

# Early results of the use of a next generation drug coated balloon for the treatment of femoropopliteal atherosclerotic lesions

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## Purpose

We wanted to investigate a next generation drug coated balloon on safety, efficacy and patency for the treatment of stenotic and/or occlusive femoropopliteal arterial lesions

## Material & Methods

PTX is an antineoplastic drug that causes a structural modification of the cytoskeleton of human smooth muscle cells, this causes a change of proliferation and migration and a reduction of inflammatory response and intimal hyperplasia. It has a rapid cellular uptake & long-lasting antiproliferative action

We used a **Legflow Paclitaxel** releasing peripheral balloon (Cardionovum, Bonn, Germany)

- Coated with nanocrystalline particles 0.1µm
- Shellolic acid/ Safe PAX (Fig. 1)
  - Balloon surface protection
  - Prevention of PTX particles loss

Because of the stable and unique balloon surface coating characteristics, it does not require the use of an extra protection and insertion tool

PTX particles cannot be wiped or fall off the balloon surface during catheter manipulation (Fig. 2)

## Results

- Single centre, prospective, consecutive, physician initiated registry
- From June 2013 till November 2014 we included **50 real-life patients** treated with the Legflow for de novo, recurrent and in-stent stenosis or occlusion in the femoropopliteal area
- Mean lesion length was 102,6 mm
- Technical success : 100 %.
- In more then 50% of the cases no predilation balloon was used
- Bail out stenting : 20 %
- No evidence for distal embolisation
- Follow-up was done with ultrasound. 6 months primary patency was 92 % and the preliminary results for 1 year seem promising with 76 % primary patency (Tables 1 & 2)

## Conclusion

The drug coated balloon technology seems to improve the mid- and long-term durability of the SFA endovascular treatment. The early results using the new generation Legflow DCB are very encouraging, it is a safe and reliable balloon but long-term results need to be obtained with larger patient groups

Parameter	n/N (%)
MACCE	0/50 (0)
TVR	2/50 (4)
TLR	3/50 (6)
Amputation	1/50 (2)
Duplex performed	
Yes	50/50 (100)
No	0/50 (0)
Binary restenosis	
Yes	4/50 (8)
No	46/50 (92)

Table 1: 6 months results

Parameter	n/N (%)
MACCE	0/22 (0)
TVR	4/22 (18)
TLR	5/22 (23)
Amputation	2/22 (9)
Duplex performed	
Yes	21/21 (100)
No	0/21 (0)
Binary restenosis	
Yes	5/21 (24)
No	16/21 (76)

Table 2: 12 months results

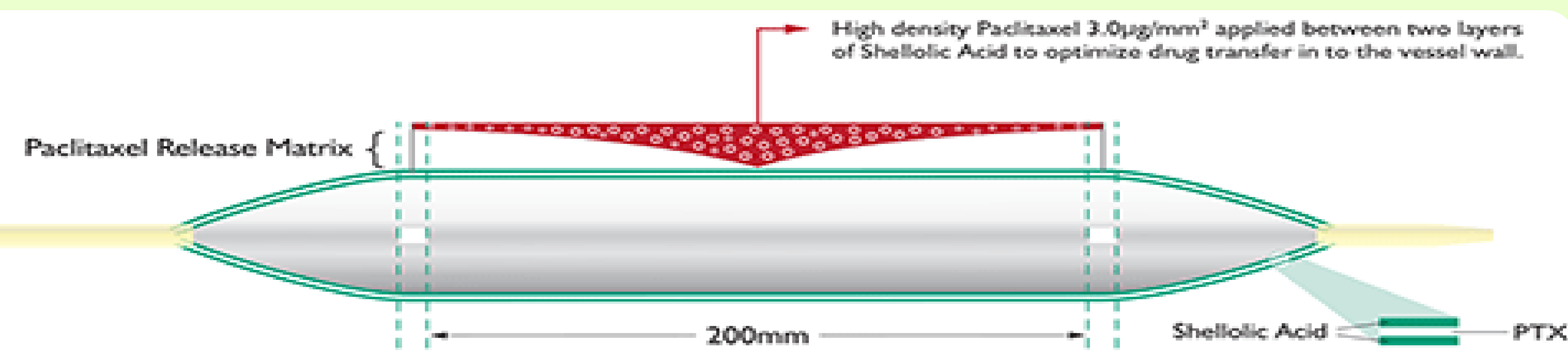


Figure 2 : Cardionovum Legflow DCB (1) vs. Competitor (2)

