Trends-in-Medicine

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by Lynne Peterson

SUMMARY

Cardiac surgeons are doing more heart valve repairs, which hospital administrators sometimes encourage because repairs are cheaper than replacements. ♦ **St. Jude**'s Biocor tissue valve appears to be taking market share from **Edwards**' Perimount, with some significant discounting by St. Jude reported. ♦ Cardiac surgeons are increasingly interested in treating atrial fibrillation during valve and other open heart procedures. Bipolar radiofrequency (RF) often with cryotherapy is the preferred technology. **AtriCure**'s bipolar RF is getting attention, and the company plans to introduce an interesting new bipolar RF device, but surgeons already using **Medtronic**'s bipolar RF are satisfied with that. Yet, both ships may rise with the growing AFib treatment tide. ♦ Most cardiac surgeons have accepted the idea that percutaneous valves are coming, and they are starting to get cross-trained in catheter procedures. ♦ Use of **Intuitive Surgical**'s DaVinci robots continues to be driven primarily by urology and gynecology; there was little interest in stand-alone robots for cardiac surgery.

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CARDIAC SURGERY UPDATE

The mood at this year's meeting of the Society of Thoracic Surgeons (STS) and the American Association for Thoracic Surgery (AATS) TechCon 2007 in San Diego from January 27 - 31, 2007, was more upbeat than last year. In 2006, ***The Sky is Falling*** would have been a good theme for the meeting, as cardiac surgeons worried about how to save their profession from inroads being made by interventional cardiologists into areas that had traditionally been reserved for surgeons – e.g., drug-eluting stents and percutaneous valves. This year, the theme was closer to ***Back to School***, with experts advising cardiac surgeons to learn new techniques, particularly percutaneous skills, that will help transform their profession.

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. But experts offered what they believe is a solution: focusing on new technology such as Accuray's CyberKnife, Intuitive Surgical's DaVinci robot, and taking courses in catheter-based procedures.

Dr. Frederick Grover, outgoing President of STS, stressed the importance of educating STS members and residents on new technology and science, predicting, "In a few years the specialty will be very different from the way we know it now."

1. STS must provide ongoing education programs to teach new technology, partnering with industry, professional societies, and local institutions. He praised programs by Medtronic and Edwards Lifesciences to teach catheter-based therapies to surgeons.
2. Cardiothoracic surgeons must develop new techniques and methods.
3. The best and brightest candidates need to be attracted to cardiothoracic residency positions. Only 91 of 126 residency positions were filled in 2007.
4. Cardiothoracic surgery residents need to be provided with an excellent educational experience.
5. Total participation in STS databases is critical. He said, "Not participating is not an option…Non-participation is detrimental to our patients and to our specialty."
6. Legislative efforts need to be increased, both in terms of time and money.

Dr. Michael Mack, a member of the STS Board of Directors, had a similar message about the future for cardiothoracic surgeons. He said, "Operations by a median sternotomy on cardiopulmonary bypass will have a diminishing role… We need to employ open, transthoracic, thoracoscopic, robotic, and percutaneous

approaches…If we say percutaneous technologies are not in our domain, our specialty will become smaller, and our impact on the treatment of heart disease will be less important. For CABG to be relatively unchanged for 30 years is a pretty good run…but that is a long shelf life for any procedure to have. Clearly, we need a makeover. You may say this is like trying to get pigs to fly, but I believe we can get pigs to fly."

Other points Dr. Mack made included:

- "On the (exhibit) floor, you will see CyberKnife, and the surgeons who embraced this are going well."
- "As soon as radiofrequency (RF) ablation is on a flexible scope, lung cancer surgery for cancer is gone…We will no longer cut out tumors. In the future, they will be ablated by RF and other sources."
- "Imaging is going to be more and more alternative images to guide therapy. I was particularly interested in 3-D echo, showing how you can watch robotic hands inside an atrium suturing an atrial defect closed. It was astounding what you could see."
- "Percutaneous valve implantation now is becoming reality."
- "Over the next four years, the number of valve procedures will increase...and most of it will be standard surgical therapy…but an increasing percentage of it will be alternatives to surgery."
- "Though CABG as a percent of total revenues is going down, there are emerging opportunities. We have a waiting list of patients for percutaneous valves…and there is a huge patient population out there that never crosses the surgical radar screen that are candidates for less-invasive, non-conventional treatments."
- "There are skills we don't have or have to a minimal degree: endovascular skills, a knowledge of materials, fluoroscopy, etc. How do we get there? Venture with your cardiologists…Open your mind. Wash out some of the concepts like, 'I don't need fluoroscopy.' Understand the limitations of technology."
- "There needs to be accredited postgraduate residency or fellowship training…but in the meantime there are alternative pathways: Simulators will give you an introduction, and there are now industry-sponsored post-graduate courses that have been endorsed by STS… Rethink, retool, invent, and partner."

A game plan for CABG vs. PCI

Dr. David Taggart of Oxford compared CABG surgery to percutaneous coronary intervention (PCI). He said, "Not surprisingly, surgery's view of the two approaches favors CABG." He emphasized that PCI "is not as effective as CABG ***in the real world***."

Dr. Taggart lamented that patients don't really get sufficient information from cardiologists who "control" patients. He said, "Cardiologists routinely lie to patients on a day-to-day basis." The American College of Cardiology (ACC), European Society of Cardiology (ESC), and British Cardiovascular Society (BSC) guidelines all say, in effect, that PCI is now the default treatment for patients with multivessel disease. None recommend patients be given the benefit of a surgical opinion.

Other points Dr. Taggart made included:

- 5-year mortality is 2-3-fold higher with PCI than CABG.
- There is a consistent survival benefit of 5% in absolute terms in 3-5 years with CABG vs. PCI, or a decrease in the risk of death of 30%-40%. He said, "This probably underestimates the ***real*** survival benefit of CABG because of increasing crossovers from PCI to CABG (~10% by 3 years)." He said cardiologists promote the "myth" that there is no survival benefit between CABG and PCI.
- CABG reduces up to 7-fold the need for further intervention in three years.
- Patients with multivessel or left main disease benefit even more from CABG. He said, "In patients with 3-vessel disease, survival is better with CABG than PCI, and physicians and patients should carefully consider this, yet most of us know this rarely happens in clinical practice." He questioned how cardiologists could ethically enroll patients in a left main trial of PCI such as SYNTAX and argued that cardiac surgeons should "absolutely insist that patients with multivessel disease are treated by a multidisciplinary team."
- The CABG survival benefit is because:
  1. "CABG treats both the culprit lesion and future culprit lesions of any complexity, while PCI only deals with 'suitable' localized proximal culprit lesions and has no prophylactic benefit against new disease."
  2. "PCI means incomplete revascularization."
- Drug-eluting stents (DES):
  - Do not improve survival, do not reduce myocardial infarction (MI), but do reduce repeat interventions vs. bare metal stents (BMS).
  - Decrease the risk of restenosis but not mortality or MI at 1-2 years.
  - Have a stent thrombosis issue. He said, "There really is a problem out there (with DES stent thrombosis), but it is still as yet undefined."
  - Are likely to be ***less*** cost-effective than CABG.
- The risk of cognitive dysfunction is the ***same*** for PCI and CABG.

While this was a bit of preaching to the choir, Dr. Taggart also had some recommendations for action by cardiac surgeons. He urged them to:

✓ Insist on a multidisciplinary team approach in their hospitals.

✓ Get the message to cardiologists who can then get the message to interventional cardiologists.

✓ Get the surgical message to legislative bodies, insurers, and the public.

The hospital perspective

Drew Rector, vice president of HCA West Florida Division, which includes 15 of HCA's 192 hospitals, with 3 diagnostic cath centers and 8 open heart surgery centers, said HCA is working on a cardiovascular (CV) plan to improve the quality of services, grow volume through new and improved services, and get higher efficiency from the CV programs. He said, "Florida Medicare reimbursement and margins mean we have to be careful…I'm pushing CV surgeons to be business-oriented. I don't go to them with a lot of cost data. I share it with them, and I want them to be candid on what they need, and I will be candid back…How can we prioritize what we need? The CV surgeons I work with try to be our business partner and understand the challenges we face as an organization…Hospitals that drive CV programs are never as good as physician-driven programs."

Surgeon response

Surgeons seemed to be getting the message. Interest was high in courses to teach percutaneous catheter technology, in multi-disciplinary approaches, and expanding atrial fibrillation therapy, with all three of these intertwined.

STS officials and other experts had high praise for Medtronic's simulator classes, called EDGE, and Edwards Lifesciences announcement that it, too, will offer a percutaneous simulator training program, the ONE program. Both programs were developed in conjunction with STS. An STS official said, " I unabashedly endorse Medtronic's effort on behalf of our specialty: The EDGE program. This is endorsed by STS. And now Edwards also has stepped up to the plate."

- **Medtronic's EDGE.** Medtronic describes this as a "skills-based training program specifically designed to make (cardiac surgeons) more competitive today and in the future." Surgeons will use a simulator to learn guidewires, catheters, balloon catheters, stents, etc. It is a hands-on course being offered six times between January 1 and July 31, 2007, and only two session still had room by the end of the STS meeting, even with Medtronic adding additional sessions. The tuition is $995 ($895 for STS members).
- **Edwards' ONE.** This program will educate cardiovascular surgeons on new heart valve technologies. It includes Basic Endovascular Skills Training (BEST) course, which includes intensive simulator-based learning for introductory guidewire, catheter, and fluoroscopic imaging. The cost is $1,095, but an Edwards official said the classes are smaller.

Cardiac surgeons also were starting to take a more pro-active approach to the threat of losing valve replacement procedures to percutaneous valves and interventional cardiologists: ***A Team Approach***. The concept of multidisciplinary approaches to valve and other surgery was getting a lot of play at the meeting. Speakers were urging surgeons to get trained in catheter-based procedures, to work with their interventional cardiology and electrophysiology colleagues.

And there appears to be early progress on this front. Many of the surgeons questioned at the meeting said they are trying to get multidisciplinary teams going at their hospital, and Atrial Fibrillation Centers are figuring prominently in this. Several hospitals (e.g., in Cleveland; Atlanta; Fairfax VA; Dallas; Milan, Italy; and elsewhere) have already set up a kind of hybrid operating room (OR), and others are planning to establish one. It isn't always easy getting cardiac surgeons, electrophysiologists, and interventional cardiologists to agree, but surgeons are trying.

Dr. Niv Ad of Inova Heart and Vascular Institute in Fairfax VA pointed out, "Most (atrial fibrillation) patients come from primary care to cardiology, and then some to electrophysiology, but I don't see any steady line from electrophysiology to us…And surgery may be better for patients. We may be able to treat more patients more successfully if we combine resources…We have competition, and we will lose because we don't own the patient. We don't have any patient control. The solution is collaborating with equipment, clinical resources, and marketing…Our hospital established an AF center. We have pretty good cooperation, a referral center, and common use of resources. Now, catheter ablation is a surgical procedure in different suites. In the future it will be in the same suite, but that is a vision for the future."

Since Dr. Ad's center started its collaborative effort in April 2005, 95 patients have been referred for AF surgery – 82 by electrophysiologists (EPs), cardiologists, or primary care doctors, and 14 by other sources, and 54 of these were operated on. He said, "You might say that is not impressive, but we started from zero…AF compensated for decreasing CABG in the same period…And we are seeing an increasing number of patients being referred to the AF Center, and 13 patients have been referred to EPs by surgeons."

Before establishing collaborative programs, Dr. Ad reminded surgeons that:

- AF is very unforgiving.
- Terminology needs to be very clear. He said, "There is huge confusion among EPs, PCPs (primary care physicians), and us on whether a patient is paroxysmal, persistent, etc."
- We need better mapping.

- The correct technology needs to be used in surgical procedures. He said, "There is no single device that can do all procedures successfully on a beating heart."
- AF is a medical disease and non-pharmacologic treatment is far from perfect. He added, "There is risk for TIA (transient ischemic attack) and collateral damage. And patients don't like surgery, and cardiologists hate surgery."

ATRIAL FIBRILLATION (AF or AFib)

More than 2 million Americans have AF, and about 160,000 new cases are diagnosed each year. From 3%-5% of people over age 65 have AF, and ~9% of people age ≥80, so as baby boomers age, the number of patients with AF is expected to mushroom. AF is a supraventricular tachyarrhythmia (an abnormal, rapid, often irregular and chaotic heartbeat starting in the atria). It can cause the heart muscle to spasm or quiver, so the atria cannot effectively pump blood to the ventricles. The lack of atrial pumping action and the resultant pooling of blood can lead to the formation of thrombi and result in an embolic stroke. In fact, AF increases the stroke risk five-fold.

Cardiothoracic surgeons increasingly are treating atrial fibrillation while they have a patient's chest open, particularly during valve repair/replacement surgery, and they are starting to try to establish multidisciplinary teams with cardiologists and electrophysiologists such as atrial fibrillation centers. The preferred technology appears to be bipolar RF, either with or without cryotherapy (most frequently Frigitonics, which is made by Cooper Medical and distributed by AtriCure). AtriCure plans to introduce some interesting new bipolar RF technology, but sources already using Medtronic's bipolar RF are satisfied with that. However, both ships may rise with the tide since treatment of AF is expected to increase substantially over the next few years.

An expert estimated that 30% of patients with AF are treated pre-CABG, and 25% of CABG patients are treated during surgery for AF. In addition, 51% of mitral valve replacement patients get surgical ablation for AF. He said, "If patients go to CABG with AF, they will be treated because there is a huge difference in survival when their AF is treated." Dr. Patrick McCarthy of Northwestern Memorial Hospital in Chicago said 86% of CABG and mitral valve patients at his hospital are ablated for AF. Why not all of them? Age was the main reason. He added, "Peri-operative AF is ***not*** a failure; those patients just need to be aggressively managed."

Yet, surgeons do not control the patients; they depend on referrals from cardiologists and primary care doctors.

- Dr. Ralph Damiano of Barnes-Jewish Hospital in St. Louis MO said, "We need to convince the medical community of the utility (of AF ablation) by publishing prospective trials, and I think that is why we don't see more referrals…We don't really compete with catheter ablation (by EPs). I think if catheter ablation increases, it will increase, not decrease, surgical referrals. If EPs can convince the medical community that catheter ablations are first-line therapy, we will be very busy dealing with their failures and the patients they can't do…The present ablation technology is far from perfect…Surgeons have tailored new operations to the available technology rather than tailoring the technology to an effective procedure… We have to understand AF better in the individual patients. It is not as simple as proximal vs. persistent AF …Surgeons need to become more electrophysiologically sophisticated."
- Dr. John Puskas of Emory University said, "Patients and referring MDs want to reduce stroke risk in AF. That is the primary driver for sending patients to surgery. EPs are presently unable to occlude the left atrial appendage (LAA), so LAA amputation/occlusion is one of the more powerful reasons for referral to AF surgery…Surgeons presently have several techniques and technologies to safely occlude the LAA, and less-invasive technologies are under development, but LAA occlusion ***must*** be accomplished without mortality. The LAA can be a fragile and unforgiving structure."
- HCA's Rector said a multidisciplinary approach to AFib is a good idea but hard to get going, "AFib requires agreement of surgeons, cardiologists, and electrophysiologists. Usually you can get two of these together, but the third is the issue. It is easier to do a multidisciplinary approach in the vascular area for endovascular procedures."
- *California:* "It's difficult to get MDs together. We don't have any formal structure, but a lot of doctors are working together on AFib…It's like herding cats."

An electrophysiologist told surgeons that ablation is ***not*** a cure. He said, "AF ablation is not 100% effective in the best centers. All centers now acknowledge that later recurrences occur. AF ablation rarely 'cures' AF permanently…Effectiveness depends on many variables…The estimated success for the optimal candidate with paroxysmal AF is 70% at one year and 50%-60% for persistent AF at 1-1.5 years."

The Heart Rhythm Society Expert Consensus statement on catheter and surgical ablations of AF, co-sponsored by STS, is expected to be published in May 2007.

The goal of ablation is to produce transmural lesions that are reproducible – and there are several systems for doing this, and sometimes surgeons use more than one on the same patient. AtriCure, Atritech, Boston Scientific, CryoCath, Frigitonics, Johnson & Johnson/Ethicon, Medtronic, and others. A speaker called it a "very crowded field." Comments experts had on the various approaches surgeons use for treating AF included:

- **Cox-Maze procedure.** This surgery involves creating precise incisions in the right and left atria to interrupt the conduction of abnormal impulses and to direct normal sinus impulses to travel to the atrioventricular node (AV

node). An expert said, "We still think there is a role for classical Maze procedure…and we still do a fair number…It has a long track record."

- **Thorascopic microwave ablation: Boston Scientific.** A speaker said long-term relief from AF is ***not*** common after this, but the approach is safe and feasible with theoretical advantages. A study of 88 patients failed to show a benefit, with only 42% having freedom from AF during follow-up. He suggested that improvements in the technology are needed.
- **Cryosurgery: CryoCath and Frigitonics (distributed by AtriCure).** A speaker said cryotherapy has only about 65% success, but many doctors use cryo in combination with RF therapy.
- **Radiofrequency (RF).** This uses radiofrequency energy to heat the tissue and produce lesions on the heart, eliminating the incisions necessary in the Maze procedure.
  - **Unipolar RF.** A speaker said, "Most of us would not consider that acceptable results." Another expert said, "In normal cases we use cryo…We happen to have it, and the long T-shaped probe is really very convenient for that…Cryo is nice because it sticks in place, and you can do something else while it freezes…We tend to do 2 minutes at -60 degrees…We also place a cryo lesion at the mitral annulus."
  - **Bipolar RF: Medtronic and AtriCure.** Dr. Damiano said, "I'm a fan of bipolar ablation…When you look at the bipolar devices, the reason we pay for them is they give the most reliable transmural lesions…We found the Medtronic device to be very, very reliable." Another time, Dr. Damiano praised the AtriCure device.

Advantages and Disadvantages of Bipolar RF

Advantages	Disadvantages
Reliable transmural lesions in animals on a beating heart.	Bulky clamps that make an endoscopic approach difficult.
Short ablation times.	Limited lesion set on the beating heart.
Focused delivery of energy which reduces the risk of collateral injury.	Adjunctive unipolar technology is needed to perform more extensive lesion sets.
Ease of use.	A single ablation does not always create a conduction block.
Safe.	

ATRICURE got a lot of attention at its booth with its bipolar RF ablation technology. A speaker described his experience with AtriCure's bipolar RF, saying 35% of patients have had a previous catheter ablation, clamp time is down to 35 minutes, median ICU stay is 1 day, and median hospital stay is 8 days. At one-year, freedom from AF and anti-arrhythmic drugs (AADs) is 69%, and he said, "I think this is a number that is tough to get down."

Another speaker related one site's experience with the AtriCure bipolar RF system. He reported on the first 52 of 81 patients treated with this approach for whom six-month follow-up is available. He said, "These are the patients the EPs (electrophysiologists) didn't want to do." Using a definition of success as absolutely no episodes of AF of ≥3 seconds, the results looked good, but the speaker concluded, "A more extensive lesion set may be necessary for permanent AF ablation…The follow-up of patients by EKG over-estimates the effective rate by 20%."

Dr. Damiano said the AtriCure device is reliable, safe, and quick and easy to use, but it also has some problems including:

- A preset device is not an ideal device.
- The ablation lines are not as reliable in patients as in the lab; a single ablation did not always create a conduction block.
- Lesions are often difficult to visualize in the OR.
- Histological lesions are very thin with this device which raises the ***theoretical*** possibility of late bridging with resumption of conduction. He said this has never been proven, but it "might be better to make the lesions wider."

How do the AtriCure and Medtronic bipolar RF devices compare? An expert said, "The AtriCure device is easier to use than Medtronic's bipolar RF, but they have comparable efficacy." Another surgeon said, "They both reliably create transmural lesions. We use both Medtronic and AtriCure devices. The patient results are similar. In terms of ease of use, AtriCure has the advantage, but Medtronic's device is flexible, which can sometimes help in small spaces, and it is a little more forgiving. For PV1 (pulmonary vein 1) alone, I like the AtriCure better for ergonomics. One (device) doesn't work better than the other. Each has its own tricks as to how to use it. And you need to be more careful cleaning the AtriCure."

AtriCure is continuing to innovate, and a newer device may solve some of these problems. The company is expecting approval of a 510(k) any day for its new Synergy RF system and plans to launch in 1Q07. Synergy utilizes two parallel electrodes embedded in the jaws of the clamp which pulse on and off alternately to create a cumulative heat base in the tissue. AtriCure claims this new design will permit increased

Results with AtriCure Bipolar RF

Timeframe	No AF ≥3 seconds by EKG
1 month	86.3%
3 months	87.5%
6 months	86.5%
6 months with Holter monitoring	70.6%
6 months off anti-arrhythmic drugs (AADs)	65.4% *

*** Frequently the decision to take patients off AADs was made at the 6 month visit, so 12 month data are needed.**

depth of penetration, better visualization, and wider and more consistent lesions. Synergy has been tested successfully in animals, but no human procedures have been done yet. A company official said, "We will do 25-30 humans after approval and then launch it." A minimally invasive version of Synergy is expected to be introduced later this year, and in 2008 the company hopes to introduce a totally endoscopic approach.

Dr. Damiano said Synergy has "tremendous ***potential*** advantages." Another surgeon also praised Synergy, saying, "I think it will increase transmurality." A third source added, "The AtriCure dual Synergy is cool, but it is not proven yet."

Physician comments

Surgeons at the meeting who were questioned about the technology they use generally preferred bipolar RF, either with or without cryotherapy.

- *Louisiana:* "The technology is evolving so fast, and there are differences of opinion among well-respected surgeons. AtriCure has very good technology because the thickness of the lesion doesn't matter, but many surgeons will also use cryo with it in an open procedure…We use the Guidance microwave catheter. A bipolar RF device has the best energy, but you can't get it everywhere in a closed case."
- *Washington DC:* "There isn't one best energy source. Bipolar RF and cryo in combination is good, and it takes less than two hours skin-to-skin…We are bringing mapping into the OR with Johnson & Johnson/Biosense Webster plus echo and ICE (intracardiac echo), but we are not getting Stereotaxis' Niobe or a Hansen device because they are too expensive…AtriCure is a very good company and has a good device."
- *Illinois #1:* "Bipolar RF is the most reliable…We are planning a hybrid OR, and the EPs are excited. We need to sit down and see what they need. Whether or not we get a Niobe will be an EP decision."
- *Virginia #1:* "I chose bipolar over cryo because bipolar is easier. All the other (modalities) are okay, but I was waiting for the expert to tell us what they thought, and I'm hearing they like bipolar."
- *Midwest:* "We use unipolar cryo by Frigitonics. They have an inexpensive, reusable probe."
- *Illinois #2:* "I use Medtronic's unipolar RF, but I find bipolar interesting. It's also interesting that some (experts) use cryo with it and not unipolar RF where the bipolar can't get."
- *California:* "We use Medtronic's bipolar RF, not AtriCure's because of the ease of use and our relationship with Medtronic."
- *Montana:* "I use Medtronic's bipolar RF. It's straightforward in an open setting and takes 10-15 minutes…We are actively developing an AFib program to capture patients, but we are not doing a combined OR."
- *New Jersey:* "I treat AFib with cryo. I do minimally invasive surgery, and cryo works best with that. Cryo has been around a long time with excellent results. I think the Frigitonics probe is bulky and stiff; I use CryoCath."
- *Arizona:* "I may start treating AFib, and probably with cryo. I prefer cryotherapy because I use it with other things in the heart."
- "CMS has gone to an unlisted code for AFib ablation, which means physicians have to appeal to get paid…I've heard it will be fixed by April."
- *Mississippi:* "A lot of AFib is industry-driven. I took a course and found one (Medtronic bipolar RF) that I'm comfortable with, and I've had sustainable results."
- *Israel:* "The jury is still out on what's the best energy source…When I was in the U.S., I used CryoCath, but it was a first generation probe, and it tended to break.

Left atrial appendage (LAA)

Should the LAA be amputated in AF patients? Among the available or investigational technology for LAA amputation are:

- **Johnson & Johnson/Ethicon's** stapling device. An expert said, "This is less than perfect. We've pretty much abandoned it. I don't think it gives you much of a safety margin in many patients."
- **Boston Scientific's Epitek**, a mechanical device to occlude the base of the LAA.
- **Atritech's Watchman**, which is in clinical testing. A speaker described it as looking like a "jellyfish or parachute." He said there is "much enthusiasm about this in the cardiology world," suggesting that 79% of patients would be eligible for this device.
- **Medtronic** also has a device in development, which was described as "essentially a rubber band, similar to what is used to make a steer out of a bull…and it also works on a pig. This will work well on long appendages."

Pros and Cons of Amputating the LAA During Surgical AF Ablation

Pro	Con
The appendage is the source of embolic stroke	It has been associated in a few catastrophic cases with morbidity and mortality
Removing the LAA has been associated with extremely low post-operative stroke	Left atrial transport function and ANP secretion are impaired by removal/occlusion of the LAA
It can be amputated safely	Surgical ablation procedures are so successful that LAA amputation is unnecessary
New devices may make LAA occlusion safer and easier	LAA can be a reservoir against atrial pressure/volume increase
Patients and cardiologists want it occluded to prevent stroke	
If AF recurs after ablation, the stroke risk may still be reduced by LAA amputation	

PERCUTANEOUS VALVES

Dr. Michael Mack of Dallas TX warned, "This is a very crowded space at the present time. This is the late 1970s and coronary angioplasty all over again. This (percutaneous valves) is here, it is here to stay, and it won't take 25 years to get where coronary angioplasty is. It will happen much sooner." Dr. Denton Cooley, founder/president/surgeon-in-chief of the Texas Heart Institute, commented, "I'm reluctant about percutaneous valves. They are more effective in patients without advanced calcification." A Florida surgeon said, "Percutaneous valves are a ***long*** way away."

While cardiac surgeons generally are skeptical about percutaneous valves, many have decided to learn the procedures anyway to protect their turf. A speaker said, "In the near future, there is no question interventional cardiologists will succeed in reducing a significant degree of mitral regurgitation (MR) – but only temporarily. It will benefit the very high risk patients and some of the functional valve disease…It will be unethical to use the argument of being less invasive to extend the indication to the great majority of valvular disease which can benefit from more reliable surgical techniques. And it will be unethical to say 30% of MR which are suitable for valvular construction are ***not*** sent to the surgeon. If surgeons are using the same palliative techniques as cardiologists just because they are easier to perform, they will lose the competition. Reconstructive valve surgery is not difficult; it only requires the effort to learn it." Another speaker said, "Personally, I think there is a place for this (percutaneous) technique in our practice…but you can't say there is nothing to lose. None of the surgeons will believe you if you say that." A third speaker said, "We are talking about a minority of patients (for percutaneous valves)…But there is a minority of patients who can be real candidates, which is why we should work together – surgeons and cardiologists – to identify patients for whom this can be a good solution." The session moderator added, "That is my impression. I feel positive on aortic valve stenosis. I don't feel so comfortable on the mitral valve field. I don't think we would accept 2+ MR in mitral valve patients…but we need to keep our eyes open and really look at it, and maybe we can find a way to accept it."

What 30-day MACE rate do surgeons consider acceptable in percutaneous valve studies? Sources insisted it depends on the patients studied, but the general consensus was that it has to be <10% (plus a stroke rate <5%) for the technology to gain acceptance. Comments included:

- *Europe:* "MACE will come down. This is emerging technology. MACE is <2% with open procedures at 30 days."
- *Military:* "MACE is only 4%-5% with open procedures, so no more than that is acceptable."
- *Midwest:* "Mortality has to be <10%, and the delta in MACE between percutaneous procedures and open surgery depends on the patients."
- *Texas:* "It is difficult to assess MACE because, unlike most devices which are in low risk patients, these are high risk patients. It is difficult to distinguish the noise…If mortality is >10% or stroke >5%, it will be a problem… We've learned that there are patients too sick even for this (percutaneous valves). They may get through the procedure but then die, and we are starting to figure out who these patients are…We screened 40 patients for a transapical (valve), and two were too good and went to open surgery, five were too sick and excluded, and 30 are in queue for a percutaneous valve…They are too high risk for conventional surgery. So, there is a large pool of potential patients (for percutaneous valves)."
- *Germany:* "It is too early to say what is acceptable. In real life in these high risk patients, mortality should be no more than 10% and stroke no more than 6%."
- *Arizona:* "Pulmonary valves will be the first percutaneous valves to find successful widespread use because of lower mortality (≤1%)…For aortic valves, MACE has to be comparable to an open procedure, which is 1%-2%."

What is the regulatory hurdle for percutaneous valves? In Europe, the first percutaneous valves could get a C.E. Mark by the end of 2007 or early in 2008. The road in the U.S. will be longer and may be tougher. An expert said, "Regulatory hurdles remain (in the U.S.), and there has been no change in that. The FDA is cautious because of Vioxx (Merck, rofecoxib) and drug-eluting stents, so they won't make the regulatory path easier…Approval is unlikely in the U.S. before 2010 in the best case scenario."

In February 2007, the FDA issued a warning letter to Edwards Lifesciences, resulting from an inspection in August 2006 of Edwards' Irvine CA manufacturing plant. The warning relates specifically to elements of the company's quality systems, including complaint handling, documentation, and quality systems training. Edwards said it has been "engaged in a broad, thorough, and systemic review" of all of its quality systems and has kept the FDA advised of these efforts, and it has hired an outside consultant to assist with quality improvements. However, the FDA will not issue any premarket approvals for devices reasonably related to those issues until they are resolved to the FDA's satisfaction – which, if Boston Scientific and Lilly are any example, could take a very long time.

Who will do percutaneous valves? Interventional cardiologists are leading the development of this technology right now, but cardiac surgeons definitely want to get involved, and many hope a multi-specialty approach will help that effort. Surgeon comments included:

- "Just like under-employed surgeons, there will be under-employed interventional cardiologists, and that will drive them to other interventions, like peripheral interventions. The problem for them is that, in the initial stages, not all interventional cardiologist can do the procedure."

- *Texas:* "Who does percutaneous valves will depend on local politics and geography. It could be surgeons, interventional cardiologists, or a team. Ultimately, there may be a new specialty: surgeon interventionalist."
- *Arizona:* "We already have a multidisciplinary team approach…We would like to be early adopters, especially of pulmonary valves, which is an exploding need."
- *Dr. Patrick McCarthy of Northwestern University:* "Percutaneous valves are definitely the new frontier, but they are very hard to do, especially mitral valves…How much will interventional cardiologists want to do something that dangerous? Do they really want to do an 85-year-old COPD patient who could die on the table? I told our residents not to lose sleep worrying that they will go out of business. Percutaneous aortic valves will be available sooner than mitral valves, but they will take longer than the companies think in the U.S."
- *West Virginia:* "Percutaneous valves are not rocket science."
- *Israel:* "We definitely have to go the route of the multidisciplinary team. Percutaneous technology is the future, and I think surgeons should administer it. Our interventional cardiologists are receptive to that idea after the stent thrombosis with drug-eluting stents, which is tempering them."

Aortic valves

At least 11 different aortic valves are in development, and experts predicted that one or two – Edwards Lifesciences' Cribier-Edwards Bioprosthesis and CoreValve's ReValving System – are likely to get a C.E. Mark and be available in Europe by the end of this year or early next year. However, Edwards, at least, plans a very controlled roll out. An expert said the company is now signing up sites, which will probably be limited initially to about 20.

Most cardiac surgeons now appear to have accepted the idea that percutaneous valves are coming. Dr. Friedrich Mohr of Germany said he has become a believer in aortic percutaneous valves, "It's the story of a non-believer becoming a believer. Five years ago I would have said this story was impossible and was not going to work…We are confronted with more and more elderly patients with (a high) perioperative risk profile. An ESC survey found a huge cohort of patients not treated surgically because the risk was deemed too high."

A speaker emphasized that there are three critical components to a percutaneous valve: the valve, the platform in which the valve sits, and the delivery system (where smaller is better). The devices need high radial strength, radio-opacity, durability, and good hemodynamics, and they must not obstruct coronary flow. Other desired features include: a covering over the valve during delivery, flexibility and tip trackability, ease of use, recoverability for repositioning, consistent deployment, flush circumferential appositions to minimize paravalvular leak, hemodynamic support or induced asystole during implantation, and embolic protection.

Embolic protection has proven to be important in carotid stenting, and Dr. Mack believes it also will be critical with percutaneous valves. He said, "Stroke has been a problem, not a serious problem, but there will be cerebral embolization, and I think embolic protection will ultimately be a part of these systems…At the present time, clinical strokes have occurred (with percutaneous valves), though that hasn't been a major problem, much less than I would have thought it would have been, but as the experience expands, and as we do all the appropriate testing from CT to MRIs post-op as well as intraoperative transcranial Doppler, we will find subclinical embolization does occur…I think it is just like carotid stenting. At the end of the day, it will be optimal to have it (embolic protection). It may not be necessary for all devices, perhaps some more than others. One of the advantages to transapical is that embolic protection is more doable than from a retrograde approach."

Asked if he has used transcranial Doppler yet with percutaneous valves, Dr. Mack said, "Not at present. This is all still an early stage procedure, and there is so much interaction just to get this right. There is an average of 18-20 people in an operating room. Ultimately, that (transcranial Doppler) will be an issue, but it (embolization) hasn't been a priority at this stage because clinically it hasn't been an issue, but ***subclinically*** I suspect it will be."

There weren't any significant new data on any percutaneous valves at STS, but speakers did review several of the ones in preclinical or clinical testing. The two percutaneous aortic valves furthest along in development are:

➢ **Cribier-Edwards Aortic Percutaneous Heart Valve (PHV).** This proprietary balloon-expandable stent is crimped on a balloon on a stainless steel stent, percutaneously threaded it into place, and the balloon expanded in the aortic valve. The device is held in place by an absorbable suture that, as it dissolves, slowly cinches down. The current version, a tri-leaflet valve made of bovine pericardium, was described as very similar to Edwards' Perimount valve. It is available in two sizes: 23 mm and 26 mm.

A key issue with this valve has been the technical difficulty of the procedure. Placement and balloon inflation had to be extremely precise, and access was antegrade. However, a retrograde approach was developed, and that has made the procedure somewhat easier, and oversizing the valve also has improved results.

Since December 2006, at least six of these valves have been implanted in the U.S. at two sites – New York and Cleveland.

A speaker reported on the experience in Germany between February and December 2006 in 44 patients. The average age was 82, all were high risk patients (Euroscore 27.2), and all received valves oversized by 2-3 mm.

- No strokes or TIAs.

- Mortality was reported to be 6.8% at 30 days and 12.2% at 131 days.
- Conversions: 2 patients intraoperatively (1 for valve dislocation and another for functional occlusion of the RCA), 1 patient re-operated during follow-up for dislocation of the valve, and 2 patients with re-thoracotomy for diffuse bleeding.
- 72% survival, which was described as "very, very comparable" to historical experience with open heart patients.
- 29 done off-pump even though the protocol called for cardiopulmonary bypass.

➢ **CoreValve's ReValving System.** This self-expanding stented valve has a multi-level support frame with a tri-leaflet porcine pericardial tissue valve. As with the Edwards valve, this valve has to be predilated. A German surgeon who has used the device – but who has no financial ties to the company – described it as easy to use, noting that because of the transfemoral approach, sizing is important.

The German surgeon reported on 63 patients (52 high risk and 11 inoperable) treated from August 2005 to August 2006, mostly in Germany (using the larger 21F delivery system).

- Average age was 80.9, 70% were female, and the average Euroscore was 25.4.
- Of the 63 patients, 6 could not get the device for technical reasons.
- Procedure time initially was 4 hours but was about 2 hours in the last patients.
- Paravalvular leak immediate post-procedure: 51% Grade 1, 1% Grade 2, and 2% Grade 3/4.
- Death 12.7%: 1 inability to cross the valve, 1 valve misplacement, 1 aortic dissection, 1 pneumonia/septicemia, 3 strokes, 1 cardiac arrest. In-hospital death was 13%. No device-related deaths.

CoreValve vs. Cribier-Edwards Valve

Characteristic	CoreValve ReValving System	Cribier-Edwards PHV
Material	Nitinol	Stainless steel
Tissue	Porcine	Bovine
Size	29 mm x 45-50 mm	23 mm or 26 mm x 16.1 mm
Delivery system	18F	22F or 24F
Can be relocated	Yes (before complete expansion and removal of delivery catheter)	No
Approach	Transfemoral	Retrograde

CoreValve Results

Measurement	High risk patients n=50	Inoperable patients n=13	Overall n=13
Euroscore	23.4	31.6	25.4
In hospital mortality	8.0%	30.8%	12.7%
Conversion to surgery	8.0%	0	6.4%
Discharged with CoreValve	86%	54%	80%

- Complications included 2 aortic dissections and 1 MI.
- Mean follow-up at 7 months: 4 deaths (brain hemorrhage, heart failure, acute respiratory failure), but no MI, stroke, or MACE. No device-related deaths.
- NYHA Class improved "somewhat."
- Little change in ejection fraction.

Another study is ongoing in a group of 38 high risk patients (average Euroscore 24.8) getting the valve using the smaller 18F delivery system, most patients were done with no cardiac assistance at all. There have been 3 technical failures – 1 due to misplacement of the valve and 2 which required surgery. No procedure-related deaths have occurred. A speaker said, "We think decreasing catheter size is important for the femoral approach."

There are at least 13 percutaneous aortic valves in development. Those mentioned by speakers included:

➢ **AorTx.** This company has a folded, sutureless, self-expanding nitinol frame with a pericardial tri-leaflet tissue valve. It is sheath-based and flexible, with a low profile (19F) delivery system. The device can be retrieved and repositioned before releasing it from the catheter. It is designed for retrograde and transapical approaches. Acute and chronic animal studies are complete, and the first 8 human patients were implanted OUS in February 2006, with no migration, excellent positioning, and good hemodynamic performance. The company reportedly feels it has proof of concept.

➢ **Paniagua.** This is a retrograde implant using a specially-treated pericardium, which allows thin leaflets and simpler retrograde insertions, which are technically less challenging. A catheter transports the replacement valve to the heart, where it expands once it is in place. The valve is 3-4 mm in size, while in the catheter can expand to 25 mm. The first human implant was in 2002, in Venezuela.

➢ **Bonhoeffer** (pulmonary valve).

➢ **Direct Flow Medical.** This company's valve has a fabric cuff cylindrical platform jointed by proximal and distal rings. It uses stentless equine pericardial tissue. The delivery system is 22F and sheath-based. First-in-man studies were done in 6 patients in Paraguay – 2 open surgical implants and 4 percutaneous implants. All patients had subsequent surgical aortic valve replacement (AVR). In those 6 patients, the average valve area was 1.7 cm^2, gradient peak was 11-27 mmHg, and there was paravalvular leak in one patient.

➢ **PercValve.** This eNitinol valve is being developed in San Antonio TX by Dr. Steve Bailey and Dr. Julio Palmaz (of Palmaz-Schatz stent fame) using nanotechnology. It has a

monolithic structure (not a composite of multiple pieces). A speaker said, "Nanotechnology allows any property to metal you want in terms of shape, conformability, and structure. It allows decreased device size, increased radial force, diminished risk of fracture, and a monolithic manufacturing process." He said one of the advantages of this valve is that it endothelializes within 10 days.

- **Heart Leaflet Technologies.**
- **M-95-C.**
- **Sadra Medical's Lotus Valve.** Boston Scientific reportedly has a stake in this. This is a 23 mm tri-leaflet valve on a self-expanding nitinol frame. It is currently using a 21F delivery system, but that is about to become a 19F catheter. Once delivered, it passively opens. Acute porcine and ovine (sheep) studies have been completed, and the valve has been implanted in 7 cadavers. The first-in-man study is expected to begin in 2Q07.
- **Sorin's Perceval.**
- **ValveXchange.**
- **Ventor Technologies.**

Four transapical approach valves also are in development:

- **ATS's Entrata.** This device was obtained with the purchase in 2005 of 3F. It is inserted into the apex of the heart, not through the femoral artery. Thus, unlike femoral access devices (where the size must be ≤25 mm), there is no limit to the size of the Entrata valve. The company believes these valves will not leak the way other percutaneous valves have.
- **CoreValve's Evalving**. This is a porcine valve.
- **Direct Access Technologies.**
- **Edwards' Sapien THV.** This porcine valve currently is unsheathed but reportedly is about to become sheathed.

Mitral valves

Percutaneous mitral valves are further behind aortic valves in development, but a speaker noted, "The whole percutaneous mitral valve field is exploding." However, another expert predicted that percutaneous mitral valves will ***not*** change surgical repairs, "I think the ideal candidate is not the severe MR patient, but patients with…moderate MR…Percutaneous edge-to-edge (E2E) is a good idea because it is the real breakthrough in mitral valve treatment of MR, and it allows us to treat the untreated patients."

The mitral valve is a one-way valve between the left atrium and the left ventricle. As the left ventricle contracts, the mitral valve closes to prevent blood from flowing backwards into the left atrium. Damage can cause the valve to leak, resulting in mitral regurgitation, or to not open fully, resulting in mitral stenosis. Degenerative aortic stenosis, the narrowing of the aortic valve, is the most frequent valvular dysfunction in adults.

There are two main approaches to percutaneous valve repair: (1) Edge-to-edge or direct valve access through a catheter – transventricular or transatrial, and (2) Coronary sinus access via a catheter, after which devices are used to cinch or reshape the misshapen valve.

Among the companies with percutaneous mitral valves and devices in development are:

- **Evalve's MitraClip.** This percutaneous MV E2E repair method uses a tiny metallic clip coated with polyester fabric that can be attached to a telescoping catheter. It imitates the edge-to-edge open surgical technique. Under full anesthesia, a catheter is placed through the skin and guided through the femoral vein to the heart. A smaller delivery catheter guides the clip into place; the clip is opened to grasp the leaflets, and the clip can then be closed and released to create a repair.

The Phase I trial included 55 patients at 6 sites, and the company has now moved to a Phase II trial in 92 non-randomized patients, the EVEREST Registry. Of the echos submitted to the core lab, 18% were deemed anatomically suitable for a MitraClip, and a speaker concluded, "Only about 5% are actually eligible (for the trial) and approached to be randomized."

Clip detachment has been a problem but a speaker said there was a redesign and there haven't been any cases since February 2006. In the failed MitraClip procedures, there was no mortality, no significant morbidity, and no detrimental effect on subsequent surgical management up to 18 months.

The EVEREST-I trial has completed 1-year follow-up, and those results will be presented at the American College of Cardiology in New Orleans in March 2007. About a third of the 184-patients required in EVEREST II, a prospective, multicenter trial comparing MitraClip to surgery, have been enrolled. About 40% of these have been treated with two clips,

MitraClip Results

Measurement	EVEREST Registry	STS repair database	STS replacement database
Median age	67	59	64
Male	62%	58%	41%
Diabetic	18%	9%	15%
Hypertension	0	47%	53%
COPD	12%	13%	21%
History of CHF	49%	40%	54%
AFib	32%	N/A	N/A
Median ejection fraction (EF)	60	55	55
Death unrelated to clip	1.1%	1.5%	6.0%
Mechanical ventilation >49 hours	0	5%	13%
Discharge home without home healthcare	98%	---	---
Freedom from death	99%	---	---
Freedom from surgery	97%	---	---
Freedom from death, surgery or MR ≥2+	71%	---	---

and some of these have been put in sequentially. The primary endpoint is non-inferiority. A high risk registry is being planned because a large number of patients were felt to be poor surgical candidates so not eligible to be randomized. A speaker told surgeons, "I urge you to support enrollment because this will prove one way or another the relative role of Evalve in this patient population, and if you believe this is going to fail, enrolling in the trial and getting it proven is going to be very important."

A speaker commented that the main advantage of E2E techniques is "to bring interesting new opportunities in interventional cardiology," and he warned that E2E repair shouldn't be used except as a life-saving procedure because:

- It increases the load on the non-prolapsed leaflet and chordae.
- The limitation of leaflet motion leads to progressive leaflet fibrosis, retraction, and calcification.
- The long-term fate of E2E repairs is valve replacement.
- It is an irreversible procedure. He said, "They claim it is reversible because if it doesn't work, you can send the patient to the surgeon, but I disagree. This is an irreversible situation after several years."

At least three other companies have mitral valve devices in human clinical trials but fewer than 75 patients in total have been treated worldwide. They are:

- **CARDIAC DIMENSIONS' Carillon.** With this percutaneous approach to annuloplasty, a device is inserted into the coronary sinus to reduce the size of the dilated mitral annulus. Feasibility studies showed that it can eliminate severe mitral regurgitation reproducibly without adversely affecting cardiac physiology. It is a reversible wire anchor, with tension applied at the time of implantation. A speaker said the real challenge is whether or not the anchor is strong enough to hold the device and still work in a delicate area, "The problem is with distal AIV/GCT anchor slippage. That is the real problem. The company redesigned the anchor, and in 10 of 20 new cases, it had to be removed. In 7 of the 10 where it was left, there was significant improvement in 6-minute walk and no MACE. The challenge will be the anchor device, but it may be surmountable."

- **VIACOR'S Percutaneous Transvenous Mitral Annuloplasty (PTMA).** With this device, an over-the-wire PTFE catheter is threaded through the coronary sinus Os, down the AIV, and three thin but stiff metal rods are advanced down the catheter. The rod then pushes the posterior portion of the mitral valve anteriorly and straightens the coronary sinus. The procedure is done under echocardiography. The catheter and the three nitinol rods are left in the patient, and they can be accessed in the future if adjustments are necessary.

The clinical program began in 2003 with pre-annuloplasty surgery cases at the Cleveland Clinic and Montreal Heart. A speaker said, "We found the device difficult to place, and redesigned it. Now, we are enrolling 30 patients in a pilot trial of permanent implants at Montreal Heart, the University of Essen, and the University of Liege…In the first-in-man in Essen…the device worked initially pretty well (in the first patient)…but 1.5 days after, the patient complained of a return of shortness of breath, and MR was back in force. We found the device had broken. It was easy to take out, but frustrating, and we went back to the design board. Now, we have rods that don't break. After a year of more animal studies, we did the first human, and the device is still in at three months with robust efficacy…These are exciting but very, very preliminary results…Since then, there have been a bunch of implants that didn't go well: 2 were not long enough, 2 were unable to be navigated through the venous anatomy, and 2 had excellent reduction of MR but migration."

He said the product is being further redesigned, "This just shows that devices that work well in animals don't necessarily work well in humans…but some patients are well suited for MR correction by this therapy."

- **EDWARDS LIFESCIENCES' Monarch.** This stent-based system anchors at the coronary sinus Os and in the AIV (anterior interventricular vein). There is a time-delay contracting bridge (a nitinol ring) that activates at 10-15 days. A speaker said, "The advantage to this system is that it has two weeks to grow in before there is any tension on it, but the disadvantage is that the cinching is done at a time and place where you can't control it…In the first 5 attempts, there were 4 successes…There was a significant reduction in MR at 4 weeks, but at 3 months, 3 of the 4 had broken and MR returned to baseline. The company went back to the drawing board and redesigned it. With the new design, they have not had any fractures in animals."

The new device is now in a 60-patient pilot study, and 40 of these patients have been implanted already. In data presented at TCT 2006 on the first 17 patients, 7 had little or no efficacy, but 10 patients had MR reduced from an average of 3.3+ to 1.9+. A speaker said, "The challenge is to flush out who responds…The early results show promise. Coronary compromise does not seem to be problematic. Evolution of the technology may allow implantation in challenging patients."

Dr. Alain Carpentier of France countered that, with open surgery, most mitral valve patients (93%) will be cured for life (25 years). Another speaker predicted that gene therapy and cell therapy will treat mitral valve disorders in the future.

SURGICALLY IMPLANTED VALVES

Surgeons said use of surgically implanted valves (bioprosthetic and mechanical) is now spread among so many companies that it is harder for those companies to show year-over-year growth. In addition, cardiac surgeons are doing more repairs, and some hospital administrators (e.g., HCA) are encouraging surgeons to do repairs rather than replacements because repairs are cheaper. St. Jude's Biocor appears to be

taking market share from Edwards' Perimount, with some significant discounting by St. Jude reported.

Physician comments included:

- *Florida #1:* "We use Biocor because we can get them for $2,000 vs. $5,000 for Edwards valves, and all the valves are comparable."
- *Montana:* "We have a contract with St. Jude and Medtronic for valves, but St. Jude's Biocor is not available to us yet."
- *Bahamas:* "We use (another) valve because it is comparable to St. Jude valves but 20% of the cost."
- "We just did a contract with Edwards, and we didn't get any of their valves for $2,000. It was more like $4,000."
- *New Jersey:* "I use Biocor because of the low profile, but I do more repairs than replacements…Valve cases are up slightly over a year ago, but it's more repairs."
- *Mississippi:* "I've only put in three Biocors. I used them because it (Biocor) was new, and I wanted to try it… There is a whole lot of dealing going on with valves. Surgeons are slow to adopt a new valve."
- "The Biocor's advantage is its low profile. The St. Jude sales reps are trying to push it, but the surgeons are slow to change. But it is a valve you should have on the shelf."
- *Minnesota:* "I like the Biocor. We changed from Edwards to the Biocor because of its profile. More and more people like Biocor because of the lower profile."
- *Kentucky:* "I don't like the Biocor. There isn't enough of a track record with it yet. It's probably no different from Edwards' Perimount or Medtronic's Mosaic."

Robotic Procedures

Intuitive Surgical's DaVinci

Intuitive officials claimed there is growing interest among cardiac surgeons in their DaVinci robot for a variety of procedures including: port placement, IMA harvest and graft mobilization, thoracotomy, target vessel stabilization and anastamosis, pericardiotomy, and target vessel identification, and mitral valve repair. Two hospitals – Cedars-Sinai and Long Beach Memorial – reportedly have a DaVinci dedicated to cardiac surgery, and an Intuitive official said the urologists/ gynecologists there are now asking for their own DaVinci.

However, cardiac surgeons expressed little interest in a stand-alone DaVinci robot for cardiac surgery. Only one surgeon said his hospital has plans to get a DaVinci just for cardiac surgery. A surgeon from that hospital said, "We are getting a dedicated DaVinci for cardiac surgery, but it takes a huge upkeep – in the six figures a year."

No other sources plan to get a DaVinci primarily for cardiac surgery. Many surgeons said their hospital already has a DaVinci, but primarily for urology, though it often also is used by gynecology and, occasionally and on a very limited basis, by cardiac surgeons. With cardiac surgeons focused on learning percutaneous procedures, they said the DaVinci is too time intensive right now for them.

Comments included:

- "If I had a million dollars to spend, it would go for an integrated OR (an operating room that can do both surgery, percutaneous procedures, and AFib treatments) with cath capability. That's more important than a DaVinci."
- *Alabama:* "Our urologists are using the DaVinci now, but we are getting trained, and we'll share it. The urologists made it famous, and we jumped in on their coattails…It will be more than two years before we would need a second DaVinci. It would have to be in constant use first."
- *Hospital administrator:* "We offered our cardiac surgeons a DaVinci, and they turned it down."
- *West Virginia:* "Our urologists use it, but there is no interest by our cardiac surgeons. At this point in time it is mostly a marketing device (for cardiac surgery). Maybe there will be a role in the future, but the current applications are experimental."
- *California:* "Our hospital has a DaVinci, and cardiac surgery has used it, minimally…Some of us see it as a more difficult way to do things."
- *New Jersey:* "We already have two DaVinci robots that are both shared with urology, and they are both pretty fully used. Use is increasing slowly. I could see us getting a third in two years, but not just for cardiac surgery."
- *Arizona:* "We have a DaVinci, and some cardiac surgeons are trying to use it, but it is mostly used by urologists. There is quite a learning curve. I won't use it."
- *Mississippi:* "One of the three hospitals where I operate has a DaVinci. It is used mostly by gynecology and urology, but there is some cardiac use, and that is going up, but the questions are: At what rate? Is it economically feasible? Is it superior? I don't think it will be ready for prime time for five or 10 years because of cost. Currently, it is a marketing tool."

Accuray's CyberKnife

While leaders in the field were suggesting this is a way cardiac surgeons and hospitals can set themselves apart, especially for lung surgery, surgeons questioned about it were not very enthusiastic, mostly because of the cost, but also because it is another technology they would have to learn – and right now, percutaneous skills are the priority. A surgeon said, "It's very neat for lung cancer, but it costs $5 million."

Intra-Aortic Balloon Pumps (IABPs)

Arrow International and Datascope were both touting the new features of their IABP devices. Datascope is the big gorilla in this space, with ~80% market share, and Arrow is trying to expand its presence. The cost of the two systems is roughly comparable.

Arrow's AutoCat 2 Wave. Arrow claims the advantage to its AutoCat 2 Wave is that it has aortic flow timing to help avoid early inflation and optimize IABP support. The company claims aortic flow timing "converts arterial pressure to aortic flow on a beat-to-beat basis to reliably anticipate and adjust to AV closures with 98% accuracy – before they occur." An Arrow sales rep said this provides beat-by-beat real-time timing, "In arrhythmic patients you can't predict the next beat. The advantage of our machine is that you won't inflate the balloon early or late." Another sales rep said aortic flow timing, which was introduced in 2004 is the newest bell and whistle. He explained it is "ultra precise aortic pressure processed and converted to aortic flow. This is important because landmarks are normally based on pressure at the dicrotic notch, which is always one beat behind. With aortic flow time, you have real time. This means a patient is supported each and every beat, regardless of the systole ejection period, even during arrhythmias." The Arrow sales rep also said AutoCat 2 Wave has software improvements over last year.

Datascope's C5300. Datascope sales reps countered that their device, the C5300, is more "patient-adaptable," that the software doesn't have a fixed point for the dicrotic notch. One explained, "You can't predict what the dicrotic notch is with sick patients, and the Arrow device has a fixed assumption of 55 ms. Also our pneumatics are faster on deflation because there is a bellows."

The competitive environment

Both Arrow and Datascope sales reps insisted that having patients in arrhythmia can justify changing a current system for their new system. An Arrow source said, "If patients are in arrhythmia, you can justify changing systems to this."

However, surgeons didn't agree. Surgeons questioned about IABP all said they did not see anything new from either Arrow or Datascope that would justify upgrading or getting a new machine before the end of the lifecycle of their current device.

- *Bahamas:* "Arrow's pacing through an arrhythmia sounds interesting, but it is not a big deal."
- *Arizona:* "The two systems are pretty comparable. We use what the hospital gives us. Pacing is not a big deal unless the patient has very severe arrhythmia that can't be controlled with medications or pacers, and that doesn't happen often."
- *Illinois:* "We use Datascope. Arrow is not an advance."
- *Mississippi:* "Arrow has a new whistle, but I won't change."
- *Minnesota:* "The Arrow device is nice, but I won't change because of it."
- *Kentucky:* "They both claim real time, but it always takes a beat or two. We recently got a new Datascope because of the new software they have. Datascope has automatic timing now, and the software finds the best trigger, where you used to have to set the trigger."

Left Ventricular Assist Systems (LVAS)

There was no news on these devices at STS, but data from a trial of Thoratec's HeartMate II may be presented as a late-breaker at the American College of Cardiology in March 2007. A surgeon said, "We spend a lot of time explaining that these (LVAS) are not resurrection devices…I expect their use will increase a little, but not dramatically, over the next year."

A World Heart official said the majority of all transplant centers today are using LVADs (left ventricular assist devices). He added that there is a proposal for CMS to allow LVADs at centers without transplant programs, and if CMS agreed to that, it would increase the number of hospitals using LVADs, and destination treatment centers, separate from transplant centers, could be developed.

Imaging

Imaging is changing in cardiology, with dramatic improvements in magnetic resonance (MR) imaging and 64-slice computerized tomography (CT).

➢ **MR.** MR has the advantages of no ionizing radiation, and a speaker predicted that within two years it will be equivalent to multislice CT.

➢ **CT.** A speaker said, "Cardiac catheterization is great. It is the gold standard. But it is expensive and invasive, and reimbursement to the physician is quite limited for the work performed. I think CT can supplant it. CT is very, very simple for patients – a 20 second test with a single breath-hold. How good is it? The strength won't be in the patients you see for bypass, but for the patients found not to need revascularization. The strength of the test lies in its negative predictive value…which approaches 99%."

64-slice CT may play a huge role in cardiac surgery. The speaker said, "In patients with valve disease, you can look at coronaries, skip a cath, and go directly to surgery. We are doing that at UCLA. We have not taken a pediatric patient to the cath lab for two years because of CT. Using CT, we can have enough data for a surgeon to operate without a cath… Cardiac CT will be a replacement for cardiac cath in select patients. In patients with MI, CT will not be that useful. They will need to go to the cath lab."

➢ **3-D Ultrasound (US).** The only real bedside imaging right now is ultrasound. A speaker said, "We all know catheter-based (valve) interventions are coming…and the problem is placement, and I think ultrasound has the ability to provide that. So, whether you are a believer in edge-to-edge (percutaneous repair) or surgical valve replacement, the ability to see in real time at least gives you the opportunity to make the correction while the heart is beating…For closed heart, beating-heart repairs, we need real-time, high resolution intra-cardiac imaging, and I argue that 3-D US is getting there."

WHAT'S HOT AND WHAT'S NOT

What's hot

The technology that cardiac surgeons pointed to as most exciting right now were:

➢ **ABIOMED'S Impella Recover,** a very small, minimally-invasive, micro pump for short-term left ventricular support. It is in clinical trials at Texas Heart, Cleveland Clinic, Cedars-Sinai, William Beaumont, and Scripps. An Alabama surgeon said, "The cardiologists need to be the point person on this first, and then surgeons have to get involved…I might use this in the OR rather than a bigger device (e.g., Abiomed's AB5000) until the patient is over shock or as a bridge-to-treatment." An Arizona surgeon said, "Impella is very cool." A Minnesota surgeon said, "Impella looks cool. They are making a pediatric size, too. It is a nice device. There is a lot you can do with it." A Kentucky surgeon said, "Impella looks cool, but I don't know where I would use it in a non-transplant center."

➢ **LEVATRONICS' CentriMag,** a magnetically-levitated centrifugal pump which is distributed by Thoratec. A Thoratec sales rep explained, "This is a device for temporary support for bridge-to-decision in open chest procedures…It is indicated for up to six hours, and the company is going for a 14-day indication. You can get up to 10 liters of output...It is bearingless, reliable, and uses standard cannulation techniques. It's good for hospitals without a transplant program, and it is a lot cheaper than an Abiomed AB5000." A surgeon said, "It doesn't build up heat. It's FDA approved, and it's really cool. We will evaluate it."

What's cold

There was simply no excitement at all over mechanical suturing devices for anastamosis, such as **CARDICA'S** Pas-Port (proximal) or C-Port (distal). A West Virginia doctor said, "We've tried different devices, but not those. The issue is the cost, which is about $8,000. Who pays for it when sutures are pennies? You would need more bang for that buck." A California doctor said, "They are cumbersome and limited, and the technical aspects are limited. They are not as anatomic as you can sew." A New Jersey surgeon said, "I don't use any suturing devices." An Arizona surgeon said, "I'm not using these now, but I'm interested in them. C-Port looks nice; a stapling device for distal has more promise than one for proximal." A Mississippi surgeon said, "I don't think the devices save time, and they certainly add cost. They would only be justified if they decreased OR time." Another expert said, "I didn't like (St. Jude's) Symmetry. I saw two early fatal complications with it…The Guidant (Boston Scientific) HeartString is a nice concept, but I'm very, very nervous about a mechanical device."

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