ASERNIP-S

2000 ANNUAL REPORT

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Chairman's Report

ASERNIP-S has completed its three year pilot project phase and has exceeded its contractual obligations in doing so.

The evidence from Healthcare Management Advisors Pty Ltd, the body commissioned to evaluate it, and from written, verbal and electronic feedback indicate that it is now well recognised amongst the surgical community of Australia and amongst other groups concerned with the standards of health care in this country.

It has become an important vehicle for assessing new surgical technologies in Australia and its performance is being followed with a great deal of interest by similar fledgling organisations in a number of other countries.

Most of its completed reviews have been published, or accepted for publication, in peer reviewed journals and they have generated a great deal of interest and feedback.

As could be predicted with such an organisation, it is not without its critics although those who regarded the wisdom of having such a body at all are diminishing in number. The selection of procedures to be reviewed, the methodology of assessment, the classification about safety and efficacy of a particular procedure, the endorsement of that classification and subsequent re-appraisal of the reviews have all been matters of debate and criticism.

Some concern has also been expressed, from time to time, that the demands for evidence on safety and efficacy being made on new technologies far exceed that which has been made on other existing ones and in particular on those technologies which the new procedures seek to replace.

ASERNIP-S could not retrospectively tackle all existing procedures, of course, although it has usually examined the evidence concerning the safety and efficacy of the relevant ones as was the case, for example, with the review on minimally invasive parathyroidectomies compared to the standard open parathyroidectomy operations.

The organisation has successfully applied for ongoing Commonwealth Government funding to continue and indeed to expand its work. The experience gained is already making it a more efficient organisation for looking at particular procedures. It will continue to evolve and to change as experience dictates and feedback is listened to.

ASERNIP-S has the opportunity to be in the vanguard of this work world wide. Professor Maddern and his staff have made a major contribution towards ensuring that it is.

Kingsley Faulkner
Chairman, ASERNIP-S Management Committee

Surgical Director's Report

The end of the year 2000 marks the completion of the three-year pilot of the Australian Safety and Efficacy Register of New Interventional Procedures - Surgical. Over that time, some substantial achievements have occurred and the results of the ASERNIP-S process have now been rewarded with additional funding for 4½ years from the Commonwealth Government through the Royal Australasian College of Surgeons.

The success of the ASERNIP-S process is due largely to the vision and enthusiasm of the College Council, as well as the time and effort provided by Fellows prepared to involve themselves in the Review Groups, and the ongoing support of the Fellows of the College who have embraced the concept of evidence based assessment of new interventional procedures. Indeed, the backlog of procedures waiting assessment is growing at an alarming rate.

This report documents not only the completed reviews but also publications appearing in peer-reviewed international journals. Such publications not only further aid the dissemination process of the ASERNIP-S reviews but also give credibility to evidence based assessments, an area which is rapidly evolving in surgery.

The underlying quality and throughput occurring from ASERNIP-S is, of course, largely due to the high quality staff employed in the Adelaide office. Administrative support, data collection and data entry, literature searching and report synthesis are performed by this group of very dedicated and talented individuals who have provided their services over the last three years.

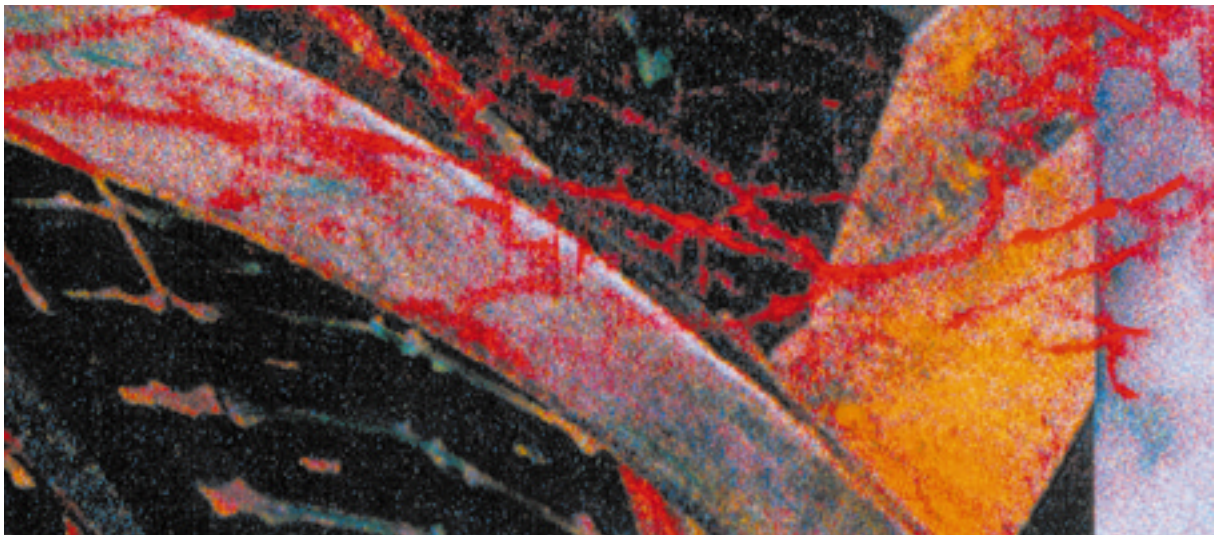
It has certainly been a great privilege to be associated with this innovative pilot program which now moves into its next phase of consolidation in providing assessments and, by also engaging in major data collection of new procedures and horizon scanning of technologies not yet in the published literature, there is potential for considerable future expansion of ASERNIP-S.

Guy Maddern
ASERNIP-S Surgical Director

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 of the peer-reviewed literature, the establishment and facilitation of clinical audits or trials, the identification of emerging Techniques and technologies by horizon scanning and the production of clinical practice guidelines. Our ultimate aim is to improve the quality of health care through the wide dissemination of our evidence-based research to surgeons, health care providers and consumers, both nationally and internationally.

Introduction



The Australian Safety and Efficacy Register of New Interventional Procedures - Surgical (ASERNIP-S) was established by the Royal Australasian College of Surgeons (RACS) to assess the safety and effectiveness of new surgical techniques and technologies. The three-year pilot phase of this project ended in December 2000.

During these first three years ASERNIP-S completed ten systematic reviews of new surgical procedures and re-appraised over half of these, one to two years after their completion. One set of clinical practice guidelines was developed and national audit databases for four of the new surgical procedures were established. In 2000 ASERNIP-S fulfilled a contract with the Commonwealth Department of Health and Aged Care of Australia to conduct a national audit on the endoluminal repair of abdominal aortic aneurysms. We also began a major "horizon scanning" initiative. This far exceeds the original contract to conduct six systematic reviews of new surgical procedures over a three-year period.

At the end of 2000, the Commonwealth agreed to continue funding ASERNIP-S to conduct systematic literature reviews and horizon scanning, through the Royal Australasian College of Surgeons, for a further period of four and a half years.

ASERNIP-S has developed a professional team, skilled in a range of disciplines, who are enthusiastic and committed to the project. Working together closely with Fellows of the Royal Australasian College of Surgeons has proved an enormous benefit to the acceptance of the project and is one of the major reasons for the project success to date.

In our next contract period we propose to consolidate our systematic review process, data collection activities (if funding allows), and production of clinical practice guidelines, as well as develop innovative methods in horizon scanning. In addition, we propose to:

- extend our activities into new areas of project promotion
- expand and diversify our services
- facilitate the establishment of national clinical trials and audits (dependent on funding)
- engage in increased international and national collaboration, and
- investigate new methods of partial self-funding, with the intent of generating a proportion of our own funding by the end of the next contract period.

We will build on our relationships with industry and government - strengthening our position at the forefront of health technology assessment in surgery. We look forward to contributing to the provision of better health care for all Australians.

Procedure Assessments

Procedure assessment at ASERNIP-S is initially by systematic literature review, which includes evidence from an international perspective. This is supplemented, where indicated, by the collection of available data from surgeons currently performing the procedure in Australasia. Based on this evidence, and the input of participating surgeons, ASERNIP-S produces a review, recommendations and a safety and efficacy classification for each procedure (see Appendix I). Procedure reviews are re-appraised after 12 months by reviewing any subsequently published literature and reporting on the outcomes of any data collection. All completed procedure assessments (see Appendix II) are available from the ASERNIP-S office and web site.

New Assessments Completed

Three new procedure assessments were completed in 2000 by ASERNIP-S and endorsed by the Council of the Royal Australasian College of Surgeons. Summaries of these assessments follow.

- Off-pump coronary artery bypass surgery with the aid of tissue stabilizers
- Laparoscopic adjustable gastric banding in the treatment of obesity
- Laparoscopic-assisted resection of colorectal malignancies

OFF-PUMP CORONARY ARTERY BYPASS SURGERY WITH THE AID OF TISSUE STABILIZERS

Background

The most common cause of cardiac mortality in developed countries is ischaemic coronary artery disease. Coronary artery bypass graft (CABG) surgery is currently the benchmark in surgical treatment for this disease but it is associated with significant mortality and morbidity. Postoperative complications such as myocardial infarction, arrhythmias, stroke, neurological disorders, organ failure, respiratory failure, nerve injury, whole-body inflammatory response, wound infection and coagulation disorders are largely attributed to the use of cardiopulmonary bypass. Recently, beating heart surgery has been pursued as a possible surgical alternative that may avoid this surgical trauma. Beating heart surgery involves immobilisation of a small area on the surface of the beating heart. The Octopus® Tissue Stabilizer is a commonly used cardiac tissue stabilizer, and consists of two suction paddles that are placed in parallel on either side of the coronary artery. This immobilises the artery and allows the surgeon to anastomose a bypass graft on the beating heart.

The objective of this systematic review was to make recommendations on the safety and efficacy of off-pump coronary artery bypass surgery (OPCAB) with the aid of the Octopus® Tissue Stabilizer (OTS), in comparison to conventional coronary artery bypass surgery (CABG) with cardiopulmonary bypass (CPB).

Methods

All original, published studies detailing the use of the Octopus® Tissue Stabilizer, in conjunction with OPCAB via full median sternotomy (OPCAB/OTS), and conventional CABG with CPB were identified by searching Medline between 1984 and 02/2000; Current Contents between 1993 and Week 12/2000; Embase between 1974 and 17/03/00; and The Cochrane Library between 1966 and 12/1999 (Issue 4).

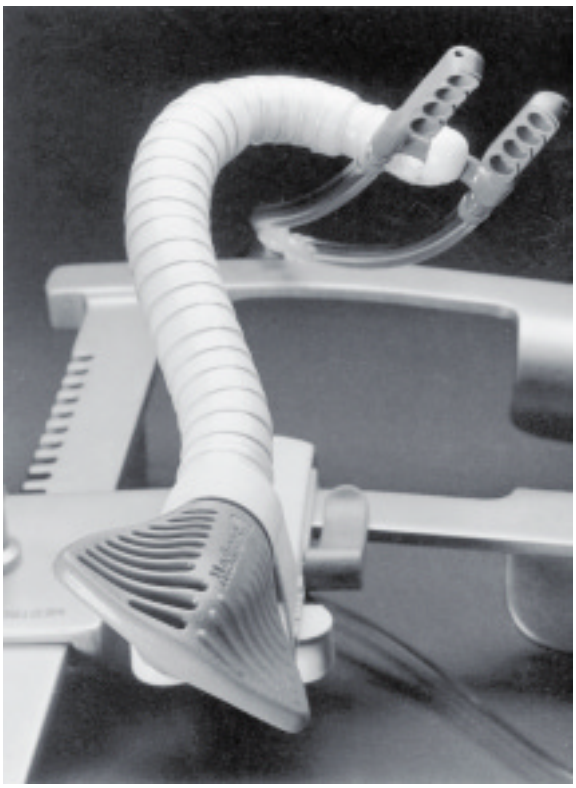
For OPCAB/OTS, human and animal studies were included. However, patient data was restricted to non-pregnant adult human subjects who were undergoing treatment for single or multiple vessel coronary artery disease. English language papers detailing randomised-controlled trials, controlled clinical trials, case series or case reports were included.

Results

There are many postulated benefits of beating heart surgery but as yet there have been no randomised controlled trials conducted to confirm these assertions. The small sample size, poor evidence quality and limited postoperative outcome reporting of many studies meant that no definitive conclusion could be made regarding the safety and efficacy OPCAB/OTS in comparison to conventional CABG with CPB. Nonetheless, the limited comparative data suggested that there was no difference in safety outcomes between OPCAB/OTS and CABG. The paucity of efficacy data reported in the higher level comparative studies meant that it was impossible to assess whether OPCAB/OTS was more efficacious than CABG.

Conclusion

The ASERNIP-S Review Group concluded that the evidence base for OPCAB/OTS was inadequate and recommended that an audit of the procedure be conducted. Additional clinical recommendations were made regarding the development and current practice of OPCAB/OTS in Australia during this audit phase.



The ASERNIP-S procedure classification is:

2. The safety and efficacy of the procedure cannot be determined at the present time due to an incomplete and poor quality evidence-base. It is recommended that further research be conducted to establish safety and efficacy.

It was recommended that an audit of the procedure be conducted in accordance with the following clinical recommendations:

1. The procedure should only be performed on appropriately selected patients by a properly trained cardiac surgeon.
2. Cardiac surgeons should obtain institutional support and appropriately inform their patients before commencing the procedure. Ideally, angiography with short-term follow-up should be performed on at least the first ten patients. This initial data can then be used by the institution to determine whether to proceed with the beating heart surgery program, continue close surveillance or recommend further surgical training.
3. Minimal access approaches, such as limited thoracotomy, should only be attempted after a minimum of thirty cases have been successfully performed via full sternotomy.

Members of the Review Group assessing Off-Pump Coronary Artery Bypass Surgery with the Aid of Tissue Stabilizers:

Advisory Surgeon	**Dr Ben Bidstrup**
Protocol Surgeon	**Mr John Knight**
Nominated Surgeon	**Dr Hugh Wolfenden**
Other Specialty Surgeon	**Mr Robert Linacre**
ASERNIP-S Researcher	**Dr Ann Scott**
Chairman	**Professor Guy Maddern**

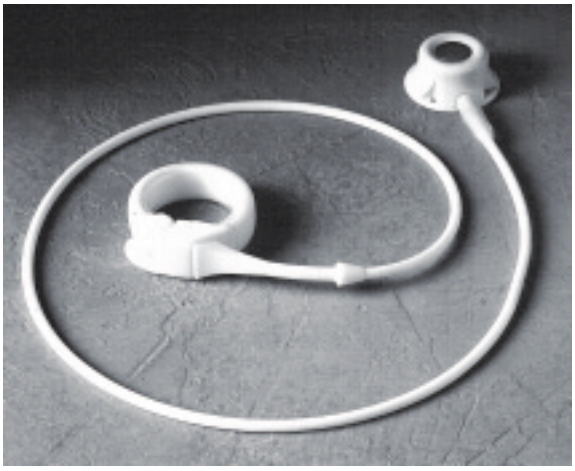
LAPAROSCOPIC ADJUSTABLE GASTRIC BANDING IN THE TREATMENT OF OBESITY

Background

The increasing weight of Australians over the past 40 years represents one of the greatest challenges confronting social scientists and health administrators in this country. In many instances a modest degree of excess weight is simply a cosmetic issue and is associated with few adverse medical consequences. However morbid obesity (Body Mass Index: BMI >35kg.m-2) is associated with a range of adverse health effects including diabetes, hypertension, dyslipidaemia, osteoarthritis and increased risk of cardiovascular disease. In addition to these physical effects there are significant psychosocial manifestations including depression, poor self-esteem, sexual dysfunction and unemployment.

Various strategies have been employed to control obesity. These include dietary advice, behaviour therapy and pharmacological intervention. However, ultimately each of these conservative strategies is associated with only a very modest degree of temporary weight reduction. Better understanding of the metabolic controls of body fat is likely to result in improved interventions in the future. At present, surgery remains the only effective option for the management of morbid obesity.

The current surgical options can be broadly classified as gastric restrictive, malabsorptive procedures or a combination of these two. Jejunoileal bypass is the archetypal malabsorptive procedure but has largely been abandoned because of profound adverse metabolic consequences that include renal calculi, vitamin deficiency, hypokalaemia, hepatic dysfunction and osteoporosis. Combined restrictive/ malabsorptive procedures result in the greatest



sustained weight loss but are also the most technically demanding, constitute the greatest assault upon the patient, and are associated with the most profound rearrangement of the normal gastrointestinal anatomy.

Virtually all weight control operations have been applied with a laparoscopic approach but the complexity of some of these procedures is daunting, and the anatomical alterations are identical to the open surgery. With the development of restrictive bands, which can be placed around the upper stomach to partition a small proximal pouch, surgeons and patients alike have embraced what is perceived to be a minimally invasive intervention. Initially non-adjustable and designed for open placement, refinement of these devices has resulted in an adjustable appliance which can be placed laparoscopically. The major benefits are considered to be minimally invasive placement, adjustability and preservation of normal gastrointestinal integrity. However, concern persists regarding the long-term efficacy of laparoscopic gastric banding, the incidence of adverse events and the requirement for re-operation in a proportion of patients.

The aim of this systematic review was to assess the safety and efficacy of laparoscopic adjustable gastric banding for the treatment of obesity.

Methods

Search Strategy: Two search strategies were devised to retrieve literature from the Medline, Current Contents, Embase and Cochrane Library databases up to February 2000.

Study Selection: Inclusion of papers was decided using a pre-determined protocol that specified suitable studies by type of participants, comparators, outcomes, and type of study. English language papers were selected. Acceptable study designs included randomised-controlled trials, controlled clinical trials, case series or case reports.

Data Collection and Analysis: Thirty-seven papers met the inclusion criteria. They were tabulated and critically appraised in terms of methodology and design, outcomes, and the possible influence of bias, confounding and chance.

Results

There was little high level evidence available and few comparative studies.

Safety: Mortality rates were less than 1 in 1000, which was less than that quoted in many reviews of other surgical procedures for the treatment of obesity. Likewise, morbidity rates did not appear to exceed those quoted for other procedures.

Efficacy: Most operations appeared to be completed in under 2 hours. Most studies reported rates of conversion to open procedures of fewer than 4%. Patients appeared to be discharged earlier than those undergoing vertical banded gastroplasty, and also appeared to become more mobile and independent after surgery, although initially positive responses to the surgery tended to diminish with time. The laparoscopic adjustable gastric band appeared to be capable of producing substantial weight loss up to 4 years, although longer term data has not been published, and the consistency of weight loss across the patient population was also unclear due to poor reporting of variance in most studies.

The ASERNIP-S procedure classification is:

2. The safety and efficacy of the procedure cannot be determined at the present time due to an incomplete and poor quality evidence-base. It is recommended that further research be conducted to establish safety and efficacy.

Specifically, it was recommended that a register of adjustable bands and a record of serious complications be established, possibly with anonymous reporting. The manufacturers of the adjustable bands should be encouraged to participate.

Members of the Review Group assessing Laparoscopic Adjustable Gastric Banding in the Treatment of Obesity:

Advisory Surgeon	Mr Philip Game
Protocol Surgeon	Mr George Kiroff
Nominated Surgeon	Professor Paul O'Brien
Other Specialty Surgeon	Mr Bruce Foster
Invited Surgeon	Professor John Ham
ASERNIP-S Researcher	Mr Andrew Chapman
Chairman	Professor Guy Maddern

Note: Since the production of this review, it has been suggested that the review be re-appraised following an altered protocol that specifically designates a comparator. This may occur during 2001.

LAPAROSCOPIC-ASSISTED RESECTION OF COLORECTAL MALIGNANCIES

Background

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 successful advent of laparoscopic cholecystectomy and the use of laparoscopic techniques in other colorectal procedures, particularly elective, non-resectional procedures, prompted the development of laparoscopic or laparoscopic-assisted techniques for resection of the colon and/or rectum.

Laparoscopic-assisted colorectal surgery has been utilised for a variety of benign conditions including inflammatory bowel disease and diverticular disease. The usual benefits associated with laparoscopic procedures in comparison to open techniques have been investigated, including less post-operative pain, shorter hospitalisation, reduced convalescence, improved pulmonary function and cosmesis. These benefits are somewhat mitigated with laparoscopic-assisted colorectal resection because an abdominal incision, albeit small, is still required to remove the resected colon.

The exact laparoscopic technique for colorectal resection varies considerably. Some procedures are wholly laparoscopic while others are laparoscopic-assisted, i.e. colonic mobilisation is laparoscopic, while some or all of the division of mesenteric vessels, bowel division and specimen retrieval occur outside the body. Port site placement, insufflation technique and maximum intra-abdominal pressure varies from procedure to procedure.

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 important, though, is an assessment of the safety and efficacy of the procedure in terms of disease recurrence, port site malignancies, and 5-year survival rates.

The aim of this systematic review was to compare the safety and efficacy of laparoscopically-assisted resection of colorectal malignancies with open colectomy.

Methods

Search Strategy: Two search strategies were devised to retrieve literature from the Medline, Current Contents, Embase and Cochrane Library databases up to July 1999.

Study Selection: Papers were included using a pre-determined protocol, independent assessments by two reviewers and a final consensus decision. Human studies of laparoscopic colectomies (but excluding abdominoperineal resections and transverse colectomies) and animal studies of tumour spread were included. English language papers were selected. Acceptable study designs included randomised-controlled trials, controlled clinical trials, case series or case reports.

Data Collection and Analysis: Eighty papers met the inclusion criteria. They were tabulated and critically appraised in terms of methodology and design, outcomes, and the possible influence of bias, confounding and chance.

Results

There was little high level evidence available, with few randomised controlled trials. The laparoscopic resection of colorectal malignancy was more expensive and time consuming. Some evidence suggested that patients may be at higher risk of short-term immune suppression, but little evidence suggested high rates of port site recurrence. The new procedure's advantages revolved around early operative recovery and reduced pain.

The ASERNIP-S procedure classification is:

2. The safety and efficacy of the procedure cannot be determined at the present time due to an incomplete and poor quality evidence-base. It is recommended that further research be conducted to establish safety and efficacy.

Specifically, because of concerns regarding a lack of evidence detailing circumferential marginal clearance of tumours in the rectum, ascending and descending colon, and the necessity of determining a precise incidence of cardiac and other major morbidity, along with wound and port site recurrence, it was recommended that a controlled clinical trial, ideally with random allocation to an intervention and control group, be conducted.

Long term survival rates also need to be clearly assessed. The proposed multi-centre Australian trial of Laparoscopic-Assisted Resection of Colorectal Malignancies would be a suitable vehicle to evaluate all of these variables. Because of its similar protocol to the large American NIH study currently underway, a meta-analysis of the combined data will be possible, and a definitive picture can be determined of the relative risks of laparoscopically-assisted resection and traditional open resection of colorectal malignancies.

Members of the Review Group assessing Laparoscopic-Assisted Resection of Colorectal Malignancies:

Advisory Surgeon	**Mr Michael Levitt**
Protocol Surgeon	**Mr Peter Hewett**
Nominated Surgeon	**Mr Rodney Woods**
Other Specialty Surgeon	**Mr Harry Sheiner**
ASERNIP-S Researchers	**Mr Andrew Chapman, Ms Daniela DeNichilo, Dr Wendy Babidge**
Chairman	**Professor Guy Maddern**

ASSESSMENT RE-APPRAISALS

ASERNIP-S completed six re-appraisals of procedure assessments in 2000, all within twelve to eighteen months of the completion date of the original assessments. For each of these assessments the ASERNIP-S review process was altered during the period between the primary systematic review and the re-appraisal. Originally the review was divided into two sections - a narrative review undertaken by the review surgeon and a methodological assessment undertaken by the ASERNIP-S researcher. These two approaches have now been synthesised. The ASERNIP-S researcher, in consultation with the advisory surgeon (previously review surgeon), now undertakes the review and re-appraisal. The ASERNIP-S researcher brings the necessary evidence-based surgery and critical appraisal skills to the task, whilst the advisory surgeon provides the invaluable clinical expertise that is required. The procedure assessments that were re-appraised in 2000 include:

- Arthroscopic subacromial decompression using the holmium:yag laser
- Laparoscopic live donor nephrectomy
- Lung volume reduction surgery
- Minimally invasive techniques for the relief of bladder outflow obstruction
- Percutaneous endoscopic laser discectomy
- Ultrasound-assisted lipoplasty

Summaries of these assessment re-appraisals follow. One further re-appraisal on the Minimally Invasive Parathyroidectomy is currently being undertaken.

ARTHROSCOPIC SUBACROMIAL DECOMPRESSION USING THE HOLMIUM:YAG LASER

Background

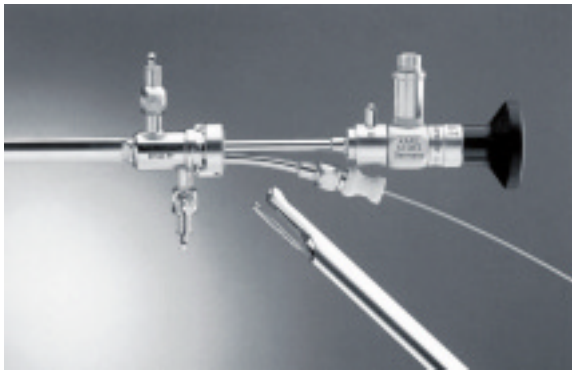
Arthroscopic subacromial decompression (ASD) is a surgical technique used to overcome shoulder impingement syndrome. Impingement syndrome results from narrowing of the space underlying the acromion and coracoacromial ligament. Pain, weakness and loss of motion are the most common symptoms and the pain 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. This technique involves an acromioplasty, coracoacromial ligament resection, and bursectomy using a motorised shaver, burr and electrocautery. As an alternative, the use of a Holmium:YAG laser has been put forward as a tool to perform the same functions as the shaver, burr and electrocautery. The reported benefit of the laser is in coagulation of small bleeding vessels in the process and reduced postoperative pain and swelling.

The original review of ASD with a holmium:YAG laser was done following a literature search conducted in September 1998. There was insufficient evidence available to assess the safety and efficacy of the procedure at that time. An update of the literature base was undertaken to cover the period up to December 1999.

Methods

Medline, Embase, Current Contents and the Cochrane Library databases were searched up to December 1999, using search terms provided in the original protocol. Inclusion and exclusion criteria for paper selection were also the same as those given in the original protocol.



Results

No new references were located for the period of one year following the primary literature search.

ASERNIP-S Safety and Efficacy Recommendation

The recommendation for safety and efficacy as formulated for the primary review remained unchanged, as no additional supporting evidence was located for the review re-appraisal. There was no reason to reconvene the Review Group.

The ASERNIP-S procedure classification is:

2. The safety and efficacy of the procedure cannot be determined at the present time due to an incomplete and poor quality evidence-base. It is recommended that further research be conducted to establish safety and efficacy.

The recommendation was that a controlled clinical trial, ideally with random allocation to an intervention and control group, be conducted.

Members of the Review Group for the Arthroscopic Subacromial Decompression using the Holmium: YAG laser:

Advisory Surgeon	Mr Andrew Shimmin
Protocol Surgeon	Mr Malcolm Wicks
Other Specialty Surgeon	Mr David Watson
Nominated Surgeon	Mr Graeme MacDougal
ASERNIP-S Researcher	Mrs Maggi Boult
Chairman	Professor Guy Maddern

LAPAROSCOPIC LIVE DONOR NEPHRECTOMY

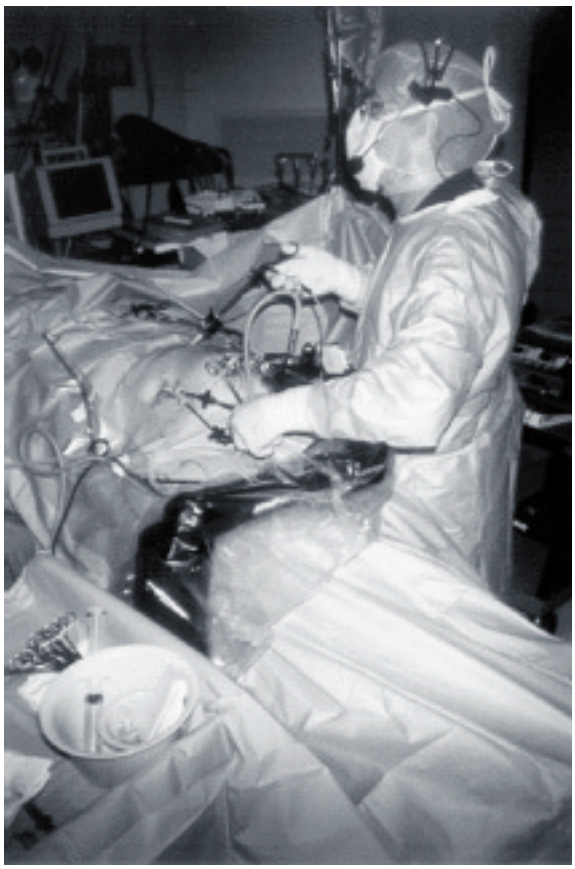
Background

With the increasing utilisation of laparoscopic live donor nephrectomy internationally, the aim of this systematic review was to compare the safety and efficacy of laparoscopic, or laparoscopic-assisted, live donor nephrectomy (LLDN) with the "gold" standard of open live donor nephrectomy (OLDN).

The original review on LLDN was based on literature searches undertaken up until August 1998. As insufficient evidence was available at that time to assess the safety and efficacy of LLDN, it was decided that literature searches would need to be repeated at a later date to determine whether any significant changes had occurred in the evidence base. The re-appraisal of this review was undertaken some eighteen months after the primary literature searches.

Methods

Search Strategy: Three search strategies were devised to enable literature retrieval from the Medline, Current Contents, Embase and Cochrane Library databases up until, and including, February 2000.



Study Selection: Inclusion of a study was determined on the basis of a pre-determined protocol, independent assessment by two reviewers and a final consensus decision. English language papers were selected and acceptable study designs included randomised-controlled trials, controlled clinical trials, case series or case reports. Each study was required to provide information on at least one of several safety and efficacy outcomes as detailed in the protocol.

Data Collection and Analysis: Thirty-five studies met the inclusion criteria. They were tabulated and critically appraised in terms of the methodology and design, sample size, outcomes, and the possible influence of bias, confounding and chance.

Results

Four laparoscopic techniques were described in the literature on live donor nephrectomy: the laparoscopic transperitoneal approach with CO2 insufflation; the hand-assisted laparoscopic transperitoneal approach with CO2 insufflation; the laparoscopic-assisted transperitoneal approach using retraction rather than insufflation; and the retroperitoneoscopic-assisted approach using retraction.

Limited low level evidence indicated the following:

Safety

There were no reported deaths in any of the donor groups in any of the controlled studies, case series or case reports. In the largest published donor series (n=338), the conversion rate was 0.9%. The major reason for converting from the laparoscopic to the open procedure was vascular injuries or the inability to control bleeding. The complication rate did not differ significantly for the laparoscopic and open approaches. However, sample sizes were small and differences would have been difficult to detect. The complications that figured prominently in the literature on LLDN were haemorrhage and blood transfusion. Most complications and conversions occurred early in the donor series reported as these laparoscopic techniques have a very steep learning curve and are exceptionally technically demanding. This may have biased the results as most of the published papers presented their early experiences with the laparoscopic techniques. Most of the larger donor series reported fewer complications and conversions after the first 20-30 cases.

Efficacy

In general, warm ischaemia times and operating times were longer for the laparoscopic procedures. However, delayed graft function and long term graft function, as measured by creatinine levels, were essentially the same for grafts harvested using either the laparoscopic or open approach. There were no differences in recipient and graft survival when the laparoscopic and open techniques were compared.

No conclusions could be drawn with respect to the risk of recipient ureteral complications from grafts harvested laparoscopically as opposed to openly. Any increased risk from the laparoscopic approach appears to be a function of learning curve and technique.

The laparoscopic approach was found to be advantageous with regard to the donor's hospital stay, convalescence, pain, and resumption of employment.

Conclusions

High level evidence comparing the safety and efficacy of LLDN with OLDN was not available at the time of this review. Limited low level evidence indicated that the safety of LLDN was comparable to that of OLDN, and that it may have some advantages with respect to efficacy. However, the new evidence on LLDN was of insufficient quality to necessitate a change in the procedure classification.

The ASERNIP-S procedure classification is:

2. The safety and efficacy of the procedure cannot be determined at the present time due to an incomplete and poor quality evidence-base. It is recommended that further research be conducted to establish safety and efficacy.

The recommendation was that a controlled clinical trial, ideally with random allocation to an intervention and control group, be conducted.

The ASERNIP-S Review Group issued the following clinical recommendations for Australian surgeons:

1. LLDN should only be done in units where there are surgeons with considerable expertise in OLDN.
2. The live donor nephrectomy surgical team planning to start laparoscopic live donor nephrectomies should include a surgeon with established experience in a range of laparoscopic procedures.
3. LLDN should be initially performed in either a large animal or a patient requiring a nephrectomy for benign disease.
4. Renal transplant units planning to undertake LLDN should plan to do a series of these cases and maintain detailed records of the theatre costs, hospital costs, morbidity and outcome in both open and laparoscopic cases.
5. Surgeons should be alert to the literature on evolving techniques of laparoscopic nephrectomy. Of particular interest is the option to use an extraperitoneal approach instead of a transperitoneal approach.

The ASERNIP-S Review Group has issued a recommendation for the cautious introduction of LLDN in Australia where the above skills exist and where there is a commitment to do 10-20 of these cases per year in order to gain the necessary experience and report the results.

To meet the fourth clinical recommendation, ASERNIP-S set up a national database in 1999 to house information on safety and efficacy outcomes from the few transplant centres in Australia and New Zealand that are currently undertaking LLDN. More information on this database is provided in the Data Collection section of this report.

Members of the Laparoscopic Live Donor Nephrectomy Review Group:

Advisory Surgeon	**Associate Professor David Scott**
Protocol Surgeon	**Mr Mohan Rao**
Nominated Surgeon	**Associate Professor David Francis**
Nominated Surgeon`	**Professor Daryl Wall**
Other Specialty Surgeon	**Mr Franklin Bridgewater**
ASERNIP-S Researcher	**Mrs Tracy Merlin**
Chairman	**Professor Guy Maddern**

LUNG VOLUME REDUCTION SURGERY

Background

The aim was to systematically review the literature regarding the safety and efficacy of lung volume reduction surgery (LVRS) in patients with emphysema.

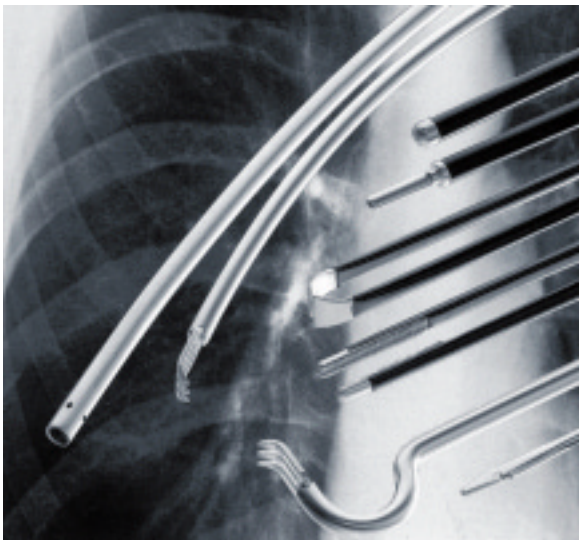
The original review on lung volume reduction surgery was based on literature searches undertaken up until October 1998. As insufficient evidence was available at that time to properly assess the safety and efficacy of lung volume reduction surgery, the literature searches were repeated nearly two years later and the review was re-appraised.

Methods

Studies on LVRS were identified to August 2000 using Medline, Embase, Current Contents and the Cochrane Library. Human studies of patients with upper, lower or diffuse distributions of emphysema were included. All types of bullous emphysema were excluded. A surgeon and researcher independently assessed the retrieved articles for their inclusion in the review.

Results

When LVRS was compared to medical management at two years, LVRS was associated with a higher Forced Expiratory Volume (FEV1) and at least equivalent survival. The use of staple excision of selected areas of lung appeared more efficacious than laser ablation. There was insufficient evidence to show preference for median sternotomy or videoscopic-assisted thoracotomy as the more safe and efficacious procedure.



Conclusions

LVRS is deemed an acceptable treatment in highly selected patients with emphysema. In order to fully evaluate the safety and efficacy of LVRS, outcomes beyond two years must be included. The results of prospective randomised trials comparing medical management and LVRS, now in progress, are essential before a final assessment can be made. The ASERNIP-S procedure classification remains unchanged.

The ASERNIP-S procedure classification is:

2. The safety and efficacy of the procedure cannot be determined at the present time due to an incomplete and poor quality evidence-base. It is recommended that further research be conducted to establish safety and efficacy.

The recommendation was that an audit be conducted.

ASERNIP-S has collaborated with the Alfred Hospital, Melbourne, to audit Lung Volume Reduction Surgery. The database has been established under the auspices of the Australian Lung Foundation, the Thoracic Society of Australia and New Zealand and the Victorian Tuberculosis and Lung Association. More information on this database is provided in the Data Collection section of this report.

Members of the Lung Volume Reduction Surgery Review Group:

Advisory Surgeon	Mr George Stirling
Protocol Surgeon	Mr Morris Peacock
Nominated Surgeons	Mr Julian Smith, Mr Kevin Matar
Invited Member	Dr Gregory Snell
Other Specialty Surgeon	Dr Deborah Colville
ASERNIP-S Researcher	Dr Wendy Babidge
Chairman	Professor Guy Maddern

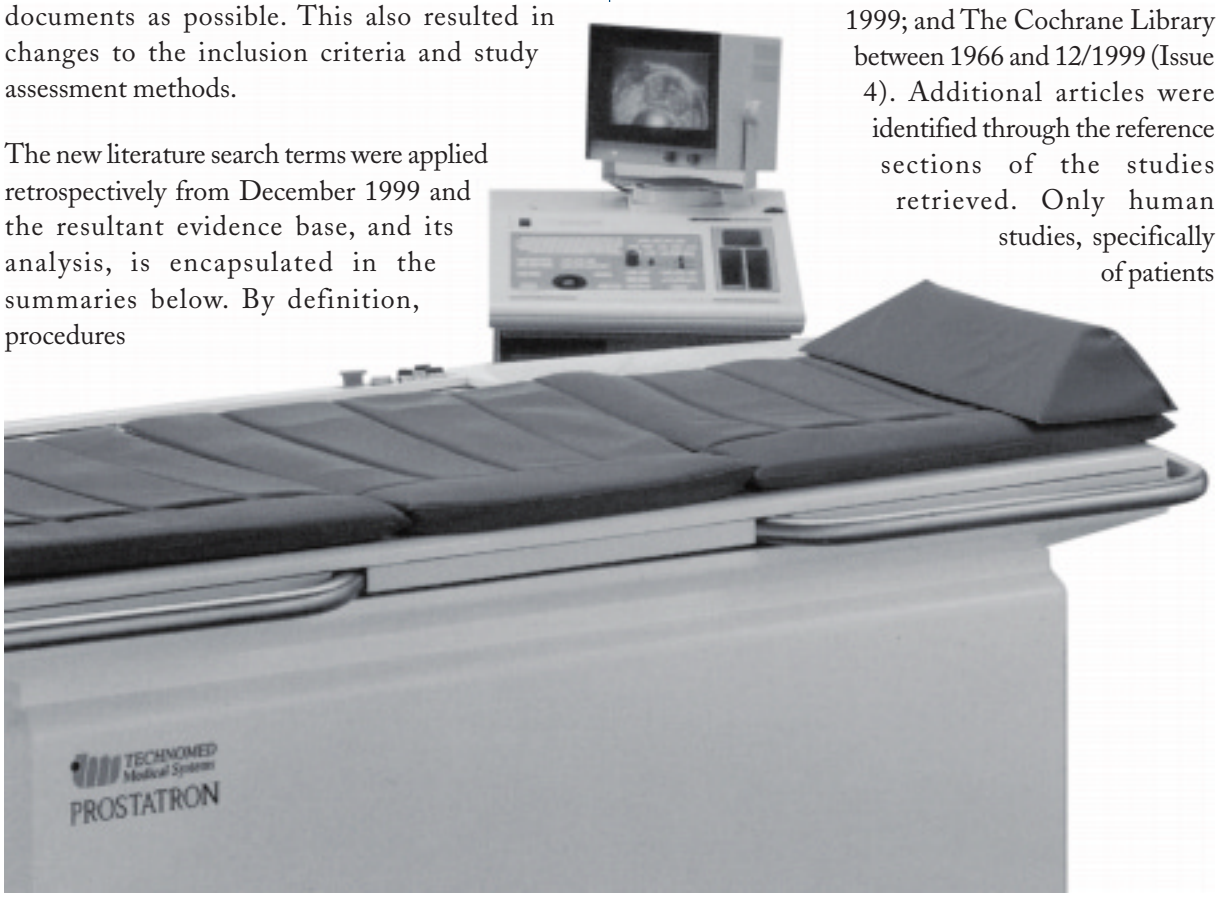
MINIMALLY INVASIVE TECHNIQUES FOR THE RELIEF OF BLADDER OUTFLOW OBSTRUCTION

Background

The original literature review assessing the safety and efficacy of Minimally Invasive Techniques for the Relief of Bladder Outflow Obstruction consisted of a narrative review of the available literature (written by the review surgeon) and a Methodological Assessment Report (written by the ASERNIP-S researcher). The Methodological Assessment Report was a systematic assessment of the evidence base.

In order to overcome the differences in approach of these two reviews, the two documents were consolidated into one coherent systematic review with a common protocol as part of the procedure assessment re-appraisal. However, in order to streamline this integration some changes were made to the original methods and content of the documents. The minimally invasive prostatectomy procedures were divided into two subcategories, namely, laser prostatectomy techniques and non-laser thermal therapy techniques. In addition, alterations were made to the original search terms in order to broaden the evidence base and include as many papers common to the two original documents as possible. This also resulted in changes to the inclusion criteria and study assessment methods.

The new literature search terms were applied retrospectively from December 1999 and the resultant evidence base, and its analysis, is encapsulated in the summaries below. By definition, procedures that have been given an ASERNIP-S classification of '1', do not require a literature re-appraisal because it is unlikely that their classification will be changed by any new evidence. However, in the present instance, an exception was made for transurethral electrovaporisation of the prostate (TUVP) in the interests of uniformity. Nonetheless, no further re-appraisal of the TUVP evidence base will be made.



Laser Prostatectomy Techniques

Objective

The aim of this review was to compare the safety and efficacy of minimally invasive laser prostatectomy techniques against the current benchmark treatment, transurethral resection of the prostate (TURP). Where possible, comparisons were also made between different laser techniques and between different treatment regimens within the one laser technique in order to determine which was the most safe, efficacious and durable.

Methods

All original, published studies on minimally invasive laser prostatectomy techniques were identified by searching Medline between 1984 and 12/1999; Current Contents between 1993 and 12/1999; Embase between 1974 and 12/1999; and The Cochrane Library between 1966 and 12/1999 (Issue 4). Additional articles were identified through the reference sections of the studies retrieved. Only human studies, specifically of patients

with bladder outflow obstruction and non-malignant enlargement of the prostate, were considered. English language papers detailing randomised-controlled trials, controlled clinical trials, case series or case reports were included.

Results

The small sample size and poor evidence quality of many studies meant that no definitive conclusion could be made as to the safety and efficacy of visual laser ablation of the prostate (VLAP), interstitial laser coagulation (ILC) or contact vaporisation of the prostate (LCV), in comparison to TURP. Nonetheless, the current limited evidence suggested that safety favoured VLAP, ILC and LCV whereas effectiveness favoured TURP. All three laser techniques achieved generally comparable improvements in objective and subjective patient measurements or parameters but LCV appeared to be safer than VLAP and ILC.

Conclusion

The ASERNIP-S Review Group concluded that the evidence base for VLAP, ILC and LCV was inadequate, and recommended that a controlled clinical trial of ILC be conducted. It was also recommended that an audit of VLAP and LCV be undertaken.

Non-laser Thermal Therapy

Objective

The aim of this review was to compare the safety and efficacy of minimally invasive non-laser thermal prostatectomy techniques against the current benchmark treatment, transurethral resection of the prostate (TURP). Where possible, a comparison was also made between different treatment regimens within the one thermal technique in order to determine which was the most safe, efficacious and durable.

Methods

All original, published studies on minimally invasive non-laser thermal prostatectomy techniques were identified by searching Medline between 1984 and 12/1999; Current Contents between 1993 and 12/1999; Embase between 1974 and 12/1999; and The Cochrane Library between 1966 and 12/1999 (Issue 4). Only human studies, specifically of patients with bladder outflow obstruction and non-malignant enlargement of the prostate, were considered. English language papers detailing randomised-controlled trials, controlled clinical trials, case series or case reports were included, depending on the quality of evidence available for each procedure.

Results

The small sample size and poor evidence quality of many studies meant that no definitive conclusion could be made regarding the safety and efficacy of high intensify focused ultrasound (HIFU), transurethral microwave therapy (TUMT) or transurethral needle ablation (TUNA), in comparison to TURP. Nonetheless, the current evidence suggested that safety favoured HIFU, TUMT and TUNA whereas effectiveness favoured TURP. A meta-analysis of TURP versus TUVP trials showed that TUVP offered a similar degree of symptomatic relief over a one to two year period, compared to TURP, but with less morbidity.

Conclusion

The ASERNIP-S Review Group concluded that TUVP was a suitable alternative to TURP for certain patient groups. The Review Group also concluded that the evidence base for HIFU, TUMT and TUNA was inadequate, and recommended that a controlled clinical trial of HIFU and TUMT be conducted. It was also recommended that an audit of TUNA be undertaken.

ASERNIP-S Safety and Efficacy Recommendations

It was determined by consensus that the original ASERNIP-S safety and efficacy classifications for VLAP, ILV, LCV, HIFU, TUVP, TUMT and TUNA should remain unchanged based on the re-appraised evidence base.

The ASERNIP-S procedure classifications are:

A. Laser Prostatectomy

i. **The classification for Visual Laser Ablation of the Prostate (VLAP) is 2.** *The safety and efficacy of the procedure cannot be determined at the present time due to an incomplete and poor quality evidence-base. An audit is recommended to assess both safety and efficacy.*

VLAP is contraindicated in patients with large prostates or median lobe enlargement.

ii. The classification for Interstitial Laser Coagulation of the prostate (ILC) is 2. *The safety and efficacy of the procedure cannot be determined at the present time due to an incomplete and poor quality evidence-base. A randomised controlled clinical trial is recommended to assess both safety and efficacy.*

ILC is contraindicated in patients with large prostates, median lobe enlargement or those in complete urinary retention.

iii. The classification for Laser Contact Vaporisation of the prostate (LCV) is 2. *The safety and efficacy of the procedure cannot be determined at the present time due to an incomplete and poor quality evidence-base. An audit is recommended to assess both safety and efficacy.*

B. High Intensity Focussed Ultrasound (HIFU)

The classification is 2. *The safety and efficacy of the procedure cannot be determined at the present time due to an incomplete and poor quality evidence-base. A randomised controlled clinical trial is recommended to assess both safety and efficacy.*

HIFU is currently considered an experimental procedure.

C. Transurethral Electrovaporisation (TUVP)

The classification is 1. *The safety and efficacy is established, and the procedure may be introduced into practice.*

TUVP may not give satisfactory outcomes for larger prostates. In addition, TUVP may result in a higher incidence of erectile dysfunction, in comparison to TURP.

D. Transurethral Microwave Therapy (TUMT)

The classification is 2. *The safety and efficacy of the procedure cannot be determined at the present time due to an incomplete and poor quality evidence-base. A randomised controlled clinical trial is recommended to assess both safety and efficacy.*

E. Transurethral Needle Ablation (TUNA)

The classification is 2. *The safety and efficacy of the procedure cannot be determined at the present time due to an incomplete and poor quality evidence-base. An audit is recommended to assess both safety and efficacy.*

Members of the Review Group assessing Minimally Invasive Techniques for the Relief of Bladder Outflow Obstruction Review Group:

Advisory Surgeon	Mr John Wheelahan
Protocol Surgeon	Professor Villis Marshall
Nominated Surgeons	Mr Ross Cartmill, Professor John Nacey
Other Specialty Surgeon	Associate Professor Randall Morton
ASERNIP-S Researcher	Dr Ann Scott
Chairman	Professor Guy Maddern

PERCUTANEOUS ENDOSCOPIC LASER DISCECTOMY

Background

Percutaneous Endoscopic Laser Discectomy (PELD) is a minimally invasive surgical procedure that combines endoscopic visualisation of the disc space with laser decompression. Proponents of the system claim this provides symptomatic relief by reducing pressure on the nerve roots from a contained disc prolapse. 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 original review on the safety and efficacy of percutaneous endoscopic laser discectomy was undertaken on literature from searches conducted in September 1998. As insufficient evidence was available to assess the safety and efficacy of the procedure at that time, the literature search was updated to cover the period following the primary search and up to December 1999.

Methods

The Current Contents, Medline, Embase and Cochrane Library databases were searched up to December 1999, using the search terms outlined in the original protocol. Papers were also selected for inclusion in the review on the same basis as described in the original protocol.

Results

No new references were located for the period of one year following the primary literature search.

ASERNIP-S Safety and Efficacy Recommendations

The recommendation for safety and efficacy as formulated for the primary review remained unchanged, as no additional supporting evidence was located for the review re-appraisal. There was no reason to re-convene the Review Group.

The ASERNIP-S procedure classification is:

2. The safety and efficacy of the procedure cannot be determined at the present time due to an incomplete and poor quality evidence-base. It is recommended that further research be conducted to establish safety and efficacy.

The recommendation was that a randomised controlled trial be conducted.

Members of the Percutaneous Endoscopic Laser Discectomy Review Group:

Advisory Surgeon	**Professor Robert Fraser**
Protocol Surgeon	**Professor Nigel Jones**
Nominated Surgeons	**Mr John Liddell, Mr Orso Osti**
Invited Surgeon	**Mr Peter Dohrmann**
Other Specialty Surgeon	**Professor Peter Donnelly**
ASERNIP-S Researcher	**Mrs Maggi Boult**
Chairman	**Professor Guy Maddern**

ULTRASOUND-ASSISTED LIPOPLASTY

Background

The aim of this review was to assess the safety and efficacy of ultrasound-assisted lipoplasty (UAL) in comparison to the "gold standard" of suction-assisted lipoplasty (SAL).

The original review on UAL was based on literature searches undertaken up until December 1998. As insufficient evidence was available at that time to properly assess the safety and efficacy of UAL, the literature searches were repeated sixteen months later and the review was re-appraised.

Methods

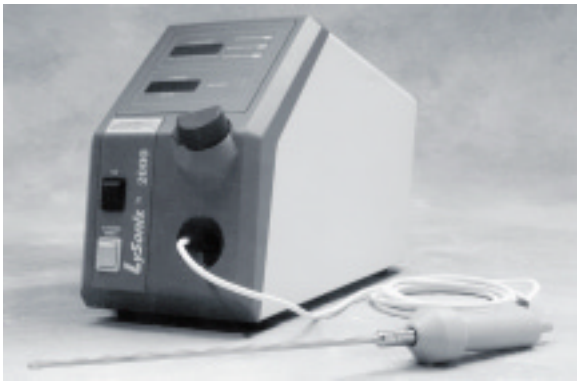
Search Strategy: Three search strategies were devised to retrieve literature from the Medline, Current Contents, Embase and Cochrane Library databases up to April 2000.

Study Selection: Inclusion of papers was largely determined using a pre-determined protocol. English language papers were selected. Acceptable study designs included randomised-controlled trials, controlled clinical trials, case series or case reports.

Data Collection and Analysis: Thirty-six papers met the inclusion criteria. They were tabulated and critically appraised in terms of methodology and design, outcomes, and the possible influence of bias, confounding and chance. Other papers were also included to provide background material.

Results

There was little high level evidence available comparing UAL and SAL, with no conclusive evidence that UAL has a safety benefit. Low quality evidence suggested that UAL was associated with reduced surgeon fatigue as well as increased operating times, slower aspiration rates and an increased learning curve. There was inadequate evidence to determine whether the theoretical potential for DNA damage from ultrasound is realised in the clinical setting.



Conclusions

The evidence base for UAL was inadequate to determine the procedure's safety and efficacy. The potential for DNA damage must be investigated with appropriate in *vivo* animal models. The ASERNIP-S procedure classification remains unchanged and recommendations for the safe use of UAL are discussed in detail in the review re-appraisal.

The ASERNIP-S procedure classification is:

2. The safety and efficacy of the procedure cannot be determined at the present time due to an incomplete and poor quality evidence-base. It is recommended that further research be conducted to establish safety and efficacy.

The recommendation was that an audit be conducted. The ASERNIP-S Review Group also recommended that ultrasound-assisted lipoplasty should not be performed to contour female breast tissue.

ASERNIP-S has collaborated with the American Society of Plastic Surgery to collect Australian patient data for the "Lipoplasty effectiveness and patient safety" (LEAPS) study. More information on this database is provided in the Data Collection section of this report.

Members of the Ultrasound-Assisted Lipoplasty Review Group:

Review & Protocol Surgeon	Mr Rodney Cooter
Nominated Surgeons	Mr Keith Mutimer, Mr David Robinson
Invited Surgeon	Mr Peter Wickham
Other Specialty Surgeon	Mr George Kiroff
ASERNIP-S Researchers	Mr Andrew Chapman, Dr Wendy Babidge
Chairman	Professor Guy Maddern

New Assessments In Progress

Four new procedure assessments are in various stages of completion. Systematic reviews are being produced to assess the safety and efficacy of:

- Tension-free urethropexy for stress urinary incontinence: Intravaginal slingplasty and the tension-free vaginal tape procedures
- Dynamic graciloplasty
- Endoscopic modified Lothrop procedure for chronic frontal sinusitis
- Methods for establishing laparoscopic pneumoperitoneum.

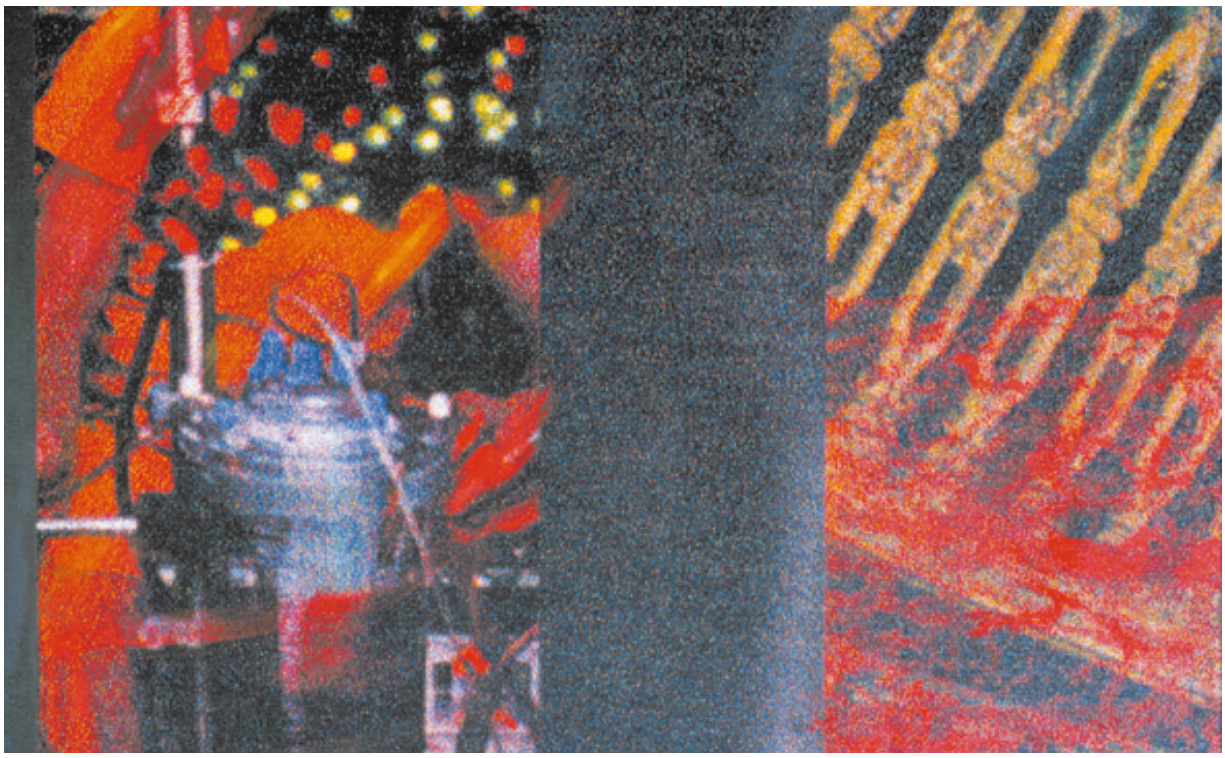
It is anticipated that the first of these reports will be released into the public domain in early 2001, while the remaining three reports will be available mid-2001.

Procedure Nominations

The demand for ASERNIP-S systematic reviews continues unabated. The following eleven procedures have been nominated to be assessed by ASERNIP-S. These nominations have been accepted and the procedures will be assessed by ASERNIP-S in the near future.

- Adult-to-adult live donor liver transplantation
- Holmium laser resection of the prostate
- Circular stapling haemorrhoidectomy
- Heart and lung transplantation
- Instrument for trans-anal microsurgery of small rectal lesions (Wolff's Operating Proctosigmoidoscopy)
- Minimally invasive paediatric surgery, particularly regarding pyloric stenosis
- Foetal surgery
- Laser skin resurfacing
- Endoscopic carpal tunnel release
- Endoscopic brow lifting
- Stented prosthesis
- Trans-oral laser resection for laryngeal cancer

Data Collection



Data Registries

ASERNIP-S has established four data registries to audit procedures that we have assessed:

- Ultrasound-assisted lipoplasty - "Lipoplasty effectiveness and patient safety" (LEAPS) study
- Lung volume reduction surgery (LVRS)
- Minimally invasive parathyroidectomy (MIP)
- Laparoscopic live donor nephrectomy (LLDN)

Australian patient data on the LEAPS study is being collected in collaboration with the American Society of Plastic Surgery. The LEAPS study is a prospective multi-centre cohort study collecting outcome data on suction lipectomy and ultrasound-assisted lipoplasty. Five Australian sites have contributed data.

The LVRS data registry was established under the auspices of the Australian Lung Foundation, the Thoracic Society of Australia and New Zealand and the Victorian Tuberculosis and Lung Association. ASERNIP-S is working to maintain this registry in collaboration with the Alfred Hospital, Melbourne, which houses and manages the database. Currently ten sites in Australia and New Zealand contribute to this registry.

The other two databases are housed by ASERNIP-S. The data collections were established as part of the pilot study phase of our project. Surgeons are offered the option of submitting data via a secure Internet site, by e-mail, or following provision of a database which can be submitted by mail or by e-mail. Paper forms are also provided.

The MIP data registry is the most recent of the ASERNIP-S databases. It was established in 2000 to enable an audit of the safety and efficacy of minimally invasive parathyroidectomy as practiced at five sites in Australia. A total of 168 cases have been submitted to date. Data is collected at the time of the procedure then at the six and twelve month follow-up. Analysis of the data will be undertaken and used to complement the re-appraisal of the systematic review of minimally invasive parathyroidectomy, due to be released in 2001.

Four sites in Australia and New Zealand are submitting data on the LLDN procedure and, as at December 2000, a total of 69 cases were recorded. Information extracted from this database (spanning 7/5/97 - 28/2/00) was used to inform the procedure assessment re-appraisal of laparoscopic live donor nephrectomy released in mid-2000. At that stage 54 procedures were performed via the laparoscopic transperitoneal approach using CO2 insufflation to remove the left kidney.

Donor data is currently entered on the LLDN registry from either paper forms or a web data entry form accessed (restricted) via the ASERNIP-S web site. Data is collected on mortality, conversions to the open procedure, complications, blood loss, donor creatinine levels, peri-operative outcomes, convalescence, and graft function and survival. ASERNIP-S will be collating kidney recipient outcome information but at present have yet to develop a collection mechanism that enables linkage between donor and recipient data.

Endoluminal Repair of Abdominal Aortic Aneurysms

The Medicare Services Advisory Committee (MSAC) assessed the safety and efficacy of Endoluminal Repair of Abdominal Aortic Aneurysm (AAA), and reported the results in May 1999. The results indicated that whilst the procedure appeared effective in the short term, there was insufficient evidence concerning the long term safety and efficacy.

One consequence of the report was that the Commonwealth Department of Health and Aged Care commissioned ASERNIP-S to manage a national collection of data for the evaluation of endoluminal and open repair of AAA. The project commenced as a pilot in February 2000, whereby systems for the collection of data from all cases of endoluminal repair were put in place, with data collected from open repair procedures as a comparison. Data was retrospectively submitted from November 1, 1999 and is being sought from patients in both the private and public sectors.

The audit aims to evaluate the safety and efficacy of the endoluminal procedure and to establish the feasibility of a trial. During the first twelve months of the pilot project the objectives were to: establish contact with all vascular surgeons and obtain data from them directly; streamline the data set to eliminate inconsistencies and promote participation; establish a comparative data set for the open repair procedure; and facilitate data entry by whatever means available. Audit data was analysed with the main consideration given to adverse outcomes.

Data will be collected for a period of three to five years. Surgeons complete an operative data set following the initial procedure. A second data set is completed at discharge/30 day follow-up. Subsequent data sets are completed at 6 months, 1, 2, 3, 4 and 5 years.

Almost 900 cases have been registered with ASERNIP-S in the first year. Of these nearly 500 are endoluminal and 400 are open procedures. There have been approximately 850 discharge forms submitted of which half are endoluminal. For the follow-up data 460 forms have been received. For the endoluminal cases 140 are for the 3-month follow-up, 120 are 6-month follow-up and 30 are 12-month follow-up cases.

An annual report for the first year of data collection has been submitted to the Commonwealth Department of Health and Aged Care.

NET-S
(New and Emerging Techniques-Surgical)

Horizon scanning is a term used to denote the identification of new and emerging techniques. The early detection of new surgical techniques and technologies can be of considerable value to clinicians, health service providers and government, enabling the development of clinical guidance, evaluation of safety and efficacy, and consideration of financial implications.

In March of this year ASERNIP-S sent a survey to all active Fellows of the Royal Australasian College of Surgeons requesting information on any new or emerging surgical techniques or technologies. Surgeons identified 185 new procedures, of which 69 were non-duplicates and specifically related to surgery. Twelve surgical specialties were represented. This survey of Fellows was such a successful method of identifying new surgical procedures that it was felt that such a technique could be regularly used by ASERNIP-S to conduct horizon scanning.

Over the past six months ASERNIP-S, in conjunction with the NTC (Royal Australasian College of Surgeons' New Technology Committee), has been working towards establishing an Australasian-based Horizon Scanning Centre, New and Emerging Tecniques- Surgical (NET-S). The aim of NET-S is to provide an early warning system for identifying new and emerging surgical techniques and technologies prior to their

publication in the peer-reviewed literature and introduction into routine clinical practice. NET-S aims not only to parallel the activities of major horizon scanning centres in Canada and Europe, but to develop unique methodologies to improve the horizon scanning process in the area of surgery.

This will occur through the following strategies:

- Direct communication with Fellows of the Royal Australasian College of Surgeons (RACS)
- Close surveillance of abstracts presented at relevant specialty meetings
- Ongoing searching of the literature describing new techniques and technologies
- Establishing links with key players and targeting other appropriate groups, such as medical device manufacturers
- Soliciting input from surgeons, consumers and other relevant groups via the NET-S web page.

NET-S will provide:

- A comprehensive and up to date database of new and emerging surgical techniques and related information that may be accessed by interested groups
- Support to the established ASERNIP-S review process through providing information on procedures warranting review
- Advance notice to the Department of Health and Aged Care, Divisions and Sections of the College and other interested agencies about new and emerging surgical techniques that might require evaluation, consideration of clinical and cost impact, or modification of clinical practice.

NET-S on the Web

The NET-S web page has now been developed and is linked to both the ASERNIP-S and RACS web sites. It includes a summary of the project, as well as the current database of new and emerging surgical techniques identified by surgeons who took part in the horizon scanning survey conducted in 2000. Each procedure is listed under the relevant specialty and will be assigned to one of two classifications: Short-term (emerging techniques identified approximately one year before their expected introduction into health care services) or Long-term (emerging procedures identified approximately five years before their expected introduction into health care services).

Forms are currently being developed for nominating new techniques and for providing feedback or comments on our existing database of surgical procedures. A registration form will also be available for new contacts wishing to be included on our database of recipients of NET-S project news. Visitors to the site will be able to view the comments provided by others. As the project progresses and feedback via the site is monitored, it is proposed that special feature articles covering selected new procedures will be posted on the site to inform interested groups and encourage participation.

Consumer Survey

In November NET-S conducted a national survey of Consumer Complaints Commissions and consumer groups to gather information to assist with the development of the NET-S database.

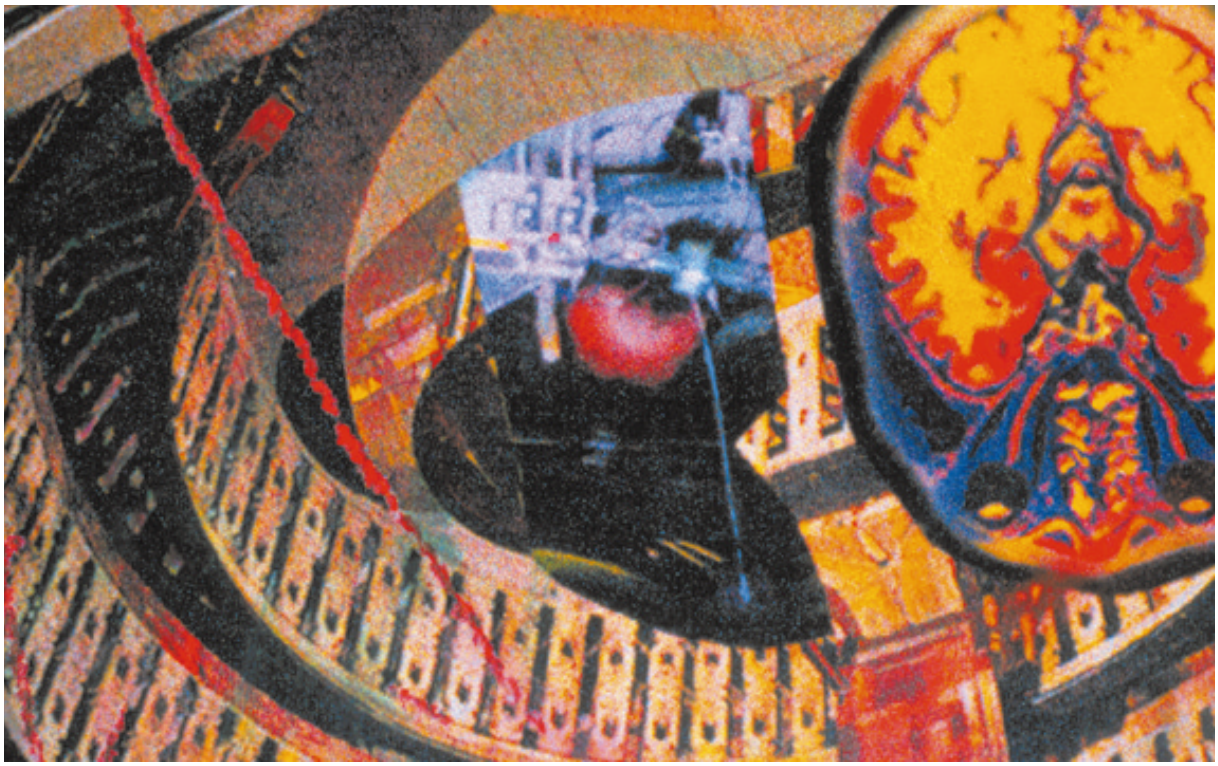
Respondents were able to provide specific details about complaints received by their organisations and several key issues emerged. Respondents considered it essential that:

- Complaints information be consolidated into a national database with NET-S input
- Outcome information on new procedures being performed overseas be sourced
- A centrally-held database of this information be used to track national trends in the outcomes of new surgical technology.

An abstract detailing these findings has been submitted to the International Society of Technology Assessment in Health (ISTAHC) for consideration as a presentation at the 17th Annual Meeting in Philadelphia in June 2001, "Building Bridges between Policy, Providers, Patients, and Industry".

We invite those interested to visit the new web site, view our list of new and emerging technologies and register any feedback, comments or new procedures.

Project Activities for 2000



Promotional Activities

Promotional activities undertaken by ASERNIP-S have been consolidated and diversified in this final year of the pilot project. The most notable activity has been the dissemination of the three new, and six re-appraised, procedure assessment reports. This has been undertaken via a number of different mediums, including: publication in international surgical journals and other relevant periodicals; presentation of findings at health technology assessment, and other, conferences nationally and internationally; publication of information on the ASERNIP-S web site; and dissemination of the Annual Report. ASERNIP-S also conducted a survey of Fellows of the Royal Australasian College of Surgeons to initially determine their awareness of ASERNIP-S, and followed this up by providing information on ASERNIP-S.

Peer-reviewed Publications

ASERNIP-S has published on several of its procedure assessments in 2000, all in nationally or internationally recognised peer-reviewed journals.

- 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.
- 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.
- 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.

ASERNIP-S has also contributed to two other publications:

- EU Hernia Trialists Collaboration. Mesh compared with non-mesh methods of open groin hernia repair - systematic review of randomised controlled trials. *British Journal of Surgery*, 2000; 87: 854-859.
- 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.

Currently, ASERNIP-S has four articles that have been accepted for publication and will appear in a peer-reviewed journal in 2001.

- Babidge WJ, Maddern GJ. Evidence-based surgery at ASERNIP-S. Can this improve quality in surgical practice? *Journal of Quality in Clinical Practice*, 2001. (In Press)
- 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. (In Press)
- Cooter R, Chapman A, Babidge W, Robinson D, Mutimer K, Wickham P, Kiroff G , Maddern G. Review of ultrasound-assisted lipoplasty: safety and effectiveness. *Australian and New Zealand Journal of Surgery*, 2001. (In Press)
- Maddern G. Evidence based medicine in practice - surgical. *Medical Journal of Australia*, 2001. (In Press)
- Stirling GR, Babidge WJ, Peacock MJ, Smith JA, Matar KS, Snell G, Colville DJ, Maddern GJ. Lung volume reduction surgery in emphysema: a systematic review. *Annals of Thoracic Surgery*, 2001. (In Press)

At this stage ASERNIP-S has also submitted two manuscripts to peer-reviewed journals for consideration.

- Chapman A, Levitt M, Hewitt P, Woods R, Sheiner H, Maddern GJ. Laparoscopic-assisted resection of colorectal malignancies: a systematic review.
- Scott NA, Bidstrup BP, Knight JL, Wolfenden H, Linacre RN, Maddern GJ. OPCAB with the aid of tissue stabilizers.

Other Publications

Information on ASERNIP-S has also been published in other fora:

- ASERNIP-S: The Australian Safety and Efficacy Register of New Interventional Procedures - Surgical. *Better Health Outcomes*. The Commonwealth Department of Health and Aged Care newsletter, Autumn 2000; 6(1): 10-12.
- ASERNIP-S update. *Surgical News*, November-December 2000; 1(10):9.
- 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.
- ASERNIP-S update: systematic review of new surgical procedures. *Better Health Outcomes*. The Commonwealth Department of Health and Aged Care newsletter, Winter 2000; 6(2): 7-8.
- ASERNIP-S. What is it? *Surgical News*, March 2000; 1(1): 4.
- 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; number 1.
- Maddern GJ, Babidge WJ. Improving quality in surgery. *The Australian Health Consumer*. The Consumers' Health Forum of Australia newsletter, Spring 2000; (3): 9-10.
- New reviews released by ASERNIP-S. *Surgical News*, April 2000; 1(3):14.
- New reviews released by ASERNIP-S. *Surgical News*, July 2000; 1(6):2.
- Sweet M. Second opinion on surgery. *The Bulletin*, January 11, 2000. [Article based on an interview with Professor Guy Maddern, concerning ASERNIP-S.]

Presentations

ASERNIP-S publicises and disseminates its findings at various health technology assessment conferences and through the College of Surgeons' Annual Scientific Congress. Presentations made this year include:

- ASERNIP-S poster display at the 2000 Royal Australasian College of Surgeons' Annual Scientific Congress, Melbourne, May 2000.
- Babidge WJ, Maddern GJ. Health technology assessment - safety and effectiveness of new surgical procedures. ISTAHC's 16th Annual Meeting. The Hague, Netherlands 18 - 21 June 2000.
- Babidge WJ, Maddern GJ, Merlin TL. Developing an evidence-based approach for surgery: lessons learned. Centre for Statistics in Medicine 3rd Symposium. Systematic Reviews: Beyond the Basics - Improving Quality and Impact. Oxford, United Kingdom, July 2000.
- Boult M, Babidge WJ, Maddern GJ. ASERNIP-S audit report: endoluminal repair of abdominal aortic aneurysms. 10th Anniversary Meeting, International Endovascular Symposium. Sydney, Australia, December 7-9, 2000.
- Boult M, Babidge W, Maddern GJ. Developing an Australian audit to examine the safety and efficacy of endoluminal grafts for the repair of abdominal aortic aneurysms. AHR-DMA Health Research in the 21st Century: Meeting the Global Challenge. Auckland, New Zealand, July 2000.
- Chapman A, Kiroff G, Game P, Ham J, Foster B, O'Brien P, Maddern G. A systematic literature review of laparoscopic adjustable gastric banding. The Surgical Research Society of Australasia Annual Scientific Meeting. Adelaide, August 10-11, 2000.
- Faulkner K, Maddern GJ, Irving M, Silagy C, Jackson B, Reeve T, Solomon M. Surgical technology assessment - can it save lives? Plenary session at the 2000 Royal Australasian College of Surgeons Annual Scientific Congress, Melbourne, May 2000.
- Maddern GJ. ASERNIP-S assessment in Australia. Vellore Christian Medical College Golden Jubilee, Vellore, India, August 2000.
- Maddern GJ. ASERNIP-S: the Australian experience in assessing new technology. Surgical Grand Round. Memorial Sloan Kettering Cancer Centre, New York, USA, 21 March 2000.
- Maddern GJ. ASERNIP-S: what is it? Flinders Medical Centre Grand Round Series, Adelaide, South Australia, 26th October 2000.
- Maddern GJ. Assessment of new technology: ASERNIP-S. United Medical Protection Sentinel Program. Sydney, Australia, 11 April 2000.
- Maddern GJ. The AHPBA perspective on adult living related liver transplantation. Transplant Society of Australia and New Zealand Meeting. Canberra, Australia, 11 April 2000.
- Maddern GJ. The safety and efficacy of new interventional procedures - surgical. Australian and New Zealand College of Anaesthetists, Melbourne, May 2000.
- Maddern GJ, Babidge WJ. Health technology assessment in surgery - a new initiative in Australia. ISTAHC's 16th Annual Meeting, The Hague, Netherlands 18 - 21 June 2000.
- Maddern GJ, Babidge WJ, Boult M. Always expect the unexpected - horizon scanning of surgical procedures, the Australian experience. ISTAHC's 16th Annual Meeting. The Hague, Netherlands 18 - 21 June 2000.
- Merlin T, Maddern G, Walsh D. Developing clinical practice guidelines for new surgical techniques: beginning with the ABBI. Poster presentation. ISTAHC's 16th Annual Meeting, The Hague, Netherlands 18 - 21 June 2000.

ASERNIP-S Web Site

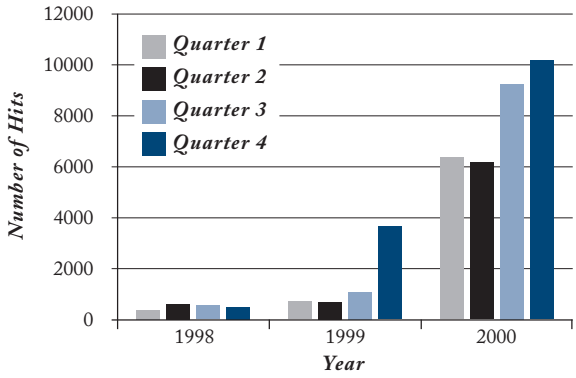
The ASERNIP-S web site address is http://www.surgeons.org/open/asernip-s.htm.

The web site is regularly updated and includes information on project activities, the ASERNIP-S review process, procedures that are currently being assessed, recent and forthcoming presentations, and contact details for the ASERNIP-S staff. ASERNIP-S publications are also available for download from the site. This includes the procedure assessment reports and re-appraisals, the

ASERNIP-S brochure, and Annual Reports. Data collection forms for the Endoluminal Audit are available for download, as is the New Procedure Nomination form. Data can also be submitted by registered users to the laparoscopic live donor nephrectomy, minimally invasive parathyroidectomy, and endoluminal audit databases through the web site.

ASERNIP-S has been monitoring its web hits on a regular basis. As can be seen from the graph below, visits to the ASERNIP-S web site have increased each year that ASERNIP-S has been in operation. In 2000 the number of hits increased exponentially, possibly due to the greater awareness of ASERNIP-S generated through the Survey, presentations and the publication of articles based on our procedure assessments. The mid-year release of two new procedure assessments, three re-appraisals and one set of clinical practice guidelines, and release of one new assessment and a re-appraisal in November of this year appears to coincide with the third and fourth quarter increase in web hits in 2000. In both of these quarters, the most popular pages on the web site were the publications download page (19% of total page requests) and the page detailing procedures that have or are currently being assessed (a further 19% of total page requests).

Web Site Hits per Quarter



Web links with a number of relevant professional associations were established in February 2000. ASERNIP-S has been accepted and listed as a recommended site with the following important organisations:

- National Horizon Scanning Centre (University of Birmingham UK)
- Australian Health Online
- Health Insurance Commission of Australia
- Australian Health Outcomes Collaboration
- Monash University Centre for Clinical Effectiveness
- Australasian Cochrane Centre
- Canadian Coordinating Office for Health Technology Assessment (CCOHTA)
- ScHARR School of Health and Related Research (Sheffield UK)

Further initiatives in establishing web links with other international organisations are ongoing.

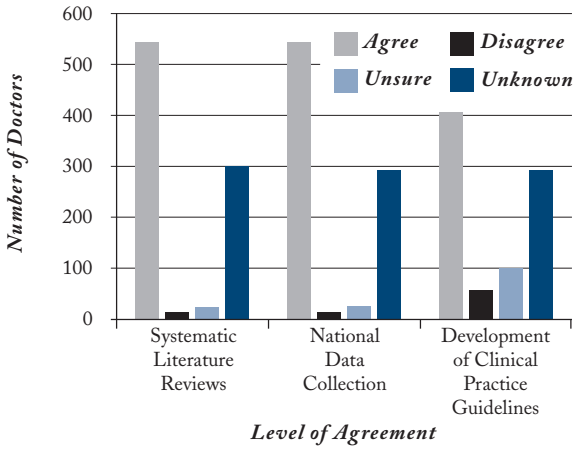
ASERNIP-S Awareness Survey

In March, all active Fellows (3,875) of the Royal Australasian College of Surgeons (RACS) were sent a survey regarding their awareness of the ASERNIP-S Project. The response rate was low, but of those responding, approximately 65% were aware of ASERNIP-S. Familiarity with ASERNIP-S was primarily acquired though the RACS Bulletin, the Annual Scientific Congress and the Sections/Divisions/Societies of the College.

Of those responding, 20% of surgeons expressed an interest in becoming involved in an ASERNIP-S Review Group. These surgeons have therefore been added to a database that ASERNIP-S will source when recruiting surgeons for Review Group roles. A further 29% of surgeons were unsure about their involvement, and have therefore been provided with information outlining the ASERNIP-S Review Group Membership and Roles.

The proportion of surgeons that believed ASERNIP-S should continue in its current roles is indicated in the figure below.

Should ASERNIP-S Continue in its Current Roles?



Education and Training

ASERNIP-S continued its educational role by presenting a Plenary Session entitled 'Surgical Technology Assessment - Can it save lives?' at the Annual Scientific Congress of the Royal Australasian College of Surgeons on 9th May 2000.

Two fourth-year medical students from the University of Adelaide - with which ASERNIP-S is affiliated - approached ASERNIP-S in November to take part in the research elective that we offer. They will be trained in the process of systematic reviewing and will complete a procedure assessment report on a new surgical procedure in 2001. A further student will perform scoping literature searches and prepare reports on a number of new and emerging surgical procedures in the horizon scanning database.

ASERNIP-S employed a trainee from the State Government Youth Training Scheme as an administrative assistant during 2000. The trainee was successful in finding full-time employment at the completion of her traineeship.

Participation in an ASERNIP-S Review Group or to an ASERNIP-S audit remains an accredited Continuing Medical Education activity.

External Evaluation

The Commonwealth Department of Health and Aged Care required that the ASERNIP-S pilot project be subject to external evaluation as a condition of granting funds. Healthcare Management Advisors (HMA) were formally appointed in June 1998 as the project evaluators for the ASERNIP-S project. Contact between HMA and ASERNIP-S staff occurred on a regular basis over the pilot phase. This culminated in a final evaluation report on ASERNIP-S which was provided to the Commonwealth Department of Health and Aged Care in July 2000 as part of the ASERNIP-S 5th Progress Report. The conclusions of the report are as follows:

"The primary aim of the ASERNIP-S pilot project, and therefore the evaluation, was to assess the extent to which the establishment of a mechanism for assessing new surgical technologies is appropriate for Australia and whether or not the initiative should continue.

The evaluation has demonstrated that:

- *Assessment of new technologies is well established internationally;*
- *The methodology developed by ASERNIP-S for the assessment is consistent with the approach (s) used by other organisations undertaking technology assessment;*
- *The ASERNIP-S initiative has been well accepted by the profession;*
- *The assessments have produced high quality final reports that have been well accepted professionally; and*
- *Assessments have been achieved on a reasonably cost effective basis – particularly when compared to the cost of a single procedure.*

We believe that the evaluation has identified sufficient evidence to conclude that each of the objectives of the pilot project has been achieved and that the ongoing desire to continually enhance health care in this country warrants further continuation of the initiative. Furthermore, the pilot project has demonstrated that it is possible to establish an independent and sound basis for assessing new procedures entering the Australian surgical field."

Membership of INAHTA

ASERNIP-S was accepted for membership in the International Network of Agencies for Health Technology Assessment (INAHTA) in 2000. This enables attendance at the annual INAHTA meeting, with the concomitant opportunity to undertake global networking and exchange of review information and documentation. Abstracts of reviews from all INAHTA agencies are available from INAHTA and the Health Technology Assessment (HTA) database - housed at the National Health Service's Centre for Reviews and Dissemination (NHS-CRD, York, UK) and disseminated as part of the Cochrane Library. INAHTA was established in 1993 and has now grown to 34 member agencies in 17 countries.

Membership is only open to organisations that:

- Assess technology in health care
- Are non-profit organisations
- Relate to a regional or national government
- Have at least 50% of their funding provided by public sources.

The Network stretches from the USA, Canada and South America to Europe, Australia, and New Zealand. The Secretariat is currently located in Sweden.

Personnel

The roles of administrative officer and assistant at ASERNIP-S have had a large degree of staff turnover in 2000. In January of this year, Fiona Wakelin and Daniela De Nichilo resigned from ASERNIP-S. Ms Robyn Leach was appointed as the administrative officer and undertook the role for six months. She was assisted by Mrs Thao Ngo - a trainee from the State Government Youth Training Scheme. On completion of her traineeship, Thao went on to a full-time position at another organisation. Ms Jane Silbereisen was appointed as a project officer in August. She was responsible for the administrative duties of the project for the remainder of 2000. Mrs Rosemary Wong was recruited in November to assist Jane with the administration of the project. However, in December 2000 recruitment of full-time administrative support was begun to enable Jane to concentrate on other aspects of the project.

Mrs Tracy Merlin returned from seven weeks maternity leave in February, whilst Dr Wendy Babidge began four months maternity leave in October.

Our current level of staffing is:

Name	Position	FTE
Professor Guy Maddern	Surgical Director	10-15 hrs/wk
Dr Wendy Babidge	Research and Administrative Manager	1 FTE
Mrs Maggi Boult	Data Manager	0.7 FTE
Mrs Tracy Merlin	Researcher	0.6 FTE
Dr Ann Scott	Researcher	1 FTE
Mr Andrew Chapman	Researcher	1 FTE
Ms Jane Silbereisen	Project Officer	0.8 FTE
Mrs Rosemary Wong	Administrative Assistant	0.6 FTE

ASERNIP-S Management Committee

The purpose of the Management Committee is to act as the decision making body for direction and support of the ASERNIP-S project. The committee is responsible to the Council of the Royal Australasian College of Surgeons (RACS) for overseeing the management of the ASERNIP-S project and associated activities.

During the latter part of 2000, Mr Brian Johnston was welcomed to the ASERNIP-S Management Committee as the representative of The Australian Council on Healthcare Standards (ACHS). He is their newly appointed Chief Executive Officer, and replaces Mr Dennis Smith who resigned from this position.

The members of the Management Committee have extensive experience in their chosen professions, which directly relate to the aims of the project. Their names and positions are as follows:

Mr Kingsley Faulkner FRACS	Chairman
Professor Guy Maddern FRACS	Project Surgical Director
Mr Bruce Barraclough FRACS	RACS President
Dr Vin Massaro	RACS Chief Executive
A/Professor David Scott FRACS	RACS Executive Director for Surgical Affairs
Mr David Robinson FRACS	RACS Fellow
A/Professor Rosemary Roberts	National Centre for Classification in Health
Professor Chris Silagy	Australasian Cochrane Centre
Mr Brian Johnston	Australian Council on Healthcare Standards
Ms Wendy Brown	Consumers Health Forum

ASERNIP-S STAFF PROFILES

Professor Guy Maddern
Surgical Director

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 the RP Jepson Professor of Surgery at the University of Adelaide and is a practicing hepatobiliary surgeon based at The Queen Elizabeth Hospital. Professor Maddern is also the Head of the Division of Surgery and Director of the Clinical Development Research Centre at The Queen Elizabeth Hospital.

Dr Wendy Babidge
Research and Administrative Manager

Dr Wendy Babidge is responsible for the management of the ASERNIP-S project and the supervision of administrative and research staff. She has been closely involved in the initial assessment of a number of procedures, including: Minimally Invasive Parathyroidectomy, Lung Volume Reduction Surgery and Ultrasound-Assisted Lipoplasty. Her expertise has been particularly directed toward the development of unique assessment methodologies for surgical procedures.

Dr Babidge is a Research Scientist and has a degree in Applied Science, with Honours in Biotechnology, and a PhD from the University of Adelaide. She completed a Graduate Diploma in Business in 2000.

Mrs Maggi Boult
Data Manager

Maggi Boult began research work at ASERNIP-S in September 1998 and has been involved in reviews of Percutaneous Endoscopic Laser Discectomy and Arthroscopic Subacromial Decompression using the Holmium:YAG laser. She has developed databases for the Laparoscopic Live Donor Nephrectomy and Minimally Invasive Parathyroidectomy audits, and is currently involved with data management for the Endoluminal Repair of Abdominal Aortic Aneurysm Pilot Project.

Maggi has an Honours Degree in Plant Science, a Graduate Diploma in Information Studies and a Diploma in Computer Programming. She has worked extensively in a diverse range of scientific environments and has written a wide range of computer applications and databases for commercial and scientific use.

Mr Andrew Chapman
Researcher

Andrew Chapman joined ASERNIP-S in July 1999. He has since completed two procedure assessments: Laparoscopic-Assisted Resection of Colorectal Malignancies, and Laparoscopic Adjustable Gastric Banding in the treatment of Obesity. He has completed a re-appraisal of Ultrasound-assisted Lipoplasty and is currently assessing Dynamic Graciloplasty. He is also coordinating the Australian arm of the Lipoplasty Effectiveness and Patient Safety Study being conducted by the American Society of Plastic and Reconstructive Surgeons.

Previously Andrew conducted research for the Disability Services Office of the South Australian Health Commission and also as a private consultant. Andrew has an Honours degree in Psychology from the University of Adelaide and a Graduate Diploma in Psychological Practice from the University of South Australia.




Mrs Tracy Merlin
Researcher

Tracy Merlin joined ASERNIP-S on a part-time basis at the project's inception. She has since completed the assessment and re-appraisal of Laparoscopic Live Donor Nephrectomy, along with the assessment of Tension-free Urethropexy for Stress Urinary Incontinence. She has coordinated the development and evaluation of clinical practice guidelines for the Advanced Breast Biopsy Instrument (ABBI) and is currently assessing the safety and efficacy of Methods for Establishing Laparoscopic Pneumoperitoneum. This last project will also be her dissertation for her Masters Degree in Public Health.

Tracy brought to her position an Honours degree in Psychology and eight years of research experience with the University of Adelaide in the fields of Aboriginal health, international health, epidemiology and medical education. She recently completed the coursework associated with her Masters Degree, specialising in various aspects of epidemiology and biostatistics. Tracy has a strong interest in critical appraisal techniques, meta-analysis and systematic review methodologies.

Dr Ann Scott
Researcher

Ann Scott joined ASERNIP-S in July 1999 on a full-time basis. She has completed an assessment and re-appraisal of Minimally Invasive Techniques for the Relief of Bladder Outflow Obstruction, and has assessed Off-Pump Coronary Artery Bypass Surgery with the Aid of Tissue Stabilizers. She is currently re-appraising Minimally Invasive Parathyroidectomy and has begun assessing Endoscopic Modified Lothrop Procedure for Chronic Frontal Sinusitis.

Ann has a Degree in Science, majoring in Zoology and Biochemistry, with Honours in Zoology. She also obtained a PhD from the University of NSW for her research on developmental endocrinology in marsupials and has recently completed a Graduate Diploma in Business Management.

Ms Jane Silbereisen
Project Officer

Jane Silbereisen joined ASERNIP-S as a Project Officer in August 2000. As Project Officer, Jane provides assistance with the general administration of the project, supporting systematic reviews and the Endoluminal Repair of Aortic Aneurysm Audit. She is also intimately involved in the NET-S Horizon Scanning Project and managing the ASERNIP-S web site.

Jane has a Bachelor of Arts Degree, is undertaking a Diploma in International Development, and has training in database programming. She has had extensive experience in the development of databases, promotional materials and publications in the health and law fields.

Mrs Rosemary Wong
Administrative Assistant

Rosemary Wong began at ASERNIP-S on a part-time basis in November 2000. She is responsible for providing general clerical support to ASERNIP-S staff, and also fulfills the role of receptionist. Rosemary assists with the day-to-day administrative functioning of ASERNIP-S and has been responsible for entering data on the Endoluminal Audit database.

Rosemary came to ASERNIP-S with diverse administrative experience in a wide variety of workplaces. She has a particular interest in health promotion and has spent a number of years at the Drug and Alcohol Services Council as a receptionist/clerical officer in the Education Unit. She has a Certificate in Secretarial Studies and a Certificate II in Business (Office Administration).




APPENDIX I

ASERNIP-S Safety and Efficacy Classifications

Reviewed procedures are classified into one of the following safety and efficacy categories, and recommendations regarding further research are also determined.

Safety & Efficacy Assessment

1. Safety and efficacy is established. The procedure is equal to, or better than, the best practice based on the current available evidence. Procedure may be introduced into practice.
2. The safety and/or efficacy of the procedure cannot be determined at the present time due to an incomplete and/or poor quality evidence-base. It is recommended that further research be conducted to establish safety and/or efficacy.
3. Safety and/or efficacy of procedure is shown to be unsatisfactory. Procedure should not be used.

Recommendations Regarding The Need For Further Research

In order to strengthen the evidence base regarding the procedure it is 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.

APPENDIX II

Systematic literature reviews have been completed on the following ten procedures:

ASERNIP-S Report no. 1
Minimally Invasive Parathyroidectomy

ASERNIP-S Report no. 2
Lung Volume Reduction Surgery [Re-appraised]

ASERNIP-S Report no. 3
Laparoscopic Live Donor Nephrectomy [Re-appraised]

ASERNIP-S Report no. 4
Ultrasound-Assisted Lipoplasty [Re-appraised]

ASERNIP-S Report no. 5
Percutaneous Endoscopic Laser Discectomy [Re-appraised]

ASERNIP-S Report no. 6
Arthroscopic Subacromial Decompression using the Holmium:YAG laser [Re-appraised]

ASERNIP-S Report no. 7
Minimally Invasive Techniques for the Relief of Bladder Outflow Obstruction [Re-Appraised]

ASERNIP-S Report no. 8
Laparoscopic-assisted Resection of Colorectal Malignancies

ASERNIP-S Report no. 9
Laparoscopic Adjustable Gastric Banding in the Treatment of Obesity

ASERNIP-S Report no.10
Off-Pump Coronary Bypass Surgery with the Aid of Tissue Stabilizers

Clinical Practice Guidelines have been developed for one procedure:

ASERNIP-S CPG Report no.1 Clinical Practice Guidelines for the Advanced Breast Biopsy Instrument

Acknowledgments

ASERNIP-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 office. The continuing participation in Procedure Review Groups and the 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.

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Medtronic Australasia

Michael Kluvanek


ASERNIP-S