Systematic Review of Percutaneous Endoscopic Laser Discectomy

ASERNIP-S REPORT NO. 5
Updated and re-appraised 2000

February 2000

Australian Safety & Efficacy Register of New Interventional Procedures – Surgical

The Royal Australasian College of Surgeons
Systematic review of percutaneous endoscopic laser discectomy
Update & Re-appraisal

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Executive Summary

Background:
The aim was to systematically review the literature on percutaneous endoscopic laser discectomy (PELD) with respect to the safety and efficacy of the procedure. Where possible the procedure was compared with open discectomy.

Methods:
Search Strategy - Studies on percutaneous endoscopic laser discectomy were identified using MEDLINE (1984 to December 1999), EMBASE (1974 to December 1999) and Current Contents (1993 to Week 1, 2000). A number of search terms were used:
   PELD (percutaneous endoscopic laser discectomy)
   PLDD (percutaneous laser disc decompression)
   Laser and (spine or lumbar) and (disc* or disk*)
The Cochrane Library was searched from 1966 to Issue 4, 1999, using the search terms Discectomy or Discotomy.
Study Selection – Papers were included on the basis of a pre-determined protocol, and independent assessment by two reviewers. Live human studies of patients with lumbar disc prolapses for whom surgery was appropriate were included. Cadaver studies were also included. Each paper was required to provide information on at least one of several safety and efficacy outcomes as detailed in the protocol.
Data Collection and Analysis - Papers that met the inclusion criteria were tabulated and critically appraised in terms of the methodology and design, sample size, outcomes, and the possible influence of bias.

Results:
Only twelve papers were identified which related to percutaneous endoscopic laser discectomy. The level of evidence for safety and efficacy was low; there were no controlled, blinded or randomised studies. The highest level of evidence came from time series studies. No quantitative analysis could be undertaken for this review.

Conclusions:
Given the extremely low level of evidence available for this procedure it was recommended that the procedure be regarded as experimental until results are available from a controlled clinical trial, ideally with random allocation to an intervention and control group.
Safety and Efficacy Classification for Percutaneous Endoscopic Laser Discectomy

The ASERNIP-S Procedure Classifications were revised in December 1999 by the ASERNIP-S Management Committee. As such, procedures already assessed by ASERNIP-S were allocated a new classification from the following list;

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.

Percutaneous Endoscopic Laser Discectomy has been allocated a category 2 classification.

References to previous classifications remain unchanged in the document.

Recommendations Regarding the Need for Further Research

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

Important Note: The information contained in this report is a distillation of the best available evidence located at the time the searches were completed as stated in the protocol. Please consult with your medical practitioner if you have further questions relating to the information provided, as the clinical context may vary from patient to patient.
Ratification

The Systematic Review of Percutaneous Endoscopic Laser Discectomy (1st revision), Recommendations and Safety and Efficacy Classification were ratified by the:

ASERNIP-S Management Committee  
May 6th 2000  
Melbourne, Australia

The Initial Systematic Review of Percutaneous Endoscopic Laser Discectomy, Recommendations and Safety and Efficacy Classification were ratified by the:

ASERNIP-S Management Committee  
December 11th 1999

The Council of the Royal Australasian College of Surgeons in  
February 2000
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Review Protocol

(Including first update for 1999)

Percutaneous Endoscopic Laser Discectomy

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Protocol Update (December 1999)

1. Background

The original protocol (see following pages) established the search criteria for percutaneous endoscopic laser discectomy. The search was undertaken in September 1998. As insufficient evidence was available to assess the safety and efficacy of the procedure at that time, the literature search will be repeated at annual intervals to determine whether any significant changes occur in the evidence base. This first update covers the period following the primary search and up to December 1999.

2. Objective

To identify literature relating to the surgical procedure percutaneous endoscopic laser discectomy that was published in the year following the primary literature search and to evaluate any extra papers located by this means with respect to the safety and efficacy of the procedure.

3. Inclusion Criteria

Papers were selected for inclusion in the annual literature review of percutaneous endoscopic laser discectomy on the same basis as described in the original protocol.

4. Exclusions

Papers were selected for exclusion in the annual literature review of percutaneous endoscopic laser discectomy on the same basis as described in the original protocol.

5. Searches

Databases and dates searched:

- Current Contents to: 17/1/2000
- Medline (Winsirs) to: 1/12/1999
- Embase to: 1/12/1999
- The Cochrane Library Issue 4, 1999

Search terms:

Search terms used were the same as described in the original protocol.
6. Literature Database  
No new references were located for the period of one year following the primary literature search.

7. Recommendations of Safety and Efficacy  
The recommendation for safety and efficacy as formulated for the primary review remains unchanged, as no additional supporting evidence was located for the first year post review. There is no reason to re-convene the Review Group.

The ASERNIP-S classification remains at level 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.
Original Protocol

1. Objective
To assess the literature relating to the surgical procedure **percutaneous endoscopic laser discectomy** and compare it to literature reviews of the “gold standard” procedure **open discectomy**. Recommendations about the safety and efficacy of this new, minimally invasive spinal surgery will then be made.

2. Background

**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 techniques for treatment of disc prolapse were first described in 1975 by Hijikata\(^1\). Various methods have been used since then and the use of lasers was described in 1987 by Choy \textit{et al.}\(^2\).

Percutaneous Endoscopic Laser Discectomy 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 major proposed advantages of PELD relate to its minimal invasiveness, with procedures being performed as day surgery cases under local anaesthesia\(^3\).

Detractors, however, have reported high rates of subsequent open surgery\(^4\).

The safety and efficacy of this procedure will be evaluated by an ASERNIP-S Review Group and compared with the Open Discectomy procedure. Open Discectomy has been in use since the mid 1930’s, and is a well established and popular procedure\(^5\). For this reason it was nominated as the “gold standard”.

4
References


3. Inclusion Criteria

Papers are selected for inclusion in this literature review on endoscopic laser discectomy on the basis of the following criteria:

- **Participants:**
  Human studies are included in the review. For the live human studies, patients with a lumbar disc prolapse, (alternatively referred to as herniated or a bulging disc) for whom surgical intervention is appropriate.

- **New Intervention:**
  If the paper to be included concerns the new intervention, it should deal with
  - percutaneous insertion of a probe into a herniated disc under local anaesthetic,
  - use of laser energy to ablate/vaporise nucleus pulposus tissue, and
  - endoscopic technique.

- **Comparative or “gold standard” Intervention:**
  Papers included for the comparative intervention are reviews of the open discectomy technique, which represent the current safety and efficacy of this technique.

- **Outcome measures:**
  For a paper to be included it must contain information on at least one of the following outcomes:

  A) Patient centred outcomes:

  1. Patient or clinician’s assessment of recovery.
  2. Proportion of patients with resolution/improvement of pain.
  3. Proportion of patients with improvement in function measured on a disability or quality of life scale.
  4. Length of hospital stay.
  5. Return to work.
  6. Rate of repeat back surgery/conversion to standard operation.
B) Objective measures of physical impairment and changes in neurological signs prior to and following surgery.

C) Complications (early and late).

- **Types of studies**
  Papers to be included in the review of the new procedure must be in one of the following forms:

  - Randomised controlled trials, controlled clinical trials (historical, non randomised), case-series and case reports.
  - Additional published material in the form of letters, commentary and discussions should be included in the submissions to the review surgeon as background information.
  - Study types other than those mentioned above may be included if they are felt to be relevant and if valid reasons are given in the protocol.

Due to the large volume of information available on the comparative technique, papers included for the assessment of the comparative “gold standard” intervention are to be review articles published during the 1990’s. Reviews provide a synthesis of the consensus opinion on the safety and efficacy of the procedure.

4. **Exclusions**
- The ASERNIP-S researcher and protocol surgeon exclude references that do not meet the inclusion criteria.
- Reasons must be documented for excluding particular references that meet the inclusion criteria.

5. **Additional Information**
- Guidelines on assessing the published material in terms of methodological design and validity (i.e. hierarchy of study designs, bias, confounding, sample size, and statistical power) will be sent to the Review Surgeon. Supplementary material on the review process will be attached, including excerpts from The Cochrane Collaboration Handbook, and the NH&MRC 1999 guidelines for assessing research evidence.
- As this review was an exclusively narrative systematic review, data is summarised in table format, rather than through meta-analysis.

6. **Literature Search Strategy for Review**
  - **Databases searched:**
    - Silverplatter Medline (WinSpirs)
    - Ovid Current Contents
    - The Cochrane Collection (Cochrane Library CD, 1999 Issue 1)
Lexis-Nexis Embase

➢ Search terms:

Search strategies were devised by the ASERNIP researcher and protocol surgeon for the Medline, Current Contents and Embase databases.

1. Search on “gold standard” procedure – open discectomy.
   This search was performed to retrieve review articles published since 1990 for the open discectomy technique. The basic search terms entered were:

   ((Dis?ectomy or Dis?otomy or Laminectomy) and (open) and (review in PT) and (English in LA) [since 1990]

   For the sake of consistency, the same search terms were used for the Current Contents and EMBASE online databases. The Cochrane Collection database was searched using the terms:

   discectomy or diskectomy
   discotomy or diskotomy

2. Search on ‘percutaneous endoscopic laser discectomy’.
   The search was performed to enable the retrieval of papers dealing with percutaneous endoscopic laser discectomy. A number of alternative search terms were used:

   – PELD – (percutaneous endoscopic laser discectomy)
   – PLDD – (percutaneous laser disc decompression)
   – laser and (spine or lumbar) and (disc* or disk*)

NB * denotes a truncation symbol, which retrieves multiple variations at the end of the word.
? denotes the wild card symbol, which retrieves single variations within a word.

➢ Search Time Frame:

1. SilverPlatter Medline (Winspirs)
   New intervention - year range = 1984 – 9/98
   Comparative intervention - year range = 1990 – 9/98

2. Ovid Current Contents
   New intervention - year range = 1993 – week 37, 1998
   Comparative intervention - year range = 1993 – week 37, 1998

3. Lexis-Nexis Embase
   New intervention - year range = 1974 – 9/98
   Comparative intervention - year range = 1990 – 9/98

   - year range = 1966 – 1999
LITERATURE DATABASE:

Endoscopic Laser Discectomy

Laserdiscect.rmd: Thirteen references formed the Reference Manager database after exclusions of duplicates and articles that clearly did not meet the inclusion criteria.

Open Discectomy

DiscectomyReview.rmd: Twenty-six references formed the Reference Manager database after exclusions by the researcher.

Background information

Nine items formed the background information for the new intervention. This included advertising material. In addition, three references were included on laser principles.

7. Formulation of Recommendations of Safety and Efficacy

Based upon data from the review process, recommendations by the Review Surgeon in the form of a Draft Review were made on the safety and efficacy of percutaneous endoscopic laser discectomy. The Draft Review and Methodological Assessment Report was then disseminated amongst members of the Review Group who further reviewed the procedure according to their particular expertise. Any concerns were then discussed at the Review Group meeting where recommendations and a classification were issued.
Percutaneous Endoscopic Laser Discectomy: A Systematic Review

Revised and Updated 2000
Review Update (January 2000)

A manuscript based on the original ASERNIP-S review on the safety and efficacy of percutaneous endoscopic laser discectomy which included the literature update for 1999, was published in the *Australian and New Zealand Journal of Surgery* 70 (7) p475-479.

Literature searches were conducted in January 2000 to update the literature base (as described in the protocol update). No new literature was available. The manuscript forms the basis of the ASERNIP-S update for the systematic review of safety and efficacy of percutaneous endoscopic laser discectomy.

The original narrative review by Professor Robert Fraser and the ASERNIP-S methodological assessment are included in the appendices.
PERCUTANEOUS ENDOSCOPIC LASER DISCECTOMY: A SYSTEMATIC REVIEW

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Summary

Background: The aim of the present paper was to systematically review the literature on percutaneous endoscopic laser discectomy (PELD) with respect to the safety and efficacy of the procedure. Where possible the procedure was compared with open discectomy.

Methods: Studies on PELD were identified using MEDLINE (1984 to December 1999), EMBASE (1974 to December 1999) and Current Contents (1993 to Week 1, 2000). A number of search terms were used:

- PELD (percutaneous endoscopic laser discectomy)
- PLDD (percutaneous laser disc decompression)
- Laser and (spine or lumbar) and (disc* or disk*)

The Cochrane Library was searched from 1966 to issue 4, 1999, using the search terms discectomy or discotomy. Live human studies of patients with lumbar disc prolapses for whom surgery was appropriate were included. Cadaver studies were also included. A surgeon and reviewer independently assessed the retrieved articles for their inclusion in the review.

Results: Only twelve papers were identified which related to PELD. The level of evidence for safety and efficacy was low; there were no controlled, blinded or randomised studies. The highest level of evidence came from time series studies. No quantitative analysis could be undertaken for this review.

Conclusions: Given the extremely low level of evidence available for this procedure it was recommended that the procedure be regarded as experimental until results are available from a controlled clinical trial, ideally with random allocation to an intervention and control group.

Key Words: Endoscopic Surgical Techniques, Discectomy, Laser Techniques, Percutaneous Laser Surgery, Review.
**Introduction**

There are three categories of treatment available for symptoms resulting from lumbar disc prolapse: conservative; percutaneous techniques; and open surgery. This review discusses the information obtained during the assessment of: percutaneous endoscopic laser discectomy (PELD) by the Australian Safety and Efficacy Register of New Interventionist Procedures – Surgical (ASERNIP-S). ASERNIP-S conducts reviews of new surgical procedures to determine the safety and efficacy from the published peer-reviewed literature base. It then makes recommendations about the use of the technique with respect to its widespread introduction, or requirements for further trials or audit.

Percutaneous endoscopic laser discectomy is a minimally invasive surgical procedure, whose purpose is to provide symptomatic relief of pain caused by a prolapsed intervertebral disc. The procedure forms part of a medley of minimally invasive surgical techniques that arose after the development of percutaneous discectomy by Hijikata *et al.* in 1975.¹ The major proposed advantages of PELD relate to its minimally invasive nature, and the procedure is performed on a day-surgery basis under local and/or neuroleptic anaesthesia.² Detractors have reported high rates of subsequent open surgery³, limited application,⁴ and have suggested that percutaneous discectomy techniques may be no more effective than conservative treatment or no treatment.⁵

Percutaneous endoscopic laser discectomy aims to reduce the size of the prolapsed disc by ablating the nucleus pulposus with laser energy. A probe is inserted into the disc through an incision in the patient’s back. Visualisation within the disc space is achieved by the use of an endoscope. For the PELD procedure the laser most commonly coupled with the endoscope is the holmium:YAG laser. The equipment is manufactured by Trimedyne (Trimedyne Inc., Irvine, CA, USA; OmniPulse Holmium:YAG laser with the Sidefire™ laser fibre) and Coherent (Coherent Inc., Palo Alto, CA, USA; laser –assisted spinal endoscopy (LASE) kit and Vera Pulse™ laser). Occasionally a Nd:YAG (neodymium:yttrium-aluminium-garnet) laser is used, and the procedure has been performed using a 1064-nm Nd:YAG-laser manufactured by Axyon (Aesculap-Meditec, Heroldsberg, Germany) with a 30° or 70° rigid endoscope. In this case the laser and endoscope are separate, whereas the Trimedyne and Coherent endoscopes have on-board lasers.

Techniques also vary according to whether mechanical instruments are used together with laser ablation to remove disc material⁶, or whether laser ablation is the only method of treatment.⁷

The number of people affected by symptomatic lumbar disc prolapse ensures that public interest in new treatments remains high. Additionally, treatments that do not require open surgery may appear more attractive and less harmful. For this reason it is important to evaluate and disseminate information regarding the safety and effectiveness of new procedures. To provide useful information on new techniques requires careful comparison with other procedures currently in use, and specifically the recognised “gold standard”. For lumbar discectomy procedures the conventional, most established and widely recognised technique is open discectomy. The purpose of this review was to evaluate the literature on PELD and compare its safety and efficacy with open lumbar discectomy.
Methods

The ASERNIP-S review process

A review protocol was written following collaboration between a neurosurgeon (protocol surgeon) and an ASERNIP-S researcher. The protocol provided details of types of studies to be included in the review. A review surgeon assessed the literature and wrote a narrative review. The ASERNIP-S researcher provided a methodological assessment of the literature. A review group then appraised the review documentation, which comprised the protocol, review and methodological assessment. The review group consisted of the review and protocol surgeons, an invited surgeon, two nominated surgeons from the Neurosurgical Society, a surgeon from another specialty and an ASERNIP-S researcher. The meeting was chaired by the ASERNIP-S surgical director. The group evaluated the information presented in the review documentation, and reached a majority decision on the ASERNIP-S classification to be allocated to the procedure. This was then put forward to the ASERNIP-S management committee for ratification, before being considered by the Royal Australasian College of Surgeons (RACS) Council for endorsement.

Search strategy

The databases searched to retrieve information relating to PELD were MEDLINE, Current Contents, EMBASE and The Cochrane Library. For the purpose of the review, MEDLINE was searched between 1984 and September 98, Current Contents between 1993 and Week 37, 1998, EMBASE between 1974 and September 98 and The Cochrane Library between 1966 and issue 1, 1999. Review articles on open lumbar discectomy were located for comparison purposes by searching the same databases from 1990 (MEDLINE and EMBASE), and 1993 (Current Contents).

A 12-month update of the literature was also conducted; for MEDLINE up to December 1999; for Current Contents to Week 3, 2000; for EMBASE to December 1999; and for The Cochrane Library to issue 4, 1999.

A number of alternative search terms were employed for the new intervention: ((PELD) or (percutaneous endoscopic laser discectomy)), ((PLDD) or (percutaneous laser disc decompression)), and (laser and (spine or lumbar) and (disc* or disk*))

The search terms for The Cochrane Library were (discectomy or diskectomy or discotomy or diskotomy).

The search terms used to locate reviews of the open discectomy procedure were:

((dis?ectomy or dis?otomy or laminectomy) and (open) and (review in PT) and (English in LA)) [since 1990].

The truncation symbols vary in each database, but each allows the retrieval of variations on root words. Alternative spellings are retrieved using the “?” symbol. Only English language articles were included for the review.

Inclusion criteria

Papers were selected for inclusion in the review of PELD if they dealt with the percutaneous insertion of a probe into the herniated disc under local anaesthetic; the use of laser energy to ablate/vaporise the nucleus pulposus; and endoscopic technique. Only human studies were included, and live human studies required that the patient had a lumbar disc prolapse where
surgical intervention was appropriate. For a paper to be included at least one of the following outcomes was required: patient or clinician assessment of recovery; proportion of patients with resolution / improvement of pain; proportion of patients with improvement in function measured on a disability or quality of life scale; length of hospital stay; return to work; rate of repeat back surgery / conversion to standard operation; objective measures of physical impairment; changes in neurological signs prior to and following surgery; and complications (early and late).

The types of studies permitted in the review included randomised controlled trials; controlled clinical trials (historical, non randomised); case series; and case reports. Additional published material in the form of letters, commentary and discussions were also included where they could be used as background information.

Data evaluation and analysis

The protocol surgeon and ASERNIP-S Researcher assessed articles for suitability based on the inclusion criteria. All the literature was assessed by the protocol surgeon and consensus reached on articles for inclusion.

The quality and quantity of information available on this procedure was poor and, as a consequence, no quantitative analysis could be conducted. Table 1 contains the guidelines used for assessing the level of evidence in the studies.

Results

Very little has entered the published literature concerning the PELD procedure. After searching the medical literature and applying the inclusion criteria only 12 articles were located prior to the review.2,4,6,7,9-16 The subsequent 12-month literature search failed to locate any additional papers. None of the papers offered high-quality evidence. There were no concurrently controlled, blinded or randomised trials. Three papers were time series studies (level III-3 evidence),7,9,10 two papers were case-series, post-test (level IV evidence).2,6 Seven articles could not be classified using the hierarchy of evidence table.4,11-16 Five of these were descriptions of the technique,4,11,12,15,16 three of which repeated results described elsewhere,4,11,12 but with no additional results and insufficient detail to aid the review. Two papers described the effect of laser ablation on cadaveric tissue.13,14 The reported risks and benefits for the PELD procedure are shown in Table 2; the design and outcomes for the time and case series studies are shown in Table 3.

For the time series articles by Casper et al.7,9 it appears that a similar data set has been used, with the authors reporting on a smaller part of the data set in the later paper, delimiting by treatment date. Hence for the purposes of the second paper 223 patients were reduced to a set of 100 by selecting a group treated operatively between February 1992 and February 1993. One consequence of this is that the success rate at 2 years appears slightly higher than reported at 1 year. In addition none of the four patients who experienced complications is mentioned in the second study and the failure rate is lower. The authors used parametric and non-parametric statistical tests to determine whether differences between groups existed. This does not alleviate the problem of selection bias, which exists when patients are not selected randomly. In both papers, patient assessment was undertaken by telephone using “independent interviewers”. There is no indication that this evaluation was blinded to limit interviewer bias.
The paper by Tonami et al. is not prima facie an analysis of PELD; rather it examines the success of magnetic resonance imaging (MRI) in evaluating intervertebral discs after PELD. The authors show that MRI is not a predictor of surgical outcome. For the 26 patients in the study, three required open surgery; a rate of 11.5%. This compares with 4-4.5% reported by Casper et al. The outcome measure used by Tonami et al. was the scoring system proposed by the Japanese Orthopaedic Association for low back pain, and therefore is not directly comparable with the modified MacNab system used by Casper et al. In addition the study was not statistically powerful, having only 26 participants.

The case series described in the papers by Mayer et al. described a technique that differed significantly from that used by Casper et al. In addition to laser ablation, mechanical shavers and cutters were used. As a consequence it would appear unrealistic to compare outcomes. In addition there was no means of knowing whether the outcome measures were valid, as these were not defined.

Discussion

The quantity of information about PELD is very limited, and the information available is of poor quality. At the present the associated use of an endoscope and laser forms a small percentage of the total number of laser procedures on the intervertebral disc conducted in the USA, although it is possible that this option may become popular in the future. Whilst the procedure does not appear to be associated with significant morbidity, this cannot be stated with certainty due to insufficient numbers and poor-quality data. Similarly the efficacy of the procedure is not evident.

With respect to the safety and efficacy of the gold standard open discectomy, an assessment of surgical interventions for lumbar disc prolapse by the Cochrane Collaboration found sufficient evidence from the meta-analysis of randomised studies to conclude that surgical discectomy produced better results than the percutaneous technique chemonucleolysis, which in turn was more effective than placebo. Other systematic reviews of the literature report similar results. Hoffman et al. concluded that standard open discectomy showed better short-term relief of sciatica (65 - 85%) than conservative treatment (36%). The rate of serious complications, including death and neurological damage was reportedly less than 1%, whilst moderate complications, including wound infections and discitis were less than 2%.

To determine the safety and efficacy of PELD it is necessary that a decision be made on the basis of well designed studies. The review surgeon recommended that randomised controlled trials be carried out testing PELD against a placebo, chemonucleolysis or open discectomy.

The recommendation for PELD reached by the review group and endorsed by the Royal Australasian College of Surgeons is that the procedure be given a level 2 classification, that is “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.” In order to strengthen the evidence base regarding the procedure it was also recommended that a controlled clinical trial, ideally with random allocation to an intervention and control group be conducted. It was recognised however, that a double blind controlled trial may not be feasible to perform.
Table 1. Designation of levels of evidence

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

Table 2. Potential benefits and risks of the PELD procedure

<table>
<thead>
<tr>
<th>Benefits</th>
<th>Risks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reduced scar tissue</td>
<td>Re-operation due to undetected sequestered fragment</td>
</tr>
<tr>
<td>Procedure does not preclude future surgical treatment</td>
<td>Lateral stenosis</td>
</tr>
<tr>
<td>Minimally invasive</td>
<td>Suspected discitis</td>
</tr>
<tr>
<td>Possible shorter recovery period</td>
<td>Transient nerve block</td>
</tr>
<tr>
<td>Possible shorter hospital stay and lower costs</td>
<td>Contralateral transient dermatomal discomfort</td>
</tr>
<tr>
<td></td>
<td>Potential injury from thermal effects of laser</td>
</tr>
<tr>
<td>Enhanced visualisation</td>
<td>Inability to treat sequestered fragments, therefore limited application</td>
</tr>
<tr>
<td>Haemostasis</td>
<td></td>
</tr>
<tr>
<td>Fibreoptic delivery</td>
<td></td>
</tr>
<tr>
<td>Possible lower risk of infection</td>
<td></td>
</tr>
</tbody>
</table>
Table 3  Design and outcome for papers with Level III and IV evidence.

<table>
<thead>
<tr>
<th>Reference:</th>
<th>Intervention</th>
<th>Design</th>
<th>Sample size</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Casper et al 7</td>
<td>PELD with Ho:YAG laser with sidefire laser fibre. 13W x 10Hz. 1296.49MJ @ 5s or 10s intervals</td>
<td>Time series: 1 week, 3,6 months, 1,2 years. No controls. Selection &amp; exclusion criteria same as Casper et al (1995) Evaluated by phone by independent interviewer using modified McNab criteria</td>
<td>N = 100</td>
<td>Excellent to good rating @ 2 years = 86.9%, n=86/99 4% required open laminectomy 5% required 2nd PELD @ same level 4% rated as fair to poor (failure) 2nd PELD performed on 10 patients; 5 @ same level, 5 @ different level, success @ 6 months = 80% Differences between year 1 &amp; 2: 11.1% improved, 14.1% got worse, no sig. diff between surgical outcomes between years 1 &amp; 2.</td>
</tr>
<tr>
<td>Casper et al 9</td>
<td>PELD with Ho:YAG laser with sidefire laser fibre. 13W x 10Hz. 2000MJ or till relief @ 5s or 10s intervals</td>
<td>Time series: 1 week, 3,6 months, 1, year. No controls. Selection criteria based on symptoms, physical examination, radiography for non-sequestered disc herniation. Exclusion: scar tissue from previous surgery, lateral recess, central stenosis, sequestered disc material Evaluated by phone by independent interviewer using modified McNab criteria</td>
<td>N = 223</td>
<td>Excellent to good rating @ 1 year = 84.2%, n = 187/222 4.5% required open laminectomy 5.4% required 2nd PELD @ same level 5.8% rated as fair to poor (failure) Complications = 1.8% 1 infection, 1 suspected discitis, 1 contralateral transient dermatomal discomfort, 1 transient nerve block Resumption of normal activities: mean = 32.4 days SSD = 42.5.</td>
</tr>
<tr>
<td>Tonami et al 10</td>
<td>Evaluation of intervertebral disc after PELD using MRI Ho:YAG laser, 1-1.6 J per pulse repeating 10 – 12 J/s. Procedure terminated when total energy = 20kJ and cavity from ablation stays open.</td>
<td>Time series: &lt; 24 hrs, 1 year Selection criteria: radicular leg pain +/- low back pain, motor sensory or reflex deficits and/or diminished straight leg raising, contained disc herniation (MR imaging), failed conservative treatment at least 3 months. Exclusion criteria: non-contained or sequestered disc herniations, previous disc surgery. Assessed using JOA score for low back pain</td>
<td>N = 26</td>
<td>Recovery rate of &gt; 25% considered successful for JOA scale 24 hours after surgery, recovery rate mean = 53.1% +/-25.9 1 year after surgery, recovery rate mean = 64.6% +/- 27.3 3 patients requiring open surgery were excluded from score. 100% procedure completed within 1 hour No significant changes in size of disc herniation No correlation between pre-op size of herniation and recovery rate</td>
</tr>
<tr>
<td>Reference: Mayer et al.</td>
<td>Intervention</td>
<td>Design</td>
<td>Sample size</td>
<td>Outcomes</td>
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<td>------------------------</td>
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<tr>
<td><strong>PELD with Nd:YAG laser, contact and non contact mode used</strong>&lt;br&gt;Possible use of mechanical cutters and shavers</td>
<td>Case series:&lt;br&gt;No independent assessment&lt;br&gt;Selection criteria: discogenic radicular symptom, protrusion, subligamentous prolapse – at level of disc space &lt; 1/3 of sagittal diameter of spinal canal, unsuccessful conservative treatment.&lt;br&gt;Exclusion criteria: severe neurological deficits, pregnancy, litigation, psychogenic aggravation, subligamentous prolapse: cranial / caudal to disc space level, &gt;1/3 of sagittal diameter of spinal canal, epidural prolapse, fragments, narrow lateral recess, narrow spinal canal</td>
<td>N = 6</td>
<td>Apparent subjective assessment of symptoms following surgery.&lt;br&gt;Hospitalisation 2 – 10 days&lt;br&gt;Patients free of radicular symptoms.&lt;br&gt;3 patients had “stress dependent” back pain.&lt;br&gt;No statistics</td>
<td></td>
</tr>
</tbody>
</table>

| Mayer et al. | PELD with Nd:YAG laser, single shots in 0.05 – 0.1s pulses, 20 – 30 W, 500 – 600J. Also use of forceps to remove herniated nucleus pulposus. | Case series<br>Inclusion criteria: patients with low back pain, radicular sciatica (permanent & stress induced), sensory disturbances, mild motor weakness.<br>Exclusion criteria: rapidly progressing or severe motor deficits | N = 40 | No definition of how ratings of excellent, good, fair or poor were derived.<br>60% reported as excellent and good<br>30% reported as fair<br>10% reported as poor<br>10% required re-operations<br>82.5% without sciatica (including 2 re-operated cases)<br>67.5% lost sensory disturbances (including 3 re-operations)<br>No motor deficits |

PELD, percutaneous endoscopic laser discectomy; Ho:YAG holmium:yttrium-aluminium-garnet; JOA, Japanese Orthopaedic Association; Nd, Neodymium.
Acknowledgements

We wish to acknowledge the Australian Commonwealth Department of Health and Family Services for their support of the ASERNIP-S project.

References


Appendix A: The original narrative review

A REVIEW ON PERCUTANEOUS ENDOSCOPIC LASER DISCECTOMY

By

Professor Robert D Fraser

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A total of 12 papers on percutaneous endoscopic laser discectomy (PELD) were presented for consideration. The paper by Kleinpeter et al. was excluded, as the endoscopic treatment did not include the use of laser. Included with the references but not listed was a paper by Kopchok et al. on percutaneous laser discectomy and it was presumed that this was to be included in the list of references in the place of the paper by Kleinpeter et al.

Examination of these 12 papers revealed that there were no randomised controlled trials, no well designed controlled trials without randomisation and no well designed cohort or case-control studies.

There were two time-series studies. Three papers were review articles in which the authors summarised the results of their experience, but with insufficient data to make meaningful assessment. There was one case-series study which described the results in six patients treated by PELD with those results also included in the brief overview of the first 40 patients.

Three of the references were review papers not describing any new information. The remaining two papers were in-vitro studies, one assessing the extent of thermal necrosis and thermal denaturation on the annulus and the other assessing the effect of laser nucleotomy on annular deviation and disc stiffness.

Thus only two clinical studies were identified with sufficient details of methodology and results to justify assessment for this report:

Casper et al. presented a two-year independent evaluation using a modified Macnab questionnaire in 100 patients treated by PELD between February 1992 and February 1993. The authors claim a satisfactory outcome in 86.9% of patients. Although a positive straight-leg raising sign was apparently observed in approximately 75% of patients, only 19% had been recommended surgery by an Orthopaedic Surgeon or Neurosurgeon. There is no definite indication of how disabled the patients were before treatment, but an impression was gained that the overall group had relatively mild symptoms even though these had been present for 6 weeks. The fact that the outcome was not affected by the presence of worker’s compensation or by previous surgery is at odds with the literature on repeat surgical procedures on the spine. Complications were not mentioned in this series but an earlier “preliminary report” of 223 patients mentioned one case each of infection, suspected discitis, contra-lateral leg pain and what was described as a transient nerve block.

The second paper was concerned with the relationship between the morphological changes produced by PELD and outcome. Tonami et al. used magnetic resonance imaging to assess the early effect of percutaneous endoscopic laser discectomy on the size of the disc prolapse and made an assessment of outcome, using the Japanese Orthopaedic Association scoring system for low back pain (JOA score), immediately after treatment and again one year later. Although immediate post-operative MR imaging demonstrated signal changes induced by laser treatment, there was no significant change in the size of the disc herniation. Of the 26 patients entered in the study, all but five were considered to have obtained a successful outcome, having gained at least a 25% improvement in the JOA score immediately after treatment. Further improvement apparently occurred during the next 12 months but three of the five patients who failed to show early recovery subsequently required surgery.
Given the dearth of scientifically acceptable clinical studies on the use of PELD, an in-depth assessment of the references on comparative or “gold standard” intervention, laser information, and new intervention/background information was considered unnecessary, particularly as a thorough and detailed assessment of the available interventions for disc prolapse had been carried out by the Cochrane Collaboration\textsuperscript{15}. This authoritative review of all randomised and quasi-randomised studies concerning the surgical management of lumbar disc prolapse, found on meta-analysis that surgical discectomy produced better clinical outcomes than chemonucleolysis, and that chemonucleolysis produced better clinical outcomes than placebo. Based on three randomised trials of percutaneous discectomy the authors’ considered there was moderate evidence that this technique resulted in poorer clinical outcomes than for standard discectomy or chymopapain. Their search failed to identify a published randomised controlled trial of laser discectomy. The authors concluded that high quality randomised controlled trials are required to determine if there is any role for automated percutaneous discectomy or laser discectomy.

In conclusion, although percutaneous endoscopic laser discectomy has been in clinical use since 1989, the list of publications measuring clinical outcome is meagre and of poor quality. Although a favourable outcome is claimed in a high percentage of cases in the two studies analysed, it is quite possible that this is purely a reflection of the natural history. As with automated percutaneous discectomy, the rationale of PELD is to reduce the volume of the nucleus pulposus with an expected secondary or indirect reduction in the size of the prolapse. Given the natural history of disc prolapse as determined by the Weber study \textsuperscript{16} and the 56% successful outcome with an intradiscal saline injection in one double blind study on disc herniation\textsuperscript{17}, it is quite possible that neither automated percutaneous discectomy nor PELD have any beneficial effect. It is therefore recommended that randomised controlled trials be carried out, testing PELD against placebo, chemonucleolysis or open discectomy. Until evidence of efficacy is provided by such RCT’s, the use of PELD must be considered experimental.
Appendix

Appraisal of: New Intervention Inclusion Papers

Casper et al. 1996

This is a two-year independent evaluation of 100 patients using a modified Macnab questionnaire. It is unclear just how disabled the patients were before treatment. A positive straight leg raising sign was recorded in 75% of the patients. Only 19 of 100 patients had been recommended surgery by an orthopaedic surgeon or neurosurgeon. The impression is that the overall group had relatively mild symptoms, even though these had been present for 6 weeks and as such a high success rate would be expected from natural history alone. The fact that outcome was not affected by previous surgery, even at the target level, is at odds with the literature on repeat procedures. There was no mention of complications.

Casper et al. 1995

This is a preliminary report of 223 patients, presumably including the 100 patients subsequently reported in 1996. In this report the complications are described. In both papers energy was delivered with the laser until the patient obtained complete relief of radicular pain or until approximately 2000 J energy had been delivered. In both papers Worker’s Compensation did not affect outcome (86.5% success compared with the overall success of 84.2%).

Casper et al. 1995

In this review of PELD the authors do not describe any new information.

Gottlob et al. 1992

This is a preliminary evaluation of the effect of Ho:YAG laser on annular material. Two distinct zones of thermal injury were noted. The authors did not assess the effect on nucleus pulposus because of difficulty in histological preparation. The authors appear not to have followed up on this preliminary evaluation, even though they claim the results were promising for the Ho:YAG laser.

Kleinpeter et al. 1995

This is a comparative study of open discectomy (313 patients) versus percutaneous endoscopic discectomy (without the laser) in 8 patients, five of whom required open surgery. The numbers of patients treated by percutaneous endoscopic discectomy are too small for this study to be of much value. In any case it was considered irrelevant to the subject of laser discectomy.

Kopchok et al. 1992

This is a review article concerning the development of laser for percutaneous discectomy and was considered unsuitable for the review.

Kutschera et al. 1997

This was an in-vitro study on the effects of Ho:YAG laser applied to the nucleus. The authors found a relatively increased external deviation in the annulus and stiffness of the disc.
decreased with increasing total energy applied. There was no information from this study which was considered pertinent to the review.

Maroon et al. 1995

This review from the Proceedings of the Congress of Neurological Surgeons in 1995, only briefly mentions laser discectomy. The authors are critical of its use because of the spread of heat beyond the confines of the laser tip and the relatively small amount of disc vaporised, thereby limiting its use in their view. This aspect of their review was largely opinion-based.

Mayer et al. 1992

The authors described techniques of percutaneous endoscopic laser discectomy and the results in six patients. The numbers were considered too small to be of value for this review.

Mayer et al. 1993

This is a review article which includes details of the results of the use of laser to assist endoscopic surgery which in the authors’ hands also includes removal of disc tissue with forceps. The technique aimed to remove nucleus pulposus from the posterior third of the disc space. Results are simply expressed as excellent, good, fair and poor and the method of deciding on this is not mentioned. There were apparently no complications. The authors describe a second method of non-endoscopic percutaneous laser disc decompression, but do not report experience with this. They stated that efficacy is difficult to define since the spectrum of indications includes patients who could be considered non-surgical candidates. The authors stated that there was no evidence that laser discectomy was superior to the automated nucleotome or chemonucleolysis. They said there was a need for controlled prospective clinical studies stating that to date there was only empirical data on the clinical use of lasers in percutaneous disc surgery. It would appear that nothing has changed in the last 6 years.

Schreiber et al. 1995

This review paper in Current Orthopaedics describes the author’s personal experience with percutaneous endoscopic spine surgery, including the use of the laser for percutaneous disc decompression. The authors state that from 1982 to 1983 they carried out 270 percutaneous disc surgeries with an overall favourable result of 75% using different methods. They do not give specific results for the use of the laser. Secondly they describe the use of the laser to clear out the disc space as part of the procedure of percutaneous lumbar endoscopic interbody fusion. They claim that a solid interbody fusion was obtained in 38 out of 44 patients. No mention was made of the clinical results. The paper was considered to be of no value for the current review.

Sherk et al. 1993

This is a review article and includes a brief description of experience in nearly 50 patients undergoing percutaneous laser discectomy. The authors claim 85% of patients experienced better than a 20% (19.6% in their table) improvement in their subjective pain responses noted on completion of a pain questionnaire (which was not described). No other details were available and the paper was considered to be of sufficient quality for this review.
Tonami *et al.* 1997

Twenty-six patients with 29 contained lumbar disc herniations treated by Ho:YAG laser discectomy had an average improvement in JOA score of 64.6% at one year with immediate recovery of pain after treatment (average improvement in JOA score of 53.1%). The MRI scan carried out 24 hours after treatment showed no change to the pre-treatment scan. There was a significant change in the signal within the disc after treatment, but neither this nor the size of the hernia had any bearing on outcome.


Appendix B: The original methodological assessment

METHODOLOGICAL ASSESSMENT REPORT

PERCUTANEOUS ENDOSCOPIC LASER DISCECTOMY
(PELD)

Mrs Maggi Boult
ASERNIP-S

August, 1999
**Background Summary**

Percutaneous endoscopic laser discectomy or PELD, is a minimally invasive surgical procedure whose purpose is to provide symptomatic relief for pain caused when a contained prolapsed disc impacts on adjacent nerve roots. The procedure forms part of a medley of surgical techniques with similar objectives that arose from Percutaneous Discectomy developed in 1975 by Hijikata et al.\(^1\).

The major proposed advantages of PELD relate to its minimal invasive nature, with procedures being performed as day surgery cases under local anaesthesia\(^2\).

Detractors, however, have reported high rates of subsequent open surgery\(^3\) and limited application\(^13\).

PELD aims to decompress the disc by ablating the nucleus pulposus with laser energy. An endoscope is used to aid visualisation during the procedure. For the PELD procedure, the laser most commonly coupled to the use of an endoscope is the Holmium:YAG laser. The equipment is manufactured by Trimedyne – who make the OmniPulse Holmium:YAG laser with the Sidefire™ laser fibre and Coherent who manufacture the Laser-Assisted Spinal Endoscopy (LASE) kit and the VeraPulse™ laser. Occasionally a Nd:YAG (neodymium:yttrium-aluminium-garnet) laser is used, for instance Mayer et al.\(^2\), performed the procedure using a 1064nm Nd:YAG-laser manufactured by Axyon and a 30° or 70° rigid endoscope. In this latter case the laser and endoscope are separate, whereas the Trimedyne and Coherent endoscopes have on-board lasers.

The technique also varies according to whether mechanical instruments are used to remove disc material in addition to laser ablation\(^4\), or whether laser ablation is the sole method of treatment\(^5\). Given the paucity of available literature, two papers by Mayer were included where mechanical instruments were used in tandem with laser ablation\(^2,4\). Whilst they provide information on the procedure it is not possible to assess the individual effect for each part of the process.

In order to assess a new technique it needs to be compared to other procedures currently in use and specifically the recognised “gold standard”, which for PELD is the Open Discectomy operation. A number of review articles were selected using the search criteria described in the protocol. The articles selected provide information about the level of safety and efficacy for various procedures including open discectomy. The reviews include a Cochrane Centre Review on Lumbar Disc Prolapse Surgery\(^6\). This was completed in 1998 and provides a recent collation of evidence derived from randomised controlled trials (RCTs) of surgical treatments for disc prolapse. For the purposes of this methodological review of PELD, the Cochrane Review provides a useful synthesis of evidence.
Assessment of Articles for Review

Percutaneous Endoscopic Laser Discectomy is being evaluated for safety and efficacy. A review group has been convened to compare this procedure with other established discectomy procedures.

There is a dearth of published literature on PELD. After searching the medical literature and applying the exclusion criteria listed in the Protocol, only twelve articles were identified. These were disseminated to the ASERNIP-S Review Group.

The articles have been assessed using the Hierarchy of Evidence [National Health and Medical Research Council] (Table 1).

<table>
<thead>
<tr>
<th>Table 1 Hierarchy of Evidence</th>
<th>Source: NH&amp;MRC</th>
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<tbody>
<tr>
<td>I</td>
<td>Evidence obtained from a systematic review of all relevant randomised controlled trials.</td>
</tr>
<tr>
<td>II</td>
<td>Evidence obtained from at least one properly designed randomised controlled trial.</td>
</tr>
<tr>
<td>III-1</td>
<td>Evidence obtained from well-designed pseudo-randomised controlled trials (alternate allocation or some other method).</td>
</tr>
<tr>
<td>III-2</td>
<td>Evidence obtained from comparative studies with concurrent controls and allocation not randomised (cohort studies), case-control studies or interrupted time-series with control group.</td>
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<td>Evidence obtained from comparative studies with historical control, two or more single arm studies or interrupted time series without a parallel control group.</td>
</tr>
<tr>
<td>IV</td>
<td>Evidence obtained from case-series, either post-test or pre-test/post-test.</td>
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</table>

Methodological review of PELD literature

None of the papers for the review offered high quality evidence. There were no controlled, blinded or randomised studies.

Three papers were time series studies\(^5,7,8\) [level III-3 evidence].

Two papers were case-series – post-test\(^2,4\) [level IV evidence].

Seven articles could not be classified using the hierarchy of evidence table\(^9-15\). Five were descriptions of the technique\(^9,10,13-15\). Three of these articles also repeated results previously described\(^9,10,13\), but with no additional results and insufficient detail to aid the review. Two papers described the effect of laser ablation on cadaveric disc tissue\(^11,12\). A brief summary of these seven articles is shown in Table 2.

The design and outcomes of the time-series and case-series studies are shown in Table 3.

The 1996 Casper paper\(^5\) examines a smaller data set than that reported in the 1995 paper\(^7\), delimiting by treatment time. Hence for the purposes of the second paper 223 patients were
reduced to 100 by selecting the group treated operatively between February 1992 and February 1993. There is no clear explanation as to why this was done. One consequence is that the success rate at two years appears slightly higher than that reported at one year (86.9% versus 84.2%). In addition none of the four patients who experienced complications is mentioned in the second study, and the failure rate is lower. The authors used parametric and non-parametric statistical tests to determine whether differences between groups existed. This does not alleviate the problem of selection bias, which exists when patients are not selected randomly. In both papers, patient assessment was undertaken by phone using “independent interviewers”. There is no indication that this evaluation was blinded to limit interviewer bias.

As mentioned previously, the Mayer papers\textsuperscript{2,4} described a technique that differs significantly from that described by Casper et al.\textsuperscript{5}. In addition to laser ablation, mechanical shavers and cutters were used. As a consequence it is not realistic to compare outcomes. In addition there is no means of knowing whether the outcome measures are valid, as they are not defined.

The Tonami paper\textsuperscript{8} is not \textit{prima facie} an analysis of PELD; rather it examines the success of MRI in evaluating intervertebral discs after PELD. The authors show that MRI is not a predictor of surgical outcome. For the 26 patients in the study, three required open surgery, a rate of 11.5%. This compares with 4-4.5% reported by Casper\textsuperscript{5,7}. The outcome measure used by Tonami et al. was the scoring system proposed by the Japanese Orthopaedic Association for low back pain, and is not therefore directly comparable with the modified Macnab system used by Casper. In addition the study was not very powerful having only 26 participants.

\section*{Safety and Efficacy of Open Discectomy}

The Cochrane Review of Surgery for Lumbar Disc Prolapse\textsuperscript{6} reviewed 27 randomised controlled trials (RCTs) and compared the outcomes. The review leveled serious criticisms about the design and implementation of most of the studies reviewed. However they were able to report that surgical discectomy produced better results than chemonucleolysis with chymopapain, which in turn was found to produce better outcomes than placebo. No RCTs on laser discectomy have been published, so this area could not be evaluated under the terms of the Cochrane Review.

A systematic review of literature conducted by Hoffman et al.\textsuperscript{16} reported similar results. The review included RCT and non-RCT literature evaluation of 81 studies. Hoffman et al. concluded that standard open discectomy showed better short-term relief of sciatica (65\%-85\%) than conservative treatment (36\%). Additional back surgery was required by about 10\% of discectomy patients. The rate of serious complications, including death and neurological damage was less than 1\%. Moderate complications, including wound infections and discitis was less than 2\%. Hoffman concludes that long-term outcomes (>10 years) for discectomy patients and those treated with conservative treatment are similar.

The open discectomy operation is regarded as the “gold standard”. It demonstrates a reasonable level of safety and efficacy, with “good” results reported for 65 - 85\% of patients. Table 4 shows reported benefits for the procedure in addition to risks and side effects.
Safety and Efficacy of Percutaneous Endoscopic Laser Discectomy

Given the low quality and quantity of evidence for the PELD procedure, very little can be concluded about its safety and efficacy.

Table 5 describes the potential benefits and risks that have been described or suggested for the PELD procedure.

McCulloch suggests that when considering surgical intervention it is necessary to prove that surgery will have a high rate of initial success (90% satisfactory outcomes), with little risk and at reasonable cost. Certainly, the new procedure needs to show similar or improved outcomes to open discectomy, in terms of safety and efficacy. In addition risks and benefits associated with the surgery must also be taken into consideration.
Table 2 – Summary of “descriptive” PELD papers

<table>
<thead>
<tr>
<th>Author</th>
<th>Year</th>
<th>Description</th>
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<tr>
<td>Casper 1995</td>
<td></td>
<td>Description of the PELD method using Ho:YAG laser (referred to here as Percutaneous Laser Disc Decompression or PLDD). Clinical indications and procedural specifications. Overview of results reported in Casper, 95. Description of problems that can arise from procedure. Author accounts for 13 patients in whom damage to vertebral end-plate(s) has been evident.</td>
</tr>
<tr>
<td>Casper 1998</td>
<td></td>
<td>Broad description of techniques for treating lumbar spine using laser energy. Clinical indications and procedural specifications. Section on PELD (referred to here as Laser-assisted disc decompression or LADD) gives overview of results reported in Casper 96.</td>
</tr>
<tr>
<td>Gottlob 1992</td>
<td></td>
<td>Study evaluates ablation rate and histopathologic effect of Ho:YAG laser on intervertebral disc tissue in saline and air (i.e. using cadaveric material). Reports ablation rate, zone of tissue necrosis, and zone of tissue denaturation relative to energy fluence. Authors reported that discoscopy enabled more accurate and complete removal of nucleus pulposus, less X-ray exposure and greater safety under direct visual control.</td>
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<tr>
<td>Kutschera 1997</td>
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<td>Study describes influence of pressure conditions and external deviation on anulus treated with Ho:YAG laser (Coherent) using cadavers. Measurements demonstrated an increase in deviation in dorsolateral portions and linear decrease in disc stiffness with increasing energy. Authors recommend puncture of disc on side of prolapse and suggest that linear negative correlation observed between energy and stiffness will mean good therapeutic correlation with laser treatment.</td>
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<tr>
<td>Maroon 1995</td>
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<td>Description of percutaneous disc techniques. Negligible mention of endoscopic technique. Mentions results reported by Mayer and Brock. Discusses complications reported for minimally invasive discectomy techniques.</td>
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<tr>
<td>Schreiber 1995</td>
<td></td>
<td>Describes development of percutaneous endoscopic spine surgery and relative merits of different types of laser. Broadly describes authors experience with fibre-optically controlled tissue ablation. Authors report success rates of up to 75%.</td>
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<tr>
<td>Sherk 1993</td>
<td></td>
<td>Paper describes laser discectomy and mentions development of on-board endoscopes. Reports efficacy of technique is unproven.</td>
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<tr>
<td>Level</td>
<td>Ref.</td>
<td>Intervention</td>
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<td>III-3</td>
<td>Casper et al. (1996)</td>
<td>PELD with Ho:YAG laser with sidefire laser fibre. 13W x 10Hz. 1296.49 MJ (* assume this is mean number of Joules) @ 5s or 10s intervals</td>
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<td>III-3</td>
<td>Casper et al. (1995)</td>
<td>PELD with Ho:YAG laser with sidefire laser fibre. 13W x 10Hz 2000J or till relief @ 10s or 5s intervals</td>
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<td>Level</td>
<td>Ref.</td>
<td>Intervention</td>
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<td></td>
<td></td>
<td>PELD involved Ho:YAG laser. 1-1.6 J per pulse repeating 10-12 J/s. Procedure terminated when total energy approx 20kJ and cavity from laser ablation does not close by pressure from surrounding tissue</td>
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Table 3: Review Table Summary

<table>
<thead>
<tr>
<th>Level</th>
<th>Ref.</th>
<th>Intervention</th>
<th>Design</th>
<th>Sample Size</th>
<th>Study Period</th>
<th>Safety &amp; Efficacy Outcomes</th>
<th>Other Statistics</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>IV</td>
<td>Mayer et al. (1992)</td>
<td>PELD with Nd:YAG laser. Contact and non-contact mode used. Possible use of mechanical shavers and cutters</td>
<td>Case series</td>
<td>n=6</td>
<td>treatment between 25.8.89 &amp; 4.4.90</td>
<td>Apparently subjective assessment of symptoms following surgery. Patients rated as satisfactory, good and excellent, according to this assessment.</td>
<td>No statistics performed</td>
<td>Hospitalisation 2-10 days</td>
</tr>
</tbody>
</table>

Selection indications:
- Discogenic radicular symptoms
- Sciatica
- Sensory disturbance
- Paresis (IV-III)
- Reflex differences
- Protrusion, subligamentous prolapse - at level of disc space - <1/3 of sagittal diameter of spinal canal.
- Unsatisfactory conservative treatment L1-S1

Contraindications:
- Severe neurological deficits:
  - Paresis (II-IV)
  - Conus/cauda syndrome
  - Segmental instability
  - Pregnancy
  - Psychogenic aggravation
- Subligamentous prolapse cranial/caudal to disc-space level. >1/3 of sagittal diameter of spinal canal, epidural prolapse, fragments, (narrow lateral recess), (narrow spinal canal), (spondylolisthesis)

IV Mayer et al. (1993) PELD with Nd:YAG laser. Single shots in .05-1 s pulses, 20-30W, 500-600J. Also use of forceps to remove herniated nucleus pulposus.

Case series | n=40 | not stated <1993, min. 2 year follow up | No definition how ratings of excellent, good, fair and poor were derived. | No statistics performed |

60% reported as excellent and good
30% reported as fair % poor
10% reoperations

No complications

82.5% without sciatica (inc. 2 reoperated cases)

67.5% lost sensory disturbances (inc. 3 reoperations)

No motor deficits.
### Table 4 – Reported benefits and risks for open discectomy

<table>
<thead>
<tr>
<th>First author</th>
<th>Reported risks/side effects</th>
<th>Reported benefits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Errico 1995</td>
<td>Technical errors such as removing wrong disc or failure to remove offending fragment.</td>
<td>Absence of; back pain, pain extending to foot, leg pain with straight leg raise, reflex asymmetry. Errico claims value of surgery should focus on relief of pain radiating down leg.</td>
</tr>
<tr>
<td></td>
<td>Erroneous or incomplete diagnosis <em>i.e.</em> lateral spinal stenosis, recurrence of persistent herniation, adhesive arachnoiditis, central canal stenosis, epidural fibrosis.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Rare complications: severe bleeding or creation of arteriovenous fistula or pseudoaneurysm, puncture of the aorta, intestine injuries</td>
<td></td>
</tr>
<tr>
<td>Hoffman 1993</td>
<td>Reoperation, mortality, deep wound infection, permanent nerve root damage, thromboembolic events, wound infections and discitis.</td>
<td>Scatica absent or mild, minimal or no restriction of physical activity and/or return to previous employment.</td>
</tr>
<tr>
<td>McCulloch 1996</td>
<td>Formation of scar tissue</td>
<td>Improved short term outcomes for patients with sciatica</td>
</tr>
<tr>
<td>Muralikuttan 1992</td>
<td>Failure to improve</td>
<td>Improved back and leg pain scores, less physical impairment, better scores for anxiety and depression.</td>
</tr>
<tr>
<td>First author</td>
<td>Risks/side effects</td>
<td>Benefits</td>
</tr>
<tr>
<td>--------------</td>
<td>-----------------------------------------------------------------------------------</td>
<td>-----------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>1993</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sherk 1993</td>
<td>Cannot treat sequestered disc fragments, therefore relatively few individuals will be able to use this technique.</td>
<td>Small size, sufficient power to ablate soft tissue, no possibility of anaphylaxis, flexible endoscopic control. Could reduce risk of vascular and neurologic complications, as well as infections, postoperative arachnoiditis and instability.</td>
</tr>
</tbody>
</table>
References


Appendix C: Safety and efficacy classification for percutaneous endoscopic laser discectomy

The ASERNIP-S procedure classifications are selected from the following list:

1. Safety and efficacy is established. Procedure is equal to, or better than the nominated gold standard. Procedure may be introduced into practice.

2. The safety and efficacy of the procedure cannot be determined due to an incomplete and/or poor quality evidence-base. One of the following recommendations is made:
   2.1 An audit is required.
   2.2 A Controlled Clinical Trial, preferably prospective with concurrent controls, is required.
   2.3 A Randomised Controlled Clinical Trial is required.

3. Safety and efficacy of procedure is shown to be unsatisfactory. Procedure should not be used.

The classification for Percutaneous Endoscopic Laser Discectomy is 2.3. A Randomised Controlled Clinical Trial is required to assess both safety and efficacy.

Appendix D: Review group commentary on original review

The Review Group members agreed that the safety and efficacy of the procedure could not be determined due to insufficient and poor quality supporting evidence.

Two members of the Review Group recommended that the classification for the Percutaneous Endoscopic Laser Discectomy should be 2.2 A Controlled Clinical Trial, preferably prospective with concurrent controls, is required. In their opinion a randomised-controlled trial would create ethical concerns and be expensive and difficult to organise.

The decision in favour of a 2.3 classification was reached by majority decision. It was recognised that this could not be a double blind controlled trial for ethical reasons, but that people could be randomised to open or percutaneous discectomy. A randomised-controlled trial (RCT) was accepted as a more rigorous scientific method.