# *Intradiscal electrothermal anuloplasty*

## *A treatment for patients with chronic low back pain due to anular disruption of contained herniated discs*

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The Medical Services Advisory Committee is an independent committee which has been established to provide advice to the Commonwealth Minister for Health and Ageing on the strength of evidence available on new and existing medical technologies and procedures in terms of their safety, effectiveness and cost-effectiveness. This advice will help to inform Government decisions about which medical services should attract funding under Medicare.

This report was prepared by the Medical Services Advisory Committee with the assistance of Dr Adèle Weston, Mr Warwick Isaacson, Mr Lachlan Standfield and Ms Alison Hillman from M-TAG Pty Ltd. The report was endorsed by the Commonwealth Minister for Health and Aged Care on 6 December 2002.

Publication approval number: 3186

***MSAC recommendations do not necessarily reflect the views of all individuals who participated in the MSAC evaluation.***

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Intradiscal electrothermal anuloplasty is an invasive procedure that provides an alternative treatment option for patients with chronic low back pain originating from internal disc disruption (IDD). Importantly, this assessment of the intradiscal electrothermal anuloplasty procedure refers specifically to heating of the anulus, rather than other intradiscal regions.[1] The procedure is undertaken using three pieces of equipment: an introducer needle (L69923), a flexible catheter (SpineCATH™, L69739) and a heat generator (ORA-50 S, L69924). The introducer needle is a contourable 17-gauge needle with stylet that provides access to the intradiscal space. The SpineCATH™ is a flexible catheter with a moveable tip that contains a heating element comprised of copper wire. The catheter is used in conjunction with the ORA-50 S programmable generator, which allows temperature-monitored heating of the catheter tip.

The procedure is performed with local anaesthesia and mild intravenous sedation. The introducer needle is inserted into the painful disc under biplanar fluoroscopic control. The flexible catheter is then threaded from within the nucleus pulposus of the disc to reach the anulus from the inside and pass circumferentially around the lateral and posterior anulus (**Figure 1**). The catheter tip is slowly heated to a temperature of up to 90°C for 15–17 minutes. During this time, the patient is monitored for onset of new radicular symptoms or severe back pain.

Directly after the procedure, the patient is monitored for a short period before being allowed to return home. In the following 6–12 weeks, a lumbar support may be worn and an appropriate course of physiotherapy administered.

## Medical Services Advisory Committee – role and approach

The Medical Services Advisory Committee (MSAC) is a key element of a measure taken by the Commonwealth Government to strengthen the role of evidence in health financing decisions in Australia. MSAC advises the Commonwealth Minister for Health and Aged Care on the evidence relating to the safety, effectiveness and cost-effectiveness of new and existing medical technologies and procedures, and under what circumstances public funding should be supported.

A rigorous assessment of the available evidence is thus the basis of decision making when funding is sought under Medicare. Medical Technology Assessment Group (M-TAG) Pty Ltd was contracted to undertake a systematic review and economic evaluation of intradiscal electrothermal anuloplasty. A supporting committee with appropriate expertise then evaluated this evidence and provided advice to MSAC.

[1]This assessment is based on evidence relating to SpineCath™, a product manufactured by Oratec Interventions Inc. and currently marketed in Australia by DePuy Australia Pty Ltd.

# MSAC's assessment of intradiscal electrothermal anuloplasty

## Clinical need

In 2000–2001, 'back complaint' was the most common musculoskeletal disease or condition managed by general practitioners in Australia (Britt et al 2001). Disability from back pain places a significant socioeconomic burden on the individual and the community. It is estimated that there are approximately 140,000–210,000 new cases of truly *chronic* back pain each year in Australia.

## Safety

At present, level III-2 and IV evidence is available to describe the safety of intradiscal electrothermal anuloplasty in the treatment of chronic back pain secondary to anular disruption of contained herniated discs, with one non-randomised, open-label, quasi-controlled study (level III-2), five uncontrolled studies (level IV), and two case reports (level IV) identified. The safety data available have been poorly reported, with adverse events either not reported or reported with little detail. However, preliminary evidence suggests that the level of complications associated with intradiscal electrothermal anuloplasty is low. It should also be noted that the safety of intradiscal electrothermal anuloplasty should be considered relative to spinal surgery (ie, spinal fusion) and conservative therapy programs.

## Effectiveness

As with safety, level III-2 and IV evidence is available to describe the efficacy of intradiscal electrothermal anuloplasty in the treatment of chronic back pain secondary to anular disruption of contained herniated discs, with one non-randomised, open-label, quasi-controlled study (level III-2), and four uncontrolled studies (level IV) identified. The preliminary data show improvements in visual analogue pain scale outcomes and return to work or previous function, as well as reduction in pain medication, for patients treated with intradiscal electrothermal anuloplasty. However, these preliminary data are based on low-level clinical evidence, which is likely to be vulnerable to considerable bias. Hence, the robustness of these results is uncertain.

## Cost-effectiveness

There are currently insufficient data to estimate the relative effectiveness of intradiscal electrothermal therapy compared with either continued conservative therapy or spinal fusion. Primarily, there is a lack of high-quality evidence regarding the intradiscal electrothermal procedure. Moreover, there was no evidence identified on which to base an indirect comparison of the procedure with continued conservative therapy or spinal fusion.

## Recommendation

Since there is currently insufficient evidence pertaining to intradiscal electrothermal anuloplasty, a treatment for patients with chronic low back pain due to anular disruption of contained herniated discs, MSAC recommended that public funding should not be supported at this time for this procedure.

- The Minister for Health and Aged Care accepted this recommendation on 6 December 2002. -

# Introduction

The Medical Services Advisory Committee (MSAC) has reviewed the use of intradiscal electrothermal anuloplasty, which is a therapeutic procedure for the treatment of chronic low back pain caused by anular disruption of contained herniated discs. MSAC evaluates new and existing health technologies and procedures for which funding is sought under the Medicare Benefits Scheme in terms of their safety, effectiveness and cost-effectiveness, while taking into account other issues such as access and equity. MSAC adopts an evidence-based approach to its assessments, based on reviews of the scientific literature and other information sources, including clinical expertise.

MSAC's terms of reference and membership are at **Appendix A**. MSAC is a multidisciplinary expert body, comprising members drawn from such disciplines as diagnostic imaging, pathology, surgery, internal medicine and general practice, clinical epidemiology, health economics, consumer health and health administration.

This report summarises the assessment of current evidence for intradiscal electrothermal anuloplasty for the treatment of chronic low back pain caused by anular disruption of contained herniated discs.

# Background

## Intradiscal electrothermal anuloplasty

In Australia, low back pain is one of the most common causes of chronic disability. Consequently, it is also one of the most common reasons for healthcare resource utilisation. Chronic low back pain represents a difficult clinical area with regard to both diagnosis and treatment. It can be caused by a number of conditions, one of which is internal disc disruption (IDD).

IDD is characterised by a degraded nucleus pulposus with radial fissures extending into the peripheral anulus fibrosis. It accounts for a considerable proportion of patients (39%, 95% CI: 29–49%) with chronic low back pain (Schwarzer et al 1995). In Australia, patients with IDD are currently treated with conservative therapy, comprising physiotherapy, exercise programs, analgesics and anti-inflammatories. If conservative measures fail, posterolateral or interbody fusion may be performed. However, there is uncertainty about the effectiveness of fusion procedures.

### The procedure

Intradiscal electrothermal anuloplasty is an invasive procedure that provides an alternative treatment option for patients with chronic low back pain originating from IDD. Importantly, this assessment of intradiscal electrothermal anuloplasty refers specifically to heating of the anulus, rather than other intradiscal regions.[2] The procedure is undertaken using three pieces of equipment: an introducer needle (L69923), a flexible catheter (SpineCATH™, L69739) and a heat generator (ORA-50 S, L69924). The introducer needle is a contourable 17-gauge needle with stylet that provides access to the intradiscal space. The SpineCATH™ is a flexible catheter with a moveable tip that contains a heating element of copper wire. The catheter is used in conjunction with the ORA-50 S programmable generator, which allows temperature-monitored heating of the catheter tip.

The procedure is performed with local anaesthesia and mild intravenous sedation. The introducer needle is inserted into the painful disc under biplanar fluoroscopic control. The flexible catheter is then threaded from within the nucleus pulposus of the disc to reach the anulus from the inside and pass circumferentially around the lateral and posterior anulus (**Figure 1**). The catheter tip is slowly heated to a temperature of up to 90°C for 15–17 minutes. During this time, the patient is monitored for onset of new radicular symptoms or severe back pain.

Directly after the procedure, the patient is monitored for a short period before being allowed to return home. In the following 6–12 weeks, a lumbar support may be worn and an appropriate course of physiotherapy administered.

[2]This assessment is based on evidence relating to SpineCath™, a product manufactured by Oratec Interventions Inc. and currently marketed in Australia by DePuy Australia Pty Ltd.

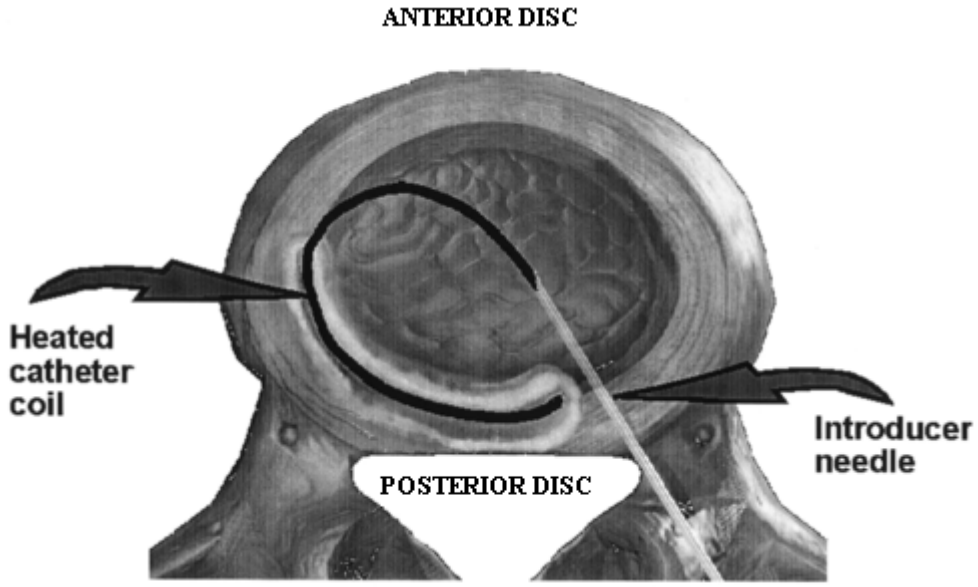


Figure 1 Placement of the intradiscal catheter, as suggested by the applicant

The pathophysiology of discogenic back pain is complex and the exact mechanisms by which the intervertebral disc causes pain have yet to be completely understood. However, it is known that IDD is a condition characterised by a degraded nucleus pulposus, with radial fissures extending into the peripheral anulus fibrosus. These radial fissures have been shown to correlate with reproduction of pain when the disc is stressed during provocation discography. It is believed that mechanical loading of areas of degenerated and disrupted anular lamellae may cause sensitisation of the anulus nociceptors. A combination of these mechanical and neural factors is thought to contribute to disc-mediated pain. The intradiscal temperatures generated by intradiscal electrothermal anuloplasty may address both components of this syndrome, ostensibly by coagulating the collagen of the anulus and any nociceptor nerve fibres in it (Saal and Saal 2000a, Karasek and Bogduk 2000).

## Intended purpose

It is claimed that intradiscal electrothermal anuloplasty provides pain relief for patients with anular disruption of contained herniated discs. In order to optimise the specificity of this assessment and its recommendation, it was determined that assessment would be limited to patients who have:

- experienced intractable lower back pain for at least 6 months
- failed at least 3 months of conservative therapy, including physiotherapy, exercise programs, simple analgesics and anti-inflammatories
- no abnormal neurological findings or other pathologies
- a contained herniated disc with preserved disc height

- a single painful disc on provocation discography (ie, with painless discs on either side)
- fissures reaching the outer third of the anulus in the painful disc
- no contraindications.

Treatment with intradiscal electrothermal anuloplasty is not recommended for patients with radicular pain and is contraindicated in patients with the following conditions: severe disc degeneration, neurological symptoms, large disc herniations or non-contained herniations, spinal instability, spinal stenosis and infection.

## Clinical need/burden of disease

### Back complaint in Australia

Back complaint includes both acute and chronic back pain. In 2000–2001, 'back complaint' was the most common musculoskeletal disease or condition managed by general practitioners in Australia (Britt et al 2001). Overall, back complaint was the seventh most common problem managed by general practitioners in 2000–2001, accounting for 2.5 per cent of the total number of general practice presentations.

Disability from back pain places a significant socioeconomic burden on the individual and the community. Back problems are the leading specific musculoskeletal cause of health system expenditure, with an estimated total cost of $700 million in 1993–1994 (Mathers et al 1999). In addition, back pain places considerable financial pressure on workers compensation systems within Australia and these costs are rising: in Victoria alone, claims lodged for back injury with the workers compensation scheme cost the community $510 million in the 1999–2000 financial year (Annual Report Victorian WorkCover Authority, 2001). Likewise, injury claims for lower back pain in NSW have risen from $590 million in 1995–1996 to $1.8 billion in 1999–2000 (WorkCover NSW, personal communication). It should be noted that a large portion of these costs are due to legal expenses, replacement of wages and rehabilitation.

### Incidence of chronic back pain in Australia

The incidence of chronic back pain in Australia was estimated from National Health Survey data at 345 per 1000 population in 1995, which equated to approximately 6 million people with chronic back pain (Mathers et al 1999). The National Health Survey relies on self-reports of chronic back pain, defined simply as 'episodes of back pain that limited activity' in the last year. It should be noted that this estimate is likely to capture respondents with longstanding back pain and therefore clouds the incidence data with cases already prevalent in the population.

### Incidence of intervertebral disc disorders in Australia

The annual incidence of intervertebral disc disorders was estimated at 9.2 per 1000 population in Australia in 1996 (Mather et al 1999). This equates to a total of approximately 143,489 episodes of intervertebral disc disorder per year. This estimate is

based on the number of hospital presentations for intervertebral disc disorders per year and is therefore likely to underestimate the incidence of this condition in the general community.

This cohort of patients would include those with displacement of the disc, loss of disc height and concurrent radicular pain. Hence, these data are not specific to patients with IDD who are suitable for intradiscal electrothermal anuloplasty. Therefore, the available epidemiological data do not provide a reliable estimate of the number of Australian patients with IDD who are suitable for intradiscal electrothermal anuloplasty.

## Current data on discography services

When epidemiological estimates are not available, annual procedure statistics may be used to estimate the size of a potential treatment population.

In 2001–2002, a total of 1390 Medicare-funded discography services (item number: 59700) were performed. Services are funded on a 'per disc' basis. As CT-discography requires provocation of the suspected painful disc and at least one 'control' disc, this figure is likely to overestimate the number of patients undergoing CT-discography by at least a factor of two. Therefore, it is estimated that approximately 700 patients undergo CT-discography in the Medicare setting per year. However, this represents only those patients treated outside of the public hospital system. If this figure is upscaled by the public:private ratio calculated for spinal fusion (0.47:1), then it is estimated that a total of 1029 patients undergo CT-discography annually (329 public:700 private).

In summary, it appears that only a modest number of patients are currently being investigated with discography in Australia. It is possible that the under-utilisation of this diagnostic procedure is a reflection of the lack of treatment options available for this cohort. It therefore appears that this method underestimates the pool of patients who would potentially be suitable for intradiscal electrothermal anuloplasty, and is not an accurate estimate of the true magnitude of this patient subpopulation.

Spinal fusion statistics were also considered to be inappropriate for estimating the number of patients suitable for treatment with intradiscal electrothermal anuloplasty, because these data were not specific to patients with IDD.

In the absence of suitable Australian epidemiological or procedure/diagnosis statistics, it is necessary to rely on epidemiological data derived elsewhere. These figures are used to estimate, in a step-wise fashion, the annual incidence of cases in Australia that are potentially suitable for intradiscal electrothermal anuloplasty (**Figure 1**).

In a review of the epidemiological features of chronic low back pain, Andersson (1999) estimated the annual incidence of back pain in the adult population to be 10–15 per cent on the basis of international data. The author indicated that more than 90 per cent of these cases resolved within three months. If applied to the Australian adult population,[3] this would suggest that there are 140,000–210,000 new cases of truly *chronic* back pain each year.

[3]In June 2000, the Australian population ≥ 18 years was approximately 14,000,000.

It is estimated that 50 per cent of these patients have intractable pain after extensive conservative treatment (expert opinion). Of patients with intractable pain after extensive conservative therapy, 90 per cent have normal neurological examination, preserved disc height, and no other pathology (expert opinion).

It is then necessary to estimate the proportion of patients with chronic low back pain who have anular disruption of contained herniated discs. A study of 92 consecutive patients found 39 per cent (95% CI, 29–49%) fully satisfied the diagnostic criteria for IDD (Schwarzer et al 1995). This proportion is further reduced by 50 per cent to account for patients with more than one painful disc (Saal and Saal 2000a; Saal and Saal 2002).

In summary, it is estimated that 9135–23,153 patients may be suitable for treatment with intradiscal electrothermal anuloplasty each year in Australia **(Figure 1)**.

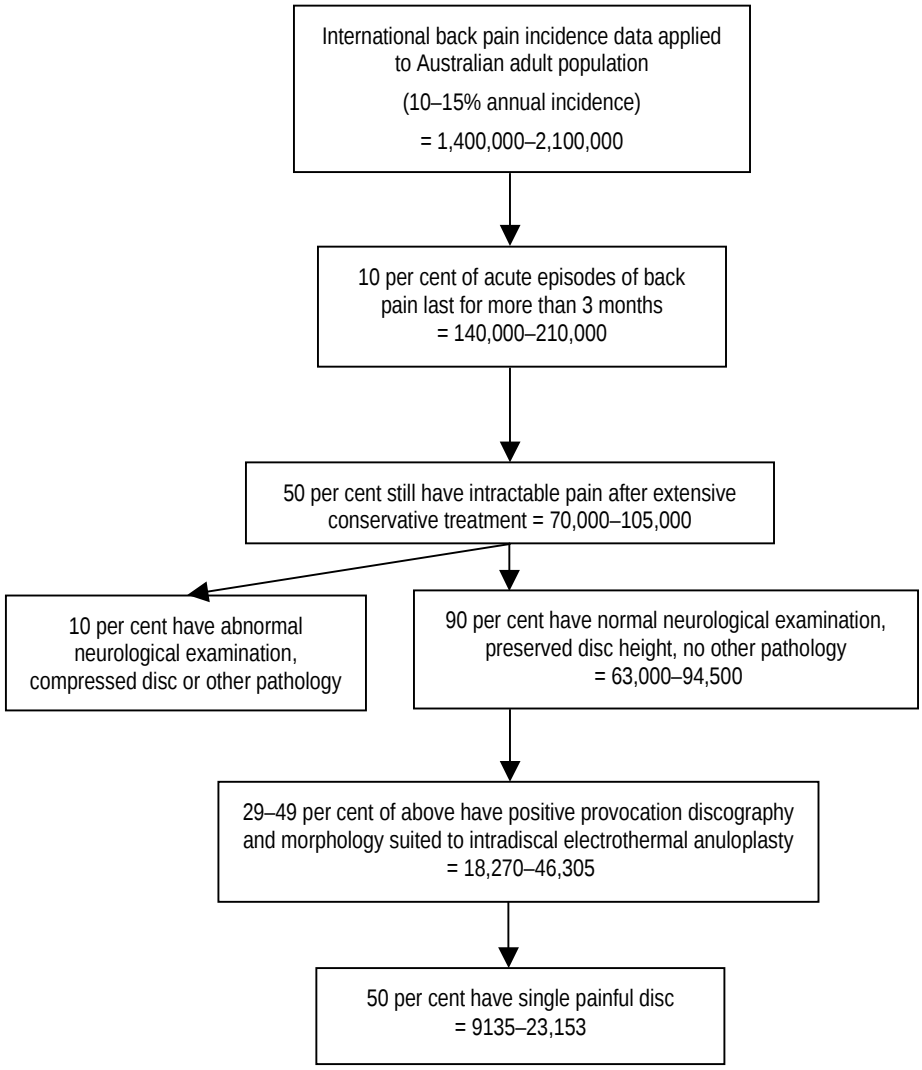


Figure 1 Estimation of the number of patients suitable for treatment with intradiscal electrothermal anuloplasty

# Existing procedures

## Diagnostic procedures

The cascade of diagnostic procedures used to identify a patient with anular disruption of contained herniated discs in Australian practice is presented in **Table 1**.

Table 1 Cascade of diagnostic procedures for Australian patients with chronic low back pain

| Diagnostic procedure | Required result | Rationale |
|---|---|---|
| Plain X-ray | No abnormalities evident<br>Preservation of disc height | Exclude overt skeletal disorders and patients with reduced disc height |
| Neurological examination | No evidence of radicular pain or other abnormalities | Exclude patients where IDD is unlikely to be the primary cause of pain |
| MRI | Preservation of disc height | Exclude patients with sinister pathology |
| | No evidence of other pathology (eg, tumour) | Exclude patients where IDD is unlikely to be the primary cause of pain |
| | Herniations must be contained | Exclude patients where discography or intradiscal electrothermal anuloplasty are contraindicated |
| | | Also often identifies the troublesome disc for discography |
| Provocation discography | Single disc reproduces the patient's pain while adjacent discs do not | Exclude patient with two painful discs (the specificity in diagnosing two discs with IDD becomes too low given the need for an adjacent pain-free 'control' disc) |
| CT discography | Presence of anular fissures reaching into outer third of disc | Exclude patients with minimal anular disruption |
| | | Exclude patients whose disc is too disrupted to allow effective catheter navigation and placement |

Abbreviations: IDD, internal disc disruption; MRI, magnetic resonance imaging; CT, computerised tomography.

It should be noted that magnetic resonance imaging (MRI) is not currently reimbursed by Medicare for patients with chronic lower back pain who have a normal neurological examination. Therefore, a recommendation to list intradiscal electrothermal anuloplasty for Medicare funding would be contingent on a successful listing for MRI in this subpopulation.

## Therapeutic procedures

A wide range of procedures is currently used to treat chronic low back pain. Non-invasive treatment procedures are commonly referred to as conservative therapies, and include various classes of pharmaceuticals, manipulative therapies, exercise therapy, acupuncture, massage, and behavioural therapy. Depending on the extent of investigation and timing of the diagnosis, a patient with anular disruption of contained herniated discs may have received one or a combination of these treatment modalities. If a combination of the above therapies is applied simultaneously, this may be considered multidisciplinary therapy.

Patients presenting with chronic back pain should be treated with conservative therapy in the first instance. Spinal fusion surgery should be considered only in patients who have not responded to 6 months of conservative therapy. In Australia, patients who undergo spinal surgery for anular disruption of a herniated disc at a single level are currently included under MBS item numbers 48648 and 48654 (ie, posterolateral fusion, posterior interbody fusion and anterior interbody fusion; **Table 2**). Unfortunately, it is not possible to calculate the exact number of services provided to these patients, as the item numbers also include patients treated for trauma or spondylolisthesis, and for MBS item number 48648, some patients treated at two disc levels.

Table 2 Annual number of publicly funded spinal fusion services provided to patients in Australia

| Medical item number – description of surgery | Medical services July 2000–June 2001 |
|---|---|
| 48648 – SPINE, bone graft to (posterolateral fusion) – 1 or 2 levels | 881 |
| 48654 – SPINAL FUSION (posterior interbody), with laminectomy – 1 level | 277 |

## Comparator

As defined in the MSAC guidelines, the appropriate comparator for a new procedure is the "service most likely to be replaced or supplemented by the introduction of the new service". For patients with chronic low back pain who have failed to respond after 6 months of a multidisciplinary conservative treatment program and who have demonstrable anular disruption of a single contained herniated disc, there are few management options. They can continue with the conservative care that has so far proven unsuccessful, or undergo a single-level posterolateral or posterior interbody spinal fusion.

Despite some debate regarding the efficacy of spinal fusion in this group of patients, expert opinion suggests that spinal fusion represents their only further option when conservative therapy fails. However, a proportion of patients choose to not to proceed with spinal fusion and continue conservative therapy. Therefore, spinal fusion and continued conservative care are the two main treatment modalities that will be replaced by intradiscal electrothermal anuloplasty and will therefore serve as the comparators for this assessment (**Table 3**).

Table 3 Potential comparators for intradiscal electrothermal anuloplasty

| Potential comparators | Definition |
|---|---|
| Continued conservative care | Non-invasive therapies including pain medication and treatment programs with therapists from various disciplines qualified in the treatment of chronic low back pain |
| Spinal fusion (posterolateral or posterior interbody fusion) | A procedure that involves fusing together two vertebrae in the spine using either bone grafts or metal rods |

## Marketing status of intradiscal electrothermal anuloplasty

The equipment used for intradiscal electrothermal anuloplasty was listed with the Therapeutic Goods Administration in Australia in 1999 (AUST L69739). The procedure

requires three pieces of equipment: an introducer needle (L69923), a flexible catheter (SpineCATH™, L69739) and a heat generator (ORA-50 S, L69924). There is no specified licensed indication for intradiscal electrothermal anuloplasty.

## Current reimbursement arrangement

Currently, there is no Medicare Benefits Schedule item number for intradiscal electrothermal anuloplasty or any similar service.

# Approach to assessment

## Review of literature

### Studies of intradiscal electrothermal anuloplasty

The medical literature was searched to identify relevant studies and reviews for the period between 1990 and 14 June 2002. Searches were conducted via the following primary databases.

- Medline 1966 to current.
- Embase 1980 to current.
- Premedline.
- Cancerlit 1975 to current.
- Econlit 1969 to current.
- HealthSTAR 1975 to current.

For completeness, searches of the following secondary databases were also performed.

- British Columbia Office of Health Technology Assessment (Canada).
- Canadian Coordinating Office for Health Technology Assessment (CCOHTA).
- Centre for Health Program Evaluation (Monash University, Australia).
- Centre for Reviews and Dissemination (University of York, UK).
- Cochrane Library.
- Health Economics Research Group (Brunel University, UK).
- Health Information Research Unit (HIRU) internal database (McMaster University, Ontario, Canada)
- International Network of Agencies for Health Technology Assessment (INAHTA).
- International Society of Technology Assessment in Health Care (Montreal, Canada).
- National Health and Medical Research Council Australia Publication list.

- National Health Service (UK).
- National Information Center on Health Services Research and Health Care Technology (HSTAT database) (US).
- Swedish Council on Technology Assessment in Health Care (SBU).
- US Office of Technology Assessment 1974–1995 (closed) then,
- US Health Care Financing Administration (HCFA), renamed Centres for Medicare and Medicaid Services (CMS).

The search strategy used for Embase is presented in **Appendix C**. Additional literature was sourced from clinical experts and from manual searching of the bibliographies of retrieved publications. After the removal of duplicate citations, 58 unique citations were obtained for intradiscal electrothermal anuloplasty.

### Study inclusion criteria

- The citation had to be an original peer-reviewed publication reporting the results of one or more clinical trials (ie, non-systematic reviews, editorials, opinion pieces and letters were excluded).
- The study had to be conducted in human patients.
- The study had to consider the intradiscal electrothermal anuloplasty intervention (studies where the intradiscal placement of the catheter was variable or not well-reported were included in the first instance, considered for relevance and excluded if necessary).
- Patients had to be diagnosed with non-specific lower back pain believed to be due to anular disruption of contained herniated discs.
- Patients had to have normal neurological findings.
- The study had to involve 20 patients or more (those with < 20 patients were assessed for relevant safety data).
- A mean follow-up period of at least 12 months had to be reported.
- Relevant clinical outcomes had to be reported (eg, pain, physical function).

After application of the inclusion criteria above, a total of seven studies (10 publications) were included in the safety assessment, and four studies (six publications) were included in the efficacy assessment of intradiscal electrothermal anuloplasty. A single conference abstract reporting a randomised placebo controlled trial of intradiscal electrothermal anuloplasty was also identified during the assessment process (Pauza et al 2002). This abstract was not peer-reviewed and did not report a mean follow-up of at least 12 months and therefore was excluded from further analysis.

A flow chart summarising the reasons for exclusion is presented in **Figure 2** and a full list of excluded publications appears in **Appendix H**.

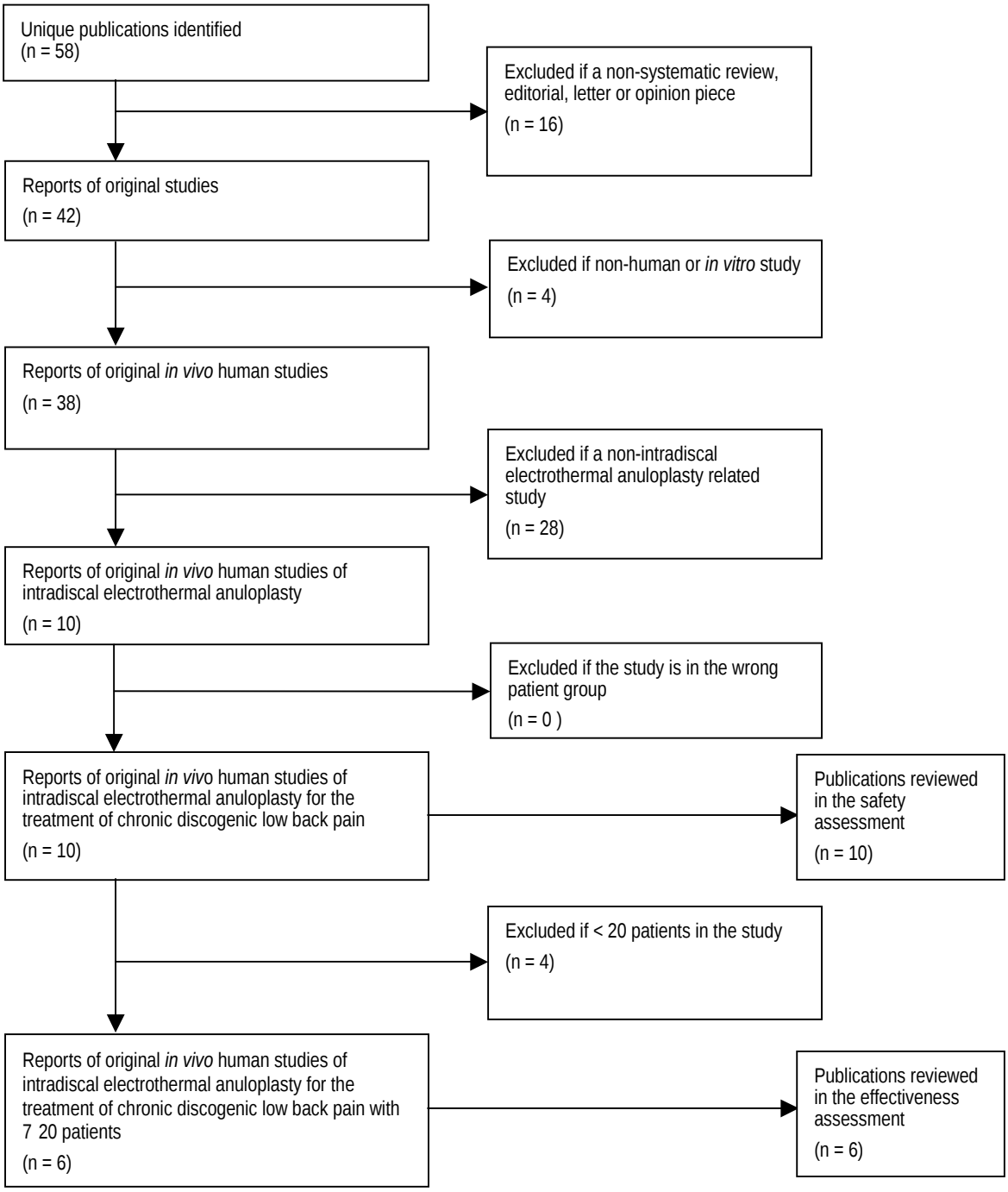


Figure 2 Intradiscal electrothermal anuloplasty literature search – reasons for exclusion

Publications that appeared to duplicate all or some of the patients in other included trials were included in the first instance. These publications were subsequently reviewed and excluded, if necessary. Similarly, publications that failed to report outcome measures adequately were subsequently excluded. All publications initially included, but subsequently excluded, are specifically referred to in the body of the review.

The evidence presented in the selected studies was assessed and classified using the dimensions of evidence defined by the National Health and Medical Research Council (NHMRC 2000).

These dimensions (**Table 4**) consider important aspects of the evidence supporting a particular intervention and include three main domains: strength of the evidence, size of the effect and relevance of the evidence. The first domain is derived directly from the literature identified as informing a particular intervention. The last two require expert clinical input as part of their determination.

Table 4 Evidence dimensions

| Type of evidence | Definition |
|---|---|
| Strength of the evidence | |
| Level* | The study design used, as an indicator of the degree to which bias has been eliminated by design* |
| Quality | The methods used by investigators to minimise bias within a study design |
| Statistical precision | The *p* value or, alternatively, the precision of the estimate of the effect. It reflects the degree of certainty about the existence of a true effect |
| Size of effect | The distance of the study estimate from the "null" value and the inclusion of only clinically important effects in the confidence interval |
| Relevance of evidence | The usefulness of the evidence in clinical practice, particularly the appropriateness of the outcome measures used |

*See Table 5.

The three sub-domains (level, quality and statistical precision) are collectively a measure of the strength of the evidence. The designations of the levels of evidence are shown in **Table 5**.

Table 5 Designation of levels of evidence

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

Source: National Health and Medical Research Council, A guide to the development, implementation and evaluation of clinical practice guidelines. Canberra: NHMRC, 1999.

Trials in which the majority (≥ 80 per cent) of the patients met the proposed indication (with respect to preserved disc height and a single nociceptive disc) are classified as primary evidence. Trials not meeting the above criteria are classified as supplementary evidence.

Additional searches were conducted to source quality of life, epidemiological and economic information, as required.

## Studies of comparator therapies

At the time of assessment, limited 'quasi-controlled' clinical evidence (Karasek and Bogduk 2000; Bogduk and Karasek 2002) was available to make a direct comparison of intradiscal electrothermal anuloplasty with continued conservative therapy, and there was no evidence available to make a direct comparison of intradiscal electrothermal anuloplasty with spinal fusion. For this reason, it was necessary to conduct an additional systematic review of the efficacy and safety evidence for the comparator treatments, continued multidisciplinary conservative therapy and spinal fusion, and then to consider the feasibility of undertaking an indirect comparison.

As the aim of these additional systematic reviews was to determine the efficacy and safety of the comparators as used in current practice, the search was restricted to 1980 onwards (Medline and Embase). Separate searches were conducted for the two comparators (details of the search strategies are included in **Appendix G**). After the removal of duplicate citations, 266 unique citations were obtained in the conservative therapies search, and 169 in the spinal fusion search. The following inclusion criteria were then applied to determine whether these citations should be included in this assessment.

- The citation had to be an original peer-reviewed publication reporting the results of one or more studies on either conservative therapy or spinal fusion for the treatment of chronic low back pain (ie, non-systematic reviews, editorials, opinion pieces and letters were excluded).
- The study had to report primarily the results of a conservative therapy program or spinal fusion procedure (ie, cross-sectional, prognostic and non-interventional studies were excluded).
- The study had to have a prospective design (ie, retrospective studies were excluded).
- The intervention reported in the study had to be consistent with the intervention the patient would receive in the Australian setting (ie, conservative therapy programs had to be consistent with currently available Australian programs, and spinal fusion studies had to report on either a posterior or anterior interbody fusion).
- The study had to include patients with the same back pain diagnosis as those included in the intradiscal electrothermal anuloplasty studies (ie, chronic low back pain caused by internal disc disruption with CT-discography indicating anular disruption of a single contained herniated disc). Studies in which fewer than 80 per cent of patients fitted these criteria were excluded.
- The study had to report the correct outcomes (ie, studies that did not report any outcomes used in the efficacy evaluation analysis were excluded).
- There had to be a mean follow-up of at least 12 months.
- The study had to include at least 20 patients in the relevant patient group.

After application of the above criteria to the abstracts of the retrieved citations, 38 papers reporting the results of conservative therapy programs and nine papers reporting

the results of spinal fusion surgery were retrieved. Subsequent review of patient characteristics not reported in the abstracts revealed that none of these papers met the inclusion criteria required for the correct patient group and all were excluded on these grounds. It was therefore not possible to conduct an indirect comparison of either conservative therapy or spinal fusion with intradiscal electrothermal anuloplasty.

A flow chart summarising the reasons for study exclusion is presented in **Figure 3**. A complete list of the citations identified in the literature search is included in **Appendix H**, together with reasons for exclusion from an indirect comparison.

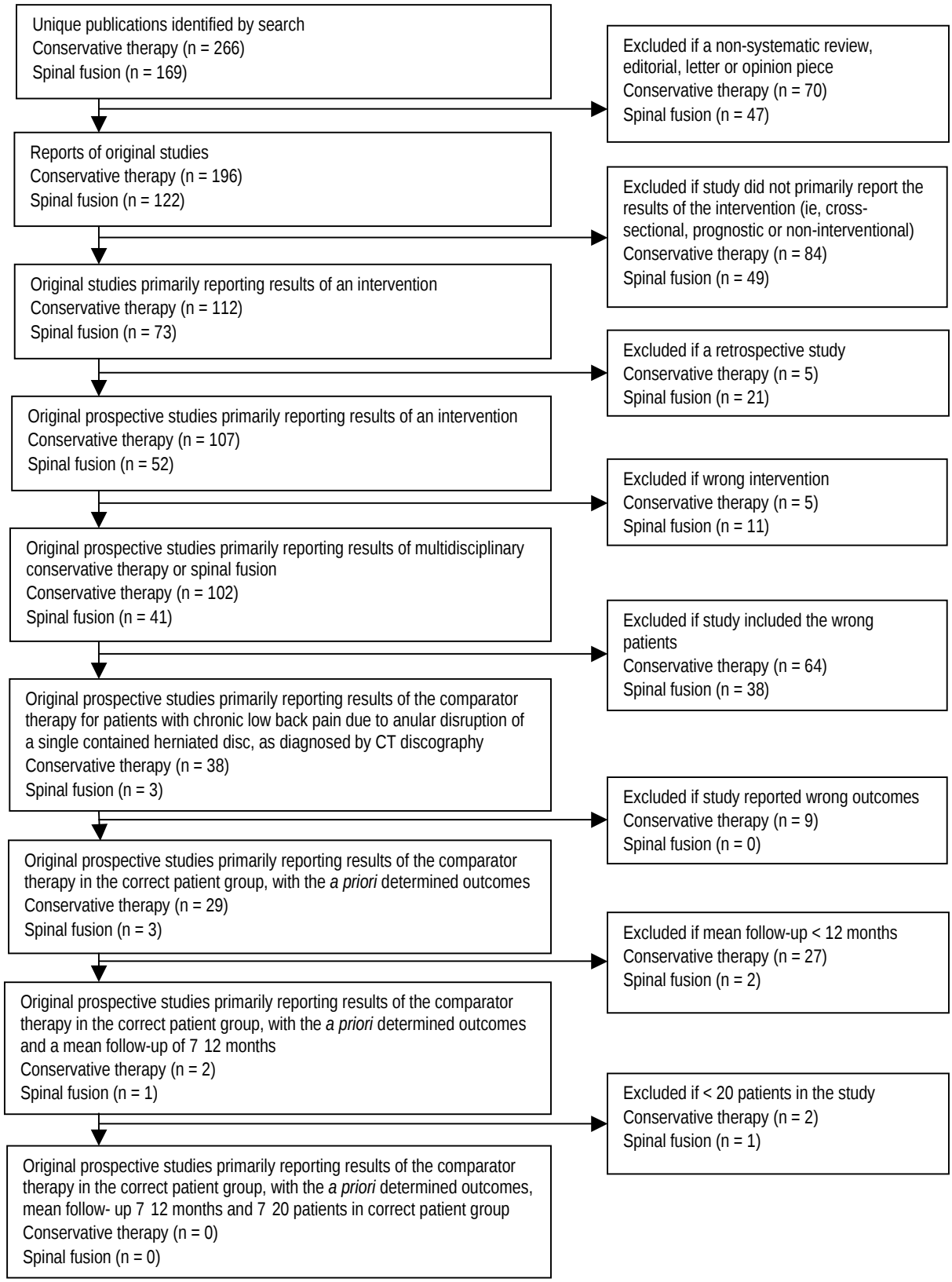


Figure 3 Literature search to identify comparators for intradiscal electrothermal anuloplasty – reasons for exclusion

## Expert advice

A supporting committee with expertise in neurosurgery, pain management, radiology, general practice and anaesthesiology was established to evaluate the evidence and provide advice to MSAC from a clinical perspective. In selecting members for supporting committees, MSAC's practice is to approach the appropriate medical colleges, specialist societies and associations and consumer bodies for nominees. Membership of the supporting committee is provided at **Appendix B**.

# Results of assessment

At present, level III-2 and IV evidence is available to describe the safety and efficacy of intradiscal electrothermal anuloplasty in the treatment of chronic back pain secondary to anular disruption of contained herniated discs. The primary evidence (Karasek and Bogduk 2000; Bogduk and Karasek 2002) is a quasi-controlled, open-label, prospective study. All remaining studies are uncontrolled. Several report duplicate data. **Table 6** indicates studies included in the safety and efficacy reviews.

There was no evidence identified on which to base an indirect comparison of intradiscal electrothermal anuloplasty and the comparators (conservative therapy and spinal fusion).

Table 6 Summary of evidence for intradiscal electrothermal anuloplasty

| First author (year) | Design | Study reviewed for safety data | Study reviewed for efficacy data |
|---|---|---|---|
| Bogduk (2002) | Prospective, quasi-controlled study | | |
| | 24-month follow-up of patients in Karasek (2000) | | |
| Karasek (2000) | Prospective, quasi-controlled study | | |
| Saal (2002) | Prospective, uncontrolled study | | |
| | 24-month follow-up of patients in Saal (2000a) and Saal (2000b) | | |
| Saal (2000a) | Prospective, uncontrolled study | | |
| | Minimum 12-month results including some patients in Saal (2000b) | | |
| Saal (2000b) | Prospective, uncontrolled study | | X |
| | Preliminary results of some patients included in Saal (2000a) | | |
| Endres (2002) | Retrospective, uncontrolled study | | |
| Derby (2000) | Prospective, uncontrolled study | | |
| Singh (2000) | Prospective, uncontrolled pilot study | | X |
| Hsia (2000) | Case report | | X |
| Djurasovic (2002) | Case report | | X |

## Is it safe?

In contrast to pharmaceutical products, the majority of devices approved for use in Australia have a Therapeutic Goods Administration (TGA) listing, rather than a registration. In practice, this means that the review of safety and efficacy undertaken by the TGA has been less rigorous than for a pharmaceutical agent. For this reason, it is necessary to consider all theoretical and reported safety issues.

Although intradiscal electrothermal anuloplasty is considered minimally invasive, it requires the insertion of an introducer needle into the painful disc, followed by circumferential intra-anular navigation of a flexible electrode, which is then heated to temperatures of up to 90°C. Theoretical concerns regarding the procedure therefore include needle-induced trauma to neural structures of the vasculature, infection of the disc, and thermal injury through incorrect electrode placement. In addition, incorrect

needle placement could result in trauma to the retroperitoneal structures, including the kidneys.

Several anecdotal reports of complications related to the intradiscal electrothermal anuloplasty procedure have been reported (Heary 2001). These include discitis, thermal nerve root injury, and catheter breakage as a result of kinking. In addition, there has been one case report of cauda equina syndrome and another case report of vertebral osteonecrosis (detailed below).

Finally, given that the exact mechanism of the procedure remains unknown, the lack of long-term follow-up data is a particular concern to any safety evaluation. Of the studies included in the safety analysis, the longest follow-up of prospectively recruited patients was in the uncontrolled study by Saal and Saal (2000a, 2002), who report a minimum of 24-month data, while an uncontrolled retrospective study by Endres et al (2002) reports follow-up data to a maximum of 108 weeks (approximately 25 months) post-procedure.

## Safety data reported in the published literature

In general, safety data have been poorly reported in the published studies, with adverse events either not reported or reported with little detail. Furthermore, it has not been evident whether adverse events were systematically investigated in these studies.

Karasek and Bogduk (2000), Bogduk and Karasek (2002) and Endres et al (2002) did not report any data on adverse events or complications in patients treated in their respective studies.

Saal and Saal (2000a) indicated that there were no adverse events or complications reported for patients treated in their study. However, they found that some patients needed analgesics for a few days after the procedure, and three patients required an epidural injection during postoperative recovery. No patients exhibited a neurological deficit or new radicular pain during the follow-up period. No additional safety data were reported in the preliminary publication (Saal and Saal 2000b) or in the follow-up publication (Saal and Saal 2002).

Derby et al (2000) stated that all patients experienced a flare in their typical pain following the procedure, which persisted for a mean of five days. Furthermore, at 12-month follow-up, 3.1 per cent of patients reported that their overall activity level was much worse than prior to the procedure. No infections, or neurological or bleeding complications were encountered during the follow-up period.

At six-month follow-up, Singh et al (2000) reported that no complications were observed in any of the 23 patients included in their study.

Hsia et al (2000) presented a case report of a 56-year-old woman who developed cauda equina syndrome following intradiscal electrothermal anuloplasty. The woman underwent the procedure for chronic low back pain for which she was taking daily analgesics. She had no history of radiating pain, numbness, weakness, or bowel or bladder abnormalities. Prior to the procedure, a lumbosacral spine MRI demonstrated no abnormalities and provocation discography reproduced her back pain. The post-procedure examination revealed urinary retention, bowel incontinence, and loss of

sensation and weakness in the left leg. No improvement in the patient's symptoms was observed after six months.

A case of vertebral osteonecrosis following intradiscal electrothermal anuloplasty was reported in a 28-year-old man by Djurasovic et al (2002). He had no symptoms of radicular pain radiating below the knee, a negative straight leg raise test and a normal neurological examination. MRI revealed a mildly degenerated disc at L5–S1. The patient underwent discography followed by an L4–L5 and L5–S1 intradiscal electrothermal anuloplasty procedure. Five months following the procedure, the patient presented with worsening of his axial lower back pain, dysaesthetic leg pain, restricted range of motion, intact motor function, symmetrical reflexes and no sign of radiculopathy. Plain radiographs revealed increased collapse of the L5–S1 disc space. MRI indicated significant oedema in the L5 and S1 vertebral bodies, and changes suggestive of severe degenerative disc disease with disc space collapse and possible osteomyelitis. Tests for infection were within normal limits and an MRI repeated at six months showed no change in the oedema pattern. Djurasovic et al (2002) did not know the aetiology of the patient's vertebral body osteonecrosis, but believed it was important to report a significant complication possibly linked to intradiscal electrothermal anuloplasty that had not previously been described in the literature.

In summary, safety data have been poorly reported in the published studies of intradiscal electrothermal anuloplasty, with adverse events either not reported or reported with little detail. However, preliminary evidence suggests that the level of complications associated with this procedure is low. It should also be noted that the safety of intradiscal electrothermal anuloplasty should be considered relative to spinal surgery (ie, spinal fusion) and conservative therapy programs.

# Is it effective?

## Available evidence

At present, there is low-level evidence to support the efficacy of intradiscal electrothermal anuloplasty, with one non-randomised, open-label, quasi-controlled study (level III-2) and four uncontrolled studies (level IV) identified. Furthermore, there is extremely limited evidence on which to base a direct comparison of the efficacy of intradiscal electrothermal anuloplasty with that of conservative therapy. Additionally, there is no evidence on which to base an indirect comparison of intradiscal electrothermal anuloplasty and the comparators (conservative therapy and spinal fusion).

One of the uncontrolled studies (Singh et al 2000) was of insufficient duration, with a maximum follow-up of six months, and was not reviewed further.

**Table 7** presents a summary of the efficacy evidence reported in the included studies. The table shows which primary and secondary efficacy outcomes were reported by each study and whether these outcomes were reported for all the patients in the study, or only for those treated at a single disc level.

By *a priori* determination, this assessment considered primary evidence to be data that were either: a) reported separately for those patients who received single-level intradiscal electrothermal anuloplasty treatment; or b) not reported separately for those patients who received single-level intradiscal electrothermal anuloplasty, but where ≥ 80 per cent of all study patients received single-level intradiscal electrothermal anuloplasty treatment. If the reporting of outcome measures met these criteria, the data were included as primary evidence (**Table 7**). Other outcomes were reported as supplementary evidence in **Appendix E**.

Table 7 Summary of efficacy evidence available in the included studies

| Level of evidence | First author (year) | Primary efficacy outcomes | | | | Secondary efficacy outcomes | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | Visual analogue pain scale | | Return to work | | Disability index | | Pain medication | | Quality of life instruments | |
| | | All[a] | Single level | All[a] | Single level | All[a] | Single level | All[a] | Single level | All[a] | Single level |
| Level I | None available | | | | | | | | | | |
| Level II | None available | | | | | | | | | | |
| Level III-1 | None available | | | | | | | | | | |
| Level III-2 | Bogduk (2002)[b] Karasek (2000) | ✔ | ✔ | ✔ | ✔ | X | X | ✔ | X | X | X |
| Level III-3 | None available | | | | | | | | | | |
| Level IV | Saal (2002) Saal (2000a)[c] | X | ✔[c] | X | ✔[c] | X | X | X | X | X | ✔[c] |
| | Endres (2002) | X | ✔ | X | X | X | X | X | X | X | X |
| | Derby (2000) | X | X | X | X | X | X | X | X | X | X |

[a] 7 80 per cent patients treated at single level.
[b] Separate data for all patients treated at a single level are not reported in Bogduk (2002) but were obtained directly from the authors.
[c] Data for patients treated at a single level are reported only in the 12-month follow-up study and not the 24-month study. The 24-month data for all patients is included in Appendix E.

Characteristics of the included studies are presented in **Table 8**. All studies were single-centre and conducted in the US. The only quasi-controlled study was that reported by Karasek and Bogduk (2000) and Bogduk and Karasek (2002). The other three studies identified were uncontrolled (Saal and Saal 2000a, Saal and Saal 2002; Endres et al 2002; Derby et al 2000).

Two studies report a minimum follow-up duration of 24-months (Karasek and Bogduk 2000, Bogduk and Karasek 2002; Saal and Saal 2000a, Saal and Saal 2002). One study reported a follow-up duration of 12 months (Derby et al 2000) and one study reported a range of follow-up durations varying between 3 and 27 months (Endres et al 2000).

Three studies were prospectively designed (Karasek and Bogduk 2000, Bogduk and Karasek 2002; Saal and Saal 2000a, Saal and Saal 2002; Derby et al 2000), and one was retrospectively designed (Endres et al 2000).

Table 8 Study characteristics

| First author (year) | Study design and patient recruitment | Study location and number. of centres | Duration | Nature of control group |
|---|---|---|---|---|
| Karasek (2000)<br>Bogduk (2002) | Consecutive patients consenting to investigation and then meeting inclusion/exclusion criteria; prospective design | Oregon, US<br>Single centre | 24 months | Patients whose insurance company would not reimburse the procedure underwent a multidisciplinary conservative rehabilitation program[a] |
| Saal (2002)<br>Saal (2000a) | Consecutive patients consenting to investigation and then meeting inclusion and exclusion criteria; prospective design | California, US<br>Single centre | Minimum 24 months follow-up | Not applicable |
| Endres (2002) | Patients who underwent intradiscal electrothermal anuloplasty in the authors' practice; retrospective design | Wisconsin, US<br>Single centre | 7 12 weeks to 108 weeks | Not applicable |
| Derby (2000) | Consecutive patients consenting to investigation and then meeting inclusion/exclusion criteria; prospective design | California, US<br>Single centre | 12 months | Not applicable |

[a]Details of the program were not reported; however, it was stated that it involved physical therapy, education, counselling and strengthening and conditioning exercises.

In all of the included studies, patients had to meet several criteria to ensure that they were suitable for the procedure. They also had to have failed some form of conservative therapy before being eligible for intradiscal electrothermal anuloplasty.

The study reported by Karasek and Bogduk (2000) and Bogduk and Karasek (2002) adhered strictly to diagnostic protocols to ensure patients had internal disc disruption (IDD) as defined by the International Association for the Study of Pain (IASP). This requires positive provocation discography and CT evidence of at least a grade 3 fissure reaching the outer third of the anulus.

Saal and Saal (2000a; 2002) were highly selective in their choice of patients. Of 1116 patients with chronic back pain who were treated with aggressive non-operative therapy for six months, only 62 patients met the inclusion criteria for treatment with intradiscal electrothermal anuloplasty (**Table 9**). The number of patients screened before selection for the study was not reported in Endres et al (2002) or Derby et al (2000) (**Table 9**).

In general, the rate of patient follow-up in all of the studies was good (**Table 9**). In the study reported by Karasek and Bogduk (2002) and Bogduk and Karasek (2002), 35 of the 36 patients in the treatment group, and 10 of the 17 patients in the control group, were available for follow-up. One patient in the treatment group did not provide 24-month data as she was diagnosed as having carcinoma of the breast; due to her emotional stress, further investigation of her back pain was postponed. In this study, it was originally planned to follow patients in the control group for only three months. However, because of the current lack of controlled evidence on the procedure, the authors continued to follow the patients opportunistically at 12 and 24 months. At 24 months, two patients in the control group were lost to follow-up, one patient had died, one declined to provide data, and three had elected to undergo intradiscal electrothermal anuloplasty.

As shown in **Table 9**, patient follow-up in the other three studies was also generally good.

Table 9 Patient screening, follow-up and inclusion criteria

| First author (year) | Number of patients screened | ITT | Patients available for follow-up | Key inclusion criteria |
|---|---|---|---|---|
| Karasek (2000) Bogduk (2002) | 150 | 53 (36 treatment, 17 control) | 45 (at 24 months) (35 treatment, 10 control) | Low back pain 7 three months, IDD as defined by the IASP, no neurological symptoms, disc height > 80% of expected normal disc height |
| Saal (2002) Saal (2000a) | 1116 | 62 | 58 (at 24 months) | Low back pain 7 six months, failed conservative therapies, positive discogram, MRI indicating no neurological symptoms |
| Endres (2002) | Not applicable | 54 | 48[a] (12–108-week follow-up) | Unrelenting low back pain 7 nine months, failed conservative therapies, positive discogram, MRI indicating no neurological symptoms, disc height 7 50% |
| Derby (2000) | Not reported | 32 | Not stated (assumed to be all 32 at 12 months) | Low back pain 7 six months, failed conservative therapies, back pain > 60% of overall pain symptoms, positive discogram, no neurological symptoms |

Abbreviations: ITT, intention-to-treat; IDD, internal disc disruption; IASP, International Association for the Study of Pain; MRI, magnetic resonance imaging.

[a]Number of patients for whom the change in visual analogue scale pain score was available; sitting and walking tolerance outcome measures were reported for all 54 patients.

The age and sex composition of treated patients in each of the four studies was similar and could be considered representative of Australian patients likely to receive the procedure should funding be recommended (**Table 10**). The key difference among the studies in the characteristics of included patients related to whether patients had preserved disc height. In the study reported by Karasek and Bogduk (2000) and Bogduk and Karasek (2002), only patients with preserved disc heights were included. However, in the other studies, patients with disc space narrowing were also treated. In these studies, outcomes for patients with preserved disc height were not reported separately.

There was also a difference among the studies in the proportion of patients treated at single and multiple disc levels. All studies treated either one or two discs per patient except for Saal and Saal (2000a, 2002), who treated 1–3 discs per patient. The study reported by Karasek and Bogduk (2000) and Bogduk and Karasek (2002) treated the greatest proportion of patients at a single level (83 per cent), while only 48 per cent of patients included in Saal and Saal (2000a, 2002) were treated at a single level.

Table 10 Characteristics of included patients

| First author (year) | Age (years) | Sex (proportion male) | Number of months of pre-procedure symptoms | All patients with preserved disc height | Number of levels treated (% treated at single level) |
|---|---|---|---|---|---|
| Karasek (2000) Bogduk (2002) | Median (inter-quartile range):<br>IDETA 45 (34–49)<br>Control 39 (31–50) | IDETA 44%<br>Control 35% | Median (inter-quartile range):<br>IDETA 30 (12–72)<br>Control 32 (14–70) | Yes | 1–2 levels<br>(83%) |
| Saal (2002) Saal (2000a) | Mean (range):<br>40.5 (20–59) | 53% | Mean (range):<br>61 (17–204) | No | 1–3 levels<br>(48%) |
| Endres (2002) | Mean (range):<br>40 (17–63) | 59% | Not reported | No | 1–2 levels<br>(70%) |
| Derby (2000) | Mean:<br>42 | 53% | Not reported | No | 1–2 levels<br>(66%)[a] |

Abbreviation: IDETA, intradiscal electrothermal anuloplasty.
[a]The proportion of patients treated at a single level was not reported in the study but was calculated *post hoc* (32 patients, mean number of discs treated = 1.34 (range 1–2); therefore, 21 treated at a single level and 11 treated at two levels).

There were differences in the electrode placement among the four included studies (**Table 11**). In the studies reported by Saal and Saal (2000a; 2002) and Derby et al (2000), the electrode was navigated from within the intradiscal space until, ideally, it rested adjacent to the posterior wall of the anulus, before being heated. However, in the study reported by Karasek and Bogduk (2000) and Bogduk and Karasek (2002), the introducer needle was inserted through the intradiscal space to enter the anulus on the opposite side of the disc and the electrode was navigated within the anulus to engage as much of the anulus as feasible, before heating commenced. A description of electrode placement was not reported by Endres et al (2002).

The electrode heating regimens used in studies were essentially the same (**Table 11**). Depending on the patient's pain levels, Karasek and Bogduk (2000), Bogduk and Karasek (2002) and Saal (2000a, 2002) gradually heated the electrode over a 13-minute period to 85–90°C and maintained this temperature for four minutes. However, as Derby et al (2000) was a pilot study, a variable heating regimen was used in the first few patients undergoing the procedure until a standardised protocol was established with electrode temperatures reaching 80–90°C. A description of the electrode-heating regimen was not reported by Endres (2002).

Table 11 Characteristics of the procedure

| First author (year) | Characteristics of the procedure | |
|---|---|---|
| | Electrode placement | Heating regimen |
| Karasek (2000)<br>Bogduk (2002) | Needle inserted toward the target disc from the least painful side under fluoroscopic guidance<br>Needle advanced to pass diametrically across the nucleus to encounter the surface of the anulus. With further insertion, the electrode entered the inner layers of the anulus and deflected circumferentially backward toward the painful side with the electrode at all times buried between the lamellae of the anulus fibrosus | Electrode heated for 17 minutes to reach up to 90ºC. If the patient's pain was intolerable, analgesia was administered. For mild or moderate pain, intravenous fentanyl was administered. If pain was severe, the temperature of the electrode was limited to 85ºC. After heating, 1 mg of cefazolin was injected intradiscally for prophylaxis against infection |
| Saal (2002)<br>Saal (2000a) | Needle placed in the centre of the disc under fluoroscopic guidance. The heating electrode was navigated as far as possible adjacent to the inner posterior anulus | Electrode temperature was gradually increased according to a uniform protocol to 90ºC during a period of 13 minutes and maintained at 90ºC for four minutes. The 90ºC electrode temperature created anular temperatures of 60–65ºC. After heating, 10–20 mg of cefazolin was injected intradiscally for prophylaxis against infection |
| Endres (2002) | No specific description of the electrode placement used in the study was given | The heating regimen used in the study was not reported |
| Derby (2000) | The electrode was typically advanced anteriolaterally inside the nuclear tissue, and was directed circuitously to return posteriorly. In an ideal position, the catheter would heat the entire posterior anulus. Catheter position was assessed based on the level of contact of the catheter with the posterior anular wall | As this was a pilot study, various heating protocols were used. Initially, heating commenced at 65ºC and was increased incrementally by 1ºC every 30 seconds to a final temperature of between 75ºC and 150ºC, terminating approximately 2–3 minutes after the patient developed back or leg pain. As the study progressed, a standardised protocol was developed, with final temperature reaching 80–90ºC and a total duration of treatment of 13.5–16.5 minutes |

The postoperative care program was reported for three of the four studies, but not for Derby et al (2000). In these three studies, graded reactivation programs were used, consisting of light exercise and stretching that was gradually increased in intensity. In addition, Endres et al (2002) instructed patients to wear a corset for one month post-procedure, while patients treated by Karasek and Bogduk (2000) and Bogduk and Karasek (2002) wore a corset for six weeks, if required.

## Definition of outcome measures

The efficacy measures reported by the studies included as primary evidence (ie, those studies which reported data on patients treated only at a single level, or those in which ≥ 80 per cent of patients were treated at a single level) are detailed in **Table 12**.

Table 12 Outcome measures reported in the studies included as primary evidence (ie, outcomes reported for patients treated only at a single disc level or 80 per cent of all patients in the study treated at a single disc level)

| Study – first author (year) | Primary efficacy measures | | | | Secondary efficacy measures | | |
|---|---|---|---|---|---|---|---|
| | Visual analogue pain scale | | | Return to work/previous function | Disability index | Use of pain medication | Quality of life instruments |
| | 50% reduction | Pain-free | Mean/median reduction | | | | |
| Karasek (2000) Bogduk (2002) | ✔ | ✔ | ✔ | ✔ | X | ✔ | X |
| Saal (2000a) Saal (2002) | X | X | ✔ | ✔ | X | X | ✔ |
| Endres (2002) | X | X | ✔ | X | X | X | X |

The primary efficacy measures used in the evaluation were the change in visual analogue scale (VAS) pain score, and the patient's return to work or to normal function status. For the VAS pain score, the predetermined outcome measure deemed most appropriate for the evaluation was the proportion of patients with ≥ 50 per cent reduction in their pain score following the procedure. In addition, the proportion of patients who were pain-free and the mean and median reduction in VAS score following therapy were reported. Secondary efficacy measures included disability scores, quality of life indexes, and the use of pain medication.

## Primary evidence

The primary effectiveness evidence consists of data from one non-randomised, quasi-controlled study (level III-2 evidence) (Karasek and Bogduk 2000; Bogduk and Karasek 2002), and limited single-level treatment data from two uncontrolled studies (level IV evidence) (Saal and Saal 2000a, Saal and Saal 2002; Endres et al 2002).

It should be noted that uncontrolled and quasi-controlled unblinded and/or non-randomised clinical studies are vulnerable to significant bias. In a clinical trial, bias may arise from several sources. For example, when a researcher or patient knows what treatment is being given, this may influence the results reported. This effect can be minimised by blinding the study participants. In addition, bias can be introduced if the patient groups in each arm of the trial are different. For example, if patients in the treatment arm of a trial are more likely to recover from their ailment without intervention than those in the control group, then the treatment may appear to provide benefit to the patients even though no benefit actually exists. To minimise this bias, researchers randomise patients to each trial arm. Randomisation is a process whereby patients in a clinical trial are assigned to different treatments in a random manner.

Randomisation minimises the difference among groups by distributing people with particular characteristics non-selectively to each of the trial arms.

There is also the problem that it is usually not possible in uncontrolled studies to determine what patient benefit is truly due to the treatment and what benefit is due to the 'placebo effect' or simply due to natural improvement in the patient's disease.

### VAS pain score outcomes

At 24-month follow-up in the study reported by Karasek and Bogduk (2000) and Bogduk and Karasek (2002), 57 per cent of the evaluable patients treated at a single level achieved a ≥ 50 per cent reduction in their VAS pain score. Of these patients, 20 per cent were pain-free (**Table 13**). In contrast, only 12 per cent of evaluable patients in the control group achieved a ≥ 50 per cent reduction in pain score and no patient was pain-free. However, it is important to note that these data are based on non-randomised quasi-controlled evidence, which may be vulnerable to considerable bias.

Table 13 VAS pain score outcomes from Karasek and Bogduk (2000) and Bogduk and Karasek (2002): patients treated at a single level who had a 50 per cent improvement, or patients who were pain-free at 24-month follow-up[a]

| Primary efficacy outcomes | Follow-up (months) | Responders in IDETA group n/N (%) | Responders in control group n/N (%) |
|---|---|---|---|
| Patients with 7 50% improvement in visual analogue pain scale score | 24 | 17/30 (57%) | 2/17 (12%) |
| Patients who become pain-free | 24 | 6/30 (20%) | 0/17 (0%) |

Abbreviation: IDETA, intradiscal electrothermal anuloplasty.
[a]Bogduk and Karasek (2002) did not report the outcomes for patients treated at a single level in the 24-month study report. Data on patients treated at a single level were obtained directly from the authors.

VAS pain scores for patients treated at a single level were also reported in two non-comparative studies by Saal and Saal (2000a) and Endres et al (2002). Saal and Saal (2000a) reported only the mean improvement in VAS scores for patients treated at a single disc level at a mean of 16 months follow-up; these patients showed a significant improvement ($p < 0.001$). Endres et al (2002) reported both the mean and median reduction in VAS scores for patients treated at a single level, but did not report the actual pre- and post-treatment scores, nor whether the observed reductions were statistically significant (**Table 14**).

Table 14 Primary evidence: level IV studies reporting improvement in VAS pain scores in patients treated at a single disc level

| Study | Follow-up | N | VAS pain scores |
|---|---|---|---|
| Saal (2000a)[a] | Minimum = 12 months<br>Mean = 16 months | 30 | Pre-treatment: 6.4 ± 1.8 (mean ± SD)<br>Post-treatment: 3.1 ± 2.2 (mean ± SD)<br>Improvement: 3.4 ± 2.4 (mean ± SD) ($p < 0.001$) |
| Endres (2002) | Minimum = 3 months,<br>Maximum = 27 months | 31 | Improvement: 2.5 (mean); 2.0 (median) |

*Abbreviation*: VAS, visual analogue scale.
[a]Only Saal et al (2000a), who reported data on patients with a minimum 12 months follow-up, reported outcomes separately for patients treated at a single disc level. Data for 24-month outcomes for patients treated at a single disc level were not reported in Saal et al (2002), but the combined data for patients treated at single *and* multiple levels are included in the supplementary efficacy analysis (Appendix E).

As 83.6 per cent of patients were treated at a single level in the Bogduk and Karasek (2002) study, all relevant outcomes were considered to be primary evidence. Data on the proportion of patients with a 50 per cent reduction in VAS, the proportion of patients who became pain-free and the median reduction in VAS were reported for 3-, 12- and 24-month follow-up.

There was an improvement in each of the VAS outcomes in the treatment group compared with the control group. At 3, 12 and 24 months, a much higher proportion of the treated group had a ≥ 50 per cent reduction in VAS pain score or had become pain-free. The treated group also had a significant reduction in median VAS score at 3 months, and this significant difference was maintained at 12 and 24 months (**Tables 15, 16** and **17**). However, it is important to note that these data are based on non-randomised quasi-controlled evidence, which may be vulnerable to considerable bias.

Table 15 Proportion of all treated patients from Karasek and Bogduk (2000) and Bogduk and Karasek (2002) who had a 50 per cent reduction in VAS pain score at follow-up

| Follow-up | Proportion of all treated patients[a] with a 50% reduction in VAS pain score | | *p* |
|---|---|---|---|
| | IDETA group n/ITT (%) | Control group n/ITT (%) | |
| 3 months | 23/36 (64%) | 1/17 (6%) | < 0.001 |
| 12 months | 21/35 (60%) | 2/17 (12%) | 0.001 |
| 24 months | 20/35 (57%) | 2/17 (12%) | 0.003 |

Abbreviations: VAS, visual analogue scale; IDETA, intradiscal electrothermal anuloplasty; ITT, intention-to-treat.
[a]30/36 (83.6%) of all patients were treated at a single disc level.

Table 16 Proportion of all treated patients from Karasek and Bogduk (2000) and Bogduk and Karasek (2002) who were pain-free at follow-up

| Follow-up | Proportion of all treated patients[a] who became pain-free (on the visual analogue pain scale) | | *p* |
|---|---|---|---|
| | IDETA group n/ITT (%) | Control group n/ITT (%) | |
| 3 months | 3/36 (8%) | 0/17 (0%) | 0.305 |
| 12 months | 8/35 (23%) | 0/17 (0%) | 0.034 |
| 24 months | 7/35 (20%) | 0/17 (0%) | 0.054 |

Abbreviations: VAS, visual analogue scale; IDETA, intradiscal electrothermal anuloplasty; ITT, intention-to-treat.
[a]30/36 (83.6%) of all patients were treated at a single disc level.

Table 17 Median VAS pain scores for all patients from Karasek and Bogduk (2000) and Bogduk and Karasek (2002)

| | Median VAS pain scores in all patients[a,b] | | | | *p*[c] |
|---|---|---|---|---|---|
| | IDETA | | Control | | |
| | N[d] | Median (interquartile range) | N[d] | Median (interquartile range) | |
| Baseline | 36 | 8.0 (7–9) | 17 | 8.0 (5–8) | 0.071 |
| 3 months | 36 | 3.5 (1–5) | 17 | 8.0 (7–8) | 0.000 |
| 12 months | 35 | 3.0 (1–7) | 12 | 7.5 (5–8) | 0.005 |
| 24 months | 35 | 3.0 (1–7) | 10 | 7.5 (4–8) | 0.028 |

Abbreviations: IDETA, intradiscal electrothermal anuloplasty; VAS, visual analogue scale.
[a]Pain scores were measured on a 10-point VAS.
[b]30/36 (83.6%) of all patients were treated at a single disc level.
[c]*p* values pertain to the difference in median VAS pain scores between the treatment and control group.
[d]Only evaluable patient numbers were available for analysis.

### Return to work or previous function

For all treated patients in the quasi-controlled study reported by Karasek and Bogduk (2000) and Bogduk and Karasek (2002), 18 of the 19 patients who were working at the time of the intradiscal electrothermal anuloplasty procedure were still at work at 24-month follow-up. Of the 16 patients not working at the time of the procedure, nine had returned to work at 24 months.

In the uncontrolled study by Saal and Saal (2000a, 2002), mean 16-month follow-up data indicated that 27/30 (90 per cent) of patients treated at a single disc level returned to work following treatment. Working status at the time of the procedure was not reported.

### Composite outcomes

For patients treated at only a single disc level in the study reported by Karasek and Bogduk (2000) and Bogduk and Karasek (2002), 6/30 patients (20%) were pain-free, had returned to work and were not using opioids at 24-month follow-up. Ten out of 30 patients (33%) had a 50–90 per cent reduction in VAS score, had returned to work and were not using opioids. Intradiscal electrothermal anuloplasty therapy was deemed to have failed in the remaining 14 patients (47%), as they had achieved < 50 per cent reduction in VAS, or had not returned to work, or were using opioids.

The outcomes at 24-month follow-up for all patients treated in the study reported by Karasek and Bogduk (2000) and Bogduk and Karasek (2002) are presented in **Table 18**. Global success was defined as: at least 50 per cent relief from pain as measured by VAS scores, plus no use of opioids, plus the patient was working.

Table 18 Global outcome for all patients in the study reported by Karasek and Bogduk (2000) and Bogduk and Karasek (2002) at 24-month follow-up

| Level of pain relief (as measured by VAS scores) | N | Opioid use | | Global outcome | |
|---|---|---|---|---|---|
| | | Yes | No | Success | Failure |
| 100% | 7 | 0 | 7 (all working) | 18/35 | 17/35 |
| ≥ 50% (but < 100%) | 12 | 1 (all working) | 11 (all working) | | |
| < 50% | 16 | 11(3 patients working) | 5 (2 patients working) | | |

Abbreviation: VAS, visual analogue scale.

At present, level III-2 and IV evidence is available to describe the efficacy of intradiscal electrothermal anuloplasty in the treatment of chronic back pain secondary to anular disruption of contained herniated discs, with one non-randomised, open-label, quasi-controlled study (level III-2) and four uncontrolled studies (level IV) identified. Data from these studies show improvements in: visual analogue pain scale outcomes, patients' return to work or previous function, and reduction in pain medication for patients treated with intradiscal electrothermal anuloplasty. However, these preliminary data comprise only low-level clinical evidence, which is likely to be vulnerable to considerable bias. Hence, the robustness of these results is uncertain.

### Secondary outcomes

#### Pain medication

Karasek and Bogduk (2000) and Bogduk and Karasek (2002) reported that at 24-month follow-up, 12 of the 35 treated patients (34%) were still using opioids.

#### Quality of life indexes

Saal and Saal (2000a, 2002) reported SF-36 scores for patients treated at a single disc level at a minimum of 24-month post-procedure. Using this 100-point scale, the single-level patients had a mean reduction from baseline in the physical function and bodily pain subscales of 34.4 and 23.7, respectively. It was not reported whether these reductions were statistically significant.

## What are the economic considerations?

Within the MSAC terms of reference it is necessary to consider the economic implications of the new health technology. This is particularly important when a new technology offers health benefits at an additional cost, as is so often the case. An economic evaluation helps to determine whether the additional cost represents value for money. To determine the value for money of a new health intervention, it is necessary to express the incremental cost associated with the new treatment relative to the incremental health benefit gained. When this information is available, an incremental cost-effectiveness ratio (ICER) can be calculated:

$$\text{ICER} = \frac{\text{Cost}_{\text{new technology}} - \text{Cost}_{\text{comparator}}}{\text{Effectiveness}_{\text{new technology}} - \text{Effectiveness}_{\text{comparator}}}$$

In cases in which a new technology offers inferior or equal health benefits at a higher cost, it does not provide value for money.

When determining the incremental cost of the new technology, it is necessary to consider the costs associated with the treatment itself, the downstream management and the treatment of any adverse reactions. Similarly, any cost-savings must be taken into account.

There are several possible ways of expressing the effectiveness of the treatment. Effectiveness measures suitable for the current assessment would be:

- additional number of pain-free patients
- additional number of patients with a 50 per cent or greater reduction in pain

Prior to conducting an economic evaluation, it is essential that an accurate measure of incremental effectiveness is available from high-quality evidence with minimal potential for bias. Conducting an economic evaluation on the basis of lower level evidence (eg, indirect comparisons) may be misleading.

After reviewing the studies identified by the literature search, it was concluded that there is currently a lack of high-quality evidence regarding the intradiscal electrothermal procedure. With insufficient efficacy data on which to base either a direct or an indirect comparison between intradiscal electrothermal therapy and continued conservative therapy or spinal fusion, it was not appropriate to conduct an economic evaluation.

# Conclusions

At present, low-level evidence is available to describe the safety and efficacy of intradiscal electrothermal anuloplasty as a treatment for patients with anular disruption of contained herniated discs.

## Safety

A single non-randomised, open-label, quasi-controlled study (level III-2), five uncontrolled studies (level IV) and two case reports were identified as being relevant to the safety analysis. The safety data available have been poorly reported, with adverse events either not reported or included with little detail. However, the preliminary evidence suggests that the level of complications associated with intradiscal electrothermal anuloplasty is low.

## Effectiveness

As with safety, level III-2 and IV evidence is available to describe the efficacy of intradiscal electrothermal anuloplasty. The single non-randomised, open-label, quasi-controlled study (level III-2) and four uncontrolled studies (level IV) used in the efficacy analysis reported improvements in visual analogue pain scale outcomes and return to work or previous function, as well as a reduction in pain medication. However, these preliminary data comprise only low-level clinical evidence, which is likely to be vulnerable to considerable bias. Hence, the robustness of these results is uncertain.

## Cost-effectiveness

There is currently a lack of high-quality evidence regarding the intradiscal electrothermal procedure. Hence, there are insufficient data on which to base either a direct or an indirect comparison between the effectiveness of intradiscal electrothermal therapy and continued conservative therapy or spinal fusion.

# Recommendation

Since there is currently insufficient evidence pertaining to intradiscal electrothermal anuloplasty, a treatment for patients with chronic low back pain due to anular disruption of contained herniated discs, MSAC recommended that public funding should not be supported at this time for this procedure.

- The Minister for Health and Aged Care accepted this recommendation on 6 December 2002. -

# Appendix A MSAC terms of reference and membership

MSAC's terms of reference are to:

- advise the Minister for Health and Ageing on the strength of evidence pertaining to new and emerging medical technologies and procedures in relation to their safety, effectiveness and cost-effectiveness and under what circumstances public funding should be supported;
- advise the Minister for Health and Ageing on which new medical technologies and procedures should be funded on an interim basis to allow data to be assembled to determine their safety, effectiveness and cost-effectiveness;
- advise the Minister for Health and Ageing on references related either to new and/or existing medical technologies and procedures; and
- undertake health technology assessment work referred by the Australian Health Ministers' Advisory Council (AHMAC) and report its findings to AHMAC.

The membership of MSAC comprises a mix of clinical expertise covering pathology, nuclear medicine, surgery, specialist medicine and general practice, plus clinical epidemiology and clinical trials, health economics, consumers, and health administration and planning.

| Member | Expertise or affiliation |
|---|---|
| Mr Stephen Blamey (Chair) | General surgery |
| Professor Bruce Barraclough | General surgery |
| Professor Syd Bell | Pathology |
| Dr Paul Craft | Clinical epidemiology and oncology |
| Professor Ian Fraser | Reproductive medicine |
| Professor Jane Hall | Health economics |
| Dr Terri Jackson | Health economics |
| Ms Rebecca James | Consumer health issues |
| Professor Brendon Kearney | Health administration and planning |
| Mr Alan Keith | Assistant Secretary, Diagnostics and Technology Branch, Commonwealth Department of Health and Ageing |
| Associate Professor Richard King | Internal medicine |
| Dr Ray Kirk | Health research |
| Dr Michael Kitchener | Nuclear medicine |
| Mr Lou McCallum | Consumer health issues |
| Dr Ewa Piejko | General practice |
| Professor John Simes | Clinical epidemiology and clinical trials |

| | |
|---|---|
| Professor Richard Smallwood | Chief Medical Officer,<br>Commonwealth Department of Health and Ageing |
| Dr Robert Stable | Representing Australian Health Ministers' Advisory Council |
| Professor Bryant Stokes | Neurological surgery |
| Professor Ken Thomson | Radiology |
| Dr Douglas Travis | Urology |

# Appendix B Supporting committee

**Supporting committee for MSAC application 1048**

| | |
|---|---|
| **Professor Bryant Stokes** (Chair)<br>AM, RFD, FRACS, FRCS<br>Clinical Professor of Neurosurgery<br>St John of God Hospital, Perth | Member of MSAC |
| **Professor Bruce Barraclough**<br>MBBS, FRACS, DDU, FACS<br>General Surgeon,<br>Department of Surgery,<br>Royal North Shore Hospital, Sydney | Member of MSAC |
| **Professor Nikolai Bogduk**<br>BSc(Med), MBBS, PhD, DipAnat, MD,<br>FAFRM, DSc, FFPMANZCA<br>Professor of Pain Medicine,<br>Department of Clinical Research,<br>University of Newcastle, Callaghan, NSW | Co-opted member |
| **Ms Rebecca Coghlan**<br>Consumers' Health Forum of Australia representative | Nominated by the Consumers' Health Forum of Australia |
| **Dr Philip Finch**<br>MBBS, DRCOG, FFARCS, FFPMANZCA<br>Medical Director,<br>Perth Pain Management Centre,<br>South Perth | Nominated by the Spine Society |
| **Dr Howard R Galloway**<br>MBBS, RANZCR<br>Director of Medical Imaging,<br>Canberra Hospital, Canberra | Nominated by the Royal Australian and New Zealand College of Radiologists |
| **Dr Roger Goucke**<br>MBChB, MRCS, LRCP, DTM&H, MRCGP,<br>FFARACS, FANZCA, FFPMANZCA,<br>FChPalMed, RACP<br>Director, Pain Management Centre,<br>Sir Charles Gairdner Hospital, Nedlands WA | Nominated by the Faculty of Pain Medicine Australian and New Zealand College of Anaesthetists |
| **Dr Ewa Piejko**<br>MBBS, DRANZCOG, FRACGP<br>General Practitioner, Melbourne | Member of MSAC |

# Appendix C Search strategy for efficacy and safety data

The search strategy used in Embase (1980 to July week 2, 2002) to identify studies of intradiscal electrothermal anuloplasty is presented in **Table A1.** This search strategy was adapted for use in Medline, Premedline, Cancerlit, Econlit and HealthSTAR.

Table A1 Embase search strategy

| | Search term |
|---|---|
| 1 | IDET.ti,ab |
| 2 | Intradis?al electrothermal therap$.ti,ab |
| 3 | IDEA.ti,ab |
| 4 | Exp back pain/ |
| 5 | 3 and 4 |
| 6 | (IDTA or IDETA).ti,ab. |
| 7 | Intradis?al electrothermal treatment$.ti,ab |
| 8 | Intradis?al electrothermal an?uloplasty.ti,ab |
| 9 | Intradis?al electrothermal modulation.ti,ab |
| 10 | Intradis?al electrothermal modul$.ti,ab |
| 11 | Intradis?al electrothermotherapy.ti,ab |
| 12 | Intradis?al thermal anuloplasty.ti,ab |
| 13 | Intradis?al navigable catheter.ti,ab |
| 14 | Thermal Intradis?al catheter.ti,ab |
| 15 | Lumbar disc anuloplasty.ti,ab |
| 16 | Lumbar dis? An?uloplasty.ti,ab. |
| 17 | Intradis?al catheter.ti,ab |
| 18 | SpineCATH.ti,ab |
| 19 | Or/1–2,5–18 |
| 20 | Limit 19 to yr=1990–2002 |
| 21 | Limit 20 to human |
| 22 | 20 not 21 |
| 23 | From 22 keep 1,4 |
| 24 | Or/21,23 |
| 25 | From 24 keep 1–43 |

# Appendix D Studies included in the review

Bogduk, N. and Karasek, M. Two-year follow-up of a controlled trial of intradiscal electrothermal anuloplasty for chronic back pain due to internal disc disruption, *Spine* **In press.**
**Notes:** Included in both the efficacy and safety evaluation.

Derby, R., Eek, B., Chen, Y., O'Neill, C. and Ryan, D. 2000. Intradiscal electrothermal annuloplasty (IDET): a novel approach for treating chronic discogenic back pain, *Neuromodulation,* 3 (2), 82–88.
**Notes:** Included in both the efficacy and safety evaluation.

Djurasovic, M., Glassman, S., et al 2002. Vertebral osteonecrosis associated with the use of intradiscal electrothermal therapy, *Spine,* 27 (13), E325–E328.
**Notes:** Included in the safety evaluation only.

Endres, S.M., Fiedler, G.A. and Larson, K.L. 2002. Effectiveness of intradiscal electrothermal therapy in increasing function and reducing chronic low back pain in selected patients, *Wisconsin Medical Journal,* 101 (1), 31–34.
**Notes:** Included in both the efficacy and safety evaluation.

Hsia, A.W., Isaac, K., Katz, J. 2000 Cauda equina syndrome form intradiscal electrothermal therapy, *Neurology,* 55 (2), 320.
**Notes:** Included in the safety evaluation only.

Karasek, M. and Bogduk, N. 2000. Twelve-month follow-up of a controlled trial of intradiscal thermal anuloplasty for back pain due to internal disc disruption, *Spine,* 25 (20), 2601–2607.
**Notes:** Included in both the efficacy and safety evaluation.

Saal, J.S. and Saal, J.A. 2000b. Management of chronic discogenic low back pain with a thermal intradiscal catheter: a preliminary report. *Spine,* 20 (3), 382–388.
**Notes:** Included in the safety evaluation only.

Saal, J.A. and Saal, J.S. 2000a. Intradiscal electrothermal treatment for chronic discogenic low back pain: a prospective outcome study with minimum 1-year follow-up, *Spine,* 25 (20), 2622–2627.
**Notes:** Included in the safety evaluation only.

Saal, J.A. and Saal, J.S. 2002 Intradiscal electrothermal treatment for chronic discogenic low back pain: prospective outcome study with a minimum 2-year follow-up, *Spine,* 27 (9), 966–974.
**Notes:** Included in both the efficacy and safety evaluation.

Singh, V. 2000. Intradiscal electrothermal therapy: A preliminary report, *Pain Physician,* 3 (4), 367–373.
**Notes:** Included in the safety evaluation only.

# Appendix E Supplementary evidence

Outcomes from studies that treated fewer than 80 per cent of patients at a single disc level, and did not report separate data for single-level patients, were considered as supplementary evidence. It should be noted that this evidence was reported in three uncontrolled studies, and is therefore vulnerable to considerable bias.

### VAS pain score outcomes

Saal and Saal (2000a, 2002) reported pre- and post-procedure mean VAS pain scores (**Table A2**). A significant and sustained mean reduction in VAS pain scores was observed at all follow-up visits.

Table A2 Improvement in VAS pain score at follow-up: supplementary evidence

| First author (year) | Follow-up | N | VAS pain score (mean ± SD) | Change from pre-procedure VAS pain score |
|---|---|---|---|---|
| Saal (2000a) Saal (2002) | Pre-IDETA | 58 | 6.57 ± 1.85 | Not applicable |
| | 6 months | 58 | 3.71 ± 1.95[a] | 2.86[c] |
| | 12 months | 58 | 3.52 ± 2.30 | 3.05[c] |
| | 7 24 months | 58 | 3.41 ± 1.96[b] | 3.16[c] |
| Endres (2002)[c] | Between 12 and 108 weeks | 31 (1 level) | Not reported | 2.5 (mean) 2 (median) |
| | | 20 (2 levels) | Not reported | 2.9 (mean) 4 (median) |
| Derby (2000) | 12 months | 32 | Not reported | 1.84 ± 2.38 |

Abbreviations: IDETA, intradiscal electrothermal anuloplasty; VAS, visual analogue scale.
[a]Significant improvement from pre-treatment score ($p = 0.0001$).
[b]Scores did not change significantly from 6 to 24 months ($p = 0.4960$).
[c]Change in mean VAS pain score was calculated *post hoc* from the pre- and post-treatment values; therefore, the standard deviations are not available.

### Return to work

Saal and Saal (2000a, 2002) reported that of the 58 patients for whom ≥ 24-month follow-up data were available, 37/38 (97 per cent) of patients paying for treatment privately and 17/20 (83 per cent) of those claiming workers compensation returned to work. In the retrospective study by Endres et al (2002), it was reported that of the 54 patients with 3–27 months of follow-up data, 35 patients (65%) returned to work, 18 patients (33%) did not, and 1 patient (2%) refused to answer.

### Disability indexes

Twelve-month follow-up disability data were available for 21 patients from the Derby et al (2000) study. These data showed that there was a decrease of 4.03 ± 4.82 (mean ± SD) in the Roland-Morris Disability Questionnaire following the procedure. Neither the baseline value nor the statistical significance of this mean change was reported.

### Quality of life instruments

Saal and Saal (2000a, 2002) included the results of patients' self-reported SF-36 questionnaires, which were completed pre-treatment and again at 6-, 12- and ≥ 24-month follow-up. The mean improvement in the SF-36 physical function (31.3, $p < 0.0001$) and bodily pain subscales (21.9, $p < 0.0001$) were considered most relevant to this assessment. However, it should be noted that the remaining six subscales (role physical, general health, vitality, social functioning, role emotional and mental health) also improved significantly at ≥ 24-month follow-up ($p = 0.0001$).

### Functional outcome measures

Of the included studies, only Endres et al (2002) reported functional outcome measures. The sitting tolerance in an automobile, sitting tolerance on a firm surface, and walking tolerance were all recorded. A statistically significant increase in the patients' mean tolerance for each of these measures was observed (**Table A3**).

Table A3 Mean sitting and walking tolerances reported in Endres (2002)

| | N | Pre-treatment tolerance (minutes) | Post-treatment tolerance (minutes) | ***p*** value |
|---|---|---|---|---|
| Sitting in an automobile | 53 | 36 | 60 | 0.005 |
| Sitting on a firm surface | 52 | 27 | 41 | < 0.001 |
| Walking | 54 | 22 | 50 | < 0.001 |

# Appendix F Study characteristics

Table A4 Characteristics of the four studies included in the efficacy analysis of intradiscal electrothermal anuloplasty

| First author (year) and level of evidence | Study design, location and duration | Study inclusion/exclusion criteria | Patient screening, follow-up, characteristics and comments | Study outcomes |
|---|---|---|---|---|
| Karasek (2000), Bogduk (2002)<br>Level III-2 | Prospective, non-randomised, quasi-controlled study<br>Oregon, US (single centre)<br>24-month follow-up<br>Note: the control group consisted of patients whose insurance company refused to reimburse the IDETA procedure (ie, non randomised convenience control) | Inclusion criteria:<br>• Patients with back pain > 3 months who underwent discography<br>• No evidence of disc prolapse, neurological disease, tumour or infection<br>• IDD as defined by the ISIS. Disc stimulation reproduced patient's accustomed pain, painful disc exhibited a radial fissure reaching at least the outer third of the anulus fibrosis but the outer perimeter of the anulus had to be intact (contained)<br>Exclusion criteria:<br>None stated – implicit in inclusion criteria | Patients screened: 150<br>Patients meeting inclusion criteria (ITT): 53 (36 IDETA, 17 control)<br>Evaluable patients at 24 months: 45 (35 IDETA, 10 control)<br>Age in years –- median (inter-quartile range):<br>IDETA 45 (34–49), control 39 (31–50)<br>Months of pre-treatment back pain – median (inter-quartile range)<br>IDETA 30 (12–72); control 32 (14–70)<br>All patients with preserved disc height: Yes<br>Number (%) patients treated at a single disc level: 30 (83%)<br>Comments: thermal electrode navigated within the anulus of the disc the disc rather than intradiscally as was the procedure used in the three other studies included in the efficacy analysis | VAS single-level patients at 24-month follow-up:<br>Patients with 7 50% relief of pain:<br>IDETA 17/30 (57%); control 2/10 (20%)<br>Patients with complete relief of pain:<br>IDETA 6/30 (20%); control 0/10 (0%)<br>VAS all patients at 24-month follow-up:<br>Patients with 7 50% relief of pain:<br>IDETA 17/30 (57%); control 2/10 (20%)<br>Patients with complete relief of pain:<br>IDETA 6/30 (20%); control 0/10 (0%)<br>Median (interquartile range) reduction in 10-point pain score:<br>Baseline: IDETA 8.0 (7–9); control 8.0 (5–8), $p = 0.071$[a]<br>24-month: IDETA 3.0 (1–7); control 7.5 (4–8), $p = 0.028$[a]<br>(a, IDETA group compared with control group)<br>Return to work at 24-month follow-up:<br>18/19 patients working at time of procedure returned to work<br>9/16 patients not working at time of procedure returned to work<br>Pain medication at 24-months follow-up:<br>12 patients continued taking opioids following treatment<br>Fusion:<br>4 patients underwent fusion having failed the IDETA procedure; this did not relieve their pain |

| First author (year) and level of evidence | Study design, location and duration | Study inclusion/exclusion criteria | Patient screening, follow-up, characteristics and comments | Study outcomes |
|---|---|---|---|---|
| Saal (2000a), Saal (2002)<br>Level IV | Prospective uncontrolled study on consecutive patients<br>California, US (single centre)<br>Minimum 24 months follow-up | Inclusion criteria:<br>• Unremitting persistent low back pain > 6 months<br>• No improvement following a comprehensive non-operative care program applied by the authors<br>• Normal neurological findings<br>• Negative straight leg raising result<br>• An MRI scan that did not demonstrate a neural compressive lesion<br>Exclusion criteria:<br>• Inflammatory arthritis<br>• Non-spinal conditions that could mimic lumbar pain<br>• Medical or metabolic disorder that would preclude appropriate follow-up and participation<br><br>Notes: 1116 patients were referred to the authors for specialty care and placed in a comprehensive non-operative treatment program;<br>62 patients who failed to improve were included in this study | Patients screened: 1116<br>Patients meeting inclusion criteria (ITT): 62<br>Evaluable patients at 24 months: 58<br>Age in years – mean (range)<br>40.5 (20–59)<br>Months of pre-treatment back pain – mean (range):<br>61 (17–204)<br>All patients with preserved disc height: No<br>Number (%) patients treated at a single disc level: 30 (48%) | VAS single level patients, mean 16-month follow-up:<br>Mean (± SD) reduction in 10-point pain score:<br>Baseline 6.4 ± 1.8, at 16-month follow-up 3.1 ± 2.2<br>Improvement = 3.4 ± 2.4, $p < 0.001$<br>Return to work, single-level patients, mean 16-month follow-up:<br>27/30 patients returned to work (working status at time of procedure not reported)<br>VAS all patients at 7 24-month follow-up:<br>Mean ± SD reduction in 10-point pain score:<br>Baseline 6.6 ± 1.9, at minimum 24-month follow-up 3.4 ± 2.0<br>$p < 0.01$<br>Return to work, all patients, 7 24-month follow-up:<br>37/38 (97%) of privately paying and 17/20 (83%) of workers compensation patients returned to work (working status at time of procedure not reported)<br>SF-36, all patients, 7 24-month follow-up:<br>Physical function subscale, 100-point scale, mean ± SD:<br>Baseline 40.5 ± 25.0, 7 24 months 71.8 ± 22.8, $p < 0.0001$<br>Bodily pain subscale, 100-point scale, mean ± SD:<br>Baseline 29.8 ± 16.0, 7 24 months 51.7 ± 22.6, $p < 0.0001$ |

| First author (year) and level of evidence | Study design, location and duration | Study inclusion/exclusion criteria | Patient screening, follow-up, characteristics and comments | Study outcomes |
|---|---|---|---|---|
| Endres (2002)<br>Level IV | Retrospective uncontrolled study<br>Wisconsin, US (single centre)<br>Follow-up between 12 and 108 weeks | Inclusion criteria:<br>• Unrelenting low back pain for > 9 months<br>• Unresponsive to conservative therapy<br>• MRI demonstrating degenerative changes (eg, disc desiccation, anular tears, or high intensity zone lesions)<br>• CT-discography – demonstration of positive concordant pain during disc stimulation at one or two discs with at least one normal disc serving as a control and anular disruption to the outer third of the anulus<br>Exclusion criteria:<br>• Disc height < 50%<br>• Patients with previous back surgery, known spinal stenosis, significant disc protrusion, or neurocompressive lesion with associated radicular symptoms | Patients screened: Not applicable<br>Patients meeting inclusion criteria (ITT): 54<br>Evaluable patients (12–108 weeks follow-up): 48<br>Age in years – mean (range): 40 (17–63)<br>Months of pre-treatment back pain – Not reported<br>All patients with preserved disc height: No<br>Number (%) patients treated at a single disc level: 38 (70%)<br>Comments: electrode placement and heating regimen used in the study was not reported | VAS single-level patients, 12–108 weeks follow-up: Improvement from baseline on a 10-point scale: n = 54 mean = 2.5, median = 2.0 (pre- and post-procedure values and statistical significance not reported)<br>Return to work, all patients, 12–108 weeks follow-up: 35 patients returned to work, 18 patients did not, one patient declined to answer (working status at the time of the procedure was not reported)<br>Functional measures, all patients, 12–108 weeks follow-up:<br>Sitting in an automobile, minutes (n = 53: Pre-procedure 35.5, post-procedure 60.4, $p = 0.005$<br>Sitting on a firm surface, minutes (n = 52): Pre-procedure 27.2, post-procedure 40.3, $p < 0.001$<br>Walking, minutes (n = 54): Pre-procedure 21.4, post-procedure 50.0, $p < 0.001$<br>Patient satisfaction, all patients, 12–108 weeks follow-up: 37 patients said they would undergo the procedure again, 12 patients said they would not and 5 patients declined to answer |

| First author (year) and level of evidence | Study design, location and duration | Study inclusion/exclusion criteria | Patient screening, follow-up, characteristics and comments | Study outcomes |
|---|---|---|---|---|
| Derby (2000)<br>Level IV | Prospective uncontrolled pilot study on consecutive patients<br>California, US (single centre)<br>12 months follow-up | Inclusion criteria:<br>• Back pain > 6 months and > 60% of overall pain symptoms<br>• Unresponsive to conservative therapy<br>• Normal neurological findings<br>• Negative straight leg raising result<br>• One or more positive discs on lumbar discography (positive disc = provocation of concordant pain with an intensity of 6/10 and an abnormal nucleogram)<br>Exclusion criteria:<br>• Patients with infections, bleeding diatheses, unstable medical conditions, radiculopathy | Patients screened: Not reported<br>Patients meeting inclusion criteria (ITT): 32<br>Evaluable patients (12-month follow-up): Not reported (assumed to be 32)<br>Age in years – mean: 40<br>Months of pre-treatment back pain: Not reported<br>All patients with preserved disc height: No<br>Number (%) patients treated at a single disc level: 21 (66%) – this number was calculated *post hoc* by the evaluators<br>Comments: pilot study; variable electrode heating regimen was used on the first few patients<br>Mean number of symptomatic discs found by CT-discography was 2.1 (range 1–4); however, a mean of only 1.3 (range 1–2) discs were treated per patient. As some patients had symptomatic discs that remained untreated, this would presumably bias the results | VAS all patients, 12-month follow-up:<br>Improvement from baseline on a 10-point scale, mean ± SD:<br>1.8 ± 2.4 (pre- and post-procedure values and statistical significance not reported)<br>24-item Roland Morris disability questionnaire, all patients, 12-month follow-up:<br>Improvement from baseline, mean ± SD<br>4.0 ± 4.8 (pre- and post-procedure values and statistical significance not reported)<br>Patient satisfaction, all patients, 12-month follow-up:<br>78% of patients stated the procedure met their expectations and they would undergo it again for the same outcome<br>Self reported overall activity level compared with before the procedure: 53% patients better or much better, 34.4% same, 9.4% worse, 3.1% much worse |

Abbreviations: CT, computed tomographic; ISIS, International Spinal Injection Society; IDD, internal disc disruption; IDETA, intradiscal electrothermal anuloplasty; ITT, intention-to-treat; MRI, magnetic resonance imaging; VAS, visual analogue scale

# Appendix G Comparator search strategies

The search strategy used in Medline (1966 to July week 2, 2002) to identify studies of conservative therapies is presented in **Table A5.** An adapted version of the same search strategy was used in Embase.

Table A5 Conservative therapy comparator search – Medline (1966 to July week 2, 2002)

| | Search term |
|---|---|
| 1 | low back pain/ |
| 2 | back pain/ and low$.ti,ab. |
| 3 | or/1–2 |
| 4 | 3 and non?specific.ti,ab. |
| 5 | 3 and internal dis? disruption.ti,ab. |
| 6 | 3 and an?ular disruption.ti,ab. |
| 7 | 3 and chronic disease/ |
| 8 | 3 and chronic$.ti,ab. |
| 9 | or/4–8 |
| 10 | 9 and exp physical therapy techniques/ |
| 11 | 9 and exp behavior therapy/ |
| 12 | 9 and manipulat$.ti,ab. |
| 13 | 9 and exp manipulation, chiropractic/ |
| 14 | 9 and exp manipulation, spinal/ |
| 15 | 9 and functional restoration.ti,ab. |
| 16 | 9 and exp exercise therapy/ |
| 17 | 9 and conservative.ti,ab. |
| 18 | or/10–17 |
| 19 | 18 and low back pain/rh |
| 20 | 18 and back pain/rh |
| 21 | or/19–20 |
| 22 | limit 21 to (human and english language and yr=1980–2002) |
| 23 | from 22 keep 1–164 |

The search strategy used in Medline (1966 to July week 2, 2002) to identify studies of spinal fusion is presented in **Table A6**. An adapted version of this search strategy was used in Embase.

Table A6 Spinal fusion comparator search – Medline (1966 to July week 2, 2002)

| Search | Search term |
|---|---|
| 1 | Low back pain/ |
| 2 | Back pain/ and low$.ti,ab. |
| 3 | Or/1–2 |
| 4 | 3 and spinal fusion/ |
| 5 | 3 and laminectomy/ |
| 6 | Or/4–5 |
| 7 | 6 and low back pain/th,dt,dh,nu,pc,rt,rh,su,tr |
| 8 | 6 and back pain/th,dt,dh,nu,pc,rt,rh,su,tr |
| 9 | Or/7–8 |
| 10 | Limit 9 to human |
| 11 | 10 and (disk$ or disc$).ti,ab. |

# Appendix H Studies excluded from the assessment

## Intradiscal electrothermal anuloplasty excluded citations

1. Anonymous (2001) Intradiscal electrothermal therapy. *Clinical Privilege White Paper* 1-8.
   **Reason for exclusion:** Non-systematic review, editorial, letter or opinion piece.

2. Baviera, B. (1991) [Training of the back: a modern therapy concept]. *Schweizerische Rundschau fur Medizin Praxis* **80**: 5-14.
   **Reason for exclusion:** Non-systematic review, editorial, letter or opinion piece.

3. Benazet, J.P., Roy-Camille, R., Saillant, G. and Menei, P. (1991) [Treatment of complete lumbar disk herniation by percutaneous discectomy]. *Chirurgie* **117**: 59-67.
   **Reason for exclusion:** Non-IDETA related study.

4. Bergmann, T.F. and Jongeward, B.V. (1998) Manipulative therapy in lower back pain with leg pain and neurological deficit. *Journal of Manipulative & Physiological Therapeutics* **21:** 288-294.
   **Reason for exclusion:** Non-IDETA related study.

5. Blattler, W. and Krayenbuhl, C. (1993) [Spinal canal stenosis syndrome by venous collateralization of an inferior cava thrombosis]. *Phlebologie* **46**: 411-414.
   **Reason for exclusion:** Non-IDETA related study.

6. Bryce, D.A. (1999) IDET article: Criticism and clarification [2]. *Wisconsin Medical Journal* **98:** 1-5
   **Reason for exclusion:** Non-systematic review, editorial, letter or opinion piece.

7. Bulbulian, R., Ball, K.A. and Seaman, D.R. (2001) The short golf backswing: effects on performance and spinal health implications. *Journal of Manipulative & Physiological Therapeutics* **24**: 569-575.
   **Reason for exclusion:** Non-IDETA related study.

8. Crombez, G., Vlaeyen, J.W., Heuts, P.H. and Lysens, R. (1999) Pain-related fear is more disabling than pain itself: evidence on the role of pain-related fear in chronic back pain disability. *Pain* **80** 329-339.
   **Reason for exclusion:** Non-IDETA related study.

9. De Looze, M.P., Boeken-Kruger, M.C., Steenhuizen, S., Baten, C.T.M., Kingma, I. and Van Dieen, J.H. (2000) Trunk muscle activation and low back loading in lifting in the absence of load knowledge. *Ergonomics* **43**: 340-344
   **Reason for exclusion:** Non-IDETA related study.

10. Devulder, J., Dumoulin, K., De Laat, M. and Rolly, G. (1996) Infra-red thermographic evaluation of spinal cord electrostimulation in patients with chronic pain after failed back surgery. *British Journal of Neurosurgery* **10**: 379-383.
    **Reason for exclusion:** Non-IDETA related study.

11. Dietz, E. and Baumann, M. (2000) Obstacles to change: opinion and point of view of health care professionals about a training upon patient-handling tasks. *Archives des Maladies Professionnelles et de Medecine du Travail* **61**: 391-395
    **Reason for exclusion:** Non-IDETA related study.

12. Gupta, A.K., Singh, R.C., Shukla, R.K. and Nath, R. (1996) Role of epidural medication in the treatment of resistant low back pain. *Journal of the Indian Medical Association* **94**: 226-233
    **Reason for exclusion:** Non-IDETA related study.

13. Haas, M., Nyiendo, J. and Aickin, M. (2002) One-year trend in pain and disability relief recall in acute and chronic ambulatory low back pain patients. *Pain* **95**: 83-91.
    **Reason for exclusion:** Non-IDETA related study.

14. Hasenbring, M., Hallner, D. and Klasen, B. (2001) [Psychological mechanisms in the transition from acute to chronic pain: over- or underrated?]. *Schmerz* **15**: 442-447.
    **Reason for exclusion:** Non-IDETA related study.

15. Heary, R.F. (2001) Intradiscal electrothermal annuloplasty: The IDET procedure. *Journal of Spinal Disorders* **14**: 253-360
    **Reason for exclusion:** Non-systematic review, editorial, letter or opinion piece.

16. Hsia, A.W., Isaac, K. and Katz, J.S. (2000) Cauda equina syndrome from intradiscal electrothermal therapy. *Neurology* **55**: 320
**Reason for exclusion:** Fewer than 20 patients.

17. Karasek, M.E. and Bogduk, N. (2001) Intradiscal electrothermal annuloplasty: Percutaneous treatment of chronic discogenic low back pain. *Techniques in Regional Anesthesia & Pain Management* **5**: 129-135.
**Reason for exclusion:** Non-systematic review, editorial, letter or opinion piece.

18. Kaufman, J. (1996) Low back pain: its causes, treatment and medicolegal implications. *Trauma* **38**: 90-96.
**Reason for exclusion:** Non-IDETA related study.

19. Kendall, N.A. (1999) Psychosocial approaches to the prevention of chronic pain: the low back paradigm. *Best Practice & Research in Clinical Rheumatology* **13**: 545-554.
**Reason for exclusion:** Non-IDETA related study.

20. Kennedy, M. (1999) IDET: A new approach to treating lower back pain. *Wisconsin Medical Journal* **98**: 17-20.
**Reason for exclusion:** Non-systematic review, editorial, letter or opinion piece.

21. Kevin, M.J. and Silber, J.S. (2001) Intradiscal electrothermal therapy for the treatment of discogenic back pain. *Applied Radiology* **30**: 11-16.
**Reason for exclusion:** Non-systematic review, editorial, letter or opinion piece.

22. Kleinstueck, F.S., Diederich, C.J., Nau, W.H., Puttlitz, C.M., Smith, J.A., Bradford, D.S. and Lotz, J.C. (2001) Acute biomechanical and histological effects of intradiscal electrothermal therapy on human lumbar discs. *Spine* **26**: 2198-2207.
**Reason for exclusion:** Non-human, in vitro or cadaver study.

23. Kruger, D.G., Zink, F., Peppler, W.W., Ergun, D.L. and Mistretta, C.A. (1994) A regional convolution kernel algorithm for scatter correction in dual-energy images: comparison to single-kernel algorithms. *Medical Physics* **21**: 175-184.
**Reason for exclusion:** Non-IDETA related study.

24. Lee, J., Lutz, G.E., Campbell, D., Rodeo, S.A. and Wright, T. (2001) Stability of the lumbar spine after intradiscal electrothermal therapy. *Archives of Physical Medicine & Rehabilitation* **82**: 118-122.
**Reason for exclusion:** Non-human, in vitro or cadaver study.

25. Lee, T.H. (2001) By the way, doctor... I work in a store and frequently lift boxes that are pretty heavy. One of my friends wears one of those thick leather back belts and swears that the extra support helps her back. My doctor doesn't have any opinion on whether these belts are a good idea. Do you? Harvard Medical School Health Letter **26**: 8.
**Reason for exclusion:** Non-systematic review, editorial, letter or opinion piece.

26. Lin, S.J., Ge, X.R., Wang, J. and Gu, Y. (1990) [Studies on antigens of human lung adenocarcinoma with McAb LC-1]. Shih Yen Sheng Wu Hsueh Pao: *Journal of Experimental Biology* **23:** 233-238.
**Reason for exclusion:** Non-IDETA related study.

27. Linton, S.J. (1997) A population-based study of the relationship between sexual abuse and back pain: establishing a link. *Pain* **73**: 47-53.
**Reason for exclusion:** Non-IDETA related study.

28. Malawski, S. Milecki, M. (1998) [Results of treatment of unilateral sacralization of transverse process of the fifth lumbar vertebrae]. *Chirurgia Narzadow Ruchu i Ortopedia Polska* **63**: 487-494.
**Reason for exclusion:** Non-IDETA related study.

29. Matheson, L.N., Mooney, V., Holmes, D., Leggett, S., Grant, J.E., Negri, S. and Holmes, B. (1995) A test to measure lift capacity of physically impaired adults. Part 2 – Reactivity in a patient sample. *Spine* **20**: 2130-2134.
**Reason for exclusion:** Non-IDETA related study.

30. Mayer, H.M. (2001) [Discogenic low back pain and degenerative lumbar spinal stenosis - how appropriate is surgical treatment?]. *Schmerz* **15**: 484-491.
**Reason for exclusion:** Non-systematic review, editorial, letter or opinion piece.

31. Mekhail, N.A. and Moufawad, S. (2000) Discography and discogenic pain. *Techniques in Regional Anesthesia & Pain Management* **4**: 127-131.
**Reason for exclusion:** Non-systematic review, editorial, letter or opinion piece.

32. Miura, M., Ideta, H., Takenaka, C., Yamamoto, C., Saiki, H. and Shimada, N. (1995) Predisposing factors of proliferative vitreoretinopathy. *Japanese Journal of Clinical Ophthalmology* **49**: 646-651.
**Reason for exclusion:** Non-IDETA related study.

33. Miura, M., Ideta, H., Takenaka, C., Yamamoto, C., Saiki, H., Shimada, N., Sorensen, J., Kalman, S., Tropp, H. and Bengtsson, M. (1996) Vitreous haze and aqueous flare in rhegmatogenous retinal detachment.
Can a pharmacological pain analysis be used in the assessment of chronic low back pain? *Folia Ophthalmologica Japonica* **47:** 930-937.
**Reason for exclusion:** Non-IDETA related study.

34. Mooney, V. and Andersson, G.B. (1994) Trunk strength testing in patient evaluation and treatment. *Spine* **19**: 2483-2485.
**Reason for exclusion:** Non-systematic review, editorial, letter or opinion piece.

35. Okuyama, M., Ideta, H., Ando, Y., Ando, E. and Negi, A. (1999) A case of familial amyloidotic polyneuropathy (FAP) with vitreous opacities as the first sign. *Folia Ophthalmologica Japonica* **50:** 878.
**Reason for exclusion:** Non-IDETA related study.

36. Rushbrook, J.I., Becker, E., Schussler, G.C. and Divino, C.M. (1995) Identification of a human serum albumin species associated with familial dysalbuminemic hyperthyroxinemia. *Journal of Clinical Endocrinology & Metabolism* **80**: 461-467.
**Reason for exclusion:** Non-IDETA related study.

37. Saal, J.A. and Saal, J.S. (2002) Intradiscal electrothermal therapy for the treatment of chronic discogenic low back pain. *Clinics in Sports Medicine* **21**: 184-187.
**Reason for exclusion:** Non-systematic review, editorial, letter or opinion piece.

38. Schneider, J. and Gilford, S. (2001) The chiropractor's role in pain management for oncology patients. *Journal of Manipulative & Physiological Therapeutics* **24**: 52-57.
**Reason for exclusion:** Non-systematic review, editorial, letter or opinion piece

39. Shah, R.V., Lutz, G.E., Lee, J., Doty, S.B. and Rodeo, S. (2001) Intradiskal electrothermal therapy: A preliminary histologic study. *Archives of Physical Medicine & Rehabilitation* **82**: 1233-1237
**Reason for exclusion:** Non-human, in vitro or cadaver study

40. Slipman, C.W., Patel, R.K., Zhang, L., Vresilovic, E., Lenrow, D., Shin, C. and Herzog, R. (2001) Side of symptomatic annular tear and site of low back pain: is there a correlation? *Spine* **26**: E165-E169
**Reason for exclusion:** Non-IDETA related study

41. Slipman, C.W., Whyte II, W.S., Lichtenstein, G.R., Lenrow, D., Braverman, D., Ellen, M. and Vresilovic, E.J. (2001) Thoracic spine spasms secondary to hemorrhagic intestinal ulcer. *Pain Physician* **4**, 100.
**Reason for exclusion:** Non-IDETA related study

42. Sorensen, J., Kalman, S., Tropp, H. and Bengtsson, M. (1996) Can a pharmacological pain analysis be used in the assessment of chronic low back pain? *European Spine Journal* **5**: 236-242.
**Reason for exclusion:** Non-IDETA related study

43. Takai, S., Sakaguchi, M., Jin, D. and Miyazaki, M. (2000) A new method for simultaneous measurements of mast cell proteases in human vascular tissue. *Clinical & Experimental Pharmacology & Physiology* **27**: 700-704
**Reason for exclusion:** Non-IDETA related study

44. Takenaka, C., Ideta, H., Watanabe, K., Nakatake, J., Shinagawa, K. and Demizu, S. (1994) Air pump for retinal detachment with macular hole. *Ophthalmic Surgery* **25**: 590-592.
**Reason for exclusion:** Non-IDETA related study

45. Thomas, K.J., Fitter, M., Brazier, J., MacPherson, H., Campbell, M., Nicholl, J.P. and Roman, M. (1999) Longer-term clinical and economic benefits of offering acupuncture to patients with chronic low back pain assessed as suitable for primary care management. *Complementary Therapies in Medicine* **7**: 91-100.
**Reason for exclusion:** Non-systematic review, editorial, letter or opinion piece

46. Vlaeyen, J.W.S., Seelen, H.A.M., Peters, M., de Jong, P., Aretz, E., Beisiegel, E. and Weber, W.E.J. (1999) Fear of movement/(re)injury and muscular reactivity in chronic low back pain patients: An experimental investigation. *Pain* **82**: 299-304
**Reason for exclusion:** Non-IDETA related study

47. Volinn, E. (1996) Between the idea and the reality: research on bed rest for uncomplicated acute low back pain and implications for clinical practice patterns. *Clinical Journal of Pain* **12**: 166-170.
**Reason for exclusion:** Non-systematic review, editorial, letter or opinion piece

48. Wetzel, F.T. (2001) Cauda equina syndrome from intradiscal electrothermal therapy. *Neurology* **56**: 1607
**Reason for exclusion:** Non-systematic review, editorial, letter or opinion piece

49. Wright, R.E., Brandt, S.A., Barkow, S.H., Vilims, B.D. and Pflueger, D.R. (2001) Quantitative annular thermometry in humans and sheep during radiofrequency and electrothermal annuloplasty. *Techniques in Regional Anesthesia & Pain Management* **5:** 139-141
**Reason for exclusion:** Non-human, in vitro or cadaver study

## Conservative therapy excluded citations

1. Alaranta, H., Rytokoski, U., Rissanen, A., Talo, S., Ronnemaa, T., Puukka, P., Karppi, S.L., Videman, T., Kallio, V. and Slatis, P. (1994) Intensive physical and psychosocial training program for patients with chronic low back pain. A controlled clinical trial. *Spine.* **19:** 1339-1349.
**Reason for exclusion:** Wrong patient group

2. Andersson, G.B.J., Lucente, T. , Davis, A.M., Kappler, R.E. , Lipton, J.A. and Leurgans, S. (1999) A comparison of osteopathic spinal manipulation with standard care for patients with low back pain. *New England Journal of Medicine* **341**(4): 1426-1431.
**Reason for exclusion:** Wrong patient group

3. Asfour, S.S., Khalil, T.M., Waly, S.M., Goldberg, M.L., Rosomoff, R.S. and Rosomoff, H.L. (1990) Biofeedback in back muscle strengthening *Spine* **15:** 510-513.
**Reason for exclusion:** Wrong outcomes

4. Bachmann, S. and Oesch, P. (2000) Rehabilitation of patients with chronic pain of the locomotor system in an interdisciplinary functional and performance restoration program - First results after 5 months. *Physikalische Medizin Rehabilitationsmedizin Kurortmedizin* **10:** 11-19.
**Reason for exclusion:** Follow-up less than 12 months

5. Barnes, D., Smith, D., Gatchel, R.J. and Mayer, T.G. (1989) Psychosocioeconomic predictors of treatment success/failure in chronic low-back pain patients. *Spine* **14:** 427-430.
**Reason for exclusion:** Does not primarily report the results of an intervention (cross-sectional, prognostic, non-interventional)

6. Basler, H.D. (1995) Interdisciplinary cooperation in prevention and treatment of low back pain. *Schmerz* **9:** 93-95.
**Reason for exclusion:** Non-systematic review, letter or opinion piece

7. BenDebba, M., Torgerson, W.S., Boyd, R.J., Dawson, E.G., Hardy, R.W., Robertson, J.T., Sypert, G.W., Watts, C. and Long, D.M. (2002) Persistent low back pain and sciatica in the United States: Treatment outcomes. *Journal of Spinal Disorders* **15:** 2-15.
**Reason for exclusion:** Wrong patient group

8. Bendix, A.E., Bendix, T., Haestrup, C. and Busch, E. (1998) A prospective, randomized 5-year follow-up study of functional restoration in chronic low back pain patients. *European Spine Journal* **7:** 111-119.
**Reason for exclusion:** Wrong patient group

9. Bendix, A.F., Bendix, T., Vaegter, K., Lund, C., Frolund, L. and Holm, L. (1996) Multidisciplinary intensive treatment for chronic low back pain: a randomized, prospective study. *Cleveland Clinic Journal of Medicine* **63:** 62-69.
**Reason for exclusion:** Follow-up less than 12 months

10. Bendix, A.F., Bendix, T., Lund, C., Kirkbak, S. and Ostenfeld, S. (1997) Comparison of three intensive programs for chronic low back pain patients: a prospective, randomized, observer-blinded study with one-year follow-up. *Scandinavian Journal of Rehabilitation Medicine* **29:** 81-89.
**Reason for exclusion:** Wrong patient group

11. Bendix, A.F., Bendix, T. and Haestrup, C. (1998) Can it be predicted which patients with chronic low back pain should be offered tertiary rehabilitation in a functional restoration program? A search for demographic, socioeconomic, and physical predictors. *Spine* **23:** 1775-1783.
**Reason for exclusion:** Wrong patient group

12. Bendix, A.F., Bendix, T., Labriola, M. and Boekgaard, P. (1998) Functional restoration for chronic low back pain. Two-year follow-up of two randomized clinical trials. *Spine* **23:** 717-725.
**Reason for exclusion:** Does not primarily report the results of an intervention (cross-sectional, prognostic, non-interventional)

13. Bendix, A.F., Bendix, T., Haestrup, C. and Busch, E. (1998) A prospective, randomized 5-year follow-up study of functional restoration in chronic low back pain patients. *European Spine Journal* **7:** 111-119.
**Reason for exclusion:** Wrong patient group

14. Bendix, T., Bendix, A.F., Busch, E. and Jordan, A. (1996) Functional restoration in chronic low back pain. *Scandinavian Journal of Medicine & Science in Sports* **6:** 88-97.
**Reason for exclusion:** Non-systematic review, letter or opinion piece

15. Bendix, T., Bendix, A., Labriola, M., Haestrup, C. and Ebbehoj, N. (2000) Functional restoration versus outpatient physical training in chronic low back pain: a randomized comparative study. *Spine* **25:** 2494-2500.
**Reason for exclusion:** Wrong patient group

16. Blake, C. and Garrett, M. (1997) Impact of litigation on quality of life outcomes in patients with chronic low back pain. *Irish Journal of Medical Science* **166:** 124-126.
**Reason for exclusion:** Wrong outcomes

17. Bolten, W., Kempel-Waibel, A. and Pforringer, W. (1998) Analysis of cost of illness of low back pain. *Medizinische Klinik* **93:** 388-393.
**Reason for exclusion:** Non-systematic review, letter or opinion piece

18. Borenstein, D.G. (1999) Epidemiology, etiology, diagnostic evaluation, and treatment of low back pain. *Current Opinion in Rheumatology* **11:** 151-157.
**Reason for exclusion:** Non-systematic review, letter or opinion piece

19. Brady, S., Mayer, T. and Gatchel, R.J. (1904) Physical progress and residual impairment quantification after functional restoration. Part II: Isokinetic trunk strength *Spine* **19**(4): 395-400.
**Reason for exclusion:** Does not primarily report the results of an intervention (cross-sectional, prognostic, non-interventional)

20. Broll-Zeitvogel, E., Grifka, J., Bauer, J., Roths, P.H. and Degryse, P. (1999) Medical training therapy in lumbar syndromes. *Orthopade Vol* **28**, 932-938.
**Reason for exclusion:** Non-systematic review, letter or opinion piece

21. Bronfort, G., Goldsmith, C.H., Nelson, C.F., Boline, P.D. and Anderson, A.V. (1996) Trunk exercise combined with spinal manipulative or NSAID therapy for chronic low back pain: A randomized, observer-blinded clinical trial. *Journal of Manipulative & Physiological Therapeutics* **19**(9): 570-582.
**Reason for exclusion:** Wrong patient group

22. Bronfort, G. (1999) Spinal manipulation: current state of research and its indications. *Neurologic Clinics.* **17** , 91-111.
**Reason for exclusion:** Non-systematic review, letter or opinion piece

23. Burke, S.A., Harms-Constas, C.K. and Aden, P.S. (1994) Return to work/work retention outcomes of a functional restoration program. A multi-center, prospective study with a comparison group. *Spine* **19:** 1880-1885.
**Reason for exclusion:** Wrong patient group

24. Campello, M., Nordin, M. and Weiser, S. (1996) Physical exercise and low back pain. *Scandinavian Journal of Medicine & Science in Sports* **6:** 63-72.
**Reason for exclusion:** Non-systematic review, letter or opinion piece

25. Carpenter, D.M. and Nelson, B.W. (1999) Low back strengthening for the prevention and treatment of low back pain. *Medicine & Science in Sports & Exercise* **31:** 18-24.
**Reason for exclusion:** Non-systematic review, letter or opinion piece

26. Casser, H.R., Riedel, T., Schrembs, C., Ingenhorst, A. and Kuhnau, D. (1999) New therapeutic strategy for chronifying back pain. The multimodal, interdisciplinary therapeutic program. *Orthopade* **28:** 946-957.
**Reason for exclusion:** Non-systematic review, letter or opinion piece

27. Cedraschi, C., Robert, J., Perrin, E., Fischer, W., Goerg, D. and Vischer, T.L. (1996) The role of congruence between patient and therapist in chronic low back pain patients. *Journal of Manipulative & Physiological Therapeutics* **19:** 244-249.
**Reason for exclusion:** Does not primarily report the results of an intervention (cross-sectional, prognostic, non-interventional)

28. Cheing, G.L. and Hui-Chan, C.W. (1999) Transcutaneous electrical nerve stimulation: nonparallel antinociceptive effects on chronic clinical pain and acute experimental pain. *Archives of Physical Medicine & Rehabilitation* **80:** 305-312.
**Reason for exclusion:** Follow-up less than 12 months

29. Cohen, I. and Rainville, J. (2002) Aggressive exercise as treatment for chronic low back pain. *Sports Medicine* **32:** 75-82.
**Reason for exclusion:** Non-systematic review, letter or opinion piece

30. Cohen, J.E., Goel, V., Frank, J.W., Bombardier, C., Peloso, P. and Guillemin, F. (1994) Group education interventions for people with low back pain. An overview of the literature. *Spine* **19:** 1214-1222.
**Reason for exclusion:** Non-systematic review, letter or opinion piece

31. Constant, F., Guillemin, F., Collin, J.F. and Boulange, M. (1998) Use of spa therapy to improve the quality of life of chronic low back pain patients. *Medical Care* **36:** 1309-1314.
**Reason for exclusion:** Follow-up less than 12 months

32. Cooke, C., Menard, M.R., Beach, G.N., Locke, S.R. and Hirsch, G.H. (1992) Serial lumbar dynamometry in low back pain. *Spine* **17:** 653-662.
**Reason for exclusion:** Wrong outcomes

33. Cottingham, J.T. and Maitland, J. (1997) A three-paradigm treatment model using soft tissue mobilization and guided movement-awareness techniques for a patient with chronic low back pain: a case study. *Journal of Orthopaedic & Sports Physical Therapy* **26:** 155-167.
**Reason for exclusion:** Follow-up less than 12 months

34. Curtis, L., Mayer, T.G. and Gatchel, R.J. (1994) Physical progress and residual impairment quantification after functional restoration. Part III: Isokinetic and isoinertial lifting capacity. *Spine* **19:** 401-405.
**Reason for exclusion:** Follow-up less than 12 months

35. Dean, B.Z., Williams, F.H., King, J.C. and Goddard, M.J. (1994) Pain rehabilitation. 4. Therapeutic options in pain management. *Archives of Physical Medicine & Rehabilitation* **75:** S21-S30.
**Reason for exclusion:** Non-systematic review, letter or opinion piece

36. Deutsch, F.E. (1996) Isolated lumbar strengthening in the rehabilitation of chronic low back pain. *Journal of Manipulative & Physiological Therapeutics* **19:** 124-133.
**Reason for exclusion:** Non-systematic review, letter or opinion piece

37. Di Fabio, R.P., Mackey, G. and Holte, J.B. (1995) Disability and functional status in patients with low back pain receiving workers' compensation: a descriptive study with implications for the efficacy of physical therapy *Physical Therapy* **75:** 180-193.
**Reason for exclusion:** Does not primarily report the results of an intervention (eg, cross-sectional, prognostic, non-interventional)

38. Dolin, S.J., Bacon, R.A. and Drage, M. (1998) Rehabilitation of chronic low back pain using continuous epidural analgesia. *Disability & Rehabilitation* **20**: 151-157.
**Reason for exclusion:** Wrong intervention

39. Donald, S.M. (2000) Rehabilitation of low back pain. *Cpd Rheumatology* **1:** 102-110.
**Reason for exclusion:** Non-systematic review, letter or opinion piece

40. Donelson, R. and McKenzie, R. (1992) Effects of spinal flexion and extension exercises on low-back pain and spinal mobility in chronic mechanical low-back pain patients. *Spine* **17:** 1267-1268.
**Reason for exclusion:** Non-systematic review, letter or opinion piece

41. Durand, M.J. and Loisel, P. (2001) Therapeutic Return to Work: Rehabilitation in the workplace. *Work* **17:** 57-63.
**Reason for exclusion:** Wrong patient group

42. Edwards, B.C., Zusman, M., Hardcastle, P., Twomey, L., O'Sullivan, P. and McLean, N. (1992) A physical approach to the rehabilitation of patients disabled by chronic low back pain. *Medical Journal of Australia* **156:** 167-172.
**Reason for exclusion:** Wrong patient group

43. Elnaggar, I.M., Nordin, M., Sheikhzadeh, A., Parnianpour, M. and Kahanovitz, N. (1991) Effects of spinal flexion and extension exercises on low-back pain and spinal mobility in chronic mechanical low-back pain patients. *Spine* **16:** 967-972.
**Reason for exclusion:** Follow-up less than 12 months

44. Eriksen, H.R. and Ursin, H. (2000) The pain of Sognsvann walks. *Spine* **25:** 137
**Reason for exclusion:** Non-systematic review, letter or opinion piece

45. Faas, A. (1996) Exercises: which ones are worth trying, for which patients, and when? *Spine* **21:** 2874-2878.
**Reason for exclusion:** Non-systematic review, letter or opinion piece

46. Farrell, J.P. and Drye, C.D. (1992) Back school programs. The young patient. *Occupational Medicine* **7:** 55-66.
**Reason for exclusion:** Non-systematic review, letter or opinion piece

47. Feine, J.S. and Lund, J.P. (1997) An assessment of the efficacy of physical therapy and physical modalities for the control of chronic musculoskeletal pain. *Pain* **71:** 5-23.
**Reason for exclusion:** Non-systematic review, letter or opinion piece

48. Follick, M.J., Aberger, E.W., Ahern, D.K. and McCartney, J.R. (1984) The chronic low back pain syndrome: identification and management. *Rhode Island Medical Journal (Providence, RI)* **67:** 219-224.
**Reason for exclusion:** Non-systematic review, letter or opinion piece

49. Foster, N.E., Thompson, K.A., Baxter, G.D. and Allen, J.M. (1999) Management of nonspecific low back pain by physiotherapists in Britain and Ireland. A descriptive questionnaire of current clinical practice. *Spine* **24:** 1332-1342.
**Reason for exclusion:** Does not primarily report the results of an intervention (cross-sectional, prognostic, non-interventional)

50. Fow, N., Sittig, M., Dorris, G., Breisinger, G. and Anthony, K. (1994) An analysis of the relationship of gender and age to MMPI scores of patients with chronic pain. *Journal of Clinical Psychology* **50:** 537-554.
**Reason for exclusion:** Does not primarily report the results of an intervention (cross-sectional, prognostic, non-interventional)

51. Frank, A.O. and De, S. (2001) Conservative management of low back pain. *International Journal of Clinical Practice* **55:** 21-31.
**Reason for exclusion:** Non-systematic review, letter or opinion piece

52. Fredrickson, B.E., Trief, P.M. , VanBeveren, P., Yuan, H.A. and Baum, G. (1988) Rehabilitation of the patient with chronic back pain. A search for outcome predictors. *Spine* **13:** 351-353.
**Reason for exclusion:** Does not primarily report the results of an intervention (eg, cross-sectional, prognostic, non-interventional)

53. French, S.D., Green, S. and Forbes, A. (2000) Reliability of chiropractic methods commonly used to detect manipulable lesions in patients with chronic low-back pain. *Journal of Manipulative & Physiological Therapeutics* **23:** 231-238.
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**Reason for exclusion:** Does not primarily report the results of an intervention (cross-sectional, prognostic, non-interventional)

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**Reason for exclusion:** Wrong patient group

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**Reason for exclusion:** Follow-up less than 12 months

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**Reason for exclusion:** Wrong outcomes

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**Reason for exclusion:** Does not primarily report the results of an intervention (eg, cross-sectional, prognostic, non-interventional)

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**Reason for exclusion:** Wrong patient group

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**Reason for exclusion:** Non-systematic review, letter or opinion piece

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**Reason for exclusion:** Non-systematic review, letter or opinion piece

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**Reason for exclusion:** Does not primarily report the results of an intervention (eg, cross-sectional, prognostic, non-interventional)

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**Reason for exclusion:** Wrong patient group

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**Reason for exclusion:** Wrong patient group

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**Reason for exclusion:** Wrong patient group

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**Reason for exclusion:** Non-systematic review, letter or opinion piece

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**Reason for exclusion:** Wrong outcomes

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**Reason for exclusion:** Non-systematic review, letter or opinion piece

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**Reason for exclusion:** Wrong patient group

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**Reason for exclusion:** Does not primarily report the results of an intervention (cross-sectional, prognostic, non-interventional)

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**Reason for exclusion:** Non-systematic review, letter or opinion piece

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**Reason for exclusion:** Wrong patient group

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**Reason for exclusion:** Wrong patient group

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**Reason for exclusion:** Non-systematic review, letter or opinion piece

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**Reason for exclusion:** Wrong patient group

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**Reason for exclusion:** Follow-up less than 12 months

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**Reason for exclusion:** Does not primarily report the results of an intervention (cross-sectional, prognostic, non-interventional)

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**Reason for exclusion:** Wrong patient group

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**Reason for exclusion:** Non-systematic review, letter or opinion piece

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**Reason for exclusion:** Does not primarily report the results of an intervention (cross-sectional, prognostic, non-interventional)

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**Reason for exclusion:** Does not primarily report the results of an intervention (cross-sectional, prognostic, non-interventional)

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**Reason for exclusion:** Does not primarily report the results of an intervention (cross-sectional, prognostic, non-interventional)

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**Reason for exclusion:** Wrong patient group

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**Reason for exclusion:** Follow-up less than 12 months

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**Reason for exclusion:** Study included less than 20 patients

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**Reason for exclusion:** Does not primarily report the results of an intervention (eg, cross-sectional, prognostic, non-interventional)

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**Reason for exclusion:** Non-systematic review, letter or opinion piece

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**Reason for exclusion:** Does not primarily report the results of an intervention (eg, cross-sectional, prognostic, non-interventional)

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**Reason for exclusion:** Wrong patient group

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**Reason for exclusion:** Non-systematic review, letter or opinion piece

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**Reason for exclusion:** Wrong patient group

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**Reason for exclusion:** Wrong patient group

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**Reason for exclusion:** Wrong intervention

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**Reason for exclusion:** Wrong patient group

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**Reason for exclusion:** Wrong patient group

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**Reason for exclusion:** Non-systematic review, letter or opinion piece

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**Reason for exclusion:** Follow-up less than 12 months

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**Reason for exclusion:** Non-systematic review, letter or opinion piece

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**Reason for exclusion:** Follow-up less than 12 months

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**Reason for exclusion:** Wrong outcomes

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**Reason for exclusion:** Wrong outcomes

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**Reason for exclusion:** Non-systematic review, letter or opinion piece

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**Reason for exclusion:** Retrospective study

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**Reason for exclusion:** Wrong patient group

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**Reason for exclusion:** Does not primarily report the results of an intervention (eg, cross-sectional, prognostic, non-interventional)

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**Reason for exclusion:** Does not primarily report the results of an intervention (eg, cross-sectional, prognostic, non-interventional)

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**Reason for exclusion:** Follow-up less than 12 months

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**Reason for exclusion:** Does not primarily report the results of an intervention (eg, cross-sectional, prognostic, non-interventional)

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**Reason for exclusion:** Retrospective study

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**Reason for exclusion:** Non-systematic review, letter or opinion piece

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**Reason for exclusion:** Does not primarily report the results of an intervention (eg, cross-sectional, prognostic, non-interventional)

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**Reason for exclusion:** Wrong patient group

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**Reason for exclusion:** Non-systematic review, letter or opinion piece

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**Reason for exclusion:** Wrong patient group

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**Reason for exclusion:** Wrong patient group

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**Reason for exclusion:** Does not primarily report the results of an intervention (eg, cross-sectional, prognostic, non-interventional)

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**Reason for exclusion:** Does not primarily report the results of an intervention (eg, cross-sectional, prognostic, non-interventional)

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**Reason for exclusion:** Does not primarily report the results of an intervention (eg, cross-sectional, prognostic, non-interventional)

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**Reason for exclusion:** Does not primarily report the results of an intervention (eg, cross-sectional, prognostic, non-interventional)

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**Reason for exclusion:** Does not primarily report the results of an intervention (eg, cross-sectional, prognostic, non-interventional)

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**Reason for exclusion:** Follow-up less than 12 months

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# Abbreviations

| | |
|---|---|
| CT | Computerised tomography |
| IASP | International Association for the Study of Pain |
| ICER | Incremental cost-effectiveness ratio |
| IDD | Internal disc disruption |
| ITT | Intention-to-treat |
| MRI | Magnetic resonance imaging |
| MSAC | Medical Services Advisory Committee |
| NHMRC | National Health and Medical Research Council |
| TGA | Therapeutic Goods Administration |
| VAS | Visual analogue scale |

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