Diseases of the Colon & Rectum

A prospective observational analysis of a novel digital rectoscope: LumenEye ®

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DISEASES OF THE COLON & RECTUM

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Dear Dr Sylla,

Thank you for considering our submission “A prospective observational analysis of a novel digital rectoscope: LumenEye®” for publication in the New Technology section of Diseases of the Colon & Rectum. This content was recently presented by James Kinross at the New Technologies Symposium at ASCRS 2021.

In this paper we present the new to market, CE-marked, LumenEye digital rectoscope. This is the first description of this novel device which maintains the point-of-care benefits and low cost of conventional rigid sigmoidoscopy whilst introducing high-definition image and video capture, biopsy capability, and vastly improving ergonomics. The article is a series of the first 50 in-man uses, with a retrospective image quality analysis by four blinded surgeons.

The video abstract provides a description of the device and its constituent parts, a brief introduction to the CHiP software which is used to run the device, and an overview of the first uses and image quality analysis.

Yours Sincerely

James Lewis
General Surgery Registrar
Clinical Research Fellow
Imperial College London

On behalf of

James Lewis, Shabuddin Khan, Henry Tilney, Jonathan Wilson, Louis Vitone, Maria Souvatzi, Baljit Singh, James Kinross

Word File New Technology Report (1,500 word limit). Required abstract format: Background, Impact of innovation, Technology

A prospective observational analysis of a novel digital rectoscope: LumenEye®

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This abstract has been presented at the New Technologies section of ASCRS 2021.

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Disclosures:

James Lewis has received funding from Surgease Innovations Ltd for work as a trial coordinator in a separate ongoing study.

James Kinross has received funding from NIH, NIHR, DASA, CRUK. He is a consultant and on the advisory boards for Johnson & Johnson and Ethicon. He sits on the scientific advisory board for Safheal, Ysopia and Surgease Ltd. He is a Director of Getwell Media Ltd and Mangetoo (digital dietetics), and a shareholder of OneWellbeck Day Surgery.

Abstract

Background This is a first in man, prospective analysis of the LumenEye® digital rigid sigmoidoscope. The technology provides digital image capture, telemedicine capabilities, improved ergonomics, and the ability to biopsy under pneumorectum whilst maintaining the low cost of conventional rigid sigmoidoscopy. The primary outcome was serious adverse events (SAE), and the secondary outcome was diagnostic view.

Provisional Results 50 patients undergoing outpatient (25) and surgical rectal assessment (25) were recruited with a mean age of 60years. This included 31males and 19 females with 12 different clinical use indications. No SAEs were reported, and no defects were reported with the instrumentation. Satisfactory diagnoses were obtained in 48/50 uses (96%), images were captured in 48/50 uses (96%), and biopsies were successfully taken in 13 uses (26%). No adverse events were recorded. Independent reviewers of recorded videos agreed on the quality and diagnostic value of the images with a kappa of 0.225 (95% C.I. 0.144-0.305) when assessing whether the target pathology was adequately visualised.

Impact of Innovation The improved views afforded by LumenEye® facilitated a satisfactory clinical diagnosis in 96% of uses. The device was successfully deployed in the operating room and outpatients irrespective of bowel preparation method, where it has the potential to replace flexible sigmoidoscopy for specific use cases. The technology provides a high-quality image and video which can be securely recorded for documentation and medicolegal purposes with agreement between blinded users despite a lack of standardised training and heterogenous pathology. We perceive significant impact of this technology for the assessment of colorectal anastomoses, the office management of colitis, 'watch and wait' and for diagnostic support in rectal cancer diagnosis. The technology has significant potential to

facilitate proctoring and training and it now requires prospective trials to validate its diagnostic accuracy against more costly flexible sigmoidoscopy systems.

Article

Background

Rigid sigmoidoscopy was the mainstay of outpatient and operative rectal examination for many years[1, 2]. A rigid endoscope permits accurate measurement of target pathology from the anal verge and sphincter complex to stratify treatment in both benign and malignant disease. However, despite considerable advances in flexible endoscopy imaging technologies, rigid sigmoidoscopy has remained resistant to innovation. Low-cost disposable devices have become available, but they have failed to provide a solution to its major flaws- restricted views, poor ergonomics, a limited biopsy capability and the absence of image capture. Flexible sigmoidoscopy has therefore largely surpassed rigid sigmoidoscopy, despite the increased costs, training, and resource requirements.

The advantages of improved views, greater insertion distances and improved patient comfort have been demonstrated using modified or prototype video rigid sigmoidoscopes [3, 4]. Despite this observation, few commercially viable technologies have been developed and none have adopted a data driven approach to rigid sigmoidoscopy. The aim of this first in man, prospective observational study was to assess the safety and utility of a novel digital rigid sigmoidoscope for use in outpatient and operating room environments.

Technology Materials and Methods

LumenEye® is a self-contained point of care rigid sigmoidoscopy device equipped with an HD camera and LED lighting, with bellows built into the handpiece allowing for single handed use. A self-sealing working channel facilitates precision biopsy using standard endoscopy biopsy forceps. Procedural images and videos are captured using the integrated CHiP software (Fig.1, 2). CHiP is a cloud-based software which can be integrated with Electronic Healthcare Record (EHR) systems for reporting and documentation. The inbuilt text, audio and video messaging features allow both remote proctoring of live rectoscopy procedures and remote video consultations. The software has a clinic scheduling application and patient invitations can be sent via SMS and email.

The device sits in a dock with a tablet running the CHiP software (Fig.3,4) which requires a live internet connection over Wi-Fi. A disposable manifold (packaged with the disposable outer sleeve and introducer) is placed onto the handset before use (Fig.5a).

With the patient positioned as required (typically the left lateral position), the outer sleeve with introducer is inserted into the anus with the lip pointing upwards. The introducer is removed, and handpiece inserted into the sleeve (Fig.5b). Air can be insufflated once the manifold contacts the seal on the outer sleeve (Fig.5d). Air can be released by removing the handpiece from the manifold (Fig.5e). The 3mm access channel allows the use of biopsy forceps or snares as needed (Fig.5c). Should the camera lens become contaminated obstructing the view, the handpiece can be removed from the manifold for cleaning without losing position in the rectum.

After use, the handpiece is removed from the manifold/outer sleeve assembly and the pneumorectum allowed to deflate before removing the sleeve. The sleeve/manifold assembly is disposed of in the clinical waste. The handpiece is cleaned using the Tristel Trio™ Wipe

System and the dock and screen with clinical surface wipes. Turnaround between uses takes less than 5 minutes.

This is a prospective, observational multicentre pilot study of the first 50 clinical uses of the LumenEye® X1. The primary outcome measure was serious adverse events, and the secondary outcome measures were image quality and diagnostic view. Patients were recruited in the outpatient setting or peri-operatively and included if rectosigmoid views were required for diagnosis, confirmation of surgical procedure or assessment of treatment response. Patients were excluded if they were unable to consent.

Use report forms were collected contemporaneously and procedural videos were retrospectively accessed on CHiP. Video quality and diagnostic value were assessed by four independent reviewers (HT, JK, JW, LV). There were no exclusion criteria. Data were analysed using SPSS® Statistics 27 (IBM Corporation, 2020).

Impact of Innovation

The LumenEye® digital sigmoidoscope allows point of care examination of the rectum in any clinical setting with quick set up, rapid turnaround and low cost. No adverse events have been encountered with this device. Cleaning and turnaround between cases can be achieved in less than 5 minutes.

In the current era of COVID-19, reduced capacity has led to delays in diagnostic evaluations for colorectal cancer [5] and reductions in the number of endoscopies for inflammatory bowel disease [6]. In this series, 9 examinations were performed for new presentations of rectal bleeding and 6 for proctitis. A satisfactory clinical diagnosis was achieved in all cases and 5 biopsies taken. These patients were cared for in the outpatient department, without

burdening endoscopy services. It has previously been suggested that the increased use of rigid sigmoidoscopy and biopsy may contribute to the reduced time to treatment for a new diagnosis of ulcerative colitis in colorectal outpatient clinics [7]. The improved ergonomics and ease of biopsy using LumenEye® may increase the rate of rectal evaluation and biopsy. Whilst diagnostic efficacy is yet to be assessed, LumenEye® may represent a means by which we can risk-stratify patients to routine rather than urgent endoscopic assessment of rectal bleeding.

The emerging watch and wait approach following a complete clinical response to chemoradiotherapy in rectal cancer involves high intensity surveillance [8]. This is currently enacted varyingly with proctoscopy, rigid sigmoidoscopy, and examination under anaesthesia. In this series, the LumenEye® has been used for 1 watch and wait first assessment and 7 follow up assessments, with satisfactory diagnoses made on all occasions, with the additional benefit of digital image capture for documentation of examination findings.

LumenEye® inspection of a colorectal anastomosis allows both air leak testing, an essential step in forming an anastomosis [9], and direct inspection of the anastomosis, with digital images available for the notes. Intraoperative inspection of a colorectal anastomosis has been shown to improve the detection rate of anastomotic defects, reducing anastomotic leak (OR 0.45) and post-operative anastomotic bleeding requiring intervention (OR 0.40) when using flexible sigmoidoscopy rather than conventional air leak testing [10]. The LumenEye® offers similar image quality and recording technology to flexible sigmoidoscopy. We believe that it confers the benefits of endoscopic evaluation of an anastomosis with the additional benefits of convenience and low cost.

We have not performed a formal cost-effectiveness calculation but estimate the cost per use to be £30. The NHS best practice tariff 2020/21 for diagnostic flexible sigmoidoscopy is £310, or £395 with biopsy and rigid sigmoidoscopy is £177 [11]. This represents a significant cost saving compared to conventional rigid sigmoidoscopy or flexible sigmoidoscopy.

Preliminary Results

In the first 50 reported uses across 13 clinical sites by 20 clinicians, the mean patient age was 60 years (S.D. 17). 31 examinations were performed for male patients and 19 for females. 25 uses were outpatient examinations, and 25 uses were perioperative. No adverse events were encountered.

The device was most frequently used for the assessment of bleeding and intraoperative assessment of a colorectal anastomosis (table 1). 11 uses were with no bowel preparation, 3 with glycerine suppository, 24 with phosphate enema, and 12 with mechanical bowel preparation. Depth of insertion and bowel preparation strategy is reported in table 2. A satisfactory clinical diagnosis at the point of care was achieved in 48 uses (96%) and images captured in 48 uses (96%). Biopsies were taken in 13 cases.

There were two uses in which a satisfactory diagnosis was not achieved – one left hemicolectomy in which the anastomosis was beyond the reach of the LumenEye, and an early post-operative colorectal anastomosis assessment performed without bowel preparation, views in this case were obstructed by stool.

Table 1. Demographics and indications for use.

Patient age (mean, S.D)	60, 17

Sex, M:F	31:19
Clinical setting, Inpatient:Outpatient	25:25
Watch and wait 1st assessment	1
Watch and wait subsequent assessment	7
IBD Proctitis new diagnosis	1
IBD Proctitis follow up	5
Rectal bleeding new patient	9
Rectal bleeding follow-up	1
TEMS intraoperative evaluation	3
Intraoperative anastomosis assessment	9
Post-operative anastomosis assessment	8
Intraoperative assessment of lesion	4
Polypectomy site check	1
Anastomotic stricture check after dilatation	1

Table 2. Distance of inspection and bowel preparation used.

Distance inspected (cm)	Cases	Preparation used			
		No preparation	Suppository	Enema	Mechanical
≤5	1	1	-	-	-
≤10	19	7	2	4	6
≤15	20	2	1	13	4
≤20	6	1	-	3	2
≤25	4	-	-	4	-

A retrospective assessment of image quality was performed on 37 cases for which a video was recorded. Anonymised videos were retrieved from CHiP and independently reviewed by four consultant colorectal surgeons. Assessors were provided with the indication for examination (categorised as per Table 1) and a novel endoscopic image quality score, assessing focus, lighting, colour, mucosal view, vasculature view, view of target pathology, and quality of bowel preparation.

A fair agreement was observed (Table 3) for the assessment of bowel preparation quality on a 3-point scale (excellent, adequate, inadequate). A fair agreement was observed in the

adequacy of mucosal view (adequate/inadequate) with a kappa of 0.326 (95% C.I. 0.14-0.512) and on the adequacy of vasculature view (adequate/inadequate). There was a slight agreement on whether the intended pathology was observed and upon the quality of lighting and colour in the videos. However, this was confounded by the heterogenous pathologies, which included surgical anastomosis and the small sample size.

Table 3. Interobserver agreement on image assessment. Interpretations are as suggested by Landis et al. [12]

				95% C.I.	
		kappa	p	lower	upper
Diagnostic View	Mucosa	0.275	**<0.005**	0.143	0.406
	Vasculature	0.297	**<0.005**	0.166	0.429
	Pathology Assessment	0.225	**<0.005**	0.144	0.305
	Bowel Preparation	0.371	**<0.005**	0.269	0.474

Kappa score interpretation	
0.01 – 0.20	slight agreement
0.21 – 0.40	fair agreement
0.41 – 0.60	moderate agreement
0.61 – 0.80	substantial agreement
0.81 – 1.00	almost perfect agreement

Conclusion

This first in man, observational study demonstrates a wide range of clinical applications for this novel point of care digital rectoscope with no adverse events. Early data suggest that diagnostic yield is high, costs are low, and this device may provide safe and efficacious rectal assessment whilst reducing the demands upon formal endoscopy units. This pilot study is limited by low numbers of cases and assessors, who did not receive training on image quality assessment.

Further investigation is needed to establish the diagnostic accuracy of the device and wider applications of the software.

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Fig.1 Examples of use. A – View of normal rectum. B – Biopsy forceps in use. C – Watch and wait scar and tattoo. D – Proctitis assessment. E – TEMS intraoperative tumour assessment. F – Colorectal anastomosis intraoperative assessment with air leak test.

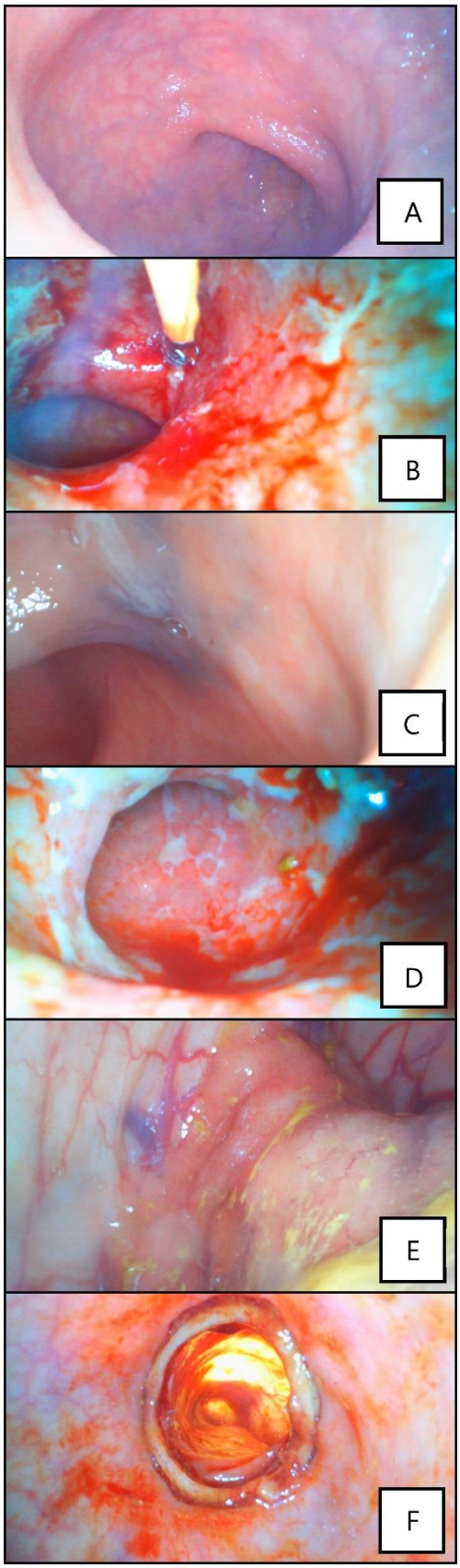


Fig. 2 Example of longitudinal use. A- Outpatient diagnostic. B – TEMS intraoperative use. C- Intraoperative lesion identification. D – Intraoperative anastomosis check. E – Post operative (day 7) anastomosis check.

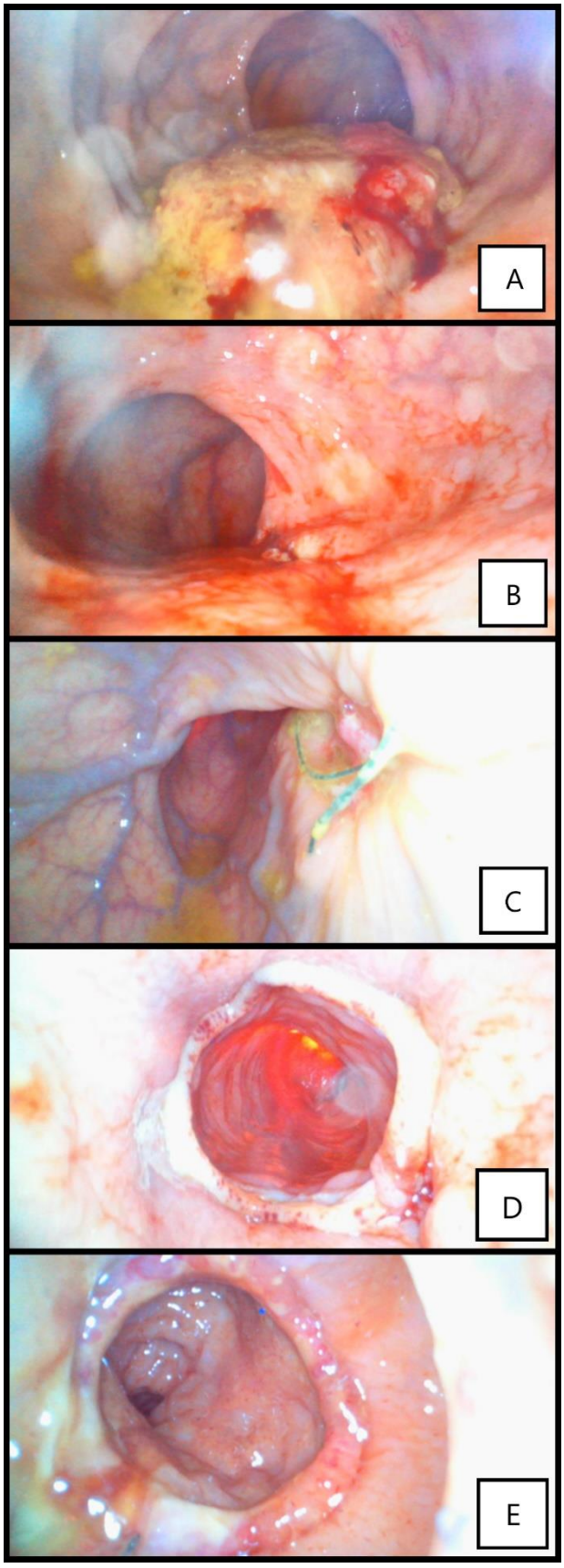


Fig.3 The LumenEye ® device on its dock with tablet running CHiP.



Fig.4 The CHiP proctoring environment during examination.



Fig.5 LumenEye® components and assembly. A – The handpiece (top), manifold (middle) and outer sleeve with introducer (bottom). B – Assembled device. C – 3mm biopsy channel. D – Insufflation using the bellows in the handpiece. E – Releasing handpiece from the manifold/outer sleeve assembly.

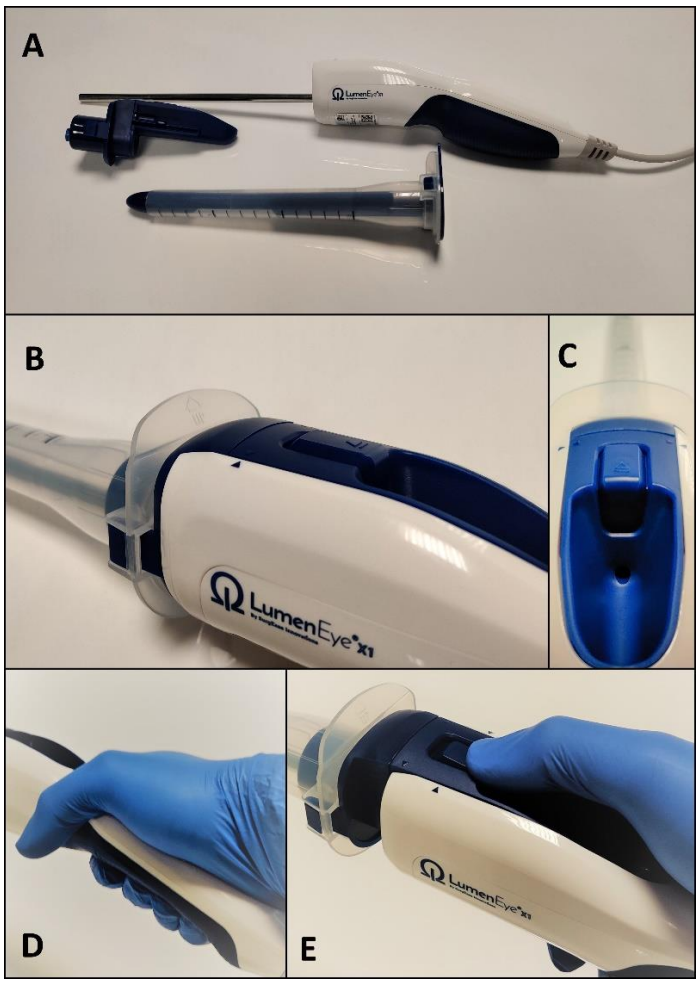


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Figure 1

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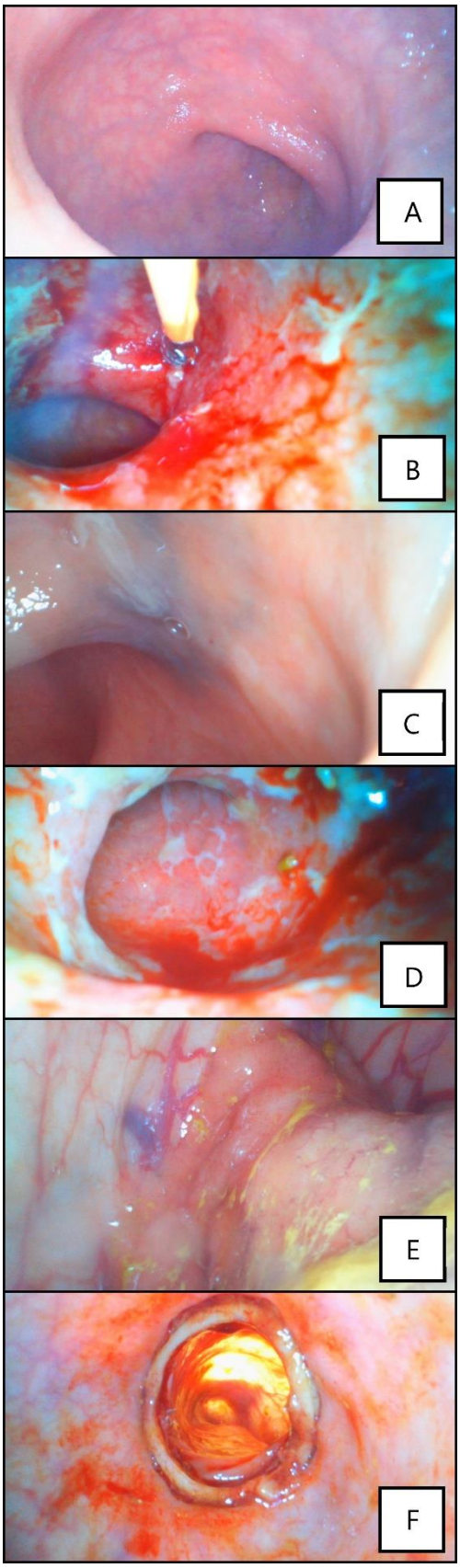


Figure 2

Fig. 2 Example of longitudinal use. A- Outpatient diagnostic. B – TEMS intraoperative use. C- Intraoperative lesion identification. D – Intraoperative anastomosis check. E – Post operative (day 7) anastomosis check.

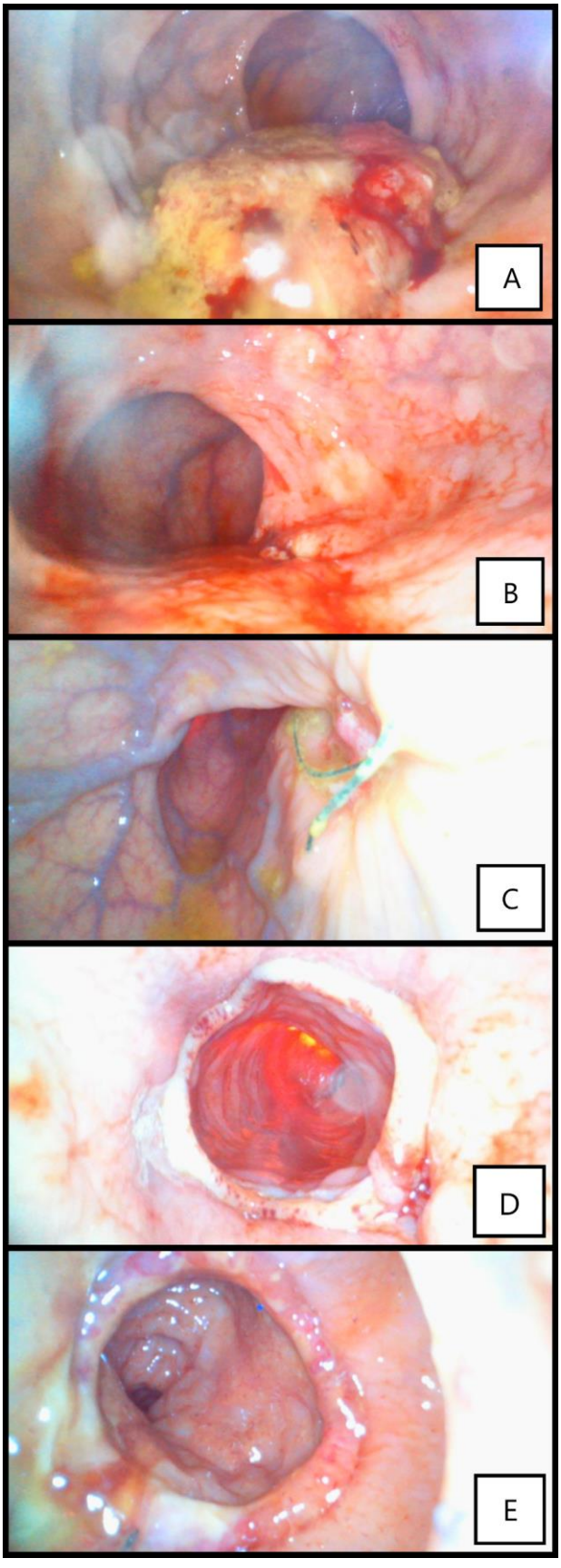


Figure 3

Fig.3 The LumenEye ® device on its dock with tablet running CHiP.



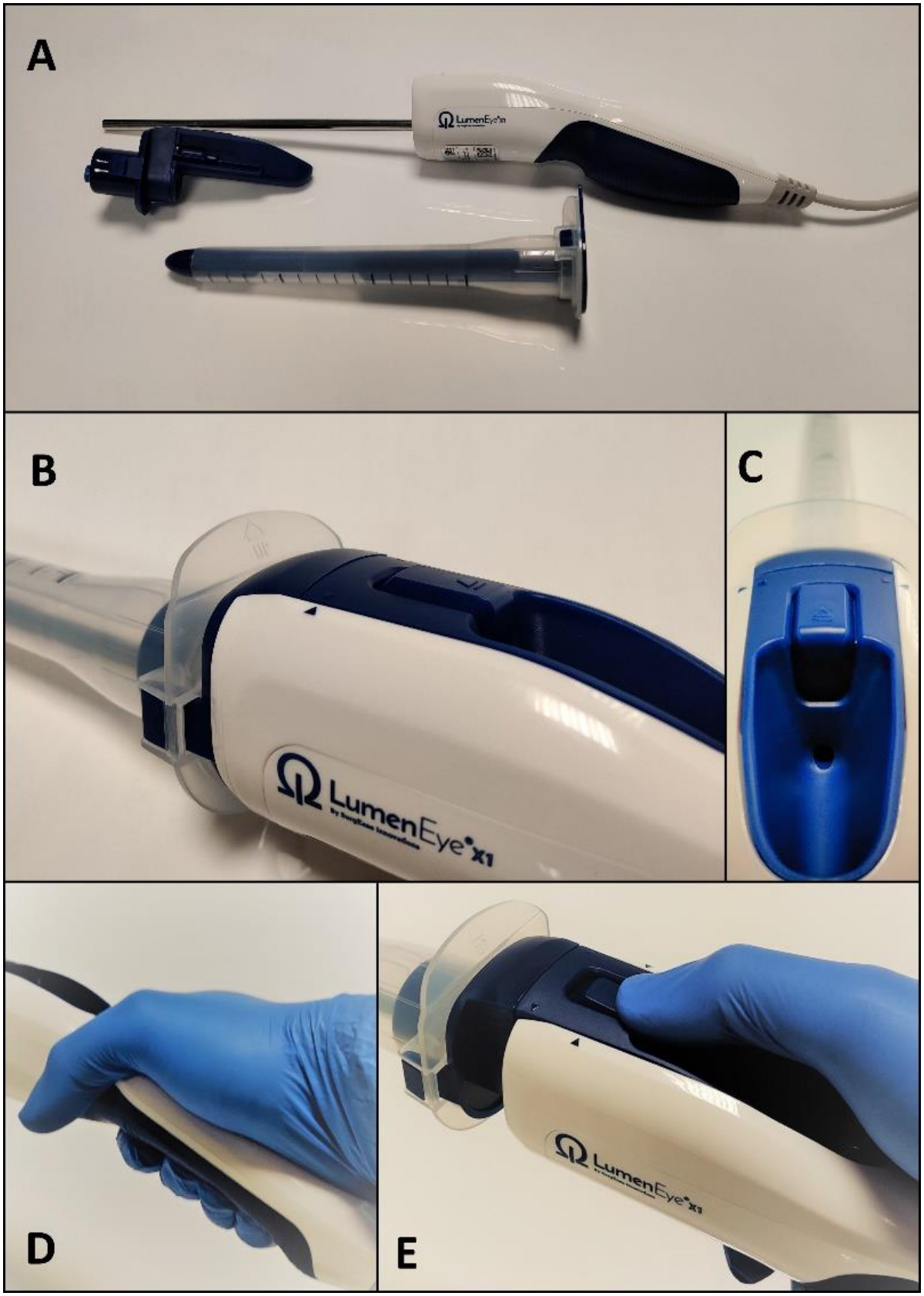
Figure 4

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Figure 5

Fig.5 LumenEye® components and assembly. A – The handpiece (top), manifold (middle) and outer sleeve with introducer (bottom). B – Assembled device. C – 3mm biopsy channel. D – Insufflation using the bellows in the handpiece. E – Releasing handpiece from the manifold/outer sleeve assembly.



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Manuscript number (if known):_____

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Time frame: past 36 months			
2	Grants or contracts from any entity (if not indicated in item #1 above).	____None	
3	Royalties or licenses	____None	
4	Consulting fees	____None	

5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events	____None	
6	Payment for expert testimony	____None	
7	Support for attending meetings and/or travel	____None	
8	Patents planned, issued or pending	____None	
9	Participation on a Data Safety Monitoring Board or Advisory Board	____None	
10	Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid	____None	
11	Stock or stock options	____None	
12	Receipt of equipment, materials, drugs, medical writing, gifts or other services	____None	
13	Other financial or non-financial interests	____None	

Please place an "X" next to the following statement to indicate your agreement:

_X_ I certify that I have answered every question and have not altered the wording of any of the questions on this form.

Conflict of Interest (COI)/Disclosure Letter
Must Be Uploaded by All Authors

ICMJE DISCLOSURE FORM

Date: 17/5/21
Your Name: MR JONATHAN MICHAEL WILSON
Manuscript Title: A PROSPECTIVE OBSERVATIONAL ANALYSIS OF NOVEL DIGITAL
Manuscript number (if known): RELTASCOPE : LUMENEYE

In the interest of transparency, we ask you to disclose all relationships/activities/interests listed below that are related to the content of your manuscript. "Related" means any relation with for-profit or not-for-profit third parties whose interests may be affected by the content of the manuscript. Disclosure represents a commitment to transparency and does not necessarily indicate a bias. If you are in doubt about whether to list a relationship/activity/interest, it is preferable that you do so.

The following questions apply to the author's relationships/activities/interests as they relate to the current manuscript only.

The author's relationships/activities/interests should be defined broadly. For example, if your manuscript pertains to the epidemiology of hypertension, you should declare all relationships with manufacturers of antihypertensive medication, even if that medication is not mentioned in the manuscript.

In item #1 below, report all support for the work reported in this manuscript without time limit. For all other items, the time frame for disclosure is the past 36 months.

		Name all entities with whom you have this relationship or indicate none (add rows as needed)	Specifications/Comments (e.g., if payments were made to you or to your institution)
		Time frame: Since the initial planning of the work	
1	All support for the present manuscript (e.g., funding, provision of study materials, medical writing, article processing charges, etc.) **No time limit for this item.**	None	N/A.
		Time frame: past 36 months	
2	Grants or contracts from any entity (if not indicated in item #1 above).	None	N/A.
3	Royalties or licenses	None	N/A.
4	Consulting fees	None	I HAVE PROVIDED CONSULTANCY WITH REGARDS TO PRODUCT DEVELOPMENT & IMPROVEMENT (SHARE OPTION REMUNERATION).

5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events	___None	See section 4.
6	Payment for expert testimony	___None	See Section 4.
7	Support for attending meetings and/or travel	___None	N/A
8	Patents planned, issued or pending	___None	N/A.
9	Participation on a Data Safety Monitoring Board or Advisory Board	___None	N/A
10	Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid	___None	N/A
11	Stock or stock options	___None	YES - SHARE OPTIONS WITH SURGEASE
12	Receipt of equipment, materials, drugs, medical writing, gifts or other services	___None	N/A.
13	Other financial or non-financial interests	___None	N/A.

Please place an "X" next to the following statement to indicate your agreement:

___ **I certify that I have answered every question and have not altered the wording of any of the questions on this form.**

17/5/20.

MR. T.M. WILSON

ICMJE DISCLOSURE FORM

Date:_____17th May 2021_____
Your Name:_____Louis Vitone-_____
Manuscript Title:_____A prospective observational analysis of a novel digital rectoscope LumenEye_____
Manuscript number (if known):_____

In the interest of transparency, we ask you to disclose all relationships/activities/interests listed below that are related to the content of your manuscript. "Related" means any relation with for-profit or not-for-profit third parties whose interests may be affected by the content of the manuscript. Disclosure represents a commitment to transparency and does not necessarily indicate a bias. If you are in doubt about whether to list a relationship/activity/interest, it is preferable that you do so.

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Time frame: past 36 months			
2	Grants or contracts from any entity (if not indicated in item #1 above).	____None	
3	Royalties or licenses	____None	
4	Consulting fees	____None	
5	Payment or honoraria for	____None	

	lectures, presentations, speakers bureaus, manuscript writing or educational events		
6	Payment for expert testimony	____None	
7	Support for attending meetings and/or travel	____None	
8	Patents planned, issued or pending	____None	
9	Participation on a Data Safety Monitoring Board or Advisory Board	____None	
10	Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid	____None	
11	Stock or stock options	____None	
12	Receipt of equipment, materials, drugs, medical writing, gifts or other services	____None	
13	Other financial or non-financial interests	____None	

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_X__ I certify that I have answered every question and have not altered the wording of any of the questions on this form.

ICMJE DISCLOSURE FORM

Date:_____17/05/2021_____
Your Name: _____Maria Souvatzi_____
Manuscript Title:_____A prospective observational analysis of a novel digital rectoscope: LumenEye®
Manuscript number (if known):_____

In the interest of transparency, we ask you to disclose all relationships/activities/interests listed below that are related to the content of your manuscript. "Related" means any relation with for-profit or not-for-profit third parties whose interests may be affected by the content of the manuscript. Disclosure represents a commitment to transparency and does not necessarily indicate a bias. If you are in doubt about whether to list a relationship/activity/interest, it is preferable that you do so.

The following questions apply to the author's relationships/activities/interests as they relate to the current manuscript only.

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Time frame: Since the initial planning of the work			
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Time frame: past 36 months			
2	Grants or contracts from any entity (if not indicated in item #1 above).	____None	
3	Royalties or licenses	____None	
4	Consulting fees	____None	

5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events	____None	
6	Payment for expert testimony	____None	
7	Support for attending meetings and/or travel	____None	
8	Patents planned, issued or pending	____None	
9	Participation on a Data Safety Monitoring Board or Advisory Board	____None	
10	Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid	____None	
11	Stock or stock options	____None	
12	Receipt of equipment, materials, drugs, medical writing, gifts or other services	____None	
13	Other financial or non-financial interests	____None	

Please place an "X" next to the following statement to indicate your agreement:

_X__ I certify that I have answered every question and have not altered the wording of any of the questions on this form.

ICMJE DISCLOSURE FORM

Date:_____13th May 2021
Your Name:_____Baljit Singh_____
Manuscript Title:__ A prospective observational analysis of a novel digital rectoscope: LumenEye
Manuscript number (if known):_____

In the interest of transparency, we ask you to disclose all relationships/activities/interests listed below that are related to the content of your manuscript. "Related" means any relation with for-profit or not-for-profit third parties whose interests may be affected by the content of the manuscript. Disclosure represents a commitment to transparency and does not necessarily indicate a bias. If you are in doubt about whether to list a relationship/activity/interest, it is preferable that you do so.

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Time frame: Since the initial planning of the work			
1	All support for the present manuscript (e.g., funding, provision of study materials, medical writing, article processing charges, etc.) **No time limit for this item.**	____None	
Time frame: past 36 months			
2	Grants or contracts from any entity (if not indicated in item #1 above).	____None	
3	Royalties or licenses	____None	
4	Consulting fees	____None	

5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events	Yes	Johnson and Johnson November 2019
		Speaker honorarium	Pharmacosmos November 2019
6	Payment for expert testimony	____None	
7	Support for attending meetings and/or travel	____None	
8	Patents planned, issued or pending	____None	
9	Participation on a Data Safety Monitoring Board or Advisory Board	____None	
10	Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid	____None	
11	Stock or stock options	____None	
12	Receipt of equipment, materials, drugs, medical writing, gifts or other services	____None	
13	Other financial or non-financial interests	____None	

Please place an "X" next to the following statement to indicate your agreement:

__X_ I certify that I have answered every question and have not altered the wording of any of the questions on this form.

ICMJE DISCLOSURE FORM

Date:____17/05/2021_____
Your Name: ____James Kinross_____
Manuscript Title:_____A prospective observational analysis of a novel digital rectoscope: LumenEye®
Manuscript number (if known):_____

In the interest of transparency, we ask you to disclose all relationships/activities/interests listed below that are related to the content of your manuscript. "Related" means any relation with for-profit or not-for-profit third parties whose interests may be affected by the content of the manuscript. Disclosure represents a commitment to transparency and does not necessarily indicate a bias. If you are in doubt about whether to list a relationship/activity/interest, it is preferable that you do so.

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In item #1 below, report all support for the work reported in this manuscript without time limit. For all other items, the time frame for disclosure is the past 36 months.

		Name all entities with whom you have this relationship or indicate none (add rows as needed)	Specifications/Comments (e.g., if payments were made to you or to your institution)
Time frame: Since the initial planning of the work			
1	All support for the present manuscript (e.g., funding, provision of study materials, medical writing, article processing charges, etc.) **No time limit for this item.**	Surgease Ltd	Supply of equipment to support study.
Time frame: past 36 months			
2	Grants or contracts from any entity (if not indicated in item #1 above).	NIHR i4i	iEndoscope grant funding
		CRUK	Research fellowship
		NIH	R01 grant
3	Royalties or licenses	NA	
4	Consulting fees	Johnson & Johnson	
		Ethicon	

5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events	Yakult	Lecture
6	Payment for expert testimony	____None	
7	Support for attending meetings and/or travel	Intuitive	Hernia symposium
8	Patents planned, issued or pending		iEndoscope
9	Participation on a Data Safety Monitoring Board or Advisory Board	Safheal	
		Ysopia	
		Surgease Ltd	
10	Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid	____None	
11	Stock or stock options	OneWellbeck Day Surgery	Day surgery unit
		Medical isight	Medical AR company
		SurgEase	
		Renegade Medical	Medical design
12	Receipt of equipment, materials, drugs, medical writing, gifts or other services	____None	
13	Other financial or non-financial interests	Getwell Media Ltd	Director
		Mangetoo (digital dietetics)	Director

Please place an "X" next to the following statement to indicate your agreement:

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