IR congress news

CIRSE 2006 - Rome
Monday, September 11, 2006

Josef Roesch Lecture

Monday, September 11, 14:30-15:15, Aula Magna

The CIRSE Roesch Lecture, established in 2003, honours Professor Josef Rösch, whose award-winning research work spans more than 50 years, covering a wide range of Vascular and Interventional Radiology. Two of his most notable achievements are the development of the TIPS technique in 1969 and the introduction of embolization into the treatment of gastrointestinal bleeding in 1971. To this day, Professor Rösch continues his work on the development of new techniques and devices for interventional treatment.

This year's Roesch Lecture will be given by a physician whose vision for IR is no less promising: Dr. Lindsay Machan. The co-founder of Angiotech Pharmaceuticals and consultant to the scientific advisory board of multiple medical device companies will speak about "Drugs and Devices - Challenges and Opportunities for Interventional Radiology".

CIRSE Foundation Party

Tuesday, September 12, 20:00
Last chance to buy your tickets

Enjoy an exquisite dinner accompanied by an outstanding entertainment programme at the fund raising party in aid of the CIRSE Foundation. The yearly event has become one of the social highlights of our meetings, providing the perfect opportunity to get together with old friends and meet new colleagues.

This year's Foundation Party will take place at Villa Miani, a wonderful mansion in Victorian style on the slopes of Monte Mario. It is immersed in a beautifully kept garden and offers a unique panorama overlooking the city of Rome all the way to St. Peter's Cathedral.

If you are interested in joining us for the Foundation Party, please contact the Kuoni booth in the registration area. Since the number of tickets is limited, we recommend early booking.

Drugs and Devices

Challenges and Opportunities for Interventional Radiology

Lindsay Machan
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Vancouver, Canada

The powerful advantages conferred to the patient by fluoroscopically guided minimally invasive procedures are well known to all interventional radiologists. However, in many cases the longevity of interventional procedures is, or is perceived to be, less in comparison with major surgical procedures. Thus most interventional procedures at present can be considered temporizing procedures. Adding pharmacologic or biological activity to a device ("drug - device combinations") can potentially improve the efficacy and longevity of minimally invasive procedures. In some cases procedures which are at present palliative could even become curative. In addition to extending the number of patients to whom they can be applied, the procedures are made even more attractive to patients and referring clinicians and more acceptable to paying agencies.

Drug - device combinations are not just being applied to minimally invasive procedures, they are being developed for virtually every area of medicine[1]. These include antimicrobial wound care products, bone graft substitutes, antibiotic bone cements, antimicrobial catheters, photodynamic therapy, pastes and sprays for prevention of post surgical adhesions, wound closure enhancers and regional gene therapies, among many others. The global market for drug-device combinations was approximately $5.4 billion in 2004 and is expected to rise at an average annual growth rate of 13.6% to $11.5 billion in 2010 [2].

A number of biologically active devices have been developed for minimally invasive therapy. The most well known of these are drug eluting stents[3], but a far from complete list also includes drug releasing embolic particles, coated embolic coils, targeted embolization agents, pharmacologic agents to optimize ablative procedures , ultrasound and energy assisted thrombolysis, implantable venous valves, coated stent grafts, anti-infective central lines, and self sealing biopsy devices. The range and diversity of biological activities associated with these devices is breathtaking. Coating a stent graft with a sclerosant or substance which induces a mural reaction might improve long-term outcomes by addressing in particular endoleaks, device migration and disarticulation. Using focused energy such as ultrasound or heat allows systemically subtherapeutic doses of otherwise toxic drugs to be released at therapeutic concentrations at the site of a percutaneous intervention to accentuate tissue ablation and potentially prevent local recurrence. Other materials such as porcine intestinal submucosal can act both as a scaffold and deliver cytokines for controlled regional tissue growth or replacement, or building upon the success of islet cell transplantation, exogenous cellular implants are being delivered by minimally invasive image guidance.

Drug eluting stents have been described as a transforming technology. They have decreased the number of referrals to cardiac surgeons as well changing the types of patients being referred[4]. They have also transformed the business of medical devices and the science by validating the concept that adding biological activity to a medical device can improve its performance, and by showing that it is possible to have such a device approved for clinical use while being financially viable. These hurdles had to be overcome before postulated therapies made possible through the merger of physical, biological and medical advances occurring over the past decade could be reduced to practice.

Multiple lessons have already been learned about the use of drug eluting stents outside the coronary circulation. It is clear that the remarkable success of drug coated balloon expandable stents in mid-sized coronary arteries cannot be repeated by merely applying the same drugs in the same manner in other arterial beds, and that considerable further research is necessary before their role in peripheral vascular and non-vascular disease can be defined. The SIROCCO trial of sirolimus coated self-expanding stents in the SFA taught us that the same profound inhibition of intimal hyperplasia can be achieved as in coronary arteries at 6 months. Nevertheless, a durable effect is quickly lost because of the very different milieu of the superficial femoral artery[5]. In the GREAT trial of balloon-expanded sirolimus stents we saw that while a reduction of restenosis was achieved (albeit less marked than in other drug eluting stent trials), this did not positively impact the clinical outcome of the patient[6]. For the first time in endovascular stenting, we have a potentially commonly used technology which is so expensive to develop and test with the rigor required of pharmaceutical agents, that even if efficacy can be demonstrated in preclinical testing, economics may prevent many applications from becoming clinical reality.

Drug -device combinations have a much more complex regulatory pathway in comparison with simple devices (Table 1). This presents unique challenges for device companies, not the least of which is that most device companies may not have the financial resources or skill sets to develop a given device from concept to approved product. One of the features of Interventional Radiology which makes it so attractive to its practitioners is the diverse number of methods of treatment we perform. This results in many individual procedures, many of which do not generate markets of sufficient size to allow companies to recover the investment necessary to develop an approved product. This may steer companies to choose to develop drug - device products for other specialties, particularly those who embrace new technologies and exploit practice opportunities enthusiastically.

In order to fully explore the potential of these biologically active therapies, more complex imaging will be required[7]. To best assess the endpoint and the effect of the therapy as well as distribution of all injected materials and their breakdown products will require accurate anatomic and functional information. At present, for most institutions this implies performing delayed contrast-enhanced cross-sectional imaging or possibly PET scanning. To optimise these therapies, it would seem that a real-time solution is necessary. There are multiple technologies that may accomplish this. One of the most promising for interventional procedures is fusion imaging. Image fusion allows data sets from one cross-sectional modality, such as MR, to be simultaneously displayed with simple real-time imaging such as fluoroscopy or ultrasound or pre and post interventional imaging to be simultaneously displayed[8]. Most of these will require imaging knowledge and skills which play to the strengths of radiologists.

Summary
A spectacular array of drug - device combinations have appeared on the horizon promising to improve and expand existing interventional procedures and further titillate the ever growing patient desire for minimally invasive treatments. Regulatory and financial issues will impact their development and distribution to a far greater extent than IRs have seen in the past with non-coated devices. Interventional Radiology meetings increasingly include gloomy sessions lamenting loss of market share due to a perceived lack of patient care skill sets. Skills which radiologists do possess and can exploit to advantage over most clinicians is the ability to interpret the advanced imaging, which will be necessary - initially as part of a tortuous regulatory process and later to use these devices to their full capability. Like any advantage, if not exploited, it will prove to be temporary.

References:

1. Wu P, Grainger DW. Drug/device combinations for local drug therapies and infection prophylaxis. Biomaterials. 2006;27:2450-67.
2. Report RB-205 Drug Device Combinations, Business Communications Company, Inc. (www.bccresearch.com).
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4. Liddicoat J, De La Torre R, HoK et al. Initial Impact of Drug-Eluting Stents on Coronary Artery Bypass Graft Surgery. Ann Thorac Surg 2006;81:1239-1242.
5. Duda SH, Bosiers M, Lammer J, et al. Sirolimus-eluting versus bare nitinol stent for obstructive superficial femoral artery disease: the SIROCCO II trial. J Vasc Interv Radiol. 2005;16:331-338.
6. Rabbia C. The Palmaz Genesis Peripheral Stainless Steel Balloon Expandable Stent in REnal Artery Treatment (GREAT) trial. Presented at 2005 Cardiovascular and Interventional Radiology Society of Europe Annual Meeting, Nice, France.
7. Daldrup-Link H, Simon G, Brasch R. Imaging of tumor angiogenesis: current approaches and future prospects. Curr Pharm Des. 2006;12:2661-72.
8. Fujioka C, Horiguchi J, Ishifuro M, et al. A feasibility study: evaluation of radiofrequency ablation therapy to hepatocellular carcinoma using image registration of preoperative and postoperative CT. Acad Radiol. 2006;13:986-94.

FACTOR	DEVICE	DRUG
Rate of technology change	Rapid	Slow
Number of pivotal trials typically required for approval	1	2
Typical pivotal study sample size to support FDA approval	500–1000	1000–3000
Reimbursement during clinical trials	Frequent	Rare
Influence of physician technique on clinical results	High	Low
Criteria for orphan status (treated patients/year)	4000	200,000

Table 1: Regulatory differences between devices and drugs

The IR Suite of the Future: How many tools can we integrate?

IR/OR Suite of the Future
Special Session 31
Monday, September 11, 10:15-11:30
Room F

Michael D. Dake
Professor of Radiology, Medicine (Pulmonary Disease), Surgery;
Chairman of the Department of Radiology,
The Harrison Medical Teaching Professor of Radiology,
University of Virginia Health System

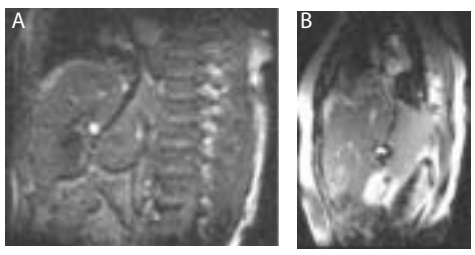

Figure 1: MR-guided puncture of portal vein during TIPS procedure
Figure 1a: Gradient recalled echo (GRE) MR image of needle entering the portal vein of a patient undergoing TIPS for portal hypertension and bleeding varices
Figure 1b: Steady state free precession (SSRE) MR image of needle puncturing the portal vein during TIPS

Recent developments in imaging technology have enabled new procedural opportunities in Interventional Radiology. During the first 10 to 15 years of the specialty's emergence, there was a rapid growth in catheter-based diagnostic angiography and non-vascular percutaneous interventions. Early vascular interventions, although less frequent in terms of case volume, included embolization procedures, often to address gastrointestinal hemorrhage. Subsequently, during the next period of specialty development (1980 to 2000), a dramatic expansion in the volume and spectrum of endovascular interventions was experienced. In concert with this trend in the early 1990's, new non-invasive vascular diagnostic modalities, including spiral CT and MR angiography, burst onto the scene.

Consequently, a distinct change occurred in the relative proportions of conventional diagnostic arteriograms and catheter-based vascular interventions performed. This shift to an expanding volume of endovascular therapy and a diminishing frequency of catheter angiography in favor of non-invasive vascular imaging continues. However, in the last few years it is increasingly clear that IR is poised to enter an interesting new procedural phase that will combine both diagnostic (non-invasive and catheter-based evaluations) and interventional vascular encounters in one physical location or suite. The development of multi-modality approaches that fuse the diagnosis and treatment of patients into imaging algorithms at a single site provides new potential opportunities for improving operational efficiencies.

The combination of MR and conventional fluoroscopy and angiography; integration of CT and angiographic units; refinement of high-speed rotational angiography and the emergence of dual energy source CT and fluoroscopy have created a new range of procedures that are being actively explored. Indeed, the current challenge for imaging equipment manufacturers and clinicians is no longer one of identifying new imaging technology, but defining the operational processes that optimally utilize combinations of imaging modalities to deliver incremental benefits to health systems and patients by more efficiently, safely, and economically evaluating and treating their disease. In this regard, initial experience has examined a number of multi-modality exam sequences that demonstrate promise and eagerly await further investigation to better understand the potential value.

The future also may include a marriage of intervention with new diagnostic studies capable of enhancing tissue differentiation (dual source CT) and evaluating tissue function (PET/CT and MR/PET). Currently, investigators are just beginning to explore the surface of what new opportunities will soon exist to increase procedural efficiency, accuracy, convenience, safety, speed, comfort, and ultimately, a better overall experience for patients than now possible with a traditional management sequence split between work-up and treatment stages separated in time, place, etc.

Simple initial pilot studies at a variety of centers around the world have provided proofs of principle validation for some of the novel opportunities that differentiate this concept of blending multi-modality diagnostic and therapeutic exams into a single encounter at a single locus. Examples include rotational angiography for improved real-time planning of inferior vena cava filter insertion; MRA of lower extremity run-off immediately prior to an expected endovascular intervention; MRA via a superior mesenteric artery catheter to evaluate hepatic arterial supply in conjunction with chemoembolization of liver tumors (Figure 1); MR guidance for TIPS creation with integrated fluoroscopic monitoring of stent placement 1, high speed rotational angiography with three-dimensional multi-planar reconstructions to facilitate a spectrum of endovascular and non-vascular interventions, etc.

It is inevitable that widespread further experience will develop a broader scope of high impact applications while identifying those that deliver objective value to patient care. Indeed, the challenge over the next few years will be in better defining the optimal operational role of these multi-modality combination processes in the IR practice.

References:

1.Kee ST, Ganguly A, Daniel BL, Wen Z, Butts K, Shimikawa A, Pelc NJ, Fahrig R, Dake MD. MR-guided transjugular intrahepatic portosystemic shunt creation with use of a hybrid radiography/MR system. JVIR. 2005 Feb;16(2 Pt 1):227-34.

"ER for AAA: an overview of the current status"

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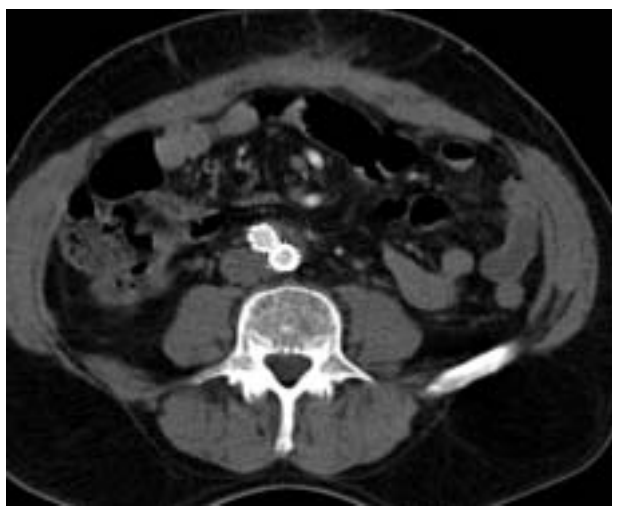


Figure 1: Surveillance CT at 6 years after successful ER showing nearly complete resolution of the aneurysm sac

More than fifteen years have passed since the original description of endovascular repair (ER) for aortic aneurysms in very unfit patients (Parodi, Ann Vasc Surg, 1991). During this time great technological advances have been made both in terms of the devices used in ER and in the imaging assessment of aortic anatomy and pathology. However, as has been the case during the introductory phase of many new procedures, the gathering of meaningful "level 1" evidence in support of the new technique has lagged behind clinical practice. Fortunately, the EUROSTAR registry was started soon after the introduction of ER in Europe and stimulated publications that have demonstrated the general level of safety and efficacy of the technique. None the less, any complacency on the part of enthusiasts for ER has been dispelled by registry evidence of the rate of failure of the early endovascular devices and a persistent small incidence of AAA rupture (Harris, J Vasc Surg, 2000).

RANDOMISED TRIALS

There are several large national multi-centre RCTs of ER versus open repair currently ongoing in Europe and North America. The early outcomes of the 2 first European trials were published in 2004, the UK EVAR trials in the Lancet and the Dutch DREAM trial in the New England Journal of Medicine. These studies clearly demonstrated the anticipated reductions in peri-operative mortality, hospital stay and (transiently) in health related quality of life measures. In fact, the gain in terms of improved peri-operative mortality was actually very large, a three fold reduction in the ER groups compared to the open surgical controls in both RCTs. The DREAM trial result did not reach statistical significance, almost certainly because the trial groups were too small. Most centres practising ER within the NHS in the UK continued to randomise cases after the appearance of the early results, or at least continued to perform cases and submit to the registries.

MID-TERM RESULTS

The follow-up data from these two trials appeared in the same journals in June 2005. After the passage of a further 15 months, the status of ER as a mainstream treatment actually appears untouched now. While this would be no surprise to the stent-graft enthusiast, the mid-term results have actually stimulated great controversy. Both trials showed that the early mortality gain in the ER groups were not associated with any significant change in all-cause mortality at 2 years (10% in both study groups of the DREAM trial) and 4 years (28% across the EVAR trial groups). There was a greater incidence of 'complications' during the follow-up of ER, but many of these did not require re-intervention and there was no additional mortality.

It has been persistently argued that the absence of a reduction in all cause mortality in the ER group at 3 years, whilst the aneurysm related mortality remained 3% less, indicates that ER has been an expensive failure, because no additional lives appear to have been saved. This argument overlooks the fact that the patient can be offered a technique associated with a risk of peri-operative death that is 3 times lower than that of the conventional, open operation. After all, the aim of AAA repair is to reduce the future chances of an aneurysm rupture. The performance of a prophylactic operation to remove the threat of an aneurysm rupture, whether by conventional open repair or ER, cannot remove the associated risk of cardiovascular death that is the constant companion of every atheromatous aneurysm.

COSTS OF ER

Aortic stent-graft devices are extremely expensive, an average of €7,400, and account for the major part of the Interventional Radiology budget in most major vascular units. The individual sections of stent-graft that may be required to repair such devices during follow-up are also proportionately expensive. The EVAR trial analysed the costs both of the primary procedure and the follow up period and estimated a mean added cost of £3,300 for ER over 4 years. This additional cost per patient clearly has a direct relationship with the cost-effectiveness of ER and has been used as an argument against the widespread funding of the technique as a routine treatment. Since devices and introduction systems are still in a phase of continued development, the overall production costs have not diminished. However, this is clearly an aspect of ER that will have to be resolved with the device industry if the technique is ever to be applied as a routine part of clinical care in the future.

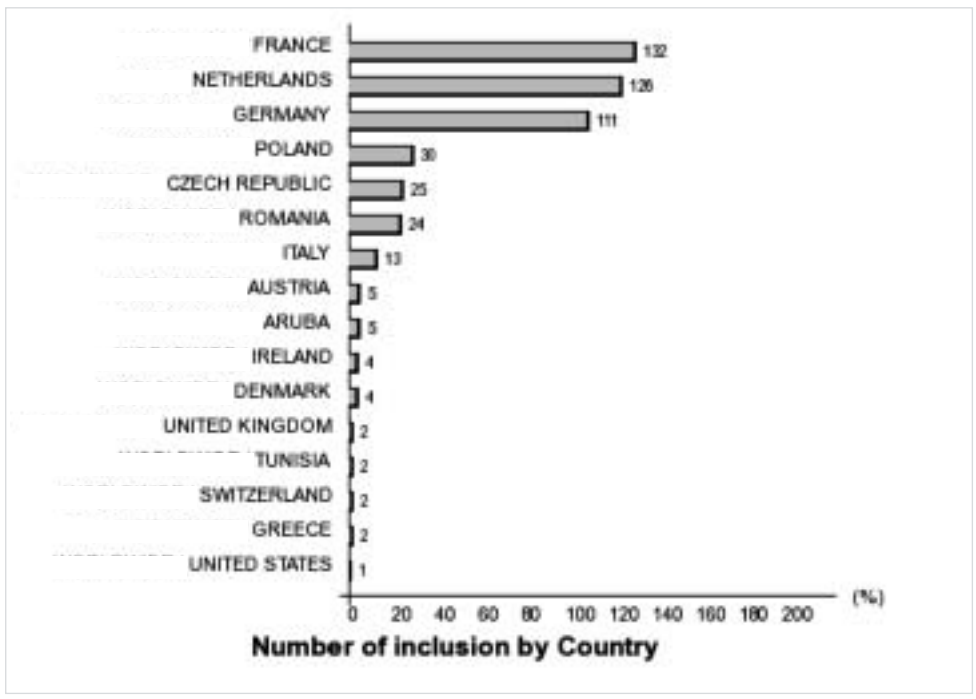
CURRENT TRENDS

The current status of ER is still that of an investigational technique which is undergoing a gradual evolution. Continuing technological development has produced fenestrated and branched stent-grafts and there is no doubt that the clinical applications of such devices will become better defined over the next year. The use of ER for ruptured aneurysms is also attracting increasing levels of interest, the provision of adequate levels of trained staff (out of hours) being the limiting factor in most units. Hybrid procedures combining open and endovascular repair for thoraco-abdominal aneurysms are also on the increase. The current fashion for monitoring endovascular devices with CT seems unlikely to be tenable in the long-term because of the radiation penalties. MRI is not suitable for monitoring purposes in at least half of the devices presently being deployed. It should soon become possible to significantly reduce the frequency of detailed device scrutiny, if anticipated performance improvements are demonstrated within the registries and trials. In the meantime, evermore ingenious methods of non-invasive monitoring are under investigation (Ellozy, J Vasc Surg, 2004).

The continuing analysis of data in the public domain, from the international registries and the trials mentioned above, has provided great publicity for the use of ER and this has reached the attention of the general public, certainly those millions with access to the internet. There has been a noticeable increase in the number of aneurysm patients who already have knowledge of stents and are anxious to avoid open surgery. These patients cannot be told that ER is better than OR on the basis of the currently available evidence. However, the trial results do give further credence to ER while discussing all the treatment options as part of the consenting process.

The UK EVAR trial has been additionally funded to provide longer term follow-up data and this should further inform the debate over the next 4 - 5 years. By this time, medium term results from the current French and American RCTs should also be available. Despite the lack of long-term data, it seems that the numbers of ERs are increasing and it is very important that each such procedure is registered and followed up. There is still a need for additional evidence and thus each ER case, if not within an RCT, should at least be entered into a national registry and undergo regular imaging surveillance.

CIRSE Foundation UFE Registry



Registry inclusion is running high. As of beginning of August 2006, participation across Europe has already resulted in 488 patient entries.
The mean age of patients entered currently stands at 42.52 (SD 15.55). Prior to embolisation patients complained of heavy menstrual bleeding (68.19%), bulk related symptoms (19.17%), and intermenstrual or menstrual pain (9.80%). 12.3 % of patients had undergone previous myomectomy. The mean pre-embolisation uterus volume was 572.65 cm^3. A microcatheter was used in 77.75 % of cases.

Recruitment of patients for the CIRSE Foundation UFE registry is continuing. The registry is designed to allow for carefree and time-efficient inclusion of all consecutive patients undergoing UFE performed by CIRSE members. A short electronic questionnaire can be filled in within a few minutes and follow-up is limited to key issues. Entry of more extensive data capture is also possible including a quality of life and a pregnancy questionnaire. All data entered by an individual site can be downloaded for statistical analysis and research purposes in excel format.

With follow-up still pending and enrolment still open CIRSE Foundation invites all CIRSE members to participate and enter their patients. For newcomers go to www.cirse.org and click on Foundation, then Registry, or simply go to www.uferegistry.com

The Principal Investigators

T.J. Kröncke *P. N. Lohle* *J.P. Pelage* *M. Sapoval*

This registry was made possible through the generous support of Terumo, Biosphere Medical, and Boston Scientific.Medical.

Advertorial

TALENT™ AAA Stent Graft - A leading stent graft technology that has improved over time.

In February 2006, the TARL (Talent AAA Retrospective Long term) study was published in the Journal of Vascular Surgery . The analysis was performed on 165 patients treated with the first generation TALENT AAA stent graft in 9 centres in Germany from 1996 to 1999. The mean follow up period was 53 months, with a maximum follow up period of up to 7 years. The study showed similar or superior outcomes achieved with the TALENT AAA stent graft compared with first generation stent grafts. The results also correlated well with those previously published in single centre studies .

Although the first generation of TALENT AAA did perform very well over time, a series of technological enhancements have been implemented over the last 10 years, which have improved the conformability and durability of the stent graft, as well as the accuracy and ease of use of the delivery system.

The first human implant with TALENT AAA in Europe was performed in 1996. Then, The LPS material was introduced in 1999 and provided a lower profile. In 2000, the CoilTrac delivery system was launched with an improved flexibility. In 2002 Medtronic began to apply a chemical surface treatment of the Nitinol springs to increase durability and changed the connecting bar in order to improve conformability. The UniDOC system was also introduced making TALENT more versatile. In 2004, Medtronic introduced TALENT AAA with the XCELERANT delivery system, which improved trackability, accuracy of delivery and ease of use. Recently, new standard sizes have become available to treat larger anatomies with proximal diameter up to 36mm.

Thanks to Medtronic's experience of working with physicians on more than 100,000 implants worldwide, and to this continuous innovation programme, TALENT AAA has become the most implanted stent graft in Europe. It has proven to be a reliable technological platform for stent grafting of abdominal aortic aneurysms, as results from the TARL study have shown.

Medtronic is committed to investing in endovascular therapy to help physicians treat more patients with easy to use and reliable technologies.

Please come to the Medtronic booth at CIRSE to learn more about long term outcomes with the TALENT AAA stent graft.

1Torsello G et al, Long-term outcome after Talent endograft implantation for aneurysms of the abdominal aorta: a multicenter retrospective study. J Vasc Surg. 2006 Feb;43(2):277-84.
2Espinosa G et al, Six-year experience with Talent stent-graft repair of abdominal aortic aneurysms, J Endovasc Ther. 2005 Feb;12(1):35-45.

Experience, the Foundation of Innovation

Over 10 years, Medtronic has been a pioneer and leader in the development of endovascular technologies. With more than 100,000 implants worldwide, our experience has allowed us to innovate and launch leading stent graft technologies such as TALENT™AAA and VALIANT Thoracic Stent Grafts. Our commitment is to help you treat more patients every day with easy to use and reliable technologies.

HEART AND VASCULAR DISEASE • NEUROLOGICAL DISORDERS • PAIN • SPINAL DISORDERS • DIABETES
UROLOGIC DISORDERS • DIGESTIVE SYSTEM DISORDERS • EYE, EAR, NOSE AND THROAT DISORDERS

Medtronic
Alleviating Pain · Restoring Health · Extending Life

How I do it: Proximal and Distal Approach

Roberto Gandini
Dept. of Diagnostic Imaging, Molecular Imaging Interventional Radiology and Radiation Therapy
University of Rome Tor Vergata

The incidence of critical limb ischemia is estimated to be 50-100 per 100,000 every year and has always been considered a primary indication for bypass surgery[2,3,4]. Limb salvage rates > 90% at one year are reported in contemporary series using bypass surgery. Unfortunately adequate vein is often unavailable and long-term results of bypasses constructed with prosthetic materials are much less satisfactory[5,6]. In recent years the use of PTA as a primary treatment for CLI has been increasing due to the continuing advances in imaging techniques, angioplasty equipment (such as low profile balloons and new guidewires) and endovascular expertise[7].

The clinical advantages of PTA are well established, especially for high-risk, elderly and vascularly compromised patients: there is no need for general or spinal anaesthesia, there are no or fewer surgical wounds especially dangerous in diabetic patients, the hospital stay is shorter, complication and mortality rates are low[8,9] and a failed PTA attempt does not preclude a subsequent by-pass graft[10]. In patients treated to avoid a major amputation due to CLI the first and most important aim is limb salvage. This can only be achieved by obtaining a direct flow to the foot.

Despite the existence of several studies that show the predominant role of PTA as primary choice for CLI treatment, the same also report high rates of technical unfeasibility in these patients. For example; in a study including over 219 selected patients submitted to endovascular treatment, the feasibility rate was 87.2% while in the remaining 12.8% the procedure was unfeasible[9]. In the audit of the Basil study, out of the 456 patients with infra-inguinal CLI presenting to the top six UK recruiting centres, only 70 (29%) were suitable for randomisation into the study. The remaining 386 patients did not qualify for randomisation and 75 (16%) of these were considered technically unsuitable for angioplasty[10]. In a recent study in 1188 diabetic patients undergoing revascularisation, PTA was performed in 83,6% while in the remaining 16.4% the procedure was unfeasible due to complete calcific vessel occlusion not allowing the passage of the balloon catheter[11].

In our experience, the use of different endovascular techniques including peripheral approaches (such as trans-popliteal and/or trans-pedal), adequately selected for each patient, allows to increase the indication for PTA to approximately 97% of the patients. Between June 2001 and June 2005 we treated 469 (305 males, 164 females; mean age: 69.5 years, range: 34-82 years) consecutive diabetic patients with deep chronic foot ulcers complicated by ischemia and infection by endovascular revascularisation. The patients were classified according to the University of Texas Diabetic Wound Classification System (16) as: stage II B in 48 (10.23%), stage II C in 59 (12.57%), stage II D in 81 (17.27%), stage III A in 12 (2.56%), stage III B in 85 (18.12%), stage III C in 95 (20.25%) and stage III D in 89 (19%) patients. Most of the patients were candidates for major amputation. Our treatment protocol, regardless of the length, number and localisation of the obstructions, involves an attempt of PTA revascularisation in all diabetic patients with stenotic and obstructive vascular lesions of the lower limb (iliac, superficial femoral and infrapopliteal artery obstructions). The lack of visualization of the vessel at the plantar arch and/or of the pedal artery was the only real criterion of exclusion. The 469 patients were all insulin-dependent dibetics. The risk factors for cardiovascular disease, besides diabetes, were smoke in 335 (71.43%) patients (225 ex smokers), hypertension in 426 (91%), dislypidemia in 89 (18.9%), chronic renal failure with hemodialysis in 58 (12.5%), coronary artery disease in 164 (35%), of whom 35 had already undergone aorto-coronary by-pass.

An angio-MRI examination indicated 12 patients had an IA obstruction, 41 patients had a segmentary obstruction of SFA and of the PA, 299 patients had an obstruction of the AT, PT and the IA; 102 patients had an obstruction both of the SFA and the PA and of limb vessels (AT, PT and IA); and 15 patients had an obstruction of PT at the plantar arch or pedal artery. In 36 patients with infra-popliteal artery obstruction, antegrade recanalisation through the transfemoral access was impossible. In these patients revascularisation of the obstructed vessels was performed using a "double approach", with a proximal access at the common femoral artery and a distal access at the foot. The distal access was the pedal artery in case of the revascularisation of the anterior tibial artery and the distal segment of the posterior tibial artery in case of the revascularisation of the posterior tibial artery itself. The cases requiring this type of "double approach" had at least one of the following conditions: 1) occlusion of the three leg vessels from their origin; 2) popliteal artery obstruction the lesion could not be passed or the vessel's origin could not be reached by an antegrade approach; 3) a large collateral vessel which could be confused with the proximal segment of one of the main leg vessels; 4) impossibility to re-enter into the true lumen of the vessel once the lesion was passed using subintimal angioplasty technique.

When there is an obstruction of the SFA or popliteal artery with just a single patent vessel in the leg, the "double approach" is the best technique to be used in order to optimize the results when we have a good inflow with only a single good outflow. Distal puncture has to be performed in a patent arterial segment with an adequate calibre and a slow blood flow using US guidance only for non-calcified arteries. In cases with heavily calcific arteries, US guidance is useful to detect the vein and therefore facilitate the orientation of the needle during puncture under fluoroscopic guidance. The rest of the procedure is carried out under fluoroscopic guide. In 22 out of 36 cases, the distal puncture was made using a 20-gauge micropuncture needle kit followed by the introduction of the PT Graphix Super Support guide wire; in 11 cases the puncture was made with an 18-gauge needle followed by the insertion of a hydrophilic 0.035 in. guide wire; only in 3 cases a short 4F introducer sheath (Terumo) had to be used to give additional support to the guide wire. After the introduction of the guide, this has to be advanced until the occlusion is passed. Subsequently, using the "rendez-vous technique" the tip of the guide has to be inserted into the catheter placed through the femoral access.

In 2 particular cases with sever alterations of lower limb vessels, a double distal puncture was performed: in one case of the anterior tibial and posterior tibial artery and in the other of the posterior tibial and peroneal artery. In both cases we obtained a direct flow to the foot. No complications related to distal puncture occurred. In 4 cases, despite of the passage of the guide wire from the distal patent vessel to the proximal patent vessel and the execution of a prolonged PTA, a direct flow could not be established, probably due to a dissection or another obstacle that could not be detected. Maybe this problem could be solved in the near future by using dedicated long stents. In these 36 cases, 80% of which were IIID/IIIC stage, we obtained a 100% technical success for recanalisation, an 89% technical success for PTA (due to the 4 cases of probable dissection and the 2 major amputations due to osteomyelitis despite of a successful PTA). Limb salvage rate in these patients was thereby 83%. This technique was associated to a higher technical success rate (96.8%) and allowed to increase the rate of limb salvage. The feasibility of this procedure is very high considering that it was performed consecutively in our entire patient population with the only contraindication being the absence of flow in the pedal artery and the plantar arch. Furthermore our technique is associated to lower costs when compared to vascular surgery, as demonstrated by the BASIL trial[1].

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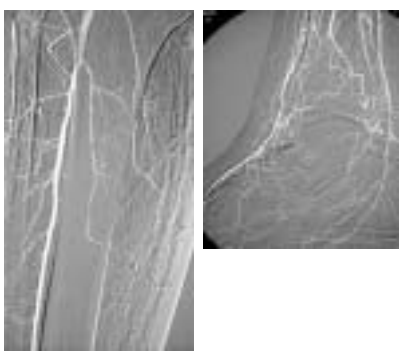


Figures 1a,1b: Preliminar angiography shows a patent peroneal artery with occlusion of anterior tibial artery at the origin and proximal occlusion of the posterior tibial artery with patent pedal artery and plantar arch

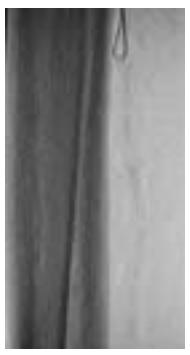
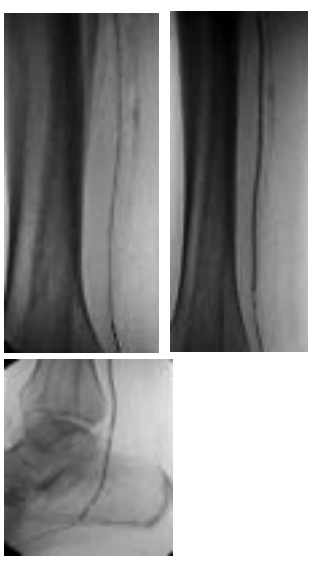


Figure 2: Recanalization of posterior tibial artery was not possible with either endoluminal or subintimal antegrade approach

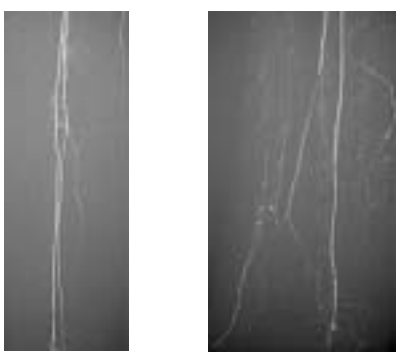
Figures 3a,b: Puncture of the distal segment of the posterior tibial artery using a 20 Gauge needle

Figure 4: Advancement of the guide wire in the true lumen delimited by the calcific vessel walls

Figure 5: Rendez-vous



Figures 6-8: PTA of the posterior tibial artery form its origin to the plantar arch using a 2-mm-diameter and 12-cm-long balloon catheter



Figures 9-10: Post-procedural angiography showing the normal patency of the posterior tibial and peroneal artery

Cerebral Protection Devices in CAS

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Carotid artery stenting (CAS) can nowadays be considered a valid therapeutic option for the treatment of stenoses of the extracranial carotid artery. However, this procedure has an incidence of neurological complications due to distal embolization ranging from 3,2 % to 10 %[12]. In order to reduce the rate of periprocedural neurological complications, various cerebral protection systems have been proposed, the purpose of these system being to capture the emboli before they can reach the brain.

The first system was described by Théron[3] in 1990. He introduced the concept of prevention of cerebral embolization and employed temporary balloon occlusion of the distal internal carotid artery (ICA) during percutaneous transluminal angioplasty. Since this initial experience, several studies have been carried out using different protection devices, which have showed a reduction of the neurological periprocedural complication rate. The global carotid artery stent registry described a perioperative stroke and death rate of 5.9% in procedures performed without protection devices compared to a rate of 2.23 % in those carried out with the devices[4]. Boltuch et al.[5] evaluated 651 patients treated both with (N=180) and without (N=471) cerebral protection and found better results for the protected population; technical success: 99% vs 95%; complications rate: 10% vs 18.3%; TIA: 2.8% vs 3.2%; MAE: 0.6% vs 2.1%.

Cerebral protection devices (CPD) can be dividend into three different types: filters, distal occlusion balloons and proximal protection systems. In filter systems, flow is maintained and emboli are captured and removed together with the device by retraction of the system. Balloon occlusion devices and proximal protection systems block the flow into the ICA and emboli are aspirated before balloon deflation and catheter removal.

Distal Occlusion Balloons

Distal Occlusion Balloons consist in a 0.014" guide-wire equipped with a distal balloon that is inflated through a small channel present within the wire. Once the lesion is crossed with the guide-wire, the balloon is positioned above the lesion and inflated in order to completely occlude the ICA, thus avoiding the passage of microemboli. After treatment of the lesion, a catheter is advanced up to the balloon and the blood proximal to the balloon, possibly containing the debris dislodged from the atheroma, is aspirated and removed. The advantages of this type of CPD are the very low profile (2.2 FR), the good flexibility and torquability of the system. On the other hand, as this system produces a complete occlusion of the ICA, that cannot be tolerated in 6-10% of the patients[7].

Filters

Filters consist of a metallic structure coated by a membrane of polyethylene which can have different shapes. The membrane presents several holes with a diameter ranging from 80 to 220 µm (Fig.1). Once the lesion is crossed, the filter is opened in the ICA lumen and then retrieved at the end of the procedure. As filters produce a marked reduction of the flow within the ICA, they should not be left in place for more than 15 minutes. Different types of distal filters are now commercially available: Angioguard XP (Cordis-Johnson & Johnson), FilterWire EZ/EX Embolic Protection System - EPI (Boston Scientific), Spider TM (EV3), AccuNet Rx Embolic protection Device (Guidant), Rubicon Filter (Rubicon), MedNova EmboShield Cerebral Protection System (Abbott), Interceptor (Medtronic), Trap filter (Microvena). Others are currently being developed.

Proximal protection systems

Proximal protection systems provide complete protection avoiding any passage of the devices through the lesion. These systems are based on the inflation of an occlusion balloon at the level of the common carotid artery (CCA) and at the origin of the external carotid artery (ECA), causing inversion (Parodi system) or the complete stop of the flow (MOMA) within the ICA. After occlusion of the common and external carotid artery, the collateral flow through the circle of Willis creates the so-called "back pressure" which prevents antegrade flow into the ICA. After the lesion has been stented, the stagnant blood present within the ICA, possibly containing embolic material, is aspirated and removed or filtrated. Proximal protection systems cannot be used in all cases, since 6-10% of the patients do not tolerate complete flow occlusion[6].

CPD may also be considered the cause of some procedural complications; the most frequent of which are: a) inability to cross a lesion, b) failure to capture the emboli and c) vasospasm or injury of the arterial wall.
Inability to cross the lesion: The deployment of a CPD should generally not be a problem in straight anatomy, while in patients with very tortuous vessels and tight stenoses it is often a technical challenge to cross the lesion without complications.

Failure to capture the emboli: Capture efficiency, obviously, is the most important aspect of CPD. It can be hindered by a number of different mechanisms and is dependent on which type of device is used. Using the distal balloon systems a rare but possible complication is the gradual deflation of the balloon resulting in inadvertent reestablishment of blood flow toward the brain. This phenomenon can be prevented by constantly monitoring the size of the balloon under fluoroscopy or by injecting contrast medium during the procedure. However an excessive inflation of the balloon will increase the risk of vessel spasm or dissection.

Another potential source of neurological effects is the embolization of the ECA territory. Since balloon occlusion causes turbulence within the occluded ICA segment, some emboli may pass in the ECA before post-procedure aspiration, thus determining ECA territory embolization. This event determines a greater risk of embolization via ECA-to-ICA collaterals which open up during ICA occlusion. Several authors have evaluated the efficacy of filters using different models. All the filters were able to capture the vast majority of particles, especially the large ones.

However, it is known that 50% of the emboli released during CAS are smaller than 100 µm[7]. Smaller pore size may decrease the chances of microembolization. However, it also resulted in a higher incidence of filter thrombosis. Filter thrombosis is related to filter plugging as a result of capturing too many particles and/or fibrin deposition. Therefore the selection of the pore size is a compromise between the risk of filter thrombosis and the risk of microembolization. Another cause for embolization despite adequate filtering capability is an incomplete adherence of the filter to the vessel wall. This condition mainly occurs in tortuous vessels where the filter is not aligned with the long axis of the ICA and particles may flow around the device. For this reason it is mandatory to place the filter in a straight portion of the vessel, whenever this is possible. A similar condition occurs when an incorrect filter size, smaller than the arterial diameter, is selected.

Figure 1: After removal of a filter protection system (Angioguard Cerebral Protection Device, Cordis-Johnson & Johnson), a large amount of debris were captured during the procedure, which is clearly visible inside the filter

Injury of the arterial wall: As we all know, the ICA is a relatively delicate vessel. Since any distal protection device exerts some forces on the vessel to achieve complete apposition, irritation of the arterial wall may occur. The degree of irritation increases with the movement of the protection device, which is inevitable even in experienced hands. Although most episodes of spasm are self-limiting and do not result in clinical sequelae, the long-term effect of such spasm in the development of intimal hyperplasia is unknown[8]. In the majority of cases spasm can be easily solved by intrarterial injection of vasodilators (Fig.2). Damage to the intimal layer may occur due to unexpected movement of the inflated balloon or deployed filter basket by the operator or neck movement by the patient. This may result in dissection of the ICA, which has been described by Muller-Hulsbeck[9].

Conclusions

Carotid artery angioplasty and stenting procedures should always correlate with distal embolization, although most embolization does not produce clinical manifestations. Several studies have proved that the use of cerebral protection devices drastically reduces the incidence of distal microembolization. For this reason a routinely use of CPDs should be considered mandatory.

Figure 2: Vessel spasm occurred during protected CAS using distal filter protection device

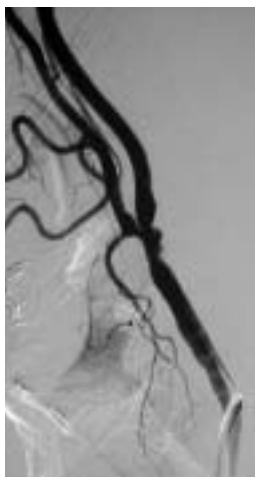

Figure 1a: The patient was a 59 year old male patient with multiple risk factors (hypertension, heavy smoker, diabetic) symptomatic for a severe stenosis of the left ICA with ulcerated plaque

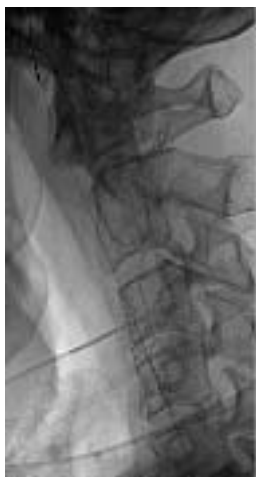

Figure 2b: In September 2005 the patient underwent a protected CAS with an Angioguard filter device (Ø 6 mm) and a Precise Nitinol stent (8x30 mm)

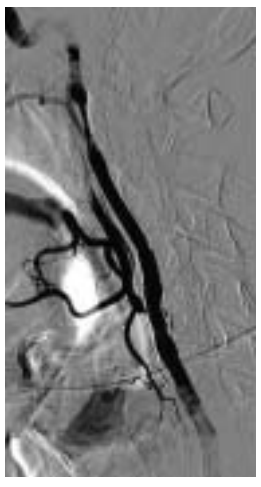

Figure 2c: At the end of the procedure a severe spasm of the ICA, at the level of the filter, was clearly evident and…

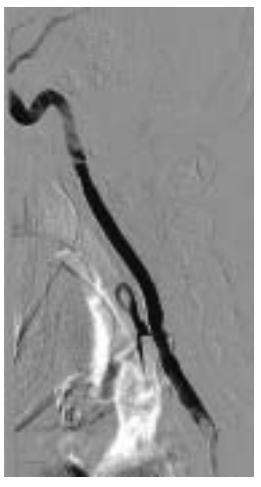

Figure 2d: …completely solved after injecting 0.2 ml of Nitro-glycerine. No symptoms occurred during the procedure and after filter removal

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Optional vena cava filter: The way I see it

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Optional vena cava filters, also called retrievable filters, are to this day the most interesting and intelligent improvement in vena cava filtration devices. Indeed for almost a century, partial interruption of the vena cava has proven to be the least damaging solution for preventing pulmonary embolisms (PE) in patients who are not eligible for conventional anticoagulation, and a lot of permanent vena cava filters have been proposed.

Unfortunately there have been many severe complications mainly due to the permanent character of the filters. Today we have at our disposal devices that can be easily withdrawn when the patient does not need them any longer or when the patient can receive regular anticoagulant therapy again. In addition, these filters can be left in place like the conventional, permanent filters, if the clinical status of the patient has changed or if the risk of pulmonary embolism remains at a high level.

At the moment five optional filters are available (see chart). Others are expected to be marketed soon (G2 from Bard, Celect Filter from Cook). In our practice we have chosen the French filter (ALN), because of its easiness of insertion and retrieval and more particularly because of its unlimited retrieval delay. With this device we have been able to perform retrieval 25 months after its insertion without experiencing any difficulties.

Our indications for an optional vena cava filter are essentially the same as for permanent filters:

- permanent or temporary contraindication to anticoagulant therapy
- recurrent PE despite adequate anticoagulation
- documented extension of venous clots despite a well adapted therapy
- PE in high risk patients for which anticoagulant may not be sufficient to prevent a fatal outcome

The possibility to retrieve the filter allows us to be more confident for previously discussed and questionable prophylactic indications:

- A floating very proximal thrombus (iliac or caval) in patient with PE
- Primary prevention in the situations with high risk such as :
  - cancer at a final stage
  - orthopaedic surgery
  - multi injury in fragile patie nts
  - pregnancy
- Preventive and exclusive treatment before surgery
- Exclusive preventive treatment for elderly patients

Beside these optional filters we limit the use of the truly temporary filters (which are very uncomfortable for the patients and their clinical monitoring, leading to thrombotic and infectious complications) to a very limited number of situations, such as the following:

- During thrombotic therapies
- As a protective device while we have decided to perform a thromboaspiration of a partially thrombosed filter
- When the filtration delay should be very short (a few days perioperative period) in order to avoid a potential second, aggressive procedure
- In the last days of a pregnancy, in which case the filter should be positioned above the renal veins

We also limit the placement of truly permanent filters to a very small number of indications:

- For patients with infrequent mega vena cava (Bird's Nest Filter)
- Due to their lateral legs, which allow better caval centering, we prefer using devices with indisputable stability (like the LGM) for very old patients in whom the retrieval is not questionable or in whom the vena cava is tortuous

For the near future, we need more evaluations of the benefit/risk ratio of these devices and above all a better analysis of the feasibility of the retrieval.

Although in our personal series we did not face any complication due to the anchoring of the struts, it is vital to organize longer studies in order to quantify the potential gross and microscopic lesions that might occur in the vena cava wall.

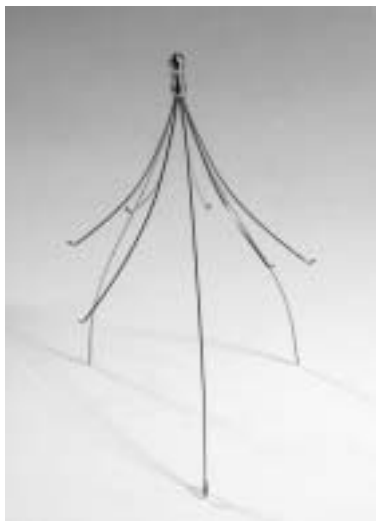

Figure 1 : ALN

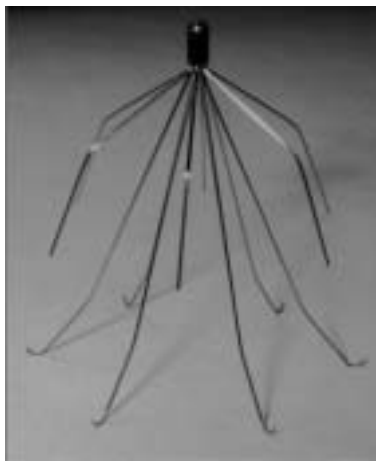

Figure 2 : Recovery

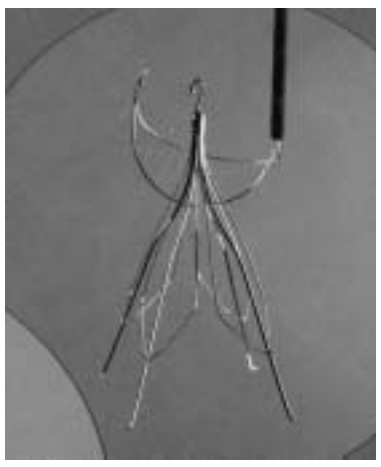

Figure 3 : Gunther Tulip

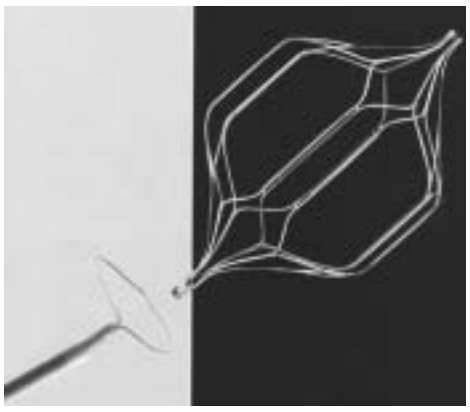

Figure 4 : Optease

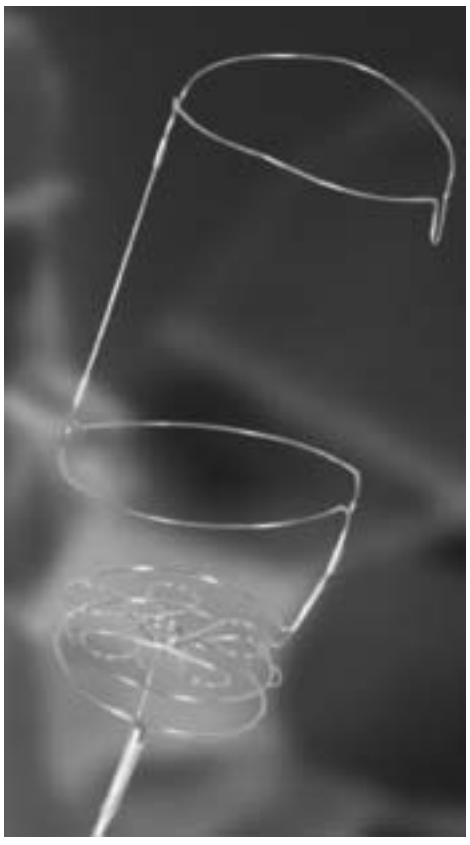

Figure 5 : Safeflo

Current Available Devices	Company	Material
ALN Vena Cava Filter	ALN	Stainless steel
Recovery Filter	Bard	Nitinol
Günther Tulip Filter	Cook	Conichrome
Optease Filter	Cordis	Nitinol
Safeflo	Rafael Medical	Nitinol

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Lung tumour ablation: Where are we going?

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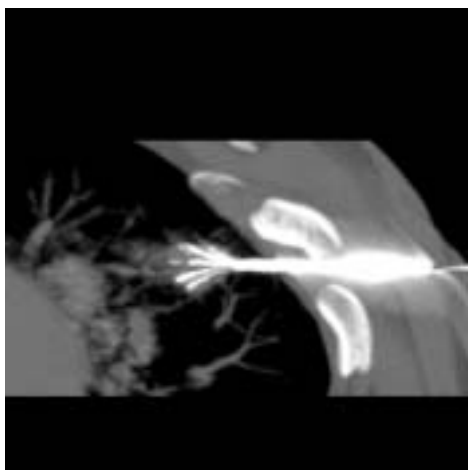

Figures 1a,b: Three-dimensional reconstructions of multidetector spiral CT data sets show correct placement of the RF needle into the tumour

Today image-guided percutaneous ablation is considered a valuable treatment option for patients with primary hepatocellular cancer or limited liver metastases. As the technology evolves, percutaneous ablation is now being evaluated for other types of tumours.

The lung is the most common site for primary cancer worldwide and a common site for metastatic disease. Many of the patients are not suitable for surgical treatment, often due to their age, poor cardiovascular or respiratory function or other serious coexisting health conditions. Hence, it is logical to extend the use of percutaneous ablation to patients with limited lung tumours not eligible for surgical resection.

A careful pre-treatment assessment is essential, including chest CT to determine the exact size and position of the target tumours. During the procedure, a radiofrequency (RF) needle electrode is positioned in the tumour, using the same guidelines as for CT-guided lung biopsy. The skin entry site is selected so as to allow the shortest and most vertical path for the needle, avoiding blood vessels, interlobar fissures and bullae. It is particularly important to ensure the correct placement of the electrode needle within the tumour, using image reconstructions in multiple planes.

Initial studies have indicated that RF ablation is well tolerated by most patients and that it can achieve complete necrosis of the targeted lesion. We recently completed a large prospective, multicentre trial in patients with primary lung cancer or lung metastases 3.5 cm or less in diameter who were not candidates for surgery. One hundred and six patients (36 women and 70 men) with 186 malignant tumours were enrolled in this trial. Thirty-three patients suffered from non-small cell lung cancer, 53 had colorectal cancer metastases and 20 had metastases from other primary malignancies; none were suitable for surgery. Patients underwent RF ablation treatment with CT guidance and under conscious sedation. No procedure-related deaths occurred. There were 27 cases of pneumothorax requiring treatment, 4 pleural effusions, 2 cases of pneumonia and one case of atelectasis.

At a CT evaluation 3 months after the procedure, complete ablation of the tumour was observed in 173 of 186 tumours, resulting in a primary effectiveness rate of 93%. Overall survival of the primary lung cancer patients was 69% at one year and 49% at two years. However, many of the deaths were not cancer related and when these were excluded, the cancer-specific survival rates were 91% at one and two years. In patients with lung metastases from colorectal cancer, the survival rates were 88% at one year and 72% at two years, after exclusion of non-cancer-related deaths.

These results are encouraging and suggest that RF ablation can improve survival, reduce pain and improve quality of life in patients with unresectable lung tumours. However, additional clinical trials are required to further evaluate the place of RF ablation in the management of primary tumours and metastases in the lung, either alone or in conjunction with chemotherapy or radiotherapy.

PET and Lung radiofrequency ablation

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Radiofrequency (RF) tumor ablation is now widely used for the treatment of primary and metastatic tumors in various organs. The thermal lesions created are caused by the application of alternating current and are influenced by the heat transfer within the tissues.
Numerous publications demonstrate the safety and efficacy of radiofrequency ablation and indicate few complications in the treatment of lung tumors. However assessment of the technical success of RF ablation is difficult because the treated tumor remains in place. Due to the necessity of ablating margins to ensure a complete treatment of the tumor, normal tissue surrounding the tumor undergoes coagulation necrosis which may lead to size increase of the imaged abnormality. After having grown the lesion progressively shrinks. In some cases no significant shrinkage is observed, and the tumor remains larger post treatment than prior to treatment, even in the case of complete treatment without any residual viable tissue.
For these reasons on CT follow up, lesion measurement based on RECIST (Response Evaluation Criteria In Solid Tumors) is not always a reliable measure of ablation success.
To perform an early assessment of the presence and location of a residual viable tumor, in order to retreat, a single CT based on tumor size is insufficient and misleading. Contrast material-enhanced CT imaging allows appreciation of the degree of tumor necrosis (Lee et al Radiology 2004; 230:125-34). Other publications describe the utility of contrast-medium injection in the follow up. After treatment an increase in contrast uptake might be due to tumoral neo-vascularisation or to inflammatory reaction. Comparing contrast uptake profiles obtained after treatment could allow depiction of a residual tumor. In this way MRI which offers high contrast and temporal resolution, could be useful.
PET is now essential in the diagnosis and staging of some cancers, and is used also for evaluation of the therapeutic response. After lung RF ablation Akeboshi et al (JVIR 2004; 15 : 463-70) demonstrated PET to be more sensitive and specific than contrast material-enhanced CT for detection of residual tumor.
A prospective study declared to the NCI (National Cancer Institute; (http://cancernet.nci.nih.gov/clinicaltrials) has been designed. This study aims to evaluate the accuracy of PET to measure the efficacy of RF ablation of lung metastasis, and also to determine the optimal delay of performing PET in this particular indication.
The ability to detect early residual tumor is an essential point in the follow up of the patients after radiofrequency ablation; assessment of lesion diameter by CT is often insufficient, other functional investigations are sometimes necessary.

This article reflects the opinion of the authors.

Learn more about PET & Lung Radiofrequency Ablation with Dr. Jean Palussière at Boston Scientific
Meet with the Experts Session on Saturday 9th from 10:30 to 11:15.

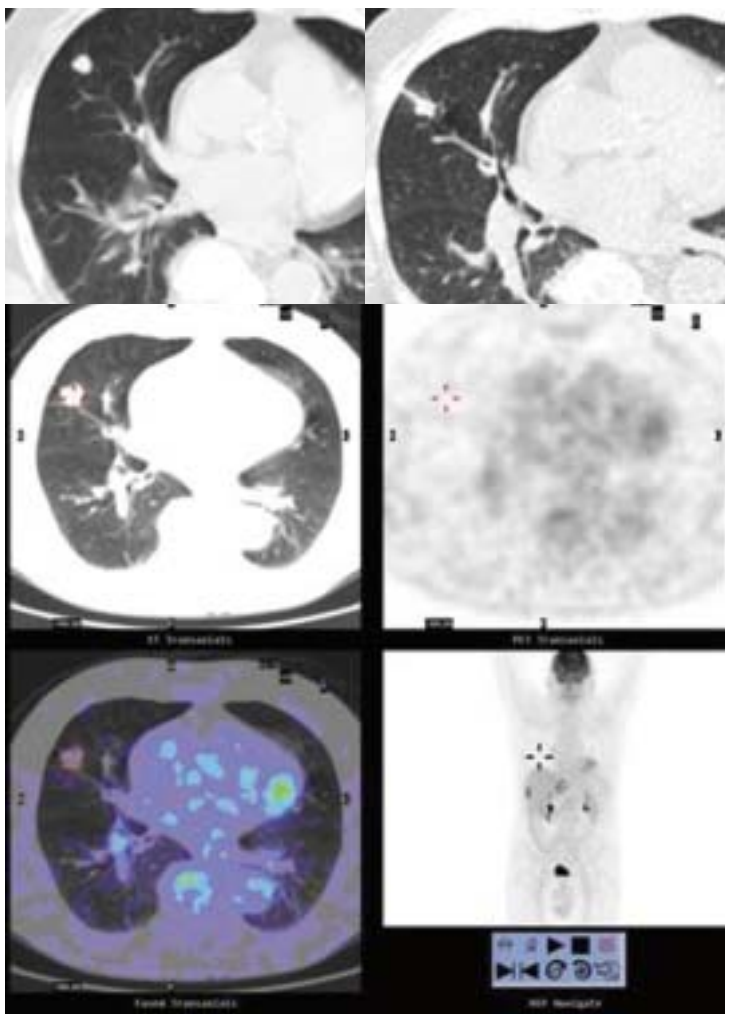

Fig 1: Lung colo-rectal metastasis treated by RF ablation. 6 Months later the lesion remained nodular and larger than before the treatment, PET indicates that a complete ablation was achieved with no captation of 18 F-FDG inside the nodule

Clinical benefits of flat panel 3D rotational angiography for vascular interventions


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C. Felix, P. Gobert, GE Healthcare, Buc, France

Background
The CHU La Timone at Marseille is amongst the first hospitals in Europe equipped with the Innova 3100 digital flat panel angiography system. The Innova 3100 system installed by GE Healthcare has a 30 cm x 30 cm digital detector designed to perform general vascular and cardiac interventional procedures, and an integrated multi-modality Advantage Workstation.

Flat panel Innova 3D, introduced in 2005, has radically changed the concept of just morphological analysis of vessels and moved closer to CT imaging, with un-subtracted cross-sectional display of soft-tissue, bone, plaque, thrombus and devices as well as the typical volume rendering of vessels.

Case 1 : Pulmonary fistula embolization

Case History
A 67 year old female suffering from the Rendu Osler disease, and who has been diagnosed on CT as having an arterio-venous fistula in the right pulmonary artery. This fistula has developed between the middle lobe branch and the superior pulmonary vein in the right lung.

Procedure details
The patient is programmed in the angio suite to undergo embolization of the pulmonary fistula. The 2D angiography images show the fistula (fig. 1), but there is difficulty in clearly delineating the feeding arteries with the projection images. A pre-therapeutic Innova 3D angiography is required in order to define precisely the angio architecture of the fistula, identifying if there are single or multiple feeding arteries. A selective catheterization is performed using a pig-tail catheter in the right pulmonary artery. A 5-second 3D rotational angiography is performed with the injection of 42 ml of contrast media at 6 ml/s.

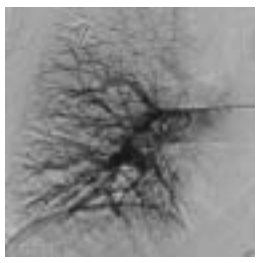


Fig.1 DSA

Fig. 2 3D VR showing fistula

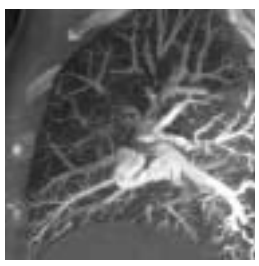


Fig. 3 Sagittal view

Discussion and conclusion
The morphology of the fistula is clearly visualized in 3D (figs. 2, 3) with the single feeding artery and a single draining vein. The fistula is measured to be around 15 mm in the 3D images. The pathway for micro-catheter positioning and the appropriate coil sizes are also defined using the Innova 3D images. The micro-catheter is placed in the fistula and the latter embolized (figs. 4, 5) using mechanically detachable micro-coils of type Detach Coil System (DCS) and of type interlocking detachable coils (IDC).

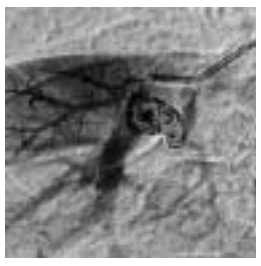


Fig. 4 During embolization

Fig. 5 At the end of embolization

At the end of the procedure, an Innova 3D rotational angiography acquisition is performed in order to verify the complete filling of the fistula (figs. 6,7). The devascularization is complete with complete exclusion of the arterio-venous malformation. The middle lobe branch and its collateral arteries are patent.

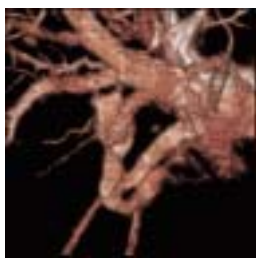


Fig. 6 Pulmonary fistula

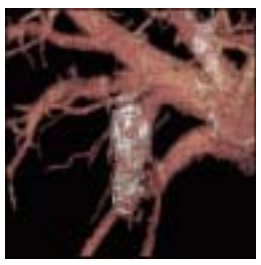


Fig. 7 Post-embolization

Innova 3D is useful for planning selective catheterization and analysis of fistula angio architecture. It is also used post-procedure to verify the embolization success.

Case 2 : In-stent restenosis of the brachiocephalic trunk

Case history
A 50 year old male having undergone angioplasty in the supra-aortic trunk for a brachiocephalic artery stenosis in April 2005. The patient complains of a symptomatic pain in the right arm.

Procedure details
2D angiography exams (fig. 1) show an in-stent restenosis of the brachiocephalic trunk, whose eccentric and tight lesion is difficult to quantify in the presence of the stent. A 5 second Innova 3D rotational angiography exam is performed (60 ml of contrast media at 12 ml/s) to visualize the stenosis morphology within the stent and quantify the stenosis using the multiplanar volume reconstructions. Both 3D volume rendered (fig. 2) and cross-sectional images are automatically computed and simultaneously displayed on the workstation.

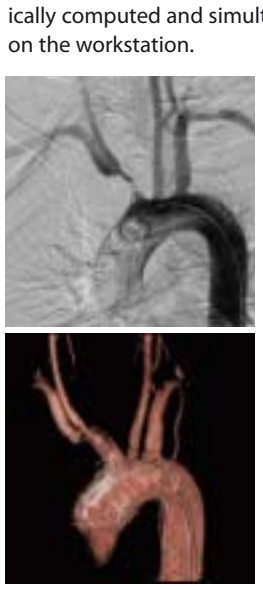


Fig. 1 2D DSA and Fig. 2 3D VR images of the arch of the aorta and its branches

Discussion and conclusions
The in-stent restenosis is clearly visualized in the double oblique MPVR views (fig. 3, 4). The stent in the brachiocephalic trunk covers the ostium in its proximal part, and distally ends 5-10 mm before the right common carotid and right subclavian bifurcation.

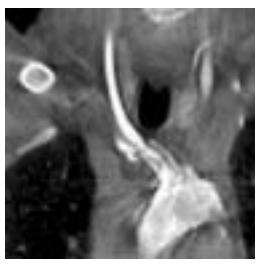


Fig. 3 0.7 mm oblique slice showing re-stenosis

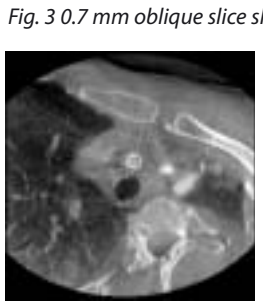


Fig. 4 0.7 mm slice orthogonal to stent axis

The in-stent re-stenosis due to myointimal thickening is evaluated at 85% in the reconstructed cross-sections, the most severe stenosis being located at the middle part of the stent (fig. 5). The diameter of the normal part of the brachiocephalic artery is measured to be 10 mm and its length is measured to be 21 mm.

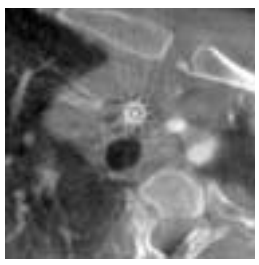


Fig. 5 Tight stenosis within stent

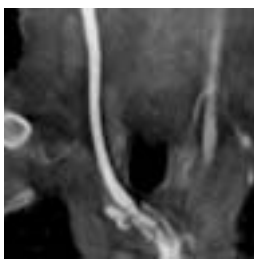


Fig. 6 Curved view of right carotid

An atheromatic calcified plaque (fig. 6, 7) extends beyond the stent edge onto the lower side of the right subclavian artery causing a 50% ostial stenosis of the right subclavian artery. The other sections of the right subclavian artery are of normal morphology (fig. 8).

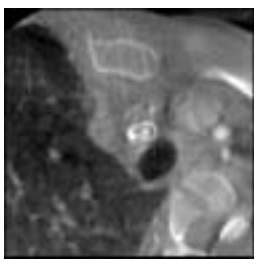


Fig. 7 Calcified plaque at subclavian ostium

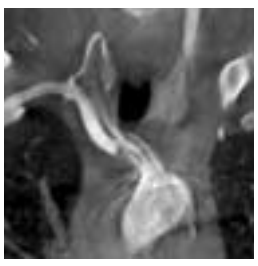


Fig. 8 Right subclavian artery

The right common carotid, the left subclavian and the left common carotid arteries are normal.
In conclusion, Innova 3D with multiplanar volume reconstruction showing vessels, soft tissues, bone structures and devices allows a comprehensive and precise evaluation of complex pathologies such as this in-stent eccentric tight lesion in the supra-aortic trunk. For such pathologies, there is a clear advantange in using a single Innova 3D rotational angiography for pretherapeutic imaging instead of acquiring multiple DSA incidences, which gives a potential for X-ray dose and contrast media reduction. The re-stenosis is treated by an in-stent re-dilatation (fig. 9) using a 7 mm balloon with satisfactory results (fig. 10).

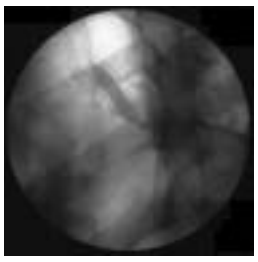


Fig. 9 Intra-stent angioplasty

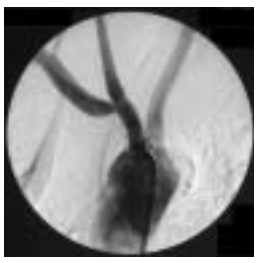


Fig. 10 Post-procedure control

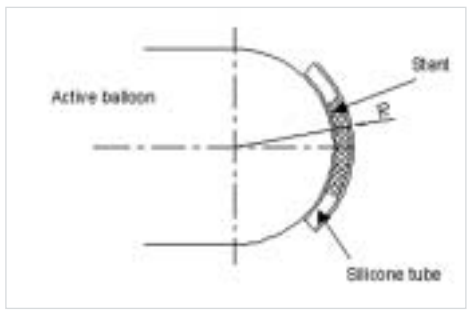
Advertorial

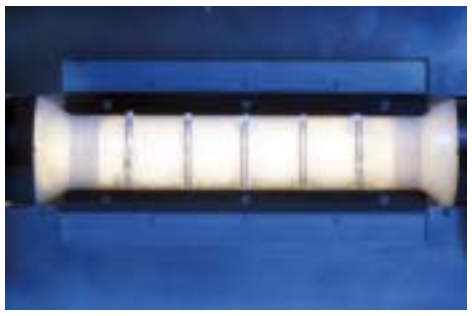
Independent test results of ev3's PROTÉGÉ® EverFlex stent™ conducted by Fortimedix B.V.

Fortimedix B.V., located in The Netherlands, is a leading medical device company in the field of vascular stents. The company has extensive experience in the field of minimal invasive device technologies, including product development, manufacture and testing. Fortimedix has also been heavily involved in contract durability testing of vascular stents. It has conducted many vascular stent fatigue tests for several major players in the medical device industry using their unique in-house built stent fatigue tester in recent years. Very recently, it has tested several types of stents designed for the SFA.

Set-up of the tests and their clinical relevance

Different self expanding stents were deployed in test tubes (silicone tube) mounted on a fatigue machine as shown in the figure below:

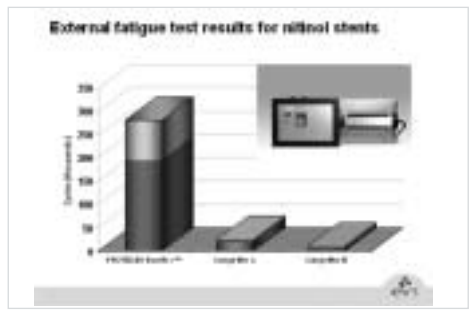




The stents were exposed to a cyclic 70º bending and 22% longitudinal elongation at 3 Hz frequency. The number of cycles to first strut fracture and to total stent separation were recorded. The purpose of this test was to assess stent structural integrity over time as a result of above loading conditions. This is important, as it is clinically shown in various studies, that there is a close correlation between stent fracture and restenosis. The SFA is subject to extreme multiaxial forces, and bending and axial elongation are the two predominate movements for the SFA stent. ev3 requested Fortimedix to comparison test its latest generation self-expanding stent, PROTÉGÉ® EverFlex™ , against two leading competitor products.

The results

The experience is that most cracks occur at the sides of the stents, where the composite load case of bending and stretching results in the highest tensile stress. In these tests, the best resistance against fatigue failure was achieved by the EverFlex™ stents, which did not fracture up to 193.000 cycles under these extreme loading conditions. As a comparison, test samples of the other two stents in the test fractured between 5.000 and 27.000 cycles. Most likely, this is due to the innovative stent design and the mechanical properties of the stent material which allows the maximum and alternating stress/strain level in the EverFlex stent design to be the lowest among the three stents which were tested.



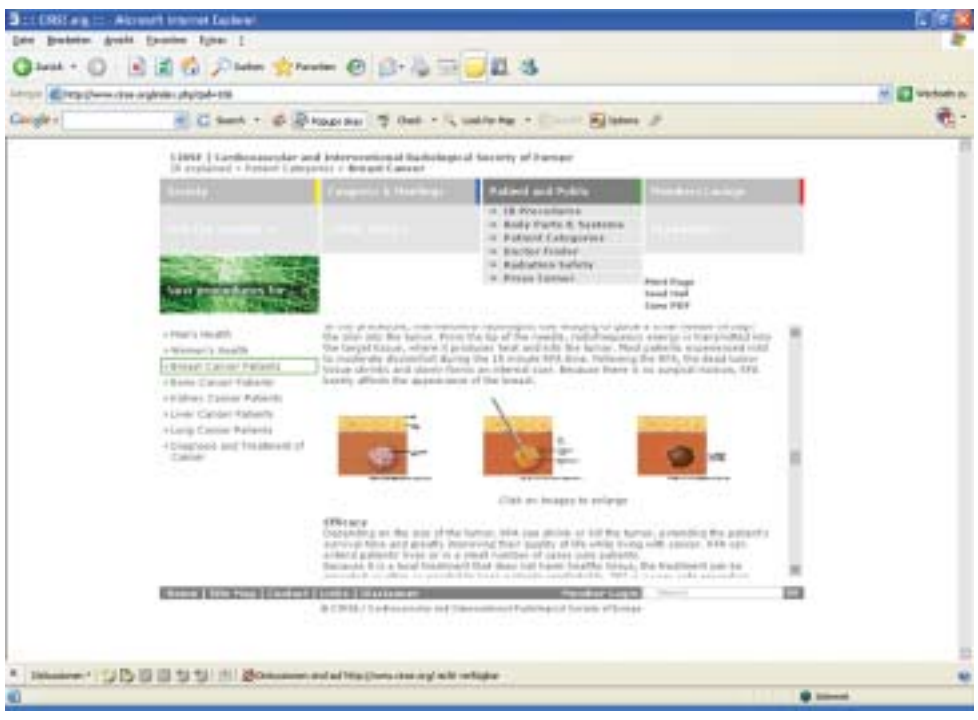
Why does the EverFlex™ design have the best fatigue performance?

New spiral connection node configuration provides greater flexibility and vessel conformability. In addition to this, the new three-wave peak design distributes stresses more efficiently and evenly.

What were the conclusions?

In bench tests, the PROTÉGÉ EverFlex™ is five to ten times more durable than competitive stents as a result of a revolutionary design.

Did you know that CIRSE ...

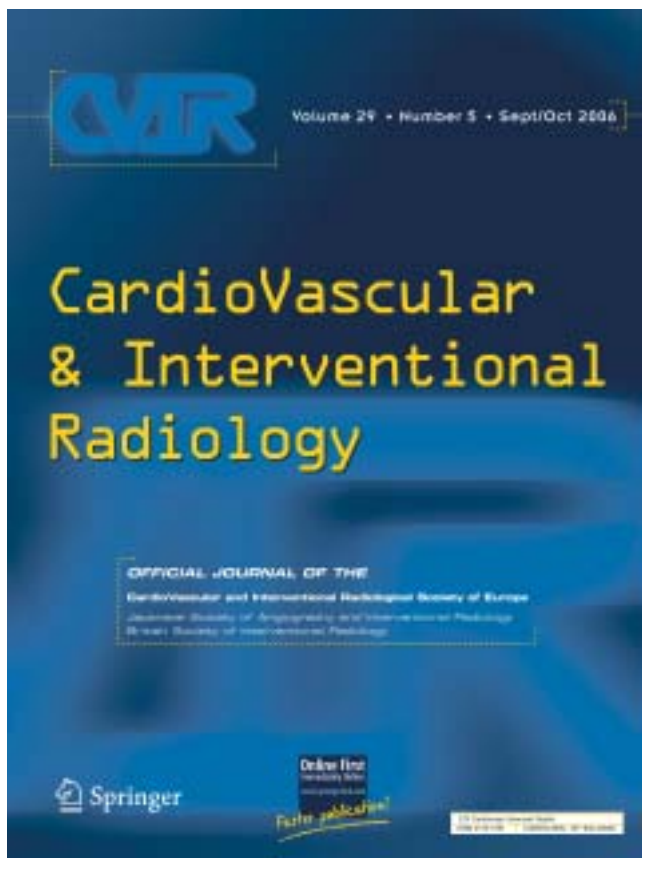


... does not only offer information for you, but also for your patients?

The "Patient & Public" section of CIRSE's homepage (www.cirse.org) offers easily understandable, patient-friendly information regarding the procedures performed by interventional radiologists and related topics such as radiation safety to the non-physician. The section is currently being reviewed and updated in order to adjust it to the present situation patients will encounter in Europe. The procedures are listed alphabetically, according to body parts and patient categories. All information is given in English and will also be available in German shortly.

Encourage your patients to get informed about IR procedures by visiting the CIRSE website! The modern, intellectual patient will feel involved in the decisions concerning his/her treatment and appreciate your suggestion.

Cardiovascular and Interventional Radiology (CVIR)



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Secrets of Rome

Rome offers a unique array of secret places and forgotten squares. Since they are off the beaten track, most people fail to discover them, missing out on some of the most interesting and beautiful places in Rome. Here are a few examples of those little secrets scattered throughout the eternal city.

Arco degli Acetari

Via del Pellegrino 19-41

The name of Arco degli Acetari or "Vinegar Makers' Arch" probably comes from sellers of vinegar water formerly offering their product in this area. Once you pass the small arch and come through the short, dark alleyway, you will find yourself in a square in which time seems to have stood still. The courtyard is closed on all four sides by picturesque red houses that have kept their mediaeval look until today.

Although located in the centre of the city, it almost looks like a country courtyard with cats sleeping on the stairs, flower-covered balconies and wooden carts. In summer the people living in the houses surrounding the square often bring out tables and chairs to enjoy their dinner al fresco. The square can only be accessed through the arch and cars cannot go in. Clothes hang from the windows and the smell of cooking wafts through the air. The traffic and pollution of Corso Vittorio and the hustle and bustle of Campo de' Fiori are just a stone's throw away, but seem like a whole different world to those enjoying the peace and quiet of Arco degli Acetari.

The architectural layering of San Clemente Basilica

Piazza di San Clemente

The Basilica of San Clemente dating back to the 12th century AD is located only a few meters from the Colosseum and is thought to owe its name to Pope St. Clement I. Apart from being a beautiful church, less well known than it deserves to be, is also a spectacular example of architectural layering.

In 1857 excavations carried out under the church and directed by the prior of the Irish Dominicans, Father Mullooly, revealed the existence of another basilica under the one we can see today. That basilica was in turn built on top of another large public building from the 1st century AD and a Roman residence in the courtyard of which a small Mithraic temple was found. Further excavations led to the discovery of a fourth layer containing buildings from the Roman Republic, probably destroyed during the fire set by Nero in 64 AD. The visit of the upper church, which is full of masterpieces, such as the frescoes and the mosaic in the apse or Saint Catherine's chapel frescoed by Masolino da Panicale and Masaccio becomes an even more exceptional experience by going down to the lower levels.

The original church is larger, dates back to the second half of the 4th century AD and is decorated with important frescoes from the 11th century AD portraying the lives of Saint Alessio and Saint Clement, as well as the tomb of Saint Cyril. It was constructed on Roman buildings that were modified considerably over the centuries. Its oldest part is made of a series of small rooms with barrel vaults and a wall of tufa blocks dating back to the 1st century AD. These rooms were probably part of the Zecca (State Mint) of Rome. In the second half of the 2nd century AD, alongside this building, a two floored domus was built overlooking an outside courtyard. Part of the stucco decoration is still visible on the vaults of some rooms. In the 3rd century, part of this house was transformed into a Mithraeum, a sanctuary to the god Mithras. Many openings were closed, an altar was built, as were a niche for a statue of the god and a starry vault to make the place cave-like by keeping with the whole nature of this underground cult. The filling material has been removed and the Mithraeum was restored on several occasions. It is mostly intact and can be visited.

The Canova-Tadolini Workshop - In the intimacy of a great sculptor

Via del Babuino 150

Another tip for those who like to leave the beaten track when traveling is the recently opened restaurant/museum created inside the studio of the famous sculptor Canova. For years Canova worked with Adamo, his most talented student and spiritual heir in this small and curious two-storey construction located in a part of the city that is traditionally animated by artists' workshops. In 1818 Canova left the workshop to his favorite student. Canova gave Adamo various assignments and the task of reproducing his most famous works. The Tadolini family remained in possession of the workshop in Via del Babuino for four generations until 1967, handing down the art of sculpture from father to son.

Today the striking space of the Canova Workshop, which restoration work has left almost intact, houses a small, refined restaurant and a bar. Don't miss the chance to enjoy an exquisite dinner or even just a simple coffee while sitting amongst marble and bronze sculptures, tools of the sculptor's trade and plaster models of statues which are now scattered in museums all over the world. Everything is laid out in the appealing disarray typical of workshops. The elegant neoclassicism of Canova and Adamo is combined with the more romantic style of Scipione and Giulio, as well as with the more intimate mode of Enrico, everything blending into a harmonious ensemble.

The order of Malta's keyhole and a surprising view

Piazza dei Cavalieri di Malta

The Piazza dei Cavalieria di Malta (Square of the Knights of Malta) is surrounded by palm trees, cypress trees and imaginative walls full of rods and obelisks designed by Giovanni Battista Piranesi. The monumental entrance of the headquarters of the Priory of Malta, which seems to hide a mysterious and untouchable world, offers a surprising detail on its outside. By placing your eye to the keyhole of the main entrance, the cupola of Saint Peter's Basilica appears in a surprising manner, framed by a green tunnel of climbing plants that is formed by the path of the inside garden.

The Grand Prior Giovan Battista Rezzonico commissioned Piranesi to arrange the area, belonging to the Sovereign Order of Malta. The architect also totally transformed the church of Santa Maria del Priorato, a simple chapel built in the 16th century. Its origins date back lo the 10th century, when, under the name of Santa Maria Aventina, it was part of a Benedictine abbey dedicated to Saint Basil of Cappadocia. In the 12th century the abbey passed onto the Templars and, at the beginning of the 14th century, to the Knights of Rhodes and then of Malta. The inside was entirely covered in white stucco, designed by the artist. The façade in the fantastic Piranesian style is in fact the only architectural work - apart from the piazza- that was carried out by Piranesi himself.

Doll's Hospital - Squatriti

Via di Ripetta, 29

On the corner of Via di Ripetta and Via del Vantaggio you can find Squatriti, the artistic restorers' shop. The grandmother of Federico, the young man who still works here today, opened this strange workshop in 1953, where initially only vases from archaeological excavations and painted Italian ceramics were restored until Federico's father branched into new activities with his wife, who began restoring fans and dolls. Today it is mostly because of the dolls that this place attracts the attention of passers-by. The shop is tiny and you instantly have the feeling of entering a timeless place. Federico and his mother work intently at two small counters around which there is hardly any room to walk. Objects fill the shelves, most of the floor and even the ceiling: vases, Italian ceramics, items made from ivory, wax, papier-mâché, plaster, porcelain and marble, but above all lots of dolls piled up in the shop windows, giving this workshop the atmosphere of an old horror movie.

From 1960 onwards, only porcelain or cellulose dolls were repaired, and once industrial plastic dolls were introduced these earlier dolls became collectors' items. Even if you have nothing to be repaired, it is worth your time glancing around the shop and meeting the owners.

Santa Maria degli Angeli - A sundial 45 meters long

Piazza della Repubblica

Santa Maria degli Angeli (Our Lady of the Angels) is a majestic basilica built in the Diocletian Baths, initially based on Michelangelo's designs and later on those of Vanvitelli. On the floor of the basilica in front of Diaz's tomb, one can admire a beautiful sundial measuring 45 metres in length called the Linea Clementina or Clementine Line, named after Pope Clement XI who inaugurated it in 1702. This beautiful bronze and marble inlay was getting rather worn out after centuries of being tread on, but restoration work carried out in 2000 rendered it all of its former beauty.

In order to check the correctness of the Gregorian reform of the calendar around 1700, Pope Clement XI asked the mathematician and astronomer Francesco Bianchini to build a monumental sundial that would indicate the Spring Equinox and therefore help to determine the exact date of Easter Sunday. According to the rules given by the Fathers of the Council of Nicea, Easter was to be celebrated on the first Sunday after the first full moon following the Spring Equinox. Therefore it was extremely important to avoid mistakes that would have inevitably moved the dates of all the other mobile religious holidays.

Along the sundial there is an old marble inlay representing the signs of the Zodiac. These were based on Maratta's drawings, using the images of Bayer's "Uranometria Nova."
To the right of the line you can see the signs of summer and autumn constellations, to the left those of spring and winter. Every day of the year at noon the sun, entering the building through the centre of the heraldic coat of arms of Pope Clement XI, touches a different point of the line, from Cancer during the summer solstice to Capricorn during the winter solstice and vice versa.

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