Institution: University of Dundee
Unit of Assessment: UoA15 – General Engineering
Title of case study: Minimal access surgery transforming general surgery

1. Summary of the impact

This case study describes a complete translational pipeline of technology research for minimal access surgery (MAS) from conceptual research, through ergonomics, training, clinical trials and on to clinical adoption.

NHS: implementation in all general surgery departments in the UK: approximately 15,000 operations/year in Scotland, with significant evidence for improved clinical outcomes.

Government policy: embedded in health policy as highlighted in the HMSO publication on laparoscopic cholecystectomy and NICE guidelines.

Commercialistion: establishment of Karl Storz Dundee facility, providing 219 UK employees and investment of £5.5million by Karl Storz GmbH.

Internationalisation: e.g. 82% of cholecystectomies in Denmark from 2006-2009 and form part of European Surgical Guidelines.

2. Underpinning research

Prior to the 1990s surgical procedures were necessarily "open" procedures with very few operations being performed as outpatient procedures. Hence procedures such as cholecystectomy incurred significant risk of adverse clinical outcomes, poor patient experience and significant cost. As a result of the revolution in Minimal Access Surgery, commonly known as keyhole surgery, in which Dundee has played a significant and seminal developmental role, many procedures are now carried out with significantly improved clinical and cost implications with completely improved patient experience.

The underpinning research and development work (EPSRC funded) [8,9] was carried out at the University of Dundee and led by Professor Sir Alfred Cuschieri and his surgical technology group who are internationally recognised as pioneers in the research of laparoscopic surgery, exemplified by Prof Cuschieri being awarded the first ever Achievement award by the Society of American Gastrointestinal and Endoscopic Surgeons [11]. The research tested the hypothesis that open surgical procedures could be replaced by significantly less invasive surgical techniques [4,5] based upon novel laparoscopic instrumentation [1,2] in partnership with the requisite ergonomics [3] and training studies [6].

From an academic perspective, Dundee built on the platform of 58 technology publications in which the laparoscopic tools were developed by implementing the necessary translation of the new surgical technologies through 19 different ergonomics studies, 15 training studies and over 75 clinical studies. This research to impact pipeline was made possible through partnership with industry (Karl Storz) and the adoption and support of these new procedures and techniques by both surgeons and government.

Only through the adoption of an approach which ranges from the initial engineering studies, through the training and ergonomics studies and on to clinical trials have procedures come through to adoption both nationally and internationally.

An example of the type of instrument developed in Dundee is shown in the figure below – a part of the Karl Storz product range, the DUNDEE ENDOCONE, used to allow minimal access instruments to be inserted into the abdominal wall and to allow easy triangulation of the instruments within the patient.

The core engineering of this work is outlined in the publications and patents [10,11] that have resulted from the research, which span a range of instruments from simple (as well as very complex) device handles through to sophisticated pieces for retracting tissues and organs in keyhole work [1]. Only through the development of these tools in partnership with industry and end users whilst in combination with ergonomic and clinical studies, can new procedures such as single incision surgery, for which the Dundee Endocone was developed, become safe and effective [REFb].

[image removed for publication]

Figure 1: The DUNDEE ENDOCONE used in MAS procedures, taken from the Karl Storz brochure on their ENDOCONE Single Port Surgical Access System.
The devices themselves have been tested within a range of surgical trials that have served to both demonstrate the validity of the research and the surgical techniques themselves (e.g. [8,9]).

3. References to the research

The research underpinning this case study can be represented by the following list of key references, including peer reviewed publications on: a) the technology which makes the procedures possible, b) ergonomics studies of how such technology needs to be used, c) clinical trials of procedures and d) studies on training of surgeons to carry out those procedures. Substantial research grants, patents and clinical/training studies are also listed.
Three key references which are indicative of the high quality of the underpinning research for this case study are denoted with an asterisk.

Peer reviewed references:

a) Technology studies

1. Cuschieri A, Shimi S, Banting S, Van Velpen G, Dunkley P. Coaxial curved instrumentation for minimal access surgery. Endosc Surg Allied Technol. 1993 Oct-Dec;1(5-6):303-5. PubMed PMID: 8081901.
2. Alijani A, Cuschieri A. Abdominal wall lift systems in laparoscopic surgery: gasless and low-pressure systems. Semin Laparosc Surg. 2001 Mar;8(1):53-62. PubMed PMID: 11337737. DOI: 10.1177/155335060100800106

b) Ergonomics studies

3. Hanna GB, Shimi S, Cuschieri A. Optimal port locations for endoscopic intracorporeal knotting. Surg Endosc. 1997 Apr;11(4):397-401. PubMed PMID: 9094288. DOI:10.1007/s004649900374

c) Clinical Studies

4. Cuschieri A, Lezoche E, Morino M, Croce E, Lacy A, Toouli J, Faggioni A, Ribeiro VM, Jakimowicz J, Visa J, Hanna GB. E.A.E.S. multicenter prospective randomized trial comparing two-stage vs single-stage management of patients with gallstone disease and ductal calculi. Surg Endosc. 1999 Oct;13(10):952-7. PubMed PMID: 10526025) DOI:10.1007/s004649901145
5. Alijani A, Hanna GB, Cuschieri A. Abdominal wall lift versus positive-pressure capnoperitoneum for laparoscopic cholecystectomy: randomized controlled trial. Ann Surg. 2004 Mar;239(3):388-94. PubMed PMID: 15075657; PubMed Central PMCID: PMC1356238. DOI: 10.1097/01.sla.0000114226.31773.e3

d) Training Studies:

6. Talebpour M, Alijani A, Hanna GB, Moosa Z, Tang B, Cuschieri A. Proficiency-gain curve for an advanced laparoscopic procedure defined by observation clinical human reliability assessment (OCHRA). Surg Endosc. 2009 Apr;23(4):869-75. Epub 2008 Sep 23. PubMed PMID: 18810544. DOI: 10.1007/s00464-008-0088-5

Policy documents:

7. Minimal access surgery: Implications for the NHS. Edinburgh: HMSO 1993

Research grants:

8. Cuschieri, Professor Sir A, Lawrenson, Mr B, Hewit, Professor J, (1999-2002). £243,550 PALPATION TOOL FOR MINIMAL ACCESS SURGERY (PATOMAS), EPSRC - GR/M60651/01

9. Sir Alfred Cuschieri (1994 -1997) £150,000 Development of Remote Handling Technology and 3-D Endoscopic Imaging for Laparoscopic Surgery. Wellcome Trust

Patents:

10. A Cuschieri, T Frank. VuMedical handling device in particular for endoscopic applications. US Patent 5,908,436 (1999)
11. A Cuschieri, TG Frank. Retractor for use in endoscopic surgery and medical instrument for introducing a retractor and method for the use of a retractor in endoscopic surgery. US Patent 6,705,989 (2004)

Awards:

12. www.sages.org/about/awards/berci/

4. Details of the impact

Clinical Trials

The development of the techniques in the Dundee group gave rise to a number of clinical studies, including one of the first (2009) to consider laparoscopic surgery for colon cancer – made possible by the engineering developments outlined here [REFa]. The outcome of the trial showed that laparoscopic techniques had similar survival rates to open surgery, but with the advantages of keyhole techniques (less postoperative pain, shorter hospital stay, quicker recovery and return to work, fewer wound complications and better cosmetic results).

Governmental and Professional Policy Impact

Procedures such as laparoscopic cholecystectomy, which are now part of government guidelines (issued 2010) [REFb], were pioneered through the instrument development, ergonomic studies, training and clinical trials led by Dundee. International Societies such as SAGES also have published guidelines on procedures, many of which have their roots in the original research done in Dundee [REFc,d]. Other examples of guidelines based in part on the work carried out in Dundee are those generated by the European Association for Endoscopic Surgery, e.g. [REFe].

Strategic Research/Training Impact

The official NICE guidance [REFb] on Laparoscopic cholesystectomy states that it "is technically challenging and should only be carried out by experienced laparoscopic surgeons who have received specific training in the procedure". This is something that was recognised early in the research done in MAS in Dundee such that the Cuschieri Skills Centre was opened in 1992 to train surgeons in safe and effective use of minimal success surgery techniques – the work carried out subsequent to the opening of the centre has been especially influenced by the research outlined above – which has produced new techniques and improved upon existing ones. The centre has, since 2008 (to the end of 2012), trained 2243 surgeons [REFf] in these techniques, from all over the world. An indicative example of this impact is that from 2008-2012, approx. 49% of Scottish [REFf] and approx. 4% of non Scottish UK based surgeons received training at the centre [REFg]. The research done in MAS in Dundee continues to influence best practice in the research and development of innovation in surgical endoscopy (2010) [REFh].

Commercial impact and creation of new businesses

The work outlined above in the development of tools and techniques for MAS led to a close research and commercial relationship between the endoscopy company Karl Storz and the Cuschieri group at the University of Dundee. This has resulted in a range of impacts:

- The research has had a significant commercial impact through the development of the devices resulting in more than 30 patents being licensed and acquired by Karl Storz, one of the major endoscopy companies. Over 700 different medical devices for minimal invasive surgey sold by Karl Storz are based on the research work, with nearly 80 sets of instruments containing these devices introduced to the market since 2008. More than 5000 instruments have been sold since 2008 with a net value of €1.8M. [REFg]
- Additionally Karl Storz has a production facility at Dundee, which was initiated by Prof. Cuschieri on the back of the research work carried out in MAS techniques. The company currently employs 219 people throughout the UK, and this has increased by 42% since 2008. The company has invested £5.5M in the company since then. [REFg]
- Karl Storz also has a commercial deal with the University of Dundee to license any of the resulting patents from the Cushieri work. Since 2009 this has totalled £2.7M. [REFi]

Internationalisation: there is significant global penetration of procedures based upon Dundee MAS research; e.g. “Laparoscopic cholecystectomy has become the standard of care for patients

requiring the removal of the gallbladder" [quoted from REFc] (now >90% of procedures), morbid obesity (>90%) and colo-rectal cancer (approx. 40%). Procedures originally developed in Dundee, such as laparoscopic cholecystectomy are now internationally adopted (e.g. 82% of cholecystectomies in Denmark from 2006-2009 [REFj]), and form part of European Surgical Guidelines [REFe].

5. Sources to corroborate the impact (indicative maximum of 10 references)

[REFa] *Evidence of impact through improved clinical outcomes:*
Survival after laparoscopic surgery versus open surgery for colon cancer: long-term outcome of a randomised clinical trial. Lancet Oncol. 2009 Jan;10(1):44-52. DOI: 10.1016/S1470-2045(08)70310-3. Epub 2008 Dec 13. PubMed PMID: 19071061.

[REFb] *Cited national guideline:* http://www.nice.org.uk/nicemedia/live/12237/48780/48780.pdf

[REFc] *Evidence of adoption in international guidelines:*
Society of American Gastrointestinal and Endoscopic Surgeons (SAGES). SAGES guidelines for the clinical application of laparoscopic biliary tract surgery. Los Angeles (CA): Society of American Gastrointestinal and Endoscopic Surgeons (SAGES); 2010 Feb. www.sages.org/publications/guidelines/guidelines-for-surgical-treatment-of-gastroesophageal-reflux-disease-gerd/?format=pdf

[REFd] *Evidence of adoption in international guidelines:*
Society of American Gastrointestinal and Endoscopic Surgeons (SAGES). SAGES guidelines for the clinical application of laparoscopic biliary tract surgery. Los Angeles (CA): Society of American Gastrointestinal and Endoscopic Surgeons (SAGES); 2010 Jan. www.sages.org/publications/guidelines/guidelines-for-the-clinical-application-of-laparoscopic-biliary-tract-surgery/?format=pdf

[REFe] *Evidence of international adoption:*
Laparoscopic approach to acute abdomen from the Consensus Development Conference of the Societa` Italiana di Chirurgia Endoscopica e nuove tecnologie (SICE), Associazione Chirurghi Ospedalieri Italiani (ACOI), Societa`Italiana di Chirurgia (SIC),Societa` Italiana di Chirurgia d'Urgenza e del Trauma (SICUT), Societa` Italiana di Chirurgia nell'Ospedalita` Privata (SICOP),and the European Association for Endoscopic Surgery (EAES). Surgical Endoscopy (2011) DOI: 10.1007/s00464-012-2331-3

[REFf] Corroboration *for numbers trained in Dundee available from:*
Data supplied by Cuschieri Skills Centre for number of training course participants 2008-2012, Cuschieri Skills Centre; data about *numbers of total number surgeons in Scotland, Calculations Associate Dean (Research), School of Engineering, Physics & Mathematics, University of Dundee:*
Data on number of surgeons in Scotland from NHS Scotland and from Royal College of Surgeons indicating total number of current surgeons in England and Wales based on total number of surgeons: https://isdscotland.scot.nhs.uk/Health-Topics/Workforce/Publications/2013-05-28/2013-05-28-Workforce-Report.pdf ; http://www.rcseng.ac.uk/media/media-background-briefings-and-statistics/surgery-and-the-nhs-in-numbers:

[REFg] *Evidence of commercial impact:*
Factual Statement: Storz: Outlining income from and relationship with MAS group in Dundee.

[REFh] *Corroboration of need for best practice in surgical innovation:*
European Association for Endoscopic Surgery (EAES). EAES recommendations on methodology of innovation management in endoscopic surgery. PubMed PMID: 20054575 DOI: 10.1007/s00464-009-0818-3

[REFi] *Corroboration of license deal/IP agreement with Storz available from:*
Business Development Manager, Research Innovation Services, University of Dundee:

[REFj] *Evidence of internationalisation:* Moll Harboe, K & Bardram, L. The quality of cholecystectomy in Denmark: outcome and risk factors for 20,307 patients from the national database, Surgical Endoscopy May 2011, Volume 25, Issue 5, pp 1630-1641. DOI:10.1007/s00464-010-1453-8