360° CLINICAL SERIES

LIBERTY 360° Study

LIBERTY is the largest, contemporary, real-world experience study to evaluate procedural and long-term clinical outcomes of endovascular device interventions in patients with symptomatic lower extremity peripheral artery disease (PAD).

STUDY DESIGN

- Prospective, observational, multicenter study that includes any FDA-cleared or approved technology to treat claudication and critical limb ischemia (CLI).
- 1204 patients enrolled at 51 sites and were followed for up to 5 years. 4 core labs used for independent analysis.
- Key endpoints: Procedural and lesion success, Major Adverse Events (MAEs), Duplex Ultrasound (DUS), Quality of Life (QoL), and Six-Minute Walk Test (6MWT).
- Key inclusion criteria: Rutherford classification (RC) 2 to 6, target lesion located within or extending into 10 cm above the medial epicondyle to the digital arteries (distal 1/3 of the SFA and below), and at least one lesion that can be treated with an endovascular device.

CONCLUSION

Peripheral vascular intervention (PVI) may be a reasonable treatment option across all Rutherford classes with durable results lasting to 3 years.[2]

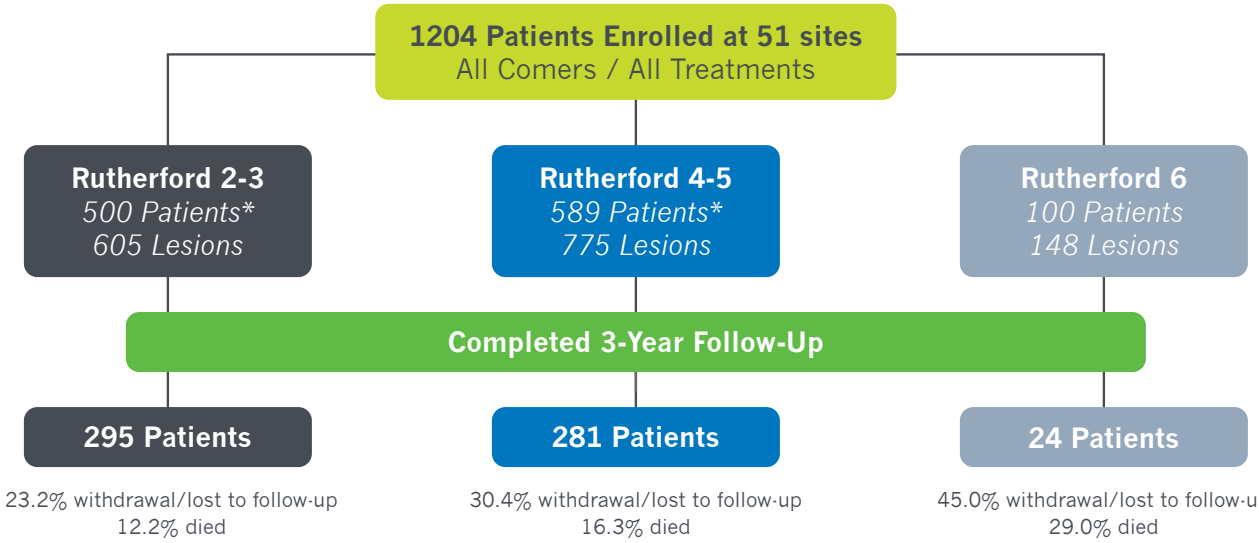
- High freedom from major amputation at 3 years across all Rutherford classes[2]
- In the OAS sub-analysis, freedom[2] from major amputation rates at 3 years were even higher than in the full patient cohort
- Improved Quality of Life post-procedure by 30 days and maintained out to 3 years across all Rutherford classes
- High long-term patency rates through 2 years in RC2-3[3]
- Improvement in mean number of wounds from 30 days to 2 years in RC4-6[3]

1. Mustapha et al. One-Year Results of the LIBERTY 360 Study. *J Endovasc Ther.* 2019;26(2):143-154.
2. Mustapha JA. LIBERTY 360 Trial 3-Year Update. Presented at AMP 2019.
3. Mustapha JA. Late Breaking: LIBERTY 360 Trial 2-Year Update. Presented at AMP 2018.

CSI®

PATIENT POPULATION

ENROLLMENT AND 3-YEAR FOLLOW-UP



*Due to site closure and lack of PI signature, baseline and procedure data from 15 patients were excluded. Rutherford 2, N=97; Rutherford 3, N=403; Rutherford 4, N=285; Rutherford 5, N=304. Core Lab reported lesions.
Mustapha JA. LIBERTY 360 Trial 3-Year Update. Presented at AMP 2019.

KEY LESION CHARACTERISTICS

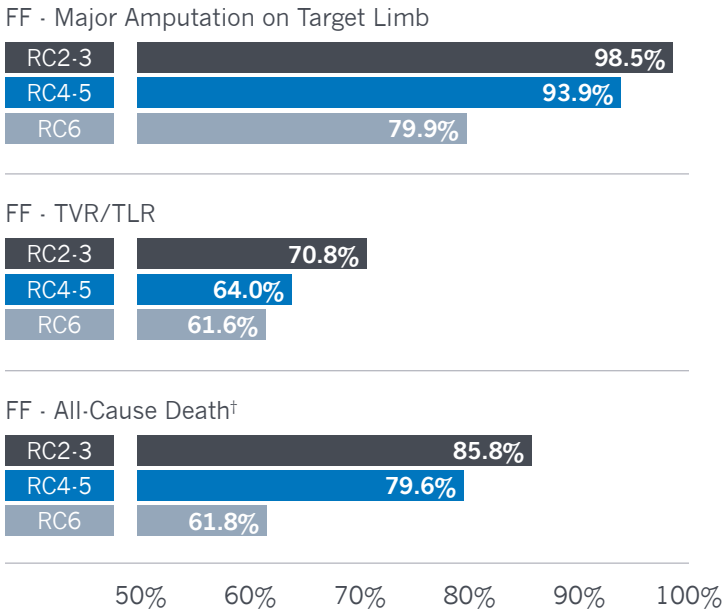
	Rutherford Category		
Patient Lesion Characteristics	**RC2-3 (N=500)**	**RC4-5 (N=589)**	**RC6 (N=100)**
Number of lesions treated	1.2 ± 0.5 N=497	1.3 ± 0.6 N=588	1.5 ± 0.7 N=99
Chronic total occlusions	181 (37.3%) N=485	307 (53.1%) N=578	50 (51.5%) N=97
Mean treated lesion length, cm	10.7 ± 9.9 (N=464)	17.0 ± 13.7 (N=563)	15.3 ± 12.2 (N=95)
Location of all lesions treated	N=497	N=587	N=98
ATK only	238 (47.9%)	130 (22.1%)	24 (24.5%)
ATK and BTK	120 (24.1%)	164 (27.9%)	28 (28.6%)
BTK only	139 (28.0%)	293 (49.9%)	46 (46.9%)
Bailout stent used	27 (5.4%) N=497	32 (5.4%) N=588	0 (0.0%) N=99

N (%) or Mean ± SD as appropriate.
Lesions with reported values may be less than total number of lesions treated in each arm.
Mustapha JA. LIBERTY 360 Trial 3-Year Update. Presented at AMP 2019.

STUDY RESULTS

TOTAL OUTCOMES THROUGH 3 YEARS BY RUTHERFORD CLASS

FF MAE: RC2-3 70.0% RC4-5 61.9% RC6 47.1%



Despite complex demographics (e.g. history of lower extremity PVI, history of (CTOs, lesion length) in this real-world study, there was high freedom from major amputation at 3 years in RC2-3, RC4-5, and RC6 and similar rates of freedom from 3-Year TVR/TLR in RC4-5 and RC6.

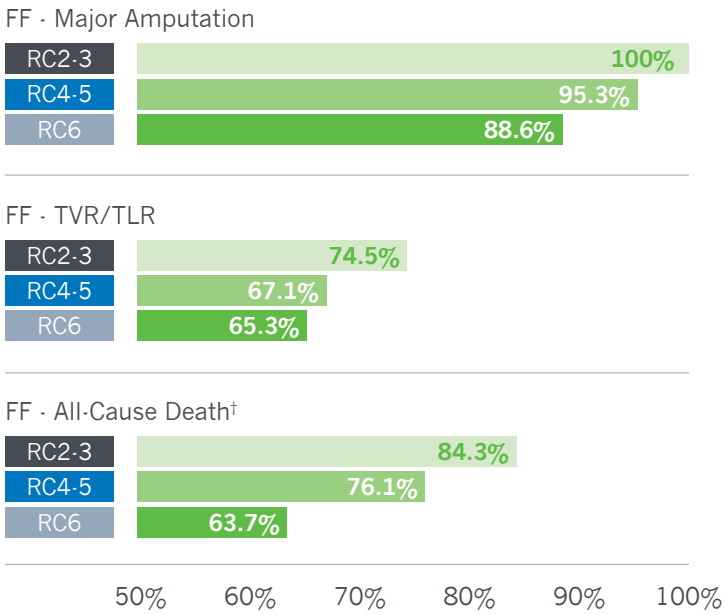
Kaplan-Meier method used to obtain estimate rates.

†All-Cause Death rate shown here is at 3 years, but the Freedom from MAE only includes death within 30-days of the procedure.

Mustapha JA. LIBERTY 360 Trial 3-Year Update. Presented at AMP 2019.

OAS SUBANALYSIS: OUTCOMES THROUGH 3 YEARS BY RUTHERFORD CLASS

FF MAE: RC2-3 73.8% RC4-5 64.2% RC6 55.8%



OAS was the most frequently used atherectomy device. High freedom from major amputation in all Rutherford classes with no additional unplanned major amputations reported after 2 years. Similar rates of freedom from TVR/TLR were seen across all Rutherford classes.

Kaplan-Meier method used to obtain estimate rates.

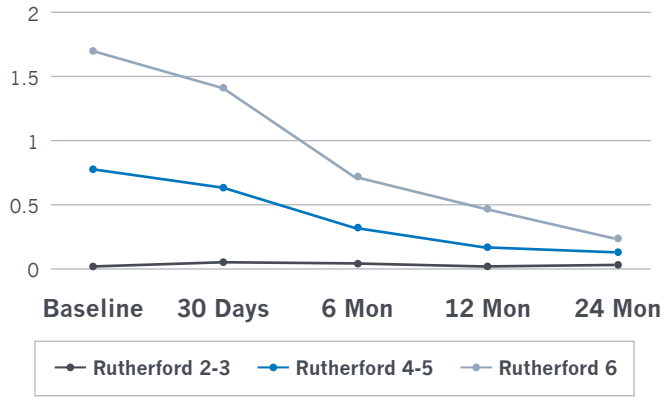
†All-Cause Death rate shown here is at 3 years, but the Freedom from MAE only includes death within 30-days of the procedure.

Mustapha JA. LIBERTY 360 Trial 3-Year Update. Presented at AMP 2019.

TARGET LIMB WOUND HEALING (2-YEAR)

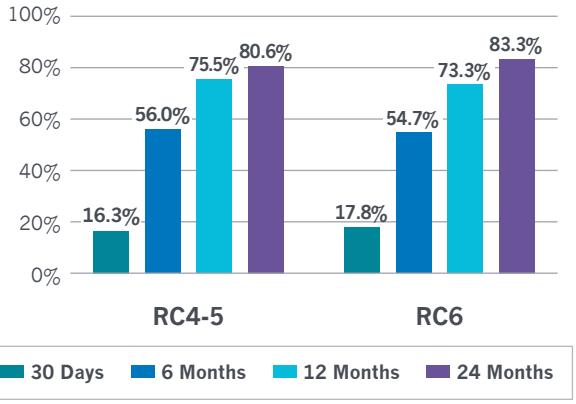
RC4-5 AND RC6 SHOW CONTINUED IMPROVEMENT IN NUMBER OF WOUNDS FROM 30 DAYS TO 2 YEARS.

Mean Number of Wounds on Target Limb



Rutherford Classification	RC2-3	RC4-5	RC6
Patients with wound data at 2 years	312	299	25
Mean ± SD	0.03 ± 0.26	0.13 ± 0.49	0.24 ± 0.83

Percentage Improvement in Mean Number of Wounds Compared to Baseline

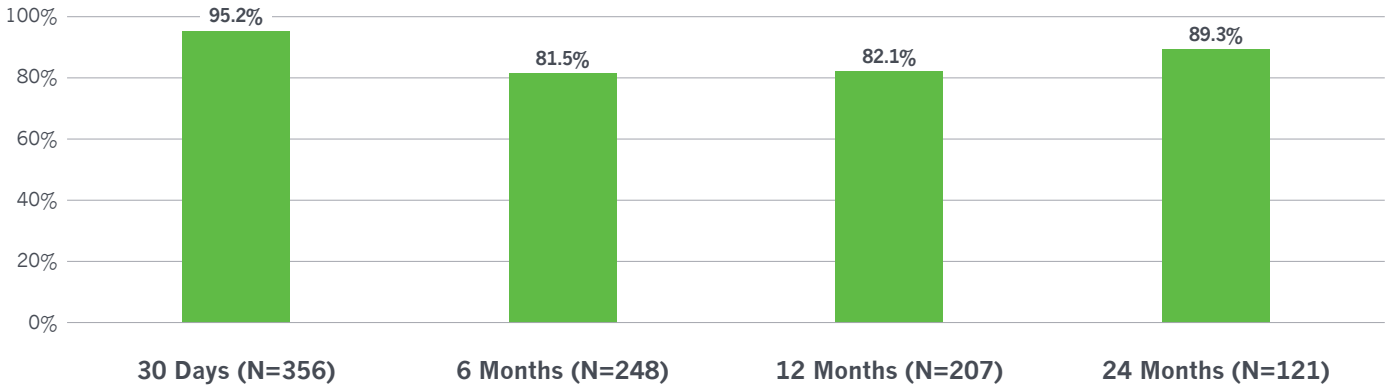


Rutherford Classification	RC2-3	RC4-5	RC6
Change from baseline to 2 years	0.02 ± 0.28	−0.53 ± 0.92	−1.2 ± 0.91
P-value*	0.318	<0.001	<0.001

*Mean number of wound differences assessed via paired t-test.
Patients with reported values may be less than total number of patients enrolled in each arm.
Mustapha JA. Late Breaking: LIBERTY 360 Trial 2-Year Update. Presented at AMP 2018.

DUPLEX ULTRASOUND (DUS) (2-YEAR)

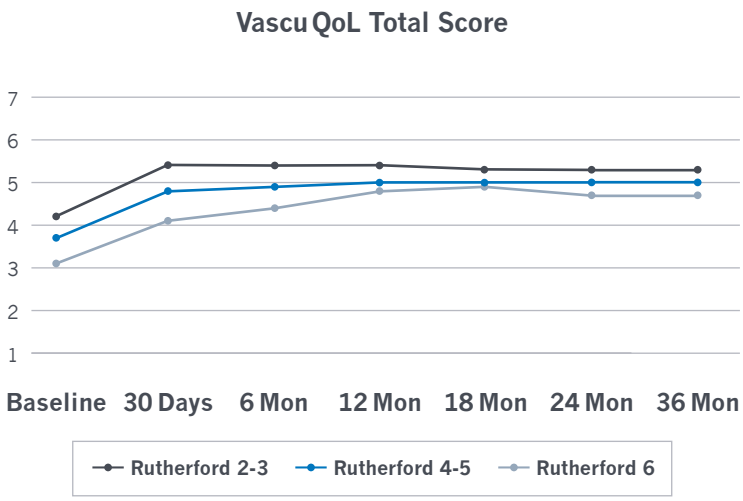
HIGH LONG-TERM PATENCY RATE IN RC2-3 PATIENTS.



DUS required only for RC2-3 patients. Patency defined as PSVR ≤ 2.4.
At baseline, previous Peripheral Vascular Intervention on target limb in 30% of RC2-3 patients.
Mustapha JA. Late Breaking: LIBERTY 360 Trial 2-Year Update. Presented at AMP 2018.

QUALITY OF LIFE: VASCU QOL

QUALITY OF LIFE IMPROVED SIGNIFICANTLY BY 30 DAYS POST-PROCEDURE AND WAS MAINTAINED OUT TO 3 YEARS IN ALL RUTHERFORD CLASSES.



Vascular Quality of Life Questionnaire; a PAD-specific health-related quality of life instrument. Higher subdomain scores indicate better rating of health.

Mustapha JA. LIBERTY 360 Trial 3-Year Update. Presented at AMP 2019.

Total Score	RC2-3	RC4-5	RC6
Change from baseline to 3 years	1.0 ± 1.3 N=274	1.1 ± 1.5 N=262	1.1 ± 1.4 N=20
P-value*	**<0.001**	**<0.001**	**0.003**

*Mean Total Score differences assessed via paired t-test.

The Diamondback 360® and Stealth 360® Peripheral Orbital Atherectomy Systems are percutaneous orbital atherectomy systems indicated for use as therapy in patients with occlusive atherosclerotic disease in peripheral arteries and stenotic material from artificial arteriovenous dialysis fistulae. **Important Safety Information:** The Systems are contraindicated for use in coronary arteries, bypass grafts, stents, or where thrombus or dissections are present. Although the incidence of adverse events is rare, potential events that can occur with atherectomy include: pain, hypotension, CVA/TIA, death, dissection, perforation, distal embolization, thrombus formation, hematuria, abrupt or acute vessel closure, or arterial spasm.

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

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