

CHRISTOPHER J. Well, good morning.

GOSTOUT:

Once again, it's an absolute pleasure to participate and be present in this now 11th Annual Endoscopic Endoluminal Surgery Course and to give the Pete Stevens Memorial Lecture.

I carefully choose the words endoluminal surgery because that is what makes this course truly unique and keeps it unique, probably in the world, because the cases that are provided really demonstrate and push forward the concept and the practice of endoluminal surgery. And I really applaud Winthrop for deciding to create an interventional practice that truly focuses on endoluminal surgery.

So for those present today and for those on the website, we're going to shift a little bit. And we're going to go from endoluminal surgery to talk a bit about GERD therapy. But before we do that, I want to draw your attention to the lower right-hand corner of the screen.

Up in Minnesota, it's been an absolutely fabulous winter. We've had snow like we've been waiting for for many, many years. That's just a picture of a snowshoe trail that I often take up at my cabin, which is, fortunately, off the grid when I'm up there. So it's a nice escape from endoluminal surgery.

So for ACCME Standards, I have to reveal my relevant financial relationships. I am the chief medical officer for Apollo Endosurgery. And I do some consulting work, as you see here, for Olympus Japan and a small startup company that's based in Kentucky, where I really have a really good friend. Hence, the other reason for taking on that assignment.

But having exposed you to my relevant financial relationships, my next question is then, would you believe this guy? So here I am years ago clowning around. Here I am in a little more mature phase in college still clowning around. Getting a little smarter, senior in college, applying to medical school, cleaned up my act. And then finally, a senior at medical school. Now, would you buy a used car from this guy?

Let's talk about GERD. And so in order to talk about endoluminal approaches to GERD, one has to address the Nissen Fundoplication. It is considered the "gold standard," and it has been thrown up as the "gold standard" against every endoluminal flexible endoscopic approach to

the management of GERD.

Why is that? What about Nissen Fundoplication? Well, it's a minimally-invasive and reproducible procedure that can be done in the hands of many.

Note the asterisk. It's relatively simple. Again, note the asterisk. I mean simple relative to the other anti-reflux procedures that had preceded it before it transformed into a laparoscopic-performed procedure.

And it can offer truly varying lasting benefit. The final asterisk.

And there is a boatload of data, because the user group is so large, because it can be done in the hands of many. However, it's not a perfect operation. But it is the gold standard only because there's nothing better.

So those asterisks that I pointed out-- minimally-invasive, available to the hands of many, simplicity, varying lasting benefit-- those three, I think, are key endoluminal opportunities to pursue GERD therapy.

So I do believe there is a role for endoluminal therapy, which can become prime time in the management of GERD. Unfortunately, the past era of endoscopic anti-reflux procedures was blemished by bad timing and negativism. These are the three procedures that you see in parentheses.

The current procedures that still prevail-- Stretta, TIFF, and MUSE-- are actually, in my opinion, flawed procedures. Why is that? They're expensive procedures. The tools are very expensive.

And some of these procedures, specifically the TIFF procedure, two operators are commonly needed.

It's a complicated procedure. The devices that are used to perform the procedures are very specific, and very complicated, and very demanding.

The Stretta procedure, as you see here outlined, involves creating a series of deep needle-point burns in a step-by-step fashion, but it has prevailed over the years.

Here we go into TIFF, a pretty complicated device that forces you to work in a retroflex position. Many maneuvers are necessary. In addition to suction, grasping the tissue,

accentuating a cuff, and then placing a set of tissue anchors. And the intent as you slap the fundus up against the distal EG junction, the intent is to create a cuff.

And then here we have an even more sophisticated opportunity to create the same basic cuff with the MUSE procedure. And this is a standalone device that instead of eye-guided placement of tissue anchors, it's ultrasound-guided.

And the intent is to do basically the same thing. Slap the fundus up against the EG junction. Try to extend, theoretically, the zone of the LES.

However, if we look at these procedures in the long-term results, meaning beyond a year, most of these patients actually return to PPI therapy, which originally is the intent for not to do is to keep the patients off the PPIs. And so they do have an eventual fade-out of their benefits.

And why is that? And that's because anatomically, given what we have to work with endoluminally, remodeling is a predictive outcome of this tunnel that the more sophisticated procedures can provide for patients.

So the next question is, so then what's missing? Even though there is literature to suggest these procedures are successful, but long-term, they gradually fade away in their effectiveness.

So what's missing in my opinion is we need a new mindset. We need to rethink a very key expectation. And that is long-term durability and displacement of the Nissen procedure. It's a pretty radical walk-away from this concept.

But first, we have to ask ourselves, what do we really want from endoluminal therapy? I think we want supplemental therapy, not necessarily primary therapy prevailing. We want supplemental therapy for the typical GERD patient that just needs an extra boost to control their symptoms. And we have a rising population of post-sleeve gastrectomy GERD patients that have real needs. And they have very limited environment within which to work.

And then we need an alternative therapy for patients with atypical reflux, whether they're non-acid refluxers, but mostly patients with altered anatomy. And we need a procedure that's not hiatal hernia restrictive.

Most importantly, we need a procedure that's very convenient, convenient not only for the patient, but ultraconvenient for the endoscopist.

And why am I showing you a box of Bic pens? The Bic pen in the 1960s revolutionized writing instruments. It threatened the leaders of ballpoint pens, such as the Parker T-Ball Jotter.

And why is that? Because the Bic pen was incredibly simple. It was packaged. It gave you everything you needed; smooth writing. You didn't have to change a refill. You didn't have to worry about a spring popping out when you change the refill on the pen. It revolutionized the writing world only because of its true simplicity.

So here, keeping that in mind, these are the must-haves that I think in resetting our thinking for prime time GERD therapy. Simplicity. It's got to be a simple procedure. It's got to be cheaper than anything that's out there.

It's got to be indefinitely repeatable, because we can't expect a permanence outcome of this procedure. There's going to be a fade factor in everything we do.

And so we need something that we can jump in, perform, do quickly, relatively inexpensively. It could serve as a primary therapy, but likely to be supplemental therapy.

It can be used in a variety of refluxing indications. And it doesn't require a very specific device-dependent code to be created to make it happen.

And most importantly, anyone should be able to perform this procedure. It should be performed lockstep in the management of a patient.

GERD patients frequently get endoscopy. It should be a procedure you can easily tack on to that screening procedure that you're going to do that won't consume a lot of time.

So there are some Bic pen approaches. Some that have been around for a while, and some that are evolving. And this is what I'm going to share with you.

Most of these approaches focus on the Z-line and the cardia immediately below the Z-line. That's the target of these Bic pen simplicity approaches.

The LES extends down to the stomach's nice thick muscle. We're going to come back to that later, when I'm going to shift gears suddenly at the end. But this is where the prime area is.

So Dr. Inoue, one of the family of our close faculty that have evolved in this course over the years, has the ARMS procedure. This is an Anti-Reflux Mucosectomy. It's, in essence, a

stricture formation within the cardia of the stomach. It can be done in the circumferential fashion. And it can be done in a crescent-type fashion. And I'll show you pictures of these.

It's been around a long time. He has reports of patients that have had this over 10 years.

There is this circumferential appearance, top left. And then eventually, you get scarring. So this is simply mucosa, submucosa. Down in the lower left, years later.

And then a chromoendoscopy to show that the esophageal mucosa remains normal after this is done in the reflux patient.

That's the crescent form procedure. So as you can see, there's still some of the cuff of the cardia left. And there's room for repeatability using that method.

And then there's this suture cardioplasty. We now have the ability to do endoluminal suturing. We know that placing full-thickness bite plications are very durable because of our ongoing experience. Thousands of patients now having sleeve gastroplasties.

One can do the same thing up in the cardia of the stomach. It's the placement of side-by-side full-thickness sutures and stacking 2-stitch plications to basically tighten the LES and tighten the cardia.

The beauty of this procedure? 15 minutes at most. Highly repeatable throughout the life of the patient. And it's not restricted to any size hiatal hernias. So you can work in any kind of space and an environment, because it's an end-on approach.

This is an appearance of a before and after. Atypical lax appearing, esophagogastric junction, and a nice snug junction with plications that have tightened that.

And then there's the RAP procedure, Resection And Plication. This is kind of the next level up in the suture cardioplasty. It requires an almost hemi-circumferential greater curve placed EMR.

And then it's actual suturing of the LES. So remodeling the LES with a different type of cardioplasty. And this is a set of photographs that demonstrate the procedure.

Again, the lax GE junction; the most patients with GERD. The highlighted area where the EMR is performed on the greater curvature side. And then you see the exposed LES, and then the marks as to the suture pattern that is used to snug up and do the cardioplasty.

So these are relatively quick procedures, simple procedures, use off-the-shelf instruments, and can generate some interesting results. If you look at this pilot study of 10 patients with the RAP procedure and you look at the top four that are extended out beyond the year, it's a pretty good outcome for a relatively simple approach for an off-the-shelf device.

Now I'm going to finish my presentation with a radical shift. I've been talking about simplicity, repeatability. Here's a different type of thinking. It's still in the embryonic stage, but I think it's worth presenting to you. And this is direct LES Augmentation.

This is a technique that uses our SEMF. We call it speed tunneling. It's blunt balloon dissection to create the submucosal tunnel on opposing walls of the esophagus.

And then a full-thickness focal myotomy is created, followed by balloon dissection of the adventitia. So we're creating a fourth space now between the LES and the surrounding adventitia in the lower esophagus. And then placement of magnets onto the LES.

This was an evolutionary program that we've been working on in our animal lab. It started with placing magnets across the LES, embedding the magnet in a foam dumbbell-shape button, basically, popping a hole in the LES, and then inserting the magnet into the LES.

And then it evolved into dispersing magnetic particles in a slow congealing polymer. So a polymer was injected into the LES, directly into the muscle, and it dispersed very small, microscopic magnets.

That worked beautifully well. It actually magnetized the LES. You could do a circumferential almost injection pattern, and truly magnetize the LES. Unfortunately, the magnetic strength of using micro magnets was just insufficient to close the lumen for what would be a satisfactory anti-reflux procedure.

And now we've evolved it into placing the magnets literally onto the outside of the LES. And this is a series of photographs that I'll take you through from left to right and top and bottom.

So the top left is just the blunt balloon tunneling, creating the submucosal tunnel. This is a standard tunnel you see for the POEM procedure.

And then once it's down to the LES pinch, we do a very focal myotomy. That's the final picture on the top right. Using this hook knife there to create a myotomy that doesn't rupture or

penetrate the adventitia.

And then in the lower left, extreme left, that's the space that's created. It's pushed the adventitia away from the LES. You're looking at the LES now and inside the adventitial space.

And then the magnets are literally clipped onto the muscle itself. There's a small suture loop on the magnet that the clip grabs. And the magnets are placed on the opposing walls. And then the tunnel is simply closed when the scope exits with clips.

This is radiographs of showing the two opposing magnets in place, closing the esophagus, and with an endoscope very easily passing through, simulating somewhat a bolus swallow.

And there's a one-month survival demonstrating that the magnets do indeed stay in place fixed onto the LES, but on the outside.

So what about this approach, LES augmentation? Well, is it truly better than the Linx procedure? Because that's what immediately you're going to conjure up. Maybe. We don't know yet. It's still in the animal lab.

It uses submucosal endoscopy. Truly an ultra minimally invasive endoluminal surgery. It requires still identification of the ideal magnetic material.

And it requires some kind of calibration, either pre-placement or calibration during placement with additive magnets. So we can put magnets there, but we don't know how strong they have to be to be truly clinically effective and not obstructive.

The difference between everything I've been saying prior to this portion on LES augmentation is this is permanence. So once those magnets are in place, that's permanent. They're not going anywhere. And LES has suddenly become lifelong magnetized.

So if it's poor-- if this technique is performed correctly, it probably could replace the Nissen, only because of the strength of the magnetic effect on the LES.

So in conclusion, I really do believe there is a role for endoluminal therapy, which can become a simple component to GERD management. It requires a major shift in thinking.

The off-the-shelf Bic pan approaches provide an appeal for on-demand convenience and simplicity to help treat GERD. And maybe fourth space adventitial magnet therapy, it's intriguing as an ultra minimally invasive, but durable therapy, potentially.

I thank you very much for your attention. And I hope I have stimulated some different thinking on your part.