Discussing the Design History of the INCRAFT® AAA Stent Graft System

The multispecialty team of expert physicians who consulted the design plan share the thoughts and experiences that led to the device's innovative development.

PARTICIPANTS:

Robert Bersin, MD
Medical Director
of Endovascular Services
Medical Director of Structural
Heart Services
Swedish Medical Center
Seattle, Washington
He has disclosed that he is a consultant to Cordis Corporation.

Takao Ohki, MD
Chariman of Surgery
Department of Surgery
Jikei University School of Medicine
Tokyo, Japan
He has disclosed that he is a consultant to Cordis Corporation.

Corey Teigen, MD
Vascular & Interventional
Radiology Department
Sanford Health
Fargo, North Dakota
He has disclosed that he is a consultant to Cordis Corporation.

When did the initial concept and design discussions for the INCRAFT® AAA Stent Graft System (Cordis Corporation) begin?

Dr. Bersin: My involvement began in 2004. Cordis had previously attempted to design a fully percutaneous stent graft some years before, and out of that came the desire to develop a next-generation percutaneous device. In the fall of 2004, a team was assembled to meet those goals and design the device.

Dr. Ohki: My involvement with the INCRAFT® System goes back to around 2004, but the seed of the percutaneous abdominal aortic aneurysm (AAA) repair was present within Cordis going back to 1997-1998.

Dr. Teigen: I was first involved with the Quantum LP graft at Cordis in the late 1990s, early 2000, and then we moved into the INCRAFT® System in 2004 when we started looking at making a graft that was small enough to meet the needs of people with smaller leg vessels.

What unmet clinical needs were you trying to solve when you embarked on the INCRAFT® System?

Dr. Bersin: There were two basic areas in which the first- and second-generation devices didn't meet all of our needs. On the access side, it was getting a lower profile, because it became clear early on that profile had a huge impact on complications and initial outcome (Figure 1).

The other area was the adverse aortic neck, the infrarenal aortic neck. This device really attempted to address the profile and be totally percutaneous and address some of the limitations of the current-generation devices as far as treating adverse necks, especially angulated necks.

Dr. Teigen: It was really about access vessels and having a low-profile graft that would treat those patients for whom the current grafts could not, especially women, people of Asian descent, and those with bad atherosclerotic disease* or small iliac vessels.

Dr. Ohki: The INCRAFT® System makes endovascular repair less invasive and gets closer to the concept that drove Cordis' innovation even in the late 1990s, which was to create a less invasive future. It's close to 20 years that we spent on creating a less invasive future.

Durability and long-term data of the INCRAFT® AAA Stent Graft System are based on 2-year clinical follow-up and benchtop data.

How would you describe the importance and the influence of having physicians from the radiology side, cardiology side, and the vascular surgery side working together as a team?

Dr. Teigen: It's absolutely necessary. We had innumerable discussions among the three of us about what would be best and all brought different skills and experiences to the table (Figure 2). I think that ultimately made the graft as great as it is.

Dr. Ohki: I think bringing the three fields together created a better, more knowledgeable team—we each have a unique strength. If you develop it just with a vascular surgeon, the surgeon would tend to give priority to the durability and give up the low-profile aspect of the stent graft. Drs. Bersin and Teigen, being interventionists, were more vocal about not giving up on low profile.

Dr. Bersin: It is crucial. Every specialty has its own perspective and experience, and that collective experience between all three major specialties proved to be an excellent mix to get consensus and question certain design elements. It worked beautifully, I think, as far as achieving the goal of getting balanced input.

What are some of the elements that have changed since the early designs? And what testing and clinical observations and animal lab observations did you perceive in order to make those changes from the initial design?

Dr. Bersin: The initial design concept centered around the idea that to get a lower profile, you had to become increasingly modular. There's just no other way to do it. The first-generation device was all-in-one,

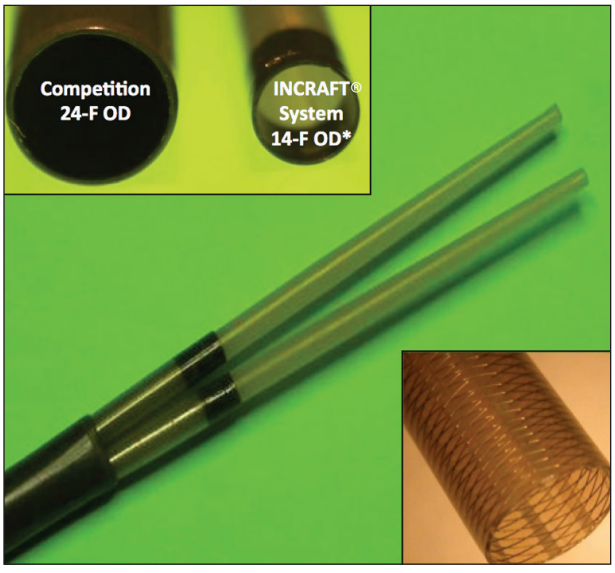

Figure 1. Comparing the profile of the INCRAFT® System aortic bifurcate delivery sheath to the profile of other major competitors. *16-F OD for the 34 mm aortic bifurcate.

Figure 2. Drs. Teigen, Bersin, and Ohki (from left to right), during some of the early deployments of the INCRAFT® System prototypes in April of 2009.

and that was the highest profile device. The current INCRAFT® System is a three-piece device (Figure 3).

Dr. Ohki: Because we wanted to create a flexible, low-profile system, the INCRAFT® System was a fairly short-pitch stent, which means that there is no support during deployment. We realized that the infrarenal design was not accurate enough, and that's when we advised the engineers to hedge risk by creating a suprarenal stent. A suprarenal stent with a mechanism to hold a top stent tip was the easiest solution to combat the windsock effect, and that's the design we have today.

Dr. Teigen: As we came up with different conflicts, we had to trade one thing for another. We pushed the engineers over and over again to solve the problem. It was a gradual process. There was a lot of durability testing, and we did a lot with the nitinol and fabric to make the stent graft last despite the fact we made it a small size.

Dr. Ohki: There is no fatigue machine that can be acquired commercially, so we had to create our own fatigue testing: pushing, pulling, twisting. The fatigue model created by the Cordis engineers compresses and twists the graft with pressured flow, and you can do 200 million cycles, accelerated. With this testing, we realized that the sharp-edge stent was no good, and if the stent was not attached to the fabric very tightly, it was prone to graft wearing.

Currently, how does the device perform for you in your patients during the INSPIRATION Trial?

Dr. Teigen: We spent 10 years working on this, so you always have some trepidation and wonder if it's really going to work—and it did; it was awesome. We enrolled 30 patients in the INSPIRATION Trial and every one of them is doing excellently. We even treated patients

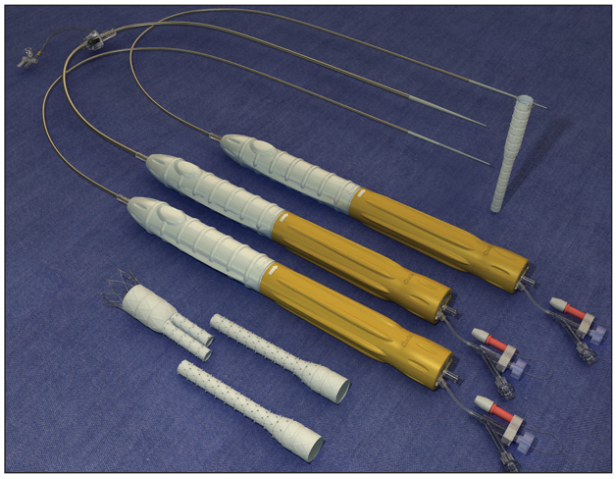

Figure 3. The trimodular design of the INCRAFT® System—implants and delivery systems.

under a compassionate use program, because there was a patient I couldn't treat any other way, and this graft treated that patient without any complication.

Dr. Bersin: The device performed excellently in the clinical trials. We could only treat up to a 60° infrarenal neck, and that was the main restriction because even small access vessels could be approached with the device's low-profile. Even up to 60° necks, this conforms as well or better than anything I have used in my experience. It truly is accurate as far as placement; we've proved that you can get within 2 mm of your intended target.[1] On an angulated neck, its ability to conform orthogonally as it's deployed is excellent because of the way the delivery system was designed.

Dr. Ohki: During the clinical trial, I performed all 30 INCRAFT® System implantations percutaneously and under local anesthesia. I was able to live up to my word that I gave my patients beforehand: the latest, state-of-the-art, cutting-edge technology. No general anesthesia, no cut down. That was a triumph. If the percutaneous success rate is 90%, then you have to worry about a one out of 10 failure, which means you have to have anesthesia backup and be prepared with a surgical kit. If you are successful with 30 out of 30 patients and have no conversion to general anesthesia, that means a lot from a clinical standpoint.

What other design elements, in your opinion, make the INCRAFT® System unique?

Dr. Bersin: I'd say number one is durability. We designed this to be durable. In our extreme bench testing, we found that this device outperformed others; freedom from frame fracture, fabric erosions, and so forth was better than any. I can say to people with confidence that this is not only lower profile, more accurate to deploy, and more orthogonal on angulated necks—it's also durable, which is quite an achievement.

The hooks for attachment (Figure 4) have more pull-out force than any other graft, so the freedom from migration is expected to be the best. The pull-out force to separate the modular limbs is expected to be the greatest.

Dr. Teigen: The low profile allows you to use it on most eligable patients. Second, the device's trackability—it goes through iliacs and aneurysms that are very tortuous.* Even in tortuous anatomies, the accuracy of placement helps you to put it right at the renal arteries where you need to. The three-piece design and being able to adjust the length of the iliacs to treat all the way down to the common iliac bifurcation have made it an excellent graft all around.

Dr. Ohki: The low profile of the INCRAFT® System allows percutaneous implantation with local anesthesia.

The in-situ customization capability of the INCRAFT® System allows you to take advantage of every millimeter of the iliac neck. With a standard stent graft, where you don't have much room on either end, you cannot make it too short or too long. The stent graft sizing would dictate the physician on where to land. With the regular, currently existing stent graft, we would land the distal end of the stent graft sometimes 1 or 2 cm away from the internal iliac artery, which means we are wasting 1 or 2 cm of neck. If we don't utilize the whole length of the distal neck, it might lead to future failure.

The other advantage was related to the flexibility of the endograft. Most stent grafts on the market straighten the aortic anatomy as they are implanted, possibly because of the stiff, large-bore delivery system. That means the aneurysm is trying to fit the endograft.

The INCRAFT® System is flexible, it goes in effortlessly and doesn't create an accordion effect. It is not intended to straighten the neck angulation. On average, we only saw about a 10% change in the infra- and suprarenal neck angulation after treatment, which supports the great conformability we observed in preclinical testing.[2]

Now, what does that mean? It might not seem bad initially, but the reality is that any aorta or aneurysm is stronger than the stent graft. With an ordinary stent graft, a 50° neck is turned into a more straightened 30° after implantation. But 6 to 12 months later, the aneurysm beats the stent graft, the 30° neck goes back to 50°, and the stent has to migrate either proximally or distally to accommodate or there is a type III endoleak.

Does the INCRAFT® System have any features that specifically help the prevention of endoleaks?

Dr. Teigen: There are several things we wanted to do to decrease the risk of endoleaks. First of all, we wanted to have an endoskeleton at the fabric on the outside have a better seal at the superior neck. We looked at having

Figure 4. The unique, sharpened, integrated nitinol barbs allows for migration-resistant suprarenal fixation of the INCRAFT® System.

Figure 5. The suture knots on the outside of the iliac limbs interlock with the endoskeletal stent struts on the inside of the aortic bifurcate legs for improved connection force in the overlap zone.

enough radial force despite the fact that it is low profile to be able to seal the proximal end zone.

We also looked at the legs and the locking mechanism between the knots and the nitinol (Figure 5). When you put the legs in, their motion is reduced, decreasing the risk of type III endoleaks. The same goes with the iliac legs—having the endoskeleton and fabric on the outside and enough radial force to seal the iliac arteries.

Is there anything that you learned about the device that makes it unique in the way that you implant it? Are there any unique deployment steps you think you would take into account when using the INCRAFT® System?

Dr. Bersin: Yes, there's actually one aspect that I found, in my opinion, to be unique about it, and it goes back to how it's designed. To be this low profile, you have to have larger and higher radial strength frame nitinol cells. You can't have as many. You can't have a tight mesh because that takes up too much room and it raises the profile. So you have to have larger cells, and to maintain the radial strength of the device, they have to be stronger. So as a result of that, the radial force of this device is quite high.

I have found that you're better off not oversizing too much because of the high radial force. Oversize this device about 10% instead of the usual 20%, and certainly not 30%.

Dr. Teigen: You want to use a relatively stiff wire. The device goes up through the iliacs and into the aorta so well. You can get it there over a floppy wire, but you really want the support of a stiffer wire when you deploy it to keep it in place because it's so accurate. You can't be too aggressive with a floppy wire.

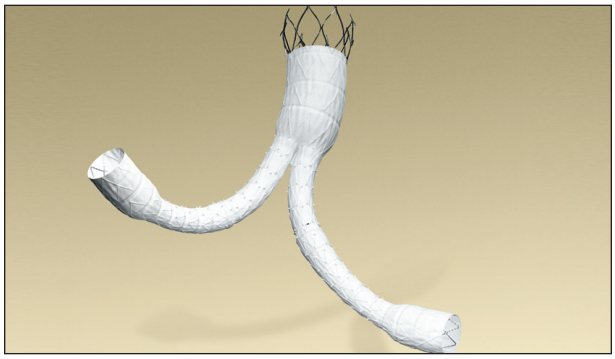

Figure 6. The INCRAFT® System, finally available after almost a decade of developmental work.

Explain to us why it took 10 years to develop the INCRAFT® System.

Dr. Bersin: Our challenge was to make this a low-profile device that is equivalent to a 12-F sheath introducer without sacrificing acute performance or durability, which is quite challenging to accomplish.

As I mentioned, you have to have fewer stent cells and higher radial force. The frames are stronger; that puts more stress on the fabric. You then have to do things in minute detail, such as change how the fabric is attached to the stent and distribute the stress force of the attachment across a broader area of fabric to prevent fabric tears and erosion.

These are very minute but important changes, and every time we made one, we did the durability testing all over again. All of the design details become exponentially more difficult as you go increasingly smaller in profile.

Dr. Ohki: The devil is in the details. Shouting, "lower profile, lower profile!" is easy, anybody can do that. But, in fact making a low-profile device with all these limitations is a conundrum—it's trying to realize two totally opposite things, and it's the engineers that made these devilish details happen.

Dr. Teigen: It's really engineering challenges. We tried to take a very large graft (originally it was 24-F) and put it down to 12- or 14 F. The engineering that it took to get it there took some time, and we wanted to make sure this was a durable graft. We put a lot of time into engineering something that was a very durable device. ■

1. Pratesi G. INCRAFT® AAA Stent Graft System 2-year clinical data from the INNOVATION Trial. Presented at: Charing Cross International Symposium. April, 2014. London, UK.
2. INNOVATION Study data on file. Cordis Corporation.

*Exercise particular care in areas that are difficult to navigate, such as areas of stenosis, intravascular thrombus, calcification, or tortuousity, or where excessive resistance is experienced, as vessel or catheter damage could occur.