

The issue of distal embolization

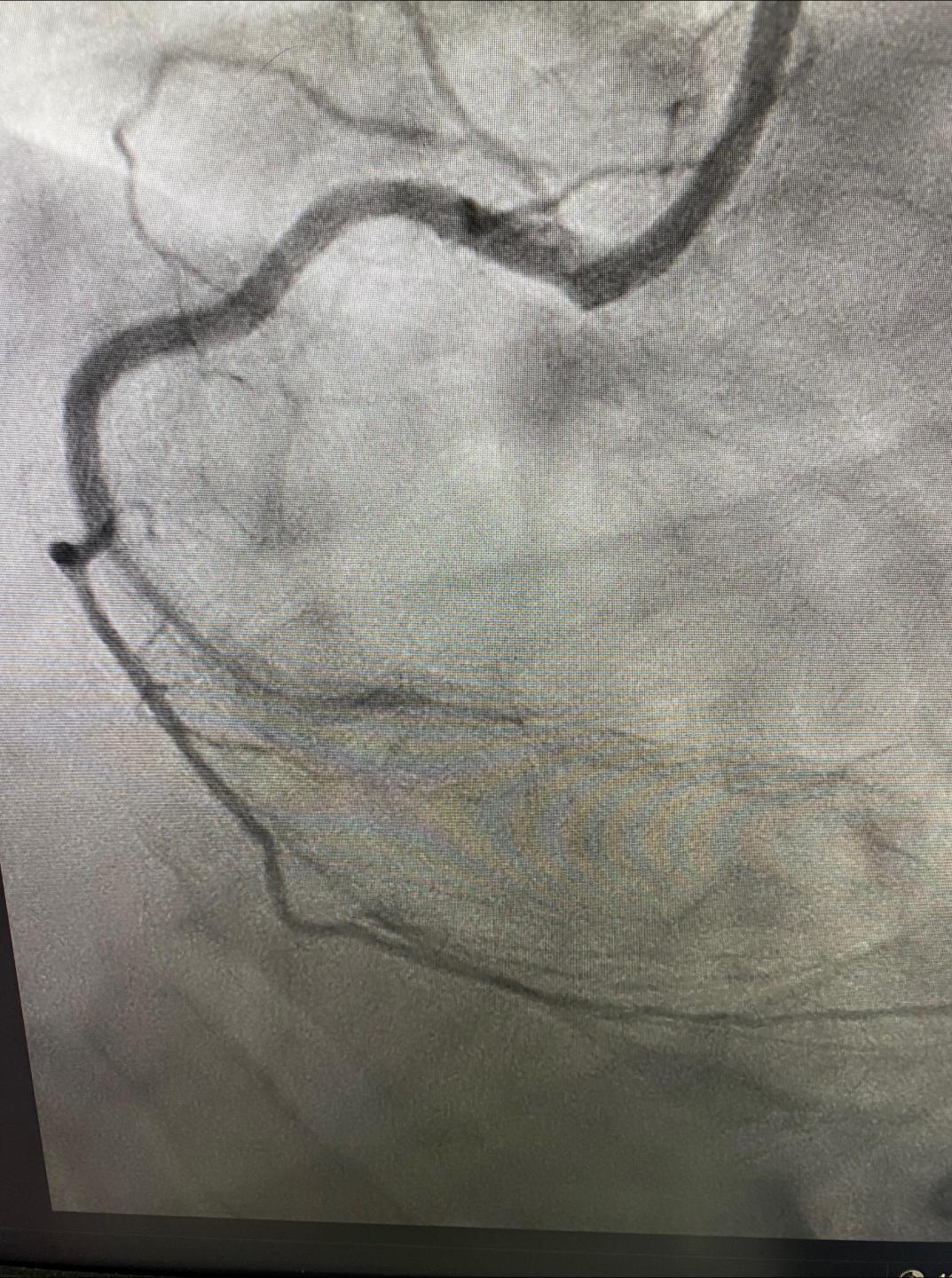
Antonio Colombo

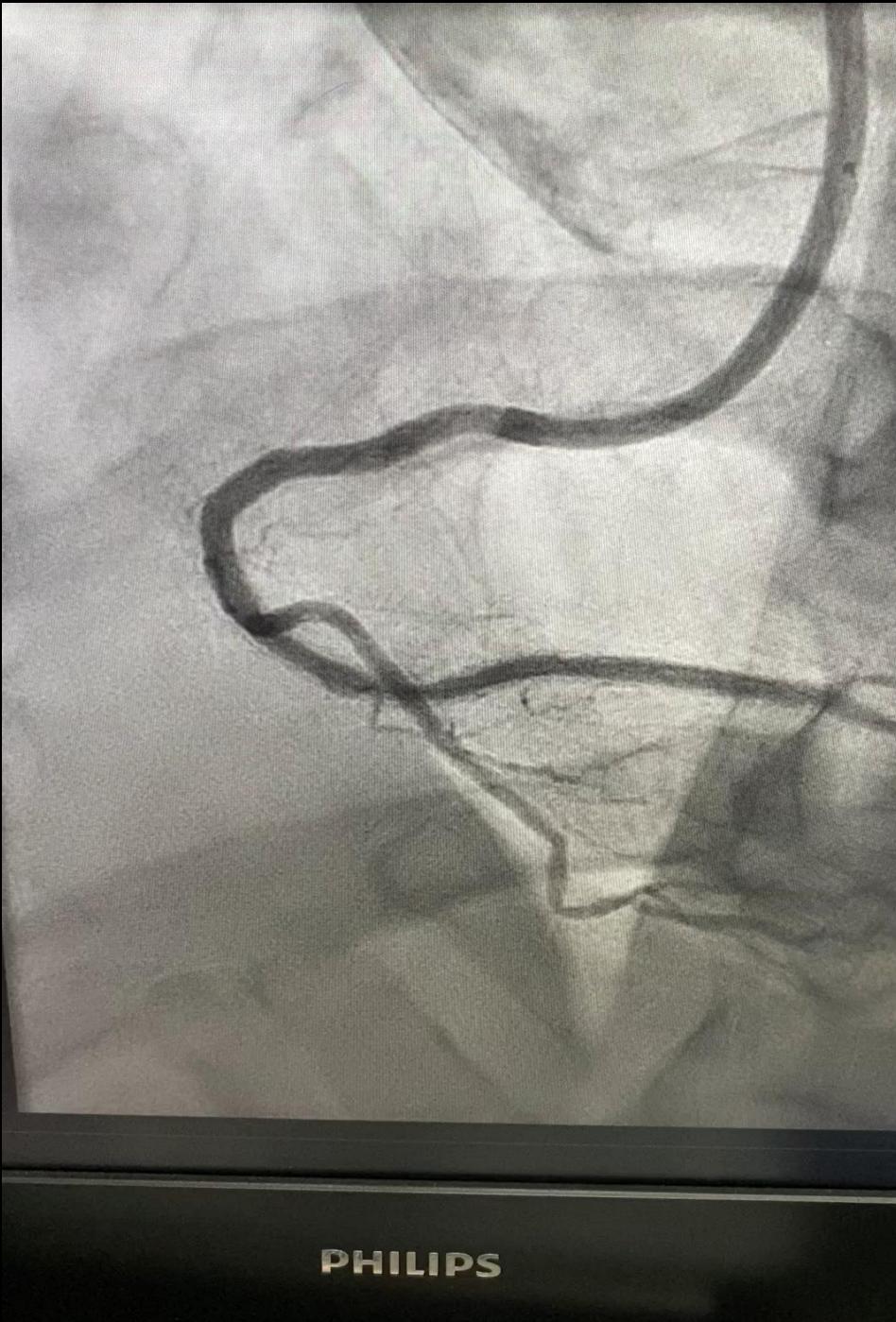
*Centro Cuore Columbus and
Humanitas IRCCS, Rozzano, Milan, Italy*

Presenter Disclosure Information

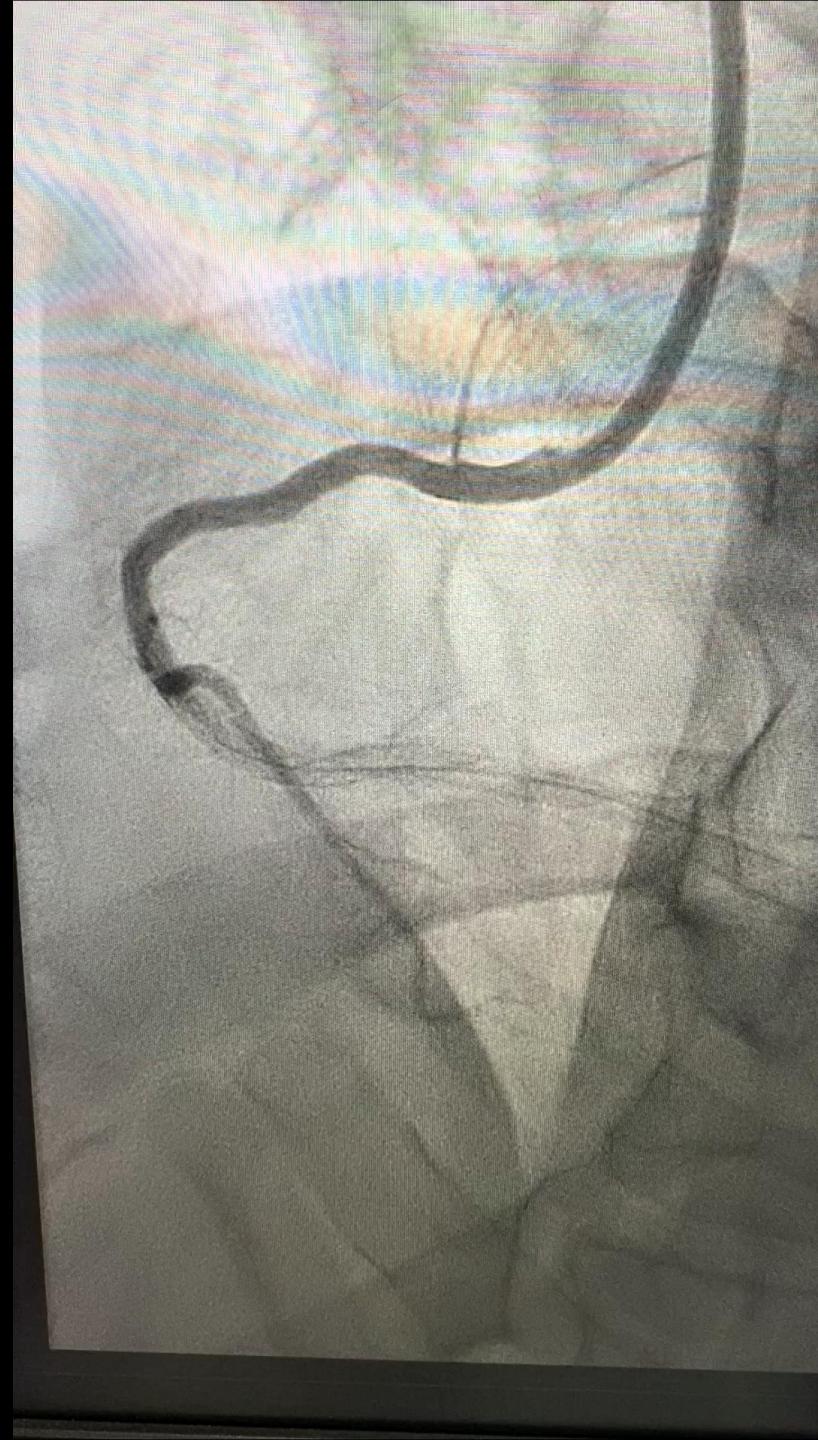
Antonio Colombo, MD

Nothing to disclose

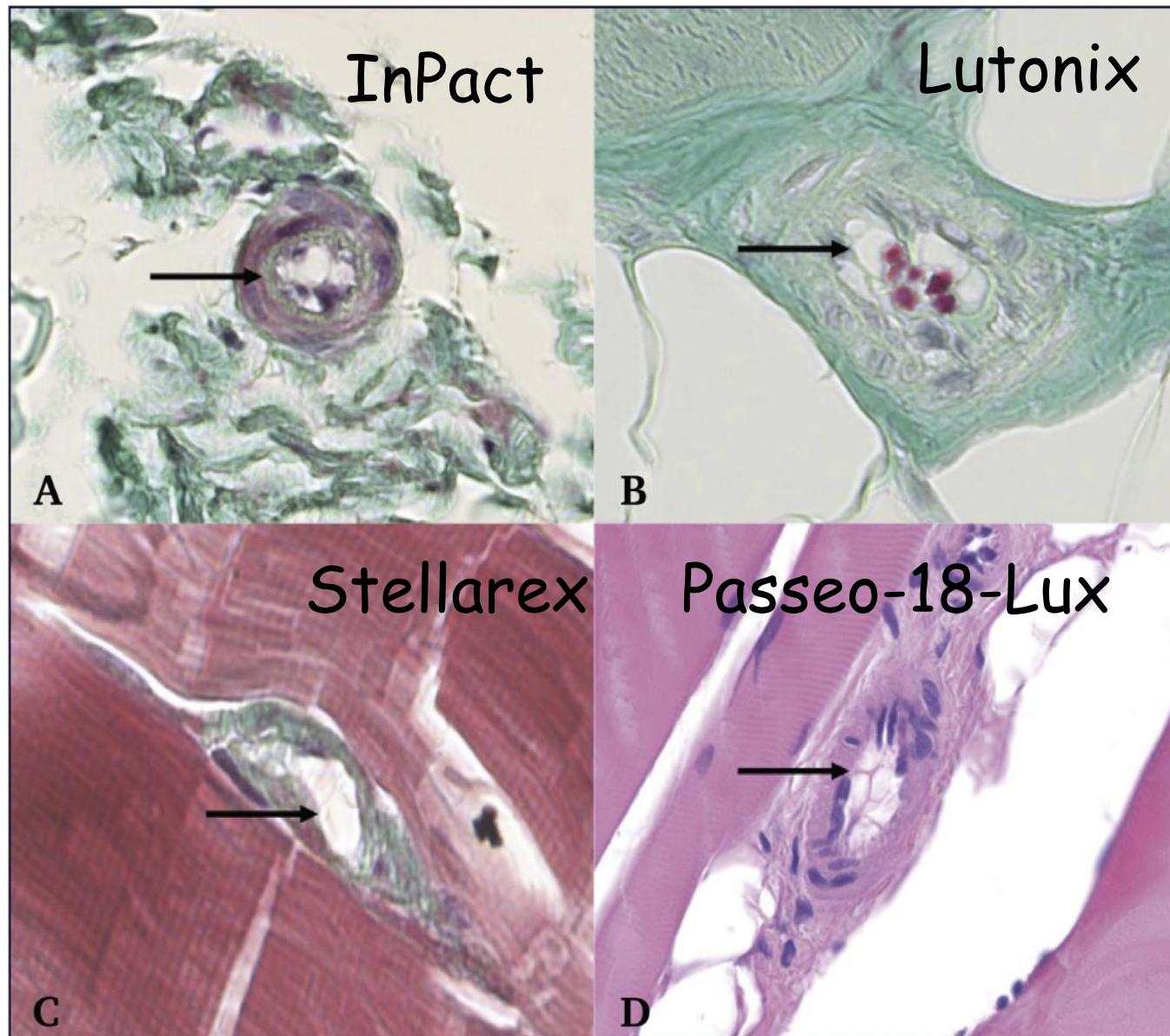


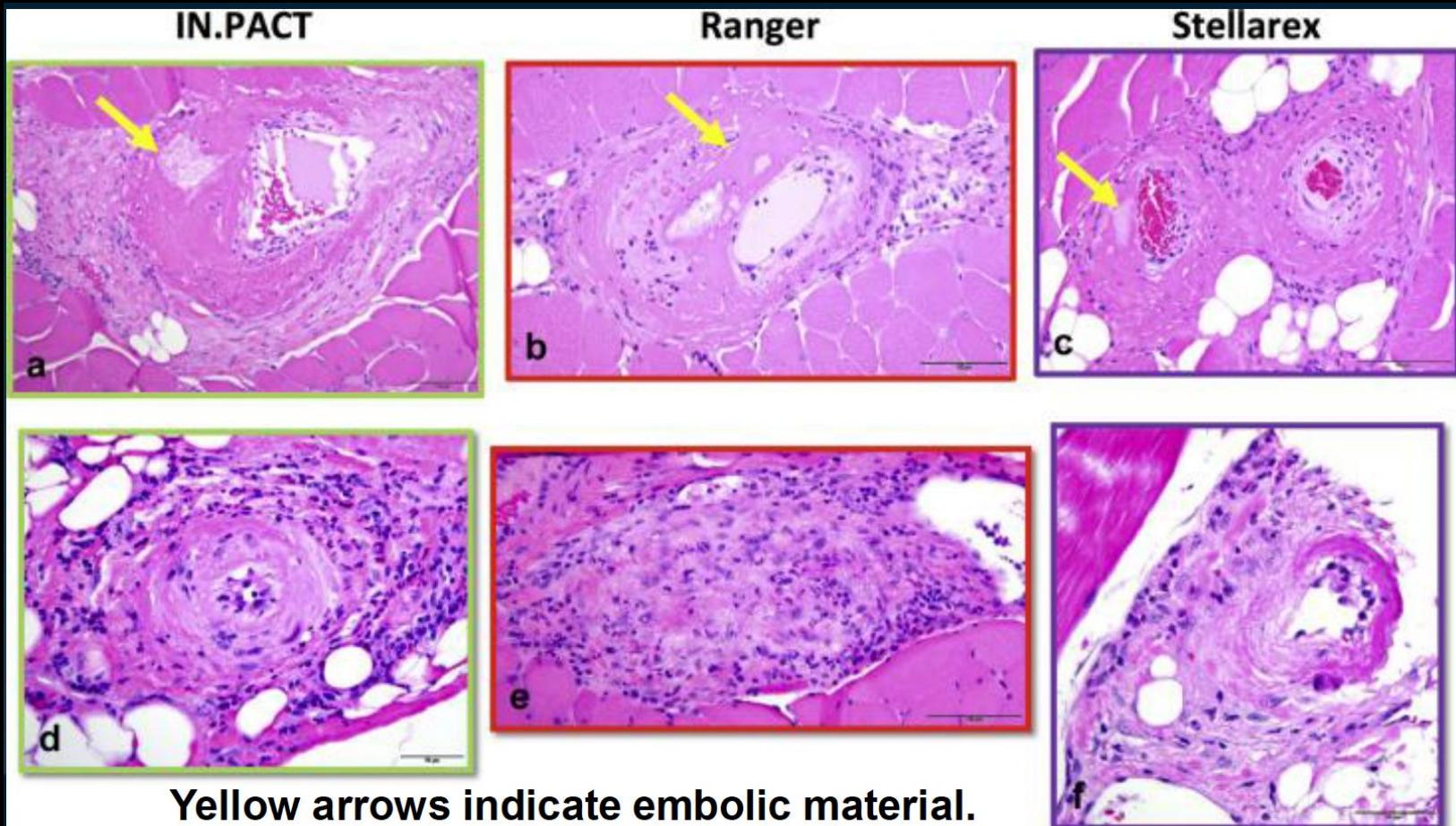






Distal embolization in femoral PTA





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

DCB

Crystal based

Amorphous or not
crystal based

Most Paclitaxel DCB

Sirolimus coated DCB:
Magic Touch, Selution

Sirolimus coated DCB by
BBraun

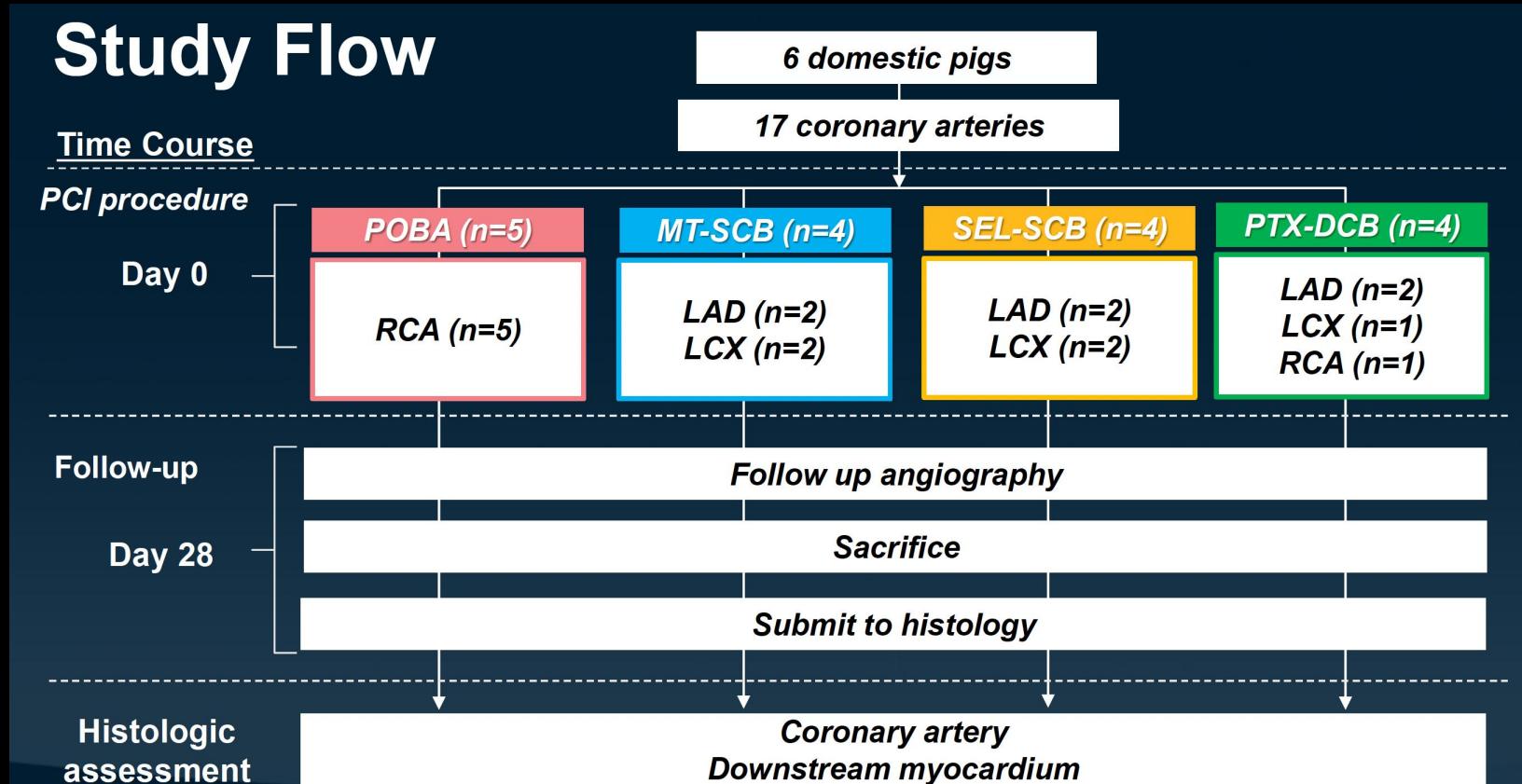
Paclitaxel DCB
RESTORE by
Cardionovum

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, Aloke V. Finn

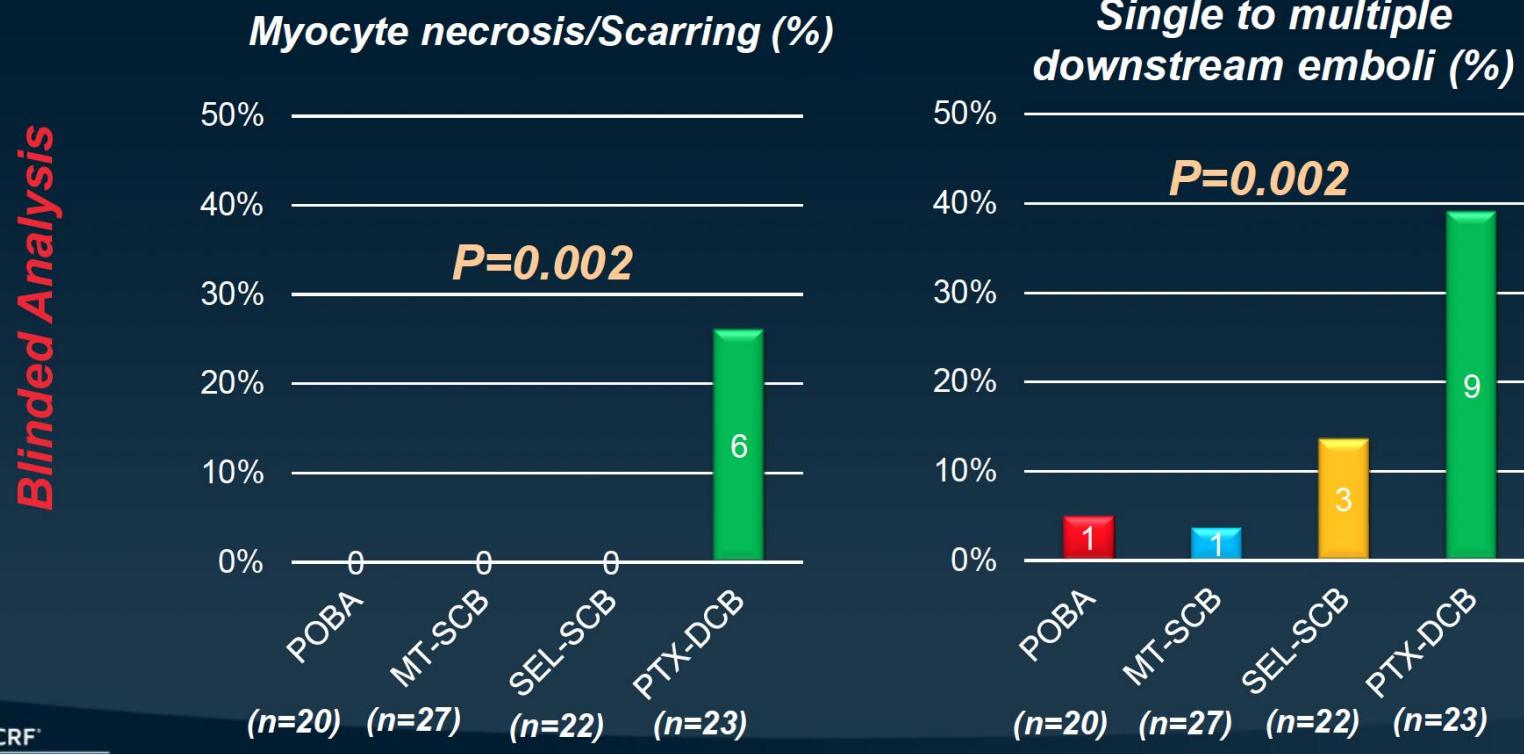
CVPath Institute, Gaithersburg, MD, USA

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	-



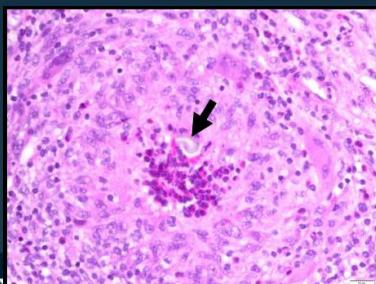
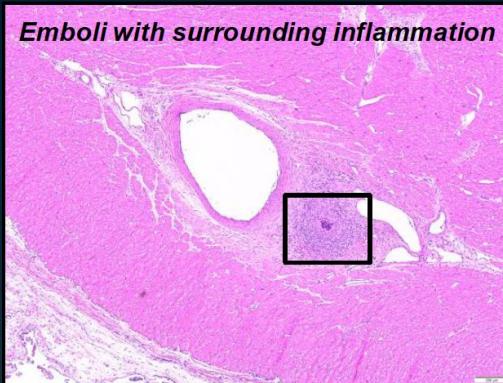
Downstream myocardium injury among 4 types of DCB

Assessment of the total 92 histology sections from 6 porcine hearts



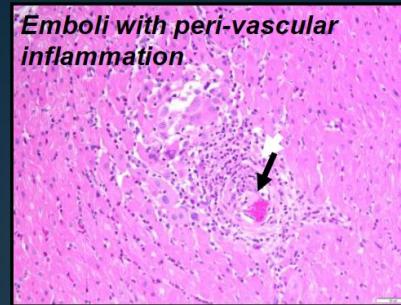
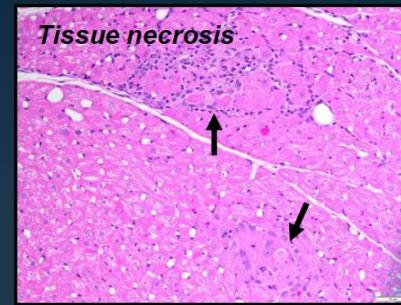
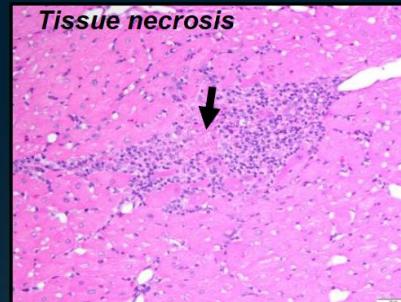
Representative Histology of Downstream Myocardium After the Treatment with SEL-SCB and PTX-DCB

SEL-SCB



Polarized Light

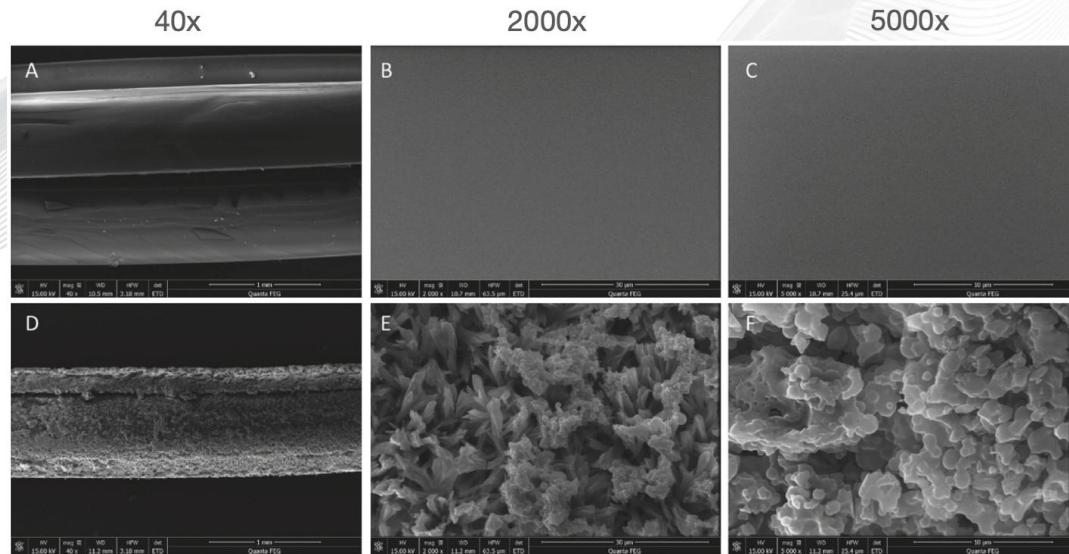
PTX-DCB



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

 **CARDIONOVUM®**
Life deserves the best
Amorphous Coating

DCB Competitor
Crystalline Coating



Swine coronary vessels

Research Article

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

Minimal

wc

Congying Xia ,¹ Yunhan Jiang,^{2,3,4} Shuangshuang Li,⁵ Dan Xiong,⁵ Xiaojie Chen,⁵ and Yufang Chen ,⁶

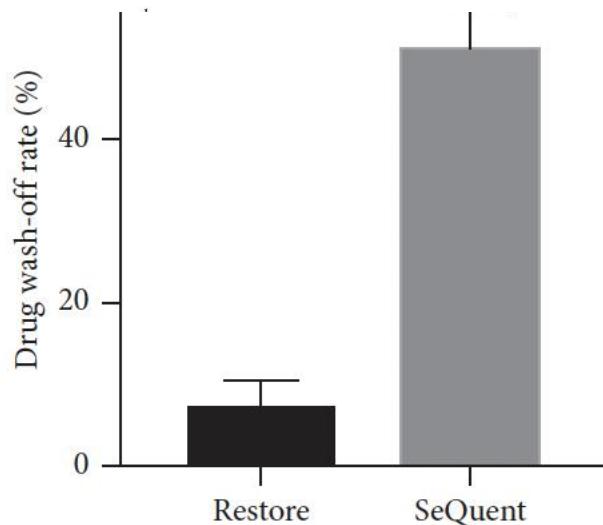
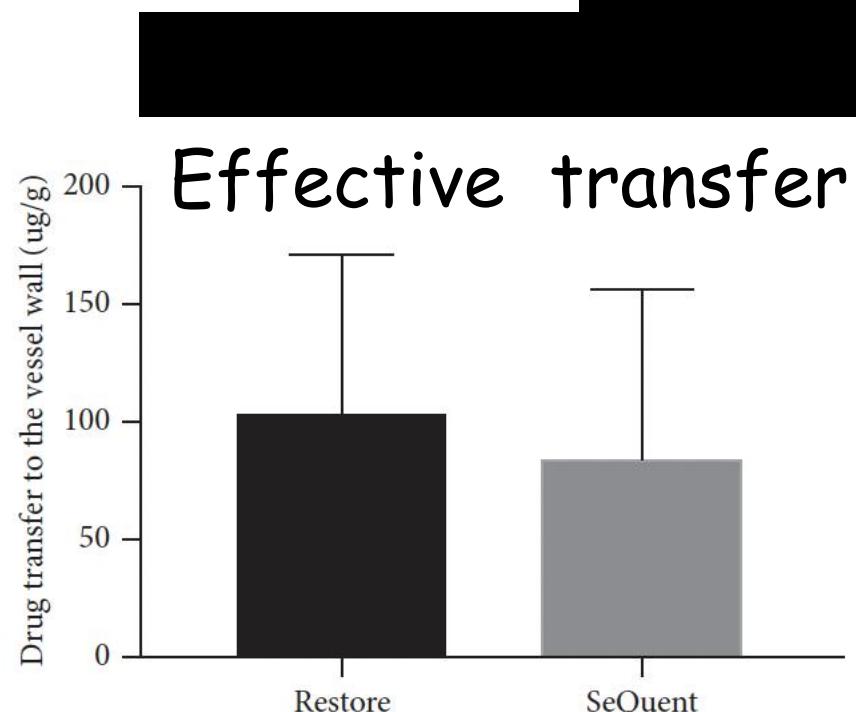


FIGURE 2: Results of quantitative analysis of drug wash-off rate. Drug wash-off rate of the Restore® group was substantially higher than that of the SeQuent® Please group (7% \pm 6% versus 48% \pm 6%, $p < 0.001$).



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 Selution vs Sequent Please upon the microcirculation (Coroventis measurement of Intramyocardial Resistance Index) after lesions preparation and after DCB delivery in 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