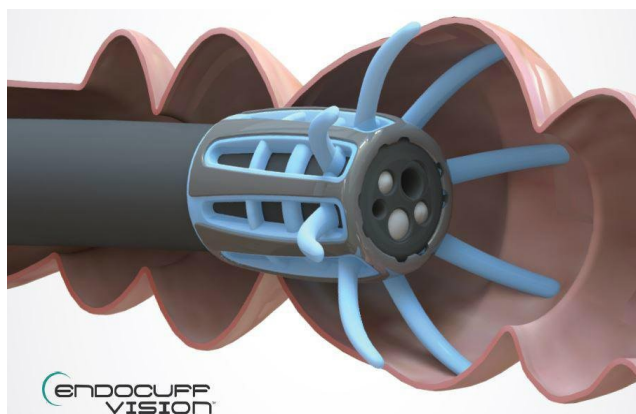


Institution: Newcastle University		
Unit of Assessment: UoA 1		
Title of case study: Endocuff Vision: a simple tool to increase early detection of cancerous lesions in the colon		
Period when the underpinning research was undertaken: 2016-2019		
Details of staff conducting the underpinning research from the submitting unit:		
Name(s):	Role(s) (e.g. job title):	Period(s) employed by submitting HEI:
Professor Colin Rees	Professor of Gastroenterology and PI	August 2016-present
Professor Linda Sharp	Professor of Cancer Epidemiology and supervisor for MD fellows	January 2015-present
Professor Matt Rutter	Co-author and lead for one of the sites, Honorary Chair	January 2018-present
Period when the claimed impact occurred: 2019-present		
Is this case study continued from a case study submitted in 2014? No		
1. Summary of the impact Adenoma detection is key to reducing deaths from colorectal cancer (CRC), which kills 16,000 people annually in the UK. However, adenoma detection rate (ADR) varies widely because folds within the colon limit the view. Newcastle investigated the effectiveness of Endocuff Vision, a single-use device that attaches to the tip of an endoscope to improve the field of view. Newcastle found that this tool significantly improved ADR to 61.7% (from 50.9% using standard colonoscopy) in bowel cancer screening patients. This research underpinned NICE approval and NHS England funding in 2019. By identifying adenomas earlier, this device can reduce the risk of fatal post-colonoscopy CRC by 24% in screened patients. Subsequent uptake of Endocuff Vision into practice was rapid, with 69,000 units supplied per year by 2019/20.		
2. Underpinning research <u>Description of the device</u> Endocuff Vision (EV) is used during colonoscopy to improve the field of vision. It is a second-generation class 1, sterile, single-use medical device and received its CE mark in August 2016. It fits securely around the tip of a compatible colonoscope and contains a single set of flexible hinged arms that form a ring around the tip. During insertion, the arms of the device lie flat against the colon, enabling easy passage of the instrument. When it is withdrawn, the arms fan out to straighten and flatten the colon. This action helps to: • Visualise any lesions on the proximal side of colonic folds • Keep the colonoscope centred to provide a panoramic view of the colon • Control withdrawal to ensure the complete mucosal surface is examined • Manage and straighten out loops during examination. An animation of EV in action can be viewed at: www.youtube.com/watch?v=T8QQiysh-o <u>Newcastle research into the effectiveness of EV</u> Since EV was new, there were insufficient data on its effectiveness for NICE approval. The manufacturer of EV therefore contacted Professor Rees, as founder and Chair of the Northern		



Region Endoscopy Group, to test the device. In collaboration with the manufacturer, Professor Rees generated data on the effectiveness of EV which would support approval by NICE and consequent uptake into practice.

The success of the initial pilot (R2) led to a multi-centre randomised controlled trial: the Accuracy of Detection using Endocuff Optimisation of Mucosal Abnormalities trial (ADENOMA; R1 and R3). The trial recruited 1,772 patients across nine sites in the North East of England and London. This is one of the largest endoscopy trials ever published and was delivered substantially ahead of time and target. In 2018, the NIHR made the ADENOMA trial its national gastrointestinal “exemplar” study for that year¹.

The ADENOMA study demonstrated that in bowel cancer screening patients (those with stool test positive for blood), EV improved ADR from 50.9% using standard colonoscopy to 61.7% with EV. This absolute increase of 10.8% is one of the largest increases in detection of any approach ever seen. As stated in R3, a previous study² found that a 1% increase in ADR was associated with a 3% reduction in CRC that occurs post-colonoscopy (PCCRC), and a 5% decrease in fatal PCCRC. EV demonstrated a statistically significant 4.7% absolute increase in ADR across both screening and non-screening patients. Results from both groups of patients indicate that, if the current trial mirrored this study, EV could reduce the risk of PCCRC by 14% and fatal PCCRC by 24%. Cancer detection rates were also significantly improved, when compared to standard colonoscopy, with a statistically significant absolute increase in cancer detection of 1.8%. Improvement in cancer detection allows the patient to access treatment more rapidly and improves the chances of successful treatment.

As testament to its clinical value, EV has received multiple awards and commendations. For example, in November 2018 it won a UK Industry Award for collaboration and an Academic Health Science Networks collaboration/innovation award; and in December 2018 it won The British Healthcare Trades Award for Best Innovation Developed in Collaboration with the NHS³. An October 2019 independent review of adult screening programmes by NHS England stated: “[EV] is an excellent example of additions and modifications to screening to improve earlier detection of cancer and save more lives⁴.” Finally, the EV research formed the basis of the Royal College of Physicians’ Excellence in Patient Care Research Award in May 2020⁵.

3. References to the research

Web of Science citations and field-weighted citation impact (FWCI) as of September 2020. Newcastle researchers in **bold**.

- R1. Bevan R, Ngu WS, Saunders BP, Tsiamoulos Z, Bassett P, Hoare Z, **Rees CJ**. (2016) The ADENOMA Study. Accuracy of Detection using Endocuff Vision™ Optimization of Mucosal Abnormalities: study protocol for randomized controlled trial. *Endoscopy International Open*. 4(2):E205-12. DOI: 10.1055/s-0041-107900. Citation count: 11. Protocol paper.
- R1. Tsiamoulos ZP, Misra R, Rameshshanker R, Elliott TR, Beintaris I, Thomas-Gibson S, Haycock A, Suzuki N, **Rees C**, Saunders BP. (2018) Impact of a new distal attachment on colonoscopy performance in an academic screening center. *Gastrointestinal Endoscopy*. 87(1):280-7. DOI: 10.1016/j.gie.2017.04.001. FWCI: 2.96. Pilot study. Tsiamoulos has provided a testimonial to confirm Newcastle’s role in this paper.
- R2. Ngu WS, Bevan R, Tsiamoulos Z, Bassett P, Hoare Z, **Rutter MD**, Clifford G, Totton N, Lee TJ, Ramadas A, Silcock JG, Painter J, Neilson LJ, Saunders BP, **Rees CJ**. (2019) Improved adenoma detection with Endocuff Vision: the ADENOMA randomised controlled trial. *Gut*. 68 (2):280-8. DOI: 10.1136/gutjnl-2017-314889. NB e-published Jan

¹<https://www.nihr.ac.uk/documents/case-studies/adenoma-impact-case-study/21824>

²Corley et al. 2014. DOI: [10.1056/NEJMoa1309086](https://doi.org/10.1056/NEJMoa1309086)

³<https://www.ncl.ac.uk/press/articles/archive/2018/12/healthawards>

⁴<https://www.england.nhs.uk/wp-content/uploads/2019/02/report-of-the-independent-review-of-adult-screening-programme-in-england.pdf>

⁵<https://www.rcplondon.ac.uk/news/rcp-excellence-patient-care-awards-2020-winners-have-been-announced>

2018. FWCI: 10.75. Main paper, one of the top five publications in the National Cancer Research Institute Annual Report 2017-18⁶.

N.B. Professor Rees joined Durham University's School of Medicine, Pharmacy and Health (SMPH) as an Honorary Chair in August 2012, a position he held during the period of research for R1 and R2. Therefore, although his affiliation is listed as South Tyneside and Sunderland NHS Foundation Trust on R1 and R2, he held an Honorary Chair at Durham University during this time⁷. In 2016, Professor Rees moved to Newcastle University as part of the TUPE of the SMPH. Research England approved the TUPE transfer, making the research eligible to underpin this impact case.

4. Details of the impact

Background

Colorectal cancer (CRC) is the second most common cause of cancer death, killing 16,000 people in the UK annually, and mostly arises from pre-cancerous adenomas. Adenomas are detected by colonoscopy, a common procedure with 40,000 performed in England for bowel cancer screening every year. The most important contemporaneous marker of colonoscopy quality is ADR; however this varies widely between individuals due to folds in the colon limiting the field of view. Improved ADR is linked to a decrease in both CRC rate and mortality risk through earlier detection. Therefore, the ADENOMA trial (R1-3) investigated the effectiveness of EV: an inexpensive, simple device to improve ADR. The impressive results of this trial directly informed NICE approval of EV and its adoption into NHS England practice, as detailed below.

Impact on NICE recommendation

In April 2018, NHS England announced EV as one of only four technologies to be fast-tracked into use through NHS England's Innovation and Technology Payment programme (EV1). This was followed in early 2019 by a NICE consultation (EV2), which lists R3 as "the only study powered to detect a difference in adenoma detection rates and the results showed a statistically significant improvement with Endocuff Vision... The EAC [External Assessment Centre] concluded that ADENOMA was a high-quality study with a low risk of bias. The clinical experts confirmed that the trial accurately represented NHS clinical practice."

This positive consultation resulted in the June 2019 recommendation by NICE for EV to assist visualisation during colonoscopy as part of the NHS bowel cancer screening programme (EV3). The document notes the main findings from R3, including:

- "Evidence supports the case for adopting Endocuff Vision in the NHS because it improves the adenoma detection rate during colonoscopy, particularly for people having a colonoscopy as part of bowel cancer screening... Endocuff Vision should be considered as an option for people having a colonoscopy as part of bowel cancer screening following a positive stool test."

This document also recognises the improvement in ADR that EV provides:

- "Clinical evidence shows that for people having a colonoscopy as part of bowel cancer screening, using Endocuff Vision improves the adenoma detection rate without increasing how long the procedure takes. Better detection of adenomas is likely to reduce the incidence of subsequent cancers."

Secondly, the modest cost saving offered by EV is mentioned:

- "Cost modelling shows that for people having a colonoscopy as part of bowel cancer screening, using Endocuff Vision provides a modest cost saving. Savings are related to the adenoma detection rate; for a colonoscopist with a baseline adenoma detection rate of 51%, using Endocuff Vision saves £53 per patient over 10 years compared with standard colonoscopy."

⁶<http://csg.ncri.org.uk/wp-content/uploads/2018/10/NCRI-Colorectal-Cancer-CSG-2017-2018-Annual-Report.pdf>

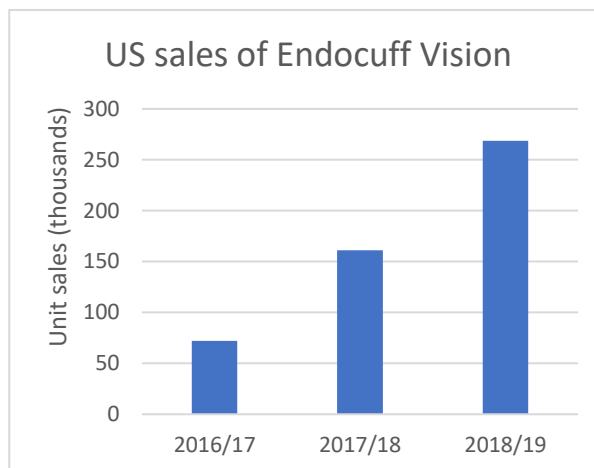
⁷A letter from the Trust to confirm this can be provided on request

Finally, the document also acknowledges the time saving offered by EV during procedures:

- “In the ADENOMA trial, inserting Endocuff Vision took 1 minute less than inserting a standard colonoscope... a notable time saving... any improvements in procedure efficiency may lead to lower levels of colonoscopist fatigue and may be of particular value in complex cases.”

Uptake into clinical practice in the UK and US

Following the ADENOMA trial, the number of EV units supplied to the NHS increased from 1,500 units across 17 sites in 2017/18 to 39,000 across 101 sites, 72% of eligible sites, in 2018/19 (EV4). In 2019/20, 69,000 units were supplied across 119 sites (EV5), even in the context of the COVID-19 pandemic which reduced screening activity by up to 50%. In the US, the success of EV drove the expansion of ownership and distribution rights to successively larger companies. Since July 2019, these rights moved region by region to Olympus (EV6), the world's leading endoscopy company with more than 70% of the market share and an Endoscopic Solutions Division worth over £3 billion (EV7). Sales have grown consistently over the past five years, as shown in the chart. Due to the COVID-19 pandemic, further sales data from Olympus are next due in 2021. The success of the EV trials and subsequent impact have led to several companies bringing research to Newcastle, who now deliver the largest endoscopy trials in the world with over 10,000 patients.



In summary, a large and well-powered RCT led by Newcastle provided the required evidence for NICE to approve, and NHS England to fund, Endocuff Vision nationally. The subsequent uptake in practice has primarily led to patient benefit in terms of a large increase in adenoma detection rate, which leads to earlier detection of CRC and therefore earlier access to treatment. In addition, the increase in sales has led to commercial benefits both in the UK and the US.

5. Sources to corroborate the impact

EV1. NHS England news item April 2018, <https://www.england.nhs.uk/2018/04/heart-patients-among-those-to-benefit-as-nhs-england-backs-innovation/>

EV2. NICE Medical technology consultation document February 2019, <https://www.nice.org.uk/guidance/mtg45/documents/consultation-document> page 7.

EV3. NICE Medical technologies guidance MTG45 June 2018, <https://www.nice.org.uk/guidance/indevelopment/gid-mt509>

EV4. June 2019 Association of British HealthTech Industries (ABHI) UK Market Conference sales data.

EV5. Dataset kindly provided by the Health Innovation Network, available on request.

EV6. Olympus webpage giving details on EV, <https://www.olympus-europa.com/medical/en/Products-and-Solutions/Products/Product/ENDOCUFF-VISION.html>

EV7. Olympus Corporation Integrated Report 2019, https://www.olympus-global.com/ir/data/integratedreport/pdf/integrated_report_2019e_A3.pdf