SOLACI DAILY

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Mexico

SOLACI 2012 Opening Ceremony

With the XVIII SOLACI Congress opening ceremony underway and after the Mexican national anthem had been played, Dr. José Luis Leiva Pons, President of the Mexican Society of Cardiology and SOLACI host, inaugurated the Congress.

Joining him were Dr. Oscar Mendiz, President of SOLACI; Dr. Joel Estrada Gallegos, President of SOCIME; Dr. Mariano Ledesma Velasco, President of ANCAM; Dr. Daniel José Piñeiro, former President of the SIAC; Dr. David Holmes, former President of ACC; Dr. Juan Granada of CRF-TCT; Dr. Thomas Cuisset, euroPCR representative; Dr. Jorge Gaspar, President of the Scientific Committee; and Dr. Steven Bailey, former President of SCAI.

Dr. Leiva Pons welcomed more than 2,000 health professionals to the Congress, marking the start of sessions that will present the most innovative treatment options for cardiac patients in Latin America. Dr. Oscar Mendiz provided brief updates on SOLACI and then gave the floor to Dr. Marco Martínez Ríos, founder of SOLACI, who spoke of the state of Interventional Cardiology 20 years after SOLACI's creation.

Attendees had the opportunity to enjoy a traditional mariachi show and during the cocktail hour they were able to greet one another and exchange opinions on Interamerican Cardiology.

SOLACI Update: From Santiago de Chile to Mexico City

By Oscar Mendiz, MD

After a year of hard work we can say that SOLACI is continuing on the arduous path of reorganization which Dr. Dario Echeverri began during his previous administration.

After the Congress of Chile, which was a major scientific event and enjoyed a higher than expected attendance, we find severe economic difficulties were a factor since the result was much less than expected. The situation forced us to accelerate the pace of reforms and it is within this framework that you must view and judge our first year of management, in which it is worth noting the commitment, support and work of the Advisory Council and the Commission Directive who accompanied me.

First we are anxious to ensure that economic difficulties do not prevent us from fulfilling our mission to promote and improve cardiovascular interventionism at LATAM and that SOLACI remains the reference point for the whole continent. For this reason the SOLACI office in Buenos Aires was completely restructured to make it more functional for management as well as more efficient, which provided us with a very noticeable reduction in operating costs. This involved a total reorganization of human resources, the administrative and accounting sector took on a new operating system which incorporated external advice from a new accounting office and auditing.

We worked very closely with local organizers of the congress in Mexico so that, according to circumstances, we could hold an annual scientific meeting on the scale we have always attended. We also invested many resources to encourage attendance and as a result Mexico finally had the Congress that it deserved. It is very important to note that the organization viewed it as imperative...

(Cont.Page 3)

SOLACI Sessions, Solid Reality, and a Promising Future

By Pedro Hidalgo Useche, MD

For more than 15 years, the Latin American Society of Interventional Cardiology (SOLACI), has reunited the initiatives of all those from across the region who, one way or another, are involved in the motivating world of vascular and structural percutaneous intervention.

Many are the countries that form this heterogeneous mosaic with its many contrasts; however, SOLACI's mission is to strengthen, integrate and develop interventional cardiology in each and every region, looking to set common criteria among our professionals dedicated to the study and treatment of cardiovascular diseases, to maintain a high standard in the practice of this subspecialty through education, updated information and clinical research.

With these ideas in mind, and thanks to Daniel Berrocal's pioneering efforts, since 2006 SOLACI has been present in all regions comprising our organization, through a scientific annual event, sharing knowledge, exchanging experiences and encouraging consensus that will help not only interventionists, but also clinical cardiologists, medical teams and paramedics.

We can count dozens of sessions carried out all along our continent, all of them successful, organized with the support of our opinion leader physicians that generously share their knowledge with our participant members, making a positive impact in our patients' health care.

Numerous results have been achieved, and while many challenges remain, I am sure they will be overcome with the enthusiasm and the cooperation of all of us who understand our regional sessions as the true democratization of SOLACI. We especially would like to mention Dr. Ariel Durán, the present Director of the SOLACI sessions, and his team for their immense effort to consolidate this project's success. We vow to help these sessions grow and to take our message to every corner of Latin America.

Pedro Hidalgo Useche, MD
President, Sociedad Venezolana de Cardiología Intervencionista (SOVECI)

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Visítenos en el stand #32

[SOLACI 2012]

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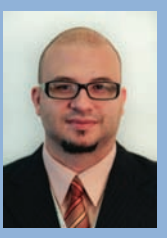
	MAIN ARENA TERRAZAS	ROOM CHAPULTEPEC	ROOM CHAPULTEPEC	ROOM ARCOIRIS	ROOM JARDÍN	ROOM TAXCO
8:00 - 10:00	Live Cases XII - XV	SBHCI @ SOLACI Key Issues in Interventional Cardiology: Scientific Evidence and Real Cases from the Daily Practice	Clinician's Forum: Acute Coronary Syndromes: SIAC @ SOLACI	Pediatric Interventions	Valvular and Extracardiac Interventionism	
10:00 - 10:15	Presentation of SOLACI-SBHCI 2013 in patnership with TCT					
10:15 - 11:45	Plenary Session 11 TAVR		Peripheral Acute Stroke	Pediatric Interventions		
11:45 - 13:15	Live Cases XVI - XVII	ACC @ SOLACI2012 Assessment of Intermediate Lesions-Aortic Regurgitation port	Clinician's-Forum: Renal Denervation	Peripheral Acute Stroke	Acute Coronary Syndromes	
13:15 - 13:30	BREAK					
13:30 - 15:00	Lunch Symposium sponsored by MEDTRONIC Actual and Future Perspectives in the Interventional Field	Lunch Symposium sponsored by BIOSENSORS Long-term Patient Benefit and Advantage in Complex Patient Subsets with Latest Des Technology	Lunch Symposium sponsored by EDWARDS	Lunch Symposium sponsored by TERUMO ALL you need to know in Contemporany Interventional Cardiology		
15:00 - 15:15	BREAK					
15:15 - 16:45	TCT @ SOLACI Updates and Controversies in Coronary intervention	Interventional Pharmacology II Anticoagulants and IIb/IIIa Inhibitors		Canned Cases: Coronary		
16:45 - 17:00	BREAK					
17:00 - 19:00	Live Cases XIX - XXII In pathernship with TCT	Complex PCI Bifurcations	Peripheral Intervention Aortoiliac and Femoral Arteries	Adult Congenital HD ASP, PFO	Abstracts Presentation	
19:15 - 20:45	Evening Symposium sponsored by MEDTRONIC Core Valve Symposium: Celebrating 1000 Implants in Latin America!	Evening Symposium sponsored by ELI LILLY: Select Don´t React: "Customizing Antiplatelet Therapy in the SICA-ICP Patient				ABBOTT Workshop Closure Devices: Learn the Technique! 17:00 - 18:00

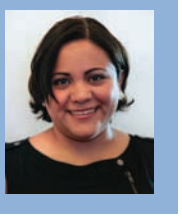
What are your expectations for SOLACI Congress and what does it represent to you?

Carla Rebeca Ortega Flores
Internist–Cuautitlán Hospital, Mexico
Learn more about the innovations in cardiology and hemodynamics. SOLACI conferences are always on the cutting edge of the field.



Ernesto Echeverría Matthew
Hemodynamic Technician –Rafael Ángel Calderón Guardia Hospital, Costa Rica
Study the variety of products and brands available and learn about cases that verify the use of technology and resources to benefit the patient. SOLACI allows us technicians to play an important role during these sessions.

Carlos Ignacio Escobar
Ecocardiographer–Santa María Cardiovascular Clinic, Colombia
SOLACI is the most important hemodynamics congress in Latin America; I am interested in interacting with professionals from other disciplines, highlighting the perspective of the echocardiogram.



Betzaida Cambero
Nurse – Specialty in Interventional Cardiology, Mexico
Update myself with the new technology; learn what is best to offer our patients. We are proud that SOLACI is being hosted in Mexico this year.

(Cont. of "SOLACI Update: From Santiago to México City") to conform to a pre-established budget and for that I am very grateful. The SOLACI workshop maintained a high level, with significant improvement in the organization thanks to the efforts of Dr. Ariel Duran and we intend to work with the new authorities who are taking over this month to continue on this path. The website has been completely restructured, with a new supplier and a new editorial board to make it more efficient and consistent with current needs. Results are displayed as the increased traffic generated sponsors' renewed interest. Reports of major world events in conjunction with SBHCI is an example of integration with other companies and an example of how to streamline the money invested by sponsors in LATAM to achieve the common goal of promoting and improving interventions and thus save and improve the lives of our brothers.

After several years of sustained effort in ProEducar direction, Dr. Hugo Londero leaves the office and we would like to express our appreciation and gratitude, as well as our confidence in the new authorities, so that together with the CD we can maintain continuity in high quality educational materials, adapted to current needs in the context of the strategic plan. SOLACI registration will be launched in the coming days after some years of interruption. It is our intention to attain the commitment of all SOLACI members with data loading routinely sustained so that everyone can have an input into what we are doing. This is also useful to companies that must invest in our continent and authorities that need data to tailor their health policies, with whom we have previously been at fault in not being able to offer that information. Information is public and freely accessible to all partners who work with the registry.

All this reorganization has not prevented us thinking about the future and making some important strategic alliances. In this regard, association "in partnership with TCT" not only allows us to go beyond the joint meetings that we had in the respective summits and to have the support of the great structure and experience of CRF to better organize our events, expand promotion, disseminate all our activities and facilitate SOLACI partners' access to information of tctmd website in its "gold" version but also to start thinking about organizing a mixed structure that can be supported by joint research in LATAM. This means we have transformed a friendship and support of many years into a formality that transcends people based on the formal structures of society and which I'm sure will be capable of sustaining major improvements and advances in the near future.

The agreement of formal cooperation with the American College Cardiology (ACC), based on the conviction and personal cooperation of Dr. David Holmes, brings us closer to the desired reference with world cardiology, in addition to joint sessions of both events providing access for SOLACI members to this society's publications (JACC journals, more information on the website). Our cooperation with EuroPCR continues and "fast track review" possibilities for the best abstracts of EuroIntervention congress has allowed us to increase and improve their quality, submit some publications from our continent and could prepare the way for near future presentations of "late breaking clinical trials." It is our intention to work with and improve this partnership and that is the compass that guides our actions.

The world is evolving rapidly and it requires our adaptation. Everything changes dramatically in a very short time and SOLACI cannot and should not remain static with structures and actions that have been very effective in the past but certainly may no longer be in the near future. In that sense the problems resulting from Chilean Congress were framed, the enormous challenge of how to select new locations for our events, how to make SOLACI less dependent on the economic performance of a conference, how to perform certain promotional activities that have always been deficient, (i.e., conferences), and also how to transmit experience and knowledge more efficiently in the immediate future. Toward these aims future actions, such as the urgent need for a financial contribution from members, must work on getting benefits and undertake to keep looking for ways to make it even more profitable.

Also with a view to a future market run by mobile communications and the replacement of personal computers with portable devices like smart phones and tablets, and also to offset information volatility, we have developed new applications for these devices, (SOLACI inMotion), that will allow users to access all our content online. Time has been scarce, despite working long hours every day, and I could not meet all the needs of our many committees and Regional delegates of SOLACI. I apologize and hope to be able to do it during this second year of my administration.

This "SOLACI YEAR" in progress, which will culminate in the next SOLACI'13 Congress in partnership with TCT, co-organized with SBHCI in the city of Sao Paulo, Brazil from 24-26 July 2013, will be a year to consolidate the changes and promote growth. We will be in touch via our online activities that I hope you will help us to transform and so become a source of frequent consultation.

On behalf of the entire Board of Directors, may I offer our thanks and our renewed commitment to continue to make SOLACI a leading organization of cardiovascular intervention in LATAM.

With my respect and consideration to each of you.

If you're interested in knowing more, visit our website!
www.solaci.org

SOLACI '12 MEXICO DF
In partnership with TCT

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Bioabsorbable Scaffolds

By José Alexandre Abizaid, MD, PhD; J Ribamar Costa Jr., MD, PhD.

Percutaneous coronary intervention (PCI) with bioabsorbable vascular scaffolds (BVS) has created interest because the need for mechanical support for the healing artery is temporary, and beyond the first few months there are potential disadvantages of a permanent metallic prosthesis. Among the several potential advantages of this novel technology we might highlight:

- Reduction in the occurrence of stent thrombosis, in special late and very late ones. Once the anti-proliferative drug and the temporary scaffold disappear, the possibility of thrombotic events in the site of PCI is considerable reduced;
- Restoration of endothelial function. Once the "rigid" scaffold structure is removed, the shear stress is restored favoring also the late luminal increasing. Furthermore, the full patency of the "jailed" side branches might be recovered;
- Potential pediatric role because they allow vessel growth and do not need eventual surgical removal;
- Possibility of vessel assessment with non-invasive imaging modalities such as coronary CT or MRI. The current technology of metallic stents results in excessive artifacts on angio CT, which precludes a definite non-invasive assessment of the stented segment. The absorbable scaffolds allow from day one a clear visualization of the entire coronary tree;
- Possibility of further revascularization therapies in the treated segments. A current complain is that the use of "full metal jacket" to treat diffuse coronary disease might preclude CABG (or even repeat PCI) in case of future failure of PCI. Since the BVS will be absorbed, in case of disease progression, the surgeon would still have coronary segments to perform the graft anastomosis.

The efforts to develop a fully degradable scaffold started about 20 years ago with the pioneering work of Dr. van der Giessen, Lincoff and Yamakawa. Despite the relative success in animal models, the initial prototypes resulted in excessive local inflammatory reaction, recoil and restenosis.

Currently there are more than ten different BVS prototypes being tested in the pre-clinical scenario. Among the programs that reached clinical evaluation, three have drug-elution and have already delivered initial promising results: ABSORB (Abbot Vascular), DESolve (Elixir Medical) and AMS (Biotronik).

The current challenges of this new revolution in the interventional cardiology comprise the expansion of indication of BVS to more cumbersome scenarios and the long-term in vivo demonstration of their theoretical benefits. At the moment, large registries with broader inclusion criteria and randomized trails versus metallic DES are ongoing with results soon to be presented. Below an example of our recent experience with Abbott BVS in the ABSORB Extend trial (figure 1).

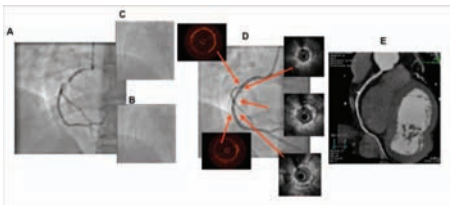


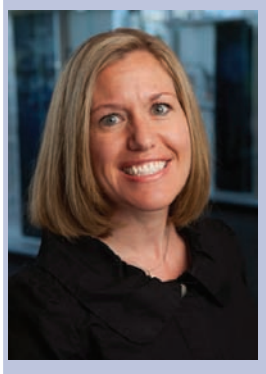
Figure 1. Long lesion in the mid RCA (panel A). Deployment of two Absorb BVS (3.0x18mm) with overlapping (panels B & C). Acute result assessed with IVUS & OCT (panel D). One-month angio CT showing stent patency with no artifact.

Alexandre Abizaid, MD, PhD; J Ribamar Costa Jr., MD, PhD
Instituto Dante Pazzanese de Cardiologia, São Paulo - Brasil

Article by Medtronic

SOCALI PCR News Transcatheter Aortic Valve Implantation Study Shows Low Mortality Rates and Improved Function at 6 Months

By Holly Vitense, PhD



Transcatheter Aortic Valve Implantation (TAVI) is now considered the standard of care in high risk patients with severe symptomatic aortic stenosis as an alternative to surgical aortic valve replacement (SAVR). Worldwide, approximately 300,000 people have been diagnosed with symptomatic, severe aortic stenosis, and approximately one-third of these patients are deemed at too high a risk for open-heart surgery.1 TAVI has emerged as a viable treatment alternative for these patients, demonstrating significant survival improvements when compared to medical management in inoperable patients, and similar survival rates to SAVR in a high surgical risk patient population.2,3 Since 2007 the CoreValve System has been implanted in more than 26,000 people in more than 60 countries outside the U.S.

Recent results for the Medtronic CoreValve ADVANCE study, the largest international, prospective, single-arm clinical study, yield positive patient outcomes. The ADVANCE study enrolled 1,015 patients (mean age of 81 years) consecutively treated "real world" at 44 experienced TAVI centers in 12 countries worldwide. Clinical endpoints in the study were calculated according to Valve Academic Research Consortium (VARC) standardized definitions. All data were independently monitored; all adverse events related to the primary endpoints were adjudicated by an independent Clinical Events Committee (CEC) consisting of experienced cardiac surgeons and interventional cardiologists. Additionally, all cerebrovascular events (including stroke and other events) were adjudicated by an independent neurologist using neuroimaging and systematic NIH Stroke Scale assessments.

Survival rates for the 996 implanted patients in ADVANCE were high at both 30 days (95.5 percent) and 6 months (87.2 percent). The procedural success rate was 97.8 percent, there were no catastrophic annulus ruptures and serious procedural events were rare (compromised coronary 0.1% and conversion to open SAVR 0.1%). Overall complication rates were low with stroke rates of 2.9 percent and MACCE (Major Adverse Cardiac and Cerebrovascular Events) rates of 8.3 percent at 30 days.

Patients in the study experienced significant improvement in valve function, mean gradient decreased from 45.6 mmHg at baseline to 9.5 mmHg at 6 months, and effective office area decreased from 0.7 cm2 at baseline to 1.7 cm2 at 6 months. Patient symptoms also dramatically reduced after the CoreValve implant with 79% of patients in NYHA III/IV at baseline and only 15% of patients in NYHA III/IV at 30 days.

In conclusion, treatment of "real world" high-risk patients suffering from aortic stenosis with the Medtronic CoreValve System by an experienced TAVI team is safe and associated with an improvement in aortic valve function in the presence of low stroke and mortality rates at 30 days and 6 months post procedure.

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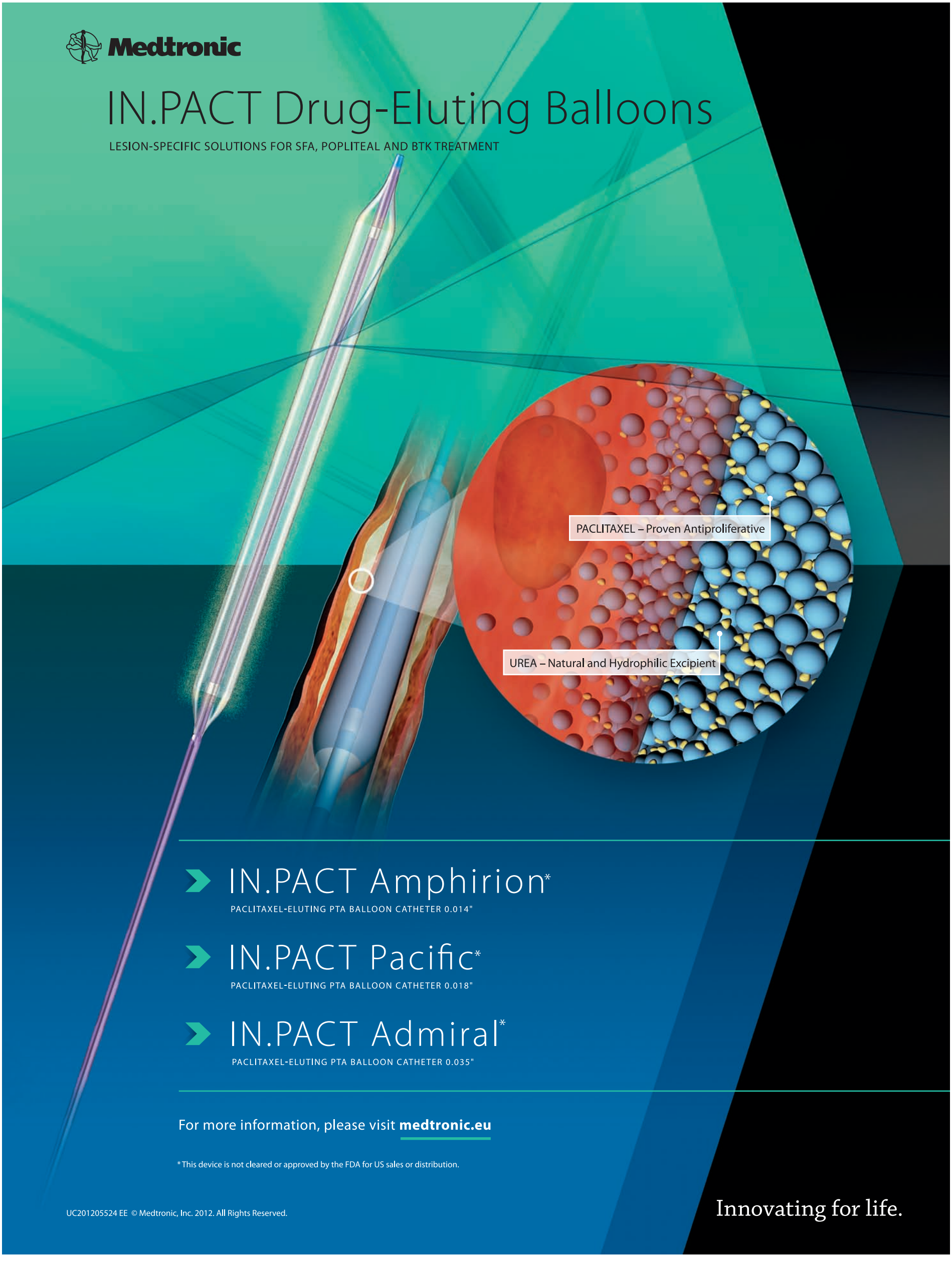

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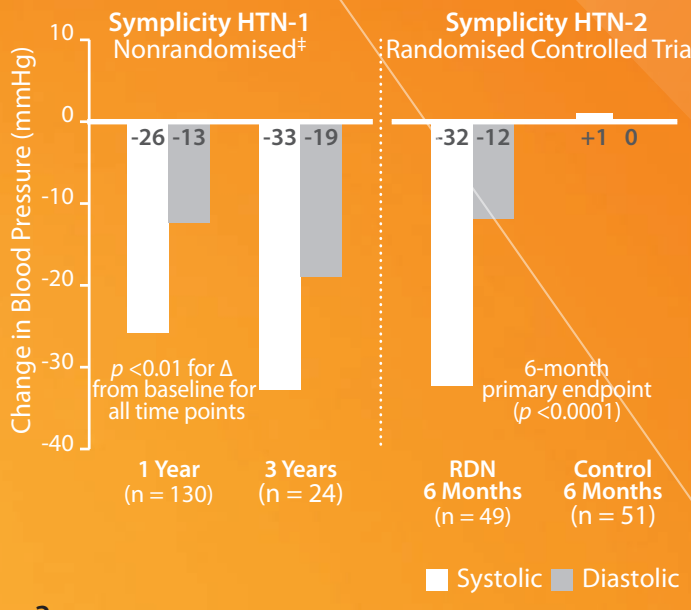

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† Symplicity HTN-2 Investigators. *The Lancet*. 2010.
‡ Symplicity HTN-1 Investigators. *Hypertension*. 2011. Expanded results presented at the American College of Cardiology Annual Meeting 2012.

ACC and SOLACI Ink Collaboration Agreement to Improve Patient Care

By David Holmes, MD

The American College of Cardiology (ACC) and the Sociedad Latinoamericana de Cardiología Intervencionista (SOLACI), led by President Dr. Oscar Mendiz, have agreed to promote quality cardiovascular care through education, research and the application of standards and guidelines.

A hallmark of this agreement is joint sessions at each organization's Congress. This will be initiated during the upcoming 2012 SOLACI Congress in Mexico City. At the Congress, former ACC President David Holmes will be presenting on Assessment of Intermediate Lesions and James Min will be presenting on Aortic Regurgitation and TAVR. The ACC is thrilled to be participating in the SOLACI Congress.

Additionally, at ACC.13 in San Francisco from March 9-11th SOLACI will be participating in the joint lunchtime sessions. This will be the first ever SOLACI joint session at an ACC Congress.

The recently signed collaboration agreement also provides SOLACI with the opportunity to contribute to the "Around the World" section of JACC Journals. Additionally, it extends to explore scientific and research opportunities that complement each society's mission as well as opening up opportunities for ACC education for cardiovascular trainees in Latin America.

About the ACC

The American College of Cardiology (ACC), a 40,000-member nonprofit medical society, is dedicated to enhancing the lives of cardiovascular patients through continuous quality improvement, patient-centered care, and professionalism.

About the SOLACI

The Latin American Society of Interventional Cardiology (SOLACI) was created to advance and promote cardiovascular intervention in South America, Latin America and the Caribbean. Since 1993, SOLACI has strived for excellence through several strategies that include education and training, research promotion, guideline development, regular meetings, regional sessions and constant exchange between members.

Today, SOLACI represents both invasive and clinical cardiologists in 20 countries, has more than 1,700 active members and strong alliances with the main interventional cardiology societies, both regional and international; among others, ESC (European Society of Cardiology), SCAI (Society for Cardiovascular Angiography and Interventions), ACC (American College of Cardiology), EAPCI (European Association of Percutaneous Cardiovascular Interventions), CRF (Cardiovascular Research Foundation), and the Sociedad Española de Cardiología (SEC).

The Role of Drug Eluting Balloons in the Diabetic Population

By Juan F. Granada, MD

Paclitaxel coated balloons (PCB) have shown to be effective in reducing restenosis among patients undergoing PCI. The clinical success achieved with the use of this technology relies on the single-time transfer of paclitaxel into the vessel wall resulting in a durable biological effect. While a potentially elegant approach, the initial loading dose transferred may be unpredictable and depend on the amount of injury inflicted at the time of delivery. Due to its prolonged tissue retention rates and tissue kinetic profiles, paclitaxel has been the drug of choice for most of PCB programs. Clinical DES trials suggest that this drug may also be more effective in the prevention of restenosis among diabetic patients.

Clinical trials of PCB in the BMS-ISR setting have demonstrated positive long term results (Figure 1). In these studies, a drastic reduction (>50%) in angiographic restenosis has been shown compared to paclitaxel eluting stents (PES) trials. The results of clinical studies involving DES-ISR have not shown similar encouraging results. The results in "de novo" lesions in which a BMS has been also used is somewhat controversial and technology-specific. Although a comparable degree (with PES) in restenosis reduction has been observed, the overall clinical outcomes appear to be similar to the ones reported in PES trials. It is hypothesized, that due to the mechanical interference of the stent with drug transfer, the resulting pharmacokinetic and vascular healing profiles may be different when both technologies are used. Therefore, although the synergistic use of both technologies appears to be logical and technically attractive, large scale prospective comparative data in regards to the implantation of BMS using PCB is still lacking.

Most of the coronary trials involving PCB technologies included a diabetic population comparable to most PES trials (30% to 40%). Although, the results of sub-group analysis of the diabetic population enrolled in some of these trials has been encouraging, large scale head to head studies are still lacking. Ali et al, recently published a paper (Eurointervention, May, 2011) in which a small group of diabetic patients were randomized to the Taxus stent vs. PCB/BMS in the novo lesions. At 9-months, clinical and angiographic outcomes were comparable. Then, it is foreseeable that the positive outcomes seen in diabetic patients with the use of PES may be also achieved by the use of PCB. However, as clinical data emerge, the current clinical application of PCB in the diabetic population must remain limited to applications in which the benefit (i.e., ISR) or safety profile (PCB only) has shown to be proven. Larger randomized clinical trials will hopefully expand the clinical applications of this technology and its role in coronary intervention.

Juan F. Granada
Skirball Center for Cardiovascular Research, Cardiovascular Research Foundation, Columbia University Medical Center, New York, USA

Article by Boston Scientific

Evidence-based Medicine in the Age of Drug Eluting Stents

By Pablo Kantor, MD

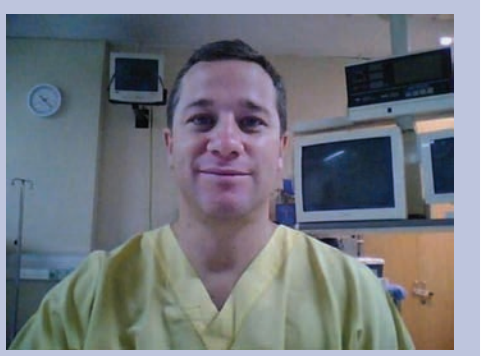
The landing of DES in the world of interventional cardiology brought about a huge number of clinical studies to endorse these devices' safety and efficacy. This is only reasonable: unlike BMS, DES are much more than mere plaque support devices; they are also a transport medium for a given drug to be released in vessel walls, with biologic effects on them depending on the drug features and release kinetics. For this reason, assessment studies for various DES required complex steps such as those taken by the pharmaceutical industry before a drug is launched to the market.

In our capacity as interventional cardiologists, we must thoroughly review this evidence and its clinical outcomes, going beyond old assessment parameters that merely used to catalogue stents as "good or bad" depending on whether they "were easy to deliver" or "crossed the lesion effortlessly."

Studies designed with angiographic end points are an important tool to anticipate, with a small number of patients, possible clinical outcomes to be expected with the use of a given device. Thus, the industry can decide whether to continue to develop a stent or to make changes to improve it. However, these preliminary studies cannot and should not replace studies powered for clinical end points in different scenarios and with appropriate long-term follow up.

Looking back, we may remember certain DES that had to be recalled from the market because their clinical outcomes were not satisfactory. It is important to remember that the recalled DES released exactly the same drug as other DES that remain in use because they had the opposite outcomes. This indicates that a drug does not determine outcomes by itself; instead, it is the platform and polymer used in perfect combination with the drug that determine clinical outcomes. Therefore, can we assume a DES is similar to another just because it releases a given drug without requiring enough studies powered for clinical end points? Can we expect DES to be taken as "generic" assuming that with or without clinical studies their outcomes will be "similar"?

Assessing a given DES entails the risk that companies may have to admit that their outcomes are lower to others with the huge costs involved in such an action. However, in our capacity as interventional cardiologists with ultimate responsibility over the results of our procedures, we must be critical at the time of deciding what devices to use, assuming that certain industries use different arguments to hide the truth: the lack of support studies.



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Staff Physician at the Interventional Cardiology Department, Sanatorio Dupuytren (Buenos Aires, Argentina)
Staff Physician at the Interventional Cardiology Department, Sanatorio Trinidad San Isidro (Buenos Aires, Argentina)
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Article by Meril Life Sciences

New Frontiers in Interventional Cardiology

This year on 8th August 2012 at SOLACI, Meril lunch symposium will showcase exciting new technologies, which are being developed to address several unmet clinical needs.

BioMime MorphTM – Sirolimus Eluting Coronary Stent matches the diameter differentials from distal to proximal in long diffused lesions. This stent system has unique tapering diameters (1/2 sized) and comes in lengths upto 60 mm.

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Article by Biotronik

Industry's First Hybrid Drug-Eluting Stent from BIOTRONIK Demonstrates Clinical Safety and Efficacy

The Orsiro Hybrid DES, which features the latest developments in BIOTRONIK stent technology, is a unique hybrid solution that combines passive and active components. The PROBIO passive coating encapsulates the stent and minimizes interaction between the metal stent and the surrounding tissue. The BIOlute active coating contains a highly biocompatible polymer that delivers a limus drug via a bioabsorbable matrix.

The Orsiro platform is based on the leading PRO-Kinetic Energy bare metal stent, with a thin strut design renowned for outstanding deliverability and conformability. The Pantera based delivery system has been optimized for DES usage and advanced stent crimping technology ensures a low crossing profile (0.99mm) for the Orsiro stent. This system is optimal for a drug coating and allows for maximum coating integrity during expansion. Following treatment with the drug and absorption of the polymer, the patient is left with a passively coated bare metal stent, reducing the potential for any lingering adverse reactions.

BIOFLOW-I was a prospective, multicenter, nonrandomized FIM trial that enrolled 30 patients with a primary endpoint of 9 month late lumen loss (LLL). The objective of the study was to assess the safety and clinical performance of the Orsiro Hybrid DES with both clinical (MACE) and angiographic (LLL) endpoints. At 9 months, the results for the primary endpoint in-stent late lumen loss were 0.05 ±0.22 mm. This result compared favorably with FIM trials of other commercially available DES.

"The results are especially encouraging considering the challenging patient characteristics, atypical for a FIM trial—a medical history including 73% previous MI and 23% diabetic patients," commented Prof. Martial Hamon of University Hospital of Caen, France, the clinical coordinating investigator. "The exceptional deliverability of Orsiro is a necessity with the degree of complex stenting that is performed in current cath lab practice."

BIOFLOW-I demonstrated sustained safety of Orsiro out to 9 months, as indicated by absence of death, stent thrombosis and myocardial infarction (MI). Clinical follow-up for the BIOFLOW-I study will continue annually out to at least 3 years.

For more information about the Orsiro Hybrid Drug-Eluting Stent, please visit www.biotronik.com.

Cardiac Interventions Total Coronary Chronic Occlusion

By Marco V. Wainstein, MD

Introduction

Recanalization of Chronic Total Occlusion (CTO) remains a challenge for the interventional cardiologist. It occurs in about one third of diagnostic catheterization but represents only 10% of all percutaneous coronary interventions. In recent years the development of guidelines and devices, as well as the emergence of new techniques, has led to increased success rates.

Review

Coronary chronic total occlusion is defined as more than three months obstruction of a coronary artery without antegrade filling of the distal vessel. Histologically it consists of varying degrees of atheromatous plaques and thrombus, according to the occlusion mechanism and duration. Percutaneous recanalization of occlusion provides great challenges, including low rates of immediate success, high costs and high risk of restenosis rates. An interventionist approach is justified when ischemia or residual myocardial viability are tested in the irrigated zone by the occluded vessel with satisfactory angiographic characteristics for stent placement.

The impact of drug eluting stents (DES) on restenosis has improved over long-term outcome after successful recanalization of chronic total occlusion (CTO). This procedure requires time and patience from the surgeon, since the patient is exposed to more radiation and contrast. The clinical outcome can be improved in symptomatic patients when recanalization is successful. Much of the evidence from observational studies and some randomized trials suggest that free of events survival is also optimized after a successful attempt to open a chronic coronary occlusion.

The introduction of improved guidelines in recent years, combined with increased surgeon experience and creative procedural techniques such as the retrograde approach and reentry tracking technique (STAR), have significantly reduced the number of coronary chronic total occlusions (CTOs) that otherwise would have been impossible to achieve. Also, new innovative devices have been developed in recent years that may increase the success rate as well as the safety of the procedure. Safe-Cross ® RF combines optical coherence reflectometry that warns the surgeon when the tip of the guide is moving less than 1 mm of the outer wall of the vessel, with the pulses of radiofrequency energy to facilitate path. Crosser® catheter mechanically vibrates against CTO face to 20 kHz at an impact depth of about 20 microns, creating a channel through CTO. The most novel approach is biological, where proteolytic enzymes that digest CTO overlap to facilitate the mechanical passage. Success rates for CTOs, which are otherwise refractory, continue to improve with the development and validation of new imaging modalities and catheters with an active power source. The cause of unsuccessful percutaneous coronary intervention is usually due to guide inability to cross CTO site, or a failure to adequately dilate or modify injury. The Frontrunner ® micro-dissection device was designed to improve the chances of guide passage through the coronary occlusion, while the device Rotablator ® of rotational atherectomy was designed for the modification of the plate, especially in resistant, elastic or calcified lesions. Both Frontrunner ® and Rotablator ® can facilitate this procedure. Combined use of these technologies can improve success rates of PCI, especially when dealing with complicated cases of CTOs. Regarding guide selection, generally CTOs must be treated with hydrophilic and/or Springwire ® guides, preferably from the Miracle ® and Conquest Pro ® (Asahi Intec) series and CrossWire ® (Terumo). According to the penetration strategy, blood vessel course with CTO is set before procedure and guide is advanced based on image data with a minimum rotation (torque of +/- 90 degrees or less). If the surgeon finds a divergence between the pre-process image of CTO and the actual course of the coronary artery, a parallel guide must be used. With this method the guide that penetrates subintimal space remains and the second guide is placed in search of a new channel.

Conclusion

Successful recanalization and percutaneous revascularization of coronary arteries with chronic total occlusion (CTO) is one of the "last frontiers" in coronary interventions. Despite the remarkable technological innovations and improved results obtained with percutaneous coronary revascularization, chronic total occlusions of coronary arteries are still a familiar source of frustration in procedures and carry a lack of clinical conviction. However, considering the recent development of specific catheter-based technologies for recanalization of chronic total occlusions and the drug-eluting stents potential to reduce restenosis and reocclusion, this subset of lesions is now recognized as the last barrier to percutaneous revascularization. In addition, other observations from recent clinical studies confirm the success of CTO revascularization to prevent subsequent adverse cardiac events and improve long-term overall survival.

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Hospital de Clínicas de Porto Alegre, Federal University of Rio Grande do Sul.

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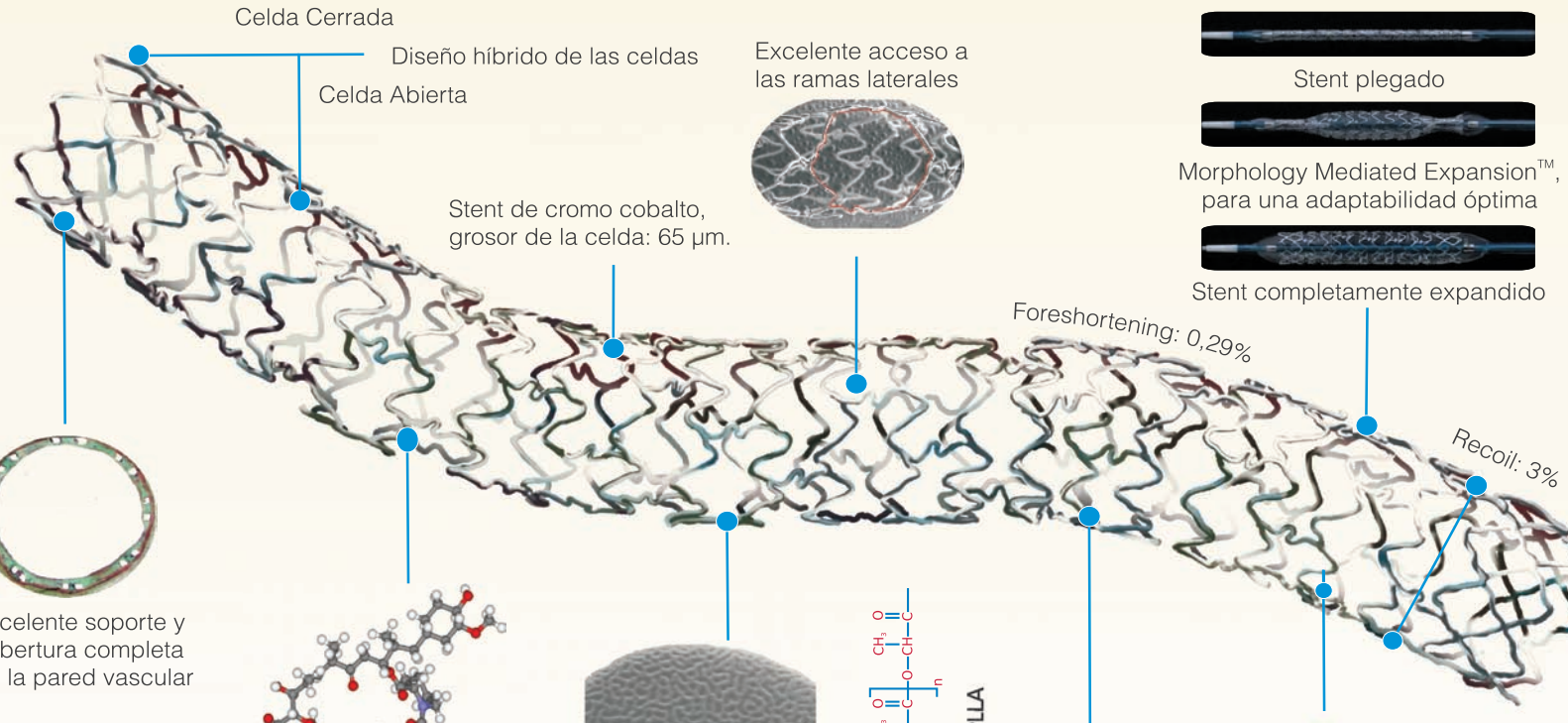

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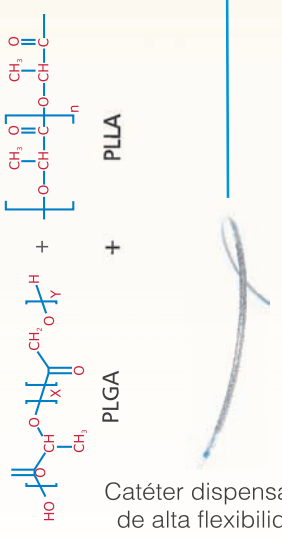

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