Luminor DCB makes it different and favourable in CLI (LUMINOR registry, 12-month data)

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on behalf of the LUMINOR collaborators
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University of Barcelona

Disclosures

Consultant/Advisor/Research

- Aptus Endosystems
- Bolton Medical
- Cordis
- Medtronic
- iVascular
- Bayer
- MSD
- Ferrer
- GE
- ASTA ZENEKA
- W.L. Gore
- Jotec

Proctor

- Bolton Medical
- Cook
- Medtronic
- W.L. Gore
- Aptus
- Cordis
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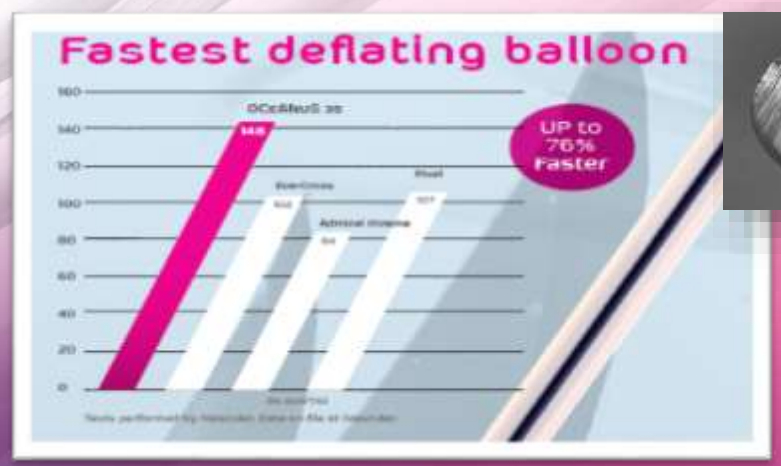
Oceanus 14 and 35 platforms

1. Long tip with high crossing capability

2. Good shape
   - Short Shoulders

3. Quick deflation time

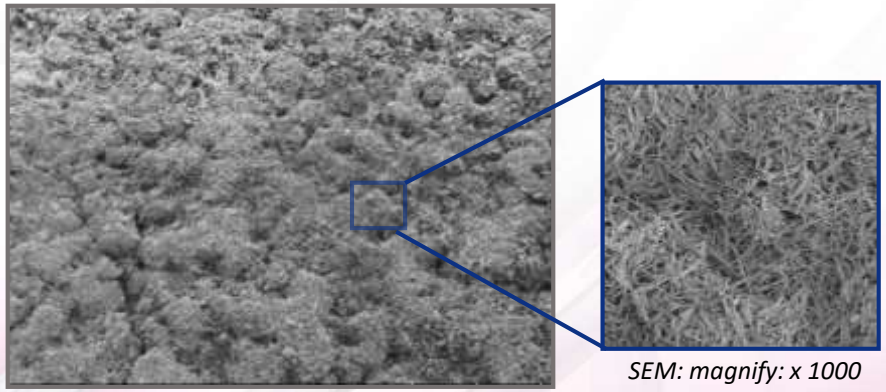


LUMINOR 14 and 35

1
- PTX microcrystalline structure
- Dosage: 3 µg/mm^2

2
- Excipient: *Water Reduced Ester*
- Drug/excipient ratio: 80/20

3
- Transfertech® Coating technology. Multilayer, Uniform nanodrops by ultrasonic spray



SEM: magnify: x250

SEM: magnify: x 1000

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Material and Methods

Luminor Registry is an observational, prospective, multicenter study with single-arm treatment for stenotic or occlusive lesions or in-stent stenosis of the femoro-popliteal (FP) and below the knee (BTK) vessels. *Clinical trials.gov identifier: NCT02458911*

PRIMARY ENDPOINTS

To analyse the performance of Luminor 14 and 35 in terms of **primary patency**, defined as freedom from >50% restenosis as indicated by duplex ultrasound peak systolic velocity ratio (PSVR) <3 in the target vessel with no re-intervention, and freedom of serious adverse events defined as **death**, **amputation** and **TLR** during a minimum of **12-month** follow-up period.

SECONDARY ENDPOINTS

Include quality of life assessment and other clinical or hemodynamic complications.

Material and Methods

- A total of **207 validated Rutherford 2-5 cases** have been recruited during a 15-month period following an intention to treat basis.
- All the procedures have followed the **instructions for use.**
- Primary stenting or atherectomy were **excluded**.
- **Adjuvant drug treatment** was applied for all patients [Clopidogrel 75 mgr/day + ASA 100 mgr/day (one month) and ASA 100 mgr/day (indefinite)].

Material and Methods (CLI)

Demographics	N	%
Patients with CLI	148	
Male	101	68.2
Age (years)	73.2±11.4	
Diabetes	106	71.6
Smoking and ex-smoking	80	54.0
Arterial Hypertension	129	87.2
Hyperlipidemia	85	57.4
Chronic Renal Failure (stage ≥3)	44	29.7
Rutherford Class		
4	24	16.2
5	124	83.8

Material and Methods (CLI)

Lesion characteristics	
Lesions (n)	180
Lesion length (mm)	77.4±50.3
Chronic Total Occlusions–CTO (%)	53.9
Stenosis (%)	46.1
BTK (%)	48.9
Severe calcification (%)	56.7

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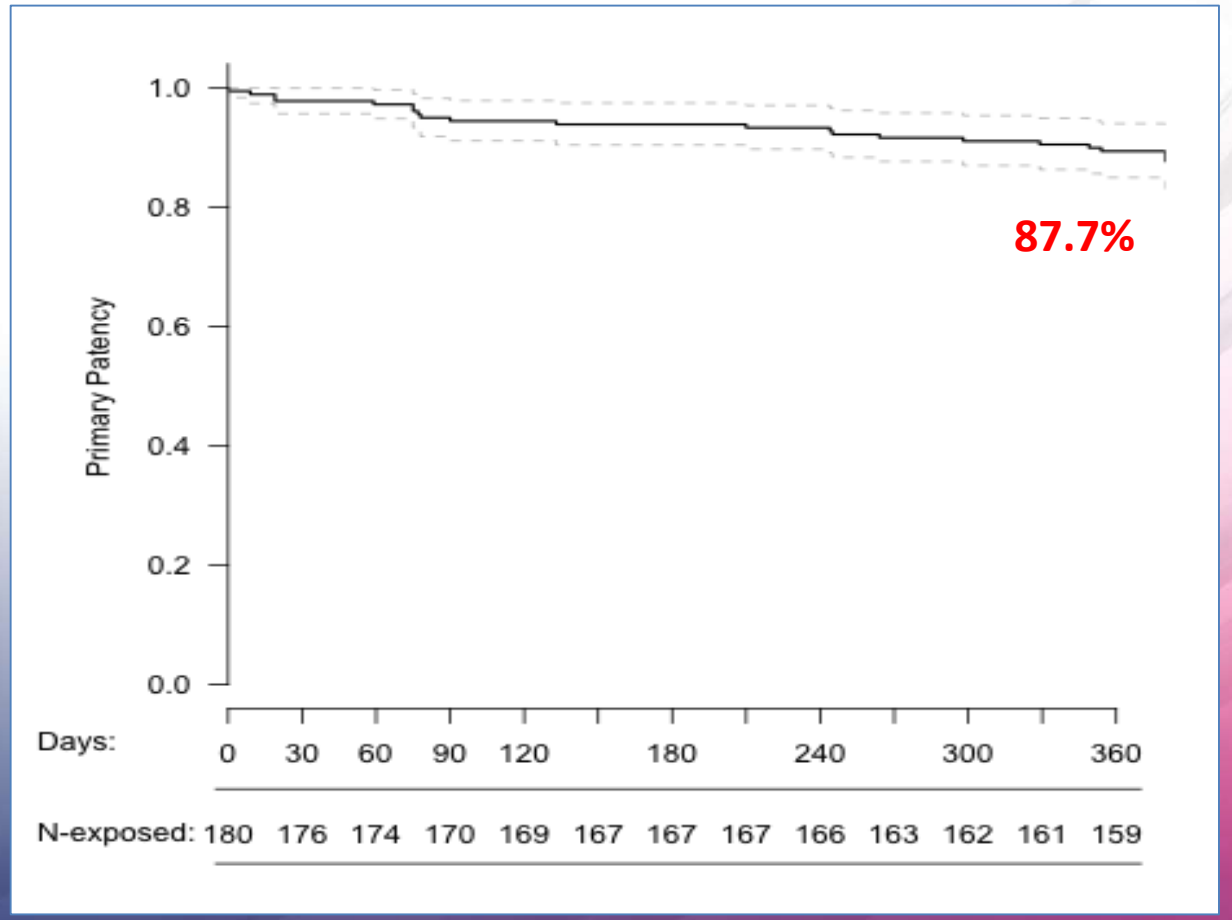
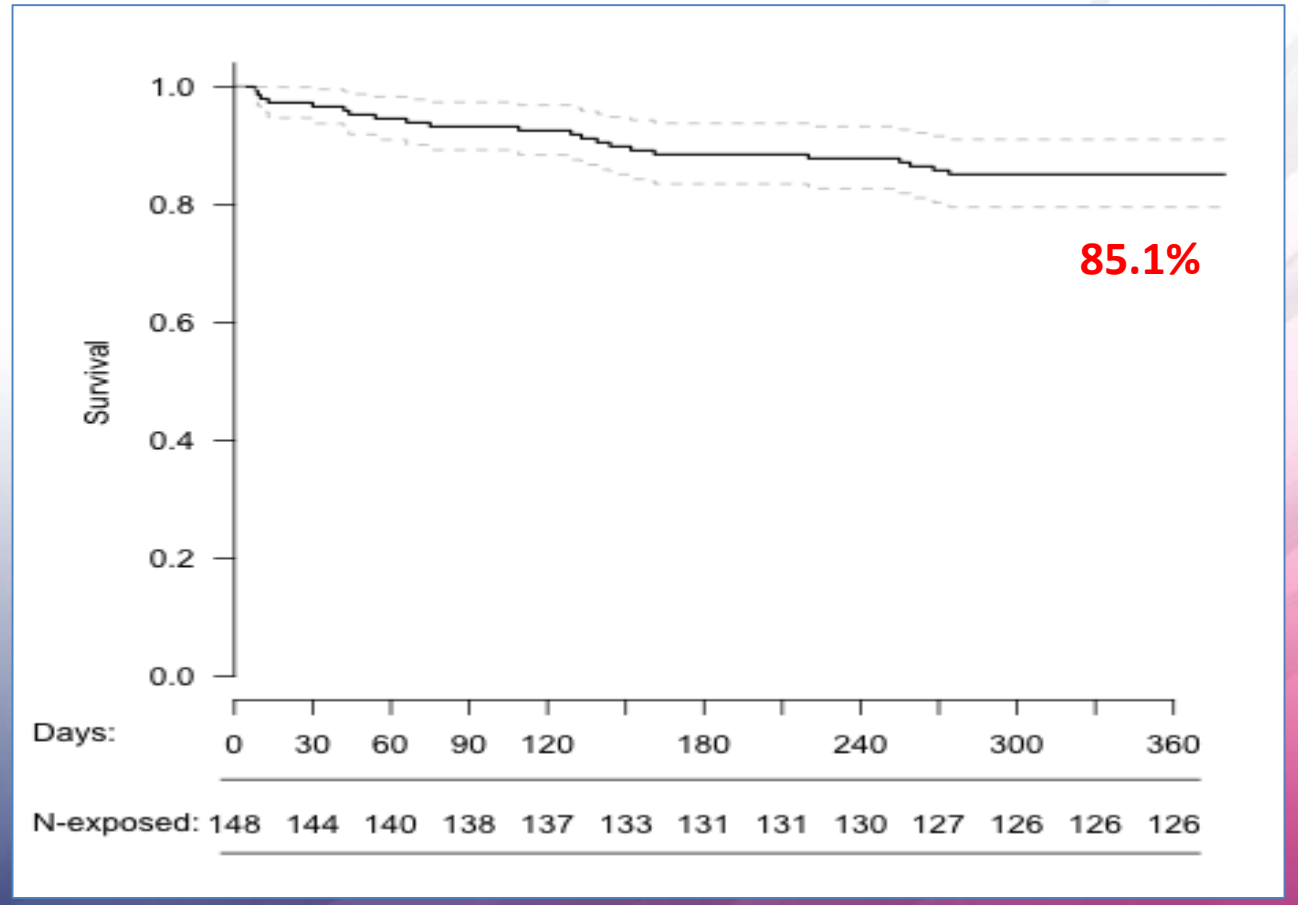
Early Results (CLI)

30-Days follow-up	
All-cause mortality	3.4%
Major amputations	2.0%
TLR	1.7%

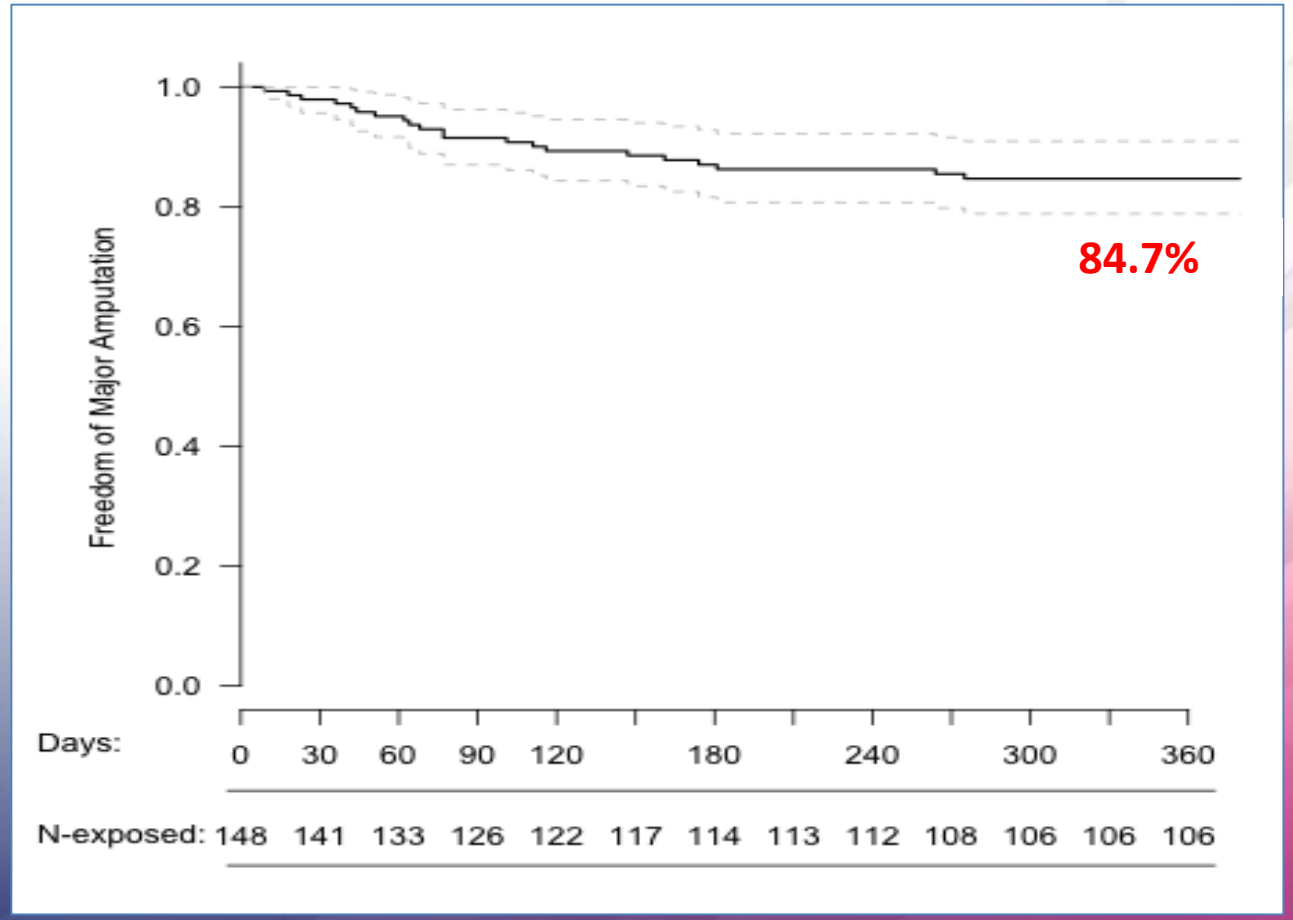
Results @ 1 year follow-up
Primary Patency



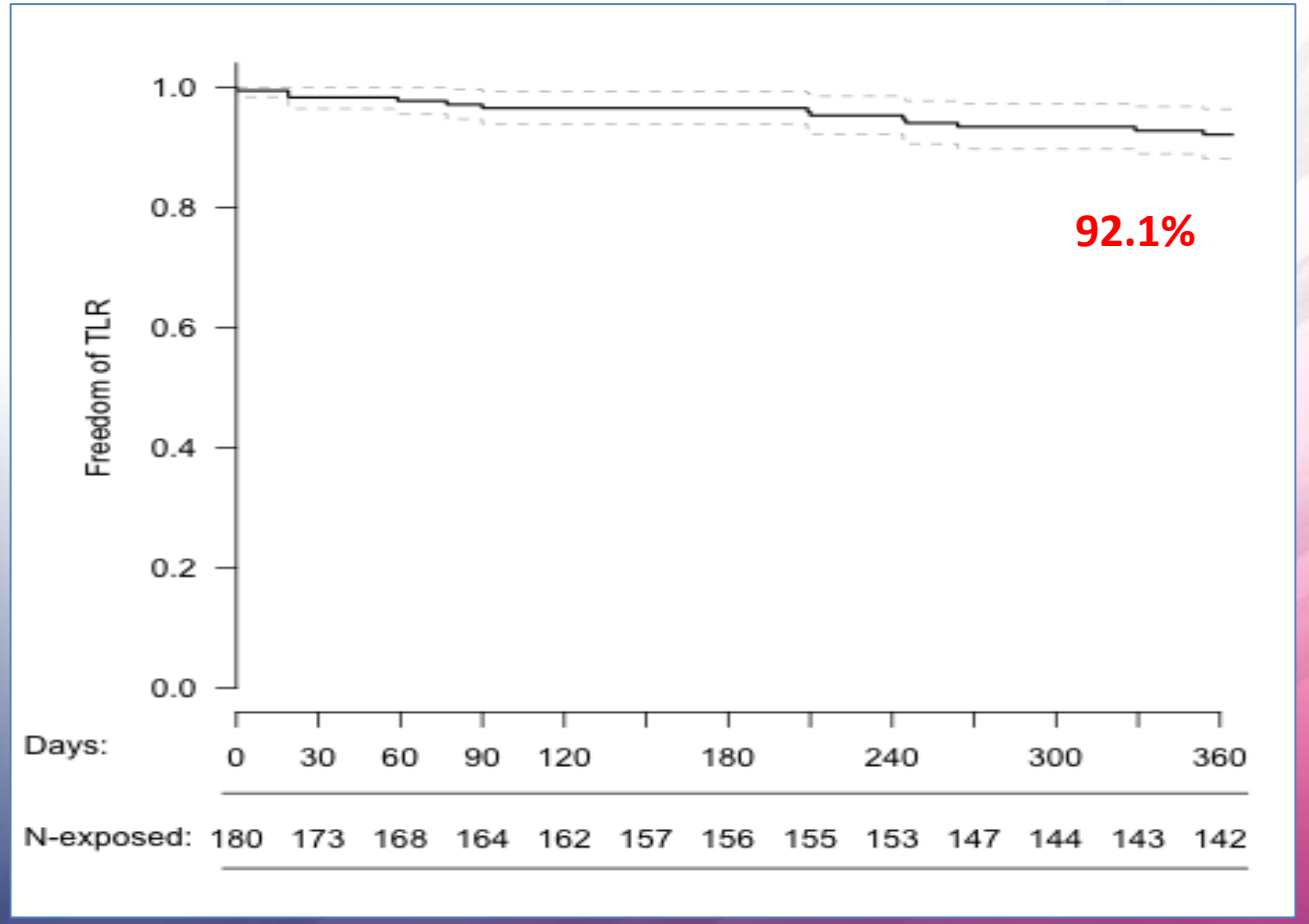
Results @ 1 year follow-up
Survival



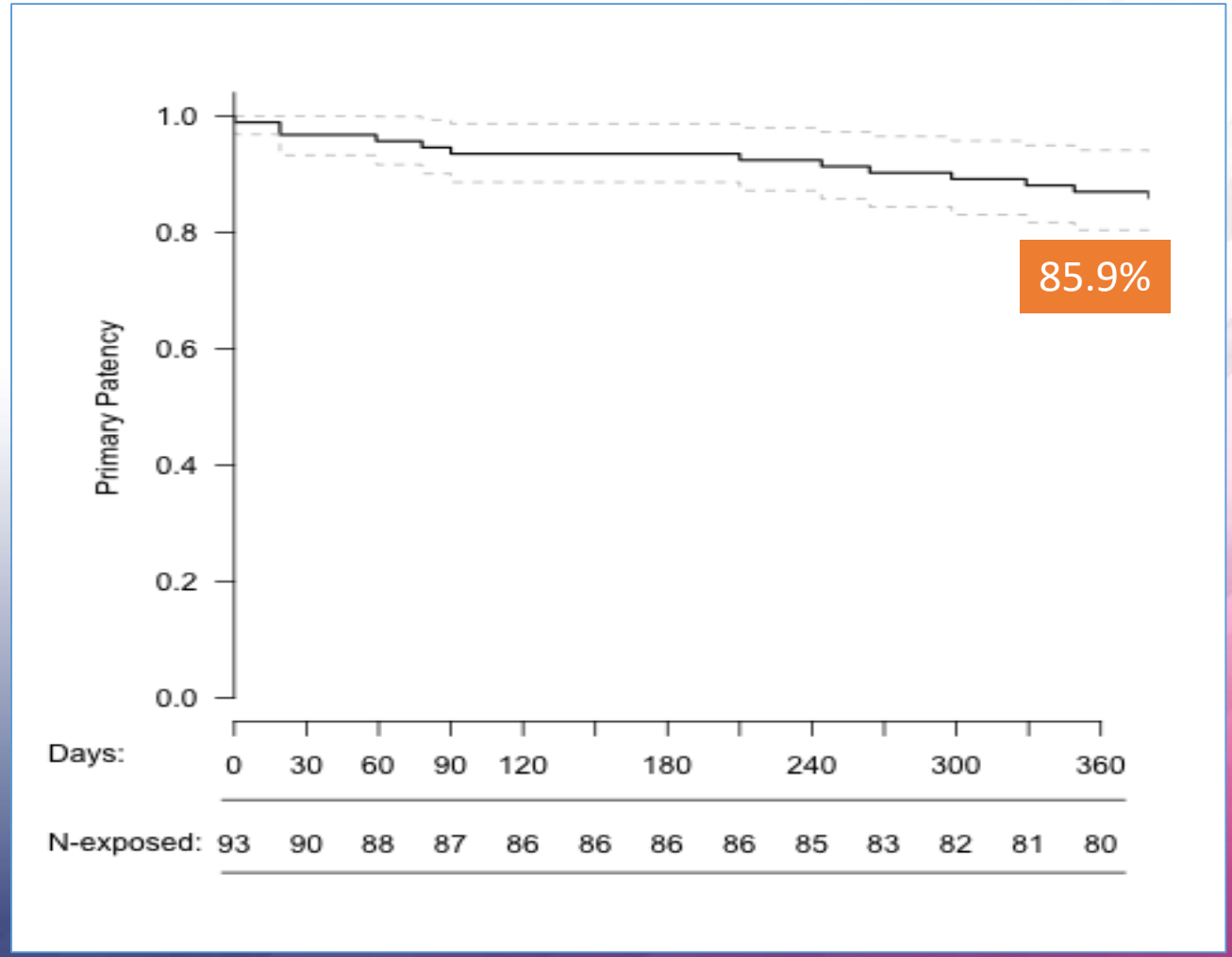
Results @ 1 year follow-up
Freedom from Amputation



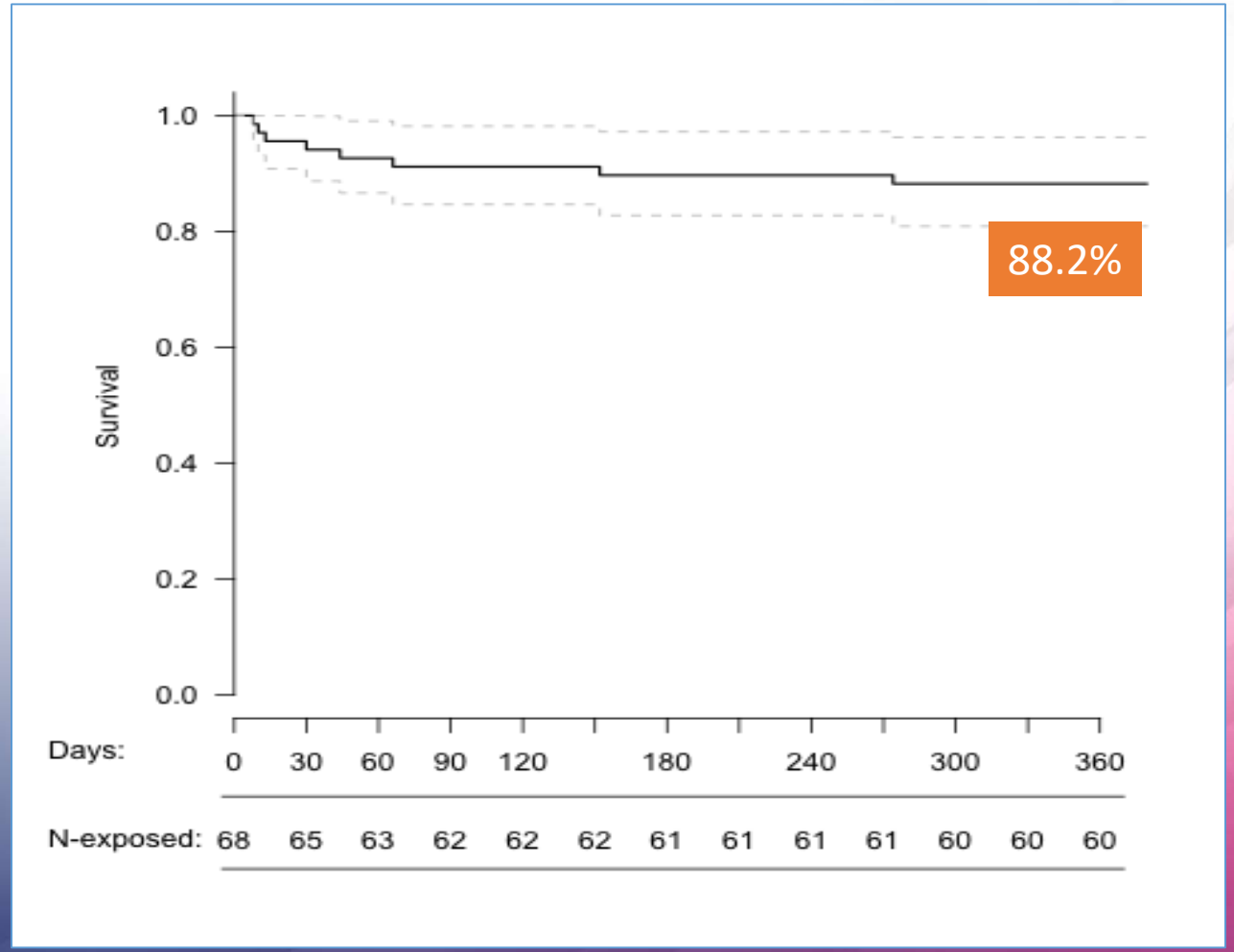
Results @ 1 year follow-up
Freedom from TLR



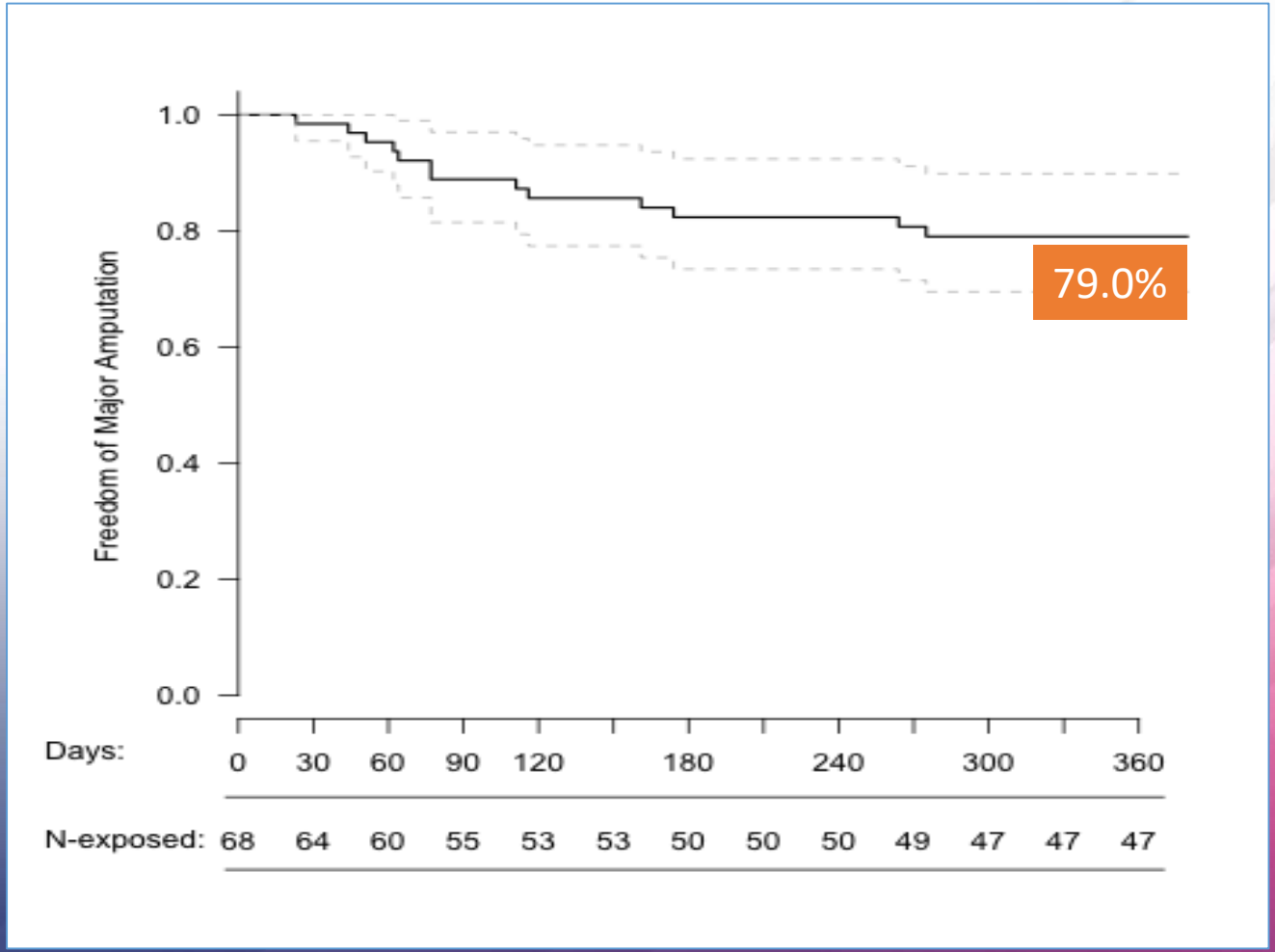
Results @ 1 year follow-up
Primary Patency



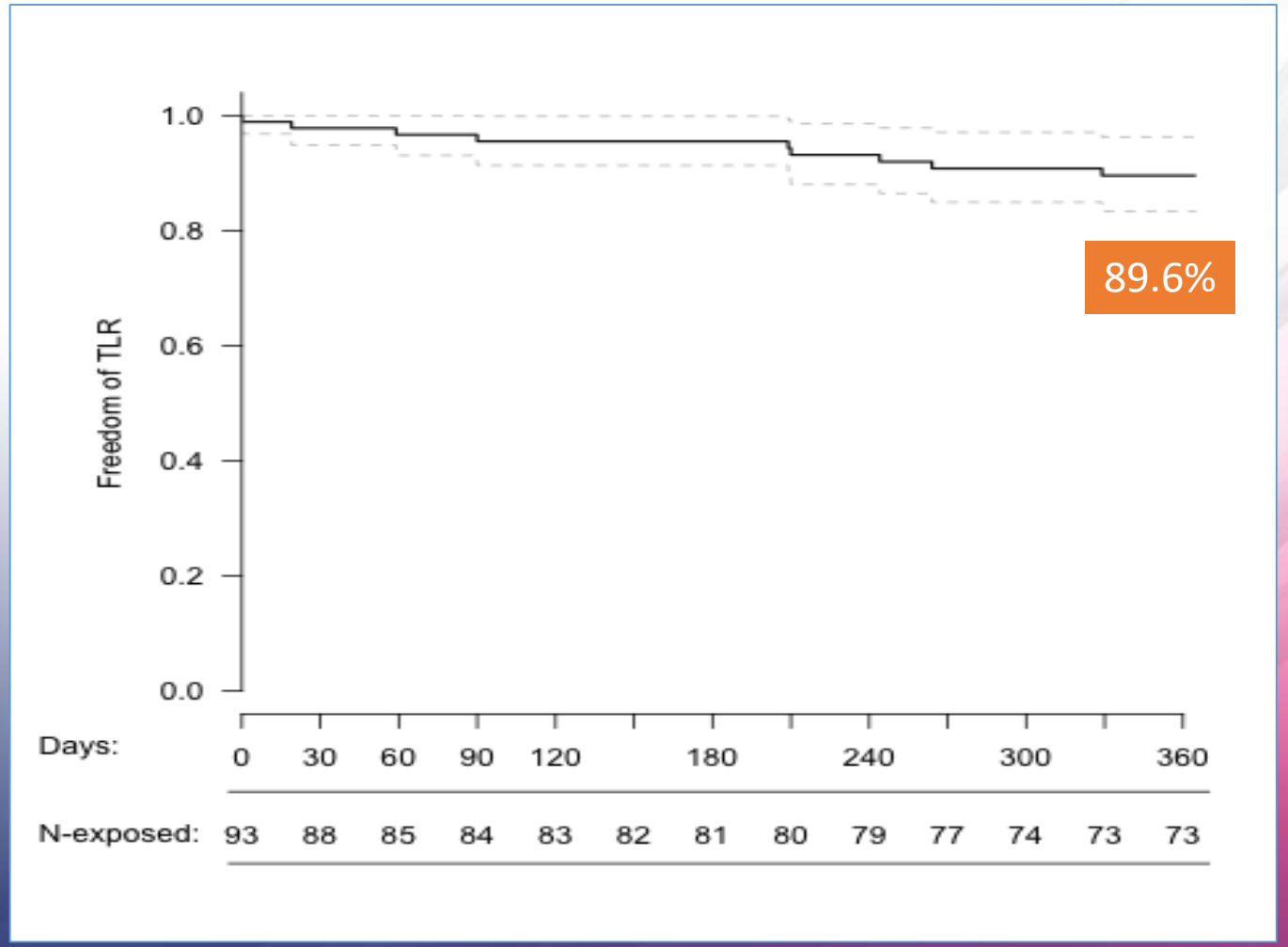
Results @ 1 year follow-up
Survival



Results @ 1 year follow-up
Freedom from Major amputatiom



Results @ 1 year follow-up
Freedom from TLR



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Summary

- **REAL WORLD experience with LUMIMOR DCB is highly positive in terms of safety and effectiveness even in patients with a very poor clinical and anatomical conditions**

LUMINOR registry Participants

Hospital	PI	Collaborator 1	Collaborator 2
1- H. Getafe	Dr Francisco Acín	Dra. Cristina Cañibano Domínguez	Dr. Ignacio Michel Guisasola
2- H. La Paz	Dr. Luis Riera del Moral		
3- H. Clínic	Dr. Vicente Riambau	Dr. Xavier Yugueros	Dr. Gaspar Mestres
4- H. Parc Taulí	Dr. Antonio Giménez Gaibar	Dra. Sara Rioja Artal	Dra. Elena González Cañas.
5- H. Ourense	Dr. Nilo Mosquera Arochena	Dr Ignacio García Fernández	Dra Rebeca Vazquez Dopazo
6- H. Asturias	Dr. Manuel Alonso	Dra. Carol Padron Encalada	
7- H. Burgos	Dr. Francisco Medina	Dr. Ignacio Agúndez Gómez	Dra. Monica Herrero Bernabé
8- H. Basurto	Dra Reyes Vega	Dr. Ricardo Asensio Garcia	Dra. Esther Bravo Ruiz
9- H. Donostia	Dr. Mariano Juan de Blas Bravo	Dra. Ainhoa Garcia	Dr. Jose María Egaña
10- H. Cruces	Dr. Juan Luis Fonseca Legrand	Dra. Ana Apodaka	Dra. Ederi Mikelarena Monteiro

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