- Hello, my name is Gustavo Oderich, I'm Professor of Surgery and Chief of Vascular Surgery at the University of Texas Health Science, in Houston.

IOPS Endovascular Navigation System

So the IOPS Navigation is actually an FDA approved navigation system manufactured by Centre Line Biomedical. This is a spin-off company of the Cleveland Clinic, and it uses an electromagnetic field, which is a portable field attached to the operating table. It has catheters and wires that have sensors, and these sensors allow you to identify the location within the patient and the anatomy, and this can be visualised in a monitor. So it is a portable, quite a versatile system, primarily applied for the vascular anatomy in the abdomen, that's what is FDA approved. And in essence is akin to the GPS system that we have. With a miniature system of that, that allows you to navigate inside the blood vessels.

 IOPS Navigation as compared to X-Ray Fluoroscopy

One basic difference is when we do fluoroscopy, we are looking in a two dimensional view. So in general, we are working in one field of view. If we need to orient our catheters and wires, we might have to move the imaging to lateral AP oblique, et cetera. The IOPS you see on almost every dimension simultaneously. So you can, you can envision that you are working your catheter and wire and pointing and knowing if you're moving upwards, laterally, almost aiming your target. At the moment, I think the two imaging modalities, fluoroscopy and IOPS are complimentary, but I do foresee the evolution of it to become more and more IOPS type oriented and less and less fluoroscopy oriented. Radiation remains a major concern. If we look at the career of vascular, cardiovascular, and interventional radiologist operators, it's mostly driven by fluoroscopic based procedures that are becoming more and more complex. So, the idea of having an imaging technology that eliminates radiation is extremely appealing. IOPS also has the potential, not only of sensorizing the catheter and the wire we use as our primary tools, but actually the devices. So conceivably, with further evolution, we are going to start seeing devices that are sensorized and can be implanted with very accurate knowledge of the location of these devices relative to their target. That I think it will be a major revolution when that happens.

Recommended Use

So currently, I think that IOPS is fair to say is on its initial phase, we have an eight French catheter with two primary shapes, a primary angled catheter equivalent to what would be a campy or a vertebral catheter, and a secondary curve catheter, which is equivalent to a SOS or a VS1 catheter. Given that it's eight French, it also creates a series of constraints in terms of access, flexibility, et cetera. Nonetheless, it allows you to navigate the catheter and the wire within the abdominal vasculature, without fluoroscopy. It can be used for selective catheterization of renal mesenteric vessels, navigation into the internal, with the cartoons or within the aorta, for occlusive disease, or any reasonable disease, or both. And for the early adopters like myself, we're also using for very complex procedures like fenestrated and branch grafting. The area that is most appealing is for example, when we have to, to use lateral projections on fluoroscopy. Lateral projections, as you know, increase significantly the radiation exposure, and also the quality of the imaging is also decreased because of the patient's body, particularly if you have the arms placed on the side of the patient. The IOPS on that situation allows you to not use the lateral projection, and, and we often couple IOPS with fluoroscopy. So we might do a short segment of flouro, position the catheter, then shift to IOPS, try to navigate the catheter and the wire into the target, and then switch back to fluoroscopy to make sure the wire is in the desired location within the target.

Data

The data is evolving. I mean, the device was approved relatively fast, and right now is mostly case experience that's been accumulated. There are, there are several centres now in the United States that have access to IOPS, we are one of them. And we are basically, quite frankly, learning the applications of it and accumulating data. There is certainly a learning curve on how to use it. I don't think at this point, I can tell you that we have objective data, that it allowed us to significantly decrease fluoroscopy and radiation, but I am very much convinced that that's going to be the case when we assess objectively and compare with procedures that are done without IOPS. And also once we learn more about it and overcome this learning curve on how to really effectively use it.

Future Directions

I think the future is very bright for this technology and it is the evolution. I don't see us doing complex procedures in 10 years based on radiation alone. So IOPS is one of the tools that has the potential to play a major role. As for the next steps, is we need more tools. We need catheters that are five french, four French, six French would already be a compromise. We need wires that are of different flexibility and interventional wires that allow us to advance stents, you know, with relative stability. Guide catheters with IOPS would be very appealing, particularly if they have a steerable technology, because then we can really leverage all that a steerable guide can offer us in terms of targeting certain areas of the vascular anatomy and providing enough support to carry the goods, the cath, that stents, the balloons, et cetera. So I think that that's the initial phase. As a secondary phase, if there is the buy-in from the industry into developing sensorized devices, then that would be the next step on the evolution where not only we are navigating the catheters and wires, but we are actually delivering the stents totally without fluoroscopy, or almost without fluoroscopy.

First Experimental Surgery without Fluoroscopy

So we presented at the VEITH meeting the first, to my knowledge, the first experiment of a total endovascular repair of an aneurysm without any fluoroscopy and using IOPS. And to do that, we created a 3D print model of an aortic aneurysm. We actually did the CT angiography off the model to create the, the basically map for the IOPS. And then we sensorize the stent grafts by basically suturing the sensors into areas of the stent graph, the top, the gate and the limb. And using the IOPS catheter and sensorized wires, we basically introduced a stent graph, deployed, and completed the entire repair without flouro. At the end of the procedure, we did actually a CT angiography to prove the concept and see how accurate we were relative to our target, which was essentially the, the lowest renal artery, and we were within a millimetre of the renal artery. So that was a remarkable, you know, shown an in vitro model of what can be done in, in the human. And what we need now is to, to have these stent graphs with wireless sensors and more catheters, more wires, so that this can actually be done not in vitro, but in vivo. It was a pleasure to work with CentreLine and the engineers and the UT and Mayo Clinic teams to achieve this experiment.