BETA-CATH™ SYSTEM

START

STents And Radiation Therapy

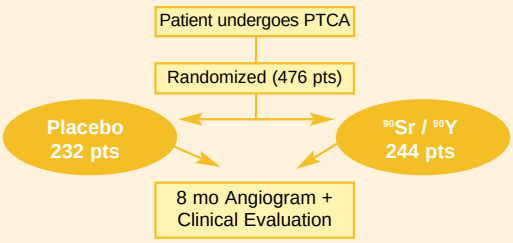
SUMMARY PRESENTATION

Novoste™

STents And Radiation Therapy (START)

Purpose: To assess the safety and effectiveness of intracoronary beta radiation using a ^{90}Sr / ^{90}Y source train following successful coronary intervention in patients with in-stent restenosis.

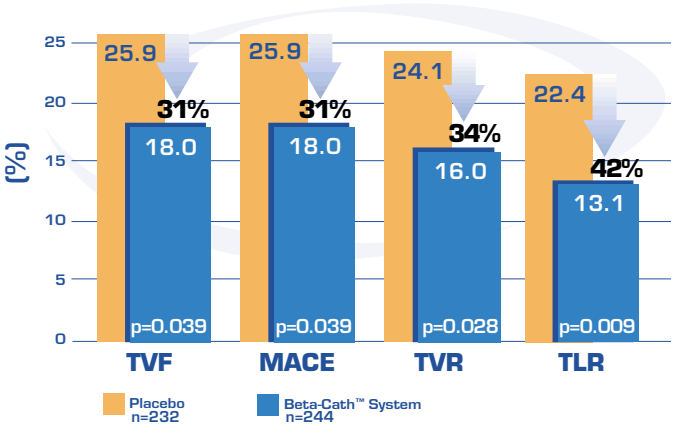
STUDY SCHEMA



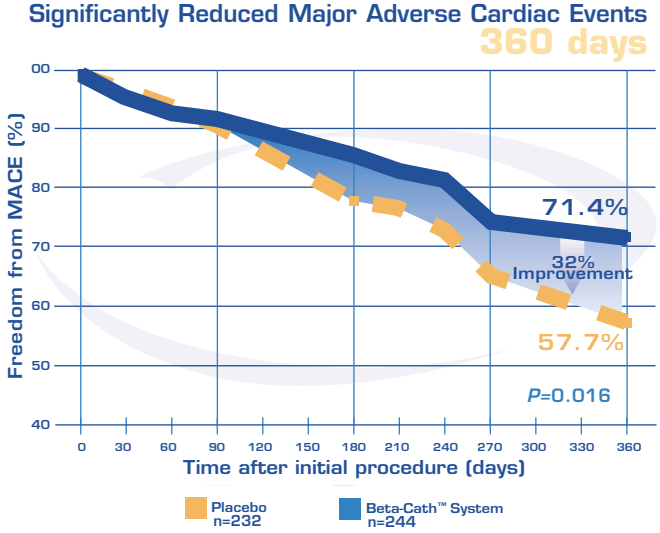
Design: Prospective, multi-center (50 sites in N. America & Europe), randomized, placebo-controlled, triple-masked clinical trial.

CLINICAL OUTCOME ANALYSIS

Mean Lesion Length 16.1 mm ± 7.4



Significantly Reduced Major Adverse Cardiac Events



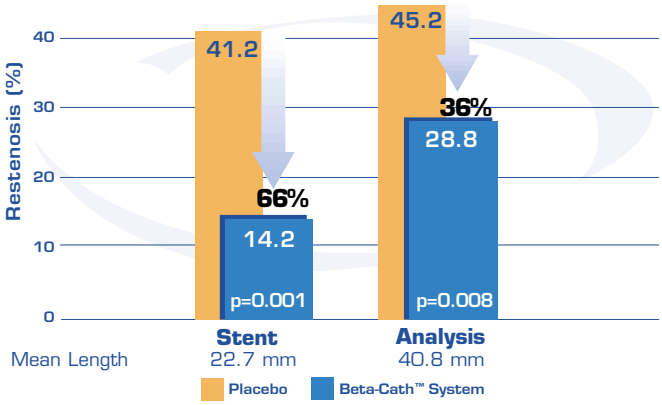
8 MONTH SAFETY RESULTS

PARAMETER	PLACEBO	Sr-90
Death	1 (0.4%)	3 (1.2%)
MI	7 (3.0%)	4 (1.6%)
Q-wave	0	0
non-Q-wave	7	4
Aneurysm[1]	0 (0%)	1 (0.5%)
Thrombosis	1 (0.4%)	0
In-hospital - 30 days	1	0
31 - 240 days	0	0[2]
Angiographic Total Occlusions	7 (3%)	8 (3.3%)
Patients with new stent[3]	4/35	3/42
Patients with no new stent[4]	3/153	5/156

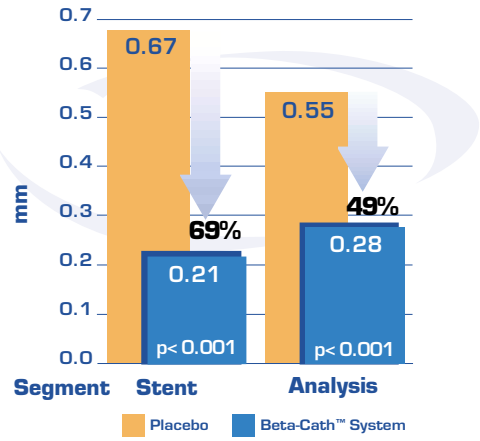
1. No new aneurysm formation: 1 patient with aneurysm present at baseline showed no significant change at follow-up
2. One patient recently adjudicated by CEC had thrombosis at day 244
3. 74% of patients received ≤ 60 days of adjunctive anti-platelet therapy
4. 88% of patients received ≤ 60 days of adjunctive anti-platelet therapy

ANGIOGRAPHIC QCA ANALYSIS

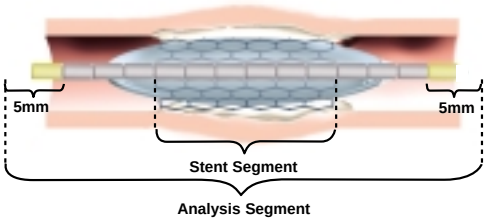
Segment Analysis



8 Month Late Loss

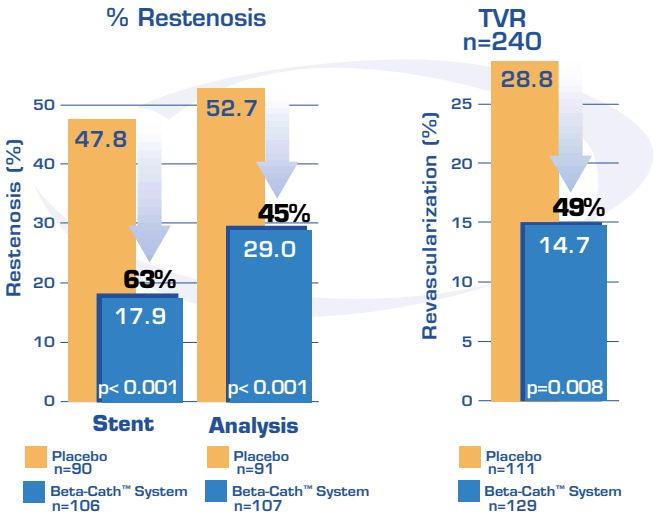


Methodology



LONG LESION SUBGROUP

Lesions ≥ 15 mm
(Mean Lesion Length: 21.8 mm ± 5.3)



Clinical Summary

Pre-specified hypotheses were achieved with statistical significance

-TVF . . . . . .reduced by 31% (p=0.039)
-MACE . . . . . .reduced by 31% (p=0.039)
-TVR . . . . . .reduced by 34% (p=0.028)
-TLR . . . . . .reduced by 42% (p=0.009)

Angiographic Summary

Pre-specified restenosis hypotheses were achieved with statistical significance

-Stent Segment . . . . . .reduced by 66% (p<0.001)
-Analysis segment . . . . . .reduced by 36% (p=0.001)

Safety Summary

Placebo vs Sr-90

No difference in Death or MI . . . . . .(8 vs 7)
No difference in Late Thrombosis . . . . . .(0 vs 1)
No difference in Total Occlusions . . . . . .(7 vs 8)
No difference in New Aneurysm Formation . . . .(0 vs 0)

Long Lesion SubGroup Summary

Sr-90 significantly reduced restenosis rate and TVR in patients presented with long lesions.

Conclusion

The Beta-Cath™ System has been shown to be safe and effective for the treatment of in-stent restenosis.

summary

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STUDY ENDPOINTS

Primary Efficacy Endpoint:

- 8 month Target Vessel Failure (TVF)

Secondary Efficacy Endpoints:

- 8 month angiographic restenosis, in-stent MLD, and late loss

Safety Endpoints:

- 8 month MACE and aneurysm formation

DOSIMETRY METHODS

- Reference vessel diameter (RVD) was determined visually after completion of coronary intervention
- Dose prescription point calculated @ 2 mm from center of source axis:

  18.4* Gy in RVD $\geq$ 2.7 - $\leq$ 3.3 mm

  23* Gy in RVD > 3.3 - $\leq$ 4.0 mm

  *NIST dose, March 2000
- ^{90}Sr / ^{90}Y has a 28.8 year half-life and a short treatment time of 3 to 5 minutes.

INCLUSION / EXCLUSION CRITERIA

Major Inclusion Criteria:

- Patients over 18 years of age
- Single lesion in single native coronary vessel (diameter 2.7 - 4.0 mm)
- In-stent restenosis > 50% (by visual estimate)
- Lesion length treatable with 20 mm balloon

Major Exclusion Criteria:

- Multivessel coronary intervention
- Unsuccessful treatment (>30% residual stenosis) of target lesion
- Recent (<72 hours) MI
- LVEF < 30%
- Unprotected left main disease
- Anticipated use of ReoPro® (Eli Lilly & Company) or placement of a second stent
- Prior chest radiotherapy

PROCEDURE DETAILS

	Placebo	Sr-90
Debulking Devices (%)		
DCA	0.9	0.0
RA	39.8	43.9
ELCA	7.4	5.7
New Stents* (%)	**19.8**	**20.9**

* "Bail-out" stent use was reserved for severe residual stenoses after radiation delivery.

DEVICE PERFORMANCE

	Patients	Percent
Total Patients Enrolled	476	100.0%
Successful Treatment	467	98.1%
Catheter not cross lesion	6	1.3%
Sources not sent	3	0.6%

BASELINE FINDINGS

	Placebo (n=232)	Sr-90 (n=244)
Clinical Characteristics		
Age (yrs)	61.1	61.5
Men (%)	63.4	68.4
Diabetes (%)	32.3	30.7
Smoking (%)	8.1	12.5
Prior MI (%)	47.8	46.7
Prior CABG (%)	23.7	21.4
Angiographic Characteristics		
Vessel Diameter, mm	2.77	2.76
MLD, mm	0.98	0.98
% Stenosis	64.2	64.2
Lesion Length, mm	16.0	16.3
% LAD	41.3	43.2

Definitions

Target Vessel Failure (TVF) = Death attributed to the target vessel, MI and TVR

MACE = Death, MI, emergent CABG and TVR

Target Vessel Revascularization (TVR) = Any clinically-driven repeat percutaneous intervention of the target vessel or bypass surgery of the target vessel

Target Vessel Revascularization (TLR) = Any clinically-driven repeat percutaneous intervention of the target lesion or bypass surgery of the target vessel

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