

The LINC logo features a stylized, abstract shape in red and orange, resembling a flame or a dynamic motion, set against a dark blue background. The letters "LINC" are positioned to the right of this graphic.

LINC

Outcomes of Paclitaxel coated technology in treating patients with Rutherford 5 and 6 peripheral arterial disease

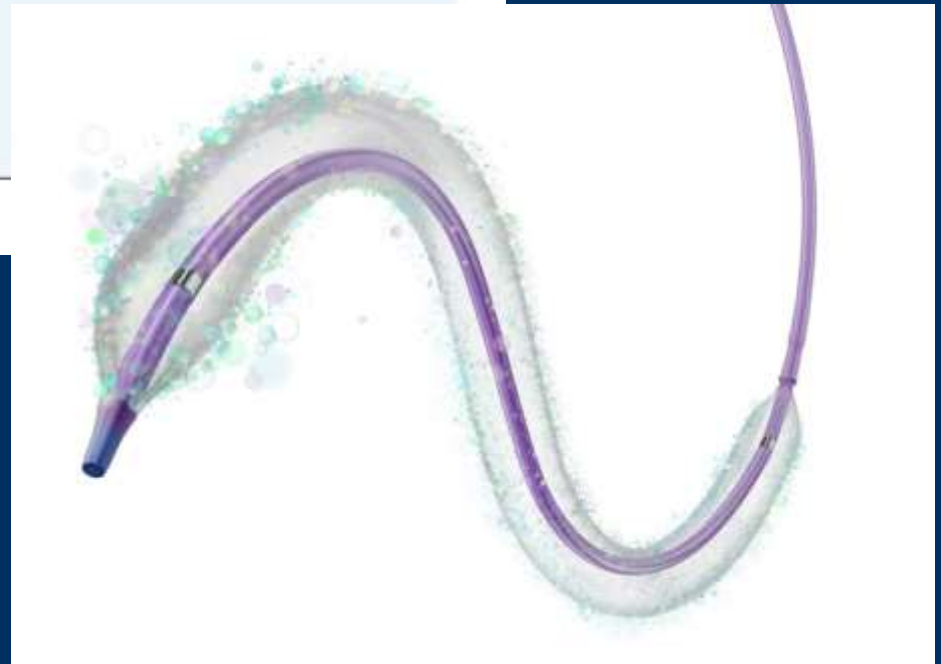
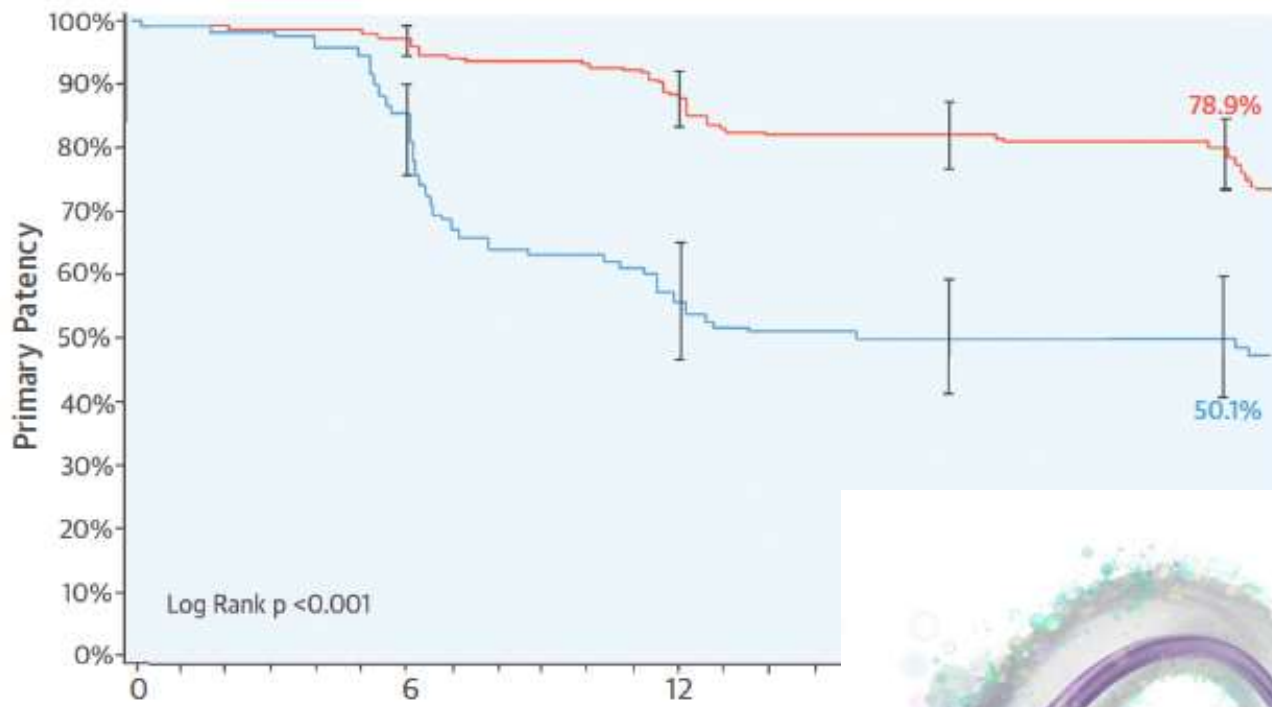
Saadat Shariff, MD

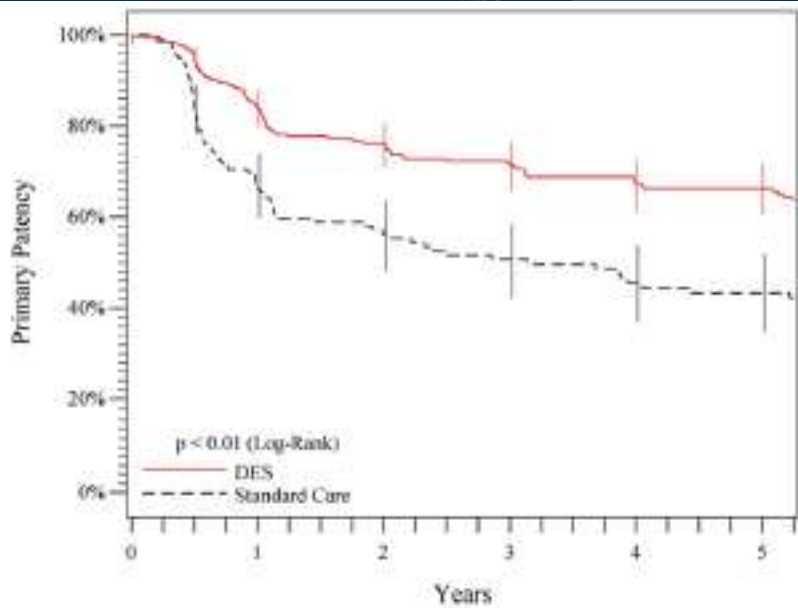
Montefiore Medical Center

Disclosure

- None

A. Primary Patency





Kaplan Meier Estimates of Primary Patency, Values Represent Lesions

Years Post-procedure	Primary Patency ± Standard Error		Cumulative Failed		Remaining at Risk	
	Standard Care	DES	Standard Care	DES	Standard Care	DES
0	100.0 ± 0.0%	99.7 ± 0.3%	0	1	383	318
1	67.4 ± 3.6%	84.4 ± 2.1%	57	48	308	246
2	56.2 ± 4.0%	76.3 ± 2.5%	73	71	64	199
3	50.7 ± 4.2%	71.5 ± 2.7%	79	83	52	163
4	45.5 ± 4.3%	67.4 ± 2.9%	84	92	44	137
5	43.4 ± 4.4%	66.4 ± 2.9%	86	94	38	109

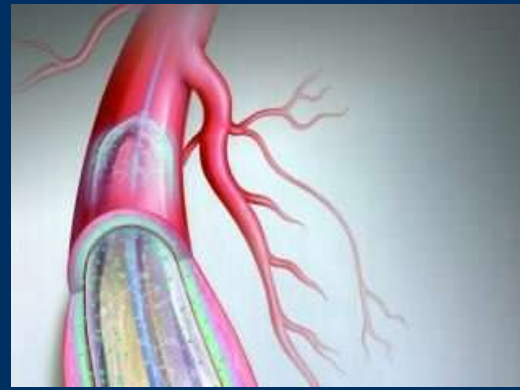
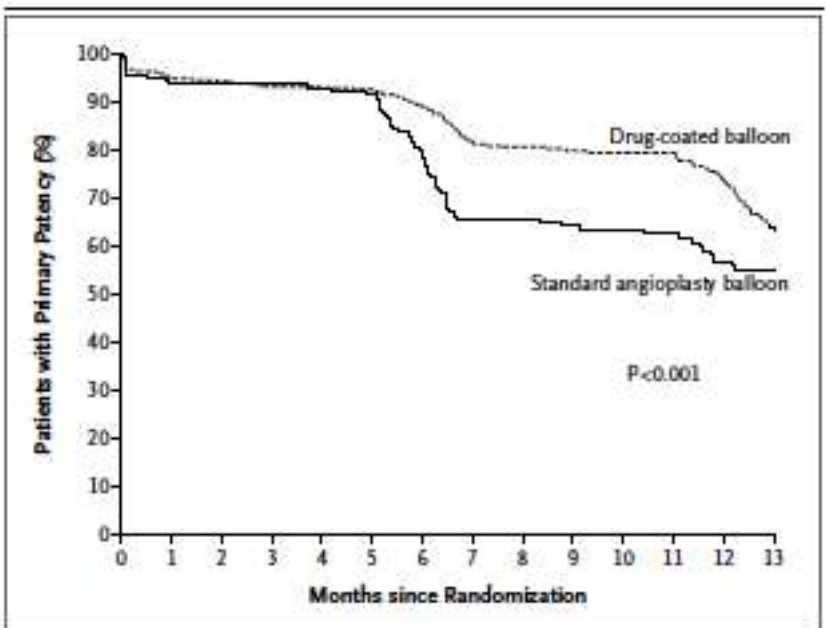
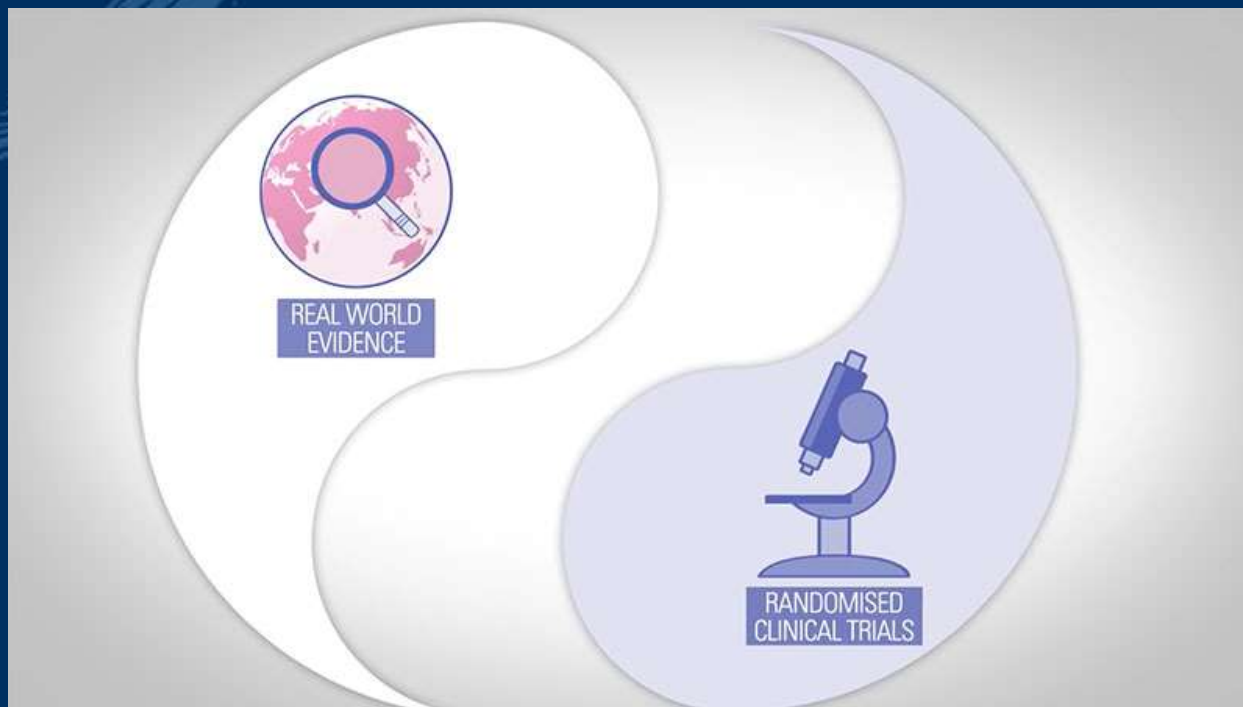


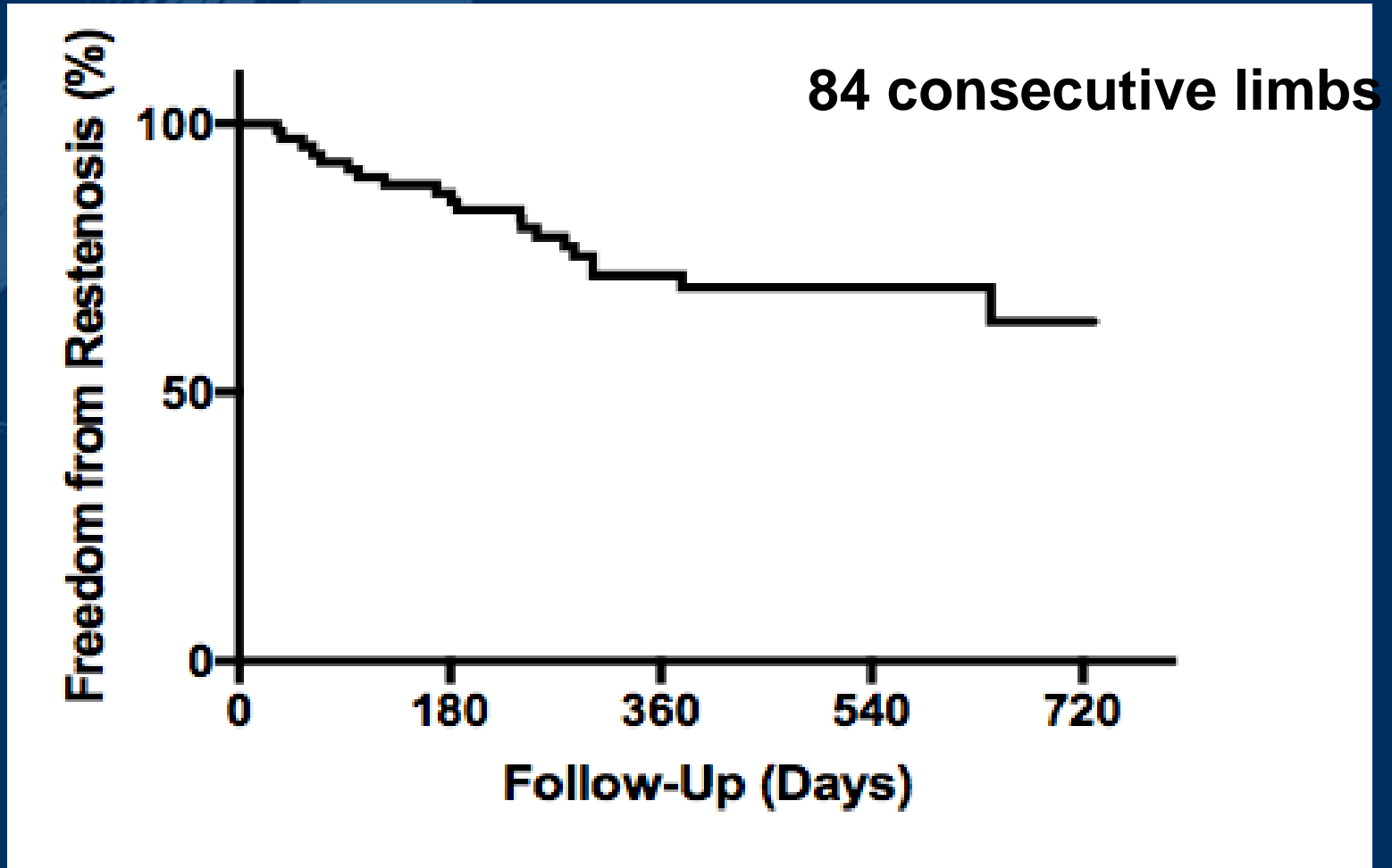
Figure 1. Kaplan-Meier Curves for Primary Patency at 12 Months.
 Primary patency was defined as the absence of target-lesion restenosis (defined by core-laboratory adjudication) and target-lesion revascularization (adjudicated by the clinical-events committee).

Trials versus the Real World

- Lesions <10 cm
- Few to no patients with Critical limb ischemia or wounds



Primary patency Long segment SFA/Pop



	Patients without Restenosis N = 60		Patients with Restenosis N = 24		P-value
Age	70	60.5 - 79	69	58.25 - 79.25	0.3107
Men	32	53%	13	54%	0.5915
Hypertension	41	68%	18	75%	0.5543
Hyperlipidemia	31	52%	13	54%	0.8364
Diabetes	33	55%	17	71%	0.4062
ESRD	8	13%	5	21%	0.052
Smoking	32	53%	15	63%	0.4157
Vessel Occlusion	20	33%	12	50%	0.283
DCB	8	13%	12	50%	0.0021
Tibial Angioplasty	17	28%	10	42%	0.1672
Lesion Length (cm)	11	10 - 15.2	12	10 - 15	0.5328
Rutherford Class					
3	10	17%	4	17%	0.6312
4	10	17%	6	25%	0.3662
5	27	45%	10	42%	0.7963
6	13	22%	4	17%	0.7611
Recurrent Lesion	3	5%	3	13%	0.1367

Data are given as counts (percentages) or median (interquartile range from the 25th to 75th percentile).

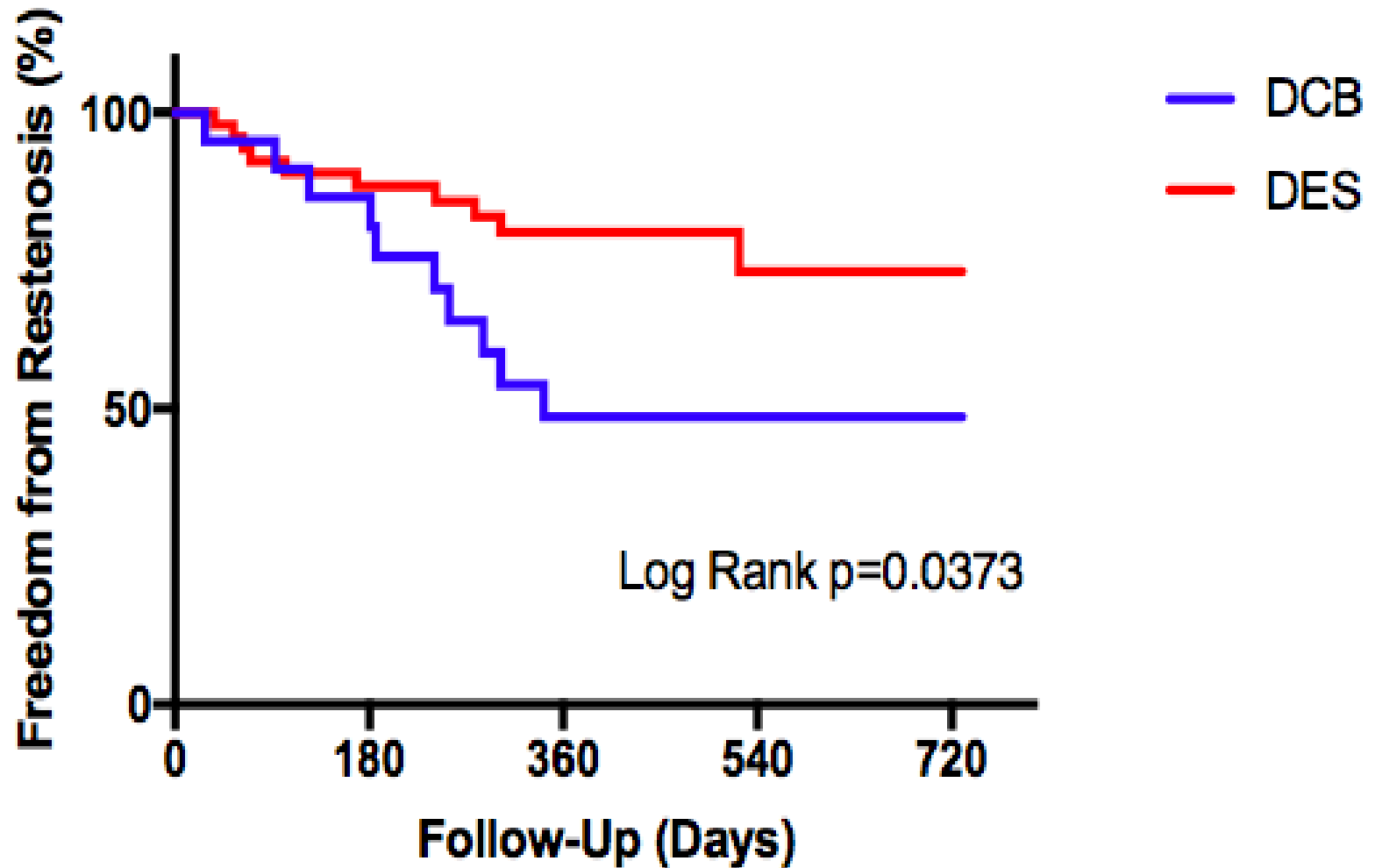
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Multivariate Analysis

	HR	95% Confidence Interval	P-value
Age	1.004	0.631 - 4.21	0.783
ESRD	1.09	0.83 - 5.1	0.186
DCB	2.41	1.11 - 3.35	0.042
Tibial Angioplasty	1.71	0.39 - 2.99	0.27
Recurrent Lesion	3.777	0.92 - 7.56	0.058

Long segment >10cm



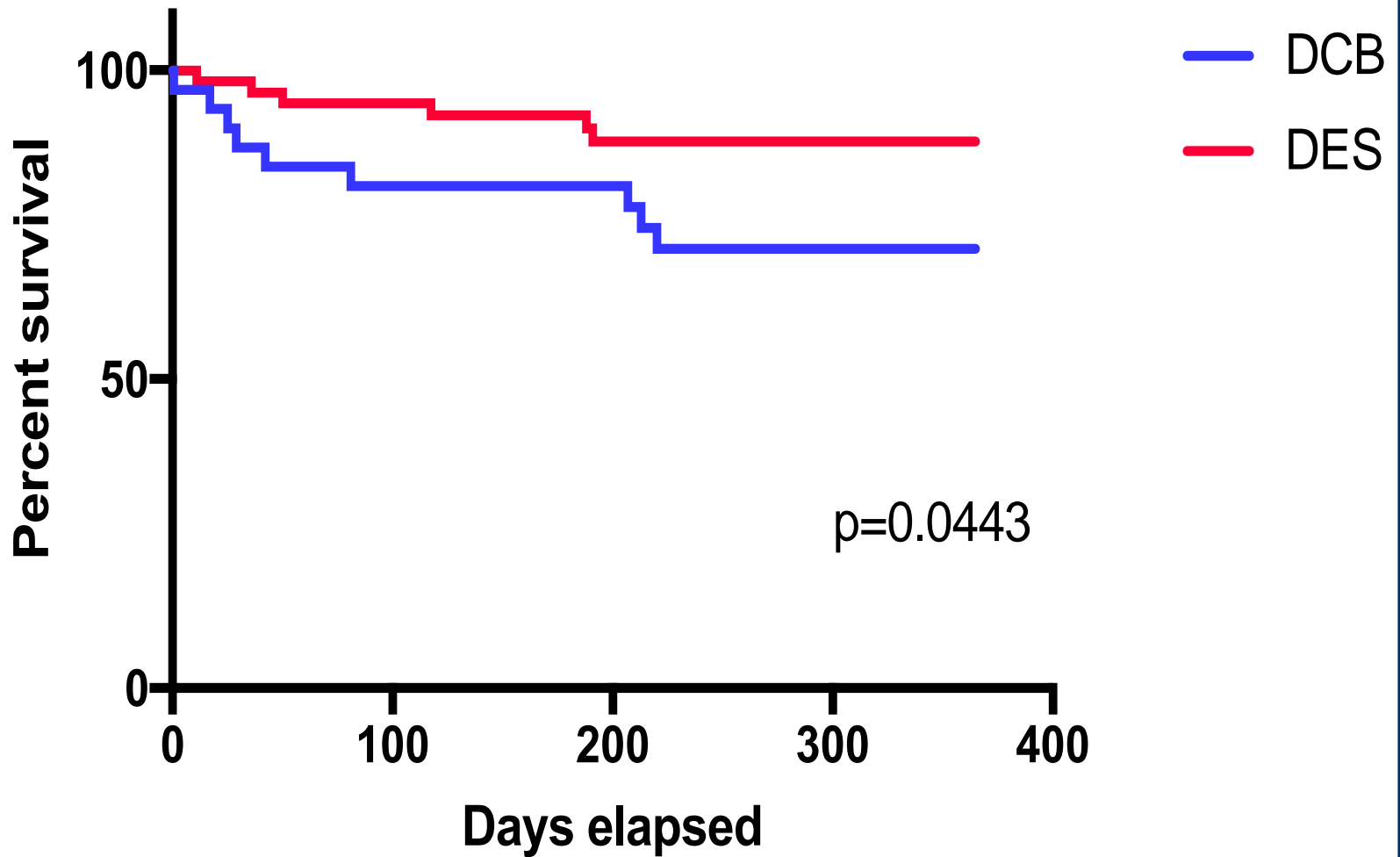
- Rutherford 5 and 6 treated with DES or DCB over 4 years
- Primary endpoint – amputation free survival
- Secondary endpoint – wound healing, freedom from reintervention and patency

Rutherford 5 and 6 patients

	PTX	DCB	p-value
Number	56	32	
Age			
Median	70.5	66	0.409132
Interquartile Range	60.75 - 78.25	58.5 - 75.5	
Male sex	34 (60.7)	15 (46.9)	0.21320
Comorbidities			
Diabetes	37 (66.1)	26 (81.3)	0.13180
Hypertension	41 (73.2)	25 (78.1)	0.35865
Hypercholesterolemia	31 (55.4)	22 (68.8)	0.22151
End Stage Renal Disease	6 (10.7)	9 (28.1)	0.03700
Coronary Artery Disease	12 (21.4)	11 (34.4)	0.18774
Previous MI	3 (5.4)	8 (25)	0.34844
Previous COPD	10 (17.9)	4 (12.5)	0.51421
Smoking Status			
Current	19 (33.9)	7 (21.9)	0.23803
Former	28 (50)	15 (46.9)	0.78090
Never	9 (15.3)	10 (31.3)	0.09811
Aspirin	46 (82.1)	24 (75)	0.56816
Clopidogrel Post-op	53 (94.6)	27 (84.3)	0.15700
Rutherford			
5	42 (75)	21 (65.6)	0.90075
6	14 (25)	11 (34.4)	0.90075

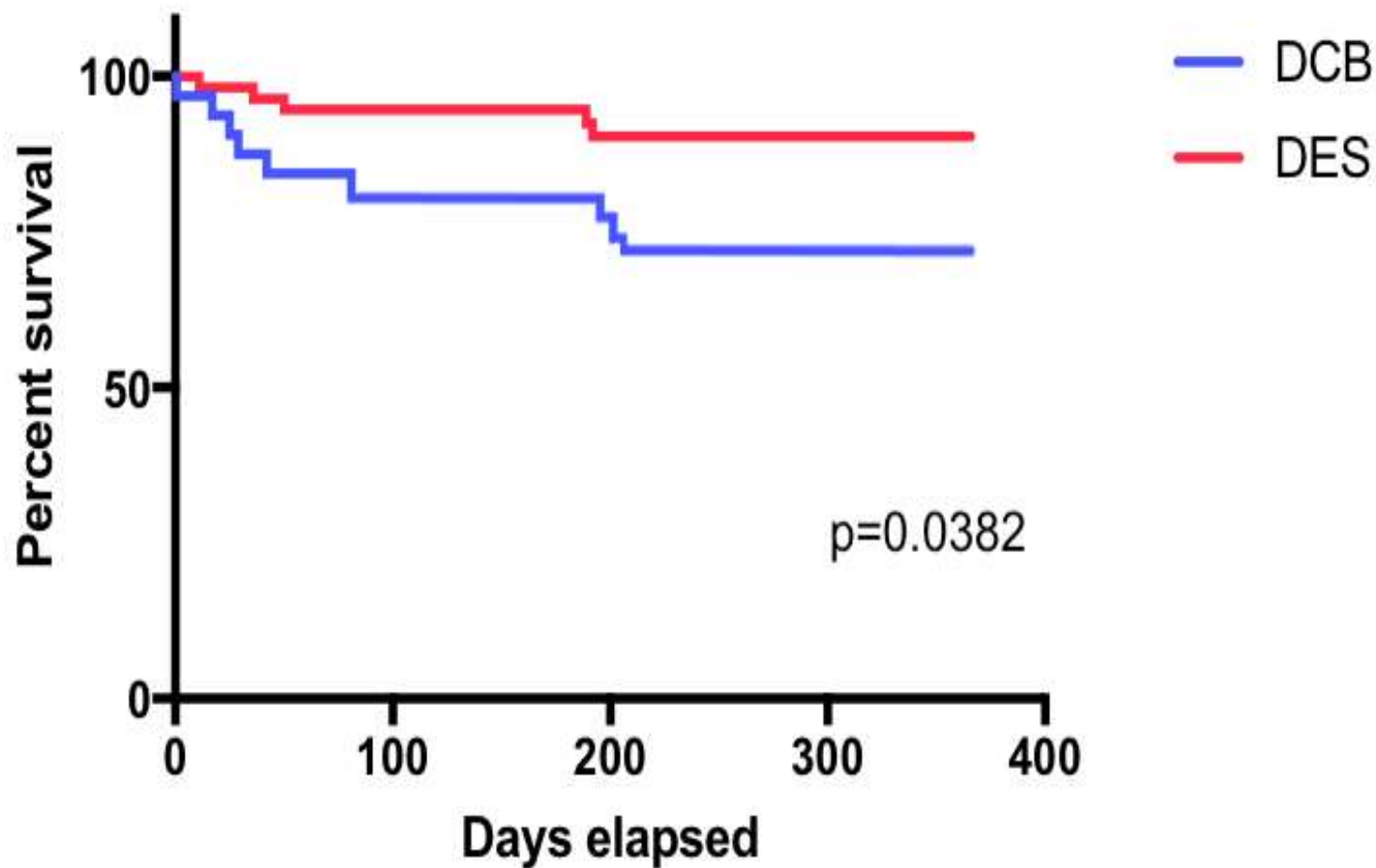
WiFi Classification			
Wound class 1	19 (33.9)	5 (15.6)	0.06484
Wound class 2	23 (41.1)	16 (50)	0.49347
Wound class 3	14 (25)	11 (34.4)	0.35393
Ischemia class 0	1 (1.8)	2 (6.3)	0.27213
Ischemia class 1	13 (23.2)	10 (31.3)	0.41502
Ischemia class 2	28 (50)	9 (28.1)	0.04614
Ischemia class 3	14 (25)	11 (34.4)	0.35393
Foot Infection class 0	27 (48.2)	16 (50)	0.87374
Foot Infection class 1	10 (17.9)	5 (15.6)	0.79171
Foot Infection class 2	13 (23.2)	11 (34.4)	0.26324
Foot Infection class 3	6 (10.7)	0 (0)	0.05600
Target Lesion			
Stenosis	33 (58.9)	28 (87.5)	0.00480
Occlusion	23 (41.1)	4 (12.5)	0.00480
Number of Stents/Balloons			
1	40 (71.4)	29 (90.6)	
2	11 (19.6)	2 (6.3)	
≥3	5 (8.9)	1 (3.1)	
Concomitant Tibial Angioplasty			
1 vessel	14 (25)	10 (31.3)	0.53201
2 vessels	2 (3.6)	3 (9.4)	0.26304
3 vessels	0 (0)	0 (0)	

Amputation Free Survival

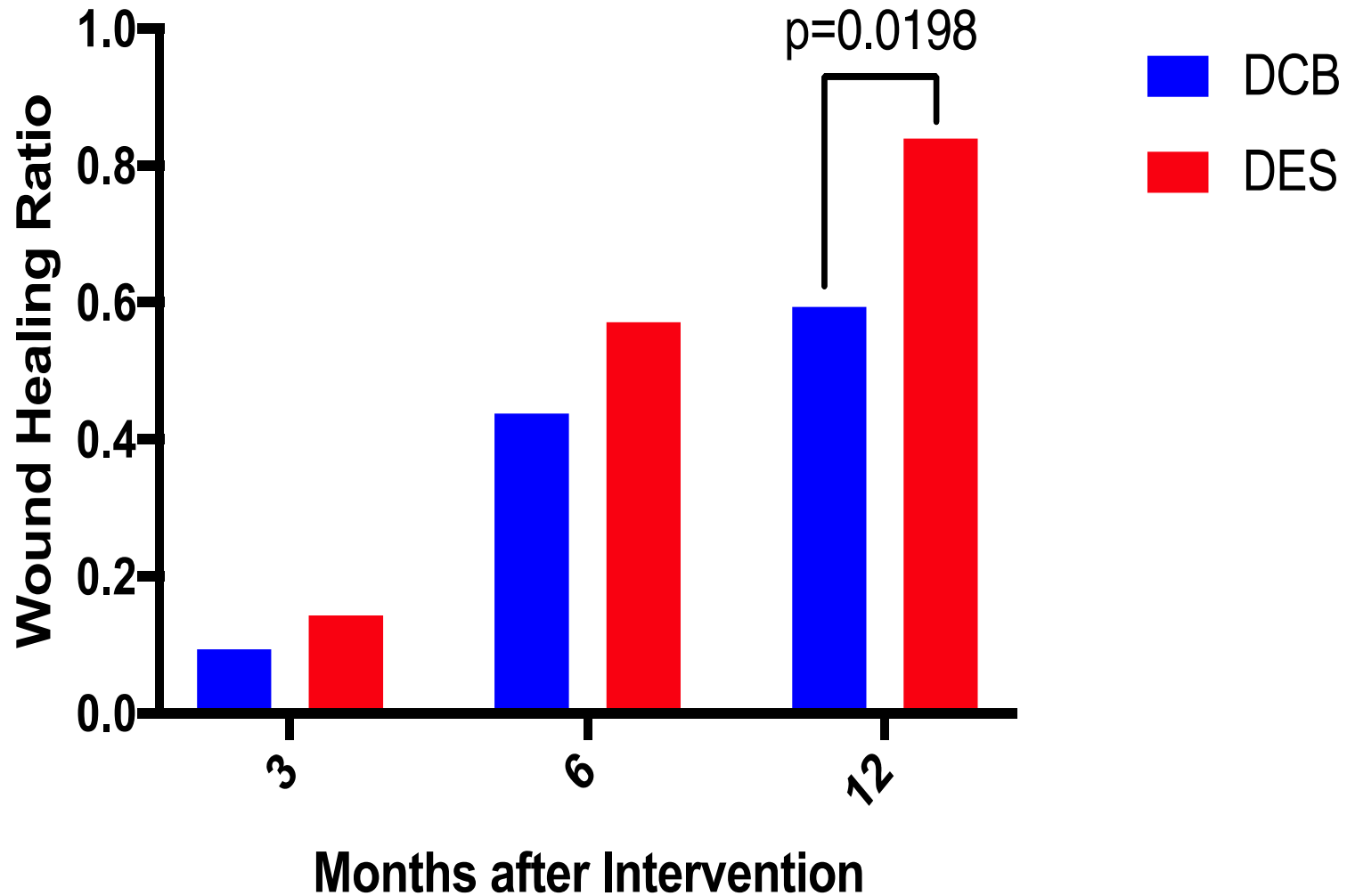


Excluding ESRD

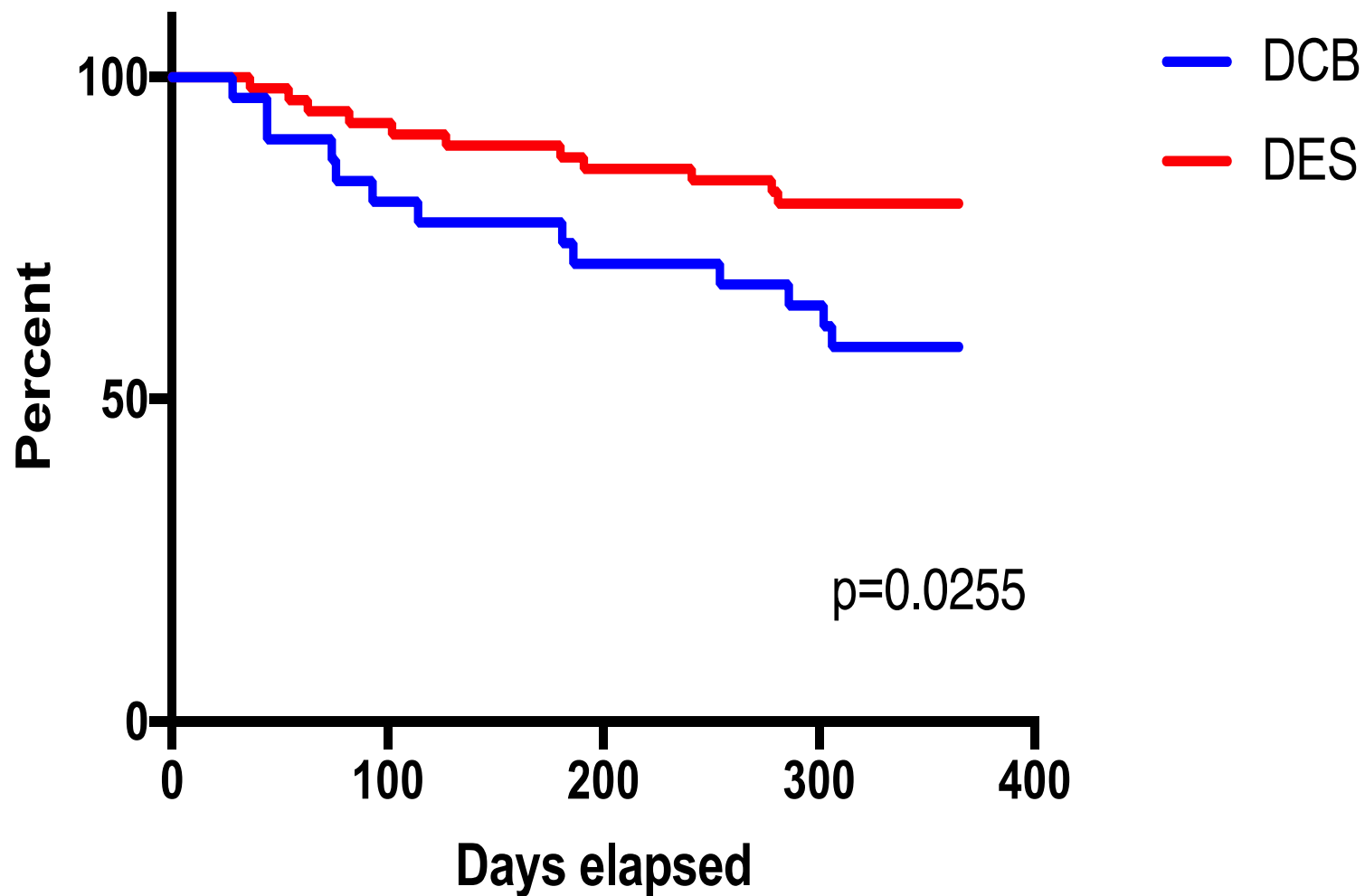
Amputation Free Survival



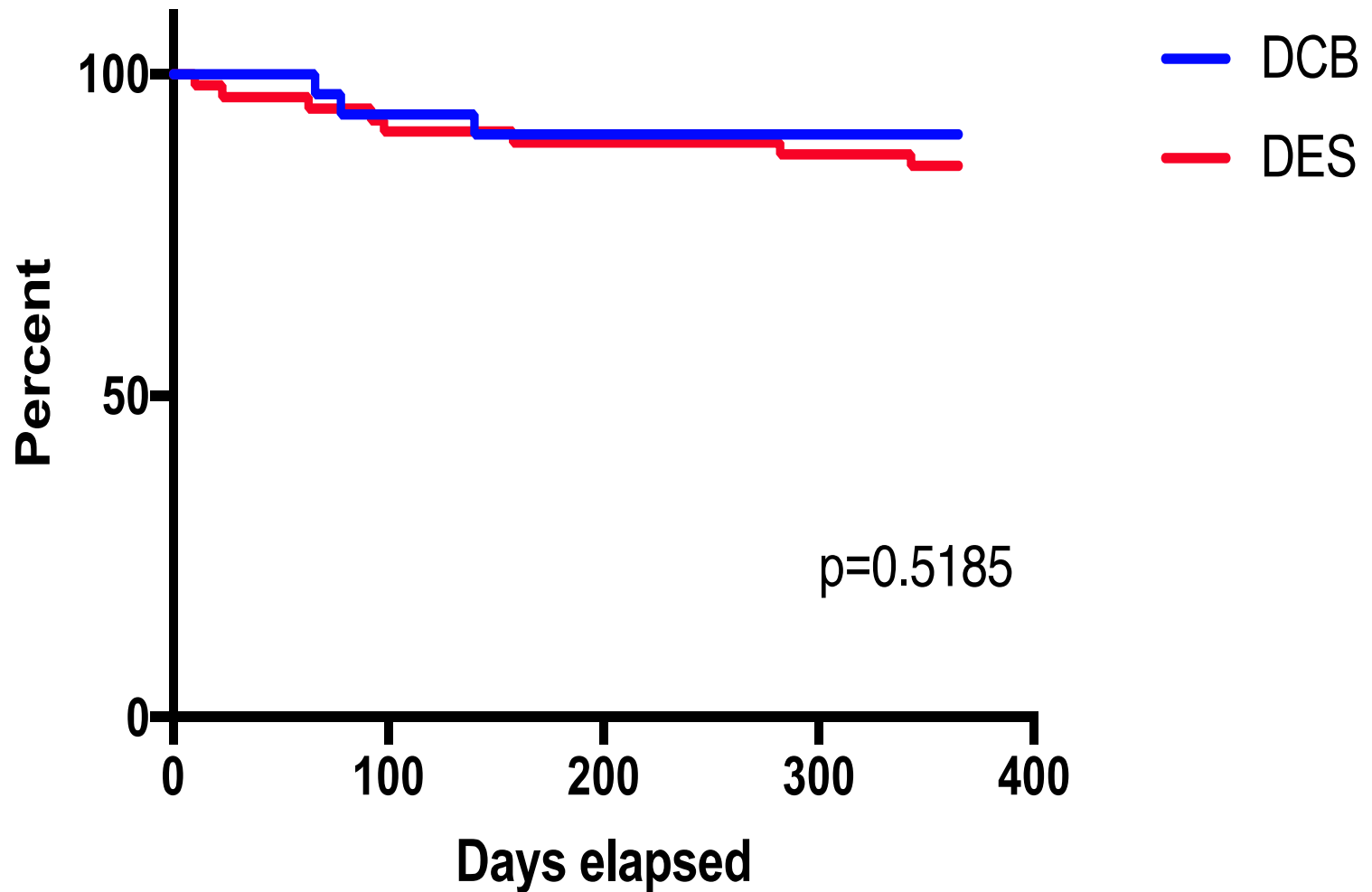
Wound Healing



Patency



Freedom from reintervention



Conclusion

- Single center, non-randomized data
- Amputation free survival and wound healing increased with DES
- Higher patency with DES
- No difference in freedom from reintervention

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