

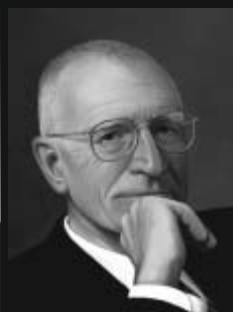
Welcome to the  
2008 CIRSE meeting,  
Welcome to Copenhagen!

# IR congress news

John E. Abele  
CIRSE 2008  
Gold Medallist



Bill Cook  
CIRSE 2008  
Gold Medallist



Jim A. Reekers  
CIRSE President



Johannes Lammer  
CIRSE Foundation  
Chairman

**CIRSE 2008 - Copenhagen**  
**Saturday, September 13, 2008**

**Join us for the CIRSE 2008**  
**Opening Ceremony and Cocktail Reception!**

**Saturday, September 13,**  
**16:00, Room A**

Over the years the CIRSE Opening Ceremony has become one of the highlights of the annual meeting's social programme, incorporating a variety of show acts from the respective local host country. Paying tribute to the traditions of Denmark and particularly Copenhagen, this year's ceremony will feature the Tivoli Boys Guard and a performance relating the story of Copenhagen's most beloved tourist attraction; the Little Mermaid. Founded in 1844, the Tivoli Boys Guard is an honorary guard watching over the finest buildings and monuments of Tivoli Gardens on festive occasions. To give you a perfect Danish welcome the Tivoli Boys Guard will perform several of their most popular songs. The Boys Guard will be followed by an exquisite dance performance relating the story of the Little Mermaid. The show act put together especially for CIRSE 2008 will include song and modern dance inspired by the most touching fairytale of Copenhagen's very own Hans Christian Andersen.

**Accompanying persons are also welcome to join the Opening Ceremony which will be followed by a welcome reception in the Exhibition Area.**

## CIRSE 2008 Awards

### CIRSE Gold Medal

CIRSE is happy to announce that two pioneers of Interventional Radiology development will receive this year's gold medals; John E. Abele and Bill Cook.

**John Abele** is the Founder Chairman, retired, of Boston Scientific Corporation. After starting with a small medical device company in 1960, he developed and marketed numerous medical devices, including the flame photometer, the osmometer and the steerable catheter. Currently Abele's major interests are science literacy for children, education and the process by which new technology is invented, developed and introduced to society.

**Bill Cook** founded Cook Incorporated in 1963, him and his wife Gayle being the only employees. Today sixty-three companies form Cook Group Incorporated, including manufacturing and sales entities specialising in the areas of cardiovascular, critical care, surgical, diagnostic and interventional products and many more. Bill Cook has supported the advancement of education and medical research through significant financial support to universities, hospitals and physicians throughout the United States.

### Distinguished CIRSE Fellowship

Professors Klaus Mathias and Hervé P. Rousseau will join the ranks of Distinguished CIRSE Fellows at CIRSE 2008.

Professor **Klaus Mathias** is head of the Department of Radiology at Klinikum Dortmund, where he has been instrumental in the foundation of multi-disciplinary centres. He has served in the organisation of 16 national and international congresses and was the president of the German Radiological Congress in 2000.

Professor **Hervé P. Rousseau** has been heading the Radiological Department of Rangueil Hospital in Toulouse since 2007. He has been in the spearhead of IR development in France since 1985, introducing many interventional procedures in his country. He has been particularly involved in research and development of stents and stent grafts.

# Welcome to CIRSE 2008



Poul Erik Andersen  
Chairman of the CIRSE 2008  
Local Host Committee

Today we are launching the 24<sup>th</sup> Annual CIRSE Meeting. It has been challenging and exciting to be part of the organisation of this brilliant international congress. CIRSE is a unique opportunity to expose Interventional Radiology to colleagues from other medical specialties, the press and the public. Through our Annual Meetings an international network of great importance to research is being established. At the same time it is also an opportunity to strengthen the bonds that unite our countries and to make contacts and friends with colleagues from around the globe.

**Witness the unveiling of CIRSE's**  
**Patient Awareness campaign**  
**Interventional Radiology:**  
**your alternative to surgery**

**Sunday, Sept. 14, 12:30-14:00**  
**Patient & Public event**

**Monday, Sept. 15, 16:30-18:00**  
**Medical Students event**

**We look forward to seeing you there!**

Interventional Radiology is a very dynamic and innovative field of medicine. This is reflected in the exciting and very comprehensive scientific programme of CIRSE 2008. It seems, however, that in the public eye Interventional Radiology is one of the best kept medical secrets, as many potential patients are not aware that Interventional Radiology has a lot to offer. Therefore one of the new and very important objectives at this meeting is to raise patients' awareness and knowledge about Interventional Radiology.

CIRSE 2008 is the first CIRSE meeting in Denmark. Copenhagen is a pulsating metropolis with over one million inhabitants. It is also very green and has a maritime touch. The population is considered to be very friendly and the city has a special atmosphere and tone. You will see that Copenhagen is a dazzling capital, offering a multitude of restaurants, bars, museums, theatres, attractions and beautiful architecture. Denmark has recently been voted the second safest country in the world (second only to Iceland). We hope that you will notice this during your stay.

As a motto for this congress I would say **"If you want to go fast - go alone; if you want to go far - go together!"** Let us go together under CIRSE's auspices at a speed that will allow Interventional Radiology to continue in its leading position not to be overtaken.

In the name of the Local Host Committee I would like to welcome you to Copenhagen and wish you a pleasant stay. We hope that you will have an unforgettable time here!

## Dear Colleagues,



Marc Sapoval  
Chairman of the Scientific  
Programme Committee

On behalf of the Scientific Programme Committee I would like to welcome you to CIRSE 2008 in Copenhagen! Following the outstanding success of CIRSE 2007, we have maintained the format of the congress divided into tracks, enabling delegates specialising on a subject to follow one of the main themes (colour coded in this programme) throughout the conference without overlap. The main disciplines are Vascular Intervention, Transcatheter Embolization, Non-Vascular Intervention, Interventional Oncology, Clinical Practice Development and, new in 2008, Imaging in Interventional Radiology. The basic educational sessions for junior interventionalists will include eight Foundation Courses focusing on the essentials of defined procedures and conditions. There will be Foundation Courses on Interventional Oncology as well as on Peripheral Vascular Disease. Participants of the Foundation Courses will again have the opportunity to test their knowledge by means of a self-assessment test, which was introduced at CIRSE 2007 and has been expanded for CIRSE 2008.

In order to facilitate your personal itinerary planning for CIRSE 2008, we have defined concrete learning objectives which will show you what exactly to expect from each session. Another novelty is that the conflict of interest declarations will be available at the beginning of each session.

At CIRSE 2008 you will be able to attend special sessions on new topics such as a tobacco cessation, the development of new interventional tools, new imaging techniques and updates on the hottest topics of our daily practice. The good clinical practice course will continue with the theme of basic medical statistics - a must for those who wish to understand basic statistics used in IR research. As with last year, there will also be a number of Interactive Case Sessions, which have proved to be very popular. CIRSE strongly believes that creating patient awareness and increasing clinical practice are two of the most critical areas for the development of Interventional Radiology. One of the main focuses of CIRSE 2008 will therefore be patient care and clinical practice development as well as marketing in IR. Since clinical practice is pivotal if we wish to maintain access to the patient and develop good clinical care according to the highest standards, a special session will focus on marketing in IR. A workshop will provide you with tips and tricks for starting clinical practice in your own hospital. In addition, CIRSE is hosting a special Patient Awareness Exhibition, "Interventional Radiology: your alternative to surgery", aimed at informing patients, the public and undergraduate medical students on Interventional Radiology and its treatment options as well as further developing the role of IR in medicine. This year, particular emphasis will be placed upon Uterine Fibroid Embolization, Peripheral Vascular Disease and Interventional Oncology. An enclosure of 120m<sup>2</sup> will house the Patient Awareness event in the main exhibition area of the Bella Center, to which admittance is offered free-of-charge. As you can see, the CIRSE programme continues to develop and I am confident that there is something for everyone at CIRSE 2008. I am also looking forward to the social events, which Professor Poul Erik Andersen and the Local Host Committee have put together for us in this beautiful city.

I wish you a fun and productive CIRSE 2008!



Advertorial

## Interview with Lombard Medical CEO, Brian Howlett on 30 July 2008 by Mike Karim, Director of Sales and Marketing International



### Q: How did Lombard Medical Start?

**Brian Howlett:** About 10 years ago Peter Phillips, who is now President of Lombard's operations in the USA and Professor Brian Hopkinson, at Nottingham University Hospital, got together to design a platform technology stent graft designed to address the unmet needs of patients suffering from AAA disease. Many doctors had highlighted the need for a device that was flexible and conformable to a patient's anatomy, with the ability to adapt to changing morphology over time and achieve good clinical outcome across such criteria as improved fixation and reduced endoleaks. Many had recognised the need for a product that could deal with both routine and complex anatomies such as high angle aortic necks and tortuous iliacs. To achieve this, a device was developed from scratch with the patient in mind that was not constrained by an existing delivery system. From this small beginning the Generation 2 Aorfix™ AAA stent graft is what we see today on the market in several countries.

### Q: What is your mission as a company?

**Brian Howlett:** Together with input from our dedicated employees we have developed the following mission statement:  
*'We provide innovative cardiovascular products which make a difference to patients, clinicians and shareholders.'*  
We believe we are making a difference to patients by offering a unique device with strong clinical outcomes, a difference to clinicians by widening the range of AAA cases that can potentially be treated by an EVAR device, and a difference to our shareholders with the promise of strong growth over the next few years.

### Q: There are many stent grafts on the market: tell me what Aorfix™ offers over the others?

**Brian Howlett:** We are offering something innovative to reach a broader patient base. Our data is indicating good results for major patient outcomes when compared to the competitor devices. With Worldwide implants nearing 600 cases, our data is showing strong positive outcomes for the criteria of fixation and endoleaks which posed challenges for several of the competitor devices used in EVAR procedures. About 20% of these cases have been in highly challenging and complex anatomies that doctors tell us could normally not be treated with competitor endografts. People who are now using the device have talked about a 'paradigm shift' from the concept of 'straightening out the anatomy' based on rigidity and columnar strength' to that of 'don't fight the anatomy, but conform to it'.

### Q: How long has the product been around?

**Brian Howlett:** The Generation 2 device with a truly flexible delivery system to match the conforming nature of the graft was launched in 2006 at the Charing Cross Symposium.

### Q: Who is using Aorfix™ and what is the feedback?

**Brian Howlett:** As a European manufacturer we now have a strong and building following of Key Opinion Leaders in Europe. In the UK in particular where we are direct and have about 6% market share we have had positive comments such as:  
*"We built our confidence in complicated high-angle cases and are now starting to use Aorfix™ in routine cases"*  
(Charing Cross 2008, Dr J Hardman, Royal United Hospital, Bath, UK)

Many clinicians have started to use Aorfix™ in this way and we are seeing more realise that in order to deal with complex anatomies, whether high angles or tortuous iliacs it is important to have regular ongoing experience with the graft across a wide range of cases to be able to optimise what the graft is capable of.  
In many countries we have key reference sites supporting to establish a data base of cases. In the US sites are signed up and performing cases as part of our clinical trial to achieve a product marketing approval that encompasses AAA neck angles up to 90 degrees.

### Q: What kind of support does the company offer its customers?

**Brian Howlett:** We are now in a position in Europe to support our key markets with a range of Pan European training programs. This involves partnerships with key Radiologists and Vascular Surgeons who are experienced with Aorfix™ running programs profiling live cases and talking about advanced techniques with the device. These proctors are also available to support new centres getting started with initial cases. Our in-house technical specialists are available to support cases as well as our clinical, engineering and development teams who have close relationships with customers. This enables us to interact with a speed and flexibility that is challenging for large companies.

### Q: What is the company's growth looking like?

**Brian Howlett:** In the first half of the year our revenue has grown by almost 100% over the same period in 2007 and the actual number of implants has grown by over 150% in the first 6 months of 2008.



### Q: What clinical Trial work are you doing?

**Brian Howlett:** We have 2 trials ongoing; one is a European multi-centre trial, namely Arbiter 2, designed to widen CE mark approval for high angle-necks aneurysms of up to 90 degrees. This has already recruited the sufficient number of patients required for follow up to gain the broader licence indication. No other stent graft has this label claim. Our US multi-centre trial, Pythagoras, is recruiting for a data set of 160 patients for up to 90 degree high angle-necks aneurysms. We are up to around 70 patients and we plan to have recruitment completed by the end of the year looking at 12 month follow up to allow us to submit for approval.

### Q: Looking ahead, how do you see the future of Lombard Medical and what new products are in the pipeline?

**Brian Howlett:** We are ambitious and are targeting to have a global market share of about 15% by 2012. This would give revenues in the region of \$200M. By this stage we plan to be highly profitable and reinvesting in our product development with a thoracic version of Aorfix™ on the global market. From the customer feedback we have had on our product, the flexibility of our technology lends itself ideally to this area. Additionally our EndoRefix™ vascular clip has a potential market opportunity of \$150M.

### Mike Karim: Thanks for the chance to discuss Lombard and Aorfix™, it sounds a very exciting time of the company.

**Brian Howlett:** Thanks Mike. For those who would like to know more about our progress and registry results with Aorfix™ we have a **lunch time symposium on Sunday, September 14, at the Bella Center, Room E at 13:00-14:00.**

## Solutions for Local Tumour Control



**RF 3000™** Radiofrequency Generator



## RF 3000™ Radiofrequency Ablation System

For more information, please visit us at our booth in the Industry Exhibition Area or contact your local Boston Scientific representative.  
[www.bostonscientific-international.com](http://www.bostonscientific-international.com)

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**Boston Scientific**  
Delivering what's next.™



# Patient Awareness: your alternative to surgery

One of the novelties at this year's meeting is the new and exclusive event dedicated to bridging the gap between Interventional Radiology and its potential patients.

A large number of very effective Interventional Radiology procedures are still virtually unknown to patients. This comes as little surprise, since many GPs and other referring specialists remain unaware of the very real and sound therapy options that minimally invasive procedures can offer. CIRSE goes above and beyond the existing initiatives to change this reality by directly addressing the patients themselves. CIRSE spreads the word that effective alternatives to surgery exist and presents Interventional Radiology as a pioneering discipline offering clinical expertise across the specialties for the benefit of the patient.

## Shaping the Future

Also incorporated into the event is the Shaping the Future programme, aimed at undergraduate medical students and sponsored by an educational grant from CORDIS®.

With the array of options available to medical students nowadays, making the right choice of specialty is no easy task. The best way to prepare for any such decision is by gaining relevant knowledge and experience and receiving the appropriate guidance. CIRSE does just that by giving students a realistic insight into Interventional Radiology and the life of an

Interventional Radiologist, from the history and development of the subspecialty to the benefits it presents to its patients.

Medical students from all over Denmark are invited to the Patient Awareness exhibition, where the next generation of medical professionals are introduced to Interventional Radiology and have the opportunity to meet Interventional Radiologists.

## CIRSE is proud to present its first major outreach event

This year, the Patient Awareness Campaign concentrates on three major diseases that affect a great part of the population and presents the minimally invasive solutions that Interventional Radiology can offer to address these;

### Uterine Fibroid Embolization Interventional Oncology Peripheral Vascular Disease

Through highlighting these select procedures, the current applications and the potential and promise of Interventional Radiology is demonstrated.

The procedures are explained in terms easily accessible for a largely non-medical audience. Other Interventional Radiology procedures are listed as well as frequently asked questions and general information on the discipline. Such information will be presented by means of wall displays, video screenings, presentations and talks.

The event, which is free of charge, commences with talks and films on the past, present and future of IR, its relation to the 3 disease areas, outlined above, and IR from the patients' perspective. These talks are held by Interventional Radiologists themselves as well as previous patients of Interventional Radiology. The event will end with a guided tour through the Patient Awareness exhibition.

Participants therefore have the opportunity to take in information at their own pace. Medical information brochures will be distributed and various workstations will provide access to Patient Information and the Doctor Finder on [www.cirse.org](http://www.cirse.org) as well as [www.uterinefibroids.eu](http://www.uterinefibroids.eu).

## CIRSE aims to achieve public recognition and acceptance of Interventional Radiology and its key role in the treatment of diseases, spanning across the broad spectrum of medical specialties.

IR has a large community in Europe and arguably one of the most credible, fastest growing disciplines in an age where patients are becoming increasingly more in the know about the options available to them. Patients are starting to take their own initiative with regard to their healthcare and CIRSE's main objective is to provide them with the information they need to improve their quality of life.

**The Patient Awareness Exhibition is located at the back of the Exhibition Hall.**

## CIRSE supports Public Awareness Campaign during 7<sup>th</sup> Athenean Days of Interventional Radiology 2007



During the 7<sup>th</sup> annual meeting of the Greek Society of Interventional Radiology awareness for IR was raised in a special campaign on the streets of Athens aiming at informing the public about IR procedures and their benefits. The programme was supported by a CIRSE grant.

### Interventional Radiology

#### THE EXAMINATION ROOM

Behind me, there are several screens which show the interventional radiology images of my disease as well as my vital signs during the course of the examination.

Around me, I can see the radiology equipment that forms images of my vessels as well as the size and condition of my lesion on the screen.

On the other side, I can see the computer that contains equipment/ software to be used during the examination: guides, balloons, stents, etc.

In the control room, I control the vessel and interventional equipment using the radiology equipment and analyse the images under the supervision of the interventional radiologist.

The interventional radiologist as well as the nurse and technicians, observe my side throughout the whole examination.

### Uterine Fibroid Embolization

#### THE MOST COMMON TUMOURS OF THE FEMALE GENITAL TRACT

##### What are uterine fibroids?

Fibroids are non-cancerous (benign) growths that develop in the muscular wall of the uterus.

The exact causes for fibroid development are unclear, but researchers believe that genetics and a subsequent development of susceptibility to hormone stimulation.

Fibroids range greatly in size from very tiny to the size of a cantaloupe or larger. In some cases, they can cause the uterus to grow into the size of a five-month pregnancy or more.

##### There are three primary types of uterine fibroids.

**Submucosal fibroids** develop inside the cavity covering the uterus and expand outward through the wall, giving the uterus a bumpy appearance.

**Intramural fibroids** develop within the lining of the uterus and expand inward, increasing the size of the uterus, making it feel larger than normal or a gynaecologist's internal exam. These are the most common fibroids.

**Subserosal fibroids** are just outside the lining of the uterus. These are the least common fibroids, but they tend to cause the most problems, from a very small subserosal fibroid can cause heavy bleeding, spotting, very heavy and prolonged periods.

### Peripheral Vascular Disease

#### ANGIOPLASTY

First of all, a guide wire is inserted up to the lesion site.

An angioplasty balloon is pushed over the guide wire.

The balloon is inflated so as to widen the artery wall and compress the plaque. Build-up of cholesterol and other fatty deposits on the artery walls.

Balloon Angioplasty

### Interventional Oncology

#### YOUR TREATMENT OPTIONS

##### LIVER CHEMOEMBOLIZATION

##### EMBOLIZATION TECHNIQUES

In some patients, embolization may shrink the tumour substantially, rendering the patient a suitable surgical candidate. In others, arterial embolization effectively eliminates tumour-related symptoms and improves patients' quality of life.

**Chemoembolization** delivers a high dose of cancer-killing drug (chemotherapy) directly to the organ while depriving the tumour of its blood supply by blocking embolizing the arteries feeding the tumour.

**Transcatheter Embolization** Interventional radiologists inject tiny particles, the size of grains of sand, through a catheter and into the artery that supplies blood to the tumour. The particles cause clotting that decreases the tumour's blood supply, reducing pain.

**Yttrium-90 Radioembolization** Radioembolization is very similar to chemoembolization but with the use of radioactive microspheres.

Under local anaesthesia, a catheter is inserted into the femoral artery. Using careful and expert manoeuvres, the interventional radiologist pushes the catheter into the hepatic artery and through.

It injects the chemotherapeutic agents at a very high dose. As injection is carried out selectively, it is possible to inject very high doses that are able to destroy the hepatic cancer.

Attendees will be guided through Patient Awareness, where information on IR, UFE, PVD and Interventional Oncology will be displayed. The illustrations and texts at the exhibition aim at explaining these IR procedures and their potential benefits.

Advertorial

# Boston Scientific

*Delivering what's next.™*



**John E. Abele**

A physics and philosophy graduate of Amherst College, he started in the medical device business in 1960 with a small company that developed and marketed several laboratory instruments (flame photometer, osmometer) and distributed the first implantable pacemaker.

John Abele holds numerous patents and has published and lectured extensively on the technology of various medical devices and on the technical, social, economic and political trends and issues affecting healthcare. Abele's major interests are science literacy for children, education, and the process by which new technology is invented, developed and introduced to society.

Current activities include participation in many not-for-profit organisations, including Amherst College, Boston Museum of Science, Harvard Partners Center for Integration of Medicine and Innovative Technology (CIMIT), Franklin W. Olin College of Engineering President's Council and the National History Club. He has served for the past four years as Chairman of FIRST which works with high school kids to make being science-literate cool and fun.

John Abele is also Chairman of the Argosy Foundation, a private family foundation whose mission includes environmental sustainability. John Abele is the owner and developer of the Kingbridge Centre and Institute, a conferencing institute whose mission is to research, develop and teach improved methods for interactive conferencing: problem solving, conflict resolution, strategic planning, new methods for learning, and generally help groups to become "collectively intelligent."

John is married with three grown children. He and his wife, Mary, live with two dogs in Shelburne, Vermont.

**This year CIRSE will recognize the contribution to Interventional Radiology of John Abele, founder chairman of Boston Scientific, by presenting him with the CIRSE Gold Medal. In this interview John discusses the early days of his relationship with Interventional Radiology, the way that he has seen the specialty develop and makes some predictions for the future of the discipline.**

**You are widely recognized throughout the industry as one of the pioneers of Interventional Radiology, and Medi-Tech's first products were aimed at radiologists - what first attracted you to the radiology market?**

The attraction to radiology was the result of the early interest of a few radiologists in an invention I became responsible for when I joined a startup company in 1969. Upon graduating from college, I spent seven years working for a small laboratory instrument company, ultimately becoming General Manager. Having always worked for someone else, I realized that I had a strong desire to run something myself. I came across a basement development company called Medi-Tech that was working with several radiologists and had invented a steerable catheter. They wanted a device that could pass through the mouth, cannulate the papilla of Vater and continue on into the gall bladder. It could also navigate arteries, veins and other body cavities which are also of great interest to radiologists. There are a lot of radiologist inventors, so they made good collaborators when it came to trying to solve new catheter diagnostic problems...and eventually therapeutic problems as well.

**The early days must have been tough, fighting the establishment for recognition of minimally invasive procedures, what kept you going and believing you were heading in the right direction?**

Any establishment always resists change and I've always enjoyed taking the underdog position. Although I found it puzzling that physicians would oppose procedures that reduced risk, trauma, cost and time; I understood that the medical community wants proof and the power elite will try to exert that power in draconian ways.

*"I'll try it but only when you show me your 20 year data."*

Fortunately there were always a few supporters that kept our hopes up and helped us continue to improve the products. They also found new applications and we worked together to write papers and develop training programs, a process which still remains fundamental to Boston Scientific.

**Interventional Radiology has come a long way since then, how do you view the specialty now and where do you see the future direction for the specialty?**

Interventional Radiology has generally had more disagreements within the sphere of radiology than it has with the surgeons. In the earliest days, it was a hard discipline to define and even the nascent societies that preceded CIRSE had major squabbles among themselves. People who think that CIRSE has always been as professional, as well organized and as strategic as it is today need to be reminded of the immense amount of negotiation, planning and organization that went into today's quite well oiled machine. That investment and the hard times that have been experienced turn out to be one of the greatest resources for the continuing challenges that face us. From turf wars to economic constraints and demanding patients to a widening array of medical problems and possibilities, the future will be challenging and the lessons learned over these past years will be a major asset.

**Is this the same world-wide or have you noticed any differences in the specialty across the world?**

The world is relatively flat in the sense that both problems and solutions are communicated around the world pretty quickly. In a field as global as IR, that has been true for quite a while.

**What do you see as being the main future challenges for the field of Interventional Radiology?**

I always worry that they may get discouraged by the poaching and other turf war activities that are always going on from the organ specialties. But IRs are great innovators and will continue to figure out ways to treat diseases better. And the increasing strength and savvy of CIRSE, SIR and JSIR will help advance those innovations that enable them to do more, better, for less.

**What are your predictions for the big technological advances in the future for Interventional Radiology?**

The list is long but will include:

- Continued advancements in the ability to detect tumors earlier and do earlier micro therapy.
- Advances in interventional tissue engineering with cells and tissue fragments precisely placed for optimum restoration of function.
- Increased use of robotics, including the performance of procedures remotely.

**With the advances in pharmaceutical treatments and the trend towards earlier diagnosis and subsequent non invasive treatment, will there still be a place in the market for endovascular minimally invasive treatments?**

Pharmaceutical treatments are slow and don't work the same in everyone. Their systemic nature guarantees that there will be some unintended side effects. There will always be plenty of need for less invasive, site specific drug and/or device intervention and the professionals to perform those procedures.

**Medi-Tech then Boston Scientific have played a role in shaping the field of Interventional Radiology, does the future of Boston Scientific still lie in this field and if so in what way?**

Ironically, radiologists have played a role in most of the fields in which BSC participates today. Interventional Radiology will continue to evolve as a specialty and individual radiologists will continue to innovate in technologies and procedures that will advance health care. I like the idea of sticking with innovators.





Stephen Haley  
European Patent Attorney and Partner  
of Gill Jennings & Every LLP

## Benefits of intellectual property protection during the development of interventional tools

The development of any product involves a significant number of challenges. In the medical field these challenges are increased by the need to support development and the regulatory approval process over a number of years. In each step of the process, from the initial stages of design to the filing stages of regulatory compliance, a developer needs the support of a significant number of people and must deal with a large array of issues. This can lead to the developer to give priority to some development areas whilst neglecting others.

In our experience one area that tends to be neglected is ensuring that adequate protection is obtained for the intellectual property created during the design and development of a product. This is often neglected because the development team lacks knowledge of the basic principles underlying the intellectual property system and how it operates. Nevertheless, protection of intellectual property has a significant role to play, particularly in terms of attracting and keeping the interests of investors during product development. In view of this it is worthwhile having at least a basic understanding of the intellectual property system, so that an appropriate intellectual property strategy can be developed and implemented as part of the overall product research and development process.

The term "intellectual property" (IP) is used to cover property rights that are created during the development, manufacture and sale of products and services. There are many types of IP, ranging from the generation of confidential information, through copyrights and trademark

registration to the rights provided by the patent system. However, the most relevant to developers in the medical field to consider and understand are those of confidential information, patents and both, registered and unregistered industrial design rights.

Confidential information can be created in a number of ways and can relate to many different types of information. It can be of a personal, commercial or industrial nature, or can concern the state and its administration. An example would be product development data. Whilst others do not have the data available to them, it can have considerable value, but once it is available in the public domain, it may have little value. To have value, it therefore needs to be handled carefully, by flagging its confidentiality and controlling its circulation to ensure that it maintains the necessary "quality of confidence".

The patent system protects the functionality of a product. The system grants the patent owner the right to prevent anyone who does not have permission from that owner from making, using, selling or importing his/her invention for up to 20 years. In return, the details of the patent application (i.e. technical disclosure of the invention) are made public 18 months after it is filed. The system requires the active participation of the developer, as such patent rights have to be applied for. The application process is quite complex, particularly if international protection is required. It also incurs cost, so it is important for a developer to consider carefully how best to use it and to ensure that it is used in concert with product development and marketing plans to maximise its benefit.

In some cases the appeal of a product lies not only in its functionality but in its appearance. In such cases there is benefit in considering the design rights associated with a product. Some design rights exist automatically and are referred to as 'unregistered'. Stronger rights exist through a registration system that requires the designer to apply for protection. When a design right exists, the owner has the right to stop others from making or selling products of the same or similar appearance.

All of these types of IP are pieces of property under law and can be bought and sold like any other personal property. An IP portfolio associated with a particular product therefore has a monetary value which is influenced by the market. In many cases, these pieces of property act to increase the investment value of the product, as investors can offset investment risk with the market value of the developer's IP assets. Accordingly, an intelligently acquired IP portfolio can significantly increase the net worth of a product, thereby making it more attractive to investors and assisting in obtaining funding for development and for bringing a product to market.

Moreover, IP provides a barrier to entry into specific markets. Investors see this as one of the most important aspects of mitigating risk in an investment. This can be seen from two angles. When considering whether to invest in a product which has not yet entered a market, the fewer the difficulties that product will have to enter the market, the lower the risk will be for the potential investor. Conversely, where a product has already entered a market, a lower investment risk exists and it is more difficult for others to compete with that product.

### Don't miss it!

Next generation interventional tool:  
from idea to product  
Special Session  
Saturday, 11:30 - 12:30, Room G

An important advantage of using IP to protect innovation is that the exclusive right which it affords its owner can itself be licensed to others in exchange for royalties or for the right to use other protected inventions. Although licensing may not always be practicable or even desirable, having it as an option can provide an IP owner with further leverage in a fiercely competitive market, thereby giving potential investors even more incentive.

The importance of IP is growing and many developers, both small and large, are now using the IP system to their advantage. Ignoring IP is no longer an option for companies and investors, as those who may not want to take advantage of the IP system may still be susceptible to infringement of their competitors' existing rights.

Well established technology-driven companies place IP at the very centre of their business development strategies and, because investors are looking to minimise risk and maximise reward when investing, it is also far more important even for smaller developers and start-up companies to show potential investors that IP has been thoroughly considered and that an IP strategy has been put in place.

In a marketplace where innovation can have truly global benefits, every opportunity should be taken to realise the potential of IP assets. Those who ignore the potential benefits of protecting their innovation do so at considerable risk.

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+ 83%  
since 2005

## CIRSE 2008 breaks all records in abstract submission!

**CIRSE 2008 will doubtlessly be an outstanding congress in CIRSE's history, the best indicator being an all time high in abstract submissions. After breaking the 1,000 mark in 2007, abstracts for the CIRSE meeting are now well beyond 1,000 with 1,120 submitted abstracts in total, surpassing last year's number by almost 10%.**

**Embolotherapy remains the most popular topic with 139 submissions, followed by peripheral PTA. In contrast to 2007 the third most discussed topic in 2008 has been vascular imaging and diagnosis. Hepato-biliary intervention saw the biggest increase in submission with a whopping 100% followed by TIPS and portal vein intervention with more than 86%.**

**CIRSE would like to thank all doctors who have submitted abstracts for CIRSE 2008!**

## EPOS Awards

Since its introduction in 2003 the Electronic Presentation Online System (EPOS) has considerably raised the bar for scientific exhibits at the CIRSE meetings, allowing much greater flexibility and better communication than traditional scientific exhibits. EPOS currently comprises more than 8,600 exhibits, including 846 CIRSE posters.

*CIRSE is happy to announce that the 2008 EPOS awards have been granted to the following presentations:*

### Magna Cum Laude

Selective C-arm CT arteriography for transcatheter arterial chemoembolization of hepatocellular carcinoma  
*Authors: J. Iwazawa, S. Ohue, H. Abe, T. Mitani, N. Hashimoto*

### Cum Laude

The effects of arsenic trioxide on radiofrequency ablation: intraarterial versus intervenous administration  
*Authors: K. Hong, C. Yoon, J.Y. Lee, S. Kang*

Techniques and "pearls" for crossing challenging atherosclerotic chronic total occlusions (CTOs)  
*Authors: T.G. Walker, S.P. Kalva, P.M. Burke, Jr., B.M. Janne d'Othee, S.R. Broadwell, S.T. Wicky*

The role of CT in the assessment of acute and chronic gastrointestinal bleeding  
*Authors: H. Stunell, C.F. Murphy, E.V. Ward, I.D. Lyburn, M. Farrell, W.C. Torreggiani*

### Certificate of Merit

Percutaneous osteoplasty with use of a cement-filled covered stent for a fracture of the long trunk bone  
*Authors: K. Nakata, N. Kawai, M. Sato, G. Cao, I. Takasaka, M. Nakai, H. Minamiguchi, H. Tanihata*

Obtaining national dose reference levels for interventional radiology procedures  
*Authors: E. Vano, R. Sanchez, J.J. Gallego, J.F. Verdu, M. Gonzalez de Garay, A. Aspiazu, A. Segarra, M.T. Hernandez, M. Canis, F. Diaz*

Complications of percutaneous cryoablation for pulmonary malignancies  
*Authors: M. Inoue, S. Nakatsuka, H. Yashiro, M. Kawamura, Y. Izumi, N. Tsukada, S. Kuribayashi*

Modification of percutaneous stent-graft: effect on the development of complicated intimal tear after stent-graft treatment for aortic dissection  
*Authors: D.Y. Lee, J.Y. Won, J.T. Lee, K. Lee, H. Ko*

Transarterial hepatic embolization (TAE) using gelatin microspheres and tirapazamine: in vivo fundamental study using rabbits  
*Authors: N. Nitta, A. Sonoda, S. Ohta, A. Seko, Y. Miyagawa, T. Tanaka, M. Takahashi, K. Murata, T. Sakamoto*

Complicated cases of cavernous sinus dural arteriovenous fistula treated by transvenous embolization: cases' review  
*Authors: Y. Sagara, H. Kiyosue, S. Tanoue, H. Mori, Y. Hori, M. Okahara, J. Kashiwagi*

CT guided spine surgery: to a micro-invasive world  
*Authors: N. Amoretti, I. Hovorka, M. Fonquerne, V. Lesbats-Jacquot, P. Marcy, A. Dignac, P. Chevallier*

Pelvic congestion syndrome: a role for radiology in the treatment of chronic pelvic pain  
*Authors: P. Crowe, J.S. Freedman*



Derek Gould  
Chairman of the CIRSE Simulation Task Force

## CIRSE Simulation Task Force: towards fully validated simulator content for Interventional Radiology training and assessment

As the CIRSE Simulation Task Force moves into its 4<sup>th</sup> year, let's take a look at its work to realise 'virtual reality' as a substitute for patient based training for Interventional Radiology.

In 2007, the Task Force published an executive summary (1) of its previous simulation strategy, and a document outlining how relevant sites for using simulation could be identified within curricula (2). Comments are welcomed on these documents. Also in 2007, a commentary on medical simulation was led by Steve Dawson with the Joint International Simulation Task Force (SIR, CIRSE and RSNA) (3). This showed the direction of medical simulation, to bring about the promise of improving safety for patients. Already much can be gained from the adoption of simulation into our curricula, though not all elements are yet in place for interventional radiology. Soon however, interventional simulation will match the predictions of William J Mayo 80 years ago, that "There is no excuse today for the surgeon to learn on the patient." A further view on this developing role and the current limitations of medical simulators was recently published by Jim Reekers and Derek Gould (4).

The real world does not need to be replicated for a simulation to provide relevant practice of many cognitive and coarse motor skills (choose a wire or catheter; advance a wire in a normal iliac artery). Things become very different when considering critical, fine motor tasks such as crossing tight renal ostial, or internal carotid origin, stenoses. These subtasks are vital to successfully completing the procedure, and we need to know whether these and other critical steps are correctly replicated in a given simulation or not.

Simulations can be evaluated to determine where content is, or is not, correctly reproduced. Bill Lewandowski and Derek Gould examined the replication of content in current simulations in a study at CIRSE, Rome 2006 and presented the results in an EPOS at CIRSE 2007 (5). Key procedure steps were identified by members of the CIRSE Task Force, and these formed the basis of a questionnaire for simulator users. Data were collected from subject experts using VIST (Mentice), AngioMentor (Simbionix) and Immersion's Accutouch simulators. It was concluded that 'The fact that the respondents tended to feel that the simulators were not as realistic in simulating fine motor skills, as they were in simulating cognitive skills, should not be construed in too negative a light' since cognitive skills are an equally important part of the procedure, though 'other means probably have to be relied upon in order to complete the learning process'.

So while simulations may lack correct replication of some key steps, they can still be of value. Given that much of what must be learnt is knowledge and cognitive procedure steps, a mentor can train using a simulation within known limits of its functionality, as a precursor to the trainee commencing learning in patients. In determining the critical steps that are missing from a simulation, there is first a need for broad consensus on which steps are actually critical to a given performance objective, something of a challenge given the variability of medical opinion! Once identified, use of these metrics will also measure proficiency, both in simulations and conventional examinations.

Identification of metrics is the aim of iTRIMS (International Task Analysis for Radiological Interventional Metrics for Simulation) now funded by CIRSE Foundation, along with BSIR and Cordis. Sheena Johnson, Occupational Psychologist at Manchester Business School, UK, and two researchers, Helen Woolnough and Carianne Hunt, are energetically performing IR task analysis for a range of procedures, including carotid, renal and iliac stenting, as well as visceral procedures such as biopsy, drainage, nephrostomy and PTC. Task analysis involves interviewing Society-recognised subject matter experts (SME), to reveal training objectives, the presence of fine motor skills, and metrics including critical steps and complications.

To objectively define interventional tasks, interviews are conducted while the SME is prompted by video-records of interventional procedures: many of these interviews have been conducted at CIRSE 2007, BSIR 2007, SIR 2008, and more will be obtained at Copenhagen in 2008. If you are a SME and are interested in participating in this, please contact sheena.johnson@dom01.mbs.ac.uk.

The carotid stent task analysis is now almost complete and a paper to the British Psychological Society has been submitted. The results will take around 6 months to complete but would then be uploaded to CIRSE website as a 'living document' where data becomes available as development unfolds. Future work will examine similarities of core skills in different procedures, as well as the presence of any

differences in procedure tasks between different countries. Also on the horizon just now is the development, with Bill Lewandowski, of standards for simulations which are to be used to train interventional radiology.

The simulation gallery at CIRSE 2008 once again offers an opportunity to test your understanding of a procedure's sequencing against a simulation. These events have been superbly organised over the past four years by David Buerstedde and Nadja Alomar. As explained above, much of the benefit to be obtained comes from the mentor, and CIRSE SMEs will be on hand to take delegates through complex procedures such as carotid, renal and iliac stent placement. We have also, for the first time, added some visceral simulations and a competition for delegates.

### The CIRSE Simulation Task Force is looking forward to seeing you at the Simulation Gallery!

#### References:

1. DA Gould, AA Patel, G Becker et al. SIR / RSNA / CIRSE Joint Medical Simulation Task Force Strategic Plan. Executive Summary. Cardiovasc Intervent Radiol. 2007 July; 30(4): 551-554.
2. DA Gould/GJ Becker/DO Kessel/ WE Lewandowski/ AA Patel; JITF; 15.03.07. Establishing the role of simulation-based training in current interventional curricula. [http://www.cirse.org/files/File/Curricular\\_insertion\\_sites\\_for\\_simulation.pdf](http://www.cirse.org/files/File/Curricular_insertion_sites_for_simulation.pdf). Accessed 4th May 2008.
3. S Dawson, DA Gould. Procedural simulation's developing role in medicine, The Lancet 2007; 369:1671-1673
4. D.A. Gould, J.A. Reekers. The Role of Simulation in Training Endovascular Interventions. EDITORIAL, Available online 04 March 2008; European Journal of Vascular & Endovascular Surgery. DOI: 10.1016/j.ejvs.2008.01.008; PMID: 18313950
5. DA Gould, WE Lewandowski. Simulator model content validation in a large conference setting. EPOS presentation. Cardiovascular and Interventional Radiological Society of Europe annual meeting, Athens, 2007.

## Test your skills at CIRSE 2008

### Virtual Reality Hands-on Workshops at CIRSE 2008

#### Saturday, September 13

**VR-HWS 1: Peripherals**  
11:00 - 13:00

#### Sunday, September 14

**VR-HWS 2: Renals**  
11:00 - 13:00

#### Sunday, September 14

**VR-HWS 3: Renals**  
16:00 - 18:00

#### Monday, September 15

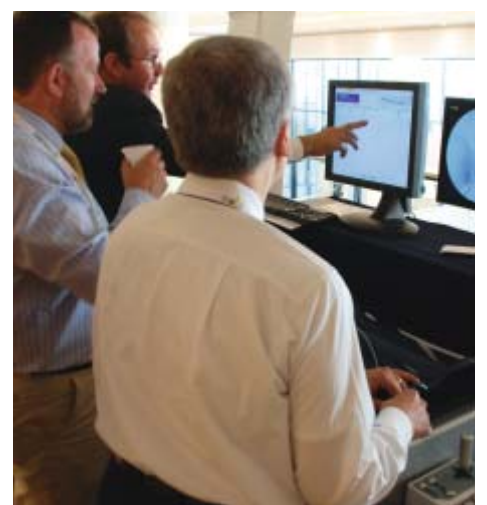
**VR-HWS 4: Carotids**  
11:00 - 13:00

#### Monday, September 15

**VR-HWS 5: Carotids**  
16:00 - 18:00

Location: Simulator Gallery

Registration fee: € 60,-





## CIRSE reaches out to Africa

**Ever since the start of his term in office it has been an important objective of CIRSE President Jim Reekers to help reaching out to young interventional radiologists from struggling countries. With a one time scholarship for Ghana radiologist Ato Quansah CIRSE has made its first step towards sharing its wealth with less fortunate regions.**

### Bringing IR procedures to Ghana

*Ato Quansah*  
Department of Radiology  
Komfo Anokye Teaching Hospital, Ghana

As far back as the year 2000 during a short rotation in my hospital's department of radiology with a visiting British radiologist I grew fond of the field of radiology. However, my dream to pursue a postgraduate programme in radiology in the teaching hospital where I was trained was impossible. A year's internship in surgery and paediatrics led me to pursue a career in surgery.

Then in February 2004 came the news that a 'white lady' radiologist had assumed duty in the hospital's radiology department as the only consultant without a resident in Komfo Anokye Teaching Hospital (KATH) in the middle belt of Ghana, West Africa.

KATH has been a teaching hospital since 1975 with a medical staff of about 700, 250 of which are doctors (one radiologist), 400 nurses and approximately the same number of orderlies who perform minor nursing duties due to a lack of an adequate number of qualified nursing staff. KATH serves a population of about 12 million including patients from the neighbouring countries of Ivory Coast and Burkina Faso. KATH also serves as a referral hospital for over 200 hospitals, clinics and health care centres in its catchment area.

KATH has a very vibrant department of obstetrics and gynaecology with about half of the hospital's doctors working in this unit. This is not sur-

prising considering that the hospital runs a large antenatal service with a very large number of deliveries per day. The department's emergency services are doubtlessly the best in the hospital.

The surgery department takes up about a quarter of the hospital doctors with a paediatric surgery team, general surgery, plastic surgery, combined trauma and orthopaedic and an over-stretched urology team made up of three consultants. An ear, nose and throat centre also serving more than half the country's population runs alongside a perpetually over-worked ophthalmology department. An oro-maxillo-facial unit is combined with the dentistry department.

The paediatrics department serves as the only specialist centre for the northern half of the country with a very active emergency unit for which I proudly served as a pioneering physician. The introduction of this emergency unit together with that for internal medicine within the past five years has quite remarkably improved patient care and reduced mortality rates.

Last but not least there are our poly clinics that see almost one thousand patients a month. The trauma emergency unit (preferably called casualty) is probably the busiest in the country. In 2002 statistics showed Ghana in seventh place among countries with the highest number of road traffic accidents (RTAs) or motor accidents.

The Ashanti region, where KATH is situated, unfortunately shows the highest number of accidents. It therefore stands to reason that the nation has invested into the construction of a new trauma centre which is said to be among the best in Sub-Saharan Africa. About five trauma surgeons and one radiologist (still under training in Germany) are expected to assist in manning this centre within the next two to three years. The radiology department is expected to respond to the needs of all these departments adequately with only one radiologist. Being an over-worked general radiologist he does not have the time or possibilities to acquire the skills for sophisticated IR procedures.

For a total period of about five months (at different intervals) I singlehandedly ran the hospital's radiology unit in the absence of the then radiologist Dr. Joeques, rendering general X-ray reporting, ultrasonography, CT scan reports, mammograms, a few Barium studies, urological studies (IVU, Urethrograms, Cystograms, etc.) and hysterosalpingographies.

The radiology department is currently run by one radiologist and two residents. We recently had partial accreditation from our local surgical college (Ghana College of Physicians and Surgeons) for formal training. Hitherto formal training was allowed either in Accra (the capital of Ghana) or in Nigeria by the sub regional college (West Africa College of Physicians and Surgeons). However, IR training is not offered in all of these institutions and residents only have the possibility of a six months observership abroad for exposure to MRI, angiography, Interventional Radiology and other sub-specialties for which there are no tutors in Ghana.

My keen interest in surgery, my love for radiology and my desire to perform less traumatic surgery rose my interest in Interventional Radiology before I could even appreciate its real scope. When later I discovered that my then colleague Dr. Joeques was an interventional radiologist I was hooked. Being introduced to percutaneous US guided as well as fluoroscopy guided nephrostomy and intra-abdominal abscess drainages even further increased my desire to learn more in this field.

Since Dr. Joeques left our hospital a year ago I have successfully performed many percutaneous guided drainages for liver and other intra-abdominal abscesses, earning myself the nickname 'Abscess Doctor'. The high prevalence of amoebic as well as bacterial liver abscesses and urinary schistosomiasis with resultant bladder tumours and ureteric strictures in the inland fishing communities and peasant farmer populations makes the acquisition of such skills invaluable. A rough average of four cases a week for these basic procedures makes IR an asset to our department which usually becomes the last point of call for diagnosis and treatment.

Previously most of the patients presenting anaemic following prolonged illness were given laparotomies in the surgery department. It is a

pity to see such patients come with scarification on their abdominal wall received from native 'doctors' who obviously worsen the already bad condition of these patients. The awe and smile on their faces when they see the pus streaming down the catheter into the drainage bag almost painlessly and yet with such instantaneous results is always a delight for me to behold.

KATH's ultramodern trauma centre is to be furnished with a multi-slice CT scanner, MRI and facilities for CT angiography. An angiography suite donated by General Electric of America has stayed unused since the departure of Dr. Joeques. Unfortunately she had to leave before she could impart the skills required for angiography to me.

My hope is that a visiting scholarship to a European radiology department with a rich experience in interventional procedures for trauma will afford me the opportunity to bring home the skills to assist at the centre. Furthermore the technique for US and CT guided biopsies, especially for breast and other lesions would be of great benefit. Our hospital's obstetric department would greatly benefit from uterine artery embolisation skills for the treatment of fibroids and severe haemorrhage before, during and after delivery. I would also greatly appreciate to observe other highly sophisticated procedures.

My training mandates a year's stay in a remote hospital where I can impart skills on colleagues who in turn can use these basic skills to better the lot of their patients. I am currently publicising the use of percutaneous US guided drainage procedures in KATH as well as the surrounding hospitals and clinics by sending treated patients back to where they were referred from with an explanation of this rather simple treatment option.

Dr. Joeques and others in a yearly ultrasound training programme also tutor the participants, usually doctors from the district hospitals, in US guided percutaneous drainage procedure. We hope to continue and expand these training programmes in order to facilitate the spread of knowledge in basic IR in my country.

I therefore immensely thank CIRSE for providing me with a visiting scholarship and hope that CIRSE will continue its support for Africa in the future.



Dr. Ato Quansah (left, teaching enema), Dr. Liz Joeques (right)



Dr. Ato Quansah performing ultrasound



Dr. Quansah using the sun as a viewing box



Main corridor of the X-ray department



Medical students at a radiology exam



Entrance of the Komfo Anokye Teaching Hospital



Patients bring their own notes to the ultrasound department



Advertorial

## Innova 3D/CT clinical benefit for peripheral interventions



**Dr. D. Bay MD**  
Head of Department, Department of Radiology  
Aker University Hospital, Oslo, Norway  
B.Wimille, P.Gobert, GE Healthcare, Buc, France

### Background:

Aker University Hospital is equipped with the Innova 4100IQ digital flat panel angiography system. The Innova 4100IQ system installed by GE Healthcare, has a 40 cm x 40 cm digital detector designed to perform general vascular interventional procedures and an integrated multi-modality Advantage Workstation.

During the following case study, Digital Subtraction Angiography and the Innova 3D/CT imaging are used during the treatment of a ruptured left hypogastric aneurysm with a stentgraft.

### Clinical Case:

This is a case of a 63 year-old male with a history of atrial fibrillation that is taking Warfarin medication. The patient has suffered left pelvic pain for 5 days. There was a suspicion of diverticulitis. He underwent a CT scan at another hospital, which revealed a ruptured left hypogastric aneurysm with a large retroperitoneal hematoma. The patient was then transferred to Aker University Hospital for intervention.

### Procedure:

The CT volume has been imported on the AW Volume Share 2 and postprocessed (see Fig.1 and Fig.2).

After catheter placement using low dose fluoroscopy, a Digital Subtraction Angiography (DSA) acquisition was performed with an injection of 8cc of Visipaque (GE) - 270mgI/mL (see Fig.3).

An Innova 3D acquisition was performed at 40°/s, taking 5 seconds with an injection of 40cc of Visipaque(GE) - 270mgI/mL at 8cc/s. This was done before the treatment (see Fig.4). The injection point was on the aorta and the X-Ray acquisition is delayed by 1.5 seconds.

An Innova CT 10d/s acquisition was performed just after in order to assess the retroperitoneal hematoma (see Fig.5)

The lesion was treated under low dose fluoroscopy, with an Excluder stentgraft (Gore) 16/14,4-120 (see Fig.6, Fig.7 and Fig.8). After the dilatation, a further Innova 3D acquisition was performed at 40°/s, taking 5 seconds, with an injection of 40cc of Visipaque(GE) - 270mgI/mL at 8cc/s. This was done after the treatment (see Fig.9). The injection point is done on the aorta and the X-Ray acquisition is delayed by 1.5 seconds.

### Discussion and conclusion:

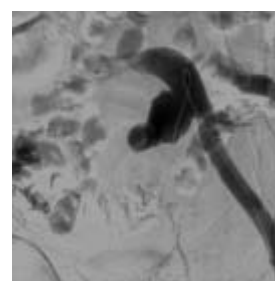
In this case, an endovascular repair of the ruptured aneurysm was possible, making open vascular surgery unnecessary. The high quality images obtained on the system, made both the planning and performance of the procedure easy. The Innova CT acquisition mode is useful to evaluate retroperitoneal hematomas avoiding transport of the patient to an ordinary CT Scanner. We will use this application - especially in cases involving the rupture of iliac arteries during PTA/stent for atherosclerotic obliterative disease.



**Fig 1 - Volume rendering of the CT showing the ruptured left hypogastric aneurysm.**



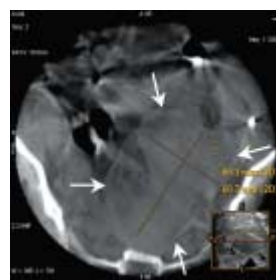
**Fig 2 - CT Sagittal cross-section showing the retroperitoneal hematoma.**



**Fig 3 - Digital Subtraction Angiography of the left hypogastric artery.**



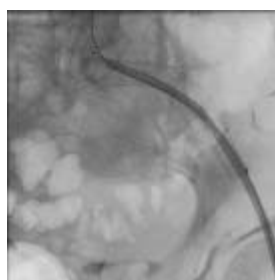
**Fig 4 - Innova 3D Volume rendering, showing the left hypogastric aneurysm.**



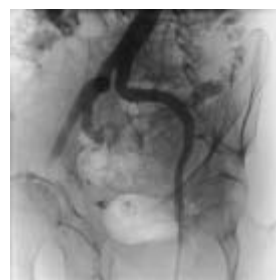
**Fig 5 - Innova CT Axial cross-section showing the retroperitoneal hematoma.**



**Fig 6 - Unsubtracted angiography image during balloon dilatation**



**Fig 7 - Unsubtracted angiography showing the stentgraft deployment.**



**Fig 8 - Angiography showing the vascularization after the stentgraft deployment.**



**Fig 9 - Innova 3D Volume rendering showing the left hypogastric artery after the dilatation.**

## Welcome to CIRSE 2008

For 45 years, Cook Medical has supported Interventional Radiology by creating valuable learning experiences that advance and promote interventional medicine.

Please join us in the Cook Medical Learning Center, Hall B for the following:

### Saturday, September 13

12:30-13:00 Prof. Dr. J.P. Pelage, Hôpital Univ. Ambroise Paré, Boulogne, France  
*How Can You Still Work Without Using Micro-Catheters?*

### Sunday, September 14

11:00-11:30 Dr. R. Fransen, A.Z. St. Lucas, Gent, Belgium  
*A Unique Randomized Multi-Center Study, Comparing Conservative Treatment with Vertebroplasty: Update and Preliminary Results of VERTOS 2*

12:30-13:00 Prof. Dr. T. Van Ha, Univ. of Chicago Hospital, Chicago, IL, U.S.  
*Techniques for Challenging Vena Cava Filter Retrievals*

14:00-14:30 Dr. O.M. van Delden, AMC Amsterdam, The Netherlands  
*Practical Biliary Intervention; Tips & Tricks*

### Monday, September 15

9:30-10:00 Prof. Dr. J. Golzarian, Univ. of Minnesota Hospital, MN, U.S.  
*Tips & Tricks for Endoleak Embolization*

### 13:00-14:00 Cook Satellite Symposium - DESTinations

Dr. M. Dake: Drug Eluting Stents:  
- Are All Drugs Equal?  
- Do We Need Polymers?

Prof. G. Tepe: - Drug Eluting Stents for the SFA - An Overview  
- Update on Zilver® PTX Trial

Dr. M. Downes: - Potential of Drug Eluting Stents For Renal Artery Stenting

14:30-15:00 Dr. R. Morgan, St. Georges Hospital, London, U.K.  
*Tips & Tricks for Catheter Recanalisation in CLI*

### Tuesday, September 16

11:00-11:30 Prof. Dr. J.I. Bilbao, Pamplona Univ. Hospital, Pamplona, Spain  
*Access Difficulties in Embolotherapy for GI Bleeding*

12:30-13:00 Dr. M. Downes, Kent and Canterbury Hospital, Canterbury, Kent, U.K.  
*Strategies, Tips & Tricks for Renal Stenting*

14:45-15:15 Prof. Dr. J. Rieke, Universitätsklinik, Magdeburg, Germany  
*MR-Guided Interstitial Interventions in Oncology*



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Christian Hohl  
Director of Radiology  
HELIOS Hospital Siegburg  
Germany

The number of patients requiring renal replacement therapy has risen steadily to reach an incidence of over 340 per million of the population (pmp) in the USA and 100-200 pmp in Europe (1). Prerequisite for haemodialysis is a functional vascular access. Whereas in the US many patients are dialysed via catheters, in Europe the majority of patients are provided with AV-shunts. Dysfunction of arteriovenous fistulae and grafts occurs frequently in haemodialysis patients and contributes significantly to morbidity and hospitalisation in the dialysis population (2). The choice of a suitable method to preserve vascular access is of increasing significance for the patients and their physicians. It must be emphasised that early diagnosis and treatment of access-related complications are vital to achieve long-term access function (3).

Three different parties are involved in the creation and maintenance of haemodialysis shunts: vascular surgeons, nephrologists and interventional radiologists.

In most cases the nephrologist is the main contact person for the patient. He decides the right time for shunt creation, performs dialysis and takes good care of a well functioning vascular access. To prevent shunt thrombosis, stenoses must be identified in time. Nephrologists differentiate between shunt monitoring and surveillance. Monitoring can be performed by pressure measurement during dialysis and clinical evaluation. Surveillance is defined as a periodic evaluation by means of tests that may involve special instrumentation such as shunt blood flow measurements or Duplex-ultrasonography (4).

## Interventions in dialysis shunts

However, who is the right contact person if monitoring or surveillance indicate potential shunt problems? Now the interventional radiologists come into play. They can offer a "one stop shop" including exact diagnosis and appropriate therapy.

If patients with potential AV-access related problems are referred to the interventional radiologist, the first goal is to assess the shunt history during the patient briefing. The shunt-intervention is started with a diagnostic angiography performed by a fine-needle arterial puncture with a 22-gauge cannula in the cubital fossa. This arterial access can be used for the diagnostic digital subtraction angiography (DSA) as well as the monitoring during the intervention. The contrast medium is injected manually and can be diluted 1:3. Typical findings are stenoses in the venous outflow tract of Brescia-Cimino (BC) shunts or stenoses of the proximal anastomosis in grafts (Fig.1).

As soon as the diagnostic angiography is completed, the appropriate therapeutic approach should be discussed with the nephrologist and/or the vascular surgeon. If the shunt is younger than 6-8 weeks or has never been used before, the patient should be referred directly to the vascular surgeon. A percutaneous intervention is not recommended either in patients with long segment venous stenosis or arterial stenosis.

### Venous stenoses

If a percutaneous intervention is considered to be promising, a retro- or antegrade venous access must be established and the stenosis is passed with a hydrophilic steerable 0.035" guide wire. A 5F or 6F sheath is inserted and

depending on the vessel size and stenosis-type, the lesion is treated with a 5-12 mm balloon with a length of 20 or 40 mm. Close to the anastomosis the balloon diameter should not exceed 4-5 mm (Fig. 2). The balloon is advanced over the wire into the stenotic segment and is inflated by hand or with manometric pressure monitoring. The dilatation is repeated several times and the pressure should be held for 30-60 seconds depending on how well the obstruction corresponds to angioplasty.

Intravenous administration of 2,500-5,000 IU heparin is essential to prevent immediate thrombosis. In highly resistant lesions the use of high pressure balloons or cutting balloons can be very helpful (5). Cutting balloons are equipped with microsurgical blades scoring the lesion with incisions, allowing the balloon to dilate the vessel. Stenting is not recommended close to the anastomosis or dialysis puncture site, as it can lead to stent fracture during dialysis or problems in future surgical interventions. A good method to avoid prolonged compression at the end of the intervention is a purse string suture around the puncture site before removing the sheath.

The primary technical success rate for PTA of venous stenoses is reported to be more than 90% with a primary and cumulative patency of 51% and 80% at 1 year for fistulas. For PTFE grafts a technical success rate of 98% could be achieved with a primary and cumulative patency of 33 and 84% (3). A common complication is mild hematoma at the puncture site. Venous rupture with potential pseudo aneurysms (<2%) or shunt infections (<<1%) are rare. Venous rupture can be handled by prolonged inflation of the balloon in most cases.

### Don't miss it!

How to manage problems with dialysis fistulas

Workshop

Saturday, 14:30-15:30, Room D

### Shunt thrombosis

In case of shunt thrombosis, only relatively fresh occlusions (<48h) should be treated percutaneously. Different techniques are available for the recanalisation: PTA, pharmacologic thrombolysis, pharmaco-mechanical thrombolysis and mechanical thrombectomy. The primary technical success rate in thrombosed AV-fistulas is reported to be almost 90% with a primary and cumulative patency of 27% and 51% at 1 year. For PTFE grafts a technical success rate of 75-94% could be achieved with a primary and cumulative patency of 18-39% and 57-69% (3). The long term success depends on how well the culprit lesion can be treated.

### Central venous stenoses

Swelling of the access arm in combination with shunt dysfunction are the most significant clinical symptoms of central venous obstruction. Several studies of patients treated with PTA alone have been published. Primary patency rates of 10% or less at 1 year and numerous restenoses were reported. Stent implantation has been shown to improve primary 1 year patency rates up to 56% or more. These figures do not differ significantly from those of surgical intervention. Nonetheless, due to the relative invasiveness of surgery for central venous obstructions the less invasive interventional therapy is recommended as first line treatment (3).

### Summary

The treatment of AV access dysfunction is a complex undertaking in which the cooperation of interventional radiologists, vascular surgeons and nephrologists is the road to success for long-term access function. Especially short segment stenoses and fresh thromboses can be effectively treated by percutaneous intervention.

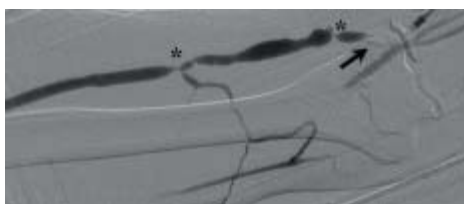


Fig. 1a: Typical venous stenoses in a Brescia-Cimino shunt close to the anastomosis (arrow) and along the venous outflow tract (asterisks).



Fig. 1b: Stenosis of the proximal anastomosis in a PTFE graft (arrow).

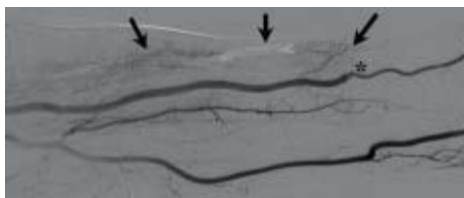


Fig. 2a: Pulseless Brescia-Cimino fistula with fresh occlusion of the anastomosis. The shunt vein is already punctured and can be delineated (arrows), the anastomosis (asterisk) is occluded.

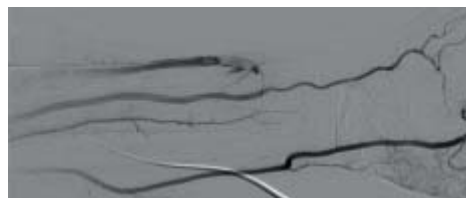


Fig. 2b: A guidewire has passed the stenosis

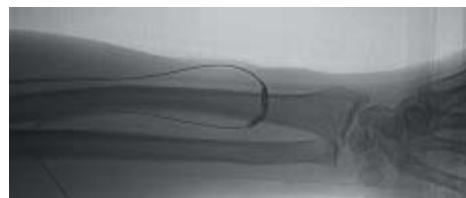


Fig. 2c: Dilatation of the stenosis with a 4/20 mm balloon at 14 atm.



Fig. 2d: Complete recanalisation.



Fig. 3a: Thrombosed PTFE-graft (arrows) on the basis of a high grade stenosis of the proximal anastomosis (asterisk)



Fig. 3b: After dilatation of the stenosis with a 5/20 mm balloon the graft is still filled up with multiple thrombi.



Fig. 3c: Mechanical thrombectomy with a 5F system (Terrotola)



Fig. 3d: Complete recanalisation.

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## Essentials in Interventional Oncology

During the past few years the use of image-guided interventions in cancer treatment has experienced unparalleled growth. Several innovative techniques and devices for direct tumour ablation and trans-arterial therapy have been introduced. Sophisticated imaging methods improving tumour targeting and treatment monitoring have been devised. A number of trials have been successfully completed in different clinical settings. Interventional Oncology is gaining increasing acceptance as a viable alternate or complementary treatment for a variety of cancers.

The 2008 CIRSE Annual Meeting features a comprehensive spectrum of educational activities in Interventional Oncology. Attendees have the opportunity to choose from several special sessions and workshops, including a number of "hands-on" courses, covering all aspects of Interventional Oncology. In addition, for the first time this year, a dedicated Foundation course entitled "The Essentials on Interventional Oncology" has been set up.

The Foundation Course is designed for radiologists in training and new consultants, but can also be a very valuable educational tool for experienced consultants who require a refresher course on the subject. The sessions will start with an overview of the current clinical scenario, including

standard medical and surgical treatment options. Then, the use of both percutaneous techniques and intra-arterial interventions will be presented in a step-by-step fashion. At the end, the participants will have the opportunity to attend a moderated e-learning presentation to deepen their knowledge through practical case discussions.

The Foundation Course "The Essentials on Interventional Oncology" will cover four key areas of clinical application of image-guided interventions: hepatocellular carcinoma (HCC), liver metastases, kidney cancer, and bone metastases.

Image-guided percutaneous ablation is currently accepted as the best therapeutic choice for nonsurgical patients with early stage HCC (1-3). Over the past two decades, several methods for chemical ablation or thermal tumour destruction through localised heating or freezing have been developed and clinically tested (4). On the other hand, transcatheter arterial chemoembolization is the accepted standard of care for patients with multinodular disease confined to the liver (5). The recent introduction of drug-eluting beads has been instrumental in improving response rates and tolerability of the procedure and has opened new prospects for combination strategies including percutaneous ablation and a controlled and sustained local drug delivery (6,7) (Fig.1).

The use of radiofrequency ablation to treat unresectable or medically inoperable patients with liver-dominant hepatic metastatic disease, especially from colorectal cancer, was proposed 10 years ago (8,9). Since then, several investigators have refined techniques and approaches and 8 cohort studies have reported long-term survival outcomes of RFA-treated patients (10,11). Recently, the interim results of a randomised controlled trial comparing chemotherapy vs. chemotherapy plus radiofrequency ablation have been presented at the annual meeting of the American Society of Clinical Oncology, providing evidence of clinical benefit (12).

Treatment of kidney cancer has become one of the most effective indications for percutaneous ablation. The technique has been optimized and reported results seem to compare very well with those of surgical management, both in terms of clinical outcomes and treatment-related costs (13,14). Interventional techniques are gaining increasing acceptance in the management of painful bone metastases. The impact on quality of life of percutaneous procedures has been well documented and technical refinements have allowed even critical locations to be successfully treated (15,16).

### Don't miss it!

**RFA-HWS 1: Starting your practice Hands-on Workshop**  
Saturday, 14:15-15:45, RFA Room  
**Controversies in non-vascular interventions**  
**Special Session**  
Sunday, 10:00-11:00, Room E

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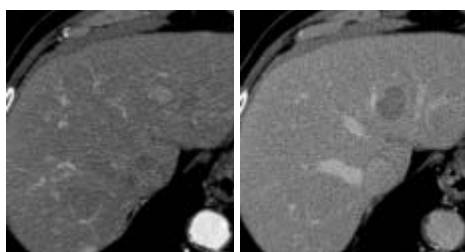


Fig.1a,b: Hepatocellular carcinoma treated with a combination of radiofrequency ablation and drug-eluting bead chemoembolization. Pretreatment CT shows hypervascular HCC located in close proximity to the heart



Fig.1c: Radio-frequency ablation is carried out under ultrasound guidance by using a multitined expandable electrode (RITA Medical System, AngioDynamics)



Fig.1d,e: Treatment is completed with intraarterial injection of 2 ml of 100-300 µm drug-eluting bead uploaded with 50 mg of doxorubicin (DC Bead, Biocompatibles)

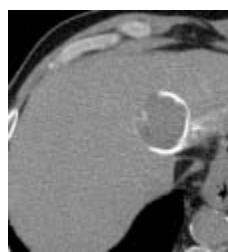


Fig.1f: CT obtained immediately after the procedure confirms accumulation of the injected material along the periphery of the ablation zone

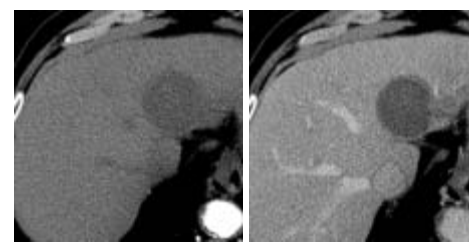


Fig.1g,h: Follow-up CT scans show complete response

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**Louis Boyer**  
Professor and Head of the Radiology Department  
University Hospital, Clermont Ferrand, France  
Lucie Cassagnes  
Pascal Chabrot  
Anne Ravel

Today PTA is considered as the first choice procedure for infrapopliteal revascularisation. Its relative safety has led several authors to use it to treat stenosis in patients with claudication. However, for long occlusions claudication is not an appropriate indication due to the high potential morbidity. The primary indication is limb salvage in patients with symptoms of critical limb ischemia (CLI) (Leriche - Fontaine stages III and IV, Rutherford categories 4-6), characterised by chronic ischaemic rest pain, ulcer or gangrene attributable to arterial occlusive disease.

Although Buerger's disease may result in ischaemic disease of the legs and feet, CLI is most commonly due to atherosclerosis. There is a clear relation between atherosclerotic, crural disease and diabetes. The highest rates of CLI are observed among older subjects, smokers and diabetics. Patients with CLI have an elevated risk of future myocardial infarction, stroke and vascular death, so CLI should not be treated as a stand alone manifestation of PAD, and management of associated risk factors is very important to influence the prognosis for each patient.

Peripheral revascularisation represents the alternative to amputation in CLI. Bypass surgery is a technically demanding procedure; the best results are obtained after distal venous bypass, which is not always technically possible. As percutaneous procedure, less or minimally invasive, yields comparable limb salvage rates in frail patients, it is considered as the first line treatment (1, 2, 3) for focal or diffuse stenoses or occlusions of the tibial and peroneal arteries whenever technically possible. It does not preclude any secondary surgical options, even in case of failure.

Performed with the usual technique, it requires femoro-popliteal arterial patency, so previous percutaneous associated treatment of these upstream arteries may be necessary (ideally during the same procedure). "In case of combined inflow and outflow disease with CLI, inflow should be addressed first - class 1, level C. In case of combined inflow and outflow disease in which symptoms of CLI or infection persist after inflow revascularisation, an outflow revascularisation procedure should be performed - class 1, level B" (4, 5).

Antegrade puncture of the CFA is the standard approach with which a kink resistance of the sheath is necessary. A crossover approach from the contralateral CFA has a lower complication rate and avoids the arterial compression bandage on the treated leg, but means less pushability, requires long sheaths and PTA balloons with long shafts and makes the management of BTK complications more difficult.

It is essential to do a complete, high quality intra-arterial DSA of the limb before endovascular intervention. A one step procedure involving the diagnostic angiography and endovascular treatment is highly preferable. Per procedure use of heparin is mandatory. Low profile materials increase the crossability and decrease the complication rate. Conventional balloon PTA is the reference technique to treat stenosis and short occlusions. 0.018 or 0.014 guidewires and small French size balloon coaxial platforms make it possible to perform angiographic controls dur-

## Below the knee intervention - an update

ing the procedure. A 0.035 inch hydrophilic guidewire may be necessary to cross occlusions. Inadvertent movement of the guidewire have to be avoided in order to spare spasm.

Subintimal angioplasty, first described by Bolia (6), enables the revascularisation of long chronic occlusion (7), although heavy calcifications may cause failure. To create a subintimal channel, a loop with a 0.035 J type hydrophilic guide wire is normally used. Re-entry is the key point, requiring skill and experience. Balloon inflation should be short, with a short balloon, allowing step by step progression of the balloon-guidewire couple. A specific 'outback catheter' has been proposed to facilitate re-entry. Spasmolytics are useful. It is only after re-entry that we give heparin.

In case of perforation, if the guide wire can be passed through, low pressure inflation for a few minutes will often seal it. If not, the re-opened vessel has to be occluded with a coil. An extension of this technique, namely using subintimal arterial flossing with antegrade-rétrograde intervention (SAFARI) (8) to re-canalize has been proposed; a distal crural vessel is punctured and a wire snared through an antegrade approach in the femoral artery. Whatever the technique, the goal is to restore at least one "straight line flow" (9, 10) down to the ankle, choosing the best vessel according to its chance of recanalisation success. Re opening of stenosis upstream large collateral vessels may be sufficient for clinical success, even if complete recanalisation is not achieved.

"Stents and other adjunctive techniques such as lasers, cutting balloons, atherectomy devices and thermal devices can be useful in the femoral, popliteal, and tibial arteries as salvage therapy for a suboptimal or failed result from balloon dilatation (e.g. persistent transluminal gradient, residual diameter stenosis greater than 50% or flow limiting dissection) (class IIa, level C)" (3,4). "The effectiveness of uncoated/uncovered stents, atherectomy, cutting balloons, thermal devices and lasers for the treatment of infra pop lesions (except to salvage a suboptimal result for balloon dilatation) is not well established" (class IIb, level C). "Primary stent placement is not recommended in the femoral, popliteal or tibial arteries" (class III, level C) (3,4).

Whether the Transatlantic Inter Society Consensus (TASC) guidelines are suitable when it comes to treating infrapopliteal lesions is questionable for some authors. Nevertheless, in our opinion today there are still few indications for stent placement to complete suboptimal results or as a bailout procedure. If stenting is necessary, it seems that results of coated stents (carbofilm or drug eluting stent) (11,12) or even bio-absorbable stents are better than with bare stents.

Cutting balloons may be of interest when treating short, rigid and calcified stenoses in which standard balloon PTA has failed. In recent months we have seen a revival of interest in the use of atherectomy and recanalisation devices, which have to be used cautiously in these small calibre arteries, where standard low profile materials produce interesting results with few complications.

Pain management, specific wound care and medical treatments including double antiplatelet medications (for 6 weeks in our practice, followed by simple medication), lipid lowering molecules and diabetes medications are mandatory. Primary technical success for stenoses and short occlusions is more than 90%.

2,3% mortality was reported in the CIRSE Foundation registry (13). Complications include myocardial infarction, wound, urinary and pulmonary infections. Immediate failure or arterial complications (spasms, thrombosis and peripheral embolisations) are related to the anatomy of the lesions, but also to the operator's expertise and ability to perform recanalisation.

The cumulative limb salvage rate exceeds 80% at 2 years (14,15). As short term patency is sufficient to allow for the disappearance of rest pain and/or the healing of ulcers, clinical success is often maintained longer than angiographic patency in accordance with the primary goal of limb salvage. There is no evidence for the need of follow up imaging if clinical success is maintained. According to our personal results, outcomes seem particularly interesting in patients with diabetes (16). Requiring only short hospitalization, PTA provides a lower care-cost ratio than other methods.

Infrapopliteal PTA in CLI performed by skilled interventional radiologists yields high limb salvage and low complication rates. It becomes more and more important with increasing rates of diabetes and PAD, and has to be proposed if technically possible as the first line treatment in these high risk cardiovascular patients.

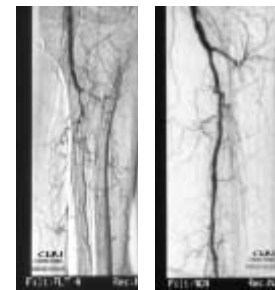
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**Don't miss it!**  
**Below the knee angioplasty -**  
**How I do it**  
**Workshop**  
Saturday, 14:30-15:30, Room C



March 12



May 20

*Fig.1: Large ulcer healing obtained 10 weeks after peroneal artery recanalisation*

## European School of Interventional Radiology - ESIR

### Local Courses

**Non-Vascular Upper GI Interventions**  
**Novi Sad (RS)**  
**October 10-11**

**Embolización**  
**Course in Spanish Language**  
**Valencia (ES)**  
**October 17-18**

**Carotid and Renal Stenting**  
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**October 31-November 1**

**Vascular Interventions -**  
**Basic Course**  
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### Institute Courses

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**Cordis Cardiac & Vascular Institute (CCVI)**  
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**Carotid Artery Stenting**  
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**Interventional Treatment of Peripheral**  
**Arterial Disease**  
**Hands-On Course**  
**Crossroads Institute (Abbott)**  
**Diegem (BE)**  
**November 27-28**





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## PTA or conservative treatment with supervised exercise for SFA claudicants?

During recent years interest in endovascular treatment for infrainguinal occlusive disease has increased as compared to open surgery, in Scandinavia as well as everywhere else in Europe. This is true, both for claudicants and patients with critical ischemia. Patients with acute ischemia are now treated by endovascular means as often as with open surgery.

Even if 30-day results are similar for open and endovascular repair, the one-year results are still better with surgery except in patients treated for acute ischemia. Surgery for claudicants still usually means that a femoro-popliteal bypass with a reversed vein or the vein in situ will be carried out. Duplex scanning of the vein to be used for bypass is performed preoperatively and vein graft surveillance postoperatively. Results of this "golden standard" treatment are excellent with a combined mortality and amputation rate of 1.4%. For TASC A and B SFA lesions there is consensus for endovascular treatment, whereas open surgery has been the main treatment for type C and D lesions. However, there is an ongoing shift in favour for endovascular treatment even in these lesions.

Percutaneous transluminal angioplasty (PTA) has been widely used in the treatment of femoro-popliteal stenosis and occlusion for many years. However, the medium and long-term results have been suboptimal due to restenosis rates of 70% with PTA alone in long superficial femoral artery (SFA) lesions. Factors contributing to poor results include the presence of occlusion rather than stenosis, the length of the lesion and the severity of run-off vessel disease.

Stents used in the treatment of arterial disease in the coronary, renal and iliac arteries have shown to have superior patency to balloon angioplasty alone with restenosis rates between 10-25%. In the treatment of SFA lesions several early studies have investigated the patency of balloon expandable stainless steel stents. Stents with low flexibility carry a high risk of deformation in SFA. Medium and long-term vessel patency is not better with stents than with PTA alone.

Self-expanding nitinol stents are stents with high flexibility and moderate to high radial force. Initial studies have shown promising results in the SFA. Early prospective randomised studies, the Sirocco I and II studies have shown a restenosis rate as low as 7% at 6 months and 18% at 12 months with self expanding nitinol stents.

The SFA is a vascular region with complex movements and forces. Cyclic flexion of knee and hip joints results in axial compression and elongation of the SFA which can be transmit-

ted to the stent after stent placement. When finally the cyclic stress is too strong, the stent might fracture. In the situation of stent overlap, axial deformations of the stent cause neighbouring stent segments to pull and push each other, which is why theoretically stent overlap might induce stent fractures.

The Sirocco studies were the first systematic studies to report on stent fractures, but the observation of fatigue stress on the material was not directly proven to be associated with restenosis or bad outcome. Later studies focused on the correlation between stent fractures and vessel flow. A reduced vessel patency in fractured stents has been shown to be correlated to the length of the stented segment of the artery and the number of stents used.

Up to now the most frequent use of stents in the SFA is "bailout" stenting, which in most studies means that there is more than 50% residual stenosis or a flow limiting dissection after PTA. The prospective randomised Absolute trial investigated patients with severe claudication or critical ischemia with long lesions (130 +/- 60 mm). Results indicated that primary stenting in the SFA was superior to PTA with bailout stenting on the following endpoints: restenosis rate, ABI and walking distance.

Two other recent trials have studied primary stenting, i.e. the FAST and the Resilient trials. The FAST trial investigated claudicants with short lesions (4,5 cm). The stent arm used Luminexx stents versus PTA alone with no significant difference in patency between both treatment arms after 12 months follow up, but a trend towards less restenosis in the stent treated group. The Resilient trial investigated patients with claudication and critical limb ischemia with 6.5 cm long lesions, with PTA alone in one arm and Edwards Life stent in the other. After a relatively short follow-up period of six months, 84% primary patency and 96% freedom of intervention was shown within the stent treated group.

To summarise, there is a relentless drive towards endovascular treatment of femoropopliteal lesions. Also, the practise is running ahead of evidence, as noted during the 2008 Charing Cross meeting and in Vascular News' June 2008 edition. Notable endovascular benefits have been claimed with the coronary technology transferred to the lower limbs' smaller vessels, even if not noted as yet in evidence-based medicine.

In the Scandinavian countries the most accepted treatment of infrainguinal claudication is the conservative best medical treatment with or without exercise, but there is a trend

towards PTA with or without stenting in certain situations. Although only a fraction of patients with intermittent claudication seek medical advice, the number of patients treated endovascularly is increasing in many countries. Formerly they were only offered conservative treatment. However, there is no significant evidence that either surgery or endovascular treatment is warranted in patients with peripheral claudication.

The natural history of SFA disease with claudication without critical ischemia is quite benign. Most patients that are offered best medical treatment are advised to "go home and walk" with a prescription of ASA, a statin and they are advised to quit smoking. Unfortunately, there is no widely accepted medication to treat claudication, even if cilostazol seems somewhat promising.

Recent studies have shown significantly better results with supervised than non-supervised exercise on the distance walked on a treadmill. The problem is that the majority does not have access to supervised training. Only two prospective randomised trials with a small number of patients have studied exercise training versus angioplasty for stable claudication. After six months mean ABIs were higher in the angioplasty groups than in the control groups. Furthermore, walking distances were greater in the angioplasty group, but not in the other trial.

At two years follow up in one trial, the angioplasty group had more patent arteries, but not a significantly better walking distance or quality of life. In the other trial, long term follow up at six years showed no significant differences in outcome between the angioplasty and control groups. These limited results suggest that PTA may have had a short-term benefit, which may not have been durable.

It might be of interest to discuss the possibilities of a multi-centre randomised controlled trial designed to compare the benefits of best medical therapy and supervised exercise with PTA with/without stent in patients with stable mild to moderate claudication due to SFA disease (Fontaine IIa and IIb). The primary outcome measure will be health-related quality of life as determined by the SF-36 and EuroQol EQ-5D surveys. A secondary objective is to follow ABI and walking distances during the study period of up to five years. Furthermore a cost-effectiveness analysis of total cost of the intervention(s) vs. conservative treatment can be discussed. A protocol for such a study is now being processed in Helsingborg Hospital and we invite all interested persons to contact Dr. Hans Lindgren at [hans.lindgren@skane.se](mailto:hans.lindgren@skane.se).

### Don't miss it!

Management of peripheral vascular disease I

Foundation Course

Sunday, 10:00-11:00, Room A

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## New developments in embolization

Vascular embolotherapy or embolization is defined as the percutaneous endovascular use of one or more of a variety of agents or materials to accomplish vascular occlusion.

Embolization has made a remarkable surge during the last two decades driven by improvements in imaging, breakthroughs in micro-catheter technology, the refinement of existing materials and the development of new embolic agents and devices. The number of applications of embolotherapy continues to expand, making this technique an important player in the daily practice of Interventional Radiology. A quick search at Pubmed using "embolization" as key word shows that there have been more than 300 publications in this field from January 2007 to July 2008. Cancer therapy, in particular chemoembolization of hepatic tumors, ranked first on this list. However, a great number of publications were dedicated to GI bleeding and gynaecologic embolizations. Although these papers haven't reported any new indications in this field, they have contributed greatly to confirm the undeniable role of this modality as a therapeutic option in different areas of medicine.

In the past two years there have been continued efforts to develop new materials and to publish the result of their usage in clinical applications. Below some of these developments will be mentioned.

## Coils and plugs

Based on neuro-interventional technology, a new pushable and detachable biopolymer-coated hydrocoil for peripheral use has been introduced and used in different centres. Hydrocoils are reported to increase in size after delivery. This should allow using smaller numbers of coils in some high flow situations or where a large amount of coils is needed. The coils have to be imbedded into saline for about three minutes before insertion into the catheter. Although it is suggested that a certain degree of over-sizing (15%) is essential for optimal coil embolization, the manufacturer (Terumo USA) recommends no over-sizing for these coils.

The usage of detachable coil for peripheral interventions is also increasing, mainly in high flow situations. One interesting new technical development presented by Dr Greben in the last GEST meeting (Global Embolization Symposium and Technologies) was related to the usage of detachable coils in patient with high flow lesions. In the so-called double micro-catheter technique two micro-catheters were used inside the same sheath. After placing the first micro-catheter at the desired level in the target vessel, the coil would be delivered, but would remain attached. This coil would be used as a filter to prevent embolization while adding more coils through the second micro-catheter. The distal coil would be detached at the end of the procedure.

For plugs there have been many more reports of using AVP II in different peripheral applications with great results. AGA medical has also

introduced the AVP III and IV that are still under clinical evaluation. The AVP III has more Nitinol layers with modified design for faster occlusion. It is indicated in high flow situations.

### Particulate agents

Recently the particulate embolics have been subject to the most interesting developments in the field of embolization. There have been several animal and in vitro publications studying the physical properties and the biological effect of available embolic spheres. In a recent study Stampfl et al compared four available microspheres and demonstrated that they are generally associated with minimal inflammatory reactions. All the vessels were recanalised within 12 weeks after embolization. However, the exact mechanism of recanalisation was unclear. In another interesting paper on embolics, Laurent et al have demonstrated that the fertility rate in animals was much higher in the group treated with embospheres. This data is the first of its kind that may have a significant impact on our practice if confirmed by clinical trials.

With the advent of the spherical particles and the possibility of loading them with radioactive elements or active drugs, several new indications have been developed in this field. This novel drug-delivery system has recently been evaluated for intra-arterial treatment of hepatic lesions. Microspheres have the potential to be loaded with different types of medications or drugs. The theoretical advantages of drug-loaded microspheres may be decisive: high local diffusion from the site of the microsphere, lower total drug doses compared to a systemic administration, and finally the possibility of using drugs that are potentially toxic via the local route.

The interaction between the drug and the polymeric microsphere is important when the drug is loaded onto the microsphere. It has been shown that it can result in a decrease of the average size of microspheres down to 50% of the initial size. The systemic level of the drug has to be either null or at least much lower than after systemic administration. Also these chemospheres have to be homogeneously distributed in the target area. The drug release should be with no adverse local or general side effect. Finally, there must be evident signs of the biological action of the drug.

In a recent study by Wassef et al, PVA hydrogel microsphere (Bead Block™) loaded with ibuprofen was studied in animal. The Ibuprofen release was effective in tissues during at least one week after embolization which interestingly corresponds to the mean duration of prescription of analgesics used in clinical practice. Clinical trials are now ongoing and results are awaited before definitive conclusions can be drawn about the clinical value of loading microspheres with ibuprofen.

Lewis et al have shown that the loading of doxorubicin has no impact on the handling and deliverability of the microspheres and the loco-regional drug delivery from microspheres caused targeted tissue damage with minimal

systemic impact. Microspectrofluorimetry analysis of pig livers embolized with doxorubicin loaded beads has shown very high levels of doxorubicin in liver tissue which persists over several months. Clinical trials of these doxorubicin microspheres in patients with hepatocellular carcinoma are being performed. The exact optimal loading dose, the locoregional toxicity and drug distribution need further studies.

The new trends and therefore the future of embolization are leading towards the use of resorbable microspheres. The ideal material should be loadable, visible in fluoro images and eventually in MR, with predictable resorption. The resorption speed is influenced by many factors such as nature, homogeneity, size, enzymatic potential and local inflammatory response. To the best of my knowledge, more than 4 universities around the world and about 5 device companies are actively working on the development of new resorbable materials.

Until recently the only available material in large sizes (150  $\mu$  and over) was gelatine microspheres (GMSs) developed by Tabata in Japan. Recently a new resorbable porous gelatin microsphere has been developed and used in Japan (Gelpart, Nippon Kayaku). Due to its porosity this material is also loadable. Preliminary studies have demonstrated that Gelpart conjugates strongly to Cisplatin with sustained drug release. With the development of resorbable agents and the possibility of controlling the resorption in time, the embolic agents will become much more organ and indication dependent. The material used in UFE will need a resorption of around 24 hours while for chemoembolization the agent may need to be resorbed after 30 days.

**Don't miss it!**

**Embolization**  
**Interactive Case Discussion**  
Saturday, 14:30-15:30, Room A

**GI Bleeding  
Special Session**  
Saturday, 8:30-9:30, Room D

Another interesting area of development is the multitude of other drugs that could potentially be loaded to the microspheres. Vasoactive drugs, prothrombotic agents and antiangiogenic factors can enhance or prolong the duration of arterial occlusion. Hormones, growth factor inhibitors and antimitotics may prevent local tumour re-growth. One extension of the use of these biologically active agents is the implantation of cells in diseased organs. Islet cells, for example, are injected as embolic agents through the portal vein (islet cell transplantation) to treat Type I diabetes mellitus. Although this process is still restricted to severely hyperglycaemic patients, it may become the standard of care in the future.

Parallel to the exciting evolution of the embolic materials, the micro-catheter technology has also evolved, allowing a much better distal vessel catheterization and superselective embolization technique. The knowledge of different peripheral and neurointerventional micro-catheters and wires is an important asset to achieve the superselective embolization goal.

Embolization therapy has become a major arm of modern interventional therapy, its applications being fundamental cores in the multi-modality treatment paradigms for trauma, oncology and endovascular therapy of vascular malformations and aneurysms. Embolization is rapidly evolving toward an excellent mode of drug delivery. The knowledge of different techniques, materials and vascular anatomy and variants are essential to obtain good clinical outcome and minimize complication.





## Be part of "Run S.M.A.R.T." in Copenhagen to increase awareness about PVD

**Sunday, September 14,  
06:30 am**

Cordis and CIRSE invite physicians, industry personnel and the local community to participate in the "Run S.M.A.R.T." initiative on Sunday, September 14. By organizing this event, Cordis aims to raise the awareness of peripheral vascular disease (PVD) and of the minimally invasive treatment options available today.

This initiative reflects an ongoing commitment to the Cordis promise 'Ground breaking, Life Changing' and the conviction that medical innovation is only truly effective when it has an impact on the patient's life.

### The importance of raising awareness of PVD

PVD is a highly prevalent, progressive atherosclerotic disease that, if left untreated, carries a high risk of stroke, myocardial infarction and premature death. In contrast to coronary and cerebral artery disease and despite high mortality rates, PVD is significantly underdiagnosed – it is estimated that more than 70% of cases go unrecognized. More than half the patients with PVD are asymptomatic and do not realize that they have the disease (the symptom of leg pain occurs in only 10% of cases). Wider patient awareness and the use of simple diagnostic assessments (e.g. the ankle brachial index test) in the primary care setting should increase the

number of patients receiving a diagnosis while still in the early stages of disease. This will increase patient referral for non-surgical interventional treatments such as angioplasty and stenting, dramatically improving the lives of millions of PVD patients.

The awareness of PVD can often be treated with lifestyle changes such as: smoking cessation, controlling diabetes mellitus, maintaining an exercise programme, reducing high blood pressure, lowering high cholesterol and/or maintaining an ideal body weight. Cordis supports these approaches as sensible and effective means of reducing the risk of PVD morbidity and mortality. Cordis also supports other initiatives to increase PVD awareness among primary healthcare providers - such as the ACTION programme that promotes referral and raises public awareness.

### Patient outcomes as a driver for innovation

When it comes to minimally invasive treatment, Cordis has the broadest portfolio in the market for the endovascular treatment of PVD. Cordis offers access devices like guidewires, sheaths and diagnostic catheters as well as interventional guiding catheters, balloons, stents and chronic total occlusion (CTO) crossing devices.

Cordis believes that patient outcomes should be the main driver in product innovation. Looking at the results for the SMART Nitinol stent in the superficial femoral artery (SFA), it is clear that SMART patients "go the distance". To quote Professor Stephan Duda, who was the primary investigator of the SIROCCO trial: "... so we learned in the past ten years that the SMART stent has a unique deliverability, it is very much conformable to the lesion and the artery, and has tremendous long term results [sic]." Indeed, the SMART stent has set the gold standard for SFA clinical studies with the highest clinical efficacy rates ever reported in a multicentre RCT and the highest documented freedom from restenosis. In 2008 the SMART Nitinol stent will also achieve the following three major milestones:

- A decade of clinical experience – SMART was the first Nitinol stent to be used in the SFA
- More than one million SMART stents placed since its launch in 1998
- The longest follow-up period for any randomised study in the SFA (approaching 5 years) from the SIROCCO study.

Cordis plans to continue its clinical investment in the SFA with three ongoing trials: SUPER SL in Germany, SUPER in the UK and SITUP in Switzerland. The initial SUPER SL data will be presented for the first time in Copenhagen at CIRSE 2008.

### Show your commitment

Cordis continues its commitment to the prevention and awareness of PVD by sponsoring the CIRSE 2008 "Run S.M.A.R.T."

We look forward to seeing many of you "going the distance" tomorrow, 14 September, 6:30 a.m. **See you there, and remember:**

### Run SMART!



**The three fastest runners will receive their official certificate during the Foundation Party on Tuesday, September 16. All delegates participating in Run S.M.A.R.T. will receive a medal and a free t-shirt. To participate in the Run S.M.A.R.T. initiative, please register at the hotels counter in the registration area.**

**A shuttle bus taking participants to Bag Sondermarken will leave from the Radisson SAS Royal Hotel at 6am. Participants are kindly asked to wait at the hospitality desk in the entrance hall of the hotel.**

## CIRSE Clinical Practice Manual

As part of CIRSE's efforts to support interventional radiologists in shifting from providing a technical service to taking full charge of the clinical care of their patients, the CIRSE Clinical Practice Task Force under the chairmanship of CIRSE President Johannes Lammer has published a manual on clinical practice. Its purpose is to help IRs promote themselves directly to referring physicians as specialists in assessing and treating organ systems or diseases.

Following the opening chapter on principles of clinical care, two chapters are dedicated to the resources required for setting up a hospital-based clinic or private office. A further chapter deals with marketing one's services to referring physicians, patients and the public. The greater part of the manual offers clinical guidance on medical conditions and indications as well as treatment options IRs need to be aware of in order to provide informed advice to patients. Cardiovascular risk factors, the metabolic syndrome, hypertension, diabetes and cardiovascular disease are discussed, just to name a few. Further chapters refer to specific conditions and their interventional treatment focus: carotid stenting, hemodialysis fistulas, hepatocellular carcinoma, neuro-endocrine tumours, uterine fibroid embolization and vertebroplasty are discussed. For the sake of readability, the information provided has been reduced to a minimum with references pointing to more detailed information in the dedicated literature. Sample medical history as well as physical and vascular examination forms can be found in the annex of the manual.

We hope that this manual will help IRs to achieve greater involvement in clinical practice for the benefit of the patient. After a careful evaluation of this first manual a second publication to focus on the management of emer-

gency and complicated situations in the cath-lab or during the postprocedure period might be published in the near future.

*A copy of the CIRSE Clinical Practice Manual was sent to all CIRSE members in August 2007.*

**Editor:** Johannes Lammer

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The new medical subspecialty curriculum comprises three years common trunk and two years subspecialisation, therefore providing the opportunity to specialise in Interventional Radiology. CIRSE has played an important role in setting standards for the general and subspecialisation curriculum which in the coming years will hopefully be implemented across Europe.

The European Interventional Syllabus is a comprehensive overview of what training in IR should be. It provides a framework for the 2 years of subspecialty training, but goes further by also offering a curriculum for dedicated fellowship IR training. Therefore most of the advanced training as described in this syllabus is for those who want to dedicate a substantial part of their working life to IR.

In the years to come CIRSE will try to drive European IR training and to establish a European training certificate in IR based on this document.

## A European Interventional Radiology Syllabus

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*If you have not received your copy of the Clinical Practice Manual and the IR Syllabus, please contact the CIRSE Office at [info@cirse.org](mailto:info@cirse.org)*

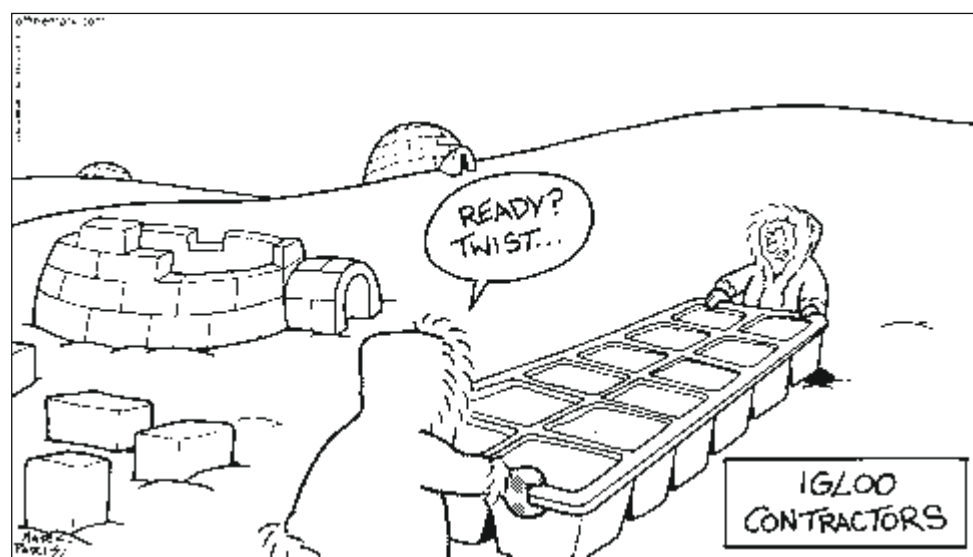
## The alternative guide to Denmark

Petra Mann  
CIRSE Office

Denmark is a country full of seemingly contradicting characteristics. Take its geography for example; despite its tininess Denmark comprises 443 named islands (the award for best name of course going to the city of Middlefart) and a coastline of more than 7,300 km which is about as long as Italy's or Turkey's and more than France has to offer. Due to Denmark's rather cold temperatures it unfortunately does not come with the associated beach beauties and tanned studs, so you might have packed your bathing suit in vain. Another apparent contradiction is that despite its rather damp and cold weather surveys have been ranking Denmark as the happiest place in the world since 2006.

And happy the Danish truly are. The first time I took a walk through Copenhagen I thought I had accidentally walked into a soft drink commercial - good looking people sat in stylishly furnished places seemingly having the time of their lives. When I realised that there were no cameras, I thought I might have unwittingly hit Copenhagen's famed Freetown of Cristiania where soft drugs are semi-legal, which would have explained the extra happiness, but as I wandered on I realised that all of Copenhagen was like that.

The Danish simply seem extraordinarily content; people who will pay up to 60% income tax and 25% VAT without returning to their axe-wielding past must have reached a state of serenity most Buddhist monks can only dream of. On a more superficial note the Danish are also an extremely good looking people. Wandering around Copenhagen you will think you have landed in an Abercrombie and Fitch catalogue. Everyone seems youthful, extremely good looking and stylish, which makes you wonder what the Danish do with their old people. Maybe that's what they have Greenland for? (This would also explain why Danish pushing 60 start looking a little worried and can often be seen buying lots of warm clothes.)



Some people say Scandinavians don't have a good sense of humour, but I personally think that anyone regarding smørrebrød with hering as a decent meal is hilarious. I also find it extremely interesting (and with interesting I mean endearingly silly) that in a country with an average of 170 rainy days per year the Danes will insist on using their bicycles to get to, well, pretty much anywhere (probably somewhere very stylish in most cases). And again, despite the drizzly weather they seem oddly serene.

You will see that many Danish ride a sort of tri-cycle with a big bucket attached to its front in which they transport pretty much anything from the day's grocery to their kids and/or pets up to industrial-sized refrigerators. The Copenhageners have very adequately dubbed them "single mom's limousines". I was told by a tour guide that they are produced in the Freetown of Cristiania, a partially self-governing neighbourhood of about 850 residents which has become famous thanks to its liberal attitude towards mind numbing drugs (And no, I do not know where you can apply to live there).

Similarly to Danish bike riders the car drivers in Copenhagen will give you the impression that they take a Valium the size of a baby's head or at least watch the infomercial channel for a couple of hours before climbing into their vehicle. Compared to the drivers in most other European cities, where pedestrians better take out life insurance if they ever plan to step off the curb, auto-propelled Copenhageners seem downright comatose.

### Great Danes (no, not the dogs)

#### Hans Christian Andersen

While most countries will choose Nobel Prize laureates, famous generals or accomplished athletes as their heroes, the Danes have made a fairy tale writer their national icon. You just have to love them for that!

H.C. Andersen was born in Odense in 1805. Nevertheless the Copenhageners like to claim him for themselves, as he moved to the capital at the age of 14 to study acting. Andersen soon realised that the world does not exactly lack aspiring actors and started writing stories. It is believed that the characters in his more than 150 fairy tales were often thinly disguised reflections of the people in Andersen's life. His most famous stories are "The ugly duckling" (apparently he was no Brad Pitt), "The emperor's new suit" (way to be sarcastic!) and "The little mermaid" which of course was the inspiration for Copenhagen's landmark, the unassuming Little Mermaid Statue.



#### Lars von Trier

Lars von Trier can probably be called one of the most famous independent film makers (Yes, I do see the irony, thank you very much). When I researched his biography I came across the following sentence: "L. von Trier was raised by nudist communists". I will give you a minute to take this in. NUDIST COMMUNISTS. Now I will give you another minute to call your mom and dad and thank them for not having read you Lenin's "State and Revolution" as a good night story and keeping their clothes on most of the time (unless of course dad has a couple of egg-nogs too many at the family Christmas party, but nobody is perfect).

Now that you have thanked your parents and made plans to finally get them the retirement home they have always dreamed of (I hear there are great ones in Greenland) let's return to poor Lars' troubled childhood. Puberty is awkward enough - imagine bringing home a date to your parents sitting around naked reading Trotsky! Considering these disturbing early experiences it is amazing that Lars von Trier became an accomplished film maker rather than ending up sitting on a street corner deeply engaged in a conversation with his herring sandwich.

And good films he has made indeed. Among his most famous works are "Breaking the waves" (1996), "Dancer in the dark" (2000) and "Dogville" (2003), which are brilliantly disturbing, although they do not feature nudists or communists of any sort, which Lars' shrink must be given some serious credit for.



#### Arne Jacobsen

No review of the most important Danes would be complete without a tribute to its world famous designers. Arne Jacobsen is one of them, his most renowned pieces being the egg, the swan and the model 3107 chairs. Allegedly the egg chair was inspired by Eero Saarinen's womb chair, the analysis of which would probably provide a psychologist with a lifetime's worth of work. One of Jacobsen's most comprehensive pieces of work is the Royal Hotel in Copenhagen completed in 1960. Even though it is the architectural equivalent of a shoebox from the outside, its interior design has become a modern classic which is definitely worth a visit for architecture (and Dr. No) enthusiasts.

#### Niels Bohr

Niels Bohr is regarded as one of the most influential physicists of the 20th century, greatly contributing to the understanding of the atomic structure and quantum mechanics. For his work he received the Nobel Prize in Physics in 1922. His father was a professor of physiology at the University of Copenhagen and first described the Bohr effect. His brother, Harald Bohr, was not only a renowned physicist as well, but also played for the Danish national soccer team on the side. One of Bohr's sons, Aage Niels Bohr, grew up to become a physicist too, earning another Nobel Prize. Way to raise the bar! Imagine being a member of the Bohr family and having to tell your parents that you just want to bum around, travel the world and "find yourself".



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