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Tools of the trade

The Royal Australian and New Zealand College of Obstetricians and Gynaecologists

O&G Magazine

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From the President

Prof Michael Permezel
President

The review of the Medical Benefits Schedule (MBS) under the chairmanship of Prof Bruce Robinson has now gained wide publicity. The colleges and professional associations have, in general, felt engaged with the process, but share many of the Australian Medical Association's concerns regarding the possibility for harm if clinical input is not paramount.

Having attended a number of consultation sessions, the most poignant question came from a member of one the surgical associations: 'What evidence will guide the MBS review?' He, like so many others, is frustrated by both state and national guidelines produced by epidemiologists and academics (sometimes with relatively little clinical exposure). The evidence that should guide clinical practice (and therefore the MBS review) is the collective interpretation of evidence by clinicians active in the field. For most disciplines in Australia and New Zealand, the closest we have to clinician-guided practice are the statements and guidelines of the professional colleges and associations. It is obvious that these need to be of the highest standard, recommending specific clinical practice where evidence is strong, but recognising that diversity is reasonable where the evidence is less strong.

Recently, I was alarmed to hear a senior colleague (who should know better) note that a College statement had recommended a course of management even though there was 'no evidence'. The collective interpretation of all available and relevant information by a group of clinical experts is, in fact, the best possible evidence. The presence or absence of a randomised clinical trial (RCT) may make a significant contribution to the information available, but does not constitute an end in itself. In fact, there are many examples where poor recommendations arise from an RCT interpreted by epidemiologists rather than clinicians active in the field. I despair for the damage done by those who incorrectly refer to sound clinical practices based on collective wisdom as having 'no evidence'.

Obstetrics has been identified as one of the areas of practice targeted for early review. An Obstetrics Clinical Committee has been formed to advise the MBS Review Task Force. The committee has obstetricians (specialist, GP and MFM subspecialist), a midwife,

an epidemiologist and extensive Department of Health support staff. One issue identified for early review includes the possibility of a single item number for first trimester antenatal blood tests and the current low weighting given to management of a second trimester fetal loss. Marked interstate differences in use of the complex birth item number (16522) suggest that the descriptors around this item are variously interpreted. Descriptors that can be more consistently interpreted would seem desirable. The College would be pleased to collect input from Fellows regarding the MBS Review and has received surprisingly little input on such an important issue to date. Please email suggestions to: mbsreview@ranzcog.edu.au .

FIGO

FIGO Vancouver 2015

The FIGO 2015 World Congress took place in Vancouver on 5–9 October and was attended by more than 6 000 specialists from around the world. This was the culmination of the three-year term of office for FIGO President, Prof Sir Sabaratnam Arulkumaran. Arul, as he is widely known, has made an outstanding contribution to global women's health and will continue to play a leading role in key FIGO projects.

FIGO World Congress – Sydney 2021

The FIGO General Assembly was asked to vote on the choice of five bidding cities for the FIGO 2021 World Congress, to be hosted within the Asia-Oceania region. In a very competitive vote, Sydney was selected by the General Assembly ahead of Seoul, Yokohama, Singapore and Hyderabad. Congratulations are particularly due to Prof Bill Ledger and Prof Ian Fraser who led the Sydney bid, aided by strong support from Business Events Sydney. FIGO 2021 in Sydney will be the largest obstetrics and gynaecology event staged in Australia. The RCOG World Congress 2015, Joint RCOG/RANZCOG Event held this year in Brisbane showed that the College can successfully run a large international meeting, but FIGO 2021 is likely to present some special challenges. We look forward to the task ahead.

Annual Scientific Meetings

Provincial Fellows

This year, the Provincial Fellows Annual Scientific Meeting was held on the coast of New South Wales at Taree. Dr Phil Walkom had done a superb job of organising an excellent venue and program. Unfortunately, recent illness prevented him hosting the meeting itself and Dr Tony Geraghty stepped in as chair to guarantee a great meeting.

New Zealand Committee

The New Zealand Committee Annual Scientific Meeting was held this year in Wellington. This was another excellent program featuring both national and international speakers. Congratulations to the New Zealand office staff, the Organising Committee led by Dr Fali Langdana and, in particular, to Dr Phil Suisted who gave an outstanding welcome in the Maori language as part of the mihi whakatau (Welcome Ceremony).

O&G audit app

The College obtained funding from the Commonwealth Government, Rural Health and Continuing Education (RHCE), in December 2014, to develop an obstetrics and gynaecology-specific online audit tool to assist and encourage rural Fellows to participate in clinical audit as part of their CPD activities. The App is simple to use and allows Fellows to collect practice data and review outcomes in comparison to data from the Australian Council on Healthcare Standards (ACHS) Clinical Indicator

Program. Three types of reports can be generated: obstetrics, gynaecology and number of procedures. The App is available on the following platforms iPhone, iPad and Android and is freely available through the AppStore and Google Play. While designed for Provincial Fellows, it is hoped that this App will also prove useful to the Fellowship in general. Thanks particularly to Jacqui Maloney, from College House, and A/Prof Ian Pettigrew and his subcommittee for their work in bringing this project to fruition.

ePortfolio

Very good progress has been made with the development of an ePortfolio for FRANZCOG Trainees. At the time of writing, it is anticipated that the logbook component of the ePortfolio will be available for the new training year in New Zealand, commencing 7 December 2015. Australian Trainees will begin using the eLogbook from 1 February 2016. Online versions of the three- and six-month training supervisor reports, along with other elements of the ePortfolio, will be progressively introduced over the next two years. While there may be some teething problems with moving more than 600 Trainees from paper-based to electronic documentation, there are many reasons why introduction of the ePortfolio has become a necessity. For example, the timely availability of Trainee procedural experience will enable better localisation of Trainees to the training sites where procedural experience is most available.

Women's health

Choosing Wisely

RANZCOG is pleased to have recently joined, along with other colleges, the Choosing Wisely® campaign. Originating in the USA, participating organisations are asked to identify areas of practice where resource use is greater than the evidence might indicate to be warranted. A number of suggestions have been received by the College, including unnecessary screening at the first antenatal visit in the absence of risk factors (for example, vitamin D, ferritin, cytomegalovirus, parvovirus) and repeated first trimester ultrasounds in the absence of any complications. Gynaecological suggestions include CA-125 measurements in the absence of any symptoms or signs of gynaecological pathology. Input to these or other suggestions can be submitted to the College via email to: choosingwisely@ranzcog.edu.au .

National Cervical Screening Program

The introduction of the renewed National Cervical Screening Program (NCSP) in 2017 will see very significant changes in the national recommendations, including a transition to primary high-risk HPV screening and five yearly testing beginning at the age of 25 years. In parallel with its substantial investment in the NCSP, the government currently supports a comprehensive quality assurance program in cervical cytology and histopathology. With the renewed NCSP, it is anticipated that submission of clinical colposcopy data to the National Cervical Screening Register will be obligatory and participation in a colposcopy quality assurance program will be encouraged. The College is striving to ensure that any such data submission and quality assurance program will be as user-friendly as possible and any recommendation for minimum numbers remains within reach of the generalist.

Selection

In August, 258 eligible applications were considered for 80 available training positions in Australia. Approximately two-thirds of the eligible applicants were interviewed, which required a total of ten panels. Although hospital references were only used in the short-listing process (and not in the final selection score), they have proved a valuable resource in assessing the various elements of the selection process. It is extraordinary to realise that there is no gold standard of performance as a doctor against which to assess the various elements of a selection process: medical education, training assessments or examinations. The assessments by hospitals as to who they perceive as the better doctors represents at least one endpoint against which the various parameters of the selection process can be assessed. Analysis of the current year's outcomes is likely to result in some refinements to the selection process for 2016. As ever, your constructive feedback is welcome.

From the CEO

Alana Killen
CEO

As 2015 draws rapidly to a close, it is interesting to reflect back on some of the issues that have faced the medical profession in general, and medical colleges specifically, during the past 12 months.

Bullying and harassment

One of the key challenges facing the profession in the past year has been the emergence of reports relating to bullying and harassment. Following public claims from a surgical trainee, the Royal Australasian College of Surgeons (RACS) commissioned a report into the levels of bullying and harassment being experienced within the surgical training program. The report highlighted significant instances of bullying, intimidation and sexual harassment and found that:

- 49 per cent of Fellows, trainees and international medical graduates reported being subjected to discrimination, bullying or sexual harassment;
- 54 per cent of trainees and 45 per cent of Fellows less than ten years post-fellowship reported being subjected to bullying;
- 71 per cent of hospitals reported discrimination, bullying or sexual harassment in their hospital in the last five years, with bullying the most frequently reported issue;
- 39 per cent of Fellows, trainees and international medical graduates reported bullying, 18 per cent reported discrimination, 19 per cent reported workplace harassment and seven per cent reported sexual harassment;
- discrimination is most commonly about cultural or racial discrimination (33 per cent), followed by sexual discrimination (16 per cent);
- the problems exist across all surgical specialties; and
- senior surgeons and surgical consultants are reported as the primary source of these problems.[1]

So what does this mean for RANZCOG? The RANZCOG Board has decided that it will conduct its own survey to determine if similar issues exist within obstetrics and gynaecology and, if so, to what extent. Although anecdotal evidence exists, concrete data have not been produced and once this evidence has been attained, decisions can be made about future actions and initiatives.

Skills shortages: supply and demand

RANZCOG, along with the other specialist medical colleges, was recently asked to provide feedback regarding the Skilled Occupations List (SOL). This information is used by the Australian Department of Immigration and Border Control to identify occupations that would benefit from independent skilled migration for the purpose of meeting the medium- to long-term skill needs of the Australian economy. Specialist medical practitioners have been on the SOL for a number of years; however, some consideration is now being given to whether or not this inclusion needs to be revised.

As you are no doubt aware, numbers of medical students have increased significantly over the past few years, which has led to problems in securing adequate intern placements and, in turn, greater competition for specialist training positions. RANZCOG is very mindful of the increasing numbers of junior doctors entering the system and the growing pressure this places on hospitals and other settings to provide adequate experience for those within the training program. While shortages do still exist in some areas, there is evidence to suggest that some metropolitan areas are close to, or have already reached, saturation point. RANZCOG is fortunate to have a dedicated Workforce and Evaluation Unit that can provide accurate and up-to-date data for workforce planning agencies. RANZCOG has recently met with the Department of Immigration and Border Control to discuss current training and future workforce issues and it is an issue that the College will continue to monitor.

Choosing Wisely Australia

Choosing Wisely® had its beginnings in 2002, with the publication of 'Medical Professionalism in the New Millennium: A Physician Charter' by the American Board of Internal Medicine (ABIM) Foundation, the American College of Physicians Foundation and the European Federation of Internal Medicine.[2] The charter provided a new set of professional responsibilities for medical practice. Among the commitments set out were: 'managing conflicts of interest, improving the quality of care, improving access to care, and promoting the just distribution of finite resources'. These principles underpin Choosing Wisely.[3]

The campaign aims to improve the quality of healthcare through considering tests, treatments and procedures where evidence shows they provide little or no benefit, or may even do harm. In Australia, this work is being led by an advisory group, which is informed by the representatives panel consisting of members from participating medical colleges responsible for driving list development and implementation within respective colleges. RANZCOG is now seeking feedback from members to assist in the creation of a list of five tests, treatments or procedures that evidence suggests are not beneficial to the patient. Should you wish to contribute to this discussion, I would welcome your feedback, which will be passed on to the Board and those responsible for representing the College as part of this initiative.

Knowledge management

Finally, I wanted to end this report by highlighting a current administration project that is specific to the College, but which no doubt affects anyone working in a large, complex organisation. The capturing, storing and sharing of information is a critical factor in ensuring organisational capability and effectiveness yet, often, this information is stored on personal drives, written notes or, worst of all, in people's heads. Although corporate memory is a difficult concept to share, the ability to pass critical information on to others can mean the difference between productive efficiency and time-wasting repetition.

One (but by no means the only) solution to this problem, is to implement an effective knowledge management system that enables individuals and teams to quickly access the information they need to complete the task at hand. Anyone who has spent hours or sometimes days searching for a critical piece of information will understand why this project is important to the College and how this will bring about improvements to the way business is conducted at RANZCOG. In common with the website and database redevelopment projects, this initiative aims to support staff in providing members with responsive and timely service and ensure that vital information is not lost when staff or key office bearers move on.

In conclusion, I would like to thank everyone who has welcomed me so warmly and provided encouragement and support in my new role. I would also like to wish all our members and their families a very safe and happy holiday season and all the best for the coming year.

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1 Expert Advisory Group on Discrimination, Bullying and Sexual Harassment Report to RACS. 2015, RACS.
2 ABIM, ACP–ASIM, and EFIM, Medical Professionalism in the New Millennium: A Physician Charter. *Annals of Internal Medicine*, 2002. 136(3).
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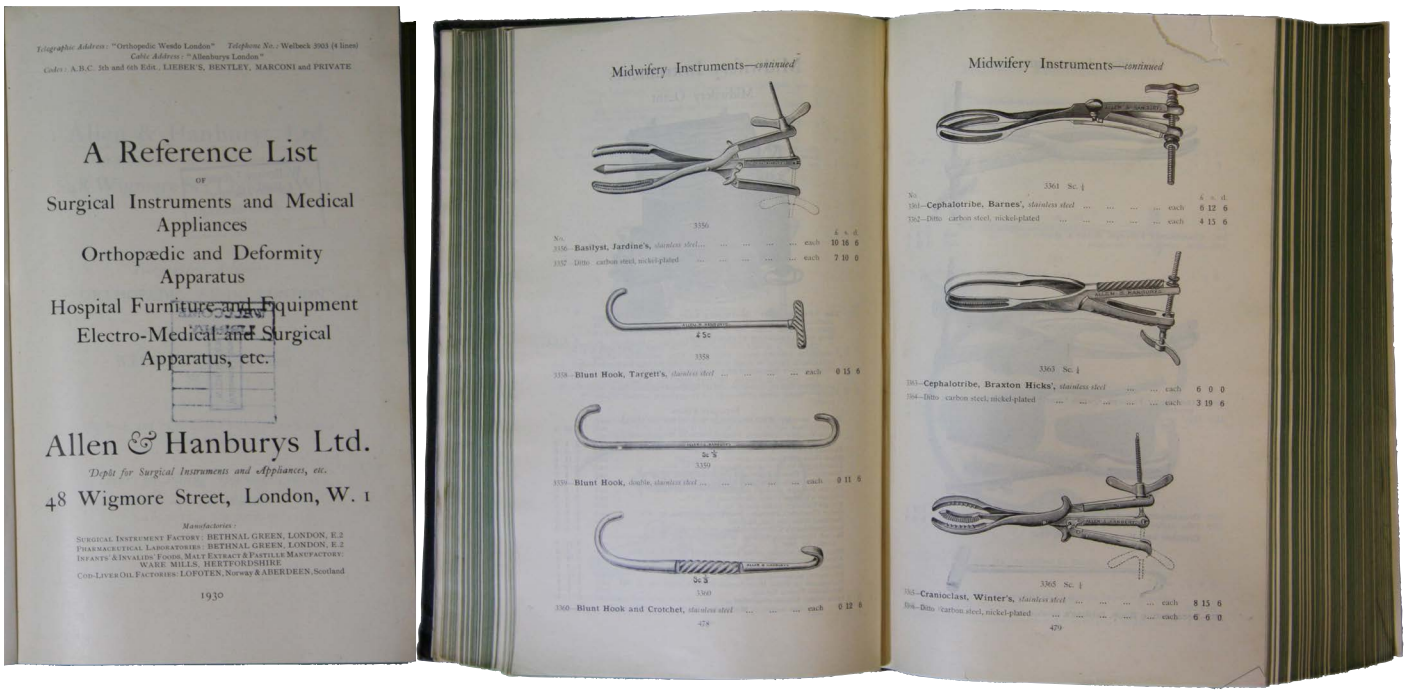
Editorial: the right tool for the job

Dr Brett Daniels
FRANZCOG

There is a simple pleasure in using the right tool for the task at hand. Whether it is a sharp knife finely slicing a tomato, the smooth sweep of a well-tuned wood plane or the satisfying feel of a good needle holder as you place a suture, the proper tool makes the performance of any task safer and easier, and gives a better result. Conversely, the wrong tool, a poorly maintained one or lack of expertise in its use leads to frustration, struggle and error. Unfortunately, in medicine, the consequences of these things are more serious than an unevenly sliced tomato.

Obstetrics and gynaecology, perhaps more than most specialties, has always attracted the inventive. Medical ultrasound was pioneered by Scottish obstetrician Ian Donald, following his experiences with radar in World War Two, while gynaecologists such as Raoul Palmer, Kurt Semm and Patrick Steptoe were innovators in the early days of laparoscopic surgery. In some cases, technology has so completely transformed our specialty that it is difficult to conceive of a time without it. For many of us, obstetric practice without the ability to safely expedite delivery with forceps, vacuum or caesarean section is almost unimaginable. Today's doctors may see the instruments of fetal destruction in the medical museums and old texts and wonder how obstetricians could bring themselves to use them, but they were life-saving at a time when our predecessors faced with a situation where saving the mother's life was all that could be hoped to be achieved. As British novelist LP Hartley wrote in his best-known novel, The Go-Between, in 1953: 'The past is a foreign country: they do things differently there.'

What is cutting edge today will, of course, be old school in the future and the practice of today is not an evolutionary endpoint, just our current best attempt. In this issue of *O&G Magazine* we highlight the current state of the tools in a wide range of areas of obstetric and surgical practice. From suture materials to cell saving technology, from inflatable devices to the impact of the internet, the range of articles reflects our quest to use all at our disposal to improve the outcomes for patients. However, as Nicole Woodrow's article on surgical innovation demonstrates, all that glitters is not gold, and not everything that is we are doing today will stand the test of time. Some may be like Chamberlen's forceps and still be in use with relatively minor modifications more than 300 years later while others, like Hogben's toad test for pregnancy, will fade into history.



Pages from one of the reference books held by the College museum. Published in 1930, many obstetric instruments are shown, including a Winter's cranioclast.

A sticky subject: preventing adhesions

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Obstetricians and gynaecologists are faced with adhesion-related problems daily. We are no strangers to challenging caesarean sections, lengthy gynaecological surgery and even inadvertent enterotomy related to pre-existing pelvic adhesions. Subfertility and tubal pregnancy secondary to tubo-peritoneal adhesions are not foreign to us either. Indeed, adhesions develop in 60–90 per cent of patients who have undergone gynaecological surgery.[1] Nevertheless, the real extent of adhesion-related complications and financial burden on the healthcare system are still largely underestimated.

The reasons may be simple: adhesion-related complications often occur unpredictably, many years after the primary procedure and they are often treated by physicians or specialists other than the initial operating surgeon. Besides, historically, there has been a long track record of failure of adhesion-prevention strategies. Many clinicians perceive adhesion formation as an unavoidable by-product of surgery. A European survey in 2014 revealed that around one-third of gynaecological surgeons considered themselves not adequately informed about measures to prevent post-surgical adhesions.[2]

Clinical consequences

While adhesions may cause few or no detrimental effects to some patients, in a considerable proportion of cases there are short- and long-term clinical consequences, resulting in patient morbidity and a mounting expense. Adhesions are responsible for peritoneal infertility in 15–20 per cent of women.[3] Besides, for patients undergoing subsequent surgery, adhesions pose an important complicating factor that significantly increases operative time and difficulty. Astonishingly, about one in two of the admissions for small-bowel obstruction are related to adhesions from previous gynaecological surgery, especially total abdominal hysterectomy.[4] The relationship between pelvic pain and adhesion is generally recognised, although their exact pathophysiological connection is still a heavily investigated topic.

For these reasons, the European Society for Gynecological Endoscopy (ESGE) released the latest version of consensus recommendations on adhesions in 2014, urging recognition of adhesions as the most frequent complication of abdominopelvic surgery.[5]

Financial burden

In the UK, the financial burden of postoperative adhesions on the National Health Service (NHS) has been strikingly illustrated by the Surgical and Clinical Adhesions Research (SCAR studies).[6] After laparotomy, around one in three patients (34.6 per cent) had at least two admissions in the following ten years for adhesion-related problems. The direct cost of readmissions related to adhesions in the first year after lower abdominal surgery was estimated to be £24.2 million, which increased to staggering £95.2 million ten years after the initial surgery.

Pathogenesis in a nutshell

Although an in-depth discussion of pathogenesis is outside the scope of this article, an overview of the mechanism of adhesion formation helps us to understand adhesion-reduction strategies.

In simple terms, adhesions are a fibrinous band formed from an aberrant healing process. Once the peritoneum is disrupted by inflammation or surgical trauma, the mesothelial layer is exposed and a fibrin matrix is formed in the following three to four days. Playing a key role in adhesiogenesis, this fibrin matrix is a product of macrophage migration, local inflammatory reactions, exudation and fibrin deposition.

If the fibrin is broken down in a few days, the injured area will be covered by normal mesothelial cells and healing occurs without adhesion formation. Conversely, if fibrinolysis does not occur for more than five days, fibroblast proliferation invades the fibrin scaffold and angiogenesis starts – this is how adhesions are formed.

Interestingly, apart from this local phenomenon, emerging evidence suggests that the peritoneal cavity may be a co-factor for adhesion formation. The standard dry and cold gas used in carbon dioxide pneumoperitoneum can cause detrimental effects to the peritoneum by inducing hypoxia, desiccation, acidosis and pressure-related damage, resulting in more adhesion formation at a surgical trauma site.[7]

Targeted at various points of the adhesion formation pathway, a number of adhesion-reduction products and strategies have been developed.

Surgical technique

It is important to remember that no commercially available products can be a substitute to good surgical technique. Minimising the initial surgical trauma is the fundamental determinant in adhesion prevention. In particular, adherence to principles of microsurgery, gentle tissue handling, careful surgical dissection that respects anatomical tissue planes,

good knowledge in electrosurgery and precise application of energy device are all imperative in achieving meticulous haemostasis while minimising tissue trauma, devascularisation, desiccation and ischaemia.

Furthermore, foreign body reactions should be reduced by removing any nidus for infection or persistent inflammation. Frequent irrigation and extensive peritoneal lavage can remove blood, bacterial soiling, fibrin and necrotic materials, especially in contaminated procedures. In fertility-sparing pelvic surgery, fine and non-reactive synthetic suture materials, such as polypropylene (Prolene®), are preferable to natural products such as silk and gut.

Compared to laparotomy, laparoscopic surgery enables surgeons to have a magnified vision of the surgical field and delicate microinstrumentation. The nature of minimal access not only imposes less direct trauma to peritoneum, but also reduces intra-abdominal contact with foreign bodies.

Even in open surgery, moistening of abdominal packs and use of latex-free gloves can lessen physiological insult to the peritoneum. Concerning parietal peritoneal closure, its benefit in adhesion reduction remains controversial. Review of the literature does not support the closure of peritoneum to prevent adhesions.[8]

Adhesion-reduction barriers

As an adjunct to surgical techniques, multiple agents have been investigated to further reduce postoperative adhesions, with varying degree of success. At present, barriers are the only available adhesion-reduction products in clinical practice.

These physical separators aim at preventing the two damaged peritoneal surfaces from apposing to each other for at least five days, in other words, during the critical period of peritoneal repair and adhesion development. An ideal barrier should have low rate of peritoneal absorption, high viscosity, absence of side effects and high biocompatibility.

Site-specific barriers

These film-form inert barriers can be introduced to the site of trauma, such as over the suture line for myomectomy.

The most commonly used site-specific barriers in abdominopelvic surgery include Interceed® (oxidised regenerated cellulose), Gore-Tex® (expanded polytetrafluoroethylene) and Seprafilm® (sodium hyaluronate/carboxymethylcellulose).

Among these, Interceed is probably the most popular choice among pelvic surgeons, particularly in laparoscopic procedures. The physical properties of the other products have limited their applicability in routine gynaecological surgery. For instance, the non-absorbable Gore-Tex needs to be

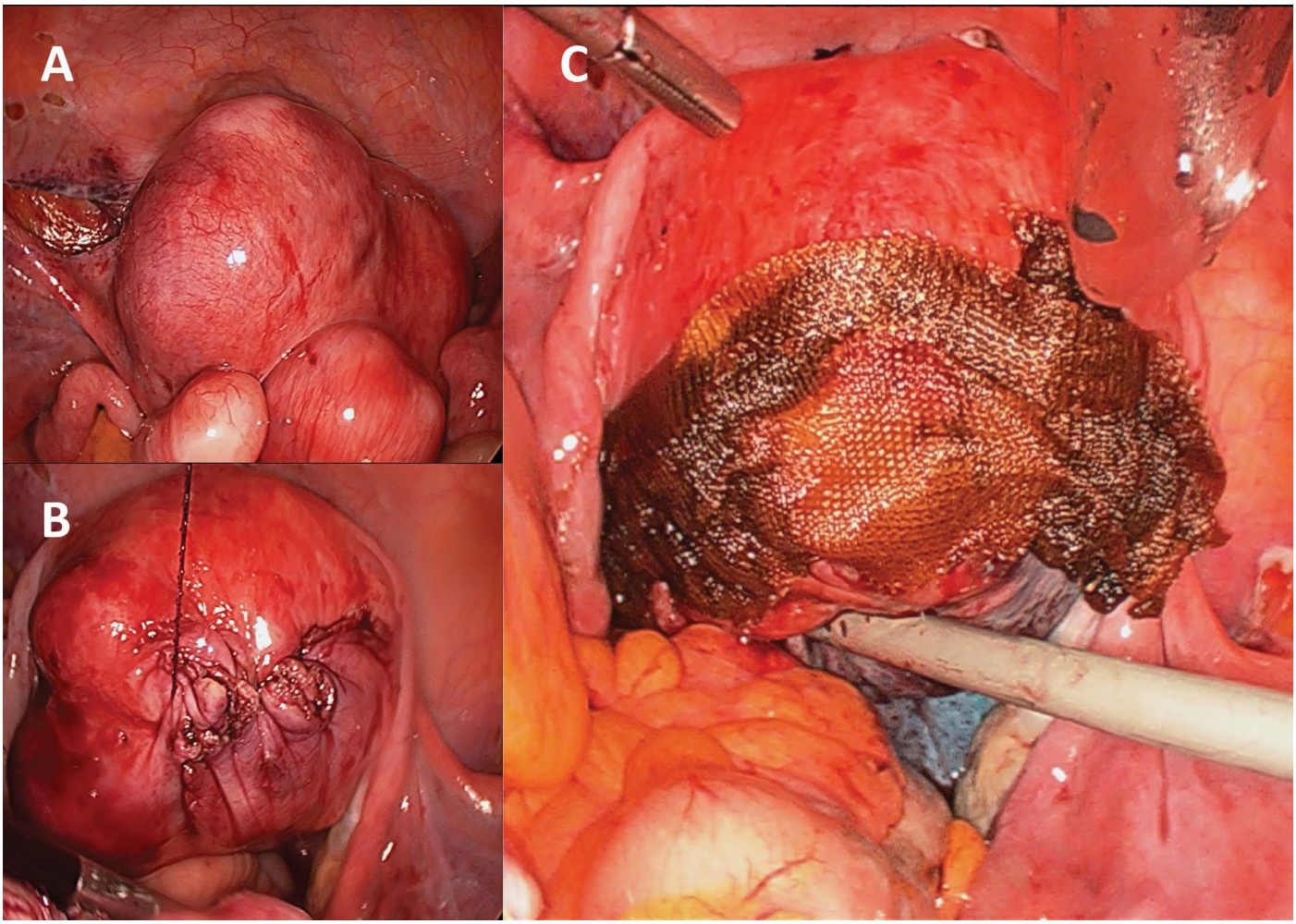

Figure 1. Application of Interceed® barrier film over the suture line of a laparoscopic myomectomy. During the excision of nine fibroids in this patient, the surgeon also endeavoured to reduce tissue trauma and foreign body reaction by multiple surgical measures: limiting the number of myometrial incisions, choosing a monofilament suture that has lower bacterial adherence than braided sutures, and minimising exposure of suture material beyond the uterine serosa. (A) Before myomectomy. (B) After repair of myometrial defects, prior to cutting of the barbed monofilament suture. (C) Barrier film over suture line.

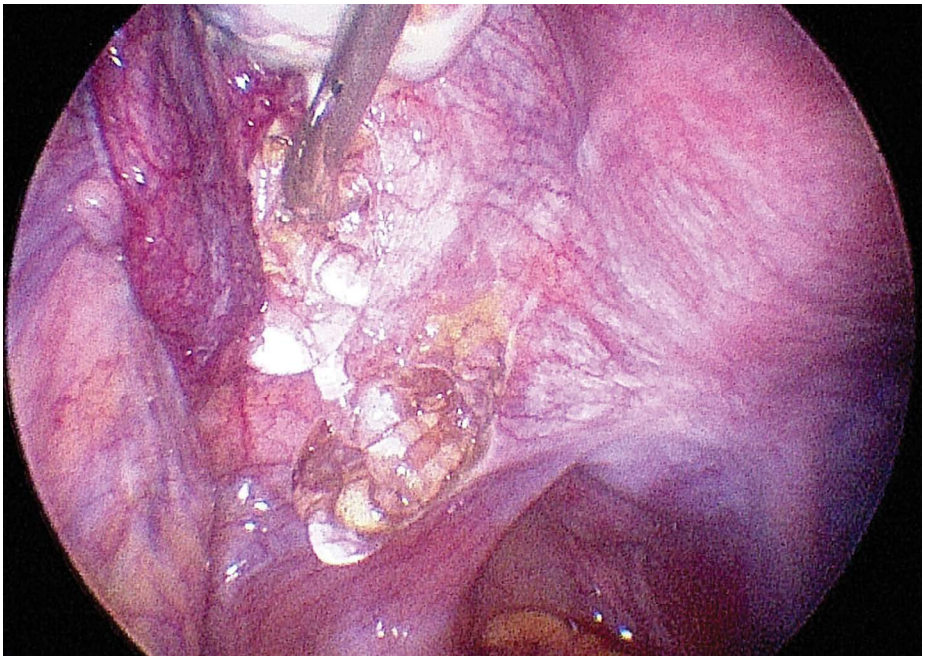

Figure 2. Application of Intercoat Gel® to the left ovarian fossa in laparoscopic excision of endometriosis. Adhesion prevention is crucial in fertility-promoting endometriosis surgery, which is one of the procedures carrying high risk of post-operative adhesion formation.

sutured in place and removed at a second procedure. Seprafilm does not confirm to the shape of pelvic organs well; therefore, it is mainly used as a barrier between bowel and anterior abdominal wall by general surgeons during laparotomy. Notably, when using Interceed, meticulous haemostasis is instrumental, since adhesion would paradoxically increase in the presence of blood together with Interceed.

Gel barriers

Gel barriers have been developed to overcome the physical limitations of solid-form barriers in endoscopic surgery. In Australia, two of the more widely available gel barrier systems are Intercoat Gel® (Oxiplex, carboxymethylcellulose [CMC]/ polyethylene oxide [PEO] composite gel) and SprayGel® (synthetic polyethylene glycol [PEG] solution).[9] Hyalobarrier® gel (auto-cross-linked hyaluronic acid) has been commercialised in European and Asian countries, with promising anti-adhesive efficacy in hysteroscopic[10] and laparoscopic[11] procedures.

Broad-coverage liquids

Peritoneal instillates work by separating pelvic organs by hydrofloatation. Crystalloid solutions, such as normal saline and Ringer's solution, have been proven ineffective because of their rapid absorption by the highly permeable peritoneum.

Adept® (four per cent Icodextrin solution) is an iso-osmotic solution that has a sufficiently long intraperitoneal residence to persist through the time period of adhesion formation. Its safety and efficacy in adhesion reduction after gynaecological laparoscopy have been established in a multi-centre randomised controlled trial.[12]

Limitations of current evidence

The efficacy of these barrier agents in reducing post-surgical adhesions has been demonstrated in a number of clinical studies; nonetheless, recent Cochrane Systematic Reviews conclude that the quality of current evidence ranged from very low to moderate only. The studies are substantially limited by small sample size, poor reporting of study methods, wide confidence intervals and publication bias.[13,14]

Leaving aside the difficulty of monitoring adhesion development with a second-look laparoscopy, one of the key issues in conducting clinical trials is the lack of a standardised adhesion scoring system. There is no simple, reliable and reproducible method to document and compare the extent and density of adhesions. The diversity in study designs and endpoints of evaluation has virtually precluded meta-analysis.

More importantly, there is no compelling evidence of improved clinical outcomes with the use of these products in pelvic surgery. In other words, most of the clinical trials merely evaluate anatomical adhesion formation, but not clinically important end points, such as pain, quality of life, pregnancy and live birth rates, bowel obstruction, or re-operative rates. That being said, on the positive side, no significant adverse effects have been reported with the use of these agents.

Cost-effectiveness

Above all, solid cost-effectiveness data are still lacking to justify the routine use of adhesion-reduction agents. The existing cost-effectiveness analyses were either performed more than a decade ago or based on a healthcare system largely different from the Medicare system in Australia.[15] The financial cost would restrict the prophylactic use of adhesion-reduction agents on a routine basis, particularly in a public hospital setting.

Future research and development

Adhesion risk score

A recently developed adhesion risk score may unveil a new strategy for gynecological surgeons to target the existing resources in high-risk cases. Proposed by the European Anti-Adhesions in Gynaecology Expert Panel (ANGEL), this practical tool consists of preoperative and postoperative sub-scores. Women are stratified into low, medium, and high risk of post-operative adhesions before and during surgery. The goal is to help surgeons make better informed decisions on adopting the surgical techniques and applying adhesion-reduction agents. More studies are awaited to validate its applicability and usefulness in daily practice.[16]

Conditioning of pneumoperitoneum

As described, the dry and cold carbon dioxide gas in laparoscopic pneumoperitoneum may catalyse adhesiogenic process over an already surgically injured area. It has been proposed that full conditioning of the insufflation gas with humidification, temperature regulation and addition of three to four per cent of oxygen to the carbon dioxide may minimise hypoxia and desiccation, hence reduction in adhesion development. Further clinical trials are needed to confirm this concept.[7]

Pharmacological agents

Numerous medications have been explored, based on their mode of action within the adhesion formation pathway. For instance, non-steroidal anti-inflammatory drugs (NSAIDs), dexamethasone and anticoagulants have been tested in animals in attempts to mediate inflammatory response, reduce fibrin deposition and promote fibrinolysis. Yet, none has been found effective and safe in the clinical

setting. With more understanding of the complex adhesiogenic and fibrinolytic pathways, research continues on newer pharmacological agents, but they are still at an experimental stage.

Conclusion

In summary, adhesion formation clearly causes significant clinical problems and financial burden, yet its prevention has been highly neglected. Although surgical barriers may help to decrease postoperative adhesion formation, it cannot compensate for poor surgical technique. While more evidence on clinical efficacy and cost-effectiveness is needed to justify the routine use of barrier products, adhesion-reduction strategies should at least be implemented in high-risk procedures, such as tubo-ovarian surgery, endometriosis resection, myomectomy and adhesiolysis. As ongoing research continues to unravel the mystery of the adhesion-forming process, more effective anti-adhesion measures and strategies will likely be available in the future.

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Endometrial ablation

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Abnormal uterine bleeding (AUB) is defined as any bleeding from the uterus that is abnormal in frequency, volume, duration or regularity.[1] It is estimated that AUB affects between ten and 30 per cent of women and has significant social and economic impact.[2] AUB may be secondary to structural issues (polyps or myomas), non-structural causes (ovulatory dysfunction, endocrine disorders) or related to a cause not yet determined. After appropriate history and clinical evaluation, medical and surgical treatment strategies may be considered. While hysterectomy remains the definitive treatment option for AUB, women may prefer a less-invasive treatment and/or to reduce the surgical risk associated with a major procedure.

Endometrial ablation is an option for the treatment of AUB in women who have completed their families, where medical treatment is either contraindicated or unsatisfactory or who choose this as an option, and has been shown to restore quality of life to the standard of the general population.[3] Compared to a composite of modes of hysterectomy (abdominal, laparoscopic and vaginal), endometrial ablation has been shown to be less costly in both the short term and at five years when direct and indirect costs are considered.[4]

A variety of endometrial ablation techniques and devices have been evaluated and used. The procedures initially developed are usually referred to as first-generation devices. More commonly used in Australasia (and throughout the world) are second-generation devices that include thermal balloon ablation (Thermablate™, Thermachoice®, Cavaterm™) and bipolar ablation (NovaSure®). These are the only devices currently used in Australia and New Zealand.

First-generation ablation

First-generation ablation devices include rollerball endometrial ablation and transcervical endometrial resection, often used in combination. Transcervical endometrial resection uses the hysteroscopic loop resectoscope to resect endometrium to the superficial myometrium, removing all basalis (see the *O&G* app for a demonstration video). Rollerball endometrial ablation applies an electrosurgical current through a specific electrode that is inserted through the working channel of an operative hysteroscope and does not remove the endometrium, rather destroys the basalis under direct hysteroscopic vision. Both of these techniques require a non-conductive fluid, such as glycine, to allow consistent current transmission to the tissue.

For these techniques, pre-treatment with GnRH agonists, danazol or progestogens has been used to thin the endometrium in an attempt to make the operation easier to perform. Although pre-treatment reduces the length of the procedure, it does not improve rates of amenorrhoea or hypomenorrhoea[5], nor does it reduce the incidence of operative complications.[6] The routine use of endometrial thinning agents prior to endometrial ablation therefore adds cost and potential side effects for the woman without significantly altering the outcome of her procedure and cannot be recommended.

Outcomes from rollerball ablation from a retrospective study of 190 patients include a 30 per cent rate of amenorrhoea at five years follow up and a further 40 per cent of women with hypomenorrhoea.[7] Reported complications from electrosurgical ablation techniques include a 4.44 per cent total complication rate, with a 2.38 per cent rate of haemorrhage and a 1.48 per cent rate of perforation.[6] Surgical inexperience is a recognised risk factor for complications with first-generation procedures[6] and these are now less commonly performed, with Australian procedure numbers from 2014 one-third the number of 20 years ago.[8]

Second-generation ablation

Second-generation devices were developed to overcome some of the limitations of first-generation ablation – including the learning curve and surgeon variability. The options available in Australia and New Zealand include thermal balloon devices and bipolar radiofrequency ablation. Other options that are available overseas include cryotherapy and free fluid thermal ablation.

Hysteroscopy should always be performed before any second-generation ablation, to ensure the correct diagnosis of the AUB, excluding malignant and pre-malignant conditions. Additionally, hysteroscopy will identify any focal pathology, such as submucosal myomas or polyps, that may not only cause AUB, but are also a recognised risk factor for failure of ablation (hazard ratio 5.22, CI 1.63-16.73).[9,10]

Contraindications to second-generation ablation include active pelvic infection and any non-lower segment uterine scar; as such scars have the potential to have thinned the myometrium and pose a potential risk of thermal injury to visceral structures. Lower segment caesarean delivery does not pose

Table 1. A summary of ablation technologies.

	Diameter	Distension medium	Time (min)	Temperature	Pressure	Outcomes
Rollerball	10mm	Glycine	Mean 30	N/A	N/A	Equal efficacy between first- and second-generation techniques for amenorrhoea and no difference in re-intervention rates (rate ratio 0.74, CI 0.33-1.66, p+0.47)[14] Lower risk of complications in second-generation procedures (RR 0.2)[16,17] Bipolar versus balloon ablation – shorter operation, improved amenorrhoea rates[14]
Endometrial resection	10mm	Glycine	Mean 30	N/A	N/A	
Cavaterm	6–7mm	Glucose 5%	10	78°C	230–240mmHg	
Thermablate	6mm	glycerine	2	173°C	180mmHg	
Thermachoice	5mm	5% dextrose in water	8	87°C	160–180mmHg	
NovaSure	7.5mm	N/A	Maximum 2	N/A	N/A	

a risk during ablation procedures, as the scar is at the level of the cervix. If symptoms of AUB persist after a second-generation ablation procedure, repeat ablation with a second-generation device is contraindicated as the initial ablation will have changed the myometrial impedance, increasing the risk of thermal injury to surrounding structures.

Pre-treatment counselling should include consideration of contraceptive needs, as ablation is not a contraceptive procedure. Pregnancy after ablation has high morbidity, with case reports of uterine rupture[11] and disordered placentation such as placenta accreta.[12] Concomitant contraceptive procedures that may be performed at the time of ablation include laparoscopic tubal sterilisation, hysteroscopic sterilisation or insertion of an intrauterine device.

Techniques

The balloon devices (Thermachoice®, Cavaterm™, Thermablate™) all have similar mechanisms of action and rely on a silicone or latex balloon that is placed within the endometrial cavity connected to an automated unit that circulates pre-heated fluid through the balloon for a specified period of time.

The NovaSure® device uses bipolar, radiofrequency impedance technology to ablate the endometrium.[13] The ablation device is an electrode array housed within a protective sheath that is deployed within the uterine cavity. The cavity integrity assessment (CIA), using carbon dioxide, must be passed before the procedure can be commenced. This is an added safety feature, as the CIA will fail and the device will not be able to be activated if there is any breach to the cavity, such as occurs in the instance of uterine perforation. Steam, blood and any tissue are removed from the cavity through continuous suction during the procedure.

Limitations to the use of the second-generation devices include abnormalities of the uterine contour such as most Mullerian tract anomalies or type 0 or 1 leiomyomas that prevent the ablation device from contacting the endometrium. Extremes of uterine length or width are contraindications for use for several of the devices (uterine length greater than 10cm (Thermachoice), 12cm (Cavaterm), or less than 4cm in length or 2cm in width (NovaSure).

Evidence

A systematic review has found first- and second-generation endometrial ablation procedures to be equally effective in improving heavy menstrual bleeding (RR 0.98, CI 0.92-1.04, P=0.50)[14] with similar patient satisfaction rates. Compared to first-generation ablation, the benefits of second-generation devices include a shorter operative time by 16 minutes (p<0.001), and a higher likelihood the procedure can be performed under local anaesthetic.[14]

Balloon and bipolar ablation have fewer minor Clavien Dindo grade 1 complications compared to first-generation procedures

Table 2. A summary of the outcomes, re-intervention rates and complications for endometrial ablation devices.

	Outcomes	Reintervention	Complications
First generation	30 % rate of amenorrhoea at five years' follow up and a further 40 % of women with hypomenorrhoea[7]	Hysterectomy rates 7–30 % at 1–5 years[24]	Complication rate up to 4.44 %, including haemorrhage and uterine perforation[6]
Balloon ablation	Initial amenorrhoea rates of 18 %[25] to 56 %[26] 30 % rate of hypomenorrhoea[26]	Hysterectomy rate 9 % at five years and 21 % at 7–10 years[27]	Reduced intraoperative complications in balloon group compared to rollerball (3.2 % versus 0 %)[16]
Bipolar ablation	Amenorrhoea rates 46–58 % at 6–12 months[28] Higher rate of amenorrhoea compared to other second-generation devices (rate ratio 2.6, CI 1.63-4.14, p<0.001)[14]	Similar rates of reintervention (RR 0.9, CI -.63-1.3) and patient satisfaction (RR 1.1, CI 0.82-1.2) between bipolar and balloon ablation after ten years[23] Hysterectomy or retreatment rates <5% at five years[29]	Lower intraoperative complication rate than first generation procedures (0.6% versus 6.7%)[14]

(0 per cent versus 3.2 per cent balloon, 0.6 per cent versus 6.7 per cent bipolar)[15-17] (RR 0.29, CI 0.14-0.57, P<0.001). However, there is no evidence of a difference in the rate of more serious complications, with these complications reported for all types of endometrial ablation technologies.[14]

When bipolar and thermal balloon ablation are compared, bipolar ablation is faster[18] and has higher initial rates of amenorrhoea (odds ratio 4.56, CI 2.24-9.26, p<0.001).[19-22] However, at ten-year follow up, patient satisfaction rates and numbers of patients requiring further treatment are similar, regardless of whether balloon or bipolar ablation is used.[23] This is likely owing to a high percentage of women becoming menopausal within this timeframe.

Other techniques

Procedures not performed in Australia include hydrothermablation (HTA) and cryoablation (Her Option®). HTA is a type of 'free fluid' ablation and is used in the USA. In this procedure, room-temperature saline is instilled inside the uterus and then heated to 90°C, with a treatment time of ten minutes. The procedure is performed under hysteroscopic monitoring. At the end

of the procedure, cooled saline is circulated within the uterus. Cryoablation involves inserting a probe into the uterine cavity, which is then cooled to -90°C using liquid nitrogen, resulting in a frozen zone involving the endometrium and myometrium. Two or three cycles of treatment may be required.

Procedures no longer performed

Techniques previously used to ablate the endometrium that have now been removed from the market include microwave endometrial ablation (MEA), Vesta balloon (radiofrequency ablation via electrodes on the surface of a balloon) and endometrial laser intrauterine thermal therapy (ELITT). These products were removed owing to production costs and the competitive market in this area of clinical medicine.

Conclusion

Endometrial ablation is a management option for women with abnormal uterine bleeding. The current evidence favours second-generation devices that have high rates of amenorrhoea and fewer minor complications when compared to first-generation devices. It is important for clinicians to have an understanding of the technology available, appropriate patient selection and potential risks associated with use of the devices.

Further information

www.ethicon.com/healthcare-professionals/products/uterine-pelvic/endometrial-ablation/gynecare-thermachoice
www.youtube.com/watch?v=Cz8nWN2ou4g
www.climate.edu.au/OandGapp/Vol17No4/Videos/Endometrial_Resection.mp4
www.climate.edu.au/OandGapp/Vol17No4/Videos/Jason_Abbott.mp4
www.climate.edu.au/OandGapp/Vol17No4/Videos/Novasure_Ablation.mp4
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Disclosure

Jason Abbott is a paid consultant for Hologic and is on their speakers' bureau. He has no shares or equity within the company.

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Hysteroscopic resections

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Advancement in endoscopic equipment has facilitated the treatment of intrauterine pathology in both the inpatient and outpatient setting.[1] These instruments allow removal of lesions under direct vision, superseding traditional techniques such as blind removal with curettage and polyp forceps. Pathology such as endometrial polyps, sub-mucous fibroids, intrauterine adhesions and septa can all be resected in this way. Increasingly, hysteroscopy is reported in the investigation and management of women with complications related to retained products of conception. Direct visualisation and excision has safety advantages in these women who are at high risk of Asherman syndrome.[2]

Intrauterine lesions may cause symptoms such as menstrual abnormalities, subfertility or miscarriage. Excision in those who are symptomatic may result in clinical improvement and is recommended in some to allow histological diagnosis, for example, endometrial polyps in postmenopausal women.[3,4,5]

The American Association of Gynecologic Laparoscopists (AAGL) advocates the removal of endometrial polyps under direct vision as gold standard and advises against blind removal with polyp forceps where possible.[4] Blind removal has been shown to have a high rate of incomplete resection (up to 59 per cent) and uterine perforation particularly where blind curettage is used.[6] Likewise, successful adhesiolysis of intrauterine adhesions and septa under direct hysteroscopic vision can be performed with a needle, hysteroscopic scissors, electrosurgery or mechanical morcellators.[7] Consequently, many consider blind curettage obsolete.[8]

The tools

Available equipment includes:

- hysteroscopic scissors and graspers;
- mechanical and electrical snares;
- monopolar and bipolar electrodes;
- resectoscopes; and, more recently,
- the mechanical morcellator.

These are all used with operative scopes, which generally have a larger outer diameter than diagnostic hysteroscopes.

Distension media and fluid-delivery

In order to appreciate the advantages and disadvantages of the available hysteroscopic tools, it is worth first mentioning the distension media used.

Gas (carbon dioxide) distention can rarely be complicated by carbon dioxide embolism. Compared to fluid, it gives inadequate views in the presence of blood and, therefore, is largely limited to diagnostic hysteroscopy.[9] Given the 'see and treat' approach of ambulatory gynaecology, this further calls into question its use in present-day practice.

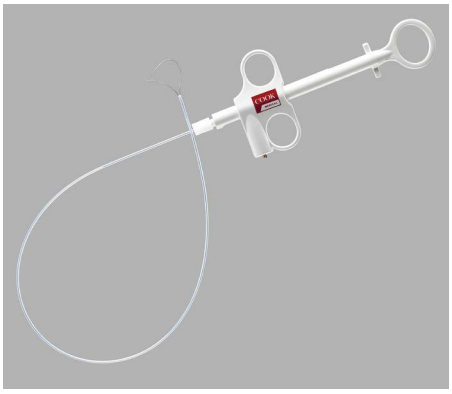
There are two commonly used fluid media: normal saline and 1.5 per cent glycine. Normal saline is the most universally used media. Although systemic absorption in large amounts may cause fluid overload, it does not result in electrolyte imbalance because it is an isotonic electrolyte-rich solution. A large maximum deficit of 2500ml is deemed appropriate, making it suitable for longer operative procedures.[9]

In addition to the risk of pulmonary oedema from fluid overload, electrolyte-free solutions (for example, 1.5 per cent glycine, three per cent sorbitol, five per cent mannitol) have the additional risk of hyponatraemia and the potentially fatal consequences of the resulting cerebral oedema.[9] Interestingly, these consequences are more likely in premenopausal women. In part, this effect can be reduced with preoperative GnRH agonists, which affect the sodium potassium pump.[9]

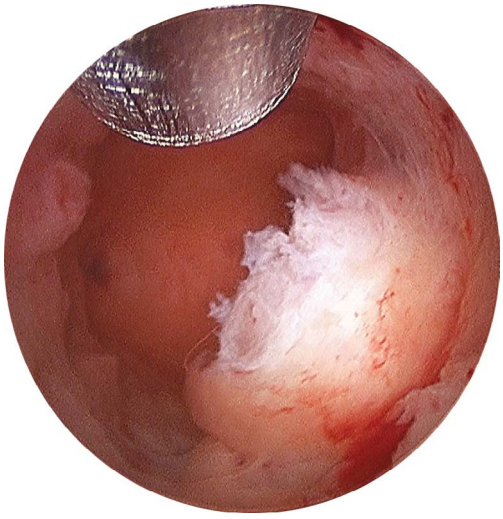
Given the potential risk of fluid absorption, monitoring fluid deficit is imperative. For diagnostic and short procedures, manual calculation is acceptable. Longer procedures, such as hysteroscopic myomectomy, have a higher risk of fluid absorption and ideally an automated delivery system should be used.[9] These systems are able to maintain a constant intrauterine pressure, measure fluid flowing in and out of the cavity and calculate the fluid deficit.[9]

Scissors and graspers

Hysteroscopic scissors and graspers are used down an operative hysteroscope and allow cold cut excision and removal of the lesion. These instruments are cheap and reusable, only requiring a five French operating channel to employ. Disadvantages include incomplete resection of polyp stalk (although recurrence rates are low at 0–4.5 per cent) and limitations related to polyp size.[5]



Disposable hysteroscopic polyp snare. (Image: Cook Medical.)



What is visualised during a procedure. (Image: Hologic.)

Snares

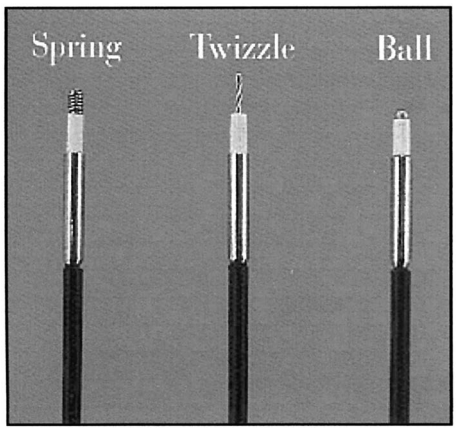
Polyp snares are generally used with operative hysteroscopes to resect polyps with or without electric current, cutting and coagulating or lassoing the polyp at the base. The polyps can be removed with the snare device, but often require polyp forceps for removal.

The Lin snare system (nickel-titanium alloy) is used with a specialised small diagnostic flexible hysteroscope. Although this technique avoids the use of electric current, analgesia or cervical dilatation, difficulty in retrieving the specimen for histological diagnosis is described.[10]

Resectoscope/electrosurgical devices

A resectoscope comprises a hysteroscope with an operative sheath down which specifically designed electrical loops are passed. Using a trigger handle, they resect tissue in a cutting fashion with either monopolar or bipolar electrosurgery. The strips of resected tissue are then removed from the cavity, usually with polyp forceps.

Whereas the conventional resectoscope used monopolar electrosurgery, newer devices using bipolar energy are available and circumvent concerns about using electrolyte-free media. Monopolar electrosurgery completes the circuit through the patient to the electrode pad or mat. An electrolyte-free media such as 1.5 per cent glycine, which is non-conductive, is required to prevent dissipation of the current. In comparison, a electrolyte-rich media, such as normal saline, is suitable for use with bipolar electrosurgery because these devices complete their own electrical circuit.



Different tipped five French Versapoint bipolar electrodes.

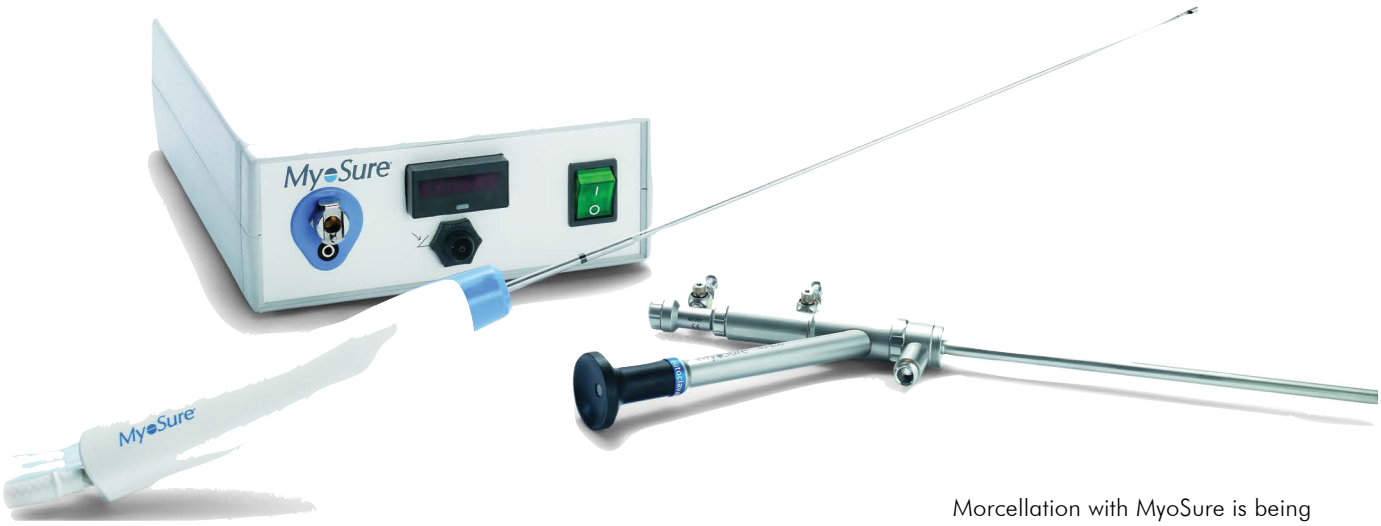
Mini resectoscopes, such as the PRINCESS™, have a small outer diameter of 7mm and have been demonstrated to be well tolerated and successful at removing endometrial polyps in the office setting.[11]

Difficulties with resectoscopes can be encountered. The use of electrosurgery heats up the distention fluid producing bubbles, which can obscure the view. The build-up of resection chips requires the passage of polyp forceps into the cavity for removal. Consequently, multiple passes of the hysteroscope are required to complete the procedure, increasing the risk of uterine perforation. In addition, the use of electrosurgery comes with the risk of thermal injury to the endometrium and, rarely, the uterus or adjacent tissues. In women with subfertility, this is obviously of concern.

Electrical resection needles, such as Gynecare Versapoint system™ and BipoTrode™, use bipolar electricity. The current passes from the tip of the device back to its own outer sleeve, cutting tissue in contact with the tip which forms part of the return circuit. Generally, graspers or polyp forceps are required to retrieve the specimen, which can require cervical dilatation.

Mechanical morcellator

The hysteroscopic morcellator was introduced in 2005 and there are several devices available (BIGATTI Shaver®, MyoSure®, TRUCLEAR™).[12] The morcellator is inserted through a specifically designed hysteroscope. It consists of two rigid tubes, an outer sheath with an operative window and an inner blade. The inner



The MyoSure system. (Image: Hololgic.)

Bipotrode bipolar electrode. (Image: Richard Wolf.)

blade oscillates when activated by a foot pedal cutting and aspirating the pathology simultaneously. The tissue is collected via the fluid delivery system, which filters the specimen into a bag. Maintaining tissue contact with the intrauterine pathology keeps procedure time to a minimum.[12] The specialised hysteroscopes operate with fluid management systems (discussed earlier) and, because the blade is mechanical use, normal saline as the distension media.[9]

There is a lack of quality data on the efficacy of mechanical morcellators; however, recent studies show promising results. A small Australian study describes the successful use of hysteroscopic morcellators to manage endometrial polyps in the outpatient setting. The resections were done under local anaesthetic using the MyoSure device. A complete resection rate of 95.2 per cent was achieved with no complications. The procedures were quick (mean time 39 seconds) and had high patient satisfaction (92.5 per cent).[13] In the UK, the National Institute for Health and Care Excellence (NICE) reviewed available efficacy outcomes for the morcellation of fibroids. Comparison to conventional resection showed equitable symptom relief at three months, reduced operating time (mean 11 versus 17 minutes) and no significant difference in fluid deficit.[14] Safety review of the morcellator estimated an adverse event rate of less than 0.1 per cent the majority of which were minor. Although complications occur these rates are lower than with conventional electrosurgical resection.[14,15]

Given current concerns regarding laparoscopic morcellation, it is worth noting that the FDA categorises hysteroscopic morcellation separately with a different risk profile.[14] The implementation of any new technology into clinical practice should be done within the process of clinical governance.[14]

Morcellation with MyoSure is being performed throughout New Zealand (within 12 of 20 district health boards) and Australia (more than 50 hospital accounts). As yet, few centres are offering this in the outpatient setting despite evidence of patient acceptability.

Comparisons

Morcellator versus electrical needle

A randomised controlled trial (RCT) has compared mechanical morcellation with the electrical resection needle (Gynecare Versapoint™).[16] When performed by an experienced operator in the outpatient setting, polyp removal with the morcellator took less time (five minutes 28 seconds versus ten minutes 12 seconds), was more likely to achieve complete polyp removal (98 per cent versus 83 per cent) and was less painful than electrical resection.[16] These findings were despite the morcellator hysteroscopes having a larger outer diameter.

Morcellator versus resectoscope

An RCT of trainees learning resection with a morcellator versus a resectoscope demonstrated a difference in mean operating time (10.6 minutes versus 17.0 minutes) and fewer scope insertions (one versus seven, respectively). Subjectively, trainees found the morcellator easier to use.[17]

Comparing morcellators

To our knowledge, there are no trials that have compared the efficiency and efficacy of different morcellators. However, a study comparing the cutting time of fibroid tissue using the TRUCLEAR and MyoSure systems demonstrated a shorter cutting time with MyoSure system.[12]

Training

When introducing new techniques,

the learning curve must be considered and compared to that of the traditional techniques they are replacing. In the previously mentioned RCT, trainees were more likely to complete morcellation independently. As a result, the authors concluded that the morcellator was a safe and effective alternative to the traditional resectoscope in inexperienced hands.[17] These newer devices allow skills in new procedures to be acquired in a safe and effective manner, despite the reduction in surgical caseload.

What is the appropriate setting for learning these techniques? The authors believe that competency in diagnostic hysteroscopy be obtained before advancing to operative procedures. How many procedures are required to gain competency? In the above RCT, trainees had performed fewer than 20 procedures entering the trial (most fewer than ten) yet 97 per cent independently performed resection with the morcellator.[17]

With the widespread adoption of newer methods, the question remains whether conventional resection techniques will become obsolete. In some units, this is already becoming the case for endometrial resection, which has been replaced with new-generation ablation devices.

Economic analysis

We have been unable to find evidence evaluating the cost effectiveness of the different resection techniques. All can be effectively performed in an ambulatory clinic setting with or without local anaesthetic. The cost of the equipment varies according to the operative scope and devices used (reusable or disposable). The cost of disposables can be prohibitive for some centres and, arguably, entirely reusable equipment is more cost effective and available.

For the small polyp and other minor intrauterine pathology, the authors advocate simple scissor and grasper techniques. For larger polyps, particularly those with a broad base, and for small fibroids, the ability to remove these in the outpatient setting we believe justifies the cost of disposable equipment, in comparison to that of an inpatient procedure.

Conclusion

There are various devices now available for safe removal of pathology under direct hysteroscopic vision. Equipment should be chosen according to the type of lesion and operator skill, considering both patient acceptability and cost. Training should aim to encompass both the simple and more advanced techniques, which with new devices should be well within the remit of a generalist gynaecologist. This will optimise the opportunity for patients to benefit from a 'see and treat' approach, ideally within the outpatient setting.

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Laparoscopic surgical tools: a review

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The journey of laparoscopy, which is now reaching single-incision and robotic surgery, began with our quest to find ways to reduce operative morbidity.[1] Since those first steps were taken, gynaecological surgery with the use of minimally invasive techniques continues to change rapidly. With computerised design and microchip-controlled safety features, the laparoscopic surgeon is dependent on the equipment and needs to understand the electromechanical function of the instruments. In this changing environment, it is vital to understand the characteristics of the commonly used surgical instruments. The basic equipment essential for any laparoendoscopic procedure includes: endoscope, camera, light source, video monitor, insufflator, trocars and surgical instruments. However, there are many variants of each available.

Disposable or reusable?

The cost effectiveness of disposable versus reusable instruments is a subject of debate. The choice of the instrument is multifactorial and depends on function, reliability and cost. So, during most laparoscopic procedures, a combination of disposable and reusable instruments is used. Frequently, disposable trocars and scissors are used, while reusable instruments can be graspers, coagulation spatula/hook and needle drivers. The commonly used laparoscopic instruments are described below.

Uterine manipulators

These allow uterine positioning and expand operating space. Several uterine manipulators are available – the HUMI® (Cooper Surgical), the RUMI® (Cooper Surgical), Spackman, Cohen, Hulka, Valtchev, Pelosi and Clearview® (Endopath). Some are reusable while others are disposable. Most come with a channel to perform chromotubation; however, some (such as Hulka tenaculum and Pelosi) lack this channel. With 210°, Clearview has the greatest range of motion in the anterior-posterior plane. Hulka tenaculum, Spackman's and Cohen's have a straight shaft, hindering their range of motion and limiting their use in advanced laparoscopic procedures.[2]

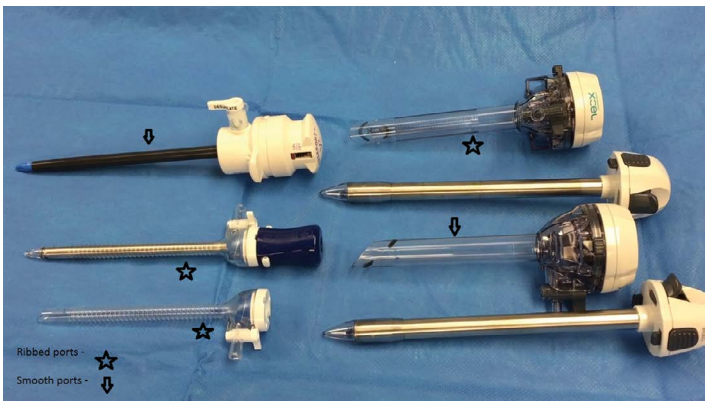

Figure 1. Trocar sleeves or collars with different textures.

Veress needle

This is a specially designed needle with a blunt-tipped, spring-loaded inner stylet and a sharp outer needle, used to achieve pneumoperitoneum while performing closed laparoscopy. It is available in disposable and reusable form, with 12cm or a 15cm length.

Most injuries in minimally invasive surgery are associated with primary port insertion, leading to an unresolved debate on the benefits of various entry techniques (open, closed or direct entry). There is no evidence that any single technique is better in preventing major vascular or visceral complications, though there is a higher risk of failed entry with closed entry. The most recent Cochrane review concluded there is a lower risk of vascular injury with the direct entry in comparison to use of Veress needle.[3]

Trocars/cannulas

These are used to create small passageways through the abdominal wall and are available in different textures (see Figure 1). Disposable and reusable trocars in various sizes are available and share the following common parts:

- Sharp tips cut an entry path through the abdominal wall while blunt tips stretch the tissues apart to gain access to the peritoneal cavity.
- Sleeve: is the working channel. Trocar sleeves or collars can have textures on the outer surface of the trocar that help it anchor to the abdominal wall. Some have an internal inflatable balloon at their tip and plastic/rubber ring to provide anchorage.
- Valve: different valve systems prevent gas leaking from trocars and allow the insertion of instruments.
- Side port: many trocars come with a side port that allows for gas insufflation or smoke evacuation.

Laparoscopes

The telescopes used in laparoscopy are available in sizes ranging from 2mm up to 12mm. The 10mm size is the one most commonly used in gynaecology. Similar to a hysteroscope, a laparoscope can come with

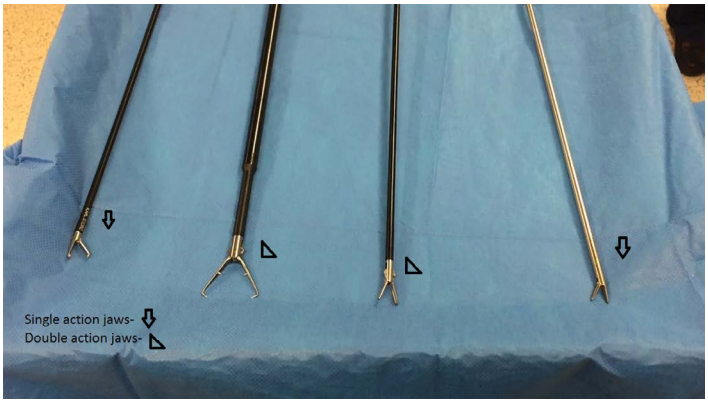

Figure 2. A range of grasper jaws.

an angle of view such as 0°, 30° or 45°. In an angled-view scope, the direction of vision points away from light source attachment. The 0° telescope offers a forward view corresponding to the natural approach and is preferred by most gynaecologists. It is useful if a less-experienced assistant is available. The 30° telescope can be rotated to enlarge field of view and can be advantageous for complicated cases. The 45° telescope is useful in single-incision laparoscopies, but is not commonly available. Every laparoscope has an engraved number by the eyepiece that specifies the viewing angle.

Instrument dimensions

The commonest diameter for laparoscopic instruments is 5mm, though they range from 2–12mm. The narrower diameter (less than 5mm) instruments have less shaft rigidity and therefore are more flexible and more fragile than the wider versions. Standard instruments' length ranges from 34–37cm. In bariatric patients or for single-site laparoscopy, 45cm-long instruments are useful.

Non-energy devices

Most laparoscopic instruments offer only four degrees of freedom of movement: in/out, up/down, left/right and rotation. In addition, certain devices called articulating/roticulating instruments offer angulation at their tips, which can be particularly useful in achieving triangulation while performing single-incision laparoscopy.[4]

Graspers and scissors usually have an insulated sheath, a central working device, a handle and a rotating capability at the working end.

Ringed handles are similar to the conventional ring handle found on most needle holders used in open surgery. They can be in line or directed 90° in relation to the working axis. Some handles are in between these two:

- a pistol handle allows integration of several functions; and
- a co-axial handle is in the instrument axis.

The handles come with different types of ratchets that provide a locking mechanism.

Scissors with curved tips, analogous to Metzenbaum, are commonly used. Most endoscopic scissors can also be attached to the electrosurgical unit. Scissors are produced with variety of tips.

Grasper jaws (see Figure 2) are either are single action (one fixed jaw and one articulated jaw) or double action (both jaws articulated). Single-action jaws close with a stronger force ideally suited for an instrument such as a needle driver. Double action allows the jaws to open wider, so they are better suited as a dissection tool. Numerous grasper variants exist, with the inner side of the jaws having different surface properties, depending on the intended use:

- Traumatic: deep serrations or toothed tip for secure grasping.
- Atraumatic: finely serrated for gentle handling.

Equally, laparoscopic tenacula are also available with single-toothed and double-toothed jaws.

Many styles of needle drivers are available and selection largely depends on surgeon's preference. The jaws are either curved or straight. They commonly have a flat or finely serrated grasping surface, enabling them to grasp the needle in all directions. Certain needle-holders (termed self-righting) have a dome-shaped indentation inside their jaws that automatically orientates the needle in a perpendicular direction, thus making it easier to grasp the needle. However, if there is a need to load the needle at an oblique angle, the indentation can make it harder. The needle drivers also have various types of handles (such as finger grip, palm grip, pistol grip) as described previously.

Myoma screws are in the shape of a probe with a corkscrew tip. They are frequently used during myomectomy.

The suction irrigator is a multipurpose piece of equipment. Most use a trumpet valve but some have a sliding valve. The irrigation system can be powered by various mechanisms including pressure bag or a pump. Omentum, fallopian tube or bowel can get drawn into the suction probe and care must be taken to release the attached tissues gently.

The aspiration needle is a 16/22-gauge needle used for aspiration and injection of fluids.

There are two types of knot pushers available: the closed-end and the open-end knot pusher. Both have their advantages and disadvantages.

Energy devices

Energy sources include monopolar, bipolar, advanced bipolar, harmonic, combined and morcellator devices. Monopolar devices are commonly used in endometriosis resection and for incising the vaginal cuff during laparoscopic hysterectomy. Various types of monopolar hooks and spatula are available and most scissors have an attachment to connect monopolar lead.

Bipolar devices contain the continuous waveform electrical current between the jaws of the forceps and hence reduce the chances of damage to adjacent tissue. They achieve tissue sealing and haemostasis by thermal coagulation, though they lack the ability to cut. The classic bipolar device is the Kleppinger bipolar forceps. Several types of bipolar devices, many of them in form of graspers, are now available.[5]

The surgical evolution of the energy devices, particularly with advanced bipolar features, has been the central point in exponential growth of laparoscopic procedures. The gain in popularity of these devices can be gauged by the fact that they are sometimes now used for open surgery and even vaginal surgery.[6]

Bipolar devices (such as LigaSure™, Gyrus PKS™ and EnSeal®) provide haemostasis for vessels up to 7mm. They provide a low voltage, have an impedance-based feedback that modifies the energy delivered and tissue temperature is regulated to be

below 100°C. The bipolar energy thus delivered denatures the collagen and elastin in vessel walls. Denatured tissue, tissue apposition and pressure seal the vessel walls in a process called coaptive coagulation. In comparison to the traditional bipolar instruments, these devices have reduced thermal spread, diminished charring and reduced sticking. However, some of these devices require a specialist electrosurgical unit and they are costly.[7]

LigaSure (Covidien) provides a continuous bipolar waveform and has an integrated cutting mechanism. GyrusPK (Gyrus ACMI) delivers a pulsed bipolar waveform that allows tissue and device tip to cool during the energy off phase, but lacks the ability to cut. Enseal (Ethicon) has nanometre-sized conductive particles that direct the energy and control temperature between the jaws. Like LigaSure, it is multifunctional, with an I-Blade™ to cut the sealed tissue.

Harmonic devices have a piezoelectric crystal in their handpiece that converts the electrical energy into ultrasonic energy. This energy is delivered to the active blade at the tip of the instrument causing it to vibrate at 55 000Hz. The tip of the device cuts mechanically with a degree of collateral thermal coagulation used for haemostasis. There is no active current in the tissue. The advantage of harmonic devices is lower temperature (<80°C) as compared to other energy devices, hence reduced thermal spread and less charring. As a result of mechanical vibrations, in lower density tissue the intercellular water is vaporised at lower temperatures (<80°C) causing a 'cavitation effect' that can help in dissection by separating tissue layers. They are FDA approved for <5mm vessel sealing. Though harmonic devices operate at low temperatures, the active blade of the device becomes very hot and can remain so for some time. Care should be taken not to touch the vital structures with the jaws of the device for several seconds after activation.

Thunderbeat® (Olympus) combines both advanced bipolar electricity and ultrasonic energy in a single, multi-functional, hand-activated instrument and can potentially reduce the surgical time.

Morcellators can be important tools for specimen removal during procedures, such as myomectomy, when a large amount of tissue is retrieved laparoscopically. Various types of morcellators are available on the market. The key safety maxim is to keep morcellator tip close to abdominal wall, to pull the tissue into the morcellator and not push the morcellator into the tissue. Morcellators require ports that are bigger than 5mm. Morcellation has recently been in news with a US Food and Drug Administration safety communication in 2014 swiftly followed by new and/or revised guidelines, including a joint statement by AGES and RANZCOG. To prevent tissue dissemination, power morcellation in an isolation bag has been proposed. Recently, an in-bag morcellation device (Alexis™ Contained Extraction System) has also been made available.[8,9,10]

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Laparoscopic energy sources

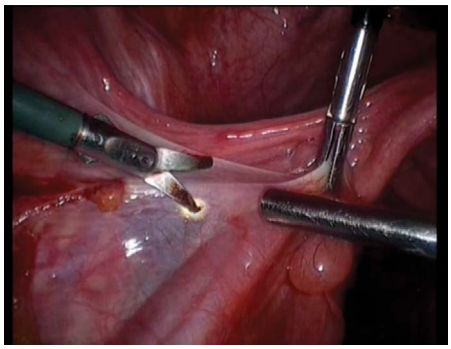

Figure 1. Monopolar scissors – tissue effect vaporisation (non-contact mode, cut waveform).

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Today's surgeons are spoilt for choice when it comes to laparoscopic energy sources, a market where there has been significant change over the last decade. Furthermore, new instruments often arrive accompanied by much fanfare and hype. Unfortunately, many of the laboratory and clinical data on new energy sources are from studies undertaken, or sponsored by, the manufacturer; data from randomised trials are often unavailable.

Irrespective, it remains the responsibility of the surgeon to acquire knowledge on the range of tissue effects available with various laparoscopic energy sources, how these devices impart their tissue effects, and the associated benefits and risks for each device. Hence, it is not an easy task for surgeons to make decisions about the energy sources they choose to use for operative laparoscopy. To this end, the American College of Surgeons has introduced a compulsory laparoscopic energy source module for trainees – Australasia will probably follow suit in the not-too-distant future.

This article provides a summary of the main laparoscopic energy sources used in Australasia; how they work, what advantage(s) they provide over other energy sources and how they can be used safely. An attempt is also made to crack the old chestnut of which laparoscopic energy source is best.

Table 1. The main classes of laparoscopic energy sources and their tissue effects.[2]

Energy source	Tissue effects
Monopolar electrosurgery	Vaporisation, fulguration, desiccation, coaptation*
Conventional bipolar electrosurgery	Desiccation, coaptation
Advanced bipolar electrosurgery**	Desiccation, coaptation, blade tissue transection
Ultrasonic technology	Desiccation, coaptation, mechanical tissue transection

**Vessel sealing achieved with coagulation and compression. **Tissue impedance monitoring optimises activation time.*

Monopolar electrosurgery

All electrosurgery is 'bipolar' inasmuch as the electrical current flows from one pole or electrode to another. In monopolar electrosurgery, the active electrode is one pole and the patient return electrode is the other. The main difference between monopolar electrosurgery and the other energy modalities is that electrical current flows through the patient. This difference avails the greatest range of tissue effects to monopolar electrosurgery.[1,2]

The tissue effects available with monopolar electrosurgery include vaporisation (tissue destruction and cutting), fulguration (tissue destruction and small vessel haemostasis), desiccation (cell wall rupture and cytoplasm boiling) and coaptation (vessel sealing owing to denaturation and renaturation of proteins) (see Figure 1; Table 1).[2] These tissue effects are primarily achieved using the 'cut' or 'coag' electrosurgical unit (ESU) settings while contacting or not contacting the target tissue (see Table 2).[3] Varying other parameters under the surgeon's control, such as power setting, duration of activation and electrode configuration, can further modify the desired tissue effect.[1-3] The scissors configuration in monopolar surgery allows the greatest tissue dissection capability, adding tissue plane dissection and cold cutting to the repertoire.[3]

All energy sources generate tissue temperatures well above 45°C, the

Table 2. Monopolar electrosurgery tissue effects.[3]

Tissue effect	Surgical effect	Current waveform	Contact with tissue	Characteristics
Vaporisation	Cutting	Continuous (cut)	No contact	Low-voltage sparks, moderate smoke
Fulguration	Haemostasis of small vessels (<1mm)	Interrupted (coag)	No contact	High-voltage sparks, significant smoke and charring
Desiccation	Haemostasis of small vessels (<1 mm)	Continuous (cut) or interrupted (coag)	Contact	Similar action to bipolar electrosurgery, pronounced lateral thermal spread
Coaptation	Sealing of small to medium vessels (<2mm)	Continuous (cut) or interrupted (coag)	Contact and compression of vessel wall	Similar action to bipolar electrosurgery, pronounced lateral thermal spread

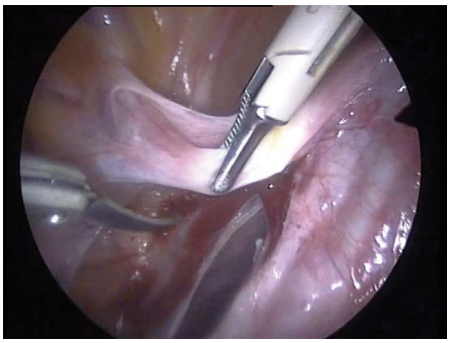

Figure 2. Bipolar forceps – tissue effect desiccation.

temperature at which irreversible cell damage occurs. Tissue temperatures with monopolar electrosurgery are ~100°C, 100–200°C and >200°C for desiccation (and coaptation), vaporisation and fulguration, respectively. Other laparoscopic energy sources are limited to tissue effects of desiccation and coaptation, and they also generate tissue temperatures of ~100°C.[1,4]

The major disadvantage of monopolar electrosurgery is the rare but unavoidable risk of stray current injury (SCI). These injuries are often not noticed during surgery as they usually occur outside of the surgeon's field of vision. They are not owing to surgeon error or lack of skill. Instead, the physics (that is 100 per cent reproducible) is to blame. Used in contact mode, there

Figure 3. LigaSure (blunt tip) advanced bipolar device. A cutting blade is incorporated into the instrument tip.

is the risk of lateral thermal spread injury to adjacent structures with monopolar electrosurgery, just as for all energy sources that yield tissue effects of desiccation and coaptation. Smoke production during monopolar electrosurgery may be problematic, especially during fulguration.[3]

So, monopolar electrosurgery is a relatively inexpensive, readily available and versatile energy source that yields the best range of tissue effects. Despite the small risk of SCI, this modality remains in common use in conventional laparoscopy, as well as in robot-assisted and single-port laparoscopy.

Conventional bipolar electrosurgery

In bipolar electrosurgery (including advanced bipolar modalities), the active and return electrodes are the two jaws of the energy source. In 1974 Rioux and Cloutier, in North America, and Frangenheim, in Germany, introduced bipolar electrosurgery as a means of eliminating the risk of SCI that had been observed with monopolar electrosurgery, while at the same time a means of sealing larger vessels was born.[5] In bipolar electrosurgery, electrical current passes through the tissue held between the jaws of the instrument, not through the patient, and results in tissue desiccation and vessel coaptation in an analogous fashion to monopolar electrosurgery performed in contact mode. Alternating current is standard output for ESUs and it is this physical property that results in efficient sealing of vessels with bipolar electrosurgery, via change of direction of current flow through the tissue compressed between the instrument jaws, as orientation of the active and return electrodes rapidly alternates (see Figure 2).[6]

A major advantage of conventional bipolar over monopolar electrosurgery is the ability to seal (coapt) vessels up to ~5mm in diameter (monopolar contact mode and fulguration mode would generally be reserved for vessels 1–2mm and <1mm in diameter, respectively). The dissection capability of the bipolar forceps is good, especially in the Maryland configuration. Bipolar electrosurgery is generally available and relatively inexpensive. Disadvantages of bipolar electrosurgery include: lateral thermal spread that will continue until device activation is ceased; no audio signal from the ESU to inform the surgeon when desiccation or coaptation is complete, which increases the risk of injury from lateral thermal spread as well as tissue charring and tissue adherence to the instrument jaws; and the need for another instrument, such as a laparoscopic scissor, for tissue cutting.[6]

Figure 4. EnSeal advanced bipolar device. Note the retracted copper-colored transection blade at the jaw hinge.

Figure 5. PKS Lyons Dissecting Forceps advanced bipolar device. This is non-bladed, although other instruments in this range offer a cutting mechanism.

Advanced bipolar electrosurgery

In addition to the features of conventional bipolar electrosurgery, advanced bipolar energy sources are revolutionary in several ways. Firstly, a propriety ESU using a computer-controlled tissue feedback system controls each device, the main players in the Australasian market being LigaSure (see Figure 3; Covidien), EnSeal (see Figure 4; Ethicon) and PlasmaKinetic System (PKS), that is, Lyons Dissecting Forceps (see Figure 5; Gyrus ACMI). The tissue impedance is monitored with continuous adjustment of the generated voltage and current to maintain the lowest possible power setting to achieve the desired tissue effect, at which time an audio signal alerts the surgeon that the endpoint has been reached. In this way, the risk of lateral thermal spread as well

Figure 6. Harmonic ACE+ ultrasonic energy source.

Figure 7. LigaSure Advance hybrid monopolar and bipolar energy source. The monopolar active electrode is at the end of the instrument's blue jaw.

Figure 8.Thunderbeat hybrid ultrasonic and advanced bipolar energy source.

as charring of the tissue and adherence of tissue to the device jaws (all of which are more likely with prolonged device activation) is minimised.[3]

Secondly, these energy sources were the first to be approved by the US Food and Drug Administration (FDA) to seal vessels up to 7mm in diameter owing to technological advances such as: tissue impedance monitoring up to 4000 times per second (LigaSure); temperature-sensitive material in the device jaws that optimises tissue temperatures at ~100 °C (EnSeal); delivery of pulsed energy with continuous feedback control to prevent tissue overheating (PK System); and jaw design that optimises mechanical compression to the vascular pedicle (LigaSure, EnSeal).[2,6] Although the ability of these newer devices to seal vessels up to 7mm in diameter is unquestioned, the expected minimisation of lateral thermal spread injuries owing to these technologies has yet to be proven in clinical trials.

The tissue effects available with advanced bipolar electrosurgery are owing to the conversion of electrical energy into thermal energy and include tissue desiccation and coaptation (vessel sealing), just as for conventional bipolar electrosurgery and contact monopolar electrosurgery.[3,6] Some devices incorporate a cutting blade into the device jaws (LigaSure, EnSeal) that decreases the need for a laparoscopic scissor. The bulky jaws of such devices, however, are generally inferior dissectors compared to Maryland forceps. Indeed, the PKS Lyons forceps has the advantage of advanced bipolar electrosurgery with good dissection capability, but does require an additional laparoscopic scissor for tissue cutting. Hence, the decision to use a particular bipolar device may come down to dissection capability versus instrument traffic. Although advanced bipolar energy sources are relatively expensive, they are generally available in most hospitals.[3]

Ultrasonic devices

The first ultrasonic energy source was described in 1993 by Amaral, called the 'laparoscopic scalpel'; it had the dual functionality of tissue cutting and vessel sealing.[6] Ultrasonic energy sources convert electrical energy into vibrations in the handpiece of the device at frequencies more than 20 000 cycles per second, that is, above the audible range. These vibrations oscillate the non-articulating jaw of the instrument. Tissue is compressed between an articulating jaw and the non-articulating jaw to impart the tissue effects derived from combination of thermal and mechanical energy: desiccation and vessel sealing is achieved at lower frequencies; and tissue cutting occurs at higher frequencies. The tissue effects arise owing to the conversion of electrical energy into thermal energy for tissue desiccation and vessel sealing, and also mechanical energy for the tissue cutting. As for the other energy sources, the generated tissue temperature is ~100°C to achieve dessication and coaptation; hence, lateral thermal spread injury is possible with ultrasonic energy sources.[2]

The laparoscopic ultrasonic devices in the Australasian marketplace include the Harmonic ACE+ (see Figure 6; Ethicon) and Sonocision (Covidien), which are both rated by the FDA to seal vessels 5mm in diameter. The Harmonic ACE+ has 'Adaptive Tissue Technology' that provides an audio signal to the surgeon when changes in the target tissue are noted – this is an indirect assessment and less reliable than the tissue capacitance monitoring used by advanced bipolar devices to indicate endpoint has been achieved. More recently, the Harmonic ACE+7 has been released that incorporates an 'advanced haemostasis' mode where an algorithm controls the phases of pre-heating, vessel sealing and tissue transection. Specifically developed for larger vessel sealing and cutting, this device has been rated by the FDA to seal vessels up to 7mm in diameter.[3]

The tissue effects obtained with ultrasonic energy are essentially the same as those achieved with contact monopolar electrosurgery or bipolar electrosurgery, with the added function of tissue cutting. These tissue effects are achieved without the passage of electric current through the patient or the tissue grasped by the device.

Advantages of ultrasonic devices include less instrument traffic, owing to the combination of vessel-sealing and tissue-cutting, and less smoke generation (a 'mist' of tissue debris and moisture results rather than smoke per se). The dissection capability is good, but less than that of monopolar scissors or Maryland bipolar forceps. Disadvantages include the risk of lateral thermal spread injuries, as well as higher and more prolonged instrument tip temperatures than other energy sources which could potentially result in organ injury. Also, the cutting mode, in particular, requires training and experience. As for all new-generation energy sources, ultrasonic devices are relatively expensive, but generally accessible in most institutions.

Hybrid devices

Laparoscopic devices have recently been developed that combine several energy source technologies. These include LigaSure Advance (see Figure 7; monopolar and bipolar electrosurgery; Covidien), and Thunderbeat (see Figure 8; ultrasonic and bipolar technologies; Olympus). Incorporation of multiple functionalities into a single device may reduce instrument traffic and the overall cost, although such benefits should be a secondary consideration if the individual functionalities are compromised in the hybrid configuration. Good-quality studies on the efficacy and safety of the hybrid devices are lacking.[6]

The dangers of energy sources

Injuries owing to laparoscopic energy sources can be divided into two groups. Firstly, there are injuries owing to surgical misadventure that occur within the surgeon's field of vision. These include iatrogenic injuries (that is, 'I did it' – a mistake by the surgeon) and lateral thermal spread injuries (lateral thermal spread occurs with all energy sources). Secondly, there are stray SCIs that may be owing to capacitive coupling, insulation failure and direct coupling. These injuries occur outside the surgeon's field of vision and are not owing to surgeon error.[6]

During the infancy of monopolar electrosurgery it was quickly realised that the passage of alternating current through the patient resulted in muscle contraction, cardiac arrhythmia and often death. The French biophysicist D'Arsonoval subsequently discovered, in 1891, that it is possible to pass high-frequency alternating current (<20 kHz) through the body without life-threatening ramifications.[7] In 1928, the American neurosurgeon Cushing and physicist Bovie introduced their ESU that incorporated all the knowledge of the day about monopolar electrosurgery, namely, electrical energy, high-frequency alternating current with continuous and interrupted waveforms, time of application, power settings and electrode size. Their ESU remained essentially unchanged until the addition of bipolar electrosurgery technology in the 1970s.[7]

Although many energy sources have been introduced since the advent of laparoscopic surgery, monopolar electrosurgery remains a commonly used and cost-effective modality. However, it is unfortunately a not-infrequent cause of unexpected injury. It is estimated that injuries owing to electrosurgery occur in 0.1–0.5 per cent of laparoscopic procedures.[8] Bowel injuries owing to laparoscopy are thought to have an incidence of 1.3 per 1000 cases and, of these, half are thought to be owing to electrosurgery.[9] Many, if not all, of these injuries could be prevented if surgeons understood the physics of monopolar electrosurgery and used the available technology.

Principles of monopolar electrosurgery

Current pathway

In monopolar electrosurgery, electrical current passes from the ESU to the active electrode, then through the patient to exit via a dispersive electrode, ultimately reaching 'electrical ground'. The potential for SCI arises because electricity within the patient will take whatever pathway it can to the return to ground, including via unintended tissue targets.[1,7]

Fortunately, the risk of one type of SCI – the so-called alternate path injury where burns result owing to the passage of electricity through unexpected paths as it exits the patient (for example at attachment points of ECG electrodes [see Figure 9], or contact points between the patient and metal parts on the operating table) – was virtually eliminated in 1970, with the introduction of adhesive patient return electrodes connected to an isolated electrical ground within the ESU.[1,4,7]

Current density

The tissue effects of monopolar current relate to the current density in the tissue. Hence, focused current from the active electrode enters the patient at the site of surgery to yield a tissue effect whereas current exiting the patient via a dispersive return electrode only results in a clinically insignificant rise in tissue temperature. An injury can occur at any part of the circuit if the current density is high enough. For example, burns have previously occurred at the patient return electrode owing to poor contact with the patient's skin, resulting high current density at the current exit point (see Figure 9). Happily, since the development of a patient return electrode that incorporates an interrogation circuit to monitor impedance increases at this site (resulting in immediate shutdown of the ESU if detected), there has not been a single verified episode of a patient return electrode burn since 1980.[1,4,7]

At the active electrode (or at the site of an insulation failure) a surprisingly low amount of energy is needed to cause a small bowel injury (~1mA/cm^2). Consequently, the use of high power settings will also increase current density and the risk of inadvertent injury.

Waveforms

The available waveforms in monopolar electrosurgery are 'cut', 'coagulation' and 'blend'. It is important to recognise that these terms do not imply a particular tissue effect, for example, the tissue effect is different when cut waveform is used in either contact or non-contact mode, yielding desiccation or vaporisation, respectively (see Table 2). Cut waveform is a continuous sinusoidal waveform with current flowing 100 per cent of the time, coagulation waveform is an intermittent or 'damped' waveform where electrical current is only delivered six per cent of the time and is off 94 per cent of the time, and blend waveforms are also intermittent waveforms, but with higher 'on:off'

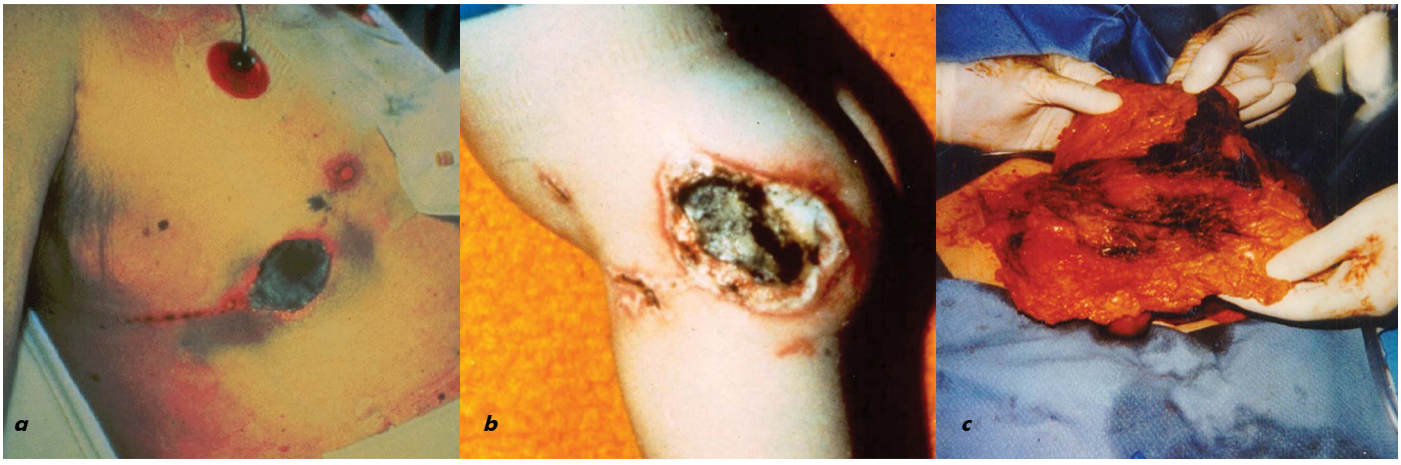

Figure 9. Types of electrosurgical injury: a) alternate path injury through an ECG electrode; b) patient return electrode burn; and c) insulation failure SCI of omentum and underlying small bowel. Types a) and b) are prevented by the mandatory use of dual-function patient return electrode pads; while entirely preventable with available technology, type c) remains a small but ever-present possibility as AEM is not mandatory.

ratios. As the coagulation waveform is intermittent, a higher voltage is needed to deliver the same current to the tissue in a given time period than with cut waveform. High voltages predispose to arcing from the active electrode (or site of insulation failure) and therefore increase the risk of injury from 'stray electric currents'. High voltages also predispose to the phenomenon of capacitive coupling.[1,4]

Capacitance

In simple terms, a capacitor is formed when two conductors are separated by an insulator (or dielectric). The role of the capacitor in an alternating current circuit is to conduct electrical current across the insulator. Monopolar instruments within laparoscopic ports act as capacitors: the active electrode is one conductor, the port (or biological fluid) is the other conductor and the dielectric separating the conductors is the instrument's insulation layer. As the capacitive resistance of a capacitor is inversely proportional to the frequency of the alternating current through the circuit, the high current frequencies produced by the ESU (0.5–33 MHz) result in a low capacitive resistance.[7]

Mechanisms of SCI

Capacitance coupling

The high-frequency alternating current used in monopolar electrosurgery and the relatively thin instrument-insulation layer allows capacitance coupling to occur, where current from the active electrode is transmitted across the intact insulation layer (up to 62 per cent of the current delivered to the device) to another conductor nearby.[10] Any nearby tissues that contact the secondary conductor are at risk of SCI. The secondary conductor could be the metal laparoscopy port – fortunately, in this scenario, the capacitive coupling current disperses safely throughout the anterior abdominal wall as it is generated.[4] More concerning is the scenario with plastic laparoscopic ports: biological fluid coating the surface of the insulation layer can act as the secondary conductor and the plastic port prevents the safe dispersal of the capacitive current through the abdominal wall. In this situation, the risk of capacitive coupling injury is theoretically higher. As most hospitals have made the move to plastic laparoscopic ports, the risk of electrosurgical injury owing to capacitive coupling is an ever-present danger during laparoscopy (see Figure 10).

Insulation failure

Only a thin insulation layer surrounding the active electrode of monopolar devices protects the patient from SCI. Insulation failure occurs at sites of micro-fractures in the insulation layer, most likely owing to capacitive coupling current (and wear and tear, including the sterilisation process for reusable devices). Studies have shown between 19 and 39 per cent of re-usable hospital instruments have insulation failures.[11,12] Routine sterilising department checks such as visual inspection and 'HiPot' testing are clearly poor predictors of insulation integrity at the end of the procedure. In addition, one of these studies showed three per cent of disposable instruments were also found to have insulation defects post-procedure.[12] So, new instruments offer some, but not complete, protection against insulation failure. The most common insulation failure is a micro-breakage, which is not visible to the naked eye – these small defects allow electrical current leakage of very high density, capable of producing a full-thickness visceral injury (see Figure 10).

Direct coupling

Direct coupling injury occurs when stray current from capacitive coupling or insulation failure is transmitted through another candidate to cause tissue damage. In this scenario, the laparoscope is the most likely conductor to contact other instruments and adjacent tissues.

Robot-assisted and single-port laparoscopy

The popularity of monopolar electrosurgery has been maintained with the evolution of robot-assisted and single-port laparoscopy. The risk of SCI with single-port laparoscopy and robot-assisted (particularly single- versus multi-site) laparoscopy is increased, primarily because of the surgeon's decreased field of vision and increased risk of instrument contact/clashing. The latter increases the risk of all of capacitive coupling, insulation failure and, in particular, direct coupling SCIs.[17]

Diagnosis of electrosurgical injuries

SCI sustained during monopolar electrosurgery at laparoscopy is often not apparent, for example, one study reported that 69 per cent of bowel injuries were unrecognised at the time of surgery.[2] The most likely explanation for this is the site of injury is usually outside the field of vision of the surgeon. These injuries typically do not present for seven to ten days after surgery. It is imperative that bowel perforation is diagnosed rapidly as it can be associated with a mortality of up to 25 per cent. Bowel perforation (and particularly small bowel perforation) may not result in overt peritonitis in the early stages, having a more indolent presentation of a low-grade temperature, moderately increased abdominal discomfort and a failure to recover at the usual rate. In this scenario a high index of suspicion of visceral injury is necessary with early investigation and early return to theatre as necessary. Delay in diagnosis substantially increases morbidity and mortality.

Prevention of SCI

As per the above discussion, the likelihood of SCI can be reduced by: using the lowest power settings possible and shortest activation times; using 'cut' rather than 'coagulation' waveform when possible; the avoidance of tissue contact by the instrument shaft (outside the surgeon's field of vision); the avoidance of contact with

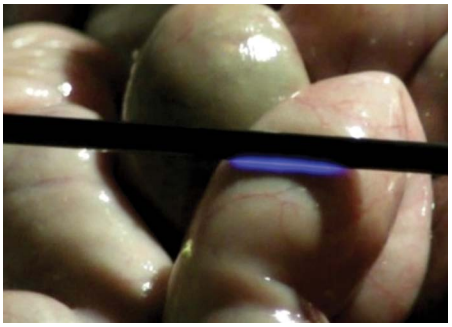

Figure 10. An animal surgery showing capacitive coupling current along the shaft of a monopolar energy source (with intact insulation) arcing to the small bowel.

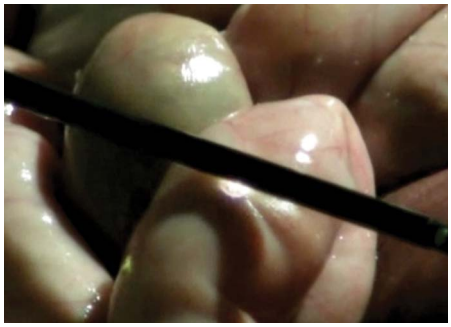

Figure 11. Insulation failure demonstrated at an animal surgery with current from the shaft of the monopolar energy source arcing to the small bowel.

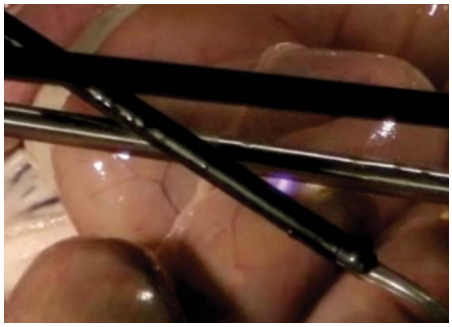

Figure 12. Direct coupling demonstrated at an animal surgery with current leaking from an insulation failure in the active electrode to the laparoscope, and then to the bowel.

Figure 13. AEM utilises a proprietary box in concert with the ESU and reusable energy sources of which there is wide choice.

other instruments, including the laparoscope (outside the surgeon's field of vision); and using metal laparoscopic ports. None of these measures, however, can completely eliminate the risk of SCI.[1,4]

Active Electrode Monitoring (AEM) was invented by Roger Odell, a former Valleylab electrical engineer, and has been commercially available since 1991 (Encision Inc). This technology performs two important tasks: capacitive coupling current is continuously channelled back to the ESU via the energy source; and an interrogation circuit triggers instant shutdown of the ESU if an insulation failure is detected.[1,4,7,13] AEM is an inexpensive and available technology that uses purpose-made reusable laparoscopic instruments controlled by a proprietary box used in concert with the standard ESU (see Figure 13). AEM prevents SCI. Indeed, since the introduction of AEM, not a single SCI has been verified in surgeries that have used it. The routine use of AEM has been highly recommended by many regulatory and professional bodies.[1,14-16] Disappointingly, the uptake of AEM in Australia and New Zealand has been low, primarily because of a lack of understanding of the technology, and a misguided belief that the technology is unnecessary. It is also important to recognise that lateral thermal spread occurs during the normal use of all laparoscopic energy sources. AEM cannot prevent lateral thermal spread injuries, just as it cannot prevent surgical errors.

Conclusion

Along with the ability to vaporise, fulgurate and desiccate tissue, as well as seal and transect vessels, the 'ideal laparoscopic energy source' should be capable of fine tissue grasping and sharp tissue dissection, and contain AEM technology. In addition, the combination of these functions should not come at the cost of compromising the functionality of the individual modalities.

Clearly, the ideal will not become reality any time soon!

So, which energy source should the laparoscopic surgeon use? It is clear that the advent of advanced bipolar and ultrasonic vessel-sealing devices, including the hybrid energy sources, has revolutionised laparoscopy. However, despite the array of different technologies and capabilities on offer, in the battle of the vessel sealers, no clear winner has yet been decided.[6] In any case, a reliance on monopolar electrosurgery persists because of its versatility; namely, the range of tissue effects and dissection capabilities. Conventional bipolar electrosurgery, too, continues to play a visible and important role.

Hence, it is likely that the surgeon will rely on two or more laparoscopic energy sources (or hybrid instruments incorporating multiple technologies) depending on the cost and availability of the devices (and their proprietary ESUs), personal preference and experience, the surgical procedure to be performed, and the presence or absence of significant pathology in the surgical field.

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Haemostatic agents in surgery

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Management of bleeding is a fundamental consideration in all surgery, so much so that many surgeons take it for granted. Effective control of bleeding is necessary to minimise the adverse physiological sequelae of surgery that affect recovery, including the need for transfusion, and also to optimise the view of the surgical field thereby reducing the risk of surgical complications. Being able to see what you are operating on reduces time taken for surgery, minimises the risk of inadvertent injury to the patient and reduces the chance of needlestick injuries. Key strategies for adequate haemostasis include ensuring the best pre-operative preparation for patients, good anaesthetic support and attention to surgical technique. Yet, despite every effort, bleeding can still complicate surgical procedures. Haemostatic agents are commonly employed to assist with the control of bleeding; this article aims to provide some background to the physiological basis of local and systemically administered haemostatic agents.

Haemostasis

If the aim is to stop bleeding, it is important to understand the normal physiological mechanisms that lead to clotting. Haemostasis results from a complex interplay of factors involving the blood vessel wall, coagulation factors and platelets (see Figure 1). Primary haemostasis promptly follows injury to the vessel endothelium: the injured vessel constricts, platelet factors are released and platelets stick together, and form a soft plug that temporarily reduces further blood loss. Platelets aggregate because they are activated by thrombin.

Once activated, the platelets release a number of potent vasoactive factors that play a role in the 'coagulation cascade' (see Figure 2). Generation of fibrin provides a framework over the relatively loose platelet plug, stabilising it. Two different arms in the coagulation cascade – the intrinsic pathway (initiated by endothelial damage) and the extrinsic pathway (initiated by transection of vessels) – both lead to a final common pathway, shown diagrammatically in Figure 2. It is important to recognise that the cascade can stall when one of the participant molecules is absent, such as can occur in the congenital haemophilias, or with the action of warfarin, and when the concentration of platelets is low.

Surgical haemostasis

There are a number of approaches to haemostasis during surgery. Primary methods include mechanical actions, such as ligation of vessels and direct pressure with packs and gauzes, and the use of energies, such as diathermy (either mono- or bipolar), ultrasound and laser. However, these methods will not necessarily achieve haemostasis to a suitable level and other methods may need to be considered. These may be either topical or systemic agents. The topical agents include:

- passive haemostats based on collagen, cellulose and gelatins;
- active agents based on thrombins; and
- sealants such as fibrin-based sealants and synthetic glues.

The systemic agents include tranexamic acid and activated factor VII.

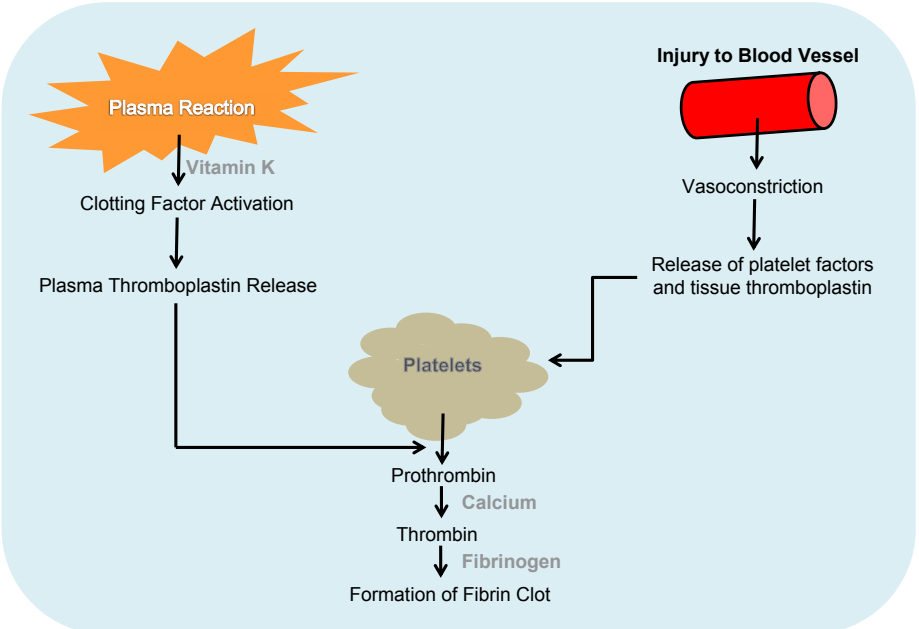

Figure 1. The physiological mechanisms involved in haemostasis.

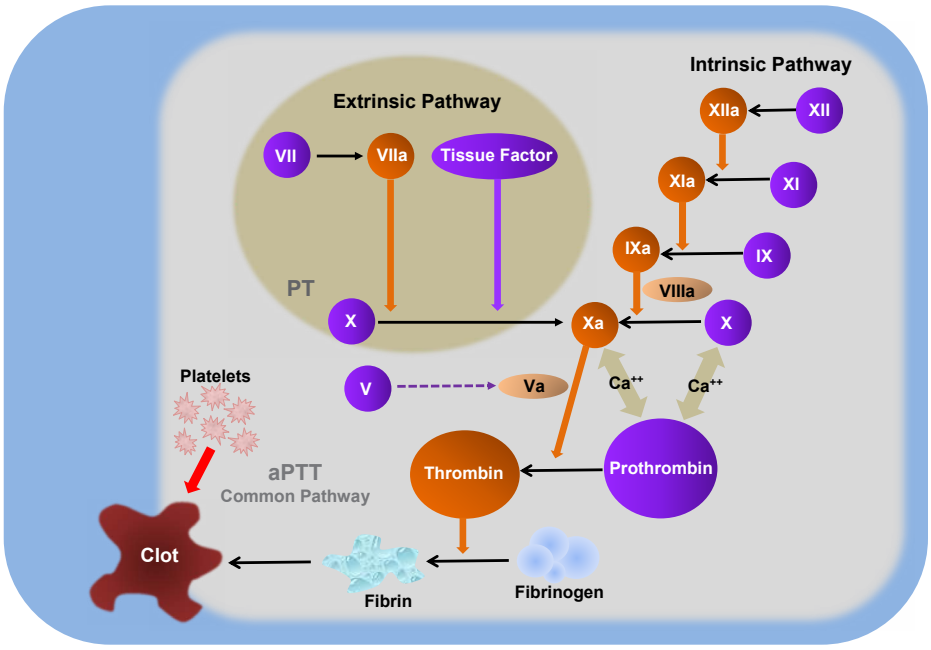

Figure 2. The coagulation cascade.

Passive topical haemostats

Passive topical haemostats act by providing a physical framework to which platelets can aggregate, allowing a clot to form over them. There are several passive haemostatic agents available, and they come in differing forms of application: 'fleeces' and sponges, or gauze-like sheets being the typical presentation.

Active haemostats have an intrinsic biological function that directly activates the coagulation cascade, with the intent of forming a clot at the bleeding site. These agents contain thrombin, part of the final common pathway that converts fibrinogen to fibrin, and have the advantage of bypassing the general cascade and proceeding straight to fibrin generation, an important consideration when there is disruption of the components of the coagulation cascade. Thrombin is also a component of the common sealant preparations.

By providing a framework around which platelets can adhere and aggregate, passive haemostats not only act as a physical barrier that impedes the flow of blood, but they also allow for the activation of platelets by providing a matrix for platelet adhesion and accelerating the formation of the platelet plug that forms the basis of the fibrin clot. This class of haemostats includes agents based on collagen, cellulose, gelatin and polysaccharide spheres. Haemostatic agents based on cellulose (or, more formally, oxidised regenerated cellulose [ORC]) are commonly used in operating theatres in Australia and New Zealand, and have been available for decades. Although these agents promote clot formation through contact activation, the fine detail of their exact mechanism is still not known. Commonly used ORC-based haemostats include SurgiCel™, which is available as a waxy gauze sheet, and Fibrillar™ (both from Ethicon), which comes as a cotton wool-like pad. Stable at room temperature, these agents can remain on the shelves of operating theatres. When ORCs are applied topically, they absorb blood and form a gel covering the site of the injury to the vessel. Contact with blood also leads to the breakdown of cellulose to cellulosic acid, which lowers the pH to cause localised vasoconstriction. Because their functional ability is reduced with exposure to saline, they should be used in a dry form; this has the advantage that they can be cut into shapes to fit specific spaces.

Cellulose-based products are not particularly effective in controlling bleeding from larger arteries, but are ideal for the control of bleeding from capillary beds and small veins.

Gelatin-based haemostatic agents are available as sponges or powders that also can be stored at room temperature. The first of these (GelFoam™ Pfizer) was used in 1945. Some gelatin-based sealants consist of a matrix made of gelatin with a thrombin component – when applied to a bleeding surface, the granules in the matrix allow high concentrations of thrombin to react with the patient's fibrinogen thus forming a stable fibrin clot. The granules in the matrix swell as blood moves through the matrix further reducing blood flow and also acting as a tamponade, which conforms to the shape of the injured vessel. An example of this is FloSeal™ (Baxter), which is mixed and prepared in the operating theatre. The fluid nature of these haemostats makes them useful for cavities and irregular surfaces. However, a number of rare adverse reactions have been noted, including allergic reactions to the gelatin and fever.

Other haemostats that are not as widely used include collagen-based agents and polysaccharide microspheres.

Passive topical haemostats are useful in heavier oozing because their absorptive capacity increases mass to provide a tamponade. This absorptive tendency also means that areas of the agent that have not participated directly in haemostasis can 'mop up' fluid effusion. However, this effect is not always completely beneficial and expanded agents can put pressure on nearby structures such as nerves or the ureter. The presence of these agents can also lead to confusion if subsequent imaging is undertaken, where it may be misidentified as an abscess formation or even a tumour. Rarely, residual agents can promote granulation and actually slow healing. For these reasons, judicious use is always recommended.

Active haemostatic agents

Active haemostatic agents promote clot formation by participating directly in the coagulation cascade. These agents include thrombin and products that contain thrombin. Thrombin has been used for many years, with products containing thrombin derived from cattle coming on to the market in the 1970s. Thrombin is at the end of the final common pathway, so its use overcomes situations where clotting factors are absent. It also means that thrombin is more likely to be effective in the setting of a coagulopathy, or when patients have been using anti-platelet or other anticoagulants. Thrombin can be used in conjunction with other topical agents and this combination may increase the efficacy of haemostasis, as mentioned above.

Sealant agents

As their name suggests, sealants form a physical barrier that occludes flow from injured vessels. Several different types of sealants have been developed: fibrin-based sealants, cyanoacrylates, PEG polymers and albumen with glutaraldehyde.

Fibrin sealants, such as Tisseel™ (Baxter),

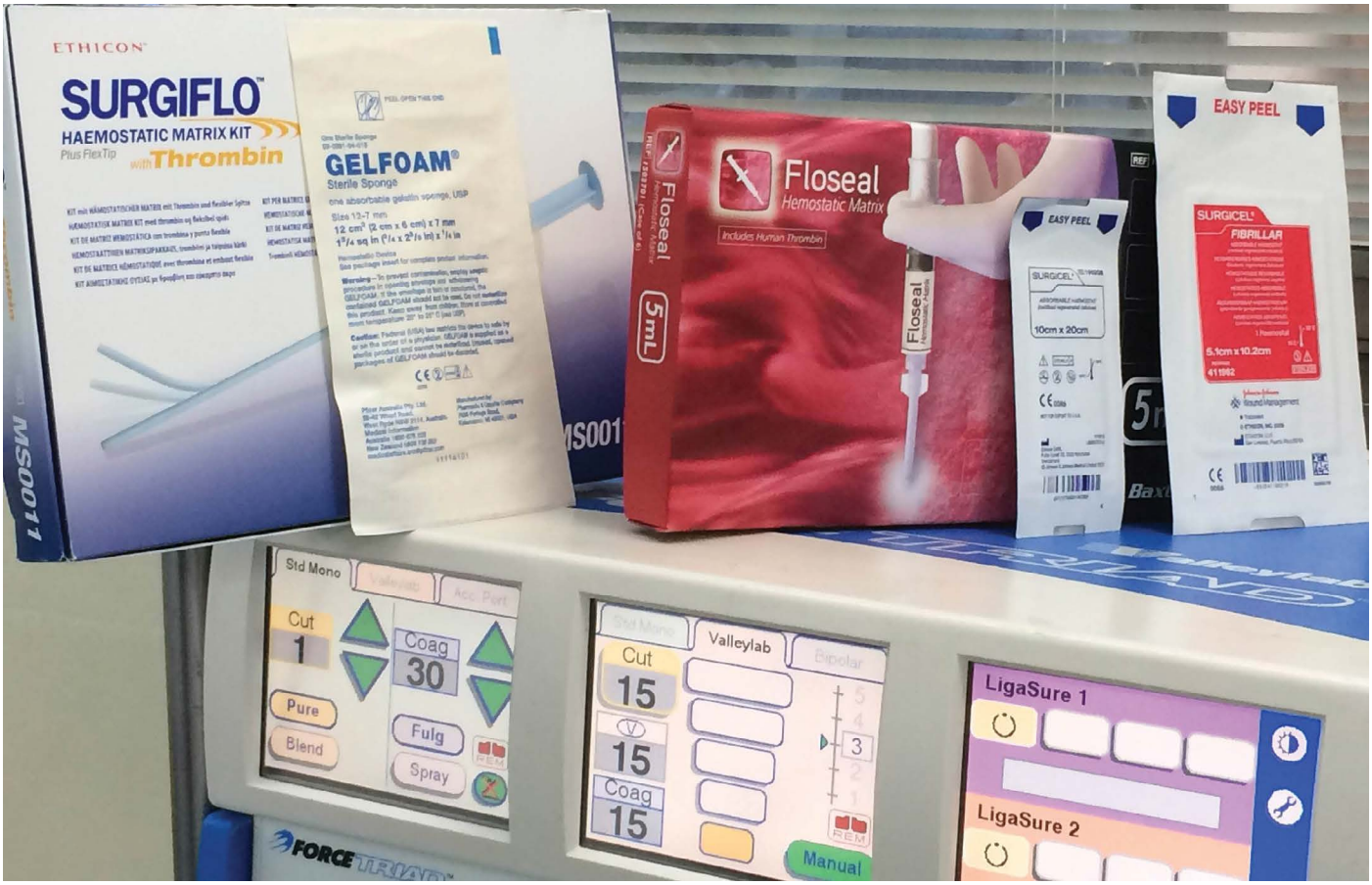

Figure 3. A selection of the haemostatic products available on the market.

are designed to mimic the conversion of fibrinogen to fibrin thus forming a stable clot which assists haemostasis. They contain fibrinogen and thrombin, and some may also contain antifibrinolytic agents, calcium chloride and Factor XIII. Tisseel is a pooled human plasma compound that requires frozen storage and warming for use. It is designed for use when trying to control diffuse ooze over a large area in a surgical field. It is not so useful when dealing with heavy bleeding, as might be encountered from an artery. However, when there is fibrin deficiency or the patient has been treated with heparin, it remains effective.

TXA and activated factor VII

Tranexamic acid (TXA) is a synthetic analogue of lysine, an amino acid that works by reducing fibrin breakdown (fibrinolysis). TXA blocks formation of the enzyme plasmin from its precursor molecule plasminogen, thus reducing breakdown of fibrin that has been generated during the coagulation cascade. Most doctors working in obstetrics and gynaecology are familiar with TXA. Systematic reviews have provided strong evidence that the use of TXA in the management of surgical bleeding is effective in reducing the need for blood transfusion. However whether it increases the risk of thromboembolic side effects remains unresolved.[1]

Recombinant activated factor VII (fFVIIa) should be reserved for patients with massive haemorrhage due to its cost, as studies have shown it to be cost effective only in patients who are likely to need a large amount of blood.[2]

How do I choose?

Dealing with surgical bleeding begins long before the operation itself, with correct patient selection – always perform the most appropriate operation for the right patient. Optimising the patient's condition before surgery is critical and this includes managing any medications or supplements that might adversely affect haemostasis. Good anaesthetic management during surgery, including attention to hydration, will greatly help. The primary approach to minimising bleeding is good surgical technique and selective use of sutures, ligations, clips and cautery. However, despite all of this, bleeding can still occur and topical or systemic haemostatic agents may be required. Cellulose-based topical haemostats have the advantage that they can be manipulated through laparoscopic ports. The use of foams can cover larger areas, but are less effective with brisk bleeding. Thrombin-based haemostats are similarly useful in a laparoscopic setting and can control bleeding over a large area. If things continue to go wrong, the use of systemic agents, such as TXA and fFVIIa, can certainly have a place. Good luck!

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Cell salvage in obstetrics and gynaecology

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The concept of transfusing blood from one human to another was first explored almost two hundred years ago, and the very first clinical setting was in treatment of postpartum haemorrhage.[1] The trials were carried out by James Blundell, an English obstetrician desperate to help the many women who succumbed to massive bleeding in an era when there was little else to offer. Blundell's transfusions were carried out before the ABO blood typing system was recognised, yet five women survived following his radical treatment. Later in the nineteenth century, a letter in the *Lancet* written by Mr William Highmore detailed the case of a woman who died from a postpartum haemorrhage. Highmore speculated that had the woman's blood been collected and transfused, it might have saved her life. The concept of auto-transfusion was thus envisioned by those providing care during childbirth.

Blood in the field of surgery

Cell salvage – the process by which blood lost during surgery is harvested for autologous transfusion – has evolved since its introduction in the 1960s. It is now recognised that blood lost during surgery has high concentrations of inflammatory mediators, free haemoglobin and cellular debris. To deal with these potential contaminants, washing and preparation of the saved blood is necessary. The four key elements of cell salvage and subsequent transfusion are:

1. collection of the blood;
2. addition of an anticoagulant;
3. processing to concentrate and harvest the blood cells; and
4. autologous transfusion.

The typical layout of a cell salvage system is shown in Figure 1.

The first step in cell salvage, collection of the blood, might seem simple, but there is considerable potential for harm in the process. Suction pressure applies mechanical forces to blood cells and shear-induced haemolysis occurs with high suction pressures. The risk of this can be increased markedly by the shape of the suction tip, as well as co-aspiration of air that causes bubble formation and cell damage. For these reasons, suction catheters specifically designed for salvage should be used, with lower negative pressures than usual. To minimise mixing with air, the catheter tip should remain below the surface of the blood pool while aspirating. Blood should also be suctioned as quickly as possible to avoid prolonged contact with the wound surfaces, thereby minimising exposure to factors initiating the coagulation cascade.

The aspirated blood is mixed with an anticoagulant to prevent clot formation in the suction tubing, reservoir and processing drum. Clotting in the system reduces the yield of cells and can necessitate changing of the tubing if it clogs. The anticoagulant typically used is heparin, because of its low

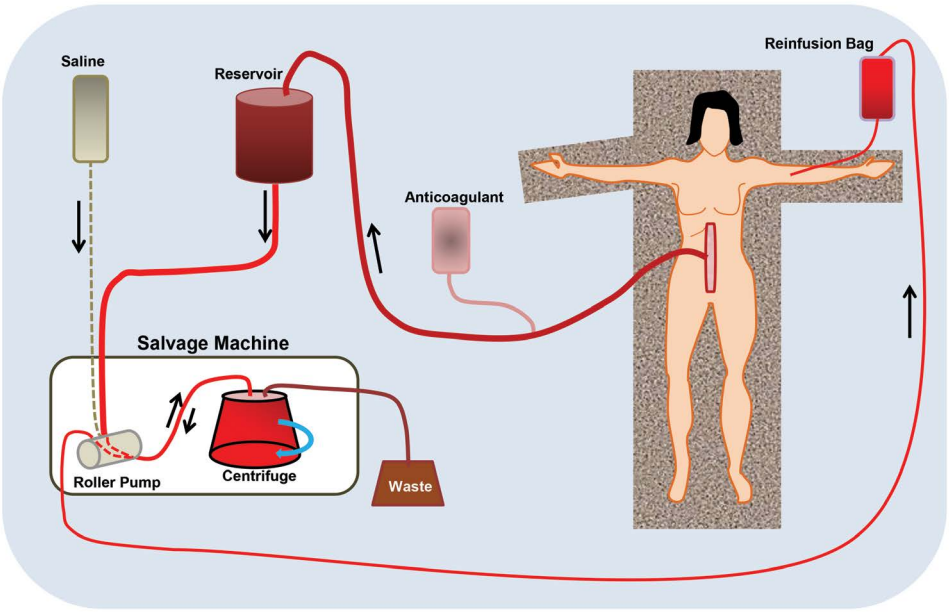

Figure 1. Schematic of a typical cell salvage system.

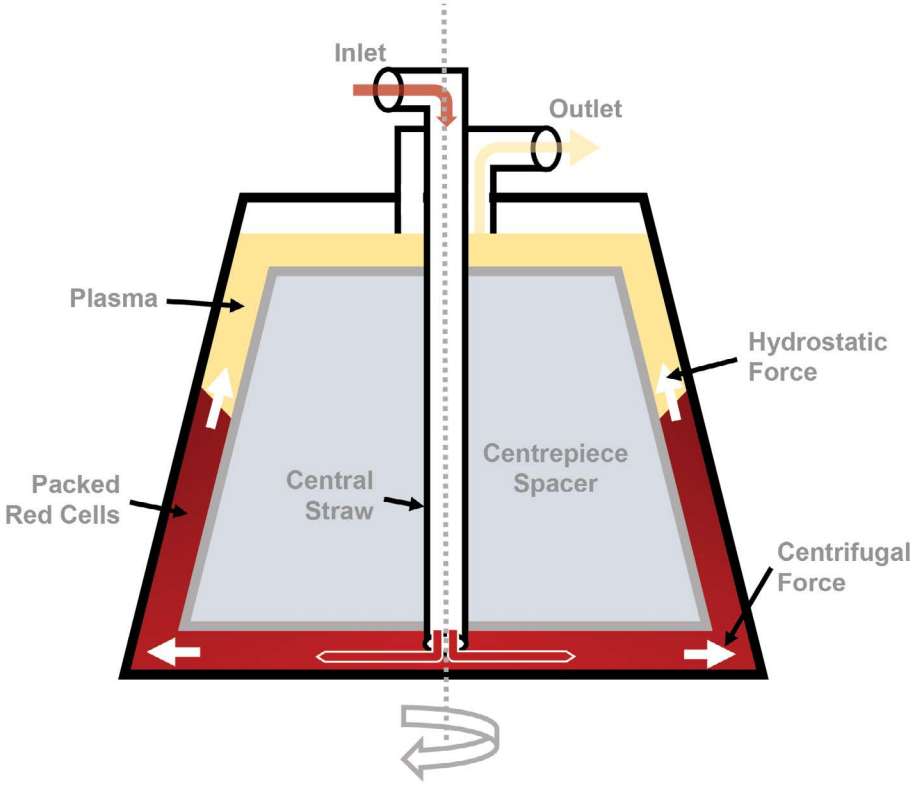

Figure 2. A cross-section of the cell salvage centrifuge drum, showing the separation process.

cost and ready availability, but citrate is also appropriate. Heparin concentrations of 30 000 units per 1000ml of saline are ideal for the purpose, and this can be mixed with the blood aspirate in a ratio of about 15ml for every 100ml of aspirated blood. There is little downside to adding too much heparin, since the large heparin molecule is easily removed from the tranfusate during the processing stage.

Before the mixture of salvaged blood and anticoagulant moves to the processing bowl, it is stored in a collection reservoir. Because of the dynamics of processing, the volume of the reservoir needs to be three to four times greater than the volume of the processing bowl. The collection reservoirs are lined with a filter where the pore size is between 50 and 100μm. The pore size makes avoidance of clotting very important, hence the desirability of the anticoagulant mixture.

The heart of the cell salvage unit is a centrifuge drum. The blood mixture is pumped from the reservoir and enters the processor through a central 'straw' (see Figure 2). The blood flows to the floor of the processor as the unit spins, moving under centrifugal force. Since the red cells have greater mass than other components of the mixture, they separate and spread out around the walls of the processor bowl. The separation of red cells from other plasma components (including heparin molecules) depends upon a balance of hydrostatic forces from the blood being pumped in and the centrifugal force generated by rotation of the bowl. When the balance is correct, the non-cellular (plasma) component of the mixture exits the bowl into the waste receptacle and the red cells remain in the bowl, allowing them to be isolated. Once the initial processing is complete, the bowl contents are washed with saline until the exiting waste appears clear to visual inspection. When the washing is complete, the roller pump is reversed, allowing collection of the washed and packed red cells into a reinfusion bag. Resuspension of the washed cells in saline yields a reinfusion solution with a haematocrit of between 50 and 80 per cent. The use of a micro-aggregate blood filter at transfusion, with a pore size of 40μm, can trap and remove bacteria and amniotic fluid components.

Complications of cell salvage

There are a number of potential complications with the use of cell salvage. These include microembolism (caused by micro-aggregates); fat and air embolism; disturbances of electrolytes; fever; haemolysis; and renal injury from free haemoglobin. A particular complication known as 'salvaged blood syndrome' can occur when the salvaged cells are diluted in large volumes of saline. This leads to deposition of cellular aggregates in the fixed bowls of the processor, and has been associated with triggering of the intravascular coagulation sequence, increasing permeability of the microvascular beds leading to lung injury and even renal failure.

It is also important to understand that salvaged blood does not contain any platelets or coagulation factors. This is a critical consideration in the management of massive haemorrhage and means that infusion of cryoprecipitate, fresh-frozen plasma and platelets will be required for additional support in these circumstances.

Cell salvage in obstetrics

Although the concepts of blood transfusion and cell salvage were initially inspired by massive obstetric haemorrhage, concerns about amniotic fluid embolism and re-transfusion of fetal debris led to great caution in its use in pregnant women. However, the contribution of bleeding to maternal death and debility has promoted re-evaluation of the role of cell salvage in these settings.

Because of the rarity of amniotic fluid embolism, study of its incidence in a setting

Cell salvage in a nutshell

1. If significant blood loss is anticipated, consult the patient and liaise with the anaesthetic team about the possibility of cell salvage
2. Use a sucker and tubing specifically designed for the cell salvage
3. Avoid aspirating from the surface of the blood pool as mixing the aspirate with air can result in cell damage
4. Avoid aspirating amniotic fluid (in obstetric cases) to minimise the risk of amniotic fluid embolism
5. Salvaged blood does not contain platelets or coagulation factors. These need to be replaced as indicated
6. The use of cell salvage in oncology remains uncertain.

Figure 3. One of the authors, right, with the cell saver equipment.

of cell salvage is almost impossible. When washed blood that had been filtered using leucocyte-depletion filters was studied, it revealed levels of fetal squames similar to those normally found in maternal blood in the postnatal period.[5] This provides reassurance, but is obviously only indirect evidence. However, to date, there are no reports of amniotic fluid embolism associated with the use of salvaged blood potentially contaminated with amniotic fluid.

Liumbruno's group have reviewed the literature and reported that cell salvage appears to be as safe as donor blood transfusion in the management of placenta accreta.[2,3] They concluded that complications associated with cell salvage were unrelated to the salvage itself. These included endometritis, staphylococcal pneumonia and hypotension – all could be explained by other factors associated with the surgery. Irrespective, caution should be exercised including minimising aspiration of amniotic fluid, and use of leucocyte depletion filters during transfusion. If leucocyte depletion filters are used, it is important not to use pressure bags or other pressurisation devices during the transfusion as this can cause the release of vasoactive substances that can lead to hypotensive reactions.

Cell salvage in gynaecology

The use of cell salvage in gynaecological settings should follow protocols associated with surgery in non-pregnant women. A typical setting might be hysterectomy for a massive fibroid uterus, where heavy blood loss is anticipated. It is important to remember that associated bowel injury presents a risk of infection and cell salvage should be commenced after decontamination and with the use of antibiotic cover. Conditions such as sickle cell disease and thalassaemia are also relative contraindications and might require special considerations.

The use of cell salvage in the setting of surgery for known or suspected malignancy is more problematic. Manufacturers of cell salvage systems typically warn against use because of the risk of reinfusion of malignant cells and the potential for assisted metastasis. That said, studies of cell salvage in radical surgery for prostatic cancer have not been reported to show any increase in the risk of recurrence or any change in survival statistics. National Institute for Health and Care Excellence guidelines in the UK support the use of cell salvage in surgery for urological malignancy, but suggest the use of leucocyte depletion filters and consideration of irradiation of the salvaged blood before reinfusion. To date, there are few data to guide usage in surgery for gynaecological cancers, so the issue remains unresolved.[4]

Conclusion

The ideas of blood transfusion and cell salvage came from doctors struggling to treat women who had massive postpartum haemorrhage. The increasing incidence of placenta accreta, with its risk for difficult-to-control bleeding at delivery, has led to a re-examination of cell salvage techniques in obstetrics. The available evidence is that cell salvage, when employed judiciously and with care, has a role to play. The use of cell salvage in gynaecological surgery where heavy blood loss is anticipated is also supported. The area where caution should be employed is in surgery for gynaecological malignancy.

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Advances in sutures and wound-closure technology

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The use of suture materials to ligate bleeding vessels or approximate tissue dates back to the 16th century BC, as evidenced in the Edwin Smith papyrus, the oldest record of a surgical procedure. Over the centuries, the list of materials used for suturing has grown to include metals (gold and silver), plant material (linen and cotton), and animal products (hair, intestinal tissue and silk). More recently, a wide selection of synthetic compositions has been developed. In the last decade, exciting suture and wound-closure technology, such as barbed sutures and absorbable staples, have been introduced. After millennia of experience, research and development, although the ideal universal suture material is yet to be discovered, we are edging closer.

Natural absorbable sutures

Plain and chromic catgut

Plain catgut is one of the oldest suture materials. Despite its name, catgut is normally obtained from sheep or cattle intestines. Since plain catgut is a foreign protein, it elicits a marked inflammatory response. As it is rapidly degraded by proteolytic enzymes, this suture loses 70 per cent of its tensile strength in seven days. Plain catgut is not commonly used in obstetric and gynaecological surgery.

Chromic catgut is treated with chromic acid salts to result in a suture that is less inflammatory and, subsequently, is more resistant to degradation. Chromic catgut therefore maintains more than 50 per cent of its tensile strength at seven to ten days. It is suitable for tissue in which long-term strength is not needed, such as uterine and vaginal tissue. Chromic catgut should not be used in skin because the inflammatory response it generates can lead to scarring and the suture often serves as a nidus to infection. Concerns regarding transmissible spongiform encephalopathies such as 'mad cow disease' have reduced supply and increased prices, leading to catgut gradually falling out of favour with surgeons globally.

Synthetic absorbable sutures

Polyglycolic acid and polyglactin 910

Polyglycolic acid (Dexon: Covidien) and polyglactin 910 (Vicryl: Ethicon and Polysorb: Covidien), two synthetic absorbable sutures, became available in the US in the 1970s. These sutures, composed of braided filaments of a synthetic polymer, were designed to be stronger, longer lasting and less inflammatory than catgut. Breakdown is by hydrolysis rather than proteolytic degradation. The result is minimal inflammatory response and a constant absorption rate. There is almost no loss in tensile strength in the first seven to ten days after implantation. These sutures are suitable for use in the closure of almost all tissue, including fascial and skin closure.

Polyglyconate and polydioxanone

These new classes of polymers allow the production of pliable monofilament sutures, which are smooth, causing less tissue trauma and are less prone to harbour micro-organisms that cause wound infection. Polyglyconate (Maxon: Covidien) and polydioxanone (PDS: Ethicon) have comparable tensile strength to that of the multifilament absorbable sutures, but these sutures undergo absorption at a much slower rate. As a result, tensile strength is maintained over a longer period of time (>90 per cent of tensile strength is maintained at seven days). Because of the delayed absorption profile, this class of suture is an excellent choice for closure of fascial layers and anal sphincter injuries.

Poliglecaprone 25, glycomer 631 and fast-absorbing polyglactin

First introduced in 1993, poliglecaprone 25 (Monocryl: Ethicon) has an absorption profile similar to chromic catgut. Poliglecaprone produces highly uniform absorption patterns and, because it is absorbed by hydrolysis, it does not induce much of an inflammatory response. This monofilament suture retains approximately 50–60 per cent of its original tensile strength at seven days and by 21 days has lost almost all tensile strength. This suture material therefore possesses the advantages of chromic catgut, but without many of the disadvantages.

Gylcomer 631 (Biosyn: Covidien) is a synthetic polyester composed of glycolide (60 per cent), dioxanone (14 per cent), and trimethylene carbonate (26 per cent). Its tensile strength profile is superior to that of poliglecaprone 25, with 75 per cent of tensile strength maintained after 14 days. Total loss of tensile strength occurs at 90–110 days.

Fast-absorbing polyglactin 910 (Vicryl Rapide: Ethicon and Velosorb Fast: Covidien) is a lower molecular weight version of polyglactin 910. The result is a braided suture with performance characteristics similar to plain catgut. Absorption is rapid, with 70 per cent of tensile strength lost in the first seven days. After 10–14 days, virtually no tensile strength remains. This suture is an excellent choice for perineal repairs as well as skin closure.

Non-absorbable sutures

Natural non-absorbable sutures

This category of suture material includes surgical silk and cotton. Silk is the gold standard against which other sutures are judged, owing to its superior handling. This

is largely because it has little 'memory' and, as a result, it not only handles well, but it also ties easily and possesses great knot security. Silk can be considered a delayed absorbable suture in that it is often not able to be found after two years. Because silk is a foreign animal protein, its presence leads to a high level of inflammatory response. This characteristic and its multifilament composition make it an unsuitable candidate in tissue at high risk of infection.

Synthetic non-absorbable sutures

A multitude of non-absorbable synthetic sutures exist. Nylon is a synthetic polyamide polymer that is available in both braided (Surgilon: Covidien and Nurolon: Ethicon) and monofilament (Dermalon: Covidien and Ethilon: Ethicon) forms. Some practitioners reports that braided nylon handles better and provides better knot security, but monofilament nylon incites less inflammatory response and may be less prone to infection.

Polyester sutures are only produced in braided forms. Polyester sutures can either be coated or uncoated. The uncoated forms (Mersilene: Ethicon and Surgidac: Covidien) offer the best knot security. When produced in tape form, this property makes it ideal for use in cervical cerclage. Suture coatings such as teflon, polybutilate (Ethibond: Ethicon) and silicone (TiCron: Covidien) reduce tissue drag and improve handling characteristics, but knot security is generally poorer.

Polypropylene (Prolene: Ethicon and Surgipro: Covidien) is a monofilament suture material composed of a linear hydrocarbon polymer. It has the least tissue reactivity of all non-absorbable sutures. It can be difficult to handle, owing to its high memory.

Metal sutures and staples

Historically, metal sutures have been used in infected areas or for repair of wound dehiscence and evisceration. Metal sutures have extremely high tensile strength and very low tissue reactivity, but their application in modern obstetric and gynaecological surgery is rare. The exception is the use of metal staples in surgical skin closure. Surgical staples have gained popularity among obstetricians and gynaecologists, owing to the ease and speed of application. A recently published meta-analysis has found operation time for caesarean sections to be shorter by seven minutes when surgical staples were used, but the rate of wound complications, mainly in the form of wound separation, was found to be increased.[1]

Newer products

Antibacterial-coated sutures

Currently, only one product is commercially available in this category. Triclosan-coated polyglactin 910 (Vicryl Plus Antibacterial: Ethicon) has been found to reduce surgical site infection rate by 30 per cent.[2] Handling and tension force of these sutures was found to be comparable to standard suture material. Although triclosan is relatively non-toxic, skin irritation and allergic reaction has been known to occur.

Barbed sutures

The invention of barbed sutures can be attributed to Dr Harry Buncke, whose US Patent was granted in 1999 for 'one-way sutures having barbs on their exterior surfaces and a needle on one or both ends.' His patents were acquired by Quill Medical (acquired by Angiotech Pharmaceuticals in 2006) in 2002 and, in conjunction with the inspired work of Dr Gregory Ruff, the first widely commercialised barbed suture, Quill Knotless Tissue-Closure Device was approved by the US Food and Drug Administration in 2004. In 2009, Covidien introduced V-Loc unidirectional barbed suture with a fixed loop. Ethicon has now introduced its own version of the barbed suture, the Stratafix, found in both unidirectional and bidirectional formats.

The complete absence of knots, the even distribution of tissue strength along the wound and the reduction of operation time are the main advantages of this type of sutures. Surgical knots are disadvantageous because they reduce the tensile strength of all sutures by thinning and stretching the material. There is also an uneven distribution of tension across the wound, with higher tension burdens placed at the knots. In laparoscopic surgery, the difficulties of tying a knot efficiently and reliably can often be challenging. This may be the reason that the use of knotless barbed sutures significantly reduced operation time in laparoscopic myomectomies[3] and laparoscopic hysterectomy vaginal cuff closures[4] with no increase in complications. However, the tensile strength of barbed sutures remains a concern, owing to the manufacturing process of these devices where barbs are produced by a blade cutting into the shaft of the suture material.

Absorbable subcutaneous staples

In 2006, INSORB, a subcutaneous absorbable stapling device, became commercially available. The staples consist of a co-polymer of 70 per cent polyactide and 30 per cent polyglycolide that breaks down by hydrolysis with substantial absorption in 10–12 weeks and with minimal inflammatory response. This novel wound closure device combines the efficiency of staples with the superior wound approximation of subcuticular sutures. Madsen et al found that for caesarean sections, compared to subcuticular suturing, skin closure time was significantly reduced while wound complication and patient satisfaction rates did not differ.[5]

Conclusion

Because the ideal universal suture is not yet a reality, practitioners need to be familiar with the properties and suitable applications of various suture materials and wound-closure technologies available to them. This article has summarised a wide range of time-tested, reliable suture materials and included newer materials and devices that have become available in recent years. Most of these products, such as antibacterial-coated and barbed sutures, have ample scientific evidence supporting their application in surgery, but more data will be welcomed for absorbable subcutaneous staples.

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Modern wound dressings

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Dressings are used clinically to help manage the wound environment and to prevent wound breakdown. Wound management is defined as: the provision of the appropriate environment for healing by both direct and indirect methods together with the prevention of skin breakdown. Wound management practices today are based on wound bed preparation and the TIME concept, first introduced into practice in 2002 and then updated in 2012. The TIME acronym stands for:

- tissue;
- inflammation/infection;
- moisture; and
- edge.

The management of a wound involves consideration of all of these areas.[1,4] To be clear, managing a wound is not just taking a product off the shelf and applying it to a wound. The ideal dressing should: maintain a moist environment; absorb excess exudate; allow gaseous exchange; provide thermal insulation; provide a barrier to bacteria; be free from particulate/toxic components; be atraumatic on removal; be comfortable and conformable; protect the wound from further trauma; and be cost effective.[1,3,6]

No one dressing will meet all the requirements of a wound, given that as the wound changes so the needs of the tissue change.[2,4,5]

Wound dressings are divided into two distinct groups – passive dressings and interactive dressings.[2,5]

Passive dressings

For many years, the products used were of the 'passive' or 'plug and conceal' concept. Passive dressings include gauze, lint, non-stick dressings and tulle dressings; they have very few of the properties of an ideal dressing. Passive dressings have very limited (if any) use as primary dressing, but some are useful as secondary dressing.

Non-absorbent passive dressings are paraffin gauze (tulle) dressings, such as Jelonet™, these were among the earliest modern dressings. These products are known to adhere to the wound, causing trauma on removal, and require a secondary dressing. Their use is limited to simple clean superficial wounds and minor burns. They are also used as a primary dressing over skin grafts. There are modern alternative dressings, which are composed of synthetic fibres tightly meshed and impregnated with materials that allow moisture to pass through, minimising maceration, that will not allow tissue to pass through and thus not adhere to the wound surface, examples include: Adaptic™, Cuticerin™, Atrauman™.[2,3,4,5,6]

Interactive dressings

These dressings help to control the micro-environment by combining with the exudate to form either a hydrophilic gel or by means of semipermeable membranes to control the flow of exudate from the wound into the dressing. They may also stimulate activity in the healing cascade and speed up the healing process. There are six classes of interactive dressings, classified according to their functionality.[2]

Film dressings

These dressings consist of a thin, polyurethane membrane coated with a layer of acrylic adhesive or an island version with a pad and are for wounds with no to low exudate. They are transparent, waterproof, gas/vapour permeable and flexible to protect from shear, friction, chemicals, microbes and spread tension forces. They are useful in superficial, clean wounds and in the prevention of breakdown and pre-ulcers in pressure wounds. They are also used as a postoperative dressing over sutures, to reduce sub-tissue tension and over closed wounds after the removal of the sutures or clips. If there is a small amount of exudate in the wound then an island film that includes a non-stick pad is best, for example, Opsite Post Op™ or Tegderm™ with pad. A new version, Opsite Post Op visible™, uses latticed foam as the pad to enable better absorption and allow the suture line to be observed. An acrylic padded version is also used on donor sites.[2,3,4,5,6]

Hydrocolloid dressings

Hydrocolloids are a combination of polymers held in a fine suspension and often contain polysaccharides, proteins and adhesives; they are used on wounds with low exudate. When placed on a wound, the polymers combine with the exudate and form a soft, moist, gel-like mass. They also encourage autolysis to aid in the removal of slough from a wound.

General rules for the use of dressings

- Allow 2–3cm of dressing greater than wound size.
- Place one-third of the dressing above and two-thirds below the wound.
- Remove the dressing when strikethrough occurs, remove with care in older patients – if necessary, remove under the shower.
- Do not pre-moisten alginate dressings.

Table 1. A summary of dressing types and their uses.

Type	Actions	Indications/use	Precautions/ contraindications
Inert NA cotton wool dressings	• Protect new tissue growth • Absorb minimal exudate	• Dry or low-exuding wounds	• Use as contact layer on superficial low-exuding wounds • Will not cope with moderate or higher levels of exudate
Tulles Low-adherent, wound contact layer (non-silicone)	• Protect new tissue growth • Atraumatic to periwound skin • Conformable to body contours	• Low- to high-exuding wounds	• Use as contact layer on superficial low-exuding wounds • May dry out if left in place for too long
Polyurethane film	• Moisture control • Breathable bacterial barrier • Transparent (allow visualisation of wound)	• Primary dressing over superficial, low-exuding wounds • Secondary dressing over alginate or hydrogel for rehydration of wound bed	• Do not use on patients with fragile/compromised periwound skin • Do not use on moderate- to high-exuding wounds
Hydrocolloids	• Absorb fluid • Promote autolytic debridement	• Clean, low- to moderate-exuding wounds	• Do not use on dry/necrotic wounds or high-exuding wounds • May encourage overgranulation • May cause maceration
Foams	• Absorb fluid • Moisture control • Conformability to wound bed	• Moderate- to high-exuding wounds • Special cavity presentations in the form of strips or ribbon • Low-adherent versions available for patients with fragile skin • Combined presentation with silver or PHMB for antimicrobial activity	• Do not use on dry/necrotic wounds or those with minimal exudate
Alginates/CMC	• Absorb fluid • Promote autolytic • debridement • Moisture control • Conformability to wound bed	• Moderate- to high-exuding wounds • Special cavity presentations in the form of rope or ribbon • Combined presentation with silver for antimicrobial activity	• Do not use on dry/necrotic wounds • Use with caution on friable tissue (may cause bleeding) • Do not pack cavity wounds tightly
Foam-like hydroactive dressings	• Absorb fluid • Moisture control • Conformability to wound bed • Similar but not the same as a foam	• Moderate- to high-exuding wounds • Special cavity presentations in the form • Low-adherent versions available for patients with fragile skin	• Do not use on dry/necrotic wounds or those with minimal exudate
Hydrogels	• Rehydrate wound bed • Moisture control • Promote autolytic debridement • Cooling and pain relieving	• Dry/low- to moderate-exuding wounds • Combined presentation with silver for antimicrobial activity	• Do not use on highly exuding wounds or where anaerobic infection is suspected • May cause maceration
Iodine	• Antimicrobial action • Debrider • Healing stimulation	• Critically colonised wounds or clinical signs of infection • Low- to high-exuding wounds	• Do not use on dry necrotic tissue • Known sensitivity to iodine • Short-term use recommended • 3 months (there is a risk of systemic absorption in larger wound with prolonged use)
Silver	• Antimicrobial action	• Critically colonised wounds or clinical signs of infection • Low- to high-exuding wounds • Combined presentation with foam and alginates/CMC for increased absorbency	• Some may cause discolouration • Known sensitivity to silver • Discontinue after 2 weeks if no improvement and re-evaluate

These dressings are flexible, waterproof, provide physical barrier, gel with exudate, are debriding and require no secondary dressing, in other words, they are occlusive. Hydrocolloid products are used in low-exudating wounds, including ulcers, and granulating wounds. The thin form is used postoperatively over suture lines (such as Duoderm®, Comfeel™, Hydrocoll®). Please note that these dressing are contraindicated in diabetic wounds. [2,3,4,5,6]

Foam dressings

These products (for wounds with medium to high exudate) are soft, open-celled hydrophobic/ hydrophilic, non-adherent dressings that may be single or multiple layers and meet many of the properties of an ideal dressing. They absorb exudate; maintain a moist environment; and are thermally insulating, cushioning, non-adherent and non-residual.

Foams are used mainly in moderately to heavily exudating wounds, including ulcers, donor sites and minor burns, and they act as a secondary dressing – particularly as a covering with the use of amorphous hydrogels. In addition to standard and waterproof foams, T and shaped cavity devices may be inserted into cavity wounds or dehisced surgical wounds – examples include Lyofoam Max™and Allevyn™. There are specialised forms coated with a silicone adhesive that allows non-traumatic removal (such as Mepilex® and Allevyn Gentle®) these are very useful for older patients with fragile skin.[2,3,4,5,6]

Alginate dressings

Alginates are the calcium or sodium/ calcium salts of alginate acid, obtained from seaweed, for wounds with medium to high exudate. When applied to a wound, the sodium salts present in the wound exchange with the calcium in the alginate to form sodium alginate, a hydrophilic gel. This fibre has the ability to absorb exudate into itself while maintaining a moist environment. The dressings are highly absorbent, form gel with exudates, provide a moist interface, are easily removed and some are haemostatic. Alginates are used on donor sites, bleeding sites and exudating leg ulcers (Kaltostat®, Algisite M™, Sorbsan™ Comfeel Seasorb™).[2,3,4,5,6]

Hydrofibre dressings

These dressings, for wounds with medium to high exudate, sharing some of the properties of alginates, are a fibre rope or dressing that forms a firm gel in contact with fluid. They are formed from a fibrous mat of carboxymethyl chitin (CMC) and are highly absorbent and have with no lateral wicking, which protects the peri-skin. Examples include Aquacel™.[2,3,4,5]

Hydroactive dressings

These dressings are for wounds with medium to high exudate. Made of highly absorbent polymer, they are similar to foams; however, instead of holding exudate, the fluid is trapped within the polymer's holes and the product swells. Hydroactive dressings are indicated for use in highly exudating surface and cavity wounds. Hydroactive dressings are not indicated for dry or lightly exudating wounds. Products in this category include Cutinova Hydro™, Biatane™ and Tielle™.[2,3,4,5,6]

Hydrogels

Hydrogels are organic polymers with a high water content and are suitable for dry or sloughy wounds. They will rehydrate dry tissue and absorb certain amounts of fluid into themselves. They are provided as amorphous gels and are used to help re-hydrate sloughy and necrotic tissue to aid in the autolytic debridement of wounds (examples include, IntraSite gel™, Comfeel Purilon Gel™,Solosite™, DuoDERM Gel®, Solugel™). They are also used in the management of burns, including sunburn, scalds and other partial-thickness bums. Amorphous hydrogels have also been used in the management of chickenpox and shingles, applied to the eruptions three to four times a day. They provide a moist environment, relieve the discomfort of the lesion and also reduce the probability of scarring. Hydrogels are also available in sheet form, consisting of a cross-linked polymer and water held in a backing (Hydrosorb™, Nu-gel™). These products are particularly useful in the management of burns and also to aid the management of simple pressure wounds.[2,3,4,5,6]

New hydrogels

Flaminal® hydrogels are based on gelled alginate and contain the enzymes glucose oxidase and lactoperoxidase to control the bioburden (by acting as an important natural antimicrobial). Flaminel has been shown to be bacteriostatic against Gram-positive organisms and exhibits pH-dependent bactericidal action against Gram-negative organisms in the presence of hydrogen peroxide and thiocyanate.[12,13,19]

Miscellaneous dressings

There are a small number of specialised dressings for use in particular wound types. Cadexomer iodine dressings (Iodosorb/ Iodoflex) feature a non-toxic iodophor, where the iodine is cross-linked into the structure of the polymer. When applied to the wound, the exudate combines with the polymer and iodine is released over 72 hours at 0.1 per cent (not cytotoxic). These dressings are used for sloughy/infected wounds, diabetic wounds and recalcitrant wounds and may stimulate healing.[5,6,10]

Silver has been used for many years and it has proven broad-spectrum antimicrobial activity, with no documented cases of bacterial resistance reported. In particular, silver has been used in the treatment of burns as a silver sulphadiazine cream. Contemporary silver dressings allow for continuous release for up to seven days. The level of silver contained in the various dressings varies greatly. Their mode of action also varies – some release the silver into the wound; some partly release the silver, while still holding some in the dressing; and some keep the silver within the dressing. The choice of dressing will depend on the level of infection, the size and depth of the wound and the amount of exudate. Examples include, Acticoat®, Mepilex Ag®,Biatain Ag®, Aquacel Ag™ and Atrauman Ag™.

Devices used in wound management

Negative-pressure wound therapy (NPWT) is a therapeutic technique that uses a vacuum dressing to promote healing in acute or chronic wounds. It was first introduced in the late 1990s, and for some years there was little clinical evidence for its use; however, there is now significant published research reporting benefits. In particular, NPWT has a role in the management of major trauma, surgical incisional breakdown, large pressure wounds and late over skin grafts and some surgical wounds. In the area of obstetrics and gynaecology, there have been studies published on the role of NPWT in prevent wound complications following caesarean section in morbidly obese women, prophylactic use after caesarean delivery and use of NPWT over clean, closed surgical incisions.[15,16,17,18,19]

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Ballooning for beginners

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I have received a few raised eyebrows from family and friends about my writing an article on the topic of 'inflatables'. I promise, you will not be disappointed. This article outlines three different inflatable devices that are available to assist us as obstetricians in managing a diverse range of familiar scenarios.

Fetal Pillow

The latest inflatable on the obstetric scene,[1] the Fetal Pillow has been designed to elevate the fetal head vaginally and is particularly useful for second-stage caesarean sections. The increased intraoperative morbidity of a full-dilatation caesarean section, particularly uterine extensions into the broad ligament or vagina with subsequent postpartum haemorrhage (PPH), is thought to be caused by the increased manipulation required to deliver a deeply impacted head with caput and moulding through a thin and oedematous lower segment.[2] The premise of this inflatable is to achieve an atraumatic delivery of the vertex from deep within the maternal pelvis without recourse to established methods for difficult head delivery, such as elevation of the vertex vaginally by an assistant's hand, use of uterine tocolytics or breech extraction via an extended uterine incision.

The Fetal Pillow is a disposable soft silicone balloon that is inserted pre-operatively behind the fetal vertex, similar to the placement of a ventouse cup for an occipito-posterior position (see Figure 1). The balloon inflates in only an upward direction when the tubing is injected with 180ml of sterile saline with its base plate resting on the anococcygeal ligament. After delivery, the balloon is deflated via the two-way tap and the device is removed from the vagina with traction. Given the need for the Fetal Pillow to be positioned prior to caesarean section, this device is ideally suited to cases where there has been an examination in theatre to assess suitability for an instrumental vaginal delivery or a prior attempt made to achieve an instrumental vaginal delivery.

The Fetal Pillow is an innovative device, but there currently remains a paucity of evidence. The National Institute for Health and Care Excellence (NICE) has recommended that the device is only used within an audit and research framework owing to the inadequate quantity and quality of current evidence.[3] A number of centres in the UK, as well as in India and Australia, have reported their positive anecdotal experience with the use of the Fetal Pillow. The initial Australian experience was evaluated in a retrospective cohort study of all full-dilatation caesareans over a 13-month period.[4] Of 265 full-dilatation caesarean sections, the Fetal Pillow was used in 35 cases while elevation of the fetal head vaginally by an assistant was used in 29 cases, with a comparison of maternal and neonatal outcomes between both groups. There were no differences in the rates of uterine extensions, PPH, blood transfusion, neonatal resuscitation or admission to neonatal intensive care. There was a significantly higher cord arterial pH in the Fetal Pillow group (pH 7.24 versus 7.19, $p<0.019$).

The best available evidence for the Fetal Pillow comes from a prospective non-randomised comparative study undertaken in India.[5] This compared the maternal and fetal complications in full-dilatation caesarean sections between women who had a Fetal Pillow inserted prior to their caesarean ($n=50$) against unmatched historical controls ($n=124$). Women in the Fetal Pillow group had a lower incidence of extensions (four per cent versus 15 per cent, $p=0.03$), shorter operating time (31.8 minutes versus 52.1 minutes, $p<0.001$), shorter length of hospital stay (4.1 versus 6.4 days, $p<0.001$). The rate of PPH above 1L was lower in the Fetal Pillow group (two per cent versus eight per cent) although this did not reach statistical significance ($p=0.18$).

Intrauterine inflatable balloons

The modern management of PPH has adopted the use of inflatable intrauterine balloon devices, replacing the former practice of uterine packing with sterile gauze, with its potential disadvantages of infection and trauma. The stepwise approach to atonic PPH involves the use of uterotonic medications, uterine rubbing and bimanual compression. If these prove ineffective, patient management becomes surgically orientated, following the exclusion of retained products, genital

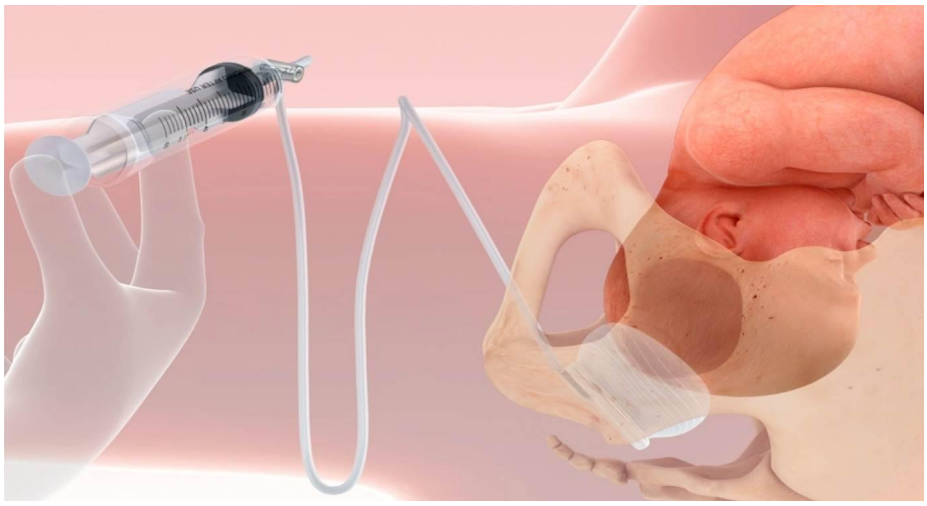

Figure 1. Positioning and inflation of the Fetal Pillow.

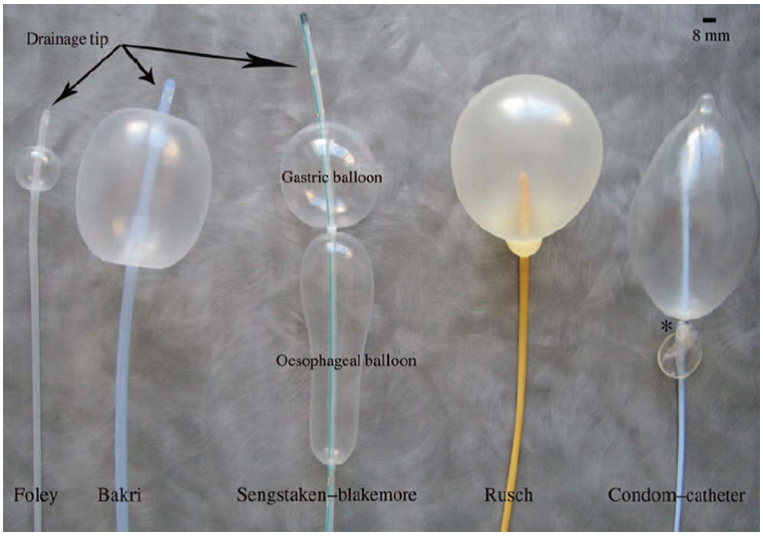

Figure 2. The range of intrauterine balloon devices.

tract trauma and coagulopathy. The intrauterine balloon is a less-invasive surgical intervention compared to uterine compression sutures (such as B-Lynch sutures), internal iliac artery ligation or peripartum hysterectomy, and avoids the serious complications of invasive surgery such as additional blood loss, visceral damage, long postoperative recovery and impact on fertility. Furthermore, its simplicity of use makes it an invaluable tool in the management of PPH in units with junior medical staff or staff inexperienced to perform invasive surgery, or where there is no access to an interventional radiology service for uterine artery embolisation.

The mechanism of action of the intrauterine balloon has long been assumed to be effected by an inward-to-outward pressure that occludes the venous sinuses within the uterine cavity. However, more recent evidence suggests that intrauterine balloons induce uterine contractility.[6]

The Bakri device, originally called the Surgical Obstetric Silicone (SOS) balloon was designed specifically as an intrauterine device for controlling obstetric bleeding. There are a number of alternative intrauterine balloon devices that have been 'borrowed' from other specialties and used in PPH management where the Bakri balloon is not available or too expensive.[7] These include the Rusch balloon (a urological device), the Sengstaken-Blakemore tube (a device used to control bleeding oesophageal varices), single and multiple Foley urinary catheters and the condom catheter, which is a low-cost option using a condom tied to the tip of a Foley's catheter (see Figure 2).

The original intrauterine tamponade technique described by Bakri involved the use of 5–10 Foley urinary catheters tied together and placed in the lower segment at the time of caesarean section for controlling bleeding from six cases of placenta praevia.[8] Ten years later, Bakri custom-designed an intrauterine balloon device for controlling PPH associated with placenta praevia and accreta.[9] The Bakri balloon is now commonly used to control atonic PPH following a vaginal delivery, with the benefit of avoidance of a laparotomy if the tamponade is effective. In some clinical settings, the Bakri balloon serves as a holding measure to enable resuscitation of the women, obtaining cross-matched blood and senior help.

The Bakri balloon is 58cm long and is made of silicone, making it suitable for use in patients with a latex allergy. The recommended volume of inflation from the manufacturer (Cook Medical, USA) is 500ml. Higher or lower volumes may be used to achieve the tamponade effect, although the balloon has a maximum capacity of 800ml. Ultrasound can be used to visualise the correct placement of the balloon, particularly in women at high risk of perforation. The Bakri balloon has a large bore channel that allows free drainage of blood from the uterine cavity and therefore immediate recognition of ongoing bleeding.

Insertion of the Bakri balloon vaginally involves using several sponge holders to hold the cervix and then threading the deflated balloon catheter through to the fundus, either digitally or using an a sponge holder. There is a double lumen shaft, one has a two-way tap for inflation of the balloon with sterile water and the other, for drainage, is attached to a collecting bag.

At caesarean section, the balloon can be introduced abdominally and the distal end of the balloon shaft passed through the cervical opening for an assistant to pull the end out vaginally. In this scenario, balloon inflation occurs after the uterine incision is closed, with potential risk of balloon puncture during uterine suturing. Alternatively, the uterus is closed and the balloon is inserted vaginally, with completion of laparotomy closure once uterine tamponade is confirmed. Whichever method is used for insertion, the original technique described by Bakri involves packing the vagina with gauze around the balloon shaft to separate the intrauterine balloon from the vagina, thereby achieving maximum tamponade effect.[9] However, vaginal packing may only be required in cases with a dilated cervix to prevent displacement of the balloon into the vagina. Most operators use a prophylactic antibiotic in theatre in view of contamination of the uterine cavity from the vaginal environment and some operators continue antibiotics for the duration of the balloon placement.

Following deflation of the balloon, the Bakri device is easily removed vaginally. The balloon can be deflated completely or sequentially, usually within a timeframe of 12–48 hours, depending on the severity of the PPH and the availability of senior staff if there is continued bleeding.

The Bakri balloon has an excellent overall success rate of 91 per cent from case reports, retrospective and prospective studies.[7] Failures of the Bakri balloon include unrecognised genital tract trauma, the development of coagulopathy or displacement of the balloon through an open cervix. It has few contraindications, the main one being active uterine infection. Several complications have been reported with the use of Bakri, including uterine perforation during insertion, uterine rupture from uterine over-distension, postoperative pain, endometritis, ulceration and pressure necrosis in the uterus or vagina and intrauterine adhesions.[7] The use of combined procedures, such as uterine compression sutures with a Bakri balloon, increases the incidence of complications.

Balloon catheters for IOL

Finally, there is increasing use of an inflatable balloon device for the most common of all obstetric interventions,

induction of labour (IOL). This might be construed as a novel method for cervical ripening without the need for pharmacological agents. However, mechanical methods of IOL are among the oldest methods of induction prior to the development of prostaglandins. Although there are single- and double-chamber balloon catheters that have been specially designed for IOL, a Foley's urinary catheter can also be employed.

There are a number of advantages to the use of a balloon catheter for IOL, including its low cost, no requirement for refrigerated storage, the option for less frequent fetal monitoring, avoidance of the side effects associated with the use of prostaglandins as well as the potential for outpatient management.

Insertion of a balloon catheter for IOL is a simple procedure performed in a lithotomy position without the need for analgesia. In some induction units, midwives are primarily responsible for balloon insertions. A preliminary cervical assessment to assess the Bishop's score is performed to redirect those women with a suitably favourable cervix to delivery unit for an amniotomy. A speculum is inserted into the vagina to visualise the cervix, which is cleansed with an antiseptic. The balloon catheter is inserted through the internal cervical os under vision using a sponge holder to assist with placement. The balloon is inflated with 50ml of sterile water and the end of catheter spigoted. The catheter is gently withdrawn until the resistance of the internal os is felt and is then secured to the woman's inner thigh with tape. The woman can mobilise freely, toilet and shower with the catheter in place. A short cardiotocograph is performed after the balloon insertion and as required for subsequent fetal monitoring. If spontaneous rupture of membranes occurs, the balloon is deflated and removed. If the catheter falls out, a cervical assessment is performed to assess favourability for amniotomy. Otherwise, the balloon is deflated and removed 24 hours after insertion to plan the next stage of the IOL process.

Mechanical methods for labour induction have been the subject of a recent Cochrane review from 2012.[10] There were 23 studies including more than 3000 women that compared the balloon catheter method with any prostaglandin. Women in the balloon catheter group had a reduced risk of hyperstimulation with fetal heart rate changes compared to the use of prostaglandins (0.4 per cent versus three per cent, relative risk 0.19, 95 per cent confidence interval 0.08–0.43) without a significant difference in risk of caesarean section between both groups (27 per cent versus 25 per cent, relative risk 1.01, 95 per cent confidence interval 0.90–1.13). Women in the balloon catheter group had a non-statistically significant increased risk of not achieving vaginal delivery within 24 hours compared to women in the prostaglandin group (48 per cent versus 38 per cent, relative risk 1.26, 95 per cent confidence interval 0.94–1.68). Interestingly, there was greater need for the use of oxytocin in the subsequent course of labour for women in the balloon catheter group (75 per cent versus 50 per cent, relative risk 1.51, 95 per cent confidence interval 1.15–1.97). Serious maternal and neonatal morbidity rates were not routinely reported in the studies but were infrequent and did not differ between the groups.

Given the evidence for a reduced rate of uterine hyperstimulation with balloon catheters, they have been rapidly adopted as the method of choice for IOL in those clinical situations in which there is a particular indication to avoid hyperstimulation, commonly women with a prior uterine scar and where there are concerns regarding fetal wellbeing, such as intrauterine growth restriction or abnormal Dopplers.

There are theoretical concerns regarding the risk of infection with the use of inflatable catheters for IOL, particularly as they are retained in the cervix for 24 hours. One systematic review from 2008 specifically addressed maternal and neonatal infectious morbidity.[11] Compared with women using pharmacological agents, women undergoing induction with mechanical methods had a higher likelihood of infectious morbidity (odds ratio 1.38) and a higher risk of neonatal infectious morbidity (odds ratio 2.03).

The most recent development in the use of balloon catheters for IOL has been in investigating their suitability for outpatient management. A recent Australian randomised trial of outpatient Foley catheter (n=50) versus inpatient prostaglandin gel (n=51) for IOL has reported no differences in safety outcomes including Apgar scores, neonatal admission rates and cord gas values.[12] Although the outpatient catheter group had a shorter hospital stay prior to birth, with less pain and more sleep during cervical preparation, they were more likely to require oxytocin and there were no statistically significant reductions in total inpatient stay.

This article has outlined the practical use of three very different inflatable balloon devices for the management of common obstetric scenarios. Whether or not you have previously used some or all of these inflatables, I hope to have inflated your knowledge and confidence in using them!

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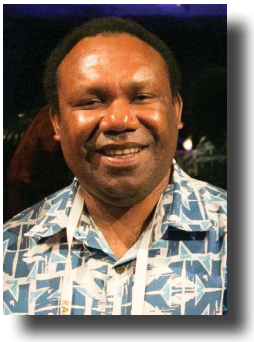
Necessity is the mother of invention



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Papua New Guinea (PNG) has a very high maternal mortality ratio. The expectation is that every health worker will work towards reducing maternal mortality at all costs. However, saving lives in a developing country is a task with many challenges. There are often situations where one is faced with a problem, only to realise there are no appropriate tools to help solve it, but the problem has to be attended to immediately. Trying to achieve such a feat with no proper tools means making use of what is available and improvising.

I trained at the Port Moresby General Hospital, PNG, and Sunshine Hospital, Melbourne, Victoria, where I spent three years working as a senior registrar. I left Sunshine Hospital in 2007, and, in 2008, was posted to Popondetta General Hospital, in the Northern Province of PNG. For avid trekkers, the famous Kokoda Track is located in this province. Popondetta is only a 30-minute flight from Port Moresby and serviced daily by LinkPNG and PNG Airlines Dash 8 aircraft. The hospital serves a population of 180 000 people.

In PNG, antenatal care is very basic: we do routine blood tests for haemoglobin, syphilis and HIV. There are no early ultrasound scans because most mothers present to the antenatal clinic for the first time in their second trimester. Working out the estimated date of delivery (EDD) is often difficult. With limited or no knowledge of the first day of a woman's last menstrual period, we apply the wizardry of fetal kicks, fundal height and fetal size, using the modified ultrasound scan (see Figure 1), to establish the EDD. At best, experience and an educated guess are sufficient, but a good tape measure and an obstetric wheel often come handy to aid the process. The ultrasound scan is used to establish the number of fetuses and fetal lie, locate placental site and provide a good estimate of fetal size. The image is not great, but any image is better than none.

In labour, the partogram and a Pinard fetoscope are handy tools. A good functional and reliable watch or wall clock is very useful. There are no infusion pumps so the oxytocin used in labour is regulated by counting the number of drops per minute in an intravenous fluid giving set. Fetal wellbeing in labour is monitored through a combination of: observation of the progress of labour; the fetal heart rate before, during and immediately after contractions; and the state of the amniotic fluid. A vaginal delivery is always the best option; however, there are circumstances that require operative delivery. Vacuum delivery is preferred over the forceps and this is attributable to the skills preference of the obstetrician. Emergency caesarean section is the other option. Only in the region of one in 15 caesarean sections are elective. The caesarean section rate is not more than five per cent of the total number of deliveries at Popondetta General Hospital each year.

Performing a caesarean section in a dilapidated building with no reliable operating theatre light and blunt surgical instruments is a nightmare. We have diving

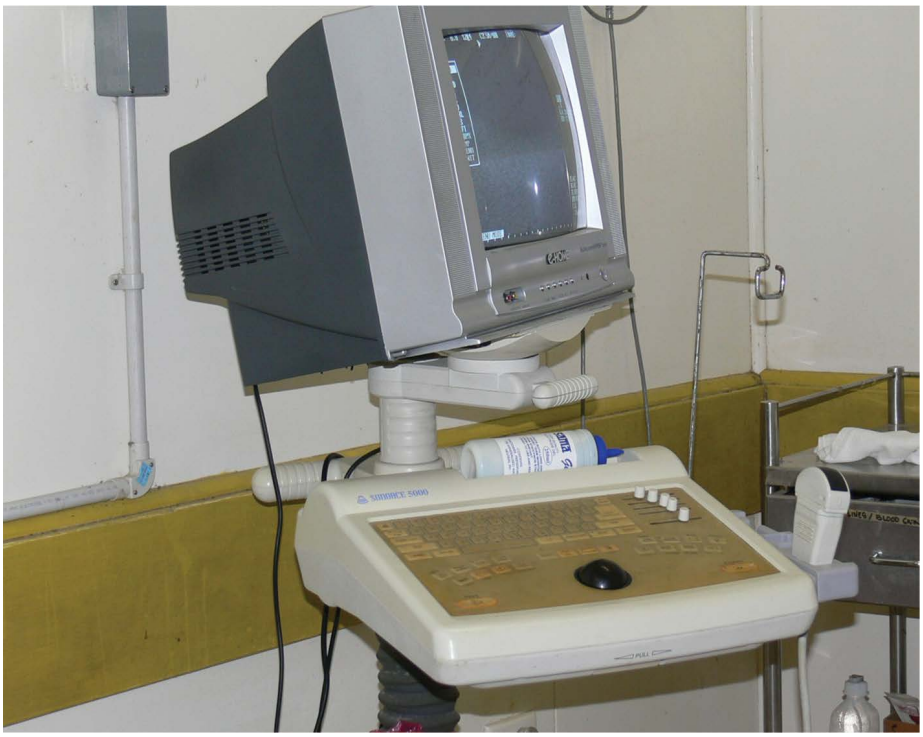

Figure 1. A 14-inch television screen mounted on an ultrasound body.

torches on standby for when the lights go out in the middle of the surgery (as shown in Figure 2). I have even done several emergency caesarean sections using the laryngoscope light as this was the only light available. Annually, we perform an average of 100 emergency caesarean sections. We have not registered a maternal death as a complication of emergency caesarean section since 2008; however, we registered one wound breakdown in October 2014 and two in early 2015.

> 'In this setting, everyone learns fast... you use what you have available and improvise if you have to.'

The total deliveries in a three-bed labour ward have increased from 800 per annum in 2007 to 1800 per annum in 2014. In the same period, the maternal death rate in the hospital has dropped significantly, from 709 to 315 per 100 000 live births. The stillbirth rate dropped from 30.7 to 21.6 per 1000 live births and the perinatal death rate from 54.4 to 34.0 per 1000 live births. We have worked hard to create an environment in the hospital where women want to come and give birth. In the last two years, we have gradually improved our unit, with the acquisition of the following equipment:

- a Philips HD7 ultrasound;
- cardiotocograph machines;
- labour ward beds;
- drip stands;
- fetoscopes;
- patient monitors;
- intravenous infusion pumps;
- reliable operating theatre lights with a back-up generator;
- new surgical instruments and gowns; and an
- improved and renovated operating room.

These improvements are all backed up by upgraded laboratory equipment to monitor other tests on request.

Since 2008, Popondetta General Hospital has been actively involved in providing training to students from UPNG for the postgraduate Diploma in Obstetrics and Gynaecology as well as the Masters in Medicine in Obstetrics and Gynaecology. The hospital has also had medical students from Victoria come and to do their attachments here. In this setting, everyone learns fast that when there are no tools around to save a life, you use what you have available and improvise if you have to.

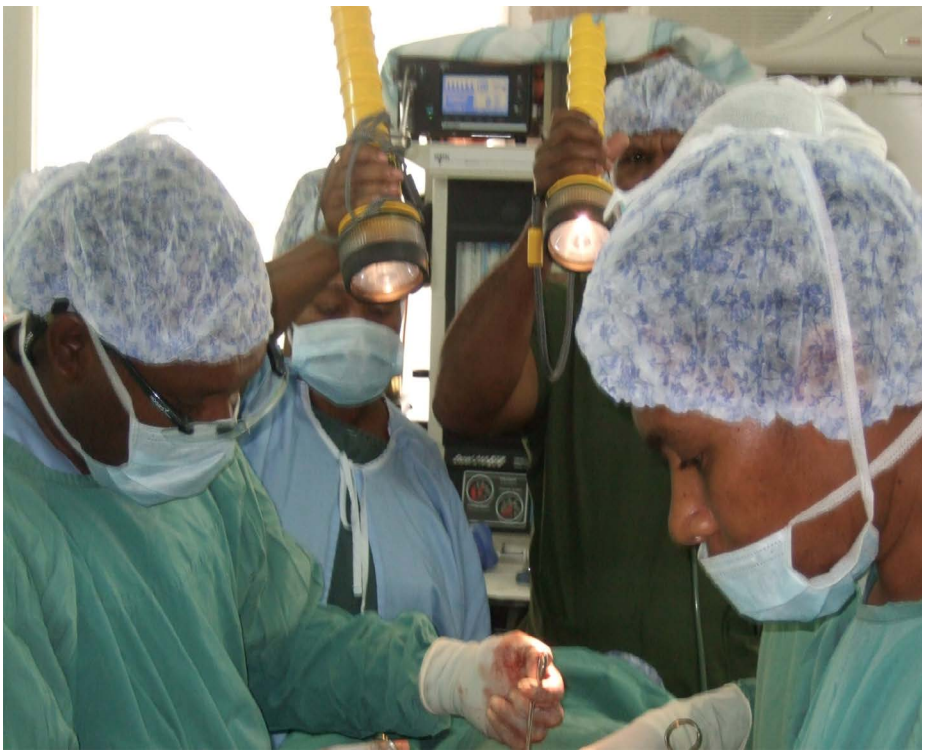

Figure 2. Using diving torches to provide light in the middle of performing an emergency hysterectomy for a ruptured uterus.

Decreasing patient harms from surgical innovations

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'Buxton's law' of investigation of a surgical innovation states: '…it is always too early for rigorous evaluation until, unfortunately, it's suddenly too late.'[1] Adoption of new surgical techniques in gynaecology is vital for the improved care of our patients and the development of the profession. A pivotal positive example is the revolution of gynaecological care by laparoscopic surgery in the 1980s. New surgical procedures and devices can appear very attractive to surgeons and patients alike. However, the diffusion of surgical innovations into common practice raises serious questions about patient safety.

Firstly, how should we decide which techniques to adopt to maximise patient benefit over existing surgical procedures? The insinuation into surgical care of new techniques because they are presumed to offer better care lays the basis for the mistaken belief that randomised controlled trials are unethical in many areas of surgery. This has led to procedures being introduced that are offered to the wrong patient population, are ineffective or inferior to established techniques, may waste resources or even endanger lives.[2]

Secondly, how can new surgical techniques be safely integrated into current surgical practice to minimise risks to patient safety? A regulatory framework is desirable to protect patients.

Drivers for change

An innovative procedure in surgery can be defined as 'a new or modified surgical procedure that differs from currently accepted local practice, the outcomes of which have not been described, and which may entail risk to the patient'.[3] There are two types of surgical innovation to consider in gynaecology: either a new procedure that uses existing devices or drugs (for example, morcellation of fibroids, progesterone-secreting IUDs) or an existing procedure that uses new devices (such as the use of transvaginal polypropylene mesh in prolapse surgery).

Wilson[4] has described the factors that determine acceptance of the new technique. They may relate to the 'intrinsic characteristics' of the technology or the contextual factors that 'promote' the technique. It is noteworthy that only some of them are amenable to any formal scientific assessment or evidence-based healthcare evaluation.

Factors determining the adoption of technology by surgeons and patients:

- operating facilities are available to easily adopt the technique into current practice;
- surgeons have an opportunity to observe the new technique;
- procedure can be offered for a trial period before full adoption;
- procedure is a 'simple modification' or easily learned;
- expected demand from patients justifies surgeons learning the procedure
- procedure appeals to patients/patients demand the procedure;
- low cost to surgeons of learning and using the procedure;
- aggressive promotion of the technology by the manufacturer; and
- magnitude of benefit perceived by each 'stakeholder'– doctors, patients, hospitals.

Models for assessing innovation

Social theory

Adoption of a new surgical technique has traditionally been viewed using a sociological model, assessing the number of surgeons who gradually embrace the procedure until it has become either accepted as standard care or is discarded.

According to Rogers[5], a social theorist, the diffusion of new technologies is initially launched by 'innovators' who are willing to take risks. The innovators are followed by the 'early adopters' (who are often opinion leaders in the industry with significant clout); then the 'early majority', the 'late majority' and finally the 'laggards'. There is a tipping point, at 10–20 per cent, whereby diffusion into the industry increases exponentially. The risks of patient harm are likely to be greatest as the innovation nears the tipping point. This is the stage at which the procedure diffuses from early expert adopters/opinion leaders to the early majority in the general surgical community. At this point, it appears vital that a hospital develops standardised training and credentialing for surgical teams. An analogy has been drawn with the aviation industry, which retrains flight crews who are inexperienced in new types of aircraft.[6]

Buxton described the introduction of a new procedure into standard practice according to our ability to assess it.[1] Initially, when a small number of surgeons are adopting a procedure, we have the opportunity to research it. However, since the procedure is still on a learning curve and technically immature, there is an inherent methodological flaw in analysis of its utility. Soon after, the technology can be very quickly embraced and the tipping point crossed. Once the procedure is adopted by a large number of operators, formal assessment is no longer feasible and we have lost the opportunity to comprehensively evaluate it.

Using scientific principles

The Balliol Collaboration (University of Oxford) has published their approach to the stages of surgical innovation, based

on the scientific principles of evidence-based healthcare.[7]

Stage 0 and stage 1: innovation
Stage 0 refers to prehuman/animal development and stage 1 is where the procedure is first used on humans. This stage hopes to establish acceptable levels of safety and proof of concept. Patient safety can be improved through the use of simulators.

The nature of the disease and proven alternative treatments determine the success of this stage. For example, in liver transplantation there was no alternative to end-stage disease and the balance between patient safety and possible benefit allowed greater surgical risk. Formal patient consent can be problematic as many risks are unknown.

Stage 2a: development
In Stage 2a the early surgical innovators deem the procedure to be safe, but are still experimenting with technical details of the operation and equipment. The surgical technique disseminates to 'opinion leaders' with high credibility who are influential in determining the success and further diffusion of the technique.

This is the most important time to research the procedure and attempts should be made to replicate early studies. Few patients are recruited and the innovative surgeons are highly selective for particular characteristics. The selected patients tend to be healthier, younger and better educated.[8] This may skew any studies assessing patient safety. A recent report in the *BMJ* addressed this issue when the rapid uptake of minimally invasive radical prostatectomy initially suggested statistically significant lower risks on all patient safety indicators over open prostatectomy. However, when adjusted for patient characteristic variables (white, healthier, better off), the association was not significant.[6]

Stage 2b: early dispersion and exploration
In Stage 2b the learning curves of the surgeons – particularly the innovators – are progressing rapidly. The indications for the surgery are becoming broader and the surgery is more efficient, with shorter operating times. The safety of the novel procedure is becoming established as well as its comparison to established techniques.

Hospitals and individuals wishing to have a competitive edge will embrace the new technique. Regulatory frameworks for accreditation need to be established, but there is little possibility of assessment of long-term harms.

Stage 3: assessment
Many surgeons are now competent in the procedure and the tipping point has been passed. The innovation has become the established standard of care and few surgeons have not learned or adopted the technique. Opportunities for formalised

assessment no longer exist and, for better or worse, the procedure has been embraced. Patient selection criteria for the procedure have been determined. Patient consent falls into the established clinical care guidelines rather than the special considerations to be given to experimental procedures. Patients are now generally aware of the availability of the procedure and are demanding it.

Stage 4: long-term implementation and monitoring

This stage concerns the use of the established procedure in surgical training of juniors and long-term monitoring for rare complications.

Implementation to minimise errors

Just like any systemic change within healthcare, implementation of a new technique must have prior assessment and planning. There are many resources available to guide healthcare professionals and organisations through this process, including the Royal Australian College of Surgeons New and Emerging Techniques – Surgical (NET-S)[9], the Australian Safety and Efficacy Register of New Interventional Procedures – Surgical (ASERNIP-S)[10] and the overarching National Safety and Quality Health Service (NSQHS) Standards.[11] In particular, attention must be paid to preventing and controlling healthcare-associated infections, patient identification and procedure matching, clinical handover (including use of a pre-procedure safety checklist), preventing and managing pressure injuries and recognising and responding to clinical deterioration.

A structured, formalised process allows for identification of safety issues at the outset, implementation of risk-management principals and regular review during implementation. This protects the interests of patients, clinicians and the organisation.[13] Any process change requires a baseline evaluation and, depending on the magnitude of the technique to be implemented, this may require the approval of an individual to perform the new technique or the assembly of a working group to evaluate widespread implementation, or something in between. Considerations prior to implementation include surgical and safety principles, the evidence for the new technique and the plan for enactment.

Pre-implementation

What is the purpose or indication for the new technique? Is it applicable to the population serviced by the organisation? Importantly, a cost and benefit analysis should be performed. Are there improved outcomes for the patient? Is there a reduction in hospital stay with conferred clinical and economic benefits? Are the consumables less expensive? Is there a short-term economic cost, but long-term benefit to the health service?

It is imperative to determine what is known already about the proposed procedure.

What clinical evaluation has been performed for the technique previously and does the evidence suggest it is efficacious? If so, is it applicable to the local conditions and patient population? To assist in answering these questions, ASERNIP-S provides access to full and systematic reviews, 'horizon scanning' for new techniques and the establishment and facilitation of clinical and research audits or studies.[10] Evidence should be reviewed during the planning stage (ideally systematic review and meta-analysis, but including controlled clinical trials and case reports), to flag any potential safety concerns, and/or lessons learned from other organisations that have implemented the technique previously.

One must assess what the training requirements are and estimate the impact of the learning curve[13]: individual, team (operative and non-operative) and organisational. Are there ways to minimise the impact on other patients caused by the redirection of personnel and service allocation? The opportunity to use preceptors and senior clinicians skilled in the new technique is invaluable and should be seized whenever possible.

Essential to the process are robust clinical governance policies, including a pathway for surgeon approval, credentialing and review of ethical issues. If the new technique also includes a new technology or device, has TGA approval been granted?

Implementation

Consumer engagement and patient informed consent is integral to the successful and safe implementation of a new technique.[13] Patients must be informed that the technique is new and/or experimental. As much as possible, they should be given information regarding expected clinical outcomes/benefit, acknowledgement of medical uncertainty (owing to the infancy of the procedure) and information regarding the safety mechanisms in place.

If the technique is being implemented in the form of a clinical trial, ethics approval should be obtained with a robust process for reporting adverse events. If outside a trial, regular clinical audit should be performed and, additionally, any problems with medical devices should be reported to the TGA as part of the Australian and New Zealand Medical Device Incident Report Investigation Scheme.[12]

Post-implementation

A vigorous clinical evaluation should be performed to assess the short- and long-term outcomes. This should include clinical, economic, training and organisational outcomes, with longevity relevant to the technique involved. If the technique is deemed successful, and thus adopted into routine clinical practice, further assessment should be performed regularly and results should be promoted and/or published in order to facilitate the implementation of the technique in other health services. A significant volume of data for innovation, in particular unsuccessful endeavours, is not currently recorded, leading to the proving of an innovation's failure to be repeated time and again.[14,15] Review at the health-service level should determine whether a critical volume of procedures using the new technique are being performed in order to maintain the necessary skillset.

Conclusion

Innovation in surgical practice should be actively encouraged, to foster improved clinical outcomes, without compromising patient, clinician or organisational safety, and with robust mechanisms for monitoring the efficacy and safety of new interventions.

While acknowledging the methodological challenges in the evaluation of surgical innovation, solid evidence is needed before formal implementation of new surgical techniques should begin. As Wilson so poignantly noted, 'in the final analysis, a surgeon's skill and ability to perform a procedure well is unimportant, in fact irrelevant, if the procedure should not be done in the first place.'[4]

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Innovative surgery: what is the evidence?

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The Australian Safety and Efficacy Register of New Interventional Procedures – Surgical (ASERNIP-S) is the only health technology assessment group in the world that focuses purely on surgical procedures. During the 17 years since its inception, this group has developed a strong international profile through the production of more than 100 reports on evidence-based surgery, surgical technologies and audit. In addition, ASERNIP-S has pioneered the introduction of national audits into the surgical community. The ASERNIP-S project has grown from a small staff of two, in 1998, to a Division of Research, Audit and Academic Surgery with close to 50 employees.

Initially, all reports produced by ASERNIP-S were systematic reviews; however, the range and scope of reports has changed over the years to include rapid reviews, technology overviews, and assessment of new and emerging surgical technologies identified by horizon scanning and input into clinical practice guidelines.

Background

The environment needed for the establishment of ASERNIP-S was created in 1996, following the release of a report by the Australian Health Ministers' Advisory Committee on Quality in Australian Health Care. The report stated that:

> '…improving safety and quality of care should be a central concern for all those in the health care system: policy-makers, managers and health practitioners. The current drive for efficiency must be matched by a drive for safety and quality.'[1]

The report also promoted evidence-based practice and the use of practice guidelines.

In 1998, the ASERNIP-S was established under the auspices of the Royal Australasian College of Surgeons (RACS). The aim was to use evidence-based methods to evaluate and document the safety and efficacy of new surgical technologies and techniques as they were introduced and preferably before they were widely accepted into the Australian healthcare system. Funding was provided by the Federal Government of Australia, which ran initially as a pilot.

In the late 1990s there was considerable interest in the emerging field of evidence-based medicine in Australia and internationally. The Australian Government established a government body known initially as the Medicare Services Advisory Committee (later changed to the Medical Services Advisory Committee [MSAC]). The principal role of MSAC is to advise the Australian Minister for Health and Ageing on evidence relating to the safety, efficacy and cost-effectiveness of new medical technologies and procedures. This advice informs Australian Government decisions about public funding for new and in some cases existing medical procedures.

During the first year, ASERNIP-S undertook to provide evidence for the Australian Government by producing systematic reviews of ten new surgical procedures. Systematic reviews are the most appropriate and best-validated tool of health technology assessment organisations. They provide critical summaries through a thorough assessment of relevant articles in the world literature. The best systematic reviews are produced when the results of several good-quality randomised controlled trials (RCTs) are available. The process of meta-analysis enables the results of several similar studies to be combined to produce an overall estimate of the combined results.

Typically, for several reasons however, few RCTs are carried out in the area of surgery. For example, the individual circumstances and needs of a patient may mean that he or she is not a suitable candidate to undergo a comparative treatment. In addition, the aim of ASERNIP-S is to review procedures before they are widely accepted into the community to identify any potential risks at an early stage; this often means that little high-level evidence (such as RCTs) on the procedure is available yet in the published work.

Reporting

It was quickly realised that wide dissemination of information from ASERNIP-S assessments, both locally and internationally, was needed to achieve quality improvements in surgical care. A website was created and information posted as it became available. A study of web hits showed increased interest each year in the information made available. However, serious consideration was also given to making dissemination a more active process, ensuring that information was directed to relevant individuals or groups.

The research community was informed of proposed, current and completed projects through the database of the International Network of Agencies for Health Technology Assessment. Additional effort has been put into writing articles on each systematic review for publication in the peer-reviewed literature to inform the wider surgical community, both in Australia and internationally. Articles are also submitted to newsletters or organisations for surgeons and consumers. The website has also undergone considerable changes over the last 17 years.

Horizon scanning

The ability to provide timely reviews of new surgical technologies was recognised as a difficult problem. Attempting to review a procedure or technology too soon means that the amount of information available is extremely limited, with the associated likelihood that the procedure may never be brought into practice. Leaving the process too late will mean that a procedure becomes so entrenched in the system that healthcare practitioners will find it harder to revert to the older procedure and may have already invested heavily (both financially and in training time) in the new procedure or technology.

In 2000, to circumvent this problem and to inform surgeons and policymakers of new techniques about to affect the Australian healthcare system, ASERNIP-S developed a horizon scanning process for the detection of new and emerging technologies. This was extremely successful and has also undergone many changes in the succeeding years. Since that time we have become a member of the Australian and New Zealand Horizon Scanning Network (ANZHSN), which is an initiative of MSAC. The ANZHSN is overseen by the Health Policy Advisory Committee on Technology, a subcommittee of MSAC, and was established to provide advance notice of significant new and emerging technologies, but is not confined to surgery and includes diagnostics and other areas of medicine.

This new collaboration led to some changes in the process for assessing new surgical procedures. Surgical procedures detected through the horizon scanning process are assessed by horizon scanning technology prioritising summaries and horizon-scanning reports.[2] Surgical procedures that have more widespread use in Australia, or are already established into routine surgical practice, are assessed by rapid systematic reviews, systematic reviews or technology overviews.

Horizon scanning technology prioritising summary

Horizon scanning technology prioritising summaries are short (approximately five to ten pages) documents that provide readers with a background on a particular technology or technique and present the evidence available pertaining to the safety and efficacy of that technology. This can be used for further deciding if the procedure should be further assessed, monitored or if no further assessment is required.

When a procedure or technology is considered to be of substantial impact and have a considerable evidence base, a more detailed assessment, in the form of a horizon scanning report, will be undertaken.

Horizon scanning report

These reports are comprehensive (approximately 30–50 pages) documents that assess surgical technologies or techniques that are new or emerging into Australian healthcare.

Systematic reviews

Systematic reviews assess surgical procedures through the use of a clearly formulated question using systematic and explicit methods to identify, critically appraise and summarise relevant studies (published and unpublished) according to predetermined criteria.[2,3] Reported outcomes can be synthesised either quantitatively or narratively or can include meta-analysis to statistically analyse and summarise the results of the included studies. Systematic reviews are fundamental tools for decision-making by health professionals, consumers and policy-makers, as they provide conclusions based on research evidence.

Rapid reviews

A rapid systematic review is an evidence-based assessment in which the methodology of the systematic review has been limited to shorten the timeline for completion. They are produced in response to an immediate need for a systematic summary and appraisal of available published reports for a new or emerging surgical procedure.[2] This urgency may arise if the uptake of a new technique or technology appears to be inappropriate; given the evidence available at the time (in other words, it may be diffusing too quickly or too slowly). Alternatively, there may be uncertainty or controversy regarding the clinical or cost-effectiveness of a new procedure, or there may be significant concerns regarding its safety or indications for use in particular populations. Rapid reviews use the same methodology as full systematic reviews, but may restrict the types of studies considered (for example, by only including comparative studies and not case series) to produce the review in a shorter time period than a full systematic review.

Funding

As with any not-for-profit, non-government project dependent on external financial support, funding has been a concern for ASERNIP-S. During the early years, the Australian Government Department of Health and Ageing supported the entire project, enabling systematic reviews, auditing and horizon scanning to be undertaken. Later, separate funding was obtained for some auditing activities. Similarly, funding has been provided separately for the different types of reviews. MSAC directly funds their reviews and additional funding was obtained for the horizon scanning project. ASERNIP-S retains some flexibility in choice of reviews with separate government funding.

Some work has been commissioned through other sources, for example, the National Institute for Health and Care Excellence in the UK. The Australian National Institute of Clinical Studies commissioned ASERNIP-S to assess the effectiveness of different strategies for increasing the uptake of prophylaxis for venous thromboembolism in hospitalised patients. The National Breast Cancer Centre also commissioned a review on intraoperative radiation therapy. ASERNIP-S has also worked on the National Health and Medical Research Council (NHMRC) Guideline Assessment Register to help developers of clinical practice guidelines achieve the requirements set out by the NHMRC for evidence-based guidelines. ASERNIP-S assisted the Australasian Paediatric Endocrinology Group to produce NHMRC-endorsed guidelines on type 1 diabetes.

Audits

Since the inception of ASERNIP-S, it has been envisaged that auditing would be an integral component of the program. Recommendations could be made following systematic reviews for further trials or audits where necessary. However, only a small number of audits were initiated following the review process. Although small in scope, these audits helped to establish protocols that would be of use in later audits.

The first audit established following a review was for laparoscopic live-donor nephrectomy. Information was collected from Australian and New Zealand surgeons between 1999 and 2003. The pooled data identified that Australasian surgical practice compared favourably with worldwide practice, both in terms of efficacy and safety for donors in the short term.

The MSAC has provided separate funding for two additional audits that were commissioned following inconclusive results from MSAC reviews. It was not considered feasible to conduct randomised controlled trials for the procedures; hence audits were considered the appropriate vehicle. One

audit of endovascular aneurysm repair ran for eight years and provided information on the mid- to long-term outcomes of the procedure, which helped inform the government funding decision. Two-year funding was provided towards the end of the audit by Cook Australia to enable the collection of long-term follow-up data.

The National Breast Cancer Audit (NBCA) was an audit that was started by the Breast Section of RACS, but later came under the management of ASERNIP-S.[4] This audit was different to the research audits resulting from inconclusive reviews. Its aim was to improve surgical care of women with breast cancer through the review of audit data and the establishment of quality standards of treatment, and is still in operation today.

As a result of the expertise gained in this area, RACS has established the binational audits of surgical mortality, now including gynaecology deaths[5], and the trainee logbooks program. It is hoped that the logbooks program will form the basis in the future for a full practice audit for Fellows.

Conclusion

ASERNIP-S has proved to be a world leader in the evaluation of new surgical techniques and technologies. By focusing on surgery, the ASERNIP-S is unique among the international health technology assessment organisations. The strong support of the Fellows of RACS has been, and continues to be, essential to the success of this important work. The role of evidence-based medicine is not often well understood by the general public or even those working in the healthcare sector. However, for surgery, it is vital that techniques and technologies being introduced into practice come under vigorous and public assessment.

The key challenge for this highly successful research group is to achieve long-term funding so that we can provide a stable work environment for our very talented group of researchers and highly skilled support staff. Appropriate funding is vital to ensure the continuation of this high-level and necessary service to the Australian healthcare sector.

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Scaling the evidence pyramid: research synthesis

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Every tradesperson needs a range of tools at their side and in medicine, particularly in obstetrics and gynaecology, surely one of the most valuable and powerful tools in our toolbox must be that of research synthesis, a process that underlies many of the principles of best clinical practice and evidence-based medicine (EBM). This article will trace the history of research synthesis and explain its key components, in addition to considering its pros and cons.

What is research synthesis?

As busy clinicians, every day we need to make decisions about which treatment or intervention is the best for a particular patient with a particular problem. Without any form of research synthesis (defined, in its most primitive form, as a way of integrating empirical research)[1], we would not be able to know which treatment or intervention is the best for our patient. The term research synthesis may also be defined as: the process by which two or more research studies are assessed, with the objective of summarising the evidence relating to a particular question. The processes that result in or encompass a research synthesis may be referred to using a range of terms, with which may be confusing to the novice. In addition to a number of terms being used, there are a range of different options or elements, which may be used in combination or as standalone tools.

Where does it come from?

Research synthesis emerged at the start of the 1900s, with the publication of key research synthesis papers in the field of typhoid, an important public health issue at the time.[2] EBM is a term that may be more familiar than research synthesis. EBM may be defined as: the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients.[3,4]

EBM, research synthesis and their related principles can be further traced to the writings of French physician, Pierre-Charles-Alexandre Louis, who encouraged practitioners not to rely on 'speculation and theory about causes of disease nor… single experiences', but rather to make a 'large series of observations and derive numerical summaries from which real truth about the actual treatment of patients will emerge.'[5] This real truth is derived, in part at least, from our ability to use the tools of research synthesis that allow us to build the top of the research evidence pyramid. Research synthesis allows us to take the idea of deriving (numerical) summaries to a much more sophisticated level[1] and to build the top floors of the research evidence pyramid by minimising bias as far as possible. The now well-known hierarchy or pyramid of research evidence ranks research methodologies based on how well potential biases are minimised (see Figure 1) and identifies systematic reviews of randomised trials to be of the highest possible quality. The process of undertaking a systematic review can be understood as way of synthesising

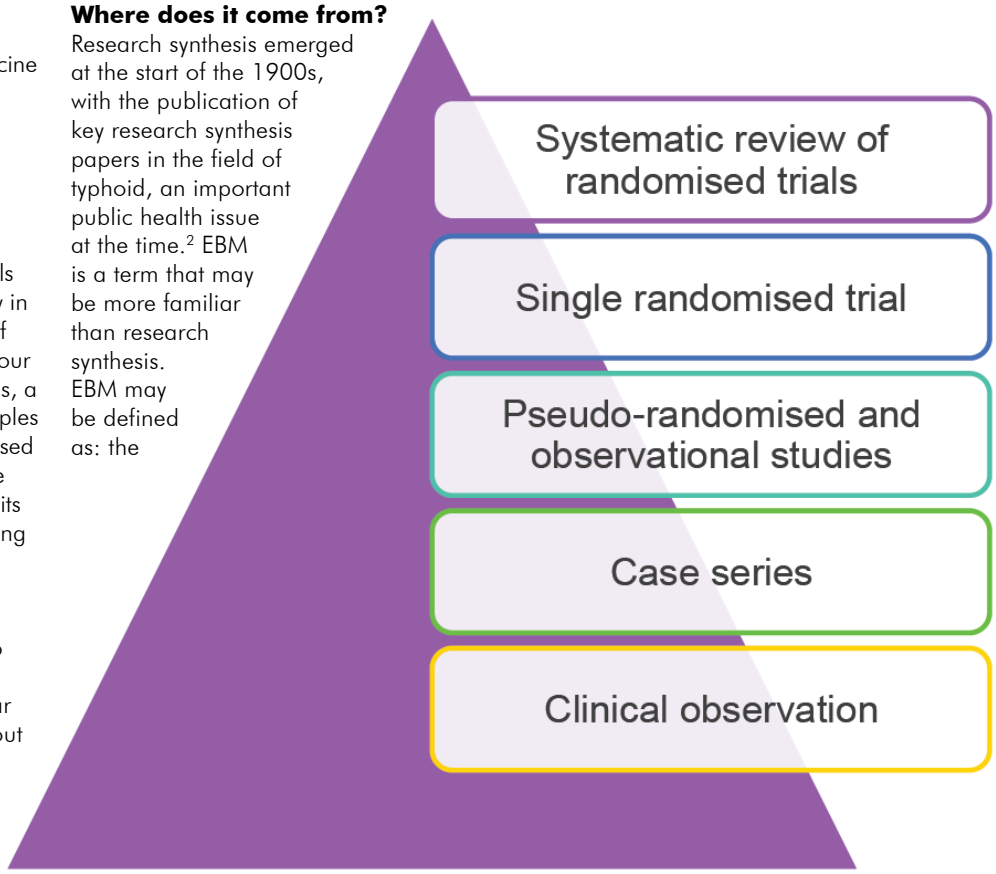

Figure 1 – The hierarchy or pyramid of evidence-based medicine. Adapted from: NHMRC levels of evidence and grades for recommendations, December 2009

Pierre-Charles-Alexandre Louis, known for inventing the 'numerical method', a precursor to modern clinical trials, and for his work on infectious diseases and bloodletting.

research, or one type of research synthesis, but there are other aspects to consider.

Types of research synthesis

The most basic form of research synthesis is one that almost all will be familiar with, that of the literature review. In a traditional literature review, the author is often an expert in the field and provides little information as to how the review was conducted or the scientific basis of any recommendations.[6] The author of a traditional or narrative review will often express his or her opinion and take a less-than-systematic approach to their review of the literature.

Systematic review, a frequently used term since the 1990s, in fact is a concept dating back to the early 20th century[2], although it almost certainly has different implications now and has evolved into a much more rigorous process. Our common understanding of the term systematic review can perhaps be attributed to Archie Cochrane in the introduction to the first bible of evidence-based care in obstetrics, Effective Care in Pregnancy and Childbirth.[2] Systematic reviews aim to identify, evaluate and summarise the findings of all relevant individual studies[7] and in their most pure form adhere to a strict scientific design, based on explicit, pre-specified and reproducible methods. However, the term systematic review is often more generally used to mean a process of literature review by which measures are taken to reduce the influence of bias.

Systematic reviews are often performed alongside of, and even confused with, an additional, but separate, quantitative process of research synthesis known as meta-analysis. Meta-analysis, a term coined in the 1970s, is used to refer to 'the statistical analysis of a large collection of analysis results from individual studies for the purpose of integrating the findings.'[2]

Why do we need research synthesis?

We are all busy in our clinical day-to-day lives and most of us lack the time and inclination to search for, identify and appraise original research when looking for the answer to our clinical questions. Many studies may be available when searching for the answer about a particular clinical question; we need to put together their results in a sensible way. Research synthesis allows us to review and make decisions about clinical questions in a timely way.

Pros and cons of research synthesis

With advanced methodologies and approaches to assessing and summarising all forms of original research – including qualitative and cohort studies, not only randomised trials – research synthesis is applicable to all types of research[6] and, indeed, to all areas of interest in our field of women's health.

The concept of a single, systematic review or any other piece of research synthesis providing the answer to a clinical question is somewhat of a fallacy, with many systematic reviews and meta-analyses raising and generating more questions than are answered. In fact, systematic reviews and meta-analyses that identify 'gaps' in the literature are often used as the basis to formulate new ideas and plan future research. It has been stated: 'Evidence does not speak for itself – it requires interpretation in light of its original context [and] limitations…in order to inform the practical decisions of other [clinicians].'[8] In view of this, clinicians require training to be skeptical and discriminating, to develop the skills required to make the best use of research synthesis and then generate positive changes in clinical practice to improve health outcomes.[9]

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Information and communication technology

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Patients and clinicians alike joke about checking with 'Dr Google', but with internet access via smartphone and other handheld devices ubiquitous, information and communication technology (ICT) is having a profound affect on how medicine is practised.

A night in the life of a clinician

It's 1am and you get a page from the call service that says 'please call Mrs Jones' and gives a mobile number. In a daze you think: 'Mrs Jones...mmmmm is that the Mrs Jones who is a 39-year-old primip at term with a background history of valvular heart disease or the Mrs Jones who is 20 weeks with no significant medical history?' Or, perhaps, 'I don't recall a Mrs Jones at all.' The ability to quickly access patient information in a concise format that gives the full clinical picture is paramount.

Electronic health records

All GPs now use medical software for their records. This is not new technology; however, what some hospitals and providers have recently begun including is electronic versions of pregnancy paper records. Many women now carry a paper copy and a link to an electronic copy. Some hospitals, such as the Mater in Brisbane, have an electronic portal for patients and providers to share.

Mater Shared Electronic Health Record (EHR) is an electronic alternative to the paper hand-held Pregnancy Health Record or blue book. It allows pregnant women, GPs and private obstetricians to collaborate with Mater Mothers' Hospitals in a safe online environment on a woman's maternity information. With real-time exchange of information, Mater Shared EHR gives quick, secure access to patients and providers alike in order to improve patient care. Mater Shared EHR is only available for maternity care at this time.

Apps for pregnancy

There are many pregnancy apps available for women to use. Most are focused on the pregnancy journey and birth plans. Apps such as Pregnancy +, developed by the UK's National Health Service (NHS), provide a combination of maternal and medical information. The apps feature kick and movement charts as well as growth plans and weights. Others, such as Baby Bump Pro, provide portals to Twitter and other social media feeds for mothers to share during their pregnancy.

Facebook and Twitter

There are many Facebook pages devoted to pregnancy and antenatal care. Pages such as RANZCOG, RCOG and OBGYN.net are supported by colleges and organisations to provide information for women and providers of obstetric care. There are also closed sites available for GPs where providers can discuss cases and ask colleagues for advice, such as GP Down Under. These pages require permission to access, usually showing evidence of registration and so forth.

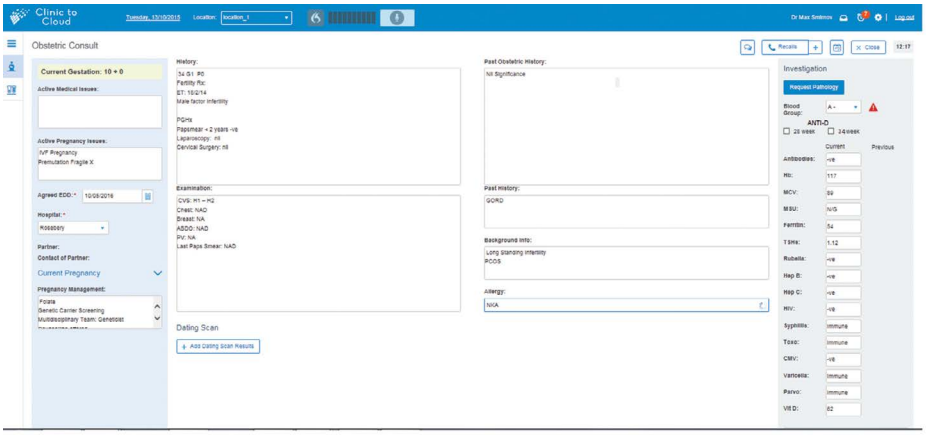
Twitter has become the go-to place for current discussion and education. There are many tweets (messages posted to the site) regarding best practice, evidence base and future treatments. Twitter hashtags such as FOAM (free online access medicine) have regular up-to-date conversations regarding medical education and now #FOAMog and many other sites (links via the website bitsandbumps.org) provide FOAM for the specialty. There are even GP obstetrician online groups being developed.

Tools and toys

There seems to be a paucity of new technology related to office obstetrics. Ultrasound is getting smaller and more hand held and there are slow improvements in cardiotocography monitoring, but we are still waiting for video specula, digital

Technology for new parents

- Pacif-i. It looks just like a normal dummy, but the Pacif-i smart pacifier measures the baby's temperature so parents can better manage their child's health.
- Mimo Onesie. Needless to say, this is the most expensive clothes parents will buy for a baby. While the organic cotton is nice, what makes this outfit even cooler is that it monitors pulse, breathing rate, heart rate and even body position. Then it sends all of that information to the parents' phones, meaning they can always rest easy that their baby is doing okay.
- Nuvo Ritmo Pregnancy Sound System. For parents who want their baby to know all about Mozart and Beethoven (or Rihanna and Prince) before they are even born. The sound system takes the form of a belt with in-built speakers that spread the music across several points across the belly, ensuring that volume is not overly concentrated in any one place. It allows mothers to play music to their unborn child through their very own sound system.



A screen shot from Clinic 2 Cloud, a file-management product for clinicians.

cervical Dilantin monitors and membrane rupture apps (or maybe not).

Head into the cloud

Cloud technology is emerging as the most secure and cost-effective way to do business for corporations small to large. There are undeniably advantages of using the cloud over owning your own server, including reduced operating expenses, a more secure datacentre and the ensured backup processes. However, unfortunately, medical software hasn't kept pace with these advances.

In the past, one of the authors had the good fortune to design and commercialise a medical rostering software package. The product was designed to be intuitive, automated (where feasible) and put in place safeguards to prevent unsafe work practices. As obstetricians and gynaecologists, we need medical software available on our desktops and smart phones that allows us unscheduled access to patient clinical data; especially in the birth suite.

The ideal medical software would make medical practice more efficient, safe, paperless, synchronise with accounting software, provide business analytics, generate audits easily and, most importantly, provide a better patient experience. It should allow for voice recognition and easy dictation directly within the program. Finally, our obstetric patients shouldn't have to carry pieces of paper with their history with them to every appointment. They should be able to access their relevant details via a smart phone application.

Today's patient is conscious of cost and our duty of care is often affected by the tools we have at hand. While we have seen significant improvements with our clinical tools, until recently there has been little effort and innovation on the software side of things. Very few improvements have been made to help us better manage patient care. To this end, one of the authors has helped to design an obstetric module. The aim is to deliver a better practitioner and patient experience. Equally, medical software products need to adapt and change with advances in technology and be flexible enough that to appeal to those who are less tech savvy than others.

Clinic To Cloud (C2C) is a product that has good logical workflow to assist the practitioner in quickly and efficiently managing their files. The primary patient page makes great use of the screen real estate, allowing the practitioner to view the complete obstetric history on one screen. The patient results are intelligently linked and displayed on the right-hand side of the screen. No doubt this system will help provide a more efficient and safer level of practice.

The evolution of the obstetric vacuum extractor

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A tool is as safe as the person using it. To use a medical tool properly, the practitioner should be able to appreciate the principles that influenced the way the tool is designed, the reasons for its design features and safe guidelines for its use. This article will outline the use and design of the vacuum extractor over the past 300 years.

After Malmström publicised his design of a vacuum extractor in 1957[1], its popularity grew.[2] Despite being promoted as safer and less complicated to use than forceps, reports in the English language literature[3] soon began to be published suggesting that fetal injury was more common and more significant than with forceps. In the UK, the USA and Australia, forceps were seen as the tool of first choice in instrumental vaginal delivery in the second half of the 20th century. Vacuum extraction developed a reputation for poor obstetric outcomes and an examination of contemporaneous literature reveals why.

As an obstetric registrar, Chamberlain (a future RCOG president) reported in the *Lancet*[4] an account of contemporary vacuum practice in 1965. Applying a vacuum extractor at 4cm dilatation to an occipito-transverse presenting fetal head in a multiparous woman, the cervix was stretched to full dilatation after 12 minutes of traction with delivery 'affected in a further three minutes'.

In another article in the *Lancet*[5], Huntingford described using vacuum to treat first stage delay. He describes the use of up to 75 minutes of traction, although five of his 11 reported cases were delivered with less than 30 minutes of traction. Another contemporary paper in the precursor journal to *BJOG* by Inman[6] suggests that the total traction time (not time to delivery) in vacuum extraction should be limited to 'not more than 40 minutes'. This paper states that in St Thomas's Hospital 'vacuum extraction is reserved almost entirely for use before full dilatation of the cervix'.

The Australian literature reported similar practices. In a 1967 article in *ANZJOG*, Fahmy[7] suggested that if the fetal head was high, the cup should only be applied if the cervix was 'at least two-thirds dilated' and if the head was engaged, applied when the cervix was 'at least half dilated'. In the 1 500 cases he reported, 236 were in the first stage of labour. To put this practice into context, the caesarean section rate when these cases were managed was only 2.2 per cent. As recently as 1997, a US study in *Obstetrics and Gynaecology*[8] reported results of continuous vacuum time of between less than five minutes to 30 minutes, with poorer outcomes with more than ten minutes of vacuum.

None of these practices would be acceptable today. It is difficult for practitioners in 2015 to appreciate what great lengths obstetricians would go to in the past in order to avoid undertaking caesarean section. The use of vacuum, when forceps was considered to be contraindicated (such as through an incompletely dilated cervix or markedly high head), and excessive periods of vacuum application and traction contributed to the reputation of vacuum as being inherently dangerous. Now, evidence-based guidelines[9] limit the use of vacuum to the same clinical preconditions as forceps.

Evolution of design

The earliest report of the use of vacuum extraction was by James Yonge, a naval surgeon, diarist and medical writer. He was the author of several papers published in the 'Philosophical Transactions of the Royal Society', including the first report in 1702 of the use of vacuum extraction in obstetrics using 'cupping'. The next recorded report was by the renowned Scottish obstetrician James Young Simpson. He reported the design and use of a vacuum extraction device to an 1848 meeting of the Edinburgh Obstetric Society, using design features that are similar to some contemporary instruments.

The Simpson[10] 'air tractor' (1848) had a brass body incorporating a vacuum pump and a leather 'skirt' (showing that combining the air pump with the vacuum device is not a new idea). This device (as displayed in the University of Edinburgh medical collection) would not have allowed any flexion or oblique traction (see Figure 1). Simpson abandoned further development of this vacuum device,

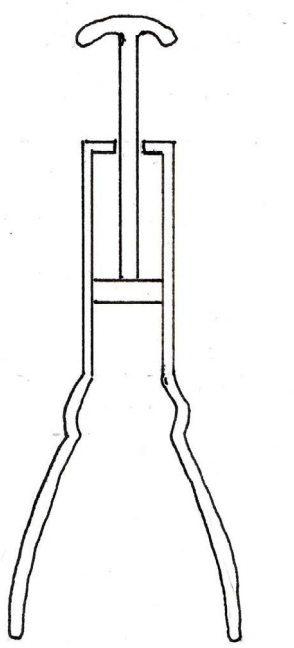


Figure 1. The Simpson air tractor, this design was abandoned in favour of forceps by its designer, James Young Simpson.

Figure 2. The Mälstrom vacuum cup design.

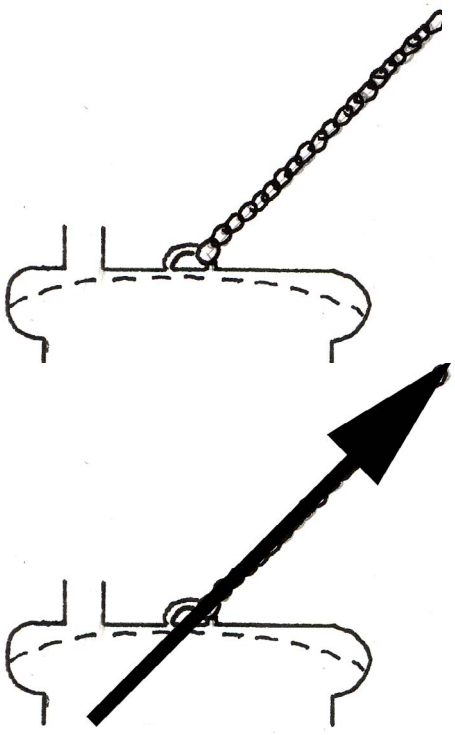
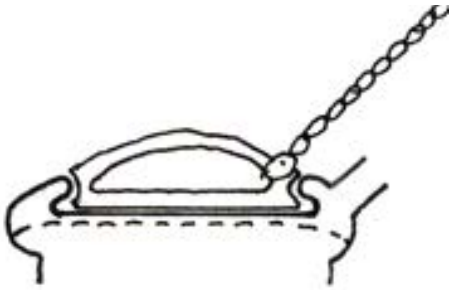


Figure 3. The Bird vacuum cup design.

and three years later demonstrated his forceps design, still used today (basically unchanged) by many obstetricians.

The original Malmström vacuum cup design (1957)[1] allowed any oblique direction of traction to create a vector that resulted in rotational forces that tilted the device and lifted the edge of the cup, resulting in loss of suction, and hence detachment (see Figure 2).

The Bird vacuum cup design (1969)[11] lowers the traction point on the cup, reducing rotational forces, and allowing better placement over the fetal head flexion point, but still creates a vector that may lift the edge of the cup (see Figure 3).



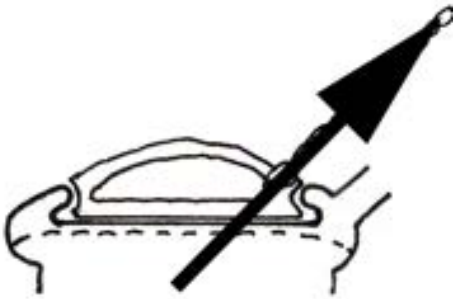


Figure 4. The O'Neil vacuum cup design.

The O'Neil vacuum cup design (1981)[12] modified the Bird design further, with a rotating ring creating a vector that will direct a traction point at the centre of the base of the cup in all but the most acute angles. This reduces rotational forces that may cause detachment (see Figure 4).

As shown in Figure 5, the Kiwi Omnicup (2001)[13] has a recessed channel that further lowers the traction point of the vacuum tube (which also supplies traction). Although this facilitates the placement of the cup over the flexion point in a deflexed fetal head, the vector of the traction point, unlike the O'Neil cup[12], is still not at the centre of the base of the vacuum cup (but is still closer to the centre and less likely to cause rotational vectors) than the Bird[11] or Malmström[1] designs).

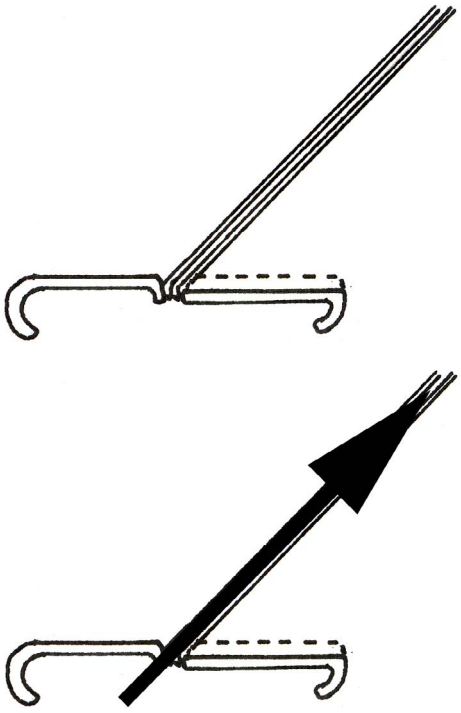


Figure 5. The Kiwi Omnicup vacuum cup design.

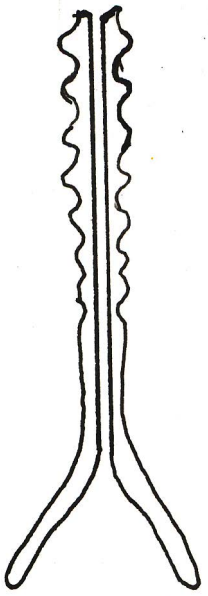


Figure 6. The Kobayashi vacuum cup design.

Soft cups, although claimed to be less traumatic to the fetal scalp, such as the Kobayashi cup[14] from 1973 (see Figure 6) or bell cups, are unable to be placed on the flexion point of the fetal head unless flexion is already present. Any oblique traction is more likely to result in detachment. The soft mushroom cup

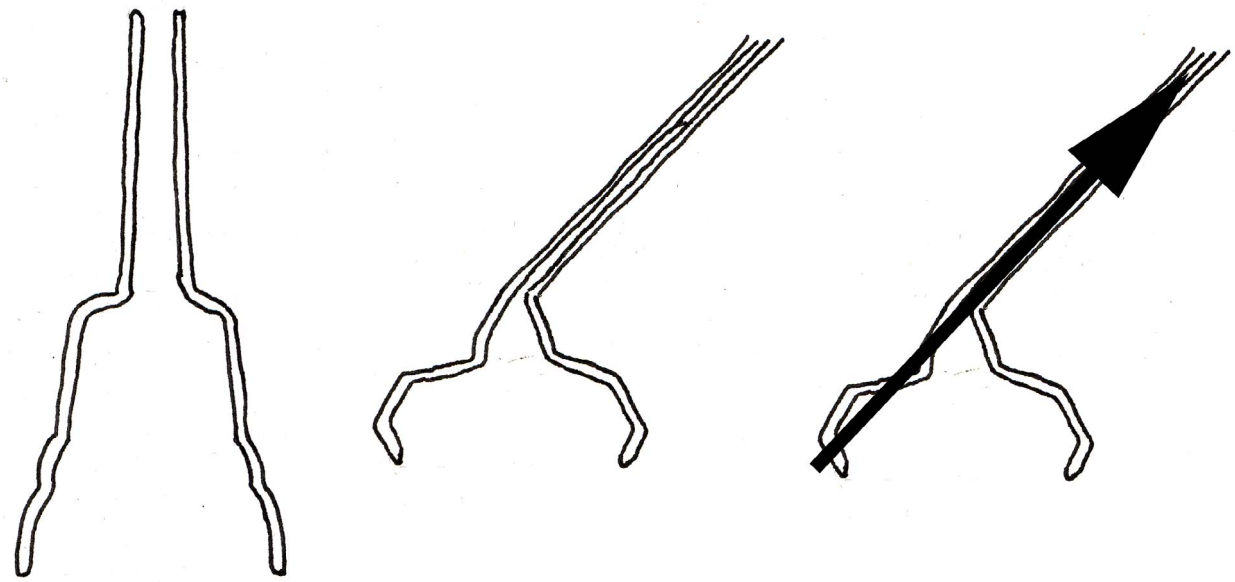


Figure 7. Bell cups are soft and it has been claimed that they are less traumatic to the fetal scalp; however, they have many limitations.

(see Figure 7) has many of the limitations of the Malmström[1] design with a high traction point and vector that is more likely to rotate the cup and lose suction.

Conclusion

The adage that a poor craftsman blames his tools is particularly relevant to vacuum extractors. If a vacuum extractor is used when instrumental delivery should not be attempted – or in ways that the instrument was not designed for (such as using a Bell cup to attempt rotation) – then the instrument may fail to achieve its intended use and potentially cause harm. Used by a practitioner with an understanding of its design and limitations, the vacuum extractor is a safe and effective instrument.

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Forceps delivery: a disappearing art?

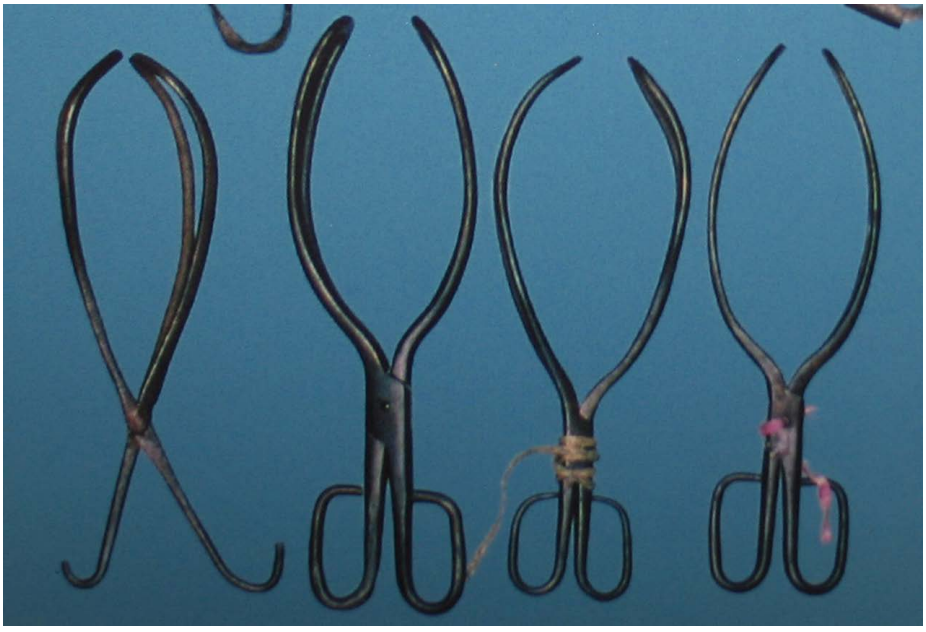
Prof Caroline de Costa
FRANZCOG

On a cold November morning in the year 1817, prostrate in her bed at the royal residence of Claremont House outside London, the 21-year-old Princess Charlotte, daughter of the Prince of Wales and third in line to the throne of England, took her final breaths. She had just endured a labour of more than 50 hours, resulting in the spontaneous vaginal birth of a stillborn son. The subsequent postpartum haemorrhage, no doubt related to the prolonged labour, finally carried her off. Throughout her confinement, royal physicians had been in attendance, but they dithered, unwilling to apply the forceps to the royal personage in order to hasten delivery. Timely application of this instrument, which had been in existence for around 200 years, might have resulted in a live infant and a healthy mother, and subsequent events – the rapid marriage of the brother of the Prince of Wales, the Duke of Kent, and the production of another heir to the throne, in the person of Queen Victoria – might never have occurred. Britain might never have known the Victorian Age.

Prolonged and obstructed labour have long been recognised as causes of maternal and perinatal mortality and morbidity and, since the Middle Ages at least, instruments have been devised to try to assist expulsion of the fetus from the birth canal. Arab physicians developed hooks and instruments with teeth to seize fetal tissue and deliver it forcefully, sometimes piecemeal. In 1554, Rueffe, a Zurich obstetrician, described a smoother instrument somewhat like later forceps, but with a fixed joint so that both blades needed to be applied simultaneously to the fetal head, rather limiting its usefulness. A single-bladed instrument, the vectis, and other lever type tools, also appeared around this time. Alternatively, if internal version could be performed, the fetus might be turned to a breech and extracted manually, with hooks to the after-coming head if there were difficulties with this. Needless to say, these techniques were often fatal for the infant and frequently injured the mother as well.

In a pre-anaesthetic and pre-antiseptic age, then, when attempts at caesarean birth were universally fatal for women, an instrument that could deliver a live baby from an obstructed labour, and limit damage to the mother, would be an enormous advance. The obstetric forceps in its present form is attributed to the Chamberlen family, French Huguenots escaping persecution whose story in England began with the arrival of Dr William in 1569. William had five children including two sons both called Peter and both doctors, of whom the younger (who I shall refer to as Dr Peter) had a son called (you guessed it!) Peter, who had a son

Princess Charlotte Augusta of Wales, who would have been Queen had she not died following childbirth at the age of 21.



The Chamberlen instruments – this photo is part of a display at College House, Melbourne.

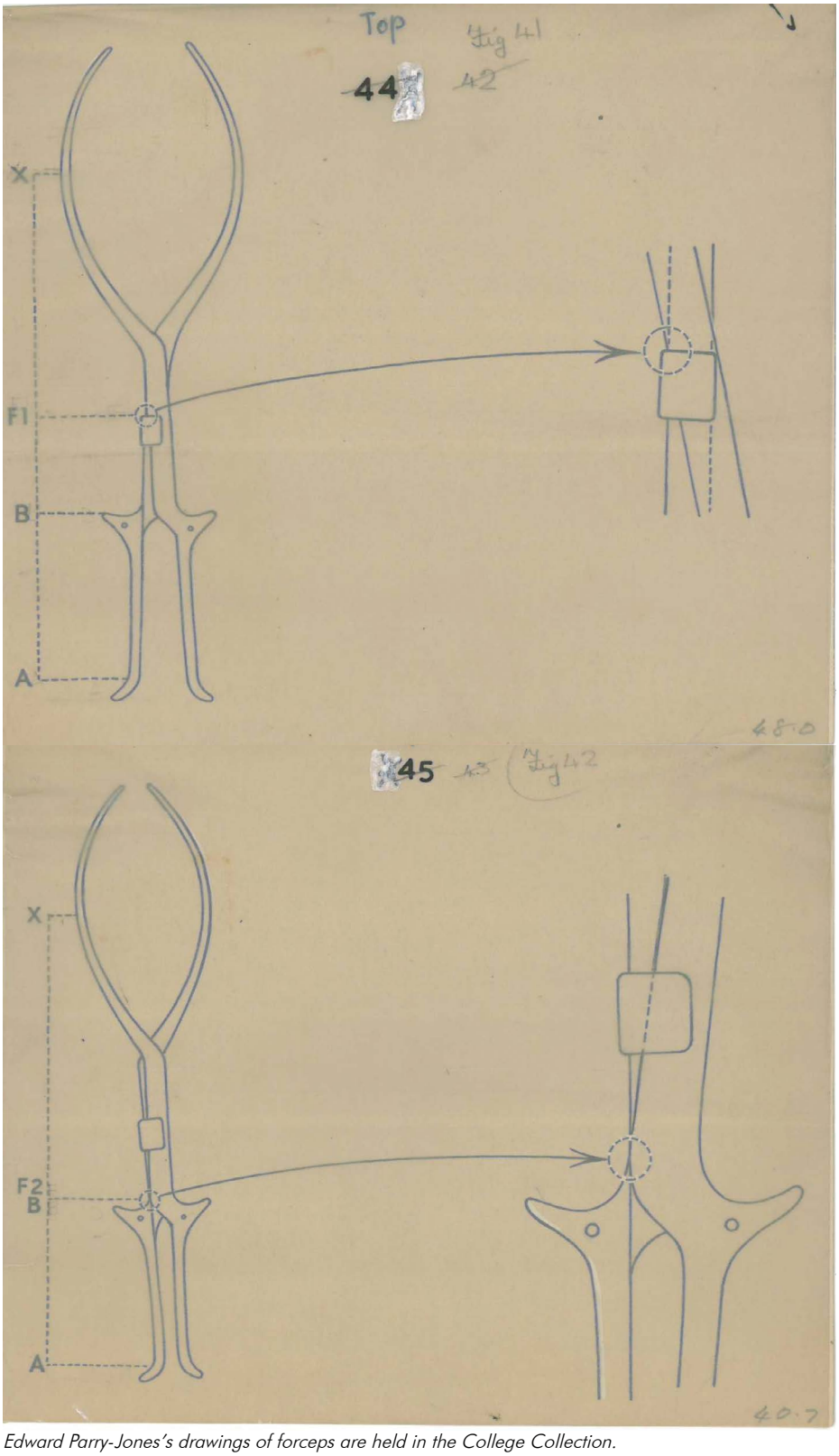
called Hugh who was a doctor, and who had a son called (yes!) Hugh, who also was a medical practitioner. All the Peters and both Hughs, as well as other Chamberlen family members practised obstetrics, and between them they managed to keep the design of their forceps secret for more than one hundred years. They achieved this by arriving at the labouring woman's house with the forceps concealed in a velvet-lined box, sending all possible spectators out of the bedchamber and performing the delivery with the blankets covering their heads and the bedsheets tied about their necks. As women at the time lay on deep feather beds the application of the forceps was indeed a skill that took some acquiring, and one largely achieved by touch rather than sight.

We now know what the original Chamberlen instruments looked like, as in 1813 some of them were found hidden beneath the floor of a house in Essex in which Dr Peter had died some 130 years earlier, and these are now displayed in the Museum of the Royal College of Obstetricians and Gynaecologists in London. They consist of four pairs of forceps, one crudely constructed and probably experimental, and probably the work of the older of the first two Peters, the three others each with some improvement on the first. The concept of two blades separately applied, but fitting together to form a single instrument was present from the beginning, as was the cephalic curve of the blades and the fenestration that reduced the weight of the instrument and hence the pressure on the fetal head. Later, an articulation was developed to lock the blades and, later still, a tape was used to tie them together. The Chamberlen instrument was very successful and family members travelled right across England bringing relief to women in obstructed labour (and, of course, reaping considerable financial benefits).

By the early 18th century the design of the Chamberlen forceps had leaked out, and soon the instrument was in use by obstetricians throughout Britain and on the Continent. In 1733, English obstetrician Edmund Chapman wrote that: '…as to the forceps, it is a noble instrument, to which many now living owe their lives.' Throughout the 1700s there were efforts to improve forceps design in order to lessen damage to mother and baby. The great English obstetrician William Smellie introduced the pelvic curve, making it possible to effect delivery from higher in the pelvis, a notched handle that was easier to grip, and a neater locking device. An example of Smellie's forceps can be seen in the College collection in Melbourne; the metal is covered with leather, to increase maternal comfort – or more likely reduce discomfort – and Smellie greased the blades with lard as a lubricant. Smellie was nevertheless cautious about interfering with nature in childbirth; he recommended a forceps rate of one in 1000 births. That there was still great caution about forceps use even in the 19th century can be seen by the demise of the unfortunate Charlotte, who spent 24 hours in the second stage of labour without an attempt at operative vaginal delivery.

The 1800s also saw the appearance of numerous variations in design – detachable handles and blades, assorted materials for construction – but the basic concept of the application of interlocking blades followed by traction remained the same. James Simpson of Edinburgh, chloroform pioneer, developed both long and short versions of his personal forceps, for mid-cavity and

William Smellie's straight forceps (c1750). The forceps are made of iron and covered in leather, fragments of which are still visible on the handles and blades.



Edward Parry-Jones's drawings of forceps are held in the College Collection.

outlet deliveries, respectively. In France, Tarnier worked on designs for axis traction device that would alter the direction of the pull through the various planes of the pelvis. In 1915, Kielland in Norway reduced the pelvic curve which enabled rotation of the fetal head using the forceps themselves (rather than manual rotation preceding application of the other forms of the instrument that retained the pelvic curve). Kielland also invented a sliding lock to allow correction of asynclitism. By the end of the 19th century forceps both long and short were in wide use; rates of around six per cent in home deliveries and 18 per cent in hospital births are quoted for many European centres.

Up till that time the instrument was used only for prolonged or obstructed labour. In 1920, the US obstetrician De Lee proposed the use of forceps 'prophylactically', achieving delivery to spare the mother and infant the effects of long labour. This further led to the idea of proceeding to a forceps delivery when there was fetal distress – diagnosable then only by the use of the Pinard horn to detect fetal bradycardia – a truly revolutionary idea. By the last decades of the 20th century, forceps delivery was widely used for a variety of indications, often along with epidural analgesia and fetal monitoring, the two latter accused by some of being a direct cause of the increased forceps rate.

What role, if any, do forceps have in 2015, when we have a national caesarean rate of more than 30 per cent, widespread use of the vacuum extractor, which itself has undergone many modifications and improvements in recent years, and a fundamental belief in obstetric practice that, in the words of London obstetrician Peter Huntingford, '…there are now only two routes of birth: easy vaginal delivery, and caesarean section'? Added to this is the fact that those of us trained in the latter decades of the 20th century, when forceps delivery, including mid-cavity, was widely practiced, are now approaching retirement. Adequate training of our younger colleagues, particularly in the safe use of rotational forceps, with fewer cases available and reduced working hours, has become problematic. Training and competence in the use of mid-cavity rotational forceps is likely to become more and more inadequate. Increasingly, I believe, we will see less use of forceps in this situation and increasing use of emergency caesarean section without a prior attempt at operative vaginal delivery.

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Case report

Just a cervical polyp? A rare and interesting diagnosis

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Case report

Ms MH, a 22-year-old para 1 was referred to the urogynaecology clinic with a history of six months of stress urinary incontinence and a symptomatic vaginal lump increasing with Valsalva. She also reported six months of postcoital and intermenstrual bleeding. She was a current smoker and had a BMI of 43, but was otherwise fit and well with one previous termination of pregnancy in 2011 and had a Mirena in for the last four years. Her first Pap test was nine months ago and was normal. She had a previous forceps delivery.

On speculum examination, there was appearance of one large, fleshy, dark-red endocervical 'polyp' that bled with contact. Bimanual examination revealed a small anteverted uterus with a broad-based polypoid soft mass extending out of the cervix. There was a significant amount of contact bleeding, which stopped with pressure. No adnexal masses or pelvic sidewall swelling was palpable. A biopsy was taken from the polyp as it looked too big to be removed in clinic and slightly unusual. Miss MH was waitlisted for a hysteroscopy, dilatation, curettage and polypectomy to be done in theatre.

Histology surprisingly reported embryonal rhabdomyosarcoma (RMS). Ms MH was referred to the gynaecology-oncology multidisciplinary team meeting. MRI pelvis revealed a 6cm-large heterogeneous multicystic mass in the vagina and cervix with invasion of the left paravaginal region and extension to the left pelvic sidewall with no lymphadenopathy. Miss MH underwent laparotomy, modified radical hysterectomy, bilateral salpingectomy and transposition of the right ovary. Histology confirmed Stage 1 cervical embryonal RMS, botyroid type limited to polyp with complete excision. She has currently completed round two of chemotherapy (vincristine, actinomycin, cyclophosphamide [VAC]) with curative intent. The number of cycles is still to be confirmed by the medical oncology team.

Discussion

RMS is the most common soft tissue tumour of childhood and represents about half of all soft tissue sarcomas in childhood and three to four per cent of all cancers.[1] However, it is extremely rare in adulthood, accounting for less than five per cent of all soft tissue sarcomas and less than one per cent of all cancers. About 20 per cent of embryonal rhabdomyosarcomas in children arise in the genitourinary tract and, of these, only 0.5 per cent of primary RMS is found on the cervix. Primary cervical RMS in adults is even rarer.[2] According to the International Classification of Rhabdomyosarcoma[3], there are four major histological subtypes: embryonal, associated with more favourable prognosis; botyroid, associated with intermediate prognosis; alveolar, with relatively poorer prognosis; and anaplastic RMS.

Establishing the diagnosis can be challenging both histologically and clinically, which can result in delayed diagnosis and a missed opportunity for early intervention. Currently there is no

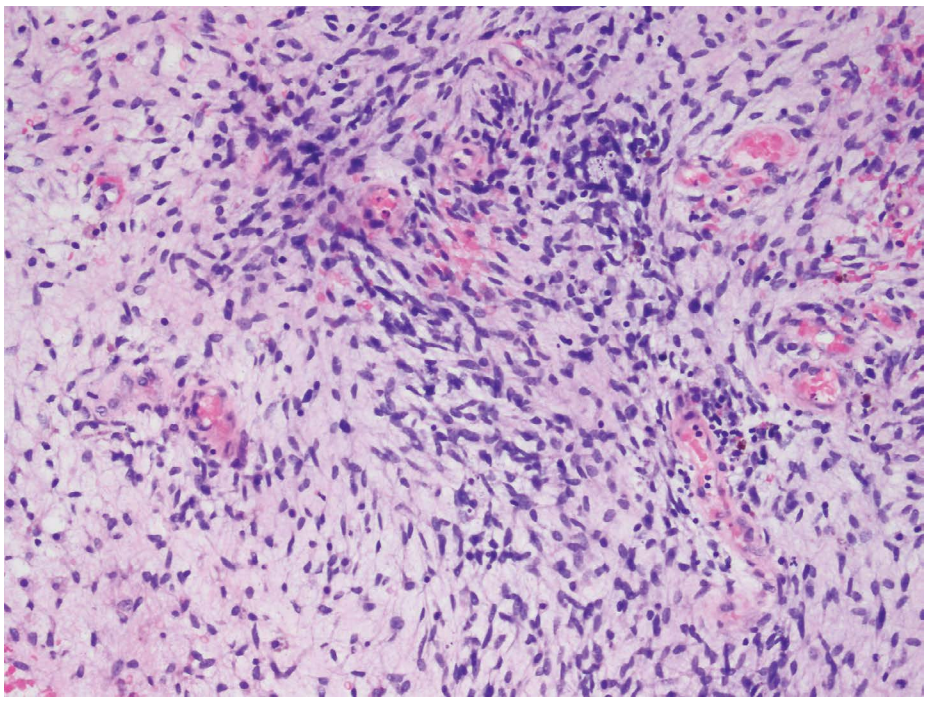

Figure 1. Embryonal RMS is composed of typical rhabdomyoblasts arranged in sheets and large nests (H&E 400 x original magnification).

standard agreed treatment for adult patients with cervical RMS; although most patients are treated with a combination of surgery and chemotherapy, and treatment is largely based on studies in children and adolescents.[4] Literature review revealed only a handful of case reports regarding embryonal RMS in adults and two case series, each comprising respectively only 11 and 25 patients over a period of more than 30 years.[5] There has only been one case report of cervical embryonal RMS in Australasia, which occurred in pregnancy.[6] The vast majority of treatment in cases of cervical RMS in adults has involved surgery, either cone biopsy or radical or total hysterectomy, followed by adjuvant chemotherapy. Patients with favourable prognostic factors, such as localised disease, single polyp and embryonal histologic subtype, and without deep invasion appeared to be treated successfully with minimally invasive surgery.

Unfortunately, overall data shows that adults diagnosed with any type of RMS had a significantly worse overall five-year survival compared to children (27 per cent versus 61 per cent), especially evident for localised disease (47 per cent versus 82 per cent).[7] Tumours in adults were more likely to be at unfavourable sites or less favourable histology. These results may reflect inadequacy of primary treatment in adults and favour adults undergoing the same treatment principles as RMS in children. However, data are lacking with regards to specifics, for example, optimal radiation dose or the best way to integrate surgery, chemotherapy and radiotherapy.

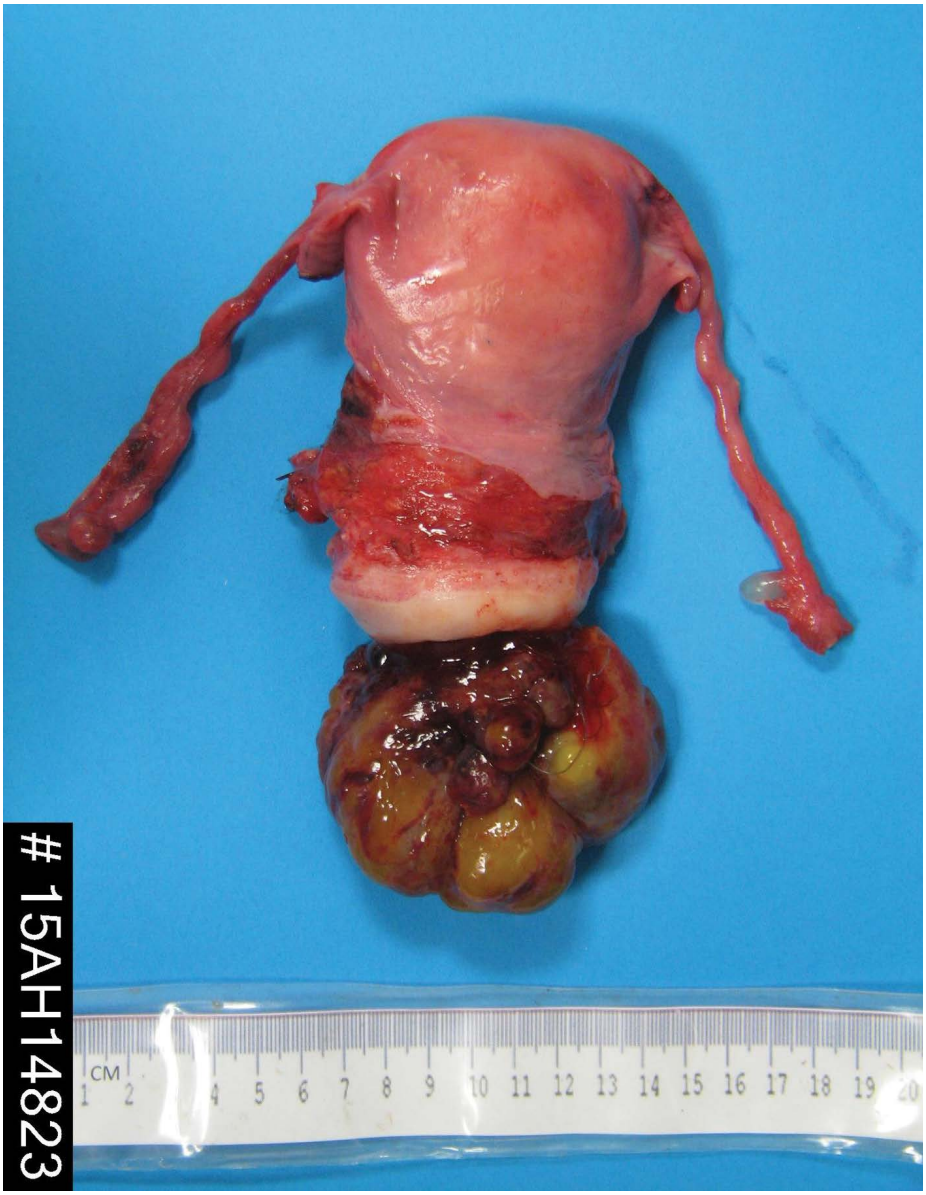

Figure 2. Macroscopic specimen cervical RMS, uterus, tubes from radical hysterectomy.

Conclusion

Ms MH presents a rare and interesting diagnosis, which was delayed by several months owing to the patient's clinical presentation to her GP and her reason for referral to clinic. Fortunately, she had early stage disease that was able to be completely surgically excised. Optimal treatment required multidisciplinary team input as well as review of current available literature regarding the condition, given the rarity of this condition at this site and in this age group. This highlights the importance of clinical skills, such as history and examination, in determining diagnosis as well as the importance of writing this case report to contribute to existing literature to determine optimal treatment of embryonal RMS in adults.

Acknowledgements

The author thanks Dr Kathryn Payne (ADHB) and Dr Irene Low (CMDHB) for the figures provided.

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Journal Club

Had time to read the latest journals? Catch up on some recent O and G research by reading these mini-reviews by Dr Brett Daniels.

Route of hysterectomy

Each year 30 000 Australian women have a hysterectomy. The method of hysterectomy may be abdominal, first performed successfully in 1853; vaginal, which as an emergency postpartum procedure dates from at least the writings of Soranus in AD 120, and as a planned procedure from 1801; laparoscopic, first performed in 1988; or robotic, first performed in 2005. While choice of route of surgery for a particular woman may depend on a number of clinical factors and resource availability, there appear to be definite trends in the type of hysterectomy performed in the past ten years. Loring et al[1] report their experience of hysterectomy in a 300-bed academic community hospital with 42 general gynaecologists and two full-time minimally invasive gynaecologists. They do not perform robotic gynaecological surgery. In 2004, only 24 (eight per cent) of the 292 hysterectomies performed for benign conditions at the hospital were laparoscopic. The rate increased to more than 50 per cent (189/365) by 2008, and, in 2012, 72 per cent (316/439) of hysterectomies were performed via a traditional laparoscopic approach. Furthermore, in 2012, 85 per cent (293/344) of laparoscopic hysterectomies at the hospital were performed on an outpatient basis, that is with discharge on the day of surgery. The increase in laparoscopic hysterectomies was mirrored by a decrease in abdominal hysterectomies, while the rate of vaginal and laparoscopically assisted vaginal hysterectomy remained relatively stable over the study period. While this is a US study, the large increase in laparoscopic hysterectomy no doubt reflects the experiences of many gynaecologists in Australia and New Zealand.

1 Loring M, Morris SN, Isaacson KB. 2015. Minimally invasive specialists and rates of laparoscopic hysterectomy. *Journal of the Society of Laparoendoscopic Surgeons* 19, DOI: 10.4293/JSLS.2014.00221.

Childhood outcomes after caesarean

This study[1] uses data from the Longitudinal Study of Australian Children (LSAC) to examine the health and developmental outcomes of more than 5000 children born by caesarean section in Australia in 2003 and 2004. Outcome measures included: global health, asthma, BMI, use of prescribed medication, general development, medical conditions and/or disabilities, special healthcare needs and socio-emotional development including temperament, social development, mental health and quality of life. Outcomes were measured at five assessments across the seven-year study period. Overall, 28.2 per cent of the babies in the study were delivered by cesarean section. Children born by cesarean delivery were more commonly preterm, low birthweight, and were more likely to require intensive care or ventilator support. Despite the large number of outcome measures in this study, there were relatively few significant differences between the children born by caesarean section and those born vaginally. Children born by caesarean delivery were more likely to have a medical condition at two to three years of age, use prescribed medication at six to seven years, and have a higher BMI at eight to nine years, although this last effect was mediated by maternal obesity. Parent-reported quality of life for children born by cesarean delivery was lower at eight to nine years, but not at younger ages. However, caesarean delivery was also associated with better parent-reported global health at two to three years and prosocial skills at age six to seven years. It appears that differences were not consistently maintained across the study period and that this makes interpretation of these data difficult. It does not seem that caesarean section confers a global cost or benefit to health and wellbeing in childhood.

1 Robson SR, Vally H, Abdel-Latif ME et al. 2015. Childhood Health and Developmental Outcomes After Cesarean Birth in an Australian Cohort. *Paediatrics*, 136, doi: 10.1542/peds.2015-1400.

Lifestyle intervention in PCOS

Polycystic ovarian syndrome (PCOS) is a common cause of anovulation and female infertility. While weight loss and lifestyle interventions are often recommended to women in an attempt to improve their fertility, there are few randomised trials of the effect of the intervention on fertility. This trial[1] randomised 149 women with infertility owing to PCOS into three groups to receive 16 weeks of the oral contraceptive pill (OCP); lifestyle modification consisting of a calorie-restricted diet with meal replacements plus weight loss medication plus increased physical activity; or a combination of the OCP and the lifestyle intervention. Following the 16 week preconception phase, women received four cycles of clomiphene ovulation induction and timed intercourse. The authors report that there was a significantly higher rate of ovulation in the combination compared to the OCP group. Live birth rates during the study were 12 per cent for the OCP group, 26 per cent for the lifestyle group and 24 per cent for the combination group. However, these were not statistically significant differences. The aim of this study to perform a randomised controlled trial of preconception lifestyle modification in PCOS was sound; however, the impression seems to be that the study was underpowered given the hypotheses in question.

1 Legro RS, Dodson WC, Kris-Etherton PM et al. 2015. Randomized Controlled Trial of Preconception Interventions in Infertile Women With Polycystic Ovary Syndrome. *J Clin Endocrinol Metab* 100, doi: 10.1210/jc.2015-2778.

Q&a

For the broader *O&G Magazine* readership, balanced answers to those curly-yet-common questions in obstetrics and gynaecology.

Q *'A 40-year-old patient saw me for her first antenatal visit at ten weeks. She has read all about cell-free DNA testing and would like this as a screening test. However, she also wants combined first-trimester screening too, "just to be sure". What should I do?'*

Dr Lisa Hui
FRANZCOG, CMFM, DDU

a All pregnant women should have a discussion about screening for Down syndrome and other chromosome abnormalities as early as possible during pregnancy.[1] While the internet and social networks have provided women with much better access to information about healthcare, they cannot replace an individualised discussion with their maternity care provider.

As the risk of Down syndrome increases with maternal age, this patient would be considered at high risk based on her age alone, with a risk of one in 100 of an affected baby at term. She and her partner's medical and family history should also be reviewed to ascertain any additional risk factors for genetic or chromosome abnormalities.

If, as this question suggests, the woman wishes to have a screening test, then her two options at ten weeks of gestation are cell-free DNA testing or combined first trimester screening.

Her comment that she wants two tests 'just to be sure' indicates that she places a high emphasis on the detection rate and is concerned about missing an abnormality.

Cell-free DNA screening (or noninvasive prenatal testing [NIPT]) is a test based on analysis of DNA from the placenta in maternal blood. This has been available in Australia since 2012, and is the most accurate screening test for Down syndrome, with a very high detection rate of 99.2 per cent and low false positive rate of 0.09 per cent.[2] It also detects trisomy 18 and 13 and provides the option of testing for fetal sex and sex chromosome aneuploidies such as Turner syndrome.

A cfDNA test would be a suitable primary screening test for this 40-year-old woman. There is extensive published data on its excellent performance in high-risk women. The woman should understand that cfDNA is not diagnostic and that false positive results do occur. If this woman has a high-risk result on cfDNA, then a confirmatory diagnostic test, such as amniocentesis or chorionic villus sampling (CVS), should be recommended. There are several overseas and local providers cfDNA testing in Australia, with variable costs from around $500 upwards.

Combined first trimester screening (CFTS) is the current publicly funded screening test in Australia and is still the standard of care for the general population. However, it is NOT advisable to perform CFTS risk calculation for Down syndrome risk after a low-risk cell-free DNA result 'just to be sure' as it will increase the chance of a false positive result (three to five per cent) without an appreciable improvement on the detection rate. Several professional societies, such as RANZCOG and the International Society of Ultrasound in Obstetrics and Gynaecology[3], have already cautioned against the use of CFTS after a low-risk NIPT result for trisomy 21 risk calculation.

However, the disadvantage of cfDNA as a primary screening test for Down syndrome is that it does not provide an early structural assessment of the fetus at 11–13 weeks. Many major fetal malformations can be detected at this stage, providing women with an early opportunity for diagnosis and further investigations. Women who have cfDNA as a primary screening test in first trimester should also be offered an 11–13 week scan for an early structural survey (but not a formal Down syndrome risk calculation). If there is a structural abnormality (including a nuchal translucency ≥3.5mm), this increases the chance of an atypical chromosome abnormality that would not be detected by the standard cfDNA panels. In this case, the woman should have genetic counselling and be offered a diagnostic test for a molecular karyotype with chromosomal microarray.

Women should also be informed about the small risk of cfDNA test failure (approximately one to five per cent). The turnaround time for a cfDNA result (four to ten days, depending on provider location) should be factored into the screening pathway so that if there is a test failure, the woman is still at an appropriate gestation to have CFTS as an alternative screen.

Finally, if the woman is extremely anxious about the risk of a chromosome abnormality, she has the option to bypass screening altogether and to choose a diagnostic test, such as CVS or amniocentesis. Advanced maternal age is decreasing as a primary indication for invasive testing in Australia, owing to its low positive predictive value and the small, but appreciable, risk of procedure-related miscarriage. If a woman chooses prenatal diagnostic testing, she needs to understand that even in this modern age of genomic medicine, no test, or combination of tests, can guarantee a child free from a genetic disease.

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Further reading

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Letters to the editor

Influenza vaccination

The article by Somerville, Dwyer and Kok (*O&G Magazine* Vol 17 No 2 Winter 2015) once again highlights the risks of influenza to the pregnant woman.[1] Despite the compelling evidence of higher rates of hospitalisation, fetal loss and maternal death, the immunisation rates continue to hover around 50 per cent. The initial rise in vaccination rates following the H1N1 pandemic has plateaued.

The reasons for the low level of vaccination stems from poor recognition of the risks of influenza among both the general population and the health community, incorrect views on the safety of the vaccination and a lack of access to vaccinations within our current model of care.

It has been shown that the likelihood of vaccination being undertaken is increased when it is recommended by a healthcare provider; this was further increased if flu vaccination was offered at the time of the recommendation. Women who received both a recommendation and an offer were 1.6 times more likely to be vaccinated (73.5 per cent) than women who received only a recommendation (45.1 per cent).[2] In the absence of either a recommendation or an offer, the rate of immunisation was only 15.4 per cent. This is of concern when combined with the recent article by Maher, Dawson, Wiley et al that found that one-third of general practitioners did not believe that influenza infection was a significant risk to either the mother or baby and half of the general practitioners had concerns regarding the safety of the vaccination.[3]

The vaccination is safe, we have demonstrated this in several trials. There have been no reported significant adverse events, the majority of reactions being mild local effects or mild systemic symptoms such as fever, headache and myalgia. Sheffield et al found no links to congenital abnormalities.[4] Naleway et al found no association between the vaccination and gestational diabetes, gestational hypertension, pre-eclampsia or chorioamnionitis.[5] In fact, the studies in to safety have predominantly found benefits, with Omer et al finding lower risk of premature birth, small for gestational age and stillbirth. The Mothers Gift Project found a 36 per cent reduction in lower respiratory infection in those receiving vaccination and a 63 per cent reduction in influenza infections in infants younger than six months.[6] The safety of the vaccination has been well established and we need to educate both our patients and fellow health professionals.

Influenza infection remains a serious health issue in pregnancy. Despite several attempts to improve vaccination levels, the overall rate has stagnated. Is it as simple as educating regarding the risks, addressing misconceptions and offering the vaccination at the time of the antenatal visit; or is it time for the government to undertake a comprehensive advertising campaign to increase the overall level of community knowledge of the risks of influenza to the mother and newborn child? The time to act is now.

Dr Stuart Prosser
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The following views expressed by the authors are their own; for more information regarding RANZCOG's position on Caesarean Delivery on Maternal Request, please see the College guideline (C-Obs 39): www.ranzcog.edu.au/doc/cdmr.html .

Caesarean on maternal request

I'd like to comment on the article 'When the professional becomes personal' in *O&G Magazine* Vol 17 No 3 Spring 2015. The author, despite having had two elective caesarean sections in private herself, states that she 'still believes that caesarean section for maternal request should be denied' (in the public sector).

This article, like little else in the entire literature on the topic, illustrates the degree to which we have been confused and misled by the ideology of natural childbirth. Should it not be possible to discuss the issue of elective caesarean on maternal request rationally? We are, after all, supposed to believe in the scientific paradigm, not ideology.

Elective caesarean has a number of indisputable benefits, which to date have rarely been disclosed to patients and are commonly ignored by obstetricians and midwives. In fact, many obstetricians in public hospitals actively try not to think about those benefits in order to reduce what can only be described as cognitive dissonance. Briefly, these can be listed as:

1. Elective caesarean is associated with reduced perinatal mortality compared to a planned vaginal birth; simply owing to the fact that elective caesarean results in earlier delivery. Every day spent in utero carries a

risk of unexplained stillbirth. Between 38+ and 40+ weeks gestation this amounts to between 1:500 and 1:2000 excess perinatal deaths[1] for planned vaginal birth.

2. Elective caesarean prevents anal sphincter tears, which are much more common than previously assumed at 10–20 per cent of the vaginally parous population[2], and the main aetiological factor for faecal incontinence in women, which requires about 10 000 surgical procedures per annum in the US alone.
3. Elective caesarean prevents levator tears and irreversible hiatal over-distension, which affect 12–35 per cent of women after a first vaginal birth[3] and which are the main aetiological factors for female pelvic organ prolapse. This likely is the strongest public health argument for elective caesarean, with an estimated 100 000 procedures per annum in the US directly or indirectly owing to levator trauma.

There are multiple other less-obvious benefits, such as the avoidance of psychological trauma up to and including post-traumatic stress disorder[4], psychosexual issues and partnership problems owing to traumatic childbirth.

Hence, there can be little doubt that, from the patient's angle, elective caesarean is a rational decision. Not inevitable, surely, given that fact that this choice has substantial downsides, but entirely rational. The older the patient and the lower the number of desired offspring, the more rational it is. The ethical precept of beneficence/non-maleficence can most certainly not be used to deny a caesarean on maternal request.

There remains the argument that elective caesarean is more expensive, that is, more resource intensive in a resource-limited environment. This is a fallacy. The difference in short- to medium-term cost has been estimated at £84 by the National Institute for Health and Care Excellence (NICE).[5] That's without accounting for prolapse, faecal incontinence or stillbirth. Hence, the ethical precept of justice cannot be used to deny an elective caesarean on maternal request.

Finally, let's consider the interests of the obstetrician. As many of our readers will be aware, the UK Supreme Court has recently delivered a decision that will have substantial consequences for antenatal and intrapartum consent. In the Montgomery versus Lanarkshire judgment the pertinent text reads as follows: 'Where either mother or child is at heightened risk from vaginal delivery, doctors should volunteer the pros and cons of that option compared to a caesarean'. Not just agree to a maternal wish – to voluntarily offer it. And do I really have to mention the universal ethical and legal principle of autonomy to affirm the right of every pregnant woman to decide on an elective caesarean herself? We're pro-choice, aren't we?

Despite disparities in health service delivery and legal systems, Australian courts tend to take UK precedents seriously, and a UK Supreme Court decision will have consequences in Australia. Hence, with at least half of antenatal women – most primiparae, anybody at age 30 or above, any gestational diabetic, anyone with a macrosomic child, with a BMI of over 30, a long closed cervix at term, a high head, anyone going over term and so on – the obstetrician will in future have to discuss the option of elective caesarean. The obstetrician will have to bring it up and, of course, will have to agree to an elective caesarean if the patient so chooses. Not doing so will end doctors up in court and may cost them their livelihood. Better change tack now before it is too late.

However, it already may be too late. The Montgomery versus Lanarkshire decision referred to a case of shoulder dystocia that occurred in 1999. A decision to deny a patient an elective caesarean that occurred within the last ten years is now probably indefensible in court, and no NSW Health Policy Directive, RCOG or RANZCOG guideline, is going to save us and our services from the resulting consequences.

Prof HP Dietz
MBChB (Heidelberg), MD, FRANZCOG, DDU, CU, PhD

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Caesarean on maternal request

It is surprising to read that women are still being denied caesarean on request (*O&G Magazine* Vol 17 No 3 Spring 2015).

Elective caesarean is no riskier than attempted vaginal delivery, because every labour carries the possibility of the much riskier emergency caesarean. The cost argument doesn't really stack up either – certainly there are six or seven staff in theatre, but the patient is usually in and out in an hour and 15 minutes, whereas a patient in labour requires attendance for 12–18 hours and, if she eventually needs an emergency caesarean, all those expensive personnel must, of course, be called in anyway.

Why are we behaving like this? Could it be that we are concocting quasi-scientific arguments against caesarean on request because we resent women usurping our hegemony?

A generation ago Australian women had to fight for rights to contraception and abortion – now it seems they must fight for caesarean rights!

Dr Donald Clark
FRANZCOG

College Statements Update

July 2015

Prof Stephen Robson
FRANZCOG
Chair, Women's Health Committee

The Women's Health Committee (WHC) reviewed the following statements in July 2015, which were subsequently endorsed by Council. College statements can be viewed on the College website.

New College Statements

The following new statements were approved by RANZCOG Council and Board in July 2015:

- Screening in Early Pregnancy for Adverse Perinatal Outcomes (C-Obs 61)

Revised College Statements

The following revised statements were approved by RANZCOG Council and Board in July 2015 with significant amendments:

- Birth After Previous Caesarean Section (C-Obs 38)
- Testing for Hypothyroidism During Pregnancy with Serum TSH (C-Obs 46)
- Depot Medroxyprogesterone Acetate (C-Gyn 4)

The following statements were approved by RANZCOG Council and Board in July 2015 with minor or no amendments:

- Pre-pregnancy Counselling (C-Obs 3a)
- Routine Antenatal Assessment in the Absence of Pregnancy Complications (C-Obs 3b)
- Categorisation of Urgency for Caesarean Section (C-Obs 14)
- Use of Prostaglandins for Induction of Labour (C-Obs 22)
- Vitamin and Mineral Supplementation in Pregnancy (C-Obs 25)
- Responsibility for Neonatal Resuscitation at Birth (C-Obs 32)
- Management of Obesity in Pregnancy (C-Obs 49)
- Menopausal Hormone Therapy Advice (C-Gyn 16)
- Guidelines for HPV Vaccine (C-Gyn 18)
- Emergency Contraception (C-Gyn 11)

New College Statements under development

- Cross-Border Reproductive Care
- IVF-Only Clinics

New Patient Information Pamphlets

- Iso-Immunisation Patient Information Sheet
- Fetal Monitoring Patient Information Sheet

Patient information pamphlets are available and freely reproducible from the RANZCOG website under Resources for Women & Practitioners.

A full list of College Statements can be viewed on the Statements and Guidelines page of the RANZCOG website.

Examinations update

Lyn Johnson
Director, Education and Training

This article summarises some of the processes and improvements that have recently been implemented to College examinations, including initiatives in the areas of standard setting; question writing and blueprinting; support and feedback to candidates; support and feedback to examiners; online marking; online examinations; and other enhancements as outlined.

Assessment Services is a component of the Education and Training Directorate at RANZCOG and, as such, is responsible for the conduct of the College's assessment processes and examinations, as overseen by the Education and Assessment Committee (EAC). The focus of the EAC, the Director of Education and Training and the Assessment Services department is to maintain a culture of best practice in RANZCOG examinations to further enhance examination processes.

Standard setting
Standard setting is the process used to select a passing score for an examination that requires a pass/fail decision. For many years, College examinations had a set or a fixed pass mark. Several years ago, after trialling alternative methods, the College replaced the set pass mark with the concept of a minimum acceptable passing standard (MAPS). The MAPS method is known as criterion-referenced standard setting and involves setting the pass mark to an absolute standard that denotes the required/acceptable level of competence or performance to be demonstrated by a candidate in order to pass each question and, ultimately, the examination.

Since its initial introduction for the MRANZCOG examinations, the application of the MAPS method has been reviewed and refined, and adopted for all College examinations. The College uses several different types of criterion-referenced standard setting methods, including modified Angoff and Rothmans, as different methods are considered more suited to particular types of examinations and cohort sizes.

Criterion reference standard setting is recognised as the method of choice for high-stakes examinations and is now a requirement of the Australian Medical Council (AMC). The College works hard to ensure that the standard is set robustly, objectively and consistently. All examiners now participate in moderation and education sessions before assessing to ensure that a fair pass mark is derived based on the knowledge expected from candidates and the examination difficulty.

Question writing, review and refinement
Statistical reviews of the MRANZCOG and DRANZCOG multiple choice question (MCQ) data banks are undertaken regularly to identify questions in need of revision, owing to poor performance ratings. When such questions are identified, they are temporarily withdrawn from the data bank and kept aside for a workshop where they are further reviewed and revised by Fellows or, if they are considered to be unrepairable or no longer current, they are withdrawn permanently from the bank. To review, refine and write new questions is time and resource intensive. To ensure high-quality questions, the relevant workshops cover areas such as the features of a good question, the principles behind writing a good question, how to ensure validity, the need for peer review and question performance. All MCQs have been blueprinted against the curriculum; areas not sufficiently addressed in existing examination questions are identified and targeted for question development at these workshops.

Feedback to examination candidates
All examination candidates now receive written information and feedback on their performance in the Written and Oral Examinations, regardless of whether they passed or failed the respective examination.

For the MRANZCOG Written MCQ examination, candidates receive the pass mark for the MCQ examination, their performance in relation to the passing mark expressed within a percentage range and their performance in the listed MCQ sub-heading topics.

For the MRANZCOG short answer question (SAQ) paper, candidates receive the pass mark for the SAQ examination, their performance in relation to the passing mark expressed within a percentage range and their performance in each of the 12 questions in relation to the MAPS score (well below, below, at, above or well above).

For the MRANZCOG Oral Examination, candidates receive the pass mark for the examination, their performance in relation to the passing mark expressed within a percentage range and their performance in each of the ten stations in relation to the MAPS score for that station (well below, below, at, above or well above MAPS). Similar written feedback is also provided to all Diploma and Subspecialty Examination candidates.

Access to question banks for candidates
To encourage learning and discussion with peers and ensure a level playing field, 100 MRANZCOG MCQs and 100 DRANZCOG MCQs have been placed on CLIMATE, the College's eLearning platform. Questions can be accessed by all candidates enrolled in the respective qualifications.

Examination revision courses
Examination revision courses are offered by most of the Regional Offices to assist local candidates in preparing for their examinations. Guidelines have been developed to ensure the programs offered are uniform in purpose, content and quality; the revision programs are applied consistently across the states and regions with respect to the delivery, teaching and topics covered; and the program covers the areas that are core to the practice of obstetrics and gynaecology and those commonly addressed in the

Written and Oral examinations. In addition, pass/fail results are now sent to Regional Offices once all results have been released to candidates, who can use the information to tailor and/or add additional revision courses and activities if deemed necessary.

Support for examiners

In order to build the reliability of the examination-marking process, strategies have been implemented to provide FRANZCOG examiners with information about standard setting, calibration and the importance of inter-marker reliability. Three 'Marking Centres' have been held for examiners marking the MRANZCOG SAQ paper over the last 12 months. The objectives of the full-day Marking Centre sessions have been to provide: support to the examiner cohort; an opportunity for examiners to confirm assessment principles and marking guidelines face-to-face; a method to encourage inter-marker consistency; and a process to expedite the marking of the many papers involved. These sessions have also allowed trialling of the new online marking portal during its development.

Feedback to examiners

For all College examinations, examiners are now provided with feedback on their performance. For the MRANZCOG and Subspecialty Written Examinations, examiners receive the average and the range of scores they awarded to candidates in comparison with that of their co-marker(s), the range of scores they assessed as being 'At MAPS' for the question(s) they marked and that of their co-marker(s) and the determined 'At MAPS' score for the relevant question(s). For the DRANZCOG, MRANZCOG and Subspecialty Oral Examinations, examiners receive information on the pass mark calculated from the standard setting process, the examiner pass mark calculated from their submitted scores during the standard-setting process and specific data on the stations they examined, which includes a comparison of their scores (median, range, mean) and MAPS with other examiners for those stations.

Providing individual feedback allows and encourages examiners to review their practice in comparison with that of their peers and is one of a range of steps implemented to ensure best practice.

Online marking and examinations portal

Considerable headway has been made with the design, development and deployment of an online marking and examinations portal located on the College's Learning Management System. The online marking function is now fully operational, with all written examination papers marked online. The portal enables secure access to examination questions and candidate papers together with allocated grading criteria, the allocation of multiple markers, online submission of marks and written feedback by examiners and better reporting mechanisms.

The online examination function is continuing to be progressively developed and refined. Three online trials have already been held at secure Computer Centres in several states, with candidates volunteering to undertake their MCQ and SAQ examinations online. Following a staged implementation, it is envisaged that online completion of all College written examinations will be in place for all candidates from 2017.

Other enhancements

Processes for marking and calculating examination results are continuously examined to ensure fairness to all candidates and to consider areas where improvements could be made. Other recent initiatives include:

- management of third marker marks to improve reliability and fairness;
- removal of discretionary marks in all SAQ papers;
- changes to the results calculations;
- trialling of alternative concurrent standard setting methods;
- SAQ writing workshops;
- updates to examination policy and regulations; and
- processes to address examination security.

The introduction of new, and the enhancement of existing, assessment processes represent significant advances in the quality and reliability of the examinations and assessment processes at RANZCOG. It must be acknowledged, however, the success of these continuous improvements is only possible because of the multiple hours, including at night and weekends, that many Fellows generously give as they work with College staff to ensure best practice.

RANZCOG Foundation

Research Scholarships & Fellowships in 2016

Delwyn Lawson
Foundation Co-ordinator

The RANZCOG Foundation offered a number of scholarships for application this year for research commencing in 2016. The process for evaluating scholarship applications aims to identify promising early-career researchers and the RANZCOG Research Grants Committee, which assesses these applications, was very impressed with the high quality of applications received.

The RANZCOG Foundation is pleased to present the following summary of recipients and research being conducted in 2016.

Arthur Wilson Memorial Scholarship, 2016–17

Recipient:	**Dr LuFee Wong**
Institution:	**Monash IVF and Monash Ultrasound for Women**
Project:	**'Reproducibility of three-dimensional ultrasound of the junctional zone in myometrial pathology and their correlation with pregnancy rates'**

Dr Wong is a COGU Fellow at Monash Health and has been awarded the Arthur Wilson Memorial Scholarship for her project which aims to examine the inter- and intra-observer reproducibility of three-dimensional ultrasound visualisation of the endometrial-myometrial junction (EMJ), and the relationship between the EMJ irregularities and pregnancy rates in IVF cycles. It is hoped that being able to accurately diagnose adenomyosis will help in the diagnosis and counselling of patients with infertility before undergoing IVF.

Fotheringham Research Scholarship, 2016–17

Recipient:	**Dr Ryan Hodges**
Institution:	**The Ritchie Centre, Hudson Institute, Monash University**
Project:	**'Fetal therapy for congenital diaphragmatic hernia: a global partnership to translate surgical and cellular innovation'**

Dr Hodges is the Head of Perinatal Services at Monash Health and holds a National Health and Medical Research Council Hamilton Fairley Early Career Fellowship at the Ritchie Centre, Hudson Institute, Department of Obstetrics and Gynaecology, Monash University. Dr Hodges has been awarded the Fotheringham Research Scholarship for his research that will endeavour to test the hypothesis that human amnion epithelial cells (hAECs), when administered antenatally to fetuses with congenital diaphragmatic hernia (CDH), can reduce lung hypoplasia and abnormal pulmonary vasculature that leads to pulmonary hypertension, by promoting tissue regeneration and repair in utero. Dr Hodges believes the findings of his project will extend to

have you bequeathed money to the RANZCOG RESEARCH FOUNDATION?

Have you left a gift to the RANZCOG Research Foundation in your Will?

Over the years, many RANZCOG members and those connected with the College have made provision in their Will to ensure their commitment to women's health lives on. If you have previously made the generous decision to leave a gift to the RANZCOG Research Foundation in your Will, we thank you for making an ongoing difference to the field of women's health and need to advise you of some important changes.

Did you know about the newly established RANZCOG Foundation?

The RANZCOG Foundation has recently been established under the umbrella of the College and brings together the College's various philanthropic activities, including research scholarships, humanitarian aid and the historical collection. As part of this, the operations of the RANZCOG Research Foundation have been transferred to the College's Foundation.

An important change needed to bequests

Should you wish to continue to support the pursuit of *Excellence in Women's Health* through making a gift in your Will, we ask that you amend any reference to 'RANZCOG Research Foundation', replacing it with 'Royal Australian and New Zealand College of Obstetricians and Gynaecologists'.

Bequests are essential for ensuring the work of the RANZCOG Foundation can continue into the future and we thank you in advance for making this required amendment.

Bequest Enquiries

Please contact the
RANZCOG Foundation
Coordinator
Ms Delwyn Lawson
t: +61 3 9412 2955
e: dlawson@ranzcog.edu.au

other fetal lung pathologies than CDH, for example oligohydramnios related pulmonary hypoplasia, the devastating consequence of early preterm pre-labour rupture of membranes and preterm birth.

Luke Proposch Perinatal Research Scholarship, 2016

Recipient:	**Dr Natalie Hannan**
Institution:	**University of Melbourne/Mercy Hospital for Women**
Project:	**'Clopidogrel: a potential treatment for pre-eclampsia'**

Dr Hannan is a C R Roper Research Fellow in the Translational Obstetrics Group, Department of Obstetrics and Gynaecology, Mercy Hospital for Women/University of Melbourne. Dr Hannan has been awarded the Luke Proposch Perinatal Research Scholarship for her project that aims to show that clopidogrel is highly effective at quenching the pathophysiological aspects of pre-eclampsia. If successful, it is hoped that her research will provide the first therapy, other than delivery, for the treatment of pre-eclampsia. For women with severe early-onset pre-eclampsia, halting or slowing disease progression would enable delivery to be safely delayed, reducing the risks of prematurity for the baby.

RANZCOG Fellows' Clinical Research Scholarship, 2016

Recipient:	**Dr Erin Nesbitt-Hawes**
Institution:	**Royal Hospital for Women**
Project:	**'Four-dimensional ultrasound of the pelvic floor'**

Dr Nesbitt-Hawes is a staff specialist gynaecologist at the Royal Hospital for Women. Dr Nesbitt-Hawes has been awarded the RANZCOG Fellows' Clinical Research Scholarship for her project which will endeavour to create a nomogram for the four-dimensional ultrasound assessment of the pelvic floor musculature for gynaecological patients and those with pelvic pain.

Taylor Hammond Research Scholarship, 2016

Recipient:	**Dr Teresa MacDonald**
Institution:	**Mercy Hospital for Women/ University of Melbourne**
Project:	**'Improving the Prediction and Detection of Contributors to Term Stillbirth: Fetal Longitudinal Assessment of Growth (FLAG) Study.'**

Dr MacDonald is a full-time PhD student and advanced obstetrics and gynaecology registrar at the Mercy Hospital for Women/ The University of Melbourne Department of Obstetrics and Gynaecology. Dr MacDonald has been awarded the Taylor Hammond Research Scholarship to undertake a prospective cohort study examining whether circulating mRNA that code eight placental specific genes in the maternal circulation at 36 weeks gestation can predict fetal growth restriction (FGR) at term. Dr MacDonald aims to develop a predictive blood test at 36 weeks gestation that can identify pregnancies at high risk of FGR at term. Such a test would enable clinicians to offer targeted surveillance and timely delivery, potentially reducing rates of stillbirth.

Brown Craig Travel Fellowship, 2016

Recipient:	**Dr Felicity Gould**
Institution:	**Department of Urogynaecology at Addenbrooke's Hospital, Cambridge, UK**

Dr Gould is a Urogynaecology Fellow at the Royal Women's Hospital and has been awarded the Brown Craig Travel Fellowship to allow her to travel to the Department of Urogynaecology at Addenbrooke's Hospital in Cambridge, UK, for the purposes of undertaking research and observation. While at Addenbrooke's, Dr Gould aims to conduct a primary research project in relation to 'Analysis and Characterisation of Squamous Metaplasia over Bladder Trigone in Women', and subsequently extend any significant research findings into a second project, as well as participating in other research underway within the Cambridge Unit, and learning and developing research skills by working alongside an experienced research team.

Scholarships continuing in 2016

Ella Macknight Memorial Scholarship, 2015–16

Recipient:	**Dr Shavi Fernando**
Institution:	**Monash Health**
Project:	**'Melatonin and infertility: Can we improve outcomes of assisted reproductive technology – a placebo controlled randomised controlled trial'**

Dr Fernando was awarded the Ella Macknight Memorial Scholarship, 2015–16, for his project that will endeavour to determine whether melatonin has an effect on pregnancy rates and live birth rates in women undergoing in vitro fertilisation. Dr Fernando aims to determine how this effect occurs and what dose of melatonin is optimal.

Glyn White Research Fellowship, 2015–16

Recipient:	**Dr Stella Liong**
Institution:	**Obstetrics and Gynaecology Department (Mercy Hospital for Women), the University of Melbourne**
Project:	**'Can dietary phytophenols prevent the development of gestational diabetes?'**

Dr Liong's project, which aims to investigate whether phytophenols will be effective in the management and treatment of gestational diabetes mellitus (GDM), and also whether these phytophenols can also improve outcomes in both mothers and babies using a mouse model of GDM, will continue to be funded in 2016.

Mary Elizabeth Courier Research Scholarship, 2015–16

Recipient:	**Dr Luke Larmour**
Institution:	**The Ritchie Centre, Monash Institute of Medical Research**
Project:	**'Factors influencing the progression of high-grade cervical dysplasia to invasive carcinoma'**

Dr Larmour was awarded the Mary Elizabeth Courier Research Scholarship, 2015–16, for his project examining how pre-cancer of the cervix of the uterus progresses to cancer. Dr Larmour's project aims to use new technologies to find changes in the genes of pre-cancer and cancer cells. The importance and interaction of these genetic changes will be studied in a new mouse model of cervical cancer that will be developed. It is hoped that this will lead to identification of new targets for urgently needed new treatments for cervical cancer.

The Brian Spurrett Foundation

Carmel Walker
Global Health Unit

In October 2014, the RANZCOG Brian Spurrett Foundation Management Committee had its last meeting. Thus concluded a chapter in the College's history that exemplifies what can be achieved by developing networks and capacity building with long-term foresight. The achievements of the Brian Spurrett Foundation have set expectations high for the future.

Recognising the need to provide a sustainable platform, it was agreed late in 2014 by the Brian Spurrett Foundation (BSF) Management Committee that the time had come to open a new door, one that offers sustainability for the work of the BSF. The newly formed RANZCOG Foundation will provide the infrastructure through which the Brian Spurrett Fund can be secured in perpetuity, as an ongoing commemoration to the work of the late Prof Brian Spurrett and the trust placed in the Foundation by his family, colleagues and friends for more than ten productive and remarkable years.

Early days

Following the death of Australian obstetrician/gynaecologist Prof Brian Spurrett, in 2000, the Brian Spurrett Trust was established by a small group of close colleagues and family to commemorate his vision of sharing skills and knowledge between reproductive health colleagues across the Pacific, Australia and New Zealand. The Brian Spurrett Trust sought to build on the work of the Pacific Society for Reproductive Health (PSRH), established in the early 1990s.

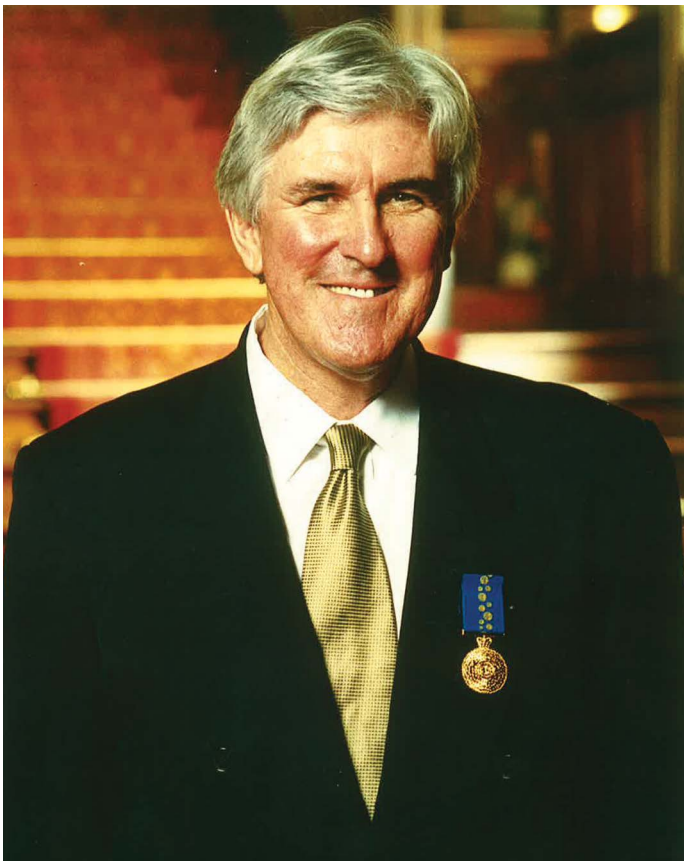
In 2002, the Brian Spurrett Memorial Trust was launched at the RANZCOG Annual Scientific Meeting, with a start-up investment of funds from the RANZCOG New South Wales Committee and the RANZCOG national office. Later, on 30 June 2004, to ensure appropriate support for the administrative and governance aspects of the work of the Trust, the Trust was vested and funds were transferred to the College under the management of the RANZCOG Brian Spurrett Foundation Management Committee. Prof Rajat Gyaneshwar became the Chair of the Management Committee, a position which he held until its disbandment. Other long-time members on the Management Committee were Mrs Kerry Spurrett, Prof Jeremy Oats, Mr Sam Spurrett (since 2011) and successive Presidents and Honorary Treasurers of RANZCOG.

Over the years, Kerry Spurrett has provided untiring fundraising support for the Foundation. Special acknowledgement is also made to the Penrith Inner Wheel Club, who were very generous contributors, and many colleagues, friends and members of the Spurrett family.

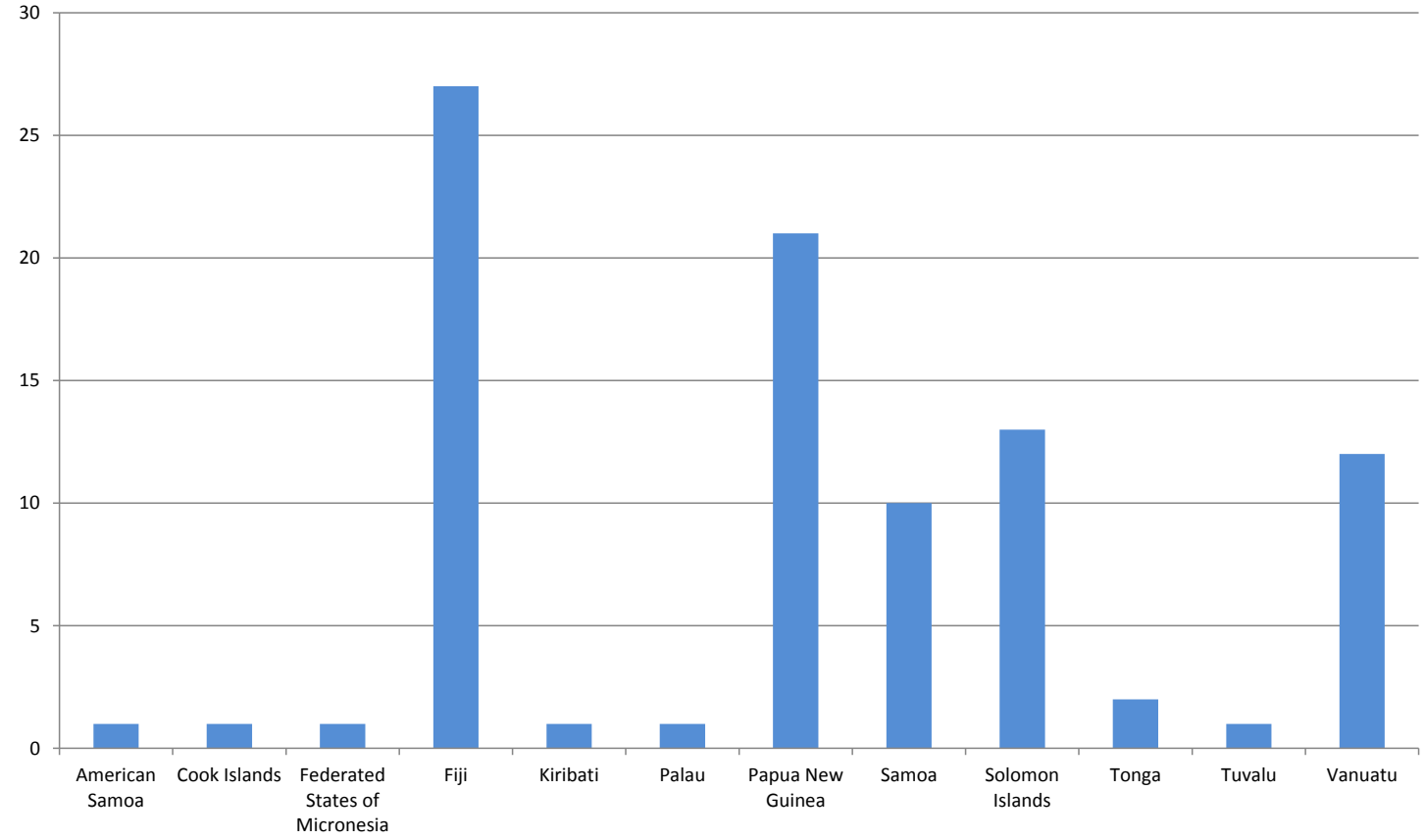
From strength to strength

The Brian Spurrett Fellowship (BSF) program has been the BSF's flagship initiative. Since 2004, 33 Brian Spurrett Fellowships have been awarded for professional development for doctors and midwives in the Pacific. Five of these Fellowships have been awarded to obstetric and gynaecology specialists or trainees to further their knowledge in an aspect of the specialty, and 28 Fellowships have been awarded to Pacific midwives, to undertake a midwifery leadership fellowship either at the Liverpool Hospital, Sydney, or the Middlemore Hospital, Auckland, New Zealand.

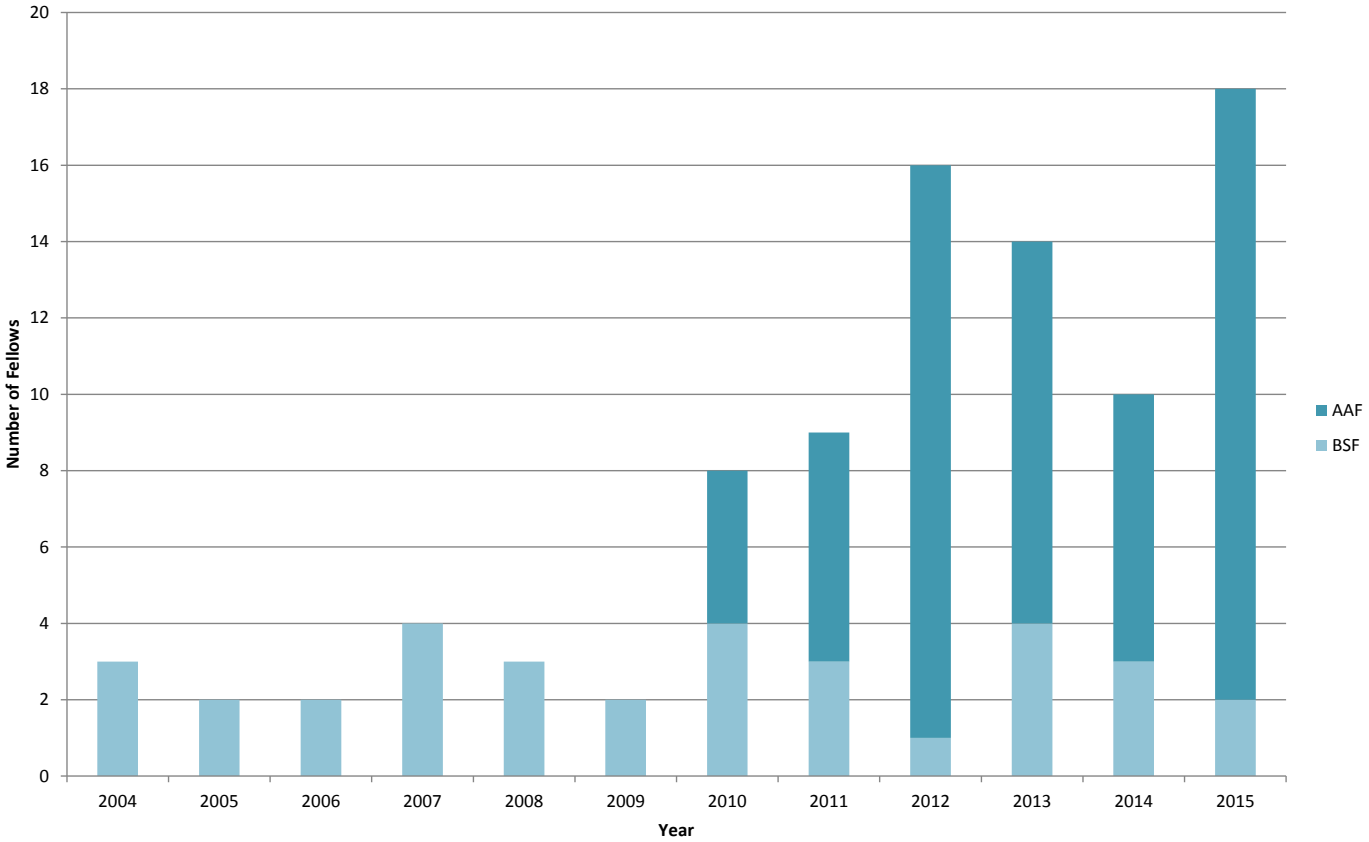
Most importantly, with the evidence and outputs from the BSF program, RANZCOG has, since 2010, been successful in applying for funding from the Department of Foreign Affairs and Trade (DFAT) for Australia Awards, which enables RANZCOG to provide the RANZCOG Pacific Midwifery Leadership Fellowship Program (PMLFP), in collaboration with the Liverpool and Nepean Hospitals. The purpose of the Australia Awards Fellowship (AAF) program is to strengthen partnerships and links between Australian organisations and partner organisations in developing countries, by providing opportunities for Fellows to undertake short-term professional development attachments in Australia. The PMLFP Fellowships are offered to current and future leaders in midwifery, selected by their Ministries of Health as those in a position to advance midwifery at the local level. The Fellowship activities in Australia are aimed at providing high-quality training, exchange of expertise, skills and knowledge and opportunities to enhance networks on issues of shared interest.



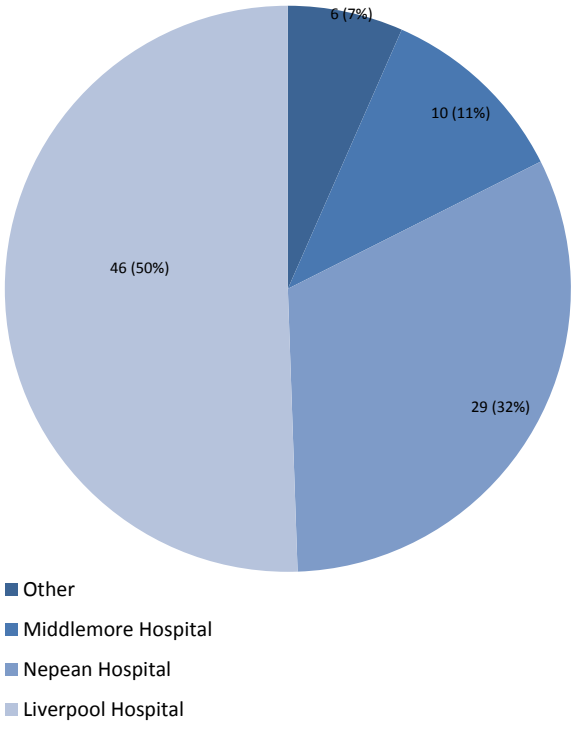
Prof Brian Spurrett, whose colleagues and family set up the foundation that bears his name to honour his memory in 2002.



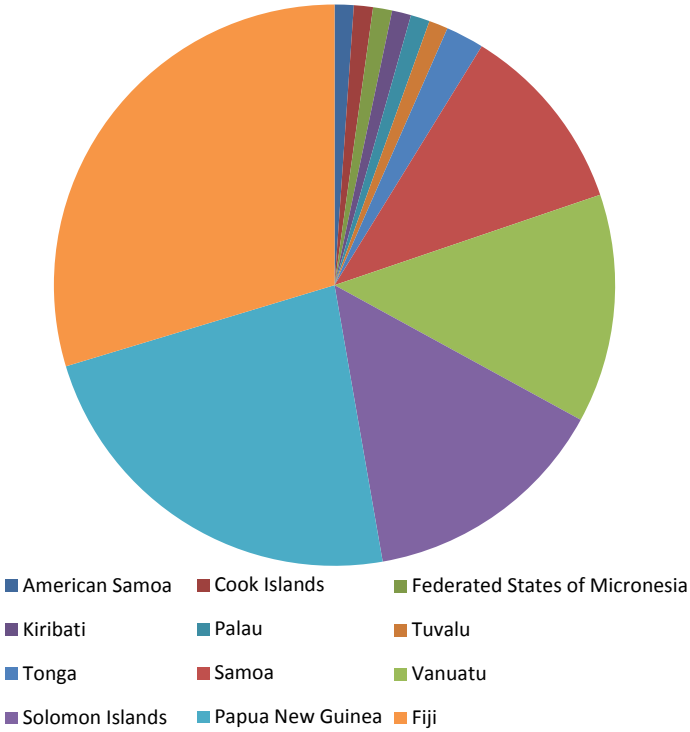
Number of Fellows, BSF and AAF, by country of origin.



Combined BSF and AAF Fellowships 2004–2015.



Number of Fellows by host hospital.



Proportion of Fellows by country of origin (labelled clockwise from top, left to right).

Through the AAF program, 58 PMLFP Fellowships have been provided to midwives from Papua New Guinea, Fiji, Vanuatu, Solomon Islands, Tonga, Federated States of Micronesia, Cook Islands, Kiribati and Palau. The PMLFP has been overseen by the BSF Management Committee, and is managed by the Global Health Unit at RANZCOG. The total number of Fellowships provided, through the BSF and the PMLFP as an extension of the BSF Fellowship program, to date is 91.

Having multiple Fellowship alumni in some of the Pacific Island Countries (PICs) has enabled collaboration and support between the local alumni to introduce the quality care ideas and initiatives they observed during their Fellowship. Their experience has also enabled program alumni to make a more meaningful and informed contribution to maternity services in their locality, by contributing at a higher level in discussions with obstetric colleagues, senior midwifery/nursing management and hospital administration. Many past Fellows have participated in local research activities and in recent years a number have gone into full-time research in Australia with funding from DFAT Scholarships.

The Practice Improvement (PI) Marketplace – held at the 2013 and 2015 PSRH meetings, in Apia, Samoa, and Suva, Fiji, respectively – has been a recent offshoot of the program. At the PI Marketplace, past Fellows run stalls where they share the activities, outcomes and initiatives developed following their Fellowship visit, in a colourful, interesting and enthusiastic setting.

The international community has recognised the value of health workforce capacity building and this focus has been, and should continue to be, the priority for governments in developing countries and partner countries. Pacific Ministries of Health have embraced the opportunity to build the capacity of their midwifery workforce, recognising that strengthening the confidence, skills and contribution of their senior midwives is a key element in improving maternity health services. Development of the PIC midwifery workforce will continue to be critical for PICs, as with all developing countries, as the health workforce around the globe moves into the next stage of the Sustainable Development Goals, building on the Millennium Development Goals that finish at the end of 2015.

Founder of the BSF program at Liverpool Hospital, Prof Rajat Gyaneshwar, said recently 'The opportunity for professional development of midwives and exposure to good role models and leadership skills is limited in Fiji and other PICs. Therefore, the opportunity to observe and interact with best-practice, patient-centred care, delivered as a matter of course in Australian and New Zealand hospitals, and experience models of good management, confidence and leadership in midwifery, struck me as a way to empower and build capacity in the Pacific midwifery workforce. A number of BSF and AAF alumni have shown growth in their ability to contribute at a higher level within their obstetric teams, use critical thinking in addressing local challenges in providing safe, quality maternity and women's healthcare, and apply innovative approaches to improvements in systems in their own hospital settings. Feedback tells us that exposure to the Australian or New Zealand model, and the new thinking and innovations they return home with is highly regarded and well appreciated by the midwives and by the Ministries of Health in the various PICs.'

Achievements

The benefits BSF and PMLFP Fellows report are personal and professional. Three-month and 12-month follow ups are conducted with past Fellows and their supervisors, to gain information on initiatives introduced as a result of participation in the program. This feedback provides data for further analysis and evaluation.

Sr Aliote Galavakadua was Sister in Charge of Labour Ward at

Aliote Galuvakadua, BSF Fellow in 2006.


Chandra Dayal, BSF Fellow in 2008.

Mary Magabe, ALA Fellow in 2010.

Colonial War Memorial Hospital (CWMH), Suva, Fiji, when she came to Liverpool Hospital in 2006 as one of the first senior midwives to undertake a Fellowship. After returning to CWMH with new perspectives on leadership and quality maternity care, Aliote progressed to Sister in Charge of Maternity Services and then the post of Matron at CWMH since 2012. She has extended her hospital leadership role and is currently President of the Fiji Midwifery Society and a member of the PSRH Executive Committee. Aliote said, 'Having a Brian Spurrett Fellowship re-energised my career and gave me a good introduction to leadership skills. It is vital we develop our staff to meet the challenges of providing the best service that we can by using effective teamwork, good management of staff and co-operation at all levels under an appropriate governance model. I understand that I am seen as a role model and I take that responsibility seriously. We need to have strong leaders, mentors and change managers in order to take health services forward in a constantly challenging environment, much of which is outside of our control.'

Chandra Dayal, a Fellow at Liverpool Hospital in Sydney in 2008, said, 'My Fellowship was a big boost in motivating me to pursue further opportunities to develop my leadership potential as a contributor to women's health in Fiji. During the Fellowship, I took every opportunity to ask questions and think about how to adapt and apply quality practice back home. My career has now taken several new pathways and in 2014, after 18 months of study, I completed by Masters in Clinical Midwifery at Monash University, Melbourne, through an AusAID scholarship. This enabled me to learn how to conduct research and collaborate with others to identify areas where evidence-based research is needed in my own setting. On return to Fiji, I took up the position of Midwifery Tutor at the Fiji School of Nursing and this position enables me to put into practice what I've learnt from my visits to Australia.'

When Sr Mary Magabe undertook her Fellowship in 2010, she was Sister in Charge of Labour Ward at Mendi Hospital in the Southern Highlands Province of Papua New Guinea. Mary said, 'Undertaking my Fellowship at that point in my career opened my eyes to many areas where we could improve our midwifery practice at our provincial hospital. The year following my Fellowship, my second in charge, Sr Anna Tikili, also undertook an AAF and together we worked to introduce a number of changes in our maternity services, including a day assessment centre (DAC). The objective of the centre was to reduce unnecessary hospital admissions and therefore hospital costs, reduce overcrowding and the incidence of absconding, and also improve the service to women in the labour ward. Our proposal was accepted and planned to be incorporated into the new hospital building which is now opened, but unfortunately the DAC is not yet operational because no one was there to push for it after I left. Stimulated by an interest in research and wanting to extend my potential, in 2014, I completed a Masters in Midwifery at Flinders University, South Australia, through an AusAID Scholarship. I was also awarded the prestigious Allison Sudradjat Award, in recognition of my leadership role, and this was presented at Parliament House Canberra, in September 2012. I now have a position with Marie Stopes as the Highlands Regional Manager, drawing on my skills and knowledge gained through my studies and experience, from associations with professional colleagues, mentors and leaders in reproductive health. I presented my research thesis, "Knowledge, practice and perception of family planning by women, of childbearing age amongst high school and college students in the Southern Highlands Province of Papua New Guinea" at the 2015 PSRH conference, and am awaiting publication. The thesis abstract was accepted to be presented at the PNG Medical Symposium in September 2015.

'I was honoured to be elected on to the PSRH Executive Committee at the PSRH conference in July 2015, and look forward to contributing to improve reproductive health services in PNG and the PICs in the future. I am a keen advocate for the power and unique position of PSRH and, using my advanced knowledge and skills in writing, I co-wrote a chapter in the Pacific Emergency Maternal

The Practice Improvement Marketplace allows past Fellows to share the activities, outcomes and initiatives developed following their Fellowship visit.

and Neonatal Training (PEMNet) Manual, which was launched at the 11th PSRH Conference. I was invited to be the PNG midwifery leadership alumni co-ordinator and am pleased to liaise with the College in this role, and any other roles where I can contribute my capabilities to support my country and other PICs. If it wasn't for RANZCOG and the Brian Spurrett Foundation I would not be where I am in my career today. I also acknowledge the Australian Government for supporting Pacific healthcare professionals to further their knowledge and skills. Thank you all.'

There are many success stories, some significant, as above, and others relatively modest, from our past Fellows. The stories above represent a small insight into the changes that the BSF brought to the lives of some of our past Fellows, and the resultant higher level of

RANZCOG Foundation

Donations are very welcome to support continuation and extension of the work of the Brian Spurrett Foundation in developing medical, midwifery and research skills in the reproductive health workforce in our neighbouring countries in the Pacific.

For further information or to make a donation to the RANZCOG Foundation, please contact the Foundation Coordinator.

e: foundation@ranzcog.edu.au
p: +61 3 9417 1699.

Supporting the healthcare workforce in the Pacific island countries.

Past BSF/AAF Fellows with Liverpool and Nepean Hospital program facilitators, College staff, Mrs Kerry Spurrett and Prof Rajat Gyaneshwar.

contribution that these three Fellows now bring to their health services. Realistically, there are other instances where the results were less successful, but our interactions tell us that all past Fellows have gone home with new insights from their experience and that small changes can also make a big difference.

Conclusion

The programs and initiatives developed and funded through the RANZCOG Brian Spurrett Foundation Management Committee have gone from strength to strength over the past 11 years, and it is planned to continue the BSF program and the PMFLP, subject to DFAT funding, through the RANZCOG Global Health Unit.

Special acknowledgement is extended to the Australian Government DFAT AAF program, the Executive Boards of Liverpool, Nepean and Middlemore Hospitals, and the facilitators and staff who supervise and contribute to the program in these hospitals.

The bond between Pacific, Australian and New Zealand reproductive health colleagues is strong. Under the multi-disciplinary network of PSRH, the Brian Spurrett Oration is delivered as part of the Opening Ceremony at the PSRH biennial conference. The Oration is given by a leading health professional with significant links to the Pacific and is a public recognition of Prof Spurrett's outstanding contribution to PSRH.

The PSRH Biennial conferences provide an opportunity to see and hear about innovative research and actions to improve care for women and their families in the Pacific, developed by midwifery and obstetric teams who are dedicated to serving their communities in what is often a challenging environment.

Recognising the need to develop research capacity and evidence-based practice in the PICs, the Global Health Committee and the RANZCOG Foundation are currently discussing the best use of Brian Spurrett funds to support research collaborations and partnerships between the Pacific, Australia and New Zealand, and how to build funds to make this initiative sustainable.

It is reasonable to conclude that the efforts of RANZCOG and the RANZCOG New South Wales Regional Committee, as well as the family, friends and colleagues of the late Prof Brian Spurrett who supported the BSF, have produced a sound investment in the reproductive health workforce in our region, by opening doors for collaborative partnerships and networks. The retiring RANZCOG Brian Spurrett Management Committee thanks the supporters of the BSF over the past 11 years.

Notice of Deceased Fellows

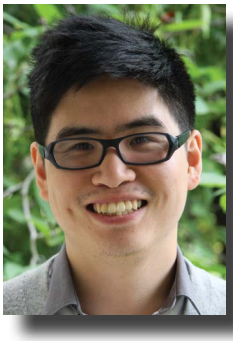
The College was saddened to learn of the death of the following RANZCOG Fellows:

Dr Matinde Thamsangele, South Africa, on 19 July
Dr John Stuart Newlinds, NSW, on 1 September 2015
Dr Keith Reginald Barnes, ACT, on 23 September 2015

Staff news

New appointments

Nicole Pascoe joined the College in September, as the HR Advisor. She brings to the role experience gained from 12 years working in human resources, most recently for the Residential Tenancies Authority, which is a Statutory Authority in Queensland.



Daniel Ip joined the College as the Accounts Payable Officer in September. He brings to the role approximately three years' work experience within the field. He holds a Bachelor of Arts degree and a Graduate Diploma of Education (secondary school teaching). He is involved in community radio work two weekends a month, discussing the issues and experiences of people with disability.

Sasha Malignaggi joined the College in October, as the Workforce and Evaluation Unit Officer. She has recently returned to Australia, having previously been teaching English in the Shape Colombia program, based in Bogotá, Colombia, run by the AIESEC and the Colombian Secretary of Education. Before this, Sasha was an Administration Assistant at Binks & Associates Strata Managers Pty Ltd, based in Melbourne. She holds a Bachelor of Arts degree from the University of Melbourne.

Sharon Huang joined the College as a full-time member of staff in October, as an Accounts Receivable Officer, having previously temped in the role. Before this she worked as a Financial Accountant at CIBT Visalink Pty Ltd. She holds a Master of Practising Accounting degree from Monash University.

Monica Yuill started at the College in October, as an Examinations Administrator with Assessment Services. She has held previous roles coordinating state-funded clinical education programs for rural and remote health professionals. Most recently, Monica has coordinated clinical bridging courses and mock OSCE examinations for international medical graduates. She holds qualifications in both business and administration. Monica will be involved with subspecialty examinations as well as CWH and DRANZCOG written examinations.

Departures

Georgina Anderson resigned from her role as Executive Officer – Board and Presidential Activities to take up a similar position at another medical college in August. We wish her well with her new role.

Joan Wong resigned from her position as Examinations Administrator in November to move to Sydney. We thank her for her work and wish her all the best.

Rosalind Winspear retired from her position as Archivist in December, following 30 years of service at the College. We wish her all the best for a happy retirement.

Have you changed your address or email account recently?

Have you notified the College of these changes?

If not, please update your contact details via the RANZCOG website (www.ranzcog.edu.au) and follow the link to 'Update contact details' or call 03 9417 1699 to notify the College of your changed contact details.

Obituary

Dr Keith Reginald Barnes AM
(1928 – 2015)

Keith Reginald Barnes was born in Queensland on 10 September 1928 and died peacefully at home in Canberra on 23 September 2015. He was a man of many parts: obstetrician and gynaecologist; negotiator on obstetric services with the Health Insurance Commission; and a widely read enthusiastic book collector. He was a good friend and above all a family man, extremely proud of his children and grandchildren.

After primary schooling, at a single-teacher school, he won scholarships to Toowoomba Grammar School and the University of Queensland, where he graduated in medicine and surgery in 1952. Following residency terms in Brisbane, he went to the UK and attained Membership of the Royal College of Obstetricians and Gynaecologists (MRCOG). On his return to Australia, he practised in Mullumbimby for eight years before moving to Canberra in 1967.

Keith's practice was primarily in obstetrics, initially at the Canberra Hospital in Acton and subsequently at the new Woden Valley Hospital. During his busiest times he delivered on average 35 babies per month – this at a time when there was no junior resident cover in obstetrics.

In 1972 Keith was elected as the first Territorial representative on the Australian Regional Council of the RCOG and was elected a Fellow of the RCOG in 1976. He served on the steering committee for the establishment of the Royal Australian College of Obstetricians and Gynaecologists (RACOG). He devoted many hours advising on various aspects of the work of the College and, in 2000, he was awarded the President's Medal for service to the College in all its manifestations as it progressed from RCOG to RACOG to RANZCOG.

In addition to his medical practice, Keith contributed to the work of the local and federal Australian Medical Association (AMA) and was a member of the Medical Benefits Consultative Committee. In 1993 he was appointed a Member in the General Division of the Order of Australia (AM).

In his spare time Keith pursued his interest in art history, particularly in the history of maps. He earned a BA (University of New England), an MA (Australian National University [ANU]) and MLitt in art history at ANU.

Keith married Meg in January 1958, and they left the next day for the UK. This was to prove a strong, happy marriage and Meg cared for and supported Keith until he died. They had two daughters, Judith and Meredith. Sadly, Meredith developed breast cancer and, despite careful treatment, was diagnosed with secondary spread and died in 2013. It was following the diagnosis of the secondaries that Keith seemed to lose all interest in life and he gradually faded away.

Dr Heather Munro AO
FRCOG, FRANZCOG