NATIONAL INSTITUTE FOR CLINICAL EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedure overview of endoscopic laser foraminoplasty

Introduction
This overview has been prepared to assist members of IPAC advise on the safety and efficacy of an interventional procedure previously reviewed by SERNIP. It is based on a rapid survey of published literature, review of the procedure by one or more specialist advisor(s) and review of the content of the SERNIP file. It should not be regarded as a definitive assessment of the procedure.

Procedure name
Endoscopic laser foraminoplasty (ELF)

SERNIP procedure number
3

Specialty society
British Orthopaedic Association

Executive summary
The published evidence on this procedure is derived from the work of one surgeon, which may be a significant source of bias. However, that body of work indicates that endoscopic laser foraminoplasty has produced significant postoperative improvements in pain outcomes and quality of life measures, whilst being associated with a very low rate of complications (1.6%). This was significantly lower than in the one study that used conventional back surgery as a comparator, although the comparison was based on historical data. Discitis was the most common complication reported.

Indication(s)
Back pain is usually a result of multilevel disc disease. It may radiate through the buttocks and legs. Approximately 2-5% of people suffer acute back pain per annum, while 0.5% of these have pain and neurological conditions requiring surgery. An unknown number experience chronic pain.

Summary of procedure
This endoscopically assisted laser technique is used to widen the lumbar exit root foramina in the spine.

Neuroleptic anaesthesia is used because patient feedback is essential. A cannulated probe is advanced into the patient's back. The probe is replaced with a guide wire and, under X-ray control, a 4.6mm dilator tube is railroaded to the exit root foramen. The trocar is removed and an endoscope with an eccentrically placed 2.5mm working channel and irrigation channel is inserted. A side-firing 2.2mm diameter laser probe is inserted through the endoscope. Disc protrusion in the epidural space is cleared by laser ablation and manual punches.

The standard intervention appears to be minimal intervention fenestrectomy and open surgical undercutting for predominantly unisegmental and unilateral recess stenosis.

The claimed benefits of endoscopic laser foraminoplasty are that it may prevent or delay a spinal fusion.

Literature review
A systematic search of MEDLINE, PREMEDLINE, EMBASE, Current Contents, PubMed, Cochrane Library and Science Citation Index using Boolean search terms was conducted, from the inception of the databases until October 2002. The York Centre for Reviews and Dissemination, Clinicaltrials.gov, National Research Register, SIGLE, Grey Literature Reports, relevant online journals and the Internet were also searched in October 2002. Searches were conducted without language restriction.

Articles were obtained on the basis of the abstract containing safety and efficacy data on endoscopic laser foraminoplasty in the form of randomised controlled trials (RCT), other controlled or comparative studies, case series and case reports. Conference abstracts and manufacturer's information were included if they contained relevant safety and efficacy data. Foreign language papers were included if they contained safety and efficacy data and were considered to add substantively to the English language evidence base. In the case of duplicate publications, the latest, most complete study was included. All identified studies were included.

List of studies found
Total number of studies : 10

Randomised controlled trials	0
Non-randomised comparative studies	3 (reported in 4 papers)
Case series	6 (reported in 7 papers)
Case reports	0

Papers were rejected for reporting no clinical outcomes, or being review articles without data, or involving techniques other than endoscopic laser foraminoplasty. Data for 5 papers are tabulated below. Papers were chosen

for tabulation firstly if they were comparative. Then case series were rated as to whether they were full reports or only abstracts, and then by length of follow-up. Studies for which data were not tabulated are listed in the annex following the reference list.

Summary of key efficacy and safety findings
See following tables.

Abbreviations

DRAM	- Distress Risk Assessment Method
MacNab	- a mobility and pain index
ODI	- Oswestry Disability Index
VAP	- Visual Analogue Pain Scale

Authors, date, location, number of patients, length of follow-up, selection criteria	Key efficacy findings	Key safety findings	Appraisal/Comments
Non-randomised comparative studies			
Knight et al.[1] 2002, UK 54 with prior failed back surgery; 85 without prior intervention. 2 year follow up. Selection criteria: patients with and without prior back surgery	Patients with prior failed back surgery demonstrated greater psychological distress, disability ($p<0.05$), and pain preoperatively. Postoperatively, both groups demonstrated significant improvement and no differences between them in Zung, DRAM, ODI and VAP.	No safety data reported	*Potential for bias*: Study reported only as an abstract. Patient groups clearly different. *Outcome measures and their validity*: Outcome measures of unknown validity. *Other comments:* Uncertain if laser was used.
Knight et al.[2] 2002, UK 716 treated with endoscopic laser foraminoplasty (958 procedures); unspecified number treated with conventional spinal surgery. 6 weeks follow-up Selection criteria: all ELFs performed at one centre; comparative group: RCTs of conventional back surgery.	No efficacy data reported	ELF: 24 complications in 23 patients (overall rate of 1.6%): 9 (0.9%) discitis (one infective), 1 (0.1%) dural tear, 1 (0.1%) deep wound infection, 2 (0.2%) foot drop (1 transient), 1 (0.1%) myocardial infarct, 1 (0.1%) erectile dysfunction, 1 (0.1%) postop panic attacks. Conventional surgery: overall complication rate for fusion of 11.8%, decompression 7.6%, discectomy 6.0%, and chemonucleolysis 9.6%. Comparison: ELF significantly lower complication rate than conventional surgery ($p<0.01$).	*Potential for bias*: Historical comparative group data gathered from a meta-analysis of published RCT data. *Outcome measures and their validity*: Complication rates. *Other comments:*

Authors, date, location, number of patients, length of follow-up, selection criteria	Key efficacy findings	Key safety findings	Appraisal/Comments
Knight et al.[3] 1998, UK & HUNGARY 1) 22 patients ELF; 2) 13 patients ELF with prior keyhole surgery; 3) 14 patients ELF with prior conventional surgery. Mean 13 months follow-up Selection criteria: unilateral back, buttock and leg pain.	VAP 0=no pain-100=unbearable: Group :Preop/Postop Group 1: 70.0 / 40.0 Group 2: 46.3 / 60.0 Group 3: 70.5 / 58.5 MacNab criteria 0=excellent-3=poor: Number of patients postop scoring 0 or 1 Group 1: 16 (72%) Group 2: 7 (58%) Group 3: 4 (33%) Mean ODI score: Group 1: 20.69% Group 2: 34.67% Group 3: 47.69% Mean Patient Satisfaction / Recommendation: 1= 'made me worse' – 5= 'op entirely successful' / 1= 'no recommendation' – 3= 'recommend'. Group : satisfaction / recommendation Group 1: 3.63 / 2.50 Group 2: 2.90 / 2.10 Group 3: 2.77 / 2.69 Revisions: Group 1: 1 (5%) Group 2: 1 (8%) Group 3: 2 (14%)	No complications were encountered.	*Potential for bias*: Patient groups clearly different, ie comparing previously unoperated with patients who had prior back surgery. *Outcome measures and their validity*: Outcome measures of unknown validity. Also patient satisfaction measured, a measure which possesses face validity only. *Other comments:*

Case series			
Authors, date, location, number of patients, length of follow-up, selection criteria	**Key efficacy findings**	**Key safety findings**	**Appraisal/Comments**
Knight et al.[4] 2000, UK 200 patients, mean 34 months follow-up. Selection criteria: not clearly specified.	ODI 55% demonstrated score ≥ 50 (good or excellent result) for back pain, 52% for buttock pain, 53% for leg pain. In patients with one prior operation these figures were 51%, 33% and 29%. 41 of 46 (89%) with prior operation(s) improved. VAP 56% of patients had > 50% improvement, with 2% having deterioration. 62% of patients satisfied with targets achieved prior to surgery; 72% satisfied with outcome of procedure.	1 (0.5%) resolving neural injury. 1 (0.5%) aseptic discitis. 5% of patients required 'index level' revision surgery.	*Potential for bias*: Reported only as abstract *Outcome measures and their validity*: Outcome measures of unknown validity. *Other comments:* This appears to be an earlier report of a smaller collection of patients reported in Knight *et al.*[5] although the follow-up period is paradoxically longer than that of the later study.
Knight et al.[5] 2001, UK 250 patients, mean 30 month follow-up. Selection criteria: first 250 consecutive patients treated by ELF.	ODI 60% demonstrated excellent or good results on ODI. Clinically relevant improvement observed in 73%. For those with no prior back surgery, these figures were 67% and 82%. At 2 years 7% of patients demonstrated poorer ODI & VAP scores ($p<0.0001$). VAP: 16% painfree, 40% ≥ 50, 6% worse at 2 years. VAP correlated with ODI ($p<0.01$). Repeat surgery in 13/250 (5%).	1/250 (0.4%) neurological deficit – severe dysaesthesia with ipsilateral foot drop; considerable recovery at 2 years. 1/250 (0.4%) aseptic discitis.	*Potential for bias*: *Outcome measures and their validity*: Outcome measures of unknown validity. *Other comments:* This appears to be the same study as Knight *et al.*[6] although some outcomes are marginally different.

Specialist advisor's opinion / advisors' opinions

The Specialist Advisors believed that the efficacy of the procedure had yet to be proven. They noted the cause of lumbar back pain is often unclear and that many back problems have a benign natural history. The Advisors also reported a small number of cases of infection and nerve injury of which they were aware.

Issues for consideration by IPAC

All the studies in this field are written by two authors working together, M. Knight and A. Goswami. Also, some patients have been included in more than one of the published studies, so the cumulative published evidence is somewhat less than the addition of the patient numbers in the studies would suggest. All of these issues present potential sources of bias in the results.

Mr Knight is also currently running a RCT of endoscopic laser foraminoplasty compared with conservative management. The National Research Register indicates that this trial began in June 2002 and is scheduled for completion in June 2007.

References

1. Knight M, Goswami A, Hothersall A. Endoscopic foraminoplasty in failed back surgery: its effect on psychological distress profile, disability and pain outcomes. *Journal of Bone & Joint Surgery - British Volume* 2002; **84-B Supplement I**:97.

2. Knight MT, Ellison DR, Goswami A, Hillier VF. Review of safety in endoscopic laser foraminoplasty for the management of back pain. *Journal of Clinical Laser Medicine & Surgery* 2001; **19**(3):147-157.

3. Knight MT, Vajda A, Jakab GV, Awan S. Endoscopic laser foraminoplasty on the lumbar spine--early experience. *Minimally Invasive Neurosurgery* 1998; **41**(1):5-9.

4. Knight M, T.N., Goswami A, K.D., Patko J. Endoscopic laser foraminoplasty. *Journal of Bone & Joint Surgery - British Volume* 2000; **82-B Supplement I**:46.

5. Knight MT, Goswami A, Patko JT, Buxton N. Endoscopic foraminoplasty: a prospective study on 250 consecutive patients with independent evaluation. *Journal of Clinical Laser Medicine & Surgery 2001 Apr;19(2):73 81* 2001; **19**(2):73-81.

ANNEX: Studies that met the inclusion criteria but which were not tabulated.

Hothersall A, Knight M, T.N., Goswami A. The use of the distress and risk assessment method in patients with chronic back pain: its failure to predict the response to endoscopic spinal surgery (ELF). *Journal of Bone & Joint Surgery - British Volume* 2002; **84-B Supplement I**:97.

Knight M, T.N., Ellison D, Goswami A, K.D., Hillier V. An assessment of safety in endoscopically assisted laser spinal surgery for the management of back pain and sciatica. *Journal of Bone & Joint Surgery - British Volume* 2002; **84-B Supplement II**:148.

Knight M, T.N., Goswami A. Endoscopic foraminoplasty in the management of spondylolytic spondylolisthesis. *Journal of Bone & Joint Surgery - British Volume* 2002; **84-B Supplement I**:97.

Knight M, Goswami A, Hothersall A. The initial and sustained benefit of endoscopic foraminoplasty in the treatment of chronic back pain is not a placebo effect. *Journal of Bone & Joint Surgery - British Volume* 2002; **84-B Supplement I**:97.

Knight MTN, Goswami A, Patko JT, Buxton N. Endoscopic foraminoplasty: a prospective study on 250 consecutive patients with independent evaluation. *Journal of Bone & Joint Surgery - British Volume* 2000; **82-B Supplement III**:216.

Knight MTN, Goswami A, Patko JT, Buxton N. Endoscopic foraminoplasty: An independent prospective evaluation. *Lasers In The Musculoskeletal System* 2001:320-329.

This overview is based on an original contribution from ASERNIP-S which was subsequently revised by NICE.