

Enabling and Facilitating Endolumenal Therapeutic Procedures

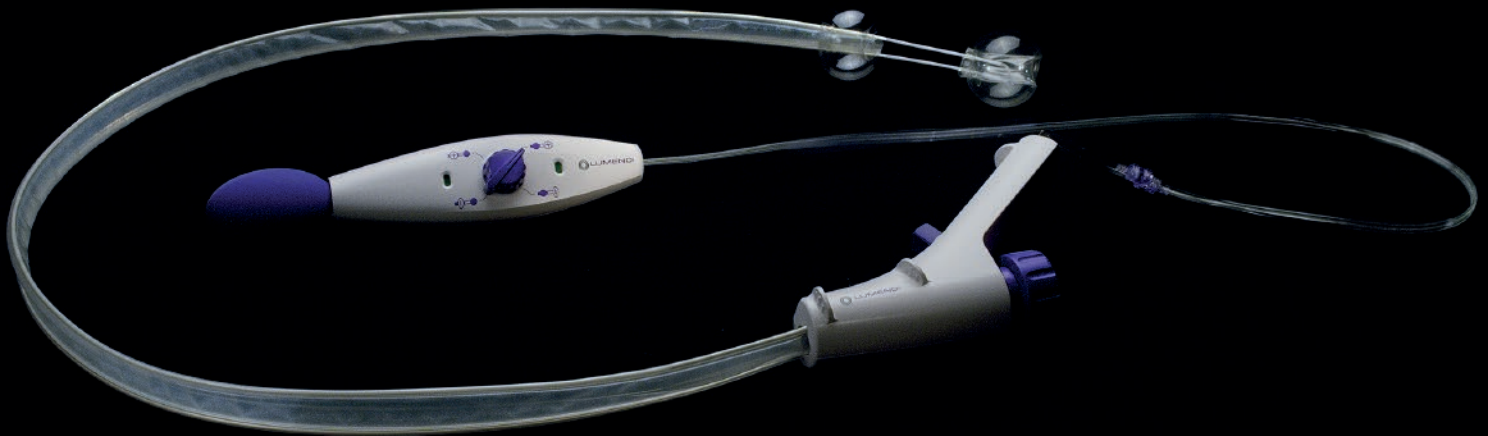
**From Surgery to Endoscopy: The Growing Adoption of
Endolumenal Intervention to Remove Benign Colon Polyps**

Reducing the Need for Surgery

How Clinical Guidelines on Polyp Removal are Evolving

Less is More: The Drive Towards Minimally Invasive Treatment

The Future of Endolumenal Therapies

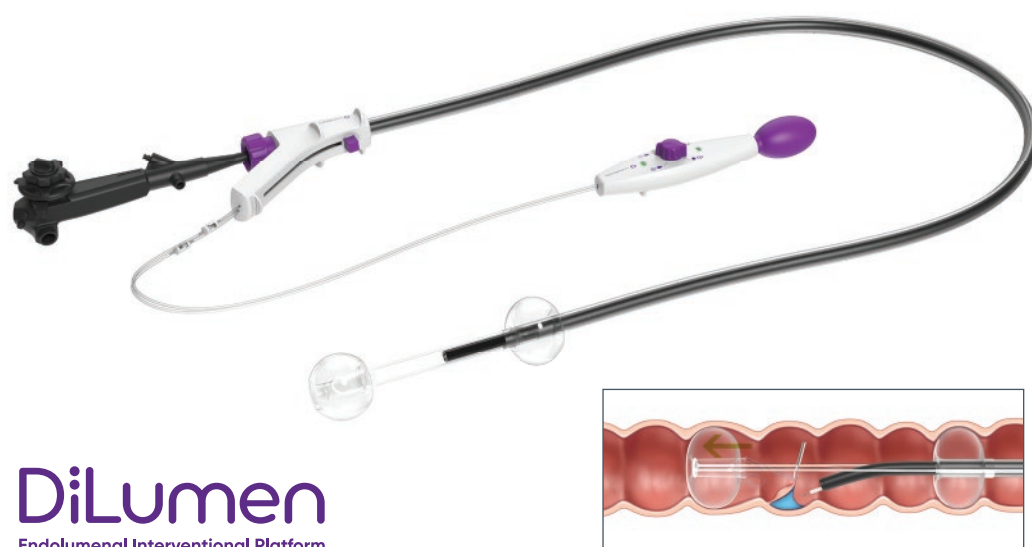


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Published by Global Business Media

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SPECIAL REPORT: ENABLING AND FACILITATING ENDOLUMENAL THERAPEUTIC PROCEDURES

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Foreword

THE NUMBER of people going for colonoscopies is rising in the developed world. Whether driven by bad diet, less exercise or our generally unhealthy lifestyles, many of us will find ourselves needing procedures to reduce the chances of something worse happening further down the line.

In many cases these procedures are straightforward and patients can be treated and discharged within a single day, but when things are a little more complex, clinicians may look at more invasive surgeries which can require a longer hospital stay. This means longer recovery times and a higher risk of complications.

However, as we see in our opening article, there are new products coming to market which will make it possible to deal with more complex issues without the need to resort to surgery. The DiLumen device can deliver more stable endolumenal therapies, even for complex conditions. Its use is enabling doctors to avoid operations and get patients back on their feet as soon as possible.

Tom Cropper, has produced articles and reports on various aspects of global business over the past 15 years. He has also worked as a copywriter for some of the largest corporations in the world, including ANZ Bank, ING and KPMG.

Elsewhere in this Report we will look at the rising number of people requiring colonoscopies and the impact surgery can have on their lives. Expanding the use of endolumenal procedures will reduce risks as well as alleviating the strain on healthcare resources.

Jo Roth will then cover how the clinical guidelines for colorectal procedures have evolved before James Butler looks at the development of solutions such as the DiLumen, which can reduce the number of people needing surgery.

Finally, we head into the future. From artificial intelligence to nanotechnology and much more, this is an environment full of exciting developments. Technology is finding new and innovative ways to reduce the invasiveness of colorectal treatments, avoid surgery and reducing recovery times. The benefits are felt by patients and healthcare resource managers alike.

Tom Cropper
Editor

From Surgery to Endoscopy: The Growing Adoption of Endolumenal Intervention to Remove Benign Colon Polyps

James White, DO, Vice President, Medical Affairs, Lumendi

THE COLON is a long, winding, narrow, tubular organ with many folds. It actively moves large quantities of fecal matter from the small intestine to the rectum. Due to factors such as these, many polyps are difficult to access via colonoscope for safe removal. As a result, clinicians often rely on invasive surgery to eradicate disease by resecting a portion of the colon to remove the polyp and then sewing the remaining sections together.

In late 2016, Lumendi., a medical device company headquartered in the U.K., received clearance in the US for an innovative technology specifically designed to assist in removing large benign polyps from the colon, thus obviating the need for surgical intervention. The new device allows for expansion of a less invasive treatment paradigm: endolumenal intervention. While hundreds of thousands of these procedures are performed globally each year^a, the shift to endolumenal intervention is now gaining momentum in the United States and Europe.

Endolumenal Intervention – Many Potential Advantages

Endolumenal intervention is a procedure performed within a hollow organ (like the gastrointestinal tract) using well-established

techniques, such as retraction, dissection and suturing, under endoscopic control. It is different from laparoscopic surgery – which saw rapid adoption in the 1990s – in that it accesses the targeted lesion for therapeutic treatment through a natural orifice, such as the anus^b, takes place entirely within the lumen without the need for skin incisions, and may involve the removal of diseased tissue via the natural orifice. As a result, endolumenal intervention preserves the patient's anatomy and can significantly help increase patient safety, reduce the need for general anesthesia, increase the number of patients eligible for treatment, significantly shorten hospital stays (often to same day), reduce financial costs, and improve patient outcomes. While there are potential complications with any procedure, they are likely to be less significant with endolumenal intervention than with traditional or laparoscopic surgery.

The DiLumen EIP™ (Endolumenal Intervention Platform) has been used in close to 800 endolumenal gastrointestinal procedures in the US and parts of Europe^c. It is used primarily as an organ-preserving endoscopic accessory for tissue manipulation and resection, opening the door to more widespread adoption of endolumenal intervention. Importantly, DiLumen

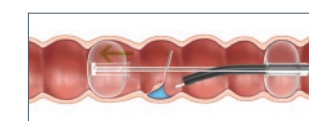


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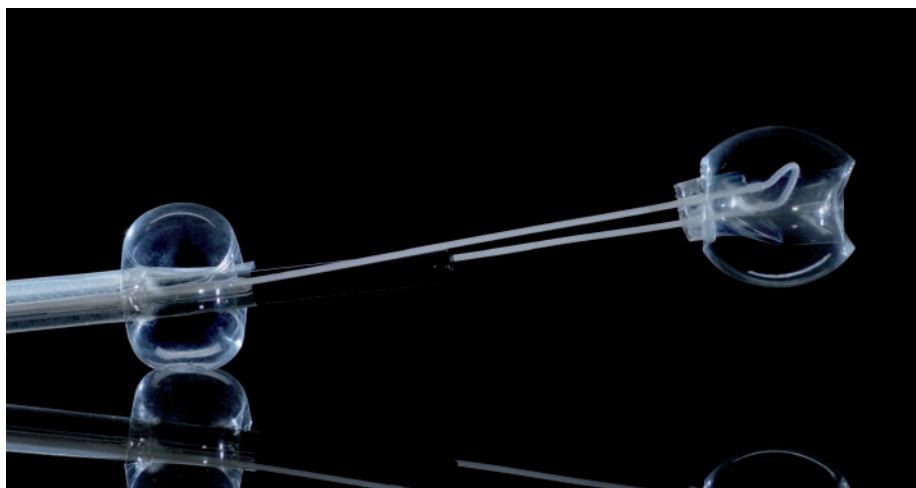


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Recently, several improvements have been made to DiLumen based on the feedback of the more than 60 clinicians that have used it over the past year



DILUMEN EIP THERAPEUTIC ZONE (TZ)

creates an isolated, stabilized Therapeutic Zone (TZ)^d within the intestine. It straightens the target area, limits fluid and stool, and flattens the folds so clinicians are better able to see and treat isolated segments of the bowel, thus preserving the colon.

"DiLumen gives me both the stability and tissue retraction necessary to facilitate a safe and complete removal of these complex polyps, preserving patients' anatomy, and saving them the possibility of having to endure a surgical resection," said Professor James East, MD, John Radcliffe Hospital in Oxford, England.

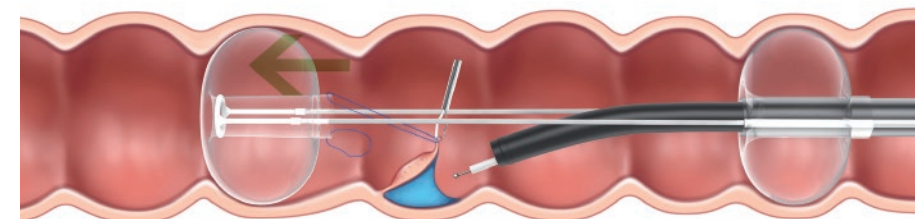
This is the first device based on the Lumendi initiative to help migrate many gastrointestinal surgeries to endolumenal procedures. The DiLumen EIP, which is intended for use with any standard colonoscope or gastroscope; is a single-use, close-fitting sleeve that fits securely over a standard endoscope. As a dual-balloon accessory, it is indicated to ensure complete positioning of an endoscope in the large intestine and assist with optical visualization, diagnosis and treatment to enhance performance during endolumenal treatment.

According to Jeffrey W. Milsom, MD, Chief of Colon and Rectal Surgery at NewYork-Presbyterian/Weill Cornell Medical Center and inventor of the DiLumen EIP, "Colon polyps can no longer escape prying eyes. The endoscope is somewhat free-floating inside the intestine; something like a boat on the water, it bobs up and down. The DiLumen stabilizes the endoscope and makes it easier to navigate through the intestine, like a boat moored to a dock."

New Innovative Devices

Lumendi continues to develop additional innovative devices in the evolution of the DiLumen. In April 2018, Lumendi received US FDA clearance for the DiLumen C²™. Similar in design to the DiLumen EIP, the DiLumen C² incorporates two 6 mm diameter tool channels, which accommodate two independent flexible articulating hand instruments. These instruments are designed to further improve tissue manipulation, cutting and coagulation in a much safer, faster, and simpler method.

"Recently, several improvements have been made to DiLumen based on the feedback of

DILUMEN C²

DYNAMIC RETRACTION OF TISSUE DURING POLYP RESECTION, A NEW FEATURE OF DILUMEN, IMPROVES ACCESS TO THE SUBMUCOSAL PLANE IN A SAFE AND EFFECTIVE WAY.

the more than 60 clinicians that have used it over the past year. These improvements include changes to enhance endoscope navigation, but, more importantly, we've incorporated a new retraction system that can be attached to tissue and manipulated to lift and retract during polyp resection," said Dr Peter Johann, CEO. This new system is a unique feature of the DiLumen EIP and is a new component of the fore balloon assembly, which can be moved back and forth during a procedure.

The Need for Screening Colonoscopy

Incidence/Prevalence Across the WHO European Region

- In Europe^e, colorectal cancer is the second most common cause of cancer death in both men and women. It is the second most common form of cancer in women, after breast cancer, and the third most common in men, after lung and prostate cancer.
- In 2008, there were 450,000 new cases of colorectal cancer and 232,000 deaths in the WHO European Region.
- Across the WHO European Region, deaths from colorectal cancer have fallen since the 1990s:

from 20.36 per 100,000 population in 1995 to 18.86 per 100,000 in 2009.

- Screening colonoscopy is the single best way to prevent colon cancer. Depending on the country, individuals are urged to have their first screening colonoscopy between their early '40s and mid '50s. Additional screenings may be required every few years should adenomas be detected.

Lumendi, Ltd is a privately held innovative, medical device company headquartered in Buckinghamshire, UK, and holds the worldwide exclusive license from Cornell University on the DiLumen™ technology. The company is focused on developing, marketing and distributing surgical tools and devices that provide safe, cost-effective solutions for minimally invasive gastrointestinal interventions.

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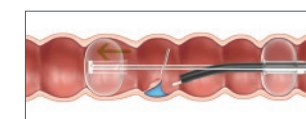
References:

- In certain countries like Japan, endolumenal treatment is quite frequent and surgery for benign polyps is virtually non-existent.
- In the gastrointestinal tract, endolumenal treatment should be performed via natural orifices and involves the use of a camera mounted on the end of a tube or endoscope. It also utilizes small therapy devices such as needles and electrocautery to lift, dissect, control bleeding and remove tissue.
- DiLumen received CE Certification and identifies the device with the CE Mark to indicate it conforms with essential requirements of Council Directive 93/42/EEC concerning medical devices. Lumendi's EU distribution network is currently being developed, with distributors in Italy, Britain, Switzerland and Spain selected.
- When both balloons are deployed, and inflated, a stable Therapeutic Zone (TZ) is created. This TZ facilitates more localized insufflation and manipulation of the colon and provides improved access to lesions to enable endoscopists and surgeons to perform precise endolumenal interventions. Once the procedure is complete, the balloons are deflated and removed along with the colonoscope.
- Source: WHO European Region <http://bit.ly/2HVN4tC>

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Reducing the Need for Surgery

Tom Cropper, Editor

Laparoscopies are on the rise, but they involve a number of risks which might not be fully understood. However, a less invasive approach could improve outcomes and save money.

Earlier identification will mean more people will present with issues such as polyps. Although these are harmless in most cases, they could potentially lead to more serious conditions such as bowel cancer if left untreated

HEALTHCARE SERVICES face a range of challenges. The cost of providing care to an aging population is rising and bed capacity is reaching critical levels. Methods which can avoid invasive procedures not only reduce the risks posed to patients, but they also alleviate many of the most pressing strains on resources and infrastructure.

Increasing Rates of Colonoscopies

Bowel cancer represents a growing health problem with a number of studies around the world point to an increase in bowel cancer rates among younger people. A study in the US found that bowel cancer rates had increased by 3.2% between 1974 and 2013 among people between the ages of 20-29¹.

There is a renewed focus, therefore, on raising awareness about the need for colonoscopies in younger people. In 2014, a national campaign was launched in the US designed to increase the rates of colorectal cancer screening rates by 80% by 2018². The focus is moving toward identifying and addressing problems at a much earlier stage and, while this will save lives, it also creates a number of issues.

Earlier identification will mean more people will present with issues such as polyps. Although these are harmless in most cases, they could potentially lead to more serious conditions such as bowel cancer if left untreated. Earlier diagnosis and removal of polyps can reduce the risk of cancer, but the procedure has risks. In some cases, the removal of polyps can increase the risk of cancer at a later date, which means further colorectal screening may be necessary.³

Depending on the position and size of the polyps, the removal procedure can present a number of risks. In an ideal world, these can be removed via an endoscopy but, if the polyps are large, have a broad base or are located in an anatomically inaccessible position, they may

require more invasive interventions. These may include a laparoscopy, or open surgery both of which increase the risk of complications setting in.

The Risks Involved with Laparoscopies

Despite evidence showing that endoscopies are both safer and less expensive, laparoscopic surgery is becoming increasingly common. A study in the US identified a significant rise in the incidence of surgery for non-malignant polyps in the US from 5.9 per 100,000 adults in 2000 to 9.4 in 2009⁴.

The number of laparoscopies has surged in recent years as technological advancements make it possible to deliver increasingly complex procedures in a safe and efficient way. However, they also bring with them a number of associated risks including infection, blood clots, adverse reaction to anaesthesia, abdominal inflammation and bleeding. There is also a significantly higher risk of damage to internal structures such as the stomach, bowel, bladder or blood vessels.

The risks become more severe with open surgeries. Patients will need several days to recover rather than being released on the same day and may require months of ongoing monitoring. Studies suggest laparoscopies lower the risk of complications when compared with open surgery as well as leading to shorter post-operative stays and earlier return of bowel functions. However, they are still significantly more invasive than endoscopic procedures.

Tightening Resources

As their use grows, therefore, laparoscopies not only present a risk to patients, but also a drain on the financial resources of the hospital. As health services struggle to cope with rising demand and tightening capacity, that is becoming a growing problem.

Hospital bed vacancies are at a premium in all health services, but the problem is particularly severe in the UK where bed shortages have become critical. According to a study from the



DILUMEN™ SYSTEM WITH DOUBLE BALLOON THERAPEUTIC ZONE, PUSHROD CONTROL HANDLE AND BALLOON INFLATION HANDLE

Kings Fund the number of hospital beds in England and Wales has halved from more than 299,000 to 142,000 in 30 years.

The UK is not alone. Most other advanced health services have also reduced their total number of beds, but the UK currently has fewer acute beds relative to its population than most other comparable healthcare systems. The publication highlights growing signs of shortages. In 2016/2017 acute and general hospital bed occupancy rates averaged 90.3% rising to 95% in winter⁵.

The rate of decrease has slowed in recent years, but to meet its capacity restrictions, health services need to identify ways in which they can reduce hospital admissions and shorten stays. The problem is made all the more urgent by the growing demands on their services. Populations in the developed world are aging. As technology evolves, we have become much more effective at treating conditions and prolonging life.

While a longer living population should be welcomed, it comes at a cost. More people are requiring increasingly complex and ongoing treatment for various conditions. They are more likely to require hospital care for much longer. New technologies also cost money. Delivering world class healthcare is becoming increasingly expensive.

Healthcare costs have risen dramatically over the past few years and are set to continue to do so. The next few decades, therefore, will be marked by a rapid and accelerating increase in the cost of care.

Across all areas, therefore, authorities are looking at ways they can reduce the level of interventions. Where possible, these might include greater education to reduce the risk of admission to hospital and, further down the line, surgical procedures, but these have to be managed in a way which minimises the risks involved to all patients.

Much of the focus, now, though, is growing on developing less invasive endoluminal therapies which can avoid laparoscopic or open surgeries. New technologies and techniques which can widen the range of conditions that can be treated endoscopically will have a dramatic impact on safety and turnaround times.

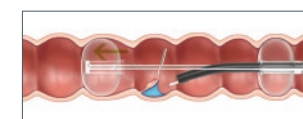
Patients who can be treated in this way will see hospital stays reduced from several days to 24 hours. Hospitals can ease the pressure on their bed capacity, and the risks of complications will be lower. It also fits in with the desires of patients who will be keen to avoid surgery if they can. This will require open communication between all parties to highlight what is available and how it can be practically applied to the clinical setting.

Healthcare costs have risen dramatically over the past few years and are set to continue to do so. The next few decades, therefore, will be marked by a rapid and accelerating increase in the cost of care.

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How Clinical Guidelines on Polyp Removal are Evolving

Jo Roth, Staff Writer

Reducing the need for surgery in the removal of colonic polyps plays an important role in delivering improved outcomes for patients, but it has to be done safely.

It is very much in the interests of both patients and clinicians to avoid surgery where possible. This reduces the risk of complications and provides a minimal impact on a patient's quality of life as well as financial resources

EVERY YEAR, thousands of patients around the world will undergo a procedure to have non-malignant polyps removed. In themselves, they are relatively harmless but in a small minority of cases they could lead to bowel cancer. Removal is recommended, but when polyps are large or in an anatomically hard to reach position, managing the procedure can be challenging. This has significant safety issues for patients and also leads to increased intervention costs for health services.

Endoscopic Removal

A doctor will use an endoscopic procedure to remove polyps within the bowel in the least invasive way possible. However, problems grow when things get more complicated. Current NICE guidelines raise major safety concerns about the removal of full thickness non-lifting colonic polyps⁶. NICE argues that current evidence is lacking in quality and quantity and, as such, the procedure should not be used unless there are special arrangements made for clinical governance, the patient has given full consent and an audit or research has been undertaken.

It makes the following recommendations for any clinicians wishing to do full thickness polyp removal:

- Inform the clinical governance leads in their NHS Trusts.
- Ensure that patients understand the uncertainty about the procedure's safety and efficacy and provide them with clear written information. In addition, the use of NICE's information for the public is recommended⁷.
- Audit and review clinical outcomes of all patients having endoscopic full thickness removal of non-lifting colonic polyps.

Patient selection, says the guidelines, "should only be done with polyp and early colorectal cancer multidisciplinary team, and the procedure should only be performed by clinicians with specific training."

When cases become more complex, clinicians may veer towards the apparently safer option of

surgery. This will normally involve a small incision into the side of the abdomen. Small tools will then be inserted laparoscopically into the abdomen which is expanded with carbon dioxide. Evidence from NICE suggests that this has a high success rate. They analysed a total of nine studies involving a total of 781 patients which showed that polyps were successfully removed in most patients. A study of 176 patients found no polyps had returned after five years. Another study of 146 patients found one polyp had returned after two years. However, there are risks.

- 14 patients developed an infection at the laparoscopic wound site.
- Four patients developed an abscess in the abdomen. Three of them managed to have this abscess drained while one required another operation.
- Two patients had problems emptying their bladder and four struggled with their bowels.
- Nine patients had a collapse of all or part of their lung, which may have been caused either by the anaesthetic or the carbon dioxide used as part of the laparoscopy.
- One patient had bleeding which needed further treatment and three patients had a build-up of clear bodily fluid in the place where the polyp had been removed⁸.

The studies analysed by NICE also show that seven patients had to be switched to open surgery during the procedure. This may be necessary in more advanced cases which need a larger incision in the abdomen. The surgeon then removes part of the colon to fully ensure all of the polyps and any associated cancer have been removed.

The problem is that the greater the level of intervention, the more likely it is that complications will set in. Much depends on the experience of the surgeons. A 2013 study published by *Digestive Surgery* covering 126 patients over the course of ten years found post-operative complications in a third of cases⁹.

Recovery time can also vary depending on the extent of the procedure. A basic polypectomy



DILUMEN C2™ GRASPER AND SCISSORS INSTRUMENTS

should last between 30 and 60 minutes and most patients will be allowed to return home the same day. A larger polyp removal may require surveillance for three to six months to ensure there is no tissue remaining.

When surgery is required, patients may need several days of rest in the hospital to recover, but this may be significantly longer if complications set in. These can include paralysis of the gut resulting from the unnatural insertion of tools into the abdomen, which can take several days to resolve.

Deciding on the Best Course of Action

The more invasive the intervention, then, the greater the recovery time and the higher the impact on healthcare resources. When planning treatments, clinicians will have to weigh up multiple factors including the risks of an endoscopic procedure for larger non-lifting polyps, the pitfalls of surgery and the likely recovery time of patients.

In making this decision, clinicians may consider the wishes of the patient. It is natural for anyone to want to avoid the risks of open surgery so there is always likely to be a push, from the patient's side, towards minimally invasive procedures which may allow them to return to their regular daily routines as soon as possible. However, all

patients will have to be made aware of the risks each option poses.

It is very much in the interests of both patients and clinicians to avoid surgery where possible. This reduces the risk of complications and provides a minimal impact on a patient's quality of life as well as financial resources. Even so, this must never put the health and wellbeing of patients at risk. The study published by *Digestive Surgery* recommends that all "clinical pathways chosen to treat colonoscopically unresectable polyps should be tailored to patients' conditions and the characteristics of their colorectal lesions." Patients and their families will need an in-depth discussion about the various options available to them.

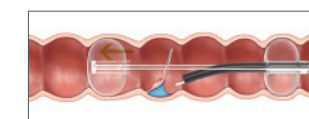
Reducing the Need for Surgery

Increasingly, though, various procedures are coming to the fore which widen the range of situations in which less invasive procedures may work effectively. These make it possible to treat more complex and harder to reach cases without needing to revert to more invasive surgical procedures. They reduce the need for surgery, which in turn reduces the length of hospital stay and also improves outcomes. As these options become more widespread, they will help health services deliver top quality care in a way which reduces the strain on their budgets.

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Less is More: The Drive Towards Minimally Invasive Treatment

James Butler, Staff Writer

Health services are turning their attention to minimally invasive approaches which can save money, reduce recovery times and improve outcomes.

By enabling the creation of a more stable zone and facilitating access to polyps, a range of innovations make endolumenal therapies possible in a wider range of situations

ACROSS MANY different areas of healthcare, the common goal is to reduce the use of invasive procedures. Endolumenal therapies have played an important role and have proved to be extremely effective at avoiding surgery, reducing risks and saving money. Even so, this is a technology with a number of limitations which impede its wider use. In this article we will look at innovations which promise to overcome these limitations and reduce the need for surgery.

Growing Interest in Endolumenal Surgeries

Endolumenal therapies offer a higher degree of safety than laparoscopies because they do not require an incision. Instead, access is made via a natural orifice using a flexible endoscope and preserving the anatomy of the patient. Although this does not come without its complications or risks, they are much lower than any kind of surgery. Several studies have pointed to a small risk of perforation or bleeding. The risk of perforation has been rated as between 0 to 0.2% while the risk of bleeding ranges between 0% and 22%. These complications, though, would not typically require further surgical interventions¹⁰.

However, the standard method has changed little in the last few decades. The tip of a flexible insertion tube can be bent vertically and horizontally, and manual insertion can be combined with rotation of the entire endoscope. Light is transmitted to the tip of the endoscope from which a chip sends image signals back from the camera lens to a monitor.

This procedure is widely used in screening for cancer, but if it can be used more widely in endoscopic treatments for procedures such as polyp removal it has the potential to significantly reduce the need for surgery with the resultant risk to patients.

Unfortunately, the risk of complications can rise in more complex incidences and this stands in the way of wider adoption. For larger objects or harder to reach areas the risks of infection can rise, and it can become more difficult to establish a stable therapeutic zone. Performing the procedure may become difficult and not all clinicians will be confident in their ability to perform it. Several colonoscopies may also be required to achieve a desirable outcome.

By enabling the creation of a more stable zone and facilitating access to polyps, a range of innovations make endolumenal therapies possible in a wider range of situations.

The aim is to increase the number of situations in which an incisionless approach to treatment is possible and reduce the need for a general anaesthesia. This reduces the risks associated with surgeries, shortens hospital stays and reduces the financial costs of care. To do this they will have to facilitate access to the tissue, improve lighting and create a more stable and reliable therapeutic area.

New Accessories

DiLumen is an accessory to an endoscope which enables a more complete positioning of the endoscope in the large intestine. It is a soft sheath which fits over standard and small diameter colonoscopes. The aim is to achieve more complete visualisation of the area and create a more stable operating environment.

Once the endoscope reaches the desired position, it inflates two balloons – one behind the bending section of the colonoscope and one at the tip. This creates a stabilised therapeutic zone within which rapid insufflation can easily be contained to facilitate access to and manipulation of the tissue. Once the therapy is complete, the balloons are simply deflated and the colonoscope can be quickly removed.



DILUMEN™ INFLATION HANDLE

The Evolution of Technology

Like many solutions, this is constantly being developed. The original design obtained FDA Clearance in 2016 and the CE Mark for use in Europe in 2017 since when it has been used in more than 600 therapeutic procedures. In November 2018 it also achieved FDA clearance for a modification which sees suture loops placed in the skirt along the trailing edge of the fore balloon. This will help to facilitate manipulation of the tissue for easier dissection and resection.

"The growing, extensive use of DiLumen validates our goal of shifting the paradigm for colon disease intervention from the traditional surgical approach to a truly minimally invasive one that utilizes novel endolumenal-based technology. This shift will increase safety and patient recovery time as well as significantly reduce costs¹¹," said Dr. Peter Johann, CEO of Lumendi, Ltd.

It addresses three key obstacles which have held back endolumenal therapies: optical visualisation, diagnosis and secure positioning to facilitate endoscopic treatment. Already it has

demonstrated significant progress in facilitating endoscopic treatment in those situations which would previously have required a more invasive and impactful treatment. By doing so it fulfils key goals of all parties. It makes treatment easier from the perspective of the specialists, it reduces the impact on the lives of patients and reduces the financial drain on resources.

Technologies such as these continue to be adopted and their use expanded as a growing body of case studies demonstrate their value. Further advances will also increase the value they offer and improve their impact on outcomes. The makers of the DiLumen say improvements have already been made based on feedback from more than 60 clinicians over the past year. Their experience is feeding into new designs which capitalise on past learnings. Wider adoption, then, is accelerating development which, in turn, pushes forward the boundaries of what is possible. Moving into the future, clinicians can have a good degree of confidence in their ability to further reduce invasive procedures.

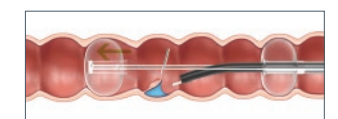
"The growing, extensive use of DiLumen validates our goal of shifting the paradigm for colon disease intervention from the traditional surgical approach to a truly minimally invasive one that utilizes novel endolumenal-based technology."

Dr. Peter Johann, CEO of Lumendi, Ltd

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The Future of Endolumenal Therapies

Tom Cropper, Editor

Artificial intelligence, nanotechnology and virtual reality can all play an important role in the future of endolumenal therapies.

Robotic surgery has many of the same benefits as laparoscopic surgery in that it can use smaller incisions to minimise blood loss. A doctor uses precise robotic arms which bend like wrists and are controlled by the doctor from a console next to the patient

TECHNOLOGY WILL play a vital role in the future of healthcare. Much of it is untested and there is still a lot of work to ensure it can deliver everything that it needs to, but it has the potential to deliver benefits across the spectrum. By expanding the range of situations in which endolumenal therapies are appropriate, health services can improve outcomes, reduce costs and, most importantly, save lives.

Artificial Intelligence

Artificial intelligence (AI) attracts a huge amount of attention – some of it justified, some not. A study in Shanghai found that an AI system could improve adenoma and polyp detection rates in colonoscopy.

"The miss rate for colon polyps can be up to 27%," said Tyler Berzin, MD, Co-Director, GI Endoscopy, and Director, Advanced Endoscopy Fellowship at BIDMC. "This limits the efficacy of screening colonoscopy, which is a critical tool for reducing the incidence and mortality of colorectal cancer by detecting and removing adenomatous polyps¹²."

The study used an automated polyp detection system developed by Wisconsin AI to investigate whether it could out-perform conventional colonoscopies. A total of 53 patients underwent a routine procedure while 522 underwent CAD colonoscopy.

The results indicated that the CAD system delivered superior results across a range of different metrics. The CAD group detected 0.97 polyps per colonoscopy compared with 0.51 for the control group and had a 1.89-fold increase in the mean number of polyps detected. The CAD group also has a slightly higher detection rate for adenomas and showed a significantly reduced procedure time compared to the conventional colonoscopy and there were no complications reported.

"The aim of a CAD system is not to show how smart the AI is, but to be useful in clinical settings,

and this reflects our commitment to innovating AI-based diagnostics with proven clinical benefits," said JingJia Liu, Chief Executive Officer at Wisconsin AI. "The study shows that use of our system did not increase procedure time, which is mainly because of the low false alarm rate. This demonstrates that the system can improve polyp and adenoma detection without negatively impacting physician and facility efficiency."

HD Imaging

Effective lighting and imaging of affected areas is crucial for successful endoscopic treatment and there have been a number of advances in this area. Fibre bundle endoscopy has been replaced, by and large, by video endoscopy and, increasingly, high definition video. Lighting is improving and manual zoom controls help doctors to more thoroughly visualise the area. These help to improve identification and diagnosis as well as the removal of polyps.

Researchers from the University of Cambridge, for example, have developed a new imaging technique which offers what they call hyperspectral imaging. The technique, as Dr Sarah Bohndiek, from the University of Cambridge explains, dramatically increases the number of colour channels which can be detected.

"In traditional endoscopy, we use white light and detectors that replicate our eyes, which detect light in red, green and blue colour channels," she explains. "We are now developing an approach called 'hyperspectral imaging', which will increase the number of colour channels that can be visualised from three to over 50."¹³

Robots and Nanotech

Robotic surgery has many of the same benefits as laparoscopic surgery in that it can use smaller incisions to minimise blood loss. A doctor uses precise robotic arms which bend like wrists and are controlled by the doctor from a console next to the patient. All the details of the operation are displayed on a 3D screen next to the doctor.



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Uptake has been slow thanks to high upfront costs. However, the technology is advancing. An overview of the current state of robotic colorectal surgery argued that the technology could advance to the point where many conventional surgical techniques are rendered obsolete¹⁴.

Moving into the realm of nanotechnology, meanwhile, offers the tantalising prospect of dramatically reducing the need for surgery. Researchers at UCSF and UC Berkeley have demonstrated a nanoscale polymeric drug delivery vehicle that can be loaded with a widely used anti-cancer agent that can cure colon cancer in mice in a single dose¹⁵.

This technique is also being used to improve the effectiveness of colonoscopies in the early identification of cancer. As things stand, the accuracy of colonoscopies is heavily dependent on the speed with which they are performed and how thoroughly doctors search for lesions. However, nanotechnology could potentially identify cancerous cells before they become visible via a colonoscopy. Researchers at the Center of Cancer Nanotechnology Excellence at Stanford University have developed a system in which gold nanoparticles can be used to seek out and bind to cancer cells. Light is shined from a device which can be inserted into a standard endoscope causing the cancer cells to stand out. They can then be removed relatively easily¹⁶.

Training and Development

As technologies expand the role of endoscopic techniques, the demands being placed on staff are evolving. Progress brings complexity. A gastroenterologist must develop a range of skills and expertise including experience in ultrasound, the macroscopic view of lesions of the gut as well as the ability and patience to follow up on thousands of images transmitted during capsule endoscopy. They will need knowledge of physics for autofluorescence imaging and

much more. The idea of what an endoscopist is is evolving and one of the key challenges will be gaining the skillsets within teams to cater to heightened demands.

The way in which endoscopists are trained is also evolving with virtual reality adding enhanced realism into training scenarios. Rather than training in a clinical environment, students can use a simulator to create a 3D image with which they can interact as if it were real. It is a popular way to provide training in a risk-free environment.

A study by Khan R, Plahouras et al into the use of virtual reality found that it did deliver improvements over no training, although they found no conclusive evidence that it improved results over traditional training techniques¹⁷. Virtual and augmented reality technology is, however, evolving at speed delivering enhanced levels of realism. The report suggested results could be improved by providing progressive learning strategies in which tasks become increasingly more difficult.

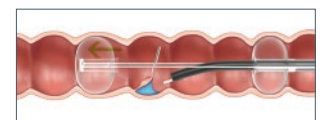
Another study into a technology using intuitive zoom in virtual reality showed that the technology could make it easier for operators to assess lesions¹⁸. By moving the head forwards, the image would expand providing a clearer view of a particular area. The endoscopist could then complete a successful biopsy of a polyp and shrink the image by moving his or her head backwards. Footage imported into VR and tracking devices in the corner of the room registered the position of the endoscopist.

Technology has an enormous role to play in the future of endolumenal therapies. It can reduce treatment times, lead to faster recoveries, improve accuracy of diagnosis and expand the use of non-invasive procedures which might previously have required surgery. By so doing, it allows many patients to avoid the stressful experience of surgery and return to their regular routines as quickly as possible.

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