

Australian  
Safety  
and Efficacy  
Register  
of New  
Interventional  
Procedures-  
Surgical

ASERNIP(S)

1998  
ANNUAL  
REPORT





## **ASERNIP)S**

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## 1 Chairman's Message

Surgery is intrinsically invasive and potentially harmful. Surgical innovations have made enormous contributions towards the welfare of patients when they have been appropriate, effective and applied with expertise and overall care. The potential for advancement and for harm of new surgical techniques, and the level of expertise necessary for their safe introduction, is not always immediately apparent.

The Surgical Profession sets high standards, and patients, the general public and governments expect nothing less. ASERNIP-S was established in its present pilot form to help ensure that new technologies which are being introduced are well proven in concept, as safe and effective as possible, and are utilised with high levels of skill underpinned by the level of training.

**Mr Kingsley Faulkner**  
Chairman, ASERNIP-S  
Management Committee



## 2 Surgical Director's Message

In its first year of operation, ASERNIP-S has made some significant advances in developing the appropriate methodology, process and infrastructure to conduct the assessment of new technologies being introduced into the Australian surgical landscape. The year has seen the establishment of our offices in Adelaide, the appointment of research and administrative staff, and excellent progress in establishing links with Fellows of the Royal Australasian College of Surgeons interested in reviewing and advising on new technological developments as they relate to the full spectrum of surgery.

The ASERNIP-S Management Committee has been keen to cover the breadth of surgical practice and also major and minor technological advances. For example, we have covered areas as far ranging as liposuction for obesity to living-related laparoscopic donor nephrectomies for renal transplant patients. The next year promises to provide the opportunity to consolidate on this excellent base and we look forward to being able to publish thorough reviews and firm recommendations for most of the procedures currently under assessment. We aim to develop a web-based entry system, which will enable selected surgeons to feed in their data on new technologies as they evolve.

It is hoped that the early enthusiasm of the College, Federal Government and the surgeons continues as this project moves into its most productive phase.

**Professor Guy Maddern**  
ASERNIP-S Surgical Director

## 3 Background

The increasing rate of introduction of new surgical technology and techniques and the recommendations of the Australian Health Technology Advisory Committee review on Minimal Access Surgery has highlighted the need for initial clinical assessment and validation of new surgical techniques. In response to this the Royal Australasian College of Surgeons has obtained funding for the establishment of the Australian Safety and Efficacy Register of New Interventional Procedures – Surgical (ASERNIP-S).

ASERNIP-S was formed in January 1998. The Hon. Trish Worth MP launched the project on the 24<sup>th</sup> February in the South Australian State office of the Royal Australasian College of Surgeons.

The purpose of the project is to establish a systematic and ongoing evaluation and documentation of the safety and efficacy of new technologies and surgical techniques, as they are being introduced and /or before they are widely accepted into the Australian health care system. The project will determine a mechanism for collecting peer reviewed data in regard to the safety and efficacy of selected new surgical procedures.

Procedure assessment will be initially by literature review which includes all available evidence from an international perspective and where possible the collection of available data from surgeons currently performing the procedure in Australia. Based on the evidence ASERNIP-S will produce a review, recommendations and safety and efficacy classification for each procedure assessed. The classification will indicate whether a procedure should be used with or without continuing audit, or if a more fully controlled evaluation is necessary.

**Mr Kingsley Faulkner**

Mr Kingsley Faulkner is currently Honorary Treasurer of the Royal Australasian College of Surgeons and Head of the Department of General Surgery at the Sir Charles Gairdner Hospital. His other appointments are at the St John of God Health Care Campus, Subiaco, The Mount Private Hospital and Hollywood Private Hospital.

He is the Royal Australasian College of Surgeons Representative on the Board of the Collaborative Training and Education Centre for Surgical and Medical Skills (CTEC) project being developed on the Campus of the University of Western Australia and is the Chairman of the ASERNIP-S Management Committee.

**Professor Guy Maddern**

RP Jepson Professor of Surgery, University of Adelaide and Surgical Director ASERNIP-S. Professor Maddern is a practising hepatobiliary surgeon based at The Queen Elizabeth Hospital and Head of the Division of Surgery and Director of the Clinical Development Research Centre. Professor Maddern's interests have been in incident monitoring and assessment of new technologies in surgical practice. He was appointed as the inaugural Surgical Director of ASERNIP-S in October 1997 and since that time has been involved in developing the pilot project for the Royal Australasian College of Surgeons.

**Professor R C Bennett**

Professor Bennett was previously Professor of Surgery at the University of Melbourne and St Vincent's Hospital. He is currently Executive Director for Surgical Affairs at the Royal Australasian College of Surgeons, Director of Surgical Oncology at the Peter MacCallum Cancer Institute, and Chairman, Melbourne Regional Board, Sisters of Charity Health Service.

**Mr Bruce Barraclough**

Mr Bruce Barraclough is currently President of the Royal Australasian College of Surgeons and Senior Breast and Endocrine Surgeon to Westmead Hospital in Sydney. His other appointments are at the Sydney Adventist Hospital and Hornsby and Ku-ring-gai Hospital in Sydney.

**Mr David Robinson**

Mr David Robinson has expertise in plastic surgery and is the Chair of the Senior Medical Staff Association, Princess Alexandra Hospital, Brisbane. He is chair of the Queensland Specialist Recognition Advisory Committee and a member of the Medicare Services Advisory Committee.

**Mr Peter Carter**

Mr Peter Carter has been Chief Executive Officer of the Royal Australasian College of Surgeons since 1989. Prior to this he was Registrar of the Royal Australian and New Zealand College of Psychiatrists for four years. Following a brief period in the academic field Mr Carter entered university administration, first at the University of New England and then at Monash University. During this time he completed a Master of Educational Administration supported by a Kellogg Research Grant.

**Professor Chris Silagy**

Professor Silagy graduated in medicine from the University of Melbourne in 1983 and completed his PhD in 1991. He was then awarded the Sir Robert Menzies Memorial Scholarship in Medicine, and spent two years pursuing post doctoral research in Oxford. During this period, he became involved in supporting the establishment of the Cochrane Collaboration; an international endeavour to prepare, maintain and disseminate systematic reviews on the effects of health care.

In November 1993, he took up his current appointment as Foundation Professor and Head of what is now called the Department of Evidence-Based Care and General Practice at Flinders University. In January 1995 he was appointed as Foundation Director of the Australasian Cochrane Centre. Since February 1996, he has also been Chair of the Steering Group for the Cochrane Collaboration. In June 1995 he was appointed Co-Director of the National Information Service and in November 1996 he was also appointed Project Director for the National Evaluation of the Co-ordinated Care Trials. His particular research interests are in disease prevention and the application of clinical epidemiology to primary health care.



### **Associate Professor Rosemary Roberts**

Associate Professor Rosemary Roberts is Director of the National Centre for Classification in Health (NCCH). The Centre is responsible for national standards relating to the use of coding and classification in Australian health services. As well as developing codes and standards, the centre produces publications, educates clinical coders and users of the classifications and develops tools and methods for measuring coding and data quality.

Rosemary's previous work has been in Australian and North American hospitals and health services in Medical Administration, Health Information Management and Quality Assurance. She has also held positions in government and education. Her interests are in classification systems, casemix, health information systems and health statistics.

### **Dr Denis A Smith**

Dr Denis Smith is the Chief Executive Officer of the Australian Council on Healthcare Standards, Australia's leading organisation promoting quality in health care and providing a national accreditation program for health care organisations. Dr Smith has extensive clinical and management experience in health care, including over five years with the ACHS as a medical surveyor. He has a medical degree and a Masters in Health Planning and is also the immediate Past State President and Fellow of the Royal Australian College of Medical Administrators.

He was instrumental in establishing the Postgraduate Medical Council of New South Wales where he continues to serve as a Councillor. Amongst his many other professional appointments, he is a member of the New South Wales Medical Board, the Academic Board of the School of Health Services Management, University of New South Wales and a Councillor of Standards Australia, serving on several expert committees. Dr Smith is also a referee for the Medical Journal of Australia.

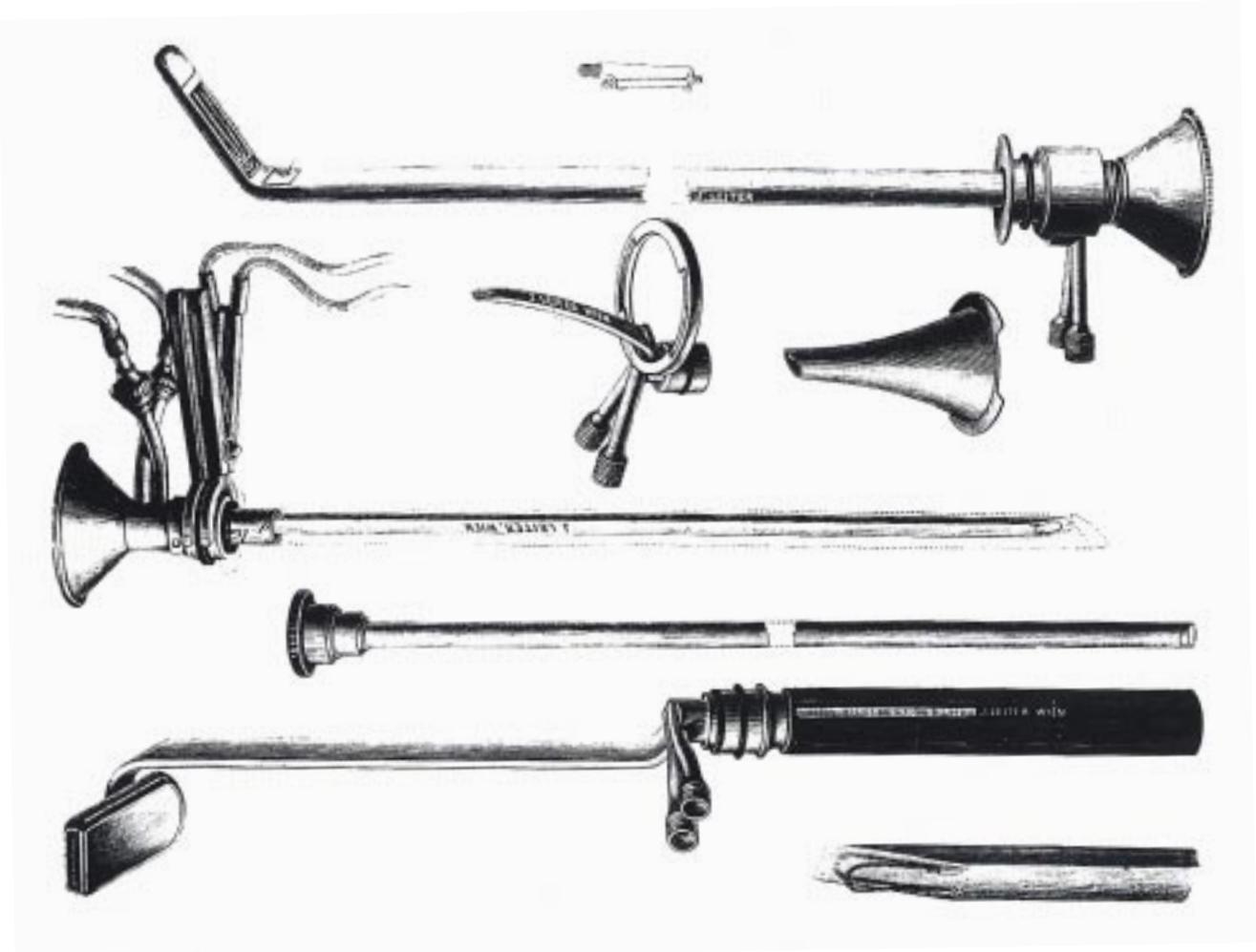
### **Ms Wendy Brown**

Ms Brown, a psychologist, is currently completing a doctorate in clinical psychology at the University of Queensland. Prior to this, she completed her General Nursing and Midwifery training at the Princess Alexandra Hospital and Royal Women's Hospital (respectively) in Brisbane, and has been employed in general nursing, education (nursing) and aged care services (both as a registered nurse and a psychologist). Her interest in the consumer's perspective of health care and her association with the Consumers' Health Forum of Australia (Inc.) has resulted in several appointments to medical device panels [e.g., Therapeutic Devices Evaluation Committee (of the Therapeutic Goods Administration)] and ASERNIP-S.



## 5 ASERNIP-S Pilot Project Aims

1. To establish a mechanism for collecting data concerning the safety and efficacy of selected new surgical procedures.
2. To collate and analyse this data in conjunction with other evidence.
3. To make recommendations concerning selected procedures according to the following:
  - I. Safety and efficacy is established. Procedure may be used.
  - II. The procedure is sufficiently close to a procedure of established safety and efficacy to give no reasonable grounds for questioning safety and efficacy. Procedure may be used subject to continuing audit.
  - III. Safety and efficacy of the procedure is not yet established. Procedure requires a fully controlled evaluation and may be used only as part of systematic research; comprising either an observational study or a randomised controlled trial.
  - IV. Safety and/or efficacy of the procedure is shown to be unsatisfactory. Procedure should not be used.
4. To promote the audit process and disseminate information on the outcomes to Fellows and Trainees of the College through CME and training programs, credentialing committees, practitioners, consumers, health care providers and governments.
5. To review the effectiveness of the pilot and make recommendations as to the scope for developing a comprehensive audit mechanism for new surgical procedures and the applicability of audit mechanisms to all new interventional procedures in the Australian health care system.





## 6 ASERNIP-S Assessment Process

Procedures are nominated to ASERNIP-S from a variety of sources including the Divisions and Sections of the College and consumers through the Consumers Health Forum. The ASERNIP-S Management Committee receives the nominated procedures and endorses them for ASERNIP-S review. The output of the procedure review process is a draft review, recommendations and a safety and efficacy classification, which is submitted to the ASERNIP-S Management Committee for ratification. The classification will indicate whether a procedure should be used with or without continuing audit, or if a more fully controlled evaluation is necessary. The completed review becomes part of a register of reviewed procedures and is submitted to the College Council before being disseminated.

The procedures are initially assessed by literature review and where possible, the collection of available data from surgeons currently performing the procedure within Australia. ASERNIP-S is currently collecting data on laparoscopic live donor nephrectomy, arthroscopic subacromial decompression using the holmium: YAG laser and will soon commence collection of data on minimally invasive parathyroidectomy.

### 6.1 The ASERNIP-S Review Group Process

The process for review of each procedure proceeds through four phases.

#### Phase 1. Review Group Establishment

- ASERNIP-S receives a nominated interventional procedure for review.
- ASERNIP-S organises a Review Group to assess the procedure.

#### Phase 2. Review Protocol Development

- The ASERNIP-S Researcher and Protocol Surgeon consult regarding the evidence / literature search protocol.
- A protocol manual is developed which outlines objectives, background, inclusion criteria, study design and search strategy.
- The ASERNIP-S Researcher performs a search of appropriate databases for peer reviewed literature concerning the procedure.
- The Protocol Surgeon reviews the results of the search for relevance.

#### Phase 3. Draft Review Preparation

- Based on the literature the Review Surgeon produces a Draft Review on the safety and efficacy of the procedure.
- The ASERNIP-S Researcher conducts an independent analysis of the literature for methodological validity.
- Each member of the Review Group critiques the Draft Review according to their particular expertise.
- The Review Group meets and discusses the draft review.
- The Review Group reaches a consensus on the recommendation concerning the safety and efficacy of the procedure.
- Each procedure is allocated a classification.  
(Refer to ASERNIP-S Aims)

#### Phase 4. Draft Review Awaiting Ratification of Management Committee

- The Draft review and recommendation is edited and a final copy is submitted to the ASERNIP-S Management Committee for consideration/ ratification.



### **6.1.1 The Review Group Membership**

Each Review Group consists of the following members.

#### **Protocol Surgeon**

The Protocol Surgeon interacts with the ASERNIP-S Researcher to draft the protocol for the review. He/she assesses the abstracts of the retrieved articles to ensure that the references are appropriate for the review.

#### **ASERNIP-S Researcher**

The ASERNIP-S Researcher assists in drafting the protocol for the review and searches the appropriate databases for peer reviewed literature on the procedure. An assessment of the methodological validity of the publications is performed during preparation of the Draft Review.

#### **Review Surgeon**

On the basis of the full papers of selected references, the Review Surgeon writes a Draft Review on the safety and efficacy of the procedure.

#### **Surgeon(s) Nominated by a Society or Division/ Section of the College**

This content expert is forwarded a copy of the Draft Review for comment.

#### **Surgeon from Another Specialty**

The surgeon from another specialty receives the copy of the Draft Review for comment.

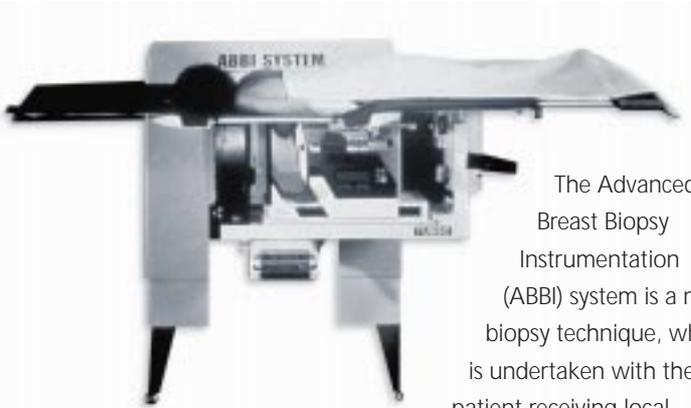
Each member of the group receives a copy of the Draft Review compiled by the Review Surgeon and critiques the document according to their particular expertise. The Review Group meets and discusses any concerns and reaches a consensus recommendation concerning the safety and efficacy of the procedure.





## 7 Procedures Currently Being Assessed

### Advanced Breast Biopsy Instrumentation System



The Advanced Breast Biopsy Instrumentation (ABBI) system is a new biopsy technique, which is undertaken with the patient receiving local

anaesthesia in a day surgery (outpatient) environment. The patient lies prone on a table equipped with a digital flat bed mammography unit and a stereotactic imaging system, which is used in combination with a large core biopsy device produced in various sizes. The system targets indeterminate, nonpalpable breast lesions with a purported high degree of accuracy through stereotactic imaging. The surgeon can visualise lesions on the video monitor in real-time throughout the entire procedure. Unlike needle core biopsies, the ABBI device needs only to be inserted once and the lesion is often completely removed through the small incision. The accuracy of visualisation enables the surgeon to minimise the amount of healthy tissue removed with the lesion. Post procedural stereomammography, undertaken by the ABBI system, confirms the complete removal of the lesion.

The ASERNIP-S Review Group is currently reviewing the safety and efficacy of the ABBI system in comparison to the "gold standard" of "open" excisional biopsy using mammographic needle or carbon localisation.

#### Review Group Membership

Protocol Surgeon	Mr Vlad Humeniuk
Nominated Surgeon	to be advised
Review Surgeon	Mr John Simpson
Other Specialty Surgeon	Mr John Windsor
ASERNIP-S Researcher	Mrs Tracy Merlin

#### Status of Assessment

Review Protocol Manual development

**Note:** The assessment of the ABBI System by ASERNIP-S is currently on hold, awaiting a decision by the Medicare Services Advisory Committee (MSAC) in regard to assessment of the procedure by MSAC.

### Arthroscopic Subacromial Decompression using the Holmium: YAG Laser

Subacromial decompression is a surgical technique used to treat impingement syndrome. Impingement results from a narrowing of the space under the acromion and coracoacromial ligament and is classified into 3 stages of increasing severity. Pain, weakness and loss of motion are the most common symptoms and pain is exacerbated by overhead activities.

Surgical management requires accurate diagnosis and documented failure of conservative therapy. Arthroscopic subacromial decompression was introduced in the mid-1980's and has proven to be a reliable alternative to open acromioplasty, especially for Stage II and Stage III (partial tear only) impingement syndrome. This technique involves acromioplasty, coracoacromial ligament resection, and bursectomy using a motorised shaver, burr and electrocautery. As an alternative, the Holmium: YAG laser has been put forward as a tool to strip away the cicatrized subacromial bursa, excising the coracoacromial ligament and removing the under surface of the acromion (including spur) to enlarge the subacromial space. The reported benefit of the laser is the simultaneous coagulation of small bleeding vessels, whilst cutting, sculpturing and ablating tissue; resulting in less bleeding, reducing post-operative swelling and pain. Laser arthroscopic subacromial decompression is a technically demanding procedure that requires assessment of its safety and efficacy in comparison with the standard arthroscopic technique.

#### Review Group Membership

Protocol Surgeon	Mr Malcolm Wicks
Nominated Surgeon	Mr Andrew Shimmin
Review Surgeon	Mr Darren Waters
Other Specialty Surgeon	Mr David Watson
ASERNIP-S Researchers	Dr Wendy Babidge Mrs Margaret Boulton

#### Data Collection

Database Manager	Mrs Margaret Boulton
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#### Status of Assessment

Review Protocol Manual development



## Intravaginal Slingplasty for Urinary Incontinence

Intravaginal Slingplasty is a new surgical procedure that is grounded in a controversial muscle-weakness paradigm known as the Integral Theory of female urinary incontinence. This paradigm suggests that stress and urge incontinence in women are mainly a product of connective tissue laxity in the vagina itself, or in its anterior and/or posterior supporting ligaments, a consequence of age, childbirth, or congenital weakness. Stress incontinence is believed to result when the muscles fail to stretch the vaginal hammock sufficiently tightly to close off the urethra from behind. Because the pelvic floor muscles effectively insert into the pelvic ligaments, lax ligaments may also inactivate the closure force. The same laxity prevents the muscles stretching the vagina to support the urine column. When the vagina is lax, the urine column causes the stretch receptors at the bladder base to “fire off” at a lower bladder volume than would occur in the normal patient. This is interpreted by the patient as urgency and frequency. In this context, “detrusor instability” records the bladder contraction acting against a urethra trying to be closed by the contracting muscles (hence the phasic pattern).

Intravaginal Slingplasty is a minimally invasive surgical technique, which reconstructs ligamental and muscle weakness in women with stress and/or urge incontinence. Artificial anterior ligaments - pubourethral ligaments – are created by positioning nylon tapes, one on each side of the mid-urethra through a 1cm incision. These artificial ligaments are constructed by “tricking” the body’s wound repair mechanism into forming scar tissue, thus developing collagenous neoligaments. These pubourethral ligaments provide a firm anchoring point for all three muscles associated with urethral closure. The anterior portion of the vaginal hammock is then re-anchored to the external urethral ligaments, and the same suture shortens the external urethral ligaments. Finally, the posterior part of the

hammock is re-attached to the anterior portion of the pubococcygeus closure muscle. It is suggested that this buttressing and reinforcement of the vaginal hammock allows it to function “properly” (as purported by the Integral Theory) - closing off the urethra and preventing stress incontinence. It also allows the vaginal hammock to be stretched into a tight membrane below the bladder base to better support the stretch receptors. It has been suggested that this then prevents “firing-off” of the nerves at a lower bladder volume, enabling bladder instability symptoms (frequency, urgency and nocturia) to be resolved.

Potential benefits of Intravaginal Slingplasty include less postoperative pain, shorter hospitalisation (discharge within 24 hours), and a faster convalescence than that associated with traditional urinary incontinence procedures for women.

It is the purpose of this review to determine whether Intravaginal Slingplasty is as safe and efficacious as two traditional urologic procedures - the Aldridge Sling and the Burch Colposuspension. These two comparative procedures were selected because the tension-free tape component of Intravaginal Slingplasty is closest to the Aldridge Sling; and the reinforcement of the vaginal hammock in Intravaginal Slingplasty is not dissimilar to the Burch Colposuspension.

### Review Group Membership

Protocol Surgeon	Dr Peter Petros
Nominated Surgeons	Mr Alistair Tulloch and Mr Peter MacTaggart
Review Surgeon	Professor Edwin Arnold
Other Specialty Surgeon	Professor Glyn Jamieson
ASERNIP-S Researcher	Mrs Tracy Merlin

### Status of Assessment

Review Protocol Manual development





## Laparoscopic Live Donor Nephrectomy

Live donor nephrectomy is a major operation performed with no direct health benefit to the individual. Potential kidney donors are often reluctant to undergo “open” nephrectomy as it is associated with significant post-operative pain and extended convalescence. To remove these disincentives for donors, the laparoscopic live donor nephrectomy was developed. Potential advantages include reduced post-operative pain, shorter hospitalisation and convalescence, less incisional morbidity and improved cosmesis.

Variations on two approaches to laparoscopic live donor nephrectomy are used. The common approach is intra- or transperitoneal with gas insufflation (although this has also been done without insufflation). This approach ensures a wider visual field and facilitates access to adequate lengths of ureter and renal vasculature. Experience with the second approach, an extra- or retroperitoneal approach without gas insufflation, is limited and it has not yet gained wider acceptance.

With the increasing utilisation of this technique internationally, it is the purpose of this review to determine whether laparoscopic live donor nephrectomy is as safe and efficacious as the traditional, open live donor nephrectomy.

### Review Group Membership

Protocol Surgeon	Mr Mohan Rao
Nominated Surgeons	Associate Professor David Francis and Mr Daryl Wall
Review Surgeon	Associate Professor David Scott
Other Specialty Surgeon	Mr Frank Bridgewater
ASERNIP-S Researcher	Mrs Tracy Merlin

### Data Collection

Database Manager	Mrs Margaret Boulton
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### Status of Assessment

Draft Review Preparation

## Laparoscopic-Assisted Resection of Colorectal Malignancies

Surgical management of patients with colon cancer involves local control by resection of the primary tumour and the regional lymph nodes. Prior to 1991 this was undertaken using the classic “open” surgical procedure.

The technique for colorectal resection is either totally laparoscopic or laparoscopic-assisted. The role of laparoscopic techniques in managing colorectal malignancies has yet to be determined. The feasibility of the procedure and the post operative laparoscopic benefits or disadvantages require assessment. More importantly an assessment of the safety and efficacy of the procedure in terms of disease recurrence, port site malignancies and 5-year survival rates is required.

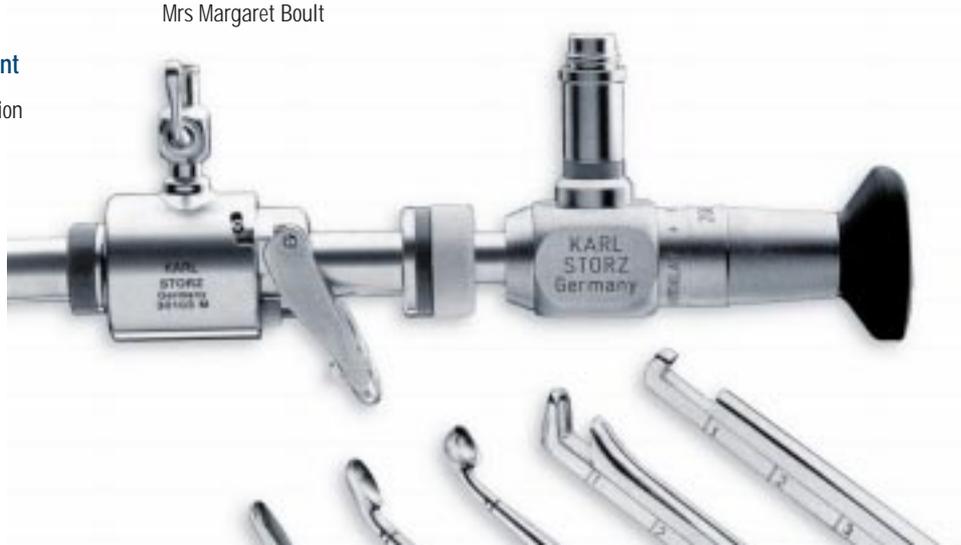
An ASERNIP-S Review Group is currently reviewing the safety and efficacy of laparoscopic or laparoscopic-assisted procedures for the resection of colorectal malignancies in comparison to the traditional “open” surgical procedure.

### Review Group Membership

Protocol Surgeon	Mr Peter Hewett
Nominated Surgeon	Mr Rodney Woods
Review Surgeon	Mr Michael Levitt
Other Specialty Surgeon	Mr Harry Sheiner
ASERNIP-S Researcher	Dr Wendy Babidge

### Status of Assessment

Review Protocol Manual development







## New Invasive Techniques for Relief of Bladder Outflow Obstruction

Prostatectomy is necessary for treatment of men with lower urinary tract obstruction due to the prostate gland. Changes in the prostate gland with increasing age leads to interference with the outflow of urine and can be relieved by surgery. Traditionally it is performed via the urethra with a resectoscope.

A variety of different procedures utilising either laser technology (employing either non-contact, contact or interstitial techniques with Nd:YAG or Holmium:YAG lasers) or other technologies such as needle ablation, electrovaporization, microwave thermotherapy and high-intensity focused ultrasound are being used for resecting or ablating prostatic tissue. These new techniques need to be investigated for their safety and efficacy in relieving outflow obstruction caused by the prostate, to determine if they are superior to the current standard which is transurethral resection of the prostate.

### Review Group Membership

Protocol Surgeon	Professor Willis Marshall
Nominated Surgeon	Mr Ross Cartmill
Review Surgeon	Associate Professor John Nacey
Other Specialty Surgeon	Associate Professor Randall Morton
ASERNIP-S Researcher	Dr Wendy Babidge

### Status of Assessment

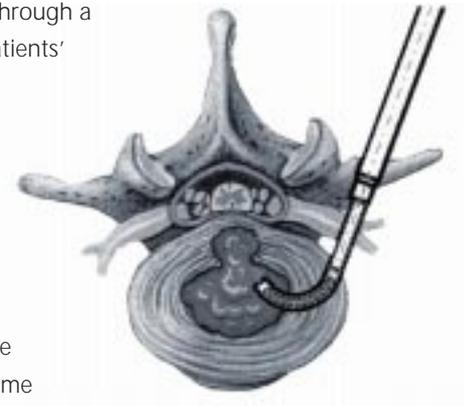
Review Protocol Manual development

## Percutaneous Endoscopic Laser Discectomy

Herniated intervertebral lumbar discs are a common cause of pain in the population. The herniation is the result of a protrusion of the nucleus pulposus through a tear in the surrounding annulus fibrosus (the capsule enclosing the gelatinous centre of the disc). The extruded nucleus pulposus may then compress one or more nerve roots, resulting in pain along the sciatic nerve.

Percutaneous Endoscopic Laser Discectomy is a minimally invasive surgical procedure that proponents of the system claim may provide symptomatic relief by reducing pressure on the nerve roots from the extruded nucleus pulposus.

During the procedure a probe is inserted into the disc through a small incision in the patients' back. Laser energy is delivered through the probe and used to vaporise part of the nucleus pulposus. The rationale for this procedure is that the laser ablation will cause a reduction in the volume of the nucleus pulposus with a concomitant decrease in the intradiscal pressure. If the protrusion is contiguous with the nucleus pulposus this may result in a migration of the extruded disc away from the nerve root.



The safety and efficacy of this procedure will be evaluated by an ASERNIP-S review group and compared with the open discectomy procedure.

### Review Group Membership

Protocol Surgeon	Professor Nigel Jones
Nominated Surgeon	Mr Richard Vaughan
Review Surgeon	Professor Robert Fraser
Other Specialty Surgeon	Mr Peter Donnelly
ASERNIP-S Researcher	Mrs Margaret Boulton

### Status of Assessment

Review Protocol Manual development



## 8 Promotional Activities

### Ultrasonic Liposuction

The development of traditional liposuction two decades ago provided plastic surgeons with a technique to remove localised areas of fat with small suction cannulae introduced through small incisions. This 'dry' technique of fat removal has been largely replaced with a 'wet' technique (also called tumescent) which involves the preparatory infiltration of fluids to help disperse the fat and thereby assist its removal. The tumescent approach allowed larger volume liposuction with reduced blood loss. Traditionally liposuction has a low complication rate and a high patient satisfaction rate.

The concept of ultrasound-assisted liposuction involves the ultrasonic liquefaction of fat by cellular fragmentation. A fatty emulsion is then extracted by low-volume suction. Proponents of ultrasound-assisted liposuction claim that it provides a more selective destruction of larger volumes of adipose tissue than traditional methods, it is less physically demanding for the surgeon, with minimal blood loss and little bruising for the patient. Ultrasound-assisted liposuction also removes more dense fibrous tissue than traditional liposuction. In addition to the equipment being more expensive, critics of ultrasonic liposuction cite the thermal effect of ultrasound, longer operating times and oil emulsion retention as areas of caution with this new technique. It is therefore necessary to determine the safety and efficacy of this new liposuction technique.

### Review Group Membership

Protocol Surgeon	Mr Rodney Cooter
Nominated Surgeons	Mr David Robinson Mr Keith Mutimer and Mr Peter Wickham
Review Surgeon	Mr Rodney Cooter
Other Specialty Surgeon	Mr George Kiroff
ASERNIP-S Researcher	Dr Wendy Babidge

### Status of Assessment

Draft Review Preparation



ASERNIP-S has undertaken a diverse range of promotional activities during this initial year. A web site has been established which includes ASERNIP-S contact details, a project news page, procedure assessment process and an update of the procedures under assessment. The web page has links to sites including the Cochrane Collaboration, Australian Council on Healthcare Standards, National Centre for Classification in Health and Commonwealth Department of Health and Family Services. The site can be visited on <http://www.racs.edu.au/open/asernip-s.htm>

A promotional pamphlet has been prepared to provide concise details of the project.

Professor Guy Maddern has met with SERNIP in the United Kingdom and ongoing correspondence with SERNIP has been maintained. In addition to correspondence with the divisions, sections and societies of the College, ASERNIP-S has attended the Royal Australasian College of Surgeons Annual Scientific Congress and provided information to the Fellows of the College. The Surgical Director has also become a member of the International Society of Quality in Health Care.

The promotion of ASERNIP-S to the broader community has been ongoing with project presentations by Professor Maddern to the following forums.

- Therapeutic Devices Evaluation Committee in Canberra, September 1998,
- The World Congress on Endosurgery in Rome, May 1998,
- 9<sup>th</sup> National Conference of the Australasian Association for Quality in Health Care in Sydney, June 1998
- As a Visiting Medical Board Lecturer at Royal Prince Alfred Hospital, October 1998,
- The Australian Gastroenterology Week, October 1998.

ASERNIP-S has featured in an editorial by Professor Maddern on "Surgery and Evidence Based Medicine" in the Medical Journal of Australia. There have also been articles in the RACS Bulletin providing information and updates on ASERNIP-S activities.



## Professor Guy Maddern

### **ASERNIP-S Surgical Director**

RP Jepson Professor of Surgery, University of Adelaide and Surgical Director of ASERNIP-S. Professor Maddern was appointed as the inaugural Surgical Director of ASERNIP-S in October 1997 and since that time has been involved in developing the pilot project for the Royal Australasian College of Surgeons. Professor Maddern is a practising hepatobiliary surgeon based at the Queen Elizabeth Hospital and Head of the Division of Surgery and Director of the Clinical Development Research Centre.

## Dr Wendy Babidge

### **ASERNIP-S Research Coordinator**

Wendy Babidge has a degree in Applied Science, with Honours in Medical and Applied Biotechnology and a PhD from the University of Adelaide. Her previous position was as a Research Officer and Chief Investigator on a National Health and Medical Research Council Grant in the Department of Surgery at the Queen Elizabeth Hospital. With a keen interest and commitment to evidence based medicine, she brings to the project many years of research experience across a range of disciplines.

## Ms Robyn Orr

### **ASERNIP-S Administrator**

Robyn Orr has a degree in Management from the University of South Australia and qualifications as a Registered General Nurse, Midwife and in orthopaedic nursing. Prior to her involvement in ASERNIP-S she was a Project Manager within the Department of Surgery at The North West Adelaide Health Service involved in the implementation of the theatre management system at the Queen Elizabeth Hospital and the Lyell McEwin Hospital.

## Mrs Tracy Merlin

### **ASERNIP-S Research Assistant**

Tracy Merlin joined ASERNIP-S in April 1998 on a part-time basis. She has responsibility for three current new surgical procedures being reviewed - the Advanced Breast Biopsy Instrumentation System, the Laparoscopic Live-Donor Nephrectomy, and the Intravaginal Slingplasty for Urinary Incontinence.

Prior to Mrs Merlin's involvement with ASERNIP-S, she spent eight years in the Department of Medicine at the University of Adelaide as a full-time Research Officer. Her research was primarily in the fields of Aboriginal health, epidemiology of infectious diseases, international health and medical education. She has an Honours degree in Psychology and is currently undertaking part-time study for her Masters degree in Public Health.

## Mrs Margaret Boulton

### **ASERNIP-S Research Assistant**

Margaret Boulton has a degree in Botany, a diploma in Computer Programming and is currently studying towards a graduate diploma in Information Management. Margaret has worked extensively in a wide range of scientific environments and has written several computer applications for commercial and scientific use.

She is currently using her computing, library and scientific skills at ASERNIP-S to research and evaluate surgical procedures and design databases using ACCESS.



## Acknowledgements

AERNIP-S would like to thank the Fellows of the College and other contributors who have participated in the project throughout the year.

The nomination of procedures for ASERNIP-S assessment should be made to the ASERNIP-S Project Office. The continuing participation in Procedure Review Groups and in submission of data by Surgeons is encouraged. For further information please contact the project office.



We would like to acknowledge the following companies/individuals who provided the photographs that appear in this report.

**N. Stenning & Co Pty Ltd**

**Auto Suture Company, Australia**

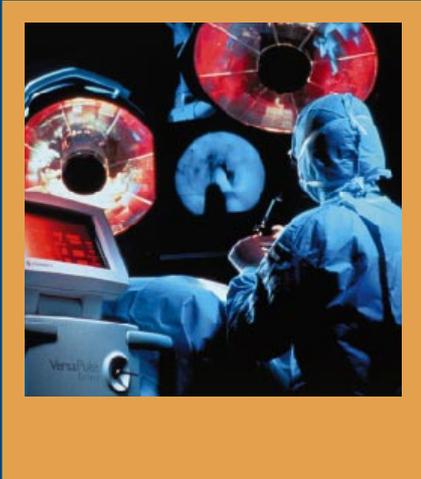
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