

stent to artery ratio 1.1:1.0 to 1.2:1.0, and were subjected to gamma-radiation using  $^{192}\text{Ir}$ . The prescribed doses were 0 Gy (controls), 15 Gy, or 30 Gy at 2 mm from the center of the source axis. Animals were sacrificed at 1, 3, and 6 months and arteries were analyzed for histomorphometry (n=36) or scanning electron microscopy (n=36). Intimal area (IA) was reduced after VBT at 3 months with 15 Gy and 30 Gy as compared to controls and at 6 months with 30 Gy (Table). There was no difference in IA at 6 months between 15 Gy and controls. The surface covered by endothelium was reduced in radiated arteries at all time points and did not increase from 1 to 6 months. Excess of platelets, macrophages, and leucocytes were seen in radiated arteries not completely covered by endothelial cells.

	1 month	3 months	6 months
Endothelialized surface			
Control	92 ± 4%	95 ± 2%	98 ± 2%
15 Gy	37 ± 4%*	32 ± 12%*	40 ± 8%*
30 Gy	37 ± 8%*	29 ± 13%*	35 ± 12%*
Intimal area, mm <sup>2</sup>			
Control	0.86 ± 0.21	1.01 ± 0.11	1.28 ± 0.26
15 Gy	0.80 ± 0.42	0.66 ± 0.07*	1.35 ± 0.37
30 Gy	0.57 ± 0.27	0.66 ± 0.04*	0.75 ± 0.09*

\* p<0.05 versus control

**Conclusions:** Re-endothelialization after VBT is not completed at 6 months after VBT. Thus, special care with prolonged antiplatelet therapy should be considered beyond this time point.

### 1128-182 Multi-Center Experience With a Novel Ir<sup>192</sup> Vascular Brachytherapy Device for In-Stent Restenosis: Final Results of the Angiorad Radiation Therapy for In-Stent Restenosis Intracoronary II (ARTISTIC II) Trial

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**Background:** Although vascular brachytherapy (VBT) reduces restenosis (RES) and major adverse cardiovascular events (MACE) after therapy for in-stent restenosis (ISR), both dose (Gy) and VBT catheter profile limit efficacy of currently available devices. **Methods:** A novel 0.0136" Ir<sup>192</sup> sourcewire (AngioRad™, Interventional Therapies, LLC, Westport, CT) and a 0.032" profile delivery catheter/centering balloon (6 Fr guide catheter compatible), which provides 18 Gy at 2 mm from the source center, was used to treat 236 patients (age 62 years; 64% male; 38% diabetes) with ISR at 11 U.S. centers. Historical controls (no VBT) were derived from the following randomized trials: ARTISTIC I (n=54) randomized trial and the Washington Radiation for In-stent Restenosis Trial (WRIST; n=50). Quantitative coronary angiography was performed periprocedurally and at 6 months; clinical follow-up evaluation was at 30 days and 6 months.

PRE PROCEDURE	Ir192 (n=236)	Control (n=104)
RVD mm (SD)	2.71 (0.5)**	2.55 (0.4)
Lesion Length mm (SD)	14.36 (7.0)**	18.74 (8.4)
POST PROCEDURE		
MLD mm (SD)	1.93 (0.4)**	1.84 (0.4)
% stenosis	28.9% ± 11.5%**	28.7% ± 11.7%
Total MACE* (30 day)	2.1%	1.9%

RVD = reference vessel diameter; MLD = minimum lumen diameter; TVR = target vessel revascularization; TSR = target site revascularization. \*Death, myocardial infarction, emergent CABG or TLR \*\*73% data complete analysis at submission

**Conclusions:** Low profile and deliverability of this novel Ir<sup>192</sup> system facilitate VBT use. Effectiveness of the Angiorad™ System is supported by low 30 day MACE, limited late loss and infrequent restenosis. Completed angiographic and clinical follow-up will be presented.

### 1128-183 Prolonged Antiplatelet Therapy After Coronary Brachytherapy: When Is It Safe to Stop Clopidogrel?

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**Background:** The objective of SCRIPPS III study was to evaluate the impact of both extended antiplatelet therapy and reduced stenting on late target thrombosis following brachytherapy.

**Methods:** At two centers (Scripps Clinic and Lenox Hill) attempts were made to avoid new stent implantation at the time of intracoronary radiation for treatment of in-stent rest-

enosis. Patients who did not receive a new stent were treated with clopidogrel for a minimum of 6 months. Patients who required a new stent at the time of brachytherapy received clopidogrel for at least 12 months.

**Results:** Of 492 patients enrolled, only 22.7% required new stents. Mean follow-up was 421.9 ± 148.4 days. Clopidogrel had been discontinued for >6 months in only 67(13.6%) patients (Table). Three patients sustained subacute thrombosis prior to 30 days. All three patients had received new stents during their index procedure. There was one late thrombosis at 20 months (0.2%) in a patient who did not receive a new stent and who completed a six-month course of clopidogrel.

**Conclusions:** A strategy of avoiding new stent implantation and prolonged adjunctive antiplatelet is associated with a very low risk of late thrombosis (0.2%). The zealous use of off-protocol clopidogrel makes it difficult to determine the optimal duration of anti-platelet therapy, particularly in patients receiving new stents. Until further data is obtained we recommend indefinite clopidogrel therapy after intra-coronary brachytherapy in patients receiving new stents.

Table 1

Plavix Discontinued	New Stent	No New Stent
>1 Month	175	35
>3 Months	58	29
>6 Months	42	25

### 1128-184 Longer Sources of Intracoronary Brachytherapy for In-Stent Restenosis Reduces Restenosis in the Real World

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**Background:** The major concern from randomized intracoronary brachytherapy (ICBT) trials was edge restenosis due to use of short source. Target lesion revascularization (TLR) with use of longer ICBT sources has not been studied.

**Methods:** We analyzed 150 consecutive patients with in-stent restenosis (170 vessels and 182 lesions) who had cutting balloon (CB PTCA) and/or rotational atherectomy followed by beta radiation using the Novoste system (30 mm source in 114 and 40 mm source in 68 lesions) and followed for mean 6±3 months.

**Results:** Mean age was 64±11 years, male sex 67%, CCS class III-IV 26%, >1 prior restenosis 50%, restenosis interval 162±52 days. Periprocedural CK-MB elevation occurred in 15.8% patients, average in-hospital stay was 2.1±2.8 days, GP IIb/IIIa use 65%. Plavix was recommended for 1-6 months. At follow-up: TVR 9.3% (14 pts, 11 TLR, and 3 non-TLR), delayed acute closure/subacute thrombosis 0%, death 2.7% (1 in-hospital, 3 at follow-up).

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<sup>2</sup> Procedural Characteristics & QCA

#### Procedural Characteristics & QCA

Lesion length (mm)	17.5±8.9	Ref. vessel size (mm)	2.91±0.04
LAD/LCX/RCA(%)	44/28/21	MLD-Pre (mm)	0.72±0.31
Total occlusion	10%	MLD-Post (mm)	2.21±0.42
CB PTCA±Rotablator	65%	MLD-Post ICBT (mm)	2.12±0.32
Rotablator	30%	Re-dilatation post ICBT	5%
Re-stent	3.3%	Vessel spasm	4%

**Conclusion:** Debulking followed by ICBT provides sustained long-term, acceptable restenosis in single digits. Compared to randomized trials, these favorable results in the real world are perhaps due to better understanding of the restenotic process after ICBT and represent the benefit of full lesion coverage by long source, leaving moderate residual stenosis and very low need for restenting.

### 1128-185 Late Stent Malapposition After Brachytherapy: An Assessment of the Incidence and Mechanisms Using Volumetric Intravascular Ultrasound

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Late stent malapposition (LSM) is a potential complication of intracoronary brachytherapy (BT). We evaluated the incidence and mechanism of LSM after gamma-BT (Ir-192) in 238 segments with in-stent restenosis (ISR) enrolled in the WRIST, Long WRIST, WRIST-PLUS, Gamma-I and ARTISTIC trials. Planar and volumetric IVUS analyses was performed every 1mm within the malapposed segment as well as within 5mm long "control" segments with complete circumferential apposition: external elastic membrane (EEM), stent, intra-stent lumen, LSM, effective lumen (intra-stent lumen+LSM), and plaque (EEM minus effective lumen) area. Dose volume histograms (DVH) were calculated for LSM segment, the wall of the vessel with complete apposition opposite the arc of LSM, and the control segments. Results: There were 11/152 LSM in the irradiated group (7.2%) vs only 2/86 in the placebo (2.3%, p=0.14). 8 LSM occurred within old stents and 5 in newly placed stents.

The length and volume of malapposition were 4.82±7.44mm and 9.52±10.31mm<sup>3</sup>. LSM segments underwent vessel enlargement that was greater than the increase in plaque while control segments showed no change in EEM or plaque. DVH calculations were similar for LSM and control segments.