What We Know: Stents May Have Limitations, Especially in Long Lesions

The performance zone of stents in long lesions is 60-80% patency at 12 months. This indicates that stents may have limitations, especially in long lesions.

Can Adding DCB Improve Outcomes?

The DEBAS treatment approach involves predilating the lesion, implanting a self-expanding nitinol stent, and delivering DCB to the entire stented segment plus 1 mm beyond.

Study Design

- Prospective, feasibility study investigating safety and efficacy of Pulsar-18/35 SES (BIOTRONIK) combined with Passeo-18 Lux DCB (BIOTRONIK) in severe femoropopliteal arterial occlusive disease.
- 65 patients enrolled in 3 centers in Perth (Australia).
- 24-month follow-up on 51 patients.

Primary Endpoint

- Primary Patency (PP) at 12, 18, and 24 months: Defined as an increase in the PSVR ≥ 2.5 with no clinically driven re-intervention at the stented segment ± within 5 mm of each side of the stented area.

Secondary Endpoints

- Secondary Patency at 12, 18, and 24 months.
- Freedom From MAE at 12, 18, and 24 months.
- Freedom From Stent Fracture.
- Freedom From TLR and TVR.
- Freedom From Major Target Limb Amputation and Death.
BASELINE DEMOGRAPHICS

- **Race**
  - White: 50 (98.0%)
  - Asian: 1 (2.0%)
  - Maori/Pacific: 0 (0)
  - ATSI: 0 (0)

- **Smoking**: 21 (41.2%)
- **Diabetes**: 28 (54.9%)
- **CAD**: 18 (35.3%)
- **HTN**: 37 (72.5%)
- **Hyperlipidaemia**: 28 (54.9%)
- **CVA**: 3 (5.9%)
- **CRF**: 3 (5.9%)
- **On Dialysis**: 0 (0)

ABI: 0.39 +/- 0.10 (0.36 - 0.41)

Indication for Treatment:
- **Rest Pain**: 18 (35.29%)
- **Acute Ischaemia**: 3 (5.88%)
- **Claudication**: 27 (52.94%)
- **Ulcer/Gangrene**: 14 (27.45%)
- **Dissection**: 0 (0.00%)

Rutherford Classification:
- Class I Mild: 0 (0.00%)
- Class II Moderate: 0 (0.00%)
- Class III Severe: 21 (41.18%)
- Class IV Ischemic Rest Pain: 16 (31.37%)
- Class V Minor Tissue Loss: 14 (27.45%)
- Class VI Major Tissue Loss: 0 (0.00%)

CLINICAL CHARACTERISTICS

- **Total Lesion Length (mm)**
  - Mean: 187.55 +/- 74.55 (167.09 - 208.01)
- **Calcification**
  - None: 1 (1.96%)
  - Minimum: 16 (31.37%)
  - Moderate: 22 (43.14%)
  - Severe: 12 (23.53%)

- **Other Intraoperative Parameters**
  - Number of Stents Used: 1.57 +/- 0.70 (1.38 - 1.76)
  - Number of DCBs Used: 2.45 +/- 1.08 (2.15 - 2.75)
  - Balloon Inflation Time [min]: 1.88 +/- 0.27 (1.73 - 1.88)

IMPROVEMENT IN RUTHERFORD SCORE

Significant Improvement in Rutherford Score at 6 months and SUSTAINED over time
IMPROVEMENT IN ANKLE BRACHIAL INDEX

PRIMARY PATENCY AT 24 MONTHS FOLLOW-UP

TARGET VESSEL RE-INTERVENTION

STENT FRACTURE RATE = 1.96%

MAJOR AMPUTATION

CONCLUSION

- DEBAS Study indicate that the Hybrid approach of DCB and thin-strut BMS is feasible with sustainable and promising Clinical outcomes at 24 months.
- Combination therapy is a viable potential future treatment option in long, TASC C/D SFA lesions however more data are required.

Summary

6-month 12-month 24-month
Primary Patency Rate (%) 96.1 92.2 88.2
Re-intervention Rate* (%) 0.00 3.92 1.96
Stent Fracture Rate (%) 0.00 1.96 1.96

Overall TLR(%) at 24 months follow-up was 9%