

Institution: Aston University

Unit of Assessment: 12. Engineering

Title of case study: Endoscope-i – new products, medical diagnostic practices and COVID-safe devices

Period when the underpinning research was undertaken: 2011-2020

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:
Mark Prince	Lecturer	09/2006 – 08/2018
	Senior Lecturer	08/2018 - present

Period when the claimed impact occurred: 2014 - 2020

Is this case study continued from a case study submitted in 2014? No

1. Summary of the impact

This case study claims the use of research-led design techniques, 3D printing and knowledge of ophthalmic instrumentation for the development of low-cost endoscopy tools and associated endoscopy products. This subsequently enabled a change the business model within the NHS and armed forces to allow decentralised clinical examinations and results sharing to confirm whether further consultant referrals are required. In addition, Aston enabled the creation of a novel PPE device for ear, nose & throat (ENT) medicine in response to COVID-19 which has further supported clinical provision and minimised the risk to clinicians when performing ENT screenings.

2. Underpinning research

The Biomedical Engineering Group has wide experience in design innovation for commercial applications over a number of years. This has included funded research for:

- The development of low-cost advanced equipment to enhance the provision of community eyecare and develop UK ophthalmic manufacturing with Birmingham Optical Group Ltd and a project with Lein Applied Diagnostics Ltd **[G1]** which developed expertise in image displays.
- This developed a collaboration with Wolffsohn in Optometry which initiated some internal research using simple displays and later higher specification iPhone displays for optical measurements of the eye and resulted in patented technology **[R1]**. This developed expertise surrounding interfacing with the iPhone camera and display.
- The development and implementation of a product design process and capability to transform ABT Products Ltd from a manufacturer of sub-contract assemblies to provider of complex original equipment **[G2]**
- The development of an advanced design and prototyping capability to enable the company to expand into new value-added areas including the fire safety market with Rotec Engineering Ltd **[G3]**.
- The development of a range of cost-effective endoscopy equipment that would reduce the risks and costs of reprocessing and contribute to significantly improve patient safety, with Partners for Endoscopy Ltd **[G4]**.

These projects built on, and further developed, the rapid prototyping and design experience of those involved in the group and their expertise on rapid prototyping using stereolithography 3D printers (SLAs) **[R1-R3]**.

Building on **[R2]** Coulson (NHS consultant) and **Prince** (Aston) worked together on an informal research project involving rapid prototyping. Subsequently, Coulson connected **Prince** with his clinical colleague Ajith George, who wanted to see if it was possible to directly capture

Impact case study (REF3)



endoscopic images using his smartphone. Mark's experience **[from G2]** in optical design and alignment meant that it was possible for him to create a solution which did not require additional optical elements and also to prototype the device using SLA printing techniques, and then to scale up to a commercial manufacturing process. After seeing significant demand from the medical sector they formed endoscope-i Limited in 2012 **[R4]**. **Prince** continues to contribute his design engineering R&D skills to the company creating new opportunities and extending the product line (https://endoscope-i.com/index.html).

In 2020 the medical world faced momentous challenges around COVID. ENT professionals were particularly vulnerable to contracting coronavirus, and certain previous routine procedures posed a significant risk of viral communication. Nasendoscopy is a procedure by which a flexible endoscope is passed through the patient's nose and into their throat and provides an unobstructed view of the back of the nose, the throat, oesophagus and larynx. This is used to diagnose cancers of the mouth and throat, and other conditions that affect breathing, swallowing and speech, as well as monitoring recovery and rehabilitation of patients that have recovered from cancer treatment or stroke. Prior to COVID-19 approximately 500,000 nasendoscopies were carried out annually in the UK but as a result of a lack of appropriate PPE, this reduced by up to 92%.

Since May 2020 he has been working for endoscope-i on a 0.4FTE secondment to address this issue and developed SNAP (**S**afe **N**asendoscopy **A**ssisted **P**rocedure). SNAP provides a hygienic port in a surgical mask that permits an endoscope to pass into the patients nose and then reseals when the endoscope is removed. This severely reduces the risk of exposure of ENT staff to viral vectors as a result of the patient speaking and coughing before, during and after the procedure, and also prevents contamination of the clinic and reduces the subsequent cleaning times. **[R5,R6]**

3. References to the research

[R1] Apparatus to measure accommodation of the eye, J Wolffsohn, M Prince, J Watkins - US Patent App. 13/822,866, GB patent number 1015282.5, 2013

[R2] Tactile Sensory Digit Feedback for Cochlear Implant Electrode Insertion, Yusuf Bulale, Mark Prince, Geoff Tansley, Peter Brett, 4/11/2015, World Academy of Science, Engineering and Technology, International Journal of Medical, Health, Biomedical, Bioengineering and Pharmaceutical Engineering, Volume 9, Issue, 12, Pages, 857-863 https://doi.org/10.5281/zenodo.1110722

[R3] An acoustic on-chip goniometer for room temperature macromolecular crystallography, CG Burton, D Axford, AMJ Edwards, RJ Gildea et al., Lab on a Chip, 2017, <u>https://doi.org/10.1039/C7LC00812K</u>

[R4] The 'endoscope-i': a mobile solution for endoscopy in otolaryngology, A George, M Prince, C Coulson, Clinical Otolaryngology 38 (1), 104-106, 2013, <u>https://doi.org/10.1111/coa.12062</u>

[R5] Safe nasendoscopy assisted procedure in the post-COVID-19 pandemic era., George, A., Prince, M. and Coulson, C. (2020), Clin Otolaryngol, 45: 844-846, 10.1111/coa.13591, https://doi.org/10.1111/coa.13591

[R6] Safe **N**asendoscopy **A**ssisted **P**rocedure, white paper, 18 August 2020, UK Patent Application No. 2005725.3

[G1] 66251 EPSRC CASE, Development of a 3D non-contact scanner for diagnosis of diseases of the anterior chamber, Prince, M., $1/10/11 \rightarrow 30/09/14$, £66,838, EPSRC CASE / Advanced Medical Optics UK Ltd.

[G2] 68050 The development and implementation of a product design process and capability to transform ABT from manufacturer of sub-contract assemblies to provider of complex original equipment, Thomson, G. & Prince, M., $26/07/11 \rightarrow 25/07/13$, £125,007, KTP / ABT Products Ltd.



[G3] 68042 - The development of an advanced design and prototyping capability to enable the company to expand into new value-added areas including the fire safety market, Prince, M. & Price, B., $21/03/11 \rightarrow 20/03/13$, £120,418, KTP / Rotec Engineering Ltd.

[G4] 60556 - To develop a range of cost effective endoscopy equipment that would reduce the risks and costs of reprocessing and contribute to significantly improve patient safety, Prince, M., McLening, C. & Thomson, G., $1/10/12 \rightarrow 30/10/14$, £126,914, KTP / Partners for Endoscopy Ltd

4. Details of the impact

Impact 1: New products for an SME that serves an international market



Since formation in 2012 endoscope-i have been committed to modernising the way healthcare is provided to ENT patients around the world. The company set out providing the only bespoke engineered solution connecting either rigid or flexible rod lens and fibre endoscopes to Apple iPhones, transforming an analogue into a high-spec digital device.

The endoscope-i is a simple solution combining high quality optics of endoscopes with the superb definition obtained from Apple iPhones. In its simplest form

endoscope-i consists of the e-i Pro app and an adapter specifically designed to securely fit an individual iPhone/iPod (bespoke for each new model).

Endoscope-i sold 3549 attachments (2014-2020) into 100 countries. The product line includes 10 different designs and has been extended to also include a low-cost endoscope, LED light source and Olympus lens adapter – designed by Prince **[S1]**.

This design expertise also enabled endoscope-i to win a [text removed for publication] contract from UCI to develop a motor detector, which in turn allowed them to tighten their rules of mechanical doping. The portable iPad system could be used quickly to scan all bikes without any disassembly required **[S2]**. It was first used in 2016 at the UCI Cyclo-cross World Championships where officials discovered the first proven use of an electric motor hidden in the under-23 world champion's carbon-framed bike. Then UCI President said: "*the case was a "major victory" for officials…*" **[S3]**. The system subsequently enabled 50,000 tests over four years including the 2016 Rio Olympics and all Tour de France stages between 2016 and 2019. **[S1]**

Impact 2: move to remote medical diagnostic delivery

ENT endoscopic tests are normally carried out in hospital centres because of the equipment cost. The endoscope-i product offers a digital endoscopy stack system a fraction of the traditional market price [text removed for publication]. It has enabled clinicians worldwide to have easier and lower cost access to digital imaging and smaller centres e.g. GP surgeries can offer a service that would have been previously unaffordable. The digital images can either be interpreted by the local clinician or relayed to endoscope-I who offer a consultancy service **[S1]**.

Several trials have either been completed or are ongoing to prove the clinical model including:

- 14 GPs in Stafford (2017) showed that this approach could reduce the number of referrals and allow most patients (85 %) to be treated within the GP Practice leading to a resource saving because they are treated within primary care. This approach can save 70% of the cost for an E&T referral. [S4]
- 2. A trial funded (09/2020) by UK Defence, Army Reform and the Joint Medical Group **[S5]** has shown that rapid ear health assessments can be conducted in the theatre of combat using endoscope-i technology such that high quality data can be relayed to ENT surgical consultants anywhere in the world for immediate diagnosis. Over 200 personnel have so



far been reviewed in this trial and a further 1200 expected by 08/21. For context, the cost of sending troops back to the UK for assessment and standing them down from active duty while awaiting assessment is about [text removed for publication]. **[S1]**

3. A Stoke trial has shown it is possible for head and neck cancer diagnosis and treatment to continue in light of COVID-19. The endoscope-i telescopic referral system forms the heart of a collaborative research project between endoscope-i and University Hospitals North Midlands (UHNM) wherein patients are imaged in a clinic with the smartphone enabled portable endoscopy system designed by **Prince**, and then the data is transmitted to specialist consultants for electronic review. This is already saving resources, improving records management, and through the use of standard letters it is providing a more consistent, auditable and higher quality of patient communication is assured. The project is now in its 2nd month and approximately 100 patient cases have been reviewed. **[S6]**

Impact 3 - the development and sale of a novel COVID-19 PPE product for healthcare



During the COVID-19 crisis, **Prince's** skills and knowledge of endoscopic procedures, and his access to the high-quality prototyping facilities at Aston allowed endoscope-i to develop the only PPE device that makes it possible for nasendoscopy procedures to be conducted safely. This procedure is vital for the diagnosis of serious throat cancers and the rehabilitation of stroke patients, and the SNAP PPE solution allows high-COVID-risk procedures such as this to be conducted in clinics whilst the patient is wearing a surgical mask and thereby substantially reducing the risk of viral communication, ultimately safeguarding both patients and staff **[S1,R5]**.

Protected by a UK patent application **[R6]**, the product was developed through crowd-funding and £75,000 governmental funding from Innovate UK. This product has now been sold through a medical distributor, DTR Medical Ltd, who are taking the product through FDA regulation for supply to clinics across the USA. To date, 5000 units have been supplied free of charge to the NHS and sales worldwide are commencing with interest in 14 countries. The device has garnered national and international press attention [e.g. BBC Midlands Today & BBC News **[S7**, **S8]** and industry recognition through winning the "MediWales Partnership with the NHS" award 2020. **[S1,S9]**

5. Sources to corroborate the impact

S1 Letter from endoscope-I, CEO, 01/2021

S2 Letter from past CTO of the Union Cycliste Internationale (UCI)), 10/2019

S3 <u>https://www.wired.co.uk/article/mechanical-doping-cycling-femke-van-den-driessche-ban</u>, Wired UK, 04/2016

S4 Cottrell, E, George, A, Coulson, C, Chambers, R. Telescopic otology referrals: Evaluation of feasibility and acceptability. Laryngoscope Investigative Otolaryngology. 2020; 5: 221–227. <u>https://doi.org/10.1002/lio2.367</u>

S5 ISRCTN register

S6 Letter from Royal Stoke University Hospital, 01/2020

S7 <u>https://twitter.com/endoscope_i/status/1350363658551963648</u>, BBC Midlands Today, 09/2020

S8 <u>https://www.bbc.co.uk/news/uk-england-54167674</u>, BBC News 09/2020

S9 <u>https://www.youtube.com/playlist?list=PLFz91WHnjCKRGwp0_flnEcfqJZuAv7_t</u>, MediWales Innovation Awards