

Australian
Safety
and Efficacy
Register
of New
Interventional
Procedures-
Surgical

ASERNIP/S



Annual Report

1999



ASERNIP-S was conceived, funded and designed because it was recognised that such a mechanism was needed for ongoing patient safety and effective use of resources.

ASERNIP'S



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Chairman's Report



ASERNIP-S HAS NOW BEEN IN OPERATION FOR ALMOST TWO YEARS WITH ONE YEAR REMAINING IN THE PILOT PROJECT PHASE. IT HAS A WELL-ESTABLISHED OFFICE, WITH AN ACCOMPLISHED RESEARCH AND ADMINISTRATIVE STAFF UNDER THE DIRECTION OF GUY MADDERN.

The methodology for assessing new technologies in surgery has been modified, with experience placing more of the onus for the review on the professional research staff, but still relying heavily on the participating surgeons for overall surveillance of the assessments. The classification system for procedure assessment, which was initially adopted from the UK model, has also been refined with experience. The Management Committee is confident that these changes will allow greater flexibility and usefulness of the classifications.

The assessment of seven procedures has now been completed, with the last three still requiring ratification by the Royal Australasian College of Surgeons Council. Another five are in the pipeline and several others are in the preliminary phase of review.

ASERNIP-S has recently been asked by MSAC (Medicare Services Advisory Council) to carry out an audit on Endovascular Abdominal Aortic Aneurysm Surgery for which an additional budget has been allocated. Strong cooperation from the Vascular Surgery Division of the Royal Australasian College of Surgeons, and its members will be necessary for the design and data accumulation necessary for the audit.

Financially, ASERNIP-S is on target. It will deliver its contractual obligations on time and within budget. An independent evaluation of the structure, functions and efficiency of the project is being conducted by Healthcare Management Advisors Pty Ltd and their report will be tabled by June 2000.

Abridged versions of the assessment reports completed so far have been placed on the internet and are creating considerable interest. ASERNIP-S has become widely known amongst the surgical community and is gaining recognition by government health agencies, hospitals, other institutions and individuals involved in health care.

ASERNIP-S was conceived, funded and designed because it was recognised that such a mechanism was needed for ongoing patient safety and effective use of resources. That need will continue, and, with major technological advances in surgery showing no sign of abating, it will increase.

A handwritten signature in black ink, appearing to read 'Kingsley Faulkner', with a horizontal line underneath.

KINGSLEY FAULKNER
CHAIRMAN
ASERNIP-S MANAGEMENT COMMITTEE

Surgical Director's Report

THE PAST TWELVE MONTHS HAVE BEEN ASSOCIATED WITH CONSIDERABLE PROGRESS WITHIN THE **ASERNIP-S** PROJECT. DURING THIS TIME, TWO ADDITIONAL FULL-TIME STAFF HAVE BEEN EMPLOYED, SEVEN REPORTS COMPLETED, ONE SET OF CLINICAL PRACTICE GUIDELINES HAS BEEN PREPARED AND THREE DATABASES CONSTRUCTED OR FACILITATED.



The ASERNIP-S project is a pilot project which is due to be evaluated in the middle of 2000, with ongoing funding to be discussed with the Commonwealth Government towards the end of next year. Already there has been a large amount of surgeon involvement and considerable interest and enthusiasm from the surgical community, with strong support from the College Council. Associated with this substantial progress within the College, there have been ongoing indications from the Commonwealth Government that the project is being seen as a valuable initiative from the College of Surgeons.

Considerable interest has also been expressed internationally in our process, from North America and the UK and, indeed, it would appear that the UK surveillance of new surgical technologies may be modelling itself more along the lines of the ASERNIP-S project.

A new initiative for the forthcoming twelve months will be the introduction of a horizon scanning technique for detection of new and emerging technologies before they even reach the peer reviewed literature. This approach requires some further refinement but there will be direct contact with the Fellows of the College over the next few months to enlist their support in providing data and information about these technologies, which are still in their infancy. An appropriate early warning system for such technologies will enable ASERNIP-S to respond in a more timely fashion than is possible at present, relying on published literature alone.

If the future of ASERNIP-S is to be judged on the quality of the outputs and the energy and enthusiasm of the staff, there can be no doubt that it deserves ongoing support. However, perhaps a more objective measure will be seen in the enthusiasm for international peer reviewed journals to take on our reports and publish them as important contributions to the scientific literature.

Nineteen-ninety-nine sees the conclusion of the second year of the ASERNIP-S project, and we look forward as an organisation to being able to report ongoing success for this initiative at the conclusion of our third year.

A handwritten signature in dark ink, which appears to read "Guy Maddern". The signature is fluid and cursive.

GUY MADDERN
SURGICAL DIRECTOR



Introduction

THE ROYAL AUSTRALASIAN COLLEGE OF SURGEONS AUSTRALIAN SAFETY AND EFFICACY REGISTER OF NEW INTERVENTIONAL PROCEDURES – SURGICAL (ASERNIP-S) PROJECT HAS NOW BEEN OPERATIONAL FOR TWO YEARS.

Procedure Assessments

ASERNIP-S has now completed four procedure assessments:

- Minimally Invasive Parathyroidectomy
- Lung Volume Reduction Surgery
- Laparoscopic Live Donor Nephrectomy
- Ultrasound-assisted Lipoplasty

Three further assessments have been completed and await consideration by the Council of the Royal Australasian College of Surgeons:

- Percutaneous Endoscopic Laser Discectomy
- Arthroscopic Subacromial Decompression using the Holmium:YAG Laser
- Minimally Invasive Techniques for Relief of Bladder Outflow Obstruction

It is anticipated that reports will be released into the public domain by March 2000. Other assessments currently underway include:

- Laparoscopic-assisted Resection of Colorectal Malignancies
- Intravaginal Slingplasty for Urinary Incontinence

New assessments are being commenced as the resources of ASERNIP-S are freed by the completion of current reviews. These include:

- Off-Pump Coronary Artery Bypass Surgery with the Aid of Tissue Stabilisers
- Endoscopic Modified Lothrop procedure for Chronic Frontal Sinusitis
- Laparoscopic Gastric Banding

Other activities undertaken by the ASERNIP-S project include the development of clinical practice guidelines for the Advanced Breast Biopsy Instrumentation (ABBI) System. Mr David Walsh has prepared the guidelines and a Review Group set up to assess these.

Minimally Invasive Parathyroidectomy

Bilateral open neck exploration has been considered the 'gold standard' treatment since 1925. The procedure involves the removal of diseased parathyroid gland(s) following identification of all four glands. Surgical failure occurs if a gland is ectopic, in undetected multiglandular disease, when supernumerary glands are present, or due to lack of surgical experience. However, the success rate for this procedure in the hands of an experienced surgeon is over 95%.



Despite the success of the bilateral operation, there has been a push towards a more limited and focussed surgical exploration. A unilateral approach was first put forward by Tibblin in 1982, whereby one side of the neck was explored first and if a diseased gland was found, the other side of the neck was not explored. This approach may result in failure to detect multiglandular disease.

As around 80% of diseased glands are single adenomas, the idea of unilateral surgery has been considered an option. In an attempt to identify the diseased gland(s) prior to surgery a variety of imaging procedures, particularly ultrasound and isotope scanning have been applied. These procedures have been used in the past prior to re-operation but have now reached a level of

accuracy to enable focused unilateral surgery. There is a possibility of missing double adenomas or hyperplasia, so the new minimally invasive techniques have combined preoperative imaging with other procedures to improve their reliability. Intraoperative scanning with a handheld probe following administration of technetium-sestamibi has been shown to be effective. Another method is a rapid intraoperative measurement of parathyroid hormone to establish successful removal of the diseased gland.

Endoscopic procedures, either total or assisted, have also been developed for this type of surgery. A space in the neck is created by using CO₂ gas or a mechanical lift device. The suggested advantage of the endoscopic approach is a magnified field of vision; however blood staining can impair this view.

The efficacy of minimally invasive parathyroidectomy results from accurate localisation of diseased glands and careful patient selection. It is also important that it is performed by a surgeon experienced in endocrine surgery. If these guidelines are followed, the minimally invasive approach should achieve similar success as that found for bilateral open neck exploration.

The systematic literature search conducted for this review retrieved 42 articles relating to minimally invasive parathyroid surgery techniques in primary hyperparathyroidism, 32 of which related to the unilateral technique. Of these, only 10 were comparative studies, that is, level III evidence or higher. Safety issues from these studies indicated no cases of mortality; the most common adverse event was transient hypocalcaemia, and transient vocal cord injury was reported in a few cases. The surgical success rates were between 92% and 100%, and in most aspects, the unilateral approach appeared to be at least as safe and effective as the bilateral procedure. Endoscopic studies also reported no mortality. Adverse outcomes such as subcutaneous emphysema, hypercarbia and pneumomediastinum were generally transient. They resulted from high insufflation pressures and lengthy operating times using the totally

endoscopic technique, which attempted to visualise all four glands. A video-assisted approach and focussing on removal of solitary adenomas (using a short period of insufflation) did not suffer the same complications.

In both the endoscopic and unilateral procedures, damage to the laryngeal nerve is a possibility. Parathyromatosis can result from rupture of an adenoma when removed through a small incision or port. In all minimally invasive procedures, the major benefit appears to be improved cosmesis and some studies have reported decreased pain and discomfort to patients. Length of hospital stay and operative times are reported to be less for unilateral surgery; however, whether this improved efficacy is clinically significant is yet to be proven. These benefits would result in decreased costs, but these savings would generally be offset by the additional costs of imaging and/or intraoperative parathyroid hormone measurement.

The Royal Australasian College of Surgeons has endorsed the recommendations by ASERNIP-S on this procedure. The Section of Endocrine Surgery has added the caveat that these minimally invasive procedures should only be undertaken in the setting of a controlled clinical trial. As a result of such studies, the most safe and efficacious minimally invasive procedure will be determined from the myriad of

procedures currently available. ASERNIP-S will receive safety and efficacy data from these studies so that local experience can guide the introduction of this new technique into clinical practice in Australia.

The ASERNIP-S procedure classification is:

2.2 The safety and/or efficacy of the procedure cannot be determined due to an incomplete and/or poor evidence-base. A controlled clinical trial, preferably prospective with concurrent controls is required
(to assess both safety and efficacy).

Members of the Minimally Invasive Parathyroidectomy Review Group:

Review Surgeon	Professor Thomas Reeve
Protocol Surgeon	Mr Robert Parkyn
Nominated Surgeon	Mr Anthony Edis
Invited Surgeon	Professor Leigh Delbridge
Other Specialty Surgeon	Associate Professor Peter Devitt
ASERNIP-S Researcher	Dr Wendy Babidge
Chairman	Professor Guy Maddern

Lung Volume Reduction Surgery

During the early part of this century a number of surgical procedures were used in an attempt to palliate the dyspnoea of severe emphysema, however most of these were unsuccessful and carried a high risk of mortality. Emphysema is usually a heterogeneous process. In the 1950s, Brantigan introduced the notion of resecting bullae in bullous emphysema to improve the function of the remaining lung. In the early 1990s Cooper resurrected and modified Brantigan's approach, which is now recognised as a useful treatment for diffuse emphysema. The hypothesis was that removal of the most seriously damaged areas of hyperinflated lung, which are virtually functionless, would result in improvement in the function of the remaining lung and so lessen dyspnoea.

A variety of different approaches to this surgery have been proposed; median sternotomy, thoraco-sternotomy or with a video-assisted thoracoscopic (VATS) technique. There are both unilateral and bilateral approaches, with equivalent benefits being achieved using unilateral surgery in appropriately selected patients. The areas for surgical removal are identified prior to surgery by computed tomography and radionuclide ventilation-perfusion scanning. Methods for sealing the site of resected lung include the use of staples or a laser (Neodymium:YAG), however prolonged air leak is a common postoperative complication. Attempts to overcome this have been to use buttressing materials along the staple line, most commonly bovine pericardium, but collagen also has been suggested as a cheaper option.

Lung Volume Reduction Surgery is a procedure that requires appropriate selection of patients who have been suitably informed of the risks of this procedure. They are encouraged to participate in a pulmonary rehabilitation program both prior to and after surgery. For patients with end-stage emphysema medical

therapy in the form of pulmonary rehabilitation may be the only option. The patient selection criteria for LVRS are rigorous, involving both functional and radiological assessment. The number of patients who qualify for LVRS is a small percentage of those originally assessed. To date, few long-term studies have been performed up to two years post-surgery, with most series suffering from large losses to follow-up.



Literature up to and including September 1998 was included for review, and of the 70 articles retrieved on LVRS, only 13 were comparative studies. The studies were either Level II or Level III evidence; that is, randomised or non-randomised controlled trials. There was only one study, however, which compared LVRS with another method of treatment, that is, medical therapy. This study compared patients who were selected for but denied LVRS due to changes in government funding arrangements in the United States. Despite higher earlier mortality in the LVRS group, at three years improvement in pulmonary function was still apparent in the LVRS group and mortality was less than in those denied the procedure. Other studies compared the different LVRS procedures, and also variations on the procedures, such as staple versus laser, stapling with and without buttressing, and unilateral versus bilateral techniques. Pulmonary function parameters were used most commonly to indicate postoperative

improvements. Stapling appeared to provide greater improvement in the short-term, while buttressing of the staple line offered no clear improvement, also no significant differences were found between bovine pericardium or collagen. Mortality of the procedure is often significant; reports vary between 0% and 28%. The most common adverse outcome of LVRS is a prolonged air leak, occurring in about 50% of cases in several studies. Other complications, which generally occurred in less than 10% of cases, included pneumonia, delayed pneumothorax, respiratory failure and wound infection. Re-operation was also necessary in a small number of cases due to pleural space problems, including bleeding.

No one technique appears to be the most safe and efficacious for LVRS and the studies to date suffer from considerable loss to follow-up and insufficiently long follow-up periods. The reviewer suggests that both bilateral and unilateral LVRS using stapling-excision and median sternotomy in highly selected cases to be a safe and reasonably efficacious procedure for treatment of diffuse emphysema. Similar results have been obtained using VATS and stapling excision. Laser ablation by VATS, despite producing encouraging results in bullous emphysema, produced higher one-year mortality, frequent late pneumothorax and less functional improvement than stapling excision in diffuse emphysema. This procedure is not recommended as a safe and efficacious treatment for diffuse emphysema at this time.

Two large multi-centre trials have been set up in both America and Canada to assess surgical treatments of LVRS and compare them to medical management. Results from these studies are still a few years away. The Australian Lung Foundation

and Thoracic Society have established a national database on LVRS which collects data from about 12 sites currently performing LVRS in Australia. This database is being expanded to include more detail on patient selection and outcomes. It is anticipated that ASERNIP-S will collaborate with this group to help assess both the safety and efficacy of LVRS procedures in Australia.

The ASERNIP-S procedure classification is:

- 2.1 **The safety and/or efficacy of the procedure cannot be determined due to an incomplete and/or poor quality evidence-base. An audit is required** *(to assess both safety and efficacy).*

ASERNIP-S endorses the strict audit of Lung Volume Reduction Surgery by collaboration with the Alfred Hospital, Melbourne, which houses the Australian and New Zealand Lung Volume Reduction Surgery database. 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.

Members of the Lung Volume Reduction Surgery Review Group:

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

Laparoscopic Live Donor Nephrectomy

The aim of this review was to compare the safety and efficacy of laparoscopic live donor nephrectomy with the 'gold' standard of open live donor nephrectomy.

The new procedure of laparoscopic live donor nephrectomy is a refinement of the traditional open nephrectomy used for live donors.

Laparoscopic nephrectomy was first described by Clayman in 1990 and is practised for both benign and malignant disease by a few surgeons who

have developed expertise with laparoscopic techniques. Laparoscopic nephrectomy in the *live donor* is, however, more technically demanding as the kidney must be removed with careful dissection of the renal vessels and ureter so that it is suitable for immediate transplantation into the recipient.

Laparoscopic live donor nephrectomy is a procedure that is still evolving, with advocates

of both a transperitoneal approach using either pneumoperitoneum or retraction, and a retroperitoneal approach using retraction and a combination of laparoscopic and open instrumentation.

At the time of searching the literature (September 1998) there was a lack of published evidence on laparoscopic live-donor nephrectomy. It has only been five years since the procedure was first developed in the animal model and only four years since it was first conducted on humans. After extensive searches of the electronic medical

databases, only thirteen papers that met the inclusion criteria outlined in the review protocol were identified and retrieved.

High level evidence comparing the safety and efficacy of laparoscopic live-donor nephrectomy and open live-donor nephrectomy was not available. Limited level III-2 evidence (two non-randomised clinical trials with concurrent controls) suggested that laparoscopic live-donor nephrectomy may have advantages over open live-donor nephrectomy with regard to the donor's hospital stay, convalescence, pain, and return to usual activities. One of these studies indicated that there may be a protective effect for morbidity associated with laparoscopic live donor nephrectomy, although the 95% confidence interval included unity (R.R.=0.75, 95% C.I. [0.1, 5.7]). There was no reported mortality associated with either laparoscopic or open live donor nephrectomy in any of the studies reviewed.

The majority of publications used for this review have been from centres with a special interest, expertise, and enthusiasm in laparoscopic surgery. The poor depth and quality of this evidence suggests that caution should be exercised in developing recommendations for Australian transplant surgeons.

Recommendations from this review are as follows:

- Laparoscopic live donor nephrectomy should only be done in units where there are surgeons with considerable expertise in open live donor nephrectomy.
- 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.
- Laparoscopic live donor nephrectomy should be done initially in either a large animal or the technique used in a patient requiring nephrectomy for benign disease.



- Renal transplant units planning to undertake laparoscopic live donor nephrectomy 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.
- Surgeons should be alert to the literature on evolving techniques of laparoscopic nephrectomy. Of particular interest is the option to use an extraperitoneal approach compared to a transperitoneal approach.

A recommendation has been made for the cautious introduction of laparoscopic live donor nephrectomy where the above skills exist and where there is a commitment to do 10 – 20 cases per year in order to gain the necessary experience and report the results.

The ASERNIP-S procedure classification is:

2.2 The safety and/or efficacy of the procedure cannot be determined due to an incomplete and/or poor quality evidence-base. A Controlled Clinical Trial, preferably prospective with concurrent controls, is required (to assess safety and efficacy).

Members of the Laparoscopic Live Donor Nephrectomy Review Group:

Review Surgeon	Associate Professor David Scott
Protocol Surgeon	Mr Mohan Rao
Nominated Surgeons	Mr Darryl Wall, Mr David Francis
Other Specialty Surgeon	Mr Frank Bridgewater
ASERNIP-S Researcher	Mrs Tracy Merlin
Chairman	Professor Guy Maddern

Ultrasound-assisted Lipoplasty

The technique of liposuction began over twenty years ago as a 'dry' technique, to remove small areas of fat with a suction cannulae through small incisions. This has largely been replaced by 'wet', 'super-wet' or 'tumescent' techniques, which involve infiltration of large volumes of fluids to aid in fat dispersal and removal. An isotonic solution containing a low dose of adrenaline is infused into the site to be treated. This is the method used when employing the 'wet' or 'superwet' techniques and being performed under general anaesthesia. If using the 'tumescent' approach a much larger volume of infusate is used to create tissue turgor, and large



volumes of lignocaine are added for the purpose of local anaesthesia. The solutions should be used at room temperature. The 'tumescent' approach allows larger volume liposuction. Traditional liposuction, that is suction-assisted lipoplasty (SAL), has a low complication rate and high patient satisfaction rate.

The potential complications of SAL relating to anaesthesia are lignocaine toxicity from the infiltrating solution or hypovolaemic shock due to intravascular fluid shifts. Other complications relating to operator techniques may result in scarring, contour defects, haematomas, seromas, skin loss, paraesthesia or pain. Swelling, bruising,

impaired physical activity, infection and thrombus or fat embolism may also occur.

The method of ultrasound-assisted lipoplasty (UAL) involves the addition of ultrasound to liquefy the fat by cellular fragmentation. The resulting fatty emulsion is then removed with a suction cannula, either concurrently (using a hollow cannula) or after the application of ultrasound energy (using a solid probe followed by suction cannula). Ultrasonic energy must be applied in a 'wet' environment and UAL uses the 'tumescent' technique. The purported benefits of UAL include less overall tissue trauma, minimal blood loss, allowing removal of larger volumes of fat, being less physically demanding on the surgeon, less bruising for the patient, improved shaping, allowing removal of more fibrous tissue and spot-specific tissue removal. The disadvantages are that the equipment is more expensive, the procedure takes longer to perform, there is possibly higher seroma rates, a potential for fat necrosis and fibrosis, hyperpigmentation, sensory alteration, care must be taken to avoid skin burns and there is a longer learning curve than with SAL.

The long-term effects of the interaction of ultrasound energy with living tissue is an issue which has been raised about this technique. However, ultrasound has been used in the past for other surgical procedures such as phacoemulsion of cataracts, ultrasonic aspiration of intra-cranial tumours and other applications in liver and renal surgery. The mechanism by which the ultrasound technique works is that sound waves which are produced in the ultrasonic frequency range cause the formation of micro-cavities or bubbles in the adipose tissue. These bubbles reach a point where they implode, causing cell disruption. High levels of energy are generated in the form of heat and light, along with the liberation of free radicals and other chemicals. To reduce the risk from thermal injury, the infiltrating fluids are at room temperature.

Experience with this technique in Europe and the United States has generally been positive despite these concerns. A prospective multicentre study has begun in the United States collecting outcome data on 2,000 patients undergoing either SAL or UAL. Australian surgeons are being invited to participate in this study, which will be coordinated through ASERNIP-S.

The Review recommends that:

- UAL is not a replacement for SAL but should be used to complement it, particularly being usefully applied in areas that are more fibrous.
- As with any surgical procedure adequate training, experience and attention to detail are mandatory.
- Caution should be raised as to excessive applications of ultrasonic energy and endpoints should be well defined as to its use.
- Patients must be appropriately selected, that is, be in good health and close to their ideal weight, specifically using only in areas where diet and exercise have been unsuccessful in reducing the excess of fat. Patients should be clearly informed of any

potential risks for both the SAL and UAL techniques. The preoperative information should present the risks along with precautions taken to reduce these.

The ASERNIP-S procedure classification is:

- 2.1 **The safety and/or efficacy of the procedure cannot be determined due to an incomplete and/or poor quality evidence-base. An audit is required** *(to assess both safety and efficacy).*

The ASERNIP-S Review Group recommends that ultrasound-assisted lipoplasty should not be performed to contour female breast tissue.

Members of the Ultrasound-Assisted Lipoplasty Review Group:

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

Minimally Invasive Techniques for Relief of Bladder Outflow Obstruction

Benign prostatic hyperplasia (BPH) is the most common non-malignant tumour in the aging male population, to the extent that two out of ten males will eventually require an operation to relieve the symptoms of BPH. Bladder outflow obstruction (BOO) is a common sequela of BPH and, until the advent of transurethral resection of the prostate (TURP) in the 1930's, open prostatectomy was the only available treatment. Open prostatectomy is the most efficient and yet most invasive form of treatment for BPH. In contrast, TURP is less invasive, less costly and has a lower morbidity. Consequently, TURP has become the benchmark treatment for men with BOO, secondary to BPH. However, at least 15% to 20% of patients develop a significant complication following the TURP procedure and a second intervention is necessary in 10% to 15% of patients within ten years. The postoperative complications can include erectile dysfunction, retrograde ejaculation (in at least two thirds of patients), urinary incontinence, bladder neck contracture, urethral stricture, as well as intra- and postoperative haemorrhage that often necessitates transfusion. In addition, mortality rates of between 0.2% and 2.5% have been reported.

To combat this lack of improved safety outcomes, a plethora of less invasive surgical techniques have been developed but there is very little data concerning their efficacy, safety and durability. Thus, the aim of this review was to compare the safety, efficacy and cost effectiveness of laser prostatectomy, transurethral needle ablation (TUNA), transurethral microwave therapy (TUMT), transurethral electrovaporisation of the prostate (TUVP) and high intensity focused ultrasound (HIFU) against the current benchmark treatment, TURP.

Laser energy is used to remove obstructing prostatic tissue through tissue coagulation (temperatures 60-100°C), vaporisation

(temperatures exceeding 100°C) or a combination of both. Thus, laser prostatectomy can be achieved by either visual laser ablation of the prostate (VLAP), interstitial laser coagulation (ILC) or laser contact vaporisation (LCV). A systematic literature search, conducted to the end of 1998, identified 25 randomised controlled trials (RCT) but only 11 of these had a postoperative follow-up period longer than 12 months. The small number of patients studied and poor evidence quality of the RCT's meant that no definitive conclusion could be made regarding the safety and efficacy of VLAP, ILC or LCV in comparison to TURP. From the limited results available, VLAP appeared to offer a significant reduction in postoperative morbidity compared to TURP, particularly for major complications such as haemorrhage and transurethral resection (TUR) syndrome. However, VLAP caused a range of other postoperative complications including transient urinary retention, irritative symptoms and urinary tract infection (UTI). This was contrasted by a lower efficacy in terms of symptomatic improvement and prostate volume reduction and a higher re-operation rate, compared to TURP. VLAP also necessitated a hospital stay and postoperative catheterisation, albeit for a shorter time period than TURP, and required the same level of anaesthesia as for TURP. The current evidence suggests that safety favours VLAP whereas effectiveness favours TURP, but an audit of long-term results is required for this to be confirmed.

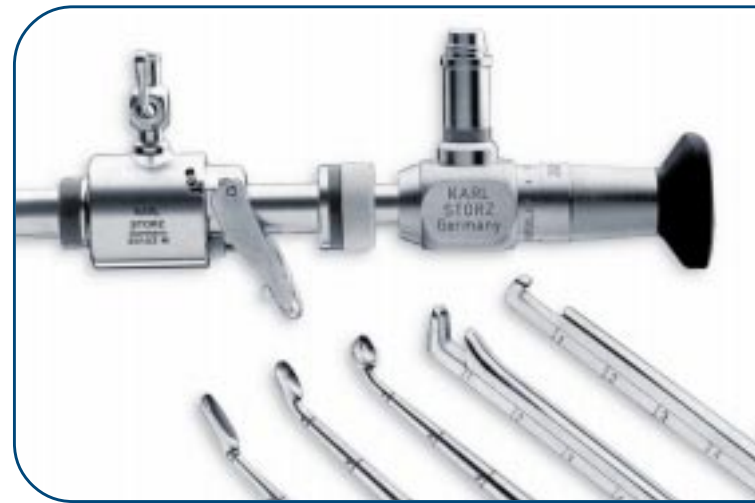
In the short-term, ILC appeared to approach the efficacy of TURP and was at least as effective as VLAP. However, a long post-operative catheterisation period was required and the re-operation rate for ILC was at least 10%. ILC is relatively safe and can be performed under local anaesthesia but the absence of long-term follow-up data makes it impossible to judge its treatment durability. Similarly, LCV may be as effective as TURP but the number of available studies is small and the long-term effectiveness of LCV is unknown.

TUMT involves the placement of a catheter, encapsulating a microwave antenna, in the urethra to deliver microwave energy to the prostate from a specially designed generator. Temperatures exceeding 45°C are generated in the prostate and this results in coagulative necrosis of the prostatic tissue. The systematic literature search identified 21 RCT's and 3 case series. Ten of the RCT's and one case series had a postoperative follow-up period longer than 12 months and their evidence quality was moderate. TUMT is a virtually bloodless operation that appeared to offer significant reduction in morbidity compared to TURP, particularly in terms of major complications and preservation of sexual function. In addition, TUMT could be performed on an outpatient basis under local anaesthesia or intravenous sedation. However, no significant change in prostate volume was achieved by TUMT and the mean re-operation rate was considerably higher than for TURP. TUMT also necessitated a lengthy postoperative catheterisation period and resulted in higher rates of UTI and urinary retention, compared to TURP. Although TUMT appears to be generally safer than TURP its durability cannot be adequately judged from the current data.

TUVP is a modification of TURP and utilises a specially designed electrode to vaporise the prostatic tissue with standard radio-frequency current. The systematic literature search identified 12 RCT's and 2 case series. Seven of the RCT's had a postoperative follow-up period longer than 12 months but the small number of patients studied hampered their value. TUVP conferred a safety benefit in terms of a significant reduction in major postoperative complications, such as TUR syndrome and haemorrhage, compared to TURP. However, the incidence of more minor complications, such as UTI and urinary retention, was similar for the two treatments. TUVP was no more effective than TURP in preserving sexual function and both procedures required general, spinal or epidural

anaesthesia. TUVP and TURP produced a similar degree of symptomatic improvement but hospital stay and duration of postoperative catheterisation was shorter following TUVP treatment. Thus, TUVP is similar to TURP in technique and short-term efficacy and offers a substantial reduction in overall morbidity compared to TURP. These results suggest that TUVP would be a suitable alternative to TURP for patient with smaller prostates.

TUNA uses low level radio-frequency energy, delivered directly to the prostatic tissue via a needle electrode, to achieve selective thermal



ablation of the parenchyma. The systematic literature search identified one RCT and 19 case series but only seven of the case series had a postoperative follow-up period longer than 12 months. The relatively small number of patients treated and the generally poor evidence quality of the literature meant that it was difficult to make any definitive decision regarding the efficacy and safety of TUNA. TUNA was generally performed on an outpatient basis with only local anaesthetic and/or supplemental intravenous sedation and offered a substantial benefit in terms of preservation of sexual function and the reduction of major complications, compared to TURP. However, a much lower symptomatic improvement and prostate volume reduction and

a higher mean re-operation rate following TUNA, in comparison to TURP offset these benefits. There are many unanswered questions regarding how TUNA achieves its outcomes and the potential contraindications of its use. Therefore, more rigorous studies must be undertaken before any reliable decision can be made regarding the safety and efficacy of TUNA.

HIFU achieves thermoablation of the prostatic tissue by focusing a beam of ultrasound waves at a selected depth in the prostate to produce a region of high energy density. The systematic literature search identified 13 case series but only four of these had a postoperative follow-up period longer than 12 months. No RCT's were available for HIFU. The poor evidence quality of the studies and the small number of patients treated meant that a valid determination of the safety, efficacy and durability of HIFU could not be made. The preliminary results suggested that HIFU was a relatively safe procedure with only minor postoperative complications that were generally self-limiting. The HIFU treatment is applied transrectally and this potentially reduces the risk of complications related to urethral instrumentation such as urethral stricture, cervical contracture and UTI. However, HIFU did not result in a significant reduction of prostate volume and it required the same level of anaesthesia as for TURP. The mean re-operation rate for HIFU ranged from 4% to 31%. Based on the current data it is impossible to assess whether HIFU offers meaningful symptomatic improvement for patients.

The development of laser prostatectomy, HIFU, TUMT, TUNA and TUVP for treating BOO is very recent. Consequently, the available information regarding the cost-effectiveness of these procedures was largely anecdotal. The value of the four studies that undertook a formal economic evaluation of TUMT and laser prostatectomy was limited by their very short follow-up period. From the current evidence it

appeared that TUVP and TUNA may offer a cost advantage compared with TURP while laser prostatectomy and TUMT do not. The cost benefit of HIFU was equivocal. However, more accurate evaluations can only be realistically made once the technologies have matured to the point where there is a greater certainty about their safety, efficacy, durability and appropriate position within the spectrum of BOO therapies.

The following recommendations and attendant caveats have been made by ASERNIP-S. It is expected that the Council of the Royal Australasian College of Surgeons will ratify these in March 2000.

The ASERNIP-S procedure classifications are:

A. Laser Prostatectomy

The classification for Visual Laser Ablation of the prostate (VLAP) is;

- 2.0. 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. The procedure should only be used with caution and it is recommended that further research be conducted to establish safety and/or efficacy.

VLAP may be introduced into practice under the proviso that it is subject to audit and its use is restricted to a subset of patients with particular clinical problems. VLAP is contraindicated in patients with large prostates or with median lobe enlargement.

The classification for Interstitial Laser Coagulation of the prostate (ILC) is;

- 2.0. 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. The procedure should only be used with caution and it is recommended that

further research be conducted to establish safety and/or efficacy.

ILC may be introduced into practice under the proviso that its use is restricted to a subset of patients with particular clinical problems. ILC is contraindicated in patients with large prostates, median lobe enlargement or those in complete urinary retention.

The classification for Laser Contact Vaporisation of the prostate (LCV) is;

- 2.0. 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. The procedure should only be used with caution and it is recommended that further research be conducted to establish safety and/or efficacy.

B. Transurethral Microwave Therapy (TUMT)

The classification is;

- 2.0. 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. The procedure should only be used with caution and it is recommended that further research be conducted to establish safety and/or efficacy.

C. Transurethral Electroresection (TURP)

The classification is;

- 1.0. Safety and efficacy is established. The procedure is equal to, or better than, the best practice based on the current available evidence. The procedure may be introduced into practice.

The qualification is that TURP may not give satisfactory outcomes for larger prostates. In addition, some reports suggest that TURP may result in a higher incidence of erectile dysfunction in comparison to TURP.

D. Transurethral Needle Ablation (TUNA)

The classification is;

- 2.0. 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. The procedure should only be used with caution and it is recommended that further research be conducted to establish safety and/or efficacy.

E. High Intensity Focussed Ultrasound (HIFU)

The classification is;

- 2.0. 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. The procedure should only be used with caution and it is recommended that further research be conducted to establish safety and/or efficacy.

HIFU is considered an experimental procedure and should only be conducted as part of a RCT.

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

Review Surgeon	Mr John Wheelahan
Protocol Surgeon	Professor Villis Marshall
Nominated Surgeons	Associate Professor John Nacey
	Mr Ross Cartmill
Other Specialty Surgeon	Associate Professor Randall Morton
ASERNIP-S Researchers	Ms Daniela De Nichilo
	Dr Wendy Babidge
	Dr Ann Scott
Chairman	Professor Guy Maddern

Percutaneous Endoscopic Laser Discectomy

Herniated intervertebral lumbar discs are a common cause of pain in the population. The herniation is the result of a protrusion of the nucleus pulposus through a tear in the surrounding annulus fibrosis (the capsule enclosing the gelatinous centre of the disc). The annulus fibrosis may rupture completely resulting in an extruded disc or may remain intact but stretched resulting in a contained disc prolapse. This may then compress one or more nerve roots, resulting in pain along the sciatic nerve.

Most herniated lumbar discs are successfully managed conservatively but some require surgical intervention. The standard procedure is an open removal of the herniated disc. This is often done with the aid of an operating microscope.

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 systematic literature search conducted for this review in September 1998 retrieved 13 articles relating to percutaneous endoscopic laser discectomy. None of the papers offered high

quality evidence. There were no controlled, blinded or randomised studies. At best, the evidence came from time studies (level III evidence), and case series (level IV). Other papers provided descriptions of the technique.

Adverse effects from the PELD procedure were reported in four patients: infection, suspected discitis, contralateral transient dermatomal discomfort and transient nerve block.

Due to insufficient and poor quality supporting evidence for the PELD procedure, nothing could be concluded about its safety and efficacy.

The recommendation for the procedure classification made by ASERNIP-S for this procedure is expected to be ratified by the Royal Australasian College of Surgeons in March 2000.

The ASERNIP-S procedure classification is:

- 2.0. **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. The procedure should only be used with caution and it is recommended that further research be conducted to establish safety and/or efficacy.**

Members of the Percutaneous Endoscopic Laser Discectomy Review Group:

Review Surgeon	Professor Rob Fraser
Protocol Surgeon	Professor Nigel Jones
Nominated Surgeon	Mr John Liddell
Nominated Surgeon	Mr Orso Osti
Invited Surgeon	Mr Peter Dohrmann
Other Specialty Surgeon	Professor Peter Donnelly
ASERNIP-S Researcher	Ms Maggi Boulton
Chairman	Professor Guy Maddern

Arthroscopic Subacromial Decompression using the Holmium:YAG laser

Arthroscopic subacromial decompression is a surgical technique used to overcome shoulder impingement syndrome. Impingement syndrome results from narrowing of the space underlying the acromion and coracoacromial ligament. The syndrome is classified into three stages:

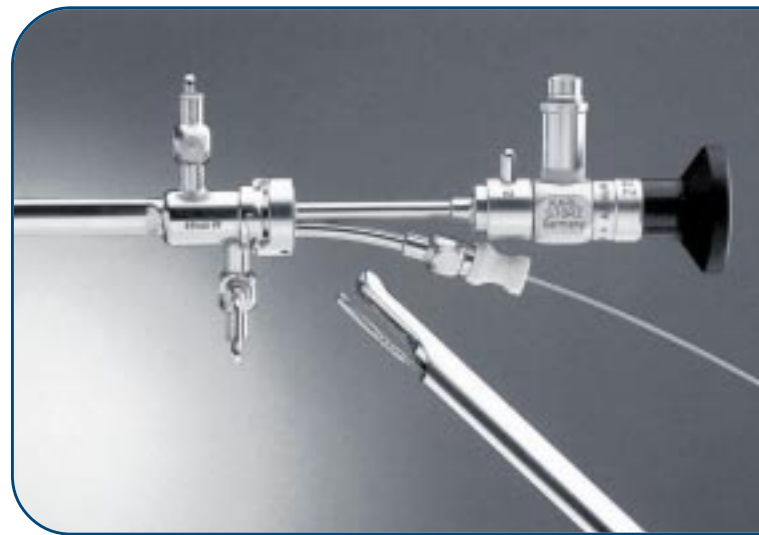
- Stage I involves oedema/haemorrhage.
- Stage II shows fibrosis and irreversible tendon changes.
- Stage III includes tendon rupture or tear.

Pain, weakness and loss of motion are the most common symptoms and the pain is exacerbated by overhead activities. Impingement tests are used to assist in clinical assessment along with diagnostic testing such as plain radiographs. Other imaging techniques such as arthrography, magnetic resonance imaging (MRI) or ultrasound are useful in diagnosing rotator cuff tears. Treatment for impingement syndrome is with non-steroidal anti-inflammatory drugs (NSAIDs), rehabilitation, subacromial steroid injection or arthroscopic subacromial decompression (ASD).

Surgical management requires accurate diagnosis and documented failure of conservative therapy. Arthroscopic subacromial decompression was introduced in the mid-1980's and has proven to be a reliable alternative to open acromioplasty, especially for Stage II and Stage III (partial tear only) impingement syndrome. This technique involves an acromioplasty, coracoacromial ligament resection, and bursectomy using a motorised shaver, burr and electrocautery. As an alternative, use of the 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, reducing postoperative pain, and swelling. Laser ASD is a technically demanding procedure, which requires

assessment of its safety and efficacy in comparison with the standard ASD technique.

The systematic literature search conducted for this review in October 1998 retrieved seven articles detailing the use of the Holmium:YAG laser for arthroscopic subacromial decompression. These papers provided very low quality evidence. There were no controlled, blinded or randomised studies. An additional paper was added following a search on author in July 1999. This paper was used to clarify information provided by the same authors in a 1996 conference abstract. It was noted however that the authors had not used the laser for acromioplasty.



Using the Hierarchy of Evidence provided by the National Health and Medical Research Council, the highest evidence provided by these papers was level III. All of the studies were flawed and badly designed. Some of the articles were descriptive and could not be classified using the Hierarchy of Evidence.

Due to insufficient and poor quality supporting evidence for the Arthroscopic Subacromial Decompression with Holmium:YAG laser, nothing could be concluded about its safety and efficacy. No reliable information is available about surgical success rates.

Proponents of the technique favoured the visualisation resulting from haemostatic control and precise dissection. There was a difference of opinion within the published literature about the efficacy of the laser to cut bone efficiently.

The recommendation for procedure classification made by ASERNIP-S for this procedure is expected to be ratified by the Royal Australasian College of Surgeons in March 2000.

The ASERNIP-S procedure classification is:

- 2.0. **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. The procedure should only be used with caution and it is recommended that further research be conducted to establish safety and/or efficacy.**

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

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

Developing Clinical Practice Guidelines for the Advanced Breast Biopsy Instrumentation (ABBI) System

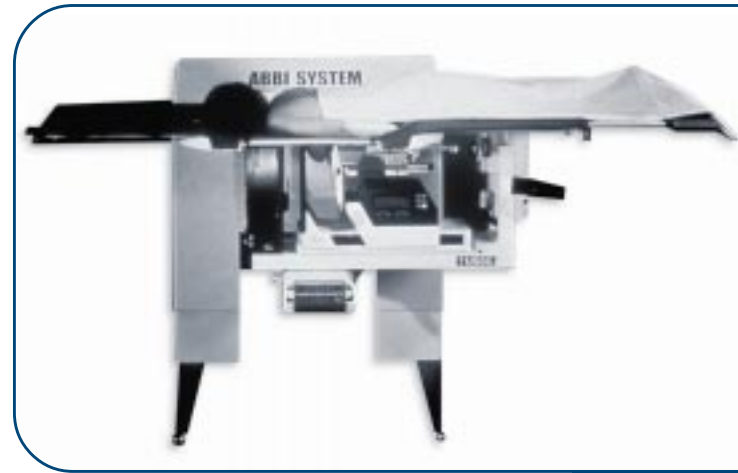
ASERNIP-S has recently expanded its role in response to a perceived need within the Australian surgical community to facilitate and produce guidelines for the use of the Advanced Breast Biopsy Instrumentation (ABBI) system in clinical practice.

The Advanced Breast Biopsy Instrumentation (ABBI) system is a new diagnostic technique that has been developed by U.S. Surgical Corporation, Norwalk, CT. The ABBI system consists of a table equipped with a digital flat bed mammography unit with a stereotactic imaging system. This is used in combination with a large-core biopsy device that is produced in various sizes. The function of the ABBI is to target indeterminant, non-palpable lesions within the breast with a high degree of accuracy through stereotactic imaging. The surgeon can visualise the lesions on the video monitor in real-time throughout the entire procedure. The lesions are then removed through a small incision. Unlike needle core biopsies, the ABBI device needs only to be inserted once and the ABBI cannula is disposable. It is proposed that the accuracy of visualisation enables the surgeon to minimise the amount of healthy tissue removed with the lesion. Mammographic (specimen X-ray) identification of the lesion is undertaken prior to closure of the incision. The ABBI system allows for post-procedural stereomammography in order to confirm complete removal of the lesion. The whole procedure is undertaken with the patient receiving local anaesthesia in a day surgery (outpatient) environment.

An evidence-based approach was taken to develop clinical practice guidelines for the use of the ABBI. A review of the literature was conducted using search strategies and search terms developed with the assistance of a surgeon practising in the area. Four electronic databases

were searched exhaustively for all research on the ABBI system. Grey literature sources were used to supplement the material (*i.e.* conference abstracts and manufacturer trial and training information). All literature was critically appraised in terms of the level of evidence it represented.

Mr David Walsh, a breast surgeon familiar with the ABBI technique, drafted the clinical practice guidelines for ABBI based on the evidence available in the literature. As expected, high quality evidence on this relatively new technique was lacking. Guidelines were, however, developed concerning lesion selection, patient selection, technical factors, credentialling, pathological specimens and financial considerations. These draft guidelines were then sent to other centres that practice the technique for comment and revision.



ASERNIP-S formed a review group or panel of experts in the field of breast surgery, along with a surgeon from another specialty and a representative from ASERNIP-S to critique the guidelines. The review group was sent the draft guidelines, literature, and a modified assessment instrument to record their comments. A further questionnaire was included, inviting members to suggest methods or processes for further developing the guidelines. Responses are

currently being synthesised and summarised and a review group teleconference will be held to amend the guidelines.

The ABBI guidelines will then be sent to the Breast Surgery Section of the Royal Australasian College of Surgeons and several national, consumer-based, breast cancer awareness and support groups for comment. Consensus expert and consumer views will be incorporated into the document, where appropriate.

After final revision, the ABBI clinical practice guidelines will be submitted to the Council of the Royal Australasian College of Surgeons for ratification and then disseminated through the Breast Surgery Section to practising surgeons, as well as to all other stakeholders and interested parties.

The ABBI guidelines will, of course, be revised as new good quality evidence concerning the procedure is produced.

Procedures Nominated for Assessment

The following procedures await assessment by ASERNIP-S:

- Instrument for trans-anal microsurgery of small rectal lesions (Wolff's Operating Proctosigmoidoscopy)
- Colonic stents
- Hepatic cryotherapy
- Trans-oral laser resection for laryngeal cancer
- Stented prosthesis
- Endoscopic carpal tunnel release
- Endoscopic brow lifting

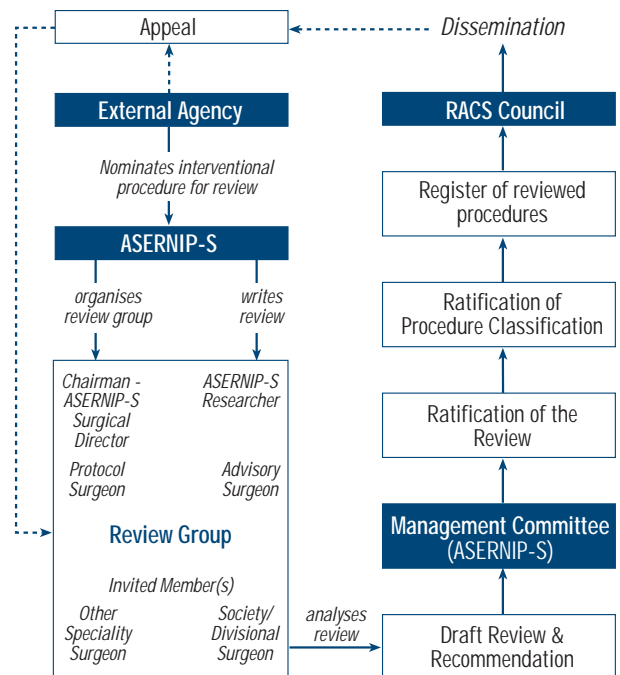


New ASERNIP-S Assessment Process

AFTER COMPLETION OF THE FIRST THREE REVIEWS, A QUESTIONNAIRE WAS SENT TO ALL REVIEW GROUP MEMBERS, SEEKING COMMENTS ON THE PROCESSES ADOPTED BY ASERNIP-S FOR THE ASSESSMENT OF NEW SURGICAL PROCEDURES. THE RESPONSE FROM THE SURGEONS WAS HIGHLY SATISFACTORY, OFFERING MANY CONSTRUCTIVE CRITICISMS. AS SUCH, THE PROCESSES ADOPTED BY ASERNIP-S THUS FAR WERE REVISITED AND REFINED.

The flow chart below illustrates the refined process adopted by ASERNIP-S to assess new surgical techniques and technologies. The process commences with nomination of procedures from a variety of sources including the Divisions and Sections of the College and consumers through the Consumers Health Forum. The ASERNIP-S Management Committee endorses the procedures for review and procedure assessment commences. The output of the process is a draft review, recommendations and a safety and efficacy classification, which is submitted to the ASERNIP-S Management Committee for ratification. The review then becomes part of a register of reviewed procedures and is submitted to the College Council before being disseminated to Sections of the College, hospital credentialling committees and the wider public.

ASERNIP-S PROCESS



The ASERNIP-S Review Group Process

After the ASERNIP-S proposal for assessment of the procedure is accepted by the Management Committee the process for review of each procedure proceeds through the following eight phases.

Review Group Establishment

- ASERNIP-S establishes the Review Group to assess the procedure.

Review Protocol Manual Development

- The Protocol Surgeon and ASERNIP-S Researcher consult regarding the evidence/literature search protocol.
- The ASERNIP-S Researcher develops the draft protocol.
- The ASERNIP-S Researcher conducts a comprehensive search of the literature, and collects and inputs references into a database. Audit data and supplementary unpublished data are collated, when available.
- The Protocol Surgeon reviews the references, supplementary information and draft protocol.
- The draft protocol is revised according to the Protocol Surgeon's comments and the Review Protocol Manual is complete.

Draft Review Preparation

- The Review Protocol Manual, reference material and data are supplied to Review Group members.
- An initial Review Group teleconference is held to provide a forum for preliminary discussions.
- The ASERNIP-S Researcher assesses the methodological validity and summarises the data extracted from the peer-reviewed literature.

- The ASERNIP-S Researcher produces a draft review on the safety and efficacy of the procedure, in consultation with the Protocol and/or Advisory Surgeon (if necessary). At this stage, no recommendation or classification of safety and efficacy is made.
- The Advisory Surgeon critiques the draft review.
- The ASERNIP-S Management Committee is provided with a copy of the draft review.
- The draft review is disseminated to the Review Group.
- Each member of the Review Group critiques the draft review according to his/her particular expertise, and develops a preferred safety and efficacy classification for the procedure.
- Each member of the Review Group completes the Draft Review Appraisal Form, which is then circulated to all members. This form provides a basis for discussions at the teleconference.

Review Group Teleconference

- The Review Group meets to discuss the review and classification via a teleconference or videoconference.
- The Review Group reaches consensus on the recommendation(s) concerning the safety and efficacy of the procedure and the classification it will receive.

Review Ratification by ASERNIP-S Management Committee

- A suitable representative of the review group presents the ASERNIP-S Report, which encompasses the review protocol, review, recommendation(s), safety and efficacy classification and a summary of the Review Group comments to the Management Committee.
- The Management Committee ratifies the ASERNIP-S Report.

Consideration of the ASERNIP-S Review by College Council

- The Council of the Royal Australasian College of Surgeons ratifies the ASERNIP-S Report.

Dissemination of the Final Report

- The ASERNIP-S Final Report is released into the public domain.

Mediation

- Should an individual or group of persons wish to appeal against the contents or recommendation of the ASERNIP-S review, a petition is first directed to the respective review group.
- The Review Group meets again by teleconference to discuss the concerns raised.
- The disagreement is reported to the Management Committee as part of a mediation process.
- If the Review Group agrees it cannot resolve the disagreement, then the petition proceeds through the Royal Australasian College of Surgeons' external appeals process.

Review Group Membership and Roles

Each Review Group consists of the following members, as outlined below. In addition to these members, other people deemed suitable for inclusion in the Review Group may be invited.

ASERNIP-S Surgical Director

The Surgical Director is the Chairperson of the Review Group.

ASERNIP-S Researcher

The ASERNIP-S Researcher coordinates the Review Process and organises the Review Group. The Researcher drafts the protocol for the systematic review, in conjunction with the Protocol Surgeon, and searches appropriate databases for peer reviewed literature on the procedure. Relevant data from other sources may

also be obtained in order to formulate a background for the review. The Researcher consults with various members of the Review Group, particularly the Protocol and Advisory Surgeons, whilst assessing the publications for the review. This information forms the basis of the systematic review. Relevant outcomes and other data are extracted from the articles and tabulated. A meta-analysis is conducted, where appropriate. The information is summarised, and along with the tabulated information is provided to the Review Group as a draft review.

Protocol Surgeon

The Protocol Surgeon is familiar with the literature and data relating to the procedure. This surgeon collaborates with the ASERNIP-S Researcher to draft the protocol for the review. The protocol defines the comparative procedure(s) for the review, as well as the inclusion criteria and the search terminology to be employed. The Protocol Surgeon assesses the abstracts of the retrieved articles from literature searches to ensure that the references are appropriate for the review.

Advisory Surgeon

The Advisory Surgeon is an expert from the specialty Division or Section, but is not intimately involved in the procedure. The Advisory Surgeon is supplied all the available literature and collaborates closely with the ASERNIP-S Researcher while the draft review is being prepared. When the draft review has been prepared the Advisory Surgeon critiques the document, before it is disseminated to the Review Group.

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

This surgeon is a representative of the related Section of the College of Surgeons and has an interest in the procedure. He or she is available for consultation throughout the review process, and is sent a copy of the draft review for comment.

Surgeon from Another Specialty Section or Division

The surgeon from another specialty provides balance to the review group. He or she receives a copy of the draft review for comment.

Other Invited Members

To maintain a balance in terms of perceived bias, other persons will be invited to join the Review Group to provide their input.

Each member of the group receives a copy of the Review Protocol and the draft review compiled by the ASERNIP-S Researcher, as well as all the relevant literature. Each member then critiques the draft review according to his or her level of expertise. The Review Group meets and discusses any concerns and reaches a consensus on recommendations and a safety and efficacy classification for the procedure.

ASERNIP-S Procedure Classifications

Safety and 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. The procedure should only be used with caution and it is also 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.





Project Activities for 1999

Promotional Activities

ASERNIP-S has undertaken a diverse range of promotional activities during this second year of operation. The most notable activity has been the dissemination of the four completed assessment reports. This has been undertaken via a number of different mediums, including publication of the outcomes in international surgical journals and other relevant periodicals; presentations of findings at health technology assessment conferences throughout Australia and the world; facilitation of educational and training activities for Fellows of the Royal Australasian College of Surgeons; and publication of information on the ASERNIP-S web site.

Publications

Once endorsed by the Council of the Royal Australasian College of Surgeons, an executive summary, a consumer summary and a copy of the full report is made available for each procedure review on the ASERNIP-S web site. However, the Lung Volume Reduction Surgery report will not be made available until MSAC release their report, which is expected to be in March 2000. Other publications such as the ASERNIP-S annual reports are also available from the web site.

A paper entitled 'Minimally Invasive Surgery for Primary Hyperparathyroidism: a Systematic Review' has been accepted for co-publication in the *ANZ Journal of Surgery* and the *Archives of Surgery*. A paper on Laparoscopic Live Donor Nephrectomy has also been submitted to the journal *Transplantation*. Papers are also being prepared on Lung Volume Reduction Surgery for submission to the *Journal of Thoracic and Cardiovascular Surgery* and on Minimally Invasive Techniques for Relief of Bladder Outflow Obstruction for submission to the *British Journal of Urology*.

The executive summaries for each completed review are submitted for publication in the RACS Bulletin and also appear on the ASERNIP-S web site. Articles have also been submitted to the New Zealand Health Technology Assessment (NZHTA) newsletter, and *Better Outcomes*, the Commonwealth Department of Health and Aged Care newsletter. A profile on ASERNIP-S has also been prepared for the International Network of Agencies for Health Technology Assessment (INAHTA) newsletter.

A summary for consumers is prepared for each report and published on the ASERNIP-S web site.

Articles are also submitted to Australian Health Consumer, which are a précis of these reports.

A promotional brochure is prepared annually for the Royal Australasian College of Surgeons Annual Scientific Congress to provide Fellows and other interested parties with information on the project. The brochure can also be viewed on the ASERNIP-S web site.

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:

- Poster display at the International Society for Quality in Health Care (ISQua) Conference, Melbourne, October 1999, Dr Wendy Babidge.
- Evidence Based Health Care Conference: Documenting Surgical Procedures and Technologies (a case study), Sydney, October 1999, Professor Guy Maddern.
- Surgical Research Society meeting, Cairns, September 1999, Professor Guy Maddern.
- International Clinical Trials Symposium: Forum on Research Strategies and Priorities in Surgery, Sydney, September 1999, Professor Guy Maddern.
- Health Services Research Conference, Sydney, August 1999, Dr Wendy Babidge.
- Poster display at the 1999 Royal Australasian College of Surgeons Annual Scientific Congress, Auckland, May 1999.
- Introduction of New Techniques/ Technologies - ASERNIP-S, Professor Guy Maddern, RACS Annual Scientific Congress, Auckland, May 1999.
- The Clearing House for Health Outcomes and Technology, NZHTA, Christchurch, May 1999, Professor Guy Maddern.

- University of Otago, Dunedin, May 1999, Professor Guy Maddern.
- United Medical Protection Grand Round, Sydney, February 1999, Bruce Barraclough.

Education and Training

The NH&MRC Clinical Trials Centre invited ASERNIP-S to arrange a half-day programme for their Clinical Trials Symposium. ASERNIP-S targeted surgeons and trainees from all around Australia, but particularly those in the NSW area to attend this forum and engaged a diverse range of speakers who espoused the merits of clinical trials. An interactive workshop followed, allowing participants to discuss the topics with the various speakers in the context of a hypothetical clinical trial. The Royal Australasian College of Surgeons approved the forum for Continuing Medical Education (CME) accreditation points for surgeons who participated.

Participation in an ASERNIP-S Review Group has also been approved as a Continuing Medical Education activity.

ASERNIP-S Web Site

The ASERNIP-S web page is regularly updated and includes information on the project activities, recent and forthcoming presentations, and contact details for the ASERNIP-S staff. The ASERNIP-S publications are also available to download from the site, including the assessment reports, the ASERNIP-S brochure and the 1998 and 1999 Annual Reports. The web site address is <http://www.racs.edu.au/open/asernip-s.htm>

Data Registries

The development of a secure internet site for the submission of data on Laparoscopic Live Donor Nephrectomy was completed in October 1999. Registered surgeons are contributing from three sites: the Queen Elizabeth Hospital, Adelaide, the

Princess Alexandra Hospital, Brisbane and Westmead Hospital, Sydney.

A similar internet site is being developed for data submission on Minimally Invasive Parathyroid surgery. Six sites contributing to the Feasibility Study of the Section of Endocrine Surgery will contribute to this database.

ASERNIP-S is to assist the Alfred Hospital, Melbourne, which houses the Australian and New Zealand Lung Volume Reduction Surgery database. 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.

Australian patient data on Ultrasound-assisted Lipoplasty will be collected in collaboration with the Lipoplasty Effectiveness and Patient Safety (LEAPS) study being conducted by the American Board of Plastic Surgery. The LEAPS study is a six-month prospective multicentre cohort study collecting outcome data on suction lipectomy and ultrasound-assisted lipoplasty.

The activities of ASERNIP-S were declared by the Minister under the *Health Insurance (Quality Assurance Confidentiality) Amendment Act 1992*. Therefore, the confidentiality of all patient data provided by surgeons is protected. Surgeons and patients will not be able to be identified under the *Freedom of Information Act 1982*.

Investigation into Current Australian Surgical Practice

To ascertain where procedures undergoing assessment by ASERNIP-S are being performed in Australia, ASERNIP-S has investigated the following:

- A survey was sent to approximately 950 general surgeons asking if they perform laparoscopic-assisted resection of colorectal malignancies. Results of this survey show this

procedure is performed approximately 400 times per year across 53 sites in Australia.

- ASERNIP-S has also contacted members of the Therapeutic Device and Instrument Subcommittee of the Urological Society of Australasia to collect similar information on minimally invasive techniques for bladder outflow obstruction.
- Manufacturers of devices for ultrasound-assisted liposuction techniques have also been contacted, and have provided ASERNIP-S with details of clinicians/hospitals performing ultrasonic liposuction.

Contact with Health Complaints Commissions

Due to continuing enquiries from various Health Complaints Commissions, ASERNIP-S wrote to each State Commission office, informing them of the ASERNIP-S activities, and inviting their continued correspondence, including nomination of procedures for further investigation. This offer of continued liaison has been welcomed, particularly the offer to nominate new procedures and to receive copies of the final ASERNIP-S Reviews.

Affiliation with the University of Adelaide

ASERNIP-S has been accepted as an affiliated organisation of The University of Adelaide.

Personnel

At the start of 1999, Robyn Orr resigned from ASERNIP-S and Fiona Wakelin was appointed to take over the administrative role vacated by Robyn Orr, as well as to function as a researcher for the project. Daniela De Nichilo also joined ASERNIP-S on a part-time basis to expedite the review process. In July 1999, ASERNIP-S appointed another two full-time Research Assistants: Dr Ann Scott and Mr Andrew Chapman.

Management Committee

Professor Dick Bennett retired from his post as Executive Director for Surgical Affairs at the Royal Australasian College of Surgeons. His successor, Associate Professor David Scott, joined the ASERNIP-S Management Committee.

Peter Carter also resigned from his post as Chief Executive Officer at the Royal Australasian College of Surgeons. His successor, Dr Vin Massaro, has joined the ASERNIP-S Management Committee.

The members of the Management Committee are:

Mr Kingsley Faulkner FRACS	Chairman
Mr Bruce Barraclough FRACS	RACS President
Ms Wendy Brown	Consumers Health Forum
Professor Guy Maddern FRACS	Project Surgical Director
Dr Vin Massaro	RACS Chief Executive Officer
A/Professor Rosemary Roberts	National Centre for Classification in Health
Mr David Robinson FRACS	RACS Fellow

A/Professor David Scott FRACS	RACS Executive Director for Surgical Affairs
Professor Chris Silagy	Australasian Cochrane Centre
Dr Denis Smith	Australian Council on Healthcare Standards

Terms of Reference

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





ASERNIP-S Staff

Professor Guy Maddern Surgical Director

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



Dr Wendy Babidge Research Coordinator

Wendy Babidge has been responsible for the day-to-day management of the ASERNIP-S project over the last 12 months. During this time the project has gained momentum and now has seven administrative and research staff. Wendy has also been closely involved with the review and data collection of three of the procedures under assessment at ASERNIP-S.

Wendy's background is in scientific research, and she has a degree in Applied Science with Honours in Biotechnology and a PhD from the University of Adelaide.

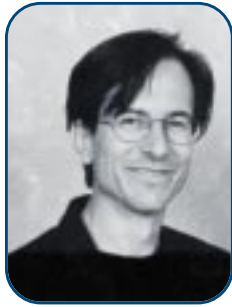


Mrs Maggi Boulton Researcher

Maggi Boulton has an Honours Degree in Plant Science, a Graduate Diploma in Information Studies and a Diploma in Computer Programming.

Maggi 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.

Her work at ASERNIP-S has included researching, writing and finalising the Percutaneous Endoscopic Laser Discectomy and Arthroscopic Subacromial Decompression reviews. She has also established the Live Laparoscopic Donor Nephrectomy database and is currently liaising with surgeons to create a database for feasibility study of the Minimally Invasive Parathyroid surgery. Additional databases are planned for the year 2000, which Maggi will develop and maintain.



Mr Andrew Chapman
Researcher

Andrew Chapman joined ASERNIP-S in July 1999 and has since worked on two of the procedures currently being evaluated: Laparoscopic-Assisted

Resection of Colorectal Malignancies and Laparoscopic Gastric Banding. 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 he 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.



Ms Daniela De Nichilo
Researcher

Daniela De Nichilo has a Bachelor of Science and Graduate Diplomas in Nutrition and Dietetics, and Business Administration. Daniela worked in clinical dietetics

at the Royal Adelaide Hospital for several years, prior to working in project management within the Division of Surgery of the Lyell McEwin Health Service, and subsequently establishing a Research Secretariat at The Queen Elizabeth Hospital. In addition to her part-time appointment at ASERNIP-S, Daniela works in research administration at the University of Adelaide. Since working part-time at ASERNIP-S, Daniela has been developing consumer summaries of the reviewed procedures for the ASERNIP-S web site.



Mrs Tracy Merlin
Researcher

Tracy Merlin joined ASERNIP-S on a part-time basis at the project's inception. She brought to the position an Honours degree in Psychology and

eight years of research experience with Adelaide University in the fields of Aboriginal health, health education, epidemiology, international health and medical education.

Tracy has completed an ASERNIP-S review on the safety and efficacy of Laparoscopic Live-Donor Nephrectomy, is coordinating the development and evaluation of clinical practice guidelines for the Advanced Breast Biopsy Instrumentation (ABBI) system, and is part-way through a review on the safety and efficacy of Intravaginal Slingplasty for Urinary Incontinence and the Tension-free Vaginal Tape procedure.

Tracy has been studying throughout her employment with ASERNIP-S. She has recently completed the coursework component of her Masters Degree in Public Health, specialising in various aspects of epidemiology and biostatistics. She will undertake her thesis, applying different evidence-based medicine methodologies to a systematic review, in collaboration with ASERNIP-S in 2000. 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 is currently responsible for the assessments of Minimally Invasive

Techniques for the Relief of Bladder Outflow Obstruction and Off-Pump Coronary Artery Bypass Surgery with the Aid of Tissue Stabilisers.

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 is currently in her last semester of study towards a Graduate Diploma in Business Management.



Miss Fiona Wakelin
Administrative Officer
Researcher

Fiona Wakelin has a degree in Statistics from the University of Auckland. Prior to her involvement in

ASERNIP-S, Fiona worked in several different positions for banks in both Australia and New Zealand. She has been involved in the general project administration of ASERNIP-S as well as assisting with Research activities since January 1999.

Fiona is currently developing the protocol for the assessment of the Endoscopic Modified Lothrop procedure for Chronic Frontal Sinusitis. Throughout 1999 she has maintained the ASERNIP-S web site and assisted with the preparation of the assessment reports.

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 Project Office. The continuing participation in Procedure Review Groups and in submission of data by Surgeons is encouraged. For further information, please contact the project office.

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

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