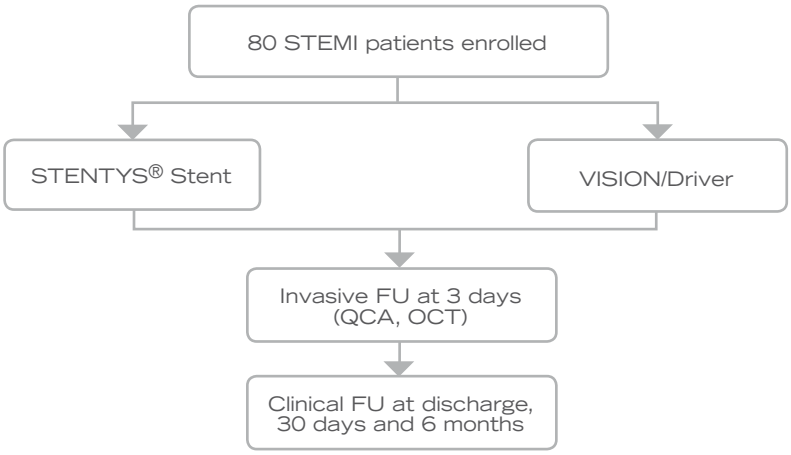
STENTYS
SIMPLE STENT SOLUTIONS

APPOSITION II TRIAL RESULTS

RAndomized ComParison between the STENTYS Self-ExPanding COronary Stent and a Balloon-Expandable Stent In AcuTe MyocardIal InfarctiON

DESIGN: International, prospective, randomized, two-arm, multi-centre trial



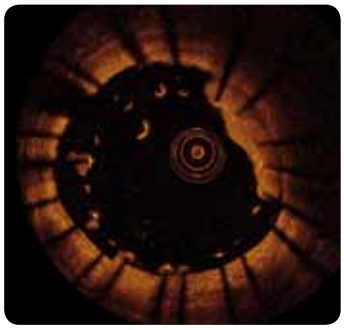
3 DAY OCT RESULTS

% MALAPPOSED STRUTS		
STENTYS® Stent	0.51%	p < 0.001
VISION / Driver Stent	5.33%	

% PATIENTS WITH STENT MALAPPOSITION*		
STENTYS® Stent	0%	p < 0.001
VISION / Driver Stent	28%	

** Stent Malapposition defined as more than 5% of struts malapposed under OCT (P. Barlis et al., Eur Heart J (2010) 31 (2) : 165-176)*

Perfect Apposition of the STENTYS® Stent



Malapposed balloon-expandable stent

CONCLUSIONS:

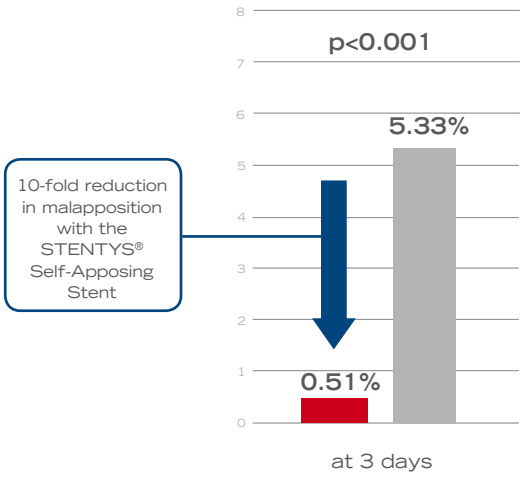
- No STENTYS patients had malapposed stents, whereas 28% of conventional stents were malapposed at 3 days.
- Safety was demonstrated with low MACE at 6 months.
- The STENTYS® Self-Apposing Stent accommodates early changes in AMI vessel anatomy that are caused by thrombus dissolution and vasodilation.

ACUTE RESULTS[1]

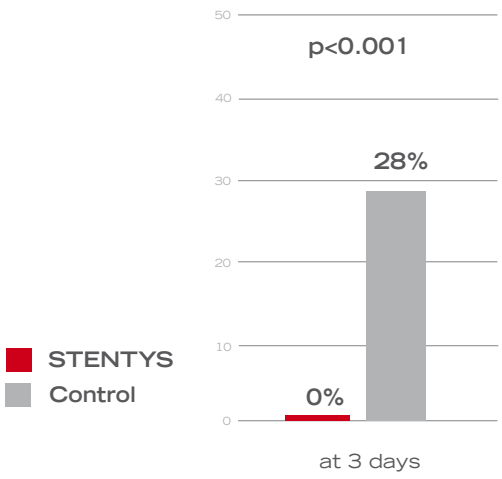
Primary Endpoint

Stent strut malapposition at 3 days measured by OCT.

Stent Strut Malapposition at 3 days



Patients with Malapposed Stents at 3 days



	STENTYS N = 43	Control N = 37	P Value
Device success	97.6%	100%	NS
Diameter largest balloon used (mm)	2.78	3.32	0.014
At least one balloon inflation	93%	100%	NS
Mean Lumen Area by OCT (mm^2)			
Post-pocedure	7.88 ± 2.32	8.92 ± 2.22	NS
3 days	8.99 ± 2.39	8.81 ± 2.18	NS
3 day in-stent lumen loss by QCA (mm)	- 0.11 ± 0.29	0.04 ± 0.21	0.01

2.3% Clinically-Driven TLR at 6 months[1]

1. Presented at TCT 2010 by S. Verheye and at PCR 2011 by R.J. van Geuns

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