BETA-CATH™ SYSTEM

START 40

STents And Radiation Therapy 40

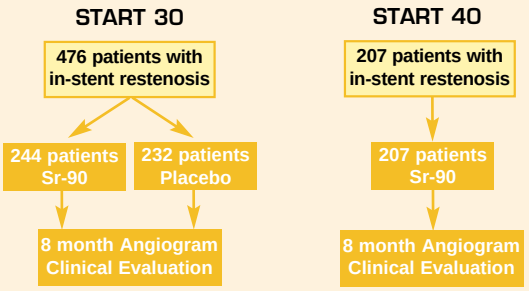
SUMMARY PRESENTATION

Novoste™

STents And Radiation Therapy 40 (START 40)

Purpose: To evaluate the safety and effectiveness of beta radiation using a $^{90}Sr/^{90}Y$ source with a wider therapeutic margin to the PTCA injury site than what was administered in the original START trial (START 30).

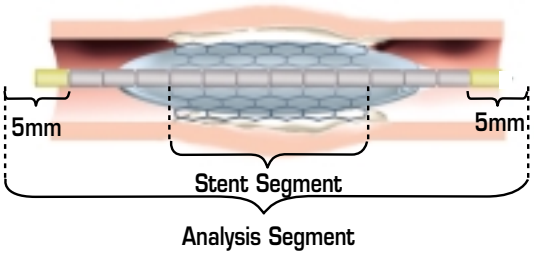
STUDY SCHEMA



Design: Prospective, multi-center (22 sites in N. America & Europe), registry clinical trial.

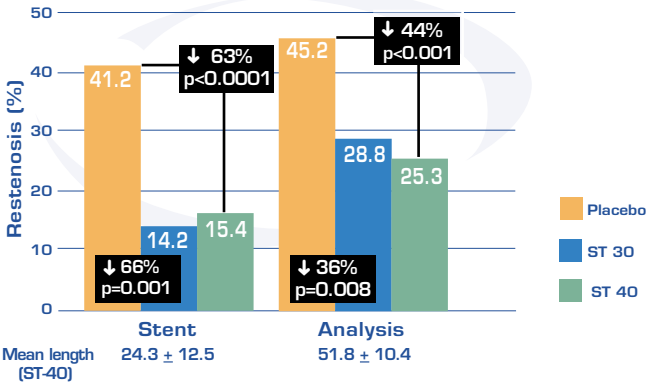
ANGIOGRAPHIC OUTCOMES

Methodology

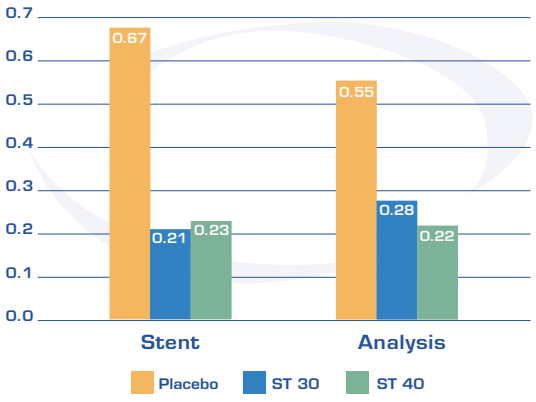


*30mm Source Train shown in illustration

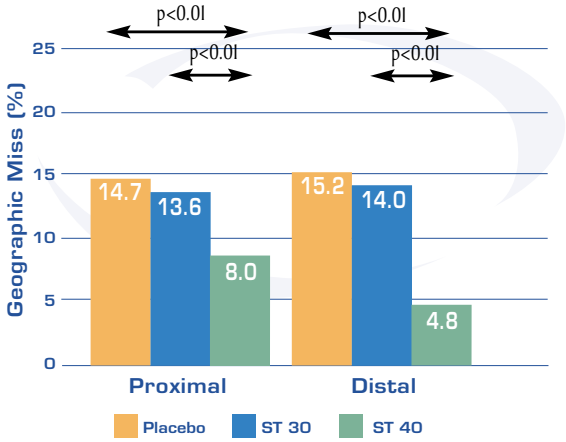
8 Month Angiographic QCA Analysis



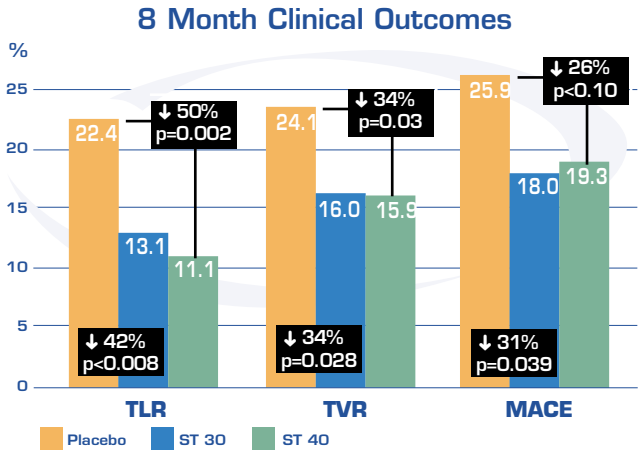
Late Loss Index



Frequency of Geographic Miss



CLINICAL OUTCOMES



8 Month Safety Results

PARAMETER	ST-30	PLACEBO	ST-40
Death	3 (1.2%)	1 (0.4%)	5 (2.4%)[1]
MI	4 (1.6%)	7 (3.0%)	9 (4.3%)
Q-wave	0	0	3
non-Q-wave	7	4	6
Aneurysm[2]	1 (0.5%)[2]	0 (0%)	1 (0.7%)[2]
Thrombosis			
In-hospital - 30 days	0 (0%)	1 (0.4%)	0 (0%)
31 - 240 days	0 (0%)[3]	0 (0%)	2 (1.0%)[4]
Angiographic Total Occlusions	8 (3.3%)	7 (3.0%)	5 (3.3%)

*p = NS for all Placebo versus ST-30 versus ST-40

1. 3 of 5 deaths were not related to the target vessel
2. No new aneurysm formation; present at baseline, without significant change at follow-up
3. One patient adjudicated by CEC had thrombosis at day 244
4. One patient had an event at day 31

Summary Comparison Start 30 versus Start 40

- Compared to the START 30 population, START 40:
  - patients were older and on an average had more unstable angina, and more prior treatments for in-stent restenosis
  - had similar RVD and lesion length
- Compared to START 30 placebo, START 40:
  - reduced restenosis in the analysis segment by 44% (vs 36% in ST 30)
  - reduced TLR by 50%, p=0.002 (vs 42% in ST 30)
  - reduced TVR by 34%, p=0.03 (vs 34% in ST 30)
  - reduced MACE by 26%, p=0.10 (vs 31% in ST 30)

Start 40 Conclusions

- Continues to support the efficacy of Sr-90 Beta radiation for the treatment of in-stent restenosis
- Shows no significant deleterious effects of adding 10mm of length to the source train
- Supports the lack of a relationship between Geographic Miss and clinical or angiographic outcome for in-stent restenosis

summary

Novoste™

START 30 AND 40 COMPARISON

What's the Same...

- Patient selection criteria
- Indications including balloon injury ≤ 20mm
- Endpoints
- Subset of same clinical centers
- Data Analysis Centers

What's Different...

- Registry
- 40mm Radiation Source Train used to treat all patients
- Expect a longer radiation margin (+ 10mm margin on each end)

DOSIMETRY METHODS

Dose Prescription

Dose prescribed at a point 2 mm from center of source axis based on visual assessment of reference vessel diameter (RVD):

- 18.4* Gy in RVD ≥ 2.7 - ≤ 3.3 mm
- 23* Gy in RVD > 3.3 - ≤ 4.0 mm

*NIST dose, March 2000

PROCEDURE DETAILS

Adjunctive Devices

%	Placebo	ST 30	ST 40
DCA	0.9	0.0	0.5
RA	39.8	43.9	22.0*
ELCA	7.4	5.7	12.7**
New Stents***	19.8	20.9	15.3

* p < 0.001 ST 40 vs. ST 30 and Placebo
** p = 0.01 ST 40 vs. ST 30
*** "Bail-out" stent use reserved for severe residual stenoses or dissection after radiation delivery

INCLUSION/EXCLUSION CRITERIA

Major Inclusion Criteria

- Single lesion, single vessel intervention
- In-stent restenosis > 50% (by visual assessment)
- Target lesion in vessels between 2.7 and 4.0 mm RVD
- Target lesion length treatable with 20 mm balloon with the 40 mm Source Train

Major Exclusion Criteria

- Multi-vessel coronary intervention
- Target lesion residual stenosis > 30%
- Unprotected left main disease
- Prior chest radiotherapy

BASELINE FINDINGS

	ST 30	Placebo	ST 40
Clinical Characteristics	n=244	n=232	n=207
Age (years) (1)	61.5	61.1	64.4
Men (%)	68.4	63.4	66.7
Diabetes (%)	30.7	32.3	26.3
Smoking (%)	12.5	8.1	9.0
Prior MI (%)	46.7	47.8	42.2
Prior CABG (%)	21.4	23.7	20.8
Unstable Angina (2)	73.8	78.9	85.0
Prior Tx for ISR (%)			
None (3)	52.5	57.0	38.8
One (4)	33.9	32.5	44.3
Two (5)	13.6	9.2	16.4
Angiographic Characteristics			
RVD, mm	2.76	2.77	2.77
Pre-MLD, mm	0.98	0.98	0.92
% Stenosis	64.2	64.2	66.6
Lesion Length, mm (6)	16.3	16.0	17.4
% LAD	43.2	41.3	44.7

(1) p-value 0.003 (placebo vs ST 40); 0.01 (ST 30 vs ST 40)
(2) p-value NS (placebo vs ST 40); 0.004 (ST 30 vs ST 40)
(3) p-value 0.0002 (placebo vs ST 40); 0.004 (ST 30 vs ST 40)
(4) p-value 0.012 (placebo vs ST 40); 0.03 (ST 30 vs ST 40)
(5) p-value 0.025 (placebo vs ST 40); NS (ST 30 vs ST 40)
(6) p-value 0.075 (placebo vs ST 40); 0.15 (ST 30 vs ST 40)

Best Vascular, Inc.
4350 International Blvd, Suite A
Norcross, Georgia 30093
Tel: +1 770-717-0904
Fax: +1 770-717-1283

1-800-NOVOSTE
(1-800-668-6783)
www.novoste.com

MT 371-00 02/01