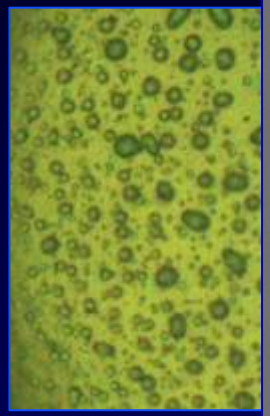
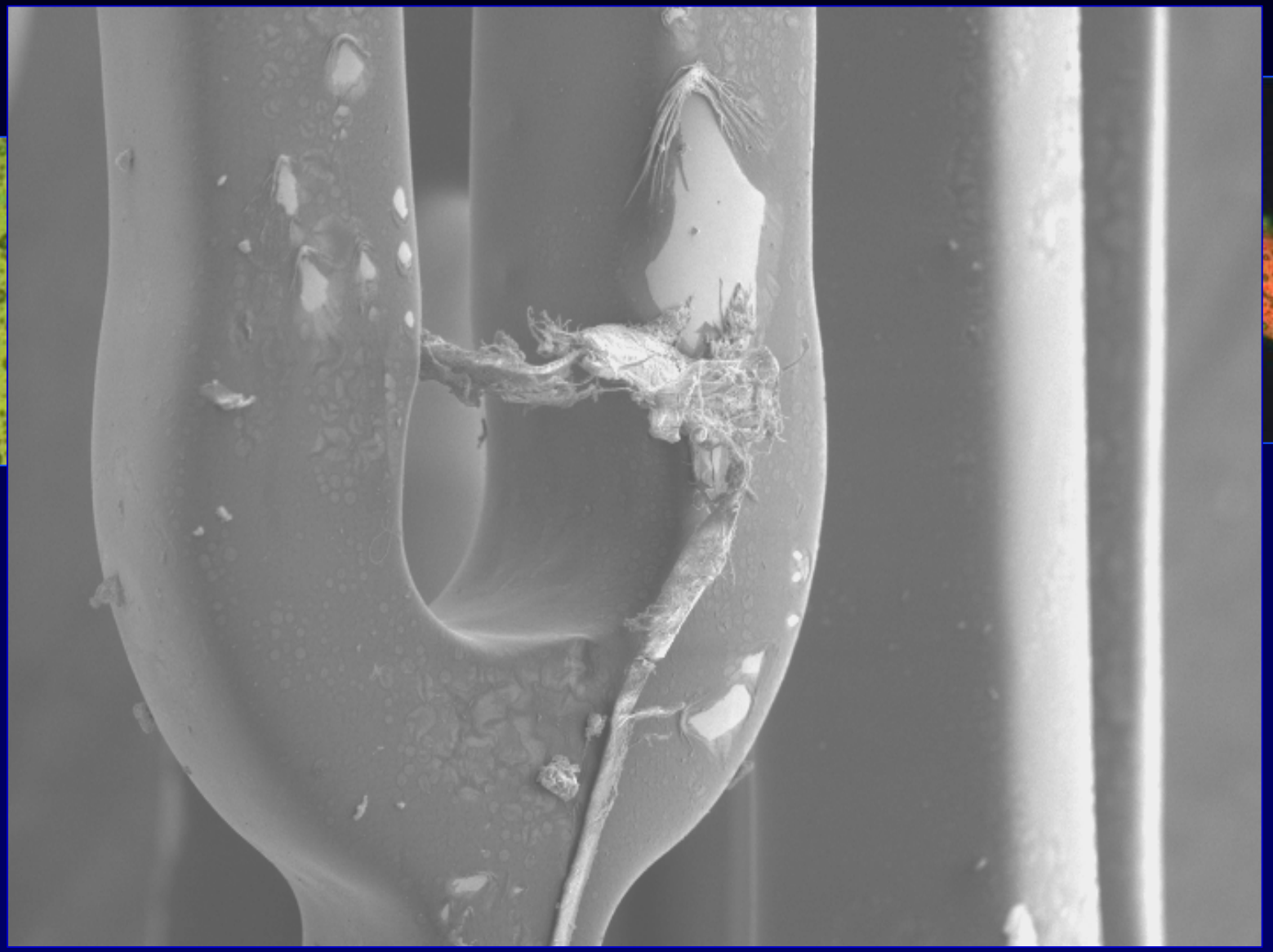
Medikamenten-beschichtete Ballons

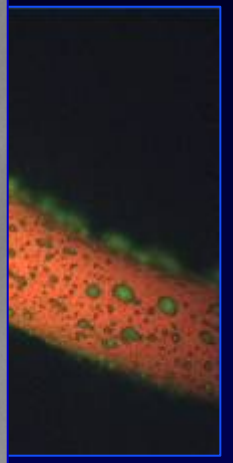
Arno Bücker
Klinik für Diagnostische und Interventionelle Radiologie – UKS-Homburg

Mitgründer von Aachen Resonance

Beschichtete Stents







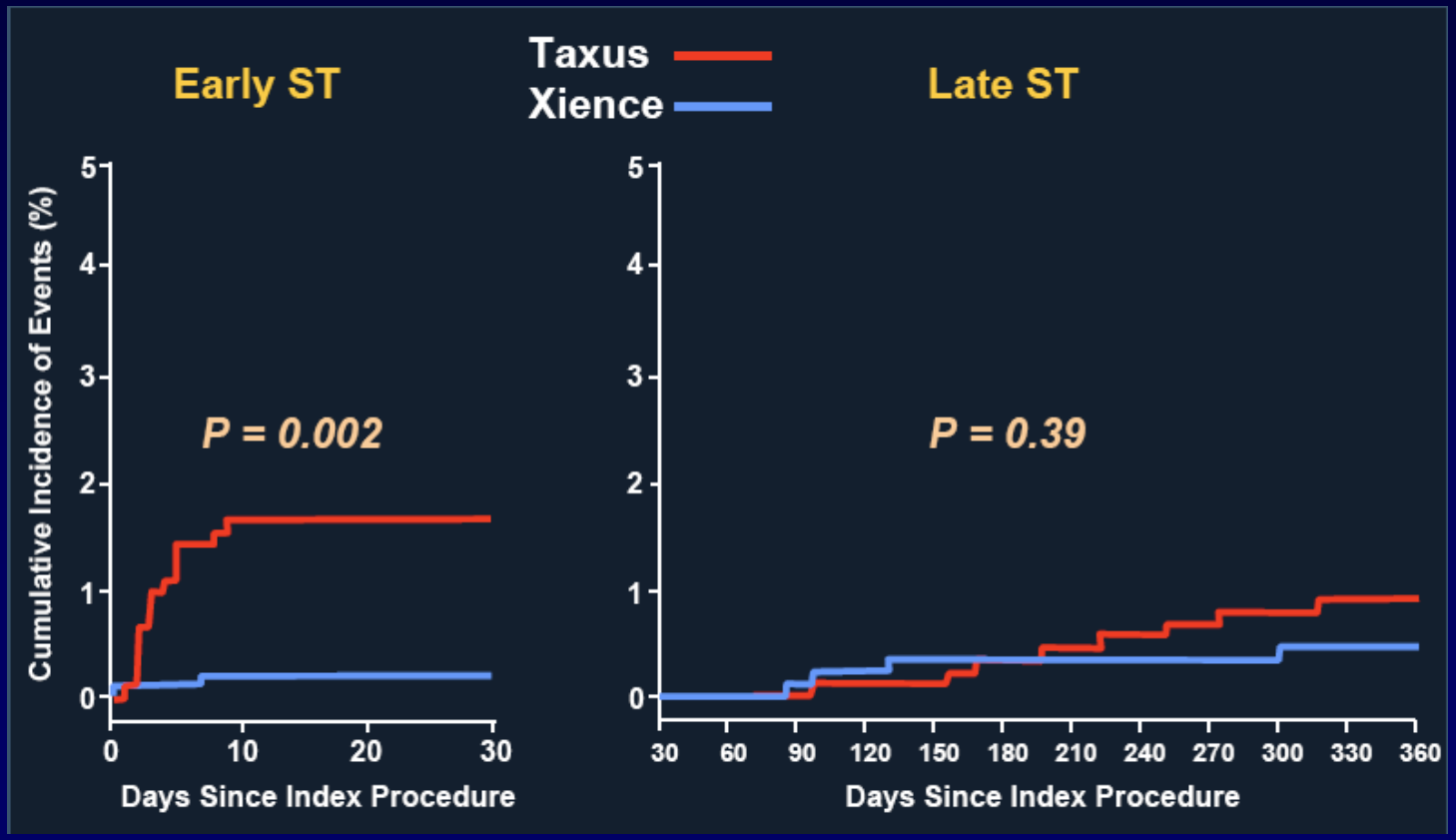
Warum Ballons?

In-Stent Restenose

Stent-Thrombose

kleine Gefäße

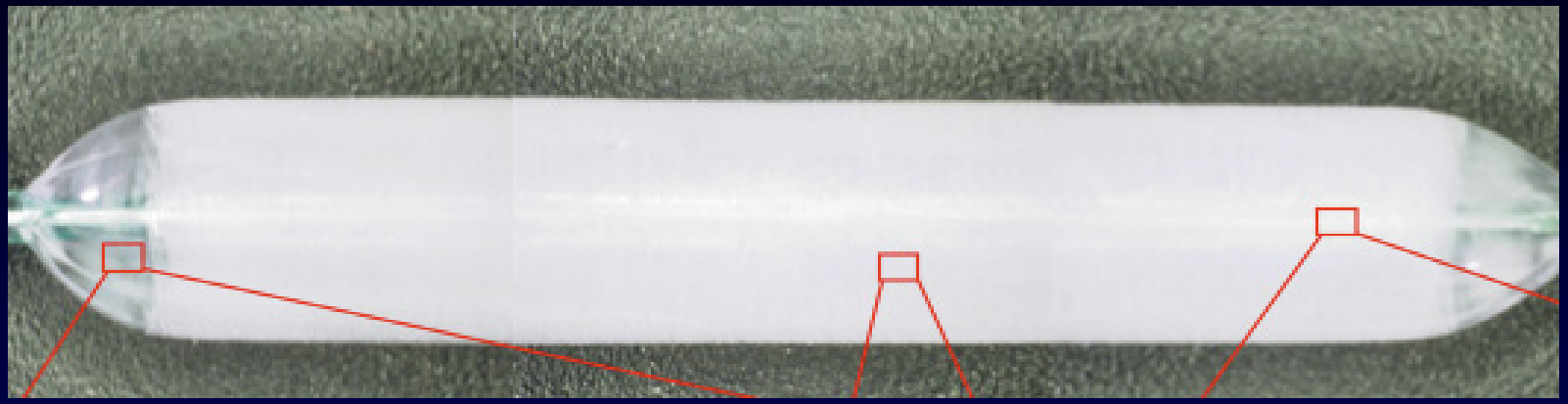
Gefäßwandabdeckung

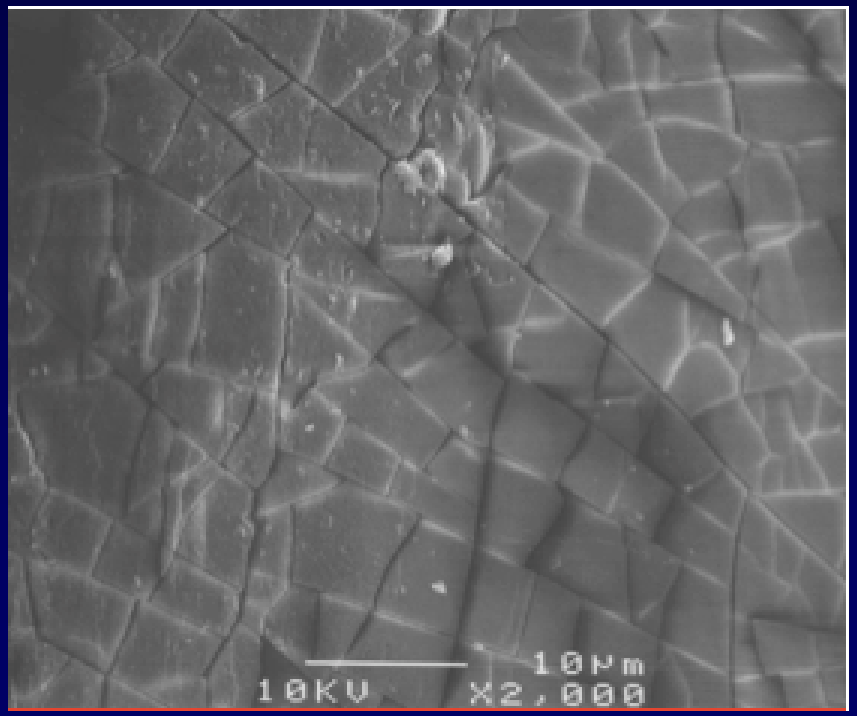


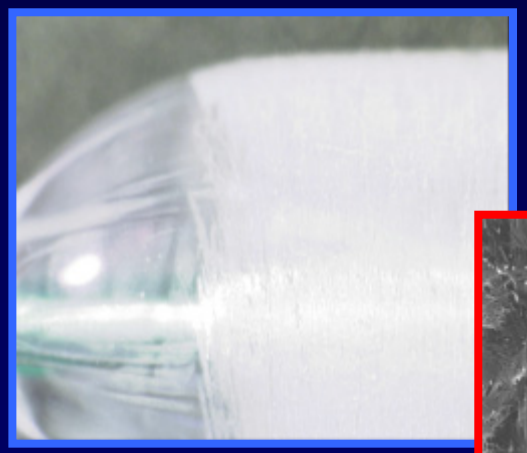
Techniken der Ballonbeschichtung

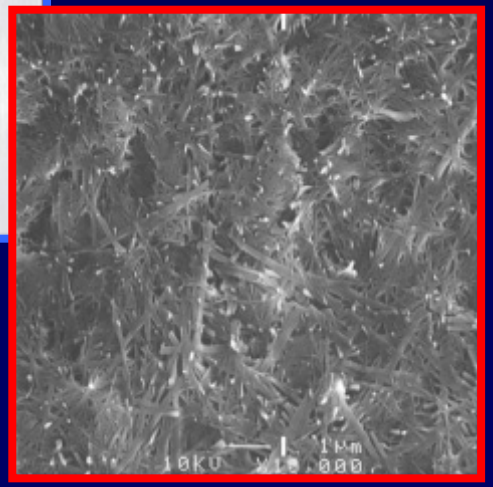
- Mischung von Paclitaxel mit diversen Additiva:
  - Sequent Please - BBraun
  - In.Pact Amphirion – Invatec
- Mischung von Paclitaxel und Shelac
  - DIOR (2nd Gen) – Eurocor
- Matrix von reinem Paclitaxel „Ice and Snow“
  - ELUTAX – Aachen Resonance

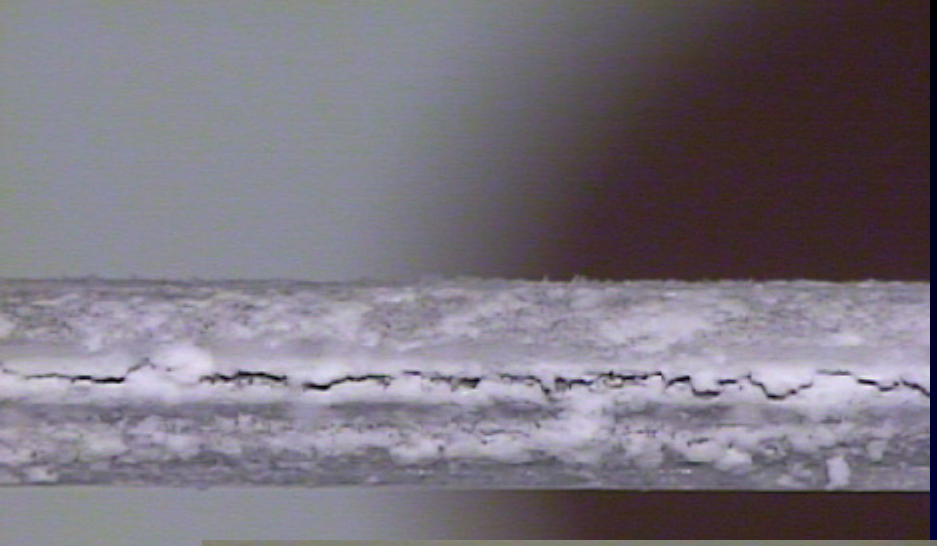
Paclitaxel-Beschichtung ohne Zusatzstoffe

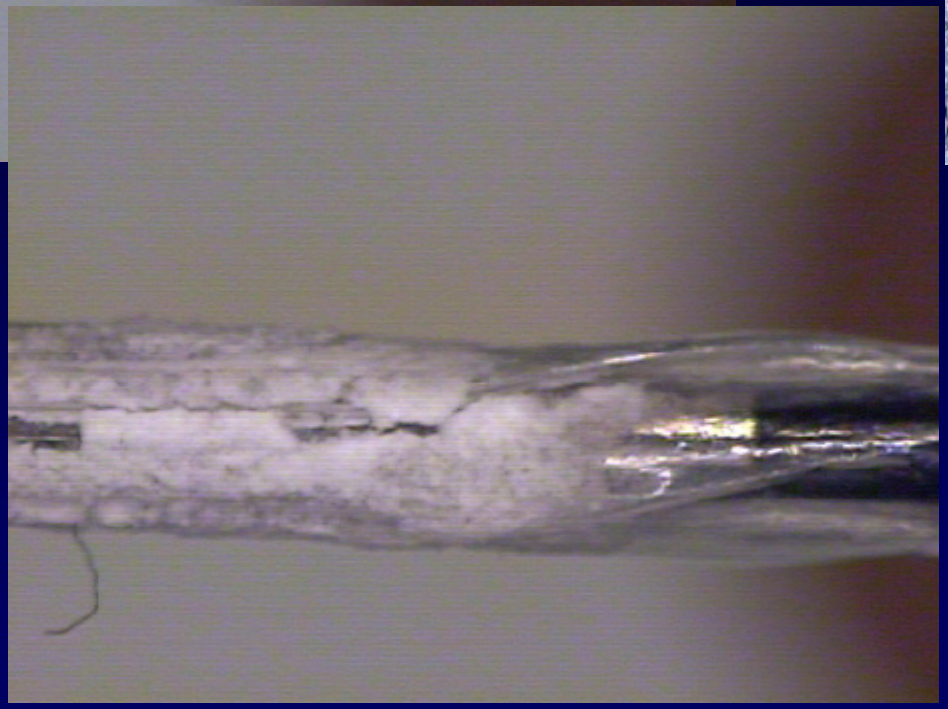


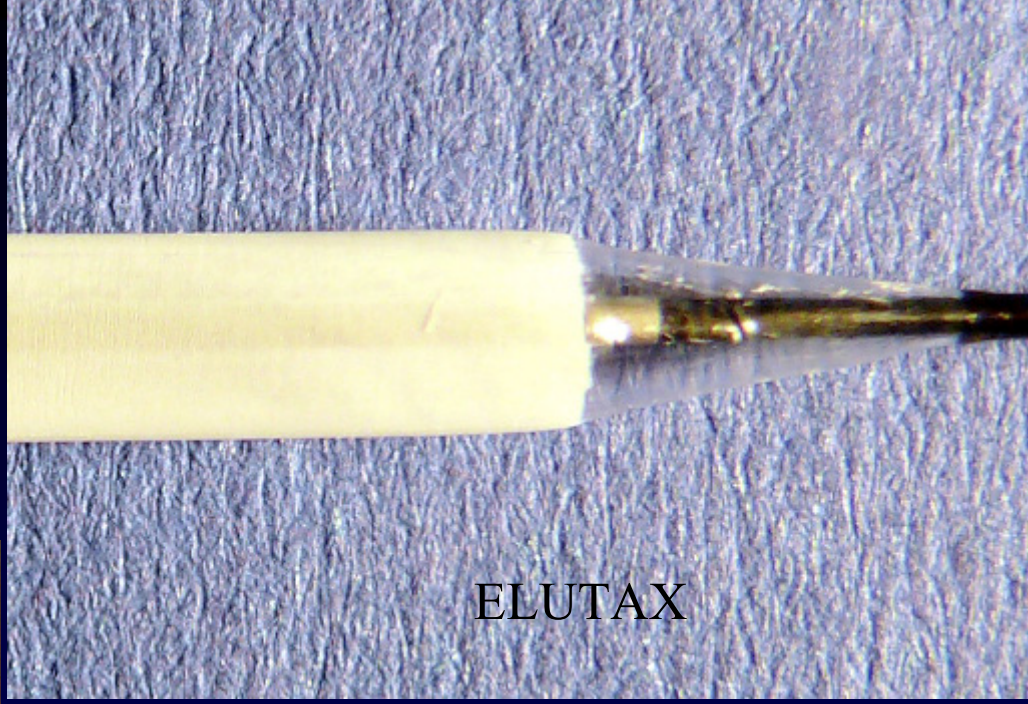




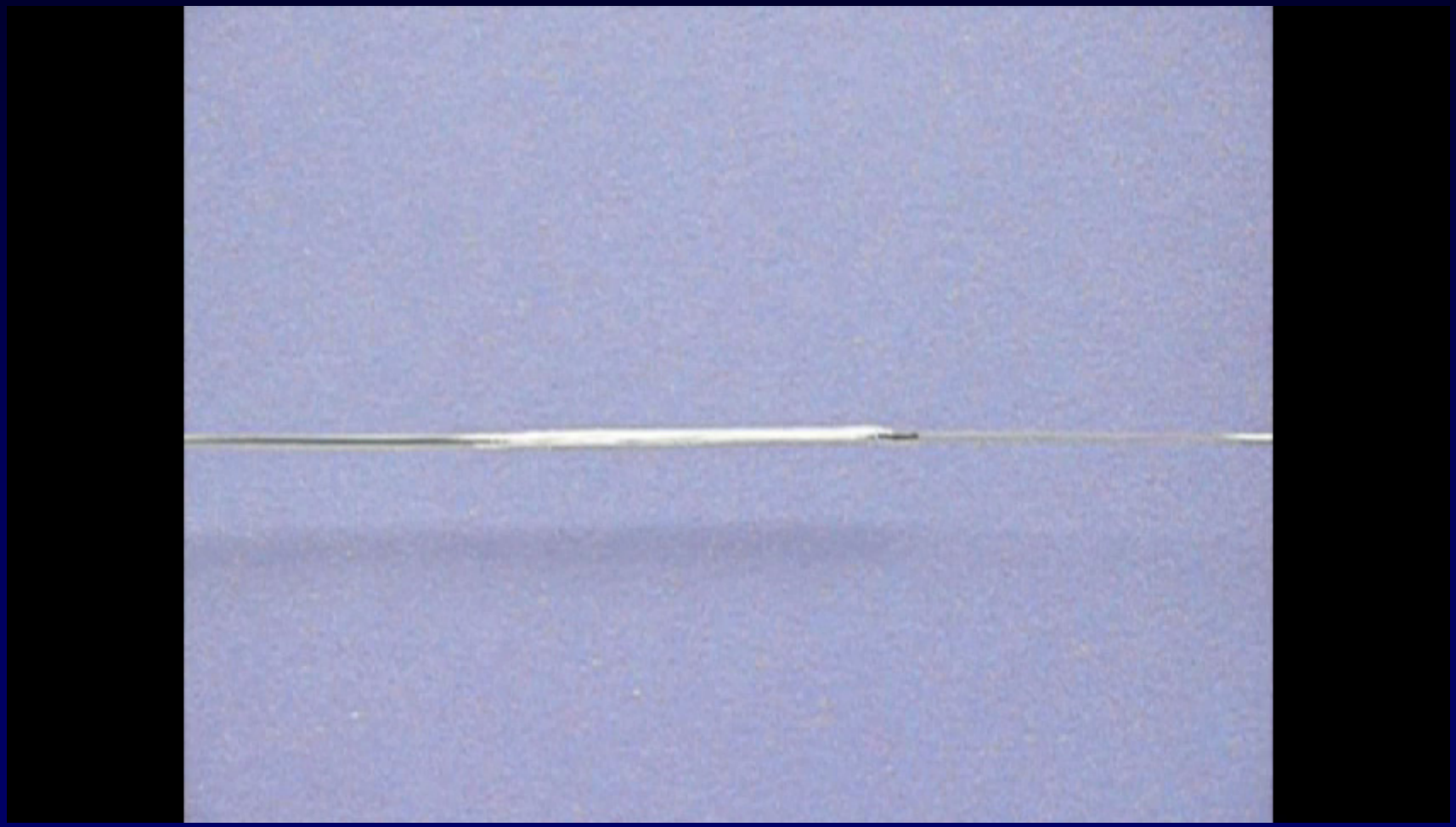




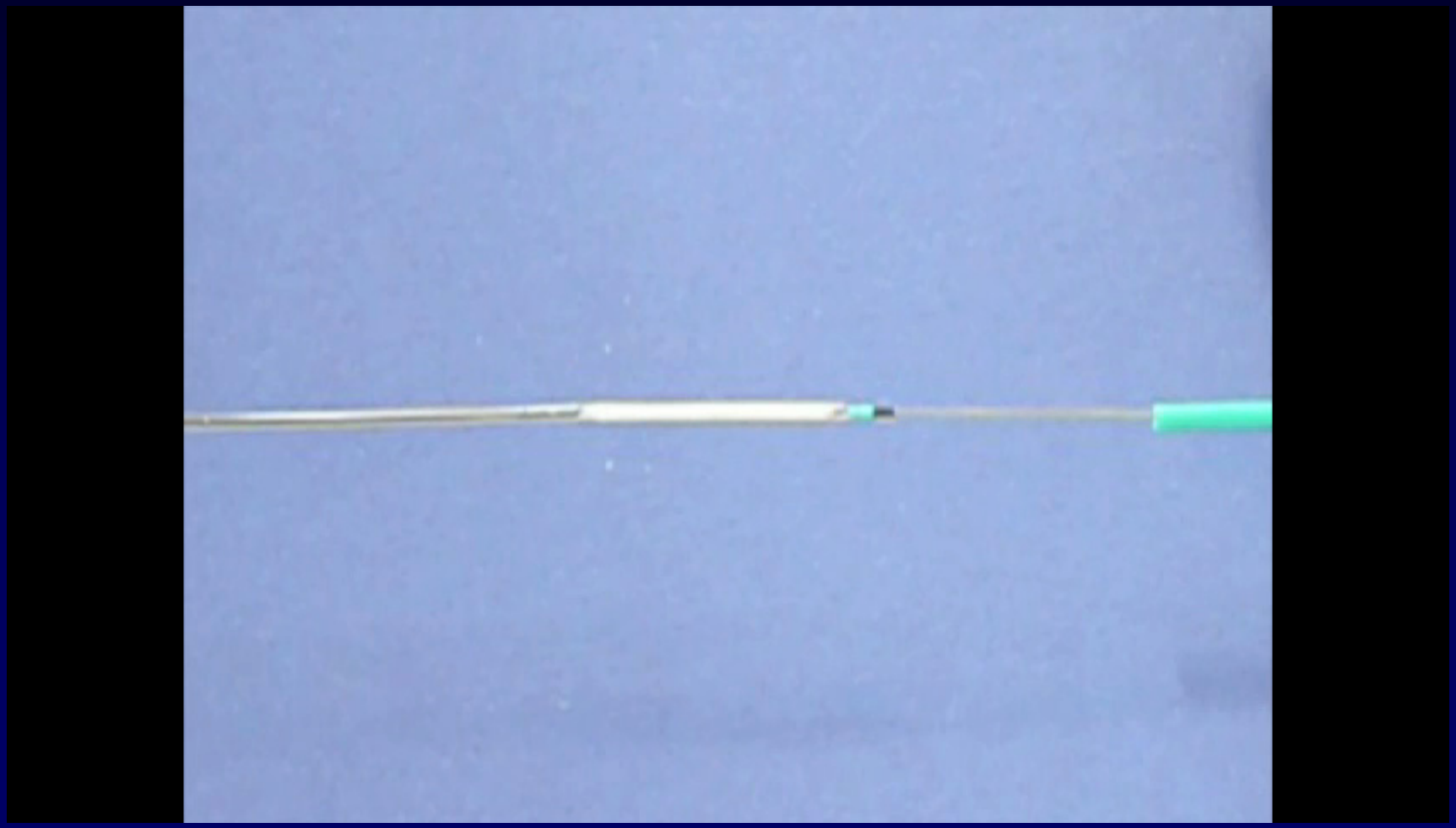



ELUTAX

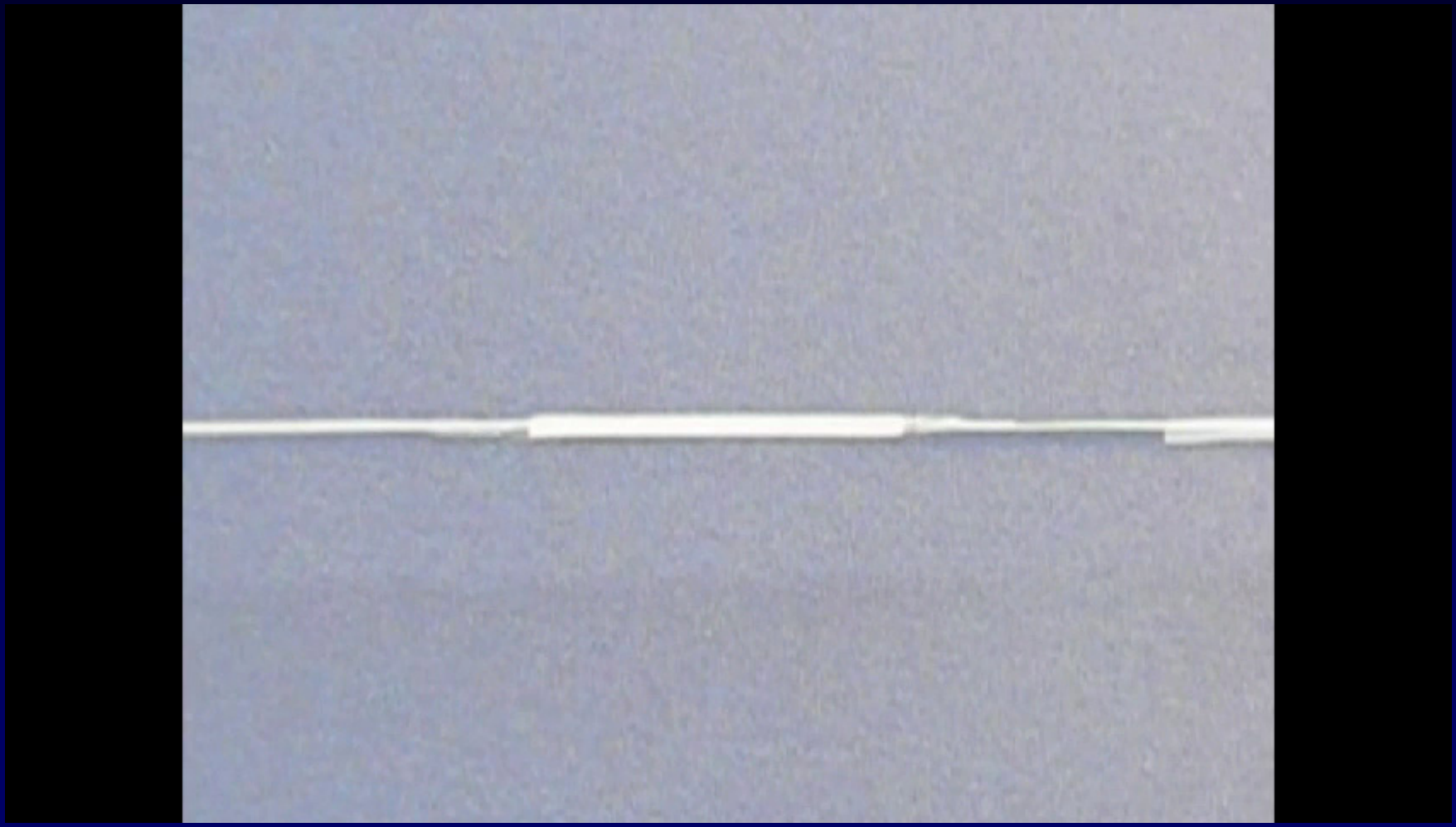
Partikelembolisation
Medikamentenverlust



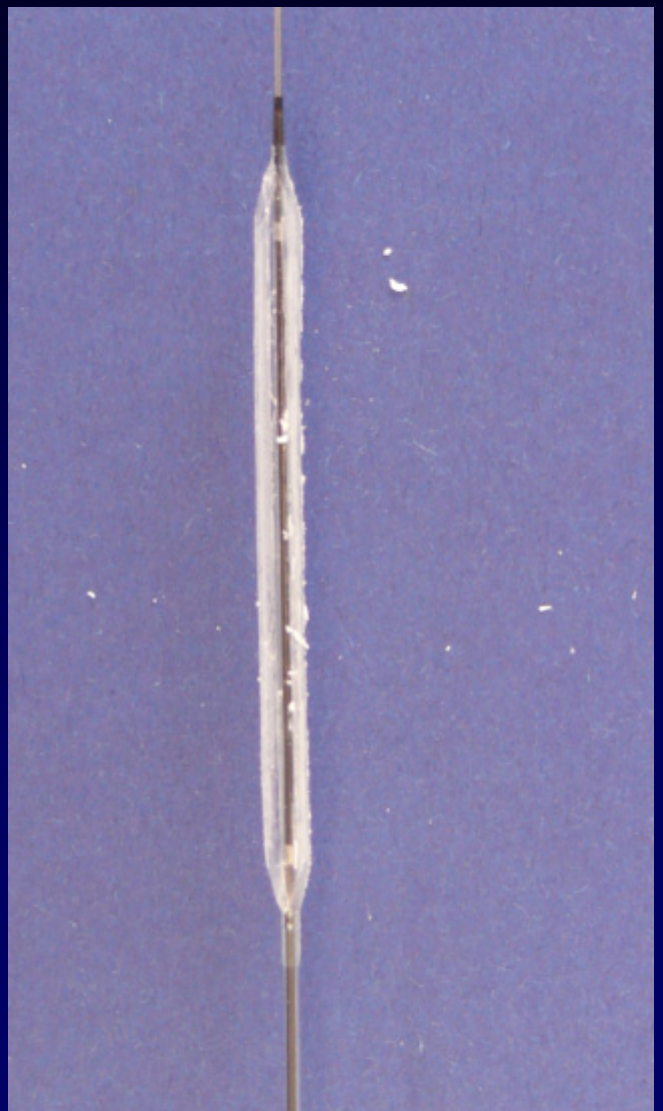
Partikelembolisation
Medikamentenverlust

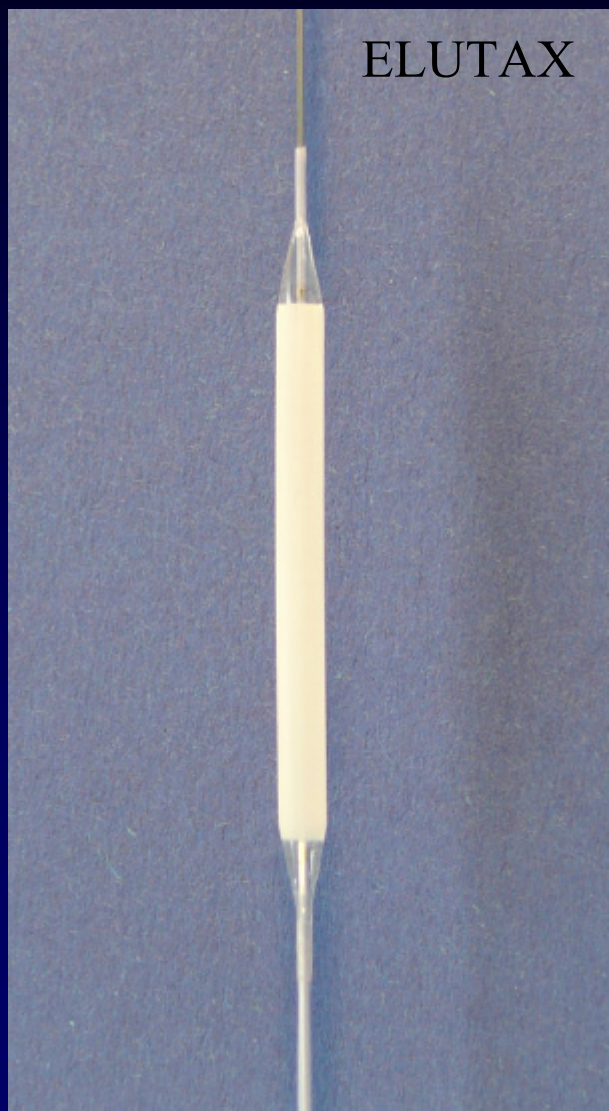


Partikelembolisation
Medikamentenverlust



Partikelembolisation
Medikamentenverlust



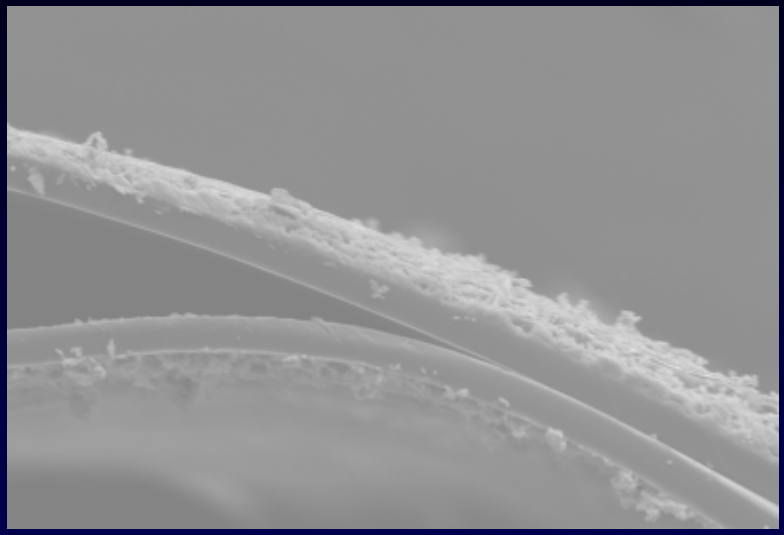


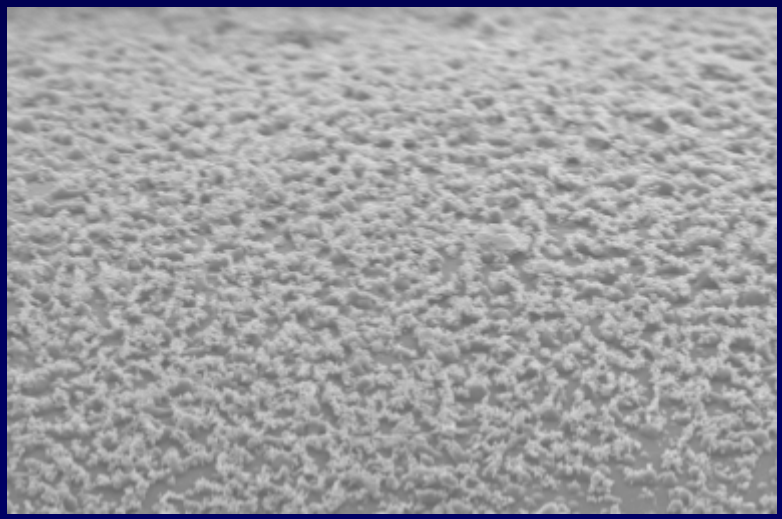
Ziel

1. Medikament auf Ballon festhalten während Steuerung zur Stenose
2. Medikament gut abgeben in das Gewebe bei Dilatation

- Resorbierbares Polymer
- Poröses Material
- Polymer Matrix
- Oberflächenbeladung

Reine Paclitaxel-Beschichtung - Elutax





The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

◄ Previous Volume 355:2113-2124 November 16, 2006 Number 20 Next ►

Treatment of Coronary In-Stent Restenosis with a Paclitaxel-Coated Balloon Catheter

Bruno Scheller, M.D., Christoph Hehrlein, M.D., Wolfgang Bocksch, M.D., Wolfgang Rutsch, M.D., Dariush Haghi, M.D., Ulrich Dietz, M.D., Michael Böhm, M.D., and Ulrich Speck, Ph.D.

These differences in technique result in a marked difference in the duration and concentration of drug exposure between drug-eluting stents and drug-coated balloons. When paclitaxel is administered with a drug-coated balloon, blood flow and other transport processes, as well as biotransformation, decrease antiproliferative activity in the tissue quite rapidly.[17,18] After the catheters were used in this trial, only about 4% of the original dose was found to be extractable from the surface of the balloon. On the basis of studies in animals,[17,18] we estimate that as much as 90% of the dose is lost in the bloodstream.

• • • estimate that as much as 90% of the dose is lost in the bloodstream.

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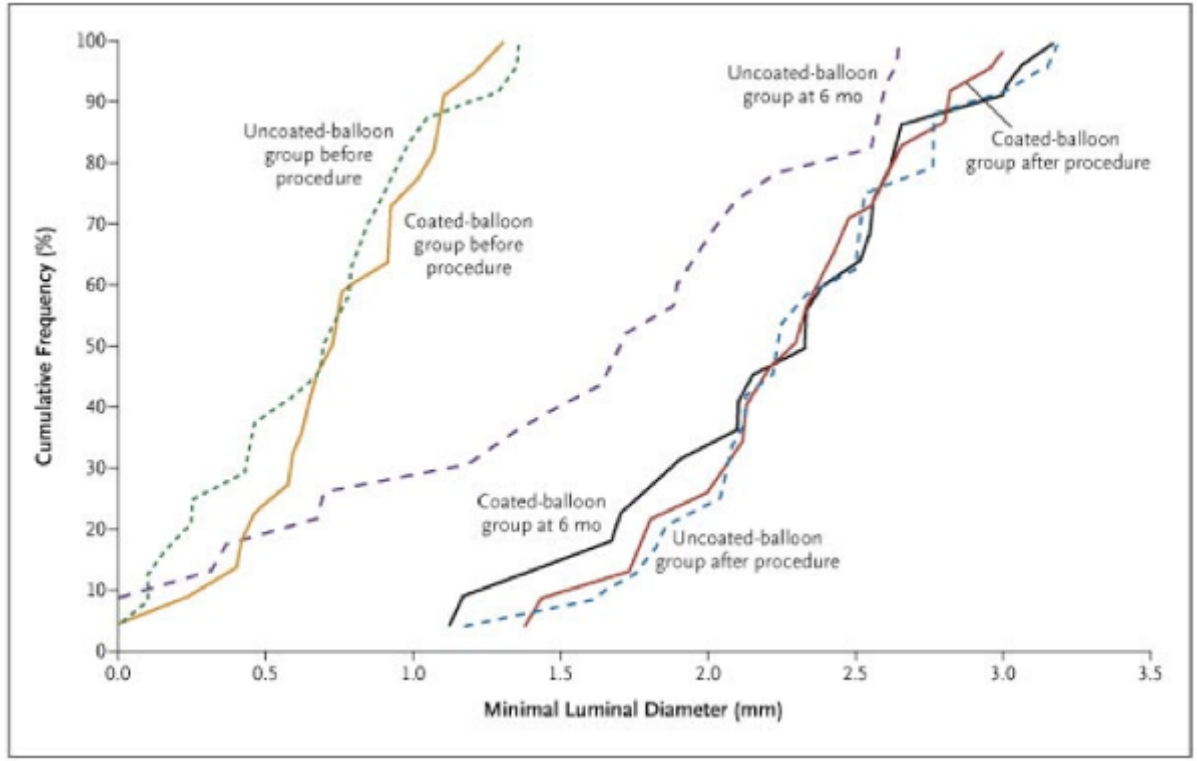
New Eng J Med 2006, 355:2113-24

Primary endpoint (late lumen loss in-segment)

Uncoated balloon	PACCOCATH
0.74 ± 0.86 mm	0.03 ± 0.48 mm

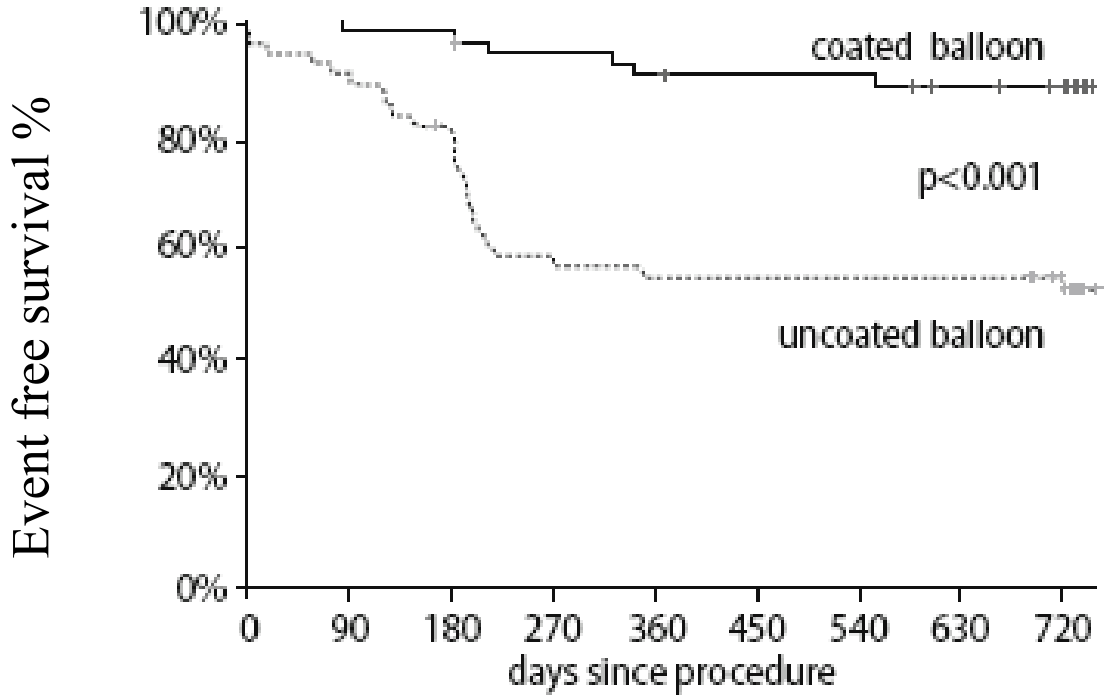


Clin Res Cardiol (2008)
DOI 10.1007/s00392-008-0682-5

ORIGINAL PAPER

Bruno Scheller
Christoph Hehrlein
Wolfgang Bocksch
Wolfgang Rutsch
Dariush Haghi
Ulrich Dietz
Michael Böhm
Ulrich Speck

Two year follow-up after treatment of coronary in-stent restenosis with a paclitaxel-coated balloon catheter



No. at risk

Drug-coated balloon	54	53	51	49	49	48	48
Uncoated balloon	54	47	32	30	30	30	29

Fig. 1 Event free survival from acute and subacute stent thrombosis, target lesion revascularization, myocardial infarction, stroke, and death to 750 days ($n = 108$). Log Rank (Mantel-Cox, intention-to-treat analysis) †

Local Delivery of Paclitaxel to Inhibit Restenosis during Angioplasty of the Leg

Gunnar Tepe, M.D., Thomas Zeller, M.D., Thomas Albrecht, M.D., Stephan Heller, M.D., Uwe Schwarzwälder, M.D., Jean-Paul Beregi, M.D. Claus D. Claussen, M.D., Anja Oldenburg, M.D., Bruno Scheller, M.D., and Ulrich Speck, Ph.D.

N = 154 Multicenter Studie

Femoropopliteale Stenose / Verschluss

Randomisierung

DEB – Paclitaxel im Kontrastmittel – einacher Ballon

Primärer Endpunkt:

Late Lumen Loss nach 6 Monaten

N Engl J Med 2008;358:689-99.

Local Delivery of Paclitaxel to Inhibit Restenosis during Angioplasty of the Leg

Gunnar Tepe, M.D., Thomas Zeller, M.D., Thomas Albrecht, M.D., Stephan Heller, M.D., Uwe Schwarzwälder, M.D., Jean-Paul Beregi, M.D. Claus D. Claussen, M.D., Anja Oldenburg, M.D., Bruno Scheller, M.D., and Ulrich Speck, Ph.D.

Primärer Endpunkt (6 Monate):	Late Lumen Loss (mm)
DEB	0,4 (± 1,2) p<0,001
Paclitaxel im Kontrastmittel	2,2 (± 1,6)
Einfacher Ballon	1,7 (± 1,8)

N Engl J Med 2008;358:689-99.

Local Delivery of Paclitaxel to Inhibit Restenosis during Angioplasty of the Leg

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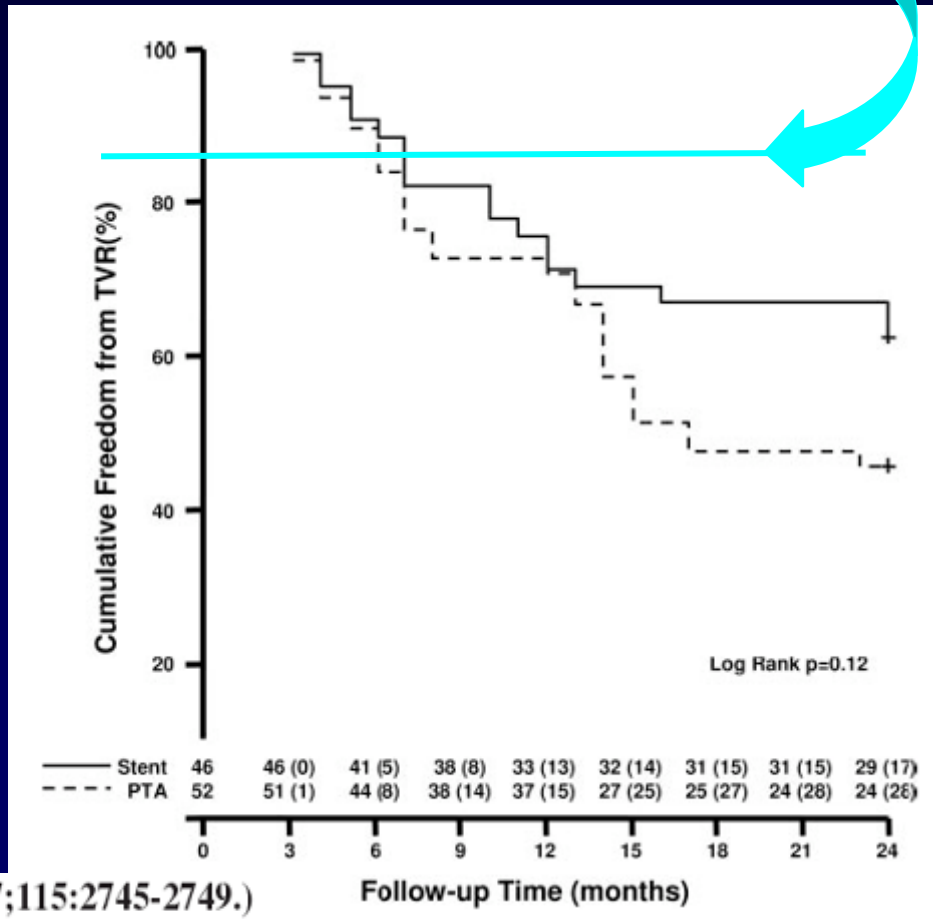
Reintervention der Zielläsion (TLR):	6 Monate	12 Monate	24 Monate
			p<0,001
DEB	2 (4%)	5 (10%)	7 (15%)
Paclitaxel im Kontrastmittel	15 (29%)	18 (35%)	21 (40%)
Einfacher Ballon	20 (37%)	26 (48%)	28 (52%)

N Engl J Med 2008;358:689-99.

Reintervention der Zielläsion (TLR):	6 Monate	12 Monate	24 Monate
DEB	2 (4%)	5 (10%)	7 (15%)

N Engl J Med 2008;358:689-99.



Sustained Benefit at 2 Years of Primary Femoropopliteal Stenting Compared With Balloon Angioplasty With Optional Stenting

Martin Schillinger, MD; Schila Sabeti, MD; Petra Dick, MD; Jasmin Amighi, MD; Wolfgang Mlekusch, MD; Oliver Schlager, MD; Christian Loewe, MD; Manfred Cejna, MD; Johannes Lammer, MD; Erich Minar, MD

(*Circulation*. 2007;115:2745-2749.)

Inhibition of Restenosis in Femoropopliteal Arteries

Paclitaxel-Coated Versus Uncoated Balloon: Femoral Paclitaxel Randomized Pilot Trial

Michael Werk, MD; Soenke Langner, MD; Bianka Reinkensmeier, MS; Hans-Frank Boettcher, MD; Gunnar Tepe, MD; Ulrich Dietz, MD; Norbert Hosten, MD; Bernd Hamm, MD; Ulrich Speck, PhD; Jens Ricke, MD

N = 87 Multicenter Studie

Femoropopliteale Stenose / Restenose / In-Stent Restenose

Randomisierung

DEB – einacher Ballon

Primärer Endpunkt:

Late Lumen Loss nach 6 Monaten

(*Circulation*. 2008;118:1358-1365.)

Inhibition of Restenosis in Femoropopliteal Arteries

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Primärer Endpunkt (6 Monate):	Late Lumen Loss (mm)
DEB (n=31)	0,5 (± 1,1)
Einfacher Ballon (n=34)	1,0 (± 1,1) p = 0,031

(*Circulation*. 2008;118:1358-1365.)

Inhibition of Restenosis in Femoropopliteal Arteries

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Michael Werk, MD; Soenke Langner, MD; Bianka Reinkensmeier, MS; Hans-Frank Boettcher, MD; Gunnar Tepe, MD; Ulrich Dietz, MD; Norbert Hosten, MD; Bernd Hamm, MD; Ulrich Speck, PhD; Jens Ricke, MD

Sekundärer Endpunkt (6 Monate):	Restenose
DEB (n=31)	6 (19%)
Einfacher Ballon (n=34)	16 (47%) p = 0,035

(*Circulation*. 2008;118:1358-1365.)

Inhibition of Restenosis in Femoropopliteal Arteries

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Sekundärer Endpunkt (6 Monate):	TLR
DEB (n=45)	3 (7%)
Einfacher Ballon (n=42)	14 (33%)

p = 0,0024

(*Circulation*. 2008;118:1358-1365.)

Inhibition of Restenosis in Femoropopliteal Arteries

Paclitaxel-Coated Versus Uncoated Balloon: Femoral Paclitaxel Randomized Pilot Trial

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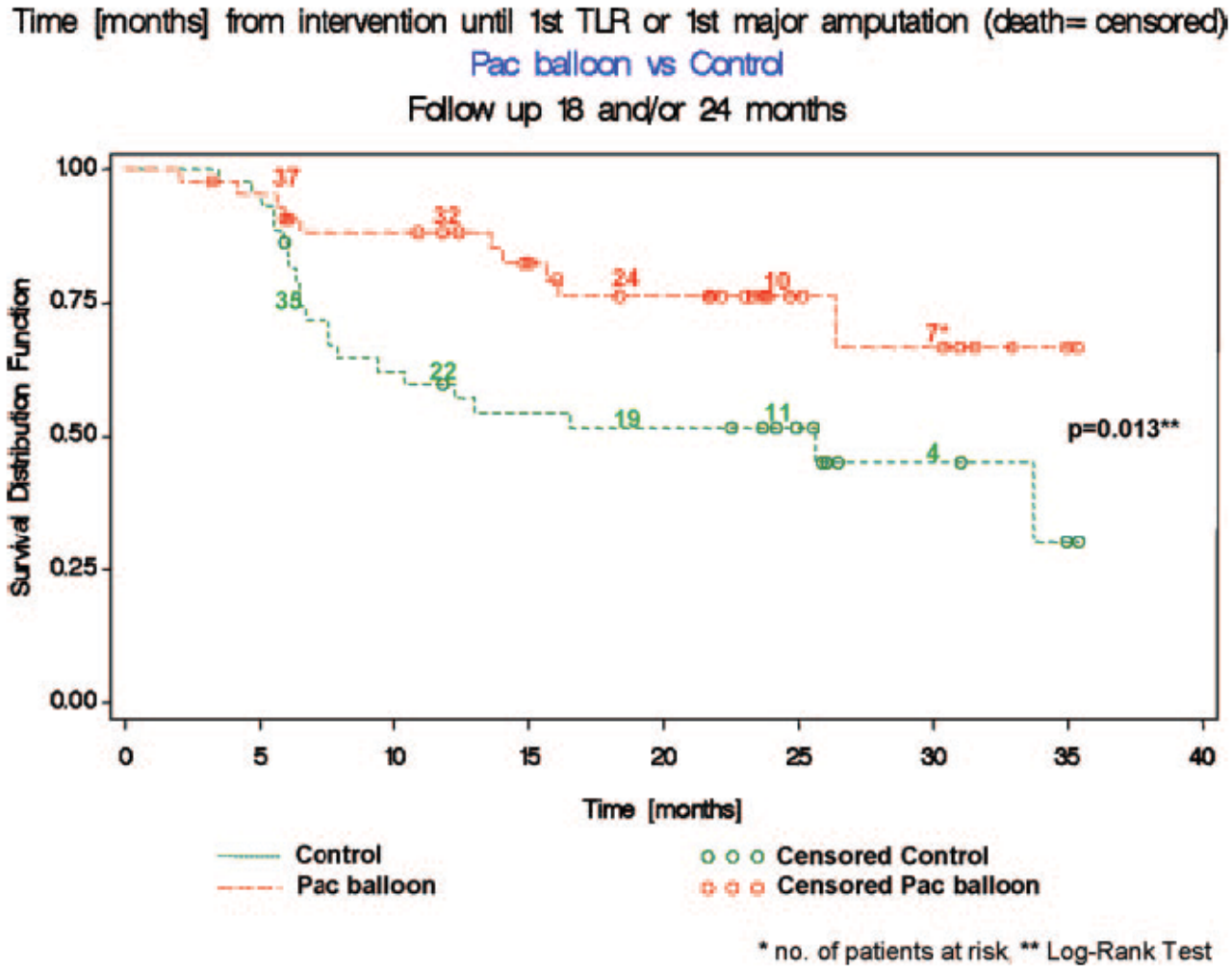
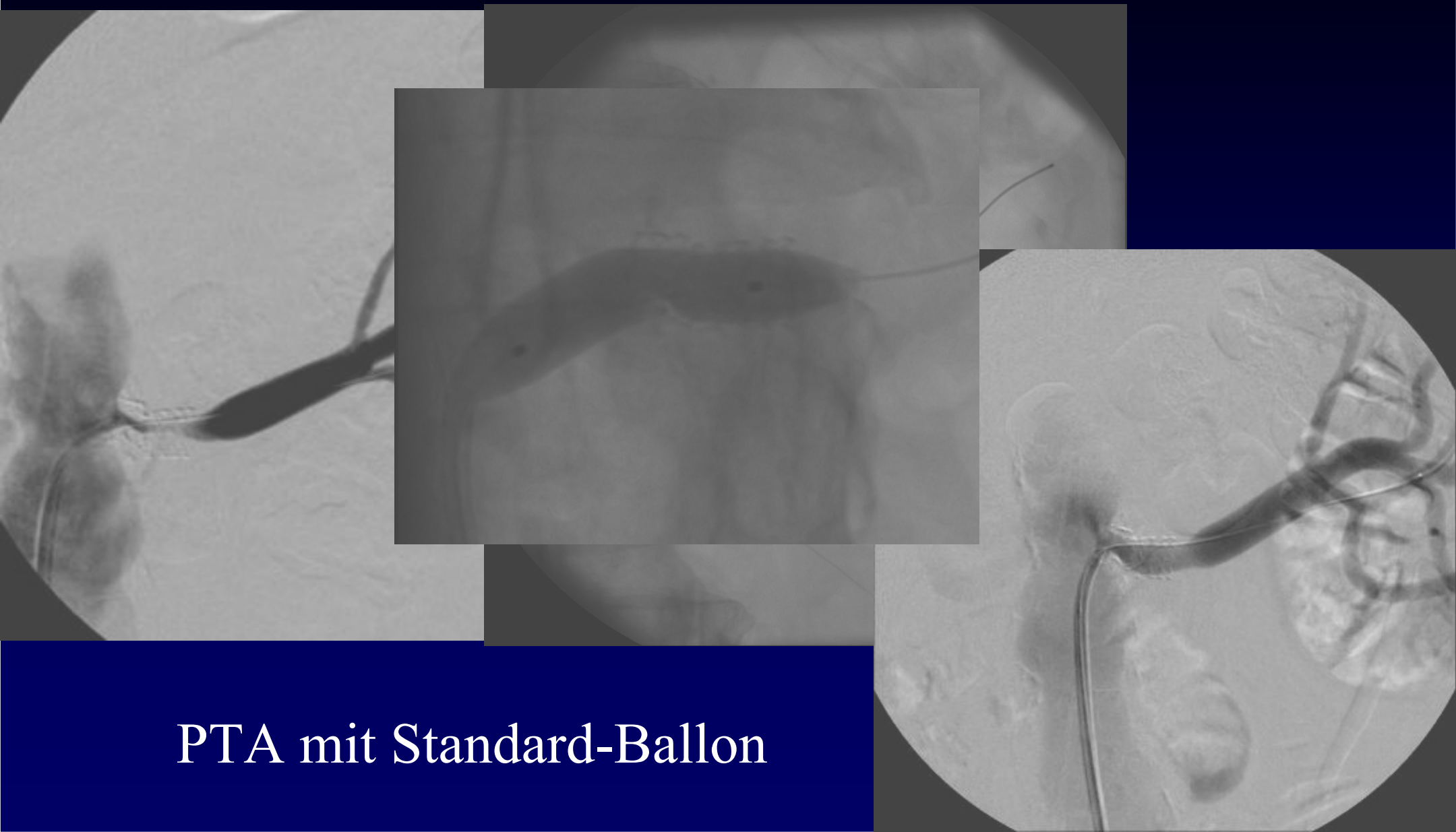


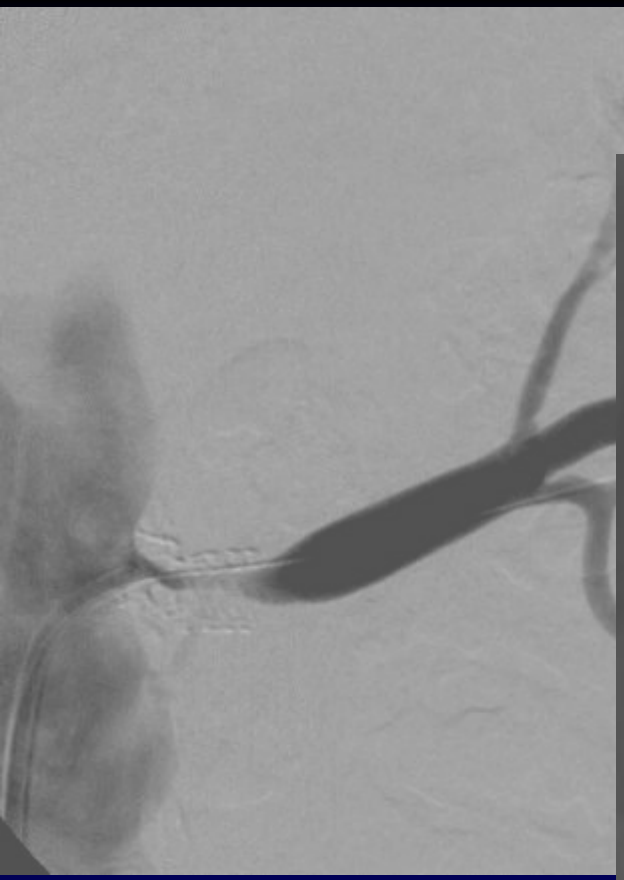
(*Circulation*. 2008;118:1358-1365.)

In-Stent-Restenose



PTA mit Standard-Ballon

In-Stent-Re-Restenose



8 Wochen nach PTA

Re-PTA mit Standard-Ballon

In-Stent-Re-Re-Restenose

Weitere 8 Wochen später

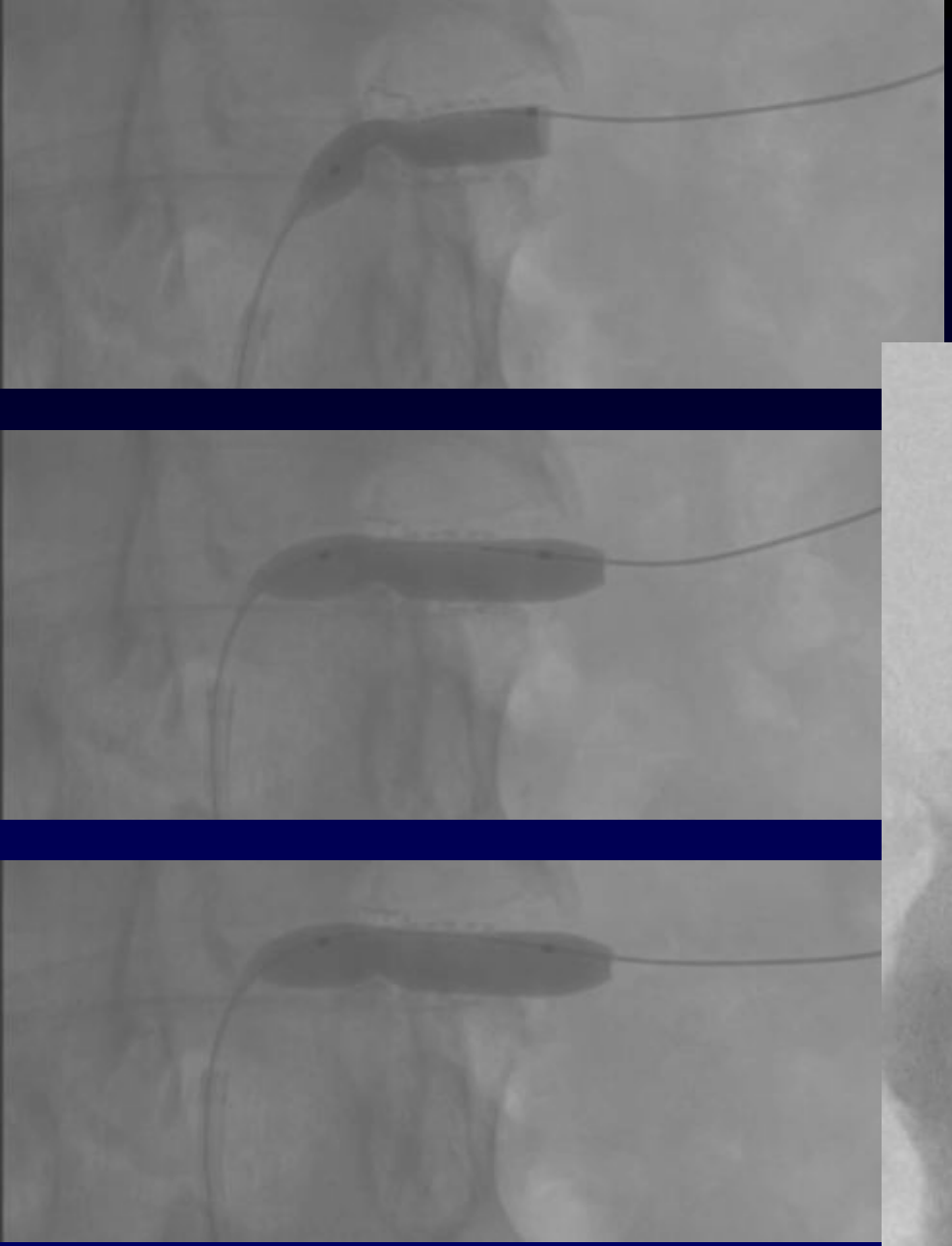
Re-Re-PTA mit Elutax

In-Stent-Re-Re-Re-Restenose

1 Jahr Kontrolle nach

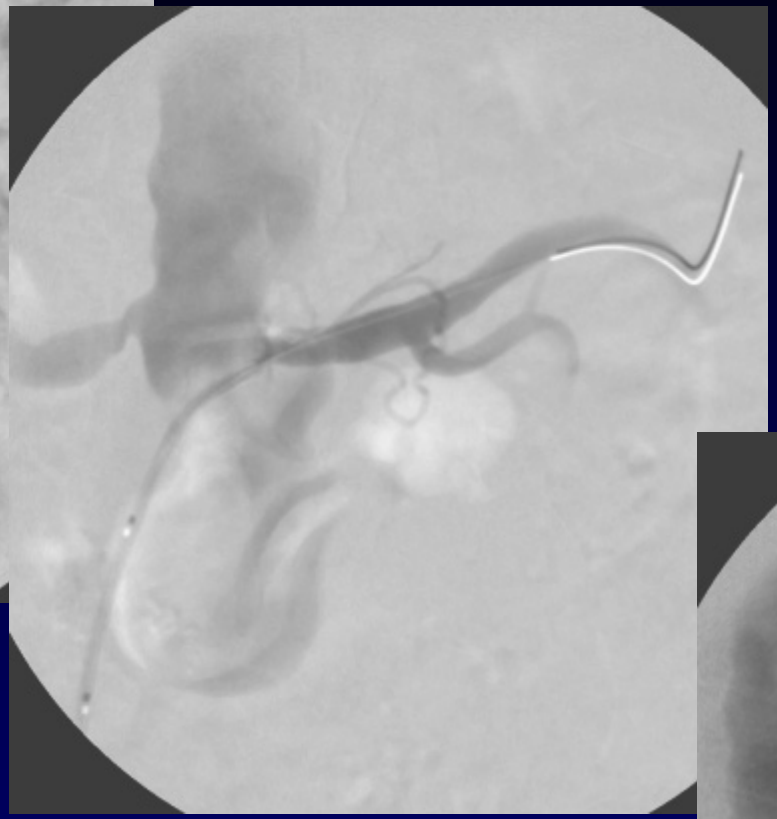
Re-Re-PTA mit Elutax

In-Stent-Re-Re-Re-Restenose



Takayasu Arteritis

Takayasu Arteritis



6 mm ELUTAX
PTA

Stent

Takayasu Arteritis

2 Monats-Kontrolle

10 Monats-Kontrolle

Medikamenten-beschichtete Ballons

Nicht DIE EINE Lösung

aber

Ein sehr nützliches weiteres Instrument

Indikationsstellungen durch weitere Studien klären