

Designing a Versatile Procedural Environment for a Rapidly Changing Interventional Field

A dyad perspective on building an advanced endovascular suite.

WITH BARRY T. KATZEN, MD



Miami Cardiac & Vascular Institute at Baptist Health South Florida recently opened the Center for Advanced Endovascular Therapies. It was born of the desire to create a state-of-the-art collaborative environment optimized to support a broad variety of complex hybrid

interventional/surgical procedures (Figure 1).

From a kernel of an idea back in 2008 emerged a near decade-long initiative to expand the Institute's services and technologies. Thus, \$120 million was allocated to expand the Institute and construct a procedural environment unlike the traditional cath lab or angio suite. Every aspect of the interventional experience was considered, from the patient to the multiple disciplines involved in complex procedures. Central to that effort was the selection of the most appropriate imaging technology.

Recognizing that these new procedures would require a fresh approach to system design, the Institute and Philips partnered to develop the next-generation advanced endovascular suite. Building a one-of-a-kind system was the first step.

OUTPACING TECHNOLOGY

As Founder and Chief Medical Executive of the Miami Cardiac &

Vascular Institute, I have had a front seat to the evolution of endovascular therapy for more than 30 years. Over the course of that time, I have seen the accelerated application of complex, minimally invasive, image-guided therapies in both the cardiac and vascular space. Too often, these procedures were performed on equipment and in spaces designed primarily for simple cardiac catheterization. Although technology continued to evolve, the multidisciplinary aspect of these new procedures outpaced capability. Over and over again,



Figure 1. The Center for Advanced Endovascular Therapies, located at the Miami Cardiac & Vascular Institute, Baptist Health South Florida.

this put undue stress on the environment, physicians, staff, and imaging technology. As a result, we saw an increase in occupational hazards, such as musculoskeletal injuries, lower back pain, neck pain, and headaches, as teams struggled to compensate for the shortcomings of conventionally designed state-of-the-art angio suites.

As time went on, more complex (often hybrid surgical) procedures called for multiple teams, bigger rooms, and more flexible systems. In some instances, as many as 20 people were in the room addressing different aspects of the patient, working with imaging equipment that was designed for outpatient angiography from a single parallel access. An aortic arch branching procedure, for example, includes a cardiac surgeon, a vascular surgeon, interventionalists, and support staff, all gathered to open the chest, debranch the aorta, and place a stent graft. This complexity puts extraordinary demand on a typical angio suite.

IDENTIFYING THE NEED

There were obvious weaknesses in both room design and system geometry. It became evident that for each discipline to have proper space and easy access to the patient and equipment, we would have to rethink the entire procedural environment. As an institution known for innovation, our institute needed something more than what was currently available. We wanted to create an environment in which we could perform any type of hybrid image-guided procedure and physicians of different disciplines could function together to create unique solutions. It was important to us that everyone be able to work in the suite without barriers.

This was our thinking as we began a \$120 million expansion of our facility. Over the course of 3 years, we added 60,000 sq ft of new space, including 40,000 sq ft of renovation. Significant investment was allocated to the development of two advanced endovascular suites. We were determined to create a procedural environment suitable for tomorrow's innovations as well as today's challenges. After visiting labs across the country, searching for the optimal imaging system to be our centerpiece, it quickly became evident that such a system did not exist.

INDUSTRY PARTNERSHIP

The Miami Cardiac & Vascular Institute and Philips have been development partners for over 30 years, most recently on development of the Philips Azurion interventional platform. This relationship led us to engage Philips in a solution engineered to help us achieve our ambition. A shared vision of the future inspired us to move forward together.

Imaging system geometry was the principal limiting factor of all the existing systems. Fifteen years ago, most procedures were performed with a frontal approach, and cardiologists started using a radial approach 10 years ago. Today, we are likely to achieve arterial access anywhere from the carotid artery to the tibio-pedal arteries. We need to be able to do this in teams of two or three (or more) people working simultaneously. Traditional ceiling-mounted C-arms are limited in their movements, and teams must move the patient and the staff to adapt.

Before we began construction, it was the perception among our physicians that they floated the table five to 10 times in a typical case. As it turned out, for many cases, it was over 100 times, making it a time-consuming and inefficient process. We needed an interventional system that was completely flexible in its ability to move at any angle.

Room space was another consideration. Our intent was to create large, surgically sterile suites with space for multiple teams around the table and an enlarged gallery area for improved observation and teaching opportunities. Any interventional x-ray system we selected would have to be easily moved in and out, as required, to accommodate hybrid procedures.

We surveyed all stakeholders—physicians, surgeons, interventionalists, anesthesiologists, technologists, nurses, and support staff—asking each of them, “If you had no limitations or boundaries, what would be most desirable in a system and space for your complex procedures?” We also discussed and studied data from hundreds of procedures to determine the pain points. The mandate seemed clear. People wanted access to the patient from head to toe. They also wanted the ability to place multiple teams around the table without restrictions and to create an environment where everyone could see what was going on, with configurations that could be changed simply.

We turned to Philips to discuss how to accomplish our goal, and the concept of creating an additional pivot point for the C-arm—a geometry that could be moved to any position—was born. Philips engineers then embarked on what would be a 3-year effort to create the Philips Azurion with FlexArm.

THE PROCESS

Philips was not given carte blanche for development. My dyad partner and colleague of 39 years, Carol Melvin, Chief Operating Officer of the Institute, made sure of that (Figure 2). Her responsibility was to make certain we created a procedural environment that worked not only for the patient and the com-

munity but for our organization as well. Justifying the expenditure had to include a defined return on investment. She insisted that the new suite be able to accommodate a variety of complex procedures, allowing our other rooms to focus more closely on routine cardiac catheterizations and coronary or peripheral interventions. Expansion of technology needed to translate to an expansion of profitable services.

In order to meet our construction timeline, our collaboration with Philips began with a decision to develop a first-of-its-kind system. Philips faced a multifaceted challenge. They had to add the new pivot point without reducing the height of the C-arm, adjusting the height of the table, or requiring a higher ceiling. Then, they needed to develop technology to precisely control that additional freedom of movement. Constantly changing angles between five, six, or more different routes increased the complexity of manipulation. Recording and storing each and every pathway, to be recalled as requested, was an unprecedented effort.

On the room construction side, we surveyed facilities around the country to see what others were doing in order to be certain we would have sufficient space for what we wanted to create. Whether cardiopulmonary bypass is required to put a patient on a pump or we need to freeze a brain, we must be able to move necessary technology in and out quickly, no matter what the procedure demanded. We needed plug-and-play capability, gases, and a way of positioning everything where teams would not collide with each other. As Philips worked on the new system, we prepared the suites.

I traveled to Philips headquarters in the Netherlands numerous times over the course of this period to meet with the engineering team, and they kept me updated with progress reports via e-mail and phone. As the system neared completion, we carefully coordinated delivery with our room construction. The first-of-its-kind Philips Azurion with FlexArm was installed in our new room 8, and a standard Philips Allura interventional x-ray system was installed in room 9. This was done so that we could conduct comparative studies on the benefits of the new system.



Figure 2. Barry Katzen and Carol Melvin, Chief Operating Officer, with the first Azurion with FlexArm at the Center for Advanced Endovascular Therapies, located at the Miami Cardiac & Vascular Institute, Baptist Health South Florida.

THE PROTOTYPE AND STUDY STAGE

From this prototype stage, we proved that we had created an environment that delivered an improvement over what existed before in terms of workspace, geometry, and the ability to achieve any number of new positions. For instance, we were able to see from one wrist to another, moving the stand in without moving people out. When we had to convert to open surgery, we could move everything out of the way in a convenient fashion; most importantly, we were able to move the system back for combined/hybrid procedures.

Upon installation, we worked with Philips to conduct a study to evaluate the new system. We included 200 total interventions: 100 using the Philips Azurion with FlexArm in room 8 and 100 using the standard Philips Allura in room 9. The procedure types were equally split between interventional cardiology and interventional radiology. For 160 interventions with logged table movements, the median distance of table movement was 969 mm in room 8 and 1,647 mm in room 9. Operators found that the new system required less patient and equipment positioning effort. They also reported a significant reduction in the risk of losing needle access and catheter or wire location as well as a reduced risk of

pulling wires, tubes, and lines connected to the patient with the new system, which could increase patient safety. The majority of physicians performing radial or other upper extremity access cases found that the new system required a considerably low effort to transition from arm to body imaging. Also, operator discomfort during structural procedures was reduced for all body areas (head/neck, shoulders/upper back, arms/hands, middle back/lower back, and hips/legs/feet) when comparing the new system with the standard Philips Allura. The results of these studies are being evaluated and will be presented at upcoming scientific meetings.

THE FINAL SYSTEM

In December 2018, the Institute received the very first commercial installation of the Philips Azurion with FlexArm (Figure 2). The commercial release included all the features of the prototype plus additional enhancements for versatility and efficiency. The Philips Azurion with FlexArm employs a unique dynamic rotating collimator, which keeps the region of interest centered while the C-arm angulates to position. This technology allows access to the patient's circulation from virtually anywhere, resulting in improved access for operators, anesthesiologists, assistants, and teams. In this new FlexArm system, pivoting the C-arm has been further fine-tuned and combined with the dynamic rotating collimator. The C-arm can be moved to its desired location in a very intuitive and predictable fashion. This feature is truly the hallmark of the FlexArm system. All these functions are available via a single control knob or, as I call it, a "magic knob."

Lastly, the Philips Azurion with FlexArm leverages the new Philips Azurion platform, which was designed to help perform procedures more efficiently and consistently with fewer complications. It also offers greater user customization and control.

THE BENEFITS OF ADVANCED ENDOVASCULAR SUITES

At the Miami Cardiac & Vascular Institute, we now have a true multipurpose suite. We can perform one complex hybrid procedure in the morning and then do a completely different, equally complex procedure in the afternoon. Using Philips Azurion ProcedureCards for quick setup, we can do each procedure in a repeatable, standardized, and efficient fashion. There is much greater ease of use working in the new suite from an operator point of view. In terms of worker discomfort, musculoskeletal stress, and fatigue, there's better physician

satisfaction compared to the conventional rooms at the Institute. We can do highly complex procedures without ever having to move the patient, which is a huge benefit.

The FlexArm rotates on no less than eight axes to create virtually unlimited flexibility to perform imaging from head to toe on the left and right sides for both two- and three-dimensional visualizations. Its positioning flexibility frees up medical teams to choose the best working position without hampering optimal team positioning and without the need to move the patient table. The system represents the optimal relationship between the end user and the technology developer. Creation of this new suite has already helped us in recruiting luminary physicians who want to work in an advanced state-of-the-art environment.

THE FUTURE

We live in a rapidly moving technological world, and it does not take long for new technology to become obsolete. Our goal was to avoid that. The Philips Azurion with FlexArm provides us with a true platform for innovation. This system is the result of years of close interaction between engineers and end users. It is a flexible, scalable system in an optimal, open-room environment, ready not only for procedures that exist today but for future procedures as well.

Carol Melvin pointed out that although it is not all about the finances, as a not-for-profit community hospital, we must be fiscally responsible for providing good long-term care. She believes our new, advanced endovascular suite positions us well as a referral center for cutting-edge treatment and allows us to provide complex procedures that patients might not be able to find elsewhere.

At the Miami Cardiac & Vascular Institute, we have spent nearly the last decade trying to design the ideal procedural environment, and I think we are 95% there. We are excited about what the Philips Azurion with FlexArm will do for our commitment to innovation. With this technology, we now have one of the most unique environments in the world for physicians to create new procedures and ideas. ■

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Disclosures: None.