

ERIC COOLIDGE: Welcome to Lumendi's DDW 2020 highlights, featuring the DiLumen endoluminal interventional platform. My name is Eric Coolidge, Lumendi's VP of marketing.

With the cancellation of DDW 2020, and during this unique time of limited travel and human contact, it has been our goal to maintain virtual touch with GI clinicians as much as is possible. Our goal with today's program is to provide you with a venue like DDW where the authors of articles and posters can have an opportunity to present their data and respond to questions as they would within a live forum.

Today, we are fortunate to have four esteemed lecturers who will be presenting their data regarding the DiLumen platform that was to have been presented at this year's DDW. Our first speaker today is Dr. Mohamed Othman, associate professor of medicine, gastroenterology and hepatitis section, Baylor College of Medicine, and chief of gastroenterology section, Baylor St. Luke's Medical Center. The title of Dr. Othman's presentation is, "Interim outcomes for a prospective multi-centered US registry utilizing a double balloon endoluminal platform to facilitate complex colon polypectomy."

If, during this program, you would like to ask a question, please feel free to use the chat box at the bottom of your screen. Following our final presenter, we will spend the last 15 to 20 minutes to ask these questions. So with that, I would like to turn it over to Dr. Othman.

MOHAMED OTHMAN: Well, thank you. Thank you for the invitation. I know all of us miss the DDW, but I'm glad to get the chance to present this data. And it was chosen as an oral presentation in one of the sessions, which was about new technology for polypectomies. The title of our abstract was "Interim outcomes for a prospective multi-center US registry utilizing double balloon endoluminal platform to facilitate complex colon polypectomy."

Before we start, I would like to highlight that this data came from three centers in the United States. Baylor College of Medicine is one of them. The other one is from University of Florida, with Dr. Peter Draganov. And also, we have Geisinger Health System with Dr. David Diehl. So it's not only my data. It's data from three academic centers. And I have the honor to present their data with me. And I would like to thank, also, then, Dr. Diehl, Dr. Draganov and their teams for helping with this data.

So when we talked about spectrum of endoscopic resection, we have endoscopic mucosal resection, submucosal dissection, and full-thickness resection. And I would like here to highlight that EMR use, we use a snare. ESD, we're going to use a specialized knife. And full-thickness resection, you use the ESD knife, but you go all the way through the wall. But for ESD and EMR, although we are utilizing different equipment, our goal is to dissect through the submucosa.

So the submucosal endoscopy or submucosal resection is a procedure that has a tool box-- an electrosurgical unit, injection devices, and snares and knives, as we just showed, hemostasis devices. Sometimes we do ablation, and tissue opposition devices such as clips and suturing devices. But there is always a problem when we do a tissue resection, which is stabilization.

And in a lot of situations, it would be in a tough area in the colon behind the fold. Lumen is redundant and unstable, so we always were in need for another tool box, which is stabilizing devices. And that's where this novel double balloon device came, Lumendi. It's helpful because it has two balloons [AUDIO OUT] the therapeutic zone. You can use it for manipulation of difficult colon anatomy and stabilization of the endoscope.

And also, we can use it for removal and insertion of the endoscope, as we're going to show in one of the videos. Also, it will help with improved visualization by inflating the balloon and depressing the folds. And we'll also use it during the dissection for dynamic attraction. So as you can see here, it's one device, but you can use it for many, many uses to highlight endoscopic resection and make it easier.

So the aim of our study was to evaluate the clinical performance of the double balloon endoluminal platform during endoscopic resections. This was a prospective sponsored multi-center IRB approved registry of up to 200 patients. It was in three US centers, as we just mentioned. The outcome data i the use of the double balloon platform was collected, and we looked at safety and performance data. We also contacted the patients after the procedure and after one month to make sure they are doing well.

Our primary efficacy endpoint was the ability to perform the procedure safely and effectively with the study device. Our statistical analysis was very simple. The study did not require complex analysis. We had 81 interventions by the time we submitted. As of now, we actually have more than 120. Our goal is to recruit 200. That's when we are going to publish this data. But today, we're going to focus in the 81 interventions that were submitted to DDW.

Among this 81, we had analysis of 79. So there's two patients who were out of the analysis. The reason is one of them, we could not find a polyp, and the other one, the procedure was aborted because of a colon carcinoma. So again, because this is intention-to-treat analysis, all patient was consented. But then, in one of the situations, although the patient consented, we find that colon cancer, we did not use the device.

So we have 79 cases when the device was used, and among the 79 cases, 70% the device was used successfully. There was no adverse event or device-related problem. So a success rate of utilizing the device was 89%. I'm going to come later to talk about why in, nine cases, we were not able to do it.

So that's the table here showing the demographic of our patients. Mean age is 64. I just want to highlight certain things here. Lesion size, 3.9 centimeters, almost 4 centimeter polyp. This was not small polyps we were using. This was really large polyp between 4 to 5 centimeters. And the location of the polyp, 62% was in ascending colon to the cecum.

This does not reflect the normal distribution of polyps in the human body, which we know more of them would be in the left side. But it does reflect a pattern of referrals. Most gastroenterologists will refer tough polyps, and most of these polyps will be in the right side of the colon. And if you happen to have a difficult anatomy or redundant colon, it will be even almost harder to remove these problems in ascending colon and the cecum.

As you can see here, our cohort highlighted that that particular area, in ascending colon cecum, is the most difficult to remove. Also, after that, you will find the transverse colon to hepatic flexure. So right side colonic polyps are more difficult.

In term of pathology, removed, most of the lesions were adenoma or villous adenoma. So in our results, we have nine patients, as we mention, that the resection was not complete due to either early user experience-- some of them, at the beginning, it was hard to complete the case-- and some of the patient had stricture or diverticulosis.

And I have to talk about that a little bit. If you have a colon narrowing, severe narrowing, it may not be a good idea to advance the device with a balloon. So sometimes, if we have a known surgery or stricture from prior IBD, this should be an exclusion criteria for using the device.

Having said that, we were successful and 70 out of 79 patients. If you were going to ask me, what is the ideal patient? I would say a patient who you have difficult polyps in a patient who have looping problems or [INAUDIBLE] and you are not able to visualize the lesion. The navigation was deemed easy in most of the cases, and the balloon was used for various maneuvers-- stability in 100% of cases, traction in 74% of cases, and navigation or colon shortening in 65% of cases.

I'm showing a video here, and in this video, that's a pulse ESD perforation. So if you can look again, we're gonna to go by the endoscope, and you can see that we have a perforation. You can see even the fat outside the lumen.

Because we're using the DiLumen platform, we're easily able to remove the endoscope, DiLumen platform in place, which allowed resection with no problem. So you can see here that we're able to-- not resection. It allowed like suturing was no problem. So you can see here that we were able to suture the area and close the perforation easily because the double lumen platform was in place and we did not have to make any changes.

That's an example of what we call dynamic traction. And the dynamic traction, we are using a suture which attached to the forward balloon, the front balloon. And that suture is attached to the edge of the section of the clamp. And then you gradually pull the balloon forward and start dissection. And you discover that technique can really expedite endoscopic resection.

So if we look at more of our data here regarding the endoscopic dissection, we'll find that we have three types of techniques done in [INAUDIBLE], which reflect the variety of what we did. We have EMR. We have ESD converted to hybrid EMR/ESD. And we also have ESD and the cases were similar-- 27, 16, and 27.

Lesion sizes were similar between both of them. Dissection time, however, was different. In EMR, the device allowed EMR to be done in 27 minutes. For ESD, our resection time for colon polyp is 52 minutes, and for hybrid, 60 minutes.

And I will have to stop here and talk a little bit about that number. 52 minutes for a mean-size polyp of 4 centimeters in the right side of the colon, that's really good results, because we would know that without the device, I would have spent even more time to do the dissection. So that's really expedited the dissection.

If we look at the different between hybrid and ESD, we'll find ESD is shorter, most likely because cases that converted to hybrid EMR/ESD were more difficult cases, were harder to do, and then that's why we end up resorting to EMR and ESD.

And the total procedure time is 67 for EMR, 106 for ESD, and the meantime, for pure ESD, not hybrid, it's 84 minutes, which is around one hour and 1/2. That's really reasonable time, and that reflects my practice of performing three to four colon ESDs a day. I'm scheduled one each two hours. And the data, the registry reflected that numbers.

In terms of safety, we had no device-related adverse events. We had some procedural adverse events in our group. Most of them were minor perforations that were treated. And there is no device-related adverse event over 30 days.

So in conclusion, in our interim analysis, we found that the double balloon device facilitated endoscopic resection of complex colon polyp by providing stability, better visualization, and also expediting the endoscopic resection. And as we saw in one of the videos, allowed rapid exchange for another device for suturing. And all of these qualities made endoscopic resection much easier.

I think the device, and from our data, will become an integral part of doing colon ESD in the United States, especially for endoscopists who are not familiar with the bucket technique or would like to use it in spite of the bucket technique. And the fact that we're able to decrease the dissection time for large polyps to 50 minutes, I think, is impressive. And I will stop here. Thank you.

**ERIC
COOLIDGE:**

OK. Thank you very much, Dr. Othman. Again, if you have any questions for Dr. Othman, please use the chat box at the bottom of your screen, and we will ask those questions at the end of this presentation-- these presentations.

At this point, I would like to introduce our next speaker, Dr. Hiroki Yamashita of the National Cancer Center Hospital in Kishiwa, Japan. The title of Dr. Yamashita's presentation is, "The Usefulness of a Double Balloon Device for Colorectal Endoscopic Submucosal Dissection by Non-Expert Endoscopists in a Porcine Model." Dr. Yamashita could not join us in person today, but he has been kind enough to pre-record his presentation, and we will play it for you at this time.

**HIROKI
YAMASHITA:**

(VIA RECORDING) Hello, everyone. My name is Hiroki Yamashita, from the Department of Gastroenterology and Endoscopy, National Cancer Center Hospital East, Japan. I'm happy to have the opportunity to make this presentation today.

The topic of my presentation is, "The usefulness of a double balloon device for colorectal endoscopic submucosal dissection by non-expert endoscopists in a porcine model."

ESD is widely accepted as a less invasive treatment for colorectal tumors. However, colorectal ESD is technically difficult, and the frequency of complications like perforation or the failure to achieve an en-bloc resection can be unacceptably high in non-experts. A device which helps non-experts to facilitate colorectal ESD more safely and efficiently is demanded.

A double-balloon device you can see here was recently released in order to assist endoscopic colorectal procedures. It consists of a sort of flexible sheath that fits over a standard colonoscope. The device employs two balloons, one behind the bending section of the endoscope, and the second the front of the tip. When both balloons are deployed, the area in between is stabilized. Also, it has a string loop on the fore-balloon that enables tissue interaction during the ESD, which I can show you the movie later.

It has been reported that dissection speed in an ex vivo model was improved with this device when ESD was performed by experts. However, the usefulness of this device for non-experts remains unclear. The aim of the present study was to assess the usefulness of the double-balloon device for colorectal ESD by endoscopists including non-experts using a porcine module.

Two pigs were used to perform eight DB-ESD and eight conventional ESD procedures. 80 lesions per pig sized 20 by 20 millimeters each were artificially designed in the rectum. Three experts who had performed more than 100 colorectal ESD cases and five experts who have done less than 10 colorectal ESD cases each resected two lesions. One lesion was resected with DB-ESD, and the other with C-ESD.

Dissection speed, total procedure time, self-completion rate, and perforation rate were recorded in both DB-ESD and C-ESD groups. We also performed a stratified analysis between non-experts and experts.

We will show you with the movie of DB-ESD procedure by expert. First, we inflated fore-balloon at the other side of the lesion and moved to the scope tip backward [INAUDIBLE] back balloon. After setting up to the double balloon device, we injected sodium hyaluronate, made a circumferential incision, and turned to the other side of the lesion.

For retraction, our loop was moved closer by pulling fore-balloon back. We fastened the loop to the other side with the lesion with clipping. We got good retraction as moving the balloon. [INAUDIBLE] to dissect the submucosa safely and speedy with the retraction.

Procedural results were shown in this table. Dissected region size was comparable between DB-ESD group and C-ESD group. En-bloc resection rate was 100% in both groups. No perforations occurred in both groups.

We show the dissection speed on left side and total procedure time on right side. Dissection speed was 13.3 in the C-ESD group, whereas 28.5 in DB-ESD group, which means faster dissection speed in DB-ESD. Total procedure time was 27.1 minutes in C-ESD, whereas 18.1 minutes in DB-ESD, suggesting shorter procedure time in DB-ESD group.

Focusing on the results in experts, dissected lesion size was comparable between DB-ESD group and C-ESD group. Self-completion rate was 100% in both groups. In experts, dissection speed was improved by DB-ESD from 19.1 to 28.8, whereas total procedure time was 13.8 minutes in C-ESD and 16.2 minutes in DB-ESD, which is almost comparable.

Focusing on non-experts' result, one non-expert could not complete C-ESD without changing the operator. Thus, self-completion rate was 80% in C-ESD, whereas all non-experts could complete ESD by themselves in DB-ESD group. No perforations occurred in both groups.

The dissection speed by non-experts was much faster in DB-ESD group than in C-ESD group, from 10.9 to 25.1. Accordingly, total procedure time was shorter in DB-ESD group than in C-ESD group.

We showed C-ESD movie comparing experts and non-experts. The movie in the left side is C-ESD by expert, and that in the right side is by non-experts. An expert could make a retraction with attachment hook, but a non-expert had difficulty in making a retraction. It takes 16 minutes to complete the procedure by an expert, but it takes 48 minutes by a non-expert.

Next we compare DB-ESD by experts and by non-experts. The movie in the left side is DB-ESD by expert, and that in the right side is by non-expert. By using this DB device, a non-expert could make good retraction and dissect submucosal as safely and speedy as an expert. It takes 16.2 minutes to complete the procedure by an expert, and it takes 24.3 minutes by non-expert.

The dissection speed by non-experts was much faster in DB-ESD group than in C-ESD group. Improvement in dissection speed with DB-ESD was also observed in experts. Self-completion rate of non-experts was higher in DB-ESD group as compared with C-ESD group.

The double-balloon device is useful for colorectal ESD by endoscopists, including non-experts, by improving dissection speed without increasing the perforation rate. Thank you all for listening.

ERIC COOLIDGE: Our next presentation is, "A novel, multitasking, non-robotic platform for endoscopic submucosal dissection." At this time, I'd like to introduce Dr. Christopher Thompson, director of endoscopy at Brigham and Women's Hospital and Professor of Medicine at Harvard Medical School. Dr. Thompson?

CHRISTOPHER THOMPSON: Thanks very much. It's great you guys are doing this. We really appreciate it. We missed being able to see everyone at DDW, and this is a wonderful way to catch up on these important studies.

So I'd like to introduce the fellow who did the lion's share of this work, actually. His name is Tom McCarty. And he's a second-year fellow at the Brigham. And he spent a lot of time with the system and has done some very good research. And he was invited to give these presentations at DDW in an oral session. So this is a great opportunity for him. So I'm gonna present the-- have Tom give the presentation.

THOMAS R. MCCARTY: Thank you so much. And again, big thank you to Lumendi for the opportunity to present our research here today. So as I said, again, the title of the talk today is "DiLumen C2 versus Conventional ESD, Results from a Randomized Pilot Study."

And as a little background endoscopic, submucosal dissection, or ESD, is widely utilized in Asian countries. However, routine use of colorectal ESD in the United States has not been widely adopted. And this is due to several potential barriers, including the fact that ESD is a complex and technically demanding procedure, increased procedure time associated with this technique, and associated with a steep learning curve as well, and as well as an increased incidence of adverse events, particularly bleeding and perforation.

But given the various sort of benefits of ESD, specifically compared to traditional surgery or EMR, there's really a need for techniques and platforms that can decrease some of the limitations of conventional ESD. One such system, the DiLumen C2 system, is a novel, multi-tasking, non-robotic ESD platform that is designed to improve the stability and manipulation of the tissue throughout the colon. This single-use, disposable device, which is shown here at the bottom of the slide, has received both FDA approval in the US, and the platform is designed to overcome many of those barriers which we discussed about earlier associated with conventional ESD and potentially simplify the training process.

Now, the DiLumen C2 platform itself consists of a flexible sheath attached over a standard endoscope with the use of two balloons, which we've already heard a little bit about earlier today, one fore-balloon and aft-balloon shown in this image here on the right. These balloons are inflated inside the colon to create a stable therapeutic working zone for endoluminal intervention. And additionally, the C2 device, the platform includes two working channels in the sheath, which allow for insertion of articulating endoluminal instruments, including interventional graspers, to provide traction and assist with tissue dissection.

Now, shown here is a setup with a flexible sheath device with a colonoscope and two endoluminal instruments introduced through the working channels. The handles shown here have a wheel and trigger mechanism to allow for easy rotation, opening, and closing of the grasper, while the joystick controls the ability of the providers to control the device. Looking at the video here, we see that the sheath also contains two 6-millimeter working channels at the 3:00 o'clock and 9:00 o'clock positions of the overtube, and as you can see in the images on the right, the interventional grasper can be used to grab tissue, facilitate traction, which may aid in tissue dissection.

So having briefly discussed the DiLumen C2 platform, let's jump into our study design and results shortly. So this was a two-part randomized study in an ex vivo bovine colon model. The first part of the study was designed to assess ease of use of the DiLumen C2 system and impact of a formalized training program. And in the second part of this trial, we really aim to compare DiLumen C2 versus conventional ESD and evaluate the efficacy, safety, as well as the mental and physical workload for both techniques.

So looking at part one of this study, nine trainees without prior ESD or DiLumen C2 experience were randomized in a 2 to 1 fashion into two groups. Group one included six trainees that received a 45-minute didactic and hands-on training session prior to use, and group two include three trainees randomized to receiving no training prior to hands-on use. Again, the goal of this first part of the study was to assess the intuitiveness of the platform as well as the ease of use. And to do this, we used a standard 2 by 2 centimeter lesion which was created in an ex vivo model and allowed an allotted time of 90 minutes to complete the procedure.

In terms of study outcomes, the primary outcome for this study was complete en bloc resection in the 90-minute period, and secondary outcomes included differences in procedure time, rate of mucosal injury or perforation, and physical and mental workload as measured by the validated National Aeronautical and Space Administration Task Load Index, or NASA Index score, which is shown here on the right. Now, it's important all trainees would fill out this NASA Index form immediately after completing each procedure.

So moving onto the results of this first part of the study, complete resection was actually achieved in all nine cases, or all nine procedures, regardless of group one or group two randomization. No perforations occurred in either group. However, one mucosal injury was noted in the group that did not receive formalized training. Overall procedure time and, more specifically, time to perform dissection was significantly decreased in the group that received training. And as you can see in the table here, there was no difference in time to perform submucosal injection or circumferential incision during the procedure.

In terms of physical and mental workload, which is shown here in the table, it was actually no difference in total or individual mental, physical, or temporal demand as measured by the NASA Index scores, highlighting, really, the C2's ease of use and intuitive design. We'll talk a little bit more about both of these results at the end. But moving on to the second part of this randomized study, we really aim to directly compare outcomes and workload for conventional ESD versus DiLumen C2.

Six novice trainees again randomized in a one-to-one fashion into two groups. The first performed conventional ESD, followed by DiLumen C2, and the second group performed DiLumen C2 followed by conventional ESD. Again, endoscopists in this study had no prior ESD experience, and each trainee performed two tissue resections for a total of 12 procedures in all. Again, we used a standard 2 by 2 templated lesion and allowed 90 minutes for procedure completion.

In terms of outcomes, these were exactly the same as the study one outcomes-- again primary outcome being complete en bloc margin negative resection, and secondary outcomes again being total procedure time, rate of mucosal injury, and physical and mental workload between the two techniques. Results from part 2 of the study demonstrated complete resection was again achieved in all cases, really regardless of conventional or DiLumen technique. While no perforations occurred in either group, and looking at the table here, mucosal injury was much more common in the conventional ESD group and occurred in three cases.

No mucosal injury occurred or was noted in the DiLumen C2 group, again, which you can see here in the table which is highlighted. With regard to procedure time, total time to complete resection and time to perform dissection were significantly lower for the DiLumen C2 group, with a total procedure duration 50% shorter compared to conventional ESD-- so quite impressive. Again, we did not notice any differences in submucosal injection or circumferential incision time between conventional ESD and DiLumen C2.

Looking at the mental and physical demand, total NASA scores, as well as individual mental, physical, and temporal demand scores, all highlighted in the table, were significantly lower for DiLumen C2 compared to conventional ESD. NASA scores across the board for DiLumen C2 were about half of those in the conventional ESD group, suggesting ESD with the DiLumen C2 platform is much easier to perform.

Now, before we talk about the conclusions and potential clinical implications of this study, I just wanted to highlight here a video showing one of the trainees using the DiLumen C2 to perform ESD which was enrolled in this trial. Here we can see the use of the endoluminal grasper to grab the tissue and retract it, making it much easier to perform dissection. The constant traction provided by the grasper allows for a more efficient dissection process and significantly shorter dissection times compared to conventional ESD. You can also see in this video the use of the dual balloon system which we talked about to create the stable therapeutic working zone for a dissection.

Eventually, dissection is continued until a complete resection is achieved. And in this specific case here and video here, we see the ESD defect with no evidence of mucosal injury. I think it's important to remind ourselves and remember, again, this was a trainee who had no prior ESD experience, and the entire procedure and resection of this 2 by 2 centimeter lesion was completed in approximately 15 minutes with the DiLumen C2 platform-- so quite impressive.

Briefly touching on limitations and strengths of this study, although this was a randomized trial, the sample size is quite small. Additionally, the study was performed in an ex vivo model with limited data in human trials, though this may actually underestimate the true benefit of DiLumen C2 because of its ability to provide stabilization, and there's no-- given a lack of peristalsis when performing incision and dissection. Ultimately, though, this is the first study to directly compare the DiLumen C2 platform to conventional ESD. Some additional strengths of the study are the inclusion of trainees with no ESD experience, as well as the use of these validated scoring systems, the NASA Load Index score, to accurately assess physical and mental workload.

So in conclusion, big takeaways from this first trial are the significant reduction in dissection time with the use of formalized training. However, no difference was noted in the first study in mental and physical demand, suggesting the platform has a quite intuitive design and is easy to use, regardless of a training session. In the second study, looking at the head-to-head comparison between DiLumen and conventional ESD, DiLumen C2 was associated with a lower rate of mucosal injury, decreased total procedure time, and reduced physical, mental, and temporal workload as measured by the NASA Load Index score.

In terms of potential clinical implications, human trials are, obviously, still needed. However, this data suggests the potential for DiLumen C2 to increase adoption of ESD in the United States. DiLumen C2 may improve the steep learning curve of ESD and decrease procedure-associated complications. Ultimately, this may reduce the need for surgery for minimal colorectal lesions, which can potentially lead to faster recovery outcomes and lower associated procedure costs.

So with that, I just want to take a final minute to thank everyone who participated in the study, who's listed here, as well as give a big thank you to Lumendi for their support and the opportunity to present our results today. Thank you.

**ERIC
COOLIDGE:**

OK. Thank you, Dr. McCarty, for that very informative presentation. At this point, again, if you want to ask questions, please place your questions-- or, text your questions to us on the monitor, or on the space below on your screen. Finally, I am pleased to introduce Dr. Sergey Kantsevov professor of medicine and director of the Center for Therapeutic Endoscopy at the Melissa L. Posner Institute for Digestive Health and Liver Disease, Mercy Medical Center, in Baltimore, Maryland. The title of Dr. Kantsevov's presentation is, "A New Endoluminal Therapeutic Platform: Results of the First 519 Colonic Interventions."

So with that, I would like to turn it over to Dr. Kantsevov. Dr. Kantsevov?

**SERGEY V.
KANTSEVOY:**

Thank you very much, Eric. Can you see my slides? Can you see my slides?

**ERIC
COOLIDGE:**

Yes, yes.

**SERGEY V.
KANTSEVOY:**

OK, so first of all, I just want to give a brief introduction. Clearly, colonic ESD is having a lot of advantages over piecemeal resection of colonic lesions by EMR. In terms of en bloc resection, there is a difference. Colonic ESD achieved 91%, whereas it was 46.7% by EMR.

In rates of R0, negative margin resection, and curative resection, the difference is also twice as much. And finally, colonic ESD provides 10 times better results in rates of recurrence. Practically no recurrence if en bloc resection with negative margins was achieved, whereas in the best sense, recurrence ranges from 12% to 20% for colonic EMR.

However, as several people already told today, ESD is difficult to learn and a labor-intensive procedure, and it require much, much longer time compared to the piecemeal resection. Colonic ESD is especially difficult comparing to ESD in the upper GI tract. First of all, there is a problem to navigate towards the lesion, especially in patients who have long and redundant colon. It's difficult to assess lesions located behind folds and behind colonic turn.

Colonoscopy instability due to peristalsis and breathing movements significantly complicates ESD. When you have a knife in your hand and patient unpredictably moves or makes a deep breath, you can damage the wall of the colon. And finally, colonic wall is thinner than gastric wall, so the risk of perforation is much higher for colonic compared to upper GI tract.

So we got an oral presentation for DDW for our study, which was a single-center, single-operator, retrospective observational study. And the aim of the study was to evaluate safety and effectiveness of the new endoluminal double balloon interventional platform for removal of the colonic lesions. Dr. Othman already talked about the lumen, so I'm not going to spend time on that slide. But I want to just summarize briefly what we expected to see in this study.

First of all, DiLumen helps to advance colonoscopy through the colon. And I practically don't use any help from outside, don't use any pressure, don't change patient position, completing advancement of colonoscopy through the cecum by just help of DiLumen. When you reach the area of interest, then you stabilize colonoscopy to perform EMR or ESD in the colon.

It allows multi-directional dynamic retraction to facilitate ESD. It creates a conduit from rectum to therapeutic zone through which you can exchange your colonoscopy to the suturing device and go back to colonoscopy. And it allows removal of multiple specimens if you are doing piecemeal dissection. And finally, the lumen facilitates, simplifies, and saves time for colonic ESD.

So that's what we expected. Now back to the study. So study, we started to use DiLumen at Mercy Medical Center in November 2017. In two years, by November 2019, we performed 519 procedures with DiLumen. Mainly, patients were in their seventh decade of life, and mean age was 66 years. About half of the study were females, and about half of this study were males-- equal representation.

Regarding the lesions, the mean size of the lesion was over 3.5 centimeters, and 25% of the lesions were over 5 centimeters in size. Most lesions-- so we were not doing it for small lesions. You can see that we were doing it for really large lesions. Most of our lesions were located on the right side of the colon. 30% of the lesions were in the cecum. 35% were in the ascending colon, and 24% were in transverse colon. So together, you can see that about 84% of the lesions were located proximal to the splenic flexure.

Now, regarding procedural characteristics, ESD was performed in 463 patients out of those 519, so practically 90% of my procedures in the colon, I removed lesions in one piece by ESD. 10%, I do it with the EMR. Most of those lesions which can fit into the snare, so I don't need to do it in piecemeal fashion, but it's just simply smaller lesions than the ones which I remove with ESD.

En bloc resection was achieved in 95% of the patients, and average time for ESD was less than an hour, 45 minutes, despite the fact that 25% of our patients had lesions over 5 centimeters in size. But even for lesions which are 3 and 1/2 centimeters of size-- which is average size for us-- still, the time of ESD less than 45 minutes is pretty significant.

Delivery of the endoscopic suturing device from rectum to mucosal defect in average occupied only 2.3 minutes. And once again, most of the lesions, 85% of the lesions were proximal to splenic flexure, and 60% of the lesions were located in ascending colon or cecum. Imagine, to get into ascending colon or cecum with the suturing device in 2.3 minutes. So total procedure time for our patients, including ESD, plus suturing, plus going back with the regular colonoscope to look at the area and make sure that you suture everything completely, so the total procedure time was barely hour and 1/2 for all our patients.

Now, conclusion of the study. As we expected, prior to formally summarizing our results, new and endoluminal double balloon interventional platform markedly facilitated colonic ESD, which resulted in significant decrease of the time of dissection itself. It also served as a conduit expediting delivery of the endoscopic suturing device to the right colon, and it significantly shortened total procedure time, and it made ESD much, much less labor-intensive procedure. Thank you very much. I'm ready to answer questions.

ERIC COOLIDGE: OK, thank you very much, Dr. Kantsevov. At this time, I'd like to open the Q&A part of the presentation. Again, if you have questions for any of these presenters on these very interesting data that they presented today, please use the chat box, and we will ask those questions as they come through.

I see that during the presentation, several questions have been asked. So we have about 15 minutes or so left today. So we'll start with the questions.

This one coming through for Dr. Othman. Dr. Othman, for cecal lesions, you cannot use the double balloon for stabilization, only one balloon. Can you still retract, and is it more difficult?

MOHAMED OTHMAN: That's a good question. So you can use both balloons for stabilization. So you can have both balloons inflated behind the lesion, and this will provide even more stability. Also, there is-- and instead of doing traction, you can do [AUDIO OUT]. So yes, you can have the balloon behind the lesion, but you have another suture which is long enough that you can connect it to the edge of the lesion in the colon, and you can gradually dissect with counter traction. So this is also possible, that you can use it for stability and traction in the cecum.

ERIC COOLIDGE: OK, thank you, Dr. Othman. Next question I have is for Dr. Kantsevov. Dr. Kanstevoy, does this device make it easier to suture in the colon, and if so, why?

SERGEY V. KANTSEVOY: So device definitely makes it much, much easier to suture. First of all, it helps you to deliver suturing device into the right colon, and it's not a simple procedure to get with the upper scope, especially double-channel upper scope with the bigger distal end, through the entire colon. But DiLumen allows you to do it painlessly and practically seamlessly.

And the lumen stabilizes that area. So when the suturing mounted on double channel scope delivers through DiLumen, and you raise, inflate the after-balloon, then the suturing device is in a very stable position, and you are not losing the area where you're working. So from that point of view, the lumen definitely helps you.

I just finished today already ESD in the [INAUDIBLE]. The polyp. It was a 2 centimeter polyp in the [INAUDIBLE] in [INAUDIBLE]. I removed it with the DiLumen, and then, after that, go seamlessly with the suturing device and closed the defect. I close all my defects post-ESD, so DiLumen helps me a lot for that.

ERIC COOLIDGE: Thank you, Dr. Kantsevov. This question I have for Dr. McCarty or Dr. Thompson. With regard to the C2, DiLumen C2 device, can you further expand on your thoughts as to how this will change ESD in the US?

CHRISTOPHER THOMPSON: Tom had to run off to clinic, I believe, so I'm happy to handle this. So I do think this will have a profound impact in the United States. And you know, in Asian countries, they have a certain way of training ESD. Gastric cancer being common there, they can use that for training purposes, right? You can practice in the stomach where it's safe to do these procedures, or considerably safer than starting in the colon. And so they have a means of training for this.

And we've really been hampered in that regard in the United States. Training is complicated when you don't have easier procedures to work on. And I think that this device, these devices will help in that regard, because now you can simplify these procedures. You've seen there's a common thread across all the presentations. It makes performing these procedures more simple and more doable for a wider range of providers.

In our studies, we had second-year fellows, for heaven's sakes, doing these procedures, and they were doing them quite well with the equipment. So I think that tells us, we're going to be able to broaden the adoption of ESD. And we really need to do that in the United States, because there's far too much colon surgery occurring for non-malignant conditions. And I think this is going to be very helpful in that regard.

ERIC COOLIDGE: OK. Thanks, Dr. Thompson. I'd just like to add that DiLumen C2 is currently FDA-cleared, so it is-- we are doing clinical cases with it in the United States, but we do not have CE mark for Europe. And Dr. Kantsevov, Dr. Othman, and Dr. Thompson are all involved in the early trials that we have on using the device clinically.

At this point, I have another question for Dr. Kantsevov. Dr. Kantsevov, in your data, most of the cases are on the right side. How is DiLumen, or is it helpful on the left side?

SERGEY V. KANTSEVOY: Yes, DiLumen definitely helps on the left side, and I published in [INAUDIBLE] big case in the rectum, which was occupying the entire rectum. And the lumen helps you to provide the same amount of traction and dynamically pull the polyp in various directions, facilitating ESD.

So I use it on the right side and on the left side. It's just more patients that are referred to me, referred with the right-side pathology. And referring physicians are mostly taking care of the left-side lesions themselves. So it may be selection bias. But otherwise, DiLumen is helpful throughout the entire colon.

ERIC COOLIDGE: OK, very good. Another question I have for Dr. Othman. 25% of ESD cases were converted to hybrid procedure. Was this a result of the device not helping to facilitate pure ESD, or were there some other reasons?

MOHAMED OTHMAN: Yes, so that's a good question. So the referral pattern in the United States is different because we get referrals for prior EMR, failed EMR, or lesions that were tattooed extensively or biopsied. And that's resulted in significant fibrosis.

Most of these cases that converted into EMR was as a result of significant fibrosis that made ESD much harder, or the region was too large, and we spent very significant amount of time/ and a hybrid technique was used in that situation just to shorten the procedure time. I do not believe, in these cases, it was related to the device itself rather than lesion characteristics.

ERIC COOLIDGE: OK, thank you, Dr. Othman. Another question for Dr. Thompson. In the US, again, with the future of ESD, this platform that you reported on is a non-robotic platform. Can you comment on what your thoughts are for the future for robotic platforms and endoluminal procedures?

SERGEY V. KANTSEVOY: [INAUDIBLE], you know, robotics are considerably more complicated and add considerable cost to these procedures. I mean, I'm hoping they're not necessary, because once you start introducing robotics into these things, you can see it with what Intuitive had to do with their system. All of a sudden, you have minimum numbers of procedures you need to do. You have a lot of help from company reps getting in there. It becomes just a whole different ballgame.

So yeah, I'm thinking that the system, the way it's designed-- and as they make C2 more ergonomically friendly, and they continue to make really good improvements with the system all the time, I think that you'll be able to accomplish what robotics are able to accomplish but without the servo engines, and without the complexity, and, hopefully, without all that extra expense as well. So I'm hopeful that this more direct-drive kind of platform, if you will, without the robotics will be good enough for these procedures.

ERIC COOLIDGE: OK, thank you. Next question I have is for Dr. Kantsevov. You conclude that DiLumen decreases dissection time, but you have no comparator. How can you conclude this?

SERGEY V. KANTSEVOY: So we had the comparison previous year. Previous DDW, we presented, we compared lesions over 50 millimeters in size with historic controls, where we did traditional ESD. And that was heavily in favor of procedures done with the help of DiLumen. So generally speaking, it was about 25% to 30% less time spent on dissection.

But in this retrospective study, we cannot really compare it with anything. It was just absolute numbers. So we recently finished prospective randomized human trial which was IRB-approved and scheduled for 200 patients, which were randomized to DiLumen or no DiLumen in one-on-one fashion. The study had a predetermined intrinsic analysis at 140 patients, and when we did that analysis, interim analysis demonstrated that we already achieve statistical significance between study and control groups. So enrollment was stopped at that point.

So that study definitely demonstrated significant improvement in ESD time and total procedure time when the DiLumen was used. We will present the results of this study on European DDW in October and maybe, if it will not happen, then probably in the ACG.

ERIC COOLIDGE: OK I have another question for Dr. Othman regarding the registry. What minor adverse events occurred, and were they device-related at all?

MOHAMED OTHMAN: So the adverse events were mainly related to the ESD procedures. We had four microperforations, which were repaired by endoscopy, two bleeding, that were also controlled during the procedure without any further intervention after the procedure, and we had one sudden mucosal hematoma from injection.

ERIC COOLIDGE: OK.

MOHAMED OTHMAN: Yeah, but nothing related to the procedure. There is one complication that happened after the procedure. It was a postpulpotomy syndrome, which happened for a prolonged stay in the hospital, more than two nights. That patient required five days of staying for postpulpotomy syndrome. But that was only one case out of 80, so--

ERIC COOLIDGE: OK, very good. And another question for Dr. Kantsevov. Most of the procedures that you perform are ESD. However, can a non-expert ESD user find value with DiLumen the way you do?

**MOHAMED
OTHMAN:**

So DiLumen is an interventional platform, and it's your choice whether to use it for ESD or for EMR in piecemeal fashion. So I think that the points which I demonstrated, it helps to advance colonoscope through the entire colon, and it's helpful for both ESD and non-ESD procedures. I'm using DiLumen for patients with difficult, very long and redundant colon, even if it is not scheduled to do ESD. It just helps me to navigate through it. Then DiLumen stabilizes your colonoscope, and it's very helpful for piecemeal EMR as well when you need to apply snare multiple times.

When you do it in piecemeal fashion and create a large number of pieces with EMR, then there, after-balloon is distended. So all these pieces are lying in one segment of the colon. You don't need to go through the entire colon collecting those pieces. You can just grab as many pieces as fit into your net, and then pull it out, and then clean the net and immediately go back in. And you can repeat it seamlessly many, many times.

So DiLumen facilitates any intervention in the colon, whether you do it as EMR or if you are novice to ESD world and you are planning to switch from EMR to ESD, it will make your transition much simpler and much easier, not to mention that DiLumen helps to suture in the colon, and it doesn't have to be closing mucosal defect post EMR or ESD. I do closure of the fistulas, post-surgical defects, and so forth through the use DiLumen and suture it anywhere in the colon. So it's helpful for any interventional procedures inside the colon.

**ERIC
COOLIDGE:**

OK, thank you, Dr. Kantsevov. I think we're coming up on the top of the hour here, so we have time for one more question. I'll ask this question of Dr. Othman. Dr. Othman, can you comment on the learning curve for the DiLumen device?

**MOHAMED
OTHMAN:**

So learning curve for DiLumen device, it varies, of course, from person to person. But I would say a maximum five to 10 procedures. One procedure is not enough, but after using DiLumen for five procedures, it allows you to understand how to use it and navigate through the folds. Also, how can you use a proximal balloon for reducing the loops. That's really important, how to reduce the lobes with DiLumen. Also, it using it for resection, dynamic retraction also requires experience. But beyond five to 10 cases, you feel very comfortable using it.

**ERIC
COOLIDGE:**

OK, great. All right, we're at the top of the hour, and I'd like to close this session. And first of all, I'd just like to thank Dr. Othman, Dr. Yamashita, Dr. Kantsevov, Dr. McCarty, and Dr. Thompson for taking the time to prepare these presentations and spending time with us in the middle of their very busy days. We really appreciate it. And I hope that you all have appreciated this session that has been sponsored by Lumendi.

And with that, I'll sign off and thank everybody again. Bye, now.