

Flash presentation: ByCross rotational artherectomy: technical aspects of a new device with a new philosophy

Jörg Teßarek

Vascular Surgery

Bonifatius Hospital

Lingen

Ralf Kolvenbach

Vascular Surgery

Augusta Hospital

Düsseldorf

Disclosure

Speaker name:

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I have the following potential conflicts of interest to report:

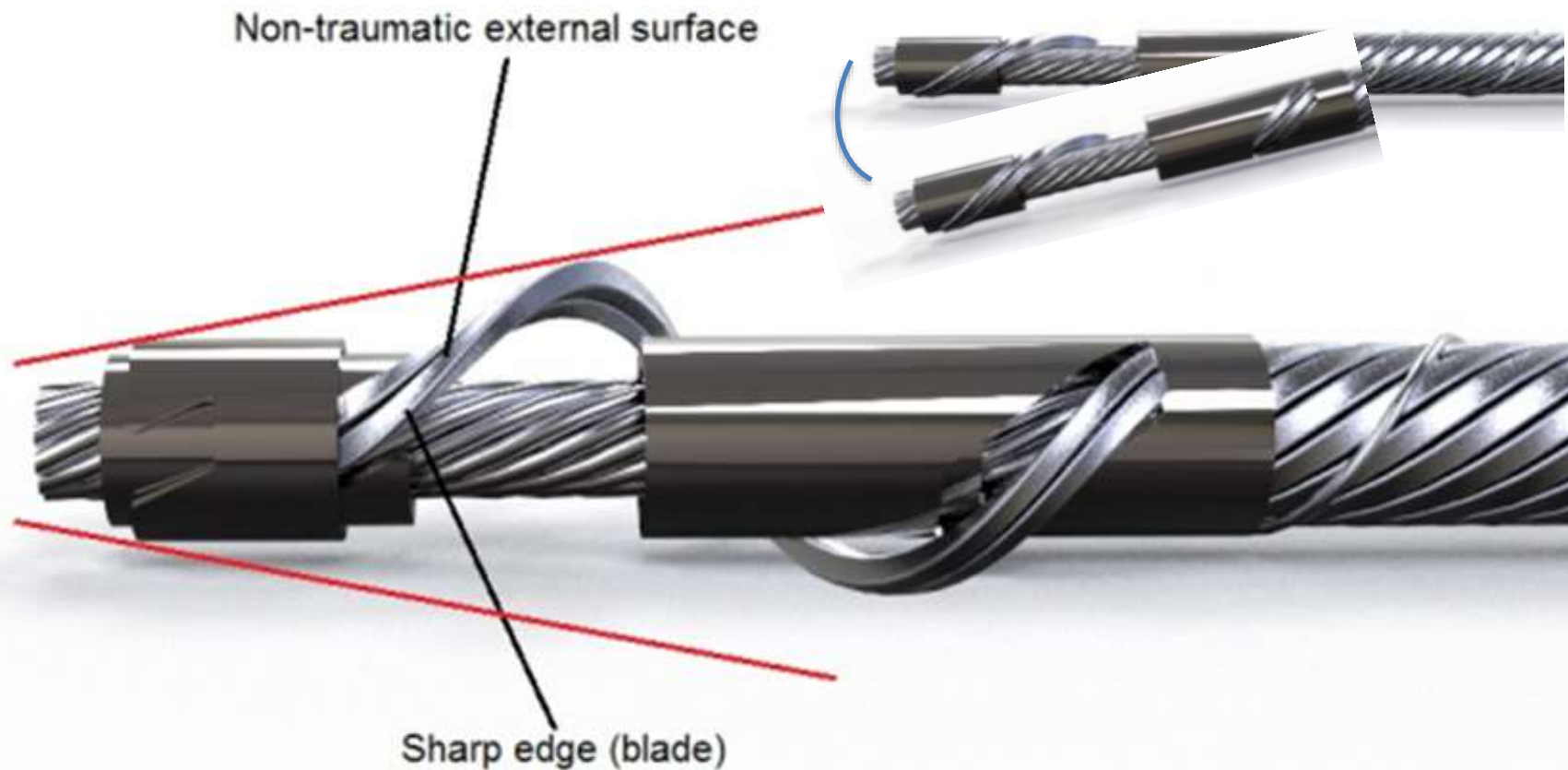
- Consulting
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Other(s)

- I do not have any potential conflict of interest

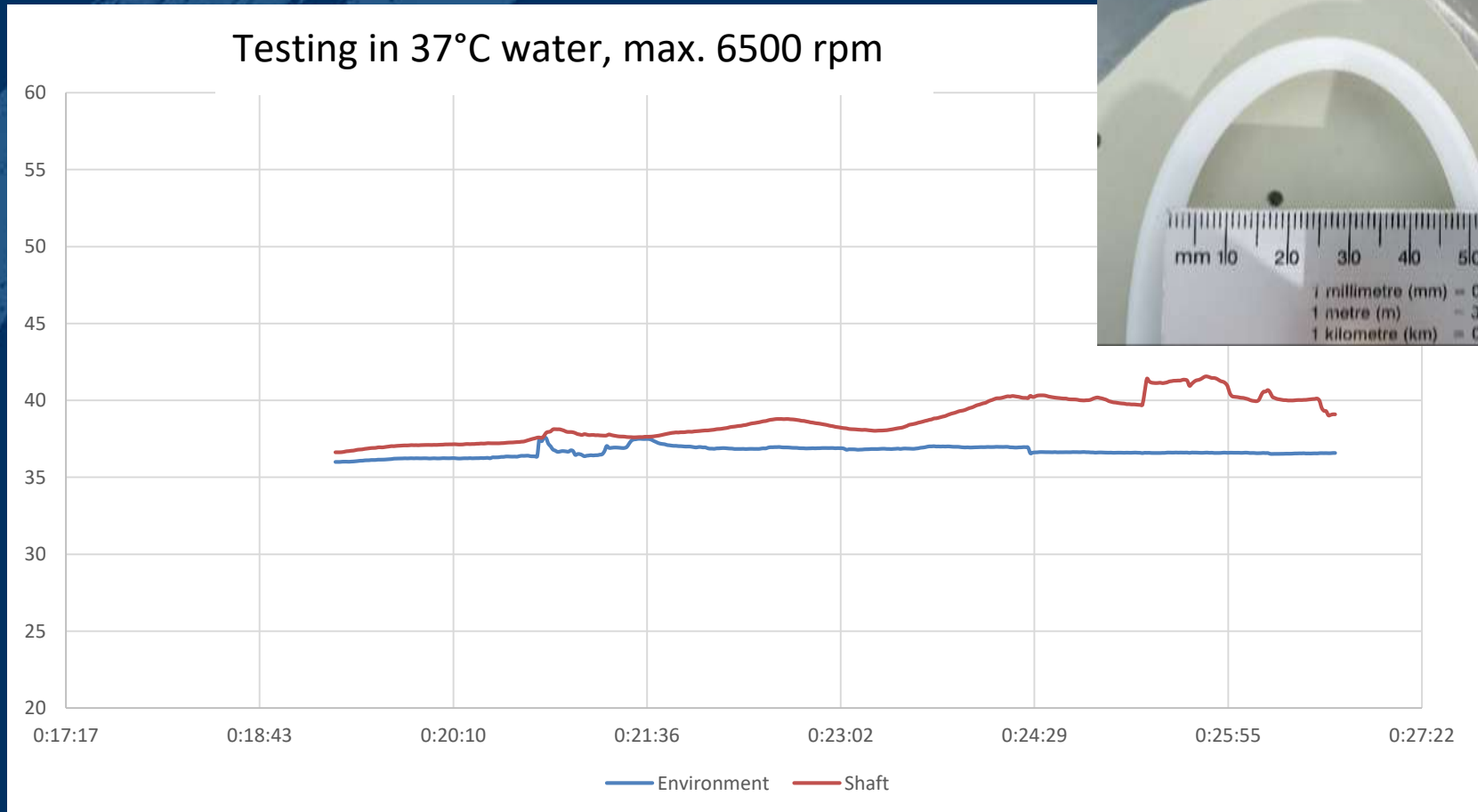
Technical details of the game changer:
Bycross *low velocity* rotational atherectomy
max rotational speed: 6500rpm



Tip design with 1.7 mm and 4.7mm diameter



Testings of shaft and environment heating with 8 min. continuous drilling in bone equivalent with 180° bend and 25mm bending radius (6F Sheath)



Temperature rise during atherectomy

Base line temperature 37° C, rotational device (up to 210k rpm)
tip temperature

Average temp rise of: 52.8 +/- 16.9 ° C.

Rotation 80T rpm 88.3 +/- 12.6°C

Rotation 20T rpm 17.3 +/- 3.8°C (p < 0.001, t-test).

Cooling with 18 cc/min: 11.8 +/- 2.9°C Anstieg

Microscopic specimen of vessel wall:

Thermal damage *of all three wall layers* at tip-to-wall contact points

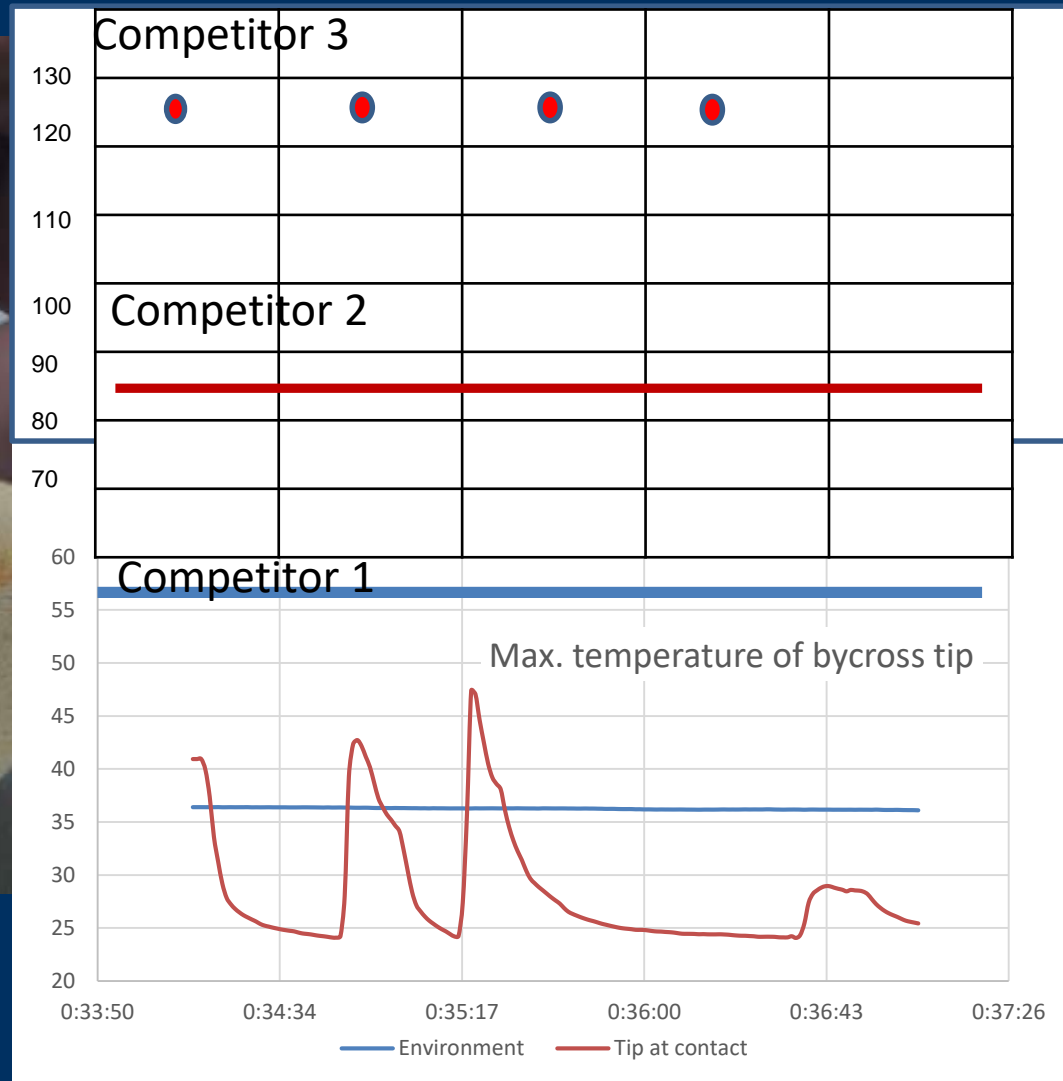
Active cooling/flushing *resulted in extensive vessel dissections*

Gehani AA, Mees MR., Can rotational atherectomy cause thermal tissue damage? A study of the potential heating and thermal tissue effects of a rotational atherectomy device. Cardiovasc Intervent Radiol. 1998 Nov-Dec;21(6):481-6.

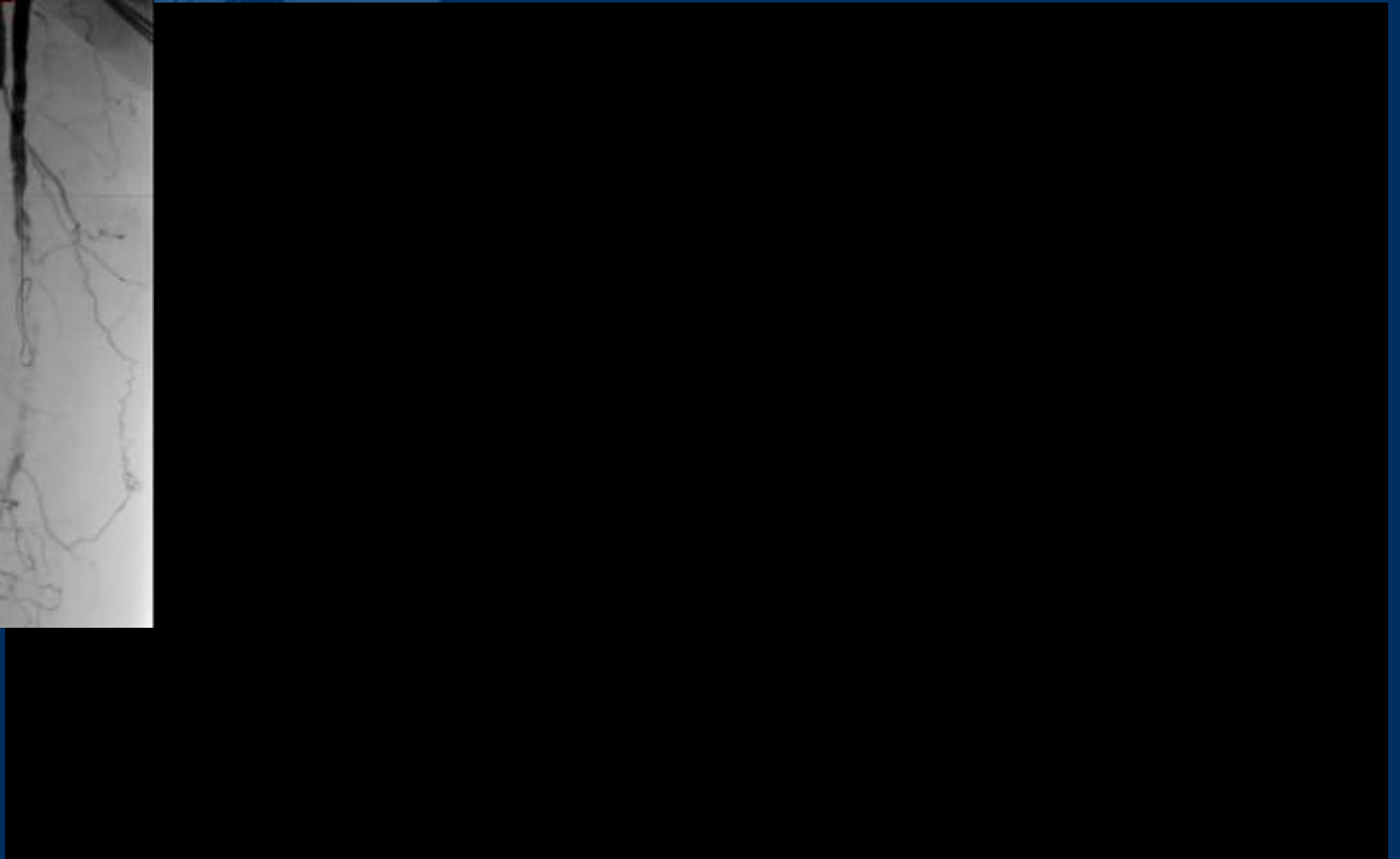
Bycross device testings: tip temperature rise with *dry drilling* in bone equivalent



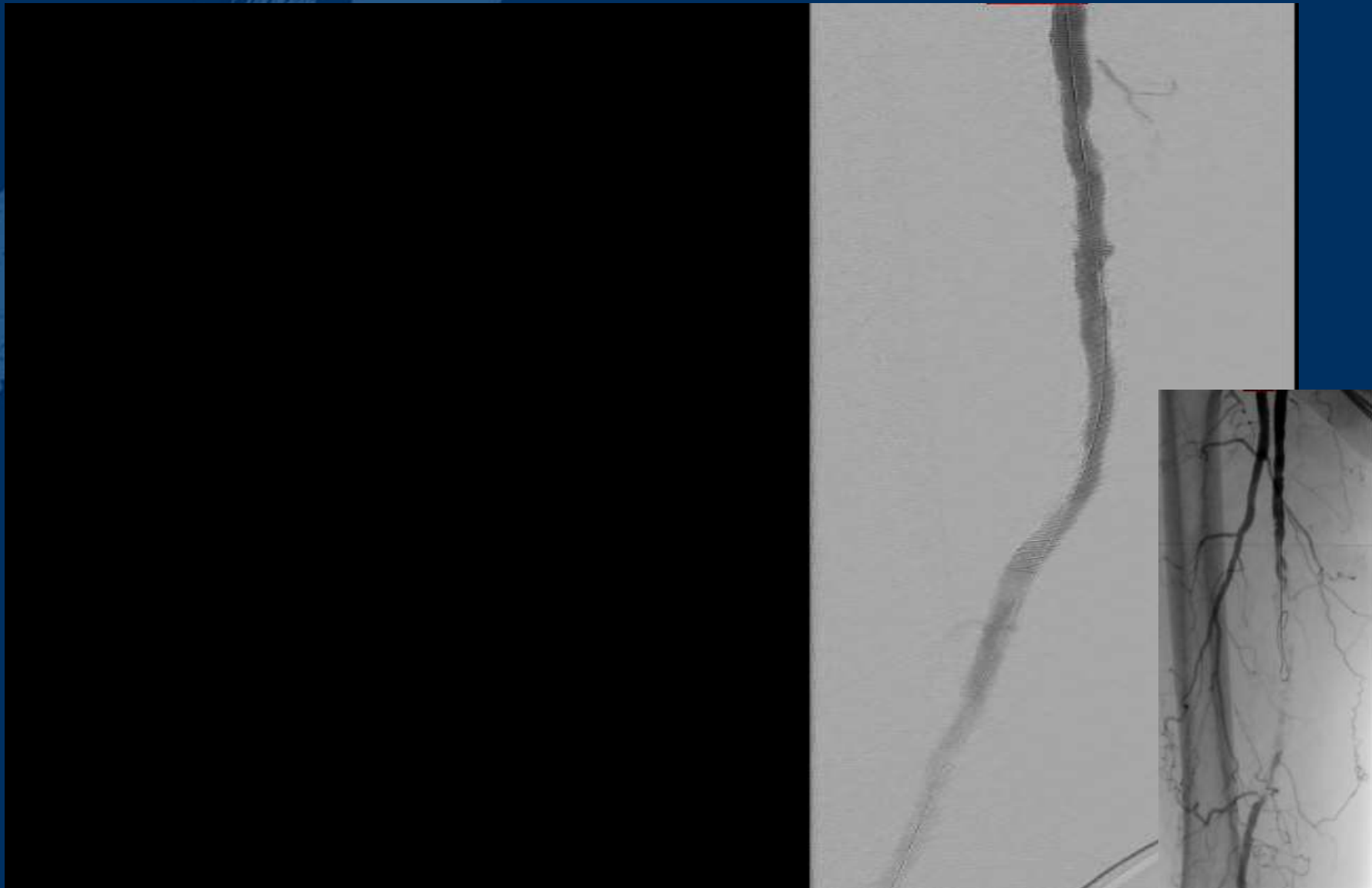
Tip temperature rise up to 47.3°C



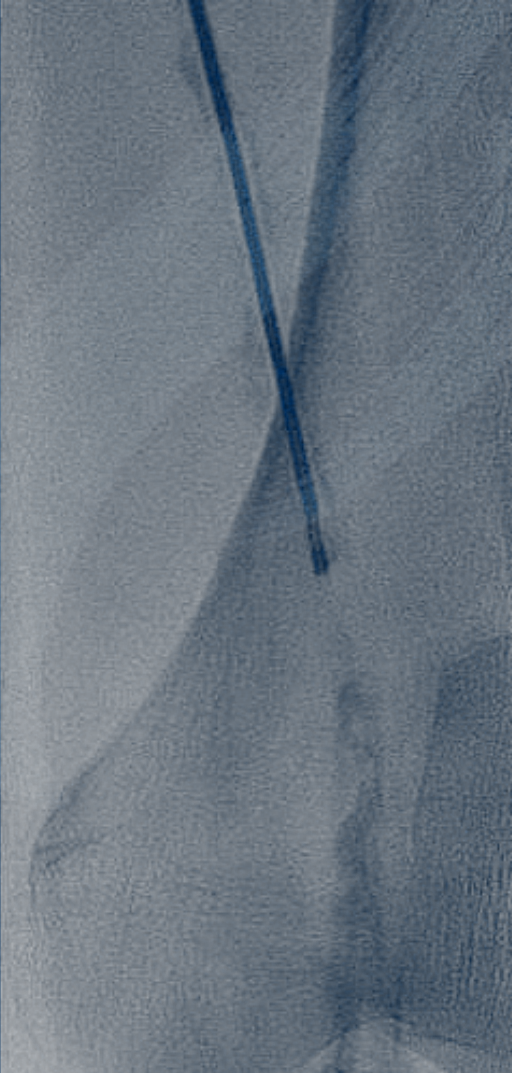
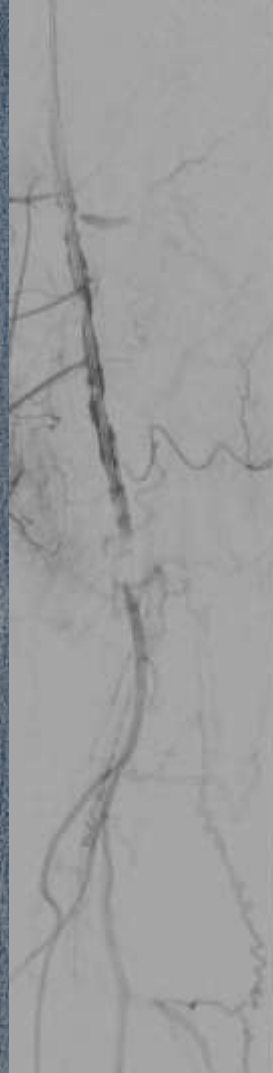
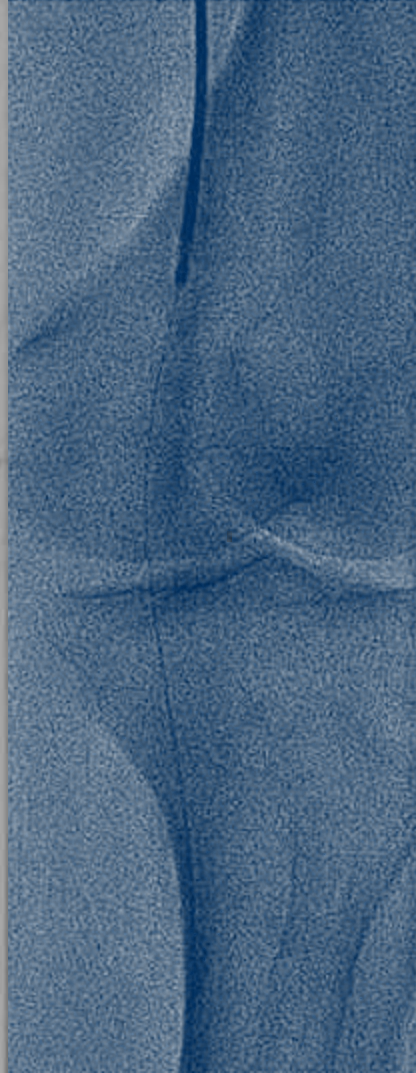
ByCross case with wireless recanalization



ByCross case with wireless recanalization



Bycross antegrad



6mo results of the CE mark trial

	Aug	Boni	total
N	25	17	42
Age	72.0	71.6	71.9
male	64%	58.82%	61.9%
PACSS	3.5	2.5	3.1
Lumen diameter	5.2mm	5.2mm	5.2mm
Lesion length	53.6mm	229.2mm	124.7mm
POBA	92%	94.12%	92.86%
Stent	12%	52.94%	28.57%
Procedural success			95.12%
30 d device related MAE	0%	0%	0%
Pre ABI	0.9 (0.4-2.0)	0.6 (0.3-0.8)	0.8
Discharge ABI	1.0 (0.8-2.0)	0.9(0.9-1.3)	1.0(0.8-2.0)
30 d ABI	0.9 (0.9-1.4)	0.9(0.9-1.4)	0.9(0.9-1.4)
6 mo ABI	0.9(0.9-1.5)	0.8(0.8-1.2)	
Pre stenosis	94.4%	99.4%	96.4%
Discharge stenosis	8.3%(0.0-21.0)	0.8%(0.0-2.77)	5.7%(0.0-21.0)
30 day stenosis	11.3%(0.0-29.28)	5.9%(0.0-24.25)	8.9%
6 mo stenosis	16.7%(0.0-28.15)	21.7%(0.0-34.06)	21.7%

the new philosophy of artherectomy: ByCross

- Sheath diameter 6F antegrade and x-over in any bifurcation angle (min. testings 2.5cm without heating or sheath damage)
- Max. 6500 rpm → no flushing, no cooling, no carbonisation, no stop for angiography (CO₂, ICM)
- Lumen gain 1.9-4.7mm with a single device ABK and BTK (3mm limit as defined by protocol)
- Dedicated for wireless recanalisation, but compatible with all 0.0014 to 0.0035" non-hydrophilic wires without runtime limitation
- artherectomy (ante- and retrograde) with dual active clearance of debris (200cc/min) → no distal protection
- A disposable with separate battery deposition

Distinct features of the ByCross device

	Bycross	Hawk family	Laser	Patheris	Rotablator	Phoenix	Rotarex	Jetstream
PACCS 4	+	+	+	+	+	+	---	+
CTO	+	---	+	---	+	+	+	+
thrombus	+	---	---	---	---	+	+	+
Front+ side cutting	+	---	---	---	+	---	---	+
Wire rear loading	+	---	+	---	---	---	---	---
dual clearance	+	---	---	---	---	---	---	+
6F for 4.7mm lumen	+	---	---	---	---	---	---	---
wireless	+	---	---	---	---	---	---	---
Angio side port	+	---	---	---	---	---	---	---
One size	+	---	---	---	---	---	---	---
investment	---	---	+	+	+	---	+	+



e-mail: joerg.tessarek@hospital-lingen.de

Thank you for your attention!

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