12-month results overview

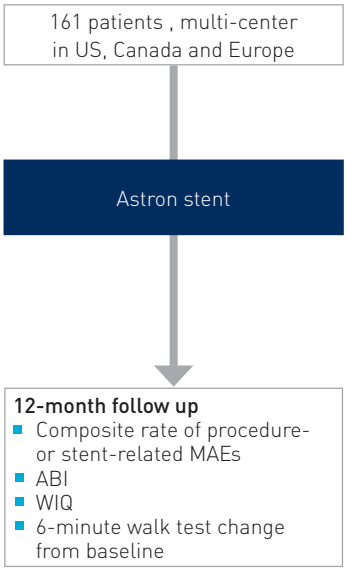
BIOFLEX-I

Conclusions

- At 12 months results show Primary Patency (PP) rates of 89.8 % (115/128[1] patients) and freedom from Target Lesion Revascularization (TLR) rates of 98.6 % (144/146[2] patients)
- At 12 months Major Adverse Event (MAE) rate is 2.1 %, showing safety of the treatment and meeting the study primary endpoint
- Improvement in Ankle Brachial Index (ABI) shows clinical benefit with mean change from baseline to 12 months of 0.23 ± 0.19
- The Astron stent is a viable option for treatment of patients with iliac disease

Study design

Prospective, international, multi-center, investigational device exemption trial evaluating BIOTRONIK Astron nitinol self-expanding stent for Iliac arteries, conducted at 30 centers in the US, Canada and Europe.
Number of patients enrolled = 161



Principal Investigators

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Endpoints

Primary endpoint

- Composite rate of procedure- or stent-related MAEs at 12 months post-index procedure (30-day mortality, 12-month clinically-driven TLR and index-limb amputation)

Secondary clinical endpoints (selected)

- Components of MAE
- Primary patency at 12 months assessed by DUS (PSVR > 2.4)[3]
- Acute procedural success
- ABI, WIQ and 6-minute walk test change from baseline to 12 months

[1] ITT (Intention To Treat population) with DUS (Duplex Ultra Sound)
[2] ITT completed subjects
[3] Loss of patency defined as or based on a clinically indicated TLR with angiographic evidence of > 50 % stenosis

BIOLFEX-I 12m, Burket M. presented at CRT conference 2015

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Patient demographics

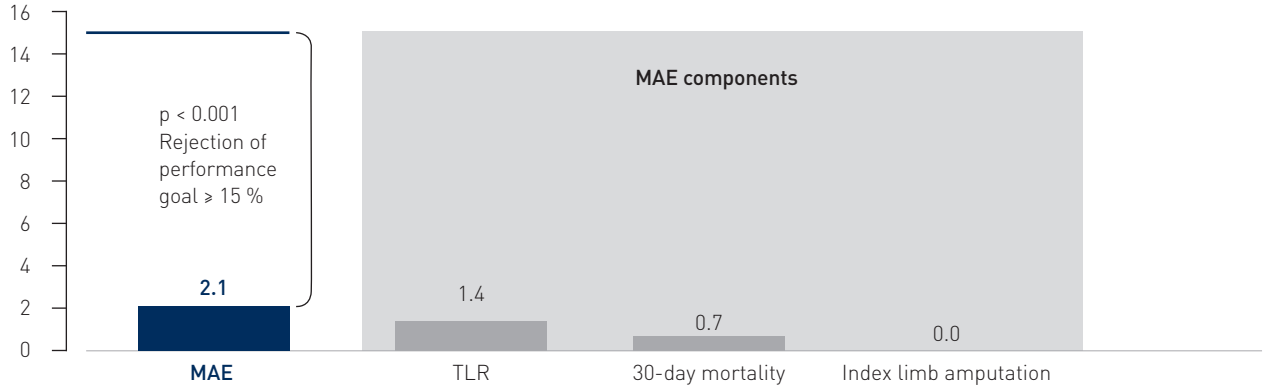
	Evaluable n = 161
Diabetes	32 (19.9 %)
Hypertension	117 (72.7 %)
Hyperlipidemia	125 (77.6 %)
Smoking status – Current	78 (48.4 %)

Lesion characteristics

		Evaluable n = 161
Lesion type (n [%])	Occlusion	13 (8.1 %)
Lesion location (n [%])	Common iliac	107 (66.5 %)
Lesion calcification (n [%])	Moderate	68 (42.2 %)
	Severe	46 (28.6 %)
Lesion length (mm)	Mean ± SD	35.9 ± 21.3
	Range	8.6 - 105.1
RVD (mm)	Mean ± SD	7.6 ± 1.5

Primary endpoint results

MAE rate composite and components at 12 months
n = 146



MAE rate of procedure or stent-related MAE at 12 months	2.1 % (3/146) 95 % CI [0.4 %, 5.9 %]

The MAE rate including imputed values accounting for missing rates, data was 3.1 % (5/161, 95 % CI [1.0 %, 7.1 %]).

12-month results (n)	Rate (95 % CI)	Treatment effect p-value[4]
MAE (3/146)	2.1 % (0.4 %, 5.9 %)	
30-day mortality (1/146)	0.7 % (0.0 %, 3.8 %)	
Index limb amputation (0/146)	0.0 % (0.0 %, 2.5 %)	
TLR (2/146)	1.4 % (0.2 %, 4.5 %)	
Primary Patency (115/128)	89.8 % (83.3 %, 94.5 %)	
Mean change in ABI (n = 141)[6]	0.23 ± 0.19	p < 0.001[4]
Mean change in 6-minute walk test (n = 131)[6]	157.5 ± 420.6 ft.	p < 0.001[5]
Subjects improved over baseline (89/131)	67.9 %	

[4] Two-sided test for difference equal to zero
[5] Test for difference equal to zero (Student's t-test, two-sided and Wilcoxon Test, two-sided)
[6] Subjects with paired data (baseline and 12 months)

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