

**SPEAKER:**

Thank you very much, Dr. Stavropoulos, for arranging this-- probably the best in the world-- course in intervention endoscopy. It's an honor to come to this course. And this year, there is not even rain outside. So everything is perfect.

Dr. Stavropoulos already said in his talk a lot about advantages of ESD over EMR. So I'm not going to spend time on that. I just want to go about the negative parts of ESD.

The negative is that although it's a very effective technique, it's definitely difficult. It's a very meticulous, labor intensive, and time consuming procedure. And on top of everything, it's extremely poorly reimbursed in the United States.

ESD in general-- if you look into ESD in the colon, it's possessive and has even more difficulties. First of all, there is a problem navigating if the lesion is located in the long, redundant, and torturous colon. So it takes time. What you actually spend in time, your taking away from the ESD itself.

Lesions can be located behind the fold or on the flexor, just like in this case. And that is especially difficult to deal with. The colonoscope can be unstable, and it can be fallen back and forth out of the proper position for ESD.

And the instability is even worse when the patient is breathing or peristalsis is working against you. Not to mention, the patient can have stool in the colon. And this may be in your way as well.

Finally, the wall of the colon is extremely thin. So, the perforation can happen in no time. And you saw how it happened today with Dr. [INAUDIBLE]. And this is, unfortunately, an additional problem with colonic ESD. So how do we deal with that?

This is my schedule for this week. And you can see this is Monday, two ESD, one in the colon, one in the stomach. Then Tuesday, five ESD, one in the stomach, the rest of them in the colon. And then Wednesday, four ESD, and yesterday five. So a total of 16 ESD, three of them in the upper, and 13 in the colon.

How can you get through that? And first of all, what motivates you to do that? The main reason for me to do so many is that it's extremely poorly reimbursed. So in Japan, the reimbursement for ESD is about 10 times more than the regular procedure. So you can

technically do one or two ESD a day, and this will be equivalent to doing 10, maybe even 20 procedures a day.

In the United States, the reimbursement for ESD in the colon is \$300. My anesthesia gets reimbursed \$680 doing anesthesia during the ESD procedure. So I can only compensate for that by doing it in high volume. So how do you do it in the volume? First of all, you need to learn the technique.

And this is one of the examples. So you see 13-01. We're starting removal of that large colonic lesion, which is approximately 6 centimeters in diameter. And I can not take time. I have to move quickly. I have to think of the way to be more efficient. And this is how you get through the day.

And this is now-- you can see-- 45 minutes later. We are finishing the procedure. The lesion is removed in one piece. And clearly, it's better than piecemeal resection for this patient. But again, 45 minutes for ESD-- that is the only way to do it in the colon in the United States and get adequately reimbursed.

So I decided to concentrate-- there is no question that the ESD procedure can be long. And unfortunately, it's a long process. So luckily there is a solution now. Now ESD in the colon can be done faster. And Dr. [INAUDIBLE] just mentioned, minutes ago, balloon overtube. And he meant this DiLumen. You can see that device outside.

So DiLumen is a big overtube, which has two balloons. One is fixed on the terminal portion of the overtube. And one can be extended forward. So this is the fore balloon. This is after balloon. And then there is a handle, which can distend both of those balloons.

We started to use this device at Mercy on November 7th, 2017. And up to yesterday, so far, I did 122 procedures. Three were diagnostic, meaning that referring physician sent me a polyp, but there was nothing left.

And six of them were EMR, and the rest is ESD. 113 colonic ESD in 3 and 1/2 months. Mostly in the right colon, cecum, ascending, colon, hepatic flexure. But still, some of them were in transverse, some of them were descending in rectum.

So what does DiLumen do for you? First of all, it saves me time to reach the lesion by facilitating advancement of the colonoscope through the colon. And this is the model which

demonstrates how it works.

So you see, this is a colon, typical colon structure with multiple turns. If we put in the colonoscope through the colon, you reach the first turn, and then when you're trying to shorten it, it's ineffective shortening. When you go forward, you practically get back to the same scene where you were before. So that is where you start to apply pressure. That's where you start to ask your staff to rotate the patient and stuff like this.

This is another example. Again, the same model-- and we're using an colonoscope with DiLumen on it. But we are not using any balloon. So DiLumen is going just over tube, which is not an active overtube in this situation. Again, you get here, you pull it back. And when you go back forward, everything is exactly the same as it was. Ineffective shortening, ineffective advancement of the scope--

Now I'm using DiLumen, the same model. And you can see, no cheating. I'm not touching it. But we will be using DiLumen as an effective overtube. So here, I can reach the first flexure. And at that point, my assistant is distending the balloon. And now I'm shortening. When I shorten it, it's effective shortening. And DiLumen is holding it as a short.

And I am advancing the endoscope forward, up to the next flexure. Now we enter a distended colon. And now I release the balloons, each with DiLumen, to the place where I stopped. And now again, I will distend the balloons, fixing the colon in and pulling it back to shorten it. This is effective shortening, which has practically eliminated that first loop in the colon.

Now from this point, the colon is shortened, sigmoid loop eliminated. Nobody helped me, no pressure, no change of position. And then that scope went up to the splenic flexure, again, releasing the balloon and advancing DiLumen up to the splenic flexure.

When DiLumen reaches the splenic flexure, I'm again-- here, you see how DiLumen is moving, now descending the colon, going forward, reaching the splenic flexure, and again descending the balloon. Fixing DiLumen in the splenic flexure-- pulling back-- and now from this point of fixation, I can easily advance the endoscope forward.

So the endoscope will not be stretched in that part of the colon, but rather moving forward. And I am straightening the transverse colon this way. I'm reaching hepatic flexure, and when I reach the hepatic flexure, I will again release the balloon, and advance-- now you can see where it is in the balloon-- and advancing DiLumen forward to the hepatic flexure.

You can see the whole colon is straight. The whole colon is friendly. And we are fixing DiLumen in the hepatic flexure, pulling back. And you can see now from that point forward, we can go back. So this DiLumen advancement to the secum cost me anywhere from four minutes to nine minutes, the most. And no help at that period of time. That's how it looks in humans.

You can see here, this is the scope guide. And you can see that I'm practically alone. My assistants are playing on the internet, sending text messages. Nobody is really there. And you can see that we are going forward, and anesthesia is not anywhere close to the patient. So you can see the same story going on.

I am distending the balloon, shortening it. And here you can see I'm in the transverse colon, approaching the secum. And now I'm in the secum and pulling everything back. No help from outside, but we reach the entire colon, and now we are deploying the DiLumen. And we are practically in the secum. That's the typical procedure when you're using this lumen or DiLumen to advance through the colon.

Because [INAUDIBLE] assigned me only 20 minutes, and I'm not a course director, and I can not use 40 minutes when you have only 20 assigned, I decided to put all the other steps, which each of them can probably be-- I can talk for at least 15 minutes for each of those bullet points. I decided to combine them together.

So what else DiLumen does for you, besides saving time on advancing the endoscope? It stabilizes the endoscope. And that's why it's helpful for doing EMR, ESD, or even full thickness resection of the colon. It creates Therapeutic Zone. When you deploy both balloons-- front balloon and after balloon-- between them, you can fix the lesion. And then you're constantly staying in that area.

It gives you dynamic retraction. And I will show you an example in a minute. And it creates a conduit from rectum to Therapeutic Zone. Meaning, you are doing the procedure, then your scope gets dirty, and you are somewhere in the proximal ascendant colon. With DiLumen in place, all you can do-- you pull out the scope, which takes seconds. You clean the scope and you go through that DiLumen, right into the place where you were. It's again, one minute to get there.

And you can deliver the same way. Suturing devices or any other devices-- it saves a

tremendous amount of time. And this is a clinical example. You can say that I am alone. Again, nobody's touching that. DiLumen is in place and DiLumen is in fixed position.

And this is the large lesion located in the hepatic flexure, about 6 centimeters in size, and very flat. So with DiLumen an ESD in the colon becomes standardized. So what I do-- I do circumferential incision around the lesion first. And the scrub guide confirmed position of the endoscope. And after circumferential incision is completed-- after circumferential incision is completed, I do a minimal dissection, like this, just a little bit edge. And after that, I'm using DiLumen for traction.

The way it is done, we are putting suture loops on the front balloon of the DiLumen. And then we grab those loops with the endoscopic clip-- just one clip is enough for the entire procedure-- and then pulling it towards the edge, and fixing it to the edge of the polyp. Here I grab the suture and approximated it towards the edge of the polyp, which is very simple.

And now I position the clip. And from that point forward, I'm pushing the front balloon forward. And it creates a very effective traction. You will see it in a minute. So now I need to do ESD with the tissue on the traction, which is practically the same as doing it during the surgery. The main idea when you do surgery, you have triangulation and you have tissue under traction. And that's what DiLumen has given me.

So you can see my submucosal space is constantly exposed. Plus, it is not a static traction. It's dynamic traction. So I can push it more forward to create more traction. Or I can pull it a little bit back and then it will be less traction, if I feel that there is too much traction.

So we started to do this dissection at about 51 minutes. And you will see how long it will take to go through the entire dissection of the 6 centimeter lesion. I'm just speeding it up a little bit.

When the tissue is on the traction, all I need to do is just touch it with electricity, and it immediately cuts it out. You can also see that all the blood vessels are exposed very well. So the procedure is very closed. It may resemble what we have done in surgery. And this is the end of it, 6 centimeter polyp. 50 and 51, we started. And this is the last cut. That's it, 10 minutes.

And look at this large area, which is exposed. And now, I can pull the endoscope out. I'm just cutting this suture so that I can retrieve the specimen. It's no longer needed inside the colon. And then I exchange it to the suturing device, go in with the suturing device right to where I

was, taking seconds, finishing suturing. And this is the end of the procedure. After the suturing is completed, again, I remove the endoscope. And that's the big lesion.

It is also effective if you are dealing with a pedunculated lesion. So this is-- you can see the case was done yesterday. So it's in 58, yesterday. And they sent me a big polyp, about four or five centimeters big lesion in the colon. And when I looked at it, I could not understand where is the attachment of the polyp. And so in order to get some exposure, again, I grabbed the loop and without dissection, I just attach it to the polyp like this, which is very easy and takes seconds.

And after that, I push forward the front balloon to reach that polyp attached. So it pulled the balloon forward. I go under the polyp and I cannot see where it is attached to the colonic wall. So I thought that if I inject, maybe I will see the place where there is attachment. I start submucosal injection, but it did not really help. So I can see that place where I'm injecting has nothing to do with the attachment of the polyp.

So what do I do? I have dynamic retraction. Meaning, I can push this polyp front or back, whatever I want. So I go behind the polyp. I go to the front, in front of the polyp. And now I am pulling this front balloon backwards. So I'm pulling the polyp towards the rectum, in anal direction. And suddenly, I can see that it is a big pedunculated lesion, located on a very thick stalk.

I actually hate those pedunculated lesions. To me, it's better if the polyp is flat, because when you're dealing with lesions like that, there are big, big blood vessels. And the biggest bleeding I had was not from flat lesions. The biggest bleeding I had was always from pedunculated lesions.

Now you can see, the exposure is very good. I intentionally put a balloon under the polyp between the polyp and the wall, so I can do dissection a little safer. So you can see with exposure like that we can easily go through. There is no way I can not put a PolyLoop on that. And here, I immediately encountered the bleeding. But what I do, I pull the DiLumen, and it stretches the stalk. And the bleeding has subsided. So I can easily control it. We use the dual knife.

I continue dissection. And again, the tissue is under significant tension. So I just touch it, and it cuts. It's much more effective than regular endoscopic submucosal dissection. But look what happened next. Again, everything looks normal. I don't expect any problem. And suddenly, I

got into the arterial bleeding. So here you can see how it is shooting. And I tried to control it with the dual knife. It did not really work. So we had to go to the [INAUDIBLE].

But pulling DiLumen stretches the vessel and decreases the bleeding. So just one application of [INAUDIBLE] was enough to stop the bleeding. And now the rest of procedure is very easy. So we started at 14-01. Now 14-15, that is the end of the dissection.

Final cut-- we're all ready through mucosal. Submucosal is already done. You can see this yellow tissue. It is mucosa. That's it. So that is the place where it used to be attachment of the polyp. The polyp is attached to DiLumen. So now, I remove the endoscope.

And I go with the suturing device, which is, again, very easy because I have a conduit between the Therapeutic Zone and rectum. So advancement of the suturing device takes no time. And I'm dropping the needle. And I'm finishing that. And this is the end of the process. Again, removing the suturing device, go in with regular endoscope, and that's how it looks. So this is the end of this procedure.

So finally, having this conduit allows you to remove multiple lesions. If you have several lesions and you don't want to mix, because one of the lesion may come back with the cancer. So you want to know that, if they are lesions with cancer, it came back from secum, or from transverse colon. Then with DiLumen in place, you can go back and forth very easy to do all this.

So in conclusion, DiLumen is a new intraluminal interventional platform, facilitates pleading and telescoping of the colon during advancement of the colonoscope, and saves me a tremendous amount of time during ESD. Our estimate is about-- for the relatively short ESD-- it saves me one hour. For the large lesion and big procedures, it saves me at least two hours. It stabilizes the lesion inside the Therapeutic Zone, provides traction and markedly facilitates colonic EMR, ESD, or even full thickness resection.

It creates conduit and simplifies endoscope withdrawal exchange and suturing closure. And it significantly shortens total procedure time. So I think that the western ESD in the colon will be all done with the help of the DiLumen. And that will make it much, much faster. Thank you.

[APPLAUSE]

Any questions?

**AUDIENCE:** [INAUDIBLE]

**SPEAKER:** Yes, please?

**AUDIENCE:** [INAUDIBLE], so, the device is expensive. Have you [INAUDIBLE]

**SPEAKER:** That's a very good question. So every device which our hospital buys goes through value assessment committees. So for value assessment committee, the first question was, how often you will use and how expensive is the device? The device cost money obviously. So I told them that I will use it probably six, seven times a year for the most difficult cases. They approved it.

During the first two weeks, I did 24 ESD with DiLumen. Most of them, the company gave for free. But six of them were the six which were approved for me for the whole year. The difference in time saving was so big that our charge nurse actually went to the value assessment committee, and she said that we are saving so much overtime. I am paying much less overtime since he started to use that device. She said, please allow us to buy it.

And from this point forward, the days when I don't use it, she comes to me and she said, why did you not use DiLumen yesterday? You did longer. So it saves time. It saves time and the hospital is happy to buy it. Yes, please?

**AUDIENCE:** [INAUDIBLE]. I have a quick question. What made you-- I'm sorry. Thank you. Thank you for the nice talk. What made you choose ESD for the pedunculated polyp over snare? Is it the size? If I could ask.

**SPEAKER:** First of all, I did not know that it was a pedunculated polyp. It was sent to me as big, flat polyp. They said it was three centimeters long in the distance. I had no idea that it was pedunculated. When I realized that it was pedunculated, I realized the head of the polyp was so big. I do not have a snare to put it all over this thing. So in that situation, I could not also put as PolyLoop. It was bigger than the diameter of the PolyLoop. I had no choice. I had to do ESD.