

NATIONAL INSTITUTE FOR CLINICAL EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedures overview of automated percutaneous mechanical lumbar discectomy

Introduction

This overview has been prepared to assist members of the Interventional Procedures Advisory Committee (IPAC) in making recommendations about the safety and efficacy of an interventional procedure. It is based on a rapid review of the medical literature and specialist opinion. It should not be regarded as a definitive assessment of the procedure.

Date prepared

This overview was prepared in February 2005.

Procedure name

- Automated percutaneous mechanical lumbar discectomy.
- Automated percutaneous lumbar discectomy (APLD).

Specialty societies

- British Society of Skeletal Radiologists.
- British Cervical Spine Society.
- British Association of Spinal Surgeons.

Description

Indications

Lumbar radicular pain, also known as sciatica, refers to pain that begins in the lower back and radiates down one of the legs. It is commonly caused by a herniated (or prolapsed) lumbar intervertebral disc. The herniation is a result of a protrusion of the nucleus pulposus through a tear in the surrounding annulus fibrosus. The annulus fibrosus 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, numbness or weakness in the leg.

Current treatment and alternatives

Conservative treatments include the use of analgesics, non steroidal anti-inflammatory medicines, physical therapy and hot or cold compresses. Epidural injections of corticosteroid may also be used. Surgery to remove disc material is considered if there is nerve compression or persistent symptoms that are unresponsive to conservative treatment.

Surgical techniques include open repair procedures and minimally invasive alternatives using percutaneous approaches.

What the procedure involves

Automated percutaneous mechanical lumbar discectomy is performed using local anaesthetic with or without conscious sedation. Under fluoroscopic guidance, a cannula is placed centrally within the disc using a posterolateral approach on the symptomatic side. A probe connected to an automated cutting and aspiration device is then introduced through the cannula. The disc is aspirated until no more nuclear material can be obtained.

There are a number of different devices available that are used to perform this procedure.

Efficacy

In a randomised controlled trial of 34 patients, 41% (7/17) of patients had an excellent or good outcome after automated percutaneous lumbar discectomy, compared with 40% (4/10) of patients after conventional discectomy. In a second randomised controlled trial, 29% (9/31) of patients had a successful outcome with automated percutaneous lumbar discectomy, compared with 80% (32/40) of patients with microdiscectomy ($p < 0.001$). A third randomised controlled trial compared automated percutaneous lumbar discectomy with chemonucleolysis and found that significantly more patients had a successful result after chemonucleolysis (61% [44/72] versus 44% [30/69], $p < 0.05$).

Two large case series reported that 68% (707/1047) and 82% (1216/1474) of patients had an excellent or good result at 6 months and 1 year respectively. A third case series reported an overall success rate of 45% (52/115) after a mean follow-up of 55 months. In two further case series reports, 94% (47/50) and 52% (95/182) of patients were satisfied after mean follow-ups of 6 months and 2.5 years respectively.

The Specialist Advisors stated that there was some uncertainty about the efficacy of the procedure.

Safety

Few complications were reported. Three studies reported that discitis was an adverse event, affecting between 0.2% (2/1146) and 1% (2/182) of patients. Two studies reported haematoma in 0.1% (1/1146) and 1.4% (1/69) of patients. Other complications included back muscle spasms, the disc protrusion appearing more bulky, minor bleeding, minor radicular injury and vasovagal syncope.

The Specialist Advisors stated that vascular and nerve damage, discitis and infection were potential adverse effects of the procedure.

Literature review

Rapid review of literature

The medical literature was searched to identify studies and reviews relevant to automated percutaneous mechanical lumbar discectomy. Searches were conducted via the following databases, covering the period from their commencement to December 2004: MEDLINE, PREMEDLINE, EMBASE, Cochrane Library and Science Citation Index. Trial registries and the Internet were also searched. No language restriction was applied to the searches.

The following selection criteria were applied to the abstracts identified by the literature search. Where these criteria could not be determined from the abstracts the full paper was retrieved

Inclusion criteria for identification of relevant studies

Characteristic	Criteria
Publication type	Clinical studies included. Emphasis was placed on identifying good quality studies. Abstracts were excluded where no clinical outcomes were reported, or where the paper was a review, editorial, laboratory or animal study. Conference abstracts were also excluded because of the difficulty of appraising methodology.
Patient	Patients with sciatica due to intervertebral disc prolapse.
Intervention/test	Automated percutaneous mechanical lumbar discectomy.
Outcome	Articles were retrieved if the abstract contained information relevant to the safety and/or efficacy.
Language	Non-English-language articles were excluded unless they were thought to add substantively to the English-language evidence base.

List of studies included in the overview

This overview is based on eight studies, which are summarised in Table 1. Three randomised controlled studies are included, each comparing automated percutaneous lumbar discectomy with a different comparator (conventional discectomy, microdiscectomy and chemonucleolysis).^{1,2,3}

Two large case series with mean follow-ups of 6 months and 18 months are included.^{4,5} Three smaller case-series are included, two with longer follow-up periods and one more recent study that uses a newer device.^{6,7,8}

Other studies that were considered to be relevant to the procedure are listed in Appendix A.

Existing reviews on this procedure

A Cochrane review on surgery for lumbar disc prolapse was published in 2004. The review included data found up to the end of 1999.⁹ Three trials on automated percutaneous discectomy were identified; two compared the procedure with microdiscectomy and the third compared it with chemonucleolysis. The report concluded that there was moderate evidence that automated percutaneous discectomy produces poorer clinical outcomes than standard discectomy or chymopapain.

A Diagnostic and Therapeutic Technology Assessment (DATTA) on automated percutaneous lumbar discectomy was published in 1991.¹⁰ The report concluded that the procedure was safe when used for patients with protruding lumbar discs who have failed conservative therapy. There was no consensus on the effectiveness of the procedure for this indication. The report states that careful patient selection is essential and that the procedure is inappropriate for herniated lumbar discs with nuclear material outside and contiguous with the annulus.

Table 1 Summary of key efficacy and safety findings on automated percutaneous mechanical lumbar discectomy

Abbreviations used: APLD = automated percutaneous lumbar discectomy, VAS = visual analogue score			
Study details	Key efficacy findings	Key safety findings	Comments
<p>Haines SJ (2002)¹</p> <p>Randomised controlled trial</p> <p>USA</p> <p>34 patients:</p> <ul style="list-style-type: none"> Automated percutaneous discectomy = 62% (21/34) Conventional discectomy = 38% (13/34) <p>Mean age (years):</p> <ul style="list-style-type: none"> Automated percutaneous discectomy = 42.2 Conventional discectomy = 35.4 <p>Inclusion criteria: predominantly unilateral leg pain or paraesthesia, age between 18 and 65 years, no previous treatment for or coexistence of lumbar spinal disease, at least two of four objective signs (dermatomal sensory loss, myotomal weakness, appropriate reflex loss, appropriate nerve stretch test), and an imaging study confirming disc herniation at the appropriate level</p> <p>Exclusion criteria: moderate or advanced lumbar spondylosis, central or lateral spinal stenosis, spondylolisthesis, progressive neurologic deficit or a variety of technical contraindications to the percutaneous procedure</p> <p>Follow-up: 12 months</p> <p>Device: not specified</p>	<p>Key outcome measures: outcome assessment matrix incorporating patient assessment of pain frequency and severity, participation in work and leisure activities, analgesic use</p> <p>'Excellent' or 'good' outcome at 6 months (according to outcome assessment matrix):</p> <ul style="list-style-type: none"> Automated percutaneous discectomy = 41% (7/17) Conventional discectomy = 40% (4/10) <p>'Fair' outcome at 6 months (according to outcome assessment matrix):</p> <ul style="list-style-type: none"> Automated percutaneous discectomy = 18% (3/17) Conventional discectomy = 10% (1/10) <p>'Poor' outcome at 6 months (according to outcome assessment matrix):</p> <ul style="list-style-type: none"> Automated percutaneous discectomy = 41% (7/17) Conventional discectomy = 50% (5/10) <p>Although both groups showed improvements in mean SF-36 physical functioning score, general health score and Modified Roland score, there were no significant differences between them</p>	<p>Not reported</p>	<p>'LAPDOG' trial.</p> <p>5735 patients were screened, 95 were eligible and 36 were enrolled. 41 patients refused consent.</p> <p>Endoscopic techniques were added to the percutaneous technique allowing treatment of free fragment disc herniations.</p> <p>Specific device used to remove disc material not stated.</p> <p>26.5% (9/34) of patients were lost to follow-up.</p> <p>The trial did not recruit enough patients to reach a definitive conclusion about the efficacy of the two procedures.</p>

Abbreviations used: APLD = automated percutaneous lumbar discectomy, VAS = visual analogue score			
Study details	Key efficacy findings	Key safety findings	Comments
<p>Chatterjee S (1995)²</p> <p>Randomised controlled trial</p> <p>UK</p> <p>71 patients:</p> <ul style="list-style-type: none"> Automated percutaneous lumbar discectomy (APLD) = 44% (31/71) Lumbar microdiscectomy = 56% (40/71) <p>Mean age:</p> <ul style="list-style-type: none"> APLD = 38.9 years (range 20 to 56) Lumbar microdiscectomy = 41.3 years (range 21 to 67) <p>Mean duration from onset of low back problems:</p> <ul style="list-style-type: none"> APLD = 18 months (range 2 to 44) Lumbar microdiscectomy = 33 months (range 2 to 60) <p>Inclusion criteria: radicular pain, imaging showed a definite contained disc herniation at a single level with height less than 30% of the sagittal canal size, conservative treatment for a minimum of 6 weeks</p> <p>Exclusion criteria: disc extrusions, sequestrations, subarticular or foraminal stenosis, multiple levels of herniation</p> <p>Follow-up: 6 months</p> <p>Device: nonflexible automated suction nucleotome (Surgical Dynamics, California)</p>	<p>Key outcome measures: Mcnab classification (success = good/excellent, failure = fair/poor)</p> <p>Successful outcome:</p> <ul style="list-style-type: none"> APLD = 29% (9/31) Microdiscectomy = 80% (32/40) <p>p < 0.001</p> <p>20 patients who had an unsuccessful outcome after APLD had subsequent microdiscectomy, 65% (13/20) of whom then had a successful outcome.</p> <p>97% (30/31) of APLD patients were treated as day cases.</p> <p>Mean length of hospital stay for microdiscectomy group = 3.5 days</p> <p>Successful outcomes for disease level L4-L5:</p> <ul style="list-style-type: none"> APLD = 33% (4/12) Microdiscectomy = 82% (14/17) <p>Successful outcomes for disease level L5-S1:</p> <ul style="list-style-type: none"> APLD = 21% (4/19) Microdiscectomy = 78% (18/23) 	<p>Not reported</p>	<p>The original study aimed to recruit 160 patients but the study was stopped prematurely because the results of one group were markedly inferior.</p> <p>Outcomes were assessed by blinded independent observer and reviewed by the surgeon.</p> <p>Patients in whom APLD failed were offered a microdiscectomy, which was performed as soon as possible (mean 6 weeks).</p>

Abbreviations used: APLD = automated percutaneous lumbar discectomy, VAS = visual analogue score																																			
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<p>Revel M (1993)³</p> <p>Randomised controlled trial</p> <p>France</p> <p>1989–1990</p> <p>141 patients</p> <ul style="list-style-type: none"> Automated percutaneous lumbar discectomy (APLD) = 49% (69/141) Chemonucleolysis = 51% (72/141) <p>Mean age</p> <ul style="list-style-type: none"> APLD = 37 years (range 21 to 55) Chemonucleolysis = 40 years (range 22 to 65) <p>Inclusion criteria: chief symptom of sciatica caused by a disc herniation unresponsive to conservative treatment for at least 30 days, at least 16 years old, disc herniation demonstrated by CT, MRI or myelography at only one vertebral level, disc herniation compressing the clinically involved nerve root</p> <p>Exclusion criteria: previous lumbar surgery or previous chymopapain injection, pregnancy, allergy to papain, unavailable for 6 month follow-up, severe neurologic problems, lateral recess or central spinal stenosis, disc migration > 5 mm from vertebral endplates, large or calcified herniation, vacuum disc, disc height < 5 mm</p> <p>Follow-up: 1 year</p>	<p>Key outcome measures: intensity of sciatica and low back pain measured on VAS, functional impairment quantified using the Waddell and Main scale, investigator's opinion according to McNab criteria, radiographic assessment</p> <p>Successful result at 6 months (improvement better than 'moderate' according to patient):</p> <ul style="list-style-type: none"> APLD = 44% (30/69) Chemonucleolysis = 61% (44/72) <p>p < 0.05</p> <p>Subsequent open surgery (results considered as failure):</p> <ul style="list-style-type: none"> APLD = 33% (23/69) Chemonucleolysis = 7% (5/72) <p>Successful outcomes for disease level L4-L5, L3-L4:</p> <ul style="list-style-type: none"> APLD = 39% Chemonucleolysis = 70% <p>Successful outcomes for disease level L5-S1:</p> <ul style="list-style-type: none"> APLD = 50% Chemonucleolysis = 55% <p>Intensity of sciatica (VAS)</p> <table border="1"> <thead> <tr> <th></th> <th>APLD</th> <th>Chemo-nucleolysis</th> <th>P value</th> </tr> </thead> <tbody> <tr> <td>Baseline</td> <td>68.1</td> <td>63.4</td> <td>NS</td> </tr> <tr> <td>At discharge</td> <td>38.3</td> <td>31.0</td> <td>NS</td> </tr> <tr> <td>At 6 months</td> <td>35.6</td> <td>17.6</td> <td>< 0.01</td> </tr> </tbody> </table> <p>Intensity of low back pain (VAS)</p> <table border="1"> <thead> <tr> <th></th> <th>APLD</th> <th>Chemo-nucleolysis</th> <th>P value</th> </tr> </thead> <tbody> <tr> <td>Baseline</td> <td>40.9</td> <td>40.1</td> <td>NS</td> </tr> <tr> <td>At discharge</td> <td>27.0</td> <td>47.7</td> <td><0.0001</td> </tr> <tr> <td>At 6 months</td> <td>30.0</td> <td>23.2</td> <td>NS</td> </tr> </tbody> </table> <p>Successful result at 1 year (according to patient):</p> <ul style="list-style-type: none"> APLD = 61% (25/41) Chemonucleolysis = 83% (48/58) 		APLD	Chemo-nucleolysis	P value	Baseline	68.1	63.4	NS	At discharge	38.3	31.0	NS	At 6 months	35.6	17.6	< 0.01		APLD	Chemo-nucleolysis	P value	Baseline	40.9	40.1	NS	At discharge	27.0	47.7	<0.0001	At 6 months	30.0	23.2	NS	<p>Complications</p> <p>Back-muscle spasms:</p> <ul style="list-style-type: none"> APLD = 10% (7/69) Chemonucleolysis = 42% (30/72) <p>p < 0.0001</p> <p>Minor radicular injury:</p> <ul style="list-style-type: none"> APLD = 1.4% (1/69) Chemonucleolysis = 4.2% (3/72) <p>Minor bleeding:</p> <ul style="list-style-type: none"> APLD = 4.3% (3/69) Chemonucleolysis = 0% (0/72) <p>Haematoma:</p> <ul style="list-style-type: none"> APLD = 1.4% (1/69) Chemonucleolysis = 0% (0/72) <p>Vasovagal syncope:</p> <ul style="list-style-type: none"> APLD = 1.4% (1/69) Chemonucleolysis = 0% (0/72) 	<p>Randomisation described.</p> <p>Patients were evaluated by rheumatologists independent from those performing the procedure.</p> <p>During the study, 32 patients withdrew from follow-up: 10% (7/72) in chemonucleolysis group (five for open surgery, two lost to follow-up) and 36% (25/69) in APLD group (23 for open surgery, two for technical failure).</p> <p>The primary outcome was assessment at 6 months.</p>
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Study details	Key efficacy findings	Key safety findings	Comments
<p>Bonaldi G (2003)⁴</p> <p>Case series</p> <p>Italy</p> <p>1987–2002</p> <p>1146 patients (1158 procedures, 1308 discs)</p> <p>Age range: 15 to 92 years</p> <p>Inclusion criteria: low back pain and/or sciatica, lumbar bulging or protruding disc (not sequestered or migrated) seen definitely on CT and/or MRI and confirmed by discography or CT discography if necessary</p> <p>Follow-up: 6 months</p> <p>Device: not specified</p>	<p>Clinical result defined as excellent with complete resolution of symptoms or good with marked reduction in pain, and general satisfaction of the patient, who could return to work or usual daytime activities, taking analgesics seldom or not at all</p> <p>Excellent or good results at 2 months = 58% (635/1058)</p> <p>Excellent or good results at 6 months = 68% (707/1047)</p> <p>Results were better in 3 sub-groups: patients aged 70 years or older; patients who had previously undergone open disc surgery at the same level and had a recurrent disc protrusion after 6 months or more; patients with purely 'discogenic' low-back pain</p> <p>12% (125/1047) patients underwent subsequent open surgery</p>	<p>Complications</p> <ul style="list-style-type: none"> • Discitis = 0.2% (2/1146) • Acute haematoma of the iliopsoas muscle = 0.1% (1/1146) • Disc protrusion appeared more bulky, extruded or sequestered = 0.7% (8/1146) 	<p>Procedure was performed on an outpatient basis.</p> <p>6% (63/1146) of patients were lost to follow-up at 2 months and 10% (111/1146) at 6 months.</p>

Abbreviations used: APLD = automated percutaneous lumbar discectomy, VAS = visual analogue score			
Study details	Key efficacy findings	Key safety findings	Comments
<p>Teng G-J (1997)⁵</p> <p>Case series</p> <p>China</p> <p>1992–1994</p> <p>1525 patients (1582 procedures)</p> <p>Mean age: 48.2 years (range 13 to 75)</p> <p>Mean time from onset of symptoms: 15.2 months (range 2 months to 15 years)</p> <p>Inclusion criteria: sciatic and/or low back pain, symptoms and physical findings corresponding to abnormal finding at CT or MR imaging, failure of at least 2 months of conservative therapy</p> <p>Exclusion criteria: inability to tolerate procedure under local anaesthesia, history of allergy to contrast material, had a technically unsuccessful procedure, condition that would prevent follow-up evaluation, previous chymopapain injection, progressive neurologic deficit or cauda equina syndrome, pregnancy, infection, intraspinal tumour, any other cause of pain as revealed by CT or MR imaging (such as spinal stenosis, lateral recess stenosis, severe degenerative facet disease, or spondylolysis)</p> <p>Mean follow-up: 18 months (range 12 to 28)</p> <p>Device: Teng instrument (Shuguang Electric & Mechanical Company, China)</p>	<p>Results were judged as excellent, good or poor: excellent = no symptoms, no restriction in daily activities; good = occasional complaints but greatly improved and could return to work; poor = no improvement or worsening</p> <p>Results at 1 year:</p> <ul style="list-style-type: none"> • Excellent = 56% (829/1474) • Good = 26% (387/1474) • Poor = 18% (258/1474) <p>Technical success at L5-S1 level = 99% (795/800)</p> <p>Excellent plus good results at 1 year, according to clinical status:</p> <ul style="list-style-type: none"> • Extrusion/sequestration = 72% (258/357) • Bulging/protrusion = 86% (819/950) • Back pain only = 89% (164/185) • Back and leg pain = 80% (1031/1289) • Symptoms > 2 years = 79% (516/652) • Symptoms < 2 years = 85% (700/822) • Age < 60 years = 76% (161/212) • Age > 60 years = 84% (1055/1262) 	<p>Complications</p> <ul style="list-style-type: none"> • Discitis = 0.6% (9/1525) <p>(all patients were fully recovered within 1–2 months, following antibiotics and complete bed rest)</p> <p>APLD was repeated in two of these patients to reduce the intradiscal pressure and allow administration of intradiscal antibiotics</p>	<p>Prospective study.</p> <p>The discectomy was performed at a minimum of three sites at each interspace.</p> <p>3.3% (51/1525) of patients were lost to follow-up at 1 year.</p> <p>If surgical discectomy or chemonucleolysis was performed during the follow-up period, the results of APLD were rated as poor.</p>

Abbreviations used: APLD = automated percutaneous lumbar discectomy, VAS = visual analogue score			
Study details	Key efficacy findings	Key safety findings	Comments
<p>Bernd L (1997)^o</p> <p>Case series</p> <p>1988–1990</p> <p>Germany</p> <p>182 patients</p> <p>Inclusion criteria: Persistent lumbos-ischialgia after minimum 6 months of conservative treatment, lumbar disc protrusion or extrusion confirmed by CT or MRI.</p> <p>Exclusion criteria: Isolated back pain from other aetiologies such as facet syndrome, degenerative disc disease and sacroiliac pathology, sequestered discs, spinal stenosis</p> <p>Mean follow-up: 2.5 years (range 1 to 3.5 years)</p> <p>Device: not specified</p>	<p>Outcome measures: change in condition according to McNab criteria (pain relief, patient satisfaction, sports activity, return to work, compensation claims)</p> <p>Patient satisfaction = 52% (95/182) Decrease in pain = 60% (109/182)</p> <p>Satisfaction was significantly different in those with preoperative sensory deficit and those without (43% versus 60%, $p < 0.03$)</p> <p>Patients who were active in sports were significantly more satisfied than patients who were not</p> <p>Pain improved with time; 9% of patients were free of pain at up to 2 years compared to 17% at 3 years or more</p> <p>Persistent pain decreased with 48% in the 1st year, 28% in the 2nd and 22% after the 3rd</p> <p>Age was a significant factor for a positive outcome (patients aged < 41 years did better in terms of pain relief and improvement in condition)</p> <p>Risk factors for further operation: age > 41 years ($p < 0.02$) and positive Lasegue's sign (sciatic stretch test) ($p < 0.003$)</p> <p>The outcome was not related to the amount of disc material removed</p>	<p>Complications</p> <ul style="list-style-type: none"> • Discitis = 1.1% (2/182) (successfully treated conservatively) 	<p>A total of 238 patients underwent the procedure during the study period, 76% (182/238) returned a questionnaire that was suitable for analysis.</p> <p>The data were analysed by an independent assessor.</p> <p>The aim of the study was to identify patient-related factors which contribute to pain relief and satisfaction.</p>

Abbreviations used: APLD = automated percutaneous lumbar discectomy, VAS = visual analogue score			
Study details	Key efficacy findings	Key safety findings	Comments
<p>Grevitt MP (1995)⁷</p> <p>Case series</p> <p>1988–1990</p> <p>UK</p> <p>137 patients</p> <p>Mean age: 33 years (range 17 to 57)</p> <p>Mean duration of disabling radicular symptoms: 16 months (range 3 to 26)</p> <p>Inclusion criteria: predominant leg symptoms, radicular pain distribution, restricted straight-leg raise, positive signs of nerve-root tension, failure of conservative treatment.</p> <p>Exclusion criteria: symptoms suggestive of facet arthrosis or neurogenic claudication, > 50% loss of disc height at relevant level, sequestered fragments.</p> <p>Mean follow-up: 55 months (range 44 to 71)</p> <p>Device: Nucleotome ® (Surgical Dynamics Inc, California, USA)</p>	<p>Outcome measures: Oswestry Back Disability form, Short Form 36, pain levels measured on VAS, Low Back outcome score (according to Greenough and Fraser).</p> <p>12% (17/137) of patients had further surgery after APLD.</p> <p>Results of Low Back outcome score at follow-up:</p> <ul style="list-style-type: none"> • Excellent = 33% • Good = 19% • Fair = 30% • Poor = 18% <p>Overall success rate (patients with an excellent or good outcome and no further surgery) = 45% (52/115).</p> <p>Of the first 50 patients, 67% (24/36) of patients initially graded as excellent or good remained in the same group. 33% (12/36) of patients had deteriorated to either fair or poor.</p>	<p>The study reported that there were no major complications</p>	<p>16% (22/137) of patients were lost to follow-up.</p> <p>Outcome analysis included 100 patients treated with APLD alone and 15 patients who had further surgery after APLD.</p> <p>The first 50 consecutive patients were traced and all responded.</p>

Abbreviations used: APLD = automated percutaneous lumbar discectomy, VAS = visual analogue score			
Study details	Key efficacy findings	Key safety findings	Comments
<p>Alò KM (2004)⁸</p> <p>Case series</p> <p>USA and UK</p> <p>50 patients</p> <p>Inclusion criteria: radicular pain associated with contained disc \leq 6 mm, duration of pain > 6 months, failure of at least 6 months of conservative therapy, good to excellent short-term (< 2 weeks) response to transforaminal injection of local anaesthetic or corticosteroid, confirmatory selective segmental spinal nerve block providing > 80% relief of radicular pain, preservation of disc height (< 50% loss)</p> <p>Exclusion criteria: progressive neurological deficit, > 2 symptomatic levels, previous open surgery at the same level, spinal instability, spinal fracture or tumour, pain drawing inconsistent with clinical diagnosis, significant coexisting medical or psychological condition</p> <p>Follow-up: 6 months</p> <p>Device: Dekompressor ® probe (Stryker)</p>	<p>Outcome measures: Visual analogue score (VAS) (0 to 10, where 10 is the worst pain imaginable), analgesic use, self-reported functional improvement, overall satisfaction of patient</p> <p>Mean reduction in pre-operative pain score (VAS) = 60.2% ($p < 0.001$)</p> <p>Reduced analgesic intake = 74% (37/50)</p> <p>Improvement in functional status = 90% (45/50)</p> <p>Overall satisfaction = 94% (47/50)</p>	<p>There were no procedure-related complications</p>	<p>Prospective study, consecutive patients.</p> <p>An independent evaluator performed data collection and statistical analysis at initial evaluation and 6 month follow-up.</p> <p>Preliminary clinical trial.</p>

Validity and generalisability of the studies

One study included patients with factors considered to be contraindications by other studies (including extrusion/sequestration type of herniation).⁵

Different devices are available to perform the procedure and they may have different safety and efficacy profiles.

There was a lack of validated outcome measures; most of the outcome measures were subjective and the studies used a variety of methods to define a successful outcome.

All the studies except one included leg pain or sciatica with or without lower back pain as the main indication. The remaining study included patients with back pain only.⁶

Efficacy results from case series studies do not allow for the fact that the condition may have improved naturally over time, without any additional intervention.

Specialist advisors' opinions

Specialist advice was sought from consultants who have been nominated or ratified by their Specialist Society or Royal College.

- The procedure is considered to be either established practice or a minor variation on an existing procedure.
- Appropriate comparators would be lumbar microdiscectomy, open discectomy and chemonucleolysis (although chymopapain is not currently available in the UK).
- The key efficacy outcome is relief of sciatica.
- The procedure is likely to have a minor impact on the NHS, in terms of numbers of patients eligible for treatment and use of resources.

Issues for consideration by IPAC

There are no additional issues for consideration.

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- 7 Grevitt MP, McLaren A, Shackelford IM, et al. Automated percutaneous lumbar discectomy. *The Journal of Bone and Joint Surgery* 1995; 77: 626–9.
- 8 Alò KM, Wright RE, Sutcliffe J, et al. Percutaneous lumbar discectomy: clinical response in an initial cohort of fifty consecutive patients with chronic radicular pain. *Pain Practice* 2004; 4: 19–29.
- 9 Gibson JNA, Grant IC, Waddell G. Surgery for lumbar disc prolapse (Cochrane Review). In: *The Cochrane Library*, Issue 3, 2004. Chichester, UK: John Wiley & Sons, Ltd.
- 10 Diagnostic and Therapeutic Technology Assessment (DATTA). Reassessment of automated percutaneous lumbar discectomy for herniated disks. *JAMA* 1991; 265: 2122–5.

Appendix A: Additional papers on automated percutaneous mechanical lumbar discectomy

Article title	Number of patients/ follow-up	Comments	Direction of conclusions
Davis GW, Onik G, Helms C. Automated percutaneous discectomy. <i>Spine</i> 1991; 16: 359–63.	518 patients.	Case series.	Overall success 85% No intraoperative or postoperative complications.
Dullerud R, Amundsen T, Lie H, et al. Clinical results after percutaneous automated lumbar nucleotomy. <i>Acta Radiologica</i> 1995; 36: 418–24.	142 patients. Mean follow-up = 21 months.	Case series. Included patients with spinal stenosis and those with predominance of low-back pain.	Overall success 56%. Spinal stenosis and disk space narrowing were associated with a poor outcome.
Fiume D, Parziale G, Rinaldi A, et al. Automated percutaneous discectomy in herniated lumbar discs treatment: experience after the first 200 cases. <i>Journal of Neurosurgical Sciences</i> 1994; 38: 235–7.	200 patients.	Case series. Patients divided into 2 groups – those with moderate pain and those with severe pain.	Success rate for patients with moderate pain = 85%. Success rate for patients with severe pain = 64%. 15% required open surgery.
Flipo RM, Draou M, Duneton O, et al. Long term results of automated percutaneous lumbar discectomy. <i>Rhumatologie</i> 1994; 46: 95–9.	45 patients. 6 month follow-up.	Case series.	Efficacy considered good or very good = 48% Moderate = 23% Open surgery = 29% 1 case of probable infectious spondylodiscitis.
Krahner T, Euinton HA, Getty CJM, et al. Automated percutaneous lumbar discectomy. <i>Journal of Interventional Radiology</i> 1997; 12: 113–5.	30 patients. Mean follow-up = 44 months.	1989 – 1996. Case series.	Success rate = 43%. Open surgery required = 46%. 10/13 failures had a bony entrapment and 2 had a sequestered disc.
Krugluger J, Knahr K. Chemonucleolysis and automated percutaneous discectomy – a prospective randomized comparison. <i>International Orthopaedics</i> 2000; 24: 167–9.	22 patients. Follow-up = 2 years.	1994 – 1995. Randomised controlled trial, comparing APLD with chemonucleolysis. Small study, limited efficacy results.	Significant improvements at 6 weeks in neurological deficits and Oswestry score for both groups. Severe back spasms in 1 st week in chemonucleolysis group. APLD group deteriorated at 2 years to give significantly poorer results than chemonucleolysis.
Onik G, Mooney V, Maroon JC, et al. Automated percutaneous discectomy: a prospective multi-institutional study. <i>Neurosurgery</i> 1990; 26: 228–32.	327 patients. Follow-up = 1 year.	Case series.	Success rate for patients meeting study criteria = 75%. Success rate for patients not meeting study criteria = 49%. 0.3% (1/327) discitis.

Article title	Number of patients/ follow-up	Comments	Direction of conclusions
Ramberg N, Sahlstrand T. Early course and long-term follow-up after automated percutaneous lumbar discectomy. <i>Journal of Spinal Disorders</i> 2001; 14: 511–7.	30 patients. Follow-up = 2 to 5 years.	1993 – 1996. Case series. Small study, mean follow-up period not stated.	Significant reduction in sciatic pain and straight leg raising test. No significant change in back pain or Oswestry score. 38% (10/26) required open surgery. Oswestry score improved in long-term.
Sahlstrand T, Lonntoft M. A prospective study of preoperative and postoperative sequential magnetic resonance imaging and early clinical outcome in automated percutaneous lumbar discectomy. <i>Journal of Spinal Disorders</i> 1999; 12: 368–74.	20 patients. Follow-up = 6 weeks.	Case series. Small study, short follow-up.	No change in sciatic pain at 6 weeks. No correlation between MRI findings and the early clinical outcome. 35% (7/20) required open surgery.
Shapiro S. Long-term follow-up of 57 patients undergoing automated percutaneous discectomy. <i>Journal of Neurosurgery</i> 1995; 83: 31–3.	57 patients. Mean follow-up = 27 months.	Case series.	70% (40/57) had reduced sciatica at 2 months. 58% (33/57) improved at last follow-up. 5% (3/57) pain-free.
Sortland O, Kleppe H, Aandahl M, et al. Percutaneous lumbar discectomy. Technique and clinical result. <i>Acta Radiologica</i> 1996; 37: 85–90.	45 patients. Follow-up = 1 year.	Case series.	7% (3/45) technical failures. 69% of patients were satisfied. No complications.

Appendix B: Literature search for automated percutaneous mechanical lumbar discectomy

The following search strategy was used to identify papers in Medline. A similar strategy was used to identify papers in EMBASE, Current Contents, PreMedline and all EMB databases.

For all other databases a simple search strategy using the key words in the title was employed.

1	high-energy shock waves/ (180)
2	eswt.tw. (108)
3	eswl.tw. (1912)
4	(extra?corporeal adj5 shock?wave\$ adj5 therap\$).tw. (77)
5	(extra?corporeal adj5 shock?wave\$ lithotripsy).tw. (582)
6	lithotripsy/ (6225)
7	orthotripsy.tw. (8)
8	or/1-7 (6620)
9	tendinitis/ (2305)
10	tendinopath\$.tw. (283)
11	(refractory adj20 tendinopathy).tw. (0)
12	(plantar adj5 fasciitis).tw. (295)
13	fasciitis, plantar/ (73)
14	heel spur/ (16)
15	(heel\$ adj5 spur\$).tw. (103)
16	or/9-15 (2831)
17	8 and 16 (113)