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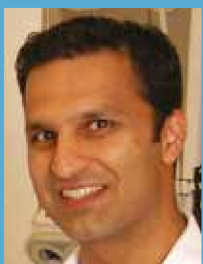
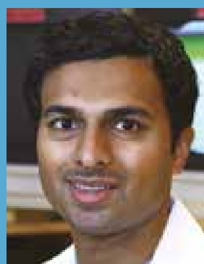
INTERVENTIONAL NEWS

EDUCATIONAL SUPPLEMENT

Magellan™ Robotic System

The age of intravascular robotics in interventional radiology





The Magellan Robotic System is an advanced technology that drives the Magellan Robotic Catheters and guidewires during endovascular procedures. Magellan is designed to offer procedural predictability, control and protection to physicians as they remotely navigate the robotic catheter through the vasculature. Magellan's remote workstation allows physicians to navigate through the vasculature while seated away from the radiation field, potentially reducing physicians' radiation exposure and procedural fatigue.

In this supplement:

INTRODUCTION

Predictability, control and protection for endovascular procedures

Hansen Medical's Magellan Robotic System is intended to be used to facilitate navigation in the peripheral vasculature and subsequently provide a conduit for manual placement of therapeutic devices. It is designed to deliver predictability, control and protection to endovascular procedures. Since its commercial introduction in the USA and Europe, the Magellan Robotic System has demonstrated its clinical versatility in many cases, in a broad variety of peripheral vascular procedures globally. The Magellan Robotic System offers several important features including:

- It is designed to enable more predictable procedure times and increased case throughput, potentially allowing hospitals to improve utilisation within their interventional business line.
- It employs an open architecture, designed to allow for the subsequent use of many therapeutic devices.
- Is designed to potentially reduce physician radiation exposure and fatigue by allowing the physician to navigate procedures while seated comfortably at a remote workstation away from the radiation field and without wearing heavy lead as required in conventional endovascular procedures.
- Its 9F and 10F robotic catheters allow for independent, robotic control of two telescoping catheters (an outer guide and an inner leader catheter), as well as robotic manipulation of standard guide wires. The 10F robotic catheter recently received US FDA 510(k) clearance and CE mark for use in the peripheral vasculature.
- The Magellan 6F Robotic Catheter allows for independent robotic control of two separate bends on a single catheter, as well as robotic manipulation of standard guidewires. This smaller catheter design may be preferred by certain physicians who favour a smaller diameter vessel access site, or in procedures in smaller vessels.

The Magellan Robotic System is designed to deliver predictability, control and protection

Incorporating intravascular robotics into embolization

Marc Sapoval, professor of Clinical Radiology and chair of the Vascular and Oncological IR department, Université Paris Descartes-Hôpital Européen Georges-Pompidou, Paris, France, gives *Interventional News* readers an overview of the current Magellan Robotic System and a sneak peek at some of the future developments. Sapoval's department, which has been collecting data on its clinical use, has been using the Magellan Robotic System for over a year now, mostly for uterine fibroid embolization, prostate artery embolization and transarterial chemoembolization (TACE) cases. "I am looking forward to trying out the Magellan system to robotically manipulate microcatheters," he says.

What are some of the reasons to integrate robotic navigation into interventional radiology practice?

The key benefits are the enhanced manipulation of catheters, and an ability to work remotely from the patient, which decreases radiation to the physician and team. I think the system has some role in marketing your institution and department to other colleagues and patients, to some extent. This aspect might have more value in the USA than in Europe. The prestige is two-fold, while colleagues might come to learn about robotic manipulation for interventional radiology cases from you, there are also some patient populations who seek advanced care. We have been gathering data on the 6F robotic catheter in embolization procedures. It gives significant help in some complex situations. The interventionist still must have basic catheter skills in order to understand how to manipulate the robotic catheter.

Could you please provide an overview of the Magellan Robotic System and some of the anticipated developments?

There are two aspects to this answer; one is the current status of the system and the other is its near future. In Europe, there are currently a 9F catheter and a 6F catheter [the 10F catheter designed for compatibility with devices requiring a 7F inner lumen has both CE mark and US FDA clearance]. The 9F is designed for procedures in larger vessels, such as the iliac and superficial femoral artery angioplasty and aortic work. The 6F is designed for more distal angioplasty and embolization. This is the catheter which is the "action arm". The robotic catheter connects to the robotic arm, which allows you to manipulate the catheter, including 360 degree rotation and bending up to 140 degrees. It goes over a wire which is also manipulated by the robotic arm and all this is manipulated by a remote control station—one at the patient's bedside and another at a completely remote console. Even at the bedside, the operator is at the foot of the patient instead of being at the level of the groin, so it is much further away [from the X-ray source]. The disadvantage of using the completely remote desk control is that you need to unscrub and then re-scrub, if you want to return into the field.

With regard to future developments, the company is working on the ability to manipulate microcatheters robotically. Being able to carry out all of the manipulation, including using microcatheters deep in the vasculature in the prostate artery for prostate artery embolization, or in the uterine artery for uterine artery embolization, will be very valuable.

In my opinion, this application is a very important development.

Marc Sapoval

There will also be more integration of the Magellan Robotic System with imaging, so that the system can recognise the position of the tip of the microcatheter without using fluoroscopy or by using very little fluoroscopy. This update would enable the operator to carry out preoperative 3D imaging and this would be then fed into the Magellan Robotic System. Then the system, by using an electromagnetic field, would be able to identify where the tip of the microcatheter is. You could drive the microcatheter using the robot, into an imaging volume that would be 3D. All this is preliminary work and it would really reduce the use of fluoroscopy, radiation and contrast dose.

What are the potential advantages of using the Magellan Robotic System in common interventional radiology procedures?

In common procedures, the Magellan Robotic System is interesting when you are in a difficult anatomical position. In situations where you require more stability, such as iliac artery work or prostate artery embolization, I see a value. Of course, there is also a clear case of radiation reduction for the operator and team when the system is used.

Anecdotally, I would say that the system was beneficial in a case of prostate embolization where I believe that we would not have succeeded without the robot (although, we did not try this). It would have been exceptionally difficult as the arteries were very calcified.

Can you comment on the learning curve?

There are many tips and tricks for manipulating the catheter that the operator can easily learn in training, before using the system on patients. As the system stands, I think there is a need to perform around 10 cases before you become confident with the use of the system.

The interventional radiology nurses and technologists also need to be trained as they have to prepare the catheter, log on to the machine and carry out specific tasks.

A look to the future

I believe that we could think about a remote manipulation programme by which we can help less experienced teams, even if they are in different countries. If the robotic arm is installed in another country, expert centres can remotely manipulate the catheter in that country, if necessary, in difficult cases. Through the programme, interventionalists from different countries could come to specific centres of robotic expertise and undergo training for a period of time in that institution, on site. They can then return to their own countries or institutions and ask for help when they schedule complex cases. For instance, if they schedule a particularly complex fibroid case, we could then take over the manipulation of the robotic catheter and help on the case from France.

PROSTATE ARTERY EMBOLIZATION

Magellan often simplifies selective catheterisation in prostate artery embolization

Having recently completed the 30th robotic prostate artery embolization procedure for the treatment of benign prostatic hyperplasia at Inova Alexandria Hospital in Alexandria, USA, Sandeep Bagla tells *Interventional News:* "The future of prostate artery embolization is exciting, not only in terms of technology, but in terms of a more widespread acceptance. As the procedure becomes more widely available, I believe patients will seek out care for benign prostatic hyperplasia directly from interventionalists, similar to other diseases such as varicose veins and uterine fibroids."

What is the place of prostate artery embolization in the treatment framework for benign prostatic hyperplasia?

Prostate artery embolization is a minimally invasive procedure for patients with benign prostatic hyperplasia who have a moderate or severe degree of symptoms. It is most often reserved for patients who cannot tolerate medication or in whom medication is no longer effective. It may be used in patients who have any size prostate, where traditional surgical procedures may be contraindicated or complicated. Its role in the treatment of men with benign prostatic hyperplasia is still evolving, but most patients with lower urinary tract symptoms from benign prostatic hyperplasia will ultimately be candidates for prostate artery embolization.

The typical prostate artery embolization patient is one who has been suffering from symptoms of benign prostatic hyperplasia, such as a weak intermittent stream, feeling as if he is not empty, or waking often at night to urinate. Patients who cannot tolerate or no longer want to take medications for benign prostatic hyperplasia, or those in which sexual potency is a primary concern. The low risk profile of embolization allows for almost any patient to be a candidate.

What are some of the technical challenges of the procedure?

The technical challenges can be primarily categorised into difficulties with selective catheterisation and anatomical recognition. The former tends to be the more significant problem. The prostatic arterial anatomy is inherently small and tortuous, often less than 1.5mm in diameter. Target arteries often originate from parent vessels at acute angles simultaneous with other non-target branches. Recognition of the target prostatic artery and collateral circulation remain challenging. However, they are more easily overcome with advanced imaging such as cone beam computed tomography (CBCT). These challenges may make prostate artery embolization somewhat less attractive for the busy practising interventionalist.

Sandeep Bagla

What are the potential advantages that Magellan Robotic System could confer to this procedure?

The Magellan Robotic System offers patients and interventionalists alike the opportunity for a more successful and consistent procedure with reliable results. While prostatic artery anatomy varies from patient to patient, the Magellan Robotic System provides a remotely controlled shapeable catheter which can allow easier microcathter selection and subsequent embolization. The ability to dynamically shape the distal tip of the catheter coupled with excellent stability gives us a major advantage when addressing this challenging procedure.

In which clinical scenarios would using a robotic system make selective catheterisation easier?

The most often clinical use for the Magellan Robot in prostate artery embolization is when the target artery arises at an acute angle from its parent vessel. Quite often, selective catheterisation without the robot will require multiple microwires, pre-shaped microcatheters and prolonged fluoroscopy time. With the Magellan robot, the distal tip of the catheter is angulated and navigated to the origin of the prostatic artery, allowing for the microcatheter to be navigated into the target vessel. This often obviates the need for multiple types of microwires and catheters and allows for reliable catheterisation.

Elderly men often have tortuous pelvic anatomy, especially at the bifurcation of the anterior and posterior division of the hypogastric artery. This tortuosity may result in poor proximal guiding catheter support for distal microcatheter catheterisation. The robotic catheter, however, provides this proximal support and may be "fixed" with a customised shape distal to the hypogastric bifurcation. This prevents the proximal catheter from backing out or not allowing for the microcatheter to be advanced distally near the prostatic parenchyma.

Are there any particular types of patients/ anatomies in which you would not use the robotic system?

Although the robotic system can be used for alternative access it does require a bit of repositioning and may not always be our choice for radial or brachial access. This may, however, change over years to come.

What do your data show with regard to outcomes, complications, radiation dose and also procedure times?

So far, we have seen that robotic prostate artery embolization does not add any time to the procedure and may allow for reduction in time when compared with the traditional technique. Radiation dose is reduced as the operator is at least four feet from the source allowing for a greater than 75% reduction in real time radiation when compared with normal physician positioning. We have not had an unsuccessful embolization with the Magellan Robotic System and have successfully performed robotic catheterisation in patients who have had failure with traditional methods.

How has the system played a role in marketing this new treatment to patients?

The healthcare climate for robotics has improved vastly from years past. Patients are active participants in their healthcare and seek out more advanced solutions for their medical problems. This has come from a recognition that technology may level the playing field and allow for professionals of varying expertise to provide excellent care. The widespread use of robotics from cars to surgery has augmented this excitement. Patients, both locally and nationally, have expressed interest in our site for prostatic artery embolization, with specific interest in the use of the Magellan Robotic System as well.

TACE AND RADIOEMBOLIZATION

The robotic catheter's stability and navigability allow for precise embolization

Ripal T Gandhi is a staff vascular and interventional radiologist at the Miami Cardiac and Vascular Institute (formerly Baptist Cardiac and Vascular Institute), Miami, USA, who has used the robotic system to perform several chemoembolization and radioembolization procedures. He tells *Interventional News* that the Magellan Robotic System helps with the "delicate touch" needed for embolization to treat cancer.

Ripal T Gandhi

Can any of the documented limitations of chemoembolization be overcome using a robotic navigation system?

Most limitations of chemoembolization are with regard to the efficacy of therapy and not related to catheterisation. Therefore, the robotic system will not overcome the inherent limitations of chemoembolization.

However, anatomy can sometimes be an issue. Intravascular robotics have been designed to facilitate complex catheterisation by improving catheter manoeuvrability while providing increased catheter stability. This can be advantageous for chemoembolization procedures including navigation of tortuous anatomy and catheterising challenging angulated vessels, which can be challenging with a manual catheter. In addition, the ability to manipulate the angle and shape of the robotic catheter minimises the number of catheters and catheter exchanges. The robotic system may be utilised for any chemoembolization procedure, including the most complex cases.

What have the early procedural outcomes of robotic chemoembolization procedures been?

We have at least 1.5 years of follow-up on the earlier chemoembolization procedures performed with the robotic system. We have had 100% technical success in performing hepatic chemoembolization and radioembolization procedures with the robotic system. We do not have enough patients or clinical data to determine clinical outcomes, but I imagine that the results would be similar to conventional manual embolization procedures as the actual embolic is equivalent.

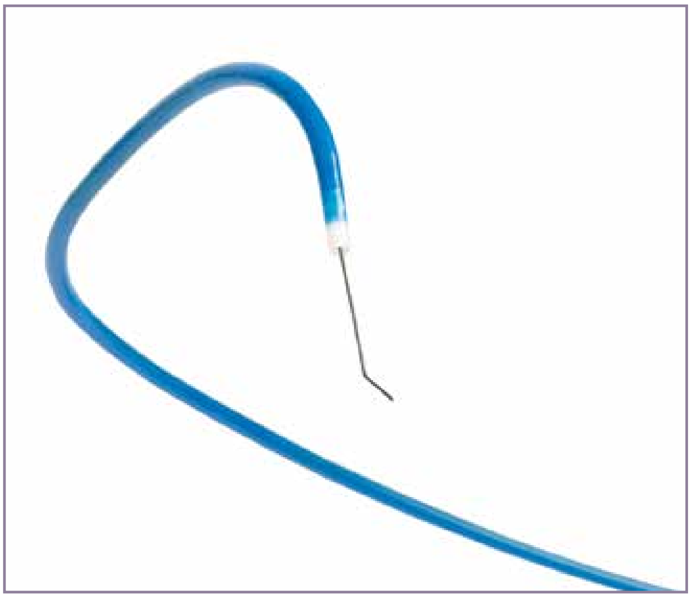
We have not encountered any complications with robotic chemoembolization. Prior to the US FDA clearance of the 6F robotic catheter, designed to catheterise and intervene in smaller vessels, we performed chemoembolization with the 9F catheter. The clearance of the 6F catheter was a significant advancement as it allowed the procedure to be performed via a 6F sheath which is our norm. Although we did not encounter any groin complications when utilising a 9F sheath, the smaller 6F catheter is safer as it requires only a 6F sheath.

Is there a decreased radiation dose to the interventionalist, technologists and patient?

We are currently obtaining data with regard to fluoroscopy time and radiation dose as a part of the ROVER registry. Although the data are not yet available, it is my prediction that radiation dose will be significantly reduced with the robotic system. An abstract presented by Sandeep Rao at the Society of Interventional Radiology meeting in 2015 demonstrated a greater than 90% reduction in radiation dose to the operating physician when compared to a bedside control (See Sandeep Rao's opinion article on pages six and seven for more data).

The purpose of the ROVER registry is to gather both retrospective and prospective case data on the use of the commercially available Magellan Robotic System and Magellan robotic catheters in accordance with the approved intended use. For prospective cases, follow-up patient data are collected at 14 days (±5 days) postprocedure to assess treatment success, primary patency of intended targeted vessel region, radiation exposure, and adverse events. Intraprocedural radiation at the bedside (typical primary operator position) and actual primary operator using RaySafe is measured.

The Magellan Robotic System has the potential to decrease fluoroscopy time and contrast use. The ability to operate the robot from a remote position may result in reduction of radiation exposure to the physician and staff. The latter may also decrease operator fatigue and occupational stress as the physician can be comfortably seated at an ergonomic robotic workstation away from radiation source, which may be even outside of the interventional suite. This eliminates the need for wearing a heavy lead apron while performing the procedure, and thus increased ergonomics. Operator performance may also be improved during long, complex cases if the physician is less vulnerable to fatigue.



6F catheter

What are the patient selection characteristics for chemoembolization

when using the Magellan Robotic System?

The stability and navigability of the robotic catheter of the Magellan robotic system are critical features which allow for the precision and delicate touch necessary when performing embolization procedures. Non-target delivery of embolic agents can lead to severe adverse complications; the stability provided by the robotic catheter is unparalleled and may be superior to manual catheterisation in the setting of precarious anatomy. We have encountered patients with very tortuous aortoiliac anatomy with acute angulation of the coeliac axis which have made manual catheterisation difficult or impossible. In such cases, the robotic catheter provided excellent stability from a femoral approach, allowing stable cannulation of the coeliac axis and subsequently the hepatic arteries.

Robotic catheterisation is currently limited for smaller vessels for which the smaller 6F system is often still too large and often requires delivery of a microcatheter through the robotic system. Hansen Medical is currently investigating smaller catheters which would be valuable in selecting and tracking into smaller vessels in this setting. We are excited about the future of robotic guided microcatheters which will further increase the utility of this system for embolization procedures.

What factors do the operator and team need to consider when undertaking chemoembolization using the robotic system?

There is certainly a learning curve when utilising any new technology, but one that is easily overcome with a few cases. We, as interventionalists, are accustomed to relying on "manual feel" when catheterising vessels and performing interventions. When selecting mesenteric vessels with the robotic catheter, the operator relies more on visual cues which takes some time to master. The remainder of the chemoembolization procedure is no different.

How does the system benefit radioembolization?

We are in our early experience with using the Magellan Robotic System in radioembolization. The stability and navigability of the Magellan Robotic System are critical features in these types of procedures that require precision and a delicate touch when delivering the Y-90 radioactive beads. When doing split-dose radioembolization requiring separate microcatheterisation and treatment of two separate hepatic vessels, manual technique typically involves complete removal of the microcatheter and advancing a new microcatheter to the second intended site for therapy. Following radioembolization of an initial hepatic vessel, we have used the robotic catheter to place an angle on the robotic system and catheterise a second hepatic vessel without having to remove the base catheter and use a new microcatheter.

UTERINE FIBROID EMBOLIZATION

First, use Magellan for routine cases

Sandeep Rao, Sierra Providence Health Network, El Paso, USA, has collected and presented data on a series of his patients undergoing robot-assisted transarterial chemoembolization (TACE) procedures with the Magellan Robotic System. He has analysed the feasibility and safety of robot-assisted TACE, as well as the learning curve and procedure times, and impact on radiation exposure to the patient and operator of performing these procedures robotically. For this supplement, Rao focuses on his early experience with the robotic system for uterine fibroid embolization.

The Magellan catheter provides me with added catheter stability, greater control of catheter tip position and reduced radiation exposure. The catheter stability is helpful during both subselective catheterisation of specific vessels and injection of embolic materials. Control of the catheter tip allows me to direct my wire into a number of directions without having to resort to different preformed shaped catheters. I have noticed marked reduction in personal radiation exposure during robotic cases, given the ability to perform these cases remotely from a safe distance.

During one of my recent uterine fibroid embolization cases, I was able to drive the Magellan catheter all the way into the uterine artery to perform the entire embolization without the need for an additional microcatheter, as is typically needed with manual catheterisation.

Sandeep Rao

Although I personally use the Magellan system routinely for all uterine fibroid embolization cases, the real value proposition of robotic embolization shines through during cases with tortuous challenging anatomy. With tortuous anatomy, I can use the 6F catheter to drive distally to the target vessel, utilising the catheter like a long stable sheath to deliver therapy.

Robotic system use for routine cases for beginners

Given the novelty of robotic navigation for most physicians, I would advocate routine use of the Magellan system even for cases with normal uncomplicated anatomy. The data we have seen regarding adoption of the robotic navigation suggest that new users should work through the learning curve, initially with basic cases before tackling complex anatomy. You do not want to reserve usage of the robotic catheter solely for challenging cases without having tested it under routine circumstances.

The availability of the 6F system has made robotic access into a wider variety of anatomy possible. Many interventionalists did not feel comfortable taking the earlier 9F system into certain vessels, given the larger size of that catheter. As these systems become increasingly smaller, I believe you will see greater usage in a wider variety of settings.

Magellan Robotic System in other types of embolization

I have performed fewer than 10 robotic uterine fibroid embolizations so far; the vast majority of my experience with the Magellan system has been with liver-directed therapy, namely chemoembolization. I have also used the system in the heart to access a pulmonary arteriovenous malformation and have carried out a series of embolizations for gastric varices (balloon-occluded retrograde transvenous obliteration procedure). I have also safely introduced the Magellan system via radial arterial access for gastric embolization.

Radiation dose results in TACE

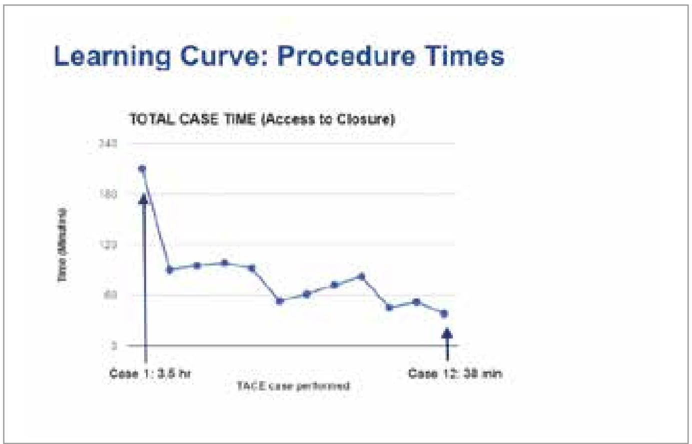
I have presented data on radiation dose reduction, procedure time and fluoroscopy time in the context of using the Magellan Robotic System at scientific meetings: users begin to see noticeable benefits in reduced operator radiation exposure, total procedure time and patient radiation exposure, as measured by total fluoroscopy time, once the user overcomes the initial learning curve of roughly seven to 10 cases.

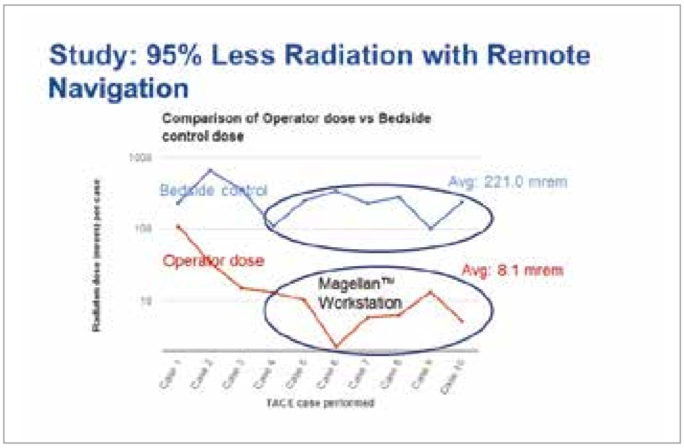
Looking at a series of cases involving liver transarterial chemoembolization, we found that the operator radiation badge readings had greater than 90% reduction in radiation exposure, when compared to control radiation badges placed in the traditional position at the patient bedside.

Additional data obtained during robotic TACE demonstrated the average total fluoroscopy time and procedure time were reduced compared with similar endpoints obtained from a retrospective analysis of traditional manual TACE.

Synergy with 3D vessel visualisation

The moment we obtain synergy by combining robotic catheter navigation with 3D vessel visualisation (eg. cone beam CT) will be a truly transformative moment for endovascular intervention.





Source: Robot-assisted transarterial chemoembolization for hepatocellular carcinoma: initial evaluation of safety, feasibility, success and outcomes using the Magellan system, Sandeep Rao, (Sierra Medical Centre, El Paso, USA), presented at the Society for Interventional Radiology's Annual Scientific Meeting 2015

RADIATION REDUCTION

Moving away from the X-ray source has a dramatic effect on radiation exposure

Barry T Katzen, founder and medical director of Miami Cardiac & Vascular Institute (formerly Baptist Cardiac & Vascular Institute), Miami, USA, tells *Interventional News* that the Magellan Robotic System significantly reduces radiation to the operator and staff by moving them away from the X-ray source.

Background

Image-guided procedures are a leading source of radiation exposure. To date, interventional procedures have required the medical staff to be positioned close to the source (4–6ft). Katzen says, "Acute exposure is typically within regulatory limits, however, stochastic exposure over a career may cause adverse health effects including cataracts, thyroid disease, reproductive health effects and brain tumours. In general, after almost four decades of using image-guided therapy using fluoroscopy, there is an increasing awareness of the unseen hazards of prolonged radiation exposure over time. I think most people who work in a radiation field were taught about radiation protection to some extent, but because radiation cannot be seen and cannot be felt or smelt, it represents an invisible hazard, and operators can get pretty lax about protecting themselves and their colleagues who work in the field. We are observing an increase in a very specific type of cataract that has been attributed to radiation and this has been identified in surveys conducted in the USA by the Society of Interventional Radiology. There have also been increasing reports of skin issues and hand damage from radiation as well as periodic reports of thyroid cancer from practitioners who may not have been wearing thyroid shields for most of their career, as 30 years ago people did not really wear thyroid shields."

Katzen emphasises: "We are seeing an increasing awareness as to what can happen after long-term exposure and increasing concern regarding protection from ionising radiation. This has served to heighten and bring to the forefront interest in making sure that we have optimum protection from radiation and also to make sure that there are maximum attempts to make sure that we reduce radiation to everyone who works in the angiosuite."

Magellan Robotic System allows movement away from the X-ray

So, how does the use of the Magellan Robotic System help to reduce radiation exposure for the interventionalist? Katzen clarifies that for physicians and technologists, the use of robotic systems can definitely contribute to radiation reduction, because it enables the moving away of the team, including the physician who would ordinarily be working closest to the X-ray, away from the beam."

Katzen refers to the inverse square law [the intensity of radiation follows Newton's Inverse Square Law. It is inversely proportional to the distance from the source] by which the radiation falls away with distance. This is a logarithmic reduction, so if you reduce the distance between the physician and the X-ray source by two, then there is a four-fold reduction in actual exposure. "So basically moving away from the X-ray source has a pretty dramatic effect on X-ray exposure reduction. The way that the Magellan Robotic System really provides radiation reduction benefit is to the operator and the staff and it is by moving them away from the X-ray source.

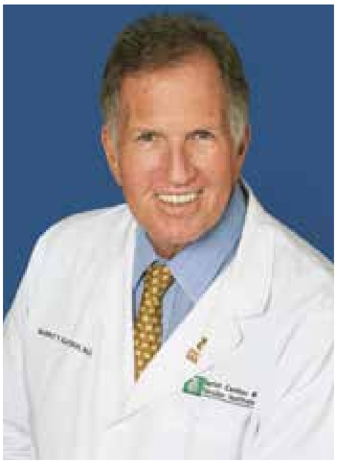
"Is there a benefit from using Magellan for patients? There is some evidence that certain tasks can be done quicker [when using the robotic system] and to that extent there is some evidence that the use of robotics reduces fluoroscopy time in terms of the number of guidewires and catheter exchanges. In theory, there could be a benefit for the patient. We are still looking at these questions," Katzen clarifies.

More than 90% radiation reduction

Katzen and others are looking at radiation exposure through a modification of the ROVER trial which is a registry ongoing in the USA. "One of the substudies that we have created involves the uniform placement of radiation sensors around the patient in five key locations including the beam itself, on the operator, and the people in the room. We have done a preliminary snapshot of that data, which are limited, because they are early registry data, and are looking to benchmark them against what would be predicted radiation exposure based on the X-ray source.

"We have seen significant radiation reduction in predicted exposure in very preliminary data for a number of different types of cases including procedures like endovascular aneurysm repair (EVAR) and transarterial chemoembolization (TACE)," he explains.

In EVAR the robotic system is used for identification of the left renal artery; contralateral gate cannulation and confirmation of intra-stent location prior to contralateral limb deployment. "Looking at how radiation reduction might be achieved, if you are catheterising a contralateral limb, even if you do not go to a remote site, you are positioned almost four feet away from the beam if you operate the robotic system from the table top. In TACE, you get the most radiation exposure through patient scatter related to the



Barry T Katzen

scattering of X-rays as it passes though the body, and so moving away from the embolization has a very dramatic effect. We have also seen reduction in crossover studies, particularly when we work from left to right in peripheral interventions and of course in carotid interventions, because of the remote location," Katzen says.

Katzen and Rao collected data during a series of EVAR and TACE procedures performed with the Magellan Robotic System. They placed badges on themselves and at the bedside, where the operator would stand during a conventional endovascular procedure. In comparing the two sets of data, Katzen experienced a 95% radiation reduction from the bedside dose control during the EVAR procedures, and Rao experienced a 92% radiation reduction from the bedside dose control during the TACE procedures.

Katzen says: "While these are all very preliminary data, we have had very positive signals that there can be benefits. Again, just as a reminder, with radiation reduction, our goal is zero radiation. There are very few cases in which the Magellan robot does the entire case, so we do not see zero radiation with the robotic system. However, there are many clinical applications that can be done in the majority of cases with using the robot. Anything that we can do to reduce radiation is good. Given the cost of the technology, there really needs to be significant radiation reduction to add value, and we are getting signals that that can be accomplished."

The principal reason is that the use of robotics allows you to move away from radiation source. Now, if we are ultimately able to show that robotic catheterisation is more effective than manual, then perhaps by reducing procedure time, you are also able to reduce radiation exposure."

Fitting intravascular robotics into a larger picture

Katzen explains the need to fit the use of the Magellan Robotic System into a larger policy to reduce radiation exposure. "When you look at the factors that can produce the greatest reduction to radiation, and you look at the patient and everybody in the field, one of the simplest things is to really look at the frame rates and look at how much exposure you are doing during fluoroscopy and during image acquisition. For instance, most modern X-ray technology has a choice of fluoroscopy dose. You should be choosing the lowest fluoroscopy dose that is necessary for you to see what you need. There are times when you need higher-dose fluoro, but most of the time you can work at a lower dose fluoro. That produces major reductions. An actual reduction in frame rate also plays a big role; if you ordinarily do an angiographic run at three frames per second and you can reduce it to two frames per second, you are producing a 33.3% reduction to the X-ray dose to the patient and everybody in the lab. The highest doses of X-ray use are during angiographic acquisition. Using more flouro-based imaging rather than dynamic imaging also helps. So the number one thing is actually reducing the source X-ray, and this produces the greatest radiation reductions. One of the things we did in our institution is that we changed the default imaging setting of frame rate to two frames per second on every suite that we have and leave it up to the operator to increase it. There is also technology that is available now with fluoro, as we saw in the CT world, to hardwire dose reduction. But the important thing is that we want to get dose reduction without compromising image quality," he explains.

"I would say that Magellan Robotic System can have a contributing benefit for the reduction of radiation to the operator and technologists around the table. It is part of our broader approach towards radiation reduction," he adds.

Learning curve

"We have found in clinical practice among the doctors who have used it, that there is a really short learning curve in terms of operating the Magellan and steering where you want to be. Of course, it depends on application. I think the learning curve has been surprisingly short due to the fact that the company has useful simulator models. Whilst this is completely opinion, I would say that the learning curve is somewhere in the order of two to four cases.

No complications, so far

"We have used the Magellan Robotic System in about 70 patients for various types of cases. So far, we have had no complications related to the system. We have had one or two failures to catheterise and this has partly been due to the limitations of the robotic catheterisation itself. However, in one patient in whom we failed catheterisation, we also failed to catheterise manually. We have also explored applications in which we were pushing the robot to its extreme. As an example, if you try and catheterise in a patient who has had an aorto-bifemoral bypass graft, ie a surgically implanted dacron graft, one of the challenges is going from the right leg over the bifurcation to the left leg because of the fabric and the angulation, and the artery of course. We have been trying to establish if the robot can be an effective way of doing that in order to treat the superficial femoral artery, for example. This has remained a challenge although we think the new 10F delivery system with different angulation characteristics may overcome that.