



Rotarex - Möglichkeiten und Grenzen

24. Norddeutsche Gefäßtage

Dr. Axel Pflugradt
Klinik für Gefäß- und endovaskuläre Chirurgie
Ev. Amalie Sieveking-Krankenhaus

Hamburg, 09.06.2017

ALI- akute Durchblutungsstörung bei AFS-Verschluss

Möglichkeiten der Revaskularisation

- Thromboembolektomie
- Selektive kathetergestützte Thrombolyse
- Aspirationsthrombektomie
- Perkutan mechanische Thrombektomie

Perkutan mechanische Thrombektomie





Prinzip- archimedische Schraube

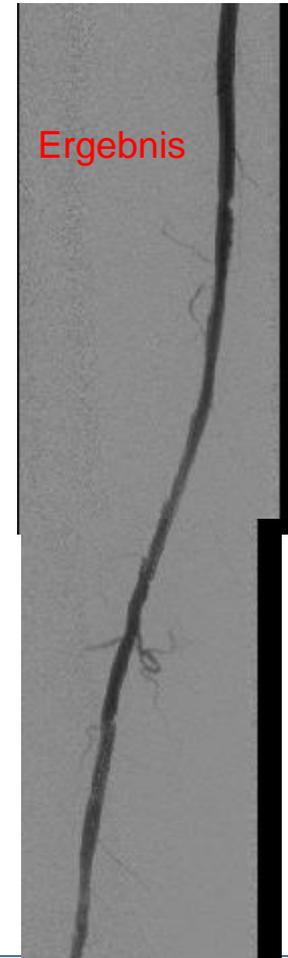
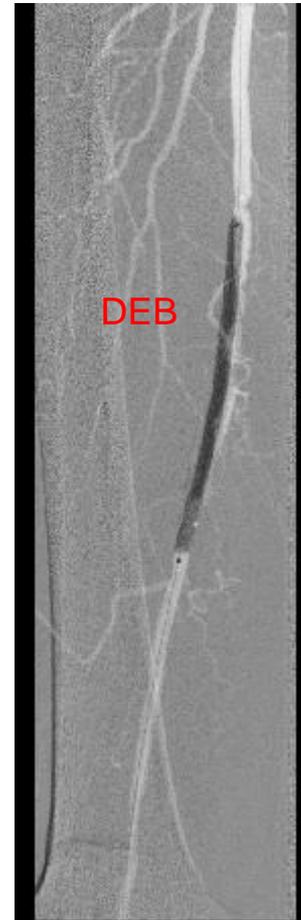
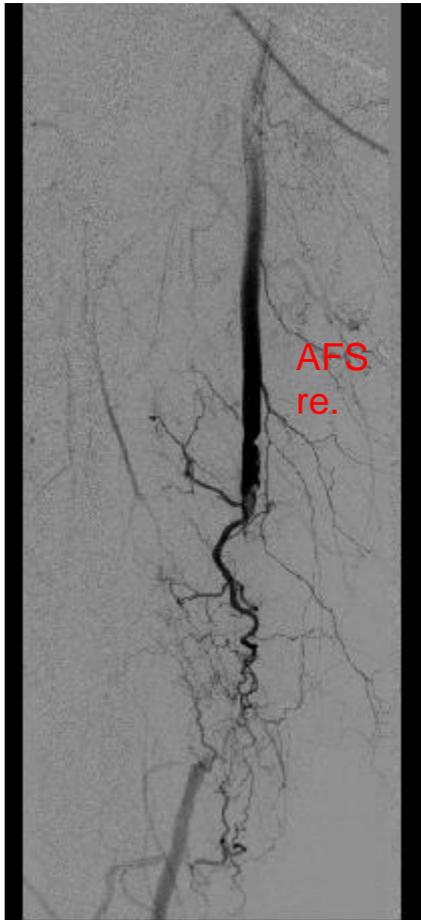
- Ablösung des thrombot. Materials von der Gefäßwand(1cm/s)
- Aspiration des gelösten Materials in den Katheterkopf
- Thrombusfragmentation
- Transport außerhalb des Gefäßsystems

Rotarex® 8F

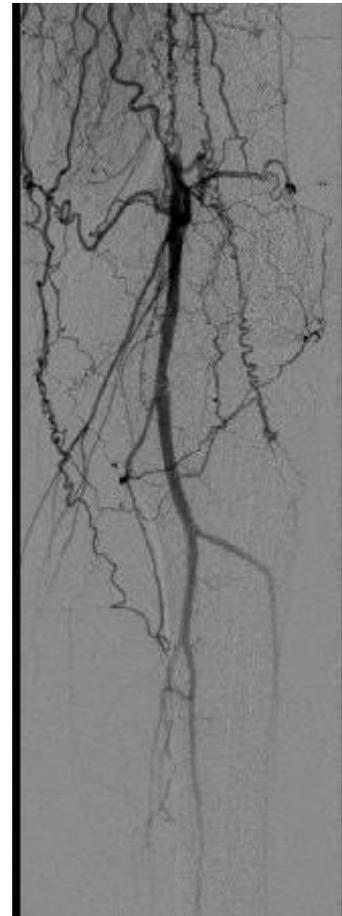
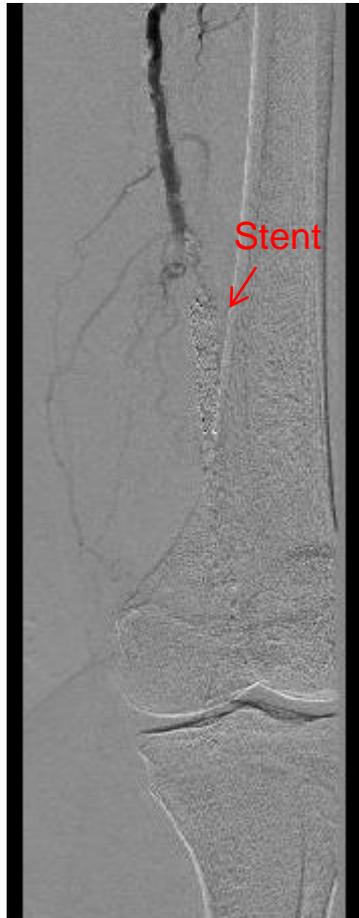


Vessel diameter 5 - 8 mm
Subacute and chronic occlusions

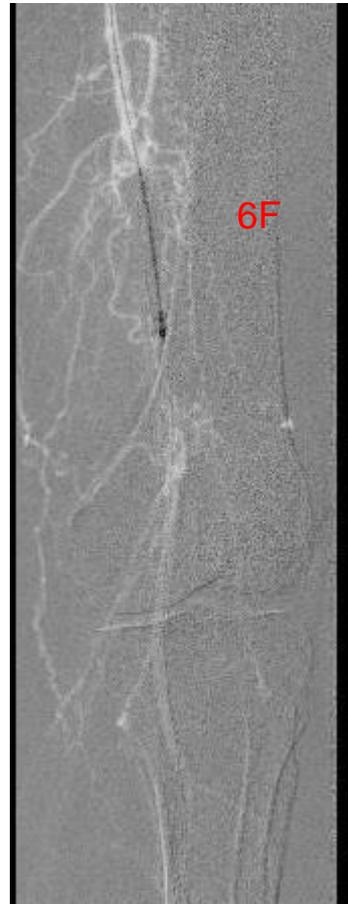
Subakuter Verschluss



In-Stent-Verschluss



In-Stent-Verschluss





Ergebnis

Beckenarterienverschluss



mglw. besseres Kurzzeitergebnis und weniger Komplikationen

• Keine randomisierten Vergleichsstudien zur Thrombolyse

Kronlage et al

Dovepress

Table 5 Major complications in the three intervention groups. Patients were additionally subdivided into critically ill (white space) and noncritically ill (gray space)

	Rotarex®	Lysis	Rotarex®+lysis	Total	P-value
Major bleeding	3.6% (5/138)	22.2% (4/18)	0	5.11% (9/176)	R vs L* R vs R+L ns L vs R+L*
	0	10% (1/10)	25% (2/8)	11.5% (3/26)	R vs L ns R vs R+L** L vs R+L ns
Aneurysma sp.	2.9% (4/138)	0	0	2.3% (4/176)	ns
	0	0	12.5% (1/8)*	3.8% (1/26)	ns
AV-fistula	0.7% (1/138)	0	0	0.6% (1/176)	ns
	0	0	0	0	ns
Compartment	0	0	0	0	ns
	0	0	12.5% (1/8)	3.8% (1/26)	R vs L ns R vs R+L* L vs R+L*
Hospital length stay (days)	1.4±0.9	4.6±3	4.4±1.8	–	R vs L*** R vs R+L*** L vs R+L ns
	21.7±34.4	13.3±4.5	18.3±9.36	–	ns

Notes: *P<0.05, **P<0.01, and ***P<0.001. Data are presented as mean ± standard deviation or % (n/N).

Abbreviations: R, Rotarex®; L, lysis; ns, nonsignificant; AV, arteriovenous.

n = 158

Kronlage et al. [Drug Design, Development and Therapy](#) ,18 Apr 2017, 11:1233-1241

gute Offenheitsraten, auch ohne additive Therapie

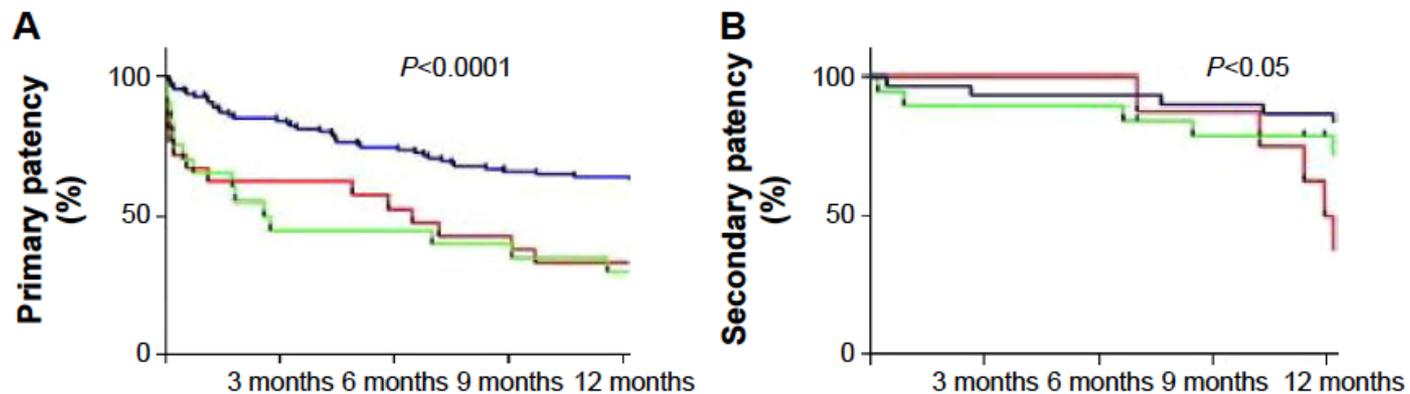


Figure 2 Twelve-month freedom from target lesion revascularization, re-occlusion, or significant restenosis is presented as Kaplan-Meier primary (A) and secondary patency (B) curves. Rotarex[®]-treated patients are coded in blue, lysis-treated in green, and Rotarex[®]+lysis-treated in red. *P*-values are attributed to the corresponding subfigures.

Kronlage et al. [Drug Design, Development and Therapy](#) ,18 Apr 2017, 11:1233-1241

- **Single-center (retrospektiv):**
n=148

TABLE 6: Comparison of our data to historical clinical trials.

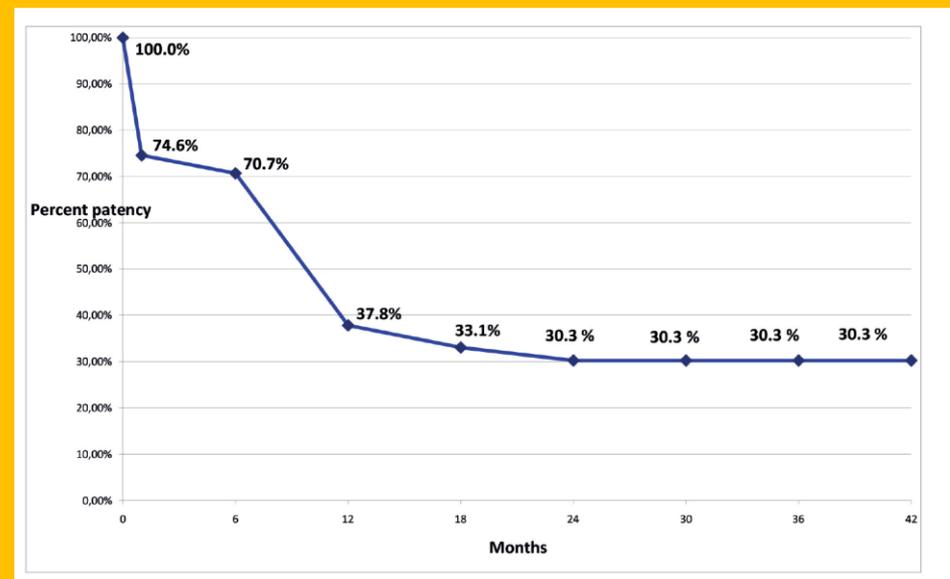
	Mortality at 30 days	Amputation rate	Success of revascularization
Rochester trial	16%	18%	70%
STILE trial	4%	5%	82%
TOPAS trial	5%	2%	80%
Our study ⁴	0.7%	2%	90.5% (68.7% + 21.8%)

⁴Mechanical thrombectomy as first-line treatment combined with overnight fibrinolysis.

single-center (retrospektiv):

n=128

Initiale Erfolgsrate
>90%



Stanek F. Vasa (2016), 45 (1), 49 – 56

n=528**TLR n. 12 Mo. 10 %**

- **PMT** allein
n=161 (27.2%)
- **+ PTA** n=232 (39.1%),
- **+ Stenting** n=169
(28.4%)
- **+ Lyse** n=77 (13.9%)

Table 6. Major Adverse Event (MAE) and Late Complication Event (LCE) at 12-Month Postoperative Day (n = 486).*

	Events	(%)
MAE		
Death	39/486	8.0
MI	15/486	3.1
TLR	49/486	10.1
Non-TLR	32/486	6.6
Major amputation	11/486	2.3
LCE		
Renal failure	21/486	4.3
Contralateral leg event	66/486	13.6
Stroke	13/486	2.7

Abbreviations: MI, Myocardial infarction; TLR, Target lesion revascularization
non-TLR, Nontarget lesion revascularization.

*Values are rate numbers (%) of observations.

Freitas B. *Angiology*. 2017 Mar;68(3):233-241

- **Typische Komplikationen**

Reversschluss (1-5%)

in bis zu 30% bei Bypassverschlüssen

periphere Embolisation (3-5%)

Perforation (1-2%)

- **Adjuvante Therapie**

begleitende Lysetherapie

Aspirationsthrombektomie

PTA/ Stent

- **Kontraindikationen**

nicht passierbarer Verschluss

subintimale Position

Gefäßdurchmesser < 4 mm

unzureichende Möglichkeit der Antikoagulation

In-Stent-Verschlüsse

Rotarex mechanical debulking: The Leipzig experience in 1.200+ patients

Intervention Feature

- In-stent procedures → 338 Procedures
- Native „virgin“ arteries
- Surgical bypasses
- Redo procedures

Rotarex mechanical debulking in In-stent procedures. Clinical Follow-up: 30-day results

Major Adverse Events (MAE) to 30 postoperative day		
MAE	Events	(%)
Death	4	1.2
MI *	6	1.8
TLR **	9	2.7
TVR ***	3	0.9
Major Amputation	7	2.1
Total	29	6.7

Table 4. Major Adverse Events (MAE) to 30 postoperative day. Values are only numbers (%) if appropriate.
* Myocardial infarction, ** Target lesion revascularization, *** Target lesion revascularization

Rotarex mechanical debulking in In-stent procedures. Acute results

- Procedural success rate: 326 (96.4%)
- Main performed procedure
 - Rotational Thrombectomy alone: 68 (20.9%)
 - Rotational Thrombectomy + PTA: 195 (59.6%)
 - Additional Stenting(re-stenting): 41 (12.6%)
 - Additional Thrombolysis: 45 (13.9%)
 - Associated BTK treatment: 75 (23.1%)
- Mean time follow-up: 12 ± 2.4 months

Rotarex mechanical debulking in In-stent procedures. Clinical Follow-up: 12 months results

Major Adverse Events (MAE) to 12-months		
MAE	Events	(%)
Death	31	9.2
MI *	7	2.1
TLR **	43	12.7
TVR ***	41	7.9
Major Amputation	47	3.9

Bypass-Verschlüsse

Table 4 Follow-up findings after rotation thrombectomy

Study	Number of patients	Technical success rate	Follow-up
Zeller et al ⁷	7	78% (7/9)	0.90 ± 0.10 (ABI at 3 months) Restenosis at 12 months: 86%
Wissgott et al ¹⁰	20	95% (19/20)	<u>Primary patency rate: 66%</u> (12 ± 3 months) <u>Secondary patency rate: 86%</u> (12 ± 3 months)
Wissgott et al ⁶	10	100% (10/10)	0.85 ± 0.10 (ABI at 1 month)
Lichtenberg et al 2011	22	82% (18/22)	0.81 ± 0.1 (ABI at 6 months) <u>No reinterventions after 6 months</u>

Abbreviation: ABI, ankle-brachial index.

Lichtenberg et al. Vascular Health and Risk Management
2012;8 283–289

Fazit

- **Vorteile**

**Eingriff auch im subakutem Stadium mgl., additive
Therapien optional (z.B. Lyse)**

Zeitersparnis durch einmalige Prozedur („all-in-one“)

Kosten-u. Ressourcenersparnis (keine IMC)

weniger Komplikationen

Refinanzierung bei guter Fallsteuerung

Fazit

- **Grenzen**

kleinkalibrige Gefäße (Unterschenkel)

kalzifizierende Plaques (kein Atherektomie-System)

Vielen Dank!

