

OPEN I STUDY RESULTS

OBJECTIVE: To evaluate the safety and feasibility of the STENTYS® drug-eluting and bare-metal stents in bifurcated lesions

DESIGN: Prospective, non-randomised, multi-centre feasibility study in 63 patients (33 BMS, 27 DES implanted) enrolled in 9 European centres

FOLLOW-UP: Clinical at 1 and 3 months; QCA and IVUS at 6 months

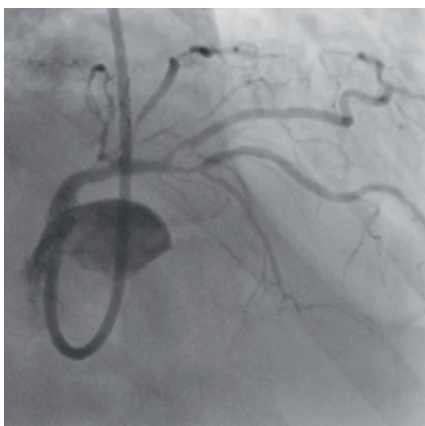
6 MONTH RESULTS

QCA

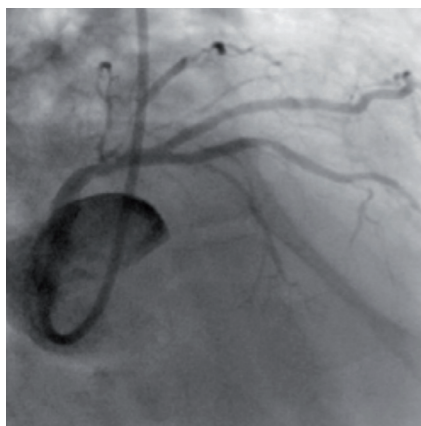
MAIN BRANCH	STENTYS DES (n=25)
In-segment restenosis	1 (4%)
In-stent late loss (mm)	
Proximal MB	0.39 ± 0.62
Distal MB	0.40 ± 0.50
SIDE BRANCH	ALL PATIENTS (n=56)
In-segment restenosis	9 (16%)
With SB balloon expandable stent (n=17)	1 (6%)
Without SB balloon expandable stent (n=39)	8 (21%)

MACE

	DES (n=27)
Cardiac Death	0
AMI	
Q-wave MI	0
Non Q-wave MI	0
Clinically driven TLR	1
TOTAL	1 (3.7%)



Baseline angiogram



Angiogram after treatment of a bifurcation lesion



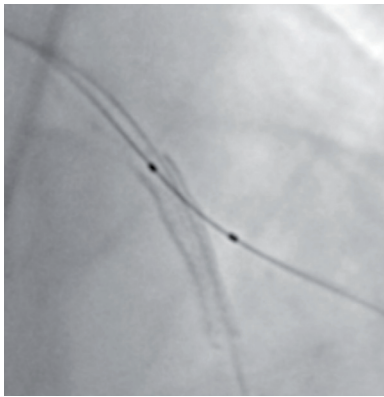
6-month follow-up angiogram

CONCLUSION:

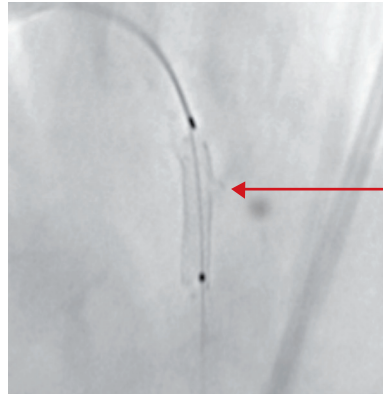
- Very good outcomes both clinically and angiographically
- Enables a provisional approach with easy side-branch access if necessary
- Excellent results when “crossing-over” to two stents
- Eliminates late acquired stent malapposition

POST PROCEDURE

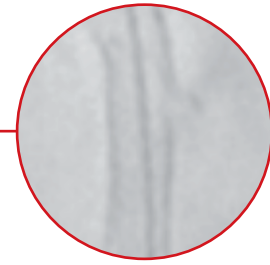
StentBoost



Balloon crossing the STENTYS® stent into the side branch

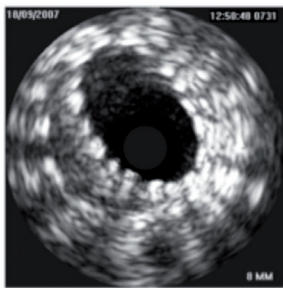


STENTYS® disconnection

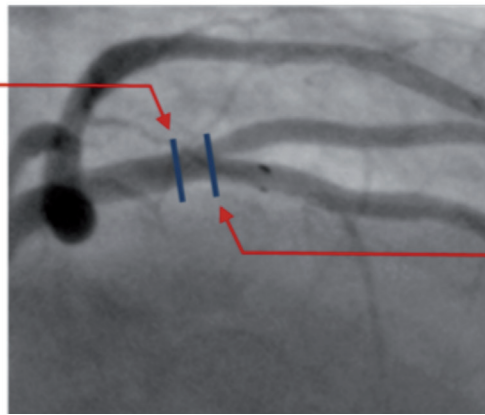


Good ostial coverage

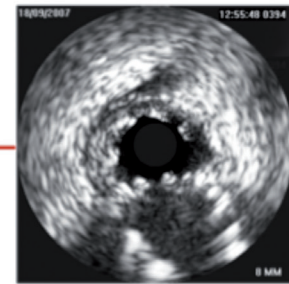
IVUS



The STENTYS® stent conforms to the non-cylindrical shape of the bifurcated vessel

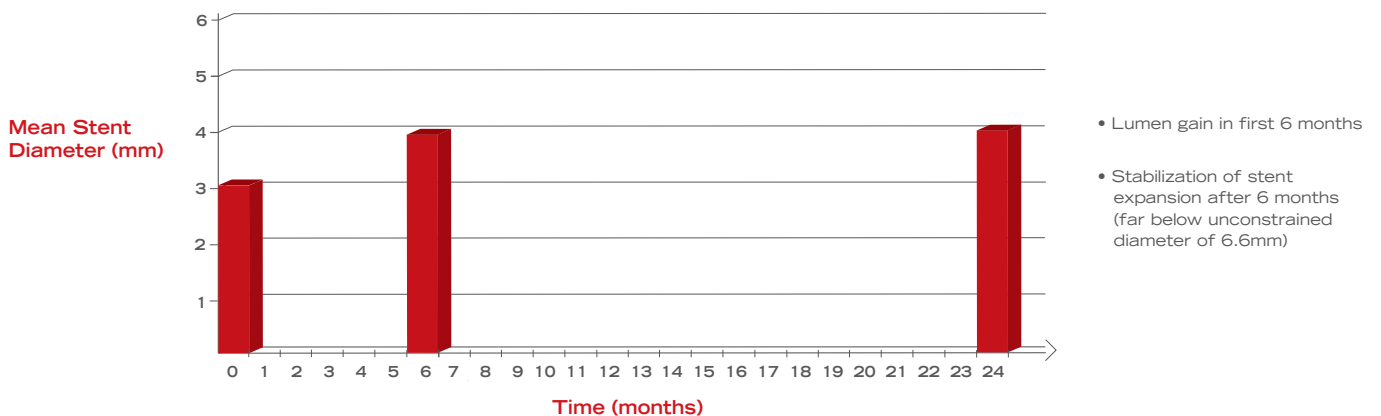


STENTYS® disconnection enables easy access to large side branches



2 YEAR IVUS FOLLOW-UP

A subset of ten patients were analysed with angiographic and IVUS follow-up at two years (6 BMS, 4 DES)



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