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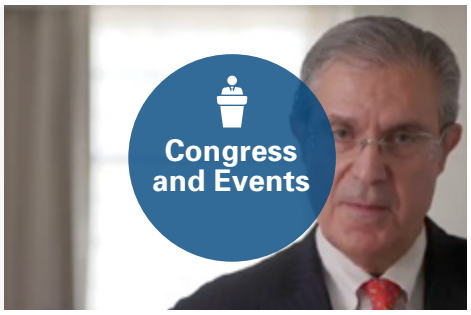
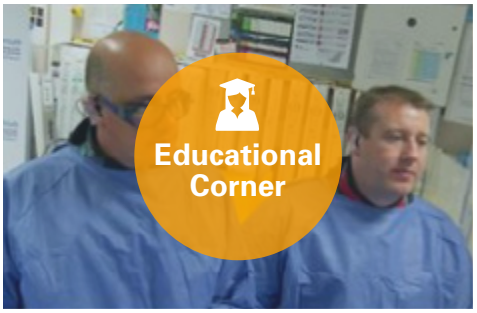
Advanced Collaborative Services

CARDIOLOGY NEWSLETTER



- Three-year Results from the EVOLVE II Randomized Trial presented at ACC
- Synergy™ BP Stent Launches 48mm Length
- Boston Scientific announces agreement to acquire Symetis

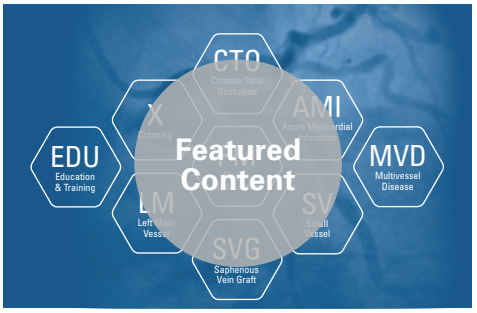


- EuroPCR LIVE case: Rotablation of LAD
- InCathlab Live Case: Antegrade Recanalization

Learning with Clinical Studies:

- Guidezilla™: back-up support for calcified, complex and tortuous anatomy

- Early Discontinuation of Dual-Antiplatelet Therapy with Synergy™ Stents in High-Risk Patients Undergoing Complex PCI
- Rotational atherectomy: You will never regret using it!
- Synergy™ Stent: ST Rates from the Academic Research Consortium



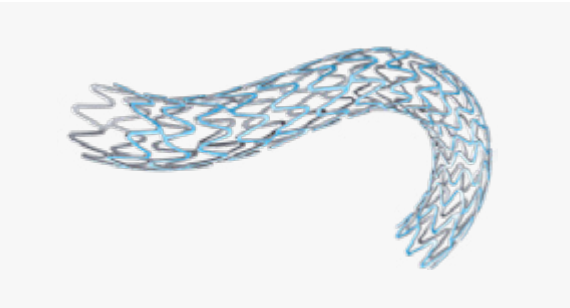
- Join the Complex PCI community
- Download New App: Stroke-Bleed Risks Calculator!

Congresses and Events

Three-year Results from the EVOLVE II Randomized Trial presented at ACC

Late Clinical Outcomes with Bioresorbable compared to Permanent Polymer Everolimus-Eluting Stents

Dean J. Kereiakes, Ian T. Meredith, Stephan Windecker, Josep Rodes-Cabau, Tommy Lee, Arthur Reitman, Andrejs Erglis, Mark Dorogy, Barry Bertolet, Louis Cannon,Juhani Airaksinen, Craig Siegel, Thomas Christen, Dominic J. Allocco, Keith D. Dawkins



Three-year follow-up from EVOLVE II trial presented by Dr. Dean Kereiakes supports longer-term safety and efficacy of the novel abluminal bioabsorbable polymer Synergy everolimus-eluting stent in a broad range of patients undergoing PCI.

Key data points:

- Definite/Probable ST was 0.8% in the Promus Element™ Plus Stent arm and 0.5% in the Synergy™ BP Stent arm
- Synergy™ BP Stent had 0.2% Definite/Probable ST after 24 hours to 3-years, while Promus Element™ Plus Stent had 0.7% (landmark analysis)
- Synergy™ BP Stent shows a 0.06% per year ST rate beyond 1 year (a ST rate 10x lower than contemporary permanent polymer stents)
- TLF was similar in both arms: 11% for Synergy™ BP Stent and 10% for Promus Element™ Plus Stent

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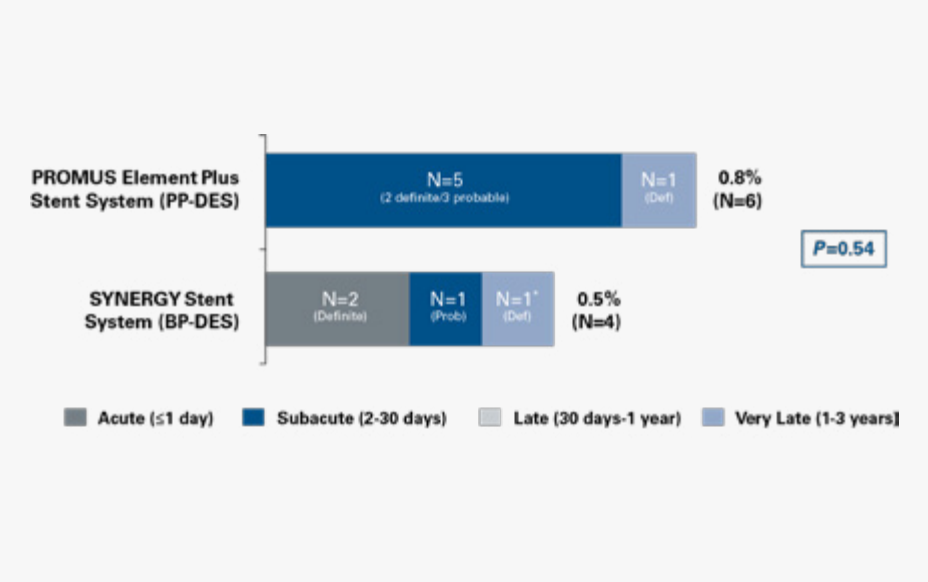
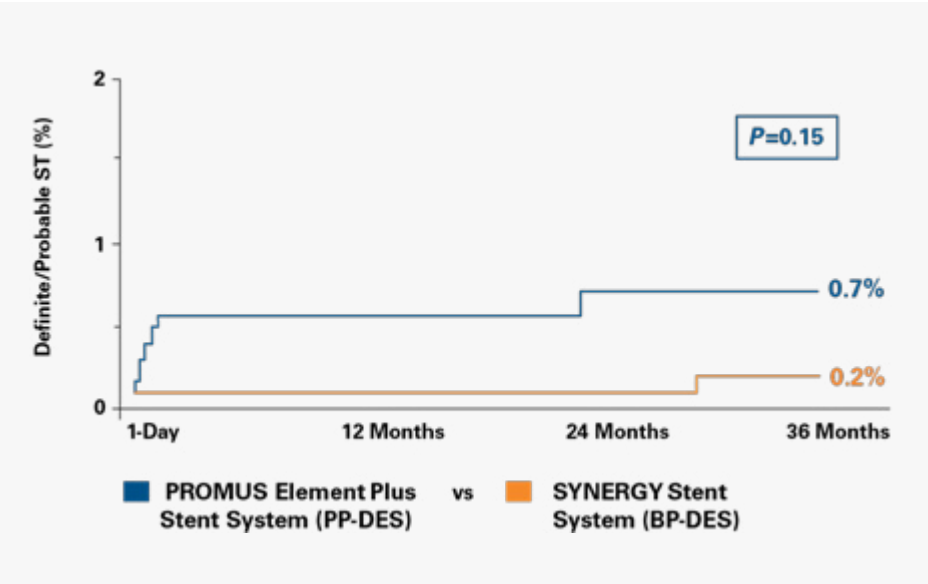
Congresses and Events

Excellent Safety Performance with Synergy™ BP Stent:



Numerically Lower ARC Definite/Probable ST with the Synergy™ BP-DES compared to the Promus™ Element™ PP-DES:



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Congresses and Events

Synergy™ BP Stent Launches 48mm Length

Long lesions represent a complex lesion subset that is associated with increased safety related events, reduced efficacy and increased procedure time. Synergy™ BP Stent was designed for quality healing and safety over time and with the addition of a 48mm length it has a complete size matrix to address these complex lesions. Synergy™ BP Stent, with its abluminal, bioabsorbable polymer, shows more complete stent coverage compared to permanent polymer stents.

Heal long lesions with confidence

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Congresses and Events

Boston Scientific announces Agreement to acquire Symetis

Lotus™ Valve System, Boston Scientific

Boston Scientific announced a definitive agreement to acquire Symetis SA, a privately-held Swiss structural heart company focused on minimally-invasive, for $435 million in up-front cash.

The Symetis portfolio includes the ACURATE TA™ and ACURATE neo/TF valve* systems for use in the treatment of high-risk patients suffering from severe and symptomatic aortic valve stenosis, which are sold in Europe and in other geographies outside of the United States. Symetis is also developing the ACURATE neo/AS** next generation valve system, currently in a clinical trial intended to serve as the basis for a future CE mark application.

This agreement follows the recent acquisition by Boston Scientific of certain Neovasc, Inc. manufacturing assets, and demonstrates the company‘s continued investment in structural heart through intellectual property, research and development, and manufacturing capabilities.

The acquisition is projected to close during the second quarter of 2017, subject to customary closing conditions.

Ian Meredith, M.D.,
Executive Vice President and Global Chief Medical Officer of Boston Scientific.

*„The steps we are taking reflect our commitment to being a leader in TAVI and structural heart technologies now and over the long-term, as we broaden our portfolio and pipeline to address the needs of our global health care providers and their patients. The ACURATE family of valve products is strongly complementary to our cornerstone Lotus™ valve*** platform, and this compelling combination of technologies will allow us to provide interventional cardiologists and cardiac surgeons with multiple TAVI offerings for varying patient pathologies and anatomy.”*

*The ACURATE TA™ and ACURATE neo/TF valve systems are not available for use or sale in the US.
**The ACURATE neo/AS valve system is not available for use or sale.
***The Lotus™ valve is currently not available for use or sale

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Educational Corner

EuroPCR LIVE case: Rotablation of LAD

Invasive physiological assessment can be used to guide revascularization of residual disease after PCI. From St‘ Thomas’ Hospital (London) a live demonstration of an optimal complete revascularization after primary PCI in patients with multivessel disease, to learn more about rotablation of LAD.

Simon Redwood, MD
St Thomas’ Hospital,
London, UK

Bernard Prendergast, MD
St Thomas’ Hospital,
London, UK

Educational objectives:

- Understand the evidence for full revascularization after primary PCI in patients with multivessel disease
- Know how to assess residual ischaemia using invasive techniques (FFR)
- Appreciate the thresholds for considering rotablation in calcific coronary artery disease

Patient History:

- 80-year old male
- Minimal stenuous activity, carries out light work and an independent lifestyle
- Hypertension, smoker, hypercholesterolemia, inferior STEMI
- 24/03: Inferior STEMI with PPCI to RCA 3 x drug-eluting stents
- 23/04: Admitted to local hospital for reassessment of residual left coronary artery disease; LAD more heavily calcified than originally appreciated; referred for physiological assessment +/- rotablation

Procedure:

1. Check right coronary angiography
2. Update left coronary angiography with physiological assessment of the LAD & LCx
3. PCI of functionally significant lesion(s)
4. Rotablation available if needed for LAD disease

Featured Content

Educational Corner

Rotablation of LAD

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Educational Corner

InCathlab Live Case: Right Coronary Artery CTO. Antegrade Recanalization

Educational objectives:
An innovative operation, the Antegrade Recanalization with Hybrid Approach, conducted with a live demonstration from London Chest Hospital.

Elliot Smith, MD
Chest Hospital, London

Simon Walsh, MD
Belfast Trust, Belfast

Patient history:
- 69 years old man, taxi driver
- PCI to RCA 2000
- 8/12 worsening angina
- Failed relicensing ETT
- Coronary angiogram June 2013
- RCA CTO (JCTO score 1)

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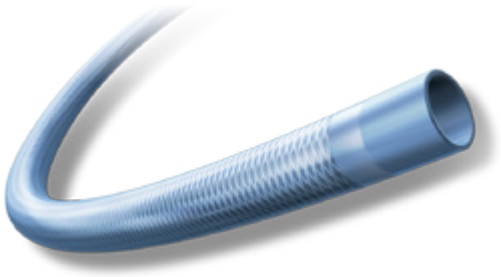
Featured Content

Educational Corner

Learning with Case Studies: Guidezilla™: back-up support for calcified, complex and tortuous anatomy

This case illustrates the need of Guidezilla™ Guide Extension Catheter as a transradial back-up support for calcified, complex and tortuous anatomy.



Brian D. Arcement MD
Gulf Coast Hospital
Fort Myers, Florida, USA

Key Learnings:

- Complex, calcified and tortuous distal lesions and transradial cases are perfect cases to use the Guidezilla™ to increase the probability of success and reduce the time spent delivering devices to lesions
- Balloon anchor technique makes delivery of Guidezilla™ through complex, transradial anatomy easy.

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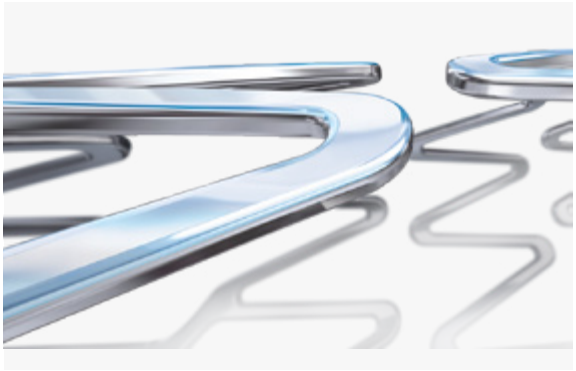
Clinical Studies

Early Discontinuation of Dual-Antiplatelet Therapy with Synergy™ Stents in High-Risk Patients Undergoing Complex PCI

Rebecca L. Noad, MB, PhD; Colm G. Hanratty, MD; Simon J. Walsh, MD. The Journal of invasive Cardiology, Epub 2016 December 15



As more elderly and co-morbid patients require percutaneous revascularization, 1 year of dual-antiplatelet therapy (DAPT) becomes concerning. Synergy™ stents allow for early cessation of DAPT. This study assessed those in our unit who underwent percutaneous coronary intervention (PCI) with a Synergy™ stent to examine a minimum of 6 months of clinical outcomes after early discontinuation of DAPT.

Conclusion:

In this small cohort, the use of Synergy stents allows for early discontinuation of DAPT, reducing the risk of bleeding complications and facilitating non-cardiac procedures, without an increase in the incidence of ST. The results for TLF and clinical outcomes are excellent for a group of patients with significant co-morbidities and complex coronary lesions.

ORIGINAL CONTRIBUTION

Initial Experience of Bioabsorbable Polymer Everolimus-Eluting Synergy Stents in High-Risk Patients Undergoing Complex Percutaneous Coronary Intervention With Early Discontinuation of Dual-Antiplatelet Therapy

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Clinical Articles

Rotational atherectomy: You will never regret using it!

EuroIntervention 2016;12:1441-1442
Teresa Strisciuglio[1], MD; Emanuele Barbato[1,2*], MD, PhD, 1. Department of Advanced Biomedical Sciences, University of Naples Federico II, Naples, Italy; 2. Cardiovascular Research Center Aalst, Aalst, Belgium

Dr. Teresa Strisciuglio (Naples. Italy) and Dr. Emanuele Barbato (Aalst, Belgium) illustrate the advantages deriving from the contemporary rotational atherectomy technique.

Rotational Atherectomy has recently gone through a surge of interest. The contemporary RA technique in fact aims to smoothen the lumen and disconnect the calcified coronary ring, thus leaving the way clear for further balloon dilatation and stent implantation. This has implied smaller burr-to-artery ratio, lower rotational speed, and burr manipulation, aiming to reduce the friction and temperature increase within the ablated coronary segment.

In addition, the procedural outcome of RA has significantly improved thanks to the evolution from the original extensive "plaque debulking" to the current "plaque modification" technique **(Table 1)**.

	Contemporary
Arterial access	Radial (6-7.5 Fr) or femoral (6-8 Fr), depending upon burr size requirement and operator experience
Guiding catheter	Single curve with strong support. Operator preference but stable catheter position required
Guidewire	Rotawire placement not always straightforward. Use of regular wire placement, with exchange using microcatheter placement often required
Burr size	Plaque modification with small burrs (1.25 mm to 1.5 mm) as initial strategy is default position. A step-up approach is encouraged to limit debris size and complications
Ablation speed	Plaque modification usually achieved at low speeds (135,000 to 180,000 rpm) to reduce risk of complications
Temporary pacemaker	Smaller burrs at lower speeds have led to lower incidence of transient heart block. Many operators use atropine to treat, avoiding any complications of temporary pacemaker placement
Rotablation flush	Rotablation cocktail with verapamil, nitrates and heparin in saline recommended

Table 1

EDITORIAL

Rotational atherectomy: you will never regret using it but you often regret not having used it!

Teresa Strisciuglio[1], MD; Emanuele Barbato[1,2*], MD, PhD

1. Department of Advanced Biomedical Sciences, University of Naples Federico II, Naples, Italy; 2. Cardiovascular Research Center Aalst, Aalst, Belgium

Table 1. Contemporary rotational atherectomy technique (modified from Barbato et al[2]).

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Articles, see page 1448 and page 1457

*Corresponding author: Cardiovascular Research Center Aalst, Moorselbaan n. 164, B-9300 Aalst, Belgium. E-mail: emanuele.barbato@ohvz-aalst.be

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Clinical Studies

Synergy™ Stent: ST Rates from the Academic Research Consortium

According to the Academic Research Consortium, Synergy™ has demonstrated very low stent thrombosis rates across multiple clinical trials.

Data in the table below show that Synergy™ Stent, with its abluminal and bioabsorbable polymer has reported consistently low sub-acute, late & very late ST in 18,000 patients across 9 studies.

	SWEET Registry	Fribourg Experience	Belfast Experience	EVOLVE II Trial	EVOLVE Trial	EVOLVE China	EVOLVE II QCA Study	SCAAR Registry	BIO-RESORT Trial
N:	820	671	185	846	94	205	100	14,979	1172
Acute	1.5%	0.3%	0%	0.2%	0%	0%	0%	0.08%*	0.1%
Sub-acute	0.1%	0.3%	0%	0%	0%	0%	0%	0.02%*	0.1%
Late	0.1%	0.1%	0%	0%	0%	0%	0%	0.2%*	0.2%
Very Late			0%	0.1%	0%			0.1%*	

SWEET Registry: Cook TCT 2015., Fribourg Experience: Arroyo CRT 2016. Belfast Experience: Noad TCT 2015., EVOLVE II: Kereiakes, et al. Circ Cardiovasc Interv. 2015;8:e002372.DOI:10.1161/CIRCINTERVENTIONS.114.002372.,EVOLVE FHU: Meredith et al. J Am Coll Cardiol. 2012; 59 (15):1362., EVOLVE II QCA: Meredith ACC 2015., SCAAR Registry: James TCT 2016 BIO-RESORT presented by Clemens von Birgelen, MD PhD, TCT 2016.

The SWEET Registry, conducted at three centers in Switzerland, demonstrated a 1.5% ST rate in the first 24 hours. This rate is higher than we have seen in other clinical trials that have evaluated the performance of Synergy. Since SWEET is an unselected registry, it included by default most patients who were excluded from other clinical trials.

Acute:	≤ 1 day
Subacute:	2 – 30 days
Late:	30 days – 1 year
Very Late:	Beyond 1 year

*Cumulative adjusted ARC def ST estimated from Kaplan Meier Curve

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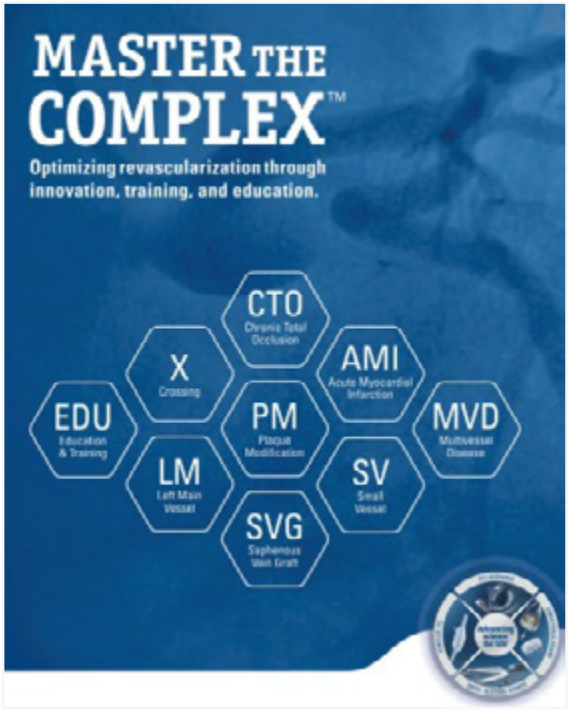

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Stay up to date with the latest advances for optimizing revascularization.

Join the Complex PCI Community and download the EuroIntervention Clinical Article: *"Rationale and design of the SYNTAX II trial evaluating the short to long-term outcomes of state-of-the-art percutaneous coronary revascularisation in patients with de novo three-vessel disease"* by Prof. Escaned et al.

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ANDROID APP ON Google play

NEW Stroke-Bleed Risks Calculator App

This App will help you easily balance the risk of stroke against the risk of bleeding prior to decide the best treatment option for your AF patients and consider the LAAC therapy.

Watch Video »

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* Lund experience with the ™ Valve in an all-comers population, Matthias Götberg, EuroPCR 2016

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