INTERNATIONAL STROKE conference 2008

Early Clinical Experiences With A New Thrombectomy Device For The Treatment Of Ischemic Stroke

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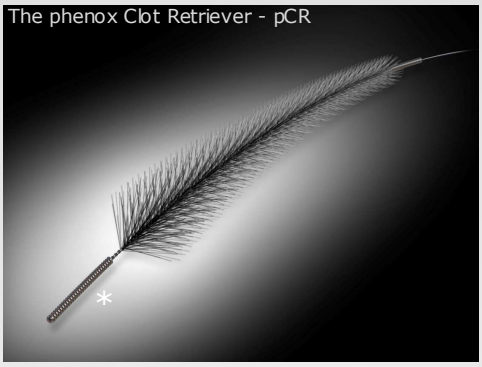
Introduction: A new flexible micro filament device for intraarterial thrombectomy, the phenox Clot Retriever (pCR) has become available for use in patients experiencing acute ischemic stroke in Europe since October 2006. So far, over 130 applications have been registered in 13 centers throughout Germany and France. More than half of these patients were treated in three centers alone (Bonn, Munich, and Stuttgart). The analysis of outcome and recanalisation rates presented here is based on a subset analysis of 60 vascular territory applications in 55 patients performed in these three centers in 2007.

The phenox Clot Retriever - pCR



Concept: The pCR is comprised of a dense array of polyamid fibres that increase in length from proximal to distal, attached to a flexible nitinol core wire. The wire also carries two platinum markers for radiopacity (*). Three sizes are available: 1-2 mm proximally, 2-5 mm distally. The small version is 1cm, the other two are 2cm in length. The pCR can be deployed through a standard microcatheter (.021" or .027"). The small version (1-2mm/1cm) is capable of reaching vessels with a diameter below 2mm, e.g. distal MCA branches.

Patients: 60 vascular territories were treated in 55 patients, 31 male (av. 63 yo) and 24 female (av. 69 yo). The most common source of thrombemboli was cardiogenic, followed by arterio-arterial (e.g. carotid stenosis), hypercoagulative state and iatrogenic after carotid stenting or aneurysm coil occlusion.

The average NIHSS pre/post treatment was 15/9 within 48h

Target vessels (mult. possible)

ICA :	11
BA :	15
MCA:	35 (20including M2 –M4)
ACA:	4
PCA:	6

Recanalisation was achieved in 46/54 pts=85% (missing data: 1)

TICI 3: 32
TICI 2: 12
TICI 1: 2
TICI 0: 8

68% distal reperfusion

A combination of pCR and local intraarterial fibrinolysis (rTPA) was performed in 38/54 patients and led to a recanalisation rate of 30/38 = 79%

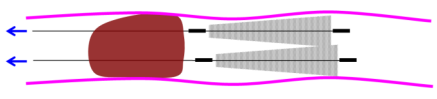
Adverse events: There were no device related adverse events that had clinical sequelae. Among the entire registry (130 pts) two detachements were recorded and attributed to vasospasm. In both cases the pCR could succesfully be retrieved by means of a microsnare. Two early failed attempts were due to extracorporal kinking of the application wire that is reinforced by the manufacturer in the current version. There were 2 microguidewire perforations in thrombus loaden segments: One M2/3 branch perforation was occluded with coils, the patients had a full clinical recovery. One acom perforation occured during a salvage attempt to establish cross flow in an acute bilateral ICA T-occlusion past 6h of onset.

Angio-to-Reperfusion-time 20-160 minutes. Average = 71 minutes

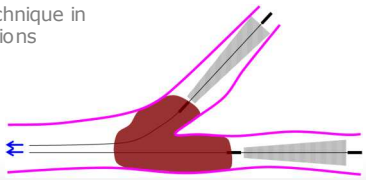
Dual device application: Performed in 12 cases – CE mark since 12/2007

Two possibilities:

1.Parallel application in larger diameter vessels



2. Y-technique in bifurcations



Conclusions: The initial assumption that the pCR is relatively atraumic was substantiated by the abscense of device related adverse events in our series.

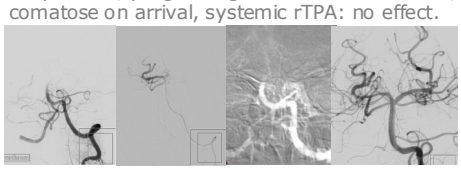
The overall recanalisation rate with distal reperfusion in 68% is satisfactory.

Especially the combination of LIF and pCR yielded good results approaching 80% distal reperfusion.

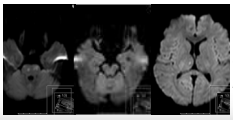
The Y-technique was particularly effective in cases of basilar tip occlusion.

One third of all target vessels had a diameter of 2mm or less; in some cases even distal segments could be reached and recanalised without difficulty.

Example case
Angio-to-reperfusion = 28 minutes
41 yo male, progressing loss of consciousness, comatose on arrival, systemic rTPA: no effect.



LVA injection showed mid basilar occlusion, sequential passage of the thrombus with a SilverSpeed 16 wire, Rebar 27 catheter and simultaneous application of two kissing 2-4-20 pCRs. Simultaneous retrieval with aspiration on guider led to complete recanalisation (TICI III).



DWI-MRI 24h post proc.: Small pontine and thalamic lesions Asymtomatic patient, no neurologic deficit.

Financial disclosures: T. Liebig, H. Lockau, J. Reinartz, C. Roth, and T. Güde have no financial interest. E. Miloslavski receives service related fees. H. Henkes is co-founder of phenox GmbH, Bochum Germany