Trends-in-Medicine

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Quick Pulse

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CARDIAC SURGERY UPDATE

The unofficial theme of the Society of Thoracic Surgeons (STS) annual meeting in Chicago from January 30 - February 1, 2006, was how to save the profession from inroads being made by interventional cardiologists. Coronary artery bypass graft (CABG) volume is down, off-pump procedures are flat instead of increasing, there is a shortage of applicants for cardiac surgery residencies, and the job market for cardiac surgeons is poor. And these are trends that are expected to continue.

Surgeons appeared to focus this year on minimally invasive procedures and robotics as keys to their future. A former president of the STS said, "We are kind of at a crossroads, but I have more optimism this year, especially in less invasive surgery. There is clear and convincing evidence that surgery is better than stenting for multivessel and left main disease. Robotics is still a peripheral technology."

A speaker at the Medtronic booth told surgeons, "Truly minimally invasive surgery has all the benefits (of open surgery) without the morbidity. It avoids bypass, sternotomy, and thoracotomy, and the morbidity is equivalent to arthroscopy or a cath intervention. There is negligible CVA (cerebrovascular accident) risk. What we need to do minimally invasive surgery is port access, 3-D visualization, precision manipulation within the closed chest, and anastomosis devices – sutures, clips, and stapling devices." Another expert said, "Of 117 residency positions in cardiac surgery, there were only 47 applicants."

In this environment, new technology – from percutaneous heart valves to cardiac assist devices – took a back seat in the meeting's formal lectures. However, 28 cardiac surgeons agreed to answer questions about technologies in development in cardiac surgery.

On average, sources estimated that they do an average of 3.5 grafts during a bypass procedure. A surgeon said, "It is rare to do one graft. Usually we do multiple grafts because of diffuse disease."

PROXIMAL ANASTOMOSIS DEVICES

At least four products are on the U.S. market to assist with proximal anastomoses:

- **Guidant's Heartstring Aortic Occluder,** a manual device which acts like an umbrella inside an aorta, providing space for conventional suturing. Sources occasionally mentioned this product, pointing out that it has a role, but there was little excitement about it. A surgeon said, "Heartstring works reasonably well, and it is not expensive."
- **Medtronic's U-Clip,** a device obtained from Coalescent Surgical that has FDA approval. An expert said, "This nitinol clip is actually a method of

securing tissue. The proximal device only facilitates firing six clips all at once and aligning the vein graft to the aortotomy…It doesn't construct an anastomosis; it just aligns the tissue…No stent is placed inside the lumen. There is nothing inside the lumen except the clip…The U-Clip hasn't received widespread acceptance because it was introduced at the time of the St. Jude device problems, and people confuse the two…The cost of the Heartstring is about the same as for the U-Clip, but the U-Clip is faster…You can't use a U-Clip on a free internal mammary artery or a radial artery; they don't work as well for that, although the next generation may." Medtronic reportedly is working on a next generation of the U-Clip.

- **Novare Medical's Enclose,** a manual device that creates a dry area for conventional suturing in aortotomies but which requires a separate insertion through the aorta. This was approved by the FDA in 2002.

St. Jude had a star-shaped, proximal anastomosis device on the market but withdrew it. Symmetry Bypass Connector was approved by the FDA in 2001. However, numerous reports started being reported of blockages, blood clots, heart attacks, and even a few deaths. Finally in 2004, after ~50,000 devices had been used, the FDA told St. Jude it must conduct a clinical trial of Symmetry. St. Jude decided, instead, to withdraw Symmetry from the market.

A St. Jude official insisted Symmetry, which lies inside the vein graft wall, didn't fail, saying the FDA wanted a "big trial" before approval, and the company did not believe the market was large enough to warrant that cost. A Midwest surgeon said, "The St. Jude device had two problems: (1) The graft was sitting at the wrong angle (90 degrees), and (2) The position and placement of the mitral clips were wrong. Using these devices is technically more difficult than most surgeons will say. When you use a proximal anastomosis device, you make the same size each time, but you need to adjust the size. It's best just to leave the clamp off the aorta." Another surgeon said, "The device didn't work in small veins. The ratio of the staple to the vein was wrong." A third surgeon said, "I used St. Jude's Symmetry, and I loved it and had great success with it. I was surprised when it was taken off the market."

Another expert offered this perspective on what went wrong with the St. Jude device: "The original St. Jude device was an adaptation of stent technology…The problem they didn't realize is that placing a stent at the anastomotic site was new technology, and no one understood the limitations of that… We know that when you place a stent in an artery, you make the stent area static – normal expansion/contraction with blood flow does not occur…One of the mechanisms some people believe leads to stent stenosis is lack of dynamic movement… There are people who believe the loss of elasticity accelerates the atherosclerotic process…That is the theory. In an animal model, if you put a non-compliant constriction around a vessel, you will get a lesion. There were two problems with the St. Jude device. There were early problems with acute closure of the vein because it would kink at the interface from the end of the stent portion to the vein. (Veins can kink, but arteries tend not to kink.) The other problem was acute closures of the device because no one realized you have a bare metal stent inside an anastomosis…So even when you released it – under the short FDA look – they had a lot of problems with acute thrombus in grafts in the first three months because no antiplatelet drugs were given…There was a quick realization that this was not correct…Then, they put people on antiplatelet drugs and location became more important, which helped the acute problem…But then a year later, after being used clinically, late stenosis became a very big problem…No one knows why they got late stenosis…It could be the continuing irritation of the stent in the vein at the anastomotic location…Everyone lost confidence in the device, and it went away."

Surgeons were all aware of the failure of the St. Jude device, and that has contributed to an air of skepticism about proximal anastomosis devices in general. Among their comments were:

- *Ohio:* "At present, they don't work well, and they are very expensive – ~$300 vs. $30 to sew a valve. There is no significant advantage to justify the cost…The advantage of the device is doing the procedure without a clamp on the aorta. It's a good concept, but the present technology is not ready yet."
- *North Carolina:* "We tried some proximal anastomosis devices, and the results were not the best, so we don't use them...We didn't like them because the patency rates were too low…(But) at a minimally invasive conference in June (2005), they appeared to have come a long way."
- *Texas:* "I'm skeptical. I have the philosophy of don't fix what's not broken. Even the guys in the innovation realm don't think that is the way to go. The devices don't save that much time, and we have seen complications with some of these in stenotic lesions at the ostium. These devices still need work. And you have to factor in the cost. Why add expense to an already decreasing reimbursement scenario? Why add the expense when we've been doing this procedure (without the devices) for 30 years. They are gadgets that we don't need."
- *Indiana:* "In the past, these devices have not worked well, but we definitely need one."
- *Missouri #1:* "They usually work, but they are an unnecessary expense. They are a gimmick and expensive."
- *Oregon:* "We are traditional and conservative, but we would try a new device. I don't care about cost, just efficiency. Does it make the procedure faster and simpler?"
- *Wisconsin:* "I'm skeptical. I don't like anything out there. Heartstring is a different concept."
- *Missouri #2:* "I don't think proximal anastomosis devices are a big step forward."

Yet, surgeons were not entirely negative about this technology, noting that a good proximal anastomosis device has to be found if robotic surgery is to expand. And they generally did not believe vein size or position would limit use, predicting that a good device would be able to be used in most patients and not require careful patient selection. A Midwest surgeon said, "The size of the vein will determine if a device succeeds, so you need multiple sizes or a device that can do multiple sizes. Heartstring is nice because it covers varying size holes." A Maryland surgeon said, "I think there would be a definite role for another device. I do 90% of CABG off-pump to limit complications, and a proximal device enables me to do operations without touching the aorta, to do a clampless technique. If a new device came on the market, I would absolutely try it. I wouldn't use it routinely, but in a high risk patient population, I would use it, and that's 20% of my patients."

An expert said, "Sooner or later these devices will work, but there are two issues:

1. **Using them when you don't want to clamp the aorta.** This is not a very common problem with solutions that are at least okay, like Heartstring, so this is not as big a deal as it used to be.
2. **As an adjunct to robotic surgery.** The lack of these devices has slowed development of robotic surgery. This is a parallel technology that is extremely important…A small company failed a year ago and folded because they were worried about funding to complete it…The expectation is very high on reliability." However, a doctor experienced in robotic surgery insisted that you can do mitral valves robotically without a proximal anastomosis device, but he admitted a connector makes it easier to facilitate the robotic surgery. Another surgeon said, "Proximal anastomosis devices will make robotic applications for coronary disease easier. They will facilitate the use of the robotic approach for the coronaries."

In assessing a proximal anastomosis device, surgeons wanted:

- **Data from randomized clinical trials,** with results comparable to the current suture procedure.
- **No increase in stenosis.**
- **Minimum patency** of:
  - >95% for the internal mammary artery.
  - 85% at five years for vein grafts.
  - 60%-70% at 7-10 years for vein grafts.
  - Short term 95%-100%.
- **Cost effectiveness.** Most sources also insisted that cost would be a big factor in the use of proximal anastomosis devices. Several noted that an additional cost would be justified only if the device were ***shown*** to reduce operating time. A surgeon said, "When you look at the cost of other things and the downside of a clamp that causes a stroke, the cost to patients (of not having a proximal anastomosis device) is great." Another said, "They will definitely cost more than sutures, so I would just use them for high risk patients." A third commented, "No matter what happens, the device will be expensive, so I won't use it most of the time…And I haven't invested in any of these devices." A fourth surgeon said, "It is naïve to say there is no need for such a device. Any way you can improve anastomosis is beneficial, but whether it is cost-effective is yet to be seen…Why are people so concerned about cost when in my hospital CABG is the No. 1 profit maker?" A fifth source said, "A $300 price is not unreasonable. How do you put a price on a stroke?"

Among proximal anastomosis devices in development are:

- **Cardica's Pas-Port.** This nitinol device has been marketed in Europe since March 2003 and in Japan since January 2004. A surgeon who has tried Pas-Port in his lab said, "The only difference from the St. Jude device is that it is steel instead of nitinol. It still uses a stent. There is a nice delivery system, but I think it will suffer the same fate as the St. Jude device…I know if the Cardica device works...It is very easy to use…It is an engineering marvel. It is one of the best engineered devices I've seen. But, that being said, because it is still a stented anastomosis device, I think it will have the same long-term problems the St. Jude device had. And it might be worse because the Cardica device is stainless steel." Another expert said, "The Cardica device is better than the one St. Jude was working on. Endothelium-to-endothelium is better."

- **Johnson & Johnson/CardioVations' Corlink,** a nitinol-based stent device with both FDA approval and a C.E. Mark. It sits outside the vein graft wall. The double-blind, randomized PASSAGE trial is underway in the U.S.

- **Ventrica's Magnaport,** a one-step device with which central lumen access is not required. It provides a self-aligning, sealing proximal anastomosis. There is no punch and it creates a side-to-side anastomosis, which can accommodate varying graft sizes. The mechanism reportedly is rare earth magnets. This device is not believed to have been tested clinically yet.

- **Medtronic's Spyder,** an automatic, nitinol clip device which is loaded on the vein. This device, which Medtronic got from Coalescent Surgical, received FDA approval in 2003. It has been launched in some OUS markets and is believed to be just beginning clinical application in the U.S.

PERCUTANEOUS VALVES

This was a hot topic at last year's STS meeting, but there was almost no discussion of it this year. Cardiac surgeons continue to oppose this technology, and they continue to

believe it is at least 5-10 years away from common use by interventional cardiologists.

At TCT 2005, an FDA official indicated the agency will loosen – just a little – the restrictions on who can get a percutaneous valve. Patients have had to be nearly dead to get a percutaneous valve, but the FDA appears ready to allow slightly less sick patients to undergo the procedure, though that almost certainly will not include relatively healthy 50-year-olds. However, surgeons at STS said they had seen no signs of the FDA loosening the patient criteria for a percutaneous valve, and they do not expect that to occur any time soon.

HEART VALVES

Use of Mechanical vs. Tissue Valves

Location	Mechanical valves	Tissue valves
Europe	45%	55%
U.S.	30%	70%

Surgeons estimated that mechanical valves account for only about 20%-30% of all heart valves implanted in the U.S. A Texas surgeon explained, "We use tissue valves in older patients because we don't want to put them on Coumadin, and you don't want active younger patients, especially those who do sports, to be on Coumadin…The disadvantage to tissue valves is that they fail in 7-15 years, but the disadvantage to mechanical valves is that patients have to take an anti-coagulant…The future is a hybrid polymer valve with a low thromboembolic event rate but with the duration of a mechanical valve. The polymer would have a surface treatment to reduce clot formation and resist calcification. Some European companies are working on that." A Wisconsin surgeon who uses 50% tissue valves and 50% mechanical valves said, "It is hard for me to use something less durable (than a mechanical valve)…I believe in mechanical valves in all patients, but there are no data on the Carpentier-Edwards Perimount valve in patients <age 70…We have patients on Coumadin where doctors are putting in mechanical valves, but for the very elderly with a low risk of anticoagulation, we use tissue valves…The future may be (Cryolife's) SynerGraft decellularized homograft prosthesis."

Cardiac surgeons are extremely brand loyal when it comes to valves. Sources pointed out that they are much more conservative than their cardiologist colleagues, who they claimed switch too often and too easily. An industry source said, "Cardiac surgeons are very slow to change valves, even more than changing companies. They like using something that is a known entity. They will evaluate a new valve for up to six months before stocking it on the shelf." As a result, companies tend to target their marketing at residents and fellows, sources pointed out. An Arizona surgeon said, "Cardiology is technology-driven. They do a little different design, and everyone has to try and use it. In cardiac surgery, when something new comes out, no one is going to use it at first. We are extremely conservative, particularly because we inflict so much morbidity from the surgery that we want to be sure we get a specific result. It is very difficult to get people to shift (brands)." A Maryland surgeon said, "We get shown a lot of stuff on a yearly basis, especially valves. There are so many valve rings out there that every few months it seems someone sticks a new one in our face. Unless there is a dramatic difference in what the company is offering, you tend to stick to what you were using."

Mechanical valves

Sources predict that use of mechanical valves will not increase unless patients don't have to take Coumadin (warfarin). There are drugs in development that could replace Coumadin, and at least one trial is currently underway exploring whether Sanofi-Aventis's Plavix (clopidogrel) plus aspirin could be substituted for Coumadin. A source said, "Plavix could change the attitude toward mechanical valves if the studies show Plavix prevents strokes and minimizes complications." Another expert said, "In Europe, 55 patients were done with just Plavix, so we may use more and more of that with mechanical valves." A third surgeon said, "If Plavix worked, that would increase the use of mechanical valves."

A five-year trial of 700-1,000 patients is being sponsored by Medical Carbon Research Institute, using its On-X mechanical valve. This trial has been approved by the FDA but is still obtaining IRB approvals and has not yet started enrolling patients. It will have three arms: aspirin + Plavix, aspirin + Coumadin at a lower target INR than standard, and aspirin + Coumadin at a higher target INR than the second arm but still <2.5 (higher risk patients). A surgeon who has used Medtronic valves for many years said he is switching to On-X, "I always had concerns with bileaflet valves, but the On-X valve has different hinge points, and the carbon coating is light years ahead. I don't know the ease of use (of the On-X valve), but I can learn it."

Home INR testing by Coumadin patients, which is common practice in Europe, is rarely done in the U.S., though it is approved here. Home testing might help keep patients in the desired INR range and reduce complications with Coumadin therapy. However, surgeons do not believe that home INR testing would make mechanical valves more attractive in the U.S.

Tissue valves

Among the new tissue valves that sources were looking at on the STS exhibit floor were:

- **Edwards Lifesciences' Perimount Magna.** This valve was bioengineered specifically to address mitral valve anatomy, with a low profile, saddle shape, and asymmetrical design.

➢ **St. Jude's Biocor.** This is a triple composite valve with a flexible polymer stent. A St. Jude official said the company intends to bundle Biocor with other cardiac products, offering hospitals "complete source agreements," adding that "hospitals like that (approach)." Surgeons said their hospitals are increasingly asking for valves on consignment, and the St. Jude official reported that the company recognizes this and is moving more and more to consignment with valves. A Texas surgeon said, "Bundling will be effective." A Midwest surgeon said, "Medtronic has done that for a long time. If you are already using a lot of a company's product, shifting to all from that company makes sense. We are all concerned with cost." Another surgeon said, "Medtronic did complete source agreements years ago. Their hook was their pump, which was not good, so we didn't go along with it."

Surgeon Comparison of Perimount Magna and Biocor Valves

Factor	Edwards' Perimount Magna	St. Jude's Biocor
Ease of use	Good	Better
Flexibility	Good	Better
Profile	Good	Lower protrusion height of the posts
Material source	Bovine	Porcine
Data	More clinical data	Longer (20 year) market experience in Europe
Longevity	---	May be longer
Hemodynamics	Edwards claims greater effective orifice area index	Good
Durability	Good	Good

One of the things that makes it difficult for doctors to compare valves is that they are sized differently. A surgeon explained, "There is no uniform way to size." Even an industry official said, "There is no definite proof that one valve is superior to another. It would take 5-10 years and be very expensive to do a head-to-head trial."

Among the comments on these valves were:

- *Texas:* "The (shorter) posts (with Biocor) are not that big a deal, but the lower the profile, the better the fit. It is not a critical advantage (for Biocor), but it is an advantage."
- *Indiana:* "Perimount has a big orifice, and it is a very good valve…But all mechanical valves are the same, and all tissue valves are the same. If our hospital said there was a significant advantage to one valve, I'd go along with that."
- *New York:* "We use more bovine (Perimount) valves than porcine valves, but that has to do with availability. There is no difference in durability or hemodynamics…We've used a few Biocor valves, but they are not very popular because they are new… We are open to Biocor if the data are convincing. The Perimount Magna is a good valve, and the hemodynamic profile is quite good. The cost is reasonable for patients who stand to benefit, which is patients with a small ring, though that is not a large percentage of my patients. The Perimount Magna has a wider orifice, so the area you need to sew is not as large (as with the Biocor)."
- *Arizona:* "I like the Perimount Magna a lot for the flow characteristics. The valve is actually one size larger than traditional stented valves. Although in the mitral position, I like the Medtronic Mosaic valves because they have a lower profile and are easier to work with in smaller ventricles."
- *Maryland:* "We've been using Biocor for about six months, but we don't use it exclusively. We also use the Mosaic and Edwards valves, but Biocor will be our preferred valve because of the low stent profile. It looks like a good valve, and it is very durable. The reason we first tried Biocor was our relationship with our (St. Jude) sales rep, and the compelling, 15-year data they showed us. The low profile is very important in the elderly population, so we decided to give it a try. And my partner and I liked it a lot. In most patients the profile doesn't matter, but in elderly patients with small ventricles, this will be a key valve."

LEFT VENTRICULAR ASSIST DEVICES AND SYSTEMS (LVADs and LVASs)

Cardiac surgeons who implant these devices want to see development continue, but most also predicted that usage will not increase until future generation devices are approved and the devices are used as destination therapy.

➢ *Texas #1:* "LVADs are still not there. The companies have improved on complications and stroke rates, but that are not necessarily durable enough."

➢ *California:* "The key issue has to do with referrals. There is still a lot of reluctance by cardiologists to refer patients, and they will stay reluctant until there is an improvement in bleeding, infection, and complications. We are the No. 1 heart transplant center – we did 94 last year – and we have good medical therapy, so for us, an LVAD is a last resort."

➢ *West Virginia:* "More and more LVADs will be used because the thrombus rate is going down, and patients are making it long enough to go to transplant. Use will increase substantially in less than five years."

Continuous Flow Devices in Development

Company	Device	Type of Bearing
Arrow	CorAide	Centrifugal – blood-lubricated
Berlin Heart	Incor	Axial – magnetic bearings
Jarvik	Jarvik 2000	Axial – blood immersed bearings
Micromed	DeBakey	Axial – blood immersed bearings
Terumo	DuraHeart	Centrifugal – magnetic levitated
Thoratec	HeartMate II	Axial – blood immersed bearings
Ventracor	VentrAssist	Centrifugal – hydrostatic levitated impeller

- *Pennsylvania:* "To spur use in adults, the devices need improved results with respect to clotting/stroke, infections, and long-term durability, and they need the willingness of payors to pay for them. In pediatrics, we need all of that plus miniaturization…Adult use has already taken off, and pediatrics will take off in the next 5-10 years. It will be another decade before the inventors collect on these devices, but LVADs address an unmet medical need, which percutaneous valves don't do. Percutaneous valves are more glitz and patient appeal. LVADs are closer than percutaneous valves."
- *Massachusetts:* "Bridge-to-transplant won't increase use because hearts available for transplant are not increasing. What might increase use is: (1) Centrifugal devices, like Medtronic/Biomedicus's (temporary, acute) magnetic device, as destination therapy, and (2) Axial flow devices for destination therapy. But this is five years away…In Europe, the Jarvik device is being used for destination therapy."
- *Tennessee #1:* "Changing practice patterns of cardiologists is different from surgeons. There is still a very competitive stent vs. CABG environment that has the adult world not on the same page, but in pediatrics we (cardiac surgeons) are more aligned with cardiologists, so there is less resistance to these technologies (LVADs) and to utilizing them in pediatrics…Destination therapy doesn't make sense, but bridge-to-transplant or bridge-to-recovery is exciting."
- *Texas #2:* "There will be a spur in pediatric use only if the Berlin Heart's Incor gets regulatory approval in North America…Right now we have to get compassionate use approval on a case-by-case basis for the Berlin Heart… We are still five or more years away from a big step forward in pediatrics. The problem for pediatrics is not heart failure patients. We need to partner and share information…There is nothing very exciting in the technology on the horizon. There is a big gap between theory and practice."
- *Ohio:* "LVAD use will not take off for the next three years…We need more translation between the research lab and community practices…The technology needs to be more available and more user-friendly."
- *Kansas:* "Patients don't want to travel (to a major medical center for an LVAD). The issue for community hospitals is not the surgeon care but the ancillary help – board-certified anesthesiologists, pulmonologists, intensive care, physician assistants, follow-up care…Destination therapy is not ready for prime time…A heart transplant is less technically challenging than some CABG, but there is massive follow-up."
- *Arizona:* "LVADs are not viable yet, not at the current cost. I think the technology will come along. There is no doubt they will have a role, but the problem is financial."
- *Tennessee #2:* "We have a large private practice, but LVADs could wipe us out on manpower. When you put in an LVAD, you have to find a place for the patient to go. It could be a financial disaster for the hospital and eat us alive taking care of them. Publicity has outstripped practicality."
- *Maryland:* "LVADs are still not moving. They are not here yet. They are being used in Europe for compassionate use, but they are at least a decade away from common use here, even for compassionate use…There are untapped thousands of patients who could benefit from some type of surgical correction – mitral valve correction, ventricle remodeling, or LVADs as destination therapy. What is frustrating in the community is finding that patients – especially asymptomatic patients – have been followed for years by primary care physicians, but they don't get referred until they have a serious problem that could have been prevented with an earlier referral."

Thoratec's HeartMate II received a C.E. Mark in the last quarter of 2005, and during STS, Thoratec announced strong 2005 earnings, but the company warned that its 2006 forecast was lower than current Wall Street estimates. Thoratec also reported that, as of January 26, 2006, 159 patients have been implanted – 82 in the bridge-to-transplant arm and 77 in the destination therapy arm – with its HeartMate II in the Phase II pivotal trial of that device, an increase of 57 patients in the last three months.

Sources had praise for HeartMate II, which Thoratec hopes to launch in the U.S. in 2007, and they were aware of positive Phase I data presented at the November 2005 American Heart Association meeting. However, they did not think HeartMate II would significantly "move the needle" for LVAD usage. Their comments included:

- *Indiana:* "HeartMate II as destination therapy for life is pretty exciting. It is opening the door to continuous flow devices."
- *Oregon:* "We would do more LVADs if HeartMate II were approved – depending on the trial results."
- *New England:* "HeartMate II is magnetically levitated, but the approval will still be for bridge-to-transplant, though it could be used for destination therapy."
- *Kansas:* "HeartMate II is not there yet."
- *Missouri:* "The kick won't come from HeartMate II but from a smaller device, and that's about three years away. HeartMate II is bridge-to-transplant."
- *Maryland:* "Even if the HeartMate II data are positive, patients are not being sent for something as a mitral valve repair, so to think that they will come for the HeartMate device is a stretch. It is the primary care physicians and the non-invasive cardiologists who need to steer these patients to us."

- *Minnesota:* "Use is definitely increasing in heart failure. Every year, more and more are being used. Most big centers are putting them in routinely…HeartMate II is nice, but its approval won't make a big difference."

Outside the U.S., the outlook is mixed for LVADs in general and HeartMate II in particular. A German surgeon said, "HeartMate II will spur use, especially in Europe." A Mexican surgeon said, "All of these devices are too expensive for us to use." A surgeon from the Middle East said, "These devices are out of the question with what they cost today."

HeartMate II appears to have a lead in next-generation device trials. A trial of World Heart's Novacor LVAD reportedly has enrolled only about 15 patients so far, and Micromed stopped enrollment in a clinical trial of its DeBakey pump in August 2005, with just 12 patients enrolled.

Do surgeons believe that development of continuous flow devices should continue? Definitely yes, they said. They were particularly interested in magnetic devices such as Ventracor's VentrAssist. Comments included:

- "There are devices on the horizon with bearings suspended in a magnetic field. It is an attempt at a frictionless environment."
- "To move the market and increase usage the need for anticoagulation has to be reduced, the devices have to last at least four years, transcutaneous energy will be needed, and the devices have to be continuous flow."
- "Spiral impeller pumps are very unique and may help with miniaturization."
- "I wouldn't continue development of an axial flow device…An Australian company is developing a magnetically-driven device where the components don't touch the blood. That looks interesting."
- "The two devices I'm watching are Ventracor's device which is very impressive, and DuraHeart."
- "There is a very gradual evolution of technology. Nothing jumps out at me. Utility will increase if we find something that increases the capacity of the heart to recovery…The most exciting to me is stem cells to provide a substrate for recovery…If we provide myocytes, some hearts might not need transplantation."
- "Axial flow devices are all very exciting. There will be a niche for each of them."
- "With the new axial flow devices, in the next five years we will do LVADs in community hospitals. It is still space age technology, but the kinks are being worked out."
- "Axial flow devices will probably have a role, but I'm not sure they are for everyone. There has been little clinical experience with them."

There was little new information on LVADs at this meeting, but at a pediatric wet lab on the last day of the STS meeting, surgeons got a chance for hands-on experience with the Thoratec, Micromed, Jarvik, and Berlin Heart devices. Sources also said they expect more data on LVADs at the International Society for Heart-Lung Transplant (ISHLT) meeting in Madrid, April 5-8, 2006.

ROBOTIC SURGERY

Intuitive Surgical was demonstrating its *da Vinci* robotic system at STS, and surgeons appeared interested. This system has primarily been used for prostate and gynecologic surgery, but the investigators reported on the first 200 mitral valve patients at the American Heart Association meeting in November 2005. A speaker at the booth said, "We started with beating heart surgery and got no tracking, and then we tried mitral valves, and the uptake was slow, and we got no traction in coronaries. However, we got a lot of traction in prostate, and we did more R&D in the cardiac area, and now we are re-energized in cardiac surgery. Seeing urologists use *da Vinci* is making cardiac surgeons more interested, and the decrease in CABG has made cardiac surgeons look at *da Vinci*."

Yet, not everyone was enthusiastic about robotics. An Arizona surgeon said, "There is extreme resistance to robotics…As more people do robotics, there will be more resistance – because the surgical community is conservative by nature. They don't like change. If they could have it their way, we would still do all CABG on-pump. But that is not reality…Consumers are more involved, and if they have choice of a minimally invasive procedure, they will go for it."

An Intuitive official said more than 300 *da Vincis* have been installed worldwide, mostly in the U.S. The robotic systems are being used for soft tissue surgical procedures from the neck to the pelvis in gynecology and urology, not orthopedics. He added, "Right now, hospitals buy them for multi-specialties: urology, general surgery, thoracic surgery, gynecological surgery, and intra-cardiac [mitral valves and atrial septal defects (ASDs)]." Some hospitals also are buying a *da Vinci* as a marketing tool, to elevate its minimally invasive surgery program and attract more patients.

Other comments about *da Vinci* included:

- *A Middle East surgeon who plans to buy a da Vinci:* "Initially, we had a lot of skepticism that it worked, but it has improved from the first generation. We aren't getting it for 'show.' We wanted a good, working product, which is why we didn't buy it initially. We will use it for cardiac surgery and put it in a pure cardiac theater. I expect we will do 25% of our valves with it." Asked what volume level he would have to reach to justify a second robot, the surgeon said he does not expect to get a second machine. He also does not plan, at least initially,

to do AF ablation with it, though he said that is something he may consider in the future.

- *California:* "We have a *da Vinci* for urology. I've used it for about six cases for harvesting the internal mammary artery, but use is not increasing. It is limited to people who use it routinely on an every day basis. It takes a lot of getting used to setting it up, and staff. The jury is out on whether this procedure has any advantage over standard surgery except for cosmesis…And a paper found an increase in stroke in the first 24 hours with minimally invasive mitral valve surgery."
- *Tennessee:* "Who can afford robotics? You need the elective cases to support it, and that depends on cardiology referrals. The only solution is capitation on cardiology."

MITRAL RINGS

The only mitral ring technology that surgeons mentioned was Edwards' GeoForm and Medtronic's Futureband. A source said, "I think that is quite intriguing. I've used a couple, and the main reason is the endorsement by Dr. (Steven) Bolling, the world authority on mitral valve repair and compromised ventricles. I think he is honest and has tremendous experience …We've also used Futureband with good success. It is a nice band. But I could just as easily switch to a St. Jude ring and be comfortable. I don't see that much difference in the rings."

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