THOMSON REUTERS STREETEVENTS

EDITED TRANSCRIPT

ATRC - AtriCure Inc Analyst Meeting

EVENT DATE/TIME: JUNE 26, 2018 / 12:30PM GMT

CORPORATE PARTICIPANTS

Michael H. Carrel *AtriCure, Inc. - CEO, President & Director*

CONFERENCE CALL PARTICIPANTS

Cecilia E. Furlong *Canaccord Genuity Limited, Research Division - Associate*

Danielle Joy Antalffy *Leerink Partners LLC, Research Division - MD, Medical Supplies and Devices*

Frederick Allen Wise *Stifel, Nicolaus & Company, Incorporated, Research Division - MD & Senior Equity Research Analyst*

Matthew Oliver O'Brien *Piper Jaffray Companies, Research Division - MD and Senior Research Analyst*

Michael Stephen Matson *Needham & Company, LLC, Research Division - Senior Analyst*

Suraj Kalia *Northland Capital Markets, Research Division - MD & Senior Research Analyst*

A. Marc Gillinov

David DeLurgio

Marc W. Gerdisch, M.D.

PRESENTATION

Michael H. Carrel *- AtriCure, Inc. - CEO, President & Director*

All right. I think we're ready to start. Hello, everyone, and welcome to AtriCure's 2018 Analyst Day. It's been about 3.5 years or so since the last time we actually got up here to NASDAQ to talk to you about AtriCure and what I believe has really been a successful story over the last several years.

I'm going to give a brief overview today just about AtriCure, the opportunity sitting in front of us and then from there, you're going to have 3 distinguished physicians who're going to talk to you about the opportunity from various different perspectives. They're going to talk about guidelines, about the EP-cardiac surgeon partnership and also about the clip and some other opportunities for growth for the company in the long term. Forward-looking statements.

So what is AtriCure about? So we are all about treating Afib. And there's a word in here that is incredibly important to understand, which is epidemic. You're going to hear a lot today about the Afib epidemic. What do we mean by Afib, it being an epidemic? Afib is bad. What you're going to learn is Afib kills you. You don't have immediate cardiac arrest because of Afib, but over the long term, you live longer if you treat the Afib. So therefore, treating Afib actually makes a big difference. And we at AtriCure are focused on reducing this epidemic worldwide. It also increases about 5 or 6x the likelihood of you having a stroke. So you're going to hear a lot about why Afib is a bad disease.

The second thing you're going to learn today is that you're going to learn that Afib is complex. It's not just a simple way, just fix it and it's gone right away. It's actually a complex disease that people have been studying for a very long period of time. I'd like to compare it a lot to cancer in the sense that there are multiple different tools to attack cancer. We are not the only tool attacking Afib out in the marketplace. We don't claim to be the only tool. In fact, what we'd like to do is to say, we're one of the tools that are going to help solve some of the problem in more complex patients. And you're going to hear all about the fact that 75% of these patients are complex patients that cannot get treated with your normal either medicine or the catheter ablation. So you're going to learn a little bit more about it. It's bad, it's complex, and you need a lot of ways to approach it.

The third thing that you're -- we're going to talk about here is, I want to give you kind of a context to what and how we think about a patient approaching the health care system. So the way a patient approaches the health care system, we view it in 2 formats and you're going to hear about it from physicians today. Either they're approaching it in a concomitant setting. They have some other cardiac disease and they also have Afib. And just to give you some numbers, there are 300,000 patients around -- in the United States that go in for open cardiac procedures every year. One -- about 30% or 90,000 of those patients, 90,000 of them have Afib and 20,000 or so get ablations. So 70,000 of those patients do not get ablated.

Now we are much better as you learn today than we were 5 years ago. Five years ago, that number was closer to 10,000 or 12,000. So with education and training, we've been able to move the needle from 10,000 to 20,000. Our next venture is to attack that market and to get that 70,000 patients treated. So you've got an open concomitant setting that is incredibly important. These patients are under-treated and is under-penetrated today, and you're going to learn about guidelines and other things that we're doing and that are happening out in the market, how physicians view it.

The second patient, all they have is Afib. So sole therapy Afib. All they're going in is, they've got Afib. That particular patient enters the health care system different. They're getting treated usually by a cardiologist or an internist that then going to an EP. And the EP is either going to diagnose them and give them drugs initially, possibly do a catheter and kind of look at them on that pathway. And that's why I talk about managing this is like managing a cancer patient. The EP is like the oncologist. They're really kind of directing the traffic. And they leverage tools like ours and the surgeons that you'll meet some of them today, they're leveraging them along with using their own catheters to kind of help that, and we'll talk about that hybrid solution that we're doing clinical trials on.

And now think about some numbers there. You talk about an epidemic. 6 million patients in the United States alone, 33 million patients around the globe have Afib. Of those 6 million patients, over 2/3 of them have the more complicated form persistent or long-standing persistent Afib. So 4 million of those patients. How many of those patients do you think might do a hybrid procedure? In the United States, that number was about 3,000 last year. Is there a market? Is there an epidemic? We need a solution for these patients. We believe we are one tool to solve some of that problem. And we'll talk about our CONVERGE trial and why that data is incredibly important. Can we make that 3,000 30,000 over the next 5 to 8 years upon getting that label and moving the needle on that? That's why we invest in clinical data.

So Afib is an epidemic. It's affecting a lot of people globally. People die of it, and we've got some solutions. Now the way that we do that at AtriCure is that we invest in 3 primary things that you all know about. The way for great medical device company to be great for the long term is the first and foremost is we got to continue to innovate. We can't rest on our laurels. The products we did yesterday are not the products of the next 5 or 10 years. So we need to continue to invest and innovate. You've seen several new products and iterations come out. Just in the AtriClip product alone, we've come out with 2 new products over the last 6 months; the PRO V, which is a minimally invasive version and the FLEX V, and both of those were from feedback that we got and were great innovations by our engineering team.

Second is that without -- it's great to have great innovation, but if you don't gather data, you will hear about that from the physicians today. If you don't gather data, you don't change the labeling, you can't educate and train and change behavior. So we invest heavily both in IDE trials. As you're well aware, we've got 2 of them ongoing right now. We're contemplating several others over the next several years. We also do many sponsored studies, both here and overseas. And we're going to continue to invest in this because this actually builds big barriers for others to enter. But more importantly, it allows us to train and educate surgeons and give them real data that they can count on.

And finally, it's the education piece that you're going to hear a lot more about later on today.

So how well are we done? What's happened within this business? Just to kind of take a step back remind ourselves what's happened over the last 5 years. Our cumulative average growth rate over the last 5 years is 20%. Over the last 5 years, we have had 22 straight quarters of double-digit revenue growth. There are not many medical device companies in the world, and that's an organic number. We've had 22 straight quarters of north of 10% growth, double-digit growth for 22 straight quarters.

You can see the growth of the business, but you can also see the evolution when you look at this chart. What do I mean by that? If you look at it, open ablation that everybody said was kind of going away because cardiac surgery was going away has not gone away. It's actually grown nicely, north of 10% over the last 5 years, most of that because we got the label and we went off and we trained and we educated. And we still think there is a lot of juice to squeeze within that.

You can also see the nice growth that we've seen on the minimally invasive side. We're going to talk about where that is today and about how trials like CONVERGE or DEEP. We're going to focus on CONVERGE today, but trials like that and the partnership with EP are going to drive our growth over the next 5 to 10 years. So we can take that 3,000 patients and make it 30,000 patients that are getting treated.

And then finally, as you saw last quarter, you see that the appendage management has obviously grown from less than 10,000 were sold in all of 2012. Just to give you some numbers, 10,000 clips were sold in 2012. We sold 10,000 clips in the first quarter of this year. We sold 34,000 clips last year. We're on a pace to sell over 45,000 clips in 2018. You can see that business is growing very fast. We've gotten benefit from the idea that managing the appendage is a good thing, and some of the surgeons will talk about that a little bit later on today as well.

So hopefully, this gives you some kind of context to kind of what we're going to talk about today and the focus. Since our last Analyst Day, we've made several big investments and, I think, progress in building out a great company. We've done an acquisition. We've made significant trial progress on CONVERGE. Dr. DeLurgio is going to talk about that. And we bought in contact CONVERGE was 19-or-so patients with 11 sites up to 25 sites today, and we're very, very close to being complete enrollment. The guidelines have been updated. We've seen growth in appendage management, and you've also seen the new product launches.

So with that, what I'd like to do is actually just introduce to you the speakers for today that are more important than listening to me speak. You're going to hear their perspectives on everything that I just talked about at a much deeper level. And we've got a distinguished guest list in front of us today. Dr. Gillinov is the chief of cardiac surgery at the Cleveland Clinic. He'll delve into some details about some of the numbers there that are darn impressive. He's going to talk about the guidelines and about the clip and about the importance of managing the appendage.

Dr. DeLurgio from Emory is the lead PI on the CONVERGE trial. He is going to talk about why it's important for surgeons and EPs to work together and what's the world is going to look like over the next 5 to 10 years, and why it's important to treat these patients, and a little bit of an update on CONVERGE and where we stand.

And then finally, we're going to round out with our #1 educator in the world, Dr. Gerdisch, who's probably done almost every course over the last 3 or so years. He's helped us develop the advanced courses, done the cadaver labs, really helped us evolve that course and trained over 3,000-or-so surgeons and physicians around the globe. So we've got distinguished guests.

So without further ado, what I'd like to do is introduce Dr. Gillinov to come up and start the presentation for us.

A. Marc Gillinov

Thanks. I'm Marc Gillinov. I'm from the Cleveland Clinic. The Cleveland Clinic has the largest cardiac surgery program in North America. We do upwards of 4,000 operations per year. And we have actually been interested in surgical ablation since AtriCure was a company with 3 people. The very first devices that AtriCure developed were brought to the Cleveland Clinic. We tested them on animals. We were not early adopters. We were the first adopters to do this in patients. And this should be actually personally important to everyone in this room because 1 in 4 of you is going to get Afib, that is that prevalent.

And if we just count off by 4s, if you're #4, you're going to get it. Yes, this is going to become something that's, "Oh, you're looking, do you want my card afterward, so that I can take care of that." But it's that common. The longer you live and god willing we all live a long time, the long you live, the more likely you're to get Afib and we have not had in the first half of the century great options for treating it and now we do. So I'm going to talk about Afib and the left atrial appendage.

When my grandmother got Afib, her biggest concern was, I might have a stroke. And she was right. She might have a stroke. She actually had mitral valve surgery at the Cleveland Clinic before AtriCure existed, before the Maze procedure existed, and she got a great operation that fixed her mitral valve. Nothing was done for her Afib. And for the next 20 years, she was on Coumadin and she had all the usual problems with Coumadin. If AtriCure had existed when she had her surgery, she would've had a better quality of life and she would have had a longer life. And now I'll take it from my grandmother to some data.

What my grandmother needed actually was open or concomitant surgical ablation or treatment. She got half an operation. She got mitral valve fixed, wonderful. She was left with her Afib. And she was left on this kind of curve. This curve shows all the bad things that happen to people once they get Afib. Time 0 is you were diagnosed with Afib. And once you have Afib, your risks of all these things, most notably death, go up dramatically over the ensuing several years.

If we look at it a different way, men versus women, the top curve shows survival in women without Afib, and we all know women live longer than men, congratulations. I concede you're going to live longer than I am. But look what happens when you get Afib. Women with Afib actually do worse than men with Afib, but the bottom line is, no matter what your gender if you get Afib, you immediately shift down to a less desirable survival curve. You don't live as long if you get Afib.

Therefore, you heard Mike Carrel allude to the idea that Afib is a little like cancer. Well, this is 5-year survival for different types of cancer, at the top pancreatic cancer 4% 5-year survival. So pancreatic cancer is the worst. Look where Afib is. Afib ranks amongst the worst cancers. Meaning if you get Afib, in many cases, it's worse to have Afib than to have cancer, yet we talk so much about the fight to cure cancer. Afib is right in there. Afib deserves to get a piece of the action in this fight to make people live longer.

This is just data from the Cleveland Clinic. We do a lot of mitral valve surgery. We do over 1,000 mitral valve operations per year, with great results.

Look at what happens, people who have preop Afib, if it's left alone, they're on lower survival curves. So that was my grandmother survival curve. We want to move people up. If they've got preop Afib, we want to treat it so that they move up to the higher survival curve so that they live longer.

This is really a common problem. Right now, at the Cleveland Clinic, there are 14 operating rooms going. There will be 21 open heart cases today, I know because I have to follow this stuff. And of those 21 patients having heart surgery today at the Cleveland Clinic, on average about 1/3, so 7 of them will have Afib. And in our hands and in Dr. Gerdisch's hands and in Emory, the penetration, the treatment is going to be 100%. All 7 of our Cleveland Clinic patients today are going to get an ablation with bipolar radiofrequency, cryo with all that stuff on the back table. Across the country though, it's only about a 1/4 of patients receiving an ablation with their heart surgery. It's almost amazing to me that surgeons today more often than not ignore it. More often than not, do not do the right operation, do not do the best operation for their patients.

So what's the deal here? Why are surgeons looking at a heart in the operating room just as open and deciding, I think I won't do my best. These are their concerns. And in each one of these categories, we have a lot of room for movement and plans to move. They're concerned about safety first. The idea that maybe if I do more surgery, that's more stress for the patient, maybe that's not a good idea. Well, actually, we've got plenty of data to show that is a good idea.

In this particular paper, they looked at patients having aortic valve surgery and bypass surgery, 2 really common operations and said, do we cause harm if we had a Maze procedure? The answer was, no. If we do an ablation, we do not increase risk. If we ask the same question with mitral valve surgery, do we increase the stress to the patient or risk to the patient by adding a Maze procedure, again, the answer is, it did not affect the procedural risk or mortality.

And then if we look at our largest database, which is the STS, Society of Thoracic Surgeons, 86,000, 87,000 patients actually across the U.S., the addition of ablation or a Maze procedure reduced mortality. So people did better in the hospital if they got the complete and correct operation. This has led to statements on our guidelines. There are 2 big heart surgery organizations; STS and AATS. These 2 organizations, it's interesting, they're the same guys in the same rooms in different cities, but when they put on the hat for the STS, they hate the AATS and vice versa. It's bizarre, but I suppose you see that in business all the time. The fact is, though, that they do agree on these guidelines.

STS says addition of a Maze procedure does not increase morbidity or mortality. AATS went a little bit further and said adding the AF surgery, adding the Maze procedure actually improves operative mortality, but basically they agree no added risk to having a Maze procedure.

So surgeons were teaching them, Dr. Gerdisch, there were courses that's letting them know. The data is out there. It demonstrates safety. Surgeons are also concerned, "Are there advantages to doing it? Does it actually work? " Well, we do know this, if we restore sinus rhythm, your chance of surviving is better. You're on the upper curve treated AF. So you live longer. You also live better if we restore sinus rhythm. You get an improved quality of life. You just feel better if you're in normal sinus rhythm than you do if you're in Afib. Ask anyone you know who is in Afib, they will tell you, "Yeah, I used to feel better when I was in sinus rhythm." It's the way you're supposed to be.

Most importantly, if you are free from Afib, if you got treated and it worked, which is more often than not does, you have a greater freedom from stroke. Stroke is the most devastating complication of atrial fibrillation, and AtriCure has got devices to dramatically reduce the risk of stroke. Restoring sinus rhythm is a big piece of that, and as you'll hear, treating the appendage is the second piece. So we've got that waterfront covered.

Of course, most importantly, you live longer if you are not in Afib. And if we look at data from surgical trials, no Afib, blue survival curve, treated Afib, moves you up. It shifts the survival curve. So if you have Afib, you get it treated, you move up to a normal survival curve. You move up to the same survival curve as that occupied by people who don't have Afib. And that's the big win. You live longer. I already said you live better, you live with greater freedom from stroke. But most importantly, you live longer if the Afib is treated. So this also makes it into our guidelines why treat Afib. We've proven it safe and you confer advantages to the patient. You have improved quality of life, you have decreased risk of stroke, and you live longer. Although these guidelines decided, let's not talk about that, let's just say, you live better and you have fewer strokes.

Still many surgeons say, "I'm not so sure that there is a consensus." I've shown you a bunch of guidelines. Here is just how they get summarized. The STS, our biggest organization, says, if you're doing concomitant surgery, you are there anyway with a mitral valve, bypass or CABG, aortic valve, any/all combination of the above, if you do a Maze procedure, you don't affect operative mortality or morbidity, meaning you don't increase risk, which means you should do it.

It's recommended with mitral surgery, recommended with almost everything we do. Why? Because it improves operative mortality, does not increase morbidity, meaning you don't get complications from it, decreases risk of stroke, improves quality of life, meaning there is very little risk to no risk, and there is a huge upside. So the case is pretty clear. And even from Europe, our colleagues in Europe agree and are seeing increased adoption, in the red box, do AF surgery if you're doing heart surgery, anyway you've got someone with Afib, do a complete operation, treat it.

And here's where Dr. Gerdisch comes in, the surgeon might say, "Okay. I get it. It's safe, it's effective, it makes people live longer. I just don't know how to do it," which to me makes me say, wow, you can do a coronary artery bypass surgery, you can sew 2 things about as big as a piece of spaghetti to each other and you're afraid you can't do this. This is an easy operation. In 10 minutes, if you guys play with these tools, we can have you trained up and if anyone's free tomorrow, we've got an OR in Cleveland and we'll take you through one. This is easier than almost any heart surgery we do.

But our guidelines have spoken about this. They've said, "All right, we buy it." This is an easy operation, anyone can do it. But let's make sure everyone does it right. Let's include in the guidelines specific training because while I do contend and I've said it's easy to do, you can screw anything up if you don't pay attention, don't learn how to do it. So AtriCure deserves a lot of credit because no company has done more extensive and more focused training in this area. No one else is doing this. And I think this has helped tens of thousands of patients across the country and around the world to teach surgeons why to do it and how to do it.

So really what it boils down to, in concomitant surgery, the surgeon has to have a really good reason to not do it and I actually can't think of a good reason not to do it, which is why all 7 patients in Cleveland today who have Afib are going to get the procedure because that is the standard of care. It's got to be the right procedure, done the right way in everyone who's got Afib, who shows up in the operating room.

Part of this procedure is treating the left atrial appendage. The left atrial appendage is a little bit like your appendix. Your left atrial appendage is over here, your appendix, over here, they actually look a little bit the same, they're kind of these long structures, maybe about as big as your thumb. The appendix, we only think about when it causes a problem appendicitis. Otherwise, it doesn't do anything. The left atrial appendage is similar. The left atrial appendage, if you said, what is its one function? It causes strokes. It causes strokes in people with atrial fibrillation. So this is a really important target.

This is an article editorial written by Dr. Jim Cox. Dr. Cox really invented the field of surgical ablation. He said, there's got to be a way to treat atrial fibrillation that every day I'm in the operating room, I've got the heart in front of me, got to figure something out. And he did. He figured out the ablation or Maze procedure, which was the first structural approach to Afib.

More recently, he said we need to look at the left atrial appendage and we need to figure out a way to close it because blood clots form in the appendage in people with Afib and those lead to strokes. So is it time to be more aggressive? The answer, of course, is yes.

And this recent publication in JAMA looked at more than 75,000 patients. Some had their appendage closed at the time of heart surgery, some did not. Overall, the people who had their appendage closed did better. What I mean by did better? They had fewer strokes and they lived longer. So treating the appendage is a huge impact on the risk of stroke.

While we've embraced this idea for a long time at the Cleveland Clinic, we've been closing the appendage with standard surgical technique, meaning we sew it shut or cut it off or staple it off. We've done this for a long time and we thought, well, we're really good surgeons. So no need to check our results. That's not very smart. We needed to check our results. And when we finally got around to checking our results with standard surgical technique, meaning we just sew it shut, we found we weren't doing a very good job. We were successful the minority of the time. When we just cut it off, 73% success, but when we excluded it, meaning we sewed up the appendage or excluded it with a stapler, it didn't work.

So what did this tell us? It told us, we need a mechanical means, we need a device, which you can see behind you, to close the appendage because regular surgery doesn't work well for this structure.

Now it's not just Cleveland. This is a paper from Northwestern University, great hospital, surgeon here Patrick McCarthy, he's -- he was in Cleveland when we were doing this and he said, "It's got to be just Cleveland. I mean, there's something wrong with the surgeons there. Yes, we're way better at Northwestern." Not so much. 57% failure when they actually did a focused trial looking at standard surgical techniques to close the appendage. At Northwestern, great surgeons failed 57% of the time. Again, the need is clear: we need a reliable way to do this because the traditional ways to close the appendage lead to bleeding, stays open, we leave a stump where blood clots can still form. So regular surgery just doesn't work.

On the other hand, this does work. This is the AtriClip you've heard over a 100,000 implants, this took a long time to design. It looks pretty simple, but there are nitinol springs at either end that deliver just the right amount of axial pressure to close the appendage without harming it and to keep it closed and the cloth covering prevents it from eroding into any cardiac structures. That's never happened. This is a remarkable record for a medical device. No problems in over 100,000 implants. Knock on wood -- it hasn't happened yet, it's not going to happen.

And this is a slide I show often from Dr. Gerdisch who is going to speak in a little while. This is looking inside the heart. And the black arrow points to where the appendage used to be. You just see a little line, just a little hint of where blood clots used to form and now they can't. So this clip works. It works well. It prevents strokes.

Why are surgeons adopting this so quickly? First of all, because this is really easy, that's nice. It's hemostatic. It never bleeds. That parallel closure profile I just mentioned based on the nitinol springs provides a nice firm closure. The data is looking great. 130,000 implants, no problem. And it mimics the gold standard perfect excision. But I would actually change this slide to, not mimics the gold standard, it is the gold standard, and standard surgical approaches don't equal this. So this is better.

What are we going to do in the future with this? We need more data. I mean, doctors are influenced by both education and data. And then we are looking at with AtriCure various structures for an IDE trial in which we will demonstrate conclusively that in all-comers this will prevent stroke over time because what you do with a patient who comes to the operating room and today, he's 72. He's never had Afib. If I do nothing about his Afib, when he gets it, he's in his 80s now, let's say, it's 10 years down the road, now he's 82, he's got Afib and he comes back to my office because I'm still in practice because I have kids in college so I'm going to be working for a long time. If he comes back to my office and he says why didn't you close my appendage when you had it right there 10 years ago? Now I got to take Coumadin or Eliquis or something. Why didn't you do it when you had the chance? This trial will provide the data to justify that practice and it will free patients like this hypothetical patient from the need for oral anticoagulation.

So the question we're going to answer is, should we treat the appendage in everyone, all 300,000 patients having surgery? Because many of them, at least 1/4 will get Afib, and I think we're going to show that the answer to that question is, yes, we should. Thank you.

David DeLurgio

Good morning. My name is David DeLurgio. I work for Emory where I have been for over 20 years, and I direct the electrophysiology lab at Emory St. Joseph's Hospital. Now unlike my 2 colleagues, I'm a cardiac electrophysiologist. So I trained as a cardiologist and then I'm board certified in

electrophysiology. I'm not primarily a heart surgeon, but I'm sort of a surgeon-lite. We do implants of devices, lots of medical devices, and catheter-based ablation procedures is a big part of our practice. And I currently perform a little over 200 AF ablations a year.

I want to talk to you about the importance of the partnership between electrophysiologist and the surgeons and how it's helped our program. And I'm primarily talking about, in the background, the idea of a hybrid AF ablation procedure for treatment of persistent atrial fibrillation, which is the type of atrial fibrillation that comes and stays as opposed to comes and starts and stops automatically.

So you heard a little bit about the epidemic of atrial fibrillation and it is considered a worldwide epidemic. There was a study recently published which looked at the global burden of atrial fibrillation and there is no country in the world where there's not a lot of atrial fibrillation.

If you look at the prevalence here shown in different colors, North America seems to lead the pack with 700 to 775 cases per 100,000 population looking at just the entire population. But other areas of the world are not far behind. And the differences may be due in part to --what I'll get to on the next slide about the developed world having more and more atrial fibrillation because we're living longer, we're surviving more diseases, but we're also reaping the benefits of a developed world, which means we're eating more, we're drinking more and things like that. Some countries do appear to have a quite low burden, for example, Japan and South Korea, but they're not far behind, and everyone is getting more and more.

Now there are differences between men and women. And importantly, there is a upward march for both men and women and for people over age 35, which is the main group. So if you look at the graph there for prevalence, you see it increasing from 1990 to 2010, which was a cut point for this study both for men and women.

But interestingly, developed countries, it's quite a bit more. Again, men always tend to be more than females. If you look at age 35 and greater though, which is the vast majority of cases of atrial fibrillation, you can see there's quite high, 181 per 100,000 patients, that's the incidence. So think about the population of patients worldwide where not only are you seeing more cases per 100,000 patients in the population, you're also seeing an increase in the rate going over time. So we're getting more new cases, resulting in a marked increase in the total number of patients with atrial fibrillation.

Now you've heard about the morbidity and mortality. Afib is a morbid condition causing all the problems you've heard about, stroke, congestive heart failure, decreased quality of life, and very interestingly, the mortality seems to be increasing with atrial fibrillation, both for men and women as well as the disability-associated life years, a measurement of loss of quality of life and loss of productivity.

So atrial fibrillation has not yet reached the point where we're treating it adequately to decrease its incidence or prevalence, much less decrease its impact on mortality and disability. So there's a lot of room to work.

This was an important study and this has been duplicated elsewhere showing that this epidemic is real and that there is actually now the point where you can measure the doubling time of atrial fibrillation. So we can say at point A, now we have x millions of patients. In 25 years, we're going to have double that number of patients with atrial fibrillation in the U.S. Knowing that kind of projection also is what I would call job security for someone like me. Plenty of patients need my help.

The impact is dramatic on the health care expenditure and loss of productivity. In the United States, currently about 564,000 patients will visit the ED with atrial fibrillation, that's emergency department. So they're going to come in because they feel terrible, they've gone into atrial fibrillation. If you come to the emergency room with atrial fibrillation, there's about a 65% chance you're going to get admitted to the hospital. That makes atrial fibrillation the #1 arrhythmia-related admission in the hospital. Now 470,000 hospitalizations overall every year. When you look at the cost of treating these patients right now, repeated ER visits, repeated admissions, the loss of productivity, et cetera, it's about $26 billion a year and that's going to keep increasing.

So what are the types of atrial fibrillation that are out there? A very important term is to know what paroxysmal atrial fibrillation is. I consider this to be early on the spectrum of atrial fibrillation. It'll start, you may go into atrial fibrillation, then it may stop minutes or hours later. It could recur at any time, go back and forth. It usually occurs in the younger patients. It usually occurs in the patients without structural heart disease. In other

words, the heart's in pretty good shape. It could even be someone who is in incredibly good shape. I often see patients who are regular runners, swimmers, cyclists and things like that who have paroxysmal atrial fibrillation. This will occur earlier in the process. It's about 25% of all AF cases.

Persistent atrial fibrillation and what was called permanent, but now we call long-standing persistent atrial fibrillation actually is about 75% of the patients with atrial fibrillation. This is atrial fibrillation that when it starts does not tend to stop on its own. The patient may have to get shocked out of it or given medications or of course have ablative techniques to use. But it's more persistent and it tends to be a little moving down the spectrum, you're going to see more evidence of structural heart disease, other things going along with it like hypertension, sleep apnea, obesity.

Now when we look at what the population is doing, what I find is that more and more I have to address patients with persistent atrial fibrillation because our population is changing. We're getting patients living longer, older patients in general. We're getting heavier. We're surviving other diseases, thanks to a lots of progress, both medically and surgically. So if you have coronary disease and have a heart attack, you're much more likely to survive to an old age now. We now see patients who had their first bypass surgery 25 years ago, 30 years ago, just not unusual at all. So patients live longer and there's much more chance to develop atrial fibrillation. So 75% of the patients are going to have persistent atrial fibrillation. There is no approved ablation product for the treatment of persistent atrial fibrillation at this time. The FDA has not labeled a product that this is for the use of persistent atrial fibrillation unlike paroxysmal Afib.

So who is being ablated, what type of Afib is ablated? Well, in this survey, this reflects, I think, what goes on in general, 2/3 of the ablations that are done for Afib are done in the paroxysmal atrial fibrillation population, which is only 25% of patients with Afib. Only 1/3 of the ablations are done currently for patients with persistent atrial fibrillation, which is 75% of the patients who have atrial fibrillation.

More experienced centers as high-volume centers may do slightly more persistent and long-standing persistent and we've certainly trended towards that. I actually do more persistent Afib ablation than paroxysmal at this time. But if you look at my institution as a whole, that's still not the case. So there is a huge opportunity of patients, who have a very morbid condition that is becoming more and more advanced that aren't being treated appropriately with ablative therapies.

One of the reasons is that we don't have the approved products and what goes along with not having an approved product to do that is we don't have an agreed-upon strategy, but there are other reasons why physicians choose not to approach patients with persistent atrial fibrillation and it has to do with the track record so far for treatment of patients with this condition using ablation.

This is a recently published series from the group in Bordeaux, France. Now the highlighted authors there, Michel Haïssaguerre and Pierre Jais, they are the electrophysiologists who invented catheter-based ablation. So Dr. Cox invented surgical-based ablation, which you've heard about, but the realization that catheters can be used for was invented by these gentlemen. And in this study, they report their experience with persistent atrial fibrillation and it's kind of horrible.

Here they show a 150 patients that they -- that have persistent or long-standing persistent atrial fibrillation, again that big population of patients. They do a procedure on a 150 patients, okay? 85% of them have recurrent arrhythmia. So already you've got a bad initial result after the first population. 15% of them are good. Of the 85% who have recurrent arrhythmia, 14% say, "Okay, I don't want to go through that again. I'm just going to stay with atrial fibrillation," but 109 of them or 85% of the 85% says let's do it again. So they do another procedure. And then they do get some of those patients after second procedure to stay in sinus rhythm. But a lot of them don't. 64% or 70% recur again.

After the second procedure, some say, "Okay, that's enough." And then it goes down, down, down. In the series, it went down to actually 6 procedures on one of the patients, 5 on some, 4. I mean, it's a lot of recurrent redos and then what's the end result of that? Well, the end result after all that work is 60% of the patients are in sinus rhythm without having to take a drug, actually 50%, 60% are able to be seen if they also take a drug, one of the things they're obviously trying to avoid in the first place. So it -- you can say, it works. We did succeed in 60% of the patients. But that's a pretty long flowchart to run through to get to that point, and it's a little disheartening, and that's why many physicians will not approach it.

Another very important study published in New England Journal of Medicine looked at different catheter-based approaches for persistent Afib and they looked at 3 different approaches, one was going around the pulmonary veins shown in the upper left, one is going around the pulmonary veins and doing some additional lesions and then one is going around the pulmonary veins and making lines, trying to mimic the Maze procedure

that we've heard about. And if we could do it as well as the surgeon, maybe we would get some good results. But when you look at the differences between the 2 in this persistent Afib population, they're all terrible and again, they're in that 50% to 60% success rate range. That number, that 50% to 60% seems to always come out in these trials of persistent atrial fibrillation. So again, a half-full kind of group.

Now another important population, which I really want to also mention is patients with atrial fibrillation and congestive heart failure because they tend to go together. It's a big connection between atrial fibrillation and congestive heart failure. Atrial fibrillation causes congestive heart failure. Heart failure causes atrial fibrillation and vice versa. They promote each other because of structural changes, electrophysiologic changes, neurohormonal changes that are going on. So they are coexisting often, they worsen each other and one causes the other. And they have the sort of similar kind of population profile that reflects what's going on in the western world of getting older or having more and more of these 2 problems.

Atrial fibrillation and congestive heart failure are the 2 biggest billing codes. Atrial fibrillation is now #1 for me and my second biggest billing code is congestive heart failure, just to give you an idea of where we are.

Now what happens if you have atrial fibrillation and you develop congestive heart failure, your mortality goes up by 3x. Same basic thing, if you have heart failure and develop atrial fibrillation, it increases your mortality 2 to 3x. So this is Framingham data, which shows that if you've got one of them, that's bad enough. If you get the other, it's much worse in triple.

And this study also helped us understand even just a little Afib can be bad. These are 1,500 patients, who all have implanted defibrillators and pacemakers that try to treat heart failure, but also tell us what's going on with rhythm. So if you have Afib, it's stored in the memory banks. And they looked at these patients and -- who had Afib and who didn't, and what they found is that, in a heart failure patient if you even have just one bad day of Afib, the risk of you getting hospitalized for worsening heart failure in the next month goes up 3.5x. So Afib really does increase morbidity in these patients.

If you look at what's happening at the heart, these are some MRIs, which -- the light pink represents scar tissue. So this is the front and the back of the left atrium where Afib comes from. And as you get to a normal person, who has no Afib and no heart disease at all, you'll see little bits of scar that develops with natural aging. But as the patient gets either more tendency towards Afib or more tendency towards structural heart disease, you see the same thing happening, more and more scar tissue. What the scar tissue does is it leads to persistent atrial fibrillation. So when you have persistent atrial fibrillation, you have some degree of scar tissue on your heart and that has to be dealt with and the ablation strategies I've shown you so far did not target the substrate or scar tissue, and that's why they really didn't have a beneficial effect.

So if we get patients with heart failure back in sinus rhythm, do they improve? And the answer is, yes. LVEF is a measurement of the strength of the heart. If you have a low EF, this is low, it's less than 55%, before the ablation these patients had this EF and after, there was far fewer patients with a low EF. Also NT-proBNP is a hormone. It goes down when you're out of heart failure and by ablating AF, we can lower that hormonal presence. A marker of success. Also other studies have shown that when you do the ablation, it has to work and if it works, the heart failure gets better. If it doesn't work, the heart failure doesn't get better.

Probably the most important current study on this is the CASTLE-AF trial, which was recently published this year in New England Journal of Medicine. It's the first catheter-based ablation procedure that showed that when you treat patients with congestive heart failure, it can improve survival and other quality of life and structural measures.

Now the interesting thing about this trial beyond the fact that it was positive and showed improvement was that, when they did the ablation, these patients all had about 50% total of Afib burden, meaning that are in AF 50% of the time on average. When they did the ablation, it went down to about 25%. So there was some improvement. But as the surgeons will be quick to point out, it's not really a successful ablation. Is it if you're still having AF 25% of the time? So this was a catheter-only approach, and again, it sort of shows what we might consider somewhere in that 50% success rate at best. But it made a difference. It helps enough patients to be statistically significant. In other words, the probability of survival or avoiding a hospitalization was better if you had the ablation than treated with a medicine. The survival overall was better if you had an ablation versus medicine, hospitalization for heart failure, less if you had an ablation, and the cumulative result was better. All right. So that just tells us we need to succeed because we can help this population.

Now we do as part of our offering at Emory the hybrid ablation procedure, which involves a surgeon doing part of the procedure and the tool is in the back, it's basically done via small incision, it's done off pump. We access the pericardial space. So the patient is under anesthesia for the combined procedure, but there is no opening the chest per se. It's done as a high abdominal incision that goes into the pericardial space, much like if you're doing a pericardial window.

In our patients, we've put a monitoring device in every single one of them so we know absolutely how much atrial arrhythmia they're having. And in our first 100 patients, we found that 90% of the patients at a mean follow up of 1 year had less than 1% AF burden. So approximately half of them had absolutely no AF at all. And then approximately 25% had less than 1% Afib. In other words, 99% of the time, there was no atrial arrhythmia, which, I think, clinically, is we could consider a success. And this is complete full disclosure. I mean, nothing is missed. Of that group, about 10% of the patients we elected to do redos within 1 year.

So this is a huge difference if you think of the Bordeaux paper where people were having up to 6 procedures and 85% of the patients required a second procedure. Here we found 10% required a second procedure. And overall burden is markedly reduced. Now this is 1-year follow-up, it's not 5-year follow-up. So we'll continue to follow these patients, but it's extremely encouraging.

We also have MRI data on a subset of our patients, the MRI performed immediately before the procedure and then 3 months later. And we were particularly interested in the patients, who start with a low ejection fraction, in other words, a reduced EF, which would be patients with 55% or less. All of those patients experienced the increase in their heart function, which is an incredibly important predictor of good outcome, reduced heart failure, et cetera, by maintaining normal sinus rhythm. And a vast majority of patients also showed reduction in left atrial volume, that was an outlier here and here, but essentially the left atrium gets smaller without doing any removal of the left atrium and in these cases, we didn't even close the appendage. So we're seeing what we call remodeling and improvement in these patients, and that's also very encouraging.

The hybrid or Convergent AF ablation procedure I'm talking about has some big advantages for us. It is truly minimally invasive. And we can do a better job than I can with catheters alone, much better. It involves me though in terms of recruitment of patients and the portion of the procedure that I do on the inside of the heart once the part that the surgeon does is completed. And of course, the follow up of the patients is very important.

Now the piece about the partnership, I think, was really important because this is what's helped driven the success of our local program. First of all, you have to have electrophysiologists who are interested. So this means we need data about ablating persistent Afib patients. So far, the data has been very discouraging, as I showed you, but we're currently completing enrollment in the CONVERGE AF trial, which is a randomized trial involving this technology compared to standard catheter-based ablation. And we think that it's likely to be positive based on our preliminary data and on our commercial data, as I've shown you. Many other centers have had a similar experience.

But EP involvement is critical. One of the things is that EPs are often the physicians that does the education for the community. So when I go out and have lunch with or talk to people or call people and say, these are the type of people that you need to refer, here are some of our data. If you don't have someone who can do that, you're not going to get as effective a program. So I think approaching physicians with our current expectation of treatment efficacy is very important.

There's a lot of opportunity for education and also, there is a lot of opportunities for the hospitals to get involved, which we found is that very successful programs, the hospital realizes that they have an important service line and then they support us with, for example, coordinator support, nursing support and help us rope in the appropriate people around the hospital, such as the hospital-based physicians in the emergency room, all of which are sources of patients. As you've seen from data given earlier, the penetration right now is very low and there's a huge opportunity to increase penetration of these therapies.

Now the engagement of the cardiothoracic surgeon is also very important. I see them as having certain challenges regarding this type of procedure. First, they have to kind of be coequal parts of a team. Often, you wouldn't know it from the surgeons we have here, but sometimes they can be a little overbearing, and they're the ones running the ship. So what we have to do is work together, and we found that to be just a great experience.

They have to be thinking about what the EP hopes to expect electrophysiologically is not just surgery, and the very successful programs have figured this out. We do some different kind of models or sometimes the patients are actually done in a room different than where the surgeon is

used to working. They have to be willing to consider this. And also realistically assess their availability. That's been a challenge we are working on overcoming, which is you have a busy surgeon then you say, "Hey, I've got a whole new service line for you." They've to be willing to embrace that and work that into their time management.

I consider there to be a couple of different models, model A and model B. Model B is what has worked for us, that's where we have a lot of teamwork together. We kind of recognize each other's weaknesses and strengths and how we can work together to get the best outcome for our patients. We also work together to drive referral business and then you have this idea like it grows. We start to talk about what other things you can do surgically, et cetera. So there's a lot more collaboration that happens.

And this is what we've seen at Emory. In 2014, we didn't do the hybrid CONVERGE Afib ablation. So you see the orange which is ablation with no concomitant procedure and the blue would be total. So this is with and without concomitant, you had 90 cases in 2014. In the light blue, we added the CONVERGE in 2015, and it helps drive a higher volume of total cases, but what it also did is it's kind of like a rising tide lifts of all ships. We all started to get more interested and the surgeon started to see the results and started to realize, "I've got to go by those guidelines more. I've got to do more concomitant. I can't leave Afib untreated." They're starting to realize that more and more. And our penetration has grown as a result of this. So this collaboration has had a very dramatic effect not only on the hybrid program, but on all surgical types of AF ablation that we do in our facility.

These are the guidelines and I'm going to -- you saw them, Dr. Gillinov showed them in much more readable slide. Now highlighted in yellow though is an important thing. Currently, the data for the hybrid is not quite there, we will have it because the study is just about completed enrollment. But it's already thought it could be reasonable to use the same guidelines for the hybrid procedure. It gives it a Class 2b. Any time you get to a Class 2a recommendation, you have full buying from insurance companies, third-party payers, et cetera. So we are moving this procedure forward and it's going to, I believe, contribute very positively to the armamentarium.

We've also explored this concept on arrhythmia surgeon. Most heart surgeons, I think, don't think primarily of themselves as arrhythmia surgeons, except in very specialized centers. They think of themselves as heart surgeons and they do heart surgery, a very complex and different types and they also do arrhythmia surgery when called upon. I think we've now are starting to get to the point where we have to have dedicated arrhythmia surgeons. Heart surgeons who are strongly dedicated and very interested in ablation of arrhythmias, not just Afib, but other arrhythmias too, such as ventricular tachycardia, but Afib would always be very high in the list because of the prevalence of this. So we're in the process of recruiting a dedicated surgeon so that we can continue to grow our program.

Left atrial management, I was asked to say some words about, but I think you've heard really about it very effectively and I don't need to spend too much time on that. I do -- I'm involved in left atrial management pretty aggressively on the endocardial side. There are products that are inserted through catheters. And since I'm a catheter jockey, I can do those. We put the left atrial appendage closure devices in the left atrial appendage.

But when it comes to surgical ablation, it's this epicardial closure that we're most interested in because where -- there, the surgeon can see the appendage, they can do that procedure and we know the closure success rate is very, very high. It could also have a positive effect on arrhythmias. This has been examined actively. It may actually help reduce Afib to clamp off that appendage and stop its electrical activity and -- while stopping its ability to cause a stroke. So this is something that's of great interest. We have been collaborating with others and we believe that we can get it closed even through just minimally invasive techniques at least 95% of the time, which is better than the catheter-only approach.

You saw this study referenced. This is starting to shape awareness. This is a very recent article on JAMA. They looked at patients who had had surgery with and without their left atrial appendage being closed. And what we're finding is that there is decreases in the rates of stroke. This is important information for us. If you close the appendage, there is decreased rates of all-cause mortality, and there is decreased rates of a composite of mortality stroke in hemorrhage. I think that's really important information. This is not randomized data, but randomized studies are being done, and if this data holds up, which I think is reason to believe it will, then I think the adoption rates of left atrial appendage closure at the time of surgery will continue to grow.

So kind of as a final slide. Atrial fibrillation for me, it's a continuum. As atrial fibrillation progresses from the early stages to persistent and to long-standing persistent atrial fibrillation, these patients are "sicker." They have more structural heart disease. They have more scar tissue in the

atrium. They may have weaker hearts overall in some cases. The disease goes from isolated areas to more diffused areas of the heart, and that's why the Maze procedure can be very useful because it really addresses the substrate. At the top, I list the kind of things we offer at our facility. For very early atrial fibrillation, we'll just freeze the pulmonary vein. The pulmonary veins, all 4 of them, because that really helps control Afib and it's a very gratifying procedure. As it gets to a little more structural heart disease, I do what is called a box Afib ablation endocardially. Again, this is catheter only. But as we get to a more persistent Afib and a little more disease then we offer the Convergent procedure and they can choose between these two. And the Convergent procedure is becoming more popular because our expectation and our experience has a higher success.

Now as we get into more persistent Afib in patients who we -- who are sort of on the cusp of really needing surgery, we can talk about stand-alone ablations or if there is a concomitant valve disease, they need a repair. They can get a robotic mitral valve repair at our facility or a Maze, a robotic repair plus Maze and left atrial appendage oversewing. So we sort of have a menu that we try to tailor to the patient. Earlier, you heard the analogy to cancer for atrial fibrillation, which is you're tailoring the therapy to the patient. I really don't like the analogy because I feel like we can do better than you can with cancer in improving the quality of life of patients with atrial fibrillation. And our #1 treatment -- our #1 reason for doing Afib ablation is for quality of life and then we also go for the ancillary things of reduced stroke and survival.

Finally, on the CONVERGE trial. The CONVERGE trial is almost completely enrolled. In fact, all the patients who will be enrolled have already been identified. 140 subjects have been enrolled. And as of Friday, it'll be 142. We're going for 153. It's 2 to 1 Convergent to Standard endocardial-only ablation. We'll have 3 months safety data in 3 months and then we'll have 1-year efficacy data next summer in which time we'll submit to the FDA for approval of the device for treatment of persistent atrial fibrillation. A very important trial because it will be a seminal trial of persistent atrial fibrillation. Those other trials that I showed you that were published were negative trials. If this trial is positive, it will be the first positive persistent AF randomized trial. And if it shows better than a catheter-only approach, it would be the first of that kind. And it will drive indications for the hybrid procedure, and I think it would be a very important endpoint.

So in conclusion, persistent Afib is way more prevalent than paroxysmal Afib, but it's treated with ablation far less often. This is a huge opportunity. It's the type of Afib that produces most of the morbidity and mortality. Patients with Afib and heart failure also are treatable by this technology and there are benefits to treatment of heart failure patients, including survival and improved quality of life as well as improved LV function, very important. There is an education gap, which we are working hard to meet. And I think, CT surgeons are big part of our success. So we work with our CT surgeons very closely and this has been very gratifying approach for us. I'll now stop there.

Marc W. Gerdisch, M.D.

All right. Good morning. So I'm going to sweep up here and I'm going to try and make this interesting from the perspective of probably incorporating a couple of things as you've already heard about a little bit. I'm Marc Gerdisch, I'm a heart surgeon in Indianapolis. I'm also a partner in the largest heart surgery group in the country. We have 35 surgeons, 24 programs, 4 states, been with the same people for 25 years. And when I started, there were 4, I was the fifth, and now we have -- we're kind of the Cleveland Clinic diffuse. We are positioned all over managing a lot of heart surgery in a lot of different places, which also gives you some perspective because my program -- my group acts a bit as a microcosm of how heart surgery is because we have this broad spectrum of heart surgeons in multiple institutions with whom we all communicate. I'm also not an academician, I have an appointment in Loyola, but I'm really not an academician. I'm a blue-collar heart surgeon. And my life has largely been dedicated to becoming a heart valve surgeon. I do every kind of valve surgery you can possibly conjure. And as a result of that, I do a lot of Afib surgeries because I recognized early that people with valve disease also had atrial fibrillation. And I made a point early of becoming trained and then training. So that's me.

This slide goes back to a couple of things that were mentioned earlier, which are 2 really important points for everybody to understand. One is that atrial fibrillation starts out as this electrical process, but over time it becomes a physical mechanical process. So once you had atrial fibrillation, you start to see changes in the substrate, changes in the atria themselves, and you develop basically a cardiomyopathy and alteration in the structure of the atria, the upper chambers of the heart. Then that leads to a situation that is not easily cured, right. So it's a spectrum across the pattern.

And I worked with a lot of EPs, so these are actually a couple of stolen slides. The first one was from (inaudible) outside of Boston; this is Dr. Kensington from Florida. And I always take their slides because they help us kind of get perspective on the broad spectrum of the disease process. And again, it's a cardiomyopathy, it's a progression of disease and it becomes eventually a disorder that requires very aggressive intervention. And that

aggressive intervention is served up well in the operating room because we have that opportunity. Atrial fibrillation is caused by all these different things, and we don't have a way to address all of these things, right. There's not a magic portion to drink. There's not a gene therapy that we can employ. So we have to go out at it from a mechanistic standpoint when it's there because this is what it is. Atrial fibrillation is this -- what appears to be a chaotic activity on the EKG, but is, in fact, these circuits that are going at their own rate, in their own pace in different places of the atria that are based off of the architectural elements of the atria. So if we were to analyze, sub-analyze the erratic-looking EKG, we would find that there are these foci of activity. Dr. Cox, everybody needs to know who Dr. Cox is because Dr. Cox invented the Maze procedure. So the Cox-Maze procedure was developed by Dr. Cox 30 years ago at Wash U. This becomes really important because over time we see convergence between what the electrophysiologist do, beginning with Dr. Haïssaguerre in Bordeaux, who is best friends with Jim Cox, and what we do in the operating room and this gray zone in between. I think, one of the things people have to recognize is we have -- you have to establish what's your goal is for the patient because, as was mentioned earlier, better is better. If you lower the frequency of somebody's atrial fibrillation, if you decrease their burden, you are making them better. Better is better. That's the CASTLE-AF trial, which shows you when you decrease the burden of atrial fibrillation, you made their heart failure better. But we, as surgeons, we are -- we have a certain mindset. And for good reason, when we have someone open, whether it's through a small incision or big incision, on the heart-lung machine, their heart arrested, we have this very definitive opportunity to treat their atrial fibrillation in a very aggressive fashion. In other words, put somebody on a table, put some wires in them, if you don't get a perfect result, it's kind of okay. But if you have somebody in the operating room and their chest is open, less than great, probably isn't okay. And we know what great is because Dr. Cox invented it 30 years ago when he developed this, the Cox-Maze cut-and-sew operation, which he developed really with the first multidisciplinary team, right. We always see multidisciplinary teams for cancer and specific cancers and heart valve diseases, et cetera, we're -- and we just talked about it in Afib. They were doing it 30 years ago. He had electrophysiologists Bruno and Schuster and they would go to the operating room, go to the lab; go to the operating room, go to the lab. They would do this over and over and over until they figured out how to treat this disorder that no one had a way to fix. Before that, they had recognized that they could just cut through one place in the heart and fix most arrhythmias whether that was with a knife or with a Cryo or with a RF. But then they found with atrial fibrillation that wasn't true because it held all these structural elements. And this is a brilliant process. So we had this and that's 30 years ago, but I, like I said, who have been at this for quite a long time, and I'm a heart valve surgeon and I'm an arrhythmia surgeon, I've done 2 cut-and-sew Cox-Maze in my career. I observed several in my training, but fortunately, by the time I was out in my career, things started to change.

So this is Ralph Damiano, who took Dr. Cox' position at Wash U. And I got the pictures off the Internet, so that includes his beautiful wife. And when he is with Marcy, it looks like this. But most of the time, he looks like this. So it is not an exaggeration when you meet Ralph, Ralph is absolutely no BS. You'd say the truth. You're on it. You understand it or you don't. And I was fortunate that Dr. Ralph took -- that Dr. Damiano took up the mantle with Dr. Cox because he was so rigorous about going after the same results as the cut-and-sew Maze. The cut-and-sew Maze has a 90% efficacy of getting rid of Afib and a 1% incidence of stroke after over a 10-year period, and it's a crazy number. So we had to try and get that some other way. And this is how it came about. So Damiano sets up a lab, uses animals, uses tissues, starts to work in humans, of course, and develops a methodology of standardizing types of energy sources that we had in the operating room that we could use to create the same lesions as the Cox-Maze all the way through the heart muscle every time and I was lucky because about 14 or 15 years ago, I went to his lab because I was trying to figure out what to do with Afib because I had always patients with Afib and people were bringing me radio frequency catheters and lasers and ultrasound things. I didn't understand how any of them works, so I went to Damiano's lab where he had everything. And I got to try everything. I said, "Oh, look at this, this clamp works, this clamp makes this thing go all the way through the heart muscle and that's what we're after, so that it could be just like we cut it and sew it together. As a matter of fact, when I teach the course, I explain to people, everything I'm going to tell you, you have to have in your head, that's the same as taking a pair of scissors and chomp, chomp, chomp, all the way across that heart muscle or whatever structure it is so that you are absolutely across the entirety of it. So that's what we're after, right. So Dr. Damiano proved this to us. Now the golden rules of lesion transmurality in connection, meaning that everything we do has to finish with a lesion that goes all the way through the heart muscle or whatever we're addressing, and we have this standardized set that everybody aspires to. Now how do I know that everybody in Afib aspires to this? I know it because I read the EP literature too and I see this beautiful elegant papers written by the electrophysiologist and as we just saw earlier with the kind of lesser degrees of disease, paroxysmal atrial fibrillation, which is not the predominant arrhythmia that we encounter, but in those disorders, they're quite successful. But when they get in the heavier, more complex or higher burden, more substrate modification, in other words, more changes in the muscle itself, more cardiomyopathy they have to do more. And so I see these beautiful diagrams that they have in the papers that I don't understand, but when I see this part that I understand because if you look at this and you go back to the images I showed you before, they're chasing a Cox-Maze.

Now they can't always get across the muscle in its entirety, but their goal is to compartmentalize what they can, the places that they have to wall off and to transect the others, those areas that are responsible for maintaining the arrhythmia. So they're after the same thing and this, we've all recognized. We started to look over the fence. We're all recognizing we're kind of after the same thing when we get into these sicker hearts. So this is it, right. Standardized bi-atrial lesion set everybody has to get this if they want to cure Afib on a consistent regular basis in sick hearts. Like I said before, if you do less to somebody and it's a benign -- relatively benign procedure and you get better, well, better is better. But if you're going to go after the disease, this complex disease, and you have to have this. And I might mention, there's only one device that's FDA approved to treat persistent or long-standing persistent atrial fibrillation. We do it in the operating room and it's the bipolar clamp, the atrial fib bipolar clamp, which is what has allowed us to make these leaps over the last several years. We have an FDA approved device on-label use to treat some of these atrial fibrillation in the operating room. One device has that and that has allowed us to do this. So what are they? It's the bipolar clamp, and it's this Cryo. The bipolar clamp is idiot-proof and as Dr. Gillinov has mentioned before, this became an easy operation. It became an easy operation because we have this thing. You just put it on, you step on the pedal, you do it the prescribed amount of times in time, and you get that transmural lesion that someone else might spend hours trying to get with a catheter through the leg, you can do it in seconds in the operating room. So -- and we always get that transmurality. So this is what happened. 1987, 30 years ago, Cox develops the operation. It's a masterful operation to be done by masterful surgeons, so it doesn't get done much. It's complicated. It's morbid for the patient, it takes time. 15 years later, we start to see signals that there are devices that we might be able to achieve this with without using a pair of scissors and sewing it back together again. And this is like -- this -- has this kind of dark period I always say, when people were using all kinds of goofy things to try and create these lesions. But fortunately, we had something, which was the bipolar RF clamp and we use in conjunction with cryo, use appropriately that allowed us then to get good results. So 2002, this is just about when I go to Damiano's lab by caveat, by luck. And by 2012, now think about that, a decade of work and you get FDA approval for a device to treat persistent or long-standing persistent atrial fibrillation, extremely difficult disorder to treat.

We say that the operation's easy, but it's actually a little bit complicated because you have to do a lot of lesions. They all have to be perfect and when I think of like when we do an aortic valve replacement, we cut the valve out, we put the stitches in, we sew the valve and everybody can do it, it's very simple, the steps are easy. There's 3 of them, that's all that is to it. In Maze procedure, you do have to study a little bit. You have to understand it. You have to understand the principles. You have to understand what's you're going after and that's what where the educational process became so important. And when the FDA approved the device that's when the handcuffs came off. Because at that point, we could teach people directly. We could say, you can use this to treat this, and here's the success. And that's a game changer for everybody. It's a game changer for the patients mostly, right.

Now you go from 2012 to 2017, 5 years, it makes it into the guidelines. That is a minute in medicine time. In other words, 5 years from going from something that you understand works to getting it into the guidelines. In 5 years, it's almost a track record because it takes forever for things to make it in the guidelines. People have to debate it. They have to go back and forth and argue about it. It made it into the guidelines. So now not only do we have the device that we've proven is worth, it's FDA approved, we also have in addition the societies as Dr. Gillinov mentioned earlier telling us that we're supposed to do it.

In other words, you have somebody in the operating room, you're supposed to treat their atrial fibrillation and I'm going to get to some of the details of that.

So the original course was an FDA mandated course. In other words, product didn't go to the hospitals unless or if they had product, they had to be trained. People who had the product had to be trained. So we had very boring course and they had to take a test at the end, and we're kind of getting our feet, what we're trying to understand how to teach these people, all the different surgeons and -- but they did have to pass the exam and we got some traction going. So this is what's really the very early phase and somebody put this -- gave me this slide actually and I laughed about it this morning because I showed it to Marc Gillinov. I was on schedule to train at the Cleveland Clinic. Blue-collar heart surgeon was going to train at Cleveland Clinic. They knocked me out of the box and put Gillinov in there, see that replace it with Gillinov. So (inaudible) I almost got to the front of the class through that. But then eventually, I did get to train. So major componency of advanced ablation course, we expanded the format, we brought the EPs into the conversation. So every time we do a course now, we don't have just surgeons telling surgeons, we have EPs telling surgeons too about the partnership, about the expanded use of the devices, about the ways that they overlap, how they can work together.

So 2 surgeons usually and an EP authority. It's the whole weekend, and what is amazing about this process is, I have never finished this course and I've taught a lot of them and not have surgeons come up to me and say, I learnt something new, this was great, this is my second time, I learned

more. So we are creating kind of enthusiasts, Afib enthusiasts. Hands-on cadaver lab, really important especially with the younger folks, post course tools. Everybody gets the videos to use and things afterwards, and that's super important. When after I went to visit Damiano, I came back with, I remember, CDs and some of those discs. I came back with a CD that had his operation on it and I used to play it every morning before I did the operation. So now surgeons have those in -- there are lots of them. We've made videos. In fact, Dr. Cox came to my operating room and videoed me doing the operation. We have that out there for people to learn how to do the operation. So this is where we are now. The Upper corner is actually one of my EPs teaching. I'm down there doing a little didactic and the best one here is that is me with the fellows and a cadaver and Duke Cameron. Duke Cameron is a storied heart surgeon, Hopkins, now MGH, bringing his fellows to be treated -- to be trained in stuff that they didn't get trained in that well. Knowing the value of this operation recognizing that we have turned a corner that we are able to get people, new young surgeons to do a Cox-Maze IV in record time in the operating room with some simple training. Brothers in Arms, of course, it's me. (inaudible) you have to mention this guy because he spent the last 16 years dedicated to this. He was in Dr. Damiano's lab for several years and now he's Chief Medical Officer for AtriCure. The bench is deep in this company with respect to respected people in the business teaching us how to do it. The engineers are spectacular and Mike Rogge is the next guy over. He's the person who puts -- helps put together the curriculum that we teach, which is constantly undergoing revision because the field is constantly changing. And on the end, might be the most important guy because he is my AATS grand fellow. So this is someone who is being trained by me. He's also being trained at Wash U in atrial fibrillation surgery. He's there because AtriCure sponsored a fellowship through American Association of Thoracic Surgeons, and so we have surgeons coming through, younger surgeons coming through and being trained hands-on with the people who do these operations a lot. These are all the people that -- these are just surgeons that we train. Now in addition to that, we trained a lot of PAs, surgical techs, everybody else shows up with their surgeons, which has been great. And now electrophysiologists are showing up in our audience as well. And then you can see that I've been dug in because as time has gone on, I've taught most of the courses because this is really a very, very passionate thing for me. Why is this so passionate? It drives me crazy that somebody is having heart surgery and doesn't get the full operation.

Now we've made progress. We made progress and I could prove it because when we did -- when they did the 30,000 foot look that led to the guidelines changing. In other words, when the STS and AATS and HRS, Heart Rhythm Society, all of them added to their guidelines, every one of them added to their guidelines that surgical Afib, concomitant surgical Afib is serious and should be done in, as a matter of fact, stand-alone surgery made it into both as well. 30,000 foot data showed that if a patient in the operating room -- goes to the operating room with Afib and they get something done for their Afib in the operating room, some ablation. The 40% -- like -- more likely to be alive in a year. So which curve do you want to be on? I want to be on the one where more likely be alive. The thing is we also know though that a lot of those people weren't getting a full Cox-Maze IV, they were something though. So we had moved things. Surgeons were using instruments. They were doing some work on the patients, but we also learned, we know from the course that they're not always doing a full Cox-Maze IV. So important, good news, the rough news is that patients who get a lesser operation have lesser outcomes. This is just 1 -- this is the 1 paper that compares a lesser lesion set to the full Cox-Maze IV in which, which column do you want to be. on. Do you want to be on the one that's close to 90%, not the one that's 50%, right? So the 50% one still exists out there. A lot of patients still go to the operating room with atrial fibrillation that's treated with a more aggressive operation, get a lesser operation and that's kind of -- that's one other things we're continuing to tick through the educational process. We have to have this. The standardized bi-atrial lesion set that we know works over and over and every time or nearly every time. So where is that going to come from? We have to get real-world data. One of the things that always happens is well(inaudible) they can do that in that academic center, we don't. We can't do it in our community hospital, well I work in a community hospital. So we have to collect that data. And AtriCure has been wonderful about helping us establish a means for doing that. Again, it's about the data, as Dr. Gillinov said, surgeons want to see it. So define lesion set and comparative potential meaning that everybody getting everybody to do the same thing. Sometimes I'll be teaching the course, some of you'll say, well, I do it this way. I'll say, fine. You've decided that you're going to do it that way, but you have to collect the data now to show us that it works because that's the thing we're trying to do to standardize the lesion set to what works. So where is it going to come from? This is the TRAC-AF database, super easy to use, totally encrypted. I dumped my 400 and now almost 500 patients into TRAC-AF that I'd already been following for decade and you can do it retrospectively or prospectively. And we're trying to get everybody on board with it so that they follow their patients. This is our experience and my experience really, and you can see that most of the patients have been persistent to long-standing persistent to more difficult atrial fibrillation.

And this is the most important slide for me personally because it shows that before 2010, I was doing, okay. Couple of years there where I'm kind of getting my perimeter going. I do better. But last 5 years, I kill it. 92% success with solid follow up in the majority of the patients, so last 250 patients, right. So that shows that right device, right operation, right training, you can get this for patients over and over again. So education drives adoption.

Patient access. I worded this last night when we were talking because I think it's not just surgeons can't do, it's, can patients get? When you go to the operating room, you have atrial fibrillation and I've had this conversation with surgeons, they say why I do this. I say, well, do you tell the patient tomorrow I'm going to do most of the procedure and it works pretty well, but it's not the whole thing, the whole thing works better. Now you don't tell them that. So this is what we're after. We're getting patient access to the full operation. We're pushing that and we're getting there.

My practice, like I said, I've got 35 surgeons. It exemplifies the steady impact of direct to surgeon training because I've watched it spread throughout all of these centers that we have in 4 states, as surgeons have gotten onboard, learned the legitimacy of the operation, learned the fast out way we can do it. Primary way to increase concomitant treatment is to get more and more surgeons comfortable with the procedures, which seems very obvious, right. But surgeons are busy, and they're focused on other things. And we need to continue to draw their focus and we've seen a lot of great positive energy in that lately. Arrhythmia surgeons -- there's a great word that our EP -- I forgot your name. Really, I'm so sorry David. David already talked about and it -- the word, arrhythmia surgeon, is super important. We have to get people recognize that there should be surgeons for arrhythmia, and they're fulfilling that legacy of Jim Cox. Couple of other things that people ask me to just kind of mention briefly. I do most of my isolated valve or double valves through a small incision on the side. And one of the things that always -- that's always kind of slow us down that is people are uncomfortable. They are hurt after that and we've been able to use technology from AtriCure to essentially eliminate that.

Hybrid ablation. I'm not going to talk much about because David already did masterfully. So I'll just mention the hybrid for us is in the middle. It's all those patients that can't be well treated by a catheter, aren't going to the operating room, but neither atrial fibrillation treated and that those hybrid procedures as David spoke of.

So cryoanalgesia, this has been and probably one of my most powerful tools with respect to just kind of the growth in my practice and the well-wishing for my patients and their families because we eliminated pain with that. And I say it's tangential technology, you think NASA, the cool things that spin off from trying to send things to the moon because we ended the pain that goes along with thoracotomy incisions. So we were able to do these small incisions, but they hurt. And now they don't hurt anymore. We use that same cryoprobe. We freeze the nerves and we just tell the patients ahead of time that for 6 weeks they're going to have an -- a band of numbness there. No one seems to mind it. They know it ahead of time and it always wears off and it always goes back to normal and they don't have any pain after surgery. So we routinely extubate them in the operating room and have them sit in their chair with their families immediately after surgery because they don't hurt. These are examples. The guy on the -- the fellow on the left actually has no legs. He walked with his arms. Basically, needed 2 valve operations and a Maze. We did that through a small incision and had him up and around. He went home 4 days after surgery. And then to the other side of that are 2 young ladies, who came in on the same day. They had their valves repaired. They're actually best friends and both of them are huggable on day 4 when they went home. So the point is that with this technology that we've used kind of tangentially, and fortunately, AtriCure is also taking seriously in looking at seriously with respect to its impact. Overall, we've been able to really lessen pain for people. So we're here to treat patients. This is kind of the bottom line. Like I said, I'm a little bit of zealot, obviously, when it comes to getting a full Cox-Maze lesion set done, but it's because I care about the patients. Education will continue to drive adoption. It's just going to lead to more people getting treated, appropriately treated and cryoanalgesia is the real deal, that's going to come full force I think as people focus on minimally invasive surgery. Thank you.

Michael H. Carrel - *AtriCure, Inc. - CEO, President & Director*

Well, I'd like to thank our guests. We're going to actually get up here for some questions, but just if I could leave with some parting thoughts before we go into some of those questions. I think what you should have learned today is that Afib is a bad disease. It kills people. It causes strokes. And we have solutions that can deal with it today in a concomitant setting and we're investing heavily in the right clinical trials to really help that large, huge market opportunity from the persistent and long-standing persistent patients with our CONVERGE trial and followed up with the DEEP trial coming after that. We're very close. You're going to walk out of here today knowing that by the end of this week, 142 out of 153 patients will have been enrolled in that trial. Every other one has been consented. We will be fully enrolled as I've talked about on our conference calls before sometime in July or early August time frame. And then it will be just kind of going fast after that.

I think the other thing though that I want you to take away is you saw the level of detail around education that Dr. Gerdisch talked about. So when you think about that pillar of success that we've got, you've got the innovation piece, you've got the clinical trials that we're running. What we've done on the concomitant setting, we have learned so much in that space. And you can see the level of faculty that we have that are training these physicians day in and day out, and we are already preparing for when we get that label for that large patient population for the stand-alone, whether

it's CONVERGE and then DEEP to follow after that. So we are doing all of that preparation. The label matters, but the education and training is going to be critical towards the full-scale adoption long term. These are big markets that we're going after. We're really excited about it. And obviously, we've shown a good success rate over the last several years with 20% cumulative average growth rate and 22 straight quarters with double-digit growth.

So with that, what I'd like to do is ask the physicians to come on up and we can open up to questions.

QUESTIONS AND ANSWERS

Michael H. Carrel - *AtriCure, Inc. - CEO, President & Director*

I'll take it up from here, it might be the easiest. Either one. Rick, why don't you go first and Matt, you're second.

Frederick Allen Wise - *Stifel, Nicolaus & Company, Incorporated, Research Division - MD & Senior Equity Research Analyst*

Rick Wise with Stifel. One question for the doc (inaudible).

I'd be curious if beyond results that are going to come from CONVERGE, do you have everything you need now to drive penetration are the Society recommendations enough, do you need something else? Do you need more reimbursement? ...It's hard for me to understand when I hear the three presentations and I'm ready to sign up please anyone, do an AF on me, I believe. It's hard for me to understand what's not there.

And Mike, I hadn't thought about the patient awareness side. How does a small company (inaudible) to consumers (inaudible)?

Michael H. Carrel - *AtriCure, Inc. - CEO, President & Director*

Okay. Thank you so much. We'll get answer to the first question.

A. Marc Gillinov

Sure. I think it's not a question of the technology that's behind you. It's more of what's not there, a mindset for surgeons. In the concomitant situation, the surgeon still think old school, I'm operating to fix the mitral valve or the aortic valve or do bypasses. And the Afib is just sort of a bystander, not a big focus. So what are we doing? People like Dr. Gerdisch and others are educating, telling them this is important, and you see a gradual uptick. So it's not waiting for a new device, it's education. And then for the sole-therapy, meaning the procedures that are hybrid procedures, it's also a mindset. And there's an activation energy to that because as Ethan discussed at Emory, the activation energy is coordination to get the surgeon and the EP together, both are busy, both have their own things to do and getting them together with the mindset that I'm interested in coordinating, and you could probably speak to how did you establish a successful program at Emory.

David DeLurgio

One of the components I wanted to address to your question, it's a little different for a nonsurgeon, for an electrophysiologist and a surgeon, the vast, vast majority of the cases I do are they are there for one thing and one thing only, it's ablation of atrial fibrillation. So for example, they're not getting bypass surgery plus Afib ablation or valve plus Afib ablation. So patients come to me and are referred to me because they have atrial fibrillation that is affecting their quality of life and that's a huge driver. Now patients just need education about the options for them because word-of-mouth is a great local thing. Patients talk to each other, for example, and they realize, "hey, I can get this problem fixed or I have a good chance of getting this fixed." So education to the patient, I think, is a big opportunity. And I think we do benefit actually from what you see on TV with anticoagulants. I mean people are trying to understand what Afib is because all those things keep mentioning, I have atrial fibrillation. So

there's a lot of awareness that's growing out of there. The other part of it that's really important is that the physicians need to know from us what is realistic expectation and what the guidelines are showing because physicians will often be the first gatekeeper on this. They're going to talk to their own physicians and then with their own patients to make a decision about referral. So we're seeing something a little different, which is a lot about education. The limiting factor right now is not number of patients with atrial fibrillation at all.

For us, the limiting factor is just throughput and really is at that point right now, making our systems more effective. With regard to how we interact with our surgeons, what we did is we tried to start a surgical AF ablation program many years ago. The surgeon wanted to do his thing, he wanted me to send them patients, I didn't kind of see how it worked, it was just too much for me, we didn't get along on that matter, nothing ever happened. New surgeon comes along, this idea of a hybrid procedure comes along. I got much more interested in what the surgeon could effectively do for us. So I changed my attitudes dramatically. Instead of looking at him as a competitor, I looked at the surgeon as a partner, and it really made a big difference and the fact that the surgeon was willing to partner as well as not looking at me as just a source of patient, those 2 factors were what really drove our program.

Matthew Oliver O'Brien - *Piper Jaffray Companies, Research Division - MD and Senior Research Analyst*

Matt O'Brien with Piper Jaffray. Question for each of the clinicians. I'll ask each of them now and then love to hear the answers. But Dr. Gillinov, the new clips that are out. You're, obviously, a big fan of the AtriCure clips already. So I'd love to hear what you think about the new clips that are coming out? And how they're being used across the Cleveland Clinic. And then Dr. DeLurgio, as far as CONVERGE goes, you've mentioned some other trials that it failed in the past. So I'd love to hear what's the difference with CONVERGE versus those trials that have failed and if there is any kind of an inclusion/exclusion criteria that might get the attention of clinicians from the skeptical perspective. And then Dr. Gerdisch, if can you talk about -- given a lot more clinicians that you are training, can you talk about conversion, utilization and then durability of that utilization of the AtriCure technologies after you've trained them?

A. Marc Gillinov

On the subject of the new clips. The new clips do 2 things. They make it easier overall. Right now, it takes a few seconds to take the old clip and feed the appendage into it. So as you see behind, these are open like a V. That makes it easier. That's good. Second thing, probably more important, it makes it more feasible to do a minimally invasive sole-therapy procedure. So you're probably all familiar with the catheter-based approaches through left atrial appendage like the WATCHMAN device. There are many people who are not anatomic candidates for that. The WATCHMAN device also requires some antiplatelet or anticoagulant therapy early on. Many patients can't take that. So now we have something with the new clips that will be more easy to deliver or more easily delivered in the sole-therapy market. So it potentially opens up a whole new market.

David DeLurgio

So the question about the effectiveness of the Convergent procedure. What the Convergent procedure does is a more durable type of ablation. The weakness of the catheter-only ablation is not that we can't make the lesions we want to and get the electrophysiologic endpoint in the lab that we desire, it's the durability over time. All of the surgical tools have proven to be more durable in terms of the lesions they make and specifically, the EPi-Sense tool, which makes the posterior wall ablation. But classically, the example is the clamps. They make very durable lesions that we can rely on. When we do catheter-only, we may get an initial good response, but then there can be tissue healing and the burns were not as durable. So by combining the 2, we're getting a much more durable response in a truly minimally invasive setting. So it has the advantage of being less invasive to the patient compared to the thoracoscopic approaches or, of course, the concomitant open approach and it improves upon the durability of a catheter-only based approach. It also addresses what is not been addressed by many of the catheter-only approaches is it attacks more of that substrate tissue, the tissue that has developed over time. I used that similar approach in my catheter-only. So the -- if you look at the electrical endpoint of my catheter-only approach versus the Convergent approach at the end of the procedure, they're identical, identical electrical endpoint, but there is a difference in the durability and that's what the hybrid procedure brings.

Marc W. Gerdisch, M.D.

I'm sorry because there was a little bit of an echo, I didn't get the last sentence as far as the question was for me.

Matthew Oliver O'Brien - *Piper Jaffray Companies, Research Division - MD and Senior Research Analyst*

Yes, just -- the conversion just among the clinicians that you trained. I think that's been increasing pretty meaningfully over the last couple of years. So you're up to 200 last year that you trained. How many of those are then going on and using (inaudible) in work?

Marc W. Gerdisch, M.D.

So it's such a great question. And I would have to say that, unfortunately, we don't have absolute numbers, but our sensibility of it has improved and in that, we get more and more feedback directly from the physicians and now has actually kind of asked AtriCure to give us more direct feedback locally with the reps working with those people to give us more of that information. What I would say is that we know that more people are being treated; therefore, we know that the course is having impact. Also, we know that the physicians follow up with us and also come back to, of course, often to make sure they understand the subtleties of it as they evolve themselves in arrhythmia surgeons. And as we had expanded the course to include some discussions about things that physicians can do other than the open concomitant operation because by virtue of having our electrophysiologist there we can talk about some of their procedures that they do in combination like Convergent. It's been kind of eye-opening for them and allowed the surgeons then go back with this appetitive to develop and forge relationships with their electrophysiologists. So my only answer I can really give you is that the number being treated is going up, the number of people coming for the course continues to increase. In other words, we feel completely every time and we always have people waiting to get into the course. And with the advent of the guidelines and the support also of some of these minimally invasive approaches, I think that that's why we see such a strong overall response. The other thing I would mention -- I would mention about the clip. I closed every appendage on every patient I do surgery on, whether they have a history of Afib or not. And as you can see, the data started to come in support of that. I would mention that the first clip I put on a patient was my administrator's mother. And after that, nobody ever questioned why is Gerdisch putting clips on everybody. The impact that we've seen from that when we go back and look at our data is that it's having a very positive impact and I think going into the future, it's going to be a huge asset both for atrial fibrillation and also just for the human beings that are being treated in the operating room.

Michael H. Carrel - *AtriCure, Inc. - CEO, President & Director*

And again, on the education front in terms of training, we do track that information. We've been tracking it for last 5 years. We tend to see increases and durability in those patients -- those physicians specifically. What we know is what sites brought product for us? What we don't know is, was the specific surgeon actually the one that increased within that account per se? We believe so. So what Dr. Gerdisch is asking us to do and he is right, it has just been complicated, just to try to get that information in terms of is it going to that specific surgeon? How many of they're doing it? The TRACK-AF will actually help us out quite a bit there. So we've got a little ways to go and actually getting it on a surgeon level, but on a site level, we know pretty well.

Danielle Joy Antalffy - *Leerink Partners LLC, Research Division - MD, Medical Supplies and Devices*

Danielle Antalffy, Leerink Partners. So just a quick question. I don't know who wants to answer this. But I understand CONVERGE is a superiority trial, but just curious what you think the bogey is as far as recurrence rate has to be for doctors to buy into it. That's the first question. And then second question is, at HRS this year, some of the catheter manufacturers were talking about working on persistent approaches. I'm just curious how you think that could come to bear?

David DeLurgio

Those are excellent questions. So currently, the market is like 60% effectiveness with multiple procedures. We're looking at achieving an 85% success rate with the CONVERGE trial and that would be very significant and I think landmark. There are competitors in the persistent field and everyone realizes that these are the patients. There is more and more of these patients as the biggest part of the populations we talk about. So everyone would like a piece of that. What Medtronic is doing with the cryoballoon is just basically doing the same ablation they do for paroxysmal atrial fibrillation. They're not really targeting a population that is nearly as advanced as what we consider truly persistent Afib patients. But they are interested in seeing if they can get decent results with the cryoballoon. They won't cover the same amount of substrate, and I would think the results will not be quite comparable. Other companies also are going after the indication using, again, very similar techniques. What you saw though with the Star AF II trial was that those techniques cannot be any better than where we currently are, still on that 60%. So people will always be knocking at the door. I think we're in a very strong position with the current -- with the CONVERGE trial. It has great pilot data behind it, and it has a concept of substrate modification that is very current and in alignment with what people are currently thinking about what can lead to successful ablation.

Marc W. Gerdisch, M.D.

And I would like to just throw in and add a little bit even though I don't do the procedure. So I have a younger partner whom I asked, can you just get in on this and start working with EP and they're doing that procedure. And I didn't like it actually. I didn't like it because I'm a purist. And I asked him to do one thing, which was every time we do the operation, close the appendage. So the -- because the appendage is what kills people. So at the end of the procedure, you put a couple of scopes in, take some 15 minutes to put a clip on like Dr. Gillinov spoke of and finishes the operation with that. I have been blown away with it. So I have patients now -- I have this kind of trickle of patients that come just for Maze surgery to me, for minimally invasive thoracotomy Maze surgery. I often shunt them off to them because they do it all in one procedure, patients spend a couple days in the hospital. I think that we may -- right now AtriCure, et cetera, maybe underselling it and even Dave, I think does a little bit. If it does what it looks like, it's going to be a complete kind of landmass shift because it's not a complicated operation. It's just about every surgeon that -- if you can enlist them, they can do this procedure along with the EP. And if they want it, they can all do it at once together. So it's really kind of -- I think it's an amazing opportunity to converge both disciplines.

Suraj Kalia - *Northland Capital Markets, Research Division - MD & Senior Research Analyst*

This is Suraj Kalia from Northland Securities. Dr. DeLurgio, couple of questions, more so on the fundamental side that at least I would like to understand. On CONVERGE, how do you eliminate the variability -- operator-induced variability either from the technique for catheter ablation or the catheter itself? How do you know across 153 patients that variable has been set aside and you're going to get a consistent result in a real-world setting?

David DeLurgio

So I think what you're getting at is that the results of the Convergent or the epicardial portion of the ablation that's done with the EPi-Sense catheter will vary somewhat from patient to patient, and this is because the access technique of getting into the pericardial space provides access to certain portion of the heart, but there is a limit on where the catheter can diverse and it may vary from patient to patient. So what we do for these cases is we map the patient after the surgeon has completed his or her portion of the operation, and we can immediately tell exactly where they've been and then we slightly tailor what we do from the catheter site to create a uniform endpoint. So the endpoint of the procedure in my hands the way I have constructed the workflow is always exactly the same for every patient who gets the Convergent hybrid AF ablation procedure. The portion that was done relative by each of us is what may vary a little bit to produce that endpoint. Now I think one of the challenges for AtriCure, which is an area of active interest is they realize that they have perhaps the superior tool for durable lesions. So everything they can do to make their portion bigger and bigger is probably in the interest of the patient. So that's an area of active development.

Suraj Kalia - *Northland Capital Markets, Research Division - MD & Senior Research Analyst*

And one of the papers, Dr. DeLurgio, I believe, it was in your presentation where you compared patients with surgical closure for left atrial appendage versus -- it was the JAMA paper, if I remember correctly. And hemorrhagic stroke curves seem to overlap between surgical and nonsurgical. And if I remember correctly, WATCHMAN also had -- at least the original trial had similar sort of -- the hemorrhagic curve numbers were pretty similar and it threw the trial into all kinds of problems. Is there a fundamental reason why hemorrhagic stroke could also be the same surgical even though endocardial approaches? What's going on there?

David DeLurgio

Well, so interestingly, when you close the left atrial appendage and, let's say, you're using the WATCHMAN device, which is FDA-approved endocardial based device and the patient then gets off of anticoagulation some time later per protocol. Those patients who have a left atrial appendage closure clearly, clearly, clearly have a lower risk of hemorrhagic stroke. In the JAMA article that I presented, which was a retrospective analysis of just sort of a large population of patients, they did not see quite that same change in hemorrhagic stroke, but they saw a composite of hemorrhagic stroke, embolic stroke and mortality being better. Now what the explanation for that is not entirely clear. Sometimes people get their left atrial appendage closed by the surgeon, but they never are stopped from their anticoagulant and that's because the surgeon and electrophysiologists aren't talking together. So -- and Dr. Gillinov gave his own data on this, which was a very eye-opening trial. Whenever we want to make the surgeon look bad, that's the trial we bring up because like they would close the appendage, but then never looked at it and never -- no one ever knew whether it was closed or not. Nowadays appendage closure is going to be more effective because of the clip, that technology is really a sea change. But we always have to do a follow-up TEE or some other scan to make sure the appendage is closed and then stop the anticoagulation.

Michael Stephen Matson - *Needham & Company, LLC, Research Division - Senior Analyst*

I'm Mike Matson from Needham & Company. I guess I'll start on the obligatory TAVR question here. So I realize that aortic valve is only part of the concomitant procedures here, but I'm just curious, particularly, when the TAVR companies get their low-risk indications, how do you see that playing out? Hasn't seemed to really impacted the surgical aortic valve market so far? But do you think it starts to cannibalize some of the surgical valves?

Marc W. Gerdisch, M.D.

This is such a cool question because I have been asked it many times and -- because all I do is valve surgery and I do a lot of TAVRs too. I love doing TAVRs, fabulous technology. There is 2 things -- 2 ways to answer that. One is that in appropriate centers, I think we're one of them. if we identify someone who is intermediate risk, but also has atrial fibrillation and has a reasonable longevity horizon because there are different types of intermediate risk, sometimes you look at -- there is a classic slide that all of us has seen of -- that Michael Mack presented very early in the TAVR screens, where he had 2 patients that were intermediate risk and you looked at 2 of them, one of them you wanted to operate on and the other one you didn't want to be near. And so those patients -- those factors, those subtleties will factor into the decision making, but we often will shunt that patient over to surgery and a Maze procedure because we have to tell them the truth that you have atrial fibrillation, you have a reasonable longevity and these are the impacts of treating your atrial fibrillation. It's not going to be like that at every center, and it's certainly not going to -- and some of those patients are quite honestly going to get run over in the mix of things, especially in very high volume TAVR centers. Something else to think about though. We -- I always am willing to concede that things have to change and we have to be able to address different scenarios. What if somebody has a transcatheter valve implantation and then they come back and get a Convergent? Is that okay? I think that's okay, especially if it turns out that it's going to be quite effective. So I don't think you have to ignore the opportunity to treat more complex atrial fibrillation just because the patient is going to get it through transcatheter valve. You just have to have a center that's willing to look at every opportunity. Some patients are just going to be usually have a Maze procedure. Others going to be -- they don't need anything, but they're appendage closed and then there's going to other people who are going to fit really nicely I think into TAVR Convergent. How they get paid for or when they get done? Those are the things they have to sort themselves out in the marketplace, but I think it's going to happen.

A. Marc Gillinov

I think TAVR is going to have a modest impact. We will see the majority of surgical aortic valves move toward TAVR, but there will still be plenty of surgical aortic valves. Meanwhile, CABG surprisingly is growing because stents seemed to have more or less topped out and you are all familiar with the failure of bioabsorbable stents. So CABG is growing and at Cleveland Clinic, we're investing in cardiac surgery. We've got $20 million set aside to build more -- 4 more operating rooms because we can't keep up with the volume.

Michael Stephen Matson - *Needham & Company, LLC, Research Division - Senior Analyst*

Okay, and then just two more quick questions. So I think at the last Analyst Day that AtriCure hosted, there was some decision around the reimbursement for the hybrid procedures. I think it was at the time from what I remember was pretty lucrative for the hospital. So can you just comment on reimbursement for the hybrid procedures and how that shakes out for the surgeons and the physicians as well as the hospitals?

David DeLurgio

My hospital wants me to do more. So they're happy. As a matter of the fact, the way we do our hybrid procedure is all same-day and the reimbursement is based on the DRG of the surgical AF ablation, which essentially covers us both and they're very happy with that. You can split them up. Some people have done that. And if you split them up by enough time, they can both be build. And as it stands currently, it is a financially successful procedure for the hospital to perform. So they like to see them done more, which is not something we can always get them to admit. We still have a problem with the clip. That's something that we have to work on.

Michael Stephen Matson - *Needham & Company, LLC, Research Division - Senior Analyst*

Okay, and then just a quick question for Mike. So when Convergent -- sorry, when CONVERGE is done and you get to the 12-month follow-up period and have the data, do you -- have you put any thought into how you're going to make that public. I mean, I imagine you want to present it at a conference, but is there any possibility we would see sort of top line data and a press release or something like that before it's actually presented? And do you think you can actually get it presented somewhere before the end of '19 or is it going to spill over into '20?

Michael H. Carrel - *AtriCure, Inc. - CEO, President & Director*

That's still to be determined because we got to figure out -- our #1 goal is to get the label because the only way to change adoption up long term is to get the label. So we don't want any compromise on our ability to do it. I think we're kind of -- we're still having conversations. We've put a lot of thought around what that would be, like what type of intermittent analysis we might do, but we haven't made any conclusions on it. Really, we want to get out the label and we want to focus on that because that's going to change adoption long term.

Michael Stephen Matson - *Needham & Company, LLC, Research Division - Senior Analyst*

In discussions with the FDA, any indication whether or not you're going to have a panel?

Michael H. Carrel - *AtriCure, Inc. - CEO, President & Director*

We'll likely have to have a panel for this, and we have not had any specific discussions with them, but we'll likely have to have a panel for it.

Cecilia E. Furlong - *Canaccord Genuity Limited, Research Division - Associate*

Cecilia Furlong from Canaccord Genuity. And I just wanted to ask about CONVERGE after the data publication, is your strategy -- if you've started to think about your algorithms in terms of the training courses and then just kind of the level of adoption, ramp, just anything around that? And then, also just an update on the subxiphoid clip as well, please?

Michael H. Carrel - *AtriCure, Inc. - CEO, President & Director*

So I can transfer some math and ask you to ask that second question again. So in terms of putting together training programs, we have already started the process from an educational standpoint to understand exactly the set of centers of excellence throughout the country. We had to do that in a lot of ways because we increased the number of sites that were trained on this and also the number of sites were part of the trial. So when we bought in contact 11 sites, we have 25 sites or so enrolling in the trial today. Many of those sites were not doing the Convergent procedure before, so we had to basically have a training site -- a training program we put together that you have roll-in cases to make sure they were doing it. We've learned from that combined with learnings we got from Dr. Gerdisch's work on that front. So we will have a detailed rollout plan ready to go. We've also invested in a team that is out there. We call them MIMs, or minimally invasive managers, that had EP expertise in understanding how to remap. They've been in the company for the last 2 years. Most of them have EP background, and so they're very comfortable having conversation of "Oh, that's what the map looks like after a Convergent procedure." And we've also been building databases and working with the faculty they have been involved in a trial relative to what that's going to look like going forward. So we've got active involvement, and we'll be ready once we get the PMA. I mean, obviously, it's several years down the road now, but we've got a lot of that kind of footing in place. I did not hear the second question though.

Cecilia E. Furlong - *Canaccord Genuity Limited, Research Division - Associate*

(inaudible) The subxiphoid clip. The sub-xiphoid clip. Can you talk just about the different clip technologies?

Michael H. Carrel - *AtriCure, Inc. - CEO, President & Director*

Oh, the subxiphoid clip. Because we've talked about the different clip technologies. As I mentioned earlier, we have the V clip technology. As Dr. Gillinov alluded to earlier, it's a much less invasive technology, and we've got the PRO V clip that goes through the trocar, they can do that today. The FLEX V is actually for the open chest procedure, just to make it easier for them to put on, so they don't have to go back and in reaching, cut the sutures on it. It's also a smaller profile device. That same clip is likely put on to the subx. We've got lots of prototypes. We've been doing lots of animal testing on that, and we anticipate sometime next year that we will be actually rolling that out, probably in a very small setting at first because it is a very innovative technology. We want to make sure that we get it right. So next year we will mostly be focused on kind of getting it right, but that will be combined with the Convergent procedure. So we wouldn't expect any kind of big revenue ramp over the next 18 months. But if you start to look out at the end of next year and into the early year after, you will start to see that. That being said, what you heard from Dr. Gerdisch, we're starting to see a lot of, which is that you're starting to see places that are doing Convergent. Let's say, we need to manage the appendage, let's get this over with, let's take care of it, it's a 15-minute procedure, concomitant to the Convergent procedure and so we've seen a big uptick relative to that already as part of that. And in fact, one of the sites, Maimonides, who is part of the clinical trial, they're doing this on every patient. They've actually got 30 patients that they've enrolled in this and they see significantly better results when they actually manage it with the appendage at the same time.

David DeLurgio

Just briefly address what I heard in the last two questions was adoption and cadence of awareness, publications, et cetera, and how it usually works for something like, which we are having active discussions on this. We get safety data before we get final data, so we can report safety data when it's available. We also have sort of materials and methods or description of the study. It gives a lot of awareness. So there is a cadence of publication that we work on in terms of being -- also at the meetings with single-center data to sort of build the awareness in advance of the outcome of the ultimate trial, which will be published. So there is a strategy for building awareness. We're focused -- laser focused, of course, on the FDA approval.

That's really critical to the whole thing. In terms of how EPs embraces, this is a very EP kind of friendly type of procedure. It is dependent upon mapping, which is what we do and it's partially dependent on the endocardial ablation, which is what we do and it's not substantially different from what we would do during normal cases. So it is not a difficult step for the EP to embrace this and to start to look at the continuum and say which patients are candidates and which patients are not. And what you will find once you start doing them is that there are many candidates for it and it's really resulted as I try to show that graph of growth in our facility. It's been a pathway towards growth, in other words, expansion of indications, expansion of the eligible patient population.

Michael H. Carrel - *AtriCure, Inc. - CEO, President & Director*

All right. We will make this last question.

Frederick Allen Wise - *Stifel, Nicolaus & Company, Incorporated, Research Division - MD & Senior Equity Research Analyst*

(inaudible).

Michael H. Carrel - *AtriCure, Inc. - CEO, President & Director*

So the first is what are we doing to -- where do we need to add resources? We're pretty good on the overall, what I would call, we call them RSMs, which are our direct reps that cover the geographies and they're kind of like your, I don't want to call them general per se because they're very deep in the Afib space, but that group, we anticipate will add several per year, maybe a little bit more, but that -- we've got very, very good coverage on that. We've complemented that team quite substantially over the last several years. First and foremost is on the clinical side, where we now have a 1:1 ratio or very close to 1:1 ratio for clinical support for each and every one of those. We will continue to add aggressively to that to make sure we've got case coverage. It's really important for us to be in the OR to build those relationships. That team does a wonderful job with them. And so we will continue to add aggressively in that area. We will also add on the minimally invasive side, primarily people that have a lot of EP experience getting ourselves ready for the label expansion on the CONVERGE side as well. And so it will be an investment as we kind of bring them up to speed, get them to understand our technology and then bring what they've got on the EP front. In terms of gross margins, we're going to march along every single year. We will make improvements to this year as we talked about in our guidance, anticipate, again, improvements in the coming years ahead. So we're pretty darn close to getting ourselves to 75%.

Great. With that, again, I appreciate all the time. Again, a big thank you to our physician presenters today. And I look forward to talk to you guys on the next conference call at the end of July. Have a great one.
