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How the field of cardiovascular surgery is changing in light of new technology and its ever-increasing coordination with interventional cardiology.

How would you describe the evolution of the cardiovascular surgeon in treating patients via minimally invasive means?

The minimally invasive evolution began some 20 years ago with cardiovascular surgeons being appropriately skeptical. A big surgery requires a big incision and that is how we were trained. There is very little margin for error in open heart surgery, and thus we equated access to safety and optimal outcomes; the better the access, the better the outcomes. At that time, this dogma was pretty accurate. The technology simply was not there to treat heart patients via a small incision. As laparoscopic technology improved, our patients had observed these successes in other fields and thus CV surgeons were dragged to the minimally invasive altar kicking and screaming.

Minimally invasive direct coronary artery bypass grafting and other less invasive technologies began to develop. When Heartport (formerly Heartport, Inc., now a private subsidiary of Johnson & Johnson, New Brunswick, NJ) hit the market in the mid 1990s, patients wanted it, and administrators demanded it to stay competitive with other hospitals. Some of us embraced at least one of the first truly minimally invasive technologies that could be used to perform mitral repair/replacement, aortic valve surgery, and even coronary artery bypass grafting. But it was hard to use and not universally adopted.

Simultaneously, angioplasty and stenting took the world by storm. Cardiac surgeons were initially resistant; however, during the past 15 years, cardiac surgeons had begun pushing the envelope with a variety of less invasive technologies including robotics. The results of these new technologies were varied, and for data-driven heart surgeons, the changes were met with justifiable resistance. Any technique that is not equal to or surpassed the accepted maximally invasive results is subject to at least healthy skepticism—which I believe is

good. I believe that our skepticism is fueled by conflicting data surrounding other technologies such as stents, which in many studies failed to show clear benefit over coronary bypass grafting for patients with three-vessel disease, left main disease, low ejection fraction, and diabetes, which are most of our patients these days.

However, stents continue to be the mainstay of treatment for coronary artery disease. Stent technology too is an ever-evolving technology.

What are some of the practical issues of balancing your surgical and interventional practices?

One of the reasons that I am so involved in TAVI (transcatheter aortic valve implantation) is because of my interventional practice. As I finished my general surgery residency, I saw my

attendings try to perform laparoscopic cholecystectomy procedures, which seemed relatively simple. In short, the younger generation arcade junkies could do it and the older generation struggled. I also saw the interventional train coming down the track with percutaneous angioplasty and stents, and I believed I should hitch a ride. However, I had no training to do so at that time.

I partnered with my senior mentors who were all doing open valve procedures. I volunteered to be the venous and arterial access guy to get the Heartport equipment in place. That was my first learning environment for catheter wire skills. It positioned me for the endovascular stent graft revolution that took place a few years later. I then partnered with an interventional radiologist who was involved with a large cardiology group. I hung around the catheterization lab at night, assisting whatever I could, if only to learn the names of all these crazy catheters and wires that I was totally unfamiliar with. As the stent graft market exploded, so did my abdominal aortic aneurysm (AAA) practice at Cardiac Surgery Associates in Chicago. We are at 25

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hospitals in several states including one of the academic centers in Chicago, so I received many referrals from varied sources including my own partners.

This arrangement allowed me to be a leading enroller in several abdominal and thoracic stent graft trials during the last decade. The natural extension of this was to expand my practice to a greater variety of catheter-based technologies. I started in the groin initially and worked my way proximally through the abdominal aorta, thoracic aorta, and ultimately to the aortic valve (TAVI) back to doing open heart surgery, but now all via that initial groin incision—I had come full circle. Balancing my interventional and surgical practices is not easy, but it is a great problem to have because I am busy doing both. I have not limited myself to one or the other.

What tips would you offer CV surgeons who are aiming to add more interventional components to their practice?

There are a number of programs for surgeons who wish to increase their interventional footprint. Medtronic (Medtronic, Inc., Minneapolis, MN), for example, sponsors an academia aortic boot camp that helps you sharpen your interventional minimally invasive skills. It directly educates heart surgeons using various didactic and hands-on workshops. This type of program is available at almost every national meeting. There are also 1:1 programs that allow you to work with and observe experienced surgeons who do a lot of interventions. If cardiac surgeons take the time to learn these techniques now, they will have plenty of time to succeed in the future. Otherwise, they are going to be left behind by the next generation of hybrid surgeons or structural heart interventionists. They must get engaged now, and how they do it is up to them, but the tools are there: the simulation suites, courses, hands-on programs, networking, Internet, and even videos. There are enough programs available so that they can get up to speed quickly and succeed in using these new technologies in their practices.

Can you tell me about some of the devices that you have developed or are currently working on?

I have been fortunate to be on the front end of this new technological wave since my Heartport days, and I have worked with a lot of bright people in the medical industry. I recently shared in one of the patents for Medtronic's next generation of percutaneous valves. I have been working on that project for the last several years, even before CoreValve was purchased. I spend a

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lot of time working on different solutions to various aortic problems, including bare-metal stent technology in dissections. Some of that technology is being investigated in Europe right now. I worked on fenestrated devices for arch pathology, and a few of these companies are developing branch devices specifically based on some of the work of heart surgeons experienced in endovascular therapies. I had been doing a lot of research with CardioMEMS pressure sensors (CardioMEMS, Inc. Atlanta, GA), which I use to follow all of my AAA patients, and it is now being evaluated for use in treating heart failure.

I think a lot of the designs and techniques that we use for abdominal and thoracic stents have helped us learn that it is not so much the destination but the journey getting there. Our experience in using AAA and thoracic stent graft technology has helped us get to the aortic valve for TAVI, and now we are using many of these same delivery system concepts that we developed for stent grafts and applying them to percutaneous valves. It is a natural extension.

What are some of the device trials that you are currently enrolled in and are there any that you are particularly excited to see the results of?

Because our practice is so far reaching, my ability to enroll in trials is equally broad. In all of these trials, there were only a few cardiovascular surgeons participating, yet they were consistently the largest enrollers in every one of the abdominal and thoracic stent graft trials, which says a lot about our catheter wire skills and our overall presence in the endovascular marketplace. Cardiac surgeons still have a lot to offer in the catheter wire dominated realm of abdominal and thoracic stent grafting. The Medtronic Endurant device will probably be approved in the very near future, and I am especially proud to be involved in that trial because it will be a game-changing stent graft that was built from the ground up using everything we have learned from years of various stent graft implants and designs. Medtronic took what was best about its previous devices, techniques, and technologies, and put them into the Endurant device. It has one of the smallest device outer profiles, but it can expand up to 36 mm in diameter. It

is the most flexible and has the most active fixation on the market, which should all but eliminate migration. I suspect that it will dominate all other grafts as it seems to be doing in Europe.

I am also excited to get the CoreValve (Medtronic, Inc.) trial started and get updates about the PARTNER trial from Edwards (Edwards Lifesciences, Irvine, CA). Hopefully that will not be too far down the road because it is long overdue that we get several percutaneous valve technologies on the market (Sapien). Edwards Lifesciences just finished their enrollment and announced some of their initial results, and CoreValve is going to be starting soon. These technologies are going to make a cataclysmic splash for doctors and most importantly patients. We are going to be treating very high-risk patients who otherwise would simply not be treated.

I don't know how the trial results will ultimately compare to the standard valve treatments that we have today (which have great 20-year results), but it is going to be a fascinating journey to see the new technological advances that will spring from these first-generation percutaneous TAVI devices. TAVI technologies will be a game changer. This singular lightening rod technology will divide or galvanize CV surgeons as a specialty. It may define our very specialty. Unlike most minimally invasive heart surgery, which has been an iteration on a theme, small incremental improvements in technology and techniques, TAVI is a truly disruptive technology. It may by its very nature turn standard open heart surgery on its head. How cardiac surgeons embrace (or fight) this technology will define their practice, their reputations, the way they train future heart surgeons, and how they take care of patients in the future. Its overall impact cannot be underestimated. ■

CAROTID WALLSTENT® MONORAIL® ENDOPROSTHESES

INDICATIONS: The Carotid WALLSTENT Monorail Endoprosthesis (Carotid WALLSTENT Endoprosthesis), used in conjunction with the Boston Scientific embolic protection system, is indicated for the treatment of patients at high risk for adverse events from carotid endarterectomy due to either anatomic or comorbid conditions who require carotid revascularization in the treatment of ipsilateral or bilateral carotid artery disease and meet the following criteria: • Patients with neurological symptoms and 50% stenosis of the common, internal carotid artery and/or the bifurcation by ultrasound or angiogram OR patients without neurological symptoms and 80% stenosis of the common, internal carotid artery and/or the bifurcation by ultrasound or angiogram, AND • Patients with a reference vessel diameter within the range of 4.0mm and 9.0mm at the target lesion.

CONTRAINDICATIONS: The Carotid WALLSTENT Endoprosthesis is contraindicated for use in: • Patients in whom anticoagulant and/or antiplatelet therapy is contraindicated • Patients with severe vascular tortuosity or anatomy that would preclude the safe introduction of a guide catheter, sheath, embolic protection system or stent system • Patients with uncorrected bleeding disorders • Lesions in the ostium of the common carotid artery.

GENERAL WARNINGS: Refer to the Directions for Use supplied with any interventional devices to be used in conjunction with the Carotid WALLSTENT Endoprosthesis for their intended uses, contraindications and potential complications. • The safety and efficacy of the Carotid WALLSTENT Endoprosthesis have not been demonstrated with embolic protection devices other than the FilterWire EZ™ System. • Risk of distal embolization may be higher if the Carotid WALLSTENT Endoprosthesis cannot be used in conjunction with an embolic protection system during the carotid stenting procedure. • The long-term performance of the Carotid WALLSTENT Endoprosthesis has not been established. • Stenting across a major bifurcation may hinder or prevent future diagnostic or therapeutic procedures. • In patients requiring the use of antacids and/or H2-antagonists before or immediately after stent placement, oral absorption of antiplatelet agents such as aspirin may be adversely affected. • The implantation of the Carotid WALLSTENT Endoprosthesis should be performed only under fluoroscopic observation with radiographic equipment providing high-resolution images. • Never advance the Carotid WALLSTENT Endoprosthesis without the guide wire extending from the tip. • Do not advance the Carotid WALLSTENT Endoprosthesis against significant resistance. • The Carotid WALLSTENT Endoprosthesis should be oversized in relation to the artery diameter by 1mm to 2mm to prevent migration. • Do not release the Carotid WALLSTENT Endoprosthesis if unusual force is required, in such a situation use another device. • Never advance a partially deployed Carotid WALLSTENT Endoprosthesis distally. • Reconstraint and repositioning of the Carotid WALLSTENT Endoprosthesis should be strictly avoided when the partially deployed Carotid WALLSTENT Endoprosthesis is already in contact with the plaque of the stenosis. • Use of this device in patients with hypersensitivity to cobalt, chromium, iron, nickel or molybdenum may provoke an allergic reaction. • Avoid using power injection in the cerebral circulation. • Implanting a stent may lead to dissection of the vessel distal and/or proximal to the stent and may cause acute closure of the vessel, requiring additional intervention (carotid endarterectomy, further dilatation, or placement of additional stents). The stent may cause a thrombus, distal embolization or may migrate from the site of implant down the arterial lumen. Appropriate sizing of the stent to the vessel is required to reduce the possibility of stent migration. In the event of thrombosis of the expanded stent, thrombolysis and PTA should be attempted. • In the event of complications such as infection, pseudoaneurysm or fistulization, surgical removal of the stent may be required. • Overstretching of the artery may result in rupture and life-threatening bleeding. • Balloon angioplasty of the carotid bifurcation may initiate transient hemodynamic instability consisting of bradycardia or hypotension. Appropriate pharmacologic therapy must be immediately available.

PRECAUTIONS: Through non-clinical testing, the Carotid WALLSTENT Monorail Endoprosthesis (Carotid WALLSTENT Endoprosthesis) has been shown to be MRI safe at field strengths of 3.0 Tesla or less, and a maximum whole body averaged specific absorption rate (SAR) of 2.0W/kg for 15 minutes of MRI exposure. The Carotid WALLSTENT Endoprosthesis should not migrate in this MRI environment. Non-clinical testing has not been performed to rule out the possibility of stent migration at field strengths higher than 3.0 Tesla. MRI at 3.0 Tesla or less may be performed immediately following the implantation of the Carotid WALLSTENT Endoprosthesis. MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the stent. MR image artifact has been evaluated at 1.5 Tesla only.

ADVERSE EVENTS: Death due to any cause • Life-threatening condition (e.g., stroke) • Persistent or significant disability/incapacity • Any event resulting in an unscheduled in-patient hospitalization or prolongation of existing hospitalization >72 hours post index procedure • Any event requiring intervention, except for comorbid scheduled events, which are scheduled and planned during the follow-up period • Congenital abnormality or birth defect • Serious adverse events have been coded using the Medical Dictionary for Regulatory Activities (MedDRA) version 5.0 and are presented by System Organ Class and Preferred Term as follows: • BLOOD AND LYMPHATIC SYSTEM DISORDERS include events such as anemia • CARDIAC DISORDERS include events such as angina, arrhythmias, cardiac failure congestive and myocardial infarction • EYE DISORDERS include events such as retinal infarction • GASTROINTESTINAL DISORDERS include events such as gastrointestinal hemorrhage and retroperitoneal hemorrhage • GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS include events such as death, multi-organ failure and pyrexia • HEPATOBILIARY DISORDERS include events such as cholelithiasis • INFECTIONS AND INFESTATIONS include events such as pneumonia, sepsis and urinary tract infection • INJURY, POISONING AND PROCEDURAL COMPLICATIONS include events such as hip fracture and stent occlusion • INVESTIGATIONS include events such as blood creatinine increased and neurological examination abnormal • METABOLISM AND NUTRITION DISORDERS include events such as dehydration and hyperglycemia • MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS include events such as arthritis and pain • NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCLUDING CYSTS AND POLYPS) include events such as carcinomas, lung cancer and neoplasms • NERVOUS SYSTEM DISORDERS include events such as cerebral hemorrhage, cerebrovascular accident, convulsions, dizziness, syncope and transient ischemic attack • PSYCHIATRIC DISORDERS include events such as confusion, depression and mental status changes • RENAL AND URINARY DISORDERS include events such as renal failure and impairment • REPRODUCTIVE SYSTEM AND BREAST DISORDERS include events such as vaginal hemorrhage • RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS include events such as chronic obstructive airway disease, dyspnea, pulmonary fibrosis and respiratory failure • SKIN AND SUBCUTANEOUS TISSUE DISORDERS include events such as skin ulcer • SURGICAL AND MEDICAL PROCEDURES include events such as aortic valve replacement, arterial stent insertion, carotid endarterectomy, coronary artery surgery and revascularization, and hip arthroplasty • VASCULAR DISORDERS include events such as hematoma, hemorrhage, hypertension, hypotension, peripheral revascularization and vascular pseudoaneurysm.

POTENTIAL ADVERSE EVENTS: Abrupt vessel closure • Additional interventional or surgical treatment (e.g., stenting or carotid endarterectomy) • Allergic reactions (including to antiplatelet agents, contrast medium or stent material) • Aneurysm • Anginal/coronary ischemia • Arrhythmia • Arteriovenous fistula • Bacteremia or septicemia • Bleeding • Bradycardia • Cerebral vascular event such as edema • Cerebral ischemia/transient ischemic attack • Congestive heart failure (CHF) • Death • Detachment and/or implantation of a component • Emboli (fat, tissue, plaque, thrombus, device or other) • Fever • Filter thrombosis/occlusion • Hematoma • Hemorrhage • Hyperperfusion syndrome • Hypotension/hypertension • Hypotonia • Infection • Ischemia/infarction of tissue or organ • Myocardial infarction (MI) • Pain • Pseudoaneurysm • Renal failure/insufficiency • Restenosis of stented segment • Seizure • Severe unilateral headache • Stent embolization • Stent/filter entanglement or damage • Stent migration • Stent malposition • Stent thrombosis/occlusion • Stroke/cerebrovascular accident (CVA) • Vessel injury/dissection/perforation/rupture/trauma • Vessel occlusion or thrombosis • Vessel spasm or recoil.

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.

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