THOMSON REUTERS STREETEVENTS

EDITED TRANSCRIPT

ELGX - Endologix Inc 2016 Investor Meeting

EVENT DATE/TIME: NOVEMBER 17, 2016 / 10:00PM GMT

THOMSON REUTERS

CORPORATE PARTICIPANTS

John McDermott *Endologix Inc. - President, CEO*

Matthew Thompson *Endologix Inc. - Incoming-Chief Medical Officer, St. George's University Vascular Surgeon*

Andrew Holden *Endologix Inc. - Clinical Investigator, Medical Advisory Board Member*

Sean Lyden *Cleveland Clinic - Department Chair, Vascular Surgery*

Vaseem Mahboob *Endologix Inc. - CFO*

CONFERENCE CALL PARTICIPANTS

Chris Pasquale *Guggenheim - Analyst*

Joanne Wuensch *BMO Capital Markets - Analyst*

Matthew Blackman *Stifel - Analyst*

Ravi Misra *Leerink Partners - Analyst*

Glenn Navarro *RTC - Analyst*

Andrew Hannover *JP Morgan - Analyst*

PRESENTATION

John McDermott *- Endologix Inc. - President, CEO*

All right. Well, good afternoon, everybody. Thank you very much for coming. My name is John McDermott; I'm the President and CEO of Endologix and I'd like to welcome everyone to our annual Investor Meeting.

It's a busy week for us. We have the VEITH Symposium, which is an annual meeting around this time every year. It turns out to be a very good time for us to have this session together with you because as has been in the past, we have a lot of great new data presentations and information to share as we had many, many presentations from the podium today, yesterday, a few more tomorrow. So it's a good time to give you an update. And also a good time for you to have an opportunity to interact with clinicians, which are really kind of the main event for tonight.

So we'll jump right into it here. Here are our Safe Harbor statements, which you can read at your leisure, by the way. What we're doing right now is simultaneously putting all of the presentations on the website, and then they will be available for you right after the meeting and there will be a transcript to follow here within the next few days, as well as the audio.

Here's the schedule. I'm going to provide a brief introduction here to the physician panelists, and then after we go through I'll come back up. So we'll have Matt Thompson, who is a vascular surgeon in Saint George's University in London. As many of you know already, Professor Thompson is joining us effective December 1st as our Chief Medical Officer. So he's also got more global implants than any other physician and is certainly well qualified to provide us with direction and insight moving forward, and you'll get a sense for that as Matt goes through his presentation.

Next, Andrew Holden. Andrew also has been an early pioneer in endovascular therapies, not just with us, but with many other companies and technologies, and also has a great experience with the Nellix device and other devices to treat complex aneurysms as well as traditional anatomies. And Andrew will give us an update today, this evening on his experience with ChEVAS, as well as review for you some of the ChEVAS clinical data results and how those data compare to other technologies and procedures to treat anatomies, as well as other applications for Nellix. So Nellix continues to be used for other indications as well.

And then last, Dr. Sean Lyden, who is the Chief of Vascular Surgery at the Cleveland Clinic. Dr. Lyden has been involved for many years now with the Ovation platform. He was involved in the early clinical work there and will also be the principal investigator for a new clinical study that we

plan here in 2017 with the Ovation Alto device. So Dr. Lyden will share with you and provide some perspectives on the Ovation platform; the current one as well as the new one. And then again I will come back up at the end and provide a company overview and kind of put all the pieces together, and then we'll move in to questions and answers.

With that I'm going to hand it over to Professor Thompson to talk about EVAS.

Matthew Thompson - *Endologix Inc. - Incoming-Chief Medical Officer, St. George's University Vascular Surgeon*

Good afternoon, everyone. So as John said, I'm delighted to be taking up the post of Chief Medical Officer from December. And John just asked me to say a couple of slides about me first so you'll know what you're dealing with.

And so, I trained in Leicester then moved to London in 2002. I've been the Professor of Surgery and Chief of Surgery there for the last 14 years. I've had quite a lot of experience in vascular surgery, and my practice is predominantly aortic. I reckon in counting up, I've done about 1,200 aortic procedures in my time.

Research wise, we're a pretty research-active department. We have about 400 peer reviewed publications and I sit on a couple of editorial boards. And recently I was chief editor for the Oxford Textbook of Vascular Surgery, which if you're looking to update your vascular knowledge, is a really good buy.

I am co-chair of the Chairing Cross Symposium and I've been a PI in several studies. And earlier this year we had a little political fallout between departments of Radiology and Vascular Surgery at my place and George's, which was in a bit of trouble. And actually at that time I had paused to consider what I was going to do in the future. And actually, I've been talking to Bob and John, actually, about wanting to get into the industry over the past three or four years and thought I might do that in a few years' time. But actually with Endologix' requirement for a fulltime rather than a part-time CMO, we decided that a move to California would be a good thing.

So in terms of being CMO, why would I go to Endologix? Well, from a physician's perspective they sort of have all the cool stuff in the aortic endovascular space at the moment. They have differentiated themselves from a standard bifurcated graft, and having this very broad portfolio of aortic grafts I think gives the opportunity for major innovation.

For me personally, it was very, very attractive to have the capacity to perhaps influence aortic therapy on a global rather than a national scale. And in terms of what I can bring, I think any firm probably does need to have access to a number of experienced clinical decision makers, and I hope I can fulfill part of that role. Clearly I see myself having a role and contributing to new products and implantation techniques as well as influencing the Medical Affairs Division. And finally, I think as we move on to my presentation today, clearly being to disseminate clinical lessons in a rapid pace is important.

So Nellix; this has been a journey and it's really been a journey of introducing and influencing new therapy rather than a product. So right at the start I think none of us realized quite how different EVAS was going to be to EVAR as we started this journey. It was certainly unknown territory, but the technology is of course potentially disruptive.

I think we've learned over the past few years with a number of clinical trials that actually you can't really mimic all clinical conditions that you put endografts into by pre-clinical data, and therefore, the introduction of any new technology is going to face some unexpected challenges, and I will talk some of those late challenges a little later on in the presentation. But what I would stress early on, however, is that EVAS is very new but it has realized quite a significant number of the expectations that we've had of that therapy.

We've had to evolve the technical aspects of the implant procedure from 2013 onwards, and I think that Andrew would probably agree with me when I say that we're probably just now getting a good implant procedure. And so, I think we have to look at the results in that context. All endo-vascular grafts are going to have a late failure mode and we're starting to see now on the imaging predominantly some of the late failure modes of EVAS, which I will touch on later. And one of the key aspects of this presentation will be to try and define the sweet spot of Nellix where it's going to have exceptional clinical results, better than anything else that we see in this space.

So going to the good stuff where the device and the technology has realized expectations; Nellix was designed and innovated to try and reduce Type 2 endoleaks, to actively manage the aneurysm sac, fill the sac with polymer and actually stop Type 2 endoleaks. And actually if you look at the results today of both the IDE Study and the Global Registry, you will see that Type 2 endoleaks, and therefore, the rates of virtually total endoleaks has been significantly reduced by the Nellix implant.

I think I have to remember the KM curves, and basically what you are seeing here is about a 4% absolute incident and delete rate. And in terms of persistent Type 2 endoleaks with the Nellix device, you are seeing 1% to 2%,; and that's really out of the boundary of what we see with conventional EVAS.

I'm desperately hoping the slides will come back on -- there we go, okay, so how do I do it? Naturally, I undersold it. So, less than 1% persistent endoleak rate and 3% incident endoleak. So this is a paradigm shift, really, that we're seeing here, are very low rates of endoleak using active sac management.

One of the things that also became apparent in our early Nellix experience was that by actively managing the aneurysm sac it looked as if you were changing the biological response to endovascular aortic repair using a traditional bifurcated graft. So by filling the sac with polymer, you're not relying on the thrombosis to stabilize the sac, you should see a reduced amount of biologic activity because the thrombus in the sac is not active and that translates to no ongoing systemic inflammation and possibly some implication on overall cardiovascular mortality.

So these are new data that we're seeing, really, for the first time in the VEITH Symposium; the two figures on your right hand side. So the top study measures the biologic response to having your aorta fixed. So clinically when you see someone after an endovascular aneurysm repair, they are pretty sick the day after. They look like they've got flu, they've got a high temperature, they're tachycardic, they feel sweaty. And that's because they've got a big ball of thrombus in their aorta.

With EVAS that goes away. And what you're seeing here is the percentage of patients who have post-implant syndrome in that top table, decreasing from 21% to just under 5%. So this is a lot less of patients feeling sick afterwards and that is manifest in their systemic markers of inflammation, c-reactive protein and their white cell count going down. So this is really interesting the first time we see something like this in endovascular therapy.

The bottom graph is actually data from [Kate Stenson], who is my research fellow, who showed the same thing, this decrease in post-implant syndrome. So that's great because it means people feel less ill immediately after their procedure, but it doesn't translate into anything else.

Well, if you look at the coronary literature there's pretty much this theory that patients who have had ongoing systemic inflammation are more prone to cardiovascular mortality particularly stroke and heart attacks. And I know that we've presented this to you before. We continue to see an ongoing signal in the Global Registry where the all-cause mortality is significantly less, is significantly less than in a similarly matched population, for example using the Medtronic Endurant Study.

So if you look at all-cause mortality through two years with EVAS we're seeing freedom from that, about 89% compared to 85% in the ENGAGE Registry. And the astonishing thing is the lack of cardiovascular mortality associated with EVAS in the EVAS Forward Registry. So you can see that, the graph on your right-hand side showing a 1% cardiovascular mortality through two years.

If you want a comparator for that, most patients post-aneurysm repair have an all-cause mortality in the region of 7% per year, so you should see 14% all-cause mortality, half of that should be cardiovascular. So we continue to see these interesting signals.

What else is good? Well, there is no neck dilatation after EVAS and this is important. So these are studies from [Janis Savlovskis] who's looked at neck dilatation following implantation of the Endurant endograft and the Nellix graft. You can see that's a flat line. There's no neck dilatation and that's probably going to be important in terms of long-term results.

If we look at EVAR results about four of the patients get neck dilatation and in those patients there's approximately a 25% incidence of clinical events.

Finally and away from the theory this is what I think we all see in practice. So if you are around a big aortic unit EVAS is pretty much essentially a neuro-aortic therapy because it has these niche applications, as well as applications to the more general population. It's very good at treating iliac aneurysms. It's extremely useful at treating patients who have an EVAR failure particularly Type 3 failure where actually the conventional revision is quite hard because the [flow divider] is high up in the aneurysm and it's difficult to manipulate your graft around that.

Andrew will talk later on about the role of EVAS in complex aneurysms and complex revisions. But these are really assuming a hard part of the [armamentarium] at the moment.

So [those were] the good stuff. There was quite a lot of stuff that we learned as well in our journey learning how to implant EVAS and I'm just going to go through a few of those.

The evolution in our implantation procedure actually has been astonishing. This implant procedure has changed very considerably over the last three years and we expect to see better clinical results because of that.

I think none of us realized quite how different EVAS was conceptually to EVAR and it's taken us a little while to learn those lessons. The procedure has been iterated considerably over three years in terms of where we place the graft, in terms of how we manufacture the lumens and how we create effective seal. But we're now seeing the results of this.

This graph just shows you patients who had a [lymph] thrombosis in terms of their stent time as compared to those who didn't have stent thrombosis. One of the issues with Nellix is you actually need to manufacture your lumen with a balloon expandable stent. And if you don't do that sufficiently you will get lymph thrombosis.

There's also some objective evidence that Andrew actually showed in his podium presentation this morning that shows that we are doing the procedure better. If you look at these two graphs they represent the percentage of available neck that was utilized by the implant procedure and comparing the Global Registry which was early on to the IDE, which was later when we learned some lessons in implantation. And we're getting to use a lot more neck in the latter procedures.

I think also when we started off we were probably unrealistic about what we expected EVAS to do, and this has been captured very nicely in this commentary by Sebastian Zerwes who said, "The sealing the entire aneurysm idea quite simply represents a very seductive concept that seems to lure the vascular surgeon beyond the IFU."

And I think we were all guilty of this, of treating patients that we wouldn't have touched with a traditional endovascular graft and thinking that just sealing the aneurysm was going to be enough. And that's clearly not the place.

We now know that we have to have realistic patient selection. We have to place our stents precisely. We've got to get a very good filling of the endo-bag and probably most importantly need to have an adequate proximal and distal seal on a parallel sided artery to get good results. And again, there's some objective evidence to say that this is important.

These are, again, data from the EVAS Forward Registry looking at the effect of the instructions for use and application of instructions for use to outcomes. And you can see here when looking at Type1 endoleak or re-interventions there is a significant delta between the outcomes that you get when you place the graft within the IFU as opposed to outside IFU.

So now to go on to late failure modes, it's a little early to be talking about late failure but we are seeing some signals that I want to discuss today. I think it's inevitable given the physiological stresses that the body puts on endografts, that we're going to see late failure in all medical devices but particularly in the aortic region.

If we look back, it probably took us 20 years-plus to define the late failure modes for EVAR. And undoubtedly EVAS itself is going to have late failure modes.

The challenge I think for us within the physician community and industry is to understand the late failure modes of EVAS, probably a lot earlier than we did for EVAR. And I think we can do that by leveraging clinical data allied to high resolution imaging.

This is the failure mode that has become most apparent with Nellix at the moment. Predominantly just looking at [CC] evidence but the occasional clinical signal, and this is device migration. But I think we all started to see approximately two years after implant of the grafts.

So Endologix has done a lot of work now to try and understand stent migration, and there's a number of factors that play a role. So how good your seal zone is in the proximal neck, how stiff the graft is which in turn is defined by how much polymer you get around the graft. But actually in addition to that the thrombus within the aneurysm seems to play a role as well. So the larger the thrombus burden, the bigger the aneurysm curvature, the more room there is for the stent to migrate laterally in the aneurysm and therefore migrate down.

So this is Roy Greenberg who is really one of the pioneers of endovascular therapy. And his mantra right from the very earliest stage of EVAR was to fit the patient to the endograft and not the endograft to the patient. And I think when we talk about late failure modes this is important because what we need to do is find the sweet spot for each individual graft and give the patient the best implant that we can.

And we do that by understanding the anatomical and morphological features that are associated with failure modes using statistical methodology to define the associated risk factors and the Alto ratios. And by doing that you can easily describe a subset of patients that have excellent outcomes and therefore it's pretty straightforward to change the IFU.

And what we're describing here is essentially personalized medicine, not saying that you've got one endograft and you must [scrunch] that into every patient, but actually saying for this patient's anatomy this is the best graft for you.

So what I want to do now is just show you the revised IFU and I know some of you have seen this already, but I then want to discuss how we approach an IFU that may be more complex than traditional.

So if you refine the IFU for Nellix based on the studies predominantly leveraged from the IDE data, you'll see better outcomes if you reduce the proximal neck diameter to 28 millimeters and stop implanting Nellix in essential aneurismal tissue.

We also want to see a change in the consistency of the neck from 20 down to the more traditional 10% and we've specified an iliac seal zone. But probably the most important change is that there is some IFU adherence to the aneurysm itself. And I think you'd expect that with Nellix because Nellix is sealing with inside the aneurysm and therefore the morphological features of the lumen and the aneurysm sac are going to be key.

So we see here this particular ratio, you will get better results if the aneurysm diameter over the lumen diameter is less than 1.4, that's relatively simple, but it does take quite a number of patients out of the IFU for Nellix.

If you have the more complex algorithm which is the one described as 4A down on the bottom right of your slide you get as good clinical results but you can treat an awful lot more patients. And essentially what this algorithm is saying is that if you've got a nice neck in terms of aortic diameter and you've not got a particularly angulated aorta then you can be much more relaxed about the ratio between your aneurysm sac and lumen.

And the question is I think for us as a physician community whether we can cope with that sort of complex IFU.

So a question to you all if this was a choice would you have the top aneurysm in your tummy or the bottom aneurysm in terms of endovascular treatment?

Well for me looking at that as a physician I'd have the bottom one but actually the bottom one if off IFU on angulation. The top one is on IFU. And the problem with IFU is it's traditionally being described for the last 20 years is that it's binary in terms of neck diameter, neck length, angulation and iliac diameter.

But actually it's clinicians, we don't really utilize the IFU as a binary structure, we integrate the various anatomical parameters and give ourselves an estimation of outcome. And actually the complex algorithm that I described earlier with regard to the ratio neck diameter and neck angle is a complex algorithm that's much attuned to modern practice.

We use these algorithms all the time to estimate GFR and to give people estimates of their outcome for [hits]. So I think this is an opportunity with this more complex analysis to set this new standard of care as to how we might manage IFUs. And it's pretty easy to see that you could incorporate this sort of equation into a relatively simple iPhone app where you input parameters.

You can assess whether the patient is on or off IFU, and probably more importantly give the physician and the patient quite a clear estimate with confidence in towards around their predicted outcomes. And you could do that for patients on IFU, patients who are slightly equivocal for the device or patients who we wouldn't recommend.

So what would happen if we change the IFU for Nellix and use the algorithm? Well this is the key Kaplan-Meier Curve. And you can see if we apply the new IFU or the algorithmic version of the IFU the outcomes are excellent.

So if you are outside the refined IFU you will have a composite outcome when looking at freedom from migrations and sac enlargement of endoleaks of around 19%, whereas if you are on either the old or the algorithmic IFU your results are excellent with a failure mode of less than 4%. And that's quite frankly not in the realm of what we see with EVAR.

If you look at a comparative estimate at two years for EVAR you will usually see a prevalence of sac expansion Type 1 endoleak and migration above 10%.

So my last slide, where is the future of EVAS and what's the next generation? Well, I think the bits of EVAS that have worked are so significant that I find it very difficult to believe that any evolution of endovascular surgery for aortic disease would not include a device that actively manages the aneurysm sac, due to the low Type 2 endoleak rate, the modification of biologic response and the absence of neck dilatation.

It would appear to me also that as a clinical tool EVAS is essentially essential for contemporary clinical practice. And I think with this new type of algorithm we're sort of moving into the modern generation and the use of Smartphones and apps for accessing everyday clinical information. And I think this has the potential to set a new standard of care.

In terms of what's the future it's clear that Endologix has a broad technological portfolio and one would want to leverage that to introduce new technologies for both the abdominal and thoracic aorta.

And with that I will sit down. Thank you very much.

Andrew Holden - *Endologix Inc. - Clinical Investigator, Medical Advisory Board Member*

Great. Thanks, Matt. I guess I'm just going to forward on, yes I am. So as John mentioned I'm going to sort of dovetail in with that message and look at some specific applications of Nellix, EVAS in complex aneurysm anatomy. Here's my disclosures, as an advisor by to Nellix.

Now just to put this in perspective we bandy around figures but generally 40% of aneurysms, 36% of aneurysms we can't treat within IFU because they are complex in the visceral segment. But what we're really talking about in the content of Chimney Nellix or ChEVAS is this group of patients, the patients who have either a short or no-neck up the renal arteries, but essentially have normal anatomy above that.

And you can see this represents at least the 20%, 20% to 25% extra opportunity to treat abdominal aortic aneurysm disease.

You will have heard of this terminology "hostile necks", so this is this group of patients who have a normal aortic above the renal arteries but they either have a very short neck, a wide neck, an angulated neck or that neck is complicated by calcium and thrombus, or has a conical shape, that conicity term.

And we know that if -- and Matt just mentioned how high the incidence of sac enlargement is after the conventional EVAR it's even higher if we treat patients outside of IFU, roughly half the patients who we're basically treating prophylactically to prevent sac expansion end up with sac expansion after conventional EVAR if they have a hostile neck.

We also know that conventional EVAR now is not a way to treat patients with hostile neck anatomy. You can see they pay a price. They have a much, much higher rate of re-intervention and they have a much, much higher rate of morbidity. Unfortunately they not only have the higher rate of morbidity they have a right rate of the lethal Type 1A endoleak and a four-fold increase in aneurysm-related mortality.

So what are the options to manage these patients who have a good aorta above the renal arteries but a hostile neck below it?

While they include open surgical repair, they also include fenestrated EVAR and Chimney EVAR. And I want to just briefly discuss those and put them in context relative to this new approach of Chimney EVAS, because essentially all of those techniques try to do the same thing.

We are used to EVAR sealing into the infra-renal neck, and we decide whether that's a good neck, a long neck, a dilated neck. But essentially with these fenestrated and Chimney techniques we're ignoring the infra-renal neck, we're paying attention to the infra-SMA neck. And we know that biologically and statistically that is generally a much healthier segment than the infra-renal neck, particularly in patients who have abdominal aortic aneurysm disease.

So let's talk about fenestrated EVAR, really, that has had the longest history and it has an advantage and that in the U.S. both the aortic endograft and visceral grafts are on label and approved for use.

There's long experiences with John Anderson who is in Adelaide, Australia and a vascular surgeon, or that he was, the late John Anderson. And I was lucky enough to be in the operating room with John when this first fenestrated EVAR procedure was performed in 1998.

There are advantages of fenestrated EVAR in that you can deliver this device from the groin, so there's no need for an upper limb access with the associated risks of stroke.

Overall we now have a lot of data about fenestrated EVAR and hostile neck anatomy and we have an acceptable 30 day mortality, considerably lower than open repair. And then also an acceptable high-pressure endoleak rate, the Type 1 and Type 3 endoleak rate of somewhere around 3% to 5%.

We also know that we need to get long-term patency of the branches. Actually that's a little more challenging than we'd like to admit. But we generally in the literature are achieving long-term branch patency of somewhere between 85% and 95%.

But fenestrated EVAR has some real limitations. These are our big access devices so we need adequate iliac artery caliber and [tortuous] or small caliber iliacs are a real problem.

We're trying to deliver a graft with fenestrations through the aorta and we need some space to do that. So narrow caliber or very angulated infra-renal necks are particularly challenging.

These devices currently have to be customized and that introduces a significant delay and that's obviously a problem for symptomatic aneurysms or patients who are concerned about that operative delay.

There have been attempts to manufacture off-the-shelf devices as we know and that's proved far more problematic in terms of long-term durability than we had expected. And unfortunately still now there is a turn-down rate for fenestrated EVAR of at least 50%.

So an alternative is to perform Chimney EVAR, ChEVAS or CHIMPS. And this involves placing parallel grafts into visceral arteries and then using this infra-SMA segment to seal. It's obviously a real advantage in that you can perform this procedure using conventional EVAR devices and conventional visceral usually balloon expandable or self-expanding covered stents.

We need to oversight the EVAR device much more than we normally do to allow channels for the parallel grafts. And really, we don't have any high level evidence about how Chimney EVAR performs, but this evidence is a multi-center registry that we can with just over 500 patients.

Once again, ChEVAS does have some limitations, and the two major limitations are the upper limb access with the associated risk of stroke, but they had even more importantly is this problem that we are creating gutters around the parallel grafts and this gutter Type 1A endoleak rate which is being reported, as you can see in the Pericles Registry at about 6% long-term Type 1A endoleak, these high-pressure endoleaks that we have, a real concern are associated with sac growth and rupture.

So here is an interesting algorithm that's being developed. This is really an algorithm that represents the current thinking I believe in where we have these technologies and how we manage hostile neck anatomy. So if a patient who has a hostile neck is put to surgery and they're young we should consider open repair. If they have a degree of -- they're asymptomatic, so there's no real urgency and their anatomy is suitable in terms of access, then we should consider fenestrated EVAR because of the level of evidence behind it. But if that is not the case then parallel graft technology ChEVAS should be considered, or perhaps we should be considering a new endovascular device, and one of those is Chimney EVAS.

And it's long had appeal to us when we started involved in Nellix. One of the early things we felt was this very compliant endo-vac sealing wasn't actually an ideal way to manage parallel grafts and reduce the incidents or remove the incidents of Type 1A gutter endoleaks. And we can preserve all the other advantages of ChEVAS in terms of immediate access and off-the-shelf devices.

And I was really fascinated with this, and this is the first multiple parallel graft that ChEVAS case performed in the world in March 2013. And here you can see the [Time Beam] CT we performed at the end of the procedure and the aneurysm looked beautifully sealed and all the visceral arteries looked to be fine.

And he's returned here and he's doing fine in April 2016 three years later. And we've been very happy with him and he's very happy with his outcome.

Now you heard just from Matt that there are some issues with regard to migration and a subset of patients who have been treated with Nellix. But migration is highly unlikely to be as much of a problem, not a problem at all for Chimney EVAS because we are sealing into a longer and a much healthier segment of vessels. I explained the infra-SMA segment.

And there are a couple of other reasons why there will be reduced migration, particularly because the proximal shelf cross-sectional area which does produce a downward distraction force is significantly reduced as you can see with ChEVAS than with EVAS.

We are looking to get a bigger group of patients from the ASCEND Registry that I will dive into shortly to really understand this a little bit better. But I took the opportunity to review outpatients who had had at least six months follow-up, up to 36 months follow-up to try and assess migration.

And you can see only one patient had migration of more than 5 millimeters. And actually this was a single Chimney patient where we really hadn't sealed anywhere the infra-SMA segment, would really seal into a disease infra-renal segment. So by and large migration seems to be not a problem with Chimney EVAS which is very pleasing.

We're really trying to analyze how Chimney EVAS will perform. A lot of work has been done including in vitro gutter endoleak analysis and actually Jan Blankensteijn and his group in Amsterdam have recently repeated this study with a very compliant model and essentially found, as you can see, in terms of the gutter areas that the gutter areas with ChEVAS are minimal. And in terms of translating into visible endoleaks, this is essentially he has not been able to produce endoleaks in the latest model which is a significant difference to ChEVAR where the endoleaks are always demonstrated.

We've done some interesting work in Auckland looking at the effects of cardiac and respiratory motion. You can see that movie playing is basically running through cardiac cycle. On the left image, you can see the impact of respiration and not surprising in the renal arteries move considerably during inspiration and expiration. But the reconstruction, the ChEVAS reconstruction is very stable and likewise there's very minimal movement of the implant during phases of the cardiac cycle.

So, certainly, our early experience has been excellent and we've seen no markers of any clinical concern in our early experience to date. So, we wanted to try and assist the outcome of this new technique and trying to let some of the international experience and this was done with the post-market registry that Matt and I co-PI'd, the ASCEND registry, an open label single arm, obviously, no prospect of screening and this was made up of 187 patients. And we're going to focus on the 154 patients who were treated primarily for hostile neck infrarenal aneurysms.

In terms of this 154 actually you can see these patients had a range of a number of parallel grafts. The single, and double, and triple parallel grafts were really the group, the majority of those had juxta renal aneurysms. That small group of quadruples probably were patients who had much more extensive aneurysm disease.

In terms of the patient demographics, you know, a significant number of these patients had chronic respiratory disease and also, these aneurysms were, juxta renal aneurysms tend to be advanced disease. So, they're all big aneurysms.

I think this is an interesting slide. Now, I think if we repeated the ASCEND registry now, we'd see a different practice because as you can see, if you only use one parallel graft then the seal zone you're achieving is much less than if you actually are putting parallel grafts in both renal arteries and sealing right up to the base of the SMA. So, in fact, the vast majority of more recent ChEVAS procedures has involved at least double grafts, parallel grafts to optimize that infra-SMA segment.

Procedural outcomes are really understandable. You can see that the more parallel grafts, you had this much higher blood loss with triple and quadruple parallel grafts. Having done these cases, that's not surprising. We do this with an axillary artery open access. And if you're putting more and more parallel excess sheets then blood loss could be a problem. So, really, I think we would think very carefully before we started to plan a quadruple ChEVAS. This really has a role to these juxta renal aneurysms with two vessel Chimneys or occasionally a third Chimney for the SMA.

How we performed in a study and I think as was mentioned just like the global registry, the ASCEND registry was very early in the learning curve, but you can see there was still a highly acceptable early endoleak rate. And in terms of a persistent endoleak rate, you can see that there's been a tremendous result, the typical low incidence of Type II and absence of Type II endoleak and a low incidence of this Type I endoleak.

Very, very pleasing target vessel patency and certainly in Chimney EVAR, this is a problem that requires significant re-intervention. But certainly the target vessel patency has been pleasing in the ASCEND registry. And largely, the secondary intervention has been driven around this renal artery patency. And so, I think we need to certainly pay some attention to our techniques and we're still some way through the learning curve in terms of what the optimum ChEVAS procedure looks like.

Once again, it's got a similar finding of a very low all-cause in aneurysm related mortality, the same kind of sign that we saw in the global registry and we're certainly watching this space. These patients typically what you would expect have higher cardiovascular mortality with these more advanced aneurysms and yet their all-cause mortality is very acceptable.

I've tried to do a comparison in terms of comparing ASCEND to ChEVAR and FEVAR data. I think this kind of a retrospective analysis is probably not particularly meaningful, but we can say that the stroke rate is similar to ChEVAR and you'd expect that because both of those have upper limb. Of course, Nellix has a dramatically decreased incidence or an absence completely of Type II endoleak, a very interesting absence of persistent Type I endoleak and a highly pleasing target vessel patency. And in the context of really the learning curve of this space, I think these figures are very pleasing.

Now, as Matt mentioned, we've also got an increasing indication of EVAS or EVAR revision and Matt showed some of these images. It's true that particularly this has an application for Type III endoleaks, repairing grafts for the short body with two tubes is quick and easy and highly effective. But also, we're using ChEVAS for repairing Type I endoleaks in addition.

And I've had experience with using Nellix, again, failing surgical grafts. So, here's bifurcated surgical graft with a Type Ia endoleak at a proximal graft anastomosis. You could not put an EVAR device in there because the body of that graph is just too short, but it's actually a very simple endovascular repair with Nellix.

So, Matt showed and went through and spent some time with this altered IFU and I just want to give my perspective on this. I mean, this altered IFU really is something that we have arrived at over the last year or so. And I'll show you what's the impact of that on our practice at Auckland, but essentially, what -- by appearing to this IFU in patients who have infrarenal abdominal aneurysms, we cannot only achieve good results. These kinds of results, to put this in perspective is way above any other device in terms of migration, Type Ia endoleak and sac expansion. I would say they would be less than 90% at two years with any other device.

If you're thinking about aneurysms that are on IFU and you could use anything, what would make one want to use Nellix? Well, apart from the strong point of the active sac management which I can't emphasize enough, there are certain anatomies that indisputably one should be considering Nellix over any other EVAR device on IFU.

Obviously, the aneurysm that have very large aortic branches, the aneurysms who have concomitant cardiac artery disease, either concomitant cardiac artery aneurysms or short iliac arteries as we see frequently in the Asian population and we have a significant number of those in Auckland and this has been a particularly useful tool for patients with iliac aneurysms as well.

And as Matt implied, really in a busy aortic practice, this concept of using active sac management in compliant end bag sealing is really a vital tool. Not only does it allow us to perform ChEVAS for patients who have hostile neck anatomy, but it allows us to use this application and really leave it to the imagination of the interventionalist to come up with ideas and solutions. The image that you can see under the "other application" is one I did for a patient who had severe and extensive aorta cardiac aneurysm disease.

The use of parallel grafts to preserve internal iliac flow as well as treating the aneurysm is something we couldn't have done with any other device. And as Matt mentioned, the future is really exciting in other territories.

Finally, I just want to touch on a little window I think. We're lucky in Auckland because we've had this experience with Nellix and we can get any other technology. We're lucky in Auckland to, I guess, give you a little window into practice a couple of years ahead of time based on the information that we have had.

So, I just want to show you for example in 2012, you can see our total utilization for a treatment of all abdominal aortic aneurysms. Around two-thirds of them were conventional EVAR and 20% were fenestrated and Chimney EVAR. And we were just getting underway with our EVAS experience with the commercial device. And in 2012, I hadn't performed ChEVAS.

Go forward to 2013 and 2014, and we were busily enrolling in the global registry and we were pretty excited about the capabilities of EVAS. We certainly hadn't seen any of these midterm complications. So, you can see suddenly now it's occupying 50% of our utilization. And we're still performing fenestrated EVAR. But what's happened is we started to get ChEVAS in there into our hands and we've started to build up some exciting experience.

And then, after we'd seen some of those issues that we needed to be careful about patient selection with ChEVAS or with EVAS, we did that, so that by restricting our IFU, what we're now doing is around about 40% of all the aneurysm cases we see are on IFU for anything. They're great Nellix cases, particularly the ones that have big branch -- excuse, branch arteries and iliac aneurysms. So, we're using EVAS in about 40% of all aneurysms.

But you can see what's died is our use of FEVAR, for hostile neck anatomy and what's risen suddenly is their use of ChEVAS which is our go-to-technique for hostile neck anatomy. And you can see that overall, therefore, we're still using about half our cases. We're using active sac management with Nellix. It's just that the mix has changed in a higher percentage of our ChEVAS patients.

So, ChEVAS now has an established and important role in endovascular aortic therapy. We've got some very thorough preclinical and clinical assessment and we've got some excellent early results for ASCEND especially given that that trial was performed or that registry was performed early in the learning curve of this application.

And you can see in our institution, we can still use this combination of treatments to manage 50% to 60% of all our abdominal aortic anatomies and we're looking forward to an ASCEND IDE registry in due time.

Thanks very much.

Sean Lyden - *Cleveland Clinic - Department Chair, Vascular Surgery*

So, I'm going to change topic a little bit and talk about Ovation. First, it's always relevant to -- but, you know, I always have complex and disclosures are always important.

So, the Ovation platform, I've been involved in using it since the original pivotal trial and it's a unique device. It's 14-French outer diameter. That 14-French outer diameter, when it came out in the U.S.ID trial was the lowest profile available on the market and it still is now five years later with the presentation of the five-year data.

It is a trimodular device and one of the unique aspects of this device is it uses a polymer to create an active sealing in the aortic neck and with the staged deployment, the accuracy of landing it within the aortic neck is really remarkable.

In the Cleveland Clinic, we trained a lot of trainees. We have five trainees a year. We have more than anybody and I say that the part of being in a training institution is relearning how to do it correctly as well as avoiding mistakes. So, I think the accuracy and to be able to place this device is actually one of the things that I actually enjoy.

It also is one of the most flexible limbs on the market and that's really -- when we talk about some of the data, it's borne out in the excellent patency within those limbs. And I think one of the unique aspects of this technology is that when the palmer is put in, it's put in with inside of the patient and so, it reduces the packing density. It allows it to be a much lower profile, but it allows it to conform to a really irregular neck anatomies whether it's calcium, whether it's thrombus, whether it's reversed tapered neck. And it uses typically an O-ring field to basically achieve that seal. And then, the other thing that affords, it takes the pressure off the aortic neck.

And so, this is first shows up the low profile, and so you can see that the inner diameter is 12-French. I always look at the outer diameter. It's the actual hole you put in the blood vessels and everybody else is much, much higher. So, there's a huge difference in doing this. This is the first device that within U.S. pivotal trial, because of how small it was, people adopted using percutaneous access before it was really so well adopted within the United States and actually we came up a label for that and also demonstrating how highly flexible those iliac limbs are and really with that being to accommodate really different tortuous anatomy.

So, we can see here some cases from many of the investors within the trial, some from Germany, some from the original sites in Santiago, Chile, and then, from Manish Mehta who was the principal investor for the IDE trial. You could see that it's treated some of the smallest access vessels of any other trial. You can see some of the tortuous iliacs and the narrow distal aorta. And I would tell you as an investigator who participated in every U.S.ID trial for every FDA-approved device, these cases would have been rejected from every other trial there was.

And I think the key thing is that the Ovation platform has a long and robust history, first, the global pivotal IDE with 36 centers. It was actually the first trial to have an outside the U.S. design. So, we had sites from both Chile, Germany, and the U.S. And like I said, we just presented here at VEITH the five-year results. It's gone on to have a European Union post-market registry. It's then gone on at sort of fast-tracking patients, so not using general anesthetic, using percutaneous access, just trying to get patients out of the hospital.

The other unique thing about aneurysms that it comes about four-to-one men-in-women and if you look in all of the trials that have led to approval within the United States, because of the large access diameters needed to treat the patients, most of the trials are six-to-eight-to-one male-to-female. And so, the Company has actually gone on it and did a study, randomizing two-to-one in 45 centers, looking specifically at a gender-specific trial, looking at the therapy in women.

In most reported trials from the other devices you looked at, women typically do not have the same outcome that men do due to both challenges in their proximal neck as well as their iliac arteries. And so, if you look at it, there's been about 10,000 worldwide implants, but almost 1-in-10 or 1,000 of those have been part of a controlled or real world registry. And then, we hope to begin the next platform, the Ovation Alto in 2017.

So, we look at -- here's one of the things when I was part of the trial. We had a lot of commercial devices and I said like many of the investors saying, "Why would I use this?" And to me, the first thing that jumped out of me was, "Well, I had women who I couldn't treat with any other commercial device." So, I started putting some of my female patients in the trial and realize pretty quickly how easy the device was to use and then quickly started putting all of my patients that qualified in the trial.

The FDA typically had defined an aortic neck as the diameter at the lowest renal artery and when that diameter changes by 10%. And so, the [on-label] on most device had needed 15-millimeter neck length. And so, when you talk about neck length, that's how the Society for Vascular Surgery and the FDA have defined it.

However, this device was very novel and unique and it really pose quite a conundrum to the FDA. Because the palmer ring occurs 13 millimeters below the lowest renal artery, if you could have a 16 and 13-millimeter diameter on label, you could treat it. And so, it really didn't apply to what the natural SVS definition was, and so it really allowed treating patients that would have been outside of the IFU for the other devices.

And so, if you look at that, in this trial, the Ovation pivotal trial with now five-year results, because of the small diameter of the device, we had access vessel patients that would have been excluded from other trials. We had patients that had short neck lengths. We had patients with conical necks and we had patients at both criteria. And so, 40% of the patients in this trial had criteria they would have been excluded from every other trial done to date.

So, if you look at the five-year results, I think it's amazingly impressive if you look at major adverse events. It was through day 365, only 3.8%, but what do the patients care about? What do you want to tell your patients? And they want to know how reliable is my device, how durable is my device. You can see ruptures through five years, 1%; conversions through five years, 0%; and Type I and Type III endoleaks through five years, 0%; the device migrating, 0%; limb occlusions through five years, 2.5% -- some of the most impressive data ever presented and it really speaks to the outstanding durability of this platform.

So, if you look at aneurism- related mortality or all-cause mortality as we talked about before, what do the patients, what can you tell them? You say, "Well, if you have this device implanted, 98% of you are going to be fine through five years." There recently was a study presented from the Medicare database that said through five years, 8% of patients being treated in the United States with endovascular repair will eventually have to have their device removed, so, clearly, totally different than what we see from the Medicare population.

So, how did that really translate to Type Ia endoleaks? So, endoleak at the proximal seal zone, so, really catastrophic failure of the device during the initial procedure, adjunctive [panasas] 3.1% of the times or 5 out of 161 patients and that's translated from a freedom for five-year re-intervention for Type I endoleak in 96.6% of the patients. And so, overall, if you look at all aneurysm related renal interventions, it was 84.2% at five years for the U.S. registry and 81.2% for the global patients.

And I think that's really important in my opinion. I know at the Cleveland Clinic, we're now pressured to become an accountable care organization. We're going to be accountable for these patients' lives for a longer period of time and really, how often we have to go back and re-intervene upon them. We're going to be held accountable for this time period. And so, I think if you have a device that has lower intervention rate, that's going to be clearly something that's going to affect your decisions moving forward.

So, I think one of the things is does the neck grow. And from our earlier experience with balloon expandable devices, one of the unique things we saw and we were concerned about is what's going to happen to the aortic neck if you put a balloon expandable stent graft in, one of the things we saw was the neck didn't dilate. Whereas, if we put a self-expanding stent graft in, they tend to have over-sizing of 15% to 20% and typically, those necks go ahead and dilate. And within two years, it's been my experience, most of the devices I've put in with self-expanding devices go to within a millimeter of the size we put them to. And that, as you can see from systemic reviews are associated with a lot of adverse clinical events.

The unique thing of the sealing ring, it takes the pressure off the aortic wall in exactly the same mechanism that balloon expandable stent does and you can see that it depressurizes the aortic wall and it doesn't grow. The core lab that independently adjudicates the aortic neck diameter in the study, you can see that here, for this Ovation system through five years, 0.1% neck growth.

So, when you put a device in, the concern is what's that neck going to do over time. I think if you heard any of the presentations at the VEITH meeting, anybody who's talking about aortic disease, if you hear Matt's talk, if you hear Andrew's talk, we talk about being able to put a device in the part of the aorta that's going to be stable over time. But I think the device probably does have some influence on it and being abve to de-pressurize that neck clearly has an influence in this device has stability in neck diameters through five years.

Why is that? I think it's the unique polymer design and the fact that you have actually created a seal and depressurized that system, when people have done finite element analysis, there's clearly a very big different change between a self-expanding device and this device when you look at the pressure on the wall.

We clearly know that women are an underserved population. We hear our government and the FDA say all the time that we need more gender specific studies and aneurysm is not a gender neutral disease as we talked about, four-to-one men-to-women for infra-abdominal aortic aneurysms. Particularly, women have had adverse outcomes when it looks at open repair or endovascular repair and that's because they tend to have shorter necks or inadequate neck length to be treated on IFU for endovascular devices. They tend to have narrow access vessels.

So, if you look at 21% of the aneurysms in the United States are women, but yet, in the IDE trials that have enrolled for endovascular aneurysm repair, it's only 6% to 15% of the patients enrolled are women. And those outcomes as I said have been uniformly worse. This is the project looking at the risk of human aortic anatomy. In terms of men with women, you can see there's clearly quite a difference.

So, we look at those EVAR outcomes over time, the percent of in-hospital deaths with EVARs, men versus women, you can see there's clearly a divergence of those two curves and clearly not the same. As I talked about, this company has a continued commitment to understanding both the disease and the therapy. And so, the LUCY trial the principal investigator is Dr. Jennifer Ash, it's going to enroll 225 patients, 75 females in the treatment arm and 150 males in the control arm. But the primary endpoint being adverse events at 30 days and will have 30-day and one year follow up and we're eager to have those presented at the Society for Vascular Surgery National Meeting this coming summer.

Lastly, what we talked is the least invasive or LIFE registry like EVAR registry. It really is to look at the clinical benefit and costs associated with having a low profile system and performed under conditions that this device allows. So, with bigger devices, typically, you may have a higher incident of doing cut downs. Patients certainly are not going to tolerate longer procedure times. They're not going to tolerate percutaneous access.

So, in this registry, there are patients who are treated percutaneously, no general anesthetic. They're not admitted to the ICU and discharged the next day. One of the amazing thing that came out of this as we look, there's no major procedure related, no device or procedure related adverse major events, and that's typically different than the objective performance goal based on the published results from other trials.

What else happened is we look at the hospital readmissions. Most EVAR readmissions are drivers that cause adverse events, patients having heart attacks, chronic kidney disease, worsening of the kidney disease for more contrast, respiratory and wound complications, also treating limb occlusions as well as proximal endoleaks. And if you look at the median EVAR readmission cost, it's almost $18,000. If you have a limb occlude, it's over $23,000 for endoleak and those drivers are due to the initial readmission surgeries, ICU services and length of stay.

Amazingly from the life registry if you look at the data from the National -- the ACS NSQIP or the National Sampling Quality Improvement Project from two publications from both 2014 and 2016 with both reporting at approximately unplanned readmission rate just under 8% and the life registry of 1.6%.

So, where does the therapy hope to go next and that's the Ovation Alto platform? And really, that's taken from the feedback from the physicians. So, the iX device, the sealing ring is at 13 millimeters below lower screen artery and we said, "Gee, if we can move that up, it's going to broaden who we can treat." So, that sealing ring is now moved up to 7 millimeters below the lowest screen artery.

One other thing is that when you're trying to cannulate the gate, because the palmer hasn't gone in and there's no stability, there's increased webbing at the bifurcation to display those limits that facilitate with gate cannulation. The aortic body limbs are now offset a little bit. So, when you're bring in your limbs, it's a little easier to identify which limb is which limb and how much overlap you need and it's still a very low profile device and it's not going to change its profile.

Fortunately, I can say that the first in man cases that have been done in New Zealand by Dr. Holden, and this is actually one of the first in human cases. You can see here this was clearly even by angiography in a regular neck with the two right and one left renal arteries, the device placed and actually the follow up C.T., and the review I've had of these cases have really gone amazingly well. And so, we're very excited that we hope to have this device ready for study within the United States soon. That study is going to be called the ELEVATE study. It's planned on and looking at 75 patients in 12 U.S. centers. And as I said before, we hope to begin enrollment in the first quarter of next year.

So, in conclusion, I think the Ovation Alto platform addresses a broad patient population across straightforward and complex anatomies. I think the thing we hear over and over again is treating patients on IFU. You can actually tell them what the results are going to be and this is durable results through five years. There's been almost 10,000 patients treated with this platform but 1-in-10 have actually been involved within a study so we can know what their outcomes are.

It's generated a robust short and long-term clinical evidence through five years and it validates the stability of this platform and has excellent safety and durability, economic utility. And we hope that the next generation device Alto further expands our endovascular options for these patients.

John McDermott - *Endologix Inc. - President, CEO*

OK. Thank you, gentlemen. I'm going to just go through this pretty quick to make sure that we've got plenty of time for questions. So, I'm not going to go too deep on any of the clinical topics. I think that's been well covered.

So I will jump through my portion pretty quickly was an area of focus on patient or device applicability and some of the market details. You've seen this slide before, as we've talked about, kind of, the unique value proposition that we bring unlike any other device or any other of our competitors is the ability to provide the best device for each individual patient.

You've got some visibility now to the clinical utility of all these different platforms and why that's so important. This is an updated slide. You've seen this format before, but you haven't seen these numbers.

And so, it's been updated to take our market estimates now through 2021. As you can see, the traditional market segment is estimated at a $1.6 billion opportunity, of that 1.3 is actively penetrated.

Jumping over to complex, $1.2 billion opportunity, only $400 million is currently occupied. So there is a tremendous amount of incremental growth opportunity. As Dr. Holden talked about a minute ago there just aren't good alternatives.

In fact, a good bit of that $400 million that is currently served in that segment is off-label use of devices, which we've already proven over and over again. It's not effective, so ChEVAS and Alto as I'll show you in a minute are great options for that segment.

And lastly, thoracic, I'm not going to talk about that here today. But what I can tell you as part of the merger with TriVascular, we got a good thoracic platform. And that's something that you can expect to hear from us in the quarters ahead. We're excited about entering the thoracic business and have some great technology to do that.

These devices have been talked about. And again, this slide is going to be up on our website for you to spend a little bit more time with later. And if there's follow up questions, we can do that. We talked about Ovation iX and Nellix and you can see where clinically these technologies offer unique advantages. I'll mention AFX briefly in that it's kind of the flagship product for Endologix, what's unique and what sets it apart from all of these other technologies is that it's really the only device, not just within our portfolio but the only device in the world that sits on the patient's native bifurcation.

It enables future crossover procedures. Should a patient need one of those procedures in the future for PAD or some other endovascular intervention, that's a unique proposition and as we go to design and develop the next generation of technologies, we hope to embody elements of all of these design advantages.

Collectively and I'll show you the patient applicability on the portfolio in a minute. But needless to say, we can sit down with a physician, look at an individual patient anatomy and really pick the best absolute device for that individual patient.

I'm going to just touch on these and Andrew presented this data earlier. And we press released it very briefly just at a very high level, 37, just under 40% of these patients were considered complex anatomies.

You can see these results. They are fantastic. One point that wasn't made earlier, no secondary interventions for Type II endoleaks. To give you, kind of, a benchmark on that, you would see secondary interventions for Type II endoleaks and the kind of the 2% to 3% a year category.

So having zero interventions related to Type II endoleaks out to two years is a nice advantage. I think the clinicians would support me when I say that when you do have to re-intervene for a Type II endoleak, they are difficult.

And it often takes more than one effort, so Type IIs are tough. And it's great to have this failure mode go away. You can see this 99% freedom from cardiovascular mortality that was talked about earlier, that's very intriguing potential advantage to EVAS.

And clearly, we believe that EVAS is going to be the platform for all future technologies treat aneurysms. I want to just take you through quickly, the PMA schedule, unfortunately, we got from a little bit of curve ball earlier this week with the agency.

We have been engaged with them on discussing the benefits of the new indications for use, which Dr. Thompson talked about. And we had a scheduled call for late Tuesday afternoon to go through how we're going to integrate those new IFUs is not the cap and start enrolling 3.5.

And upon more rigorous review on their end they said, "We feel a lot better if you had two-year follow up on the entire data set instead of just the subset." So that wasn't expected, but nonetheless, we're confident.

Based on what we've seen so far, you've seen the two-year KM curves and how we've been able to generate such compelling data. So, we'll gather up that data as quickly as we can. This, kind of, gives you a timeline for that, so as you can see we'll gather up all of the data from the IDEs.

So, those will be roll-in patients and the 150 pivotal patients. And we'll gather that data up to two-year results. We'll analyze it. We'll apply the new IFU. Submit that to the agency in the second quarter.

We will also plan in the quarter following that. Submit an IDE for the ChEVAS procedure. And you'll see the ChEVAS procedure and the timeline to get that procedure approved here in a few minutes.

We expect then to have our panel meeting. The agency hasn't confirmed there will be a panel yet. But we want to put it on the timeline rather than have a question hanging out there. Let's assume we go to panel.

And assuming that also goes well, then we're set for a PMA approval time frame estimated at Q2 2018. So, this is updated based upon the information we shared earlier this week and based upon our conversation with the agency Tuesday afternoon.

Dr. Lyden touched on this. I think there is just one other point I'd want to emphasize is this major adverse event rate at that half a percent, that was not device related. That's the lowest MAE rate ever generated in the history of endovascular aneurysm therapy.

So what that tells you is this low profile fast-track approach is safer. Somebody ask me today, actually, we were at the Canaccord meeting for a minute and asked me about the 30-day readmission rate being so low and the major adverse event rate being so low. And does it really matter? Does anybody really look at this stuff? It reminds me of several years ago when we came to the market with PVAR,when we first started talking about the benefits of treating patients with PVAR and it was really mixed.

Five years ago, you could talk to physicians and some said, "It doesn't really matter. It's not that big a deal." And others had started to embrace it and seen clinical benefits. This is the kind of result you can get with PVAR, local anesthesia, no ICU.

And I think that as this data gets embraced and this process gets implemented in hospitals, this will become the way you do it. The benefit of that you could say, "Well, can you apply that approach to other devices?" You can. But it's easiest with the lowest profile system.

And this is the only device that has this, kind of, supporting data. So, I think we're uniquely positioned to really capitalize on these clinical data. The clinical data that we're published yesterday and then the clinical data that will be published with the LUCY study at the SVS. We've got a nice cadence of clinical results coming to support the Ovation product line.

Transitioning to complex neck treatment. As you saw earlier, with the large market opportunity and largely unserved and what patients are treated, they are still unfortunately predominantly off label. So, we've got two product offerings to really address this. Ovation Alto, as Dr. Lyden pointed out, we moved that sealing ring up, we can treat these patients with short necks. That's highly attractive as opposed to having to involve the visceral vessel.

So to be able to stay infra-renal and treat a short neck aneurysm is going to be very attractive for physicians. And then you saw from Dr. Holden, the great results,the preliminary results now we're getting with ChEVAS.

This is an important slide. This is new. You haven't seen this. So, I'm going to take a minute here. What we've done is we've segmented the market. As you've heard us talk about before, the traditional market segment and the complex market segment. And then each of our existing devices and devices that are planned to show you, what percent of each of those market segments we think will be applicable for these technologies. So, there's been a lot of discussion lately about after we implement the IFU, this updated IFU that you say, by the way, Dr. Thompson showed this iPhone version.

This is a very progressive, frankly, a better way to custom-fit an indication to get the best possible outcomes. Right now, all of the IFUs have very binary measurements. And the docs end up having to go off label a lot because they make the trade-offs in their head.

We're going to have a tool now to enable them to get the best possible outcome and take into consideration each individual patient's anatomical measurements and features. So it's an exciting way to go to take the therapy.

After the application of the updated IFU, 40% of the patients in the traditional segment will be good candidates Nellix. Then if you look over Nellix ChEVAS in the complex segment, we believe, based upon two vessels.

So what you saw here earlier, single, double, triple, and quads, two vessel would include the singles and doubles. So if we just limit our indication to two that will enable us to treat about 50% of that market segment, okay? Which is, today, significantly undertreated. And you also saw from Dr. Holden that the results we've generated so far are superior to the results that have been generated with the other technology. So, it's a less competitive segment. We seem to have a real clinical advantage here. And we think we can get a big portion of that share.

Next, AFX2 is really designed for and is used primarily in the traditional market segment, applicable to about 55% of those patients. You've heard me say, although it didn't mention it tonight, specifically; the patients that will be excluded from the Nellix IFU or actually well-treated; easily treated with either AFX or vation iX or in the future Ovation Alto. So, the Company doesn't lose that patient. It's not a suitable candidate for Nellix, all right? Still gets treated well within the portfolio. Ovation iX, as you can see here, treats 69% of the patient in the traditional segment.

We could actually even stretch that a little bit. As Dr. Lyden pointed out, there was about 8% of the patients in the Ovation IDE were treated with less than 10 millimeter necks. That has to do with the neck definition that he talked about, but I haven't even really pushed this.

If wanted to push this, we could get up above 69%. And then lastly, Ovation Alto. This might be a little bit of an eye-opener for you. I think it was for all of us. We knew that Alto was going to offer some real advantage as it relates on IFU. But until you get into the details and you start studying these market segments carefully, we didn't appreciate that it could treat up to 80% of the traditional market and 26% of the complex.

So, it really becomes of the products in the portfolio in terms of a single product to treat patients on IFU, it represents the product that's likely got the broadest bandwidth. But each of the individual products again have such great clinical utility for specific anatomies that when you roll it all up, you can see that we've got very good coverage of the overall market.

When you overlay that and you want to compare our portfolio to the competitive portfolios and this has been updated. You've seen a version of this before, but you haven't seen this in detail because what we try to do is take the competitive devices, look at their IFUs in total and also take products that they had.

So, for example, the Cook number here, these are all diagnosed aneurysm, includes, for example, their fenestrated number. That wasn't the case before. So, the Cook number includes their fenestrated procedures. Gore includes their new iliac branch device, for example.

So, we've tried to include everything that they've got commercially available. Medtronic, we think treats about 50%. When you combine our portfolio that gets us to 58%. This is again, on IFU. When you add Alto and ChEVAS to that that tops us up to another 19% for total when we get ChEVAS and Alto approved of 77%.

So, we've got a substantial advantage from a portfolio perspective to treat patients on IFU, which you've heard over and over again tonight. And if you were in the sessions today, I hope you heard the same thing.

This is going to generate the best results. So, we think this is a compelling competitive advantage. This is a busy slide. I'm not going to go through each one of these. I think you've seen this.

We've updated this to include our latest best timeline estimate for Nellix device based upon the two-year requirement in terms of follow up data. We have assumed for purposes of this slide that we would start enrolling patients.

Our Gen2 device, we started those patients in the cap in first quarter. And that study would be around 75 patients with six-month follow up. That gets to set this up for about a one year lag behind our anticipated Gen1 approval.

We'll try to pull that in, but today, based upon what we know, we think it's about a one-year delay. And then you can see also in the U.S. the anticipated ChEVAS approval in 2020 that seems we start that study in Q3 this year as we've talked about.

A lot of new products to launch. Alto, as you can see here is scheduled for the first part of 2019. In the U.S., we expect to actually launch that device in Europe in 2017. As do we expect by the end of '17 to get the ChEVAS indication and launch that in Europe.

So, we got a busy schedule, lots of growth drivers here. This, kind of, highlight '17, when you think about what are we going to be focused on? What are the priorities? What are the Company going to really be delved into in '17.

I just touched on these launches -- Alto in Europe, Nellix, ChEVAS in Europe. AFX2 launches in Japan. We've got a partner there. Japan Lifeline are doing a great job. A lot of growth opportunity there.

Our clinical and regulatory, obviously, the Nellix panel will be a major focus for us, so we'll get in that two-year follow update in Q2. Have wildly successful panel meeting in Q4. The ELEVATE IDE, we should get that IDE approved, literally any day now. I thought we might even have it today, so anytime now we'll get that IDE approved and get that study started.

The ChEVAS IDE, I showed you that. That's scheduled for Q3. The Nellix Gen2 in the cap, I've talked about that also. We're anticipating to get that started in the first quarter. And then we'll also run a Phase II of the global registry.

So, we did Phase I. You saw those two-year data today. By the way, I think the two-year data that we presented today will also be supportive of our efforts with the FDA to demonstrate. We've got a device with good two-year outcomes, especially with so many of those patients treated off label and especially on a broader IFU.

I mean, if you look at those mortality curves, as they compare to EVAR, there is clearly an advantage. But, anyway, I think we got a lot of data to support this pending PMA. And we'll do the Gen2 device in EVAS global with the new IFU. So, we'll be gathering prospective data with the new IFU in the Gen2 device also in Europe.

On the R&D, side we'll be focused on the NextGen EVAS, as I touched on earlier. We'll be combining these technologies. We think EVAS is the way of the future. You're seeing some of these benefits as cardiac mortality advantage that's unique to EVAS. It's clearly the way that these patients need to be treated long-term as well as start up our thoracic program.

So these would be the topics that we provide you with updates on as well as our progress with the FDA moving through the process here over the next few months. Here is our guidance. We talked about this on the third quarter call recently. The only thing we've done that's slightly different from what we talked about on the call a few weeks ago, it's a little difficult for us to predict precisely what will be the reaction in the marketplace as we go to integrate the new IFU and interact with clinicians.

So far, they have been very supportive. They like the fact that we're being conservative. In fact, some of them have told us we're being too conservative, but nonetheless, it's all about patient outcomes.

So, our view is that Q4 we're probably in the 7% to 10% growth. The only difference from that is previously we thought it would be about 10. We want to make sure we give ourselves a little leeway here just in case there is a little bit of softening as physicians transition into the IFU.

And just to summarize here quickly. Clearly, the innovation leader, compare us to any of the portfolios of any of our competitors. It's really not close, granted we got a lot going on, but the potential, as I showed you a minute ago, 77% of the patients on IFU with this portfolio is pretty exciting for us. The major growth driver.

Here they are, the launches I just talked on. I'm not going to reiterate those. One thing I would point out though as part of the growth, it's not just launching the products. It takes years to build and support a good sales and clinical team in this space. And we have that. We've invested a lot over the last decade to gradually build up. We've got a very talented team of sales and clinical professionals that can provide support to these clinicians, so that's an installed base. As we develop and drop these new products into the hands of these very capable individuals, I expect them to be very successful.

And lastly, a good financial profile. You saw it from the numbers. I'm not going to in too many details here. We can ask questions on the financial stuff, but improving gross margins you saw that in the last call. Improving operating leverage, so sales went up. Margins went up. Operating expenses as a percent of sales went down. And we think we've got adequate liquidity to get us through to the launches of these new devices.

So with that, I think we want to open it up to questions. What I would ask you, just in the sake of timing here, I know that Dr. Lyden has got a time commitment, so I'd like to start with any questions that you have about Alto, Ovation, any of those clinical data so that if he needs to sneak out he can do that.

Yes, Chris?

QUESTIONS AND ANSWERS

Chris Pasquale - *Guggenheim - Analyst*

Chris Pasquale, Guggenheim. Dr. Lyden, I'll start one for you. So, I think it's interesting how the conversations around Ovation has evolved, particularly now as we're appreciating better some of the limitations of Nellix. And Ovation is now actually seen as the more versatile graft.

So, I'm curious -- one, why do think given that versatility, given the strong data we have now to five years that that product hasn't been embraced more widely by your peers? And then as you think about your practice are you being a big Ovation user, what's the unmet need that you think Nellix fills in the infrarenal space for you?

Sean Lyden - *Cleveland Clinic - Department Chair, Vascular Surgery*

So, my mike is on? So, I think a lot of it is when TriVascular first came out, when I was asked by investors where I thought they'd be. I mean, sales teams for endovascular aneurysm repair are critical.

The people in academic centers generally do not need as much support as the average physician in the world or in the United States. And it takes some time to build up that community. I have friends who say, "Wait, that may want to try some of that." But they're just so worried about having that qualified sales person to help them.

And so, I think it takes time, the advantage of these two companies coming together that they see doubled their amount of value of sales reps. I think that's helping along. But I think when I find people trying it they're like, "Oh, that's really a lot easier to use than I thought and wow, I can now do it percutaneously."

And so I find when people sort of get over the hump of trying something new. The other thing is that vascular surgeons as a whole are very reluctant to try new things when there was prolonged data sets out there for the other devices.

So last to market, it didn't have five-year data. And I know I sat there many times saying, well, once there is three, four and five-year data, my enthusiasm for a device clearly goes up, so I think with a five-year reported data set out there that is basically better than just about everything else out there, I think that provides some market subset for it.

With this Nellix set, I'll give you an example. I was on call exactly one and a half weeks ago and one of my transfers was a ruptured aneurysm from an outlying hospital. A patient came in on a helicopter. I can tell you that this will be a very expensive visit.

It was a patient with a Type II endoleak with a stable aneurysm who got admitted to our ICU after getting off the helicopter only to be told he has no issues and can go home. So, whether we like it or not, whether we're treading endoleaks, it terrifies patients.

The average ER physician, the average radiologist doesn't know how to interpret it, doesn't know what to do with it and a lot of patients are travelled on helicopters throughout the United States of America for non-essential problems.

I think the data relative to inflammation is very intriguing and if this is actually something that bears out, I think that builds up a whole new understanding. And as John pointed out when we go to treat Type II endoleaks, typically it is not always successful on their first therapy.

We have data we presented from the Cleveland clinic that the average number of interventions to try and treat an endoleak once you deem it's a problem, it's about three times. Whether you're going from a transarterial approach or a translumbar approach, they can be very difficult to deal with.

And if you don't have an endoleak, I can tell you, if you present a patient an option, if you might have an endoleak, 30% of the time at one month, 10% to 15% of the time at one year. And I have to reassure you, every year it's not a problem. That's a stressor on patients. And if you don't have that what is your patient going to tell you? Well, I can have an endoleak and we can watch it or we can have no endoleak. And so, I do think it adds definitely something to it, and I think that's why as they look to merge the best of all their devices going forward, I think the aneurysm sealing concept is something that physicians definitely have excitement about.

Chris Pasquale - *Guggenheim - Analyst*

Dr. Thompson? I'm sorry, Dr. Thompson, one if I could for you. I think we can all agree that the Nellix results under the revised IFU look pretty good. But that's a retrospective analysis. So particularly, as we think about going to an FDA panel sometime next year, how do you make the argument that that recut data is what people should be looking at and avoid the perception that you're cherry-picking patients?

Matthew Thompson - *Endologix Inc. - Incoming-Chief Medical Officer, St. George's University Vascular Surgeon*

Sure. I think that's a very fair point. I mean, I think the data will become much more robust as follow up goes on. So as you see the entire IDE cohort and the post enrollment cohort go in, we're going to get a lot more data which actually allows you to refine your selection criteria much better.

If we do decide to go to an algorithm as opposed to a binary selection process, then actually one of the advantages is that you can refine that algorithm with every data cut, so that you can try and include more patients and still get better outcomes.

I think you're right there. If you look at robust scientific methodology, we've generated the algorithm on a data set, applied it to the data set and looked at excellent results, so it's quite clear we have work to do to apply those revised IFU criteria to other data sets.

And I think we'll be looking to our physician partners, to go into big single center series and apply the algorithm retrospectively in those results. We would, of course, be applying the algorithm prospectively in the global registry when it restarts. So, I think there's a number of avenues for us to go forward, to actually validate those selection criteria.

Chris Pasquale - *Guggenheim - Analyst*

Based on what we know right now, I know it's incomplete follow up, but under the original IFU, the tier data that you've seen so far, if it has to stand on its merits with the entire data set, what's your level of confidence that that data set even with the increased event rates is good enough for this to be an approvable device?

Matthew Thompson - *Endologix Inc. - Incoming-Chief Medical Officer, St. George's University Vascular Surgeon*

I think that's too difficult to guess at the moment. Andrew and I sort of sat there when we looked at the global registry data and actually three years ago if you'd have said to me you'll be here discussing migration, I would have said, "No," because Nellix is an anti-migratory device.

So the biology when we put these into endo-grafts into patients, you just can't predict. We're seeing an early signal on clinical imaging at the moment in the IDE study. I'm not saying a particularly strong signal with clinical events. I think the clinical imaging is the thing that allows us to leverage that to actually almost look at a window in the future of what the device is going to perform like clinically. I honestly think they have to wait and see.

And I wouldn't want a second guess that at the moment. The numbers that we've looked at are small, so as John said, the Company has taken a conservative approach for this to put patient safety first. And I think as a physician that's the correct thing to do. One would hope that using the algorithm you can broaden the applicability, but I think wait and see what the data looks like.

Joanne Wuensch - *BMO Capital Markets - Analyst*

Joanne Wuensch from BMO Capital Markets. You said something near the end, John, about you didn't know how the physician community was going to respond to the new IFU. We have a couple of physicians here. What are you hearing in the field both in Europe and, well, even in the United States, the people who are, sort of, preparing or anticipating this product near-term? Or they were near-term.

Matthew Thompson - *Endologix Inc. - Incoming-Chief Medical Officer, St. George's University Vascular Surgeon*

Yes. I can give you a European perspective. So, it's entirely dichotomized, the reaction to the new IFU with virtually no one in the middle. So a lot of physicians have said this is far too conservative.

Our results from our big single center series are absolutely fine. You shouldn't touch it. You should wait until you get more data. Other people have said, "Well, that's fine, but it's going to reduce our patient applicability to levels that would be concerning."

And I think it's for that reason that the algorithmic IFU is much more attractive because it gives you retrospectively, admittedly very good results, but with a broader patient applicability. So it's, sort of, dichotomized.

But the one thing I would say is that if you speak to most of the physicians in Europe this, sort of, whole IFU being a binary process is really quite historic now. It's, sort of, 20 years old. And most physicians have their own, sort of, integration in their head to say what's a good candidate. What's a poor candidate.

So actually, although I'm not sure any of us wanted to be here. I think the opportunity to refine how we put IFUs and actually how we put that information about aneurysm morphology and predictive outcomes into physician's hand is quite topical.

Most of the guys who are qualifying now are an expert generation. They're very comfortable with digital data. They're very comfortable we're using algorithms on their phones and on the internet. And actually, I think it's a big opportunity.

Andrew Holden - *Endologix Inc. - Clinical Investigator, Medical Advisory Board Member*

Yes. I get that reiterated, that, I mean, the response, I think overall has tended to be, "Hey listen, these new IFUs are somewhat restricted." And so, the five-year of an algorithm gets into a more realistic situation.

I mean, you can have a situation where you've got 3-centimeter long infrarenal neck. It's some small caliber. You've great iliacs and you kick the case out based purely on the ratio. And our experience over the last few years has told us that's not the group who are going to migrate. And so certainly the algorithm will allow us to do that. So, I think the overall reaction has been kudos to the Company for being conservative.

Possibly the impression has been that that's slightly over conservative, but if you jump forward to how our practice has evolved because that signal is something that we've had some concern about, our practice has evolved that we are looking at cases on IFU for anything. There'll be various physicians' preferences in terms of the graft they feel most comfortable with. Or some people who don't fully buy in as yet to this active set management argument and I'll say, I'm well used to Endurant or I'm well used to Gore Graft and I'll use that for on IFU.

But what they won't do is use that for on IFU if the patient has large, big [IMA] and lumbar branches or an iliac aneurysm. And that collectively represents a significant percentage of the patients who are on IFU, 30% or so, where there is consensus that Nellix is the best way to go. And, of course, all those hostile neck patients we now have a lot of confidence with ChEVAS. So, really, I think we've looked at this and said, well, if this restrictive IFU is successful with the results and we do need more patients into this for this to gain more confidence, these are outstanding results, possibly have the benefit of the concept of active set management, which I agree. As, John, mentioned I think increasingly there's going to be consensus of whatever devices we have in the future, and other companies are certainly taking positions on this, we need to consider active set management.

Joanne Wuensch - *BMO Capital Markets - Analyst*

Can you give us some level of comfort that this is, sort of, with the FDA that there isn't some sort of another FDA surprise? And then the other question which has come up as we've spoken to investors the last two days is the financing. Do you have enough cash? Thank you.

John McDermott - *Endologix Inc. - President, CEO*

Yes. So I don't mean to laugh because it's certainly not funny about is this, what degree of certainty do we have with the FDA, it has been -- it's been challenging for us. I guess it comes part and parcel with developing a whole new therapy so we're -- I think we're learning together with the FDA, what does it mean to manage the sac and what are -- as the clinical data evolves. like Matt said, two or three years ago, none of us thought we'd be having a migration conversation because we felt like we were securing the device with the aneurysm sac.

That said, I feel like the degrees of variability both with the technology and our interactions with the agency are narrowing in. We're basically getting more conservative. I don't think we want to lose sight of the fact that we have a successful IDE trial. We didn't just meet the endpoints, we beat them by a wide margin. So we've got a successful study. We've seen a signal in two-year results and we've been really conservative at then further going and narrowing the indications to get results that are superior to anything that's ever been generated for EVAR.

So our view is from an approvability perspective and from a risk profile for the agency, we're really trying to make this easy. And that said, I think that -- we just had this call with them on Tuesday afternoon. We got a little bit of a curveball. We want to get together with them here and get deep into the details about exactly what they're going to need.

They said we'd like to see two-year data. I think we need to flush that out and understand exactly what that means. It sounds very doable. We can do a lot of other things. We have -- just as you saw tonight, two-year global registry data. We can harvest two-year patients from that that fit the profile of the IDE.

There's a lot of other independent data sets. We have plenty of clinical evidence. It's just now getting clear and getting their agreement on what we can use and what will influence their decision. I strongly believe we have pieces here. I just -- what I don't want to do is tell you I think it's going to be this and then stand in front of you again and say, I'm sorry, we've got -- we're going in different direction.

So we're going to work hard to gain a consensus with them. And as soon as we have that completely ironed out, then I'll stand in front of you and tell you what we've agreed to and we'll document our minutes from the meetings with the FDA and then we'll have a clear roadmap. Based on the conversation Tuesday afternoon, that's what we tried to do quickly to put together for you to give you our best estimate based on the assumptions we have today. And I'm sorry, the second part, do we have enough cash. I'll let, Vaseem is sitting right next to you.

Vaseem Mahboob - *Endologix Inc. - CFO*

So we ended Q3 at about $63 million of cash, we'll end the year in the $50 to $55 million range. And the reason I'm giving you a range is because of the revised estimate for Q4. We also have a $50 million-dollar revolver that we haven't tapped into yet which was the facility that we signed [MedCap] at the end of second quarter, it's at four and a half percent. It's very attractive.

And our plan at the end of next year is going to be at $30 million of cash in the bank, plus we have the revolver. So we feel we have enough cash to see us to cash flow positive in 2018. Earlier we were forecasting with Nellix in the early part of '18 to be cash flow positive, now we have kind of pushed that to the second half of '18. So at this point, we are adequately financed and have enough liquidity to run the Company.

John McDermott - *Endologix Inc. - President, CEO*

There's a question over here if you have that mic.

Matthew Blackman - *Stifel - Analyst*

Thanks. [Matt Blackman] from Stifel. John, first for you. And I think it's probably a clarification on that slide where you have the patient applicability of each of the devices, the 40% for Nellix. And hopefully I'll phrase this right. Is that 40% the ratio-driven IFU or is that the algorithm-driven?

John McDermott - *Endologix Inc. - President, CEO*

Yes, it's a great question. And since, as you can tell, we're fine-tuning the ratio, that's based up our current cut with the ratio. I want to manage expectations. I don't want you to walk out of here thinking that we're going to take the 40 to 60 because if I surprise you any more, I want to surprise you the other direction. So that's our current best estimate in using the anticipated ratio which we're fine-tuning in larger data sets.

Matthew Blackman - *Stifel - Analyst*

The next question is probably for the clinicians. And, again, I was struck by the persistence of the all-cause mortality signal, the separation of those curves now out to two years and obviously primarily driven by the lower cardiovascular risk. I'm just curious, how long does this have to persist before it really starts to resonate clinically? And we've got two years, we've got several patients. Do we need five years? Is it two and a half years? When does the clinician community start to think this is real?

Matthew Thompson - *Endologix Inc. - Incoming-Chief Medical Officer, St. George's University Vascular Surgeon*

Yes, that's a great question. So I think the -- I think when we first presented this to you with the one-year global data, I think we all said, that's quite interesting, isn't it? And we'll review it and see if that signal persists. The signal has persisted to two years. Naturally, if you look down the KM curves without probably significant patients, it looks like the trends are continuing.

So I think if you got to another year out, you've still got divergent curves, I think maybe you'd have to take that very seriously. But the reason why I think I'd probably take it more seriously now is that there does appear to be a reasonably cogent explanation for it.

So if you do this sort of ballpark figure of patients with aneurysms generally have an all-cause mortality between 6 and 8% per year. Half of that is cardiovascular. So that's 3% to 4% per year. So we'd expect the cardiovascular mortality now somewhere between 6% and 8% and we've got 1%.

And if you look at the causes of death in the global registry albeit it's not an FDA study, so the level of monitoring is not as high. The level of cancer deaths are what you would expect. So it does seem to fit with the hypothesis. I think there's a couple of things that we can do to try and firm up those findings and that is maybe stop comparing it solely to the ENGAGE data set and start looking at some big administrative data sets and do some cohort propensity matching studies and see if the signal looks good at that stage.

But I think the thing that's changed between last year and this year is that we now have a better handle on the causes of death and I think the cardiovascular mortality is compelling.

John McDermott - *Endologix Inc. - President, CEO*

I think it also depends on right now, it's not, in the United States, a device I have to study. So there was a signal, people started looking at inflammatory markers to try and see if there was maybe some biologic basis to explain those data sets and typically what you'd be doing is in your own administrative data set trying to get those tests on your patients because we just have continued access, I cannot go to my IRB and say, I want to add more tests on these patients because maybe there's a signal and I think that we're really reliant now on our European colleagues and outside of the U.S. to start collecting some of this data that really sort of validate the significance of this finding.

But I think that if this can be validated, it'll be humongous. I mean to say to a patient that you have an inflammatory state, this eliminates inflammatory state. It predicts your overall mortality, nothing to do with your aneurysm. This can be patient-driven. I think there's a signal now.

The problem is that without a commercial device, it's very hard to enroll patients and then study and really define, is this real and what is the mechanism of action why this is happening.

Matthew Blackman - *Stifel - Analyst*

And then just quick one last one for Vaseem. I'm sure you're anxious to give 2017 guidance in November but there are a lot of moving parts next year with Nellix particularly with what's going to happen with the label in Europe. But is there any sort of framework you'd like us to -- as we think about and reflect on our '17 numbers, any sort of framework we should be thinking about when we think about our sales numbers for next year in particular.

Vaseem Mahboob - *Endologix Inc. - CFO*

Thanks, Matt. I think what we what we have talked about previously was that we would -- with the October launch being the 5 to 10% range, on whatever the exit number was going to be for 2016. I think there is a real impact of what we've been talking about here on the indication narrowing for Nellix particularly on our European business, so that is a clear impact which was going to draw that 5 to 10% down and also the fact that the street took out all of the Nellix revenue.

So at this point the best estimate and we only had 12 hours to think about it, is really that we should at least grow with the market and maybe not take market share with what we have, but we will continue to kind of look at that again and see as we give our guidance most probably in the JPMorgan or February earnings call to see what that number looks like. But at this point, suffice to say that market growth in the low single digits is a right way to think about it, because there's clearly an impact on '17.

John McDermott - *Endologix Inc. - President, CEO*

Yes. Before we take the next question, I've been -- within the spirit of no regulatory surprises, I'm going to give you one. A good one. We've been close the last few days working with the agency on the Alto IDE, getting approval for that. We kind of hoped we were -- if possible that we'd have that done but we came in here tonight, we were -- I went over to [Sherry], I said, "Have you heard?" She said, "No, I haven't heard."

Well, I just got the thumbs up sign from her so we just -- just now, I think just today or just this afternoon got the letter from the agency that they've green-lighted us to start the Alto IDE. So maybe this is a trend of a new wave of positive surprises from the FDA. Let's go with that. But anyway, that's just hot off the press literally a minute ago so I thought I'd share that with you. So next question?

Ravi Misra - *Leerink Partners - Analyst*

Thanks. Ravi Misra from Leerink Partners. Just had a question maybe on Ovation Alto. It sounds like you're looking into that as kind of a workhorse course device and just -- with fast track and that study, do you see that as an enabling procedure that can get more patients into that sort of fast track protocol or is fast track just applicable to a certain patient subset?

John McDermott - *Endologix Inc. - President, CEO*

Absolutely. Good question for these guys.

Sean Lyden - *Cleveland Clinic - Department Chair, Vascular Surgery*

I can just speak from my own clinical experience is that with that device I'd do everybody percutaneous, nobody goes to the ICU, they're almost all going home the next day. With a 14-French outer diameter device, we're doing percutaneously the failure risk is so low and the patients are up. I'm -- they're not -- they're up in the chair, they're really not hurting much and so they're anxious to get home. I would say the only patient of mine that tends to fail is the man who has a -- some urinary retention. I think the biggest driver of prolonged length of stay in my own practice is delayed

urinary retention in somebody, but when you don't put them to sleep, general anesthetic alone causes urinary retention. And so I do think I've seen that evolve in my practice and for me, I think the great thing about their portfolio is they a little bit of everything.

I see patients with lower extremity disease, that pushes me to AFX. When patients have accessory renals and other things, I've been able to put them in a continued access for Nellix but all other things being equal, having that lower profile has been in the broadened IFU in terms of the abnormal necks that device can treat, it's been my dominant device I use in my practice.

Andrew Holden - *Endologix Inc. - Clinical Investigator, Medical Advisory Board Member*

I just just had sort of an OUS comment, and this kind of hasn't been raised really. One of the things that a lot of clinicians have had a problem with Ovation is trying to rationalize the fact that the sealing ring was 13 millimeters below the top of the material. And I know Sean explained very nicely how we need to think of neck limitations differently with Ovation. But that's a leap that a lot of physicans can't do. So they look at an IFU that might be seven or ten millimeters and they say, hang on, how the hell can you do that when the ring's 13 and it has put them off Ovation.

I can tell you from my experience that when they've seen Alto, it's suddenly given them a lot more confidence to use this technology. So in my group of seven vascular surgeons I have, there are some people who say, we understand Nellix for those particular indications we talked about but we'd use a conventional graft with good data for - on IFU other cases.

Previously, they would not have used Ovation because of this concept. But now, Alto does exactly what you expect it to do because the sealing ring is so near the top of the material. And I think as well as perhaps increasing its applicability to shorter necks, on IFU, it's going to be taken far more seriously as an option not only in the U.S. but globally. It just adds up to making a lot more sense and my early experience with that now has been that it's performed tremendously well.

John McDermott - *Endologix Inc. - President, CEO*

I think you have to realize the definitions we have for neck we came up with the 90s. And the problem is that both the Nellix device and the TriVascular device don't work within that mold. And I think one of the things that I think we see a growing issue is that is how a neck is defined.

It's going to really end up being how the device works specific. And I think this is -- if you look at -- to me, my issues -- the agency has a brand new device in Nellix and so they're nervous because the last thing the agency wants to do is come out wrong. And so the problem is that we have devices that don't conform to our guidelines of how we define anatomy.

So a 13-millimeter neck could be treated with this device but so can a 6-millimeter neck and that's because its definition is diameter change. So if that aorta is 22 at the renals but 30 at IR plus 13, that's not a neck. All the other devices, it wasn't treatable. With Ovation, it is. And so TriVascular early on struggled to how you explain this to clinicians because we were all in the framework that self-expanding stent grafts had to have a parallel wall to attach and if there was a 10% diameter difference, you couldn't use it.

And so physicians struggled with the concept of this works in a different way, and I think what we really need to do as a physician community is redefining those definitions that can help accommodate because there's different ways of achieving both fixation and sealing today that didn't exist when our guidelines were written.

Ravi Misra - *Leerink Partners - Analyst*

Great. Thanks. And then just one more on Dr. Holden. You mentioned your use of ChEVAS and Nellix was about the mid 50s down from the 63%, 64% a few years ago. Is that sort of the new normal that we should expect for -- I mean is that institution representative you think of the broader population? Is that the new normal or can it move higher or where do you see that going in the next few years?

Andrew Holden - *Endologix Inc. - Clinical Investigator, Medical Advisory Board Member*

I think it's safe to, of course it can move higher if we start I guess making some device developments with Nellix, say something that dealt with anti-migrational so you could take on some more cases. But I think it is -- at the moment, we've kind of been already using the device according to the altered IFU for the last 12 to 18 months. So that's where that sat at that 35% to 38% with the additional ChEVAS. The real growth has been in that hostile neck. And to be honest, I see that as -- until we - that's based on appropriate patient selection with our current information.

I think the next thing that would make it even expand more would be further device development. But I think having Alto available will also enable me to treat a group of patients not well-treated by those other technologies, particularly [accessed] and perhaps more angulated neck and those kind of things. So that adds another ability if we're talking about an Endologix package, but I think as we've all been saying if the active set management story comes true that will present a huge paradigmt shift.

John McDermott - *Endologix Inc. - President, CEO*

If I can impromptu build on the 50% comment. First of all, it looks like we have some opportunity for growth in your account, is that fair to say? Thinking about it in terms of 50% is a pretty fair way to go. I don't want to push that or create an expectation that we will do better but I'd remind you as you think about the applicability of Nellix across all those aneurysms, is it represents some very unique advantages in those 50%.

It's not competing equally with the other devices for that 50%. It represents really a superior option for that segment. That 50%, I could argue should -- you should --we should get a disproportionate share of that 50 because it includes ChEVAS and the patients that are well-suited for Nellix are challenging patients for the other EVAR devices with the side branches and everything else.

So while it's 50, I think we've got a strong, strong position in that 50. I don't want to be afraid of the 50. I think we should embrace the 50 and then go after a meaningful segment of that 50 which in -- for a company our size and given our current share position globally represents a lot of growth potential. Other questions? We got one in the back here. Here comes the mic.

Unidentified Audience Member

I'm not sure how sales go in Europe and you're all academics. The United States sales are so, so dependent on the relationship between the sales rep and the doctor. And I don't know how it goes in New Zealand or how it goes in Europe but that is a very critical part in your planning. With the ease of the Nellix, the ease and the efficiency of reduced time, the product will sell itself but you're going to have to have a very strong sales force out there.

You say you feel like you're ready for it, but that's an important part of selling this product, is having somebody in the office presenting the Nellix to the -- most vascular surgeons come to all these vascular meetings. They've been hearing about it for a couple of years and they're anxious to start using it. Are you all ready?

John McDermott - *Endologix Inc. - President, CEO*

Yes. To be perfectly honest, in the U.S., we're not ready today. But we have the tools and the plan to be ready in conjunction with the approval. And I think what we'll do and what we've learned from our experience with these physicians and others is it's all about getting it right.

To your point, that training, that case planning, case execution is critical to the overall success of the platform. And we have, collectively, if you look at our sales force, about 125 reps and clinical specialists in the U.S. On average, within that team, we've got hundreds of years of EVAR experience. And a dedicated tool these -- to help our reps in clinicals and the physicians plan these cases, I think we will be exceptionally well-prepared.

When we rolled it out in New Zealand, in Europe, in other markets, we didn't have simulators so we can actually take now your CT, put it into the simulator, and let you practice your Nellix case before you do that procedure. So the tools have gotten better. All of the procedural issues that we

learned kind of on the fly in Europe have all been refined. The team is actually a lot more experienced now. We just need to get them certified and trained on Nellix. I think we'll be very well-prepared. Are we ready today? No, but we'll certainly be ready when we launch. It's a good question.

Unidentified Audience Member

Thanks. What will be the mechanism of action behind the lower rate of mortality and the lower incidence post-implantation syndrome? So what is the hypothesis behind, what will drive that?

John McDermott - *Endologix Inc. - President, CEO*

So when you look at the aneurism sac, it's not an inert substance. There is turnover, there's flow with that thrombus. There is activation of the component cascade, there's active of breakdown and active making of clot. All those things also interact with our inflammatory system. And so you see patients with aneurysms and they have elevated, you know, elevated markers of inflammation within them. And so we know that the aortic sac sometimes, it's very mature, very hard thrombus, sometimes it's very sort of squishy thrombus. And we know that that's biologically active. And so at least in theory when you fill up that space and you don't have that endoleak, you don't have that continued activation of that inflammatory cascade. And I would say that's at least my rudimentary understanding of the potential mechanism.

Unidentified Audience Member

Do you see a difference in the stroke rates and do you manage these patients differently from an anti-coagulation perspective?

John McDermott - *Endologix Inc. - President, CEO*

Can you say that again?

Unidentified Audience Member

Do you see a spread, a difference in the stroke rates? If what you're saying is true, there should be a difference in stroke rates. And also I'm wondering do you manage these patients differently from an INR perspective or you have to calculate differently?

John McDermott - *Endologix Inc. - President, CEO*

Yes. So the current standard for all devices is not to anti-coagulate and they may be on an aspirin alone so they're not on any anticoagulation and I think it's too early to say what that mechanism is, whether or not it's going to relate to future myocardial infarctions or cerebrovascular events I think. We clearly see a difference in mortality to meds, the early data shows the cancer risk is the same but I don't think anybody's defined it well enough. I would tell you the academicians in the group, the guys sitting up here are very eager to study it because the person who figures it out is going to look really smart. What we know today is that your mortality rate with Nellix is lower than it is with EVAR devices. Now we need to get the science to support that but after two years, your survival's better with Nellix.

Glenn Navarro - *RTC - Analyst*

[Glenn Navarro] with RTC. John, that one slide that you had up there with the two-year Nellix results, was that from the IDE study?

John McDermott - *Endologix Inc. - President, CEO*

No, that's from the registry that was presented today.

Glenn Navarro - *RTC - Analyst*

And do we know what the migration rates were between year one and year two?

John McDermott - *Endologix Inc. - President, CEO*

Yes, it's a good question, [Rick]. So one of the things we've learned in retrospect about the registry is the imaging that was with the phase one of the registry was physician standard of care which varies by physician. So some physicians had CT, others had ultrasound. So we don't have the same kind of imaging fidelity with the registry that we do and migration is really an imaging finding. So we don't have, what I would consider reliable migration findings from the registry.

What we do have, and I think I'm going to quote these numbers from my head, but I believe I'm right, what we do have though is re-interventions related to migration. So what we can capture in the registry is any time there are events, we can do the analysis of those patients to determine what was it. And I think what we reported in the registry today was there were three re-interventions related to migration out of that 277 patients.

Unidentified Participant

[One single lead].

John McDermott - *Endologix Inc. - President, CEO*

Yes. So even though I can't tell you what was the migration rate in the registry, I can tell you what that -- there were three patients that required a re-intervention related to migration out to two years.

Glenn Navarro - *RTC - Analyst*

And in the IDE study, you've got patients now already out to two years?

John McDermott - *Endologix Inc. - President, CEO*

Yes.

Glenn Navarro - *RTC - Analyst*

The FDA has already seen that. Can you share with us were there migration issues in that subset of patients that the FDA already saw and is that why they're saying give me the two years for everybody?

John McDermott - *Endologix Inc. - President, CEO*

Yes. So everybody saw the one-year data which was 2.3% of patients had a 10 millimeter migration or more at one year. What we saw was when we did an updated data cut for our response, some of those patients went on to migrate more and there were some patients that hadn't displayed any migration at one year that showed signed of migration in year two.

And although most of those findings were still hadn't triggered interventions, there were some and I'm not going to tell you there were zero intervention. I honestly, right now, don't know the exact number off the top of my head, but it was really the change in the rate. It was the increase in the rate from year one to year two and that's what drove the discussion.

For us we saw that. We quickly analyzed those patients and we saw common themes. Thankfully the failure analysis led us very clearly to these certain kind of anatomical features that we were able to isolate and therefore the development of the algorithm.

So we think we've got those isolated when we applied the new IFU, we set those patients aside and it looks very encouraging.

Glenn Navarro - *RTC - Analyst*

Just last one question and this is maybe for the docs. We were all at a Medtronic meeting two days ago and they talked about risk sharing and offering this warranty if like the device, if Endurant fails I think after three or four years. To me it just sounds like a lot of marketing stuff, but I'm just curious what you guys think. Do you think this is just a bunch of marketing stuff, like if something fails and you call up a company and say, "Hey, I want my money back"? I'm just curious at how it really works in the marketplace.

John McDermott - *Endologix Inc. - President, CEO*

You might think, if I can direct a question, so you probably don't know although Sean is the chief at the clinic, prior to that position, you were responsible for all procurement at the clinic right?

Sean Lyden - *Cleveland Clinic - Department Chair, Vascular Surgery*

I was the medical director for supply chain for the Cleveland Clinic Health System and I'm still the Chief Medical Officer for the purchasing organization. So I would tell you that collecting on that, I'm not sure how they would happen. I think it sounds really great, but how that happens? And I also spend a lot of time preaching to people on IFU because the other academic pursuit I've had, I've written about EVAR failures and when you write about it, all of a sudden they all come to you.

And so I would tell you that Matt in Australia and sometimes Matt in London and New Zealand, when you have access to these technologies, you see a lot of the non-IFU failures and I think the fact that this broadens IFU labelling, you don't need a guarantee because we do know that we have five-year data set on patients in IFU with good results. You can do that within competence.

I reported our series of our first 100 x plants. The vast majority happening within one year were for patients done in [ABI] outside of IFU, so patients that we know it won't work but yet still done every day. There's no guarantee who's going to collect on that except for maybe some law firms.

John McDermott - *Endologix Inc. - President, CEO*

Any other questions? We've got one right over here.

And while it goes over, the risk sharing, because we were at a conference thing, I've got a few questions on that and just so we're clear, that's not a proprietary thing. So if in fact it does ever evolve into a scenario where companies have to provide risk sharing kind of arrangements for EVAR devices, there's no patent on that right? And I think at the end of the day, I believe that the primary decision making is going to come down to clinical data, physician, familiarity and those will be the drivers.

And I think what happens is when the portfolio starts to get kind of commodity like, you got to start thinking more on commercial level activities instead of clinical and technical activities. That's our view. If we ever had to play at that level, we could, but strategically we're going to continue to focus on best device for each individual anatomy, but lots of questions about it today. Yes.

Andrew Hannover - *JP Morgan - Analyst*

Andrew Hannover from JP Morgan. Dr. Thompson or Dr. Holden, I was just wondering, can you remind us what the EVAR re-intervention rates are from migration both on and off label?

Matthew Thompson - *Endologix Inc. - Incoming-Chief Medical Officer, St. George's University Vascular Surgeon*

So EVAR migration, right, I think -- oh gosh, so we sort of have to go back to the very old IDE studies for migration because they're the only ones that were called out. So I would guess 2% two years something like that.

Andrew Hannover - *JP Morgan - Analyst*

OK. And then going back to your commentary specifically about the EU response and the dichotomy between the two groups of docs, some are saying you're being too conservative and some are saying they're going to lower their patient usage of Nellix. At this meeting at least there was a lot of discussion about 50%, 60% of these cases are done off IFU and the results kind of show lower level of efficacy. And I guess the question back to you is what's driving visceral type of response from a surgeon community out there?

Matthew Thompson - *Endologix Inc. - Incoming-Chief Medical Officer, St. George's University Vascular Surgeon*

So if you look at how this sort of technological pathway evolved, when we kicked this off in the late '90s, early 2000s, this was again a paradigm shift and suddenly you were seeing a quarter of the mortality within the vascular surgery than you did with open surgery, but your number of devices were limited. They pretty much all work in the same way and if you couldn't squeeze one of those devices into a patient's anatomy, then you had very little other option. And that's why an awful lot of the docs decided to go off IFU.

I think there's now been a complete change in that. We know that if you're off IFU for any device, your results are pretty poor, but today, we have many more options. So we have an increase number of devices which work in different ways and that's a good example of others, what John showed you with Endologix portfolio, if you take all three, you're going to get up close to 70%.

But also we have the option these days that if we want to extend our seal zone upwards or downwards, we have devices to do that. So we have custom-made branches. We have Chimney solutions. We have iliac branch solutions. So we have more options these days and therefore I think we can give the physician community a much better option to stay on label for most patients.

Andrew Hannover - *JP Morgan - Analyst*

And then last one, John, it's good that we can talk about biological act of effective Nellix, but then that becomes a question of how do you promote that from a marketing standpoint?

John McDermott - *Endologix Inc. - President, CEO*

Yes.

Andrew Hannover - *JP Morgan - Analyst*

Do you have to do some type of bio-techy type of clinical trial or how do you approach this with the FDA?

John McDermott - *Endologix Inc. - President, CEO*

Yes, it's a good question. And we've talked about, and one of the things that I think Matt will help us in his new role is really to design, determine what is the best way to get at this? How to organize a study and what is the study and how to end up with some definitive evidence.

To be perfectly honest it's kind of happening around us. I think one of the physicians, Dr. Berg, has a paper that's in press. So some physicians are already starting to do some of their own work and publish that work, so I think there's a growing awareness. But you're right to really provide definitive proof, we're going to have to do something on a prospective basis. And we'll design that some time here over the next year and hopefully execute that, but I don't know exactly what it looks like just yet.

Stay tuned. It looks like an exciting opportunity.

Sean Lyden - *Cleveland Clinic - Department Chair, Vascular Surgery*

So the next iteration is the LEOPARD trial, is the LEOPARD trial looking at AFX versus other commercial devices because of its expanded indications? I mean I can see it trying to someday convince John when Nellix is commercially available to say, I want to do basically the same design of LEOPARD, but I'm supposed to be looking at all-cause mortality as the primary driver of endpoint. So I'm now challenging Nellix against the other commercial devices.

And I think that a signal of change in all-cause mortality is something that will get patients willing to be involved in a trial.

John McDermott - *Endologix Inc. - President, CEO*

Yes, I mean, when you get diagnosed with a rupture, the first thing you worry, your first question is, am I going to die? So it's not unlike cancer patients, the first thing you do is you go look at the mortality tables. So I hope we can turn this into something. It's early but it's exciting and we've got some work to do.

Andrew Holden - *Endologix Inc. - Clinical Investigator, Medical Advisory Board Member*

(Inaudible - microphone inaccessible), and that's the obvious one; some sort of prospective rate. The only thing I'll say about that is there's a time delay with that and some things we need to do. One of the things we have is a huge data set on all-cause mortality with EVAR already and we've got propensity scoring.

What we really need to do is we're about to start the global two registry, we've got the IDE trial, we've got the global registry, with time we want to see that this sign is being replicated. And actually I think in the next year or so with propensity net scoring of the database, we can get some pretty powerful lines on this without the need, well without -- you may do that in time, but we can get it earlier by the data we are already accumulating.

Sean Lyden - *Cleveland Clinic - Department Chair, Vascular Surgery*

With U.S. approval, we have the vascular quality initiative which follows patients through one year and so once this is an approved device and you have the implants of it, within a year and a half of that happening, you would have a very large cohort that you can compare. The growing number of centers in the United States that are a part of the vascular quality initiative that follows outcomes including death through 365 days and so you could quickly, with that commercialization of the device, a year and a half down the road have a pretty strong signal because overall mortality is captured.

John McDermott - *Endologix Inc. - President, CEO*

And I think that's a good suggestion. We haven't thought about VQI, but I know that there're a lot of answers in Europe to get going on something now. There's been quite a few. So I'm sure there will be some interim activities as well. We'll keep you posted on how that evolves.

Any other questions? I know we're kind of bumping up to our time constraints here, so maybe we'll take one more if there is one. Nope, all right, well great.

Thank you very, very much for making time for us tonight. Hopefully this is good update. Any follow-up questions, feel free to reach out to me and our team and we'll talk to you soon. Thank you.