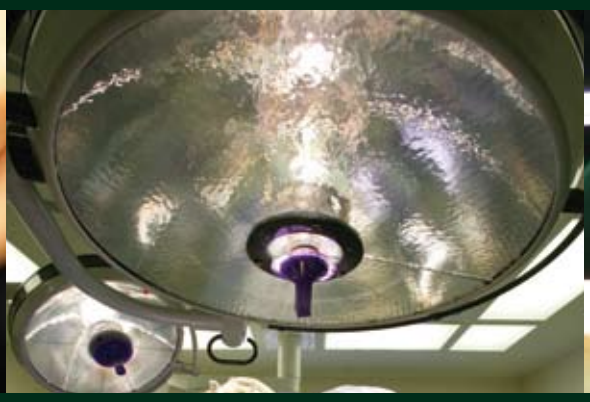
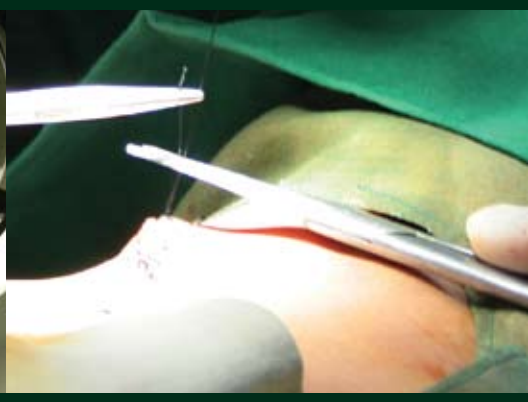
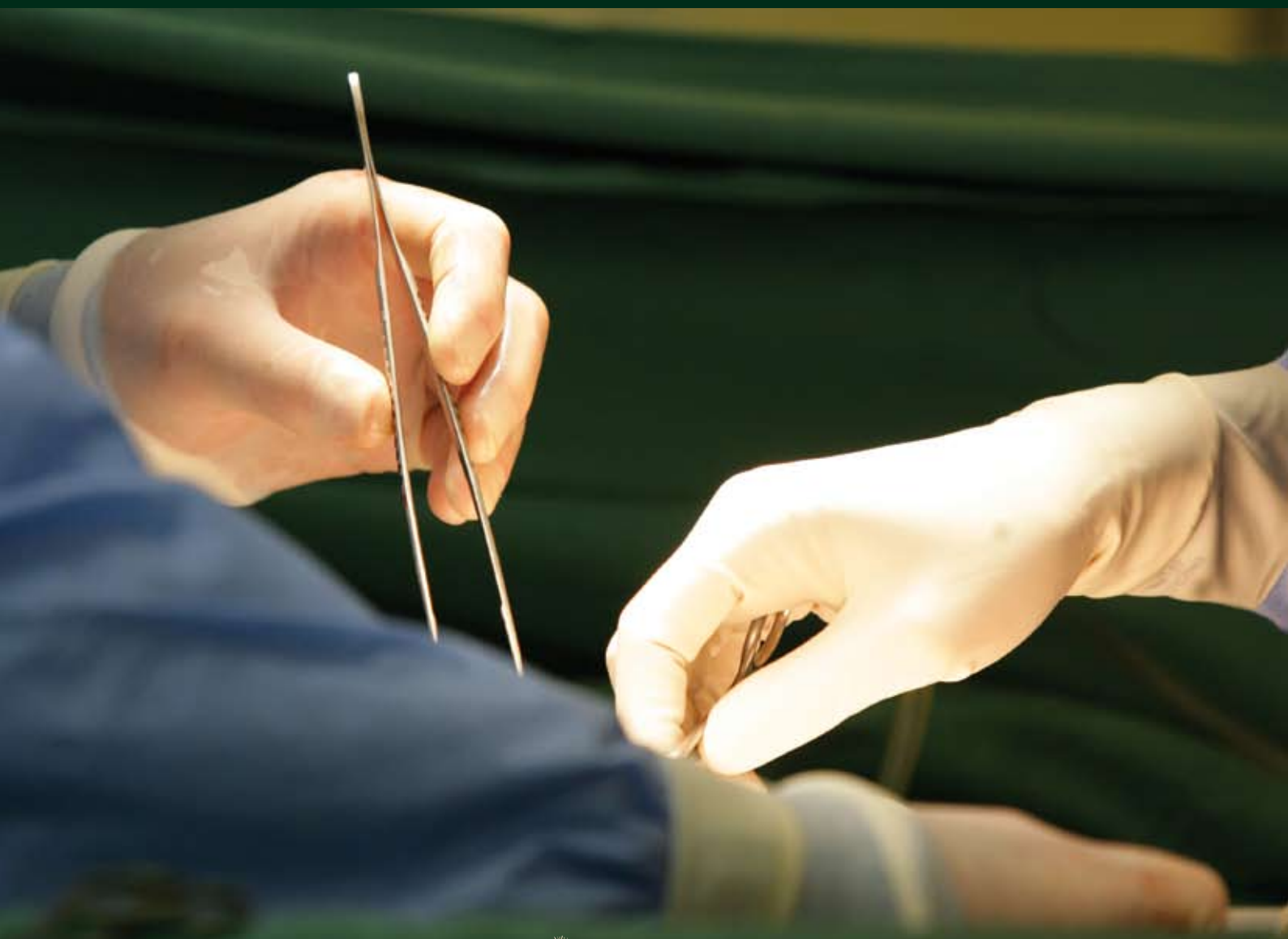
Annual Report 2006







ASERNIP-S

Australian Safety & Efficacy Register of New Interventional Procedures – Surgical

Royal Australasian College of Surgeons

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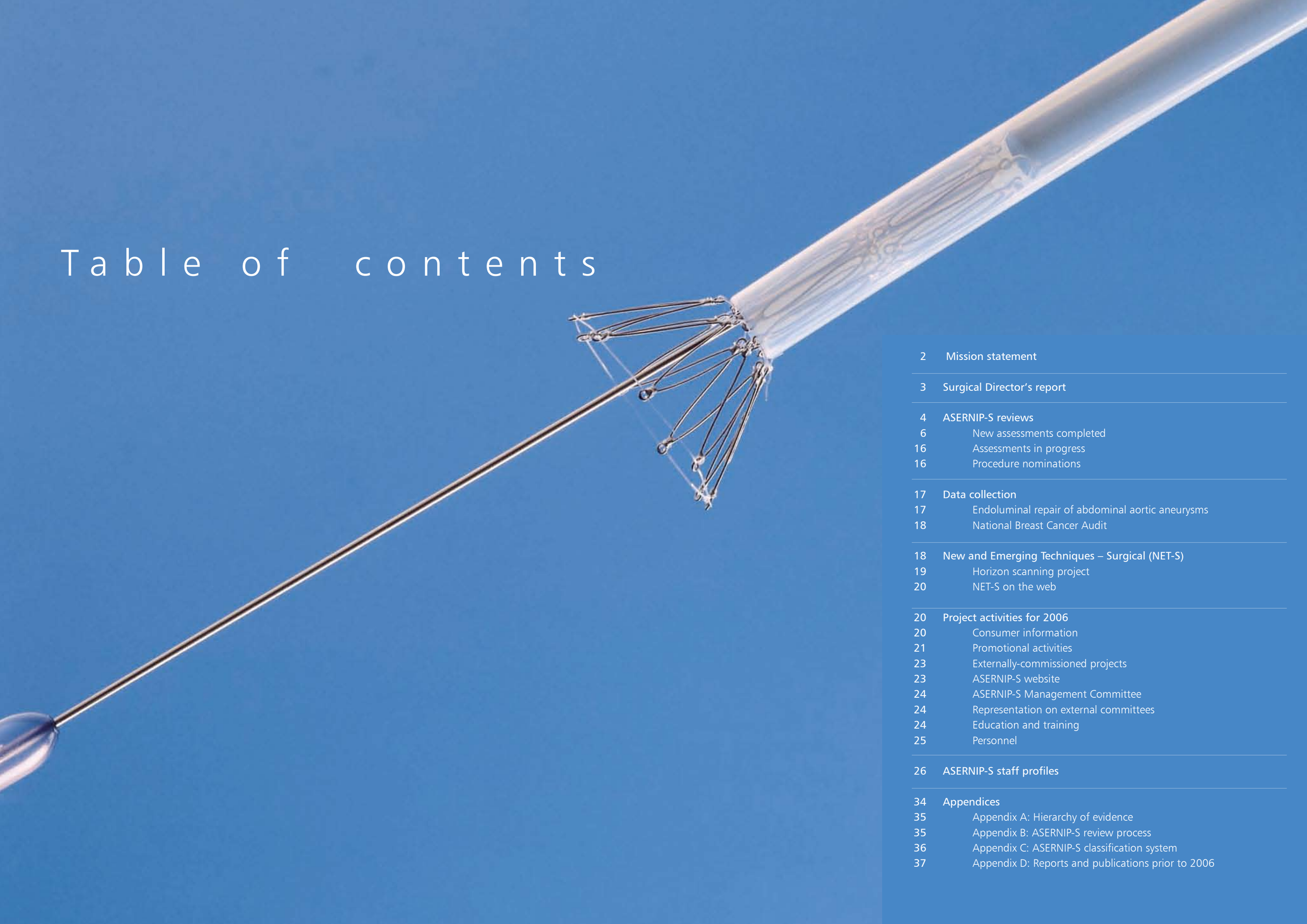

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Mission statement

The ASERNIP-S mission is to provide quality and timely assessments of new and emerging surgical technologies and techniques. Services provided include systematic reviews, accelerated systematic reviews and technology overviews of the peer-reviewed literature; the establishment and facilitation of clinical and research audits or studies; the assessment of new and emerging techniques and technologies by horizon scanning; and input into the production of clinical practice guidelines.

Our ultimate aim is to improve the quality of healthcare through the wide dissemination of our evidence-based research to surgeons, healthcare providers and consumers, both nationally and internationally.

Surgical Director's report

Guy Maddern
Surgical Director

ASERNIP-S continues to move forward on a number of fronts. The organisation has now been recognised as a provider of review services to the Medical Services Advisory Committee, which advises government on new procedures that require reimbursement through the Medical Benefits Schedule. This is an important recognition of the high quality work that ASERNIP-S has achieved over the past eight years. We have also been retained as a horizon report centre generating reports on new surgical technologies for the Australian and New Zealand Horizon Scanning Network. This is an area that ASERNIP-S also pioneered within Australia looking specifically at new surgical technologies. It remains important for the organisation to keep its focus in the surgical arena and not stray too far into medical or pharmacological areas, as these are well-catered for by other organisations both in Australia and around the world.

ASERNIP-S remains a valuable resource for the Royal Australasian College of Surgeons, providing a core group of expert data assessors and audit managers.

Additionally in 2006 the Commonwealth Government provided ongoing support for a further twelve months to carry out some high priority reviews on scalpel safety, centralisation of surgical procedures, incision-less surgery, translation of simulated environments into the operating theatre, validity of rapid versus full systematic reviews and guidelines for the safe introduction of a new technology into surgical practice. These represent important resources for all surgeons worldwide, including those in Australasia.

In addition to these core activities, the ASERNIP-S group has also continued its work in the area of audit. Work is ongoing on the audit of endoluminal repair of abdominal aortic aneurysms and the National Breast Cancer Audit. The latter is a bi-national audit of the surgical management of breast cancer which is continuing with support from the National Breast Cancer Centre. In addition, a national mortality audit, soon to be operational in all states in Australia, is being run alongside these audits as part of the Research and Audit Division.

ASERNIP-S remains a valuable resource for the Royal Australasian College of Surgeons, providing a core group of expert data assessors and audit managers. The organisation needs to remain flexible and innovative if it is to continue to provide the types of service and direction required for surgery in the future. To this end, the ASERNIP-S group is approaching the Commonwealth Government for funding to: provide a 48-hour turnaround on reliability of print media reports and research on which they are based as they pertain to surgery; increase availability of consumer summaries on new procedures; develop an index of the evidence of surgery as it exists currently in the world literature; and provide some insight into outmoded surgical interventions with clearer guidelines for their use. This type of innovative and relevant input into the public domain and, in particular, surgical practice should ensure that ASERNIP-S remains relevant and supported by surgeons and government alike.

It goes without saying that none of these enterprises would be occurring or as successful without the outstanding and dedicated staff within the ASERNIP-S group. The College of Surgeons is fortunate to have such a talented resource and should do all it can to retain it. Indeed, the success of the ASERNIP-S program was recently recognised by basing the Health Technology Assessment International meeting in Adelaide, where over 600 international visitors came to hear about new developments in health technology assessment, of which ASERNIP-S is an important part. It also now provides the Chairman of the International Network of Agencies for Health Technology Assessment, which is a worldwide federation devoted to sharing information obtained from health technology assessments. ASERNIP-S also holds the Honorary Secretary position on the Health Technology Assessment International Board, enabling well-coordinated involvement in international health technology assessment.

The future for ASERNIP-S remains exciting and challenging.

ASERNIP-S

reviews

New assessments completed

Systematic literature reviews

- Bioengineered skin substitutes for the management of burns ASERNIP-S Report no. 46
- Self-expanding metallic stents for relieving malignant colorectal obstruction ASERNIP-S Report no. 49
- Bioengineered skin substitutes for the management of wounds ASERNIP-S Report no. 52
- Surgical simulation (update) ASERNIP-S Report no. 53
- Radiofrequency ablation for the treatment of liver tumours (update) ASERNIP-S Report no. 56

Accelerated systematic reviews

- Endoscopic treatments for gastro-oesophageal reflux disease ASERNIP-S Report no. 54

Systematic reviews for other organisations

- Endovascular treatments for the treatment of intracranial aneurysms (MSAC reference 33)
- Endovascular neurointerventional procedures (MSAC reference 1093)
- Intersphincteric injection of silicone biomaterial for severe passive faecal incontinence (MSAC application 1100)

Assessments in progress

Procedure nominations

Systematic reviews

Systematic reviews involve a review 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. 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.

Accelerated systematic reviews

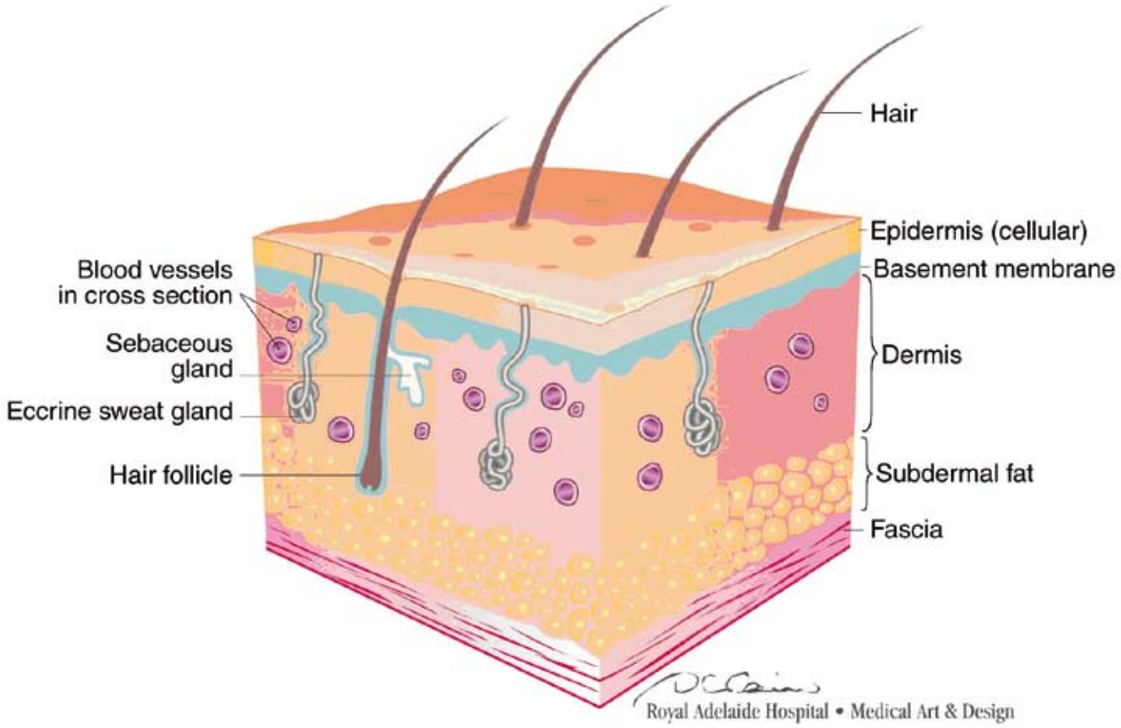
Accelerated systematic reviews (ASRs) are produced in response to a pressing need for a systematic summary and appraisal of the available literature for a new or emerging surgical procedure. ASRs use the same methodology as full systematic reviews, but may restrict the types of studies considered (for example, by only including comparative studies and not case series) in order to produce the review in a shorter time period than a full systematic review.

Technology overviews

A technology overview aims to provide information to assist decision-makers to make their own evidence-based recommendations. Unlike a systematic review, the technology overview does not attempt to compare a new intervention with a standard intervention or provide a recommendation for use.

New assessments completed

Systematic literature reviews



Bioengineered skin substitutes for the management of burns

ASERNIP-S Report no. 46

Objective

The objective of this review was to assess the safety and efficacy of bioengineered skin substitutes in comparison with biological skin replacements and/or standard dressing methods in the management of burns, through a systematic review of the literature.

Methods

Search strategy: Studies were identified by searching MEDLINE, EMBASE, The Cochrane Library, Science Citation Index and Current Contents from inception to April 2006. The Clinical Trials Database (US), NHS Centre for Research and Dissemination, NHS Health Technology Assessment (UK), National Research Register (UK), National Institute of Health (US) and Meta Register of Controlled Trials were also searched in April 2006.

Study selection: Only randomised controlled trials in humans were included for review. Efficacy outcomes included wound infection, wound closure, wound healing time and wound exudate. Patient-related outcomes included pain and cosmesis. Safety outcomes included complications and mortality.

Data collection and analysis: Data from the included studies were extracted by an ASERNIP-S researcher using standardised data extraction tables developed a priori and checked by a second researcher. Statistical pooling was not appropriate due to the study and result heterogeneity.

Results

A total of 20 randomised controlled trials were included in this review. Due to the diversity of skin substitutes and methods for burn management and the way in which outcomes were reported in the included studies, it was not possible to investigate differences in the effectiveness of bioengineered skin substitutes in partial thickness compared with full thickness burns, in paediatric patients compared to adult patients, and for total burn surface area (TBSA). However, from the available evidence it was possible to draw some conclusions about the different bioengineered skin substitutes considered in the review.

For partial thickness burns (less than 15%TBSA), Biobrane® and TransCyte® appear to be more effective than silver sulfadiazine, avoiding the need for painful daily dressing changes and prolonged hospital stay. Biobrane® may also offer cost advantages over other bioengineered skin substitutes.

For burns between 20% and 50% TBSA, allogeneic cultured skin and Apligraf® combined with autograft both appear to be effective. Dermagraft® was also found to be effective for these burns (as effective as allograft); however, the validity of this comparison is questionable as Dermagraft® is permanently integrated whereas allograft is a temporary biological dressing.

Integra® may be better suited to selected patients with burns less than 45% TBSA due to the high rates of infection reported in one study managing patients with burns greater than 45% TBSA. However, in clinical practice, Integra® is commonly used in the treatment of major burn injury where a paucity of available donor area precludes early autografting. Its successful take still has to be followed by definitive epidermal closure (by autograft or cultured epithelial autograft).

TransCyte® appears to be good for facial burns, providing good adherence to the contours of the face. However, considerations with the storage, pre-use preparation and high cost of TransCyte® may limit its clinical use.

In terms of safety, no major complications were reported with the use of bioengineered skin substitutes for the management of burns or donor sites. The mortality rate was relatively high; however, it was unclear whether these deaths could be attributed to the use of the bioengineered skin substitute or the actual burn injury. In practical terms, this distinction would be difficult to assess since the use of bioengineered skin substitutes is largely confined to patients with larger TBSA burn areas, more complicated pathophysiological insults and significantly poorer prognoses. The available evidence could not resolve the question of the long-term safety of bioengineered skin substitutes with respect to viral infection and prion disease. Thus, at present, autograft remains the gold standard for the management of excised burns as it is effective at closing the wound and there are no issues with graft rejection and viral contamination.

Conclusion

On the basis of the evidence presented in this systematic review, the ASERNIP-S Review Group agreed on the following classifications and recommendations concerning the safety and efficacy of bioengineered skin substitutes for the management of burns:

Evidence rating

The evidence base in this review is rated as average. The included randomised controlled trials were limited by small sample size and poor reporting of methodological detail. The numerous sub-group analyses and the diversity of skin substitutes limited the ability to draw any conclusions from it.

Safety

The evidence suggests that bioengineered skin substitutes, namely Biobrane®, TransCyte®, Dermagraft®, Apligraf®, autologous cultured skin and allogeneic cultured skin, are at least as safe as biological skin replacements or topical agents/wound dressings. The safety of Integra® could not be determined as one study reported a high rate of infection and the trial was terminated early. The long-term safety of the use of bioengineered skin substitutes, with respect to viral infection and prion disease, could not be determined.

Efficacy

For the management of partial thickness burns, the evidence suggests that bioengineered skin substitutes, namely Biobrane®, TransCyte®, Dermagraft® and allogeneic cultured skin, are at least as efficacious as topical agents/wound dressings or allograft. Apligraf® combined with autograft is at least as efficacious as autograft alone. For the management of full thickness burns, the efficacy of autologous cultured skin could not be determined based on the available evidence. The efficacy of Integra® could not be determined based on the available evidence.

Clinical and research recommendations

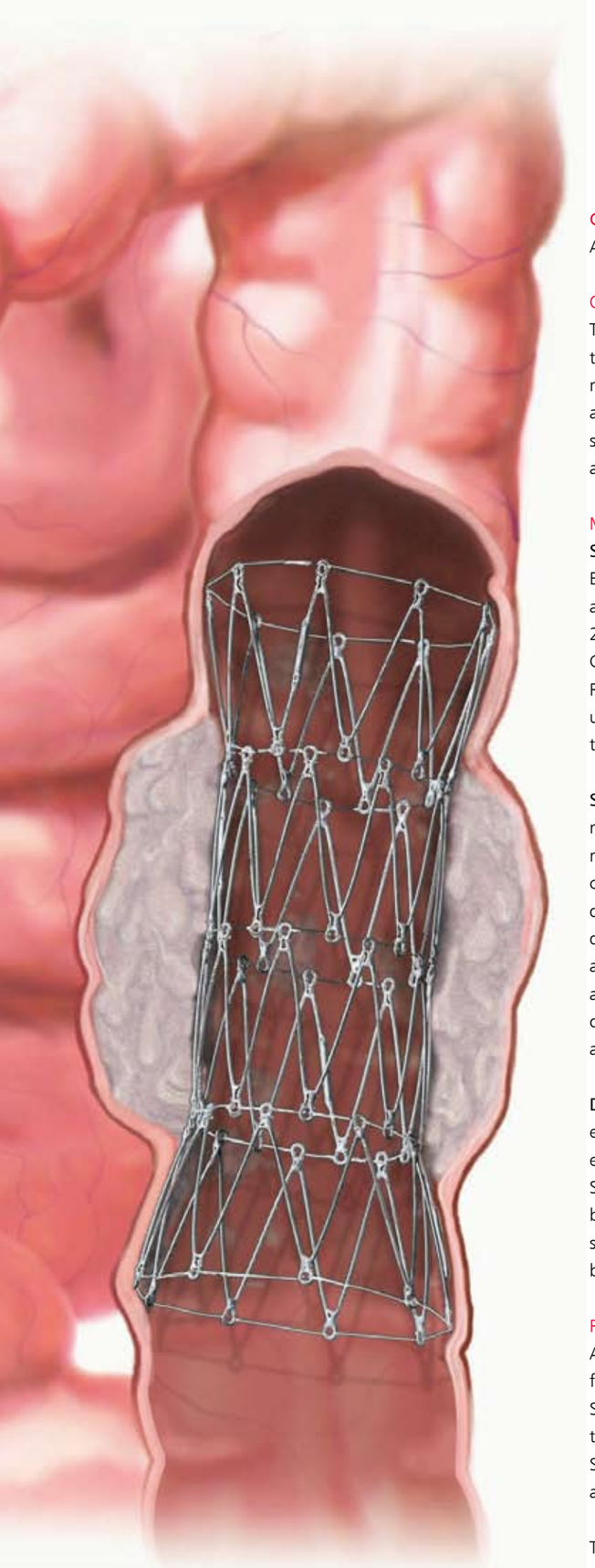
Additional methodologically rigorous randomised controlled trials would strengthen the evidence base for the use of bioengineered skin substitutes. However, it is acknowledged that it is unlikely that randomised trials of patients with large, deep burns will be carried out, as these burns are uncommon and usually involve complex clinical decision pathways and possibly the use of several products, which may differ between patients and make comparisons difficult. Therefore, it is recommended that randomised trials of patients with smaller burns be undertaken as these burns are more common and patient accrual should be easier. Furthermore, clinical equipoise should be more easily obtained in these less life-threatening situations. Additionally, studies with sufficient follow-up should be conducted to evaluate the long-term safety of bioengineered skin substitutes and future studies should define and document outcomes for partial and full thickness burns separately.

There is also a need for randomised controlled trials on cultured epithelial autograft, in particular cultured epithelial autograft suspensions, as there is a lack of evidence to support its safety and efficacy and its use is largely based on anecdote.

Review Group membership

Protocol Surgeon: Mr John Greenwood; Advisory Surgeon: Dr Heather Cleland; Other Specialty Surgeon: A/Professor Peter Woodruff; ASERNIP-S Surgical Director: Professor Guy Maddern; ASERNIP-S Researcher: Ms Clarabelle Pham.

For the full review and executive summary, please visit the publications page of our website at http://www.surgeons.org/asernip-s/publications.htm.



Self-expanding metallic stents for relieving malignant colorectal obstruction

ASERNIP-S Report no. 49

Objective

The objective of this review was to make recommendations regarding the safety and efficacy of self-expanding metallic stents (SEMS) for relieving malignant colorectal obstructions on the basis of a systematic assessment of the peer-reviewed literature. SEMS were compared to surgical procedures utilised to relieve colorectal obstruction, and were also assessed in isolation.

Methods

Search strategy: Studies were identified by searching MEDLINE, EMBASE, CINAHL, Current Contents, Science Citation Index, PubMed and the NHS Centre for Reviews and Dissemination Database in April 2005. Clinical Trials Database (US), National Research Register (UK), Current Controlled Trials, the Cochrane Library, Australian Clinical Trials Registry and ACP Journal Club were also searched in April 2005 and updated in February 2006. Additional articles were identified through the reference sections of the articles retrieved.

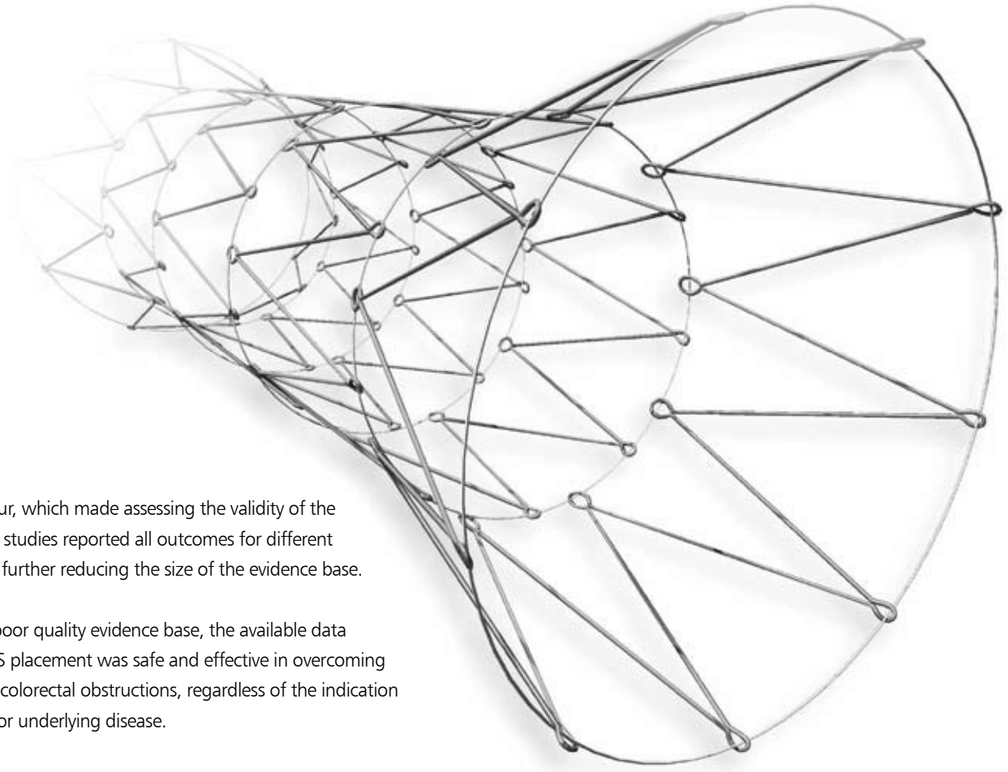
Study selection: Randomised controlled trials, historical and/or non-randomised comparative studies, case series and case reports reporting complications were included for review. Included comparative studies concerned the comparative interventions, defined as surgical intervention or any internal comparison of different types of stent. Efficacy outcomes included technical and clinical success, duration of patency, progression to surgery and rates of re-intervention, anastomosis and colostomy. Safety outcomes included complications such as perforation, migration and stent obstruction.

Data collection and analysis: Data from the included studies were extracted by the ASERNIP-S researcher using standardised data extraction tables developed a priori and checked by a second researcher. Statistical pooling was judged to be inappropriate for this data set, but narrative pooling was utilised where appropriate. Data have been stratified where possible by intent of stent placement (palliative or bridge-to-surgery) and patient population.

Results

A total of 15 comparative studies and 73 case series were identified for inclusion in this review. There were nine studies comparing SEMS to surgery (of which two were randomised controlled trials), three studies comparing elective surgery after decompression with SEMS to emergency surgery, and two studies comparing covered and uncovered stents.

The review was limited by the quality and quantity of the available evidence. Many of the included studies suffered from a lack of methodological rigour, which made assessing the validity of the data difficult. Not all studies reported all outcomes for different patient populations, further reducing the size of the evidence base.



However, despite a poor quality evidence base, the available data suggested that SEMS placement was safe and effective in overcoming left-sided malignant colorectal obstructions, regardless of the indication for stent placement or underlying disease.

Additionally, SEMS placement had positive outcomes when compared to surgery, including overall shorter hospital stays and a lower rate of serious adverse events. Post-operative mortality appeared comparable between the two interventions. Combining SEMS placement with elective surgery also appeared safer and more effective than emergency surgery, with higher rates of primary anastomosis, lower rates of colostomy, shorter hospital stays and lower overall complication rates. However, the small sample sizes of the included studies limited the validity of these findings.

Conclusion and Recommendations

On the basis of the evidence presented in this systematic review, the ASERNIP-S Review Group agreed on the following classifications and recommendations concerning the safety and efficacy of SEMS for relieving malignant colorectal obstruction:

Classifications

Evidence rating

The evidence base in this review is rated as poor.

Safety

The safety of SEMS placement compared to surgery cannot be determined from this evidence base. However, considered in isolation, the evidence included in this review (primarily from case series and case reports) suggests that SEMS placement is a safe procedure for relieving left-sided colorectal obstructions.

Efficacy

The efficacy of SEMS placement compared to surgery cannot be determined from this evidence base. However, considered in isolation, the evidence included in this review (primarily from case series and case reports) suggests that SEMS placement is an effective procedure for relieving left-sided colorectal obstructions, with high levels of technical and clinical success.

Clinical and research recommendations

The results of current ongoing trials should assist in more clearly defining the safety and efficacy of SEMS placement compared to surgery. The undertaking of a multi-centre randomised controlled trial of stent placement as a bridge-to-surgery is both feasible and desirable. However, the difficulties inherent in randomising patients seeking palliative treatment may preclude the possibility of conducting a randomised controlled trial of palliative stent placement.

Review Group membership

Advisory Surgeon: Associate Professor Nicholas Rieger; Advisory Surgeon: Mr Ian Faragher; ASERNIP-S Surgical Director: Professor Guy Maddern; ASERNIP-S Researchers: Ms Amber Watt, Dr Tabatha Griffin.

For the full review and executive summary, please visit the publications page of our website at http://www.surgeons.org/asernip-s/publications.htm.

Bioengineered skin substitutes for the management of wounds

ASERNIP-S Report no. 52

Objective

The objective of this review was to make recommendations on the safety and efficacy of bioengineered skin substitutes for the management of wounds based on a systematic assessment of the peer-reviewed literature. Bioengineered skin substitutes (BSS), either epidermal, dermal or both, were compared to standard care/dressings or allografts.

Methods

Search strategy: Studies were identified by searching MEDLINE, EMBASE, The Cochrane Library, Science Citation Index and Current Contents from inception to April 2006. The Clinical Trials Database (US), NHS Centre for Research and Dissemination, NHS Health Technology Assessment (UK), National Research Register (UK), National Institute of Health (US) and Meta Register of Controlled Trials were also searched in April 2006.

Study selection: Only randomised controlled trials in humans were included for review. Efficacy outcomes included wound closure, wound healing time, pain, exudate and cosmesis. Safety outcomes included complications such as infection and local allergic reactions.

Data collection and analysis: Data from the included studies was extracted by the ASERNIP-S researcher using standardised data extraction tables developed a priori and checked by a second researcher. Statistical pooling was not appropriate due to the study and result heterogeneity.

Results

In total, 23 RCTs were identified for inclusion in this review. These included eight studies for venous leg ulcers, six studies for diabetic foot ulcers and nine studies of other wounds. Collectively, the definition of success was defined as complete wound closure across all studies; however, other outcomes such as wound healing time and percentage of wound closure were not consistently reported, making comparisons between studies difficult.

For the indication of venous leg ulcers, Apligraf®, cryopreserved cultured allografts, cultured keratinocyte allografts, Dermagraft®, EpiDex™, OASIS™ Wound Matrix and Promogran™ were comparable with the standard treatment in terms of wound healing time, wound closure and decreased ulcer area. There was no difference for pain, recurrence and wound infection.

For the indication of diabetic foot ulcers, the use of BSS appeared to offer an advantage over standard care. Wound healing time appeared to be better overall with the use of BSS (Apligraf®, Dermagraft®, GraftJacket®, Hyalograft™and Laserskin™, OrCel™ and Promogran™), and wound closure appeared to be favourable with the use of Apligraf®, GraftJacket® and OrCel™. Infection rates were lower and where reported, there was no difference in recurrence between the BSS groups and the comparator.

Healing across different wounds was no better with BSS than the relevant comparator, although the evidence suggested that pain might be lower with their use. The evidence suggested that Apligraf® used for micrographic and post-excisional wounds produced similar results to standard therapy, and Biobrane® used for donor sites was not as good as the standard therapy. The evidence for Promogran™ in the treatment of pressure sores suggested it was as good as the standard therapy, and cultured epidermal allografts were more favourable than the standard therapy in terms of wound healing time and pain; however, in several studies the small sample sizes may limit the validity of the conclusions which may be drawn.

The BSS with more favourable outcomes commonly had a dermal matrix component in their composition, possibly offering a scaffold in which granulation tissue and angiogenesis may proceed. This may have contributed to the faster time to closure reported in these studies.

Conclusion

On the basis of the evidence presented in this systematic review, the ASERNIP-S Review Group agreed on the following classifications and recommendations concerning the safety and efficacy of bioengineered skin substitutes for the management of wounds:

Classifications

Evidence rating

The evidence-base in this review is rated as average, limited by generally small sample sizes, short follow-up periods, and lack of methodological rigour.

Safety

The evidence suggests bioengineered skin substitutes for the management of venous leg ulcers, diabetic foot ulcers and other wounds are at least as safe as standard therapies for these indications.

Efficacy

The efficacy of bioengineered skin substitutes for the management of venous leg ulcers, diabetic foot ulcers and other wounds could not be determined based on the available evidence. Insufficient data on treatment durability were available to establish long-term efficacy.

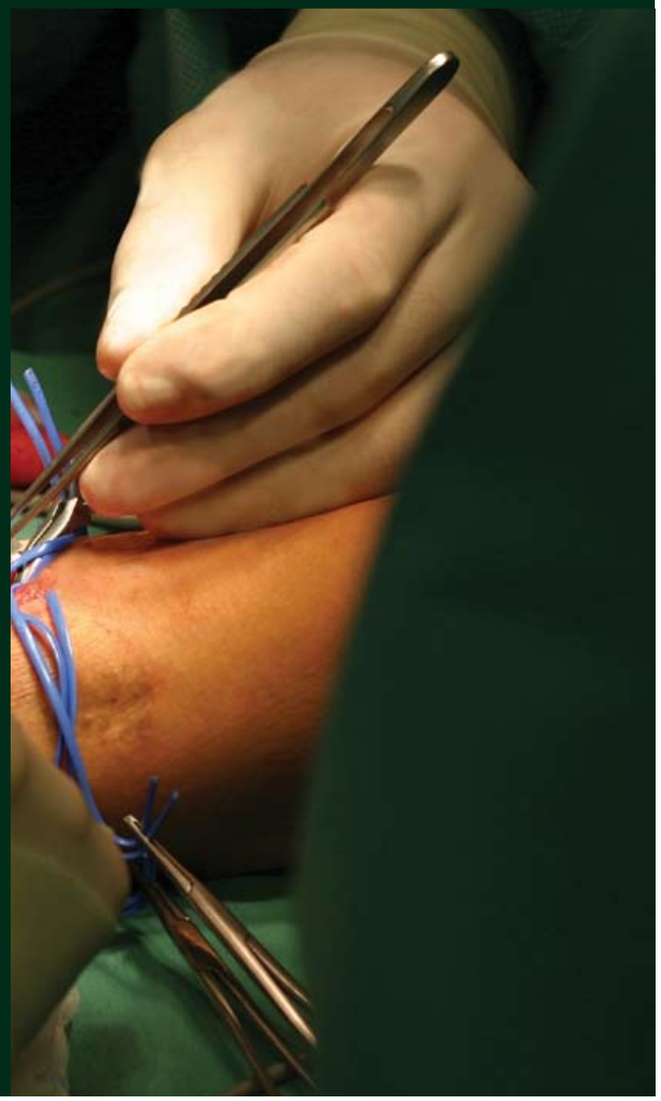
Clinical and research recommendations

Additional high quality, prospective, randomised controlled trials with longer follow-up periods would strengthen the evidence base for the use of bioengineered skin substitutes, particularly in terms of recurrence. Standard outcome measures should be developed so that investigators and clinicians can report primary outcomes (specifically in terms of ulcer healing) consistently. Cost-effectiveness studies, taking into consideration the Australian healthcare context, should also be considered.

Review Group membership

Protocol Surgeon: Mr Anthony Penington; Advisory Surgeon: Mr Keith Mutimer; Other Specialty Surgeon: Mr Mark Edwards; ASERNIP-S Surgical Director: Professor Guy Maddern; ASERNIP-S Researchers: Ms Christine Barber, Ms Amber Watt, Ms Clara Pham.

For the full review and executive summary, please visit the publications page of our website at http://www.surgeons.org/asernip-s/publications.htm.



Surgical simulation (update)

ASERNIP-S Report no. 53

Objective

Simulation is a way of representing situations that are likely to actually occur, with sufficient realism to suspend the disbelief of the participant. Virtual reality is a computerised, three-dimensional form of simulation, which allows participants to become immersed in an artificial, yet realistic, environment and be able to use components of their senses in real time. Simulation is particularly attractive in the field of surgery training because it can help to reduce the reliance on patient, cadaver or animal-based surgical training for skills practice and ensures that trainees have had some practice before treating humans.

The aim of this review was to evaluate the effectiveness of surgical simulators in comparison to each other, no training, or other methods of surgical training, on the basis of a systematic assessment of the literature.

Methods

Search strategy: Studies were identified by searching MEDLINE, EMBASE, PreMEDLINE, Current Contents, The Cochrane Library (issue 2, 2005), scholar.google.com, metaRegister of Controlled Trials, National Research Register (UK) and NHS Centre for Research and Dissemination (UK) in April 2005. PsycINFO, CINAHL and Science Citation Index were searched on March 25, 2003. Additional articles were identified through the reference sections of the studies retrieved.

Study selection: Randomised controlled trials (RCTs) assessing any training technique using at least some elements of surgical simulation compared with any other method of surgical training or no surgical training were included for review. The articles included must have contained information on at least one of the following outcomes of the new or comparative intervention: measures of surgical task performance, whether objective or subjective, and measures of satisfaction with training techniques.

Data collection and analysis: Data from the included studies were extracted by the ASERNIP-S Researcher using standardised data extraction tables developed a priori and checked by a second researcher. It was not considered appropriate to pool results across studies, because outcomes were not comparable. Relative risks (RR) for dichotomous outcome measures or weighted mean differences (WMD) for continuous outcome measures with 95% confidence intervals (CI) were calculated for some outcomes in individual RCTs where it was thought that this would aid in the interpretation of results.

Results

Thirty-one RCTs with 806 participants were able to be included, although the quality of the RCTs was often poor. Computer

simulation generally showed better results than no training at all (or physical trainer/model training in one RCT), but was not convincingly superior to standard training (such as surgical drills) or video simulation (particularly when assessed by operative performance). Video simulation did not show better results than groups with no training at all, and there were not enough data to determine if video simulation was better than standard training or the use of models. Model simulation may have been better than standard training, and cadaver training may have been better than model training. None of the RCTs made a comparison between computer simulation and model training.

Conclusion

On the basis of the evidence presented in this systematic review, the ASERNIP-S Review Group agreed on the following classifications and recommendations concerning the safety and efficacy of surgical simulation:

Classifications

Evidence rating

Poor - on the grounds that there was insufficient evidence because most of the RCTs were flawed and outcomes were often not comparable across studies.

Safety

Not applicable for this review.

Efficacy

Efficacy could not be determined. The inconclusive outcome of this review may be related to small sample sizes and the validity and reliability of outcome measurements.

Clinical and research recommendations

It was recommended that further research must be done in the context of training to particular performance standards. Ideally studies should be multicentre trials with standardised approaches, with sufficient participants. The skills being evaluated should be part of a standard surgical skills training course, not just stand-alone technical skills. Additionally, once efficacy has been determined economic analyses could be attempted.

Review Group Membership

Protocol Surgeon: Mr Adrian Anthony; Advisory Surgeon: Mr Patrick Cregan; Other Specialty Surgeon: Professor David Scott; ASERNIP-S Surgical Director: Professor Guy Maddern; ASERNIP-S Researchers: Dr Leanne Sutherland, Ms Philippa Middleton, Dr Jim Wang.

For the full review and executive summary, please visit the publications page of our website at http://www.surgeons.org/asernip-s/publications.htm.

Radiofrequency ablation for the treatment of liver tumours (update)

ASERNIP-S Report no. 56

Objective

The aim of this review was to update the original ASERNIP-S systematic review on radiofrequency ablation for liver tumours, October 2002. This review was initiated in order to assess new studies examining the safety and efficacy of radiofrequency ablation (RFA) for primary hepatocellular carcinoma or metastatic colorectal liver carcinoma, in comparison to other surgical and non-surgical therapeutic techniques, on the basis of a systematic assessment of the literature. The surgical comparative techniques included resection or hepatic artery infusion chemotherapy. The non-surgical comparative interventions included local ablative therapies such as percutaneous ethanol injection (PEI); cryotherapy; or procedures that produce local heat such as microwave coagulation therapy (MCT) or laser-induced thermotherapy (LITT).

Methods

Search strategy: Studies were identified by searching MEDLINE, EMBASE, Current Contents, Cochrane Library, and Science Citation Index, from 18 May 2002 to 14 April 2006. Clinical Trials Database (US), NHS Centre for Research and Dissemination (UK), NHS Health Technology Assessment (UK), National Research Register (UK), EORTC Protocols Database, National Institute of Health (US) and CancerLit (US) were searched in April 2006. This was supplemented by hand-searching recent conference proceedings from specialist societies and conducting internet searches. Additional articles were identified through the reference sections of the studies retrieved.

Study selection: Randomised controlled trials, quasi-randomised controlled trials and non-randomised comparative studies assessing patients treated with RFA and either one or more other comparative invention/s were included for review. Patient safety outcomes for RFA were assessed in terms of common end points reported for surgical treatment or non-surgical ablative treatments, which included major and minor complications. In terms of efficacy, the question was whether radiofrequency ablation produced at least equivalent clinical outcomes to surgical treatment or non-surgical ablative treatments.

Data collection and analysis: Data from the included studies were extracted by the ASERNIP-S researcher using standardised data extraction tables developed a priori and checked by a second researcher. Methodological heterogeneity within study designs and the lack of consistency in comparators and outcomes again prevented any pooling of data. It was not considered appropriate to pool results across studies. Relative risks (RR), weighted mean differences (WMD), or odds ratios (OR) and the 95% confidence intervals (CI) were calculated individually for the same outcomes in the RCTs and the quasi-RCT.

Results

As an update of a previous ASERNIP-S review which originally contained 12 studies, this systematic review has incorporated a further 12 studies bringing the total of included studies to 24. However, the limitations of the studies in the original systematic review are present in this update, i.e. small sample sizes, short follow-up times and a lack of comparability between the reported outcome measures. Despite the limitations of the data, RFA generally resulted in larger and more complete areas of ablation and may also be associated with higher survival rates compared to the other ablative techniques assessed in this review. Surgical resection was associated with a lower rate of recurrence and an increased time interval to recurrence compared to RFA. However, these two procedures are usually performed on different patient groups, with RFA being performed on patients who are unable to undergo surgical resection.

However, conclusions regarding safety and efficacy of RFA remain largely unchanged. At this time results are still inconclusive for the use of RFA in the treatment of hepatocellular carcinoma and colorectal metastases. Additionally, there is a paucity of comparative evidence regarding the use of RFA for colorectal metastases. Further studies, on both forms of cancer, need to be produced which contain adequate patient numbers and a focus on long-term local and overall recurrence and safety outcomes. The standardisation of outcome measures across studies would also greatly benefit any analysis.

Conclusion

On the basis of the evidence presented in this systematic review, the ASERNIP-S Review Group agreed on the following classifications and recommendations concerning the safety and efficacy of radiofrequency ablation for the treatment of liver tumours:

Classifications

Evidence rating

The evidence base in this review is rated as average.

Safety

The treatment of radiofrequency ablation for liver tumours is at least as safe as other treatments.

Efficacy

From the data included in this systematic review the efficacy of RFA cannot be determined in relation to other ablation techniques.

Clinical and research recommendations

More information is required to conclusively determine the advantages and disadvantages of radiofrequency ablation for primary hepatocellular carcinoma or metastatic colorectal liver carcinoma over other ablative treatment techniques. Further studies are also necessary to compare the safety and efficacy of percutaneous, laparoscopic and open approaches to radiofrequency ablation. The relationship of patient safety and efficacy outcomes and tumour size also requires additional research. Lastly, it is recommended that, through the increasing use of health informatics, cancer registries incorporate data items designed to gather information on treatment outcomes of ablative techniques for both hepatocellular carcinoma and metastatic colorectal liver carcinoma.

Review Group membership

Protocol Surgeon: Mr Tony Williams; Advisory Surgeon: Dr Robert Padbury; ASERNIP-S Surgical Director: Professor Guy Maddern; ASERNIP-S Researchers: Mr Nicholas Marlow, Dr Rebecca Tooher.

For the full review and executive summary, please visit the publications page of our website at http://www.surgeons.org/asernip-s/publications.htm.

Accelerated systematic reviews

Endoscopic treatments for gastro-oesophageal reflux disease

ASERNIP-S Report no. 54

Background

Gastro-oesophageal reflux disease (GORD) is a common gastrointestinal disorder, estimated to affect between 10% and 20% of the population in many Western countries. It is characterised by chronic heartburn, which if left untreated can lead to more serious health problems such as ulcers and oesophageal cancer. Traditionally, the two competing treatment pathways for the condition have been long-term pharmaceutical therapy with anti-reflux medications or surgical intervention with laparoscopic fundoplication. Endoscopic treatments for GORD potentially offer a minimally invasive alternative to current treatment options.

Objective

To assess the safety and efficacy of the following endoscopic anti-reflux treatments currently used for treating GORD:

- Radiofrequency energy ablation (Stretta® Procedure)
- Endoluminal gastroplication (Bard® EndoCinch™, Wilson-Cook Endoscopic Suturing Device and NDO Plicator™)
- Injection/implantation techniques (Enteryx®, Gatekeeper™ Reflux Repair System and Plexiglas®).

Methods

A systematic search of MEDLINE, EMBASE, CINAHL, PubMed, The Cochrane Library, Science Citation Index, the York Centre for Reviews and Dissemination, Clinicaltrials.gov, the National Research Register, relevant online journals and the internet was conducted without language restriction through to May 2006.

Systematic reviews, randomised controlled trials (RCTs) and non-randomised comparative studies with at least ten patients in each study arm and case series studies of at least ten patients examining the efficacy and safety of the various endoscopic procedures were included for review.

Results

Limited evidence suggested that in a select group of patients the Stretta Procedure produces improvements in symptoms and quality of life that are comparable to laparoscopic fundoplication and superior to sham treatment. Another intervention is generally required in up to 10% of patients two years after treatment. The main advantage of the Stretta Procedure is that it causes fewer serious complications than fundoplication and rarely requires general anaesthetic.

Results from a single RCT comparing EndoCinch to sham treatment indicated EndoCinch reduced oesophageal exposure and medication usage more than the sham procedure. Evidence from three small non-randomised comparative studies suggested that EndoCinch provided the same or slightly inferior results compared to laparoscopic fundoplication. Although EndoCinch was associated with a re-intervention rate of up to 55% within two years, patients had fewer serious adverse events following EndoCinch than laparoscopic fundoplication.

Two small case series studies on the NDO Plicator noted a positive effect on symptom and quality of life scores and medication usage between six and twelve months after treatment.

Evidence from a small RCT reported that Enteryx improved GORD-HRQL scores at three months compared to the sham group. Up to a quarter of patients may need re-treatment within two years. A single RCT that compared Enteryx and EndoCinch found no significant difference in safety or efficacy between the two treatments. Enteryx was recalled by the manufacturer in September 2005 after serious adverse events and one death were reported after the procedure.

One case series study with the Gatekeeper Reflux Repair System reported significant improvements in both symptoms and quality of life. Similarly, medication usage improved at six months after treatment although this was not statistically significant. The evidence for Plexiglas was confined to only one very small case series study reporting significant improvements in symptom severity and oesophageal acid exposure with nearly three quarters of patients no longer requiring medication at an average of seven months after treatment. Both Gatekeeper Reflux Repair System and Plexiglas procedures were relatively safe.

Conclusions

The scope, applicability, efficacy and cost-effectiveness of endoscopic anti-reflux therapies for the treatment of GORD have not been established. These procedures may provide an alternative treatment for selected patients with mild to moderate GORD who are dependent on medication and are reluctant or unable to undergo surgery. However, endoscopic results were generally inferior when compared with laparoscopic fundoplication and doubts about the durability of the therapeutic effect remain since the follow-up period in most studies was short.

Future studies should include concurrently controlled patient groups to reduce the effect of secular trends when assessing endoscopic techniques. Clearly defined patient selection criteria, especially with respect to medication usage, will help resolve the question of where these procedures fit in the spectrum of treatment choices available for patients with GORD.

While the endoscopic anti-reflux procedures are relatively safe when performed in the setting of a clinical trial, their use in routine clinical practice should be closely monitored. Guidance from professional bodies, such as the Upper Gastrointestinal section of the Royal Australasian College of Surgeons and the relevant section of the Gastroenterological Society of Australasia, on the minimum training requirements for performing these procedures would be of assistance.

Review Group membership

Protocol Surgeon: Professor Glyn Jamieson; ASERNIP-S Surgical Director: Professor Guy Maddern; ASERNIP-S Researcher: Ms Pauline McLoughlin.

For the full review and executive summary, please visit the publications page of our website at http://www.surgeons.org/asernip-s/publications.htm.

Systematic reviews for other organisations

- Endovascular treatments for the treatment of intracranial aneurysms (MSAC reference 33)
- Endovascular neurointerventional procedures (MSAC reference 1093)
- Intersphincteric injection of silicone biomaterial for severe passive faecal incontinence (MSAC application 1100)

Assessments in progress

Systematic literature reviews

- Permanent and semi-permanent dermal fillers
  Report no. 55
- Centralisation of low volume surgical procedures
  Report no. 57
- Guidelines for the safe introduction of a new technology into surgical practice
  Report no. 58
- Scalpel safety in the operative setting
  Report no. 59
- Rapid review process versus full systematic reviews
  Report no. 60
- Surgical simulation for training
  Report no. 61
- Incision-less surgery
  Report no. 62

Accelerated systematic reviews

Systematic reviews for other organisations

- Intrastromal corneal ring segments for ectasia and keratoconus
  (MSAC reference 1083)
- Repetitive transcranial magnetic stimulation as a treatment for major depression
  (MSAC reference 1101)
- Endoscopic argon plasma coagulation of gastro-intestinal bleeding
  (MSAC reference 1106)

Procedure nominations

The following nominations have been received by the ASERNIP-S Management Committee for future assessment by ASERNIP-S:

- Computer-assisted cardiac surgery
- Endoscopic ablation of Barrett's oesophagus for severe dysplasia
- Endoscopic stapling of pharyngeal pouch
- Injectable silicone for incontinence, reflux and other indications
- Laparoscopic adhesion division
- Laparoscopic hemi-hepatectomy
- Palatal procedures for snoring
- Radiofrequency ablation of tumours (not liver)
- Refractive keratoplasty
- Small vessel angioplasty
- Spinal endoscopy
- Spinal fusion apparatus
- Thermal capsular shrinkage (for shoulder ligament laxity)
- Trans-oral laser resection for laryngeal cancer
- Transpupillary thermotherapy
- Use of biological osteoinductive agents for treatment of fractures (non-union).

To nominate a new procedure for review by ASERNIP-S, visit the website and use an online form or download a PDF version at http://www.surgeons.org/asernip-s/publications.htm

data collection

- Endoluminal repair of abdominal aortic aneurysm
- National Breast Cancer Audit

Audit of endoluminal repair of abdominal aortic aneurysms

The procedure

The procedure involves the elective repair of abdominal aortic aneurysms (AAA) using an endovascular graft. The graft is inserted through an incision in the femoral artery and positioned within the aorta at the site of wall weakening (the aneurysm) in order to prevent rupture. The procedure is more commonly referred to as endovascular aneurysm repair (EVAR).

Objective

The audit was established to review the mid- to long-term safety and effectiveness of the endovascular graft within the Australian setting. Audit information will help inform future funding decisions for the procedure. The procedure has been given interim funding on the MBS pending the results of the audit.

Methods

Participating surgeons enrolled 961 patients who underwent the endoluminal repair of abdominal aortic aneurysms between 1 November 1999 and 16 May 2001 in the audit. Information obtained at the time from the Health Insurance Commission (now Medicare Australia) suggested the audit captured 90% of all privately performed cases (n=677). Initial patient information included pre-operative details, procedural information and early post-operative complications. Ongoing follow-up data collected for this cohort includes aneurysm size, additional procedures and complications relating to the original procedure.

Results

The majority of patients were male (86%) and the average age at the time of the procedure was 75 years. Nearly half of the patients listed were regarded as unsuitable candidates for open surgical repair. Peri-operative mortality (death within 30 days of the procedure) was 1.8%. Around 60% of patients survived to 5 years. Mid-term clinical success was 85%. Four percent of clinically successful patients required additional endovascular repair (assisted success) and 1.2% had additional surgical procedures (secondary success) performed to ensure continued exclusion of the aneurysm. To date, 16 aneurysms have ruptured post-procedure and 23 patients have had their EVAR converted to open repair. During mid-term follow-up, 36 patients had type I endoleak. Statistical analysis indicates that pre-operative aneurysm diameter is the most significant predictor of the various measures of success. Audit results are comparable with those reported worldwide.

The future

Results of the audit were submitted in a final progress report to the Australian Government Department of Health and Ageing in October 2006, signalling the conclusion of the 5-year funding contract with the Government. Additionally, full statistical analyses were prepared by the CSIRO, along with a predictive model proposed as a new tool for surgeons that will help inform pre-operative decisions. The audit is now covered by a funding agreement with Cook Australia, which will allow for data collection and analysis to continue for a further two years.

Members of the Audit Reference Group

Mr John Anderson; Mr Michael Denton;
A/Professor Robert Fitridge; Professor John Harris;
Mr Michael Lawrence Brown; Professor James May;
Professor Kenneth Myers; Professor Guy Maddern,
ASERNIP-S Surgical Director

The current and previous reports submitted to the Government and information about the audit are available to surgeons and the public via the ASERNIP-S website and through publications in peer-reviewed literature.

National Breast Cancer Audit

The National Breast Cancer audit entered its eighth year of operations during 2006, under the continued leadership of Mr James Kollias (Audit Clinical Director). Around 50,000 episodes of early breast cancer have now been submitted to the audit.

A new version of the web-based data entry system was launched on 4 April. The system was revised to improve security, accommodate changes in the treatment of early breast cancer and incorporate suggestions made by participants. The new website has been very well received. It is far more stable and accessible to surgeons and also easier for staff to access for administrative purposes. Accordingly, we have ceased supporting Microsoft Access and successfully moved 42 participants to the online system.

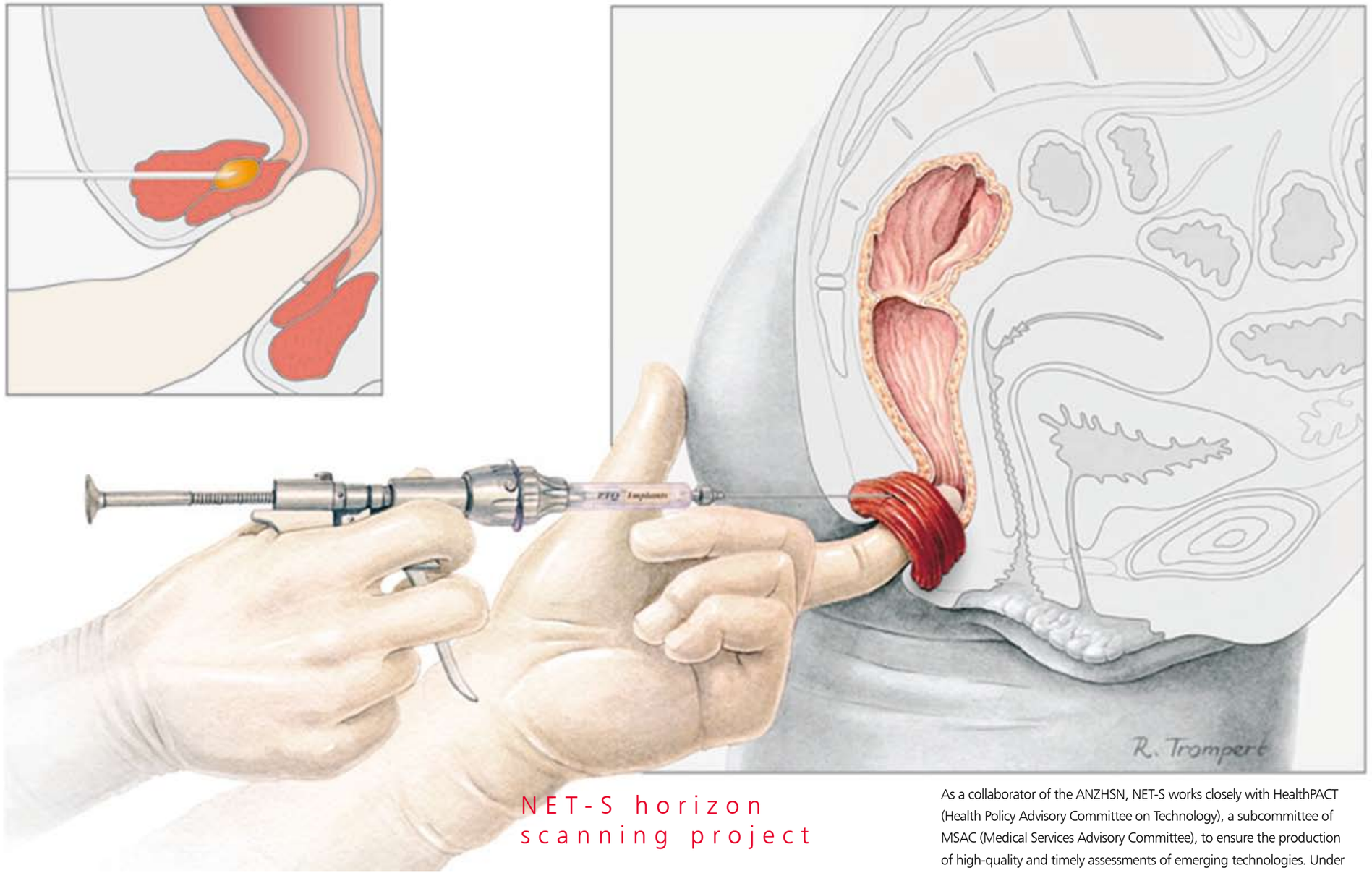
The breast audit has made ongoing progress towards obtaining data directly from institutions which collect similar breast cancer data. This is an area where error prevention and security are paramount. Draft plans of the methodology are being distributed to the first test sites early in the New Year. This activity is one of our key focus areas for 2007.

New quality thresholds were proposed in 2006 and are currently under development. They relate to referral rates to radiotherapy after mastectomy and referral to a medical oncologist for high risk cases.

Our consumer partner, Breast Cancer Network Australia (BCNA), has continued to be a strong advocate for the audit and provides valuable consumer input to the management of the audit. We are particularly grateful for their help in securing sustained long-term funding.

The National Breast Cancer Centre (NBCC) has strongly supported the audit in 2006 and has agreed to fund the ongoing business of the audit for the next three years. Our key performance indicators with regard to this contract include increasing participation and improving data completeness, accuracy and feedback to participating surgeons.

We have also conducted research using data collected by NBCA and published regularly during 2005-2006. The most recent publication is in the Australia and New Zealand Journal of Surgery on invasive breast cancer management. Further research will be carried out in this area to assess the breast cancer treatment pattern and trends in order to improve overall patient care based on evidence-based medicine principles.



NET-S

New and Emerging Techniques - Surgical

- Horizon scanning project
- NET-S on the web

NET-S horizon scanning project

The New and Emerging Techniques - Surgical (NET-S) project was established in 1999 with the primary aim of identifying and assessing advances in surgery that are likely to cause a significant impact on the Australian and New Zealand health systems in the near future. Assessments of these new technologies are presented in the form of prioritising summaries or horizon scanning reports. Prioritising summaries are concise documents that provide the reader with some background of the technology and present the evidence available pertaining to the safety and efficacy of the technology or procedure. If a substantial amount of evidence is available for an emerging technology/procedure, a horizon scanning report will be written. These documents can be used for clinical guidance as well as provide the information required for government policy and planning. Both prioritising summaries and horizon scanning reports are available on the NET-S website (http://www.surgeons.org/asernip-s/nets.htm) and the Australia and New Zealand Horizon Scanning Network (ANZHSN) website (http://www.horizonscanning.gov.au/).

As a collaborator of the ANZHSN, NET-S works closely with HealthPACT (Health Policy Advisory Committee on Technology), a subcommittee of MSAC (Medical Services Advisory Committee), to ensure the production of high-quality and timely assessments of emerging technologies. Under the current contract, NET-S produces 24 prioritising summaries and 4 horizon scanning reports per annum.

The NET-S database has over 900 procedures/technologies and serves as a guide during the scanning process, allowing project officers to monitor the development of new devices or procedures over time. In addition to this, the database serves as a means of tracking the progress of technology assessments. ANZHSN is also a member of Euroscan, a collaborative network of health technology assessment agencies which facilitates information exchange on the evaluation of emerging technologies. All prioritising summaries are uploaded to EuroScan and can be viewed at the Euroscan website (http://www.euroscan.bham.ac.uk/index.htm).

The NET-S project continues to evolve and provide valuable assessments of emerging surgical technologies, as well as alerting the Australian health system of technologies which may significantly benefit Australians.

NET-S on the web

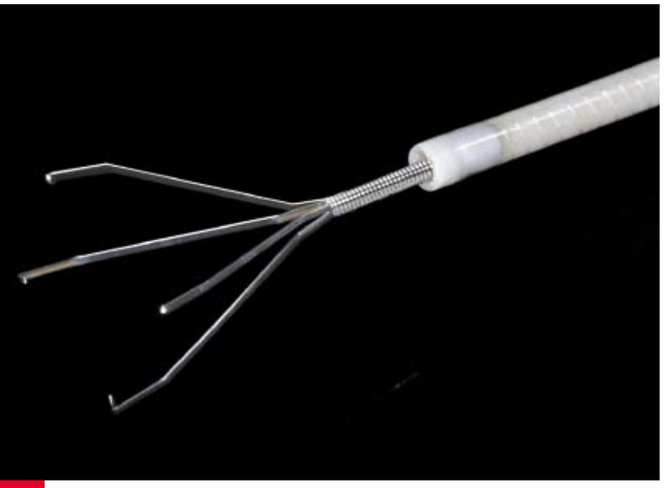
All summaries and horizon scanning reports are available for download on the NET-S website (http://www.surgeons.org/asernip-s/nets.htm) and the ANZHSN website (http://www.horizonscanning.gov.au/). Contact details are provided for readers who wish to nominate a new technique or comment on completed summaries or reports.

There are 16 new prioritising summaries available:

- AcrySof® ReSTOR® multifocal intraocular lens
- C-Port® distal anastomosis system
- Cryoplasty utilising the PolarCath™ peripheral dilation system
- IntraLase® femtosecond laser
- Magnetic resonance image (MRI) guided cryotherapy for the treatment of uterine fibroids
- Percutaneous mitral valve repair utilising MitraClip®
- ProACT™ therapy for male stress urinary incontinence
- Renessa® radiofrequency micro-remodelling treatment for female stress urinary incontinence
- Sonablate® 500 system
- StarClose™ vascular closure system
- TandemHeart® percutaneous ventricular assist device
- Total temporomandibular joint (TMJ) replacement system
- Vivostat® system (Vivolution A/S, Denmark) for perioperative preparation and application of an autologous fibrin sealant
- X STOP® interspinous process decompression system.
- Pumpless extracorporeal interventional lung assist (iLA) system (Novalung)
- Intracranial angioplasty and stenting (WingSpan™ self-expanding stent) for cerebral atherosclerotic stenosis.

There are 2 new NET-S horizon scanning reports available:

- OP-1 Putty for posterolateral lumbar fusion
- Enterra therapy gastric electrical stimulation system for the treatment of the symptoms of medically refractory gastroparesis.



- Consumer information
- Promotional activities
- Externally-commissioned projects
- ASERNIP-S website
- ASERNIP-S Management Committee
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- Education and training
- Personnel

project activities

Consumer information

ASERNIP-S informs consumers and surgeons of the latest surgical research through our consumer summaries. These are short summaries of the systematic literature reviews, written in easy-to-read language and posted on the consumer information and publications pages on our website (http://www.surgeons.org/asernip-s/). Double-sided patient information leaflets are also available for some of our reviews.

In 2006 ASERNIP-S staff continued to prepare consumer information in collaboration with surgeons and consumers. We were pleased to welcome our new consumer representative Margaret Charlton from the Health Consumers Alliance and look forward to working with her on consumer issues. We also thank Jane Doyle, who has represented consumers on the ASERNIP-S Management Committee since 2002, for her ongoing commitment to this work.

This year the following plain English summaries were prepared:

- Bioengineered skin substitutes for burn management
- Self-expanding metallic stents for obstruction of the colon and rectum caused by cancer
- Bioengineered skin substitutes for wound management
- Surgical simulation training (review update)
- Radiofrequency ablation for the treatment of liver tumours (review update)
- Endoscopic treatments for gastroesophageal reflux disease (accelerated systematic review)

Publications on the work of ASERNIP-S have appeared in RACS Surgical News (January/February, October, November), SADI Statewide (June), HealthInsite news (November), and General Surgeons Australia newsletter (December). A presentation was given at the July HTAi conference at the Adelaide Convention Centre entitled 'Consumer input evolves at ASERNIP-S'. We are members of the HTAi Special Interest Group on patient/citizen involvement in HTA, which met during that conference.

ASERNIP-S is developing a web-based survey to obtain feedback from consumers about our patient information. We aim to use this knowledge to improve our product and dissemination processes and thus better inform consumers of our latest research findings.

For more information please visit the consumer information page of our website at http://www.surgeons.org/asernip-s/consumer.htm or contact us at consumer.asernip@surgeons.org.

Promotional activities

Peer reviewed publications 2006

Cuncins-Hearn A, Boult M, Babidge W, Zorbas H, Villanueva E, Evans A, Oliver D, Kollias J, Reeve T, Maddern G. The National Breast Cancer Audit: Overview of invasive breast cancer management. *Australia and New Zealand Journal of Surgery 2006*; 76: 745-750

Boult M, Babidge W, Maddern G, Barnes M, Fitridge R on behalf of the Audit Reference Group. Predictors of success following endovascular aneurysm repair: mid-term results. *European Journal of Vascular and Endovascular Surgery 2006*; 31: 123-129

Maddern G, Middleton P, Tooher R, Babidge W. *E*valuating New Surgical Techniques in Australia: The Australian Safety and Efficacy Register of New Interventional Procedures-Surgical Experience. *Surgical Clinics of North America 2006;* 86 (1): 115-128

Middleton P, Duffield M, Lynch S, Padbury R, House T, Stanton P, Verran D, Maddern G. Living Donor Liver Transplantation-Adult Donor Outcomes: A Systematic Review. *Liver Transplantation* 2006; 12: 24-30

Pham CT, Middleton PF, Maddern GJ. *T*he safety and efficacy of topical negative pressure in non-healing wounds: a systematic review. *Journal of Wound Care 2006*; 15 (6): 240-250

Sutherland L, Middleton P, Anthony A, Hamdorf J, Cregan P, Scott D, Maddern G. Surgical Simulation: A Systematic Review. *Annals of Surgery 2006*; 243 (3): 291-300

Sutherland Leanne M, Williams John AR, Padbury Robert TA, Gotley David C, Stokes Bryant and Maddern Guy J. Radiofrequency ablation of liver tumours: a systematic review. *Archives of Surgery 2006*; 141: 181-190

Tooher R, Swindle P, Woo H, Miller J and Maddern G. Laparoscopic radical prostatectomy for localized prostate cancer: a systematic review of comparative studies. *Journal of Urology 2006*; 175: 2011-2017

Other Publications 2006

ASERNIP-S. *RACS Surgical News*, Vol. 7 No.1, January / February 2006

National Breast Cancer Audit News. *RACS Surgical News*, Vol. 7 No. 4, May 2006

Australian Safety and Efficacy Register of New Interventional Procedures – Surgical, *Newsletter of SA Divisions of General Practice Inc*, Vol. 3 Issue 1, June 2006

Surgical simulation. *RACS Surgical News*, Vol. 7 No.9, October 2006

New reviews on surgical interventions. *HealthInsite news*, 14 November 2006

Bioengineered skin substitutes for wound management. *RACS Surgical News*, Vol. 7 No. 10, November/December 2006

ASERNIP-S update. *General Surgeons Australia Newsletter*, December 2006

2006 Presentations

Maddern G. *Cost effective health delivery*. Health & Lifestyle Expo, Clinician Networking Dinner, Auckland, New Zealand, March 2006

Maddern G. *Australian and New Zealand Audit of Surgery Mortality.* Health & Lifestyle Expo, Consumer Forum, Auckland, New Zealand, March 2006

Maddern G. *New surgical technologies: The ASERNIP-S experience.* Health & Lifestyle Expo, Consumer Forum, Auckland, New Zealand, March 2006

Fitridge R, Boult M, Babidge W, Maddern G on behalf of the ASERNIP-S EVAR reference group. *Effect of pre-operative variables on the mid-term outcomes for patients treated in Australia for endovascular repair.* Annual Scientific Congress of the Royal Australasian College of Surgeons, Sydney, Australia, May 2006

Kollias J. *RACS National Breast Cancer Audit update.* Annual Scientific Congress of the Royal Australasian College of Surgeons, Sydney, Australia, May 2006

Maddern G. *The process of assessment of new technology.* Royal Prince Alfred Hospital Medical Officers Association 72nd Annual Reunion, Royal Prince Alfred Hospital, Sydney, Australia, June 2006

Ahern E, Babidge W, Williams K, Doyle J, Maddern G. *Consumer input evolves at ASERNIP-S.* 3rd Annual HTAi meeting, Adelaide Convention Centre, Adelaide, Australia, July 2006

Babidge W. Rapid Reviews: *Speed or accuracy?* 3rd Annual HTAi meeting, Adelaide Convention Centre, Adelaide, Australia, July 2006

Maddern G, Facey K. *Examples of HTA in surgery: The 'theatre' of HTA* (Plenary session). 3rd Annual HTAi meeting, Adelaide Convention Centre, Adelaide, Australia, July 2006

Maddern G. *Biotechnology and Emerging Technologies: The value of innovation – Clinician perspective (workshop).* 3rd Annual HTAi meeting, Adelaide Convention Centre, Adelaide, Australia, July 2006

Maddern G. *HTA in the Asia-Pacific: Challenges for the Medical Device Industry (panel)*. 3rd Annual HTAi meeting, Adelaide Convention Centre, Adelaide, Australia, July 2006

Barber C. *Careers in Biology. Non-laboratory based research: The ASERNIP-S Program*. Careers in Science Seminar Series, Careers & Employer Liaison Centre, Flinders University, Adelaide, Australia, September 2006

Golledge J, Parr A, Boult M, Maddern G, Fitridge R. *The outcome of endovascular repair of small abdominal aortic aneurysms. "Vascular 2006"*. The Australian and New Zealand Society for Vascular Surgery, Cairns, Australia, September 2006

Maddern G. *Horizon scanning: the next steps.* SBU/Euroscan Horizon Scanning Workshop, Högberga Conference Centre, Stockholm, Sweden, September 2006

Maddern G. *Stretching the Boundaries. Private health insurance reforms: Opportunities and challenges. New surgical technologies: the ASERNIP-S experience.* Australian Health Insurance Association Conference, Star City Hotel, Sydney, Australia, November 2006

Externally-commissioned projects

In March 2006 ASERNIP-S was commissioned by the National Breast Cancer Centre (NBCC) to undertake an appraisal of the current therapeutic information about intra-operative radiation therapy (IORT) and partial breast irradiation for breast cancer treatment. The literature search sought to determine whether there were any significant new developments in the use of IORT and partial breast irradiation since ASERNIP-S reviewed the topic in 2002.

This project was conducted in a collaborative manner, with NBCC providing input into the direction of the research throughout the project. This process was considered a most productive use of resources from the perspective of both groups.

Findings from this work are being considered by NBCC and may lead to further collaborations in the future.

ASERNIP-S website

The ASERNIP-S website has continued to provide numerous users with detailed information regarding the work of ASERNIP-S. The website, which is accessible directly or via links from the RACS homepage, is regularly updated with the systematic reviews, accelerated systematic reviews and consumer summaries produced by ASERNIP-S. The reciprocal relationship established with HealthInsite has been successful, with ASERNIP-S reports appearing as key search results when consumers utilise the HealthInsite search portal.

Additionally, the website for the New and Emerging Techniques – Surgical (NET-S) horizon scanning project appears as a link on the ASERNIP-S homepage and continues to be updated with new reports.

The ASERNIP-S website address is http://www.surgeons.org/asernip-s/

The RACS website address is http://www.surgeons.org

The NET-S website address is http://www.surgeons.org/asernip-s/nets.htm

ASERNIP-S Management Committee 2006

The members of the ASERNIP-S Management Committee are:

Dr Russell Stitz	Chairman, and RACS President
Professor Bruce Barraclough	RACS Fellow
Ms Margaret Charlton	Consumer Representative, Health Consumers Alliance
Ms Jane Doyle	Consumer Representative
Professor Kingsley Faulkner	RACS Fellow
A/Professor Sally Green	Director Australasian Cochrane Centre
Dr David Hailey	Health Technology Assessment Expert
Dr David Hillis	RACS Chief Executive Officer
Mr Brian Johnston	Chief Executive, Australian Council on Healthcare Standards
Professor Brendon Kearney	MSAC Representative
Professor Guy Maddern	ASERNIP-S Surgical Director
Dr John Quinn	RACS Executive Director for Surgical Affairs (Australia)

We were pleased to welcome Professor Brendon Kearney and Margaret Charlton to the committee this year.

Terms of Reference

- To meet on a regular basis.
- To agree on program schedules, plans and tasks required to meet program objectives.
- To provide leadership and guidance to the program - to focus on a strategy to meet program objectives.
- To be responsible for identifying resource requirements and, wherever possible, organising provision of these resources.
- To exercise direction over program activities, approve plans and monitor their execution.
- To make decisions on issues which threaten to affect the progress of the program and ensure adequate contingency management is in place.
- To delegate measures of effectiveness and efficiency and monitor program performance against these criteria.

Representation on external committees

ASERNIP-S was represented on the following committees:

- Medical Device Evaluation Committee (MDEC), a statutory committee which provides independent advice to Therapeutic Goods Administration (TGA) – Professor Guy Maddern
- National Breast Cancer Centre Data Advisory Group – Professor Guy Maddern
- International Network of Agencies for Health Technology Assessment (INAHTA) – Professor Guy Maddern, Director
- Medical Device Incident Review Committee (MDIRC), a sub-committee of the Medical Device Evaluation Committee (MDEC) – Professor Guy Maddern, Chair
- Health Technology Advisory Group (HTAG) – Professor Guy Maddern, Chair
- Health Technology Assessment International (HTAi) – Professor Guy Maddern, Secretary

Education and Training

Training opportunities for staff

Courses and conferences attended by staff members in 2006 included:

- Australian Science Communicators workshop, Adelaide, March
- Annual Scientific Congress of the Royal Australasian College of Surgeons, Sydney, May
- Australasian Cochrane Centre workshop – 'Developing a protocol for a systematic review', Adelaide, May
- Australasian Cochrane Centre workshop – 'An introduction to analysis', Adelaide, May
- Australian Centre for Evidence Based Clinical Practice – 'Introduction to evidence based clinical practice', Adelaide, May
- Cochrane Consumer Network/Joanna Briggs workshop, Adelaide, June
- HTAi conference, Adelaide, July
- 14th Annual Meeting of INAHTA, Adelaide, July
- 4th Australasian Conference on Safety and Quality in Health Care, Melbourne, August
- CRE in patient safety seminar – 'The role of IT in improving patient safety', Royal Melbourne Hospital, August
- Multimodality management of colorectal liver metastases, Melbourne, October
- Short course 'Economic methods for evidence-based health technology assessment', Adelaide, November
- The AETMIS (Agence d'Evaluation des Technologies et des Modes d'Intervention en Santé) distance learning course entitled 'Health Technology Assessment: Decision-making for health'

Medical students

ASERNIP-S has supervised research proposal development for two students this year. Kate Penrose worked with the audit staff of the National Breast Cancer Audit to develop a research proposal examining the incidence of contralateral breast cancer in women undergoing bilateral mastectomy, bilateral oophorectomy or five years of Tamoxifen therapy. Balaji Varatharaju investigated how surgeons would prefer to receive feedback from the audit of surgical mortality.

Personnel

During 2006 we welcomed new Research Officers Dr Jim Wang, Lana Sturm and Eliana Della Flora; a new Office Manager and Personal Assistant to the Director, Belinda Tarca; and a new Administrative Officer, Deborah Clapp. Dr Jim Wang recently moved to the Breast Audit to take up a new position as Research Officer. The following staff left ASERNIP-S: Ann Duff, Dr Tabatha Griffin, Amy McClennan, Clarabelle Pham, Dr John Pockett, Dr Rebecca Tooher, Sarah Devitt and Kerin Williams.

In 2006 we benefited from the expertise of two consultants:

- **Dr Karen Facey, ASERNIP-S Consultant**
  Dr Karen Facey worked with ASERNIP-S as a consultant for 4 weeks in November 2004 and is now providing advice virtually from her home in Scotland. Karen is a Certified Statistician with a PhD related to interim analyses in clinical trials. She is an Honorary Member of the UK Faculty of Public Health and a Fellow of the Royal Society of Medicine. She is a visiting Research Fellow at the University of Glasgow and is an independent evidence-based health policy consultant with a wide variety of experience in industry, HTA Agency and government. Since August 2006 she has been reviewing ASERNIP-S HTAs and horizon scanning reports.

- **Ms Brita Pekarsky, ASERNIP-S Consultant**
  Brita Pekarsky is a Senior Research Fellow at the Centre for Regulation and Market Analysis at the University of South Australia. Brita is an experienced analyst of the Australian healthcare system. She was a member of the National evaluation team for the Coordinated Care Trials (1997 to 2000). In the last 10 years she has worked on more than 40 consultancies in the area of healthcare evaluation. Brita has been a member of the Economic Subcommittee of the PBAC since May 1997. Since March 2006 Brita has worked as a senior consultant for ASERNIP-S on projects for the Medical Services Advisory Committee, primarily in relation to economic evaluation.

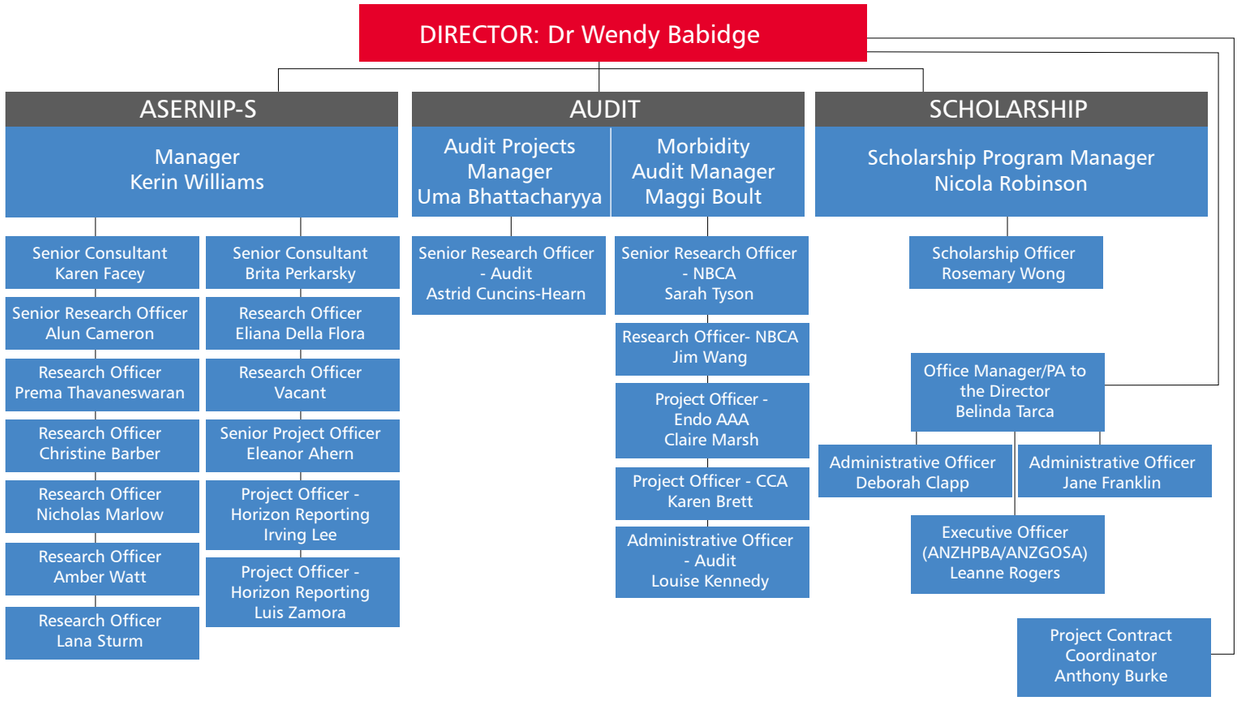
staff profiles

Professor Guy Maddern
Dr Wendy Babidge
Kerin Williams
Eleanor Ahern
Christine Barber
Maggi Boult
Alun Cameron
Deborah Clapp
Eliana Della Flora
Sarah Devitt
Ann Duff
Dr Michael Duffield
Jane Franklin
Dr Tabatha Griffin
Louise Kennedy
Irving Lee
Nicholas Marlow
Claire Marsh (nee Miller)
Amy McLennan
Clarabelle Pham
Dr John Pockett
Lana Sturm
Belinda Tarca
Prema Thavaneswaran
Dr Rebecca Tooher
Sarah Tyson
Dr Jim Wang
Amber Watt
Luis Zamora

Research and Audit Division – Royal Australasian College of Surgeons

Organisational chart

December 2006



Professor Guy Maddern

RP Jepson Professor of Surgery, University of Adelaide, was appointed inaugural Surgical Director of ASERNIP-S in October 1997. Since that time Professor Maddern has been involved in developing the ASERNIP-S program for the Royal Australasian College of Surgeons. Professor Maddern is a practising hepatobiliary surgeon based at The Queen Elizabeth Hospital, Head of the Division of Surgery and Director of the Basil Hetzel Institute for Medical Research in Adelaide.

Director, Research and Audit, Royal Australasian College of Surgeons
Dr Wendy Babidge

Dr Wendy Babidge was made a Director of the Royal Australasian College of Surgeons (RACS) in June 2005 and is responsible for the Division of Research and Audit. This Division currently supports 27 staff members, working in the areas of ASERNIP-S, Audits and Scholarships. As well as directing the ASERNIP-S program, Wendy oversees the administration of the RACS morbidity and mortality audits, the provision of scholarships for surgical research and the fundraising activities associated with this. Wendy has an Honours Degree in Biotechnology, a PhD from the University of Adelaide and a Graduate Diploma in Business. Another major focus of the Division is to establish a secure web-based system at the RACS for the purpose of training.

ASERNIP-S Manager
Kerin Williams

Kerin Williams joined ASERNIP-S in November 2005 as Manager of ASERNIP-S. She has a Bachelor of Arts (Psychology, Sociology and Philosophy), Graduate Diploma Social Science and an Advanced Diploma in Management (Business), has commenced a Master in Public Health/Business Management qualification and is a Registered Nurse. Kerin has managed State and National projects for the Department of Health and Ageing over the past 10 years in the area of adolescent mental health and suicide prevention. She has recently been employed as Program Manager for the Southern Division of General Practice, and has also managed her own consultancy practice specialising in health and education projects where there is a need to develop multidisciplinary collaborative working relationships.

ASERNIP-S Senior Project Officer - Consumer
Eleanor Ahern

Eleanor joined ASERNIP-S in October 2000. She has a Master of Arts Degree in International Relations and an Advanced Diploma of Arts in Professional Writing. She has a background in medical studies. Eleanor has worked as a freelance editor and now writes consumer information for ASERNIP-S.

ASERNIP-S Research Officer
Christine Barber

Chris Barber joined ASERNIP-S in August 2005 to conduct systematic reviews. She previously worked as a researcher at the Institute of Medical and Veterinary Science investigating the relationship between the intervertebral disc and the vertebral body in osteoporosis of the human lumbar spine. She has a Bachelor of Science degree majoring in molecular biology and genetics from Flinders University. Chris recently completed a Bachelor of Health Sciences, Honours in Pathology from the University of Adelaide, focusing on the assessment of osteoporosis and bone quality in the human lumbar spine.

ASERNIP-S Morbidity Audit Manager
Maggi Boult

Maggi Boult has an Honours Degree in Plant Science, a Graduate Diploma in Information Studies and a Diploma in Computer Programming. She joined ASERNIP-S in 1998 and during her tenure has developed and implemented surgical audits for RACS and for the Federal Government. Maggi is also the ASERNIP-S Privacy Officer.

ASERNIP-S Research Officer
Dr Alun Cameron

Dr Alun Cameron joined ASERNIP-S in August 2005. He has a BSc in Biochemistry (with Medical Biochemistry), and studied cell signalling mechanisms in African trypanosomes during his PhD. Since then he has worked in the field of connective tissue research at Manchester University in the UK, prior to moving to Adelaide.

ASERNIP-S Administrative Officer
Deborah Clapp

Deborah Clapp joined ASERNIP-S in August 2006 to provide additional administrative support to the program. She has a background in administration in the health sector (cosmetic surgery industry), a Bachelor of Arts Degree majoring in English, and certificates in Medical Computing, Medical Terminology and Business Administration.

ASERNIP-S Research Officer
Eliana Della Flora

Eliana joined ASERNIP-S in November 2006 to conduct systematic reviews. She has a Bachelor of Medical and Pharmaceutical Biotechnology Degree with Honours from the University of South Australia. Her Honours project was conducted at the Hanson Institute, where she investigated the role of a novel gene in angiogenesis and apoptosis.

ASERNIP-S Administrative Officer
Sarah Devitt

Sarah joined ASERNIP-S in June 2005 as an administrative assistant to the Audit Manager. Sarah came to ASERNIP-S with extensive administrative experience in private enterprise at the executive secretary level. Sarah has a Degree in Commerce and has previous experience in marketing and hospital administration. Sarah left ASERNIP-S in 2006.

ASERNIP-S Office Manager and PA to the Director, Research and Audit
Ann Duff

Ann Duff joined ASERNIP-S in February 2005 having most recently worked for the Royal District Nursing Service of South Australia. Ann had extensive administrative experience working for many years in the State Government, predominantly in Ministerial offices. At ASERNIP-S Ann was the Office Manager and Personal Assistant to the Director, Research and Audit. Ann left ASERNIP-S in 2006 to take up another position.

ASERNIP-S Research Officer
Dr Michael Duffield

Dr Michael Duffield joined ASERNIP-S in September 2003 to conduct systematic reviews. He has a Bachelor of Science degree, with Honours, from the University of Adelaide, and has completed his PhD, which involved a molecular biological and electrophysiological investigation of ion channel gating. In 2005 Michael commenced studies in medicine at Flinders University, but he still works at ASERNIP-S on a part-time basis.

ASERNIP-S Administrative Officer
Jane Franklin

Jane Franklin joined ASERNIP-S in January 2001 to provide administrative support to the program. Jane has a background in banking and customer service and a Certificate II in Business (Office Administration).

ASERNIP-S Senior Research Officer
Dr Tabatha Griffin

Dr Tabatha Griffin joined ASERNIP-S in April 2003. She has a Bachelor of Science degree in plant and environmental biology with Honours. She also completed a PhD at Flinders University in 2001 in the fields of ecology and entomology. At ASERNIP-S Tabatha conducted systematic literature reviews and managed the website, then moved to a position as Senior Research Officer in the Breast Audit. Tabatha left ASERNIP-S in 2006 to take up another position.

ASERNIP-S Administrative Officer
Louise Kennedy

Louise Kennedy joined ASERNIP-S in December 2002, on a part-time basis. She has a Certificate III in Business (Office Administration) and has studied several Information Technology subjects. Louise previously worked in clerical positions for the Commonwealth Public Service. At ASERNIP-S, Louise provides assistance to the administrative officers and audit projects.

ASERNIP-S Project Officer – Horizon Reporting
Irving Lee

Irving Lee joined ASERNIP-S in January 2005 as the NET-S Project Officer. His academic qualifications includes a Bachelor degree in Science (Biomedical) majoring in Physiology and Pharmacology, and an Honours degree in Obstetrics and Gynaecology. At ASERNIP-S, Irving conducts daily horizon scanning for new surgical techniques, writes prioritising summaries/reports and maintains the NET-S database.

ASERNIP-S Research Officer
Nicholas Marlow

Nicholas Marlow joined ASERNIP-S in November 2005. Nicholas holds a Bachelor of Arts majoring in Anthropology and Japanese, an Honours degree in Anthropology and a Graduate Diploma in Public Health, all from the University of Adelaide. At ASERNIP-S, he has assisted with a number of reviews as well as recently leading his own systematic review. Nicholas has also provided design assistance for internal and external presentations.

ASERNIP-S Research Officer
Claire Marsh (nee Miller)

Claire Marsh joined ASERNIP-S in August 2005. She has a Bachelor of Health Sciences Honours degree from the University of Adelaide, and majored in public health and psychology throughout her undergraduate course. Her Honours thesis focused on health behaviours and attitudes around self administered cancer screening techniques. At ASERNIP-S Claire has been involved with the National Breast Cancer Audit and is now dividing her time between this project and the Audit for Endoluminal Repair of Abdominal Aortic Aneurysms.

ASERNIP-S HTA Project Officer
Amy McLennan

Amy McLennan joined the ASERNIP-S team in November 2005. She has a Bachelor of Medical Science with majors in physiology and neuroscience, a Diploma in French from Flinders University and a Bachelor of Science with Honours in anatomical sciences from the University of Adelaide. At ASERNIP-S, Amy provided support to several committees that dealt with aspects of health technology assessment and organised the Health Technology Assessment International (HTAi) conference in Adelaide in July 2006. Amy left ASERNIP-S in 2006 to take up another position.

ASERNIP-S Senior Research Officer
Clarabelle Pham

Clara joined ASERNIP-S in January 2003. She has a Bachelor of Science Degree, majoring in Physiology and Pharmacology, an Honours Degree in Obstetrics and Gynaecology, and a Graduate Diploma in Public Health from the University of Adelaide. At ASERNIP-S Clara conducted systematic literature reviews, supervised review projects and trained research staff. Clara left ASERNIP-S in 2006 to take up another position.

ASERNIP-S Research Officer
Dr John Pockett

Dr John Pockett joined ASERNIP-S in November 2005 to conduct systematic reviews. He recently completed a PhD in Materials Science. This follows a Bachelor of Science degree in Physics and Maths and a career mainly in research and development across a range of industries including with medical devices such as gamma cameras, X ray image intensifiers and laser equipment. He has also run a consultancy in industrial research and development. John left ASERNIP-S in 2006.

ASERNIP-S Research Officer
Lana Sturm

Lana joined ASERNIP-S in May 2006. She has a B App Sc (Env Hlth) and a B Sc (Hons) from Flinders University. She has a Grad Dip Comms (PR) from Uni SA. Lana has spent the last five years working as an Environmental Health Officer in local government. At ASERNIP-S she conducts systematic literature reviews.

ASERNIP-S Office Manager and PA to the Director, Research and Audit
Belinda Tarca

Belinda Tarca joined ASERNIP-S in September 2006 having most recently worked at the Flinders Medical Centre. Belinda has had extensive administrative experience working for many years in the State Government. At ASERNIP-S Belinda is the Office Manager and Personal Assistant to the Director, Research and Audit.

ASERNIP-S Research Officer
Prema Thavaneswaran

Prema Thavaneswaran joined ASERNIP-S in January 2005 to conduct systematic reviews. She has a Bachelor of Science degree with Honours from the University of Adelaide. Prema is in the final stages of completing her PhD, which involved investigations of the prenatal programming of the Insulin Resistance Syndrome in the aged guinea pig.

ASERNIP-S Senior Research Officer
Dr Rebecca Tooher

Dr Rebecca Tooher joined ASERNIP-S in August 2002. A qualified audiologist, Rebecca has a Bachelor of Arts and a Postgraduate Diploma of Audiology. Her PhD (awarded in 2003) focused on the quality of life and psychosocial wellbeing of young people who use cochlear implants to hear. At ASERNIP-S, Rebecca wrote systematic literature reviews, contributed to applications for funding, conducted evaluation research of ASERNIP-S activities and was involved in external consultancies. She helped the Research Manager supervise review projects and trained research staff. Rebecca left ASERNIP-S in 2006 to take up another position.

ASERNIP-S Senior Research Officer
Sarah Tyson

Sarah Tyson joined ASERNIP-S as a researcher in November 2002 after operating the RACS Breast Audit as a separate project since March 1998. She has a science degree from the University of Adelaide majoring in Clinical and Experimental Pharmacology and Toxicology, and Biochemistry. Prior to her appointment Sarah was engaged in several other complex projects in the health and disability sectors.

ASERNIP-S Research Officer
Dr Jim Wang

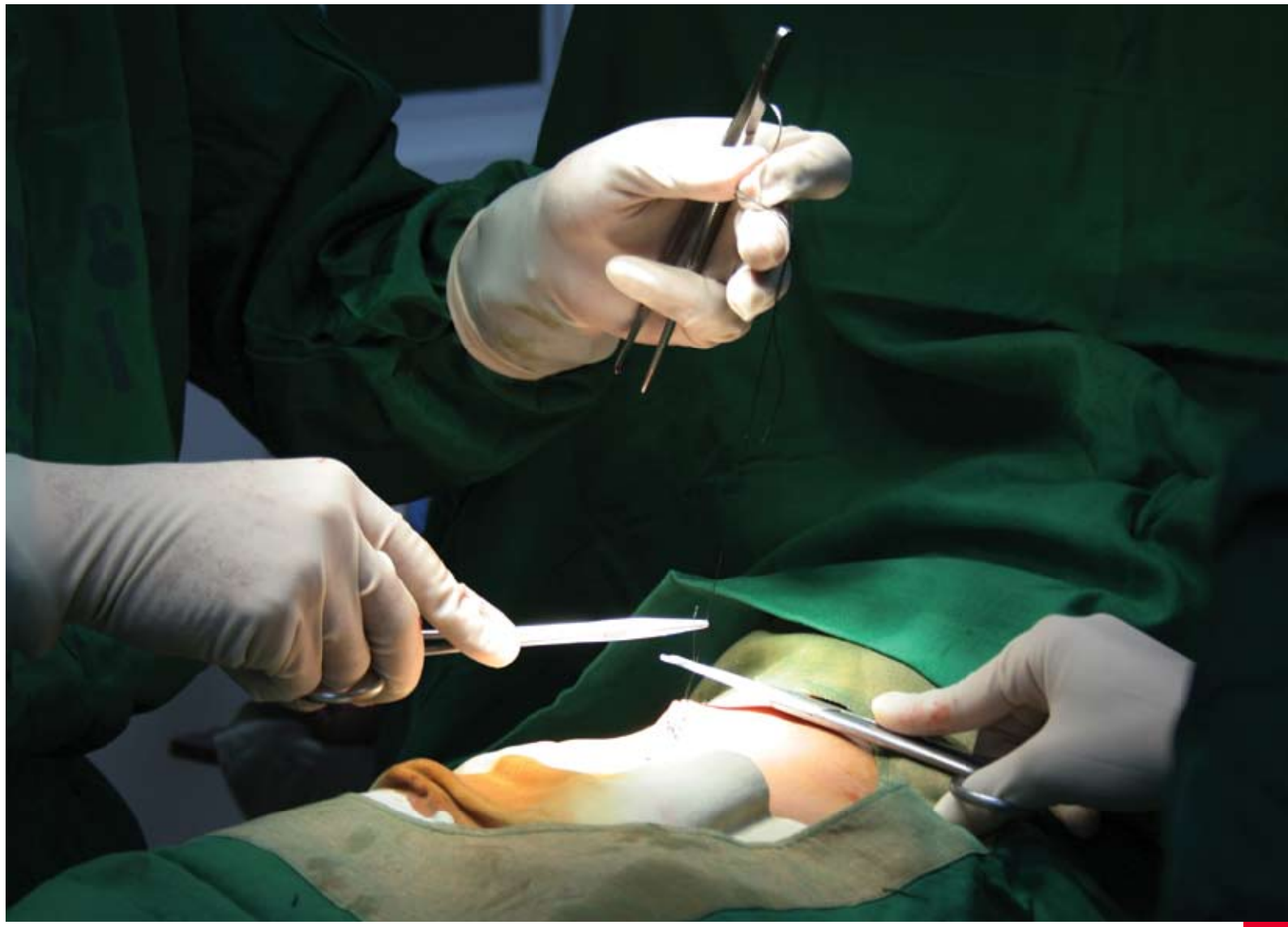
Dr Jim Wang joined ASERNIP-S in January 2006. He has a BSc in Agriculture and a Master of Public Health from University of Adelaide. Jim has worked extensively in research environments. At ASERNIP-S he has been involved in conducting systematic literature reviews and other research projects. In November he moved to the National Breast Cancer Audit. He is interested in analysing the audit data and using this data to assess the utilisation of available evidence in clinical practice.

ASERNIP-S Research Officer
Amber Watt

Amber Watt joined ASERNIP-S in August 2005. She holds a Bachelor of Medical Science from Flinders University, with majors in Physiology and Neuroscience, and is currently undertaking studies in Public Health at The University of Adelaide. At ASERNIP-S, Amber conducts systematic literature reviews and undertakes a variety of other project work.

ASERNIP-S Project Officer – Horizon Reporting
Luis Zamora

Luis Zamora joined ASERNIP-S in November 2005 as a Research Officer. He has a Bachelor of Biotechnology Degree majoring in Biochemistry and Microbiology, and an Honours Degree in Obstetrics and Gynaecology from the University of Adelaide. At ASERNIP-S Luis is involved in the NET-S horizon scanning project.



appendices

Appendix A :
Hierarchy of evidence

Appendix B :
The ASERNIP-S review process

Appendix C :
The ASERNIP-S classification system

Appendix D :
Reports and publications prior to 2006

Appendix A
Hierarchy of evidence

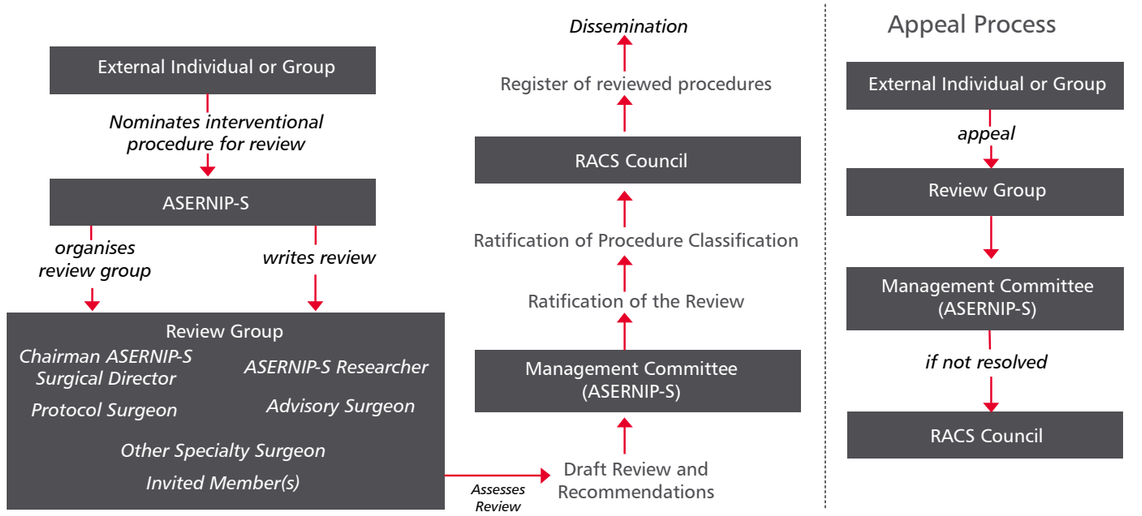
Designation of levels of evidence[1]

Level of Evidence	Study Design
I	Evidence obtained from a systematic review of all relevant randomised controlled trials.
II	Evidence obtained from at least one properly designed randomised controlled trial.
III-1	Evidence obtained from well-designed pseudo-randomised controlled trials (alternate allocation or some other method).
III-2	Evidence obtained from comparative studies (including systematic reviews of such studies) with concurrent controls and allocation not randomised, cohort studies, case-control studies, or interrupted time-series with a control group.
III-3	Evidence obtained from comparative studies with historical control, two or more single arm studies, or interrupted time series without a parallel control group.
IV	Evidence obtained from case-series, either post-test or pre-test/post-test.

This table should be referenced in the reference list of the review as follows:

1. NHMRC. How to Use the Evidence: Assessment and Application of Scientific Evidence, pp 8. Canberra: NHMRC. 2000.

Appendix B
ASERNIP-S review process



Appendix C
ASERNIP-S classification system

Following the systematic review of a new surgical procedure a statement is prepared covering each of the following three areas. If further research is required to obtain data on either the safety and/or efficacy of a procedure then recommendations will be given regarding the most appropriate method for doing this.

Evidence rating

The evidence for ASERNIP-S systematic reviews is classified as Good, Average or Poor, based on the quality and availability of this evidence. High-quality evidence is defined here as having a low risk of bias and no other significant flaws. While high-quality randomised controlled trials are regarded as the best kind of evidence for comparing interventions, it may not be practical or ethical to undertake them for some surgical procedures, or the relevant randomised controlled trials may not yet have been carried out. This means that it may not be possible for the evidence on some procedures to be classified as good.

Good

Most of the evidence is from a high-quality systematic review of all relevant randomised trials or from at least one high-quality randomised controlled trial of sufficient power. The component studies should show consistent results, the differences between the interventions being compared should be large enough to be important, and the results should be precise with minimal uncertainty.

Average

Most of the evidence is from high-quality quasi-randomised controlled trials, or from non-randomised comparative studies without significant flaws, such as large losses to follow-up and obvious baseline differences between the comparison groups. There is a greater risk of bias, confounding and chance relationships compared to high-quality randomised controlled trials, but there is still a moderate probability that the relationships are causal.

An inconclusive systematic review based on small randomised controlled trials that lack the power to detect a difference between interventions and randomised controlled trials of moderate or uncertain quality may attract a rating of average.

Poor

Most of the evidence is from case series, or studies of the above designs with significant flaws or a high risk of bias. A poor rating may also be given if there is insufficient evidence.

Safety

At least as safe compared to comparator* procedure(s)

This grading is based on the systematic review showing that the new intervention is at least as safe as the comparator.

Safety cannot be determined

This grading is given if the evidence is insufficient to determine the safety of the new intervention.

Less safe compared to comparator* procedure(s)

This grading is based on the systematic review showing that the new intervention is not as safe as the comparator.

Efficacy

At least as efficacious compared to comparator* procedure(s)

This grading is based on the systematic review showing that the new intervention is at least as efficacious as the comparator.

Efficacy cannot be determined

This grading is given if the evidence is insufficient to determine the efficacy of the new intervention.

Less efficacious compared to comparator* procedure(s)

This grading is based on the systematic review showing that the new intervention is not as efficacious as the comparator.

Recommendations regarding the need for further research

In order to strengthen the evidence base regarding the procedure it may be recommended that either:

- an audit be undertaken, or
- a controlled clinical trial, ideally with random allocation to an intervention and control group, be conducted.

The Royal Australasian College of Surgeons recognises that it may not always be possible to undertake a controlled clinical trial. Under such circumstances, it is recommended that, at the very least, data be contributed to an audit for further assessment, in collaboration with ASERNIP-S, until such time as a controlled clinical trial is undertaken.

**A comparator may be the current "gold standard" procedure, an alternative procedure, a non-surgical procedure or no treatment (natural history).*

Appendix D
Reports and publications prior to 2006

1998

Maddern G. Surgery and evidence-based medicine. A new Australian registry promises to strengthen the push towards evidence-based surgery. *Medical Journal of Australia* 1998; 169: 348–349

1999

ASERNIP-S Report No. 1
Minimally Invasive Parathyroidectomy, June 1999

ASERNIP-S Report No. 2
Lung Volume Reduction Surgery, June 1999

ASERNIP-S Report No. 3
Laparoscopic Live Donor Nephrectomy, June 1999

ASERNIP-S Report No. 4
Ultrasound-Assisted Lipoplasty, October 1999

Introducing ASERNIP-S: The Australian Safety and Efficacy Register of New Interventional Procedures – Surgical (1999). *Keeping You Informed (New Zealand Health Technology Assessment newsletter)* December 1999; Issue No. 5

2000

ASERNIP-S Report No. 5
Percutaneous Endoscopic Laser Disectomy: Update & re-appraisal, February 2000

ASERNIP-S Report No. 6
Arthroscopic Subacromial Decompression using the Holmium: YAG Laser: Update & re-appraisal, February 2000

ASERNIP-S Report No. 7
Minimally Invasive Techniques for Relief of Bladder Outflow Obstruction, February 2000

ASERNIP-S Report No. 8
Laparoscopic-Assisted Resection of Colorectal Malignancies, February 2000

ASERNIP-S Report No. 15
Laparoscopic Live-donor Nephrectomy: Update & re-appraisal, May 2000

ASERNIP-S Report No. 18
Lung Volume Reduction Surgery: Update & re-appraisal, May 2000

ASERNIP-S Report No. 9
Laparoscopic Adjustable Gastric Banding in the Treatment of Obesity, June 2000

ASERNIP-S Report No. 17
Ultrasound-Assisted Lipoplasty: Update & re-appraisal, July 2000

ASERNIP-S Report No. 10
Off-Pump Coronary Artery Bypass Surgery with the Aid of Octopus Tissue Stabilisers, November 2000

ASERNIP-S Report No. 16
Minimally Invasive Techniques for Relief of Bladder Outflow Obstruction: Update & re-appraisal, November 2000

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Boult M, Fraser R, Jones N, Osti O, Liddell J, Dohrmann P, Donnelly P, Maddern G. Percutaneous endoscopic laser discectomy: a systematic review. *Australian and New Zealand Journal of Surgery* 2000; 70(7): 475–479

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EU Hernia Trialists Collaboration. Laparoscopic compared with open methods of groin hernia repair — systematic review of randomised controlled trials. *British Journal of Surgery* 2000; 87: 860–867

Maddern GJ. Evidence-based surgical research – consumers to benefit. The Australian Health Consumer. *The Consumers' Health Forum of Australia newsletter Summer* 2000; (1): 12-13

Maddern GJ. This is ASERNIP-S. *International Network of Agencies for Health Technology Assessment (INAHTA) Newsletter* 2000; VIII(1): 3

Maddern GJ, Babidge WJ. Improving quality in surgery. The Australian Health Consumer. *The Consumers' Health Forum of Australia newsletter Spring* 2000; (3): 9-10

Merlin T, Scott D, Rao M, Wall D, Francis D, Bridgewater F, Maddern G. The safety and efficacy of laparoscopic live-donor nephrectomy: a systematic review. *Transplantation* 2000; 70(12): 1659–1666

Reeve TS, Babidge WJ, Parkyn RF, Edis AJ, Delbridge LW, Devitt PG, Maddern GJ. Minimally invasive surgery for primary hyperparathyroidism: a systematic review. Co-published in Archives of Surgery 2000; 135(4): 481–487, and *The Australian and New Zealand Journal of Surgery* 2000; 70(4): 244–250

Sweet M. Second opinion on surgery. *The Bulletin* January 11, 2000. [Article based on an interview with Professor Guy Maddern, concerning ASERNIP-S.]

Wheelahan J, Scott NA, Cartmill R, Marshall V, Morton RP, Nacey J, Maddern GJ. Minimally invasive laser techniques for prostatectomy: a systematic review. *British Journal of Urology International* 2000; 86: 805–815

Wheelahan J, Scott NA, Cartmill R, Marshall V, Morton RP, Nacey J, Maddern GJ. Minimally invasive non-laser thermal techniques for prostatectomy: a systematic review. *British Journal of Urology International* 2000; 86: 977–988

Clinical Practice Guidelines for the Advanced Breast Biopsy Instrument (ABBI), May 2000

ASERNIP-S. What is it? *Surgical News* 2000; 1(1): 4

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ASERNIP-S awareness survey result. *Surgical News* 2000; 1(8): 12

ASERNIP-S update. *Surgical News* November-December 2000; 1(10): 9

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ASERNIP-S update: systematic review of new surgical procedures. *Better Health Outcomes.* The Commonwealth Department of Health and Aged Care newsletter, Spring 2000; 6(3): 14-15

2001

ASERNIP-S Report No. 11
Tension-Free Urethropexy for Stress Urinary Incontinence: Intravaginal Slingplasty and the Tension-Free Vaginal Tape procedures, February 2001

ASERNIP-S Report No. 12
Endoscopic Modified Lothrop Procedure for the Treatment of Chronic Frontal Sinusitis, June 2001

ASERNIP-S Report No. 14
Minimally Invasive Parathyroid Surgery: Update & Re-appraisal, June 2001

ASERNIP-S Report No. 19
Dynamic Graciloplasty for the Treatment of Faecal Incontinence, June 2001

ASERNIP-S Report No. 25
Off-pump Coronary Artery By-Pass Surgery (MSAC), September 2001

ASERNIP-S Report No. 26
Minimally Invasive Direct Coronary Artery By-Pass Surgery (MSAC), September 2001

ASERNIP-S Report No. 13
Methods Used to Establish Laparoscopic Pneumoperitoneum, October 2001

ASERNIP-S Report No. 20
Off-Pump Coronary Artery Bypass Surgery with the Aid of Octopus Tissue Stabilizer: Update & re-appraisal, October 2001

Boult M, Shimmin A, Wicks M, MacDougal G, Watson D, Maddern G. Arthroscopic subacromial decompression with a holmium:YAG laser: a review of the literature. *Australian and New Zealand Journal of Surgery* 2001; 71(3): 172–177

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ASERNIP-S: Systematic review of Off-pump Coronary Artery Bypass Surgery. *Better Health Outcomes.* The Commonwealth Department of Health and Aged Care newsletter Summer 2001; 7(1): 20-21

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2002

ASERNIP-S Report No. 21
Autologous Fat Transfer for Breast Augmentation, February 2002

ASERNIP-S Report No. 24
Stapled Haemorrhoidectomy, February 2002

ASERNIP-S Report No. 31
Laparoscopic Adjustable Gastric Banding for the Treatment of Obesity — Update & Re-appraisal, June 2002

ASERNIP-S Report No. 27
Intraoperative Radiotherapy for Early Stage Breast Cancer, October 2002

ASERNIP-S Report No. 28
Radiofrequency Ablation of Liver Tumours, October 2002

Boult M, Babidge W, Anderson J, Denton M, Fitridge R, Harris J, Lawrence-Brown M, May J, Myers K, Maddern G. Australian audit for the endoluminal repair of abdominal aortic aneurysm — the first 12 months. *Australian and New Zealand Journal of Surgery* 2002; 72(3): 190–195

Boult M, Babidge W, Roder D, Maddern G. Issues of consent and privacy affecting the functioning of ASERNIP-S. *Australian and New Zealand Journal of Surgery* 2002; (72)8: 580–582

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Sutherland LM, Burchard AK, Matsuda K, Sweeney JL, Bokey EL, Childs PA, Roberts AK, Waxman BP, Maddern GJ. A systematic review of stapled haemorrhoidectomy. *Archives of Surgery* 2002

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ASERNIP-S: Literature Reviews: autologous fat transfer for breast augmentation and stapled haemorrhoidectomy. *Surgical News* 2002; 3(5): 16

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Acknowledgments

ASERNIP-S wishes to thank the Fellows of the Royal Australasian College of Surgeons, the Australian Government Department of Health and Ageing, the South Australian Department of Health, the Australian Commission for Safety and Quality in Health Care (formerly known as the Australian Council for Safety and Quality in Health Care), the Department of Surgery at the Queen Elizabeth Hospital, the National Breast Cancer Centre, Breast Cancer Network Australia, Cook Australia and other members of the health care industry who have participated in and contributed to the program throughout 2006.

Thank you to companies and individuals who supplied graphics for use in ASERNIP-S reports and publications in 2006:

Boston Scientific Australia
Cook Australia
Department of Surgery, the Queen Elizabeth Hospital and Basil Popowycz, Clinical Photographer
Endotherapeutics Pty Ltd
Kate Mooney, Bridgehead Australia Pty Ltd
Mentice AB, Sweden
Microvention
Royal Adelaide Hospital, Medical Art & Design
Royal Australasian College of Surgeons
Smith & Nephew, Inc., USA
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