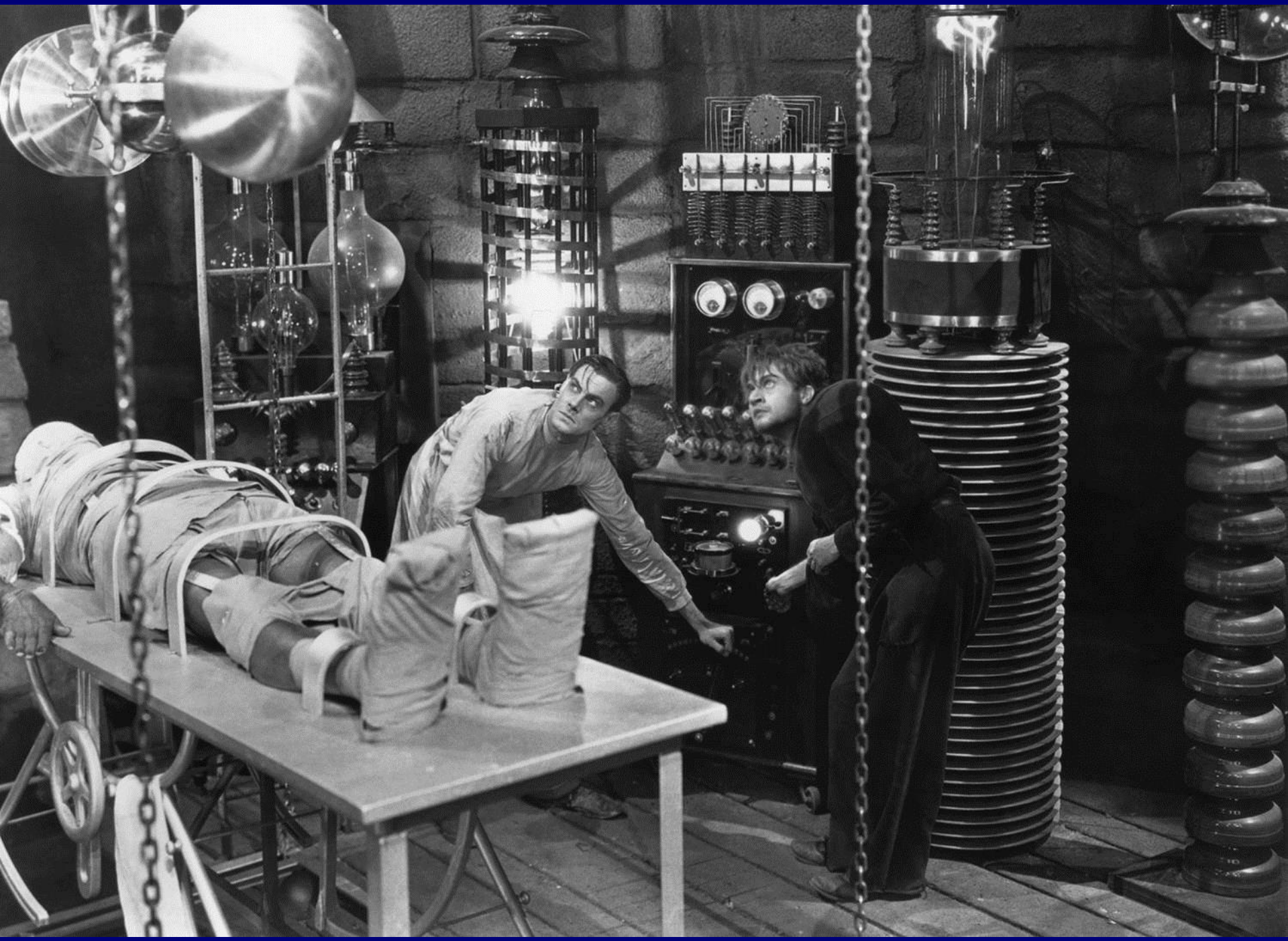
HTA and Surgery: the Australian Experience

Guy Maddern

RP Jepson Professor of Surgery,
University of Adelaide
Surgical Director,
Research and Evaluation RACS
Past Chair, INAHTA
Past President, HTAi



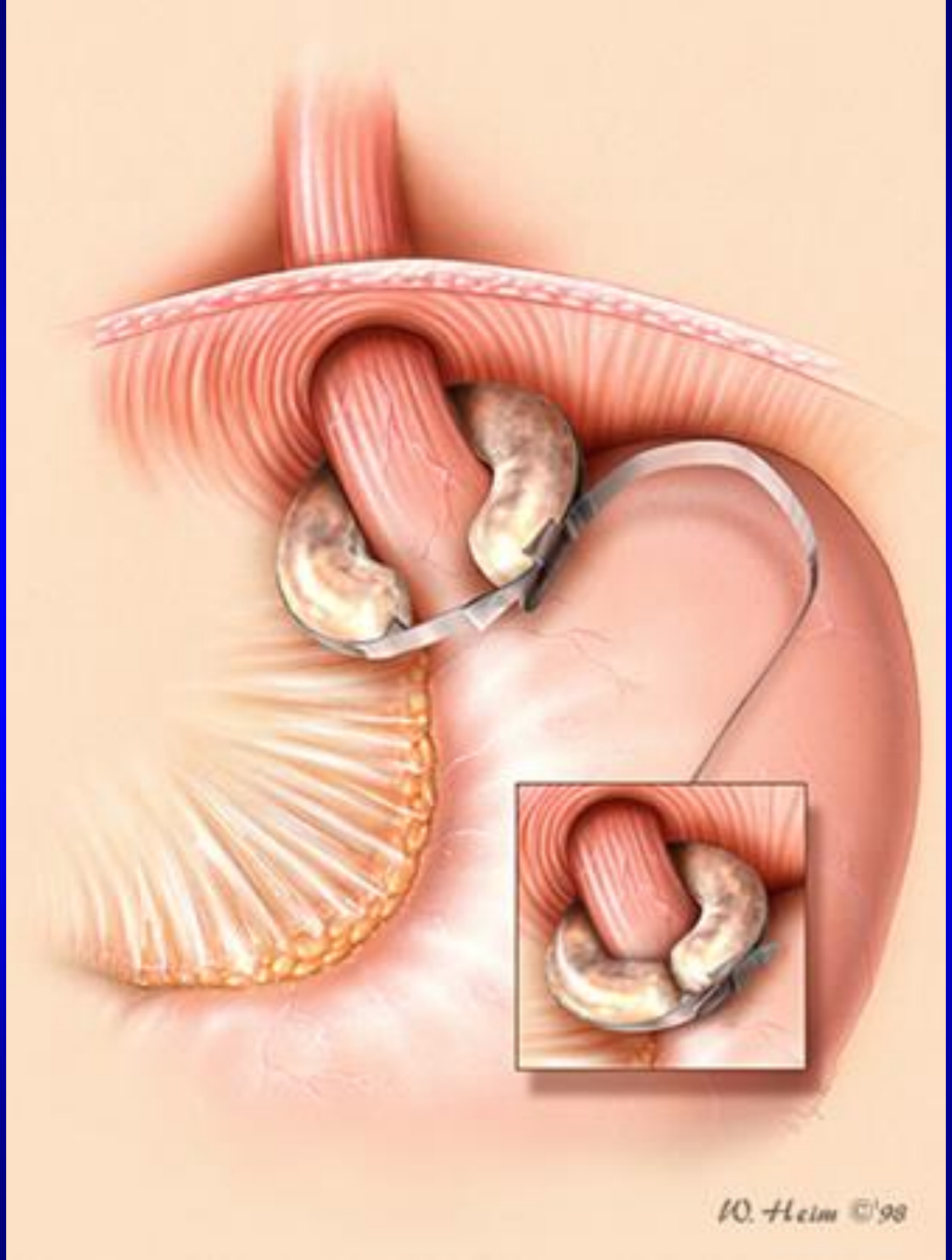
“ Medicine used to be simple, ineffective and relatively safe.

Now it is complex, effective and potentially dangerous”

Chantler, Lancet 1999:353:1178-81

“97% of items on the MBS have never undergone consideration to determine whether or not they are actually clinically-effective, cost-efficient or safe.”

It’s time to fix our healthcare system for doctors and patients.
29 Sept 2015.
ABC news.

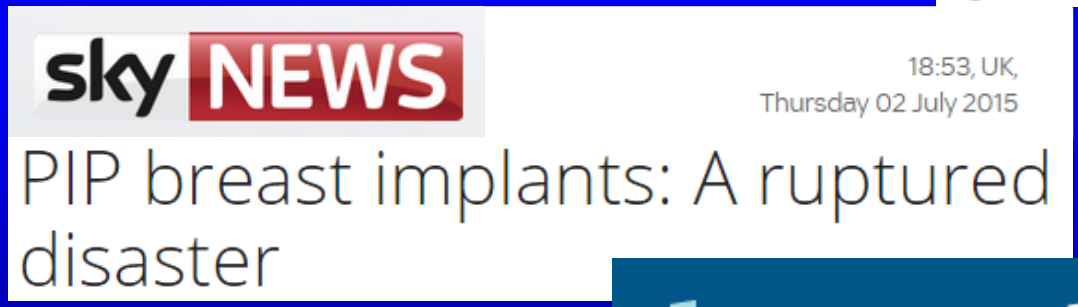

M. Heim ©'98


Belfast Telegraph
Victims of PIP breast implants scandal now in line for payout after ruling by a French court
By Victoria O'Hara
PUBLISHED
01/11/2014
SHARE


theguardian
Friday 16 March 2012
04.55 AEDT
PIP breast implant scandal may involve 7,000 more British women

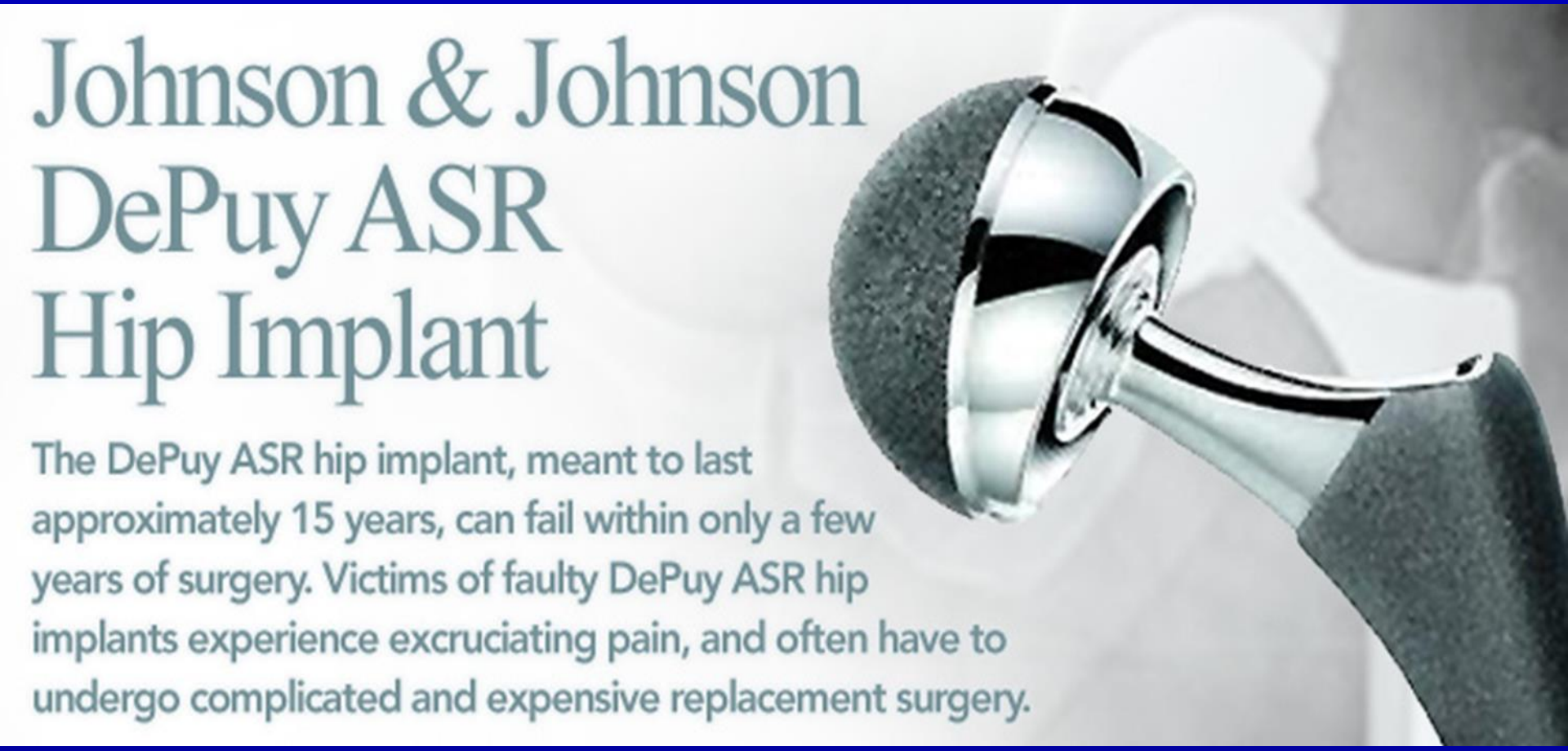

theguardian
Tuesday 10 December
2013 21.37 AEDT
French breast implant firm PIP's founder jailed


BBC
NEWS
PIP breast implant scandal: Compensation ruling upheld
21 January 2014
Europe


sky NEWS
18:53, UK,
Thursday 02 July 2015
PIP breast implants: A ruptured disaster


theguardian
Thursday 3 October 2013
00.09 AEST
French watchdog 'did not act fast enough on faulty PIP breast implants'

ASR Joint


Johnson & Johnson
DePuy ASR
Hip Implant
The DePuy ASR hip implant, meant to last approximately 15 years, can fail within only a few years of surgery. Victims of faulty DePuy ASR hip implants experience excruciating pain, and often have to undergo complicated and expensive replacement surgery.

Johnson & Johnson 'failed to take action' on defective hip implants

Four Corners By Quentin McDermott: exclusive

Updated 26 May 2014, 1:54pm

National Breaking News

The Advertiser

Class action starts against hip implants

March 2, 2015 5:33pm

AAP

The Sydney Morning Herald

National

Hip replacement patients fight DePuy and Johnson & Johnson in medical class action

March 3, 2015

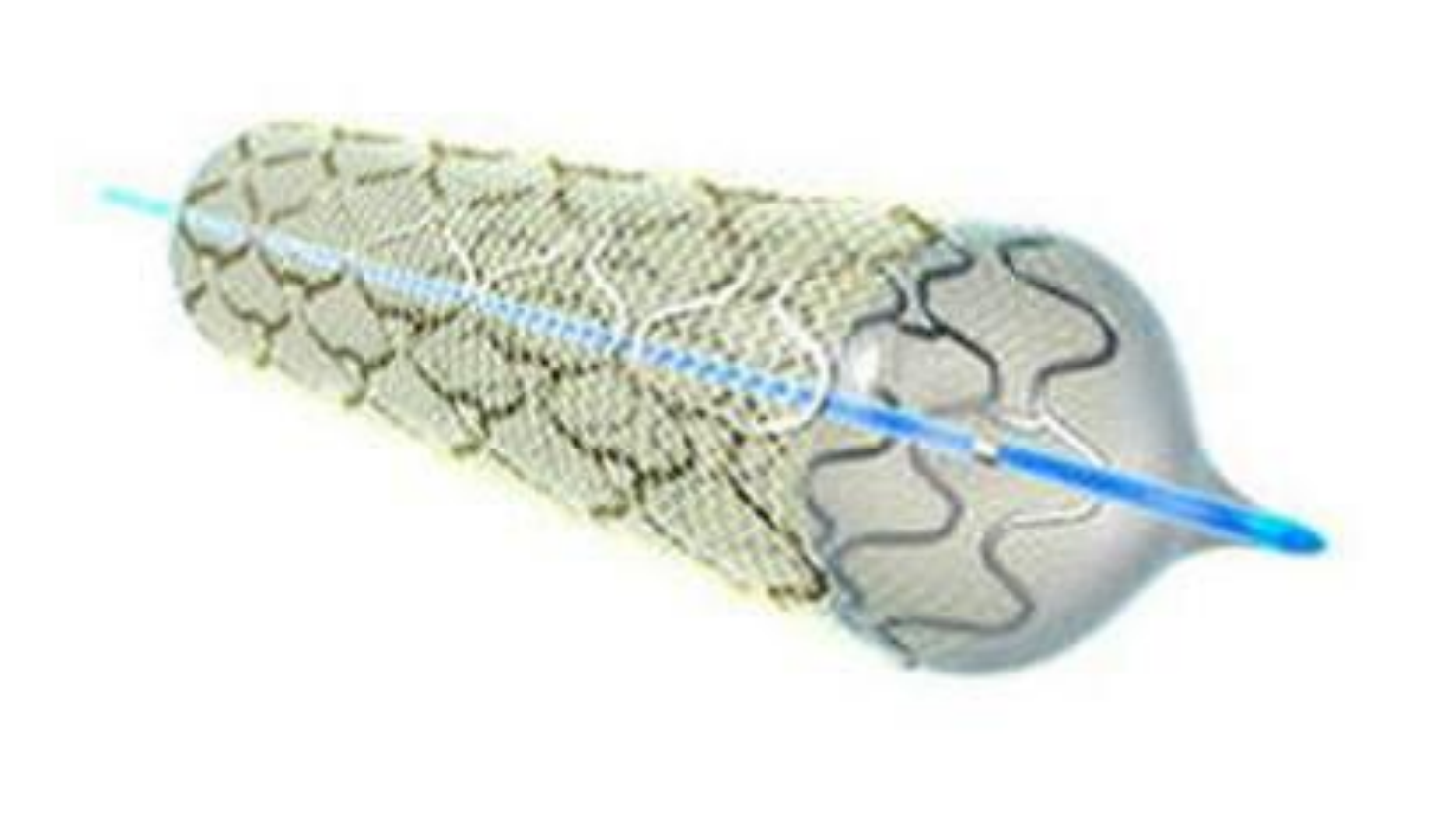
Class action over defective DePuy ASR hip replacements settles for $250 million

By Michelle Brown

Posted 31 Mar 2016, 1:39pm


The EndoBarrier™ System
Metabolic Control for the Treatment
of Type 2 Diabetes and Obesity

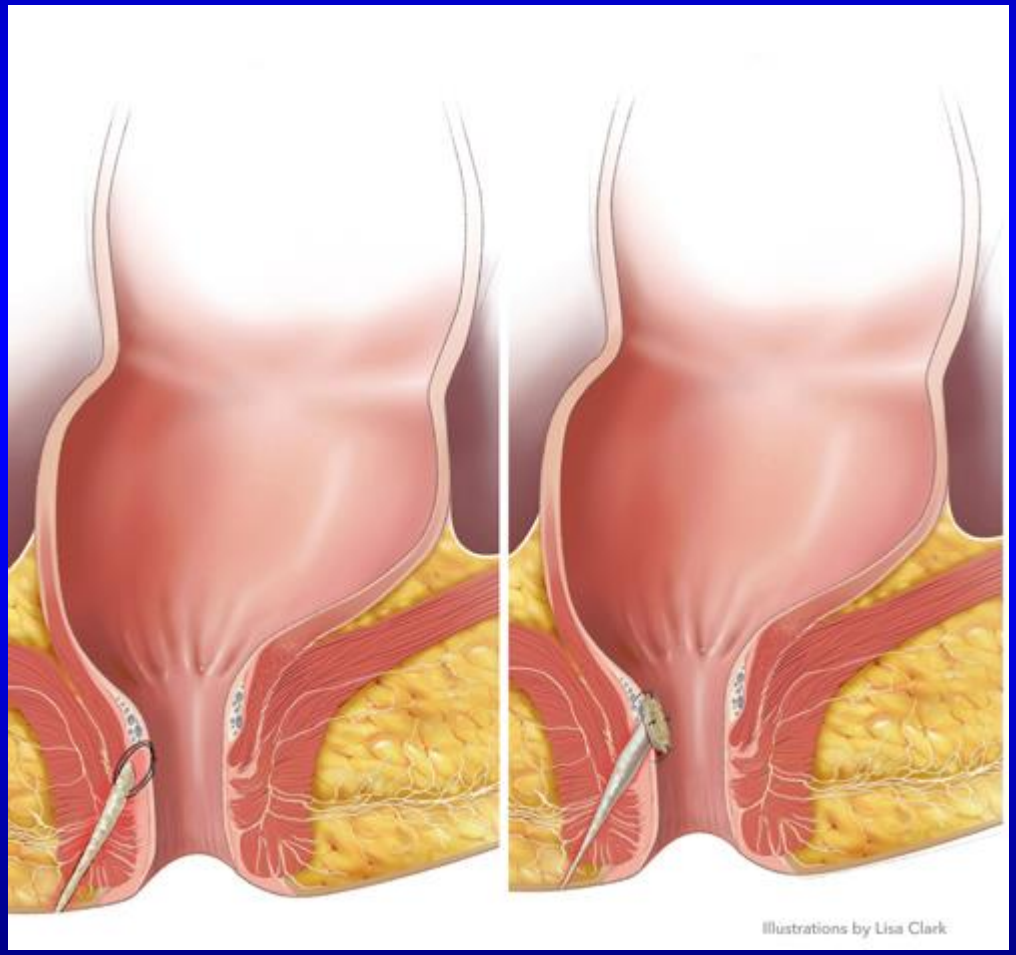
MGuard Stent



MarginProbe System

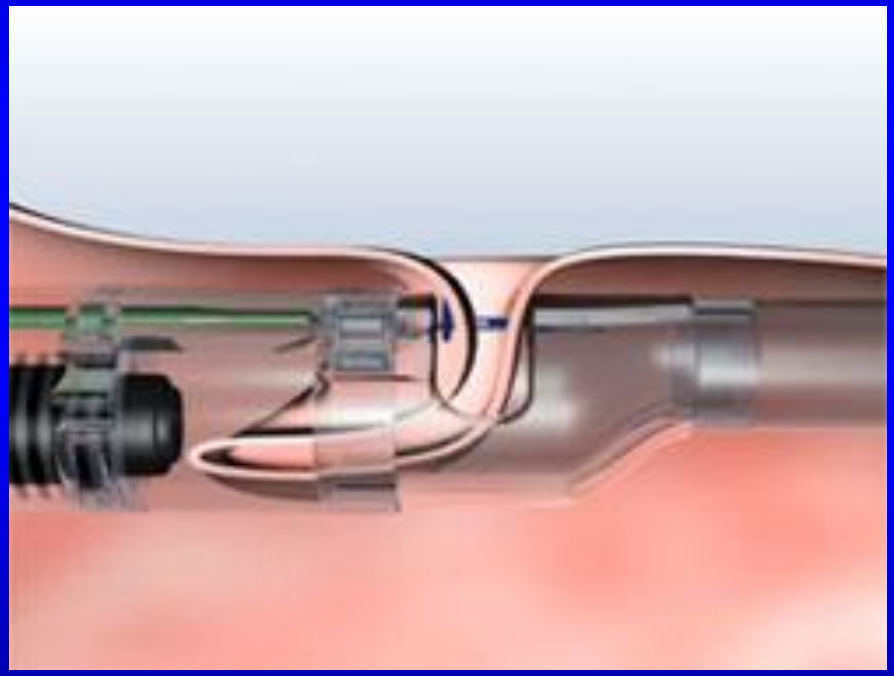
Total Artificial Heart

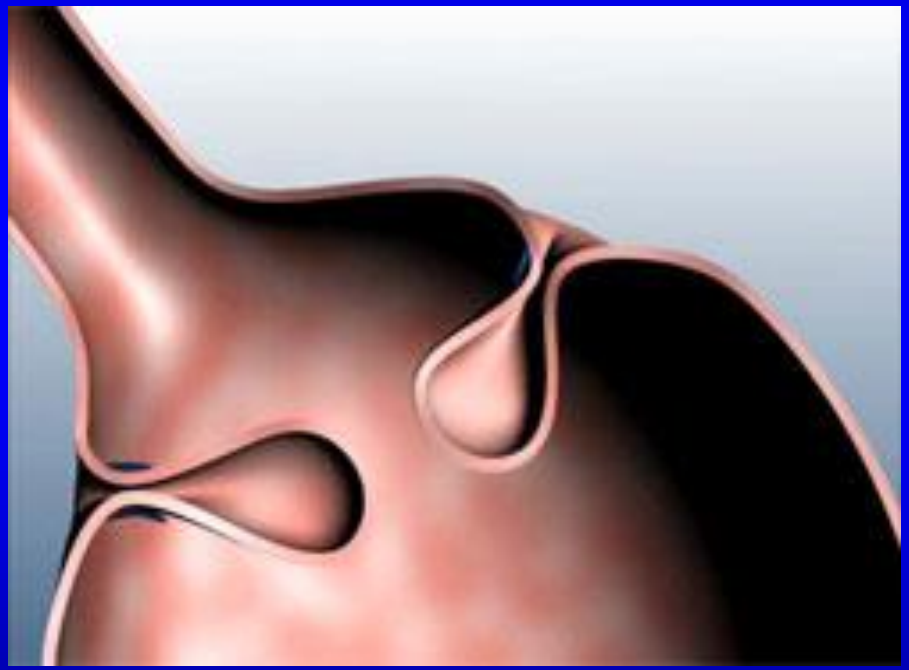
Anal Fistula Plugs



Circumferential, Endoscopic, Radiofrequency Ablation of Barrett's Oesophagus

StomaphyX





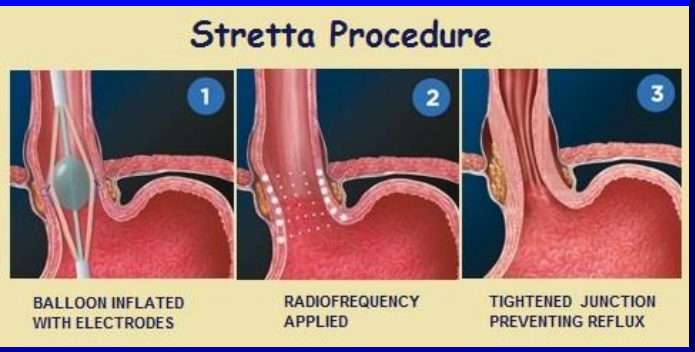
Systematic review

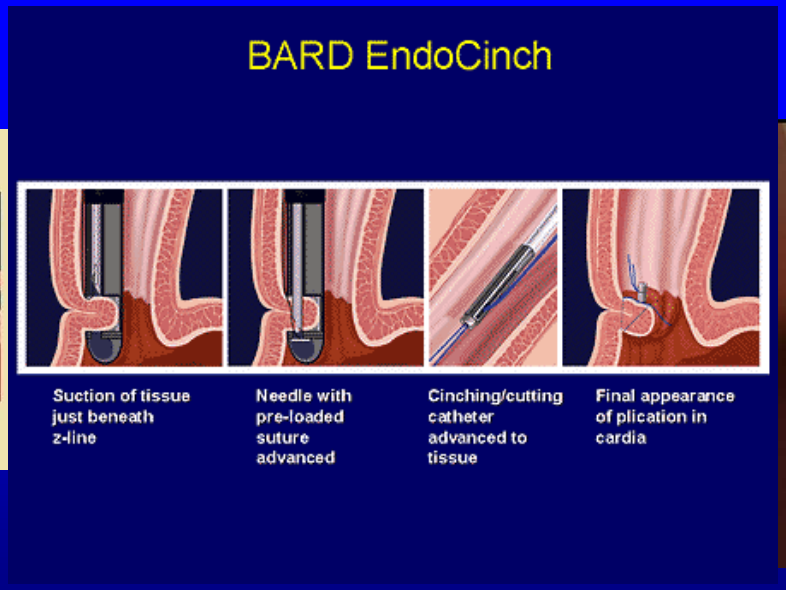
Systematic review of endoscopic treatments for gastro-oesophageal reflux disease

D. Chen[1], C. Barber[2], P. McLoughlin[2], P. Thavaneswaran[2], G. G. Jamieson[3] and G. J. Maddern[1,2]

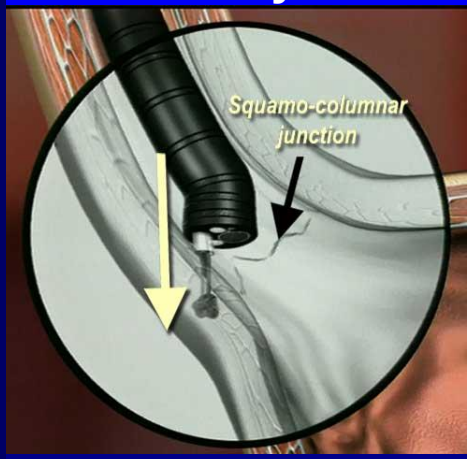
[1]Department of Surgery, University of Adelaide and The Queen Elizabeth Hospital, [2]Australian Safety and Efficacy Register of New Interventional Procedures – Surgical, Royal Australasian College of Surgeons, and [3]Department of Surgery, Royal Adelaide Hospital, Adelaide, South Australia, Australia

Correspondence to: Professor G. J. Maddern, ASERNIP-S, PO Box 553, Stepney SA 5069, Australia (e-mail: guy.maddern@adelaide.edu.au)





Enteryx®



Australia


Arafura Sea
Timor Sea
Darwin
Coral Sea
Pacific Ocean
Northern Territory
Queensland
Western Australia
South Australia
Indian Ocean
Brisbane
New South Wales
Perth
Sydney
Adelaide
Canberra
Victoria
Melbourne
Australian Capital Territory
Tasman Sea
Southern Ocean
Hobart
Tasmania

TGA Health Safety Regulation

Australia 2017

- MDEC (Medical Device Evaluation Committee)
- MDIRC (Medical Device Incident Reporting Committee)
- MSAC (Medical Service Advisory Committee)
- ASERNIP-S (Australian Safety and Efficacy Registrar of New Interventional Procedures – Surgical)

Issues

- Poor long term data
- Poor study design
- Cost/benefit difficult
- Crowded market

Health Technology

Main Driver of Health and Hospital Costs

Health costs are rising (AIHW)

- $50.3 billion to $154.6 billion

  (89/90 - 13/14) (adjusted for inflation).
- 6.5% to 9.7% of GDP (89/90 - 13/14).

Health care economists estimate that…

- **40–50%** of annual cost increases attributed to **new technologies** or the intensified use of old ones.

Australia Institute of Welfare and Health (AIWH) 2014 Australia's Health 2014
The Hastings Center, New York

Health Technology Assessment (HTA)

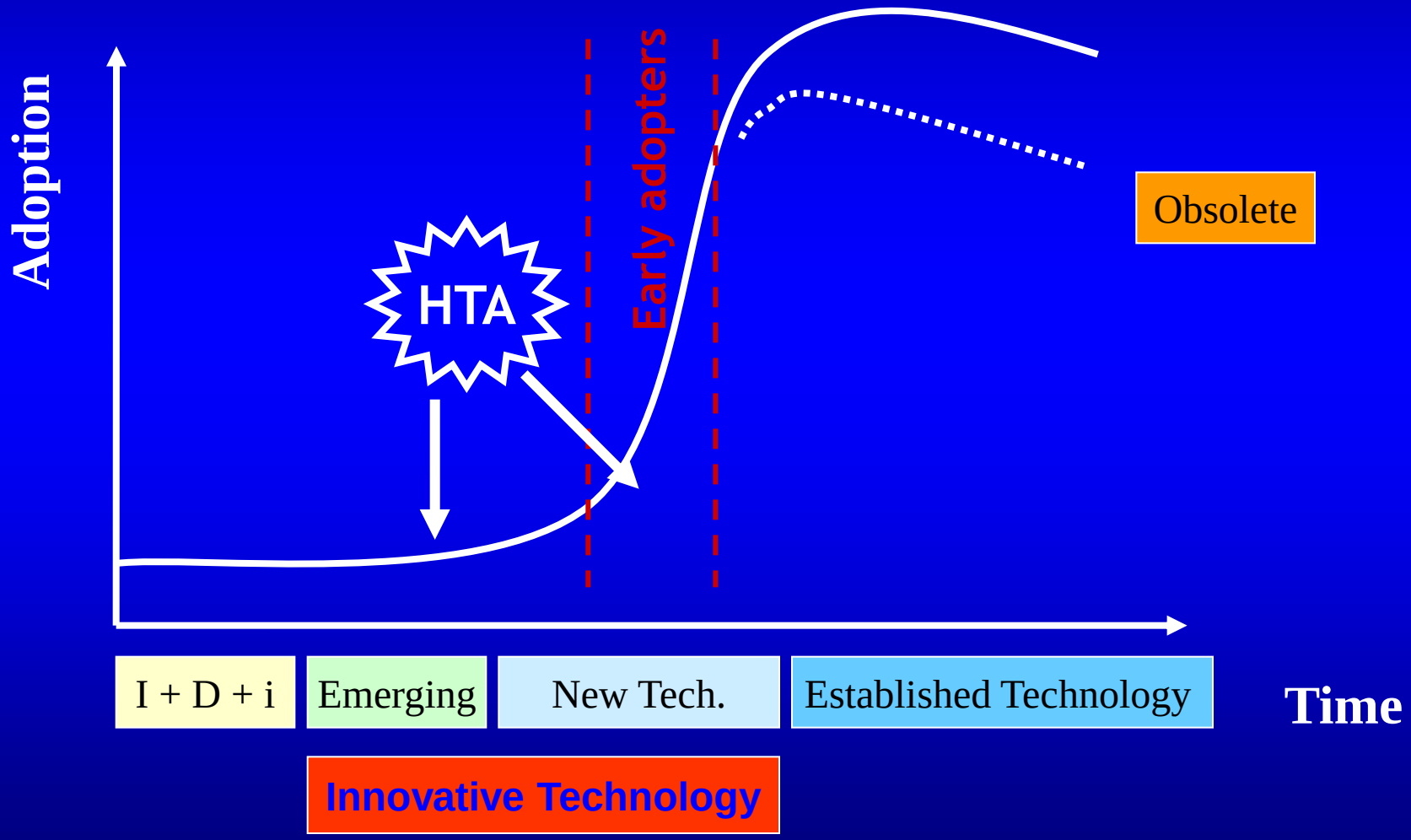
A multi-disciplinary field of policy analysis that examines the medical, economic, social and ethical implications of the incremental value, diffusion and use of a medical technology in health care.

Health Technology

Any intervention that may be used to promote health, to prevent, diagnose or treat disease or for rehabilitation or long-term care. This includes pharmaceuticals, devices, procedures and organizational systems used in health care.

International Network of Agencies for Health Technology Assessment (INAHTA)

Health Technology Life Cycle



Ironic victims of their own medical advances

Claims generally take the form of allegations involving:

a. The adoption of new technology before adequate testing or when contraindicated
b. Failure to use new technology when it was available
c. Failure to undertake or use new technology competently

Ongoing Risks

Tele-Health

- Issues surrounding informed consent obtained via tele-consultation (how information is provided to patients and consent is documented)
- Patient confidentiality and privacy can be compromised during video consultations
- Diagnostic errors

Robotic Surgery

Electronic Medical Records

National

Thirteen clinicians caught spying on medical records of Phil Walsh's son Cy Walsh

February 24, 2016 3:45pm

Daniel Wills, Brad Crouch The Advertiser

SA News

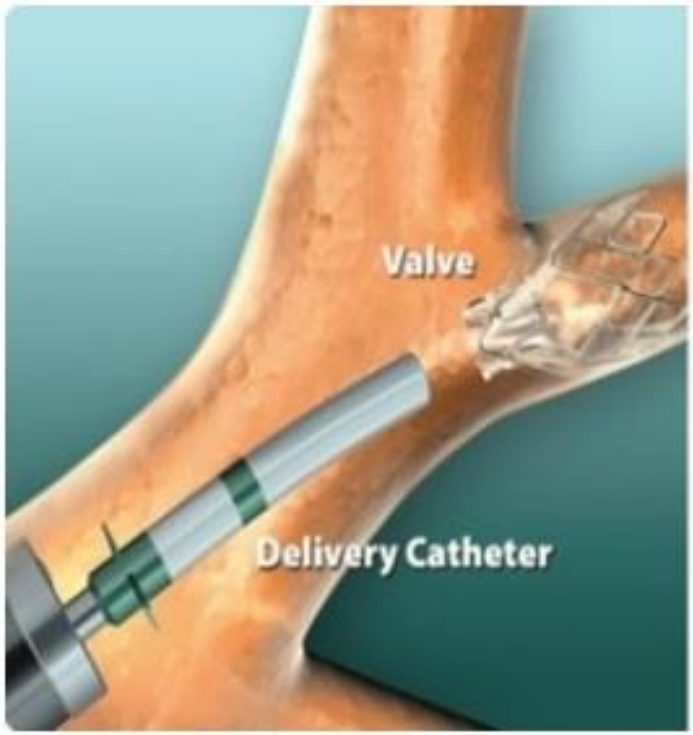
SA Health staff sacked, disciplined as 21 caught spying on patient records

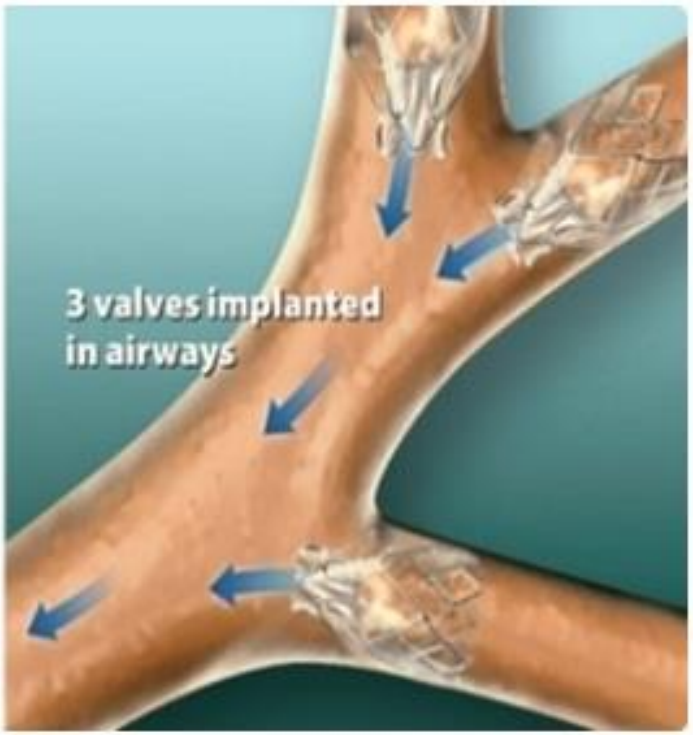
February 25, 2016 12:14pm

Brad Crouch, Daniel Wills The Advertiser

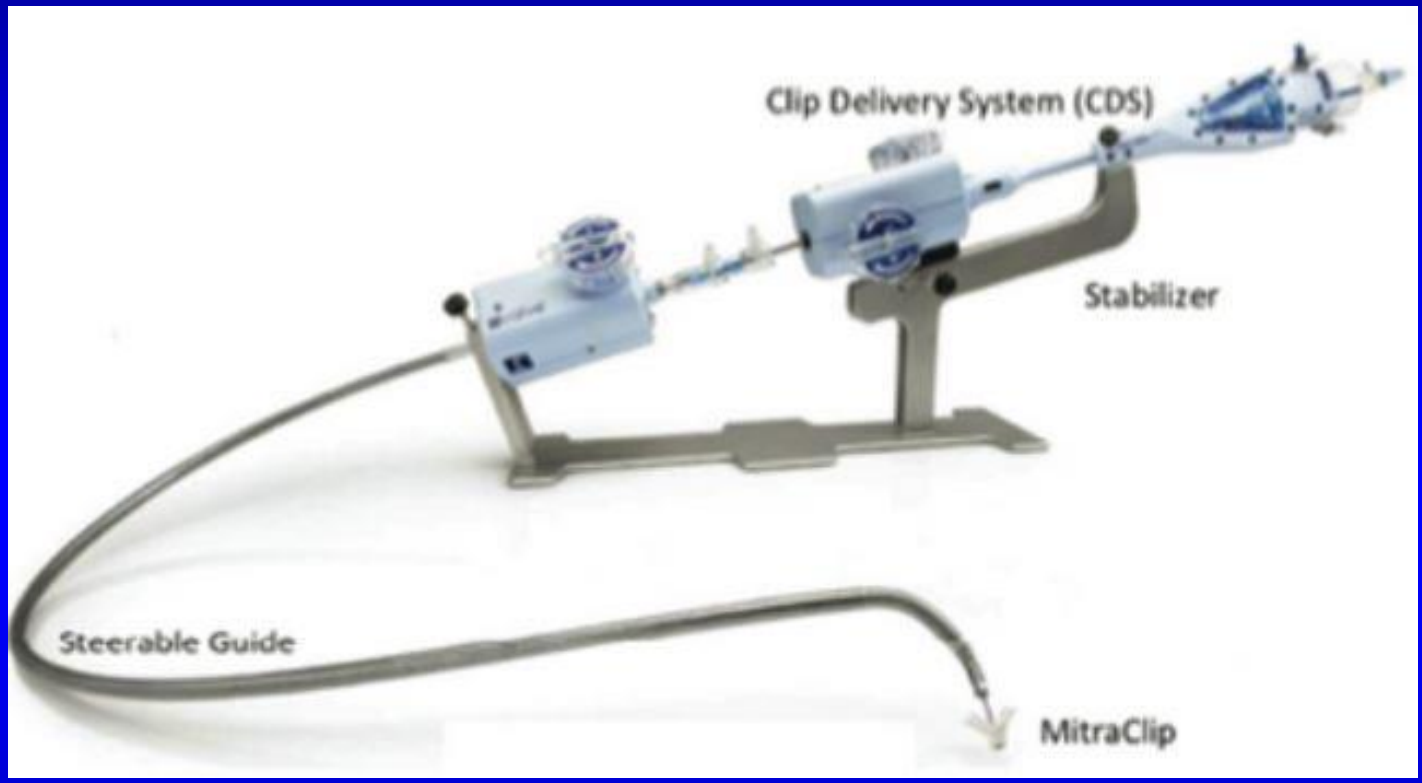
Endobronchial Valves

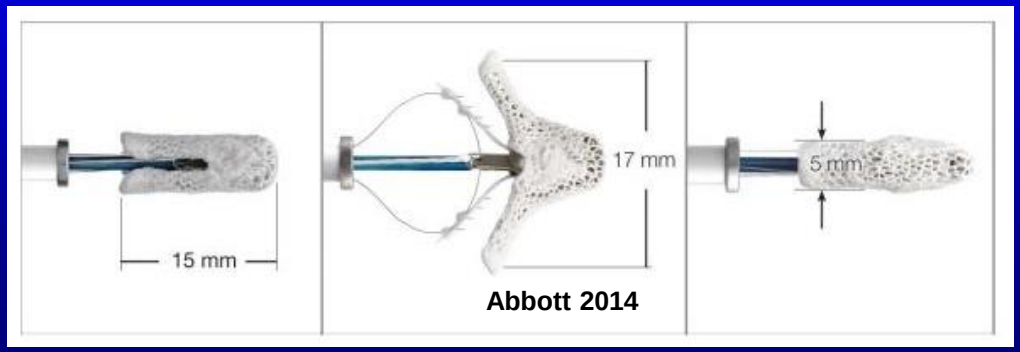
pulmonX
Interventional Pulmonology



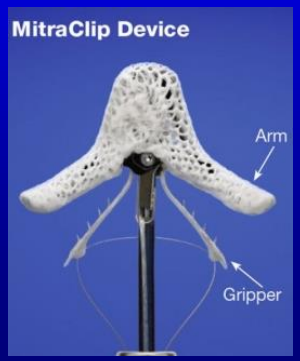


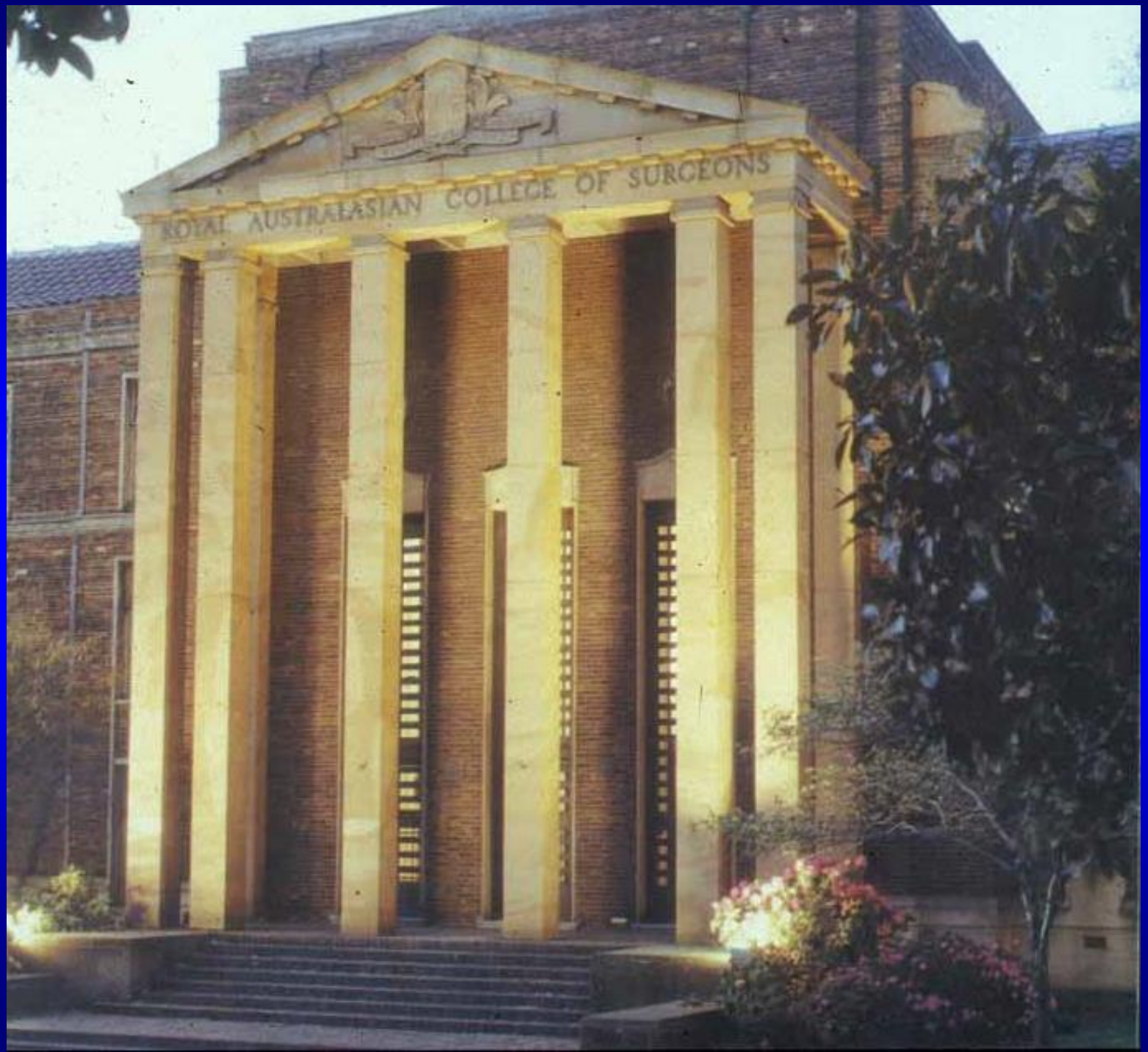
MitraClip





Abbott 2014




ROYAL AUSTRALASIAN COLLEGE OF SURGEONS

Australian
Safety and
Efficacy
Register of
New
Interventional
Procedures –
Surgical

PAPER

Innovative surgery: the ethical challenges

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Received 23 December 2010
Revised 18 April 2011
Accepted 24 May 2011
Published Online First 22 June 2011

ABSTRACT

Innovative surgery raises four kinds of ethical challenges: potential harms to patients; compromised informed consent; unfair allocation of healthcare resources; and conflicts of interest. Lack of adequate data on innovations and lack of regulatory oversight contribute to these ethical challenges. In this paper these issues and the extent to which problems may be resolved by better evidence-gathering and more comprehensive regulation are explored. It is suggested that some ethical issues will be more resistant to resolution than others, owing to special features of both surgery and innovation.

INTRODUCTION

Innovation in surgery has contributed to progress in medicine and to enhanced longevity and quality of life. It has led to new devices and procedures, such as heart valves and organ transplants, yet in spite of its considerable potential for good, innovative surgery generates significant ethical challenges. Roughly speaking, these can be grouped around concerns about patient harm, informed consent, distribution of healthcare resources and conflicts of interest. In this paper we argue that some of these issues may be resolved through better evidence gathering and more comprehensive regulation, but that others will be more resistant to resolution owing to special features of both surgery and innovation. We begin by briefly canvassing various definitions of surgical innovation before expanding on the ethical issues surgical innovation creates. Finally, we consider to what extent regulation and evidence can deal with these ethical concerns.

WHAT IS INNOVATIVE SURGERY?

One major difficulty in exploring the ethics of innovative surgery lies in the lack of a clear definition of innovation, which lies somewhere on a spectrum between the necessary variations of usual practice and surgical research. Heart valves and organ transplants are examples of innovation in surgery, as they are devices and procedures that were (at least for a period of time) regarded as innovative. However, there is little consensus in the literature as to how to define surgical innovation. For instance, is innovation a process or an event? If it is a process, how can we identify the start and end points, and how long does an innovation remain so? Laparoscopic cholecystectomy ('keyhole' surgery to remove the gall bladder through a series of small incisions rather than a single large incision) is now a standard procedure rather than an innovation, but single-port laparoscopic cholecystectomy (using only one incision rather than two to four) is currently an innovation. If innovation is an event, how many times can the event occur and still be regarded as innovative? A second set of questions arise in relation to whether an innovation is absolute or relative to a particular surgeon, institution or healthcare jurisdiction. An operation that is standard in one hospital may, for example, be new to surgeons and healthcare teams at another hospital. Owing to the 'learning curve' phenomenon to be described below, this is an ethically relevant dimension of innovation.

Despite the difficulties in attempting to define innovation, the exercise is important, since for both ethical and regulatory purposes it is central to ensuring all parties (surgeons, patients, regulators, bioethicists, etc) are referring to the same phenomenon. However, this task is not our main focus. For our purposes we will define surgical innovation as involving some form of deviation from standard surgical practice and/or as relative to the surgeon.

ETHICAL ISSUES GENERATED BY SURGICAL INNOVATION

Categorising the ethical issues generated by innovative surgery is an important philosophical exercise. It is possible to carve up the issues in a number of ways, such as by how they are generated (eg, from epistemological shortcomings, regulatory failings, etc) or according to whom or what they bear on (eg, individual patients, surgeons, hospitals, healthcare or public health generally). In this paper, however, in order to capture the central concerns most economically and in terms that readily appeal to established ethical debates, concerns will be grouped into four categories: harm to patients, informed consent, distribution of healthcare resources and conflicts of interest,[1] each of which will be briefly discussed in turn.

Surgical innovations have the potential to cause increased mortality and morbidity in comparison with standard treatments, thereby generating the most obvious source of patient harm. The relevance and potency of this concern is borne out by historical cases where innovative surgery has harmed patients. Examples include routine episiotomy during childbirth; treating angina by tying off one of the arteries in the chest wall, and stomach ulcer disease by freezing the lining of the stomach; early efforts to artificially sustain circulation with implant devices; uptake of laparoscopic (or 'keyhole') surgery; and various procedures to treat a range of cancers.[1] In these cases, performance of the innovative procedures could

[1]In addition to representing a standalone ethical issue, conflicts of interest may also contribute to patient harm.

Ethical Challenges of Innovative Surgery

- Potential harms to patient
- Compromised informed consent
- Unfair allocations of health care resources
- Conflicts of interest

Learning Curve – Laparoscopic Fundoplication

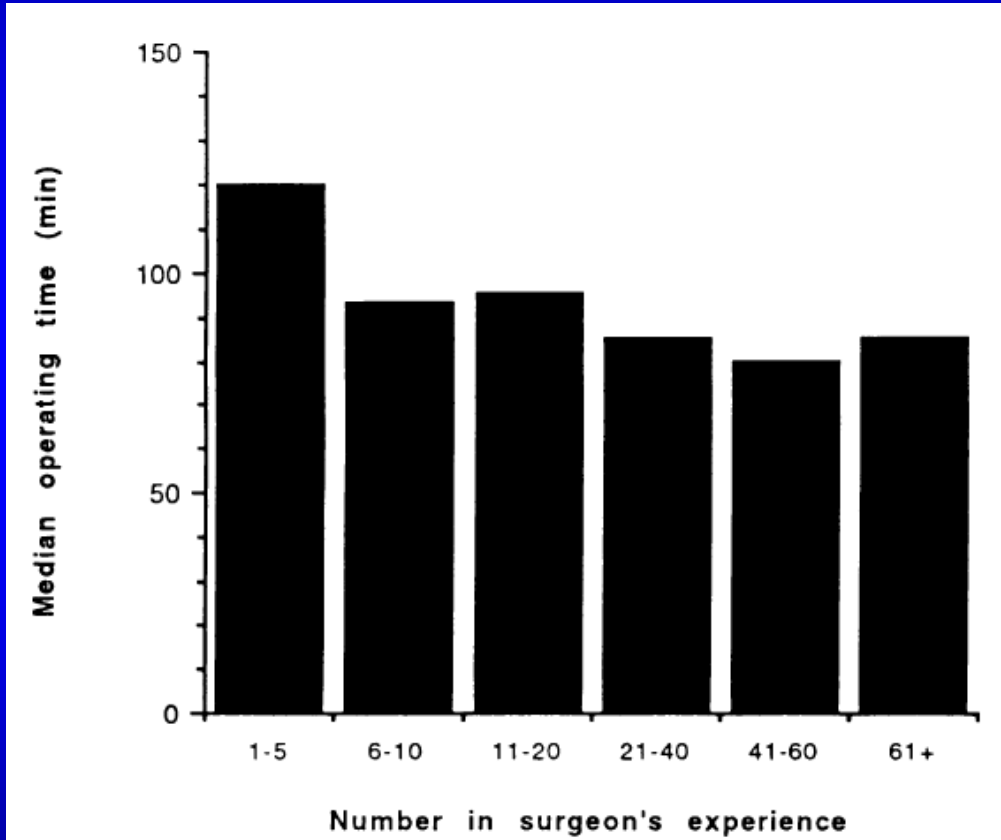
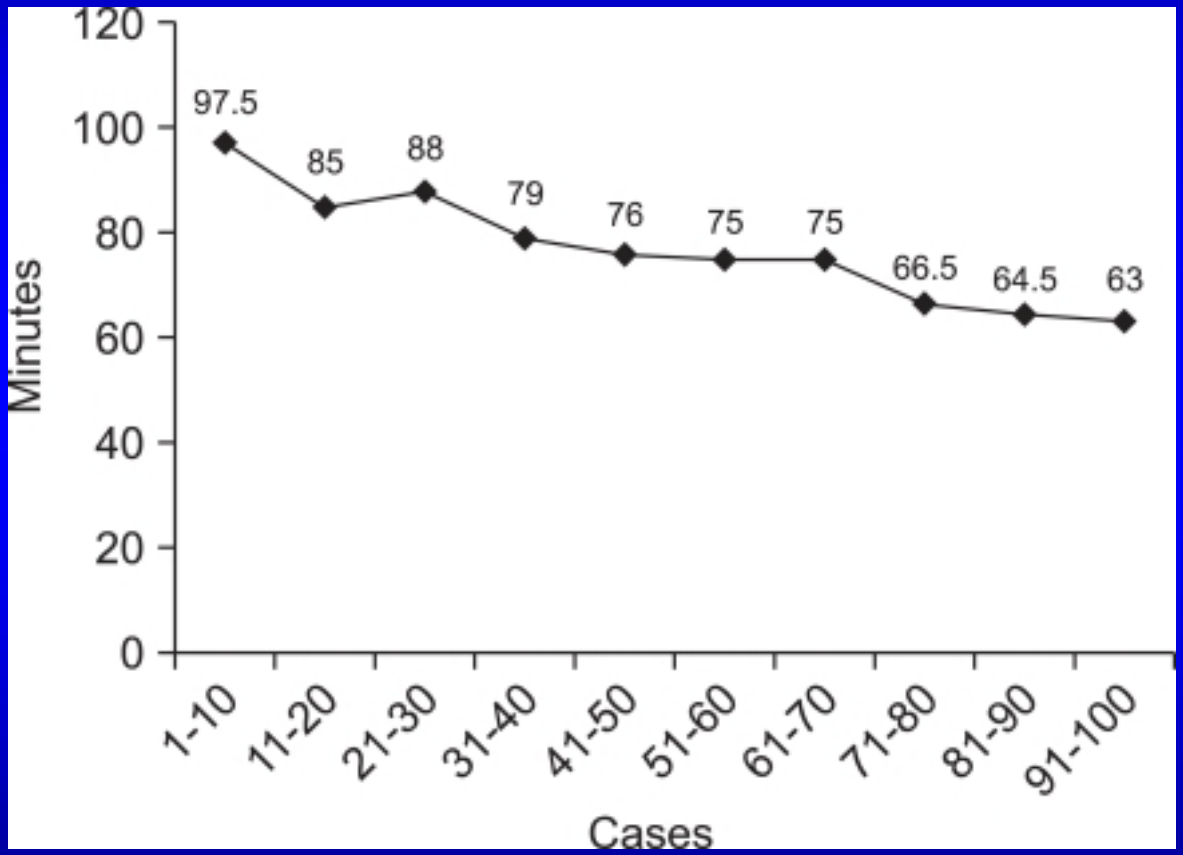


Figure 6. Operating time rate *vs.* surgeon's experience.

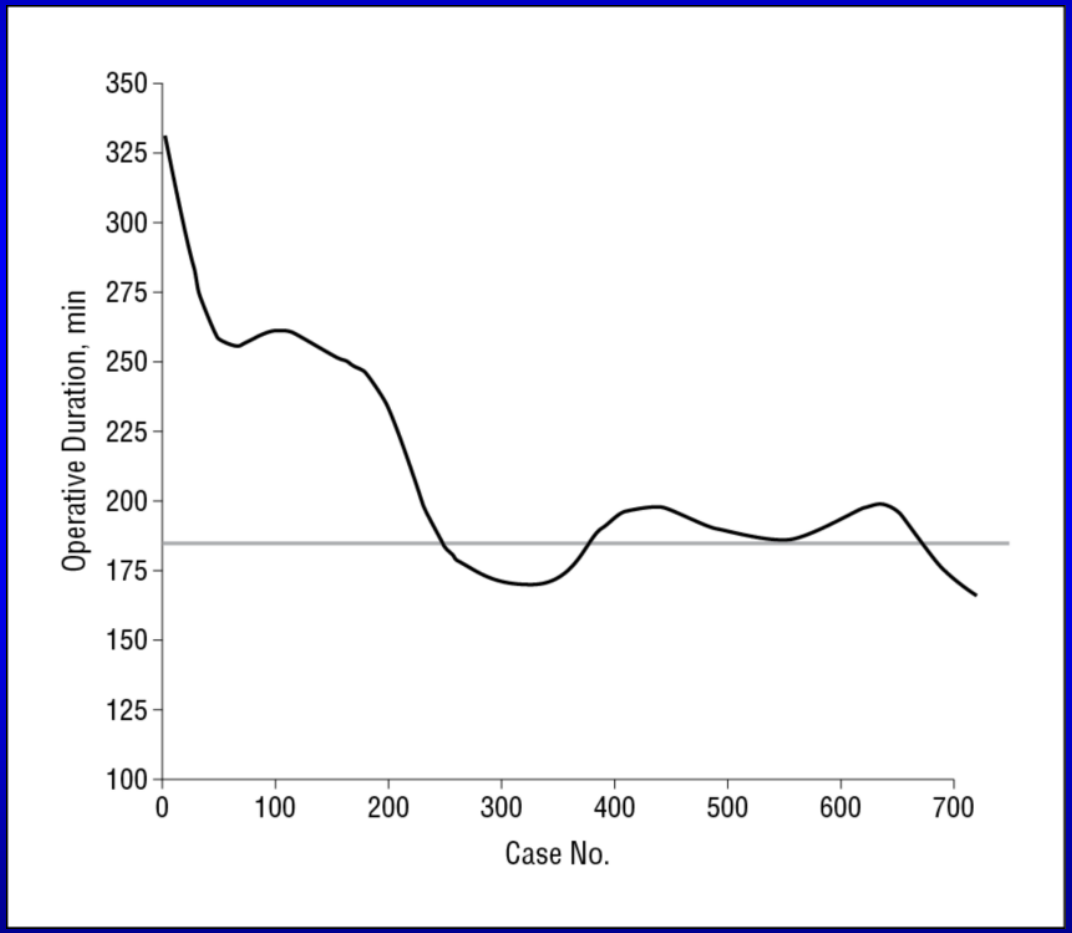
Watson DI, Baigrie RJ, Jamieson GG. A learning curve for laparoscopic fundoplication. Definable, avoidable or a waste of time? Annals Surg 1996; 224: 198-203

Learning Curve – Single Port Laparoscopic Cholecystectomy



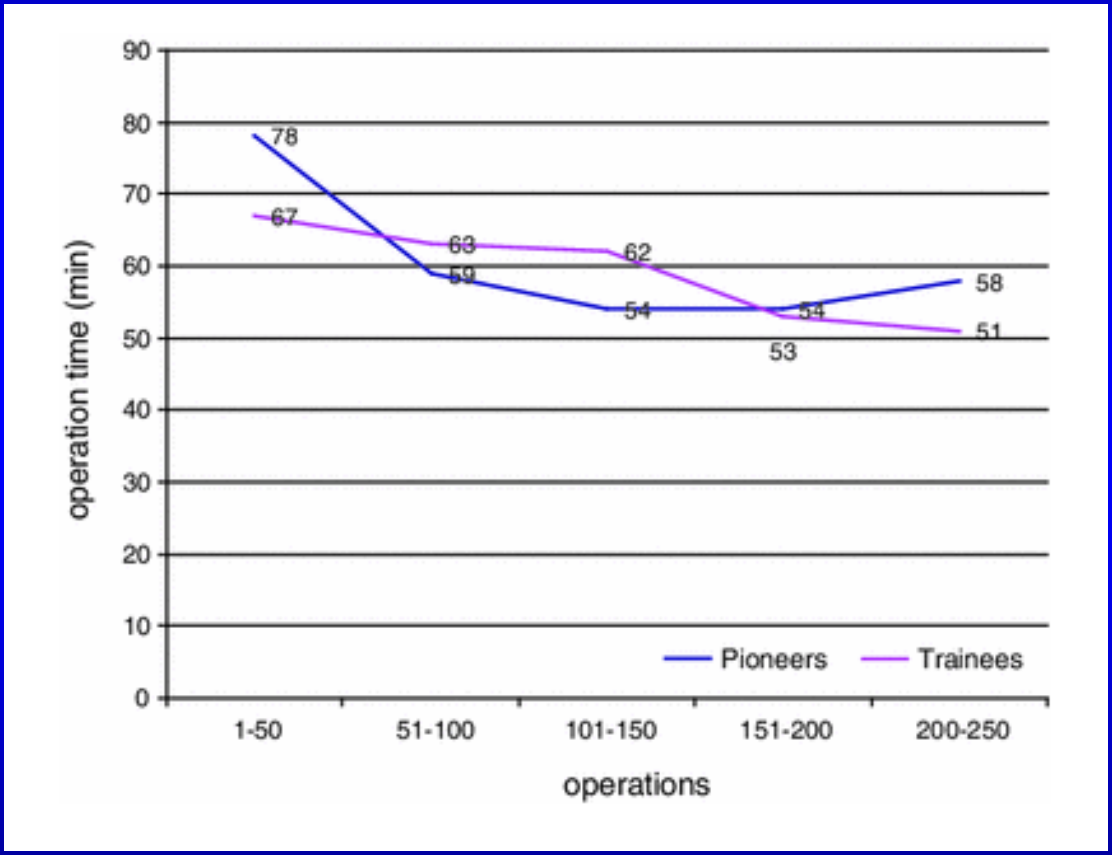
Koo EJ, Youn SH et al. Review of 100 cases of single port laparoscopic cholecystectomy. JKSS 2012; 82: 179-184

Learning Curve – Laparoscopic Colorectal Surgery



Technical Proficiency in Hand-Assisted Laparoscopic Colon and Rectal Surgery: Determining How Many Cases Are Required to Achieve Mastery. Arch Surg. 2012;147(4):317-322

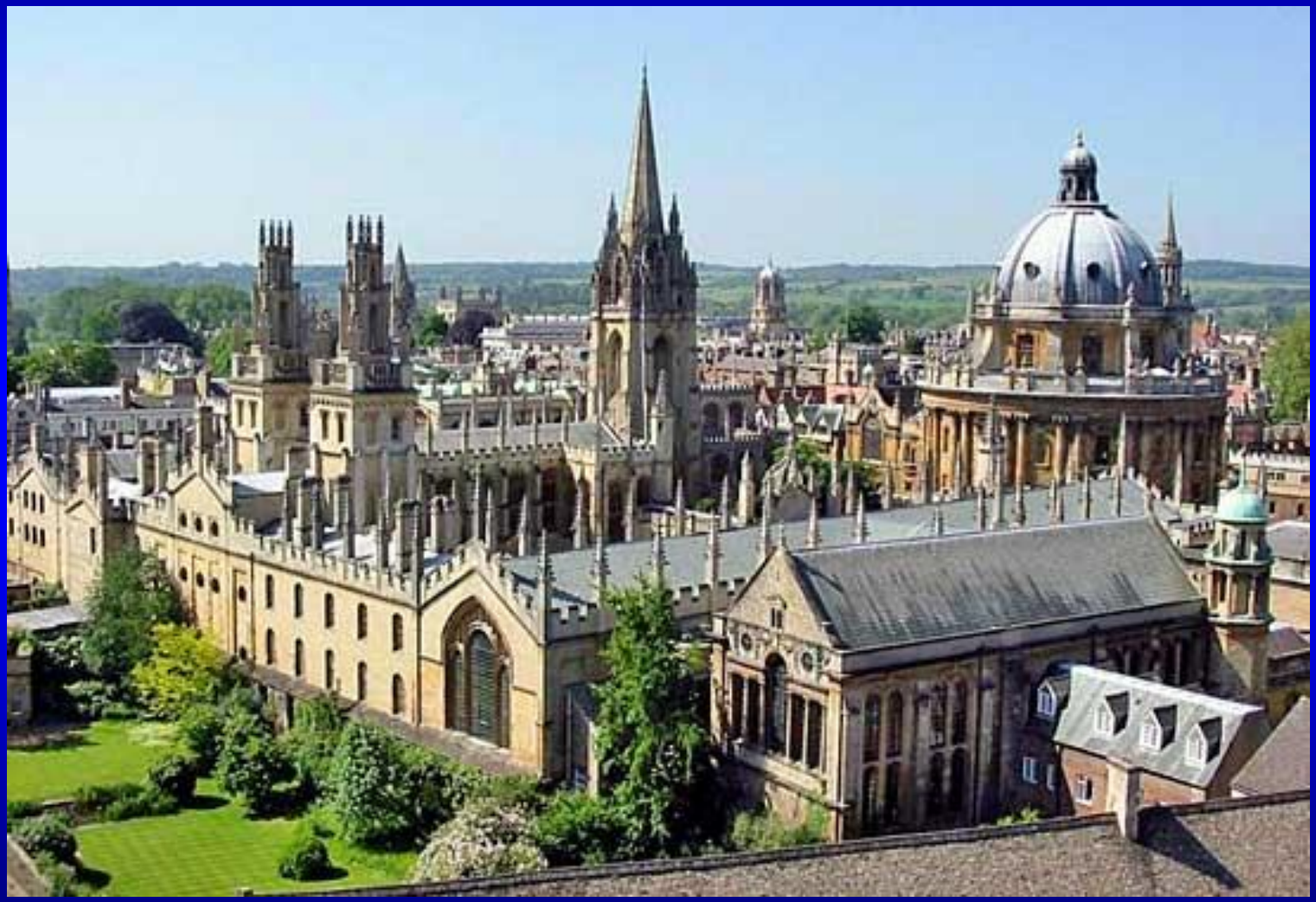
Learning Curve – Laparoscopic Hernia Repair



Boker U, Schwarz J, Bittner R et al. Teaching and training in laparoscopic inguinal hernia repair (TAPP): impact of the learning curve on patient outcome. Surg Endosc 2013; 27: 2886-2893

Conflict of Interest

Ideal Collaboration



IDEAL Framework

Stage 1: Idea

Question

- Can the procedure or device achieve a specific physical or physiological goal?

Aim

- Proof of concept

Patient Base

- Single to few

Optimal Study Design(s)

- First-in-man study, structured case report

Cook JA et al. BMJ 2013; 346: f2820

Example of procedure at this stage

- Stem cell based tracheal transplant for tracheal stenosis

IDEAL Framework

Stage 2a: Development

Question

- What is the optimal technique or design, and for which patients does it work best?

Aim

- Safety, efficacy

Patient Base

- 10s

Optimal Study Design(s)

- Prospective development study

Cook JA et al. BMJ 2013; 346: f2820

FEATURE

Right Portal Vein Ligation Combined With In Situ Splitting Induces Rapid Left Lateral Liver Lobe Hypertrophy Enabling 2-Staged Extended Right Hepatic Resection in Small-for-Size Settings

Andreas A. Schnitzbauer, MD, Sven A. Lang, MD,* Holger Goessmann, MD,† Silvio Nadalin, MD,§ Janine Baumgart, MD,|| Stefan A. Farkas, MD,* Stefan Fichtner-Feigl, MD,* Thomas Lorf, MD,¶ Armin Goralcyk, MD,¶ Rüdiger Hörbelt, MD,# Alexander Kroemer, MD,* Martin Loss, MD,* Petra Rümmele, MD,‡ Marcus N. Scherer, MD,* Winfried Padberg, MD,# Alfred Königsrainer, MD,§ Hauke Lang, MD,|| Aiman Obed, MD,¶ and Hans J. Schlitt, MD**

IDEAL Framework

Stage 2b: Exploration

Question

- What are the outcomes of more widespread use? Can consensus equipoise be reached on a trial question?

Aim

- Efficacy

Patient Base

- 100s

Optimal Study Design(s)

- Prospective collaborative observational study (Phase IIS) or feasibility randomised controlled trial (or both)

Cook JA et al. BMJ 2013; 346: f2820

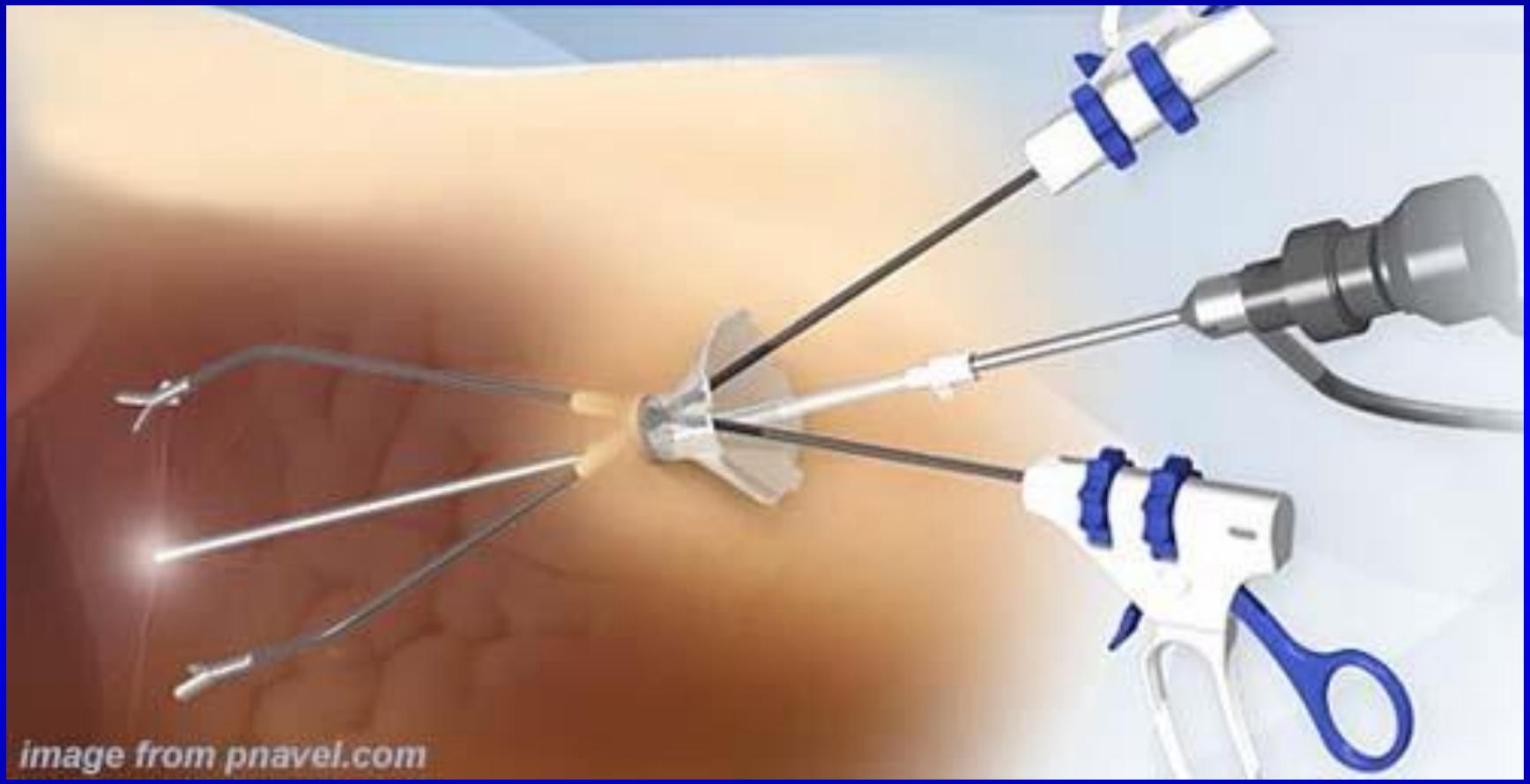


image from pnavel.com

IDEAL Framework

Stage 3: Assessment

Question

- How well does this procedure work compared with current standards of care?

Aim

- Comparative effectiveness

Patient Base

- 100s+

Optimal Study Design(s)

- Randomised controlled trial

Cook JA et al. BMJ 2013; 346: f2820

Robotic Pancreatectomy

IDEAL Framework

Stage 4: Long term study

Question

- What are the long term effects and outcomes of the procedure?

Aim

- Quality assurance

Patient Base

- 100s+

Optimal Study Design(s)

- Observational study or randomised trial nested within a comprehensive disease based registry

Cook JA et al. BMJ 2013; 346: f2820

Laparoscopic Liver Surgery

Macquarie Surgical Innovation Identification Tool

The *technique, instruments and/or devices* to be used in the operation for which the patient has consented:

Have all been used before in this *hospital* ☐ Yes ☐ No

Have all been used before by this *surgeon* ☐ Yes ☐ No

The *techniques, instruments and/or devices* to be used in the operation for which the patient has consented are routinely used:

For this *indication* ☐ Yes ☐ No

In patients of this *sex* (where relevant) ☐ Yes ☐ No

In patients of this *age* (paediatric/elderly) ☐ Yes ☐ No

In patients with this *comorbidity* ☐ NA ☐ Yes ☐ No

The checklist tool is published Annals of Surgery
(Hutchinson et al, doi:10.1097/SLA0000000000001174)

Context specific


E-Z CRUSHER
FRITZ ENTERPRISE
734-362-3200


25

ROYAL AUSTRALASIAN COLLEGE OF SURGEONS / ASERNIP-S

General Guidelines for Assessing, Approving & Introducing New Surgical Procedures into a Hospital or Health Service