

ASERNIPS



Australian
Safety
and Efficacy
Register
of New
Interventional
Procedures-
Surgical

Annual Report 2001



Address:
51 - 54 Palmer Place
North Adelaide
South Australia
5006

Contact Details:
PO Box 688
North Adelaide
South Australia 5006

Telephone: (08) 8239 1144
Facsimile: (08) 8239 1244

E-mail: College.asernip@surgeons.org
Web site: <http://www.surgeons.org/open/asernip-s.htm>

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Chairman's Report



ASERNIP-S HAS BEGUN THE SECOND PHASE OF ITS FUNDING

with well-established project processes and an expanding group of talented researchers and support staff. These processes continue to evolve, with a significant change in the procedure classifications coming into place mid-year. The major thrust of this has been to rate the evidence that the classifications have been based on. Thus clinicians and decision-makers should be better informed of the significance of each assessment and its relevance to clinical practice. These changes have stemmed from some criticisms of the classification system, which was

considered to be potentially misleading. ASERNIP-S aims to produce assessments of new surgical procedures that are not only scientifically rigorous but provide clear recommendations for their future use in practice within Australia. Therefore, we are happy to receive feedback, both positive and negative, on any aspects of the project.

Systematic reviews are being conducted on behalf of the Medical Services Advisory Committee (MSAC). ASERNIP-S is also collaborating with MSAC on the audit of Endoluminal Repair of Abdominal Aortic Aneurysms. These partnerships between ASERNIP-S and MSAC strengthen the area of health technology assessment in surgery and help to inform funding decisions by the Commonwealth Department of Health and Aged Care.

The Horizon scanning project set up by ASERNIP-S in 1999 (New and Emerging Techniques - Surgical, NET-S) is well underway. Summary information is now available on the internet about long and short-term horizon scanning procedures and a second survey of all Fellows is due to be conducted in February 2002. This initiative is being further developed as a means of informing ASERNIP-S of procedures requiring more thorough assessments once evidence of sufficient quality becomes available.

ASERNIP-S has now completed 20 systematic literature reviews and re-appraisals. We continue to publish widely in national and international peer-reviewed journals with 11 systematic reviews and four other articles published or approved for publication to date. Acceptance in this arena is an indication of the high quality outputs from the project, which I am sure will continue in the future.

A handwritten signature in blue ink, reading 'Kingsley Faulkner'. The signature is fluid and cursive, with a long horizontal stroke at the end.

Kingsley Faulkner

Chairman

ASERNIP-S Management Committee

Surgical Director's Report

THE YEAR 2001 HAS BUILT ON THE EARLY SUCCESS of the pilot phase of the ASERNIP-S project. Over the last twelve months in excess of 10 reports or re-appraisals have been completed and all new reports have found their way in manuscript form to international journals for consideration regarding future publication. This dissemination of the ASERNIP-S output by way of refereed journals is a vital ingredient if the widest possible audience is to be reached and the information provided by the ASERNIP-S Systematic Reviews is to be critically appraised and acted upon by the world-wide surgical community.



During the year we were also delighted to have visiting us some representatives from the National Institute for Clinical Excellence (NICE) in the UK to discuss the mechanisms by which ASERNIP-S functions and how it differs from the SERNIP project in the UK. This interaction with NICE is an important one and we hope over the forthcoming years it will develop in order to enable ASERNIP-S to have as broad an influence as possible on the direction of assessment of surgical effectiveness.

The year 2001 also began a more formal relationship between ASERNIP-S and MSAC. Over the next three and a half years ASERNIP-S will deliver three reviews annually to MSAC relating to surgical matters. During the year three reviews have been completed or nearly completed, including one on the availability of registries within Australia and two relating to cardiothoracic surgery. This close working relationship with MSAC will do much to enhance the lines of communication between the two organisations and will hopefully provide the surgical community within Australia a chance to interact effectively with a body such as the Medical Services Advisory Committee which advises Government on the appropriateness of new technologies being introduced within Australia.

To this end, the successful Endoluminal Audit has moved into its second year and data is now being collected on approximately 800 patients enrolled into the original assessment. This is a very challenging project requiring considerable enthusiasm and inconvenience to a large number of vascular surgeons around the country. Their response has been extraordinarily supportive and we look forward to seeing valuable data coming from this ongoing audit over the next three to four years.

None of the advances that are occurring within the ASERNIP-S project would be possible without the outstanding research and administrative staff housed in the Adelaide office of the Royal Australasian College of Surgeons. The Research and Administrative Manager, Dr Wendy Babidge, has been essential to this ongoing success and she has been well supported by all staff currently working within the ASERNIP-S project.

ASERNIP-S remains funded for a further three and a half years and it will be vital over that time that the project can clearly demonstrate to Government and the Australian community its value and importance within the current health framework in which we operate.

A handwritten signature in blue ink, appearing to read 'Guy Maddern'.

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 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 efficacy of new surgical techniques and technologies.

During the first three years, as a pilot project, ASERNIP-S completed 10 systematic reviews of new surgical procedures of which six have been updated and re-appraised. At the end of 2000, the Commonwealth Department of Health and Aged Care agreed to continue to fund ASERNIP-S for a further four and a half years. This year has seen completion of another four systematic reviews which have been endorsed by the RACS Council, and two updates and re-appraisals. ASERNIP-S is continuing, under contract with the Commonwealth to conduct a national audit on the Endoluminal Repair of Abdominal Aortic Aneurysms. We are also furthering the development of the New and Emerging Techniques - Surgical (NET-S) horizon scanning project. This year we have introduced the NET-S website and procedure brief downloads are available.

The ASERNIP-S team has grown considerably this year, with five additional staff bringing new and varied skills to the project. The close working relationship with Fellows of the Royal Australasian College of Surgeons continues to contribute to the acceptance of the project.

The main thrust of our work over the next few years will continue to be the production of systematic literature reviews and NET-S procedure briefs. Additionally, the methodologies for such work will be assessed on a regular basis. Fostering of national and international collaboration has been an important part of 2001, and is being further developed. We continue to investigate methods of partial self-funding to ensure continuity of this important project and hope to be able to generate a proportion of our own funding by the end of the contract period.

In the coming year we will further our industry and government relationships and continue to disseminate our findings. We look forward to continuing to contribute to the provision of better healthcare for all Australians.



Systematic Reviews

Procedures are assessed at ASERNIP-S by a systematic review of the peer-reviewed literature. Evidence from peer-reviewed journals is appraised and based on this information, ASERNIP-S produces a review which contains a safety and efficacy classification for each procedure along with any clinical or research recommendations.

Every 12 to 18 months, the peer-reviewed literature is re-scoped to determine whether there is sufficient new evidence to warrant a re-appraisal. If the re-appraisal is conducted, it may also include evidence from ASERNIP-S data collections within Australia and New Zealand.

A new classification system has been in place since July 2001 (See Appendix I). All but one of the completed assessments, in 2001, were classified according to the old ASERNIP-S classification system (See Appendix II). Completed procedure assessments (See Appendix III) are available from the ASERNIP-S office or web site. (<http://www.surgeons.org/open/asernip-s/publications2.htm>).

New Assessments Completed

Four new procedure assessments were completed in 2001 and endorsed by the Council of the Royal Australasian College of Surgeons.

- > Tension-free Urethropexy for Stress Urinary Incontinence: Intravaginal Slingplasty and the Tension-free Vaginal Tape Procedures
- > Endoscopic Modified Lothrop Procedure for the Treatment of Chronic Frontal Sinusitis
- > Dynamic Graciloplasty for the Treatment of Faecal Incontinence
- > Methods used to Establish Laparoscopic Pneumoperitoneum.

Summaries of these assessments follow.



Tension-free Urethropexy for Stress Urinary Incontinence: Intravaginal Slingplasty and the Tension-free Vaginal Tape Procedures

BACKGROUND

Tension-free urethropexies are new surgical sling procedures for treating stress urinary incontinence in women. From the prototype tension-free urethropexy, known as Intravaginal Slingplasty (IVS), two procedures were developed - the two-stage IVS and the Tension-free Vaginal Tape (TVT) procedure. These procedures are similar short-stay operations that are minimally invasive and aim to reconstruct ligamental and muscle weakness in women with stress urinary incontinence. Both rely on a tension-free tape positioned below the middle third of the urethra to provide support and prevent urine leakage.



The objective of this systematic review was to assess the safety and efficacy of tension-free urethropexy, in comparison to the two "gold standard" procedures for treating stress incontinence - the Burch colposuspension and Pubovaginal sling.

METHODS

Search Strategy

Medline, Current Contents, Embase and the Cochrane Library were searched using text words and MeSH terms, for all studies on tension-free urethropexy up until August 2000. The same databases were searched, by publication type, for literature on the Pubovaginal sling and Burch colposuspension up until June 2000. Recent grey literature was also canvassed. Literature searches were not restricted to a specific language.

Study Selection

All controlled trials on tension-free urethropexy (specifically IVS and TVT) were included in this review, along with interrupted time series, and case series. In the event that there were no comparative studies between the new and "gold standard" procedures, systematic reviews, meta-analyses and randomised controlled trials on the Burch colposuspension and Pubovaginal sling procedures were included to provide benchmark information. Only studies on human females were included, and objective diagnosis of urinary incontinence was a requirement. Various safety and efficacy outcomes determined *a priori* were of interest. Non-English language papers were not translated unless they added substantially to the quality of the evidence-base.

Data Collection and Analysis

All studies were independently assessed by two reviewers as to whether they met the inclusion criteria outlined in the protocol. Tables developed *a priori* were used to extract information on study characteristics and safety and efficacy outcomes from the 17 peer-reviewed studies identified. Each study was critically appraised with respect to level of evidence, internal validity and external validity using a pre-determined checklist. There was insufficient methodological detail to allow critical appraisal of the grey literature - results of these studies were included but did not inform the



NEW ASSESSMENTS COMPLETED CONT.

discussion or conclusions. Due to the lack of comparative studies, measures of effect (with confidence intervals) and meta-analyses, were not conducted. Descriptive statistics were calculated.

RESULTS

The published studies available were of the lowest level of evidence. On the basis of this evidence, tentative conclusions were made regarding the comparative safety and efficacy of tension-free urethropexy (IVS and TVT).

Safety

The incidence of bladder laceration, haemorrhage and urinary tract infection were similar for tension-free urethropexy and the "gold standard" procedures. Whereas, the risk of blood transfusion, urinary retention, outflow obstruction and micturition difficulty appeared to have been slightly higher for the Burch colposuspension and Pubovaginal sling procedures.

The incidence of wound infection and defective vaginal healing were similarly low for tension-free urethropexy and the Pubovaginal sling. There were no published reports of infection or erosion associated with the use of Prolene® tape in the TVT procedure.

Evidence concerning the comparative risk of *de novo* detrusor instability after the new and "gold standard" procedures was equivocal.

Efficacy

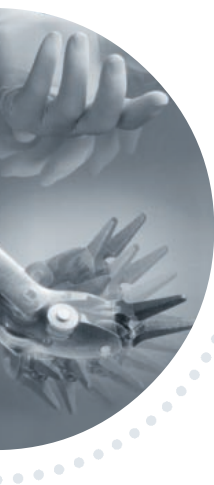
Tension-free urethropexy was associated with shorter operating times, lower levels of postoperative patient catheterisation, and shorter times until the resumption of spontaneous voiding, than either of the "gold standard" procedures.

Convalescence appeared to be faster for tension-free urethropexy compared to colposuspension or sling surgery. Both hospital stay and resumption of usual activities or employment were reported as shorter for patients undergoing tension-free urethropexy.

The short and medium term objective cure rates for stress incontinence for tension-free urethropexy appeared to be very similar to the Burch colposuspension, and perhaps slightly higher than for the Pubovaginal sling. Data on the long term (> 3 years) objective cure rates for stress incontinence for tension-free urethropexy have not yet been published.

CONCLUSION

There was no peer-reviewed, good quality evidence available to determine the safety and efficacy of any of the tension-free urethropexy procedures in comparison to the "gold standard" surgical procedures for stress incontinence.



It was recommended that a randomised controlled trial should be conducted to assess the safety and efficacy of the two-stage IVS. Ideally, the two-stage IVS should be compared to the TVT procedure, along with the Burch colposuspension as the "gold standard".

For the TVT procedure, it was recommended that a randomised controlled trial be conducted, with the Burch colposuspension as the control arm. Such a trial is currently underway in the United Kingdom and full publication of its short and long-term results are awaited with interest.

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.

Members of the Review Group assessing Tension-free Urethropexy for Stress Urinary Incontinence: Intravaginal Slingplasty and the Tension-free Vaginal Tape Procedures:

Advisory Surgeon	Professor Edwin Arnold
Protocol Surgeon	Dr Peter Petros
Nominated Surgeons	Mr Peter MacTaggart
	Mr Alastair Tulloch
Other Specialty Surgeon	Professor Glyn Jamieson
ASERNIP-S Researcher	Mrs Tracy Merlin
Chairman	Professor Guy Maddern

**ENDORSED BY THE ROYAL AUSTRALASIAN COLLEGE OF SURGEONS
COUNCIL - FEBRUARY 2001**



Endoscopic Modified Lothrop Procedure for the Treatment of Chronic Frontal Sinusitis

BACKGROUND

Despite significant advances in modern medical technology and pharmacology, sinusitis is still an insidious disease that is capable of causing significant morbidity and even death. The obliterative osteoplastic flap (OPF) technique, with or without fat obliteration, is currently the benchmark surgical treatment for chronic frontal sinusitis but it is highly invasive, associated with a higher than average blood loss, and may result in cosmetic deformities such as frontal bossing and depression. Recently, the endoscopic modified Lothrop procedure (EMLP) has been pursued as a minimally invasive alternative to the osteoplastic flap procedure.

There are many postulated benefits of the EMLP but as yet there have been no randomised controlled clinical trials conducted to confirm these assertions. Therefore, the aim of this systematic review was to make recommendations on the safety and efficacy of EMLP, performed either wholly intranasally or in combination with an external approach, against the OPF, with or without fat obliteration, on the basis of a systematic assessment of the peer-reviewed literature.

METHODS

All original, published studies on EMLP and OPF, with or without fat obliteration, were identified by searching Current Contents between week 1/1993 and week 8/2001; Embase between week 1/1974 and week 5/2001; Medline between 01/1984 and 16/02/01; and the Cochrane Library between 1966 and 2001 (Issue 1). For both EMLP and OPF, only studies of patients diagnosed with chronic frontal sinusitis were included for review. English language papers detailing randomised-controlled trials, controlled clinical trials, case series or case reports were included.

RESULTS

The limited comparative data suggested that EMLP caused fewer adverse postoperative outcomes but was more likely to generate a perioperative cerebrospinal fluid leak than OPF. However, none of the morbidity traditionally associated with OPF was evident following EMLP. EMLP appeared to have a shorter operative time and a lower perioperative blood loss than OPF, but little could be determined regarding the long term efficacy and durability of EMLP because of the relatively short follow-up of the majority of the studies.

CONCLUSIONS

The ASERNIP-S Review Group concluded that the evidence base for EMLP was inadequate and recommended that a national audit, with standardised data reporting, of centres currently performing the procedure be conducted to establish safety and efficacy. The Otolaryngology Head and Neck Surgeons of the Royal Australasian College of Surgeons would ideally manage this, and any new centres embarking on the use of EMLP would be recruited into the audit. A concurrent national audit of the osteoplastic flap procedure was also recommended.



The ASERNIP-5 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 following clinical recommendations were made to guide the development of EMLP during this audit phase:

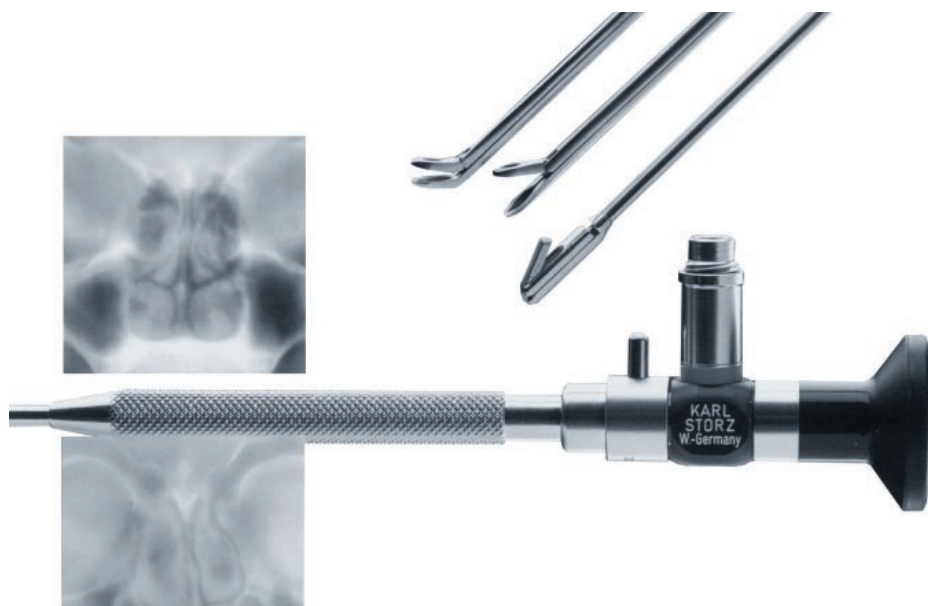
1. Otolaryngological surgeons should obtain institutional support and appropriately inform their patients before commencing EMLP.
2. EMLP is a technically demanding procedure. Therefore, EMLP should only be performed on appropriately selected patients by a properly trained otolaryngological surgeon who is accredited in the use of this procedure. Before performing EMLP, the surgeon should participate in a formal training workshop that includes surgical theory, endoscopic anatomy, and cadaver dissection. A minimum prescribed number of cadaver dissections and supervised surgical procedures should be performed before full accreditation is awarded.

Members of the Review Group assessing Endoscopic Modified Lothrop Procedure for the Treatment of Chronic Frontal Sinusitis:

Advisory Surgeon
Protocol Surgeon
Nominated Surgeon
Other Specialty Surgeon
ASERNIP-S Researcher
Chairman

Mr David Close
Professor Peter Wormald
Dr Richard Gallagher
Mr Adrian Anthony
Dr Ann Scott
Professor Guy Maddern

**ENDORSED BY THE ROYAL AUSTRALASIAN COLLEGE OF SURGEONS
COUNCIL - JUNE 2001**





Dynamic Graciloplasty for the Treatment of Faecal Incontinence

BACKGROUND

Faecal incontinence is a debilitating symptom which may result from a number of causes, including absence of or injury to the anorectum or its sphincters. Other causes, however, may include surgical removal of the anorectum, damage to the pelvic floor or the neurological pathways to the rectum. Methods to manage faecal incontinence depend upon the cause and severity of the condition. Surgery can also be used to treat faecal incontinence using anorectal muscle repairs, artificial anal encirclement, muscle transfers and - as a treatment often of last resort - colostomy.

The dynamic graciloplasty combines a graciloplasty procedure with electrical stimulation in order to train the transplanted gracilis muscle to sustain prolonged contractions that will allow faecal continence. While it seems likely that the dynamic graciloplasty offers a good functional result for some patients, it is possibly associated with a high incidence of infection and hardware-related complications. Therefore, the aim of this systematic review was to assess the literature regarding the procedure of dynamic graciloplasty for the treatment of faecal incontinence and make recommendations on the safety and efficacy of this technique compared to colostomy.

METHODS

Search Strategy

A search strategy was devised to retrieve literature from the Medline, Current Contents, Embase and Cochrane Library databases up until October 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

Forty 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

No high level evidence was available and there were no comparative studies.

Safety

Mortality rates were around 2% for both graciloplasty and colostomy. Morbidity rates reported for graciloplasty varied widely across studies, with an average of one morbidity reported for each patient. Morbidity rates for colostomy were reported in a single study to be around 50%. There were no data available directly comparing the two surgical procedures.



Efficacy

Dynamic graciloplasty was clearly effective at restoring continence in between 42% to 85% of patients, whereas colostomy is, by its design, incapable of restoring continence. The dynamic graciloplasty is associated with a significant risk of re-operation, with rates reported to range between 0.14 per patient up to 1.07 per patient. Re-operation rates for colostomy were reported at 0.13 per patient up to a cumulative risk of 0.17 at 11 years. There were no data available directly comparing the two surgical procedures.

The ASERNIP-S procedure classification is:

For Safety

2. The safety 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.

Specifically, since the procedure appears to have a higher morbidity rate than colostomy and owing to the technical demands of the dynamic graciloplasty, it is recommended that this operation is only performed in centres where this operation is routinely performed. It is further advised that patients must be informed as to the probability that the procedure may have to be converted to colostomy some time in the future if serious morbidity results. The actual relative risk of morbidity that dynamic graciloplasty presents in comparison to colostomy remains undetermined and should be assessed by a non-randomised, controlled clinical trial, as randomisation may prove impossible for ethical or practical reasons. Since quality of life outcomes likewise remain undetermined, these measures should also be included in any such comparative trial.

For Efficacy

1. 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.

Specifically, although dynamic graciloplasty appears to be an efficacious alternative to colostomy for restoring continence in around 60% of patients (including patients who have had congenital disorders of the anorectum), it is recommended that patients be well informed of the probability of failure of this operation.

Members of the Review Group assessing Dynamic Graciloplasty for the Treatment of Faecal Incontinence:

Advisory Surgeon	Mr Jim Young
Protocol Surgeon	Mr Peter Hewett
Nominated Surgeon	Mr Tony Evers
Other Specialty Surgeon	Mr George Kiroff
ASERNIP-S Researcher	Mr Andrew Chapman
Chairman	Professor Guy Maddern

**ENDORSED BY THE ROYAL AUSTRALASIAN COLLEGE OF SURGEONS
COUNCIL - JUNE 2001**



Methods Used to Establish Laparoscopic Pneumoperitoneum

BACKGROUND

The majority of complications associated with laparoscopy occur during peritoneal access and the establishment of pneumoperitoneum. There are two forms of access - open and closed. Open laparoscopy is usually undertaken via an Hasson-type approach. Closed laparoscopy can occur using a blind approach, with either pre-insufflation before laparoscope insertion (needle/trocar method) or insufflation after laparoscope insertion (direct trocar method). One other hybrid form of closed laparoscopy involves limited visual access through the use of an optical trocar or needle.



There has been considerable debate as to which of these access methods is the safest and/or most effective. The objective of this systematic review was to inform this debate by testing the following three hypotheses:

1. open access is safer and/or more effective than closed access
2. the hybrid visual/closed access method is safer and/or more effective than the blind/closed methods
3. the direct trocar technique is safer and/or more effective than the Veress needle/primary trocar technique.

METHODS

Search Strategy

Six medical electronic databases were searched for relevant literature - Medline, Current Contents, The Cochrane Library, Embase, HealthStar and the Web of Science citation index. The search period extended from when the databases began inputting references (1966 or later) until May 2001. Grey literature and unpublished trials were identified through the Cochrane Library. This was supplemented by hand-searching recent conference proceedings from specialist societies and conducting internet searches. Finally, "primary pearling" was undertaken on the reference lists of all studies that met the inclusion criteria.

Study Selection

Randomised, quasi-randomised and non-randomised, or cohort, studies on human patients were included - if they compared access methods and provided relevant safety and efficacy outcome information. Patient safety outcomes identified *a priori* included peri- and postoperative mortality, major and minor complications and conversion to laparotomy. Efficacy outcomes included the ability, and average time taken, to establish pneumoperitoneum, mean operating time (by surgical procedure), gas usage and cost. Case series studies on a minimum of one thousand cases were included to estimate the prevalence of rare complications (e.g. death or major blood vessel injury). Studies in languages other than English were translated in full if randomised controlled trials - other study designs that met the inclusion criteria had their English abstracts assessed separately in the review.



Data Collection and Analysis

Singular data extraction was undertaken using tables that were developed previously, in conjunction with outcome definitions provided in the review protocol. A profile of each study was also produced, including information on institution, authors and publication year, intervention, methodology, study population characteristics, inclusion/exclusion criteria, length of follow-up and loss to follow-up, and surgical experience. All of the comparative studies identified for the review were critically appraised using a validated checklist to determine the internal and external validity of their results. For each hypothesis, meta-analyses of randomised or non-randomised studies were conducted for the identified outcomes. Measures of effect (relative risk [RR], pooled relative risks [RR_p], or pool weighted mean differences [WMD_p]) and 95% confidence intervals were calculated. Tests for statistical heterogeneity and publication bias were performed. Sensitivity analyses were conducted to investigate reasons for heterogeneity, including stratification on known confounders.

RESULTS

Open Access versus Needle/Trocar Access

Comparative information on safety was largely provided by pooling the results of non-randomised studies. Deaths were only reported in the needle/trocar access group - however, the rarity of the outcome meant it could not be determined whether the comparative risk of death was lower in the open access group [RR=0.98, 95%CI 0.04, 24.07]. Studies contributing data on the risk of major complications were found to be heterogenous ($\chi^2=11.12$, df=5, p=0.049). Stratification indicated possible differences related to patient selection. Prospective studies on patients with similar levels of previous abdominal surgery in both groups, showed a trend towards a reduced risk of major complications in open laparoscopy compared to needle/trocar laparoscopy [RR_p=0.30, 95%CI 0.09, 1.03]. Retrospective studies that appeared to have selected the higher risk patients (previous abdominal surgery) for open access had nearly three times the risk of major complications, relative to needle/trocar access [RR_p=2.7, 95%CI 1.57, 4.63].

56% of all major complications associated with access in non-randomised studies related to bowel injury. The risk of bowel injury was higher with open access compared to needle/trocar access [RR_p=2.17, 95%CI 1.14, 4.10], although selection bias may have influenced the results. Conversely, for open access there was an overall trend towards a decreased risk of access-site herniation [RR_p=0.21, 95%CI 0.04, 1.03]. In non-obese patients there was also a 57% reduced risk of minor complications [RR_p=0.43, 95%CI 0.20, 0.92] for those undergoing open access, along with a trend for fewer conversions to laparotomy [RR_p=0.21, 95%CI 0.04, 1.17].

Pooled estimates from randomised controlled trials suggested that the total time to establish pneumoperitoneum [WMD_p=-0.78 min, 95%CI -1.46, -0.10], as well as operating time [WMD_p=-6.42 min, 95%CI -6.95, -5.90], were slightly reduced during open access.

Direct Trocar versus Needle/Trocar Access

No deaths were reported as a consequence of direct trocar access. However, the relative risk of death and/or major complications for the direct trocar and needle/trocar techniques could not be established due to the rarity of these complications, and the exceptionally large sample size required to detect them.



NEW ASSESSMENTS COMPLETED CONT.

Minor complications in randomised trials were found to be reduced by 81% using direct trocar access as opposed to needle/trocar access [$RR_p=0.19$, 95%CI 0.09, 0.40]. A large proportion of these minor complications were due to extraperitoneal insufflation - the risk of which was substantially reduced with the direct trocar technique [$RR_p=0.07$, 95%CI 0.02, 0.25].

The comparative efficacy of the direct trocar and needle/trocar techniques could not be established.

Optical Trocar versus Needle/Trocar Access

There was a paucity of information comparing the optical trocar and needle/trocar access routes in closed laparoscopy. Tentative conclusions regarding their comparative safety and efficacy could not be drawn.

ASERNIP-S CLASSIFICATIONS

On the basis of the evidence presented in this systematic review, the ASERNIP-S Review Group agreed on the following classifications and recommendations concerning the safety and efficacy of access methods for establishing pneumoperitoneum.

Open laparoscopy via an Hasson-type approach

Evidence Rating - The evidence-base was considered to be of average strength, quality, precision and magnitude.

Safety and Efficacy - Definitive differences in the safety and efficacy of open laparoscopic access, relative to needle/trocar access, were not demonstrated.

Needle/trocar laparoscopy

Evidence Rating - The evidence-base was considered to be of average strength, quality, precision and magnitude.

Safety and Efficacy - Definitive differences in the safety and efficacy of needle/trocar access, relative to open access or direct trocar access, were not demonstrated.

Direct trocar access

Evidence rating - The evidence-base was considered to be of average strength, quality, precision and magnitude.

Safety and Efficacy - Definitive differences in the safety and efficacy of direct trocar access, relative to needle/trocar access, were not demonstrated.

Optical trocar access

Evidence rating - The evidence-base was considered to be of poor strength, quality, precision and magnitude.

Safety and Efficacy - Definitive differences in the safety and efficacy of optical trocar access, relative to needle/trocar access, could not be ascertained.



ASERNIP-S RECOMMENDATIONS

The ASERNIP-S Review Group acknowledges the very low rate of injury or complications associated with primary access. It is therefore considered that it would not be feasible, or of real clinical benefit, to conduct adequately powered trials enabling the statistical detection of differences in the safety and efficacy of the various access techniques.

However, existing population-based observational data that is routinely collected in Australia could well provide useful information on the mortality and morbidity associated with specific access techniques, particularly as there is the likelihood that access-related adverse events are under-reported in the literature.

This is an area where careful technique and anatomical knowledge are the most important attributes a surgeon can have - both of which are amenable to teaching. Therefore, in the absence of firm clinical evidence regarding the comparative safety and efficacy of these access techniques, it is recommended that the relevant professional societies (General Surgeons Australia / GSA and New Zealand Association of General Surgeons), should be asked to formulate some Training and Practice Guidelines, with indications, for the various techniques available for primary access in laparoscopic surgery, utilising the best quality evidence available.



Members of the Review Group assessing Methods used to Establish Laparoscopic Pneumoperitoneum:

Advisory Surgeon	Professor Glyn Jamieson
Protocol Surgeon	Professor Guy Maddern
Nominated Surgeon	Mr Alastair Brown
Other Specialty Surgeon	Mrs Anne Kolbe
Invited Member	Professor Janet Hiller
ASERNIP-S Researcher	Mrs Tracy Merlin
Chairman	Professor Guy Maddern

**ENDORSED BY THE ROYAL AUSTRALASIAN COLLEGE OF SURGEONS
COUNCIL - OCTOBER 2001**



Assessment Re-Appraisals

ASERNIP-S completed two re-appraisals of systematic reviews. The procedures that were re-appraised were:

- Minimally Invasive Parathyroidectomy
(Original Systematic Review - June 1999)
- Off-pump Coronary Artery Bypass Surgery with the Aid of Tissue Stabilizers
(Original Systematic Review - November 2000)

Minimally Invasive Parathyroidectomy

BACKGROUND

Bilateral neck exploration (BNE) is the current benchmark surgical treatment for primary hyperparathyroidism and involves bilateral exploration of the neck through a collar incision in order to locate and remove abnormal parathyroid tissue. The procedure has a reported success rate ranging from 95 to 98%, but this is highly dependent upon the experience level of the surgeon. Less or minimally invasive procedures have been pursued as possible surgical alternatives that may cause less pain, provide a smaller scar and leave one side of the neck pristine after surgery. These less or minimally invasive procedures generally rely on some form of preoperative and/or intraoperative imaging technique(s) that identifies unitary pathological features and allows a more limited and focused surgical exploration. However, there is still controversy regarding the accuracy of these localisation techniques and the dangers of over-reliance on their veracity. Therefore, the aim of this review re-appraisal was to compare the safety and efficacy of less or minimally invasive parathyroidectomy techniques against BNE.

METHODS

All original, published studies on less or minimally invasive laser parathyroidectomy techniques were identified by searching Medline between 01/1966 and 07/2000; Current Contents between week 1/1993 and week 35/2000; Embase between 01/1980 and 08/2000; and The Cochrane Library between 1966 and 2000 (Issue 3). Human and animal subjects were included for review. For human studies, only adult patients undergoing treatment for primary hyperparathyroidism were included. Papers that included patients with secondary or tertiary hyperparathyroidism, parathyroid carcinoma or multiple endocrine neoplasia, types I and II, were excluded.

RESULTS

The small sample size, poor evidence quality and limited methodological rigour of many studies meant that no definitive conclusion could be made as to the safety and efficacy of scan-directed unilateral exploration, video-endoscopic parathyroidectomy or minimally invasive radio-guided parathyroidectomy in comparison to BNE. Nonetheless, the current limited evidence suggested that the less or minimally invasive parathyroidectomy procedures were likely to approach BNE in terms of safety and efficacy.



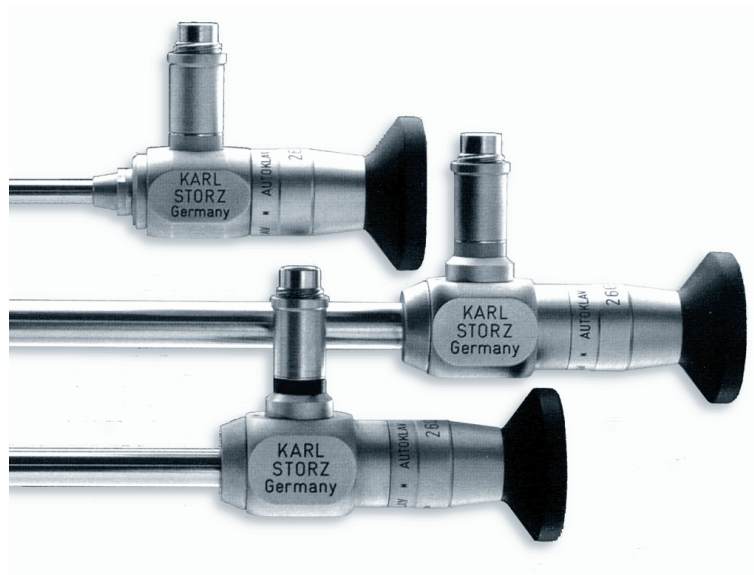
CONCLUSIONS

The ASERNIP-S Review Group concluded that the updated evidence base for less or minimally invasive parathyroidectomy techniques was still inadequate for establishing their safety and efficacy. The original ASERNIP-S safety and efficacy classification of '2' ('the safety and efficacy of the procedure cannot be determined at the present time due to an incomplete and poor quality evidence-base'), with a recommendation for a controlled clinical trial of less or minimally invasive parathyroidectomy techniques, was upheld.

Members of the Review Group assessing Minimally Invasive Parathyroidectomy:

Advisory Surgeon	Professor Thomas Reeve
Protocol Surgeon	Mr Robert Parkyn
Nominated Surgeon	Mr Jonathan Serpell
Other Specialty Surgeon	Associate Professor Peter Devitt
Invited Member	Professor Leigh Delbridge
ASERNIP-S Researcher	Dr Ann Scott
Chairman	Professor Guy Maddern

**ENDORSED BY THE ROYAL AUSTRALASIAN COLLEGE OF SURGEONS
COUNCIL - JUNE 2001**





Off-pump Coronary Artery Bypass Surgery with the Aid of the Octopus Tissue Stabilizer®

BACKGROUND

Coronary artery bypass graft surgery (CABG) with cardiopulmonary bypass is currently the benchmark surgical treatment for ischaemic coronary artery disease but it is associated with significant mortality and morbidity. Postoperative complications such as myocardial infarction, arrhythmias, stroke, neurological disorders, organ failure, respiratory failure, whole-body inflammatory response, and coagulation disorders are largely attributed to the use of cardiopulmonary bypass. Beating heart surgery is a less invasive alternative to CABG that avoids the use of cardiopulmonary bypass. The Octopus® Tissue Stabilizer is a commonly used cardiac tissue stabilizer that immobilises a small area on the surface of the beating heart and allows the surgeon to anastomose a bypass graft to the occluded artery.

The aim of this review re-appraisal was to compare the safety and efficacy of off-pump coronary artery bypass surgery with the aid of the Octopus Tissue Stabilizer® against conventional CABG with cardiopulmonary bypass.

METHODS

All original, published studies detailing the use of the Octopus Tissue Stabilizer®, in conjunction with off-pump coronary artery bypass surgery via full median sternotomy (OPCAB/OTS), and CABG were identified by searching Medline between 01/1966 and 02/2001; Current Contents between week 1/1993 and week 6/2001; Embase between week 1/1974 and week 5/2001; and the Cochrane Library between 1966 and 2001 (Issue 1). 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

The updated literature added little that could clarify the safety and efficacy issues of OPCAB/OTS. The poor evidence quality, limited postoperative outcome reporting and deficient methodological rigour of many studies meant that no definitive conclusion could be made as to the safety and efficacy OPCAB/OTS in comparison to CABG. Nonetheless, the limited comparative data suggested that OPCAB/OTS was likely to approach CABG in terms of safety outcomes. The paucity of long-term efficacy outcomes in the higher level comparative studies remained a significant drawback and made it impossible to assess whether OPCAB/OTS was more efficacious than CABG.



CONCLUSIONS

The ASERNIP-S Review Group concluded that the updated evidence base for OPCAB/OTS was still inadequate for establishing its safety and efficacy. The original ASERNIP-S safety and efficacy classification of '2' ('the safety and efficacy of the procedure cannot be determined at the present time due to an incomplete and poor quality evidence-base') with a recommendation for an audit of OPCAB/OTS, was upheld.

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

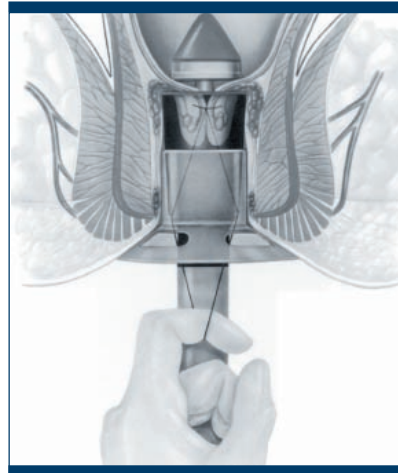
**ENDORSED BY THE ROYAL AUSTRALASIAN COLLEGE OF SURGEONS
COUNCIL - OCTOBER 2001**



New Assessments In Progress

The following seven procedures are currently undergoing systematic review:

- > Stapled Haemorrhoidectomy
- > Autologous Fat Transfer for Breast Augmentation
- > Adult-to-Adult Live Donor Liver Transplantation
- > Intraoperative Radiotherapy for Early Breast Cancer
- > Radiofrequency Ablation of Liver Tumours
- > Laparoscopic Adjustable Gastric Banding for the Treatment of Obesity [Re-appraisal]
- > Two reviews have been undertaken on behalf of MSAC in the area of cardiothoracic surgery.



The first of these systematic literature reviews will be released into the public domain in early 2002.

Procedure Nominations

The following nominations have been accepted by the ASERNIP-S Management Committee and will be assessed by ASERNIP-S in the near future:

- > Surgical Simulation
- > Holmium Laser Resection of the Prostate





Data Collection

ASERNIP-S data registries

Following two systematic reviews by ASERNIP-S, data registries were established:

- > Minimally Invasive Parathyroidectomy (MIP) - established 2000
- > Laparoscopic Live Donor Nephrectomy (LLDN) - established 1999

These audits aimed to address the recommendations made by the respective Review Groups.

The MIP data registry was established to evaluate the Australian experience of the procedure, with data being collected from all participating sites. A total of 168 cases have been submitted to date. Data were collected at the time of the procedure then at the six and twelve month follow-up. The data were analysed and used to complement the re-appraisal and update of the systematic review of minimally invasive parathyroidectomy (June 2001).

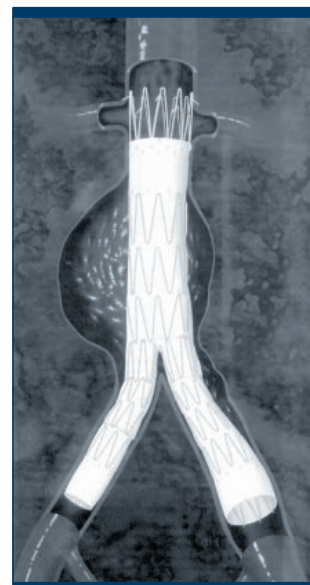
The LLDN register receives data from four sites in Australian and New Zealand. To date 99 cases have been submitted from these sites. Information from the register (spanning 7/5/97 to 28/2/00) was used to inform the re-appraisal of the procedure that took place in mid-2000.

In the current phase of the ASERNIP-S project, funding has not been provided to cover these audits or to facilitate the establishment of any further audits following on from recommendations of ASERNIP-S systematic literature reviews. At the present time ASERNIP-S is continuing to maintain the two established audits, but has not been proactive in obtaining data from its various sources. In the longer term the audits may need to be housed elsewhere.

Endoluminal Repair of Abdominal Aortic Aneurysms

ASERNIP-S has been fully funded to collect data for the procedure "Endoluminal Repair of Abdominal Aortic Aneurysms". It is anticipated this audit will continue for at least five years. MSAC established the audit after their review of the procedure (in 1999) showed that whilst the procedure appeared effective in the short-term, there was insufficient evidence concerning the long-term safety and efficacy of endoluminal graft repair.

The aim of the audit is to collect data from all surgeons who are performing the procedure in Australia. At the present time ASERNIP-S is holding data relating to 817 procedures performed in the public and private sector. In addition to operative information, surgeons are also providing follow-up for patients on a yearly basis. Summary reports of the audit data are submitted to the Commonwealth Department of Health and Aged Care at 6-month intervals; the 18-month report was submitted in October 2001.





DATA COLLECTION CONT.

The audit has evolved considerably during its first two years of operation. During the first (pilot) year, data was collected for both open and endoluminal procedures for the repair of abdominal aortic aneurysms. The requirement to collect open data however was removed with the commencement of the second funded period of the audit. In addition no new patients have been enrolled in the audit following 16 May 2001. The data set therefore covers all patients who received the endoluminal graft between 1 November 1999 and 16 May 2001. Follow-up data is being collected from all of these patients. Much effort is being put into making the audit data set as complete as possible. This will enable ASERNIP-S to provide the Commonwealth Department of Health and Aged Care with valuable information regarding the Australian experience with this procedure.

Audit reports can be obtained through the ASERNIP-S website at <http://www.surgeons.org/open/asernip-s/publications4.htm>.

Data collection and privacy

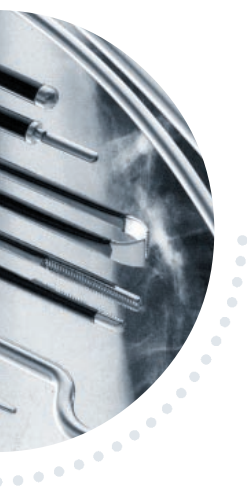
In the course of establishing data registries, ASERNIP-S has also appraised the requirements for privacy as laid down in the National Privacy Principles (NPP's). The NPP's have been updated slightly during 2001 following changes to the Privacy Act. (Information relating to these changes can be obtained through the Office for the Privacy Commissioner: <http://www.privacy.gov.au>.) ASERNIP-S has reacted to these changes in law by updating its practices and ensuring that its audit procedures maintain high standards of privacy. The RACS Ethics Committee have reviewed and approved these procedures. One consequence of the updated NPP's is that patients enrolled in the Endoluminal Audit of Abdominal Aortic Aneurysms will be provided with an information sheet explaining the purpose and background of the audit. Surgeons will also be required to obtain patient consent at follow-up. These procedures will not be undertaken for the other pre-existing audits where de-identified data was collected.

Reports

In December 2000, ASERNIP-S produced a report entitled "Health Registries: How, why and for whom?" on behalf of the Royal Australasian College of Surgeons for the Commonwealth Department of Health and Aged Care. This document aimed to increase the understanding of the role of health data registries. Recommendations included: making funding for register development the responsibility of the Commonwealth Department of Health and Aged Care; the creation of a central oversight body to coordinate the development of all Australian health registries; an audit of all existing health registers; data linkage between health registers and the adoption by Australian health register of definitions associated with generic elements outlined in the National Health Data Dictionary.

One outcome from this report was a publication by the National Health Information Management Group; Minimum guidelines for health registers for statistical and research purposes. September 2001. Commonwealth of Australia.

For information on other articles relating to data collection please refer to the Publications section of this report.





NET-S (New and Emerging Techniques-Surgical)

ASERNIP-S Horizon Scanning Project



Early identification of new surgical techniques and technologies can provide valuable information to clinicians, health service providers and governments. This information enables the development of clinical guidance, evaluation of safety and efficacy and consideration of financial implications. The term "Horizon scanning" is used to denote the identification of new and emerging surgical techniques and technologies that are on the "horizon" of introduction into Australian health care.

ASERNIP-S in conjunction with the NTC (Royal Australasian College of Surgeons' New Technology Committee), established an Australian-based Horizon Scanning Centre for New and Emerging Techniques - Surgical (NET-S). NET-S was developed with the aim of providing an early warning system for identification of new and emerging surgical techniques and technologies prior to their publication in 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 also to develop unique methodologies for improvement of the horizon scanning process, particularly in the area of surgery.

This is occurring through the following strategies:

- > Direct communication with Fellows of the Royal Australasian College of Surgeons
- > 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 site.

A survey, conducted in 2000, of all active Fellows of the Royal Australasian College of Surgeons identified 69 new techniques and technologies within 12 surgical specialties. These procedures were classified as one of the following:

- > Long Term - new or emerging technology identified approximately one to five years before its expected introduction into Australasian health care services (Horizon Scanning procedure)
- > Short Term - new or emerging technology identified up to one year before its expected introduction into Australasian health care services (Horizon Scanning procedure)
- > Evolving Technique - may include a surgical technique that involves a variation of a technique or device previously established
- > Awaiting Review - the nominated surgical technique has already been established into routine surgical practice and is now appropriate for review by ASERNIP-S
- > Under Review - the nominated procedure is currently being reviewed by ASERNIP-S.



NET-S (NEW AND EMERGING TECHNIQUES-SURGICAL) CONT.

Procedures classified as on the Long-term or Short-term horizon have now been assessed and "Procedure Briefs" for some of the techniques are now available for download via the NET-S website (http://www.surgeons.org/asernip-s_net-s/procedures.htm). Procedures classified as an "evolving technique" are not routinely assessed, however they may be if deemed appropriate.

NET-S provides:

- > An up-to-date database on new and emerging surgical techniques
- > Support to the established ASERNIP-S systematic review process through providing information on procedures warranting review.

Currently under development are mechanisms for the provision of advanced notice to the Department of Health and Aged Care, Divisions and Sections of the College and other interested agencies.



NET-S on the Web

The NET-S website is accessible via:

http://www.surgeons.org/asernip-s_net-s/index.htm

It is also accessible through the ASERNIP-S and the RACS websites.

The NET-S website includes a summary of the project, as well as the current database of new and emerging surgical techniques. Each procedure is listed under the relevant specialty and is assigned a classification pertaining to its horizon scanning status. Completed "Procedure Briefs" are available to download. Forms for nominating new techniques or for providing feedback or comments on techniques in our existing database are available. A registration form is also available for new contacts wishing to be included on our database of recipients of NET-S project news.





Project Activities for 2001

Promotional Activities

During 2001 ASERNIP-S completed four new systematic literature reviews which were endorsed by the Council of the Royal Australasian College of Surgeons and two review re-appraisals. The information was disseminated in several ways, including: publication in international surgical journals and other relevant periodicals; presentation of findings at national and international health technology assessment conferences; posting of information on the ASERNIP-S website (<http://www.surgeons.org/open/asernip-s/presentations.htm> and <http://www.surgeons.org/open/asernip-s/publications.htm>); and dissemination of the Annual Report. Two surveys of Credentials Committees were also conducted during 2001, determining their awareness of ASERNIP-S and the NET-S project. Information on recently completed systematic literature reviews are sent to Credentials Committees three times per year.

Peer-reviewed Publications

ASERNIP-S has published a number of its procedure assessments and other aspects of its work in national and international peer-reviewed journals.

- > Babidge WJ, Maddern GJ. Evidence-based surgery at ASERNIP-S. Can this improve quality in surgical practice? *Journal of Quality in Clinical Practice*, 2001; 20(4): 164-166.
- > Boulton M, Shimmin A, Wicks M, MacDougall G, Watson D, Maddern G. Arthroscopic subacromial decompression with a holmium:YAG laser: Review of the literature. *Australian and New Zealand Journal of Surgery*, 2001; 71(3): 172-177.
- > Chapman A, Levitt M, Hewett P, Woods R, Sheiner H, Maddern G. Laparoscopic-assisted resection of colorectal malignancies: a systematic review. *Annals of Surgery*, 2001; 234(5): 590-606.
- > Cooter R, Chapman A, Babidge W, Robinson D, Mutimer K, Wickham P, Kirov G, Maddern G. Ultrasound-assisted lipoplasty. *Australian and New Zealand Journal of Surgery*, 2001; 71(5): 309-317.
- > Maddern GJ. Evidence-based medicine in practice - Surgery. *Medical Journal of Australia*, 2001; 174(10): 528-529.
- > Merlin T, Arnold E, Petros P, MacTaggart P, Tulloch A, Faulkner K, Maddern G. A systematic review of tension-free urethropexy for stress urinary incontinence: intravaginal slingplasty and the tension-free vaginal tape procedures. *BJU International*, 2001; 88(9): 871-880.
- > Stirling GR, Babidge WJ, Peacock MJ, Smith JA, Matar KS, Snell GI, Colville DJ, Maddern GJ. Lung volume reduction surgery in emphysema: A systematic review. *Annals of Thoracic Surgery*, 2001; 72(2): 641-648.



PROJECT ACTIVITIES FOR 2001 CONT.

Currently ASERNIP-S has three articles that have been accepted for publication in 2002.

- > Boulton M, Babidge W, Anderson J, Denton M, Fitridge R, Harris J, Lawrence-Brown M, May J, Myers K, Maddern G. Australian audit for the endoluminal repair of abdominal aortic aneurysm - the first 12-months. *Australian and New Zealand Journal of Surgery*. 2002 (In press).
- > Boulton M, Babidge W, Roder D, Maddern G. Issues of consent and privacy affecting the functioning of ASERNIP-S. *Australian and New Zealand Journal of Surgery*. 2002 (In press).
- > Chapman A, Geerdes B, Hewett P, Young J, Evers T, Kiroff G, Maddern G. Systematic review of dynamic graciloplasty in the treatment of faecal incontinence. *British Journal of Surgery*. 2002 (In press).

Other Publications

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

- > ASERNIP-S: Systematic review of Off-pump Coronary Artery Bypass Surgery. *Better Health Outcomes*. The Commonwealth Department of Health and Aged Care newsletter, Summer 2001; 7(1): 20-21.
- > ASERNIP-S: Systematic review of tension-free urethropexy for stress urinary incontinence: intravaginal slingplasty and the tension-free vaginal tape procedures. *Better Health Outcomes*. The Commonwealth Department of Health and Aged Care newsletter, Winter 2001; 7(3): 20-22.
- > Keeping tabs on new surgical techniques. *Surgical News*, 2001; 2(4): 8.
- > Maddern GJ. ASERNIP-S: An Australian safety and efficacy register for new interventional procedures. *New United Medical Protection*, 2001; Issue 1: 5-7.
- > Maddern GJ and Babidge WJ. The Australian Safety & Efficacy Register of New Interventional Procedures - Surgical (ASERNIP-S). *Coding Matters*, 2001; Volume 8, Number 1: 12.

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:

- > Babidge WJ, Maddern GM. The impact of evidence-based medicine on the introduction of new surgical procedures. 4th International Conference on the Scientific Basis of Health Services, Sydney, Australia, 22-25 September 2001.
- > Babidge W, Silbereisen J, Scott A, Maddern G. Contribution of consumers to assessment of emerging technologies in health care. ISTAHC's 17th Annual Meeting. Philadelphia, United States of America, 3-6 June 2001.
- > Boulton M. Ethics and the Law - Some Issues involved in Data Collection, Australasian Health Research Data Managers Association, Melbourne, Australia, 13-14 September 2001.
- > Faulkner K. Royal College of Physicians and Surgeons of Canada, Annual Conference, 20-22 September 2001.
- > Maddern G. ASERNIP-S. An Australian experiment. *Hong Kong Surgical Forum*; July 2001.



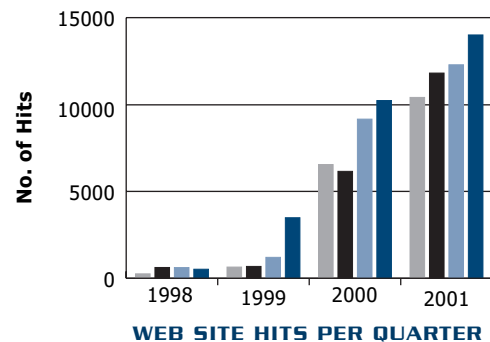
- > Maddern G. Introduction of new technology into neurosurgery. *Department of Neurosurgery*, Royal Adelaide Hospital; July 2001.
- > Maddern G. The introduction of new technology into clinical practice; the role of ASERNIP-S. *Safety and Quality in Surgery and Anaesthesia*, St John of God Hospital, Perth, Australia, November 2001.
- > Maddern G, Babidge W, Silbereisen J, Emmanuel N, Liddell J. Establishing an Australasian early warning system of new and emerging surgical techniques (NET-S). *Royal Australasian College of Surgeons Annual Scientific Congress*, Canberra, Australia, May 2001.
- > Scott A, Babidge W, Maddern G. Are assessments without RCT's a valid option? *ISTAHC's 17th Annual Meeting*. Philadelphia, United States of America, 3-6 June 2001.

ASERNIP-S Website

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

The website is regularly updated and includes information on procedures that are currently being assessed (including forms for nomination of new procedures); publications, which includes a document on the ASERNIP-S review process, the ASERNIP-S brochure, ASERNIP-S Annual Reports and systematic literature reviews (full reviews, executive summaries and consumer summaries); contact details for the ASERNIP-S staff; data submission forms for the Endoluminal Repair of Abdominal Aortic Aneurysms audit; links to affiliated organisations, journals, and other organisations as well as consumer links; news; recent and forthcoming presentations.

ASERNIP-S has been monitoring its web hits on a quarterly basis for the past four years. As can be seen from the graph below, web hits continue to increase, possibly due to increased promotional activities. The most popular pages on the website were the publications download page (23% of total page requests) and the page detailing procedures that have or are currently being assessed (18% of total page requests). The website has undergone recent modifications and now has a search function.



NET-S Website

The NET-S website address is http://www.surgeons.org/asernip-s_net-s/index.htm
(The website is also accessible from the ASERNIP-S and RACS websites).

The website for New and Emerging Techniques - Surgical became operational in 2001. The NET-S website is regularly updated and the NET-S database of new and emerging techniques is accessible, with procedures classified into long- or short-term horizon, evolving technique, awaiting (systematic) review or under (systematic) review. The procedures are also searchable by specialty. Forms are available for nominating a procedure or commenting on a procedure. Applications to receive NET-S news may also be made through this website.



PROJECT ACTIVITIES FOR 2001 CONT.

ASERNIP-S Credentials Committee Survey

Credentials Committees of Australian hospitals were surveyed in April 2001. The rate of return was only 20%, but of these, 85% found that the notification of ASERNIP-S reviews was useful. A good percentage of respondents (62%) had seen the ASERNIP-S reviews, 22% had visited the ASERNIP-S website and 28% had used ASERNIP-S systematic literature reviews to inform policy. There were changes in practice as a result of the ASERNIP-S reports, where 39% implemented centre-based audits, 17% disallowed usage and 11% changed usage of a procedure. Results of the survey indicated that the preferred way to have the review information provided was via executive summaries.

A second survey of Credentials Committees of Australian Hospitals is currently being conducted. Results are expected to be presented at the International Society for Technology Assessment in Health Care being held in Berlin, Germany in June 2002.

Education and Training

ASERNIP-S is affiliated with the University of Adelaide and offers several research projects to fourth-year medical students. In 2001, two students completed a systematic review on a new surgical procedure and a third student performed scoping literature searches and prepared reports on a number of new and emerging surgical techniques and technologies for the NET-S horizon scanning project.

In 2002, three students will be undertaking work on the NET-S horizon scanning project and a fourth student will undertake a systematic review on a new surgical procedure.

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

Personnel

ASERNIP-S has expanded during 2001. Jane Franklin joined ASERNIP-S in January 2001, to job share in the role of administrative officer. Four new researchers joined ASERNIP-S this year; Philippa Middleton in April 2001, Leanne Sutherland in May 2001, Astrid Cuncins-Hearn in September 2001 and Bronni Simpson in October 2001. Philippa, Leanne and Astrid are undertaking systematic literature reviews, while Bronni is working on the NET-S horizon scanning project as well as other project-wide activities. Both Tracy Merlin and Jane Silbereisen left ASERNIP-S this year.



ASERNIP-S Management Committee

The ASERNIP-S Management Committee acts 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 for overseeing the management of the ASERNIP-S project and its associated activities.

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	ASERNIP-S Chairman & Royal Australasian College of Surgeons President
Mr Bruce Barraclough	Royal Australasian College of Surgeons Fellow
Ms Wendy Brown	Consumers Health Forum
Mr Brian Johnston	Australian Council on Healthcare Standards
Mr Michael Kitchener	Medical Services Advisory Committee
Professor Guy Maddern	ASERNIP-S Surgical Director
Dr Vin Massaro	Royal Australasian College of Surgeons Chief Executive
A/Professor Rosemary Roberts	National Centre for Classification in Health
Mr David Robinson	Royal Australasian College of Surgeons Fellow
A/Professor David Scott	Royal Australasian College of Surgeons Executive Director for Surgical Affairs

We will sadly miss the contributions of Professor Chris Silagy from the Australasian Cochrane Centre, who passed away in December 2001.



ASERNIP-S Staff Profiles

PROFESSOR GUY MADDERN

Surgical Director

Professor Maddern was appointed Surgical Director of ASERNIP-S in October 1997 and since that time has been involved in developing the ASERNIP-S 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 Administration Manager

Dr Wendy Babidge is responsible for the management of the ASERNIP-S project and the supervision of administrative and research staff. She is a Research Scientist and has a degree in Applied Science, Honours Degree in Biotechnology and a PhD from the University of Adelaide. Wendy also completed a Graduate Diploma in Business in 2000, is a member of the Australian Institute of Management (AIMM) and a Certified Practicing Manager.



Wendy has been involved in the initial assessment of a number of procedures at ASERNIP-S and has a particular interest in the development of unique assessment methodologies for surgical procedures. Wendy is also involved in fostering collaboration between Health Technology Assessment groups worldwide.

MRS MAGGI BOULT

Data Manager

Maggi Boulton 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 project. Maggi is especially interested in the privacy legislation in relation to submission of data for audit.

Maggi 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 computer applications and databases for commercial and scientific use.

MR ANDREW CHAPMAN**Senior Researcher**

Andrew Chapman joined ASERNIP-S in July 1999. He has since completed three procedure assessments: Laparoscopic-Assisted Resection of Colorectal Malignancies, Laparoscopic Adjustable Gastric Banding in the Treatment of Obesity and Dynamic Graciloplasty for Faecal Incontinence. Andrew has also completed a re-appraisal of Ultrasound-assisted Lipoplasty, and is currently completing the assessment of Autologous Fat Transfer for Breast Augmentation

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. He previously conducted research for the Disability Services Office of the South Australian Health Commission and also as a private consultant.

ASTRID CUNCINS-HEARN**Senior Researcher**

Astrid joined ASERNIP-S in September 2001. She is currently assessing Intraoperative Radiotherapy for Early Stage Breast Cancer.

Astrid has Bachelor and Masters Degrees of Science specialising in biomechanics from the University of Guelph in Canada. She has worked in the areas of surgical biomechanical research and trauma and cancer outcomes databases in both Canada and Australia.

JANE FRANKLIN**Administrative Assistant**

Jane Franklin joined ASERNIP-S in January 2001 on a part-time basis to provide additional administrative and clerical support to the project. Jane brings with her a sound background in Banking and Customer Service, and has a Certificate II in Business (Office Administration).

**PHILIPPA MIDDLETON****Senior Researcher**

Philippa Middleton joined ASERNIP-S in April 2001. She is a member of the Cochrane Collaboration (an international group which produces and maintains systematic reviews of health care interventions) and her employment with the Collaboration has included the positions of Associate Director of the UK Cochrane Centre and Assistant Director of the Australasian Cochrane Centre. She is currently working on a review of Adult-to-Adult Living Donor Liver Transplantation and a MSAC review in the area of cardiothoracic surgery.

Philippa has an Honours Degree in Science, a Graduate Diploma in Library Studies and she completed her Masters in Public Health this year. She is particularly interested in how to minimise bias and maximise the quality of biomedical research, so that decisions in health care can be based on the most reliable evidence available.



ASERNIP-S STAFF PROFILES CONT.

DR ANN SCOTT

Senior Researcher

Dr Ann Scott joined ASERNIP-S in July 1999. She has completed assessments and re-appraisals of Minimally Invasive Techniques for the Relief of Bladder Outflow Obstruction and Off-Pump Coronary Artery Bypass Surgery with the Aid of the Octopus Tissue Stabilizer®. She also conducted the re-appraisal for Minimally Invasive Parathyroidectomy and the systematic literature review of the Endoscopic Modified Lothrop Procedure for the Treatment of Chronic Frontal Sinusitis. She is currently involved in a MSAC review in the area of cardiothoracic surgery. Ann is especially interested in improving the quality of systematic reviews and ensuring the relevancy of health technology products to clinicians.

Ann has a Degree in Science, majoring in Zoology and Biochemistry, an Honours Degree in Zoology and a PhD from the University of NSW for her research on developmental endocrinology in marsupials. She completed a Graduate Diploma in Business Management in 2000.

BRONNI SIMPSON

Researcher - Project Wide

Bronni Simpson joined ASERNIP-S in October 2001 and is working on a number of research projects, including development of the New and Emerging Techniques - Surgical (NET-S) horizon scanning project.

Bronni has a Degree in Science, an Honours Degree in Animal Nutrition from the University of New England, NSW and has recently completed her PhD, investigating the structural and functional characteristics of the major skeletal muscle chloride ion channel.

LEANNE SUTHERLAND

Senior Researcher

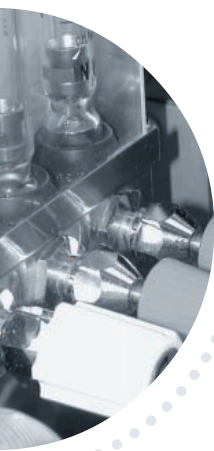
Leanne Sutherland joined ASERNIP-S in May 2001. She has completed an assessment of Stapled Haemorrhoidectomy and is currently assessing Radiofrequency Ablation of Liver Tumours.

Leanne has a Degree in Science, majoring in Genetics and Molecular Biology, and an Honours Degree in Biochemistry from the Flinders University of South Australia. Leanne has recently completed her PhD, investigating stretch-induced differentiation and programmed cell death in type II alveolar lung cells.

ROSEMARY WONG

Administrative Assistant

Rosemary joined ASERNIP-S in November 2000 on a part-time basis to provide administrative-assistance to the project and clerical support for the research staff. Rosemary previously worked 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 CLASSIFICATION SYSTEM

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

EVIDENCE RATING

- > Poor
- > Average
- > Good

(This gives an idea of the strength, quality, precision & magnitude (where appropriate) of the evidence-base)

SAFETY

- > Safe compared to comparator* procedure(s)
- > Safety cannot be determined
- > Unsafe compared to comparator* procedure(s)

EFFICACY

- > Efficacious compared to comparator* procedure(s)
- > Efficacy cannot be determined
- > Not efficacious compared to comparator* procedure(s)

RECOMMENDATIONS REGARDING THE NEED FOR FURTHER RESEARCH

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

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

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

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

Effective July 2001



Explanation of Classifications

EVIDENCE RATING

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

Good

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

Average

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

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

Poor

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





SAFETY AND EFFICACY CLASSIFICATION

Safety

- > Safe compared to comparator* procedure(s)

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

- > Safety cannot be determined

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

- > Unsafe compared to comparator* procedure(s)

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

Efficacy

- > Efficacious compared to comparator* procedure(s)

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

- > Efficacy cannot be determined

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

- > Not efficacious compared to comparator* procedure(s)

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

RESEARCH RECOMMENDATIONS

It may be recommended that an audit or a controlled (ideally randomised) clinical trial be undertaken in order to strengthen the evidence base.

CLINICAL RECOMMENDATIONS

Additional recommendations for use of the new intervention in clinical practice may be provided to ensure appropriate use of the procedure by sufficiently qualified/experienced centres and on specific patient types (where appropriate).

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



Appendix II

ASERNIP-S Safety and Efficacy Classifications (pre July 2001)

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 III

Systematic Literature Review and Guidelines Reports

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

ASERNIP-S Report no. 1
Minimally Invasive Parathyroidectomy (June 1999)

ASERNIP-S Report no. 2
Lung Volume Reduction Surgery (June 1999)

ASERNIP-S Report no. 3
Laparoscopic Live Donor Nephrectomy (June 1999)

ASERNIP-S Report no. 4
Ultrasound-Assisted Lipoplasty (October 1999)

ASERNIP-S Report no. 5
Percutaneous Endoscopic Laser Discectomy [Re-appraised] (February 2000)

ASERNIP-S Report no. 6
Arthroscopic Subacromial Decompression using the Holmium:YAG laser
[Re-appraised] (February 2000)

ASERNIP-S Report no. 7
Minimally Invasive Techniques for the Relief of Bladder Outflow Obstruction
(February 2000)

ASERNIP-S Report no. 8
Laparoscopic-assisted Resection of Colorectal Malignancies (February 2000)

ASERNIP-S Report no. 9
Laparoscopic Adjustable Gastric Banding in the Treatment of Obesity (June 2000)

ASERNIP-S Report no.10
Off-Pump Coronary Bypass Surgery with the Aid of the Octopus Tissue Stabilizer®
(November 2000)

ASERNIP-S Report no.11
Tension-free Urethropexy for Stress Urinary Incontinence: Intravaginal Slingplasty and
the Tension-free Vaginal Tape Procedures (February 2001)

ASERNIP-S Report no.12
Endoscopic Modified Lothrop Procedure for Treatment of Chronic Frontal Sinusitis
(June 2001)



APPENDIX III CONT.

ASERNIP-S Report no.13

Methods used to Establish Laparoscopic Pneumoperitoneum (October 2001)

ASERNIP-S Report no.14

Dynamic Graciloplasty for the Treatment of Faecal Incontinence (June 2001)

ASERNIP-S Report no.15

Laparoscopic Live Donor Nephrectomy [Re-appraised] (May 2000)

ASERNIP-S Report no.16

Minimally Invasive Techniques for the Relief of Bladder Outflow Obstruction
[Re-appraised] (November 2000)

ASERNIP-S Report no.17

Ultrasound-assisted Lipoplasty [Re-appraised] (July 2000)

ASERNIP-S Report no.18

Lung Volume Reduction Surgery [Re-appraised] (May 2000)

ASERNIP-S Report no.19

Minimally Invasive Parathyroidectomy [Re-appraised] (June 2001)

ASERNIP-S Report no.20

Off-Pump Coronary Bypass Surgery with the Aid of the Octopus Tissue Stabilizer®
[Re-appraised] (October 2001)

Clinical Practice Guidelines have been developed for one procedure:

ASERNIP-S CPG Report no.1

Clinical Practice Guidelines for the Advanced Breast Biopsy Instrument





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ASERNIP-S would like to thank the Fellows of the Royal Australasian College of Surgeons and other contributors from the Health Care industry who have participated in the project throughout the year.

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The nomination of procedures for assessment by ASERNIP-S should be made to the ASERNIP-S office on the appropriate form. The continued participation of surgeons in Procedure Review Groups and the submission of data on procedures under audit by ASERNIP-S are encouraged.

ASERNIPS