Office-Based Labs: A Clinical Overview of Therapies and Devices

The second in a four-part series discussing office-based labs (OBLs) and ambulatory surgery centers (ASCs) from the perspectives of three physicians. This article takes a look at the clinical overview of the OBL, including therapies and capital equipment/devices in the hybrid and OBL environments. The first article in this series explored the development and key issues related to OBLs and discussed lessons learned. Subsequent articles will focus on best practices in operating and growing an OBL and trends and predictions for the future of OBLs.

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CLINICAL OVERVIEW OF THE HYBRID OBL/ASC MODEL

What are the major procedures you perform in your hybrid office-based lab (OBL)/ambulatory surgical center (ASC)?

Dr. Cross: By far, the most prevalent procedures in the OBL part of our hybrid lab are diagnostic heart catheterizations and peripheral angiograms/interventions. Something we've started to do more of is intervening through radial artery access. Although not new to us, we decided to increase our use of this technique versus the femoral approach. While it is technically challenging, we are more experienced now, and the benefits to our patient—including less discomfort, improved time to ambulation, reduced costs, and a reduction in potentially life-threatening complications—are too compelling to pass up. It was purely a patient satisfaction decision.

Our patient profile is pretty similar on both sides of our model, with the ASC enabling us to treat patients who require slightly more complex therapies than the OBL (but less complex than the hospital) and with general anesthesia when required. On the ASC side of our hybrid lab, we primarily perform the device cases, such as pacemaker and defibrillator implantations. In fact, patients oftentimes need a procedure in the OBL and subsequently need a device implantation in

the ASC. Additionally, there are times that we'll perform peripheral procedures in the ASC because a patient's insurance will authorize a peripheral procedure in the ASC but not in the OBL. By in large, the ASC has really enabled us to capture a larger percentage of procedures outside of the hospital.

What were the biggest changes required for your ASC?

Dr. Cross: We did go through a fairly major design change and reconstruction. To receive licensing for an ASC, you have to meet higher standards. Things such as the width of doorways, the number of preoperative and postoperative beds, emergency backup power, and a 1-hour–rated firewall were some of the additional requirements we had to meet to become certified. Unfortunately, we could not merely expand our OBL into an ASC; we had to start a new construction site in a different but proximal location. It was a pretty large evolution with its attendant costs.

Do you have any lessons learned to share with our readers?

Dr. Cross: I wish we had planned for a larger location to accommodate growth or opened up as a hybrid from the start. My advice is if a physician or group practice is capable of performing the various therapies performed in an ASC, then jump straight to the hybrid. By planning ahead and at least preparing to be an ASC, you can avoid having to pay for construction twice.

Another lesson I recall from our first discussion involved our alliance with National Cardiovascular Partnership, the management group that does most of the day-to-day business operations. For us, this was the way to go—an equity partner that helped spread financial risk, got us up and operating quickly, and remained involved substantially in running the business end. However, some OBLs might want to team with a full-service provider, such as Philips, who can provide entrepreneurial physicians with a fully integrated solution. Specific capabilities include outfitting OBLs and ASCs with capital equipment, medical devices, and related disposables; offering financing options; and delivering physician-assisted training and other advisory services. Of course, it all boils down to physician preference, experience, and the specific business model you want to execute.

Do you use Philips capital equipment or medical devices to support your therapies?

Dr. Cross: We use digital intravascular ultrasound (IVUS) and the Phoenix atherectomy system. Frankly, the innovation and technologic advances from companies like Philips and other health care companies have facilitated this current outpatient trend, and they will likely contribute to further therapy migration away from the big hospitals in the future.

The role of digital IVUS in our office has been key to increasing our diagnostic accuracy of stenotic areas within the vascular system. With IVUS, you can better assess how occluded an area of the vessel is when angiography is inconclusive. IVUS complements angiography, ensuring we intervene when necessary and don't when it's not.

We also use IVUS to evaluate the density or plaque burden, help guide the balloon or stent into position and, after intervention, get a good sense of how well our devices are improving the luminal area and whether anything else needs to be done. With recent technologic enhancements like the bioresorbable scaffold, precise sizing and placement of the stent can lessen the chances of malapposition, edge dissection, and other postimplantation problems.

The Phoenix 2.4-mm device is nice because it provides a rotational process to help cut and clear the plaque, and it is also a directional device, so you can change the direction of the head in cases where the vessel is larger than the diameter of the cutting blade.

In addition, Phoenix's capability to capture and clear matter while you're working is helpful. This feature helps me to work more confidently with a reduced concern of distal embolism or other problems. Although there is no single atherectomy tool for all situations, the Phoenix device performs well in many settings and I use it frequently.

CLINICAL OVERVIEW OF THE OBL MODEL

What types of vascular disease do you treat in your OBL?

Dr. Gonzalez: We have a robust collection of therapies to treat chronic venous insufficiency–related conditions such as spider and varicose veins and iliac vein compression syndrome as well as peripheral artery disease. I'm doing about 75% arterial work and some dialysis access and maintenance work. Although dialysis access/maintenance is a small percentage of our workload and is often disruptive to the lab (due to it preempting scheduled work), we take it very seriously for those few patients who must endure it.

What device has had a significant impact on your practice?

Dr. Gonzalez: IVUS has singularly improved our treatment of all lesions—arterial and venous. It gives us

Figure 1. Visions PV IVUS Catheters.

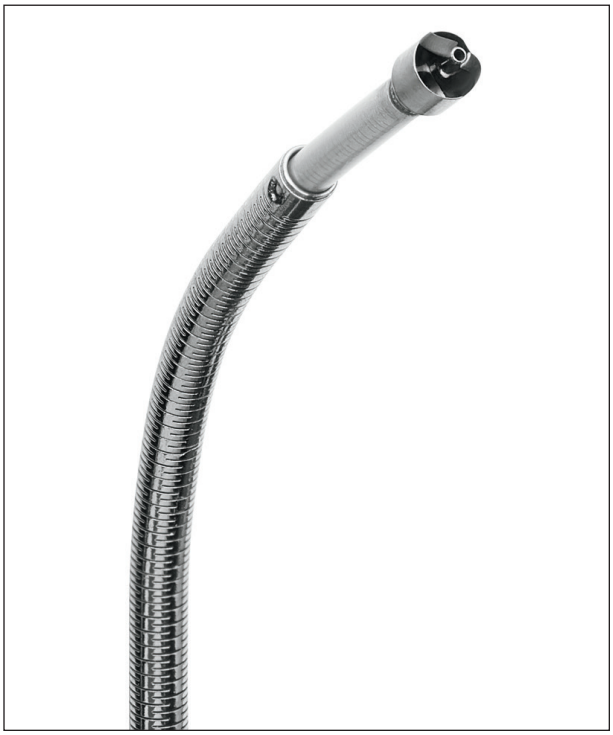

Figure 2. Phoenix Atherectomy System 2.4 mm.

detailed information, such as luminal versus subintimal and plaque morphology. I think one of the biggest challenges we have as physicians is accurate stent sizing. With IVUS, it has helped us diagnose, size, place, and assess our work to ensure that we have enlarged the lumen area and created longer patency of the stent. We have used IVUS in nearly all of our cases because, radiographically, a vessel could be patent, but you don't know if there's external compression because it is virtually undetectable with angiography.

Dr. Wright: When I first started the OBL about six years ago, 100% of peripheral angiograms were done in the hospital. Now I would estimate that more than 90% are done in an outpatient setting. Even the use of angiography is starting to decline as imaging technologies change and improve. IVUS is a perfect example. When you perform angiography, you have a two-dimensional image that you're trying to use to make a three-dimensional assessment of lumen diameter, plaque extent and hardness, and whether it's a new or old lesion. IVUS really helps you delineate between those elements based on its image clarity and, more importantly, whether you need to intervene or not and how extensive your treatment zone is. IVUS also enables you to identify and treat venous compression, and in my view, is the best tool to quantify if you have accomplished what you wanted to do with your treatment. IVUS helps you better define the lesion, and I believe that my results and outcomes are better because of it. I'm a huge fan.

Do you also use atherectomy devices?

Dr. Wright: We do. There are a number of devices used in the atherectomy market, which is heavily driven by personal preference—and something I support for our physicians. If I were going into a heavily calcified, occlusive lesion, then I would choose the Phoenix atherectomy system. The choice of devices is both physician- and procedure-driven and based on the anatomic location and morphology. And, again, those markers cannot be assessed properly without IVUS.

What are your considerations at this stage of planning your new OBL?

Dr. Gonzalez: We selected a facility that was already an office building. It was very new, fairly large, and built by another physician hoping that someone would come in to rent or buy the other part of the building. We

bought that office space, and basically it's an empty shell and we're building it to our specifications. We've talked to a lot of people, including Philips, on planning out the space. Philips helped us understand the requirements for the different types of labs and, more importantly, the option of perhaps spending a little more money on future capacity to support either growth or maybe a different kind of OBL model. So we're thinking about putting oxygen into the walls, ensuring walls are leaded appropriately, that the 42- and 52-inch doors as well as the double doors are located properly—basically planning for the future as we envision it.

Dr. Wright: In our evaluation, we will look at the comprehensive package, not just the equipment. We will also look at the financing options, warranty, and service options, and we will factor in the benefits of the entire package versus purchasing a la carte. Philips is creating comprehensive suites of products and services to be the go-to partner for physicians opening their first OBL. This makes a lot of sense even if it costs a bit more up front. It just takes most of the legwork out of the process and greatly reduces risk, which can save a lot of time and money downstream.

To my knowledge, Philips is the only company that offers the complete package of construction services, consulting, financing, and a full set of equipment and disposables. There are individuals who are trying to serve as a liaison and aggregate all of those services for an outpatient center. It is a viable option and worth entertaining. However, I would be more inclined to go with a major supplier that is an established name because you know that they are going to be around in 10 or 20 years. In our industry, you have to consider more than just price when you are dealing with patient safety and quality issues.

Do you find that Philips helps you stay abreast of technology?

Dr. Wright: A benefit with a company like Philips is their ability to bring new technology. You can't be viable in peripheral artery disease if you aren't staying up on the latest trends and equipment. Coupled with having your own outpatient lab, this gives you the opportunity to implement new technology faster.

What are the benefits of a comprehensive approach?

Dr. Gonzalez: One of the primary benefits is the compatibility of the capital equipment and devices. For example, knowing that the C-arm works well with the beds, being confident that the equipment and devices will interconnect and communicate appropriately and the resulting gain in speed of execution. Plus, we are building mutual respect and can help each other out. If problems arise, you do not have to deal with five or six different companies; you have one person showing up, with just one phone call. ■