3-year outcomes of the novel Kanshas drug-coated balloon in treatment of femoropopliteal occlusive disease:

The First-In-Human KANSHAS 1 study results

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on behalf of the KANSHAS 1 study investigators
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Disclosure

Speaker name:

Dr. Michael Lichtenberg.....

I have the following potential conflicts of interest to report:

- [x] Consulting
- [ ] Employment in industry
- [ ] Stockholder of a healthcare company
- [ ] Owner of a healthcare company
- [ ] Other(s)

- [ ] I do not have any potential conflict of interest

Background and aim

- **Drug-coated balloon (DCB)** therapy has demonstrated a **higher effectiveness** compared to **standard PTA** and has been widely accepted as a valuable treatment option for patients with **femoropopliteal disease**.

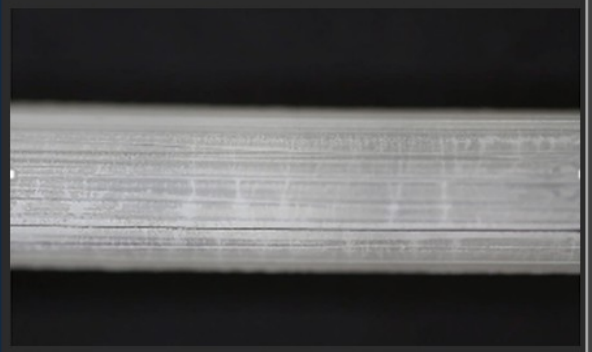
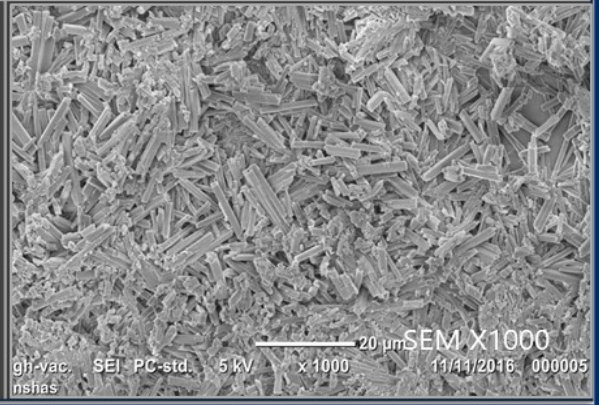
- **Kanshas DCB** has been **developed to address** some **limitations** of first generation DCBs **related to coating integrity**.

- **KANSHAS 1** first-in-human study aims at **investigating** the **safety** profile and **therapeutic advantages** of the novel Kanshas DCB in treatment of **de novo femoropopliteal lesions**.

Kanshas DCB device

Specification:

Drug: Paclitaxel (3.2µg/mm^2)
Excipient: L-Serine Ethyl Ester HCl
Balloon diameter: 4.0 – 7.0 mm
Balloon length: 40 – 200 mm
Catheter length: 150 cm
Compatible GW size: 0.018”
Nominal pressure: 8 atm (RBP 10-14 atm)
Rapid exchange type

Uniform coating	Crossing profile	Microcrystalline Paclitaxel
	 * Crossing Profile of Ø 6.0mm balloon	

CE marked since June 2018

KANSHAS 1 study

To assess **safety** and **efficacy** of the Kanshas DCB catheter in the treatment of **de novo lesions** in the **superficial femoral** and/or **popliteal arteries**

Prospective, multi-center, open-label, single arm study

50 patients enrolled at 6 sites in Germany and Belgium from April 2017 to January 2018

- Karolinen-Hospital: Klinikum Arnsberg
- Universitäts-Herzzentrum Freiburg-Bad Krozingen
- Ev Luth Diakonissenanstalt zu Flensburg Zentrum für Gesundheit und Diakonie
- RoMed Klinikum Rosenheim

- AZ St. Blasius Dendermonde
- Imelda Ziekenhuis Bonheiden

Enrollment completed /
Follow-up ongoing (extended to 5-years)

Study management

- Steering Committee
- Clinical Event Committee (CEC)
- Data Monitoring Committee
- Angiographic Core Laboratory (BIDMC)
- Ultrasound Core Laboratory (Vascore)
- Managed and sponsored by Terumo Europe

100% source data verification up to 2-year follow-up
Independent Core laboratory assessment.
Adverse events **adjudication by CEC**

Clinical Follow-up

0d — 30d — 6mo — 1yr — 2yr — 3yr — 4yr → 5yr

Primary endpoint
Freedom from Composite Safety* **at 6 months**

*Defined as freedom from device- and procedure-related deaths through 30 days, freedom from target limb amputation, and clinically-driven target lesion revascularization (TLR) through 6 months

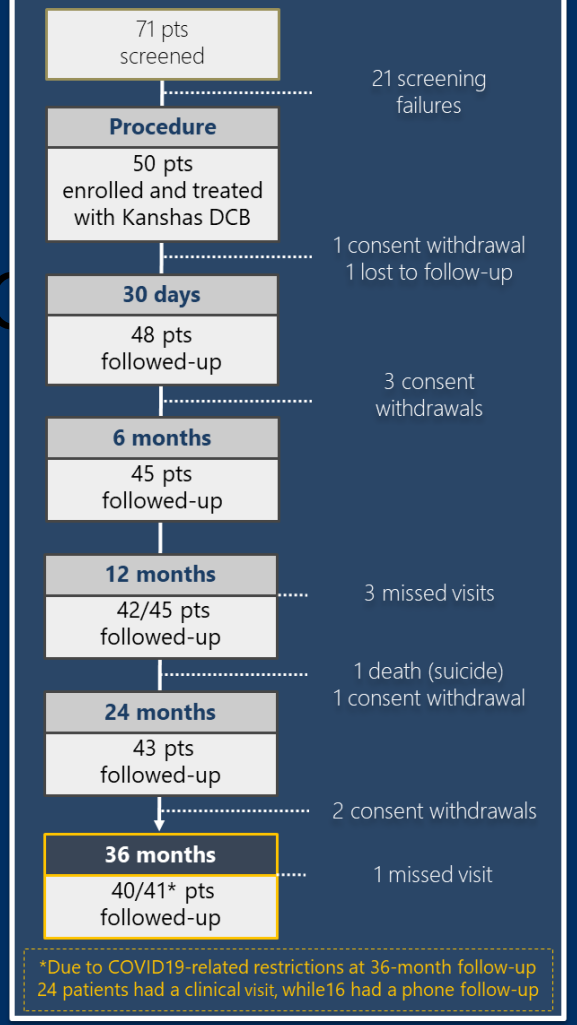
Main Inclusion Criteria:

- Clinically significant symptomatic leg ischemia, requiring treatment of the **SFA and/or PA**
- **Rutherford Clinical Category of 2-4**
- **Resting ABI of < 0.9 or abnormal exercise ABI**
- **Cumulative lesion length 4-15 cm**
- Clinically and hemodynamically significant **de novo stenosis (>70% stenosis) or occlusion including P3 segment**
- Patent inflow artery (≥50% DS)
- At least one patent outflow artery

Main Exclusion Criteria:

- In-stent restenosis
- **Vessel injuries after predilatation; flow-limiting dissection, requiring stenting, or perforation**
- Subintimal recanalization
- **Severe calcification** in the target lesions that precludes endovascular treatment
- Previous treatment with DCB or DES in target vessel

Study Flow Chart



SFA: superficial femoral artery, **PA:** popliteal artery, **ABI:** ankle-brachial index, **DS:** diameter stenosis, **DCB:** drug-coated balloon, **DES:** drug-eluting stent

Baseline patient & lesion characteristics

Patients	N=50
Age, years	69.0 ± 10.5
Male	34 (68.0)
Hypertension	43 (86.0)
Hyperlipidemia (n=49)	36 (73.5)
Diabetes Mellitus	18 (36.0)
Smoker (n=49)	
Current	21 (42.9)
Previous	19 (38.8)
Ischemic heart disease[a]	17 (34.0)
History of PAD (n=49)	23 (46.9)
Renal insufficiency	4 (8.0)
COPD	6 (12.0)
Cerebrovascular disease[b]	6 (12.0)
Rutherford category	
2	8 (16.0)
3	39 (78.0)
4	3 (6.0)
ABI (n=48)	0.67 ± 0.14

Target lesions[c]	N=50
Lesion location	
SFA proximal	1 (2.0)
SFA mid	25 (50.0)
SFA distal	21 (42.0)
Popliteal proximal	9 (18.0)
Popliteal mid	8 (16.0)
Popliteal distal	2 (4.0)
Cumulative lesion length, mm	88.6 ± 36.5
Single lesion	45 (90.0)
Multiple lesion[d]	5 (10.0)
Reference vessel diameter, mm	5.4 ± 0.6
Diameter stenosis, %	91.0 ± 9.4
Calcification	
None	21 (42.0)
Mild	19 (38.0)
Moderate	9 (18.0)
Severe	1 (2.0)
Total occlusion	15 (30.0)
Ipsilateral inflow lesion	4 (8.0)
Successful treatment	4/4 (100.0)
Patent run-off vessels	
1 vessel	
2 vessels	
3 vessels	

Data are shown as mean ± SD or n (%).

COPD: chronic obstructive pulmonary disease, **PAD:** peripheral artery disease

a: History of myocardial infarction, angina pectoris, or previous percutaneus or surgical revascularization. **b:** Known carotid artery disease or history of minor or major stroke or transient ischemic attack. **c:** Assessed by visual estimate.

d: Multiple focal lesions separated by a gap of ≤30mm were counted as one lesion.

Procedure characteristics & outcomes

Procedural characteristics[a] (n=50)	
Pre-dilation	
Total inflated length, mm	
Balloon/ artery ratio	
Residual DS, %	
DCB per lesion (58/50)	
Balloon transit time, sec	44.3 ± 54.7
Total inflated length, mm	
Balloon/ artery ratio	1.04 ± 0.07
Maximum pressure, atm	
Inflation time/balloon, min	
Post-dilation	
Total inflated length, mm	
Balloon/ artery ratio	0.97 ± 0.11
Stenting*	14 (28.0)
Due to flow-limiting dissection	1 (2.0)
Due to residual stenosis >50%	3 (6.0)

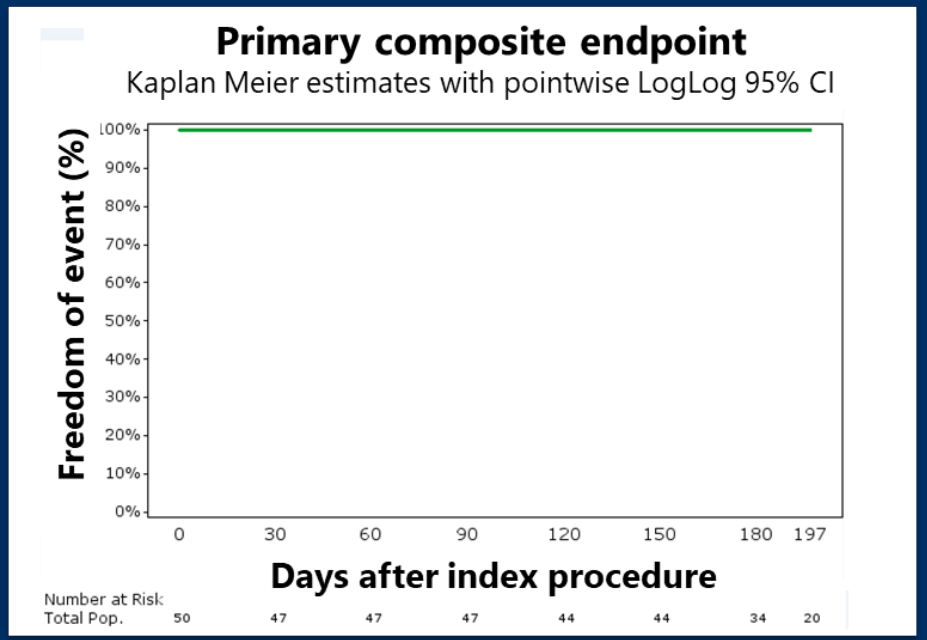
Procedural outcomes	
Device success**	
Residual diameter stenosis[a] , %	11.2 ± 7.8
Length of hospital stay, days	1.7±0.6

Data are shown as mean ± SD or n (%)
a: Assessed by visual estimate.
***** After unsuccessful post-dilatation for a residual stenosis >50% or significant dissection after the use of Kanshas DCB, bailout procedures with commercially available nitinol stents were allowed at the discretion of the operator.
****** Device success defined as no device malfunction

Primary Endpoint

composite safety at 6 months

Defined as:
Freedom from device- and procedure-related deaths **through 30 days**,
freedom from target limb amputation, and clinically-driven target lesion revascularization (CD-TLR) through **6 months**



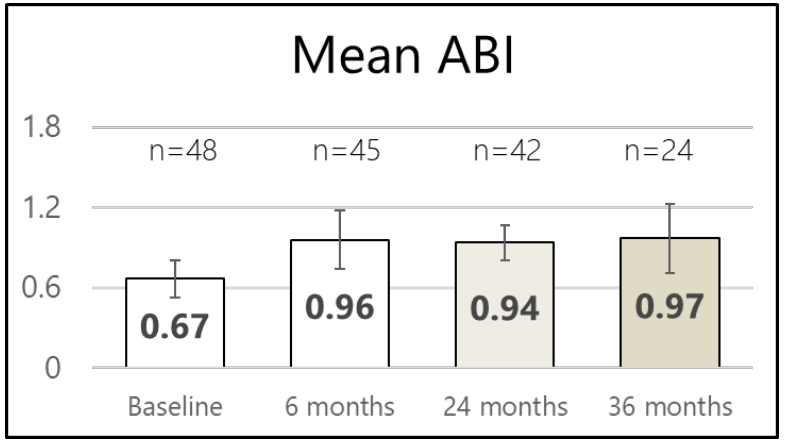
Primary endpoint components	
Device-/Procedure-related deaths	0%
Target limb amputation	0%
CD-TLR	0%

CD-TLR: defined as 50% or more stenosis with worsening symptoms or 70% stenosis without symptoms

No device- and procedure-related Severe Adverse Events (SAE) have been reported up to 6-month follow-up

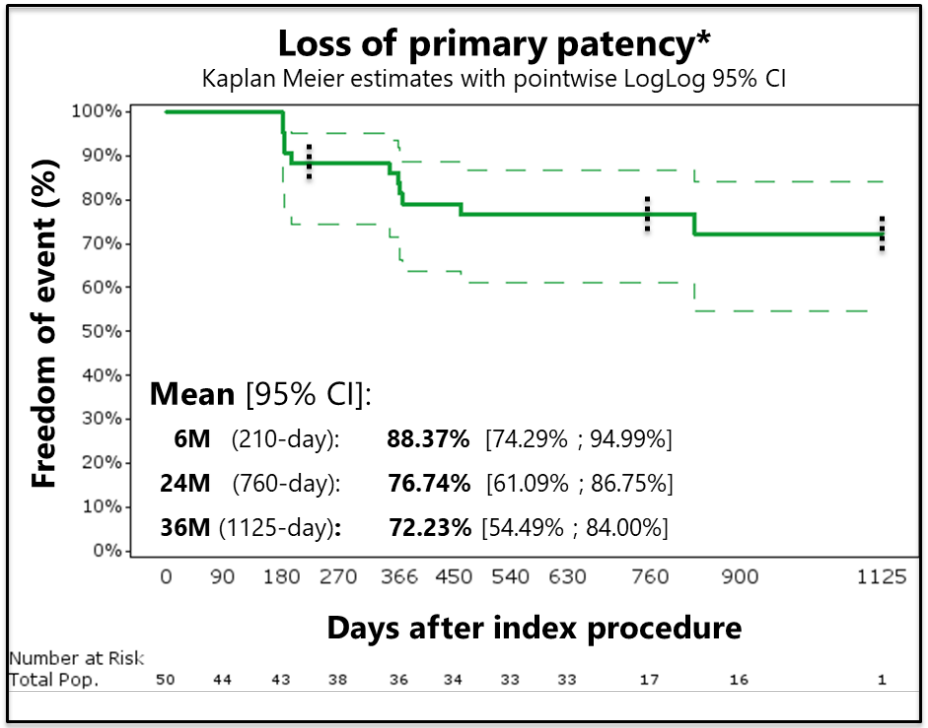
CI: confidence interval

Outcomes up to 36-months



ABI change vs baseline **(matched)**		
6 months	24 months	36 months
0.28±0.24 (n=43)	0.26±0.17 (n=40)	0.24±0.16 (n=23)

Data are shown as mean ± SD

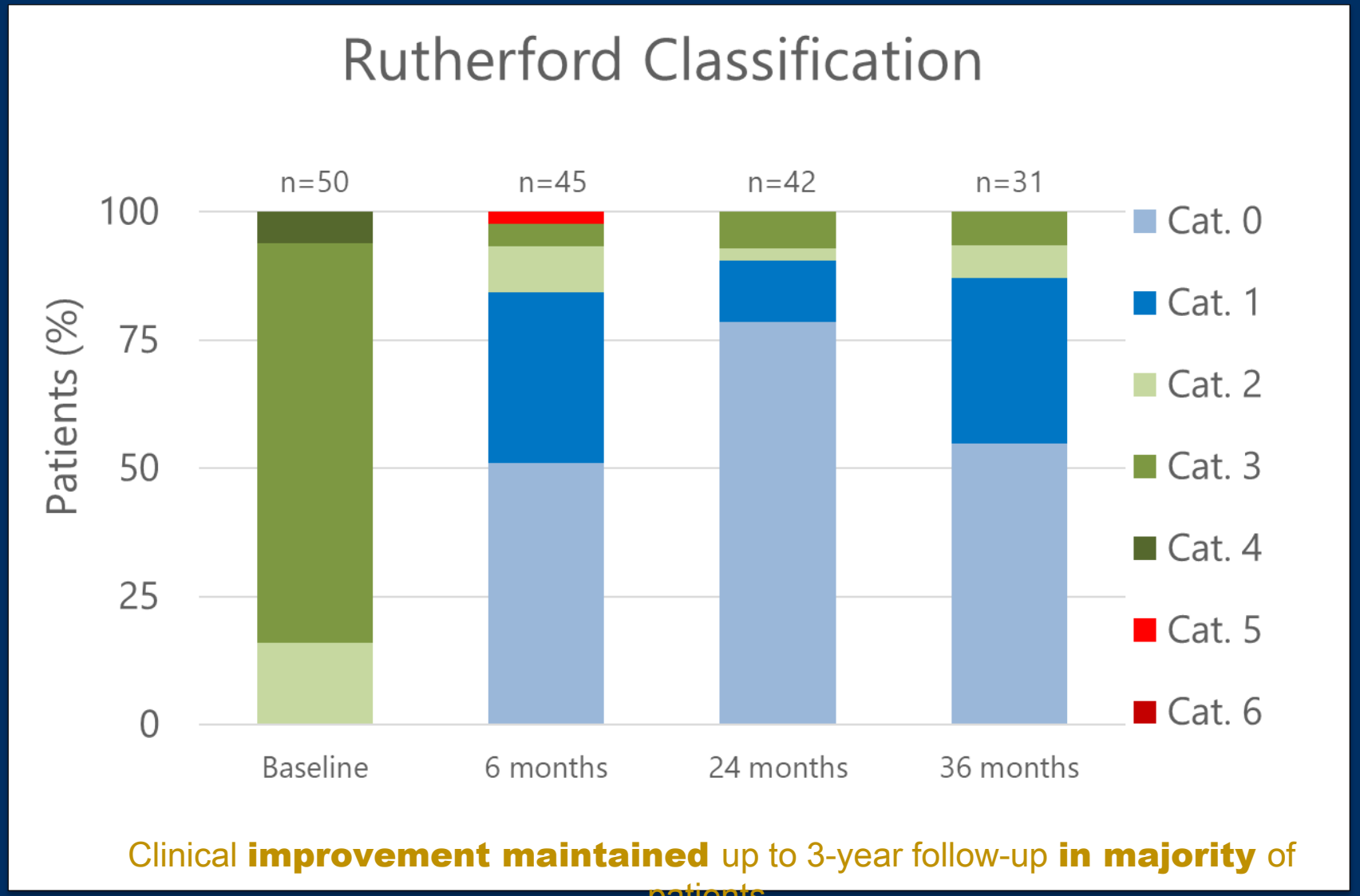


* **Primary patency** is defined as freedom from clinically-driven target lesion revascularization and absence of target lesion stenosis >50% per (analysable) Duplex Ultrasound (peak systolic velocity ratio (PSVR) ≤2.4), as independently assessed by Core laboratory and CEC. CI: confidence interval.

Hemodynamic **improvement maintained** up to 3-year follow-up **in majority** of patients

Note that at 36-month follow up, primary patency and ABI data were collected in a limited number of patients who underwent a clinical visit (n=24).

Outcomes up to 36-months



Clinical **improvement maintained** up to 3-year follow-up **in majority** of patients

Outcomes up to 36-months

Rutherford class change vs. baseline (**matched**)

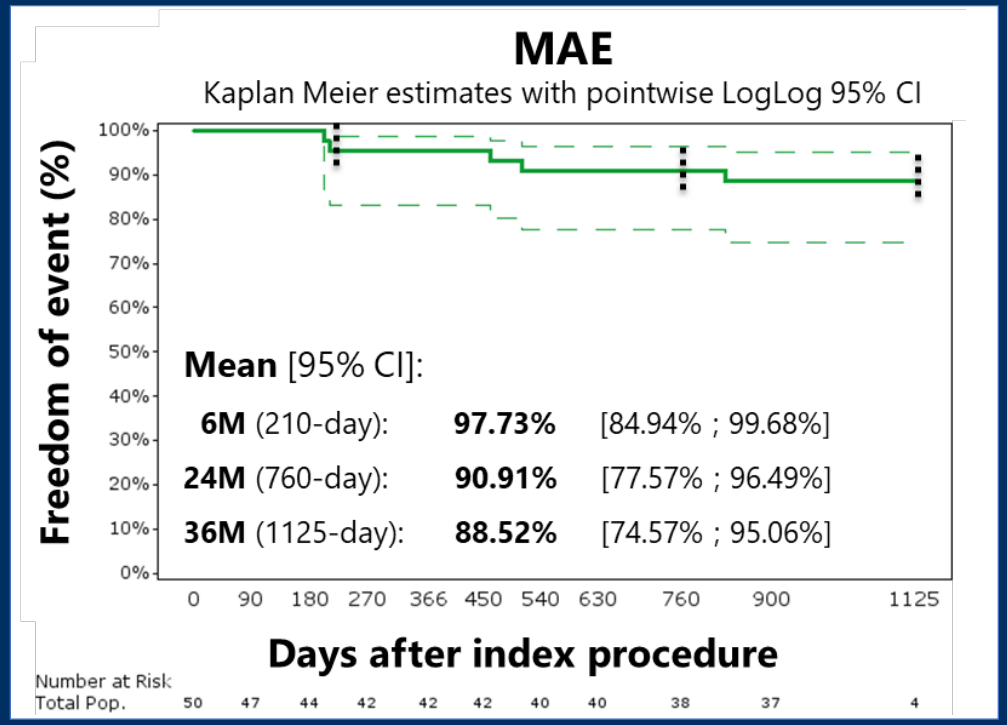
	6 months (n=45)	24 months (n=42)	36 months (n=31)
Improvement	42 (93.3%)	39 (92.8%)	27 (87.1%)
-1 Cat. change	6 (13.3%)	2 (4.8%)	2 (6.5%)
-2 Cat. change	**18 (40.0%)**	**10 (23.8%)**	**10 (32.3%)**
-3 Cat. change	**17 (37.8%)**	**25 (59.5%)**	**13 (41.9%)**
-4 Cat. change	**1 (2.2%)**	**2 (4.8%)**	**2 (6.5%)**
No change	2 (4.4%)	2 (4.8%)	3 (9.7%)
Worsening	1 (2.2%)	1 (2.4%)	1 (3.2%)

Improve throughout **3-year** follow-up

Secondary Endpoint

Major Adverse Event (MAE) rate at 36 months

Defined as:
Freedom from all death, target limb amputation, and clinically-driven target lesion revascularization (CD-TLR) through **36 months**



Components of secondary endpoint at 36 months	
All deaths	1 (suicide)
Target limb amputation	None
CD-TLR	4/41 (9.8%) (1) after 204 days (2) after 211 days (3) after 462 days (4) after 829 days

CD-TLR: defined as 50% or more stenosis with worsening symptoms or 70% stenosis without symptoms

CI: confidence interval

Conclusions

- Angioplasty using the novel **Kanshas DCB** for the treatment of **de novo femoropopliteal** artery lesions **displays good safety** and **efficacy** throughout the period of **36-month** follow-up.
- **Hemodynamic** and **clinical improvement is** maintained in **majority** of patients.
- **No** sign of **abnormal late mortality signal** is observed in the studied population, with only a **few target lesion revascularizations** noted**.**