BIOMATRIX™ alpha
DRUG ELUTING CORONARY STENT SYSTEM

BA9™ BIOLIMUS A9™ WITH BIODEGRADABLE PLA

Clinical Outcomes with Cobalt Chromium Biolimus A9™ DES compared with Stainless Steel Biolimus A9™ DES in All-Comers Patients after 2 years

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- (on behalf of the Biomatrix Alpha Registry Investigators)

BIOSENSORS INTERNATIONAL™

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Disclosure Statement of Financial Interest

Speaker’s name: Ian Menown

✓ I have the following potential conflicts of interest to declare

Receipt of honoraria or consultation fees Biosensors Europe SA

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Why this study?

- Thin strut BMS showed improved clinical outcomes compared to thicker strut BMS in the ISAR-STEREO trials.

- However, reducing strut thickness may effect drug delivery and there is limited data comparing otherwise similar thin and thick strut DES.

- We compared the clinical outcomes of patients treated with the thin strut (84-88µm) cobalt chromium biodegradable polymer Biolimus A9™ eluting stent (CoCr-BP-BES) to patients treated with the stainless-steel biodegradable polymer Biolimus A9™ eluting stent (SS-BP-BES).

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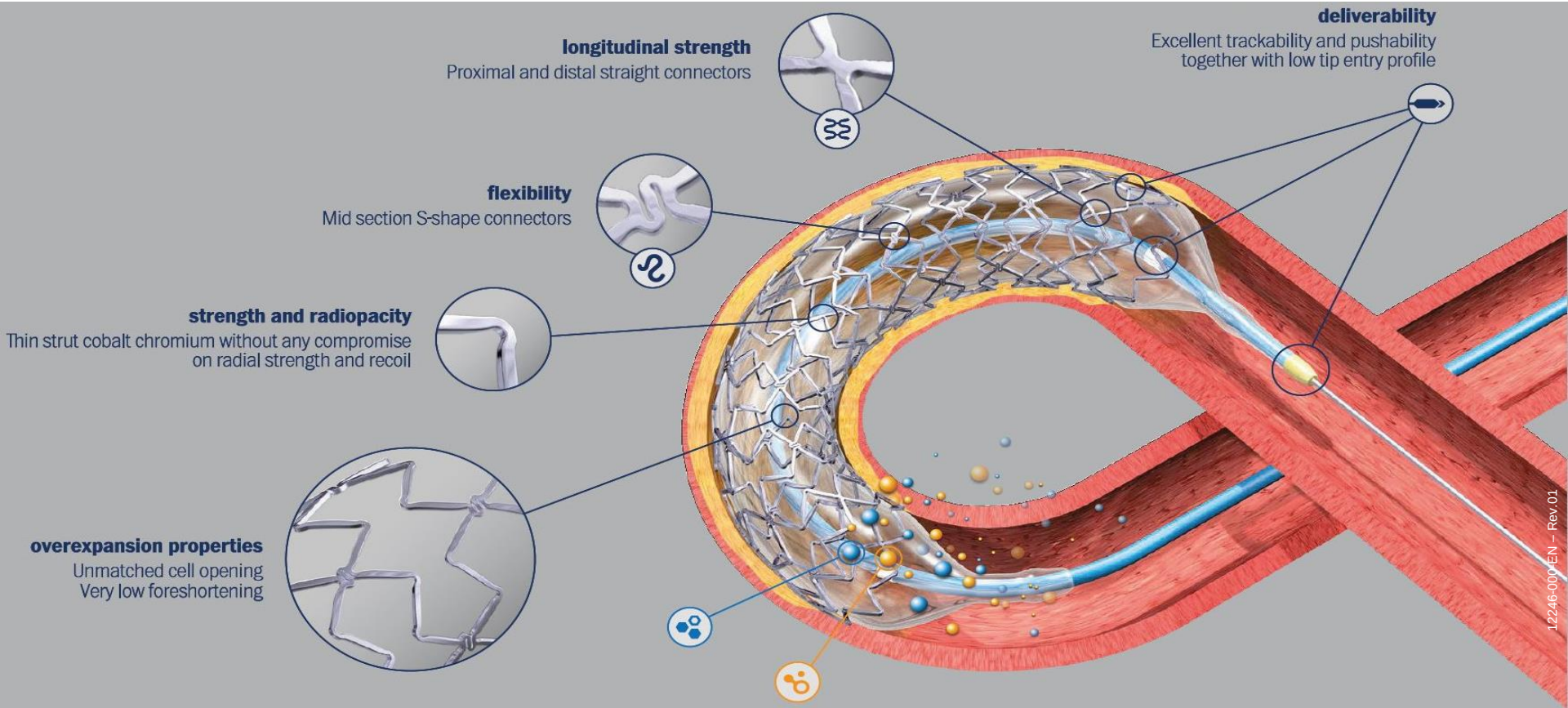
Biomatrix™ Alpha (CoCr-BP-BES)



How was the study executed?

- 400 patients from 12 centres receiving at least one BioMatrix Alpha were prospectively enrolled into the Biomatrix™ Alpha registry.

- A pre-specified comparison was conducted to 857 patients who received at least one BioMatrix™ stent in the LEADERS study.

- The primary endpoint was MACE at 9 months (composite of cardiac death, MI or clinically driven target vessel revascularization).

- Now we present the 2 year follow-up data.

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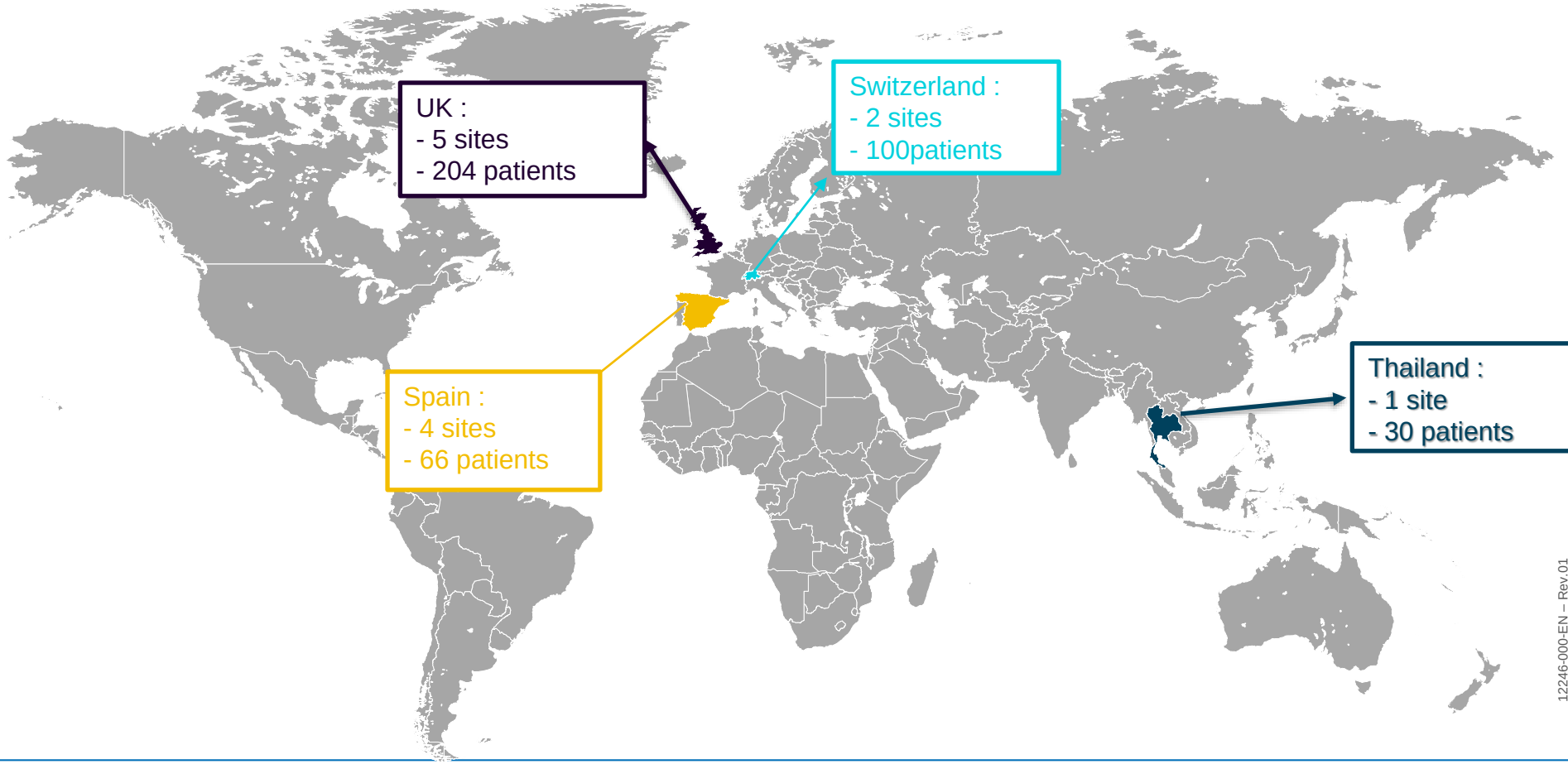
Biomatrix Alpha Registry Enrollment by country and sites



Biomatrix Alpha Registry vs LEADERS

Baseline Demographics

	BioMatrix™ Alpha n=400[1]	BioMatrix™ n= 857[1]	P value
Mean age (years)	64.7±11	64.6±10.8	0.892
Female gender (%)	21.5	25	0.178
STEMI or NSTEMI (%)	41.1	32.7	0.004
Unstable angina (%)	14.0	22.2	<0.001
Prior MI (%)	18.8	32.2	<0.0001
Previous PCI or CABG (%)	24.6	40.9	<0.0001
Previous stroke (%)	6.3	4.7	0.292
Current smoker (%)	21.0	24.1	0.229
Hypertension (%)	57.3	73.6	<0.0001
Dyslipidemia (%)	56.7	65.4	0.003
Diabetes (%)	19.3	26.1	0.009
Renal insufficiency (%)	11.5	5.4	<0.0001
Staged procedure (%)	5.5	4.4	0.476

Biomatrix Alpha Registry vs LEADERS
Procedural Characteristics

		BioMatrix™ Alpha n=400[1]	BioMatrix n=857[1]	p value
Target lesion coronary artery (%)	LAD	47.4	37.2	<0.0001
	LCX	20.1	28.0	<0.001
	LM	2.3	2.6	0.399
	RCA	26.9	30.7	0.112
De novo lesions (%)		95.9	94.0	0.123
Bifurcation lesions (%)		25.8	22.4	0.132
Number of stents per lesion		1.34±0.70	1.20±0.48	<0.0001
Severe calcification (%)		16.2	13.1	0.09
Lesion length (mm)		21.7±12.8	15.2±11.7	<0.0001
Reference vessel diameter (mm)		3.0±0.5	2.6±0.61	<0.0001

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Biomatrix Alpha Registry vs LEADERS
Propensity Adjustment

- Some differences in baseline characteristics were present between the populations.
- A propensity adjustment method (inverse probability of treatment weight) utilising 15 variables was thus used to adjust for these differences.

	Weighted p values (after IPTW adjustment) CoCr-BP-BES vs. SS-BP-BES
Mean age (years)	0.689
Female gender (%)	0.523
BMI	0.426
Family History	0.707
Current smoker (%)	0.541
Hypertension (%)	0.505
Dyslipidemia (%)	0.585
Diabetes (%)	0.614
Renal insufficiency (%)	0.934
Previous Stroke	0.971
Prior MI (%)	0.953
Previous PCI or CABG	0.508
STEMI (%)	0.894
Staged procedure	0.900
Multilesion procedure (%)	0.881

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Biomatrix Alpha Registry Primary end-point: MACE at 9 months

	BioMatrix™ Alpha n=400[1]	95% CI
MACE (Cardiac death or MI or cd-TVR)	15 (3.94%)*	[2.39-6.47]
Cardiac death	3 (0.76%)	[0.25-2.33]
Myocardial Infarction	4 (1.11%)	[0.41-2.95]
Clinically-driven target vessel revascularization (cd-TVR)	10 (2.6%)	[1.41-4.79]

***: p < 0.001 for non-inferiority vs BioMatrix™ (objective performance criteria)**

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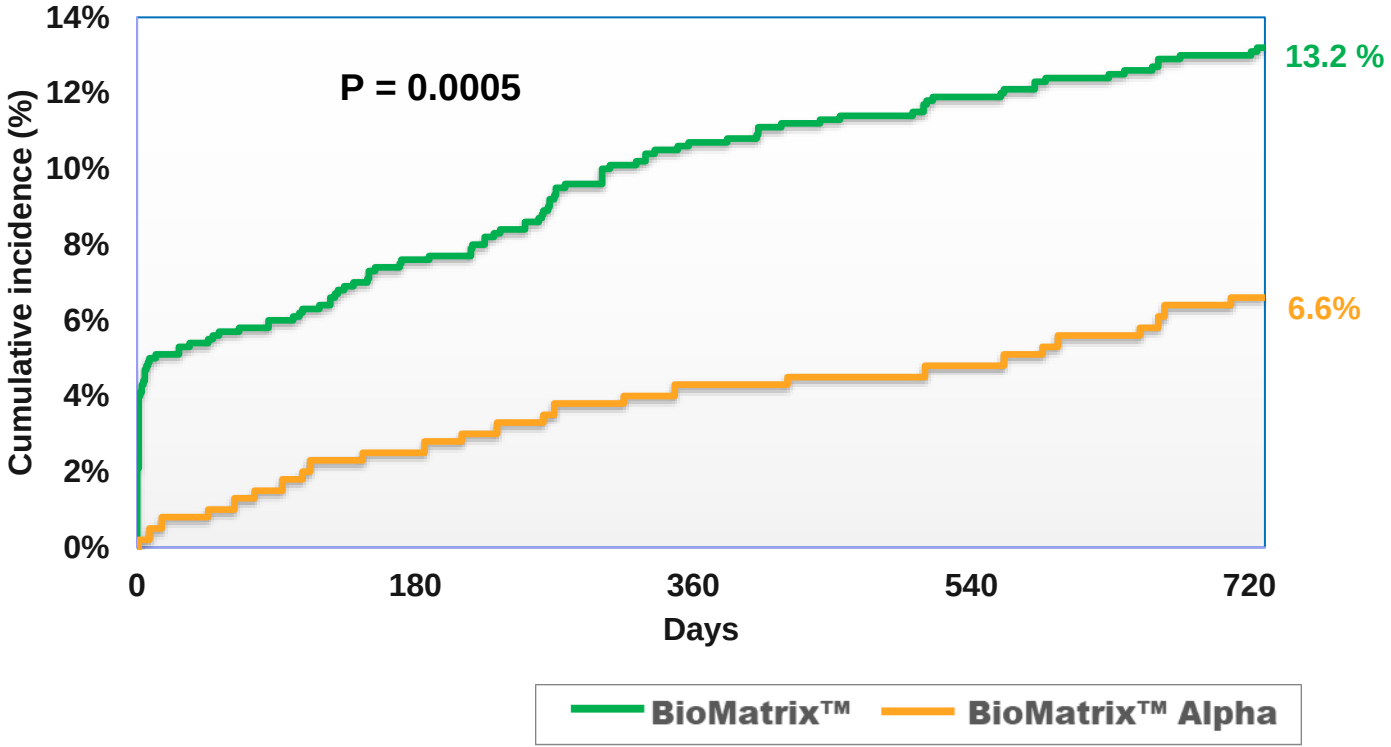
Biomatrix Alpha Registry[1] vs LEADERS[2]:
Unadjusted MACE at 2 years



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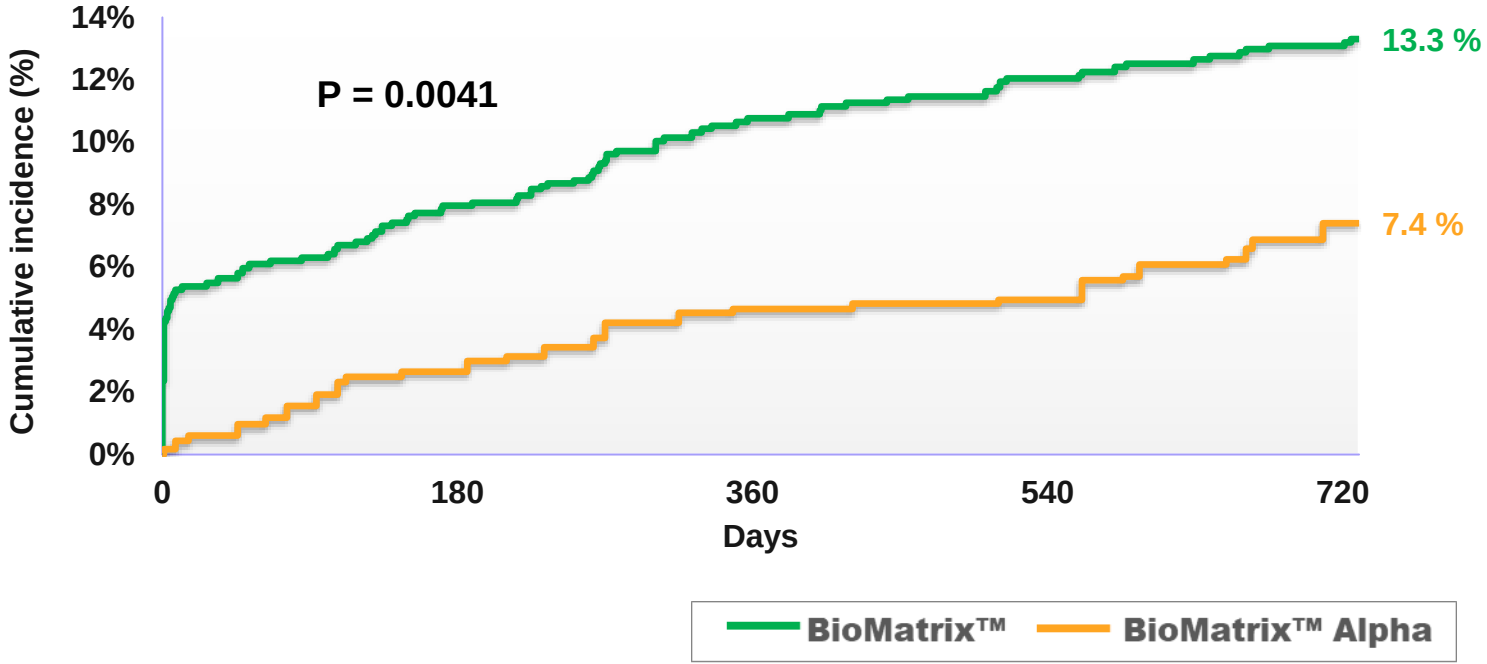
Biomatrix Alpha Registry vs LEADERS:
Unadjusted comparison

	BioMatrix™ Alpha (n=400)[1]	BioMatrix™ (n=857)[1]	Hazard ratio	P
MACE	26 (6.65%)	112 (13.23%)	0.48[0.31-0.73]	0.0005
- Cardiac death	4 (1.01%)	27 (3.21%)	0.31 [0.11-0.89]	0.022
- Myocardial infarction	12 (3.13%)	55 (6.48%)	0.46 [0.24-0.85]	0.012
- cd-TVR	16 (4.09%)	65 (7.8%)	0.51 [0.3-0.89]	0.0152
All death	15 (3.82%)	40 (4.72%)	0.79 [0.44-1.44]	0.449
Target vessel MI	5 (1.29%)	27 (3.18%)	0.39 [0.15-1.03]	0.048
Definite or probable ST	3 (0.81%)	26 (3.07%)	0.25 [0.08-0.82]	0.013
Any revascularization	29 (7.46%)	143 (17.14%)	0.40 [0.27-0.60]	<0.0001
TVF (cardiac death or TV-MI or cd-TVR)	20 (5.09%)	96 (11.36%)	0.43 [0.27-0.7]	0.0004
POCE (all death or any MI or any revasc)	43 (10.9%)	192 (22.58%)	0.44 [0.32-0.61]	<0.0001

Biomatrix Alpha Registry[1] vs LEADERS[2]:
Propensity adjusted MACE at 2 years



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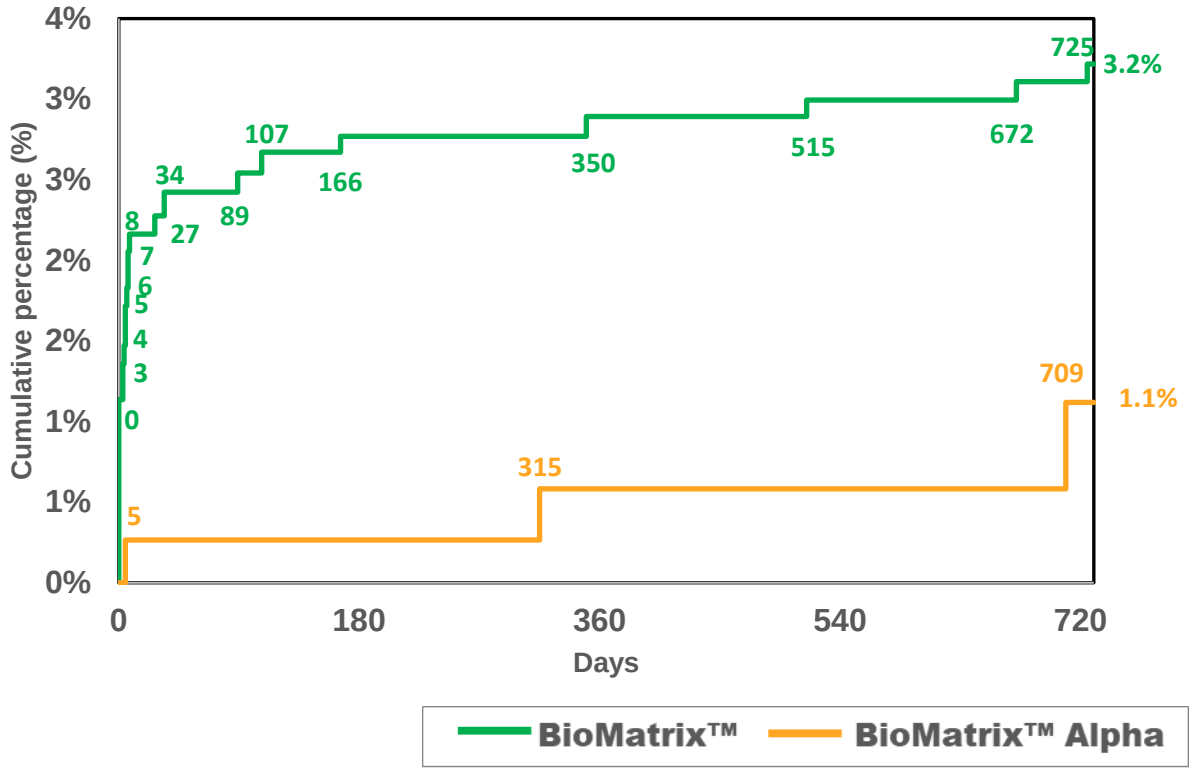
Biomatrix Alpha Registry vs LEADERS:
Propensity adjusted comparison

	BioMatrix™ Alpha[1]	BioMatrix™[1]	Hazard ratio	P
MACE	7.41%	13.3%	0.53 [0.35-0.79]	0.0041
- Cardiac death	1.29%	3.26%	0.39 [0.15-1.00]	0.064
- Myocardial infarction	2.82%	6.62%	0.4 [0.21-0.76]	0.010
- cd-TVR	4.73%	7.64%	0.61 [0.36-1.02]	0.084
All death	4.12%	4.74%	0.86 [0.49-1.52]	0.638
Target vessel MI	0.9%	3.22%	0.27 [0.09-0.82]	0.029
Definite or probable ST	1.12%	3.22%	0.32 [0.11-0.9]	0.034
Any revascularization	8.36%	16.63%	0.47 [0.32-0.68]	0.0003
TVF (cardiac death or TV-MI or cd-TVR)	**5.99%**	**11.21%**	**0.52 [0.33-0.81]**	**0.008**
POCE (all death or any MI or any revasc)	11.84%	22.25%	0.49 [0.35-0.67]	<0.0001

Biomatrix Alpha Registry[1] vs LEADERS[2]:
Definite or Probable Stent Thrombosis



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Biomatrix Alpha Registry vs LEADERS:
Type 4a MI

- Although the Biomatrix Alpha Registry protocol was designed to emulate the LEADERS protocol, the updated Third Universal Definition of Myocardial Infarction (2012) was used only in the registry.

- Recognizing that the different definitions might introduce a potential discrepancy in MI reporting, particularly for periprocedural (Type 4a) MI, we conducted a landmark analysis censoring clinical events contributing to the primary end-point that occurred up to and including day 3.

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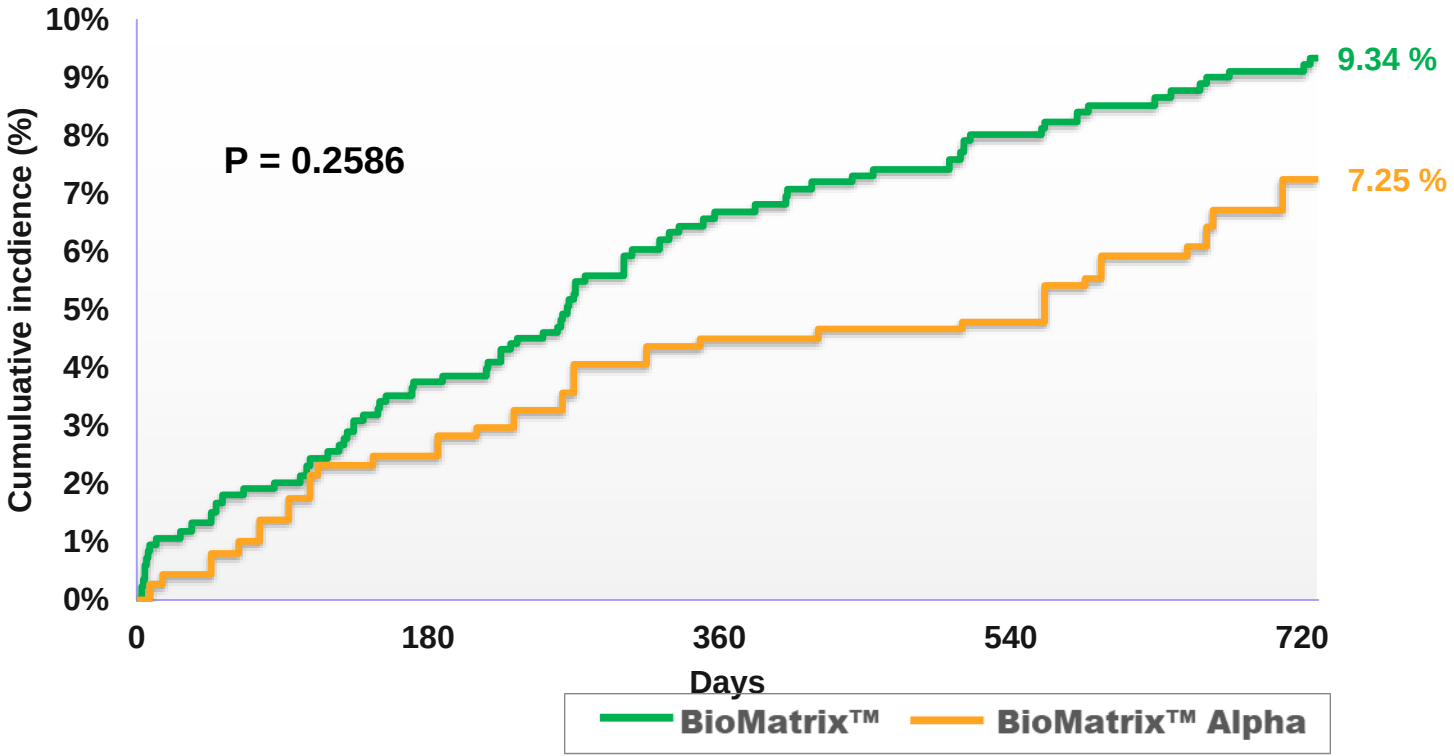
Biomatrix Alpha Registry[1] vs LEADERS[2]:

Propensity adjusted MACE: landmark analysis @ 3 days



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Biomatrix Alpha Registry vs LEADERS:

PS adjusted comparison – landmark analysis @ 3 days

	BioMatrix™ Alpha[1]	BioMatrix™[1]	Hazard ratio	P
MACE	7.25%	9.34%	0.76 [0.5-1.17]	0.259
- Cardiac death	1.29%	3.26%	0.39 [0.15-1.00]	0.064
- Myocardial infarction	2.82%	2.36%	1.17 [0.56-2.47]	0.721
- cd-TVR	4.57%	6.39%	0.65 [0.38-1.10]	0.152
All death	4.12%	4.74%	0.86 [0.49-1.52]	0.638
Target vessel MI	0.9%	0.91%	1.01 [0.28-3.59]	0.991
Definite or probable ST	1.12%	2.11%	0.5 [0.17-1.45]	0.238
Any revascularization	8.2%	15.47%	0.5 [0.34-0.73]	0.001
TVF (cardiac death or TV-MI or cd-TVR)	5.83%	9.08%	0.63 [0.4-1.00]	0.078
POCE (all death or all MI or any revasc)	11.69%	18.39%	0.6 [0.43-0.83]	0.006

Conclusions

After 2 years of follow-up, a propensity adjusted comparison of all-comers patients from the Biomatrix Alpha Registry and LEADERS study showed that the thin strut (84-88µm) cobalt chromium biodegradable polymer Biolimus A9™ eluting stent (BioMatrix™ Alpha) had improved outcomes compared to the thick strut (120µm) stainless steel biodegradable polymer Biolimus A9™ eluting stent (Biomatrix™).

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References & Disclaimer

1. I Menown Presentation TCT CONNECT October 2020

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