THE FREEWAY™ STENT STUDY

FREEWAY™ DRUG-ELUTING BALLOON FOR POST STENT DILATATION

- Prevention of restenosis by FREEWAY™ drug-eluting balloon dilatation after stenting
- International, multicenter, randomized study in more than 200 patients
- Proven safety & efficacy[1]
- Independent, blinded corelab

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Baseline Demographics (n=204)

Nitinol stent + FREEWAY™ (DEB) vs. Nitinol stent + Standard balloon (PTA)

- Gender: male (79% vs. 76.8%; ns)
- Age (64.7 ± 9.4 vs. 64.3 ± 9.8; ns)
- Diabetes mellitus (26.7% vs. 26.3%; ns)
- Hypertension (75.2% vs. 73.7%; ns)
- Hyperlipidemia (60.0% vs. 57.6%; ns)
- Smoking (88.6% vs. 81.8%; ns)
- History of PAD (37.1% vs. 44.4%; ns)
- History of CAD (24.8% vs. 23.2%; ns)

Baseline Lesion Characteristics*

		FREEWAY™ DEB + Stent n=105	PTA + Stent n=99	P-value (ns >0.05)
Lesion location	SFA proximal	6.7 %	7.1 %	ns
	SFA mid	48.6 %	43.4 %	ns
	SFA distal	43.8 %	50.5 %	ns
	PI	1.9 %	0.0 %	ns
Lesion length		77 ± 42 mm	83 ± 41 mm	ns
Diameter stenosis		91.7 %	90.9 %	ns
Total occlusion		63.8 %	63.6 %	ns
Ref. vessel diameter		4.7 ± 0.8 mm	4.6 ± 0.9 mm	ns
Infrapopliteal patent vessels		2.26± 0.85	2.06 ±0.85	ns

* Determined by an independent, blinded corelab (Bad Krozingen)

Baseline Procedural Data

		FREEWAY™ DEB + Stent n=105	PTA + Stent n=99	P-value (ns >0.05)
Predilatation		73.3 %	69.7 %	ns
Stent	Length	97.9 ± 37.1 mm	98.9 ± 36.0 mm	ns
	Diameter	6.2 ± 0.7 mm	6.3 ± 0.6 mm	ns
Postdilatation study balloon	Length	86.9 ± 26.7 mm	80.3 ± 26.9 mm	ns
	Diameter	5.4 ± 0.6 mm	5.4 ± 0.6 mm	ns
	Inflation pressure	9.1 ± 2.0 atm	8.9 ± 1.5 atm	ns
	2nd study balloon used	54.3 %	58.6 %	ns

Ankle-brachial-index (ABI) – Baseline and 6 and 12 Months Follow Up

ABI	FREEWAY™ DEB + Stent			PTA + Stent		
	n=101 Baseline	n=94 6 Months	n=85 12 Months	n=97 Baseline	n=85 6 Months	n=76 12 Months
>1.2	4.0%	5.3%	11.8%	2.1%	8.2%	6.6%
1.0 – 1.2	1.0%	55.3%	48.2%	2.1%	35.3%	32.9%
0.9 – 1.0	5.0%	21.3%	16.5%	1.0%	20.0%	26.3%
0.8 – 0.9	9.9%	12.8%	9.4%	5.2%	23.5%	6.6%
0.5 – 0.8	58.4%	5.3%	12.9%	69.1%	11.8%	25.0%
<0.5	21.8%	0.0%	1.2%	20.6%	2.4%	2.6%

Principal Investigator

Prof. Dr. Josef Tacke (Passau, Germany)

Patency, TLR and Clinical Status – 6 and 12 Months Follow Up

Primary Patency Rate*	FREEWAY™ DEB + Stent % (n)**	PTA + Stent % (n)**	p-value (ns > 0.05)
6 Months	90.3 (93)	69.8 (86)	0.001
12 Months	77.4 (84)	61.0 (77)	0.027

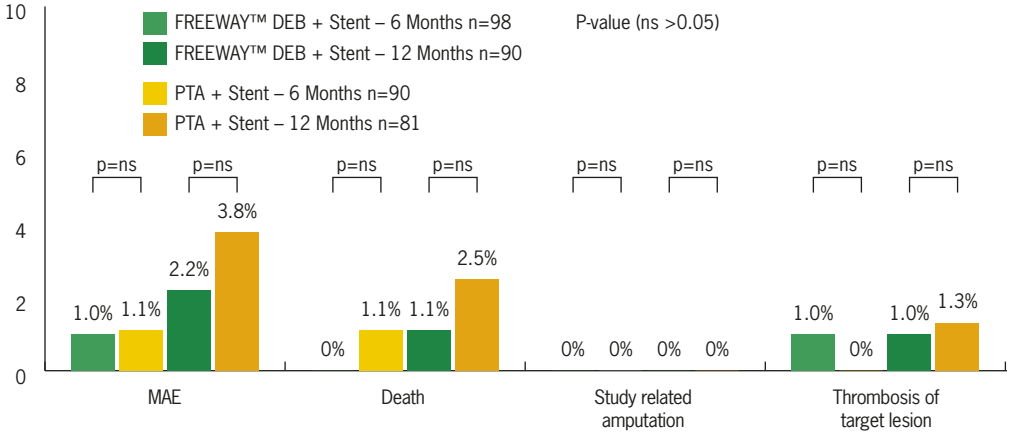
* Determined by an independent, blinded corelab (Bad Krozingen)

Clinical driven target lesion revascularization (TLR)	FREEWAY™ DEB + Stent % (n)**	PTA + Stent % (n)**	p-value (ns > 0.05)
6 Months	4.1 (98)	9.0 (89)	0.234
12 Months	7.9 (89)	17.7 (79)	0.0637

Shift in Rutherford from baseline ≥ 1	FREEWAY™ DEB + Stent % (n)**	PTA + Stent % (n)**	p-value (ns > 0.05)
6 Months	94.9 (98)	84.3 (89)	0.027
12 Months	95.5 (88)	79.9 (79)	0.003

** n = number of evaluated patients

MAE – 6 and 12 Months Follow Up



Conclusion

- **Majority of patients presented at baseline with total occluded lesion**
- **Significant higher patency rate for the Stent + FREEWAY™ DEB arm at 6 and 12 months**
- **Highly favored TLR rate for the Stent + FREEWAY™ DEB arm at 6 and 12 months**
- **Significant better improvement of ≥1 of Rutherford clinical category in the Stent + FREEWAY™ DEB arm at 6 and 12 months**
- **Proven safety & efficacy[1]**

[1] Tacke J et al. „The Randomized Freeway Stent Study: Drug-Eluting Balloons Outperform Standard Balloon Angioplasty for Postdilatation of Nitinol Stents in the SFA and PI Segment." Cardiovasc Intervent Radiol 2019 Aug 20. doi: 10.1007/s00270-019-02309-3.

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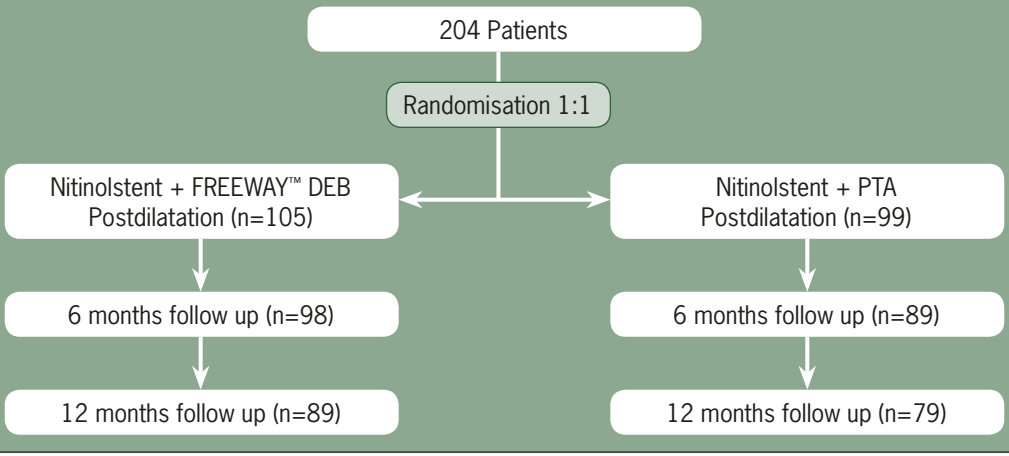
Participating Centers

- Jüdisches Krankenhaus, Berlin, D
- Gemeinschaftskrankenhaus, Bonn, D
- St. Johannes Hospital, Dortmund, D
- Diakonissenkrankenhaus, Flensburg, D
- Asklepiosklinik Hamburg-Altona, Hamburg, D
- Asklepiosklinik Hamburg-Harburg, Hamburg, D
- Klinikum Idar-Oberstein, Idar-Oberstein, D
- Klinikum Klagenfurt, Klagenfurt, A
- Elisabethinen Krankenhaus, Linz, A
- Klinikum Passau, Passau, D
- Klinikum Rosenheim, Rosenheim, D
- Klinikum Straubing, Straubing, D
- Allgemeines Krankenhaus Wien, Vienna, A

FREEWAY Stent Study – Flow Chart



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