LUMINOR registry: a real world experience with a new DEB in advanced limb ischemia

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on behalf of the LUMINOR collaborators

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Disclosures

Speaker name:

V. Riambau.....

I have the following potential conflicts of interest to report:

- [X] Consulting (Bolton Medical/ Medtronic/ Cordis/ iVascular)
- [ ] Employment in industry
- [ ] Stockholder of a healthcare company
- [ ] Owner of a healthcare company
- [X] Other(s) Proctoring (Cook/ Bolton Medical/ Medtronic/Cordis)
- [ ] I do not have any potential conflict of interest

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Background

Luminor is a new drug-coated angioplasty balloon from iVascular (CE-marked), with the unique TransferTech® technology that provides a durable crystalline coating.

Fig. 1 Macroscopic aspect of Luminor DCBs with an uniform coating (A) in comparison with a competitor (B) *Folded – Outside the wings*

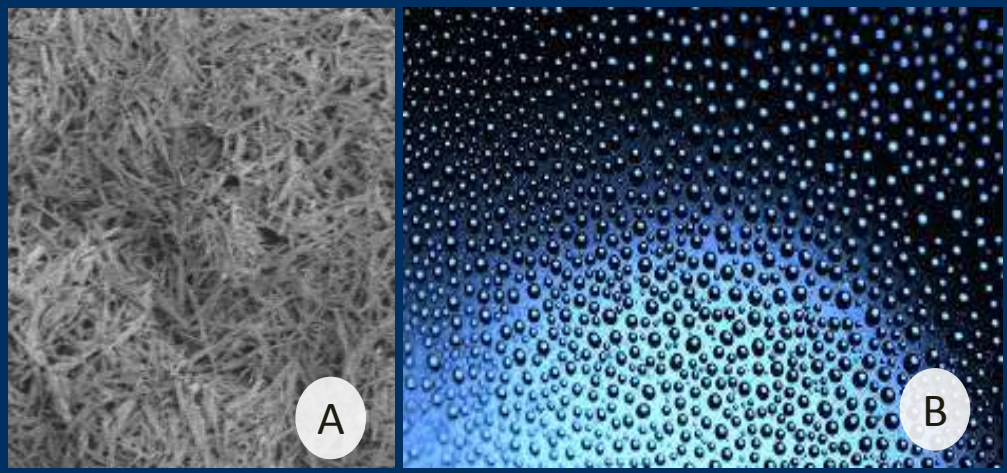

Fig. 2 Microscopic Cristalline structure of Paclitaxel coating (A) and ultrasonic coating technology by nanodrops (B)
Excipient: *Water Reduced Ester*
Drug/excipìent ratio: 80/20

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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 219 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

Baseline Demographics

	N	%
Patients	219	
Lesions	252	
Male	156	72.6
Age (years)	70.6±11.7	
Diabetes	140	65.1
Smoking and ex-smoking	136	63.3
Arterial Hypertension	175	81.4
Hyperlipidemia	124	57.7
Chronic Renal Failure	51	23.7
Rutherford Class		
2	13	6.1
3	47	22.1
4	25	11.7
5	128	60.1

Material and Methods

Lesion Characteristics

Lesion length (mm)	77.8 (20-200)
Chronic Total Occlusions	48.01%
Stenosis	48.01%
Stenosis intra-stent	**3.98%**
Target Vessels	
Femoropopliteal	61.2%
Below the Knee	34.2%
Combined segments	4.6%

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Early Results

30-Days follow-up	
Technical success	91.4%
Bailout stenting	6.8%
All-cause mortality	1.9%
Major amputations	1.9%
TLR	1.4%

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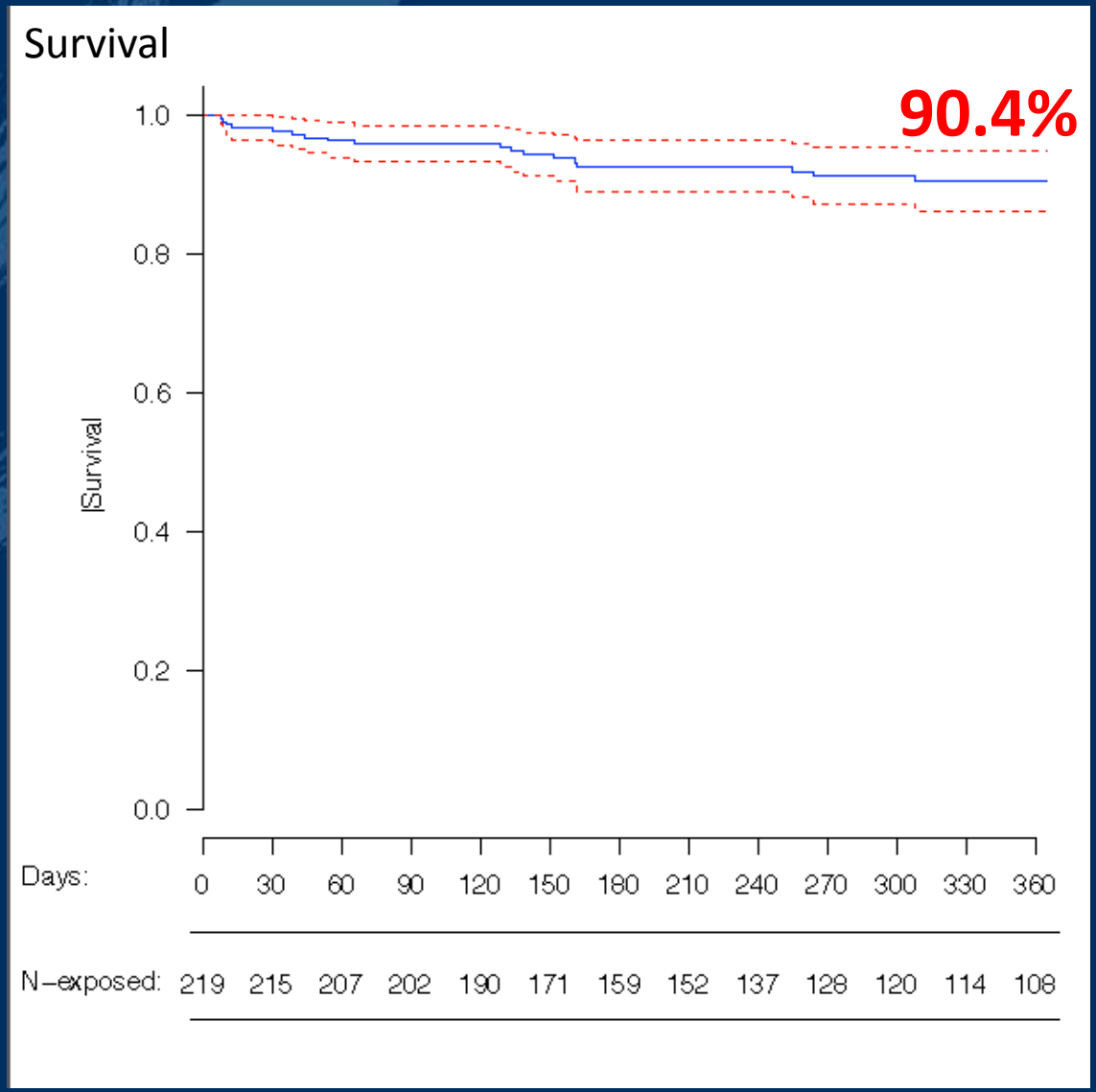
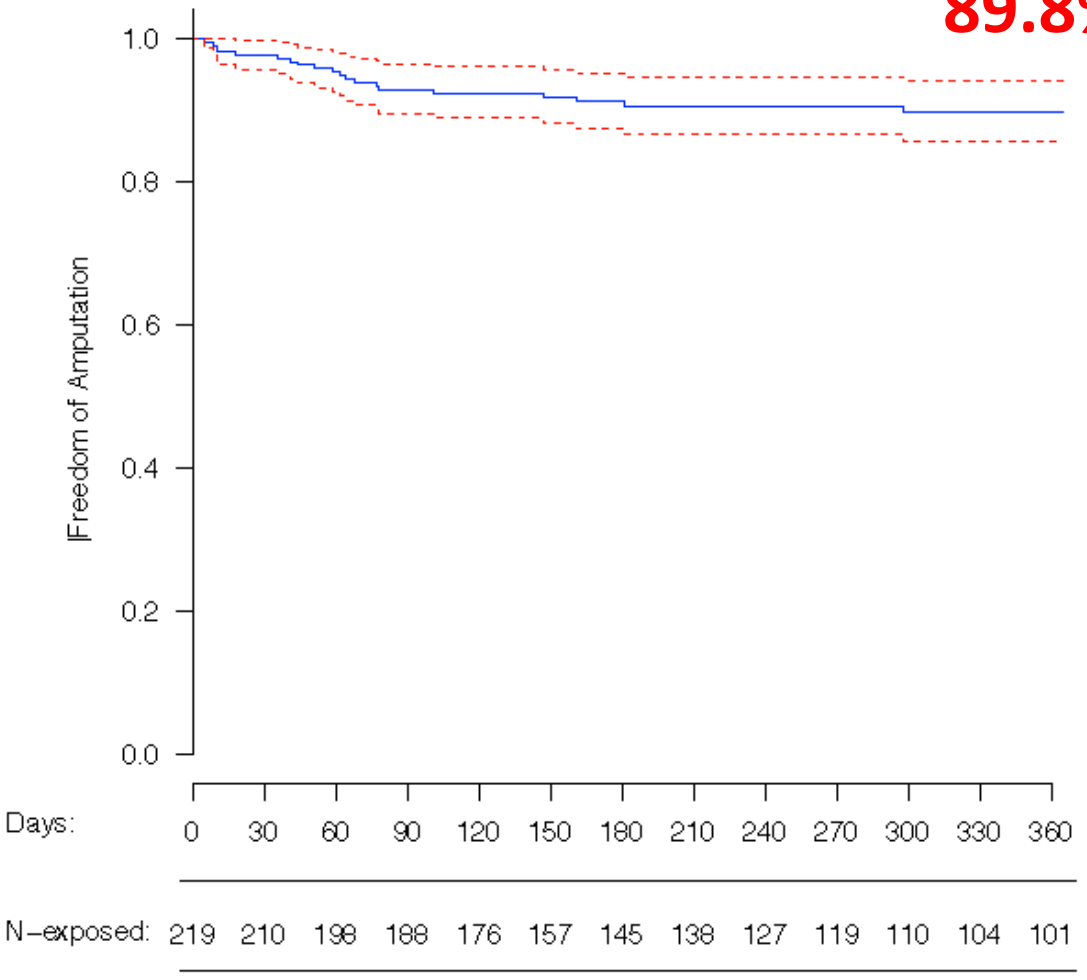
Results @ 1 year follow-up



Results @ 1 year follow-up

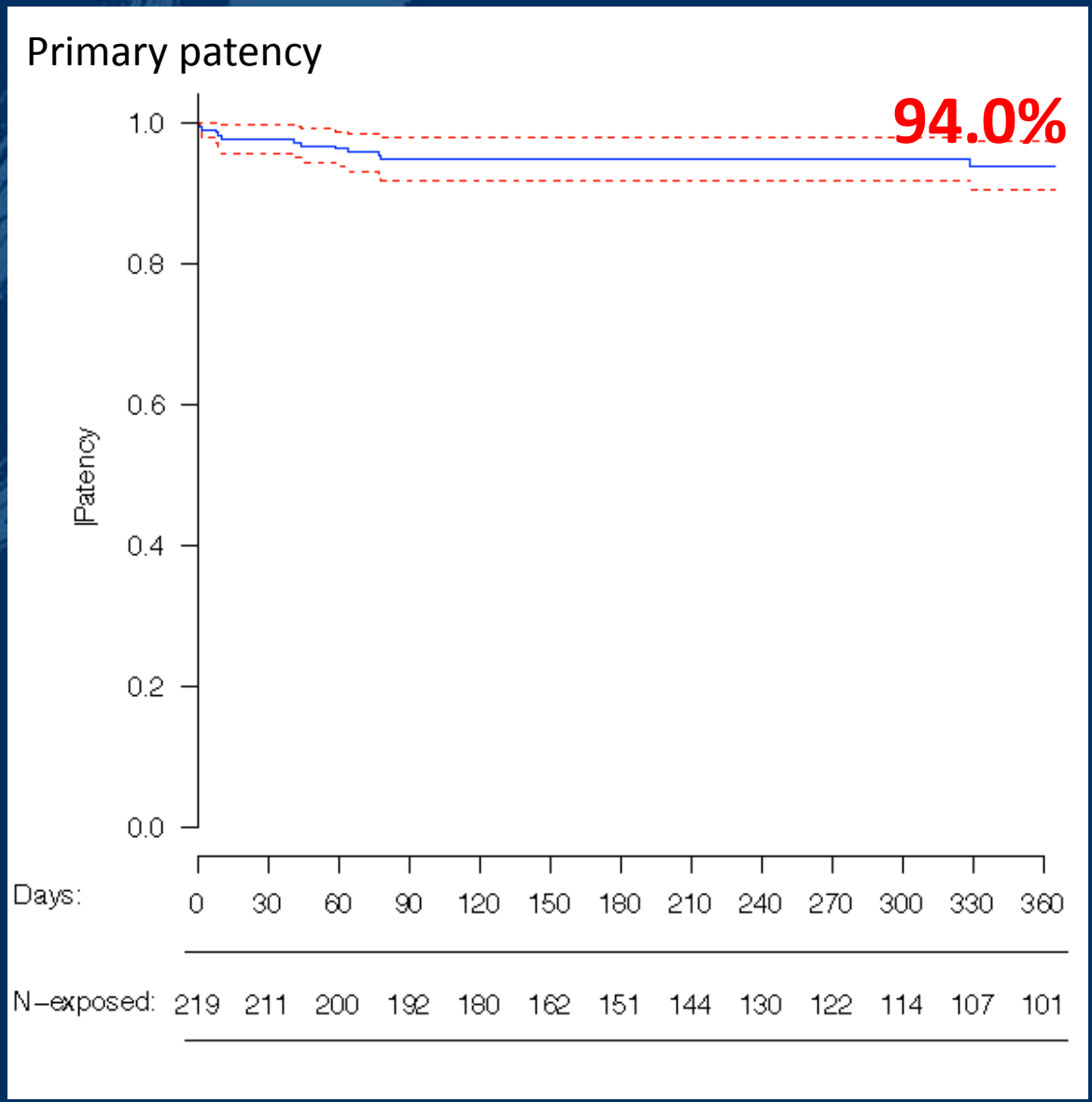
Freedom from amputation

89.8%



Results @ 1 year follow-up

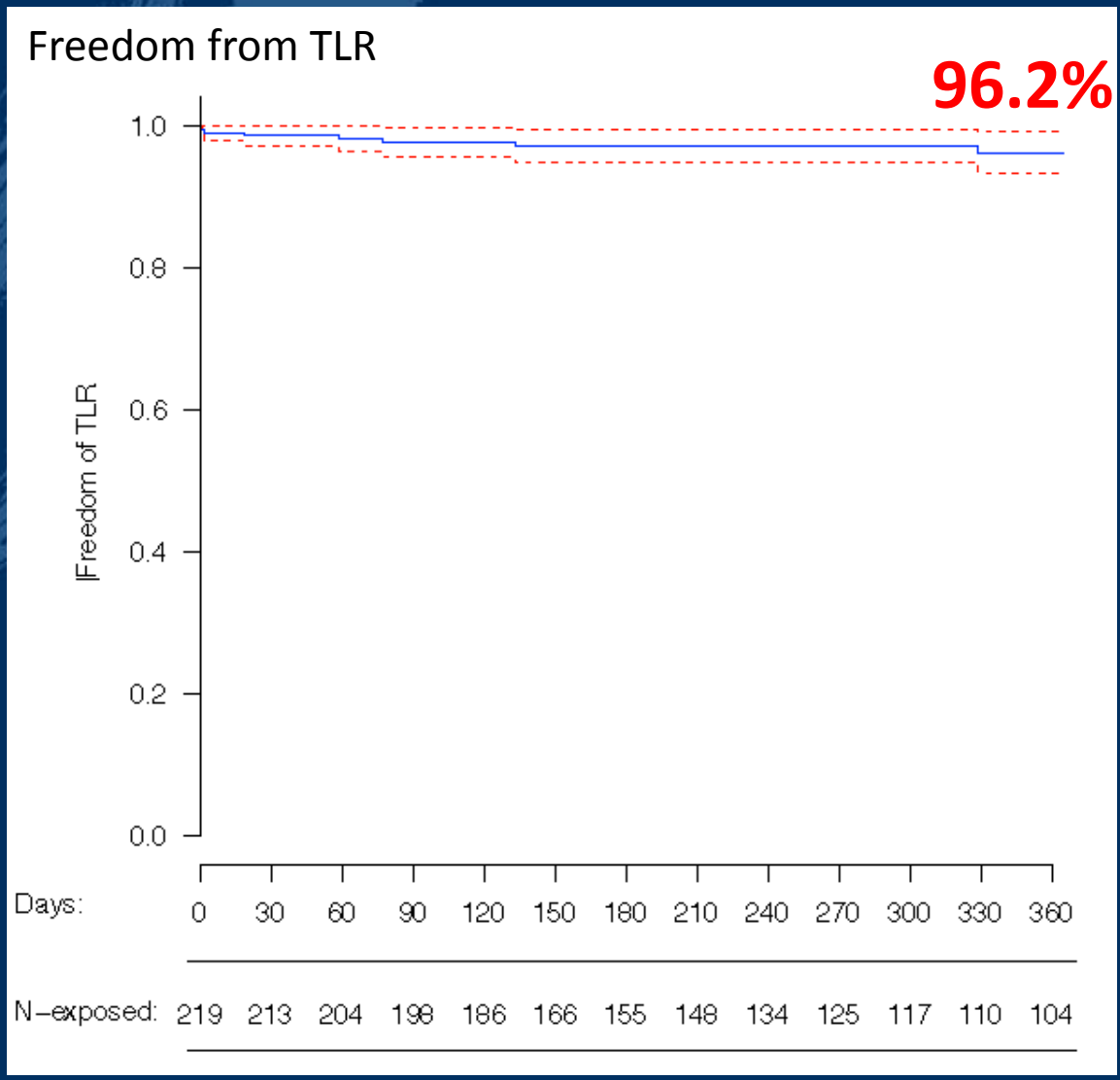
Primary patency



Results @ 1 year follow-up

Freedom from TLR

96.2%



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Material and Methods (BTK)

Demographics	N	%
Patients	98	
Lesions	116	
Male	70	71.4
Age (years)	72.6±11.4	
Diabetes	73	74.5
Smoking and ex-smoking	51	52.0
Arterial Hypertension	83	84.7
Hyperlipidemia	52	53.1
Chronic Renal Failure	27	27.6
Rutherford Class		
2	2	2.1
3	5	5.2
4	7	7.2
5	84	85.6

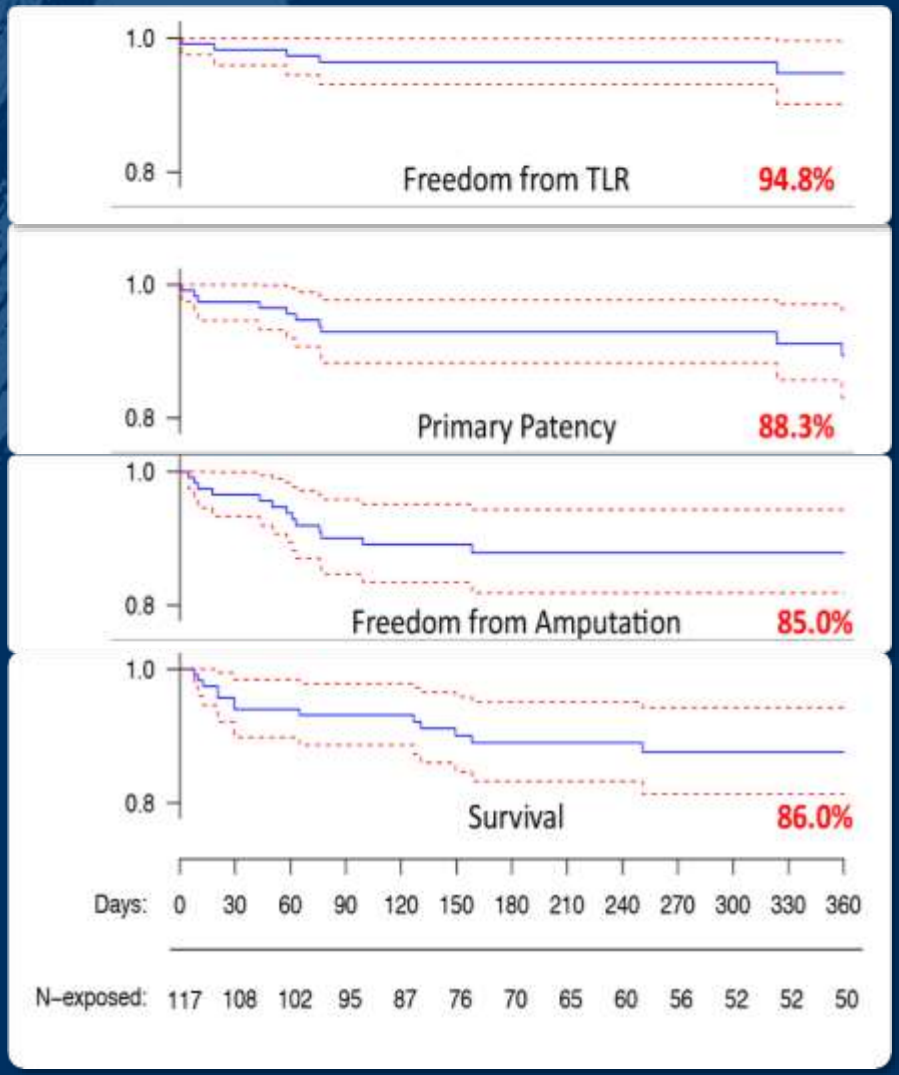
Material and Methods

Lesion characteristics	
Lesion length (mm)	77.9 (20-200)
Chronic Total Occlusions (CTO)	61.2
Stenosis	38.8

Early Results

30-Days follow-up	
All-cause mortality	7.1%
Major amputations	5.1%
TLR	0%

Results @ 1 year follow-up



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Summary

- Initial primary outcomes are encouraging taking into account the ischemic status severity of this cohort of patients.
- BTK results are specially positive and re-open the door for DCB technology in this challenge field.
- LUMINOR Spanish registry will complete the final results by May 2017. Interim and final results will be published in future reports.

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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