# BEnefit of arterial preparation by LONGitudinal scoring before paclitaxel eluting balloon angioplasty of the superficial femoral and popliteal artery: concept and inclusion status of the swiss multicentric BELONG Study

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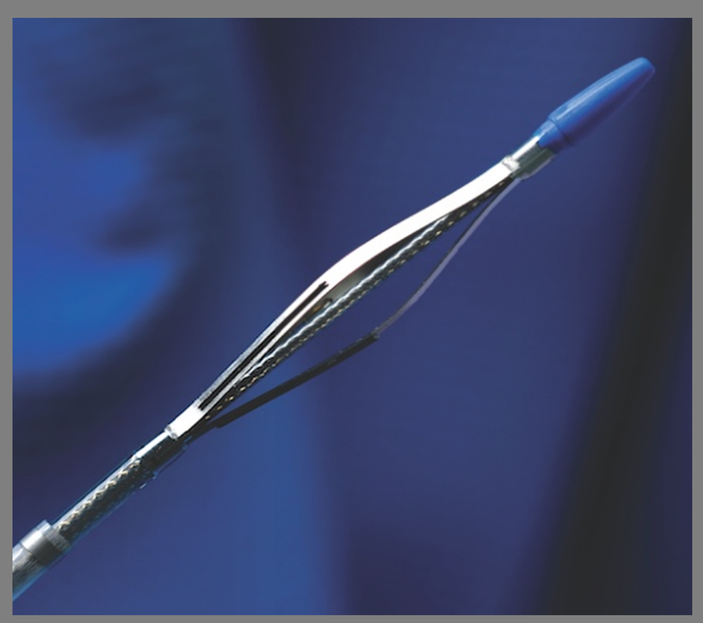
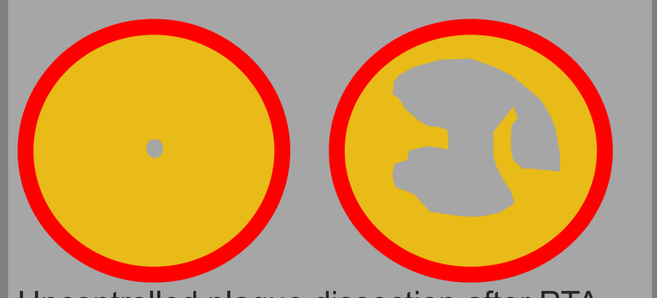
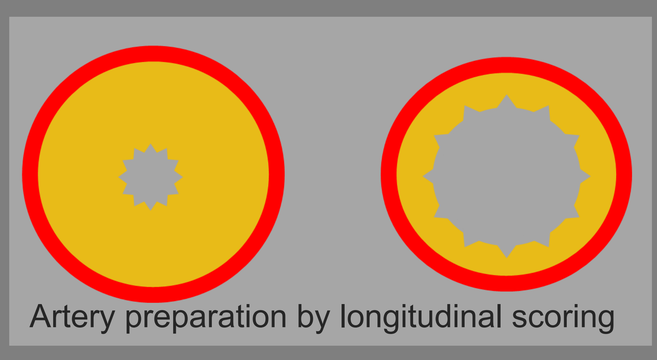
Rational:

Angioplasty of SFA and popliteal artery frequently results in uncontrolled plaque dissections that limit the blood flow through the lesion and may require stenting. The purpose of artery preparation by the FLEX Scoring Catheter® is to perform regular longitudinal slits on the inner side of the artery that promote a regular expansion of atheroma by balloon inflation. This step provides a better lumen patency and lowers the necessity of stent placement. The regular spread of atheroma is also thought to allow better diffusion of paclitaxel to its target tissue and to reduce restenosis.





Uncontrolled plaque dissection after PTA



Artery preparation by longitudinal scoring

6Fr introducer, 0.018 GW, OTW

Dynamic longitudinal scoring by pull-back

2-4 passages with 30° rotation

Incisions depth 250 microns

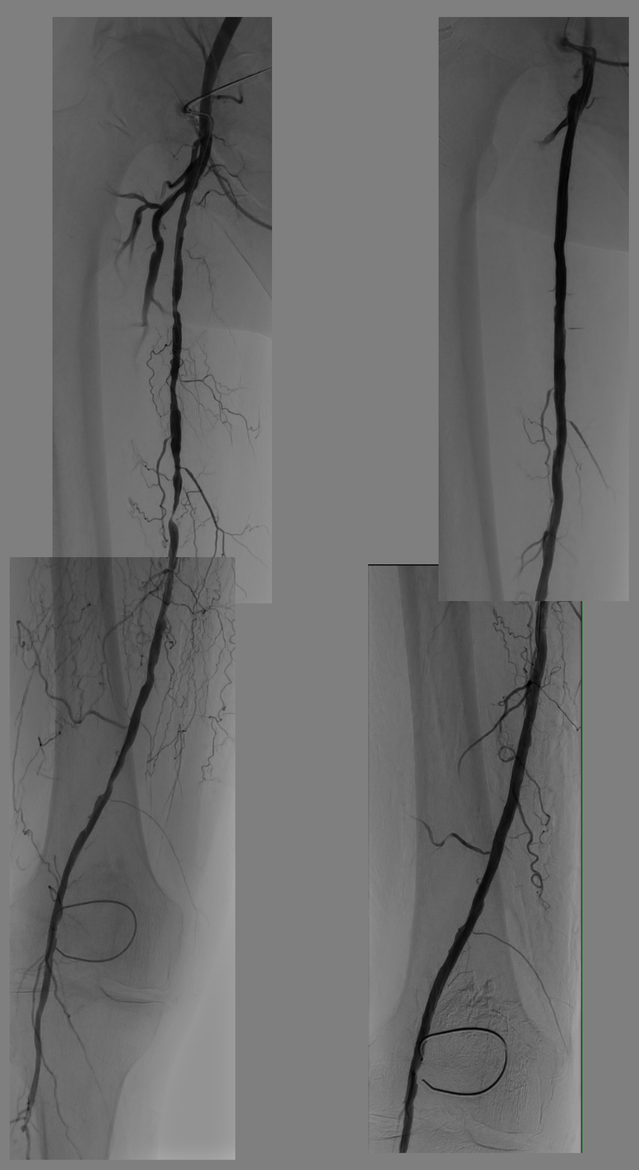
Manufactured by VentureMed Group

Preliminary experience:

Before initiation of the BELONG study, 68 interventions on SFA/POP (n=64) and saphenous fem-pop bypass (n=4), (46% CTO, lesion length 235 mm, de novo lesion 20.5%) were prepared by longitudinal scoring (4 passes) before DEB angioplasty. Post-dilatation was necessary in 22.5%, and stenting in 13.2%. The mean stented segment length was 53 mm. These results, particularly the low rate of stent requirement despite long and CTO lesions encouraged us to evaluate the 12 months patency rate of SFA/POP lesions treated by FLEX Scoring Catheter®.

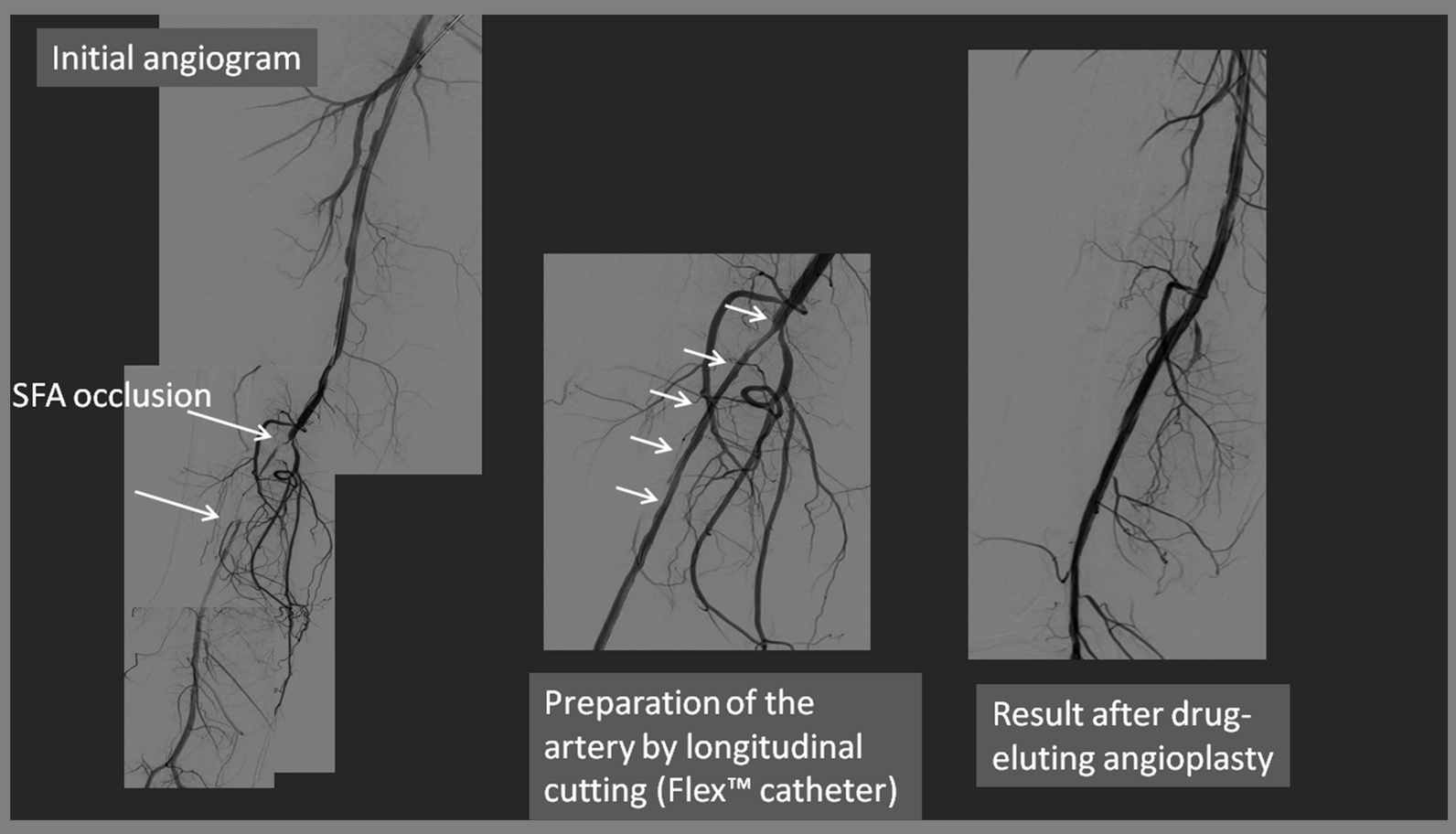
| interventions n =68 | result |
|---|---|
| target vessel: | |
| SFA/POP | 64 (94%) |
| saphenous fem-pop bypass | 4 (5.8%) |
| de novo lesion: | 14 (20.5%) |
| restenosis/reocclusion | 54 (79.4%) |
| occlusion | 31 (45.6%) |
| stenosis | 37 (54.4%) |
| mean degree of stenosis | 84% |
| mean lesion lenght (mm) | 235 (20 - 380) |
| predilatation | 6 (8.8%) |
| DEB angioplasty | 68 (100%) |
| post-dilatation | 15 (22%) |
| stenting | 9 (13.2%) |
| mean lenght of stented segment (cm) | 5.3 |

Preliminary experience with longitudinal scoring (before inclusion in the Belong study)



Initial angiogram

After Flex and DEB




Inclusion criteria

Patients ≥ 18-year-old, with symptomatic lower extremity occlusive arterial disease

Rutherford class of symptom 2 to 5

Atheromatous ≥ 70 % stenosis or occlusion of SFA and/or PA

Absence of > 50% residual stenosis of the run-in vessels at the end of procedure

Presence of at least one patent (no ≥ 50 % stenosis) run-off tibial or fibular vessel to the foot at the end of procedure

De novo or restenotic lesions, including in-stent restenosis

Willingness to participate in the study and signature of informed consent

Outcomes

Primary efficacy outcome:

Absence of clinically driven target lesion revascularization (CDTLR) at 12 months

Secondary efficacy outcomes:

- 3 and 12 months primary patency of the treated lesion (defined by PSVR ≤ 2.5 at duplex scan) (core lab for the 12 months duplex scan)
- Absence of CDTLR at 3 months
- 3 and 12 months absence of major amputation
- 3 and 12 months change in ankle brachial index (ABI)
- 3 and 12 months change in Rutherford class of symptom
- Technical success of the scoring procedure
- Lumen gain and residual stenosis after scoring and after angioplasty±stenting at angiography (Core lab)
- Proportion and degree of dissection at end of procedure (Core lab)
- Proportion of stent implantation at procedure

Primary safety outcome:

- Composite of (1) death from cardiovascular origin or (2) major amputation of target limb

Secondary safety outcomes:

- Proportion of adverse event associated to the scoring step

Exclusion criteria

Renal failure with glomerular filtration rate (GFR) 30 ml/min or below, estimated by the Cockroft-Gault equation.

Women who are pregnant, lactating, or planning to become pregnant during the duration of the study

Recent artery thrombosis, at risk of distal embolization during percutaneous procedure

Previous use of a PCB in the lesion during last 15 months

Extremely calcified lesions, defined by calcification involving ⊘ 270° of the artery circumference over ⊘ 15 cm.

Sub-intimal recanalization

Tortuous contra-lateral femoral access with difficult cross-over

Previous or planned surgery of the target lesion

High risk of bleeding

Contra-indication to dual antiplatelet therapy for one month, and/or to single antiplatelet therapy for 1 year

Allergy to aspirin, clopidogrel or heparin

Life expectancy less than one year