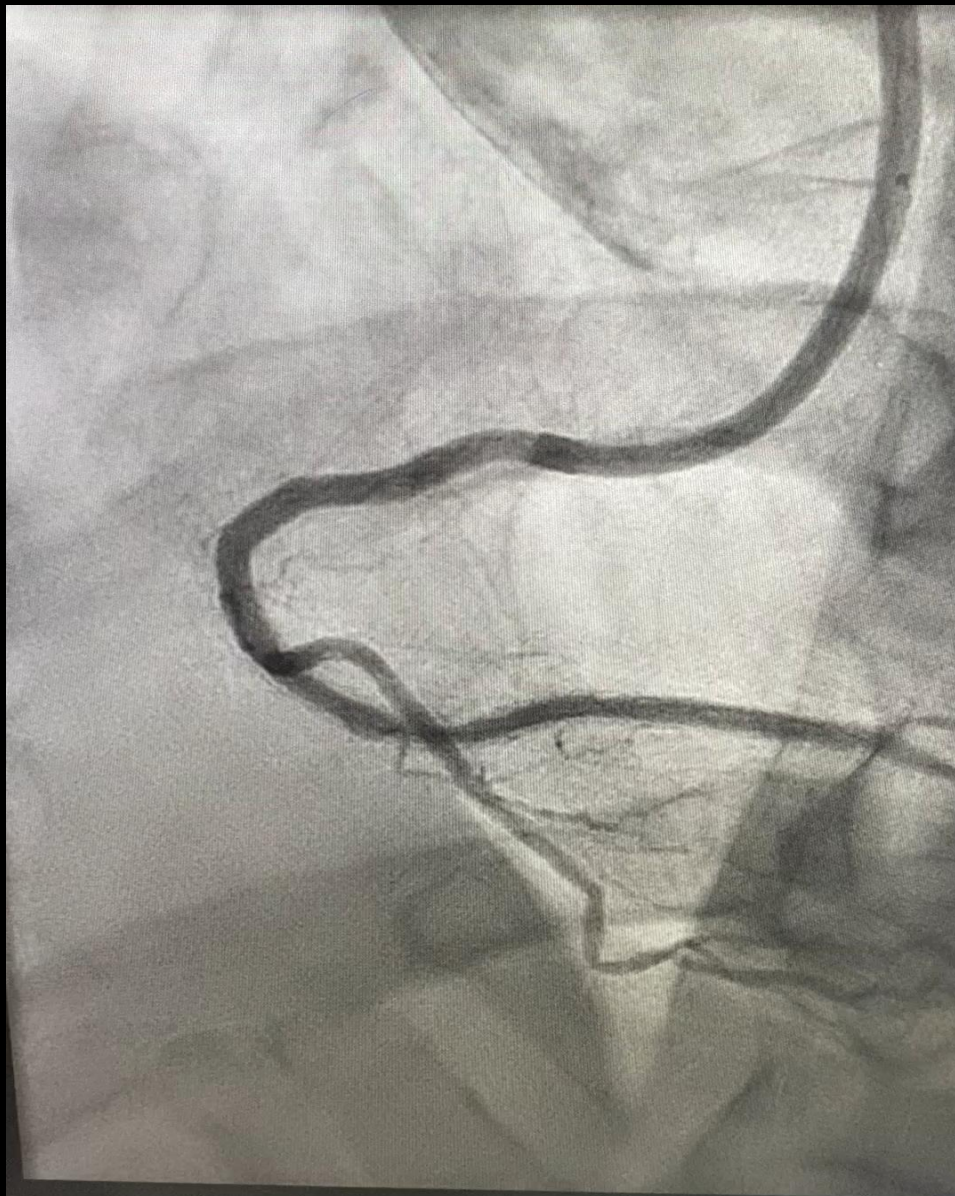
*Centro Cuore Columbus and
Humanitas IRCCS, Rozzano, Milan, Italy*

Presenter Disclosure Information

Antonio Colombo, MD

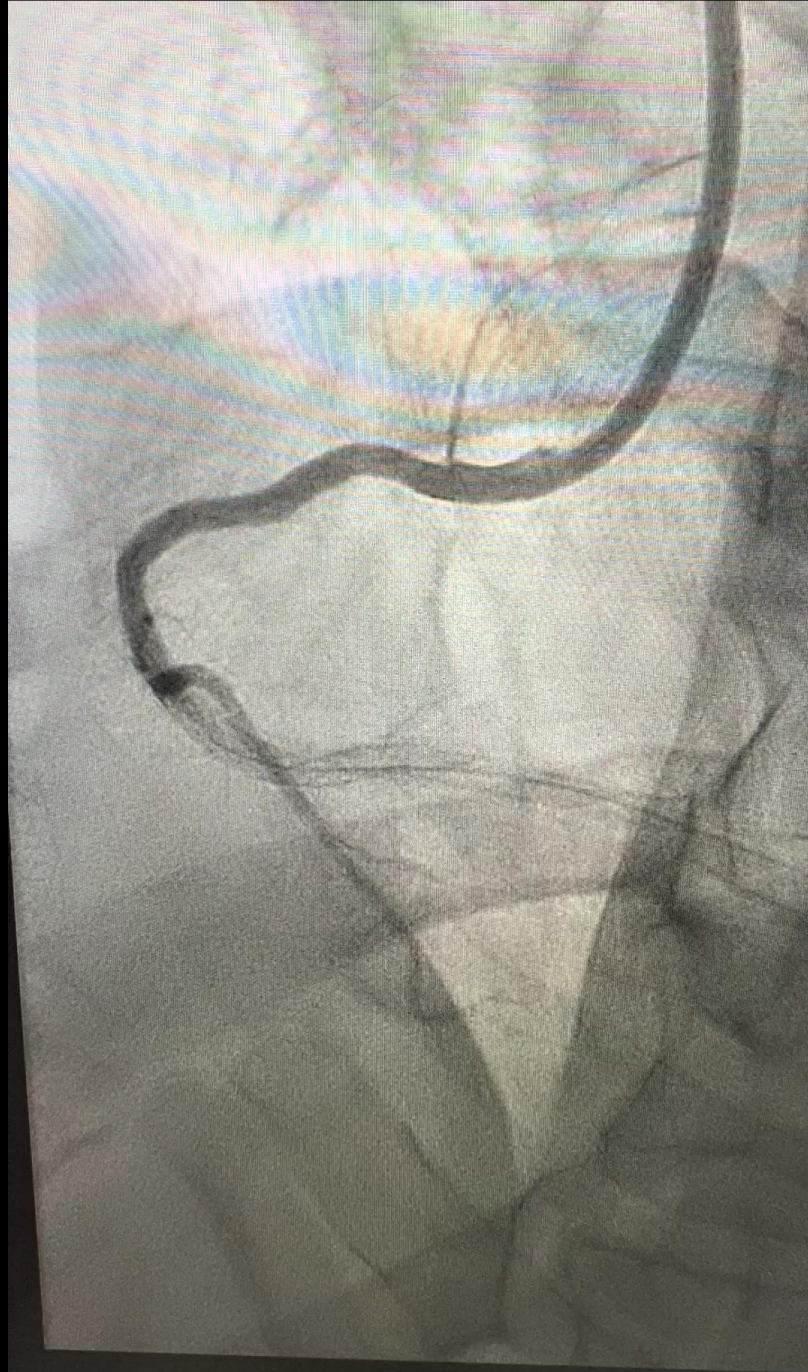
Nothing to disclose



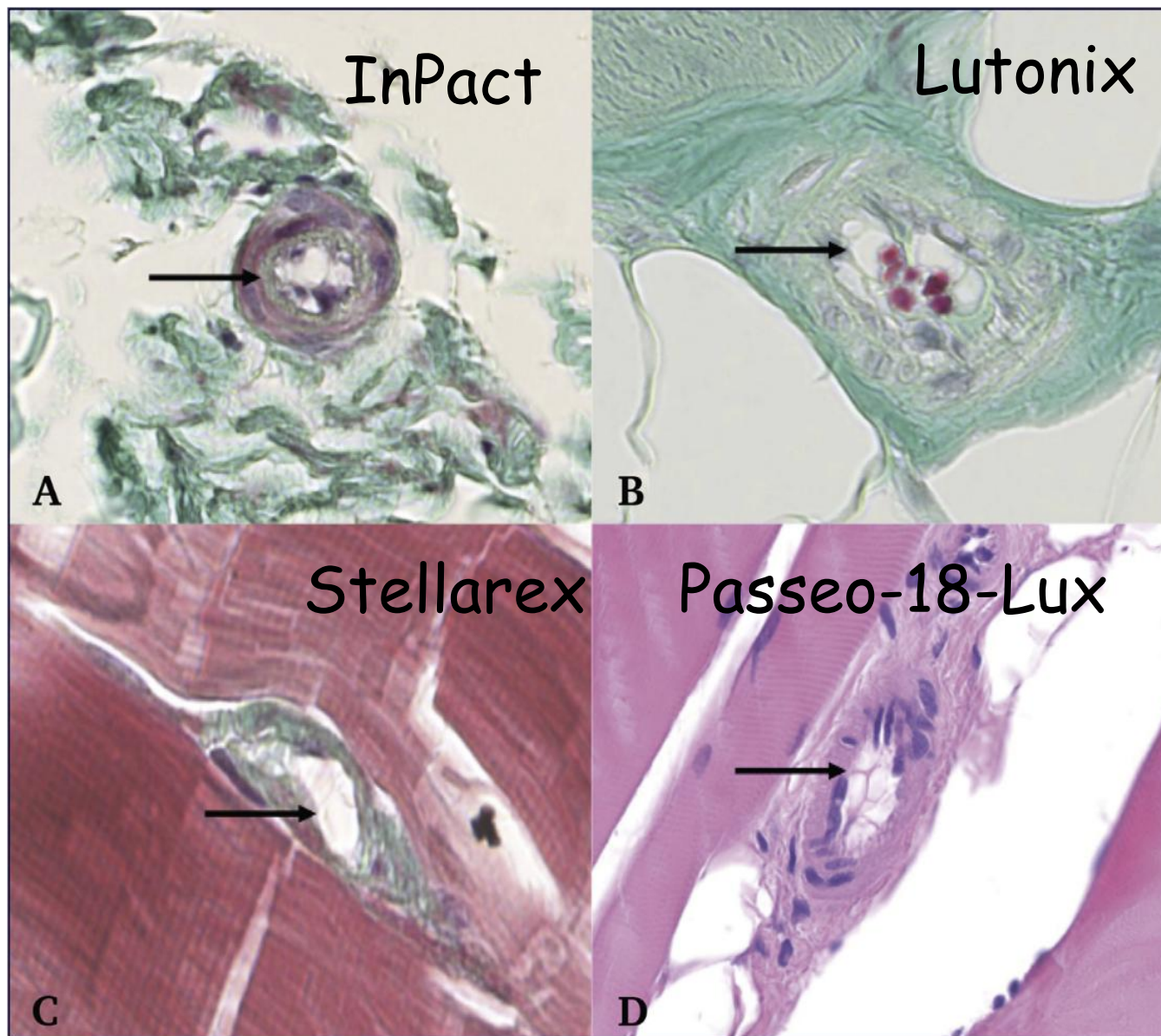


PHILIPS

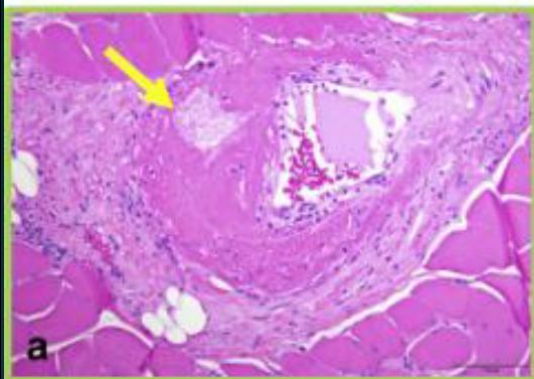




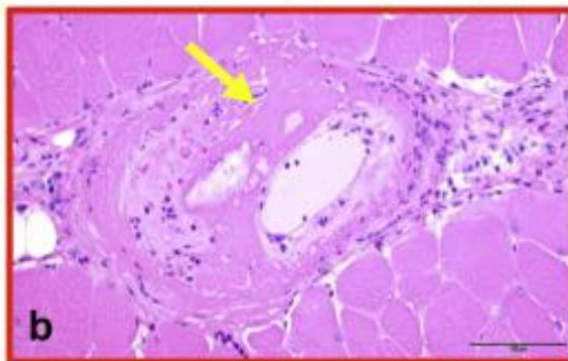
Distal embolization in femoral PTA



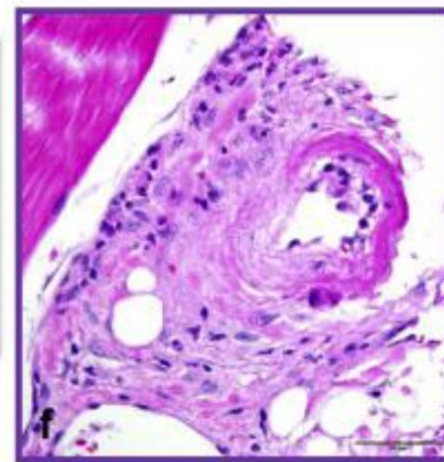
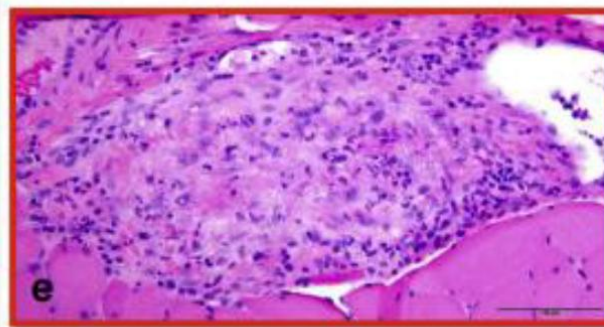
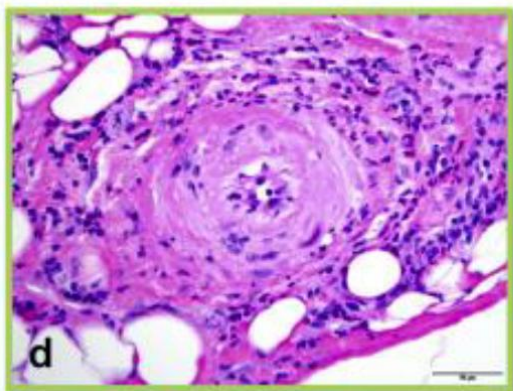
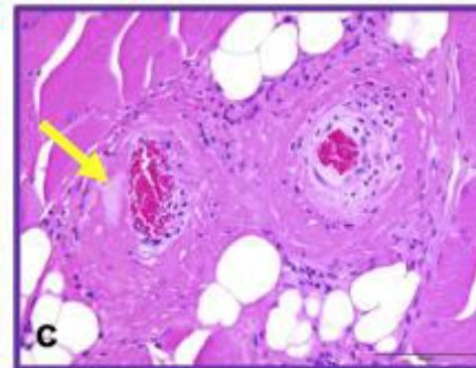
IN.PACT



Ranger



Stellarex



Yellow arrows indicate embolic material.

Torii S, et al. J Vasc Interv Radiol.2016

DCB

Crystal based

Most Paclitaxel DCB

Sirolimus coated DCB by
BBraun

Amorphous or not crystal based

Sirolimus coated DCB:
Magic Touch, Selution

Paclitaxel DCB
RESTORE by
Cardionovum

Comparison of Downstream Effect and Arterial Responses Among Sirolimus- and Paclitaxel-coated Balloons in Swine Heart Model

Kenji Kawai, Teruo Sekimoto, Frank D. Kolodgie, Rika Kawakami, Takao Konishi, Tatsuya Shiraki, Takamasa Tanaka, Renu Virmani, Alope V. Finn

CVPath Institute, Gaithersburg, MD, USA

Types of device	Drug	Device	Abbreviation	Company
DCB	Sirolimus	Magic Touch	MT-SCB	Concept medical
DCB	Sirolimus	SELUTION SLR™	SEL-SCB	MedAlliance
DCB	Paclitaxel	Agent™	PTX-DCB	Boston Scinentific
POBA	NA	POBA	POBA	-

Study Flow

Time Course

PCI procedure

Day 0

POBA (n=5)

RCA (n=5)

MT-SCB (n=4)

LAD (n=2)
LCX (n=2)

SEL-SCB (n=4)

LAD (n=2)
LCX (n=2)

PTX-DCB (n=4)

LAD (n=2)
LCX (n=1)
RCA (n=1)

Follow-up

Day 28

Follow up angiography

Sacrifice

Submit to histology

Histologic assessment

Coronary artery
Downstream myocardium

6 domestic pigs

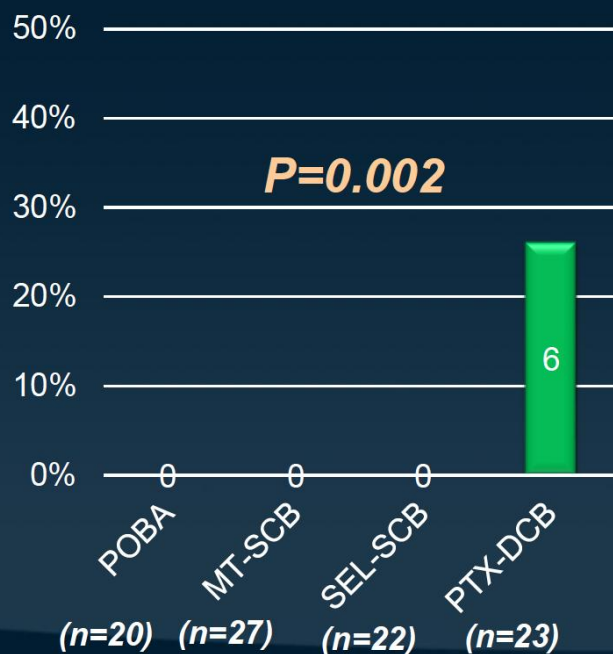
17 coronary arteries

Downstream myocardium injury among 4 types of DCB

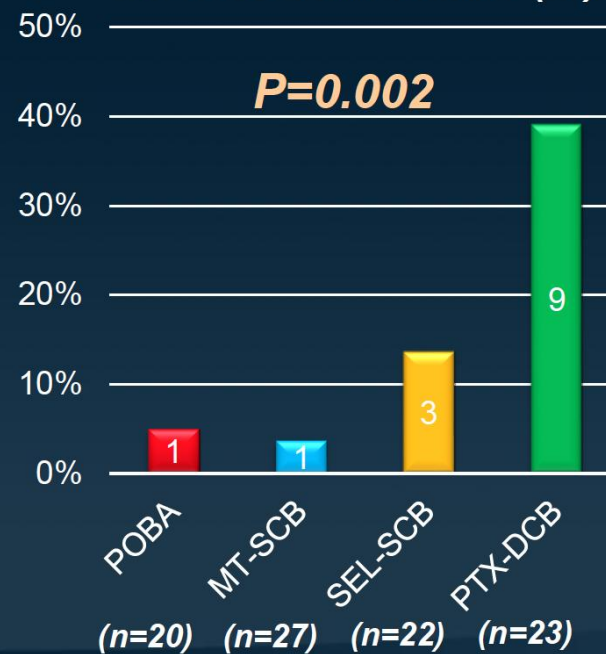
Assessment of the total 92 histology sections from 6 porcine hearts

Blinded Analysis

Myocyte necrosis/Scarring (%)



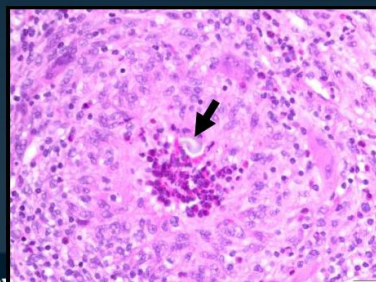
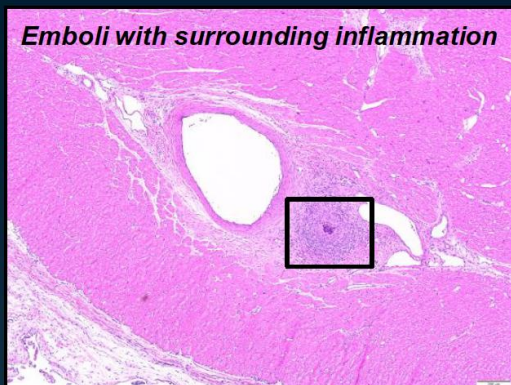
Single to multiple downstream emboli (%)



Representative Histology of Downstream Myocardium After the Treatment with SEL-SCB and PCB

SEL-SCB

Emboli with surrounding inflammation

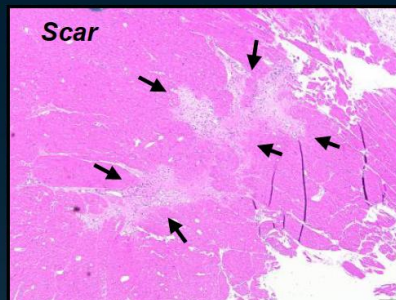


Polarized Light

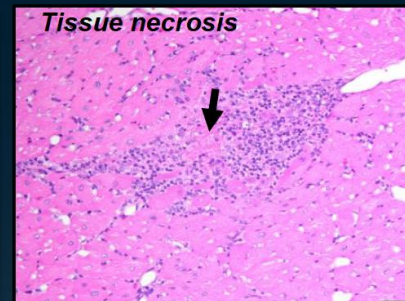


PTX-DCB

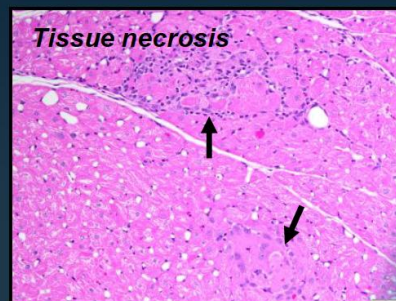
Scar



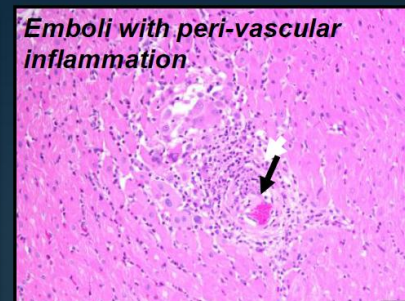
Tissue necrosis



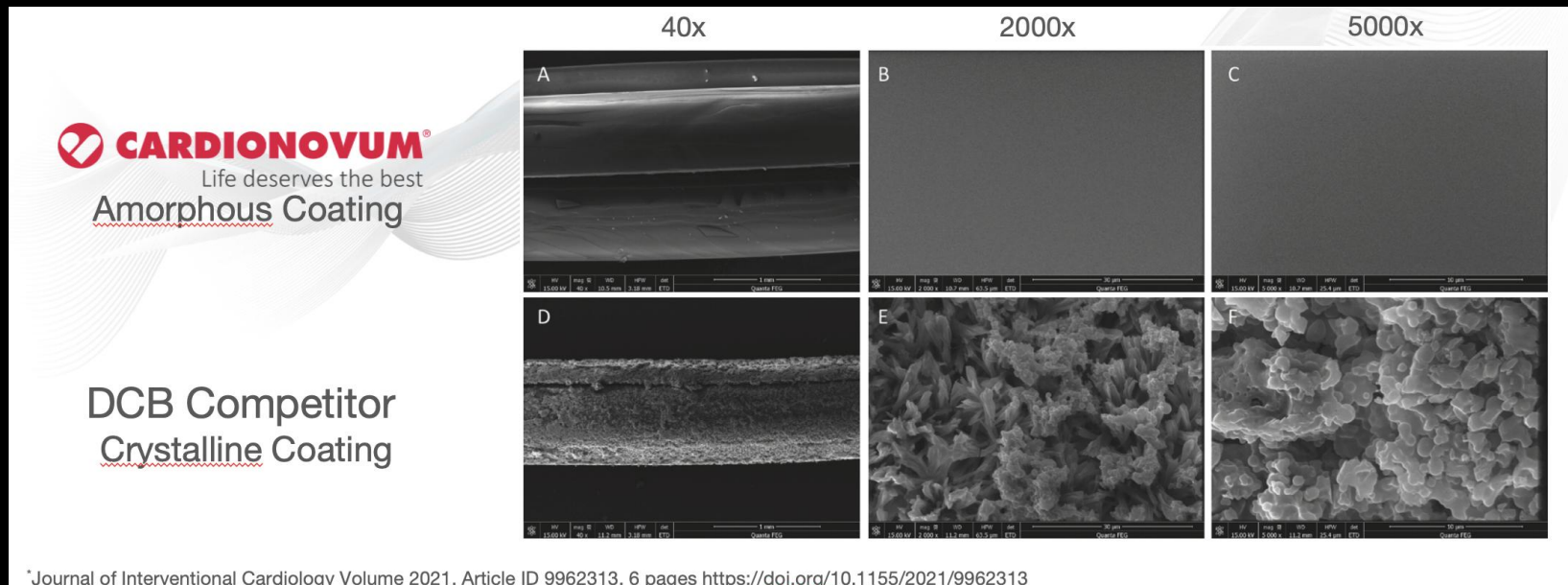
Tissue necrosis



Emboli with peri-vascular inflammation



Restore by Cardionovum: an interesting amorphous based technology to deliver paclitaxel without crystalline formulations



*Journal of Interventional Cardiology Volume 2021, Article ID 9962313, 6 pages <https://doi.org/10.1155/2021/9962313>

Swine coronary vessels

Research Article

In Vitro and In Vivo Comparative Evaluation of a Shellac-Ammonium Paclitaxel-Coated Balloon versus a Benchmark Device

Congying Xia¹, Yunhan Jiang^{2,3,4}, Shuangshuang Li⁵, Dan Xiong⁵, Xiaojie Chen⁵, and Yufang Chen⁶

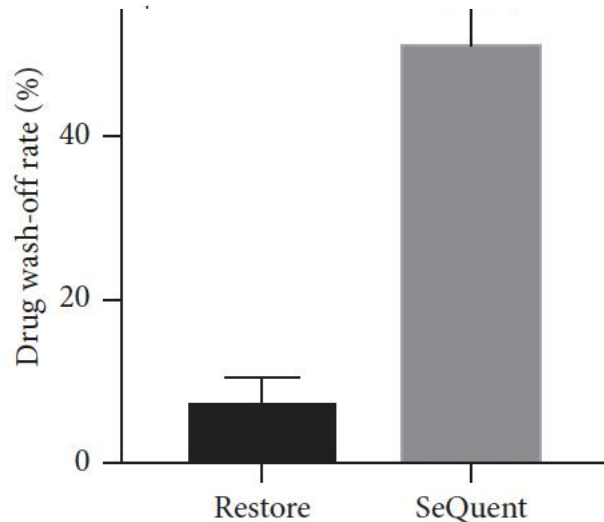
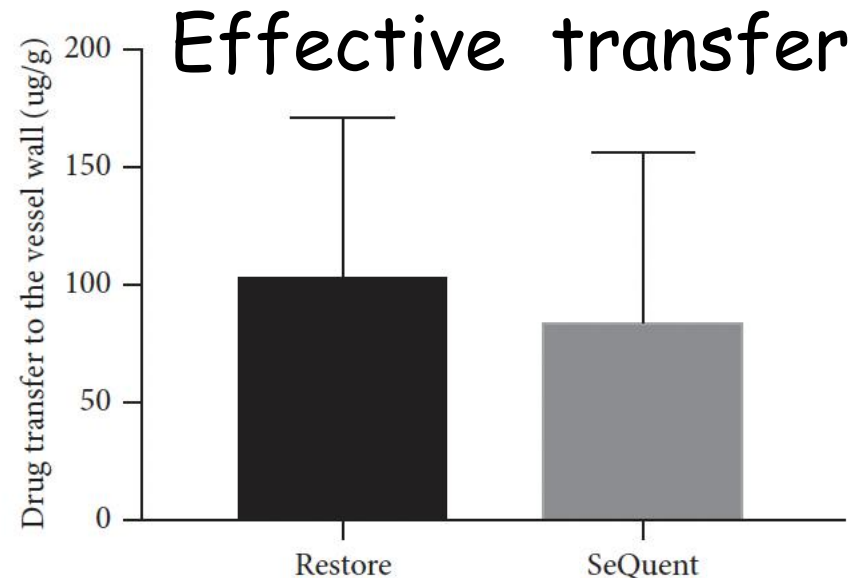


FIGURE 2: Results of quantitative analysis of drug wash-off rate. Drug wash-off rate of the Restore® group was substantially lower than that of the SeQuent® Please group (7% ± 6% versus 50% ± 6%, $p < 0.001$).



Presently the issue of microcrystal embolization had/has an impact in below the knee interventions and a ? is present regarding coronary procedures

Coronary interventions were mainly performed in discrete lesions

No specific study protocol was established to evaluate this issue

The SPAGO (Sirolimus vs Paclitaxel Angiographic Gain Objective) Trial

will evaluate the impact of DCB Solution vs
Sequent Please upon the microcirculation
(Coroventis measurement of Intramyocardial
Resistance Index) after lesions preparation and
after DCB delivery il long lesions (30 mm or
longer) in a prospective randomized study

50 patients for each DCB without prespecified
end point

If this study will show a difference (amount of difference in IMR; abnormal values over 25) between the two DCBs, this finding may have a clinical impact in patients treated with long DCB especially in patients with baseline reduced ejection fraction